

In addition, indicators of adherence to the critical management procedures should be assessed with standard indicators. Appendix 1, Table 2 provides a suggested list of indicators for these management practices, and their means of verification. The methods of verification include observation, interviews with clinical staff and review of records. Some of the indicators, such as the facility having a written breastfeeding policy and a summary of the policy being visible to pregnant women, mothers and their families, are easily verifiable.

External assessments should be conducted regularly; this should be done at least every 5 years but preferably more often. The depth and frequency of the external assessments depends on the quality and frequency of internal monitoring, and which information is reported to higher levels.

It might be necessary to select a reduced number of indicators for mainstreaming into other certification/quality-assurance systems. At a minimum, the sentinel indicators on early initiation of breastfeeding and the rate of exclusive breastfeeding throughout the hospital stay should be included in such systems, since breastfeeding should be the norm in all maternity and newborn care.

If integration of external assessment in other quality-assessment systems is inadequate to guarantee compliance with breastfeeding standards, a vertical stand-alone assessment can be developed instead of, or in addition to, an integrated assessment. An argument in favour of a vertical assessment is that it might be able to include more specific indicators on breastfeeding. Vertical assessments, however, might be more costly and more difficult to sustain in the long term.

Alternatively, spot checks may be used. If adequately resourced, a department of the ministry of health could manage an external assessment system. Embedding it within existing professional organizations or well-functioning NGOs might also be an option in certain settings. In the latter case, it is important that the ministry of health and NGO work together on implementing an effective programme.

3.5. Incentives and sanctions

Develop and implement incentives for compliance and/or sanctions for non-compliance with the Ten Steps.

Health-care facilities make decisions about their policies and procedures, based on a number of considerations, including review of scientific evidence, national or international recommendations, regulations, costs, case-load, client satisfaction and public perceptions. National programmes need to consider what incentives or sanctions are most appropriate to get facilities providing maternity and newborn services to make the necessary changes to fully protect, promote and support breastfeeding. Incentives for change in public and private facilities may be different. Table 1 lists several options for incentivizing compliance with the BFHI standards, which countries are expected to adopt as national standards, and lists key benefits and considerations for each.

A strong incentive would be to financially tie payments for facilities providing maternity and newborn services to an external assessment process in those countries in which this is practised. For example, facilities identified as having more deficiencies in practices might receive a lower rate of reimbursement per delivery compared to those in full compliance with all the standards. This “performance-based financing” or “payment-for-performance” model of health-care payment is increasingly being used to incentivize quality and efficiency (87). A review of 12 payment-for-performance case-studies from 10 countries concluded that payment for performance: “did not lead to ‘breakthrough’ performance improvements in any of the programmes. Most of the programmes did, however, contribute to a greater focus on health system objectives, better generation and use of information, more accountability, and in some cases a more productive dialogue between health purchasers and providers. This also can be described as more effective health sector governance and more strategic health purchasing”.(88)

Table 1. Options for incentivizing compliance with the standards of the Baby-friendly Hospital Initiative

Description	Benefits	Challenges	Country type for which this option would be most suitable
Performance-based financing	Meeting the standards would financially benefit the facility	Compliance must be monitored externally Costly if the schema is to pay “extra” for meeting the standards	Countries already applying performance-based financing for other relevant intervention
Inclusion in performance contracts	Clear accountability	Requires indicators that help ensure the sustainability of appropriate facility practices (and not only meeting a specific target)	Countries already using performance contracts
Public recognition of excellence/award/designation	Staff efforts are acknowledged Motivating for staff Meeting the standards would improve the image of the facility and lead to an increase in the number of clients and therefore revenue	Compliance must be monitored externally Often perceived as an end-point by national and facility managers and staff The meaning of the designation needs to be communicated to the public Only relevant when time-bound and removed when compliance falters Is at odds with the principle that breastfeeding is the norm; allows non-compliance with standards to be seen as “normal care”	Countries with a successful BFHI designation programme
Public reporting of quality indicators and outcomes	Might not need external assessments with specific frequency	Reliance on self-reporting could be biased (although external spot checks could improve quality) Requires public understanding of what practices and outcomes are good	Countries in which public opinion is an important driver of health-care delivery

Alternatively, third-party payers or insurance companies might give preference to facilities with better compliance with the national standards.

Some countries use performance contracts for managers and/or staff of public services that include specific goals to be met. It can be useful to include one or more indicator related to the protection, promotion and support of breastfeeding in facilities providing maternity and newborn services in these contracts.

Public recognition of excellence can also serve as an incentive for improving the quality of care. Hospitals can gain esteem when they achieve certain awards for excellence, as determined by an external assessment. Public recognition of excellence for adherence to the updated Ten Steps might incentivize facilities to comply with the Baby-friendly standards. With this kind of incentive, it is crucial that internal and external quality-assurance systems are in place to sustain the quality of services once the desired level is reached. These need to be designed by national authorities (the national coordination body), so that they are feasible with the available financial and human resources.

The traditional Baby-friendly model was largely organized around the naming of Baby-friendly facilities. While designation is one option that countries can consider to encourage change in facilities providing maternity and newborn services, it is only one of a number of useful options to consider.

Public reporting of quality indicators and outcomes is another way to hold facilities providing maternity and newborn services accountable for the quality of care they provide, and incentivize improvements. A public listing of all facilities in the country providing maternity and newborn services, with their rates of exclusive breastfeeding at discharge, would probably encourage those with the lowest rates to make improvements. Similarly, reporting on rates of skin-to-skin contact would highlight the importance of this practice and call upon individual facilities to catch up with the rest. Consumers' and patients' or clients' groups can also play a role in this accountability process.

Countries need to examine which of these incentives would work best in their context. Some require greater political will but would have long-lasting effects. Others may be more politically feasible but require ongoing engagement and resources.

3.6. Technical assistance to facilities

Provide technical assistance to facilities that are making changes to adopt the Ten Steps.

Facilities will require external assistance to adopt the Ten Steps as the standard of care, from experts who have managed the change process in other facilities or who understand the intricacies of each step in great detail. Providing technical assistance to facilities on an individual basis is likely to be resource intensive and thus it may take years to reach all facilities in the country. This goes for both public and private facilities.

Countries should develop or strengthen and update a cadre of trained professionals to provide technical assistance to facilities working through the change processes. Specific resources and time commitment from the trained professionals and their organizations (where relevant) need to be ensured.

Working with groups of facilities to support one another in the change process can be very effective. The IHI has developed a process for quality improvement through “collaboratives”, or groups of similar facilities that engage in policy and practice change through group learning and mutual support (89). Groups may be formed on the basis of geography (e.g. provincial groups), bureaucracy (e.g. all military facilities together), or another relevant grouping. In some countries, hospital systems that own and operate a series of facilities have the power to set policy for many hospitals at once. Such systems provide an opportunity to change many facilities at the same time, with a more streamlined approach.

Where resources are constrained, it may be necessary to phase in technical assistance over time, with a clear plan to achieve national coverage in a set period of time. A variety of strategies for which facilities to target first could be considered:

- A strategic geographic focus, such as starting with one facility in each province, would ensure that throughout the country, all facilities have a nearby facility to look to as a role model in implementing the recommended policies and practices.

- Focusing first on facilities that are most likely to comply with the recommendations (e.g. facilities previously designated as “Baby-friendly”, facilities with a history of quality-improvement successes) could provide early wins and demonstrate to other facilities the feasibility of the recommendations.
- Large facilities are also an important early target because the health of a large number of mothers and babies can be improved with changes in only one place. Also, large facilities often serve as a point of comparison for smaller facilities, so having optimal practices in place at these facilities is helpful for scaling up.
- Targeting teaching hospitals may be particularly effective in ensuring that new health professionals are well grounded in the Ten Steps before they are assigned to facilities throughout the country.

3.7 National monitoring

Monitor implementation of the initiative.

Just as individual facilities need to monitor their activities in protecting, promoting and supporting breastfeeding, as well as feeding behaviours, countries need to monitor their activities and breastfeeding outcomes at the national level (and the subnational level where appropriate). Key indicators of breastfeeding outcomes, clinical practices and BFHI programme activities to be monitored at national and subnational levels are listed in Appendix 1, Table 3.

WHO has developed a Global Nutrition Monitoring Framework, which was approved by the WHA in 2015 (37, 38). All countries were recommended by the WHA to report on the indicators in the framework. Two of the indicators are particularly relevant for the BFHI: Prevalence of exclusive breastfeeding in infants aged 6 months or less and Percentage of births in Baby-friendly facilities.

The latter has been defined as the percentage of babies born in a calendar year in facilities that are currently designated as “Baby-friendly”. For countries that opt not to operate a “designation” programme, an alternative indicator will be needed to reflect the percentage of babies born in a calendar year that experience care in line with the Ten Steps. This could be calculated from the number of births occurring in facilities that pass national assessment standards, or

from reports of mothers on their experiences following birth. In addition to reporting to WHO, countries are recommended to report progress on BFHI coverage in reports to the Committee on the Right to Food, the Committee on the Rights of the Child, and the Scaling Up Nutrition movement.

Various data sources can be used for countries to assess adherence to the Ten Steps:

- Household surveys, such as demographic and health surveys, may be used to estimate the percentage of mothers whose maternity experiences adhere to recommended standards. The Demographic and Health Survey (90) already includes questions on early initiation of breastfeeding, exclusive breastfeeding during the facility stay, and skin-to-skin contact. Client satisfaction surveys or exit interviews are routinely conducted in many countries and could also provide an opportunity to collect national data on selected aspects of maternity care.
- Where facilities providing maternity and newborn services routinely report data to health management information systems, the data collected at the facility level can be reported to the district, provincial or national database. These reports can be used to document the overall percentage of babies experiencing recommended care, or the percentage of facilities that are meeting a given threshold for acceptable practices.
- Some countries have developed ongoing survey mechanisms in which key informants from facilities report on their adherence to the Ten Steps. The reports may be based on actual clinical records or on perception of usual practice or facility policies. While such surveys could be subject to reporting bias, they may be useful for documenting trends and identifying weak points. These surveys may be based on a random sample of facilities or on a complete assessment of all facilities in the country.

3.8. Communications and advocacy

Advocate for the BFHI to relevant audiences.

The national coordination body will need to undertake ongoing communications and advocacy efforts to ensure sustained implementation of the BFHI. A communications plan should include the elements listed next.

1. Identification of key audiences

- Facility leaders (both governmental and nongovernmental), such as hospital directors or chiefs of obstetrics, are critical decision-makers in implementing the Ten Steps.
- Professional associations of nurses, midwives, paediatricians, obstetricians, neonatologists and dietitians are directly affected by changes in standards for breastfeeding care and therefore need to be key targets for communications and advocacy. Hospital associations can become important allies in advocating for systems changes.
- Legislators and funders (including ministries of finance and donors) are an important audience to be kept informed about the BFHI, and breastfeeding programmes more broadly, to ensure their ongoing engagement with and investment in BFHI programmes.
- Pregnant women, their families and other community members are a pivotal audience to increase the demand for improved protection, promotion and support of breastfeeding in facilities providing maternity and newborn services.
- Additional audiences that are important for breastfeeding programmes and the BFHI should be defined by each country.

2. Identification of existing knowledge and attitudes

- It is important to understand what the target audiences already understand about breastfeeding and the BFHI before developing communication interventions. Audience research will identify key opportunities where actors are ready to take action, as well as challenging areas where perceptions need to be altered or information gaps filled.

3. Development/adaptation of key messages

- The messages need to be tailored to each audience and informed by each audience's knowledge and attitudes, as well as their expected role in supporting and/or implementing the BFHI. An example of a set of messages on the importance of breastfeeding is given in reference (91). For some audiences, it will be important to communicate the Ten Steps in simple language ([Annex 2](#) gives an example of how this could be done). The importance of implementing the Ten Steps for achieving optimal health outcomes is a core message. It is important to emphasize the need to extend the BFHI to all facilities providing maternity and newborn care for countries that have not yet achieved this.

4. Identification of key communication channels

- Each audience needs to be reached through the channel(s) they most rely on. For communication to the public, use of mass media communications and social media may be relevant, to complement interpersonal communication channels. Involvement of consumers' and women's organizations, where these exist, and/or work with community leaders, could be important channels for advocating to legislators. Regular presentations at professional association meetings and conferences are needed to maintain the ongoing support of health professionals. Targeted communications messages to facility leaders through direct mailings or at planned (regional) meetings can be useful.

3.9. Financing

Identify and allocate sufficient resources to ensure the ongoing funding of the initiative.

Funding for the protection, promotion and support of breastfeeding in facilities providing maternity and newborn services should primarily come from government resources, with multi-year commitments. The activities need to be incorporated into regular government budget processes so that they can be funded in a sustainable way. Governments need to ensure that strategies and activities are designed in such a way that they can be funded by the government in a sustainable manner, in either the short or medium term. Suggestions for lower-cost and cost-effective approaches include:

- invest in updating and strengthening the coverage of breastfeeding and the skills required for the Ten Steps in the pre-service curricula for all relevant professionals (nurses, midwives, paediatricians, obstetricians, neonatologists, dietitians, etc.); over time, this will reduce the need for in-service training;
- if in-service training is needed, identify options that require less time (including travel time) from trainers, and that are flexible with regard to the hours when they are done (this might include electronic or online training), while ensuring quality and skills-building;
- incorporate BFHI-relevant indicators into existing systems for hospital licensing, monitoring, quality assurance and/or accreditation.

Where practicable, the costs of conducting external assessments of the BFHI standards could be charged to the facilities providing maternity and newborn services themselves. However, it is important that these charges do not create a barrier to participation in the assessment process.

While the BFHI should be a government responsibility, additional funders may be needed if the national budget cannot sustain the initiative because of competing priorities or inadequate resources. External funding sources, such as international donors, foundations or NGOs, may be necessary, either for specific interventions related to the BFHI, or for ongoing operational costs. However, there should be a concerted effort to shift towards government funding wherever possible, since external funding is generally unsustainable. Funding sources for the BFHI cannot have a conflict of interest with breastfeeding and should never be accepted from companies that market foods for infants and young children, or feeding bottles and teats.

4. Coordination of the Baby-friendly Hospital Initiative with other breastfeeding support initiatives outside facilities providing maternity and newborn services

Clearly, facilities providing maternity and newborn services constitute only one of many entry points for protecting, promoting, and supporting breastfeeding. Many other interventions are needed in antenatal care, postpartum care, communities and workplaces. It is critical that those working to improve policies and programmes in facilities providing maternity and newborn services integrate their work with those working in other areas.

For example, health-professional education on breastfeeding is typically quite weak and needs to be strengthened. Training on BFHI standards will need to be integrated into broader pre-service breastfeeding education for health professionals. The WHO *Model chapter for textbooks for medical students and allied health professionals* provides standard information on breastfeeding (85). Development of a medical school curriculum on breastfeeding would not generally be the responsibility of a BFHI coordination body, but contribution of the information on the BFHI standards for such a curriculum probably would.

Similarly, while the BFHI coordination body would not be responsible for improving breastfeeding counselling in primary health-care facilities or antenatal clinics, it would need to ensure that national standards for antenatal care do provide mothers with adequate knowledge about breastfeeding before they enter the facility providing maternity and newborn services.

The BFHI programme needs to work with existing programmes and initiatives to ensure that there are sufficient breastfeeding-support structures in the community to connect mothers to upon facility discharge, even though the programme itself does not carry out services in the community. Improved community support for breastfeeding, including improved quality of primary health care and strong peer networks, is critically important to ensure that mothers are able to successfully breastfeed. Pérez-Escamilla (2016) identified community support as a critical step for sustaining breastfeeding beyond the first few weeks of life (42). Interventions to increase breastfeeding rates have been shown to be much more effective when health services interventions are combined with community interventions (92).

The UNICEF- and WHO-led Global Breastfeeding Collective (93) has identified linkage between health facilities and communities, and encourages community networks that protect, promote and support breastfeeding as a top priority. The national BFHI coordination body should foster the development of numerous types of community breastfeeding support through primary health-care centres, community health workers, home visitors, breastfeeding clinics, nurses/midwives, lactation consultants, peer counsellors, and mother-to-mother support groups.

Improved
community support
for breastfeeding...
is critically important
to ensure that mothers
are able to successfully
breastfeed

5. Transition of BFHI implementation

This implementation guidance for the BFHI describes substantive changes to the Ten Steps and introduces a number of new strategies for national action and facility implementation. As such, countries will need to examine how to transition existing activities related to the BFHI, in light of these changes.

5.1. Countries with a well-functioning national “Baby-friendly” hospital designation programme

This updated implementation guidance moves the BFHI away from a traditional model that focused on facility designation as a main outcome and driver of practice changes. For those countries that currently have a well-functioning designation programme that is able to reach the majority of facilities providing maternity and newborn services nationwide, this new guidance should not be viewed as a reason to discontinue a successful programme.

The coordinating bodies in the countries in this category should develop a plan to incorporate the updated Ten Steps into the national BFHI standards. A transition plan is needed to indicate when facilities are expected to adhere to the updated standards and to use the new tools. Facilities that have already been designated and those in the pipeline for designation will need to be granted a reasonable amount of time to make changes to their practices before the new standards become mandatory. The coordinating body will need to:

- revise public materials on the Ten Steps;
- revise training courses and materials;
- develop or update materials to assist facilities with internal monitoring;
- revise external assessment standards.

In the past, many countries used Picasso’s picture, Maternity, for plaques or posters when designating facilities as “Baby-friendly”. WHO and UNICEF will no longer provide reproductions of this image and countries that are using designation as an incentive for BFHI compliance will need to develop their own imagery for this.

Where “mother-friendly” criteria that go beyond the Ten Steps have been incorporated into the designation criteria, these can remain in place, unless there is a reason to update them.

While maintaining a designation programme, these countries also need to work on integration of the Ten Steps into national policies and quality-improvement and maternal and child health programmes, as described in section 3. The responsibilities of a national breastfeeding or BFHI coordinating body summarized in Box 3 are equally applicable whether a country operates a designation programme or not.

5.2. Countries without an active or successful BFHI programme

For countries where the BFHI is currently not implemented, or where it has not been possible for “Baby-friendly” designation to reach a majority of facilities, it is recommended to focus on integration and institutionalization of the Ten Steps, with a quality-improvement approach at facility level and a solid, supportive policy environment and monitoring and accountability mechanisms. The activities in section 3 lay out priority actions to revitalize the BFHI in a sustainable way. Staff and management of facilities that were designated a while ago will need to be informed of the policy changes and updated standards and about the actions to undertake to comply with these standards.

Annex 1. Ten Steps to Successful Breastfeeding – revised 2018 version: comparison to the original Ten Steps and the new 2017 WHO guideline

Ten Steps to Successful Breastfeeding – revised 2018	Corresponding recommendations from WHO Guideline: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services (2017) (3)	Ten Steps in Protecting, promoting and supporting breast-feeding: the special role of maternity services (1989) (23)
Critical management procedures		
1a. The International Code of Marketing of Breast-milk Substitutes (25–27): Comply fully with the <i>International Code of Marketing of Breast-milk Substitutes</i> and relevant World Health Assembly resolutions.	N/A	N/A (incorporated in the hospital self-appraisal and monitoring guidelines and the external assessment)
1b. Infant feeding policy: Have a written infant feeding policy that is routinely communicated to staff and parents.	Recommendation 12: Facilities providing maternity and newborn services should have a clearly written breastfeeding policy that is routinely communicated to staff and parents.	Step 1: Have a written breastfeeding policy that is routinely communicated to all health-care staff.
1c. Monitoring and data-management systems: Establish ongoing monitoring and data-management systems.	N/A	N/A
2. Staff competency: Ensure that staff have sufficient knowledge, competence and skills to support breastfeeding.	Recommendation 13: Health-facility staff who provide infant feeding services, including breastfeeding support, should have sufficient knowledge, competence and skills to support women to breastfeed.	Step 2: Train all health-care staff in the skills necessary to implement this policy.
Key clinical practices		
3. Antenatal information: Discuss the importance and management of breastfeeding with pregnant women and their families.	Recommendation 14: Where facilities provide antenatal care, pregnant women and their families should be counselled about the benefits and management of breastfeeding.	Step 3: Inform all pregnant women about the benefits and management of breastfeeding.
4. Immediate postnatal care: Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.	Recommendation 1: Early and uninterrupted skin-to-skin contact between mothers and infants should be facilitated and encouraged as soon as possible after birth.	

Ten Steps to Successful Breastfeeding – revised 2018	Corresponding recommendations from WHO Guideline: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services (2017) (3)	Ten Steps in Protecting, promoting and supporting breast-feeding: the special role of maternity services (1989) (23)
	Recommendation 2: All mothers should be supported to initiate breastfeeding as soon as possible after birth, within the first hour after delivery.	Step 4: Help mothers initiate breastfeeding within a half-hour of birth.
5. Support with breastfeeding: Support mothers to initiate and maintain breastfeeding and manage common difficulties.	<p>Recommendation 3: Mothers should receive practical support to enable them to initiate and maintain breastfeeding and manage common breastfeeding difficulties.</p> <p>Recommendation 4: Mothers should be coached on how to express breast milk as a means of maintaining lactation in the event of their being separated temporarily from their infants.</p>	Step 5: Show mothers how to breastfeed and maintain lactation, even if they should be separated from their infants.
6. Supplementation: Do not provide breastfed newborns any food or fluids other than breast milk, unless medically indicated.	Recommendation 7: Mothers should be discouraged from giving any food or fluids other than breast milk, unless medically indicated.	Step 6: Give newborn infants no food or drink other than breastmilk, unless medically indicated.
7. Rooming-in: Enable mothers and their infants to remain together and to practise rooming-in throughout the day and night.	Recommendation 5: Facilities providing maternity and newborn services should enable mothers and their infants to remain together and to practise rooming-in throughout the day and night. This may not apply in circumstances when infants need to be moved for specialized medical care.	Step 7: Practise rooming in – allow mothers and infants to remain together – 24 hours a day.
8. Responsive feeding: Support mothers to recognize and respond to their infants' cues for feeding.	<p>Recommendation 6: Mothers should be supported to practise responsive feeding as part of nurturing care.</p> <p>Recommendation 8: Mothers should be supported to recognize their infants' cues for feeding, closeness and comfort, and enabled to respond accordingly to these cues with a variety of options, during their stay at the facility providing maternity and newborn services.</p>	Step 8: Encourage breastfeeding on demand.

Ten Steps to Successful Breastfeeding – revised 2018	Corresponding recommendations from WHO Guideline: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services (2017) (3)	Ten Steps in Protecting, promoting and supporting breast-feeding: the special role of maternity services (1989) (23)
<p>9. Feeding bottles, teats and pacifiers: Counsel mothers on the use and risks of feeding bottles, teats and pacifiers.</p>	<p>Recommendation 9: For preterm infants who are unable to breastfeed directly, non-nutritive sucking and oral stimulation may be beneficial until breastfeeding is established.</p> <p>Recommendation 10: If expressed breast milk or other feeds are medically indicated for term infants, feeding methods such as cups, spoons or feeding bottles and teats may be used during their stay at the facility.</p> <p>Recommendation 11: If expressed breast milk or other feeds are medically indicated for preterm infants, feeding methods such as cups or spoons are preferable to feeding bottles and teats.</p>	<p>Step 9: Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants.</p>
<p>10. Care at discharge: Coordinate discharge so that parents and their infants have timely access to ongoing support and care.</p>	<p>Recommendation 15: As part of protecting, promoting and supporting breastfeeding, discharge from facilities providing maternity and newborn services should be planned for and coordinated, so that parents and their infants have access to ongoing support and appropriate care.</p>	<p>Step 10: Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.</p>

Annex 2. Ten Steps to Successful Breastfeeding in lay terms

	Hospitals support mothers to breastfeed by ...	Because...
1. Hospital policies	<ul style="list-style-type: none"> • Not promoting infant formula, bottles or teats • Making breastfeeding care standard practice • Keeping track of support for breastfeeding 	Hospital policies help make sure that all mothers and babies receive the best care
2. Staff competency	<ul style="list-style-type: none"> • Training staff on supporting mothers to breastfeed • Assessing health workers' knowledge and skills 	Well-trained health workers provide the best support for breastfeeding
3. Antenatal care	<ul style="list-style-type: none"> • Discussing the importance of breastfeeding for babies and mothers • Preparing women in how to feed their baby 	Most women are able to breastfeed with the right support
4. Care right after birth	<ul style="list-style-type: none"> • Encouraging skin-to-skin contact between mother and baby soon after birth • Helping mothers to put their baby to the breast right away 	Snuggling skin-to-skin helps breastfeeding get started
5. Support mothers with breastfeeding	<ul style="list-style-type: none"> • Checking positioning, attachment and suckling • Giving practical breastfeeding support • Helping mothers with common breastfeeding problems 	Breastfeeding is natural, but most mothers need help at first
6. Supplementing	<ul style="list-style-type: none"> • Giving only breast milk unless there are medical reasons • Prioritizing donor human milk when a supplement is needed • Helping mothers who want to formula feed do so safely 	Giving babies formula in the hospital makes it hard to get breastfeeding going
7. Rooming-in	<ul style="list-style-type: none"> • Letting mothers and babies stay together day and night • Making sure that mothers of sick babies can stay near their baby 	Mothers need to be near their babies to notice and respond to feeding cues
8. Responsive feeding	<ul style="list-style-type: none"> • Helping mothers know when their baby is hungry • Not limiting breastfeeding times 	Breastfeeding babies whenever they are ready helps everybody
9. Bottles, teats, and pacifiers	<ul style="list-style-type: none"> • Counselling mothers about the use and risks of feeding bottles and pacifiers 	Everything that goes in the baby's mouth needs to be clean
10. Discharge	<ul style="list-style-type: none"> • Referring mothers to community resources for breastfeeding support • Working with communities to improve breastfeeding support services 	Learning to breastfeed takes time

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Appendix: Indicators for monitoring

Protecting, promoting and supporting

BREASTFEEDING IN FACILITIES

providing maternity and newborn services:
the revised Baby-friendly Hospital Initiative

Table 1. Recommended indicators for facility-based monitoring of the key clinical practices for the protection, promotion and support of breastfeeding

Key clinical practice	Proposed indicator definition	Target	Primary source	Additional sources
Step 3: Discuss the importance and management of breastfeeding with pregnant women and their families.	The percentage of mothers of preterm and term infants who received prenatal care at the facility who received prenatal counselling on breastfeeding	≥80%	Interviews with mothers of preterm and term infants	Clinical records
Step 4: Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.	The percentage of mothers of term infants whose babies were placed in skin-to-skin contact with them immediately or within 5 minutes after birth and that this contact lasted 1 hour or more	≥80%	Interviews of mothers of term infants	Clinical records
	SENTINEL INDICATOR: The percentage of term infants who were put to the breast within 1 hour after birth	≥80%	Clinical records	Interviews with mothers of term infants
Step 5: Support mothers to initiate and maintain breastfeeding and manage common difficulties.	The percentage of breastfeeding mothers of term infants who are able to demonstrate how to position their baby for breastfeeding and that the baby can suckle and transfer milk	≥80%	Interviews with mothers of term infants	
	The percentage of breastfeeding mothers of term infants who can describe at least two indicators of whether a breastfed baby consumes adequate milk	≥80%	Interviews with mothers of term infants	
	The percentage of mothers of breastfed preterm and term infants who can correctly demonstrate or describe how to express breast milk	≥80%	Interviews with mothers of preterm and term infants	Clinical records
Step 6: Do not provide breastfed newborns any food or fluids other than breast milk, unless medically indicated.	SENTINEL INDICATOR: The percentage of infants (preterm and term) who received only breast milk (either from their own mother or from a human milk bank) throughout their stay at the facility	≥80%	Clinical records	Interviews with mothers of preterm and term infants
Step 7: Enable mothers and their infants to remain together and to practise rooming-in 24 hours a day.	The percentage of mothers of term infants whose babies stayed with them since birth, without separation lasting for more than 1 hour	≥80%	Interviews with mothers of term infants	Clinical records

Key clinical practice	Proposed indicator definition	Target	Primary source	Additional sources
Step 8: Support mothers to recognize and respond to their infants' cues for feeding.	The percentage of breastfeeding mothers of term infants who can describe at least two feeding cues	≥80%	Interviews with mothers of term infants	
Step 9: Counsel mothers on the use and risks of feeding bottles, teats and pacifiers.	The percentage of breastfeeding mothers of preterm and term infants who report having been taught about the risks of using feeding bottles, teats and pacifiers	≥80%	Interviews with mothers of preterm and term infants	
Step 10: Coordinate discharge so that parents and their infants have timely access to ongoing support and care.	The percentage of mothers of preterm and term infants who report that a staff member has informed them where they can access breastfeeding support in their community	≥80%	Interviews with mothers of preterm and term infants	

Table 2. Recommended indicators for facility-based assessment of critical management procedures for the protection, promotion and support of breastfeeding

Recommendation	Proposed indicators	Target	Means of verification
Step 1a: Comply fully with the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions (the Code).	Evidence that all breast-milk substitutes, feeding bottles and teats used in the facility have been purchased through normal procurement channels and not received through free or subsidized supplies	Demonstrated	Review of facility purchasing records
	Display of products covered under the Code or items with names or logos of companies that produce breast-milk substitutes, feeding bottles and teats, or names of products covered under the Code	Not displayed	Observations in the facility
	Existence of a policy that describes how it abides by the Code, including procurement of breast-milk substitutes, not accepting support or gifts from producers or distributors of products covered by the Code and not giving samples of breast-milk substitutes, feeding bottles or teats to mothers	Exists	Review of infant feeding policy
	The percentage of health professionals who provide antenatal, delivery and/or newborn care who can explain at least two elements of the Code	≥80%	Interviews with clinical staff
Step 1b: Have a written infant feeding policy that is routinely communicated to staff and parents.	Existence of a written infant feeding policy that addresses the implementation of all eight key clinical practices of the Ten Steps, Code implementation, and regular competency assessment	Exists	Review of infant feeding policy
	Display of a summary of the policy for pregnant women, mothers and their families	Displayed	Observation of posted policy
	Alignment of clinical protocols or standards related to breastfeeding and infant feeding with BFHI standards and current evidence-based guidelines.	In alignment	Review of clinical protocols and standards
	The percentage of clinical staff who provide antenatal delivery and/or newborn care who can explain at least two elements of the infant feeding policy that influence their role in the facility	≥80%	Interviews with clinical staff

Recommendation	Proposed indicators	Target	Means of verification
Step 1c: Establish ongoing monitoring and data-management systems.	Existence of a protocol for an ongoing monitoring and data-management system to comply with the eight key clinical practices	Exists	Documentation of protocol
	The frequency with which clinical staff at the facility meet to review implementation of the system	At least every 6 months	Documentation meeting schedule
Step 2: Ensure that staff have sufficient knowledge, competence and skills to support breastfeeding.	The percentage of health professionals who provide antenatal, delivery and/or newborn care who report they have received pre-service or in-service training on breastfeeding during the previous 2 years	≥80%	Interviews with clinical staff
	The percentage of health professionals who report receiving competency assessments in breastfeeding in the previous 2 years	≥80%	Interviews with clinical staff
	The percentage of health professionals members who provide antenatal, delivery, and/or newborn care who are able to correctly answer three out of four questions on breastfeeding knowledge and skills to support breastfeeding	≥80%	Interviews with clinical staff

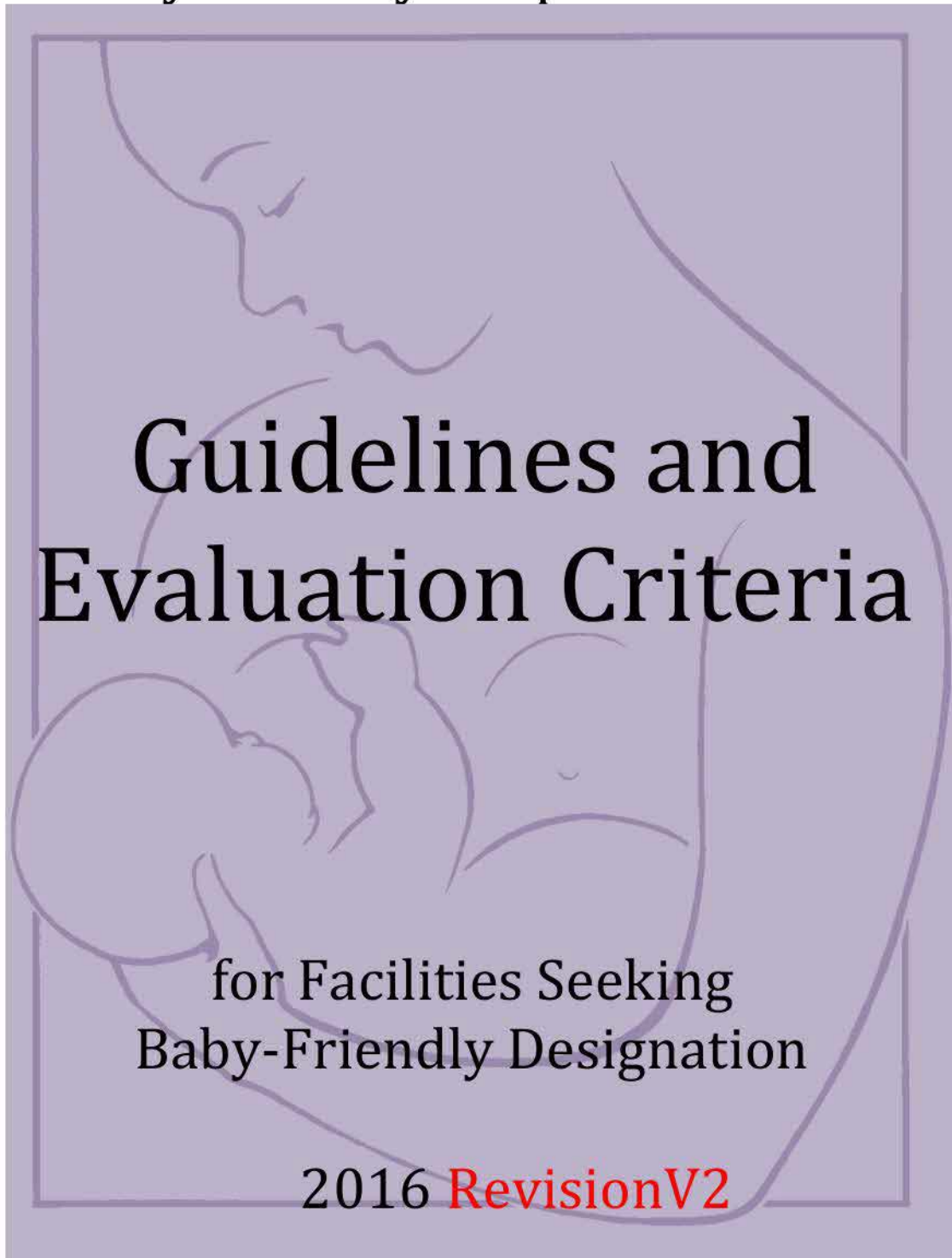
Table 3. Indicators for national and subnational monitoring of protection, promotion and support of breastfeeding in facilities providing maternity and newborn services

Indicator	Definition	Primary source	Possible additional sources
Global Nutrition Monitoring Framework Indicators			
Exclusive breastfeeding in infants aged under 6 months	The percentage of infants aged 0–5 months who received only breast milk during the previous day	Household surveys (MICS, DHS, etc.)	
Births In Baby-friendly facilities (“BFHI coverage”)	The percentage of births occurring in facilities that have been designated as “Baby-friendly”, have “passed” external assessment, or have met a specific level of compliance with BFHI standards (as per the national programme) within the past 5 years	Reports on programme implementation; national database where present	
Clinical practice indicators			
Antenatal counselling	The percentage of mothers of who received antenatal counselling on breastfeeding	Household surveys (MICS, DHS, etc.)	HMIS, exit interviews, facility surveys
Early skin-to-skin contact	The percentage of mothers who had skin-to-skin contact with their baby immediately or within 5 minutes after birth that lasted 1 hour or more	Household surveys (MICS, DHS, etc.)	HMIS, Exit interviews, facility surveys
Early initiation of breastfeeding	The percentage of mothers who put their infant to the breast within 1 hour after birth	Household surveys (MICS, DHS, etc.)	HMIS, exit interviews, facility surveys
Support with breastfeeding	The percentage of mothers who received support with learning to breastfeed after delivery	Household surveys (MICS, DHS, etc.)	HMIS, exit interviews, facility surveys
Exclusive breastfeeding during facility stay	The percentage of mothers reporting that their infants received only breast milk (either from their own mother or from a human milk bank) throughout their stay at a facility	Household surveys (MICS, DHS, etc.)	HMIS, exit interviews, facility surveys
Rooming-in	The percentage of mothers whose babies stayed with them since birth, without separation lasting for more than 1 hour	Household surveys (MICS, DHS, etc.)	HMIS, exit interviews, facility surveys

Indicator	Definition	Primary source	Possible additional sources
Referral to community support	The percentage of mothers who report that they were informed where they can access breastfeeding support in their community	Household surveys (MICS, DHS, etc.)	HMIS, exit interviews, facility surveys
Overall compliance with BFHI standards (alternative BFHI coverage indicator)	The percentage of mothers answering affirmatively on at least 6 of the above 7 practices	Household surveys (MICS, DHS, etc.)	HMIS, exit interviews, facility surveys
BFHI programmatic output indicators			
Regulation of BFHI standards (if regulation is decentralized to provincial level)	The percentage of provinces/states/districts with regulations on Baby-friendly standards	Reports (to be defined at country level)	
Pre-service training on the BFHI standards	The percentage of newly graduated health professionals who received training on the updated BFHI standards	Reports (to be defined at country level)	
In-service training on the BFHI standards	The percentage of practising health professionals who received in-service training on the updated BFHI standards	Reports (to be defined at country level)	
Ongoing operation of the external assessment process	The percentage of facilities providing maternity and newborn services that have completed an external assessment in the past 3–5 years	Reports (to be defined at country level)	

BFHI: Baby-friendly Hospital Initiative; DHS: demographic and health survey; HMIS: health management information system; MICS: multiple indicator cluster survey.

The Baby-Friendly Hospital Initiative



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This document is an adaptation of the following documents:

- The UNICEF/WHO *Global Criteria for the Baby-Friendly Hospital Initiative*, developed in 1991
- The *Guidelines & Evaluation Criteria for the U.S. Baby-Friendly Hospital Initiative*, developed in 1996 by the United States Fund for UNICEF and Wellstart International
- The 2004 adaptation of the U.S. *Guidelines & Evaluation Criteria for the U.S. Baby-Friendly Hospital Initiative*
- The 2006 UNICEF/WHO *Global Criteria for the BFHI*
- The 2010 adaptation of the U.S. *Guidelines and Evaluation Criteria for Facilities Seeking Baby-Friendly Designation*

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Dedication



Audrey J. Naylor, MD, DrPH

Baby-Friendly USA, Inc. dedicates the 2016 edition of the *Guidelines and Evaluation Criteria* to Audrey J. Naylor, MD, DrPH. Dr. Naylor was a visionary and passionate leader who devoted her career to improving maternity care practices throughout the world to support breastfeeding and mother-baby bonding. In 1985, she co-founded Wellstart International, a nonprofit organization established to educate health care providers on the importance and management of optimal infant and young child feeding. She was a driving force in both international and U.S. efforts to promote breastfeeding as the normal way to feed infants and young children. She was a staunch advocate for the Baby-Friendly Hospital Initiative, helping to shape both the Ten Steps to Successful Breastfeeding and the Initiative itself.

Dr. Naylor was a founding member of the World Alliance of Breastfeeding Action, the United States Breastfeeding Committee, the Academy of Breastfeeding Medicine, the Section on Breastfeeding of the American Academy of Pediatrics and helped to launch the U.S. Baby-Friendly Hospital Initiative. She was an experienced medical school educator and had been a member of several medical school faculties, including Ohio State University College of Medicine, the University of Southern California School of Medicine, The University of California San Diego School of Medicine and The University of Vermont College of Medicine where she was a Clinical Professor of Pediatrics (voluntary, part-time).

Dr. Naylor passed away on June 23, 2016. The field of lactation has lost one of its greatest leaders. Her legacy is substantial and will continue to live through our work.

Preamble to the U.S. Baby-Friendly Guidelines and Evaluation Criteria

Human milk provided by direct breastfeeding is the normal way to feed an infant. There are very few true contraindications to breastfeeding and scientific evidence overwhelmingly indicates that it is nutritionally superior, offers substantial immunological and health benefits, facilitates mother-baby bonding, and should be promoted and supported to ensure the best health for women and their children. Breastfeeding is the single most powerful and well-documented preventative modality available to health care providers to reduce the risk of common causes of infant morbidity. Significantly lower rates of diarrhea, otitis media, lower respiratory tract infections, Type 1 and Type 2 diabetes, childhood leukemia, necrotizing enterocolitis, and Sudden Infant Death Syndrome occur among those who were breastfed.¹ Women who breastfeed have a lower risk of Type 2 diabetes and breast and ovarian cancers.² Evidence suggests that reduction in the risk of cardiovascular and other related diseases may be added to the benefits of breastfeeding for women.³ The American Academy of Pediatrics, the American Congress of Obstetricians and Gynecologists, the Centers for Disease Control and Prevention, and the World Health Organization all recommend exclusive breastfeeding for about 6 months and continued breastfeeding while adding complimentary foods for one year and beyond.

The U.S. Department of Health and Human Services has included breastfeeding among the national Healthy People (HP) objectives since their inception for the year 1990. The HP2020⁴ objectives state:

MICH-21.1	Increase the proportion of infants who are ever breastfed	Target 81.9%
MICH-21.2	Increase the proportion of infants who are breastfed at 6 months	Target 60.6%
MICH-21.3	Increase the proportion of infants who are breastfed at 1 year	Target 34.1%
MICH-21.4	Increase the proportion of infants who are breastfed exclusively through 3 months	Target 46.2%
MICH-21.5	Increase the proportion of infants who are breastfed exclusively through 6 months	Target 25.5%
MICH-23	Reduce the proportion of breastfed newborns who receive formula supplementation within the first 2 days of life	Target 14.2%

¹ Stanley Ip, et al. "Breastfeeding and maternal and infant health outcomes in developed countries," Evidence Report/Technology Assessment NO. 153 (Prepared by Tufts-New England Medical Center Evidence-Based Practice Center, under Contract No. 290-02-0022), AHRQ Publication No. 07-E007, (Rockville, MD: Agency for Healthcare Research and Quality, 2007).

² Ibid.

³ E. B. Schwarz, et al. "Duration of lactation and risk factors for maternal cardiovascular disease," *Obstetrics & Gynecology* 113, 5 (2009): 97482.

⁴ Healthy People 2020, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion Accessed June 21, 2016, <https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives>

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MICH-24 Increase the proportion of live births that occur in facilities that Target 8.1%
provide recommended care for lactating mothers and their babies

Despite the significant gains made during the past few years, the initiation, duration, and exclusivity of breastfeeding continue to lag behind the national objectives, particularly among the most vulnerable populations of African American and low income women. In 2012, approximately 80% of all women initiated breastfeeding; however, only 66% of non-Hispanic black women and 74% of women with incomes below the poverty line initiated breastfeeding.⁵

While causes of this trend are multifactorial and complex, health care practices have been shown to play a fundamental role in impacting breastfeeding initiation, exclusivity, and duration. Unsupportive practices during the perinatal period can disrupt the unique and critical link between the prenatal education and the community postpartum support provided after discharge from the birthing facility. Conversely, supportive practices positively impact breastfeeding outcomes. The Ten Steps to Successful Breastfeeding, which form the foundation of the Baby-Friendly Hospital Initiative, are a package of evidence-based practices shown to improve breastfeeding outcomes. Studies have shown that the more steps a mother reports experiencing, the more likely she is to meet her breastfeeding goals.^{6,7}

Numerous government and professional organizations actively encourage a strong program of information and support to promote the successful establishment and maintenance of breastfeeding, including:

- ❖ [Academy of Breastfeeding Medicine](#)
- ❖ [Academy of Nutrition and Dietetics](#)
- ❖ [American Academy of Family Physicians](#)
- ❖ [American Academy of Nursing](#)
- ❖ [American Academy of Pediatrics](#)
- ❖ [American College of Nurse-Midwives](#)
- ❖ [American Congress of Obstetricians and Gynecologists](#)
- ❖ [American Nurses Association](#)
- ❖ [American Public Health Association](#)
- ❖ [Association of Women's Health, Obstetric and Neonatal Nurses](#)
- ❖ [Centers for Disease Control and Prevention](#)
- ❖ [National Academies of Science, Engineering and Medicine](#)

⁵ "Rates of Any and Exclusive Breastfeeding by Socio-demographics among Children Born in 2012," *National Immunization Survey, Centers for Disease Control and Prevention, Department of Health and Human Services*, Accessed June 21, 2016, www.cdc.gov/breastfeeding/data/nis_data/rates-any-exclusive-bf-socio-dem-2012.htm

⁶ Ann M. DiGirolamo, Laurence M. Grummer-Strawn, Sara B. Fein, "Effect of maternity-care practices on breastfeeding," *Pediatrics* 122, 2 (2008)

⁷ Rafael Perez-Escamilla, Josefa L. Martinez and Sofia Segura-Perez, "Impact of the Baby-friendly Hospital Initiative on breastfeeding and child health outcomes: a systematic review," *Maternal & Child Nutrition*, doi: 10.1111/mcn.12294.

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- ❖ [National WIC Association](#)
- ❖ [Office on Women's Health – United States Department of Health and Human Services](#)
- ❖ [United States Breastfeeding Committee](#)
- ❖ [United States Preventive Services Task Force](#)
- ❖ [United States Surgeon General](#)

The diverse benefits of breastfeeding translate into hundreds of dollars of savings at the family level and billions of dollars at the national level through decreased hospitalizations and pediatric visits. Researchers have estimated that were the national initiation and 6 months goals (above) to be met, between 3.6 and 13 billion dollars would be saved on pediatric health care costs.^{8,9} Consequently, activities to promote the national objectives are clearly among the best and most cost-effective health promotional strategies available.

The Baby-Friendly Hospital Initiative (BFHI) was established in 1991 by the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO). The BFHI is a global program to encourage and recognize birthing facilities that offer an optimal level of care for infant feeding and mother-baby bonding. The core components of the BFHI are the UNICEF/WHO Ten Steps to Successful Breastfeeding, which are designed to facilitate the role of the birthing facility in providing women the information, care practices, and opportunity to breastfeed, regardless of the method of birth. More than 170 countries have undertaken implementation of the Ten Steps to Successful Breastfeeding, resulting in the designation of more than 20,000 birth facilities throughout both the developing and industrialized world. The BFHI has been endorsed by hundreds of organizations worldwide.

In the United States, Wellstart International, in cooperation with the U.S. Fund for UNICEF, piloted the development of tools for the assessment of the first U.S. Baby-Friendly hospitals, including the original *Guidelines and Evaluation Criteria*, which provided the basic guidance for birthing facility implementation of the program. In 1997, Baby-Friendly USA, Inc. was created at the request of the U.S. Fund for UNICEF to administer the BFHI program in U.S. birthing facilities.

⁸ Jon Weimer, "The Economic Benefits of Breastfeeding: A Review and Analysis," *ERS Food Assistance and Nutrition Research Report* 13, (2001)

⁹ M Bartick, A Reinhold, "The burden of suboptimal breastfeeding in the United States: a pediatric cost analysis," *Pediatrics* 125, 5 (2010): 104856.

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The Guidelines and Evaluation Criteria for Hospital and Birthing Center Implementation of the U.S. Baby-Friendly Hospital Initiative

The *guidelines* in this document describe the standard of care which facilities should strive to achieve for all patients, while the accompanying *criteria* provide the specific quantifiable measures used by Baby Friendly USA (BFUSA) assessors to determine the birthing facility's conformity with the BFHI.

The U.S. BFHI *Guidelines and Evaluation Criteria* and the assessment and accreditation processes are predicated on the following tenets:

1. Well-constructed, comprehensive policies effectively guide staff to deliver evidence-based care.
2. Well-trained staff provide current, evidence-based care.
3. Monitoring of practice is required to assure adherence to policy.
4. Breastfeeding has been recognized by scientific authorities as the optimal method of infant feeding and should be promoted as the norm within all maternal and child health care facilities.
5. The most sound and effective procedural approaches to supporting breastfeeding and human lactation in the birthing environment that have been documented in the scientific literature to date should be followed by the health facility.
6. The health care delivery environment should be neither restrictive nor punitive and should facilitate informed health care decisions on the part of the mother and her family.
7. The health care delivery environment should be sensitive to cultural and social diversity.
8. The mother and her family should be protected within the health care setting from false or misleading product promotion and/or advertising which interferes with or undermines informed choices regarding infant health care practices.
9. When a mother has chosen not to breastfeed, when supplementation of breastfeeding is medically indicated, or when supplementation is chosen by the breastfeeding mother (after appropriate counseling and education), it is crucial that safe and appropriate methods of formula mixing, handling, storage, and feeding are taught to the parents.
10. Recognition as a Baby-Friendly institution should have both national and international credibility and prestige, so that it is marketable to the community, increases demand, and thereby improves motivation among facilities to participate in the Initiative.
11. Participation of any facility in the U.S. BFHI is entirely voluntary and is available to any institution providing birthing services. Each participating facility assumes full responsibility for assuring that its implementation of the BFHI is consistent with all of its safety protocols.

Step 1: Have a written breastfeeding policy that is routinely communicated to all health care staff.

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- 1.1 Guideline:** Breast milk should be the standard for infant feeding. All infants in the facility should be considered to be breastfeeding infants unless, after giving birth and being offered help to breastfeed, the mother has specifically stated that she has no plans to breastfeed. (See Steps 4 and 5.) The facility should have a written policy that addresses the implementation of Steps 2 through 10, as well as the International Code of Marketing of Breast-milk Substitutes (International Code), and communicates the Baby-Friendly philosophy that mothers room with, care for, and feed their own well infants and should be protected from the promotion of breast milk substitutes and other efforts that undermine an informed feeding choice. All areas of the facility that potentially interact with childbearing women and infants will have language in their policies about the promotion, protection, and support of breastfeeding. Policies of all departments will support, and will not countermand, the facility's breastfeeding policy, and will be based on recent and reliable scientific evidence.
- 1.1.1 Criterion for evaluation:** The facility will have written maternity care and infant feeding policies that address all Ten Steps, protect breastfeeding, and adhere to the International Code. All areas of the facility that potentially interact with childbearing women and infants will have language in their policies about the promotion, protection, and support of breastfeeding. Policies of all departments will not countermand the facility's breastfeeding policy. Review of all clinical protocols, standards, and educational materials related to breastfeeding and infant feeding used by the maternity services indicates that they are in line with the BFHI standards and current evidence-based guidelines.
- 1.1.2 Criterion for evaluation:** The nursing director/manager will be able to identify the health care professional(s) who has ultimate responsibility for assuring implementation of the breastfeeding policy.
- 1.2 Guideline:** The designated health care professional(s) should ensure that maternity care and infant feeding policies are readily available for reference by all staff who care for mothers, infants, and/or young children and are communicated to new employees in their orientation and at other times as determined by the health care facility. The facility should have a mechanism for monitoring the effectiveness of the maternity care and infant feeding policies that is incorporated into routine quality improvement procedures.
- 1.2.1 Criterion for evaluation:** The nursing director/manager of the maternity unit and/or the designated health care professional within the facility will be able to locate the maternity care and infant feeding policies and describe how the other staff, including new employees, are made aware of the content.
- 1.2.2 Criterion for evaluation:** Of randomly selected maternity staff members, at least 80% will confirm that they are aware of the facility's maternity care and infant feeding policies, know where the policies are kept or posted, and have received orientation regarding the policies.

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1.2.3 Criterion for evaluation: The nursing director/manager of the maternity unit and/or the designated health care professional within the facility will be able to produce evidence of routine quality improvement procedures that have monitored the maternity care and infant feeding policies.

1.3 Guideline: The Ten Steps to Successful Breastfeeding (Ten Steps) and a statement indicating the facility's adherence to the WHO International Code requirements related to the purchase and promotion of breast milk substitutes, bottles, nipples, pacifiers, and other infant feeding supplies should be prominently displayed in all areas that serve mothers, infants, and young children. This information should be available in the language(s) most commonly understood by patients, and, if needed and possible, should be available in appropriate formats for illiterate and visually impaired patients.

1.3.1 Criterion for evaluation: The Ten Steps and the statement indicating the facility's adherence to the WHO International Code restricting the promotion of breast milk substitutes, bottles, nipples, and other infant feeding supplies will be prominently displayed in all areas of the health care facility which serve mothers, infants, and/or young children, including labor and delivery, the postpartum unit, all infant and child care areas, affiliated prenatal services, ultrasound, screening, antenatal testing, and the emergency room. This information will be displayed in the language(s) most commonly understood by patients.

Step 2: Train all health care staff in the skills necessary to implement this policy.

2.1 Guideline: A designated health care professional should be responsible for assessing needs, planning, implementing, evaluating, and periodically updating competency-based training in breastfeeding and parent teaching for formula preparation and feeding for all health care staff caring for mothers, infants, and/or young children. Such training may differentiate the level of competency required and/or needed based on staff function, responsibility, and previously acquired training and should include documentation that essential skills have been mastered.

Training for nursing staff on maternity should comprise a total of 20 hours, inclusive of the 15 sessions identified by UNICEF/WHO and 5 hours of supervised clinical experience. (See Appendix A.) Clinical competency verification will be a focus of all staff training. Maternity staff will receive training and mentorship necessary to attain competence in counseling the feeding decision, providing skin-to-skin contact in the immediate postpartum period and beyond, assisting and assessing the mother and infant in achieving comfortable and effective positioning and attachment at the breast, counseling mothers regarding maintaining exclusive breastfeeding, learning feeding cues, assuring rooming-in, teaching and assisting mothers with hand expression of milk, teaching formula preparation and feeding to parents when necessary, and assisting mothers in finding support upon discharge.

Health care providers (physicians, midwives, physician assistants, and advanced practice registered nurses) with privileges for labor, delivery, maternity, and nursery/newborn care

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should have a minimum of 3 hours of breastfeeding management education pertinent to their role. At minimum, all health care providers must have a true understanding of the benefit of exclusive breastfeeding, physiology of lactation, how their specific field of practice impacts lactation, and how to find out about safe medications for use during lactation. If health care providers do not teach specific skills, it is not expected that they be able to describe or demonstrate them. However, it is expected that they will know to whom to refer a mother for help with matters for which they do not possess the skills.

The facility should determine the amount and content of training required by staff in other units and roles by their anticipated workplace exposure to mothers and infants. The content and number of hours of training for staff working outside maternity will be developed by each facility, based on job description and workplace exposure to breastfeeding couples.

Examples of training for staff outside of maternity include, but are not limited to:

- Pharmacist - importance of exclusive breastfeeding, medications acceptable for breastfeeding
- Social worker, discharge planner - importance of exclusive breastfeeding, community resources that support breastfeeding
- Anesthesiologist - importance of exclusive breastfeeding, importance of immediate skin-to-skin contact
- Radiology - importance of exclusive breastfeeding, where to find out about safe medications for use during lactation, where to find appropriate information on use of radioisotopes during lactation
- Dietary - importance of exclusive breastfeeding, practices that support breastfeeding
- Housekeeping staff - importance of exclusive breastfeeding, practices that support breastfeeding, the facility's philosophy on infant nutrition, who to call when a mother needs help

2.1.1 Criterion for evaluation: The head of maternity services will report that all health care staff members who have any contact with pregnant women, mothers, and/or infants have received sufficient orientation on the infant feeding policies.

2.1.2 Criterion for evaluation: The head of maternity services will be able to identify the health care professional(s) responsible for all aspects of planning, implementing, and evaluating staff training in breastfeeding and parent teaching for formula preparation and feeding.

2.1.3 Criterion for evaluation: The designated health care professional(s) will provide documentation that training for breastfeeding and parent teaching for formula preparation and feeding is provided for all health care staff caring for mothers, infants and/or young children and that new staff are oriented on arrival and scheduled for training within 6 months (for example, by providing a list of new staff who are scheduled for training).

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- 2.1.4 Criterion for evaluation:** If training acquired prior to employment with this facility is accepted as a means of meeting the minimum competencies, the designated health care professional will be able to describe the process used to verify the previously acquired competencies.
- 2.1.5 Criterion for evaluation:** The designated health care professional(s) will provide documentation of training offered to staff outside the maternity unit.
- 2.1.6 Criterion for evaluation:** A copy of the curricula or course outlines for competency based training in breastfeeding, lactation management, and parent teaching for formula preparation and feeding will be available for review and a schedule for training all newly hired staff will exist. Maternity staff training will cover Steps 3 through 10 and include the topics and subtopics of all 15 sessions identified by the UNICEF/WHO 20 hour curriculum. (See Appendix A.) The training will include a minimum of five hours of supervised clinical experience.
- 2.1.7 Criterion for evaluation:** Of randomly selected maternity staff members, including the nursery staff and health care providers with privileges, at least 80% will confirm that they have completed the described training and competency verification, or, if they have been on the unit less than 6 months, have at minimum been oriented.
- 2.1.8 Criterion for evaluation:** Of health care providers with privileges, at least 80% will be able to correctly answer 4 out of 5 questions demonstrating they have a true understanding of the benefit of exclusive breastfeeding, physiology of lactation, how their specific field of practice impacts lactation, and how to find out about safe medications for use during lactation.
- 2.1.9 Criterion for evaluation:** Of randomly selected maternity staff members, at least 80% will be able to answer 4 out of 5 questions on breastfeeding management correctly.
- 2.1.10 Criterion for evaluation:** Of randomly selected maternity staff members and health care providers, at least 80% will be able to identify 2 topics to discuss with women who are considering feeding their infants something other than human milk.

Step 3: Inform all pregnant women about the benefits and management of breastfeeding.

Guidelines and criteria only for facilities with an affiliated prenatal clinic or services

- 3.1 Guideline:** Education about breastfeeding, including individual counseling, should be made available to pregnant women for whom the facility or its associated services provide prenatal care. The education should begin in the first trimester whenever possible.

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- 3.1.1 Criterion for evaluation:** If the facility has an affiliated prenatal clinic or services, the nursing director/manager will report that individual counseling or group education on breastfeeding is given to at least 80% of the pregnant women using those services.
- 3.2 Guideline:** The education should cover the importance of exclusive breastfeeding, nonpharmacological pain relief methods for labor, the importance of early skin-to-skin contact, early initiation of breastfeeding, rooming-in on a 24-hour basis, feeding on demand or baby-led feeding, frequent feeding to help assure optimal milk production, effective positioning and attachment, exclusive breastfeeding for the first 6 months, and that breastfeeding continues to be important after 6 months when other foods are given. Individualized education on the documented contraindications to breastfeeding and other special medical conditions should be given to pregnant women when indicated.
- 3.2.1 Criterion for evaluation:** A written description of the content of the prenatal education will be available and will cover, at minimum, the importance of breastfeeding, the importance of exclusive breastfeeding for about 6 months, and basic breastfeeding management.
- 3.2.2 Criterion for evaluation:** Of the randomly selected pregnant women in the third trimester who are using the facility prenatal services, at least 80% will confirm that a staff member has talked with them or offered a group talk that includes information on breastfeeding.
- 3.2.3 Criterion for evaluation:** Of the randomly selected pregnant women in the third trimester who are using the facility prenatal services, at least 80% are able to adequately describe what was discussed concerning 2 of the following topics: importance of skin-to-skin contact, rooming-in, or risks of supplements while breastfeeding in the first 6 months.

Guidelines and criteria for all facilities with or without an affiliated prenatal clinic or services

- 3.3 Guideline:** All facilities should foster the development of or coordinate services with programs that make education about breastfeeding available to pregnant women. All facilities should foster relationships with community-based programs that make available individual counseling or group education on breastfeeding and coordinate messages about breastfeeding with these programs. The education should begin in the first trimester whenever possible.
- 3.3.1 Criterion for evaluation:** The nursing director/manager will report that the facility fosters relationships with community-based programs that make available individual counseling or group education on breastfeeding and coordinates messages about breastfeeding with these programs.
- 3.3.2 Criterion for evaluation:** The nursing director/manager will report that the facility has fostered the development of or coordinated services with one or more of the following

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programs: in-house breastfeeding education, childbirth education, hospital preregistration visits, hospital tours, in-patient services, etc.

- 3.4 Guideline:** Prenatal education should cover the importance of exclusive breastfeeding, nonpharmacological pain relief methods for labor, the importance of early skin-to-skin contact, early initiation of breastfeeding, rooming-in on a 24-hour basis, feeding on demand or baby-led feeding, frequent feeding to help assure optimal milk production, effective positioning and attachment, exclusive breastfeeding for the first 6 months, and the fact that breastfeeding continues to be important after 6 months when other foods are given. Individualized education on the documented contraindications to breastfeeding and other special medical conditions should be given to pregnant women when indicated.

- 3.4.1 Criterion for evaluation:** A written description of in-house and/or community-based programs and projects the facility has fostered will be available and will cover, at minimum, the importance of breastfeeding, the importance of exclusive breastfeeding for about 6 months, and basic breastfeeding management (e.g. skin-to-skin contact, rooming-in, and risks of supplements while breastfeeding in the first 6 months).

Step 4: Help mothers initiate breastfeeding within one hour of birth.

This Step is now interpreted as:

Place infants in skin-to-skin contact with their mothers immediately following birth for at least an hour and encourage mothers to recognize when their infants are ready to breastfeed, offering help if needed.

This Step applies to all infants, regardless of feeding method.

- 4.1 Guideline:** All mothers should be given their infants to hold with uninterrupted and continuous skin-to-skin contact immediately after birth and until the completion of the first feeding, unless there are documented medically justifiable reasons for delayed contact or interruption. Routine procedures (e.g. assessments, Apgar scores, etc.) should be done with the infant skin-to-skin with the mother. Procedures requiring separation of the mother and infant (bathing, for example) should be delayed until after this initial period of skin-to-skin contact and should be conducted, whenever feasible, at the mother's bedside. Additionally, skin-to-skin contact should be encouraged throughout the hospital stay.
- 4.1.1 Criterion for evaluation:** Of randomly selected mothers in the postpartum unit who have had normal vaginal births, at least 80% will confirm that their infants were placed in skin-to-skin contact with them immediately after birth and that skin-to-skin contact continued uninterrupted until the completion of the first feeding (or for at least one hour if not breastfeeding), unless there were documented medically justifiable reasons for delayed contact.

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- 4.1.2 Criterion for evaluation:** Of randomly selected mothers in the postpartum unit who have had normal vaginal births, at least 80% will confirm that they were encouraged to look for signs that their infants were ready to feed during this first period of contact and offered help if needed. (The infant should not be forced to feed, but rather, supported to do so when ready.)
- 4.1.3 Criterion for evaluation:** Observations of vaginal births, if necessary to confirm adherence to Step 4, show that (regardless of the mother's feeding intentions) at least 80% of infants are placed skin-to-skin with their mothers within 5 minutes after birth and are held continuously skin-to-skin until completion of the first feeding, or for at least one hour if not breastfeeding, unless there were documented medically justifiable reasons for delayed contact.
- 4.1.4 Criterion for evaluation:** Observations of vaginal births, if necessary to confirm adherence to Step 4, show that (regardless of the mother's feeding intentions) at least 80% of mothers are shown how to recognize the signs that their infants are ready to feed and offered help, or there are documented justifiable reasons for not following these procedures.
- 4.2 Guideline:** After cesarean birth, mothers and their infants should be placed in continuous, uninterrupted skin-to-skin contact as soon as the mother is responsive and alert, with the same staff support identified above regarding feeding cues, unless separation is medically indicated.
- 4.2.1 Criterion for evaluation:** Of randomly selected mothers in the postpartum unit who have had cesarean births of a healthy infant, at least 80% will confirm that their infants were placed in skin-to-skin contact with them as soon as the mother was responsive and alert and that skin-to-skin contact continued uninterrupted until completion of the first feeding (or at least one hour if not breastfeeding), unless there were documented medically justifiable reasons for delayed contact.
- 4.2.2 Criterion for evaluation:** Of randomly selected mothers in the postpartum unit who have had cesarean births of a healthy infant, at least 80% will confirm that they were encouraged to look for signs that their infants were ready to feed during this first period of contact and offered help if needed. (The infant should not be forced to feed, but rather, supported to do so when ready.)
- 4.2.3 Criterion for evaluation:** Observations of cesarean births and recovery, if necessary to confirm adherence to Step 4, show that (regardless of the mother's feeding intentions), at least 80% of infants are placed with their mothers and held continuously skin-to-skin as soon as the mother was responsive and alert and until completion of the first feeding.
- 4.2.4 Criterion for evaluation:** Observations of cesarean births and recovery, if necessary to confirm adherence to Step 4, show that (regardless of the mother's feeding intentions), at least 80% of mothers are shown how to recognize the signs that their infants are

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ready to feed and offered help, or there are documented justified reasons for not following these procedures.

- 4.3 Guideline:** In the event that a mother and/or infant are separated for documented medical reasons, skin-to-skin contact will be initiated as soon as the mother and infant are reunited.

- 4.3.1 Criterion for evaluation:** Of randomly selected mothers who gave birth either vaginally or via cesarean, at least 80% will confirm that in the event of medically-indicated separation, skin-to-skin contact was initiated when they were reunited with their infants.

Recommendation for facilities with an affiliated special care nursery or neonatal intensive care unit

- 4.4 Recommended guideline:** Mothers whose infants are being cared for in the special care nursery should be given the opportunity to practice Kangaroo Mother Care as soon as the infant is considered ready for such contact.

- 4.4.1 Recommended criterion for evaluation:** The facility has a quality improvement goal and tracking method to assure that at least 80% of randomly selected mothers with infants in special care will have the opportunity to practice Kangaroo Mother Care, unless there are documented medically justifiable reasons why they could not.

Step 5: Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.

- 5.1 Guideline:** Health care professionals should assess the mother's breastfeeding techniques and, if needed, should demonstrate appropriate breastfeeding positioning and attachment with the mother and infant, optimally within 3 hours and no later than 6 hours after birth. Prior to discharge, breastfeeding mothers should be educated on basic breastfeeding practices, including: 1) the importance of exclusive breastfeeding, 2) how to maintain lactation for exclusive breastfeeding for about 6 months, 3) criteria to assess if the infant is getting enough breast milk, 4) how to express, handle, and store breast milk, including manual expression, and 5) how to sustain lactation if the mother is separated from her infant or will not be exclusively breastfeeding after discharge.

- 5.1.1 Criterion for evaluation:** Of randomly selected postpartum mothers, at least 80% will report that nursing staff offered further assistance with breastfeeding the next time they fed their infants or within 6 hours of birth, or of when they were able to respond.

- 5.1.2 Criterion for evaluation:** Of randomly selected postpartum mothers, at least 80% of those who are breastfeeding will be able to demonstrate correct positioning and attachment with their own infants and will report that breastfeeding is comfortable for them.

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- 5.1.3 Criterion for evaluation:** Of randomly selected postpartum mothers, at least 80% of those who are breastfeeding will report that they were shown how to express their milk by hand.
- 5.1.4 Criterion for evaluation:** Of randomly selected health care staff caring for postpartum mothers, at least 80% will report that they teach mothers how to position and attach their infants for breastfeeding and are able to describe or demonstrate correct techniques for both.
- 5.1.5 Criterion for evaluation:** Of randomly selected health care staff caring for postpartum mothers, at least 80% will report that they teach mothers how to hand express breast milk and can describe or demonstrate an adequate technique for this.
- 5.2 Guideline:** Additional individualized assistance should be provided to high risk and special needs mothers and infants and to mothers who have breastfeeding problems or must be separated from their infants. The routine standard of care should include procedures that assure that milk expression is begun as soon as possible, but no later than 6 hours after birth, expressed milk is given to the infant as soon as the infant is medically ready, and the mother's expressed milk is used before any supplementation with breast milk substitutes when medically appropriate. For high risk and special needs infants who cannot be skin-to-skin immediately or cannot suckle, beginning manual expression within one hour is recommended. Assistance should be provided as needed.
- 5.2.1 Criterion for evaluation:** Of randomly selected mothers with infants in special care, at least 80% of those who are breastfeeding or intending to do so will report that they have been offered help to begin expressing and collecting milk as soon as possible, but no later than 6 hours after their infants' births, unless there is a medically justifiable reason to delay initiation of expression.
- 5.2.2 Criterion for evaluation:** Of randomly selected mothers with infants in special care, at least 80% of those who are breastfeeding or intending to do so report that they have been shown how to express their milk by hand or other method.
- 5.2.3 Criterion for evaluation:** Of randomly selected mothers with infants in special care, at least 80% of those who are breastfeeding or intending to do so can adequately describe and demonstrate how they were shown to express their milk.
- 5.2.4 Criterion for evaluation:** Of randomly selected mothers with infants in special care, at least 80% of those who are breastfeeding or intending to do so will report that they have been told they need to breastfeed or express their milk 8 times or more every 24 hours to establish and maintain their milk supply.
- 5.3 Guideline:** Mothers who feed formula should receive written instruction, not specific to a particular brand, and verbal information about safe preparation, handling, storage, and feeding of infant formula. Staff should document completion of formula preparation instruction and

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safe feeding in the medical record. This information should be given on an individual basis only to women who are feeding formula or mixed feeding their infants.

- 5.3.1 Criterion for evaluation:** Of maternity staff members, at least 80% can describe how mothers who are feeding formula can be assisted to safely prepare and feed formula to their infants.
- 5.3.2 Criterion for evaluation:** Of mothers who are feeding formula, at least 80% will report that someone discussed their feeding choice with them.
- 5.3.3 Criterion for evaluation:** Of mothers who are feeding formula, at least 80% will report that they have been provided education about preparing and giving their infants feeds and can describe the advice they were given.

Step 6: Give infants no food or drink other than breast milk, unless medically indicated.

Exclusive breast milk feeding shall be the feeding method expected from birth to discharge.

Each facility should track its rate of formula supplementation of breastfed infants. Facilities should strive to reach the Healthy People 2020 goal for exclusive breastfeeding. The rate of supplementation for nonmedical reasons should be analyzed and compared to the annual rate of supplementation of breastfed infants reported by the Centers for Disease Control and Prevention (CDC) National Immunization Survey data for the geographic region in which the facility is located. In addition, a year-by-year reduction in non-medically indicated supplementation is expected in Baby-Friendly designated facilities.

6.1 Guideline: When a mother specifically states that she has no plans to breastfeed or requests that her breastfeeding infant be given a breast milk substitute, the health care staff should first explore the reasons for this request, address the concerns raised, and educate her about the possible consequences to the health of her infant and the success of breastfeeding. If the mother still requests a breast milk substitute, her request should be granted and the process and the informed decision should be documented. Any other decisions to give breastfeeding infants food or drink other than breast milk should be for acceptable medical reasons and require a written order documenting when and why the supplement is indicated. (See Appendix B.)

- 6.1.1 Criterion for evaluation:** Of randomly selected mothers who are breastfeeding, at least 80% will report that:
- to the best of their knowledge, their infants have received no food or drink other than breast milk while in the facility, or
 - that formula has been given for a medically acceptable reason, or
 - that formula has been given in response to a parental request.
- 6.1.2 Criterion for evaluation:** Of breastfeeding mothers whose infants have been given food or drink other than breast milk, at least 80% of those who have no acceptable medical

reason will report that the health care staff explored the reasons for and the possible negative consequences of the mother's decisions.

- 6.1.3 Criterion for evaluation:** Of infants who have been given food or drink other than breast milk, at least 80% will have the reasons for supplementation and evidence of parental counseling (in the event of parental choice) clearly documented in the medical record.
- 6.1.4 Criterion for evaluation:** Of randomly selected mothers who have decided to feed formula, at least 80% will report that the staff discussed with them the various feeding options and helped them to decide what was suitable in their situations.
- 6.1.5 Criterion for evaluation:** Of mothers with infants in special care who have decided to feed formula, at least 80% will report that staff have talked with them about the risks and benefits of the various feeding options, including feeding expressed breast milk.
- 6.1.6 Criterion for evaluation:** Observations in the postpartum unit/rooms and any well-baby observation areas show that at least 80% of breastfed infants are being fed only breast milk, or documentation indicates that there are acceptable medical reasons or fully informed choices for formula feeding.

Step 7: Practice rooming in - allow mothers and infants to remain together 24 hours a day.

- 7.1 Guideline:** The facility should provide rooming-in 24 hours a day as the standard for mother baby care for healthy term infants, regardless of feeding choice. When a mother requests that her infant be cared for in the nursery, the health care staff should explore the reasons for the request and should encourage and educate the mother about the advantages of having her infant stay with her in the same room 24 hours a day. If the mother still requests that the infant be cared for in the nursery, the process and informed decision should be documented. In addition, the medical and nursing staff should conduct newborn procedures at the mother's bedside whenever possible and should avoid frequent separations and absences of the newborn from the mother for more than one hour in a 24-hour period. If the infant is kept in the nursery for documented medical reasons, the mother should be provided access to feed her infant at any time.
- 7.1.1 Criterion for evaluation:** Of randomly selected mothers with vaginal births, at least 80% will report that their infants were not separated from them before starting rooming-in, unless there are documented medical reasons for separation.
- 7.1.2 Criterion for evaluation:** Of randomly selected mothers with healthy term infants, at least 80% will report that since they came to their room after birth (or since they were able to respond to their infants in the case of cesarean birth), their infants have stayed with them in the same room day and night except for up to one hour per 24-hour period for facility procedures, unless there are documented justifiable reasons for a longer separation.

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- 7.1.3 Criterion for evaluation:** Observations in the postpartum unit and any well-baby observation areas and discussions with mothers and staff confirm that at least 80% of the mothers and infants are rooming-in or have documented justifiable reasons for separation.

Step 8: Encourage breastfeeding on demand.

This step applies to all infants, regardless of feeding method, and is now interpreted as:

Encourage feeding on cue.

- 8.1 Guideline:** Health care professionals should help all mothers, regardless of feeding choice: 1) understand that no restrictions should be placed on the frequency or length of feeding, 2) understand that newborns usually feed a minimum of 8 times in 24 hours, 3) recognize cues that infants use to signal readiness to begin and end feeds, and 4) understand that physical contact and nourishment are both important.
- 8.1.1 Criterion for evaluation:** Of randomly selected mothers of normal infants (including those of cesarean birth), at least 80% will report that they have been told how to recognize when their infants are hungry and can describe at least 2 feeding cues.
- 8.1.2 Criterion for evaluation:** Of breastfeeding mothers, at least 80% will report that they have been advised to feed their infants as often and as long as the infants want.
- 8.1.3 Criterion for evaluation:** Of mothers who are feeding their infants formula, at least 80% will report that they have been taught appropriate formula feeding techniques, including feeding on cue, eye-to-eye contact, and holding the infant closely.
- 8.1.4 Criterion for evaluation:** The nursing director/manager on the maternity unit will confirm that no restrictions are placed on the frequency or length of feeds.

Step 9: Give no pacifiers or artificial nipples to breastfeeding infants.

- 9.1 Guideline:** Health care professionals, including nursery staff, should educate all breastfeeding mothers about how the use of bottles and artificial nipples may interfere with the development of optimal breastfeeding. When a mother requests that her breastfeeding infant be given a bottle, the health care staff should explore the reasons for this request, address the concerns raised, educate her on the possible consequences to the success of breastfeeding, and discuss alternative methods for soothing and feeding her infant.

If the mother still requests a bottle, the process of counseling and education and the informed decision of the mother should be documented.

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Any fluid supplementation (whether medically indicated or following informed decision of the mother) should be given by tube, syringe, spoon, or cup in preference to an artificial nipple or bottle.

9.1.1 Criterion for evaluation: Of breastfeeding mothers, at least 80% will report that:

- to the best of their knowledge, their infants have not been fed using bottles, or
- if they are using bottles, bottle use was requested after receipt of appropriate education and counseling from staff

9.1.2 Criterion for evaluation: Observations in the postpartum unit and any well-baby observation areas will indicate that at least 80% of breastfeeding infants are not using bottles, or, if they are, their mothers have been informed of the risks and this education is documented in the medical record.

9.1.3 Criterion for evaluation: The nursing director/manager will confirm that breastfed infants are not routinely given bottles.

9.2 Guideline: Health care professionals, including nursery staff, should educate all breastfeeding mothers about how the use of pacifiers may interfere with the development of optimal breastfeeding. Breastfeeding infants should not be given pacifiers by the staff of the facility, with the exception of limited use to decrease pain during procedures when the infant cannot safely be held or breastfed (pacifiers used should be discarded after these procedures), by infants who are being tube-fed in NICU, or for other rare, specific medical reasons.

When a mother requests that her breastfeeding infant be given a pacifier, the health care staff should explore the reasons for this request, address the concerns raised, educate her on the possible consequences to the success of breastfeeding, and discuss alternative methods for soothing her infant.

If the breastfeeding mother still requests a pacifier, the process of counseling and education and informed decision should be documented.

9.2.1 Criterion for evaluation: Of breastfeeding mothers, at least 80% will report that:

- to the best of their knowledge, their infants have not sucked on pacifiers, or
- that pacifier use was limited to painful procedures, or
- that pacifier use was chosen by the infant's parents after receipt of appropriate education and counseling from staff.

9.2.2 Criterion for evaluation: Observations in the postpartum unit and any well-baby observation areas will indicate that at least 80% of breastfeeding infants are not using pacifiers, or, if they are, their mothers have been informed of the risks and this education is documented in the medical record.

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- 9.2.3 Criterion for evaluation:** The nursing director/manager will confirm that breastfeeding infants are not routinely given pacifiers and that use of pacifiers in term infants is restricted to cases where there is a medical indication.

Step 10: Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

- 10.1 Guideline:** The designated health care professional(s) should ensure that, prior to discharge, a responsible staff member explores with each mother and a family member or support person (when available) the plans for infant feeding after discharge. Discharge planning for breastfeeding mothers and infants should include information on the importance of exclusive breastfeeding for about 6 months and available and culturally-specific breastfeeding support services without ties to commercial interests. Examples of the information and support to be provided include giving the name and phone numbers of community-based support groups, breastfeeding support services, telephone help lines, lactation clinics, home health services, and individualized specialized resource persons. An early post-discharge follow-up appointment with their pediatrician, family practitioner, or other pediatric care provider should also be scheduled. The facility should establish in-house breastfeeding support services if no adequate source of support is available for referral (e.g. support group, lactation clinic, home health services, help line, etc.).

- 10.1.1 Criterion for evaluation:** The nursing director/manager on the maternity unit will report that mothers are given information on where they can find support if they need help with feeding their infants after returning home.

- 10.1.2 Criterion for evaluation:** The nursing director/manager on the maternity unit will report that the facility fosters the establishment of and/or coordinates with mother support groups and other community services that provide breastfeeding/infant feeding support to mothers, and the designated staff member can describe at least one way this is done.

- 10.1.3 Criterion for evaluation:** The nursing director/manager on the maternity unit will report that the staff assures that mothers and infants receive breastfeeding assessment and support after discharge (preferably 2 to 4 days after discharge and again the second week) at the facility or in the community by a skilled breastfeeding support person who can assess feeding and give any support needed.

- 10.1.4 Criterion for evaluation:** The nursing director/manager on the maternity unit will report that the staff can describe an appropriate referral system and adequate timing for the visits.

- 10.1.5 Criterion for evaluation:** A review of documents indicates that printed information is distributed to mothers before discharge on how and where mothers can find help on feeding their infants after returning home and includes information on the types of help available.

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- 10.1.6 Criterion for evaluation:** Of breastfeeding mothers, at least 80% will report that they have been given information about how to get help from the facility and how to contact support groups, peer counselors, or other community health services if they have questions about feeding their infants after they return home, and can describe at least one type of help that is available.

Compliance with the International Code of Marketing of Breast-milk Substitutes

- 11.1 Guideline:** The facility will demonstrate its compliance with the International Code by refusing to accept supplies of breast milk substitutes and feeding supplies at no cost or below fair market cost (see Appendix C), by protecting new parents from the influence of vendors of such items, by practicing in accordance with its vendor and ethics policies regarding appropriate interaction between vendors of such items and facility staff, and by educating staff members about the International Code and its role in ethical health care practices.
- 11.1.1 Criterion for evaluation:** The nursing director/manager on the maternity unit will report that no employees of manufacturers or distributors of breast milk substitutes, bottles, nipples, pacifiers or other infant feeding supplies have any direct or indirect contact with pregnant women or mothers.
- 11.1.2 Criterion for evaluation:** The nursing director/manager on the maternity unit will report that the facility and its staff members do not receive free gifts, non-scientific literature, materials or equipment, money, or support for breastfeeding education or events from manufacturers or distributors of breast milk substitutes, bottles, nipples, pacifiers or other infant feeding supplies. All other interactions with these manufacturers/distributors are in compliance with the facility's vendor/ethics policy.
- 11.1.3 Criterion for evaluation:** The nursing director/manager on the maternity unit will report that pregnant women, mothers, and their families are not given marketing materials or samples or gift packs by the facility that include breast milk substitutes, bottles, nipples, pacifiers, or other infant feeding supplies, or coupons for any of the above items.
- 11.1.4 Criterion for evaluation:** The nursing director/manager on the maternity unit will report that any educational materials distributed to breastfeeding mothers are free of messages that promote or advertise infant food or drinks other than breast milk.
- 11.1.5 Criterion for evaluation:** The nursing director/manager on the maternity unit will report that no educational materials used refer to proprietary products or bear a product logo, unless specific to the mother's or infant's needs or condition. (For example, information about how to safely use a needed product such as a formula or breast pump would be acceptable to give to a mother or infant needing such a product. Marketing information for such products would not be acceptable.)

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- 11.1.6 Criterion for evaluation:** A review of records and receipts indicates that any breast milk substitutes, including special formulas, bottles, nipples, pacifiers and other infant feeding supplies are purchased by the health care facility at a fair market price. (See Appendix C for definition.)
- 11.1.7 Criterion for evaluation:** Observations in the antenatal and maternity services and other areas where nutritionists and dietitians work indicate that no materials that promote breast milk substitutes, bottles, nipples, pacifiers or other infant feeding supplies are displayed or distributed to mothers, pregnant women, or staff.
- 11.1.8 Criterion for evaluation:** Infant formula cans and prepared bottles are kept out of view of patients and the general public.
- 11.1.9 Criterion for evaluation:** Of randomly selected staff members, at least 80% can give 2 reasons why it is important not to give free samples or other items from formula companies to mothers.

Appendix A:

20-Hour Course Topic and Competency Skills List for the U.S.

Adapted for use in the United States from the WHO/UNICEF International Guidelines

Objectives	Content
Discuss the rationale for professional, government and international policies that promote, protect and support breastfeeding in the United States.	Session 1: The BFHI – a part of the Global Strategy <ul style="list-style-type: none"> The Global Strategy for Infant and Young Child Feeding and how the Global Strategy fits with other activities The Baby-Friendly Hospital Initiative How this course can assist health facilities in making improvements in evidence-based practice, quality care and continuity of care
Demonstrate the ability to communicate effectively about breastfeeding.	Session 2: Communication skills <ul style="list-style-type: none"> Listening and learning Skills to build confidence and give support Arranging follow-up and support suitable to the mother's situation
Describe the anatomy and physiology of lactation and the process of breastfeeding.	Session 3: How milk gets from the breast to the baby <ul style="list-style-type: none"> Parts of the breast involved in lactation Breast milk production The baby's role in milk transfer Breast care
Identify teaching points appropriate for prenatal classes and in interactions with pregnant women.	Session 4: Promoting breastfeeding during pregnancy <ul style="list-style-type: none"> Discussing breastfeeding with pregnant women Why breastfeeding is important Antenatal breast and nipple preparation Women who need extra attention
Discuss hospital birth policies and procedures that support exclusive breastfeeding.	Session 5: Birth practices and breastfeeding <ul style="list-style-type: none"> Labor and birth practices to support early breastfeeding The importance of early skin-to-skin contact Helping to initiate breastfeeding Ways to support breastfeeding after a cesarean birth BFHI practices and women who are not breastfeeding

Objectives	Content
Demonstrate the ability to identify the hallmarks of milk transfer and optimal breastfeeding.	Session 6: Helping with a breastfeed <ul style="list-style-type: none"> Positioning for comfortable breastfeeding How to assess a breastfeeding Recognize signs of optimal positioning and attachment Help a mother to learn to position and attach her baby When to assist with breastfeeding The baby who has difficulty attaching to the breast
Discuss hospital postpartum management policies and procedures that support exclusive breastfeeding.	Session 7: Practices that assist breastfeeding <ul style="list-style-type: none"> Rooming-in Skin-to-skin contact Baby-led feeding Dealing with sleepy babies and crying babies Avoiding unnecessary supplements Avoiding bottles and teats
Discuss methods that may increase milk production in a variety of circumstances.	Session 8: Milk supply <ul style="list-style-type: none"> Concerns about “not enough milk” Normal growth patterns of babies Improving milk intake and milk production
Identify teaching points to include when educating or counseling parents who are using bottles and/or formula.	Session 9: Supporting the non-breastfeeding mother and baby <ul style="list-style-type: none"> Counseling the formula choice: a pediatric responsibility Teaching/assuring safe formula preparation in the postpartum Safe bottle feeding; issues with overfeeding and underfeeding
Discuss contraindications to breastfeeding in the United States as well as commonly encountered areas of concern for breastfeeding mothers and their babies.	Session 10: Infants and mothers with special needs <ul style="list-style-type: none"> Breastfeeding infants who are preterm, low birth weight or ill Breastfeeding more than one baby Prevention and management of common clinical concerns Medical reasons for food other than breast milk Nutritional needs of breastfeeding women How breastfeeding helps space pregnancies Breastfeeding management when the mother is ill Medications and breastfeeding Contraindications to breastfeeding
Describe management techniques for breast and nipple problems.	Session 11: Breast and nipple concerns <ul style="list-style-type: none"> Examination of the mother’s breasts and nipples Engorgement, blocked ducts, and mastitis • Sore nipples

Objectives	Content
Identify acceptable medical reasons for supplementation of breastfed babies according to national and international authorities.	Session 12: If the baby cannot feed at the breast <ul style="list-style-type: none"> • Learning to hand express • Use of milk from another mother • Feeding expressed breast milk to the baby
Describe essential components of support for mothers to continue breastfeeding beyond the early weeks.	Session 13: Ongoing support for mothers <ul style="list-style-type: none"> • Preparing a mother for discharge • Follow-up and support after discharge • Protecting breastfeeding for employed women • Sustaining continued breastfeeding for 2 years or longer
Describe strategies that protect breastfeeding as a public health goal.	Session 14: Protecting breastfeeding <ul style="list-style-type: none"> • The effect of marketing on infant feeding practices • The International Code of Marketing of Breast-milk Substitutes • How health workers can protect families from marketing • Donations in emergency situations • The role of breastfeeding in emergencies • How to respond to marketing practices
Identify barriers and solutions to implementation of the Ten Steps to Successful Breastfeeding that comprise the Baby-Friendly Hospital Initiative.	Session 15: Making your hospital or birth center Baby-Friendly® <ul style="list-style-type: none"> • The Ten Steps to Successful Breastfeeding • What “Baby-Friendly” Practices mean • The process of becoming a Baby-Friendly hospital or birth center

Skills Competencies for Maternity Staff:

1. Communicating with pregnant and postpartum women about infant feeding
2. Observing, assessing and assisting with breastfeeding
3. Teaching hand expression and safe storage of milk
4. Teaching safe formula preparation and feeding

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Appendix B:

Acceptable Medical Reasons for Use of Breast Milk Substitutes

Almost all mothers can breastfeed successfully, which includes initiating breastfeeding within the first hour of life, breastfeeding exclusively for the first 6 months, and continuing breastfeeding along with giving appropriate complimentary foods up to 2 years of age or beyond.

The facility should develop a protocol/procedure that describes the current, evidence-based medical indications for supplementation. Staff and care providers should be trained to utilize the protocol/procedure as guidance in the case of supplementation. A facility may utilize the recommendations of national and international authorities (e.g. Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), and Academy of Breastfeeding Medicine (ABM)) in developing this protocol/procedure, however the facility is responsible for ensuring that its medical indications for supplementation are supported by current evidence.

Appendix C:

Definitions of Terms and Abbreviations Used in this Document

Affiliated prenatal services – Primary prenatal care delivered through a close formal or informal association with a birthing facility. For Baby-Friendly purposes, the affiliation is determined through completion of a questionnaire regarding specific aspects of the relationship, such as business relationship, personnel relationship, and marketing of services.

Criteria for evaluation – The minimum standards which must be achieved in order to achieve Baby Friendly designation.

Exclusive breast milk feeding – Refers to the optimal practice of feeding infants no food or drink other than human milk unless another food is determined to be medically necessary.

Fair market price – The International Code of Marketing of Breast-milk Substitutes, and subsequently, the BFHI, call for health systems to purchase infant foods and feeding supplies at a fair market value. Fair market pricing can be determined by calculating the margin of retail price the facility pays on other items available on the retail market.

Guidelines – The standards of care which facilities strive to achieve for all patients.

Kangaroo Mother Care (KMC) – In this document, the term Kangaroo Mother Care refers to skin-to-skin care provided by the mother or father of a preterm infant. The infant is worn against the parent's naked chest in such a fashion that the infant is held upright. The parent is then wrapped in a blanket or other clothing to secure the infant against her or his chest. Infants may be held continuously in this fashion for many hours. Optimally, KMC begins as soon as the infant is judged ready for skin-to-skin contact.

Policy – An enforceable document that guides staff in the delivery of care. At the facility level, this may include policies, practice guides and protocols.

Skin-to-skin contact (STS) – Skin-to-skin contact or skin-to-skin care refers to contact between the newborn infant and its mother. (In the case of incapacitation of the mother, another adult, such as the infant's father or grandparent, may hold the infant skin-to-skin.) After birth, the infant is completely dried and placed naked against the mother's naked ventral surface. The infant may wear a diaper and/or a hat, but no other clothing should be between the mother's and infant's bodies. The infant and mother are then covered with a warm blanket, keeping the infant's head uncovered. STS should continue, uninterrupted, until completion of the first feeding, or at least one hour if the mother is not breastfeeding. STS should be encouraged beyond the first hours and into the first days after birth and beyond.

ABM – Academy of Breastfeeding Medicine

BFHI – Baby-Friendly Hospital Initiative

CDC – Centers for Disease Control and Prevention

KMC – Kangaroo Mother Care

NICU – Neonatal Intensive Care Unit

STS – Skin-to-skin contact

UNICEF – United Nations Children's Fund

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WHO – World Health Organization

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Appendix D:

Guidelines and Evaluation Criteria Clarification Statements

Safety of Baby-Friendly Practices

Safety is an important component of the Baby-Friendly Hospital Initiative (BFHI). This is addressed in the *Guidelines and Evaluation Criteria (GEC)*, which clearly state, “Each participating facility assumes full responsibility for assuring that its implementation of the BFHI is consistent with all of its safety protocols.” It also indicates that all practices associated with the Ten Steps to Successful Breastfeeding be implemented in a sensitive manner that is responsive to the family’s needs.

Immediate Skin-to-Skin Care

Skin-to-Skin Care has been shown to have numerous benefits for both mothers and infants. The **AAP Neonatal Resuscitation Program (NRP)** offers a Flow Diagram for assessing infant stability and care that is an excellent protocol for initiating skin-to-skin care immediately following birth. The NRP Flow Diagram for routine care starts with assessing if the infant is:

- Term Gestation
- Good Tone
- Breathing or Crying

If the answer is “yes” to all of those questions, the direction is to remain with the mother and provide routine care which includes maintaining normal temperature, positioning the airway, clearing secretions if needed, drying, and conducting ongoing evaluation.¹⁰

Rooming-in

Rooming-in has been recommended for infant health and safety for decades. It is an evidenced-based practice that is beneficial to both mothers and infants. The GEC call for rooming-in to be the routine standard of care. The BFHI does not call for newborn nurseries to be closed.

Facilities are encouraged to review the American Academy of Pediatrics’ “*Clinical Report: Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns*” for suggested safe skin-to-skin care and rooming-in care practices.¹¹

¹⁰ American Academy of Pediatrics and American Heart Association, Textbook of Neonatal Resuscitation (NRP), 7th Ed, Edited by Gary M. Weiner and Jeanette Zaichkin, 2016.

¹¹ Lori Feldman-Winter, Jay P. Goldsmith, AAP Committee on Fetus and Newborn, and AAP Task Force on Sudden Infant Death Syndrome. “Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns.” *Pediatrics* 138, no. 3 (2016): e20161889. doi: 10.1542/peds.2016-1889

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Exclusive Breastfeeding, Pacifiers, and Safe Sleep

Baby-Friendly USA (BFUSA) promotes exclusive breastfeeding and the safe implementation of practices that support exclusive breastfeeding while also reinforcing safe sleep and Sudden Infant Death Syndrome (SIDS) reduction messages and practices. BFUSA believes strongly that the promotion of exclusive breastfeeding, safe sleep, and SIDS reduction are complementary initiatives. In fact, breastfeeding is recommended as a strategy for reducing SIDS and other sleep-related infant deaths.¹² The protective effect of breastfeeding increases with exclusivity.

BFUSA has received some questions from professionals working on safe sleep initiatives regarding the designation criteria related to pacifier use. The BFUSA *Guidelines and Evaluation Criteria (GEC)* related to Step 9 state that breastfed infants should not be given pacifiers by hospital staff and that mothers who request that their infants be given a pacifier be educated about how pacifier use could affect the success of breastfeeding. Early and frequent breastfeeding in the newborn period is essential to building up a mother's milk supply. Pacifier introduction too early in the breastfeeding relationship may interfere with this important biological process and mask potential breastfeeding problems. Furthermore, the *GEC* is also in alignment with the American Academy of Pediatrics' (AAP) recommendation for pacifier use found in the *2012 AAP Policy Statement: Breastfeeding and the Use of Human Milk*. The policy statement recommends that mothers of healthy term infants be instructed to use pacifiers at infant nap or sleep time after breastfeeding is well established, at approximately 3 to 4 weeks of age.¹³ While it is acknowledged that the exact timeframe for the establishment of breastfeeding may vary from mother to mother, it rarely occurs during the first 2 days of life.

BFUSA acknowledges the evidence pertaining to pacifier education related to SIDS prevention. Safe sleep and SIDS prevention information is important for parents to receive during the birth hospital stay. This education may be compatibly provided to parents by using safe sleep materials that also promote breastfeeding. Since the *AAP SIDS and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment* continues to call for pacifiers to be delayed until breastfeeding is firmly established, BFUSA will require hospitals distributing safe sleep materials to provide additional verbal and written education to mothers that includes the following:

1. Pacifier use in the breastfed infant should be delayed until breastfeeding is well established, usually around 3-4 weeks of life.
2. How mothers can know that breastfeeding is well established.
3. Breastfeeding is associated with a reduced risk of SIDS, and the protective effect increases with breastfeeding exclusivity.

¹² American Academy of Pediatrics Task Force on Sudden Infant Death Syndrome, SIDS, and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment. *Pediatrics*. no. 138 (2016) 138(5). doi: 10.1542/peds.2016-2938.

¹³ Lawrence M. Gartner, Arthur I. Eidelman, Jane Morton, Ruth A. Lawrence, Audrey J. Naylor, Donna O'Hare, and Richard J. Schanler. "Policy Statement, Section on Breastfeeding: Breastfeeding and the Use of Human Milk." *Pediatrics* 115, no. 2 (2005): 496–506. doi: 10.1542/peds.2004-2491.

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Powdered Infant Formula Preparation

Guideline 5.3 and Criterion 5.3.1 and 5.3.3

The BFUSA *Guidelines and Evaluation Criteria* specify that mothers who feed formula should receive written instruction and verbal information; not specific to a particular brand; about safe preparation, handling, storage, and feeding of infant formula. Verbal and written education must address the following seven topics:

1. Appropriate hygiene
2. Cleaning utensils and equipment
3. Appropriate reconstitution
4. Accuracy of measurement of ingredients
5. Safe handling
6. Proper storage
7. Appropriate feeding methods

In regards to appropriate reconstitution, the following is the BFUSA decision statement for preparation of powdered infant formula:

According to leading national health authorities, in most cases, it is safe to mix powdered infant formula following manufacturer's instructions. However, very young infants (less than 3 months of age), infants born prematurely, or infants with weakened immune systems may require extra precautionary measures when preparing powdered infant formula to protect against *Cronobacter*. The extra precautionary measures include boiling water for powdered infant formula preparation and not allowing the water to cool below 158° F/70° C. Good hygiene, mixing the powdered infant formula with water hot enough to kill germs, and safely storing powdered infant formula can prevent growth of *Cronobacter* and other germs, like *Salmonella*.¹⁴

As the Baby-Friendly Hospital Initiative practices are specifically geared towards the very young infant, BFUSA requires that facilities prepare and teach mothers to reconstitute powdered infant formula using boiled water, cooled to no less than 158° F/70° C. The water should be cooled for no more than 30 minutes after boiling.¹⁵ After reconstituting the formula, the temperature of the formula should be checked before feeding the formula to the infant.

¹⁴ Centers for Disease Control and Prevention; National Center for Emerging and Zoonotic Infectious Diseases (NCEZID); Division of Foodborne, Waterborne, and Environmental Diseases (DFWED). *Cronobacter*: Prevention and Control. <https://www.cdc.gov/cronobacter/prevention.html> (accessed July 28, 2017).

¹⁵ Ibid.

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2016 BFUSA GEC Criteria	2018 WHO Global Standards	BFUSA Discussion Comments/Questions
<p>11.1.1 Criterion for evaluation: The nursing director/manager on the maternity unit will report that no employees of manufacturers or distributors of breast milk substitutes, bottles, nipples, pacifiers or other infant feeding supplies have any direct or indirect contact with pregnant women or mothers.</p> <p>11.1.2 Criterion for evaluation: The nursing director/manager on the maternity unit will report that the facility and its staff members do not receive free gifts, non-scientific literature, materials or equipment, money, or support for breastfeeding education or events from manufacturers or distributors of breast milk substitutes, bottles, nipples, pacifiers or other infant feeding supplies. All other interactions with these manufacturers/distributors are in compliance with the facility's vendor/ethics policy.</p> <p>11.1.3 Criterion for evaluation: The nursing director/manager on the maternity unit will report that pregnant women, mothers, and their families are not given marketing materials or samples or gift packs by the facility that include breast milk substitutes, bottles, nipples, pacifiers, or other infant feeding supplies, or coupons for any of the above items.</p>	<p>1. All infant formula, feeding bottles and teats used in the facility have been purchased through normal procurement channels and not received through free or subsidized supplies.</p> <p>2. The facility has no display of products covered under the Code or items with logos of companies that produce breast-milk substitutes, feeding bottles and teats, or names of products covered under the Code.</p> <p>3. The facility has a policy that describes how it abides by the Code, including procurement of breast- milk substitutes, not accepting support or gifts from producers or distributors of products covered by the Code and not giving samples of breast-milk substitutes, feeding bottles or teats to mothers.</p> <p>4. At least 80% of health professionals who provide antenatal, delivery and/or newborn care can explain at least two elements of the Code.</p>	<p>(b)(5)</p>

<p>11.1.4 Criterion for evaluation: The nursing director/manager on the maternity unit will report that any educational materials distributed to breastfeeding mothers are free of messages that promote or advertise infant food or drinks other than breast milk.</p> <p>11.1.5 Criterion for evaluation: The nursing director/manager on the maternity unit will report that no educational materials used refer to proprietary products or bear a product logo, unless specific to the mother's or infant's needs or condition. (For example, information about how to safely use a needed product such as a formula or breast pump would be acceptable to give to a mother or infant needing such a product. Marketing information for such products would not be acceptable.)</p>		
<p>11.1.6 Criterion for evaluation: A review of records and receipts indicates that any breast milk substitutes, including special formulas, bottles, nipples, pacifiers and other infant feeding supplies are purchased by the health care facility at a fair market price. (See Appendix C for definition.)</p> <p>11.1.7 Criterion for evaluation: Observations in the antenatal and maternity services and other areas where nutritionists and dietitians work indicate that no materials that promote breast milk substitutes, bottles, nipples, pacifiers or other infant feeding supplies are displayed or distributed to mothers, pregnant women, or staff.</p>		
<p>11.1.8 Criterion for evaluation: Infant formula cans and prepared bottles are kept out of view of patients and the general public.</p> <p>11.1.9 Criterion for evaluation: Of randomly selected staff members, at least 80% can give 2 reasons why it is important not to give free samples or other items from formula companies to mothers.</p>		

2016 BFUSA GEC Criteria	2018 WHO Global Standards	BFUSA Discussion Comments/Questions
<p>1.1.1 Criterion for evaluation: The facility will have written maternity care and infant feeding policies that address all Ten Steps, protect breastfeeding, and adhere to the International Code. All areas of the facility that potentially interact with childbearing women and infants will have language in their policies about the promotion, protection, and support of breastfeeding. Policies of all departments will not countermand the facility's breastfeeding policy. Review of all clinical protocols, standards, and educational materials related to breastfeeding and infant feeding used by the maternity services indicates that they are in line with the BFHI standards and current evidence-based guidelines.</p> <p>1.1.2 Criterion for evaluation: The nursing director/manager will be able to identify the health care professional(s) who has ultimate responsibility for assuring implementation of the breastfeeding policy.</p>	<p>1. The health facility has a written infant feeding policy that addresses the implementation of all eight key clinical practices of the Ten Steps, Code implementation, and regular competency assessment.</p> <p>2. Observations in the facility confirm that a summary of the policy is visible to pregnant women, mothers and their families.</p> <p>3. A review of all clinical protocols or standards related to breastfeeding and infant feeding used by the maternity services indicates that they are in line with BFHI standards and current evidence-based guidelines.</p> <p>4. At least 80% of clinical staff who provide antenatal, delivery and/or newborn care can explain at least two elements of the infant feeding policy that influence their role in the facility.</p>	(b)(5)
<p>1.2.1 Criterion for evaluation: The nursing director/manager of the maternity unit and/or the designated health care professional within the facility will be able to locate the maternity care and infant feeding policies and describe how the other staff, including new employees, are made aware of the content.</p> <p>1.2.2 Criterion for evaluation: Of randomly selected maternity staff members, at least 80% will confirm that they are aware of the facility's maternity care and infant feeding policies, know where the policies are kept or posted, and have received orientation regarding the policies.</p>		
<p>1.2.3 Criterion for evaluation: The nursing director/manager of the maternity unit and/or the designated health care professional within the facility will be able to produce evidence of routine quality improvement procedures that have monitored the maternity care and infant feeding policies.</p>		
<p>1.3.1 Criterion for evaluation: The Ten Steps and the statement indicating the facility's adherence to the WHO International Code restricting the promotion of breast milk substitutes, bottles, nipples, and other infant feeding supplies will be prominently displayed in all areas of the health care facility which serve mothers, infants, and/or young children, including labor and delivery, the postpartum unit, all infant and child care areas, affiliated prenatal services, ultrasound, screening, antenatal testing, and the emergency room. This information will be displayed in the language(s) most commonly understood by patients.</p>		

2016 BFUSA GEC Criteria	2018 WHO Global Standards	BFUSA Discussion Comments/Questions
N/A	<p>1. The facility has a protocol for an ongoing monitoring and data-management system to comply with the eight key clinical practices.</p> <p>2. Clinical staff at the facility meet at least every 6 months to review implementation of the system.</p>	(b)(5)
	<p>Appendix 1 lists clinical records as the primary source for these sentinel indicators.</p> <p>1. The percentage of term infants who were put to the breast within 1 hour after birth. (Step 4)</p> <p>2. The percentage of infants (preterm and term) who received only breast milk (either from their own mother or from a human milk bank) throughout their stay at the facility (Step 6)</p>	
	<p>Appendix 1 lists clinical records as the secondary source for these indicators.</p> <p>3. The percentage of mothers of preterm and term infants who received prenatal care at the facility who received prenatal counselling on breastfeeding (Step 3)</p> <p>4. The percentage of mothers of term infants whose babies were placed in skin-to-skin contact with them immediately or within 5 minutes after birth and that this contact that lasted 1 hour or more (Step 4)</p> <p>5. The percentage of mothers of breastfed preterm and term infants who can correctly demonstrate or describe how to express breast milk (Step 5)</p> <p>6. The percentage of mothers of term infants whose babies stayed with them since birth, without separation lasting for more than 1 hour (Step 7)</p>	

2016 BFUSA GEC Criteria	2018 WHO Global Standards	BFUSA Discussion Comments/Questions
<p>2.1.1 Criterion for evaluation: The head of maternity services will report that all health care staff members who have any contact with pregnant women, mothers, and/or infants have received sufficient orientation on the infant feeding policies.</p> <p>2.1.2 Criterion for evaluation: The head of maternity services will be able to identify the health care professional(s) responsible for all aspects of planning, implementing, and evaluating staff training in breastfeeding and parent teaching for formula preparation and feeding.</p> <p>2.1.3 Criterion for evaluation: The designated health care professional(s) will provide documentation that training for breastfeeding and parent teaching for formula preparation and feeding is provided for all health care staff caring for mothers, infants and/or young children and that new staff are oriented on arrival and scheduled for training within 6 months (for example, by providing a list of new staff who are scheduled for training).</p> <p>2.1.4 Criterion for evaluation: If training acquired prior to employment with this facility is accepted as a means of meeting the minimum competencies, the designated health care professional will be able to describe the process used to verify the previously acquired competencies.</p>	<p>1. At least 80% of health professionals who provide antenatal, delivery and/or newborn care report they have received pre-service or in-service training on breastfeeding during the previous 2 years.</p> <p>2. At least 80% of health professionals who provide antenatal, delivery and/or newborn care report receiving competency assessments in breastfeeding in the previous 2 years.</p> <p>3. At least 80% of health professionals who provide antenatal, delivery and/or newborn care are able to correctly answer three out of four questions on breastfeeding knowledge and skills to support breastfeeding.</p>	(b)(5)
<p>2.1.5 Criterion for evaluation: The designated health care professional(s) will provide documentation of training offered to staff outside the maternity unit.</p> <p>2.1.6 Criterion for evaluation: A copy of the curricula or course outlines for competency-based training in breastfeeding, lactation management, and parent teaching for formula preparation and feeding will be available for review and a schedule for training all newly hired staff will exist. Maternity staff training will cover Steps 3 through 10 and include the topics and subtopics of all 15 sessions identified by the UNICEF/WHO 20 hour curriculum. (See Appendix A.) The training will include a minimum of five hours of supervised clinical experience.</p> <p>2.1.7 Criterion for evaluation: Of randomly selected maternity staff members, including the nursery staff and health care providers with privileges, at least 80% will confirm that they have completed the described training and competency verification, or, if they have been on the unit less than 6 months, have at minimum been oriented.</p>		
<p>2.1.8 Criterion for evaluation: Of health care providers with privileges, at least 80% will be able to correctly answer 4 out of 5 questions demonstrating they have a true understanding of the benefit of exclusive breastfeeding, physiology of lactation, how their specific field of practice impacts lactation, and how to find out about safe medications for use during lactation.</p> <p>2.1.9 Criterion for evaluation: Of randomly selected maternity staff members, at least 80% will be able to answer 4 out of 5 questions on breastfeeding management correctly.</p> <p>2.1.10 Criterion for evaluation: Of randomly selected maternity staff members and health care providers, at least 80% will be able to identify 2 topics to discuss with women who are considering feeding their infants something other than human milk.</p>		

2016 BFUSA GEC Criteria	2018 WHO Global Standards	BFUSA Discussion Comments/Questions
<p>3.1.1 Criterion for evaluation: If the facility has an affiliated prenatal clinic or services, the nursing director/manager will report that individual counseling or group education on breastfeeding is given to at least 80% of the pregnant women using those services.</p>	<p>1. A protocol for antenatal discussion of breastfeeding includes at a minimum:</p> <ul style="list-style-type: none"> o the importance of breastfeeding; o global recommendations on exclusive breastfeeding for the first 6 months, the risks of giving formula or other breast-milk substitutes, and the fact that breastfeeding continues to be important after 6 months when other foods are given; o the importance of immediate and sustained skin- to-skin contact; o the importance of early initiation of breastfeeding; o the importance of rooming-in; o the basics of good positioning and attachment; o recognition of feeding cues. 	(b)(5)
<p>3.2.1 Criterion for evaluation: A written description of the content of the prenatal education will be available and will cover, at minimum, the importance of breastfeeding, the importance of exclusive breastfeeding for about 6 months, and basic breastfeeding management.</p> <p>3.2.2 Criterion for evaluation: Of the randomly selected pregnant women in the third trimester who are using the facility prenatal services, at least 80% will confirm that a staff member has talked with them or offered a group talk that includes information on breastfeeding.</p>	<p>2. At least 80% of mothers who received prenatal care at the facility report having received prenatal counselling on breastfeeding.</p> <p>3. At least 80% of mothers who received prenatal care at the facility are able to adequately describe what was discussed about two of the topics mentioned above.</p>	
<p>3.2.3 Criterion for evaluation: Of the randomly selected pregnant women in the third trimester who are using the facility prenatal services, at least 80% are able to adequately describe what was discussed concerning 2 of the following topics: importance of skin-to-skin contact, rooming-in, or risks of supplements while breastfeeding in the first 6 months.</p>		
<p>3.3.1 Criterion for evaluation: The nursing director/manager will report that the facility fosters relationships with community-based programs that make available individual counseling or group education on breastfeeding and coordinates messages about breastfeeding with these programs.</p> <p>3.3.2 Criterion for evaluation: The nursing director/manager will report that the facility has fostered the development of or coordinated services with one or more of the following programs: in-house breastfeeding education, childbirth education, hospital pre-registration visits, hospital tours, in-patient services, etc.</p>		
<p>3.4.1 Criterion for evaluation: A written description of in-house and/or community-based programs and projects the facility has fostered will be available and will cover, at minimum, the importance of breastfeeding, the importance of exclusive breastfeeding for about 6 months, and basic breastfeeding management (e.g. skin-to-skin contact, rooming-in, and risks of supplements while breastfeeding in the first 6 months).</p>		

		BFUSA Discussion Comments/Questions
2016 BFUSA GEC Criteria	2018 WHO Global Standards	
<p>4.1.1 Criterion for evaluation: Of randomly selected mothers in the postpartum unit who have had normal vaginal births, at least 80% will confirm that their infants were placed in skin-to-skin contact with them immediately after birth and that skin-to-skin contact continued uninterrupted until the completion of the first feeding (or for at least one hour if not breastfeeding), unless there were documented medically justifiable reasons for delayed contact.</p> <p>4.1.2 Criterion for evaluation: Of randomly selected mothers in the postpartum unit who have had normal vaginal births, at least 80% will confirm that they were encouraged to look for signs that their infants were ready to feed during this first period of contact and offered help if needed. (The infant should not be forced to feed, but rather, supported to do so when ready.)</p>	<p>1. At least 80% of mothers of term infants report that their babies were placed in skin-to-skin contact with them immediately or within 5 minutes after birth and that this contact lasted 1 hour or more, unless there were documented medically justifiable reasons for delayed contact.</p> <p>2. At least 80% of mothers of term infants report that their babies were put to the breast within 1 hour after birth, unless there were documented medically justifiable reasons.</p>	(b)(5)
4.1.3 Criterion for evaluation: Observations of vaginal births, if necessary to confirm adherence to Step 4, show that (regardless of the mother's feeding intentions) at least 80% of infants are placed skin-to-skin with their mothers within 5 minutes after birth and are held continuously skin-to-skin until completion of the first feeding, or for at least one hour if not breastfeeding, unless there were documented medically justifiable reasons for delayed contact.		
4.1.4 Criterion for evaluation: Observations of vaginal births, if necessary to confirm adherence to Step 4, show that (regardless of the mother's feeding intentions) at least 80% of mothers are shown how to recognize the signs that their infants are ready to feed and offered help, or there are documented justifiable reasons for not following these procedures.		
<p>4.2.1 Criterion for evaluation: Of randomly selected mothers in the postpartum unit who have had cesarean births of a healthy infant, at least 80% will confirm that their infants were placed in skin-to-skin contact with them as soon as the mother was responsive and alert and that skin-to-skin contact continued uninterrupted until completion of the first feeding (or at least one hour if not breastfeeding), unless there were documented medically justifiable reasons for delayed contact.</p> <p>4.2.2 Criterion for evaluation: Of randomly selected mothers in the postpartum unit who have had cesarean births of a healthy infant, at least 80% will confirm that they were encouraged to look for signs that their infants were ready to feed during this first period of contact and offered help if needed. (The infant should not be forced to feed, but rather, supported to do so when ready.)</p>		
<p>4.2.3 Criterion for evaluation: Observations of cesarean births and recovery, if necessary to confirm adherence to Step 4, show that (regardless of the mother's feeding intentions), at least 80% of infants are placed with their mothers and held continuously skin-to-skin as soon as the mother was responsive and alert and until completion of the first feeding.</p> <p>4.2.4 Criterion for evaluation: Observations of cesarean births and recovery, if necessary to confirm adherence to Step 4, show that (regardless of the mother's feeding intentions), at least 80% of mothers are shown how to recognize the signs that their infants are ready to feed and offered help, or there are documented justified reasons for not following these procedures.</p>		
4.3.1 Criterion for evaluation: Of randomly selected mothers who gave birth either vaginally or via cesarean, at least 80% will confirm that in the event of medically-indicated separation, skin-to-skin contact was initiated when they were reunited with their infants.		

2016 BFUSA GEC Criteria	2018 WHO Global Standards	BFUSA Discussion Comments/Questions
<p>5.1.1 Criterion for evaluation: Of randomly selected postpartum mothers, at least 80% will report that nursing staff offered further assistance with breastfeeding the next time they fed their infants or within 6 hours of birth, or of when they were able to respond.</p> <p>5.1.2 Criterion for evaluation: Of randomly selected postpartum mothers, at least 80% of those who are breastfeeding will be able to demonstrate correct positioning and attachment with their own infants and will report that breastfeeding is comfortable for them.</p> <p>5.1.3 Criterion for evaluation: Of randomly selected postpartum mothers, at least 80% of those who are breastfeeding will report that they were shown how to express their milk by hand.</p> <p>5.1.4 Criterion for evaluation: Of randomly selected health care staff caring for postpartum mothers, at least 80% will report that they teach mothers how to position and attach their infants for breastfeeding and are able to describe or demonstrate correct techniques for both.</p>	<p>1. At least 80% of breastfeeding mothers of term infants report that someone on the staff offered assistance with breastfeeding within 6 hours after birth.</p> <p>2. At least 80% of mothers of preterm or sick infants report having been helped to express milk within 1–2 hours after birth.</p> <p>3. At least 80% of breastfeeding mothers of term infants are able to demonstrate how to position their baby for breastfeeding and that the baby can suckle and transfer milk.</p> <p>4. At least 80% of breastfeeding mothers of term infants can describe at least two ways to facilitate milk production for their infants.</p> <p>5. At least 80% of breastfeeding mothers of term infants can describe at least two indicators of whether a breastfed baby consumes adequate milk.</p> <p>6. At least 80% of mothers of breastfed preterm and term infants can correctly demonstrate or describe how to express breast milk.</p>	(b)(5)
<p>5.1.5 Criterion for evaluation: Of randomly selected health care staff caring for postpartum mothers, at least 80% will report that they teach mothers how to hand express breast milk and can describe or demonstrate an adequate technique for this.</p>		
<p>5.2.1 Criterion for evaluation: Of randomly selected mothers with infants in special care, at least 80% of those who are breastfeeding or intending to do so will report that they have been offered help to begin expressing and collecting milk as soon as possible, but no later than 6 hours after their infants' births, unless there is a medically justifiable reason to delay initiation of expression.</p> <p>5.2.2 Criterion for evaluation: Of randomly selected mothers with infants in special care, at least 80% of those who are breastfeeding or intending to do so report that they have been shown how to express their milk by hand or other method.</p>		
<p>5.2.3 Criterion for evaluation: Of randomly selected mothers with infants in special care, at least 80% of those who are breastfeeding or intending to do so can adequately describe and demonstrate how they were shown to express their milk.</p> <p>5.2.4 Criterion for evaluation: Of randomly selected mothers with infants in special care, at least 80% of those who are breastfeeding or intending to do so will report that they have been told they need to breastfeed or express their milk 8 times or more every 24 hours to establish and maintain their milk supply.</p>		
<p>5.3.1 Criterion for evaluation: Of maternity staff members, at least 80% can describe how mothers who are feeding formula can be assisted to safely prepare and feed formula to their infants.</p> <p>5.3.2 Criterion for evaluation: Of mothers who are feeding formula, at least 80% will report that someone discussed their feeding choice with them.</p> <p>5.3.3 Criterion for evaluation: Of mothers who are feeding formula, at least 80% will report that they have been provided education about preparing and giving their infants feeds and can describe the advice they were given.</p>		

2016 BFUSA GEC Criteria	2018 WHO Global Standards	BFUSA Discussion Comments/Questions
<p>6.1.1 Criterion for evaluation: Of randomly selected mothers who are breastfeeding, at least 80% will report that:</p> <ul style="list-style-type: none"> •to the best of their knowledge, their infants have received no food or drink other than breast milk while in the facility, or • that formula has been given for a medically acceptable reason, or • that formula has been given in response to a parental request. <p>6.1.2 Criterion for evaluation: Of breastfeeding mothers whose infants have been given food or drink other than breast milk, at least 80% of those who have no acceptable medical reason will report that the health care staff explored the reasons for and the possible negative consequences of the mother's decisions.</p>	<p>1. At least 80% of infants (preterm and term) received only breast milk (either from their own mother or from a human milk bank) throughout their stay at the facility.</p> <p>2. At least 80% of mothers who have decided not to breastfeed report that the staff discussed with them the various feeding options and helped them to decide what was suitable in their situations.</p> <p>3. At least 80% of mothers who have decided not to breastfeed report that the staff discussed with them the safe preparation, feeding and storage of breast- milk substitutes.</p> <p>4. At least 80% of term breastfed babies who received supplemental feeds have a documented medical indication for supplementation in their medical record.</p>	(b)(5)
<p>6.1.3 Criterion for evaluation: Of infants who have been given food or drink other than breast milk, at least 80% will have the reasons for supplementation and evidence of parental counseling (in the event of parental choice) clearly documented in the medical record.</p> <p>6.1.4 Criterion for evaluation: Of randomly selected mothers who have decided to feed formula, at least 80% will report that the staff discussed with them the various feeding options and helped them to decide what was suitable in their situations.</p>	<p>5. At least 80% of preterm babies and other vulnerable newborns that cannot be fed their mother's own milk are fed with donor human milk.</p> <p>6. At least 80% of mothers with babies in special care report that they have been offered help to start lactogenesis II (beginning plentiful milk secretion) and to keep up the supply, within 1–2 hours after their babies' births.</p>	
<p>6.1.5 Criterion for evaluation: Of mothers with infants in special care who have decided to feed formula, at least 80% will report that staff have talked with them about the risks and benefits of the various feeding options, including feeding expressed breast milk.</p> <p>6.1.6 Criterion for evaluation: Observations in the postpartum unit/rooms and any well-baby observation areas show that at least 80% of breastfed infants are being fed only breast milk, or documentation indicates that there are acceptable medical reasons or fully informed choices for formula feeding.</p>		

		BFUSA Discussion Comments/Questions
2016 BFUSA GEC Criteria	2018 WHO Global Standards	
<p>7.1.1 Criterion for evaluation: Of randomly selected mothers with vaginal births, at least 80% will report that their infants were not separated from them before starting rooming-in, unless there are documented medical reasons for separation.</p> <p>7.1.2 Criterion for evaluation: Of randomly selected mothers with healthy term infants, at least 80% will report that since they came to their room after birth (or since they were able to respond to their infants in the case of cesarean birth), their infants have stayed with them in the same room day and night except for up to one hour per 24-hour period for facility procedures, unless there are documented justifiable reasons for a longer separation.</p> <p>7.1.3 Criterion for evaluation: Observations in the postpartum unit and any well-baby observation areas and discussions with mothers and staff confirm that at least 80% of the mothers and infants are rooming-in or have documented justifiable reasons for separation.</p>	<p>1. At least 80% of mothers of term infants report that their babies stayed with them since birth, without separation lasting for more than 1 hour.</p> <p>2. Observations in the postpartum wards and well- baby observation areas confirm that at least 80% of mothers and babies are together or, if not, have medically justifiable reasons for being separated.</p> <p>3. At least 80% of mothers of preterm infants confirm that they were encouraged to stay close to their infants, day and night.</p>	<p>(b)(5)</p>

		BFUSA Discussion Comments/Questions
2016 BFUSA GEC Criteria	2018 WHO Global Standards	
<p>8.1.1 Criterion for evaluation: Of randomly selected mothers of normal infants (including those of cesarean birth), at least 80% will report that they have been told how to recognize when their infants are hungry and can describe at least 2 feeding cues.</p> <p>8.1.2 Criterion for evaluation: Of breastfeeding mothers, at least 80% will report that they have been advised to feed their infants as often and as long as the infants want.</p> <p>8.1.3 Criterion for evaluation: Of mothers who are feeding their infants formula, at least 80% will report that they have been taught appropriate formula feeding techniques, including feeding on cue, eye-to-eye contact, and holding the infant closely.</p> <p>8.1.4 Criterion for evaluation: The nursing director/manager on the maternity unit will confirm that no restrictions are placed on the frequency or length of feeds.</p>	<p>1. At least 80% of breastfeeding mothers of term infants can describe at least two feeding cues.</p> <p>2. At least 80% of breastfeeding mothers of term infants report that they have been advised to feed their babies as often and for as long as the infant wants.</p>	<p>(b)(5)</p>

2016 BFUSA GEC Criteria	2018 WHO Global Standards	BFUSA Discussion Comments/Questions
<p>9.1.1 Criterion for evaluation: Of breastfeeding mothers, at least 80% will report that, to the best of their knowledge, their infants have not be fed using bottles.</p> <p>9.1.2 Criterion for evaluation: Observations in the postpartum unit and any well-baby observation areas will indicate that at least 80% of breastfeeding infants are not using bottles.</p> <p>9.1.3 Criterion for evaluation: The nursing director/manager will confirm that breastfed infants are not routinely given bottles.</p>	<p>1. At least 80% of breastfeeding mothers of preterm and term infants report that they have been taught about the risks of using feeding bottles, teats and pacifiers.</p>	<p>(b)(5)</p>
<p>9.2.1 Criterion for evaluation: Of breastfeeding mothers, at least 80% will report that:</p> <ul style="list-style-type: none"> •to the best of their knowledge, their infants have not sucked on pacifiers, or • that pacifier use was limited to painful procedures, or • that pacifier use was chosen by the infant's parents after receipt of appropriate education and counseling from staff. <p>9.2.2 Criterion for evaluation: Observations in the postpartum unit and any well-baby observation areas will indicate that at least 80% of breastfeeding infants are not using pacifiers, or, if they are, their mothers have been informed of the risks and this interchange is documented in the medical record.</p> <p>9.2.3 Criterion for evaluation: The nursing director/manager will confirm that breastfeeding infants are not routinely given pacifiers and that use of pacifiers in term infants is restricted to cases where there is a medical indication.</p>		

		BFUSA Discussion Comments/Questions
2016 BFUSA GEC Criteria	2018 WHO Global Standards	
<p>10.1.1 Criterion for evaluation: The nursing director/manager on the maternity unit will report that mothers are given information on where they can find support if they need help with feeding their infants after returning home.</p> <p>10.1.2 Criterion for evaluation: The nursing director/manager on the maternity unit will report that the facility fosters the establishment of and/or coordinates with mother support groups and other community services that provide breastfeeding/infant feeding support to mothers, and the designated staff member can describe at least one way this is done.</p> <p>10.1.3 Criterion for evaluation: The nursing director/manager on the maternity unit will report that the staff assures that mothers and infants receive breastfeeding assessment and support after discharge (preferably 2 to 4 days after discharge and again the second week) at the facility or in the community by a skilled breastfeeding support person who can assess feeding and give any support needed.</p>	<p>1. At least 80% of mothers of preterm and term infants report that a staff member has informed them where they can access breastfeeding support in their community.</p> <p>2. The facility can demonstrate that it coordinates with community services that provide breastfeeding/ infant feeding support, including clinical management and mother-to-mother support.</p>	(b)(5)
<p>10.1.4 Criterion for evaluation: The nursing director/manager on the maternity unit will report that the staff can describe an appropriate referral system and adequate timing for the visits.</p> <p>10.1.5 Criterion for evaluation: A review of documents indicates that printed information is distributed to mothers before discharge on how and where mothers can find help on feeding their infants after returning home and includes information on the types of help available.</p> <p>10.1.6 Criterion for evaluation: Of breastfeeding mothers, at least 80% will report that they have been given information about how to get help from the facility and how to contact support groups, peer counselors, or other community health services if they have questions about feeding their infants after they return home, and can describe at least one type of help that is available.</p>		

COMMENTARY

Guideline panels should not GRADE good practice statements

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In the first article in JCE's series presenting guidance for the application of grades of recommendation, assessment, development and evaluation (GRADE) methodology [1], we identified a number of limitations associated with the GRADE approach. One of these limitations related to a category of recommendations that guideline panels may feel are important but that are not appropriate for rating the certainty of the evidence (synonyms: confidence in estimates, quality of the evidence). Because, for such recommendations, a formal rating of certainty is inappropriate, they fall outside the domain of the standard GRADE process.

That article did not place the description of this category of recommendations in a prominent place. Perhaps as a consequence, our informal experiences with guideline panels, and two formal assessments, suggest that most guideline panels applying GRADE are unaware of good practice statements. The purpose of the present editorial to clarify the issue and to provide a more prominent exposition that will increase awareness and appropriate use.

In the original article, we described what we called “an ill defined set of recommendations” labeled as “motherhood statements” or “good practice recommendations”—here, we will refer to them as “good practice statements.” Perhaps the best way to understand the sort of statement to which we are referring is to consider a number of examples: please look now at the [Box 1](#) that presents recommendations that would optimally be characterized as good practice statements.

In our initial discussion of such recommendations, we struggled how guideline panels could best recognize these situations when it may be inadvisable to apply formal

GRADE methodology. We suggested that it was obvious that such recommendations would do substantially more good than harm (or vice versa) and that therefore no one would consider doing a study to definitively establish the answer to the implicit question.

We made an additional suggestion that we now believe is the best way to recognize recommendations that should not be graded but characterized as good practice statement. Before presenting that suggestion, we will consider how guideline panels have typically dealt with good practice statements. Panels using GRADE to address these issues offer strong recommendations with the evidence classified as warranting low or very low certainty (low confidence or low quality evidence). Such recommendations are not uncommon: indeed, in a systematic examination of Endocrine Society recommendations, of 121 strong recommendations based on low or very low certainty evidence (discordant recommendations), investigators classified 43 (36%) as good practice statements [2]. Furthermore, in a similar examination of World Health Organization recommendations, of 160 discordant recommendations, 29 (18%) were classified as good practice statements [1,3].

Is it true that the evidence supporting all these statements warrants low or very low certainty? Clearly, it is not. If one asked panellists recommending these clinical behaviors if they are confident that the behaviors will result in more desirable than undesirable consequences, they would invariably answer in the affirmative.

Their response (ie, implicitly expressing moderate or high certainty in estimates of effect), in the face of formally classifying evidence as low or very low quality, is clearly contradictory and highlights a common misunderstanding of GRADE methodology. In the absence of randomized trials—indeed, in the absence of any formal studies addressing the question of interest—guideline panels believe that they should classify evidence as low or very low quality. In doing so, they have not grasped GRADE's definition of quality of evidence as confidence in estimates of effect.

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Box 1 Examples of good practice statement previously mistakenly presented as GRADEd recommendations

For patients with congenital adrenal hyperplasia, we recommend monitoring patients for signs of glucocorticoid excess [5].

Triage (ie, take different courses of action for low vs. higher pretest probability) people with tuberculosis symptoms [6].

Health services should be made available, accessible, and acceptable to sex workers based on the principles of avoidance of stigma, nondiscrimination, and the right to health [7].

In patients presenting with heart failure, initial assessment should be made of the patient's ability to perform routine/desired activities of daily living [8].

Guideline panellists considering good practice statements have failed to make the connection that their high level of certainty in net benefits would mandate a corresponding rating of high quality, and they are therefore mistaken in classifying the evidence as low or very low quality. Good practice statements typically represent situations in which a large body of indirect evidence, made up of linked evidence including several indirect comparisons, strongly supports the net benefit of the recommended action.

Although indirectness often results in diminished certainty in effects, this is not always the case. An amusing example repeatedly used is the difference in outcome when one does or does not use a parachute when jumping from an aircraft. Panels should consider making good practice statements when, without a formal literature search, they are confident that indirect evidence is at or near this level of certainty in the net benefit of the intervention. Furthermore, panels might reasonably consider making good practice statements when it would be an onerous and unproductive exercise to collect the indirect linked evidence supporting the recommendations.

Why are we confident that it is wise to monitor patients with congenital adrenal hyperplasia for glucocorticoid excess? The reason is that relevant symptoms and signs appear not infrequently, that patients will suffer if clinicians fail to recognize these signs, and that clinical action can ameliorate the problem.

It would be possible to accumulate and summarize the relevant evidence. There have been no randomized trials or observational studies that have directly compared monitoring to no monitoring of glucocorticoid excess in patients with congenital adrenal hyperplasia—thus, we have no direct evidence. The panel could, nevertheless, build a case for the benefits through indirect evidence. They could collect all the reports of the adverse

consequences of glucocorticoid excess. They could then collect the evidence that supports the usefulness of the relevant symptoms, signs, and laboratory tests in the diagnosis of glucocorticoid excess. Then, they could collect and summarize the evidence of the benefits of the candidate management strategies. Finally, they could describe how they link these three bodies of evidence to make the case for their high level of certainty regarding the net benefits of monitoring for glucocorticoid excess. The case for the good practice statement is the poor use of time in collecting and summarizing the relevant evidence.

To turn to another of our examples, why are we confident that it is wise to triage every patient with symptoms that might even remotely suggest possible tuberculosis? By triage, the guideline developers mean isolation and investigation of patients with suspected tuberculosis for only those patients with a sufficiently high pretest probability. The reason we are confident in the advisability of triage is that failure to do so—that is, fully investigating every individual with symptoms even remotely suggestive of tuberculosis rather than restricting investigation to those with a higher pretest probability—will lead to over investigation and wasteful use of scarce health resources.

Why the confidence in providing appropriate health services to sex workers? First, confidence is based on an underlying value we place in equitable access to health care. Second, because a large number of health care interventions do more good than harm sex workers will therefore have better health if they have access to services.

In each case, although there is a great deal of evidence supporting the recommended behaviors, teasing out the nature of this evidence would be challenging and a waste of time and energy. Given that time and energy is typically at a high premium in the guideline development exercise, their expenditure in turning good practice statements into GRADEd recommendations (strong recommendations based on high or moderate not low or very low certainty) is likely to be inadvisable.

1. Reservations regarding good practice statements

A word of caution is required: good practice statements may be subject to abuse. They potentially allow guideline panels to issue strong recommendations that may be unwarranted (which guideline panels seem prone to do [2,3]) and to do so without the intellectual work that formally applying the GRADE process demands. Furthermore, judgments about what are incontestable net benefits are inevitably subjective. Thus, good practice statements represent a temptation, and panels should therefore use them sparingly.

We would suggest that guideline panels explicitly address the following issues before they make good

Table 1. Questions guideline panels considering good practice statement should ask themselves

i) Is the statement clear and actionable?
ii) Is the message really necessary?
iii) Is the net benefit large and unequivocal?
iv) Is the evidence difficult to collect and summarize?
v) If a public health guideline, are there specific issues that should be considered (eg, equity)?
vi) Have you made the rationale explicit?
vii) Is this better to be formally GRADED?

practice statements (Table 1). First, as with all recommendations, good practice statements should be clear, specific—including specification of the population of interest—and actionable. For instance, in the statement in the Box 1 regarding congenital adrenal hyperplasia, the associated text should specify the frequency and nature of the monitoring, and the action to be taken should the clinician identify signs of glucocorticoid excess.

Note that, if what is meant by monitoring is multiple additional visits to the physician specifically to check for glucocorticoid excess, whether such monitoring is beneficial and not simply a waste of resources would be called into question. As a result, this would no longer be a good practice statement. This highlights the necessity for very clearly specifying the intervention and alternative in best practice statements—which, when clearly specified, may in fact warrant formal GRADE appraisal.

Second, the message should be necessary: that is, without the guidance, clinicians might fail to take the appropriate action. Is it really plausible that clinicians who are the target audience for the guideline and who look after patients with congenital adrenal hyperplasia will fail to monitor for signs of glucocorticoid excess? If the answer is that it is not plausible, there is no need for the good practice statement.

Third, the proposed course of action should be feasible in the context considered, and it should be associated with minimal harm and cost: in other words, from the patient's point of view, the net benefit should be large and unequivocal. Furthermore, the intervention should not be associated with excessive opportunity cost—that is, panellists should consider what other, possibly more useful, interventions might be jeopardized by instituting the proposed course of action.

The fourth criterion, that evidence should indeed be difficult to collect and summarize, is an issue of opportunity cost: is the guideline panel's limited time and energy better spent on other efforts to maximize the guideline's methodological quality and overall trustworthiness? With regard to this criterion, consider the following recommendation: women with severe hypertension during pregnancy should receive treatment with antihypertensive drugs. A guideline panel issued this as a strong recommendation based on very low-quality evidence [4]. If the panel really did believe the quality of evidence was very low (ie, they

were very uncertain there was net benefit), they should not have made a strong recommendation.

Is it possible, however, that the panel actually was sure there were benefits (ie, they really believed the evidence warranted high certainty) and was misapplying GRADE in the certainty judgment? If so, should this recommendation be transformed into a good practice statement?

The answer is that it should not. Presumably, the panel's logic starts with the fact that we have evidence warranting high certainty that, in nonpregnant individuals, treating severe hypertension over long periods of time results in important benefits in morbidity and mortality. This evidence is easy to find and summarize. The panel is then presumably deducing that treatment of pregnant individuals over shorter periods of time may also reduce long-term morbidity and possible mortality. The certainty that is warranted by this deduction might be a matter of debate but should be made explicit. If only low or very low certainty is warranted, a weak recommendation is appropriate. In any case, the recommendation requires a formal application of the GRADE approach.

Fifth, although the principles enunciated here apply to all guidelines, additional considerations may be required for public health guidelines intended for global audiences. Such considerations may include the cultural and ethical standards of particular populations.

Finally, given the subjective nature of the judgment that appreciable net benefit from the recommended behavior is incontestable, the rationale for that judgment should be explicit. Earlier in this article, we have provided such rationales for three of the best practice statements in the Box 1. The fourth might be “the relation between physiological measures and patients' function in heart failure is weak. Patients value their function highly, and management should be tailored to optimizing function. Without an inquiry into function, such tailored management will not be possible.” The explicit statement of the rationale for the belief in benefit allows that judgment to be open to question.

2. Conclusion

We suggest that guideline panellists can best understand GRADE principles and apply these principles to the recognition of recommendations that warrant good practice statements rather than rigorous application of GRADE, by asking themselves how certain they are in estimates of effect. When they have a high level of certainty in these estimates based on the previously mentioned principles, they will also be confident that the associated clinical actions will do more good than harm, or vice versa. There will be instances in which they indeed have a high level of certainty in estimates and that high level of certainty is based on a large body of linked evidence. Because that evidence is not well described or published, formally accumulating and summarizing the evidence will be a poor use of their

time and energy. Under such circumstances, they could forego the formal GRADE process and issuing a formal GRADED recommendation and instead make a good practice statement. In doing so, they should make clear to their audience how their good practice statements differ from formal GRADED recommendations.

Finally, panels should be cautious and sparing in their use of good practice statements, carefully considering the necessity for the statement, making explicit their rationale, and seriously considering the possible merit of a formal GRADE assessment of the indirect linked evidence and the extent of the indirectness.

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REVIEW ARTICLE

Imprinting, latchment and displacement: a mini review of early instinctual behaviour in newborn infants influencing breastfeeding success

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ABSTRACT

Instinctive behaviours have evolved favouring the mother–infant dyad based on fundamental processes of neurological development, including oral tactile imprinting and latchment. Latchment is the first stage of emotional development based on the successful achievement of biological imprinting. The mechanisms underpinning imprinting are identified and the evolutionary benefits discussed.

Conclusion: It is proposed that the oral tactile imprint to the breast is a keystone for optimal latchment and breastfeeding, promoting evolutionary success.

INTRODUCTION

Imprinting is the term which was chosen by Konrad Lorenz in 1935 to describe the rapid visual acquisition of the ability of newly hatched goslings to recognise and socially bond to the mother for evolutionary survival (1).

Lorenz was surprised that most precocious birds did not recognise their species through instinct. He found that the first three-dimensional representation of a moving sighting had by the newly hatched gosling, would be visually recognised as the mother. The recognition would occur at a sensitive time, usually near the day of hatching, and a following response would become established even when the sighting was an inanimate decoy. Similar social reactions are readily released in the human infant by other than the genetically based biological object as we see with a decoy bottle teat/pacifier/dummy/thumb replacing the absent or deprived maternal nipple when the newborn has not been given the opportunity to orally imprint with the mother's breast during the stage of alertness following birth and preceding sleep. The infant may awaken sometime after the post-birth sleep and find its decoy mother,

commonly the self-thumb unless a dummy has already been introduced, while the real mother sleeps. Imprinting has been extensively studied in precocial birds such as geese, ducks and chickens (1–4).

This study aims to review the process of mammalian imprinting, focusing on human term newborn behaviour, imprinting and latchment. Such an understanding may assist

Key Notes

- Imprinting and subsequent latchment is a primary stage of emotional and neurobehavioural development in which the infant recognises its mother through oral tactile memory for continuing evolutionary survival.
- Displacement of the normal imprint from the mother's breast may lead to a range of adverse outcomes for both mother and her infant.
- Elucidating these processes and their consequence on development may assist in generating improved strategies for breastfeeding and neonatal development.

in breastfeeding strategies and secondary nutritional and immunological newborn development. Human mammalian imprinting has previously been investigated, initially without discovery of a process (5). Mobbs, in 1989, hypothesised that the human behavioural imprint was mediated by oral tactile sensory stimuli and was necessary for evolutionary survival (6). This hypothesis was supported by the finding that one teat preference was predominant across the mammalian spectrum with humans included (6,7). The human baby deprived of the mother's breast has been observed to suck one digit or combination of digits out of ten to the exclusion of all others and become distressed if the imprinted decoy is physically denied (6). Thumbsucking is the earliest and most common habit in children affecting as many as 45% of the young population in the world (8). From birth through adolescence decoy, non-nutritive sucking of an unique object has been significantly correlated with jaw and dental problems in both first and permanent teeth (8,9). Oral tactile recognition is achieved through Merkel cell mechanosensors. Merkel cells proliferate in the human foetus from the ninth gestational week and spread through a significant part of the buccal mucosa with an appropriately related neuronal coverage in the sensory cortex (10). The behavioural observations that we see are consistent with the hypothesis of Merkel cell sensory nerve mechanotransduction supporting the learning mechanism of human imprinting (11,12).

For the purposes of this review, the literature was extensively and objectively researched using Google Scholar, Medline, PubMed and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). Articles were qualitatively assessed for their relevance to 'imprinting', 'latchment' and 'attachment' in the newborn. Articles were unrestricted regarding language, but only those written in English were included. The use of certain key terms is made within this paper, and we believe that consistency in understanding these definitions will lead to improved infant care (Table 1).

EARLY INSTINCTUAL BEHAVIOUR IN ANIMALS AND NEWBORN INFANTS

Imprinting

Sluckin in 1970 identified five principal tests that, if satisfied, would identify imprinting in precocial birds (18).

- Choice test
- Recognition at reunion test
- Distress at separation test
- Run to mother test
- Work for reunion test

These tests can be used, with some modification, to identify imprinting in other species. A newborn survival instinct is fundamental to each branch of the animal kingdom with the expectation that converging features lead to success. Mobbs in 1990 modified Sluckin's tests to suit the semi-altricial human mammal as follows (7).

Table 1 Definitions regarding imprinting, latchment and displacement in the human mammal

Imprinting	The behavioural process that takes place during a sensitive period in the early hours of life during which the baby's evolutionary biology enables it to orally fixate to a stimulus feature (normally the mother's nipple and the surrounding milking area) and learn its tactile characteristics (13)
Latchment	The first emotional stage of development during which the baby recognises its mother through the oral tactile perception of the stimulus feature in the mouth for evolutionary survival ('mother in the mouth') (13)
Attachment	This is the second emotional stage of development commencing sometime after six months when the baby visually recognises its mother as a whole person ('mother in the eye'). During this biologically instinctive attachment phase, the baby will seek close proximity to its mother as a safe haven for evolutionary survival and as a secure base from which to explore and become independent. Attachment is a behaviour directed by the infant to the carer, and the characteristic is a predictor of social and emotional outcomes (14,15). Latchment behaviour is maintained during the attachment phase as baby will seek and continue non-nutritive sucking of the stimulus feature (14,16). This phase continues throughout toddlerhood
Bonding	The repeated behaviour chosen by the caregiver (attachment figure) to support the infant physically and emotionally and facilitate the release of the infant's instinctive ability to attach to the caregiver for evolutionary advantage (16)
Latch and latching	The physical positioning of the mother's nipple and the milking area of the breast within the baby's oral cavity
Decoy	Any object (pacifier, dummy, thumb, bottle, teat, etc.) that replaces the stimulus feature which evolution designed (mother's breast). 'Pacifier' is a marketing term or branding device with the pretence to normalise the use of foreign objects
Displacement	The transference of an imprint to a decoy (17)
Imprinted object	The Imprinted Object is that upon which the baby is emotionally fixated (breast, thumb, dummy, pacifier, bottle teat or other decoy). The fixation is most evident at sleep time when baby can only be comforted by the imprinted object
Maternal nipple deprivation	The mother's unwillingness to allow baby normal access to the nipple (often in response to extraordinary societal pressures and the absence of role modelling)

Choice test

The newly born human baby held in the mother's arms, eyes at nipple level, skin to skin, front to front, in a position of comfort for the mother and safety for the baby, may be favoured by breast odour as the initial maternal directional stimulus to guide the baby to the breast (19).

Sequential spontaneous behaviour of wide eye opening followed by the seeking mouth gaping and the tongue

moving downwards and forwards, usually in the first fifteen minutes of life, signals the mother, who has evolved as an active participant in the latching process, of the nearing readiness to feed (20,21).

The neonate's instinctual goal-directed behaviour continues, and aided by proximity for visual accommodation, a response to a specific stimulus feature of the mother, the mother's nipple and the surrounding pigmented milking area, ensues and baby is now ready to draw the breast into the mouth for the first feed (22).

Oral tactile recognition

Mobbs in 1989 proposed that the activation of Merkel cells in baby's buccal mucosa in response to a tactile stimulus was the first step in oral recognition of the nipple and milking area of the breast as 'mother in the mouth' (6). Virtually all vertebrates have a buccal region rich in Merkel cells, and these have been of scientific interest as they were identified in 1875. Their main function is as a mechanoreceptor of tactile stimuli. Mechanotransduction as part of our evolutionary process dates back to single cell organisms 1.7 billion years ago (23).

The Merkel cell-neurite complex receives information through mechanosensation in the buccal mucosa and passes on an encoded neural image of the imprinting object to the baby's central nervous system. The encoded features embrace shape, edges and curvatures. The response is maintained throughout the stimulus which allows these cells to distinguish two points of discrimination close together which includes texture. This is the process which identifies fine spatial details such as Braille-like characters (24). The buccal region of the human has a sensory innervation well represented by Penfield's sensory homunculus. This region is comparable to the sensory human hand with a large area of the cerebral cortex devoted to it to facilitate imprinting through teat identification (25).

One teat preference

Mobbs observed that a human baby would suck one digit out of ten to the exclusion of all others and to a degree of excoriation and pain (6). Mobbs also observed that orphaned, human-reared, maternal nipple-deprived mammals could suck down to the bone of the digit chosen to replace the displaced mother (26). The choice of such a single object preference decoy was a feature seen across the mammalian spectrum and consistent with the memory enabled through Merkel cell sensory identification and the emotional consequence of latchment (13).

Maternal teat preference supports the evolved physiological correlate of feedback inhibition of lactation and autonomy of the breast (27). The following sample of mammals demonstrates teat preference: pigs, hyrax (an elephant relative), domestic kittens, Antechinus (marsupial mouse), kangaroos, marmosets, pine voles, snow leopards, chimpanzees and humans (13). If oral tactile recognition of a non-nutritive object as the mother occurred in animals, this would preclude survival of the individual without human intervention. The concept of one teat preference extends to decoy pacifiers/dummies with human infants showing emotional

distress following change of object shape or texture as the new pacifier/dummy replaces the old (28). These are the behaviours of Merkel cell encoding recognition (oral tactile memory) promoting teat preference fixation.

Newborn returns to stimulus feature

The baby's discovery stimulus of the nipple and surrounding pigmented milking area is initially innate through odour and visual feature recognition (19). The oral tactile imprint is a learnt form of perceptual recognition via Merkel cell mechanosensation which governs the imprinting process (24). The baby's return to the nipple ('mother in the mouth') is an emotionally directed process termed 'latchment' (9). The latchment phase serves its strategy for evolutionary survival until the infant is able to recognise the mother visually as a whole person sometime after six months of age when the emotional relationship is termed 'attachment' (14,16). The first emotional relationship latchment period, although nameless until described by Mobbs, has been broadly researched (29,30). The findings from Ainsworth and Bell showed that a maternally sensitive and more importantly a rapid response to the infant's needs (to promote evolutionary survival) in the first three months of life was associated with a more harmonious mother-infant relationship in the final three-month period of the first year of life (30). The provision of contact stimulation through hugging and cuddling was also found to be a significant affectionate act related to the development of secure attachment (31). Furthermore, oxytocin research has supported our understanding of the levels of affectionate contact favouring the child-mother relationship (32). The studies carried out by Ainsworth and her colleagues concur that parenting methods which favour evolutionary survival in the early latchment months of life lend support to the achievement of earlier and more secure attachment which again favours evolutionary survival.

Works for reunion

The semi-altricial human baby will work for reunion with the imprinted stimulus feature by signalling the need through the innate behaviours of crying and emotional distress designed by evolution to aid survival.

Displacement

If deprived of the stimulus feature, displacement will occur. Displacement from the mother's nipple to a decoy has been reported in many mammalian species (13). Lorenz believed that once the early newborn sensitive period of the precocious gosling was completed, the object preference was permanent and could not be changed by subsequent experience (1). Sluckin and Salzen regarded imprinting (visual for precocious birds) as a perceptual learning phenomenon in which the sensitive period is experience dependent and stabilised by the amount of experience (33). Their observation is consistent with and supports the encoding process carried out by Merkel cells in the buccal mucosa at a sensitive time. Consider the human baby fixated on a pacifier/dummy or thumb; a change of imprint back to the maternal breast may be achieved, despite great

emotional distress, by bed-sharing skin to skin with baby for a few days with mother's nipple; the only stimulus feature made available. We believe that this is not inconsistent with Sluckin's, Salzen's and Meyer's opinion (33,34). It has been observed that the unrestricted availability of the nipple in the birthing room with baby in skin to skin contact with the mother until the first breastfeed has been completed with sleep is associated with baby adopting an innate, anatomically efficient, deep latch breastfeeding skill with subsequent improved success and duration of breastfeeding (35,36). This process has similarities, such as in other species, where a precocial bird hatchling innately recognises the real mother for evolutionary survival during the sensitive period, in a natural nesting environment free of alien biological and nonbiological stimulus features.

Importantly, maternal nipple deprivation may be followed by apparent emotional confusion and frustration leading to an inappropriate replacement of mother in the mouth by a decoy thumb or pacifier/dummy. This process is best described as 'Freudian displacement', displacement being one of Freud's original defence mechanisms (17). Distress from maternal nipple deprivation may lead to displacement, with redirection of emotions, to a substitute decoy target, thereby promoting risk of maternal fragmentation. The decoy target may be observed as a displacement promoting superstimulus (37). Examples include the macropod digit of an orphaned wallaby, tail, thumb or penis in a monkey, thumb or digit pair in the human, tongue sucking in ruminants, penis sucking in pen-mate male calves and the bottom of a boat by an orphaned whale calf (13). A non-body part decoy such as a plastic teat, pacifier or dummy may be chosen for the animal by a carer.

DISCUSSION

The importance of the latchment phase is highlighted by the emotional development which is proceeding during the first six months of life, at a time of rapid growth which notably includes baby's brain (38). Evolutionary success requires close maternal contact and frequent breastfeeds to provide nutrition for the promotion of brain metabolism and optimal growth of myelinated white matter (39,40).

The anthropologist Margaret Mead observed that in societies where there was free access to the breast with the correlate of breastfeeding success, that decoy sucking did not occur (41). In other societies, the childcare issue of sucking decoys such as pacifiers, dummies, bottle teats and thumbs together with the concept of nipple confusion has received much attention (42–45). This issue has been described as a commerciogenic problem as it is the provider of the dummy, the giver of the bottle or the depriver of the maternal nipple who as an adult is the one confused in their own understanding of infant care (45). Understanding oral tactile recognition of decoys as mother in the mouth directs attention to the mammalian norm evolved from precursors over a period of 300 million years to produce a species-specific primate milk (46). The behavioural and health risks resulting from impairment of this defining mammalian relationship deserve

attention as there is considerable contrary information provided by multinational commercial interests (47).

Harlow's orphaned and isolated monkey experiments have been of great importance in understanding emotional relationships. On comparing the videos of the wire frame mother with milk and what appears to be the socially preferred cloth mother without milk, the baby monkey thumb or body part sucks throughout the experimental room and it is probably the comfort of the cloth mother material rather than emotion which is the directive. Harlow and other observers did not realise the significance of the thumb (or other decoy) probably because thumbsucking was considered a societal norm at that time (48–50).

CLINICAL APPLICATIONS OF LATCHMENT

The outcomes for mother and baby may be improved if clinicians and mothers alike become aware of the evolutionary significance of the oral tactile imprint and the outcomes of each mode of latchment. These outcomes are wide-ranging and are described below.

Optimal latchment

Optimal latchment may be facilitated by:

- Ensuring baby's close and unrestricted proximity to the breast (skin to skin contact) until well after initial latching has commenced and baby is sleeping.
- Ensuring that the mother is aware that introducing any decoy (thumb, dummy/pacifier, bottle teat, etc.) should be avoided.
- Safe co-sleeping with the infant.
- Rapid response to distressed infant.

Oral tactile imprinting and the emotional component of latchment are the forerunners of a sensitive and quickly directed response to baby's needs. Carer body contact and rapidity of response are most easily and readily provided by breastfeeding. There is evidence from observational studies that the rapidity of response to infant needs, which has over the millennia been a component directed at evolutionary success, favours secure attachment (16,29–31,51).

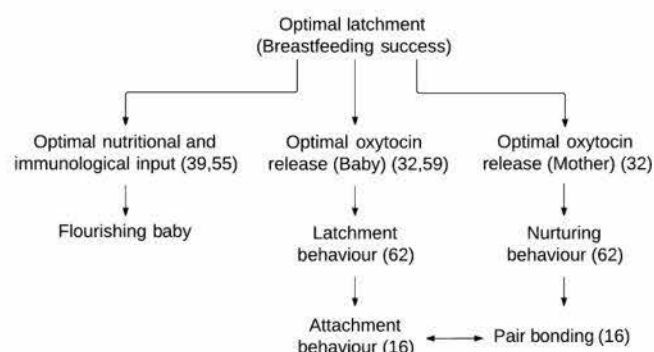


Figure 1 Physiological and psychological outcomes of optimal latchment.

Awareness of a positive relationship between latchment behaviour and attachment should be seen as a noteworthy clinical application. The physiological and psychological outcomes of optimal latchment are summarised in Figure 1.

Suboptimal latchment

Clinical practices that are inconsistent with the evolutionary process of latchment should be avoided. These include:

- A delay in the introduction of baby to the breast.
- Maternal nipple deprivation.
- Displacement with a thumb, dummy/pacifier or other decoy.
- Distancing mother and baby during sleep.

Maternal nipple deprivation may be seen in the birth room when there is failure in recognising the sensitive time heralding baby's readiness to suckle. At other times, the suckling may be restricted with insufficient time given for stabilisation of the imprint. The oral tactile imprint has evolved as a survival strategy associated with birth and the achievement of a latch to the breast for optimal milk transfer. The emotional component, termed latchment, will continue for evolutionary success. Restricted access to the breast for suckling results in stasis of milk within the breast and subsequent release of feedback inhibitors of lactation will lead to dwindling of milk production (27).

Parenting attitudes that limit physical contact with children and restrict affection by distancing have resulted in relationship deprivation at sleep time (52). The imprinted object is the one suckled (mammalian breast) or sucked (other than the mammalian breast) when baby is passing to sleep (53). Untimely absence or planned deprivation of the maternal nipple with onset of decoy sucking is causally related to the way of falling asleep where the infant may be painfully aware of separation (54). Displacement of an oral tactile imprint is an important concept and provides a reason why decoy usage of pacifiers/dummies/thumbs as the mother hinders breastfeeding success (17,56).

Nutritional and immunological deficits together with emotional and cognitive changes which are associated with formula feeding are of concern, and continued exploration of the effects of formula feeding is vital for our understanding of this field. The physiological and psychological outcomes of displaced latchment are summarised in Figure 2.

FUTURE RESEARCH

This paper has identified and drawn together a broad range of published research supporting the hypothesis that human imprinting is an oral tactile mechanism with consequential clinical implications. Due to a paucity of relevant literature, a quantitative meta-analysis was not able to be performed. There remain areas of research that would lend further supporting evidence for the hypothesis, in particular the spontaneous and instinctual behaviours indicating readiness for latching, and secondly the transition from latchment behaviour to attachment behaviour. This future work may consider quantitative rather than qualitative methods of investigation, including newer radiological techniques such as magnetic resonance brain imaging, serological markers and precise developmental monitoring during early life.

Instinctual behaviours indicating readiness for latching

It has been observed that newborn babies proceed to open their eyes widely after birth (20) occurring about 5–20 minutes after an initial blinking phase. Following this, the mouth opens and the tongue descends and protrudes. Further research may confirm whether this transition indicates readiness to commence latching. Such a study may involve confirming the proportion and temporal association of babies that undergo this transition and a longitudinal study that measures breastfeeding success against the first imprinted object.

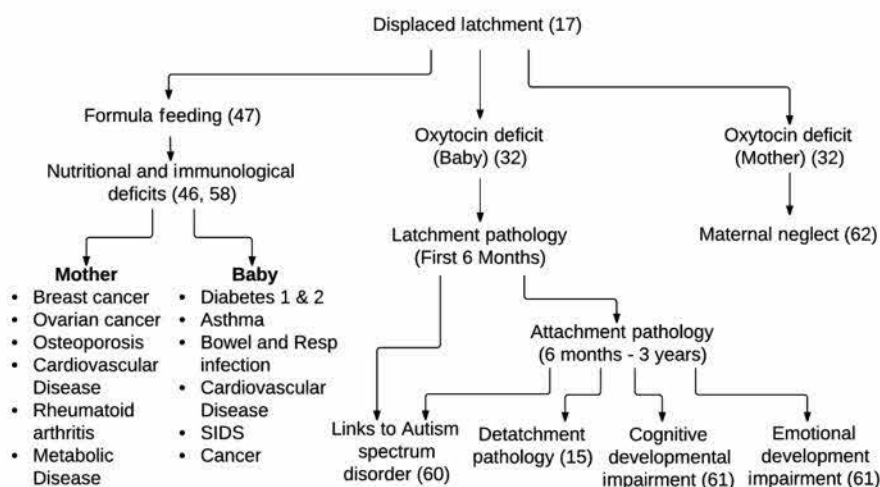


Figure 2 Physiological and psychological outcomes of displaced latchment.

Transition from latchment behaviour to attachment behaviour

It is proposed that attachment characteristic (second stage of emotional development) is largely dependent upon successful latchment (the first stage of emotional development). A longitudinal study may consider three groups of newborns involving an exclusively breastfed control as an evolutionary standard, partially breastfed group and formula-fed group to identify the correlation with the security and timing of attachment. Analysing the dose relationship of formula feeding to illness, behaviour, public health costing and management would provide a useful contribution to our further understanding in this area (57).

CONCLUSION

We have provided evidence that imprinting is a process by which babies orally fixate to a stimulus feature, normally the mother's nipple and surrounding milking area, for evolutionary survival. Imprinting is soon followed by latchment which is the first stage of emotional development in which the baby recognises its mother through oral tactile memory for continuing evolutionary success. Displacement of the normal imprint from the mother's breast may lead to a range of adverse outcomes for both mother and baby. We believe that the understanding of these processes and their evolutionary survival significance may help us to better serve and support the choice to breastfeed and the breast-feeding mother and her baby.

DISCLOSURE STATEMENT

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Proposed guidelines for skin-to-skin care and rooming-in should be more inclusive

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Dear Editor,

We read with interest the recent commentary “The Baby Friendly Hospital Initiative and the ten steps for successful breastfeeding. A critical review of the literature” published in the *Journal of Perinatology* [1]. Table 2, created by Gomez-Pomar and Blubaugh, provides a potential order set for “safe skin-to-skin care,” reportedly based on recommendations provided by the AAP [2] and Davanzo [3]. However, the guidance provided is unnecessarily restrictive and is inconsistent with recommendations endorsed by the American Heart Association/American Academy of Pediatrics/International Liaison Committee on Resuscitation (AHA/AAP/ILCOR) neonatal resuscitative guidelines [4]. There is no evidence that near-term newborns (37–38 weeks gestation), or those with no prenatal care, maternal fever, history of drug exposure, prolonged rupture of membranes, non-life-threatening congenital anomalies, infants <2500 g, or suspicion of chorioamnionitis require stabilization on a warmer bed. These newborns may be stabilized and assessed on the mother while in skin-to-skin care (SSC). Infants with meconium staining with normal respiratory effort, good tone, and heart rate >100 may also be placed immediately in SSC. Furthermore, late preterm newborns (≥35 weeks gestation) may have SSC if stable, with good tone, normal heart rate, respiratory effort, and Apgar score of ≥7 at 5 min. In the event of positive pressure ventilation, SSC should be postponed until the infant is stabilized, but is not precluded [5].

Suggestions for monitoring during SSC included in Table 2 are also overly conservative and may be impractical. The AAP Clinical Report [2] and others [6] recommend the following guidance for monitoring:

- Continuous observational monitoring: staff member at the bedside of the dyad, preferably for the first 2 h, until transitioned to the mother–infant unit; the first 2 h after birth poses the highest risk for sudden unexpected post-natal collapse (SUPC).
- Vital signs obtained at 10, 30, 60, 90, and 120 min until transitioned to the mother–infant unit/postpartum unit.
- Color is pink after circulatory transition has occurred.
- Respiratory rate is 30–60 breaths/min.
- Temperature obtained (axillary) at 60 and 120 min is 36.5–37.5 °C, not hypothermic (<36.5 °C).
- Routine continuous pulse oximetry is unnecessary; however, if pulse oximetry is used, the oxygen saturation should be >90%.

Given the recognized benefits of SSC, unnecessary limitations pose a risk for adverse outcomes, such as hypothermia, hypoglycemia, and decreased breastfeeding [7]. Finally, while the authors indicated proposed guidelines for rooming-in, these do not appear in Table 2, despite the table’s title. We agree there are safety considerations for rooming-in, outlined in the AAP Clinical Report; however, we disagree with the authors that there is little evidence to support this practice. The results of the randomized controlled trial involving 176 dyads were inconclusive, not negative, regarding breastfeeding outcomes [8]. Additional benefits of rooming-in include bonding, maternal self-efficacy, and newborn comfort, especially in newborns suffering from neonatal abstinence syndrome. Evidence that mothers are “made to feel guilty is lacking;” on the contrary, patient satisfaction scores have increased after rooming-in has been instituted [9]. Patient safety is paramount and can be implemented along with the AAP’s endorsement of the ten steps to successful breastfeeding.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.


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Extended author information available on the last page of the article.

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From: Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 15 Dec 2016 08:47:35 -0500
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Subject: FW: Breastfeeding/Baby Friendly F/U meeting today
Attachments: RE: BFHI and website , Baby Friendly Hospital Initiative - agenda.docx, BFHI - clean version.docx, DRH VERSION_ AFT Talking points_BFHI safety_CGP_jmn_cko_SPB_abel._cko_dt....docx

[fyi](#)

From: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, December 15, 2016 6:49 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>; Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP) <rnf2@cdc.gov>; Murphy, Paulette (CDC/ONDIEH/NCCDPHP) <pem1@cdc.gov>; Black, Erin (CDC/ONDIEH/NCCDPHP) <epm7@cdc.gov>; Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; Torres, Monica (CDC/ONDIEH/NCCDPHP) <enz2@cdc.gov>; Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfi2@cdc.gov>
Cc: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>
Subject: Breastfeeding/Baby Friendly F/U meeting today

Hi everyone,

In preparation for our meeting today, I wanted to share the following documents:

- Agenda
- Proposal to update the website
- Draft talking points (clean and track changes version)

One note about the talking points: The clean version includes my recommendations and comments. I initially tried to include these in the track changes version, but it was getting too difficult to read.

Many thanks to Erin, Ashley, and Monica for helping to shepherd these along.

Karen

From: Black, Erin (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 12 Dec 2016 14:35:58 -0500
To: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Cc: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR); Torres, Monica (CDC/ONDIEH/NCCDPHP); Black, Erin (CDC/ONDIEH/NCCDPHP); Borda, Ashley (CDC/ONDIEH/NCCDPHP) (CTR)
Subject: RE: BFHI and website
Attachments: 596.full.pdf

We had a call this afternoon to discuss the website. Erica proposed for Phase 1 to add the following links to the [CDC BF website](#) under the 'guidelines and recommendations' section in a new section called (b)(5). Ashley is out (b)(6) today, but hopefully she'll feel better tomorrow and can work with Curtis to create a mock up for you and Deb to review and then hopefully it can go live shortly.

(b)(5)

Phase 2 will include more CDC description/content and links to the following (and possibly others we are able to identify as being useful)

(b)(5)

From: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Sent: Monday, December 05, 2016 2:23 PM
To: Black, Erin (CDC/ONDIEH/NCCDPHP) <epm7@cdc.gov>; Borda, Ashley (CDC/ONDIEH/NCCDPHP) (CTR) <WRG5@cdc.gov>
Cc: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR) <yhm7@cdc.gov>; Torres, Monica (CDC/ONDIEH/NCCDPHP) <enz2@cdc.gov>
Subject: RE: BFHI and website

Hi all,

If we could include some links related to what has already been published in the short term (i.e. by the end of the month) that would be ideal. (b)(5)

(b)(5) Daurice may have some other ideas.

I don't know if it's urgency...more that we have asked Baby Friendly USA to be a little bit more out front on this issue and we want to ensure that we have something on our website as well.

Hope that makes sense.

Thanks.

Karen

From: Black, Erin (CDC/ONDIEH/NCCDPHP) <epm7@cdc.gov>
Date: December 5, 2016 at 10:18:14 AM EST
To: Borda, Ashley (CDC/ONDIEH/NCCDPHP) (CTR) <WRG5@cdc.gov>, Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Cc: Torres, Monica (CDC/ONDIEH/NCCDPHP) <enz2@cdc.gov>, Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR) <yhm7@cdc.gov>
Subject: RE: BFHI and website

Karen can answer.

From: Borda, Ashley (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Monday, December 05, 2016 10:17 AM
To: Black, Erin (CDC/ONDIEH/NCCDPHP) <epm7@cdc.gov>; Torres, Monica (CDC/ONDIEH/NCCDPHP) <enz2@cdc.gov>
Cc: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR) <yhm7@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Subject: RE: BFHI and website

Erin,

Do you know what the level of urgency is for this request? It is built into our overarching web plan, but we are not at that section yet.

Ashley

From: Borda, Ashley (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Monday, December 05, 2016 9:01 AM
To: Black, Erin (CDC/ONDIEH/NCCDPHP) <epm7@cdc.gov>; Torres, Monica (CDC/ONDIEH/NCCDPHP) <enz2@cdc.gov>
Subject: RE: BFHI and website

Hi Erin and Monica,

Can you give me some time to pull together what Erica and I have discussed re: BFHI/safety and website updates?

We have been working on this for some time and it would help set up the conversation w/Daurice and Jennifer. That way we can ask them for gaps/specifics to get the pages done.

Thanks!
Ashley

From: Black, Erin (CDC/ONDIEH/NCCDPHP)
Sent: Monday, December 05, 2016 8:00 AM
To: Torres, Monica (CDC/ONDIEH/NCCDPHP) <enz2@cdc.gov>
Cc: Borda, Ashley (CDC/ONDIEH/NCCDPHP) (CTR) <WRG5@cdc.gov>
Subject: Fw: BFHI and website

Can you set up a meeting with you, me, Ashley, Daurice and Jennifer Nelson to discuss.
Thanks

From: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Sent: Monday, December 5, 2016 6:59 AM
To: Black, Erin (CDC/ONDIEH/NCCDPHP)
Cc: Torres, Monica (CDC/ONDIEH/NCCDPHP); Borda, Ashley (CDC/ONDIEH/NCCDPHP) (CTR)
Subject: BFHI and website

Hi Erin,

During the last meeting that we had on the BFHI and safety, we thought it would be a good idea to update our website with some language and links to some of the new documents that have been developed [REDACTED] (b)(5)

[REDACTED] (b)(5) Can you work with Ashley and Monica on this? This may entail connecting with Daurice and/or Jennifer Nelson.

Let me know if you have any questions.

Thanks.

Karen



Skin-to-Skin Care for Term and Preterm Infants in the Neonatal ICU

Jill Baley, MD, COMMITTEE ON FETUS AND NEWBORN

abstract

“Kangaroo mother care” was first described as an alternative method of caring for low birth weight infants in resource-limited countries, where neonatal mortality and infection rates are high because of overcrowded nurseries, inadequate staffing, and lack of equipment. Intermittent skin-to-skin care (SSC), a modified version of kangaroo mother care, is now being offered in resource-rich countries to infants needing neonatal intensive care, including those who require ventilator support or are extremely premature. SSC significantly improves milk production by the mother and is associated with a longer duration of breastfeeding. Increased parent satisfaction, better sleep organization, a longer duration of quiet sleep, and decreased pain perception during procedures have also been reported in association with SSC. Despite apparent physiologic stability during SSC, it is prudent that infants in the NICU have continuous cardiovascular monitoring and that care be taken to verify correct head positioning for airway patency as well as the stability of the endotracheal tube, arterial and venous access devices, and other life support equipment.

FREE

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BACKGROUND

“Kangaroo mother care” (KMC) was first described as an alternative method of caring for low birth weight infants in resource-limited countries, where neonatal mortality and infection rates are high because of overcrowded nurseries, inadequate staffing, and lack of equipment. In the original version of KMC, the infant is placed in continuous skin-to-skin contact in a vertical position between the mother’s breasts and beneath her clothes and is exclusively (or nearly exclusively) breastfed. A meta-analysis of 988 infants enrolled in 3 randomized controlled trials of continuous KMC begun in the first postnatal week in low- or middle-income countries found a 51% reduction in mortality among infants with a birth weight <2000 g (relative risk: 0.49 [95% confidence interval: 0.29–0.82]).¹ Although the methods of this review have come under question,² a Cochrane meta-analysis of 18 trials of continuous KMC begun before postnatal day 10 in infants with a birth weight <2500 g also showed significantly reduced mortality and morbidity at discharge or 40

to 41 weeks' postmenstrual age and at follow-up; it also found a decreased incidence of health care–related sepsis and an improvement in some measures of infant growth, breastfeeding, and mother–infant attachment.³ Thirteen of these 18 studies were conducted in low- to middle-income countries.

Intermittent skin-to-skin care (SSC) in NICUs in resource-rich countries differs from traditional KMC in that it is usually used for varying, shorter periods of time; can be offered to less stable and technology-supported infants; and can be performed by both parents. Intermittent SSC in resource-rich countries has not been associated with decreased mortality, although data are currently insufficient to determine an effect.³ However, it is widely offered to parents for other perceived benefits, such as enhancing attachment, parental self-esteem, and breastfeeding.^{4,5}

EVIDENCE

Benefits

The most substantial evidence of benefit from SSC is for breastfeeding. Individual randomized controlled trials and a systematic review have shown that intermittent SSC is associated with longer and more exclusive breastfeeding and higher volumes of expressed milk.^{6,7} The systematic review reported that short periods of SSC (up to 1 hour at all visits) increased the duration of any breastfeeding, variably reported by different studies as 1 month after discharge (relative risk: 4.76 [95% confidence interval: 1.19–19.10]) or for more than 6 weeks (relative risk: 1.95 [95% confidence interval: 1.03–3.70]) among clinically stable infants in industrialized nations.⁷ A number of studies have also indicated that SSC may improve a mother's attachment or bonding and her feeling of being needed by or comfortable with her infant.^{3,8–12}

In addition, SSC promotes the participation of the mother and father in the infant's care, strengthens the family role in the care of a fragile infant, and decreases feelings of helplessness.¹⁰ Mothers report less stress and more satisfaction with NICU care, and both parents are more responsive to their infant's cues.^{3,8–12}

The evidence is less clear for a beneficial effect regarding sleep and neurobehavioral maturation. One report found increased frontal brain activity during both quiet and active sleep, which is thought to be predictive of improved neurobehavioral outcomes.¹³ Other studies using electroencephalography and polysomnography data indicate that preterm infants who receive SSC have more mature sleep organization, with increased total and quiet sleep, decreased REM sleep and arousals from sleep, and an improvement in sleep cycling.^{14,15} They also appeared more alert and observant and spent less time crying. Two cohort studies found that infants receiving SSC demonstrated better autonomic regulation and maternal–infant interactions at term gestation, as well as higher scores on the Bayley Scales of Infant Development–Second Edition at 6 or 12 months of age.^{8,16} Of the infants enrolled in the second study, 117 were followed up to 10 years of age, and the authors reported that those who received SSC showed attenuated stress response, improved autonomic functioning, better-organized sleep, and better cognitive control.¹⁷

SSC has also been advocated for the nonpharmacologic management of procedural pain. A Cochrane review of the effect of SSC for relief of procedural pain concluded that it seemed to be effective for a single painful procedure such as a heel lance, as measured by using composite pain indicators.¹⁸ The review found that behavioral indicators of pain tended to favor SSC, whereas physiologic indicators were

generally not affected, suggesting possible observer bias in scoring behavioral indicators. However, small studies have reported reduced cortisol concentrations and decreased autonomic indicators of pain in preterm infants during SSC.^{19,20} The authors of the Cochrane review recommend confirmatory studies of previous findings and call for new studies examining optimal duration of SSC, use in different gestational age groups, effects of repeated use, and long-term effects.¹⁸

Risks

Investigators initially postulated that continuous KMC would promote colonization with maternal flora rather than resistant hospital flora. Consistent with this hypothesis, meta-analyses of randomized controlled trials in resource-limited countries have exhibited fewer episodes of sepsis, necrotizing enterocolitis, and pneumonia.^{1,3} However, infections may be spread among mothers, infants, and caregivers, particularly in multiple-bed units, as has been reported for respiratory syncytial virus and tuberculosis.^{21,22} Although a recent report described an association between SSC and development of methicillin-resistant *Staphylococcus aureus* infections among infants in 1 NICU (particularly those with very low birth weights), the authors did not believe that there was a causal relationship.²³ Parents should be monitored for skin infections and might need cleansing of the skin before infant contact. Some experts consider infants with open lesions (eg, open neural tube defects, abdominal wall defects) to be particularly at risk.

Most studies of physiologic stability during SSC have been performed on stable, nonintubated infants. One meta-analysis reported a statistically but not clinically significant increase in body temperature (0.22°C) and a decrease in oxygen saturation (0.60%) in 190 term and 326

preterm infants receiving SSC compared with incubator care.²⁴ These effects were most pronounced in nurseries in low- and middle-income settings and in cold environments. There was no change in heart rate before, during, or after SSC, and no difference was noted between preterm and term infants. Although 1 study of 22 infants reported an increase in desaturation and bradycardia during SSC,²⁵ other studies have shown no significant increase in desaturation, bradycardic or apneic events, or in oxygen consumption.^{26–28} Despite apparent physiologic stability during SSC, it is prudent that infants in the NICU be continuously monitored and that care be taken to verify correct head positioning for airway patency as well as the stability of the endotracheal tube, arterial and venous access devices, and other life support equipment. Any infant who requires careful temperature regulation or a high-humidity environment might have SSC delayed until he or she is more stable.

There may be resistance among health care providers regarding offering SSC. This resistance could stem from fear of harm to the infant or from lack of experience, time, or assistance to transfer the infant to the parent and/or monitor the infant's well-being. A nursing simulation training program may help promote acceptance of SSC.²⁹ Multiple guidelines for the provision of SSC have been published,^{30–33} and each facility needs to consider staffing, experience, and resources in the development of its institutional guidelines. Because SSC has been shown to be feasible and safe in the NICU in infants as young as 26 weeks' gestation,³⁴ with benefits for both parents and infants, facilities are encouraged to offer this care when possible.

IMPLICATIONS FOR CLINICAL PRACTICE

1. It has been shown that skin-to-skin care results in improved

- breastfeeding, milk production, parental satisfaction, and bonding.
2. Both parents can be encouraged to provide skin-to-skin care, with appropriate guidelines and protocols, for both preterm and term infants in the NICU.
3. Despite apparent physiologic stability during skin-to-skin care, it is prudent that infants in the NICU have continuous cardiovascular monitoring and that care be taken to monitor correct head positioning for airway patency as well as the stability of the endotracheal tube, arterial and venous access devices, and other life support equipment.

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ABBREVIATIONS

KMC: kangaroo mother care
SSC: skin-to-skin care

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Skin-to-Skin Care for Term and Preterm Infants in the Neonatal ICU

Jill Baley and COMMITTEE ON FETUS AND NEWBORN

Pediatrics 2015;136:596; originally published online August 31, 2015;

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American Academy of Pediatrics

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OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Skin-to-Skin Care for Term and Preterm Infants in the Neonatal ICU

Jill Baley and COMMITTEE ON FETUS AND NEWBORN

Pediatrics 2015;136:596; originally published online August 31, 2015;

DOI: 10.1542/peds.2015-2335

The online version of this article, along with updated information and services, is located on the World Wide Web at:

[/content/136/3/596.full.html](http://content/136/3/596.full.html)

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American Academy of Pediatrics

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(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Fri, 20 Nov 2015 09:36:57 -0500
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Subject: FW: Call about Baby-Friendly and safety

FYI

-----Original Message-----

From: Winter, Lori [<mailto:Winter-Lori@CooperHealth.edu>]
Sent: Thursday, November 19, 2015 5:22 PM
To: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: RE: Call about Baby-Friendly and safety

More specifically, 12/8 from 1-2, 12/11 anytime after 2 pm or 12/15 after 4 pm. The last date 12/15 we (AAP Task Force on SIDS) meet to discuss final version of clinical report. Not that I am permitted to share details but at least I'll have a better idea of timeline for publication.

Lori

Lori Feldman-Winter, MD, MPH
Div. Head, Adolescent Medicine
Cooper University Hospital
Professor of Pediatrics
CMSRU

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) [kxs5@cdc.gov]
Sent: Thursday, November 19, 2015 4:49 PM
To: Winter, Lori; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Subject: RE: Call about Baby-Friendly and safety

Thank you Lori - Tuesday and Friday afternoons generally work best for me for meetings. A call will be very helpful. Kelley

-----Original Message-----

From: Winter, Lori [<mailto:Winter-Lori@CooperHealth.edu>]
Sent: Thursday, November 19, 2015 3:50 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>
Subject: RE: Call about Baby-Friendly and safety

Absolutely. The AAP is finalizing a clinical report on the subject as the new Executive Director has also been getting pressure to make a statement. Actually one member complained about the AAP endorsing the BFHI. which it has never done, even though AAP does endorse the Ten Steps.

(b)(5)

Let me know good days and times. Best days and times for me are Monday mornings, and Tuesday and Friday afternoons.

Great to see you too and best regards Kelley!

Lori

Lori Feldman-Winter, MD, MPH
Div. Head, Adolescent Medicine
Cooper University Hospital
Professor of Pediatrics
CMSRU

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) [hgk3@cdc.gov]
Sent: Thursday, November 19, 2015 3:40 PM
To: Winter, Lori
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Subject: Call about Baby-Friendly and safety

Hi Lori, it was great to see you in Mississippi last week! Since I've been back CDC has been contacted about SUPC, falls, and deaths as an unintended consequence of Baby-Friendly, particularly from skin-to-skin and rooming in. The cases presented were mostly from bed sharing, so not recommended in Baby-Friendly or by AAP, but we are still hearing concerns from hospitals. Also, Baby Friendly USA does not evaluate on skin-to-skin after the immediate postpartum period, but the General Evaluation Criteria does encourage it. (b)(5)

(b)(5)
(b)(5) Would you be available for a call in early December to give us a little more information and your thoughts?

Best,
Cria

Cria Perrine, PhD
LCDR, US Public Health Service
Team Lead, Infant Feeding Team
Division of Nutrition, Physical Activity, and Obesity Centers for Disease Control and Prevention * Phone: 770.488.5183 | * Email: cperrine@cdc.gov<mailto:cperrine@cdc.gov>

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From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 5 Jan 2016 22:05:23 -0500
To: MacGowan, Carol (CDC/ONDIEH/NCCDPHP); Murphy, Paulette (CDC/ONDIEH/NCCDPHP)
Subject: FW: Call to discuss Baby Friendly Hospital Activities

FYI

From: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Sent: Monday, January 04, 2016 10:21 AM
To: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>
Cc: Posner, Sam (CDC/OID/NCIRD) <shp5@cdc.gov>
Subject: FW: Call to discuss Baby Friendly Hospital Activities

Kelley, let's talk soon about how to respond to Dr. Bass. Who else from the division should be involved in the conversation?

PB

From: Bass, Joel L.,M.D. (b)(6)
Sent: Wednesday, December 23, 2015 9:12 AM
To: Briss, Peter (CDC/ONDIEH/NCCDPHP) <pxb5@cdc.gov>
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>; Posner, Sam (CDC/OID/NCIRD) <shp5@cdc.gov>
Subject: RE: Call to discuss Baby Friendly Hospital Activities

Thanks Peter... I appreciate these efforts and think that is a good first step in addressing the skin to skin issue. That is however only one of several problems regarding the CDC endorsement. There are problems with several other baby friendly steps and safe sleep particularly the emphasis on exclusivity , 24/7 rooming-in, and pacifier use to name a few. There are also legitimate issues re the value of universal certification (which the CDC has called for) and its actual impact on breastfeeding rates. I think our original plan to put together a package of published research materials and review them together still make sense. This is a complex issue with important ramifications.

Regards...

Joel

*Joel L Bass MD
Chair, Department of Pediatrics
Newton-Wellesley Hospital
Professor of Pediatrics, Part-time
Harvard Medical School*

From: Briss, Peter (CDC/ONDIEH/NCCDPHP) [mailto:pxb5@cdc.gov]
Sent: Wednesday, December 23, 2015 8:56 AM
To: Bass, Joel L.,M.D.

Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Posner, Sam (CDC/OID/NCIRD)

Subject: RE: Call to discuss Baby Friendly Hospital Activities

Joel,

Thank you for your follow up. As you'll see from the detailed response below from our program, CDC, Baby-Friendly USA, and the AAP are taking your concerns very seriously. Please let us know if you have additional thoughts.

Peter

Dear Dr. Bass,

Thank you for speaking to CDC on November 18, 2015 regarding your concerns about unsafe implementation of the *Ten Steps to Successful Breastfeeding* and the potential for unintended and serious consequences such as sudden unexpected postnatal collapse (SUPC) and falls in the hospital maternity ward. We take your concerns seriously. Infant safety is of the highest priority whether hospital practices are implemented within or outside of the Baby Friendly Hospital Initiative (BFHI). The purpose of this letter is to inform you of the actions we have taken to emphasize safe implementation of the *Ten Steps*.

In response to the specific concerns you raised that hospitals may be implementing the *Ten Steps* incorrectly or in an unsafe manner when referring to the Guidelines and Evaluation Criteria (GEC) posted by Baby-Friendly USA, we immediately contacted the Executive Director of Baby-Friendly USA, Trish MacEnroe, and had a call on November 19 to discuss the GEC. Although the GEC document includes clear language on page 5 of the Preamble that "Each participating facility assumes full responsibility for assuring that its implementation of the BFHI is consistent with all of its safety protocols, existing agreements, and legal obligations," we requested that language on safe implementation be made more prominent throughout the document when each step is described. We also requested clarification in the GEC that skin-to-skin contact beyond the immediate post-partum period is not part of the *Ten Steps* and not part of the evaluation criteria for Baby-Friendly designation. Baby Friendly USA is currently revising the GEC for release in April 2016. However, we encouraged that revisions be included sooner to the version currently online.

In a follow up call with Trish MacEnroe on December 4, we learned that Baby-Friendly USA is taking action. The Program Committee of Baby-Friendly USA, which is made up of physicians and nurses, is currently revising the GEC; the Executive Director is communicating with the organization that accredits training for lactation care providers to confirm that providers are assessed on safe implementation of the *Ten Steps*. Further, Baby-Friendly USA was already developing a webinar series on safe and friendly implementation of the *Ten Steps* and is now considering more focused webinars on safe implementation of practices for hospitals. We will continue to meet with Baby-Friendly USA to emphasize safe implementation of the *Ten Steps*.

We also have discussed your concerns with the American Academy of Pediatrics. On December 11 we learned that the Academy has a committee addressing safe implementation of the practices included in the *Ten Steps*.

We will continue to monitor all available data on these issues and take additional steps to ensure that hospital practices to support breastfeeding are implemented safely. Thank you for your time and concern on these very critical issues.

Kelley S. Scanlon, PhD RD
Chief, Nutrition Branch
Division of Nutrition, Physical Activity, and Obesity,
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Email kscanlon@cdc.gov

From: Bass, Joel L.,M.D. (b)(6)
Sent: Monday, December 21, 2015 3:28 PM
To: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Subject: RE: Call to discuss Baby Friendly Hospital Activities

Peter... Just following up on this. It is an issue of great concern.

Thanks..

Joel

*Joel L Bass MD
Chair, Department of Pediatrics
Newton-Wellesley Hospital
Professor of Pediatrics, Part-time
Harvard Medical School*

From: Posner, Sam (CDC/ONDIEH/NCCDPHP) [<mailto:shp5@cdc.gov>]
Sent: Friday, December 11, 2015 1:47 PM
To: Bass, Joel L.,M.D.; Briss, Peter (CDC/ONDIEH/NCCDPHP)
Subject: RE: Call to discuss Baby Friendly Hospital Activities

Joel,
Thank you for following up. I apologize for taking a day or two to respond. I am in the process of transitioning to a job in a different part of the agency. Dr. Peter Briss (Medical Director for the Center) will be picking this conversation up in my place. He will be contacting you in the next few days to follow-up on the discussion.

Best,
Sam

From: Bass, Joel L.,M.D. (b)(6)
Sent: Wednesday, December 09, 2015 3:55 PM
To: Posner, Sam (CDC/ONDIEH/NCCDPHP) <shp5@cdc.gov>
Subject: RE: Call to discuss Baby Friendly Hospital Activities

Sam... Just following up on this,,

Regards,,

Joel

*Joel L Bass MD
Chair, Department of Pediatrics
Newton-Wellesley Hospital
Professor of Pediatrics, Part-time
Harvard Medical School*

From: Posner, Sam (CDC/ONDIEH/NCCDPHP) [<mailto:shp5@cdc.gov>]
Sent: Monday, November 23, 2015 2:49 PM
To: Bass, Joel L.,M.D.
Cc: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP); Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Briss, Peter (CDC/ONDIEH/NCCDPHP)
Subject: RE: Call to discuss Baby Friendly Hospital Activities

Joel,

Thank you for talking with us on Wednesday and your follow-up e-mail this morning. I believe that we heard your concerns very clearly and have already started discussing what needs to be done. We took the immediate action to talk with Baby Friendly USA about steps that might be taken to enhance the safety of mothers and infants. We are working actively to determine what the appropriate actions CDC might take moving forward to maximally improve the range of maternal and infant outcomes. We are all committed to making decisions based on all of the best available evidence at this time.

I would respectfully propose that we take a bit of time to review the evidence and put together documentation we can share so we have a common set of materials for any further discussion. I believe a common set of materials will facilitate the discussion and help clarify any remaining issues that need to be addressed.

Best regards,
Sam

From: Bass, Joel L.,M.D. (b)(6)
Sent: Friday, November 20, 2015 9:49 AM
To: Posner, Sam (CDC/ONDIEH/NCCDPHP) <shp5@cdc.gov>

Cc: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>; Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>

Subject: RE: Call to discuss Baby Friendly Hospital Activities

Sam.... Thanks for organizing a conference call Wednesday. I had hoped we could discuss the scientific evidence that is emerging regarding sudden unexpected postnatal collapse in infancy (SUPC) and other potential adverse outcomes from some of the established Baby Friendly practices. Unfortunately the focus of the discussion did not really address these issues because of a significant disagreement about the role of skin to skin care in the Baby Friendly program.

It is important to recognize that skin to skin care beyond the first hours of life is a major risk factor for SUPC, and a principle tenet for Baby Friendly Hospital certification, a program strongly endorsed by the CDC. Instead of focusing on the science behind SUPC and the consequences of endorsing all of the principles of the Baby Friendly initiative, we ended up discussing the details of implementation of Baby Friendly education and certification.

In an effort to clarify the issue I have attached a copy of the current certification guide which is posted on the Baby Friendly website. If you look on pages 11 and 31 it is clearly stated that skin to skin should be encouraged for the first days after birth. This has always been a core component of the program and a key point of concern as two thirds of the SUPC events take place after the first two hours of life.

In addition, while co bedding or co sleeping is not a Baby Friendly program recommendation, the requirements for breastfeeding exclusivity and 24 hour rooming-in often have the unintended consequence of unobserved mothers falling asleep with their newborn in the skin to skin position. This is a common observation of bedside clinicians, both nurses and physicians. As a result the Baby Friendly program often produces outcomes that conflict with both AAP and NIH safe sleep policies.

Regarding the role of the CDC in promoting universal Baby Friendly certification, in addition to written recommendations in the Oct 2015 issue of CDC Vital signs, I would suggest you take a look at the following CDC link in which the CDC director is quoted as stating:

"Ideally, we would like every birth hospital in this country to adopt all of the ten steps and become baby friendly"

<http://www.cdc.gov/media/releases/2015/t1006-breastfeeding-support.html>

It is clear that the CDC is actively promoting this program and given the written Baby Friendly recommendation to implement prolonged skin to skin contact and the published review which I shared documenting 400 cases of SUPC in the first days of life, I hope that we can have a more substantive discussion in the future that focuses exclusively on how the CDC can take constructive steps going forward which will safely support our mutual professional goals to enhance both breastfeeding and safe sleep for all infants.

Regards...

Joel

Joel L Bass MD

Chair, Department of Pediatrics

Newton-Wellesley Hospital

Professor of Pediatrics, Part-time

Harvard Medical School

From: Posner, Sam (CDC/ONDIEH/NCCDPHP) [<mailto:shp5@cdc.gov>]

Sent: Thursday, November 12, 2015 7:44 AM

To: Bass, Joel L., M.D.

Cc: Tuggle, Deborah (CDC/ONDIEH/NCCDPHP) (CTR); Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP); Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)

Subject: Call to discuss Baby Friendly Hospital Activities

Dr. Bass,

Dr. Cono and I briefly discussed your interest in discussing potential unintended consequences of the Baby Friendly Hospital initiative. Drs. Deb Galuska, Scanlon and I would like to schedule a call next week to discuss the issues with you. Please send Debbi Tuggle who and I some potential times for a conference call and we will get something scheduled. We look forward to talking with you.

Best regards,

Sam

Samuel F. Posner, PhD

Associate Director for Science

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

(770) 488 6398 (ph) shp5@cdc.gov

(404) 641 2118 (Mobile)

(770) 488 4219 (FAX)

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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 21 Sep 2016 00:33:39 +0000
To: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Subject: FW: Call to discuss Baby Friendly Hospital Activities

Am looking through old emails to add to your timeline. See highlighted below.

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Friday, November 20, 2015 1:13 PM
To: Murphy, Paulette (CDC/ONDIEH/NCCDPHP) <pem1@cdc.gov>; Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Subject: FW: Call to discuss Baby Friendly Hospital Activities

To keep you all posted on this issue

From: Posner, Sam (CDC/ONDIEH/NCCDPHP)
Sent: Friday, November 20, 2015 12:28 PM
To: Bauer, Ursula (CDC/ONDIEH/NCCDPHP) <iws8@cdc.gov>; Cucchi, Sean (CDC/ONDIEH/NCCDPHP) <axz7@cdc.gov>; Briss, Peter (CDC/ONDIEH/NCCDPHP) <pxb5@cdc.gov>
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>; Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>; Collins, Janet L. (CDC/ONDIEH/NCCDPHP) <jlc1@cdc.gov>
Subject: FW: Call to discuss Baby Friendly Hospital Activities

All,

Below are three e-mails relevant to the discussion that we had yesterday in triage about concerns over endorsement of the Baby Friendly Initiative. The initial call from Dr. Bass came to OADS/Joanne Cono. She forwarded this to me and we scheduled the call with Dr. Bass on Wednesday. Below are three e-mails that provide the follow-up summary of the call and a proposed response. The first e-mail is a follow-up from Kelley, second is a follow-up from Dr. and third a proposed response to Dr. Bass that I drafted this morning. I would like your thoughts on the response and who it should come from. (b)(5)

(b)(5)

(b)(5)

Perhaps

we can discuss on Monday.

Best,
Sam

EMAIL 1
Sam,

Thank you for setting up the call with Dr. Bass. It was an important call, but I found it difficult to finish my responses to Dr. Bass as he became angry. It was also difficult not to respond or engage when his statements were not fully accurate or not consistent with Baby-Friendly USA designation criteria. I learned a lot from this interaction. For the next call I would like to meet with you in advance to plan the time we each have to speak.

Dr. Bass raised some valid concerns on the call. I am following up on his concerns regarding sudden unexpected postnatal collapse (SUPC) and falls in the hospital maternity ward to be certain that Baby-Friendly USA is doing everything possible to ensure the safety of infants. We had a call with the Executive Director of Baby-Friendly USA yesterday and I requested that the safety procedures be clarified and made more prominent in their Guidelines and Evaluation Criteria (GEC) because some hospitals are implementing the *Ten Steps to Successful Breastfeeding* without going through the extensive training that is required for Baby-Friendly designation. Further, clarification of the practices and safety procedures in the GEC will ensure that all training is consistent in emphasizing infant safety and the practices that are evaluated for Baby-Friendly designation. The Executive Director is meeting with the Board of Baby-Friendly USA today to discuss safety of practices and hospital interpretation and implementation of the guidelines and evaluation criteria. I will keep you posted on this issue.

Sincerely, Kelley

Kelley S. Scanlon, PhD RD
Chief, Nutrition Branch
Division of Nutrition, Physical Activity, and Obesity,
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Email kscanlon@cdc.gov

EMAIL 2

From: Bass, Joel L.,M.D. (b)(6)
Sent: Friday, November 20, 2015 9:49 AM
To: Posner, Sam (CDC/ONDIEH/NCCDPHP) <shp5@cdc.gov>
Cc: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>; Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>
Subject: RE: Call to discuss Baby Friendly Hospital Activities

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be encouraged for the first days after birth. This has always been a core component of the program and a key point of concern as two thirds of the SUPC events take place after the first two hours of life.

In addition, while co bedding or co sleeping is not a Baby Friendly program recommendation, the requirements for breastfeeding exclusivity and 24 hour rooming-in often have the unintended consequence of unobserved mothers falling asleep with their newborn in the skin to skin position. This is a common observation of bedside clinicians, both nurses and physicians. As a result the Baby Friendly program often produces outcomes that conflict with both AAP and NIH safe sleep policies.

Regarding the role of the CDC in promoting universal Baby Friendly certification, in addition to written recommendations in the Oct 2015 issue of CDC Vital signs, I would suggest you take a look at the following CDC link in which the CDC director is quoted as stating:

“Ideally, we would like every birth hospital in this country to adopt all of the ten steps and become baby friendly”

<http://www.cdc.gov/media/releases/2015/t1006-breastfeeding-support.html>

It is clear that the CDC is actively promoting this program and given the written Baby Friendly recommendation to implement prolonged skin to skin contact and the published review which I shared documenting 400 cases of SUPC in the first days of life, I hope that we can have a more substantive discussion in the future that focuses exclusively on how the CDC can take constructive steps going forward which will safely support our mutual professional goals to enhance both breastfeeding and safe sleep for all infants.

Regards...

Joel

*Joel L Bass MD
Chair, Department of Pediatrics
Newton-Wellesley Hospital
Professor of Pediatrics, Part-time
Harvard Medical School*

EMAIL 3

(b)(5)

(b)(5)

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 21 Sep 2016 00:35:27 +0000
To: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Subject: FW: Call to discuss Baby Friendly Hospital Activities

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Tuesday, January 05, 2016 10:04 PM
To: Briss, Peter (CDC/ONDIEH/NCCDPHP) <pxb5@cdc.gov>
Cc: Posner, Sam (CDC/OID/NCIRD) <shp5@cdc.gov>; Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: RE: Call to discuss Baby Friendly Hospital Activities

Hi Peter,
I would also like to have Deb Galuska and Cria Perrine involved in the conversation. -Kelley

From: Briss, Peter (CDC/ONDIEH/NCCDPHP)
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PB

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To: Briss, Peter (CDC/ONDIEH/NCCDPHP) <pxb5@cdc.gov>
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Subject: RE: Call to discuss Baby Friendly Hospital Activities

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Regards...

Joel

*Joel L Bass MD
Chair, Department of Pediatrics
Newton-Wellesley Hospital
Professor of Pediatrics, Part-time
Harvard Medical School*

From: Briss, Peter (CDC/ONDIEH/NCCDPHP) [<mailto:pxb5@cdc.gov>]
Sent: Wednesday, December 23, 2015 8:56 AM
To: Bass, Joel L., M.D.
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Posner, Sam (CDC/OID/NCIRD)
Subject: RE: Call to discuss Baby Friendly Hospital Activities

Joel,

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Peter

Dear Dr. Bass,

Thank you for speaking to CDC on November 18, 2015 regarding your concerns about unsafe implementation of the *Ten Steps to Successful Breastfeeding* and the potential for unintended and serious consequences such as sudden unexpected postnatal collapse (SUPC) and falls in the hospital maternity ward. We take your concerns seriously. Infant safety is of the highest priority whether hospital practices are implemented within or outside of the Baby Friendly Hospital Initiative (BFHI). The purpose of this letter is to inform you of the actions we have taken to emphasize safe implementation of the *Ten Steps*.

In response to the specific concerns you raised that hospitals may be implementing the *Ten Steps* incorrectly or in an unsafe manner when referring to the Guidelines and Evaluation Criteria (GEC) posted by Baby-Friendly USA, we immediately contacted the Executive Director of Baby-Friendly USA, Trish MacEnroe, and had a call on November 19 to discuss the GEC. Although the GEC document includes clear language on page 5 of the Preamble that "Each participating facility assumes full responsibility for assuring that its implementation of the BFHI is consistent with all of its safety protocols, existing agreements, and legal obligations," we requested that language on safe implementation be made more prominent throughout the document when each step is described. We also requested clarification in the GEC that skin-to-skin contact beyond the immediate post-partum period is not part of the *Ten Steps* and not part of the evaluation criteria for Baby-Friendly designation. Baby Friendly USA is currently revising

the GEC for release in April 2016. However, we encouraged that revisions be included sooner to the version currently online.

In a follow up call with Trish MacEnroe on December 4, we learned that Baby-Friendly USA is taking action. The Program Committee of Baby-Friendly USA, which is made up of physicians and nurses, is currently revising the GEC; the Executive Director is communicating with the organization that accredits training for lactation care providers to confirm that providers are assessed on safe implementation of the *Ten Steps*. Further, Baby-Friendly USA was already developing a webinar series on safe and friendly implementation of the *Ten Steps* and is now considering more focused webinars on safe implementation of practices for hospitals. We will continue to meet with Baby-Friendly USA to emphasize safe implementation of the *Ten Steps*.

We also have discussed your concerns with the American Academy of Pediatrics. On December 11 we learned that the Academy has a committee addressing safe implementation of the practices included in the *Ten Steps*.

We will continue to monitor all available data on these issues and take additional steps to ensure that hospital practices to support breastfeeding are implemented safely. Thank you for your time and concern on these very critical issues.

Kelley S. Scanlon, PhD RD
Chief, Nutrition Branch
Division of Nutrition, Physical Activity, and Obesity,
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Email kscanlon@cdc.gov

From: Bass, Joel L.,M.D. (b)(6)
Sent: Monday, December 21, 2015 3:28 PM
To: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Subject: RE: Call to discuss Baby Friendly Hospital Activities

Peter... Just following up on this. It is an issue of great concern.

Thanks..

Joel

*Joel L Bass MD
Chair, Department of Pediatrics
Newton-Wellesley Hospital
Professor of Pediatrics, Part-time
Harvard Medical School*

From: Posner, Sam (CDC/ONDIEH/NCCDPHP) [<mailto:shp5@cdc.gov>]

Sent: Friday, December 11, 2015 1:47 PM

To: Bass, Joel L.,M.D.; Briss, Peter (CDC/ONDIEH/NCCDPHP)

Subject: RE: Call to discuss Baby Friendly Hospital Activities

Joel,

Thank you for following up. I apologize for taking a day or two to respond. I am in the process of transitioning to a job in a different part of the agency. Dr. Peter Briss (Medical Director for the Center) will be picking this conversation up in my place. He will be contacting you in the next few days to follow-up on the discussion.

Best,

Sam

From: Bass, Joel L.,M.D. (b)(6)

Sent: Wednesday, December 09, 2015 3:55 PM

To: Posner, Sam (CDC/ONDIEH/NCCDPHP) <shp5@cdc.gov>

Subject: RE: Call to discuss Baby Friendly Hospital Activities

Sam... Just following up on this,,

Regards,,

Joel

Joel L Bass MD

Chair, Department of Pediatrics

Newton-Wellesley Hospital

Professor of Pediatrics, Part-time

Harvard Medical School

From: Posner, Sam (CDC/ONDIEH/NCCDPHP) [<mailto:shp5@cdc.gov>]

Sent: Monday, November 23, 2015 2:49 PM

To: Bass, Joel L.,M.D.

Cc: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP); Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Briss, Peter (CDC/ONDIEH/NCCDPHP)

Subject: RE: Call to discuss Baby Friendly Hospital Activities

Joel,

Thank you for talking with us on Wednesday and your follow-up e-mail this morning. I believe that we heard your concerns very clearly and have already started discussing what needs to be done. We took the immediate action to talk with Baby Friendly USA about steps that might be taken to enhance the safety of mothers and infants. We are working actively to determine what the appropriate actions CDC might take moving forward to maximally improve the range of maternal and infant outcomes. We are all committed to making decisions based on all of the best available evidence at this time.

I would respectfully propose that we take a bit of time to review the evidence and put together documentation we can share so we have a common set of materials for any further discussion. I believe a common set of materials will facilitate the discussion and help clarify any remaining issues that need to be addressed.

Best regards,
Sam

From: Bass, Joel L.,M.D. (b)(6)
Sent: Friday, November 20, 2015 9:49 AM
To: Posner, Sam (CDC/ONDIEH/NCCDPHP) <shp5@cdc.gov>
Cc: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>; Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>
Subject: RE: Call to discuss Baby Friendly Hospital Activities

Sam.... Thanks for organizing a conference call Wednesday. I had hoped we could discuss the scientific evidence that is emerging regarding sudden unexpected postnatal collapse in infancy (SUPC) and other potential adverse outcomes from some of the established Baby Friendly practices. Unfortunately the focus of the discussion did not really address these issues because of a significant disagreement about the role of skin to skin care in the Baby Friendly program.

It is important to recognize that skin to skin care beyond the first hours of life is a major risk factor for SUPC, and a principle tenet for Baby Friendly Hospital certification, a program strongly endorsed by the CDC. Instead of focusing on the science behind SUPC and the consequences of endorsing all of the principles of the Baby Friendly initiative, we ended up discussing the details of implementation of Baby Friendly education and certification.

In an effort to clarify the issue I have attached a copy of the current certification guide which is posted on the Baby Friendly website. If you look on pages 11 and 31 it is clearly stated that skin to skin should be encouraged for the first days after birth. This has always been a core component of the program and a key point of concern as two thirds of the SUPC events take place after the first two hours of life.

In addition, while co bedding or co sleeping is not a Baby Friendly program recommendation, the requirements for breastfeeding exclusivity and 24 hour rooming-in often have the unintended consequence of unobserved mothers falling asleep with their newborn in the skin to skin position. This is a common observation of bedside clinicians, both nurses and physicians. As a result the Baby Friendly program often produces outcomes that conflict with both AAP and NIH safe sleep policies.

Regarding the role of the CDC in promoting universal Baby Friendly certification, in addition to written recommendations in the Oct 2015 issue of CDC Vital signs, I would suggest you take a look at the following CDC link in which the CDC director is quoted as stating:

"Ideally, we would like every birth hospital in this country to adopt all of the ten steps and become baby friendly"

<http://www.cdc.gov/media/releases/2015/t1006-breastfeeding-support.html>

It is clear that the CDC is actively promoting this program and given the written Baby Friendly recommendation to implement prolonged skin to skin contact and the published review which I shared documenting 400 cases of SUPC in the first days of life, I hope that we can have a more substantive discussion in the future that focuses exclusively on how the CDC can take constructive steps going forward which will safely support our mutual professional goals to enhance both breastfeeding and safe sleep for all infants.

Regards...

Joel

Joel L Bass MD

Chair, Department of Pediatrics

Newton-Wellesley Hospital

Professor of Pediatrics, Part-time

Harvard Medical School

From: Posner, Sam (CDC/ONDIEH/NCCDPHP) [<mailto:shp5@cdc.gov>]

Sent: Thursday, November 12, 2015 7:44 AM

To: Bass, Joel L.,M.D.

Cc: Tuggle, Deborah (CDC/ONDIEH/NCCDPHP) (CTR); Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP); Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)

Subject: Call to discuss Baby Friendly Hospital Activities

Dr. Bass,

Dr. Cono and I briefly discussed your interest in discussing potential unintended consequences of the Baby Friendly Hospital initiative. Drs. Deb Galuska, Scanlon and I would like to schedule a call next week to discuss the issues with you. Please send Debbi Tuggle who and I some potential times for a conference call and we will get something scheduled. We look forward to talking with you.

Best regards,

Sam

Samuel F. Posner, PhD

Associate Director for Science

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

(770) 488 6398 (ph) shp5@cdc.gov

(404) 641 2118 (Mobile)

(770) 488 4219 (FAX)

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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 8 Sep 2016 01:08:04 +0000
To: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Cc: Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP); Murphy, Paulette (CDC/ONDIEH/NCCDPHP)
Subject: FW: CDC response to questions about the Ten Steps to Successful Breastfeeding

Follow up from Kelley with AAP about safety issues of Baby-Friendly after they were also contacted by Dr. Bass.

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, December 09, 2015 6:33 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>
Subject: Fw: CDC response to questions about the Ten Steps to Successful Breastfeeding

Keeping you posted.

From: Dreyer, Benard <(b)(6)>
Sent: Wednesday, December 9, 2015 4:38 AM
To: Remley, Karen; Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Auerbach, John (CDC/OD/OADP)
Cc: Collins, Janet L. (CDC/ONDIEH/NCCDPHP); Perrin, James, M.D.; O'Connor, Ann E. (CDC/ONDIEH/NCCDPHP); Dreyer, Benard; Hassink, Sandra; Suchyta, Roger; Tait, Fan
Subject: RE: CDC response to questions about the Ten Steps to Successful Breastfeeding

Dear Kelley,

I want to add my thanks to those of Karen. I am extremely impressed with your response to this issue and look forward to ongoing follow-up. As a pediatrician who works in two hospitals who went through the Baby Friendly 10 Steps successfully and as one of the lead pediatricians in both those endeavors, I appreciate the rigorous process that Baby Friendly has designed as well as the concerns of some practicing pediatricians regarding safety (especially SUPC and falls). Your involvement is much appreciated.

Best,
Benard

Benard P. Dreyer, MD, FAAP
President-Elect, American Academy of Pediatrics (AAP)
Professor of Pediatrics
Director of Developmental-Behavioral Pediatrics
NYU School of Medicine
Director of Pediatrics, Bellevue Hospital Center
Follow me @BenardDreyer
Phone: (212) 263-0788

Cell: (b)(6)
Fax: (646) 501-6933

From: Remley, Karen (b)(6)
Sent: Tuesday, December 08, 2015 7:40 PM
To: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Auerbach, John (CDC/OD/OADP)
Cc: Collins, Janet L. (CDC/ONDIEH/NCCDPHP); Perrin, James, M.D.; O'Connor, Ann E. (CDC/ONDIEH/NCCDPHP); Dreyer, Benard; Hassink, Sandra; Suchyta, Roger; Tait, Fan
Subject: RE: CDC response to questions about the Ten Steps to Successful Breastfeeding

Dear Kelley,

Thank you very much for sharing with me the conversations and subsequent actions you have taken to address this pediatrician's issues. I am impressed by your thorough and thoughtful response, resulting in better care for babies.

I will share your email with our leadership.

This is a great example of how the AAP and CDC work closely together addressing concerns of our members and the public.

Thank you for your service.

Very best
Karen

Karen Remley, MD, MBA, MPH, FAAP
CEO/Executive Director
The American Academy of Pediatrics
Professor Pediatrics, Eastern Virginia Medical School
141 Northwest Point Blvd.
Elk Grove Village, IL 60007-1098
1-847-434-7500

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) [<mailto:kxs5@cdc.gov>]
Sent: Monday, December 7, 2015 2:40 PM
To: Remley, Karen (b)(6)
Cc: Collins, Janet L. (CDC/ONDIEH/NCCDPHP) <jlc1@cdc.gov>; O'Connor, Ann E. (CDC/ONDIEH/NCCDPHP) <fx8@cdc.gov>
Subject: CDC response to questions about the Ten Steps to Successful Breastfeeding

Dear Dr. Remley,

Thank you for reaching out to Dr. Collins to discuss information shared with the AAP Board about the Baby-Friendly Hospital Initiative. We were also contacted by Dr. Joel Bass, Chair of the Department of Pediatrics at Newton-Wellesley Hospital in Massachusetts, about CDC's endorsement of the Baby-

Friendly Hospital Initiative. I want to share with you our conversation with Dr. Bass and the follow up we have had with Baby-Friendly USA.

When we spoke to Dr. Bass on November 18 we learned that he was specifically concerned about unsafe implementation of the *Ten Steps to Successful Breastfeeding* resulting in potential unintended and serious consequences such as sudden unexpected postnatal collapse (SUPC) and falls in the hospital maternity ward. Newton-Wellesley Hospital is not a Baby-Friendly designated hospital, but Dr. Bass implied that the Guidelines and Evaluation Criteria (GEC) document posted on the Baby-Friendly website is used to promote and implement the *Ten Steps*. He is correct that Baby-Friendly USA added this document to their website in recent years to be more transparent about the Baby-Friendly process. However, the document should not serve as a substitute for what is a rigorous process to implement the *Ten Steps to Successful Breastfeeding* and achieve the Baby-Friendly designation, including completion of all required trainings and an onsite assessment by Baby-Friendly USA. Dr. Bass raises a valid concern if hospital staff are implementing the *Ten Steps to Successful Breastfeeding* without or prior to going through the extensive training that is required for Baby-Friendly designation and the technical assistance provided by Baby-Friendly USA.

We are unaware of any specific evidence of an increase in SUPC or falls in the hospital maternity ward when a hospital moves to Baby-Friendly designation. However, Dr. Bass forwarded to us case reports of SUPC that emphasize the importance of safe maternity care practices. In one of the papers (Thach 2014), 18 cases of SUPC are described. While there is no mention as to whether any of the cases occurred in a Baby-Friendly designated hospital, 14 of the 18 cases occurred after a mother and infant fell asleep together in the maternity ward bed, often while breastfeeding. The author incorrectly states that the Baby Friendly Hospital Initiative encourages bed sharing. Baby-Friendly USA does not recommend bed sharing and bed sharing is not part of step 7 ("Practice rooming-in – allow mothers and infants to remain together twenty-four hours a day).” Further, 1 of the 18 cases in the report by Thach occurred while the mother and infant were in skin-to-skin contact that was not supervised by hospital staff. A second manuscript forwarded to us by Dr. Bass includes a collection of SUPC cases from various reports. Dr. Bass was specifically concerned with a report from Spain reporting an increase in SUPC considered to be associated with increased practice of skin-to-skin contact without adequate surveillance. We are obtaining the primary paper to evaluate the methods used but we agree that skin-to-skin should not be practiced without adequate supervision.

In response to the concerns raised by Dr. Bass that hospitals may be implementing the *Ten Steps* incorrectly when referring to the Guidelines and Evaluation Criteria (GEC), we contacted the Executive Director of Baby-Friendly USA, Trish MacEnroe, and had a call on November 19 to discuss this issue. We requested that the safety procedures be clarified and made more prominent in the GEC. For example, we asked Baby-Friendly to clearly state in the GEC that bed sharing is not recommended and to emphasize that the immediate skin-to-skin contact that is part of step 4 ("Help mothers initiate breastfeeding within one hour of birth.”) be supervised by hospital health care staff as described in the training materials. We also requested clarification in the GEC of a practice that is encouraged but is not part of the *Ten Steps* and not part of the evaluation criteria for Baby-Friendly designation, specifically skin-to-skin contact beyond the immediate post-partum period. Baby Friendly USA is currently revising the GEC for release in April 2016. However, we encouraged that revisions be included sooner to the version currently online. I had a follow up call with Trish MacEnroe on December 4 and learned that Baby-Friendly USA is taking action. The Program Committee of Baby-Friendly USA, which is made up of physicians and nurses, is currently working on the language in the GEC and is aware of the issues raised by CDC; the Executive Director is communicating with the organization that accredits training for

lactation care providers; and Baby-Friendly USA is developing a webinar series on safe and friendly implementation of the *Ten Steps* and is now considering more focused webinars on safe implementation of practices for hospitals. I will continue to meet with Baby-Friendly USA to emphasize safe implementation of the *Ten Steps to Successful Breastfeeding*.

Please let me know if you have any questions or would like to discuss any of these issues by phone.

Sincerely,
Kelley

Kelley S. Scanlon, PhD RD
Chief, Nutrition Branch
Division of Nutrition, Physical Activity, and Obesity,
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Email kscanlon@cdc.gov

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From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 15 Feb 2018 12:56:40 +0000
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Subject: FW: Celebrating Black HerStory

See below.

From: Kimarie Bugg (b)(6)
Sent: Thursday, February 15, 2018 5:36 AM
To: Andrea Serano (b)(6); Tenesha Sellers
(b)(6); Mary Jackson (b)(6); Mia Burrell
(b)(6); Asia Ivey (b)(6); Rubye Stafford
(b)(6); Betty Neal (b)(6); Georgina Howard
(b)(6); Muswamba Mwamba (b)(6)
Wendell <gbugg@emory.edu>; Wanda Holder (b)(6); Robert Jackson
(b)(6); Sahira Long <slong@dcbfc.org>; Michal Young <m_a_young@howard.edu>;
Jeretha McKinley (b)(6); Burnham, Laura (b)(6)
carolyn.frazier (b)(6); Kimberley Broomfield-Massey
(b)(6); Diana Derige (b)(6)
Cc: Vijaya K. Hogan (b)(6); Merewood, Anne (b)(6)
Subject: Celebrating Black HerStory

<https://www.babyfriendlyusa.org/newsviews-pages/mothers-of-memphis>

This is a blog ROSE coordinated to assist in combating some of the press "fed is best" is getting. **PLEASE share widely!!**

k

--

Kimarie Bugg, DNP(s)/MSN/FNP-BC/MPH/CLC/IBCLC
President/CEO and Change Leader
Reaching Our Sisters Everywhere, Inc (ROSE)
Chair, Nominating Committee,
United States Breastfeeding Committee (2015-2017)
404-719-4297
3035 Stone Mountain St. #1076
Lithonia, Georgia 30058
<https://www.youtube.com/watch?v=PA8hdfoblqw&t=19s>
ROSE Summit 2017
www.BreastfeedingRose.org
www.facebook.com/BreastfeedingRose
www.twitter.com/Support_Rose

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Fri, 12 May 2017 17:50:20 +0000
To: Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP)
Subject: FW: ControlledCorres_ASD and hyperbili_04292014_2
Attachments: ControlledCorres_ASD and hyperbili_04292014_2.docx

FYI, this is the original correspondence from Christie del Castillo-Hegyi, one of the co-founders of Fed is Best. Kelley asked that we limit sharing because it contains her personal story. She tells her story on the Fed is Best website, so that may be of less concern now. Attached is the joint response from Kelley and Cindy Moore from Birth Defects.

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, May 21, 2014 9:19 AM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: FW: ControlledCorres_ASD and hyperbili_04292014_2

Fyi - please do not forward original email from mom

From: Moore, Cynthia (CDC/ONDIEH/NCBDDD)
Sent: Tuesday, April 29, 2014 11:01 AM
To: Belser-Vega, Elizabeth (CDC/ONDIEH/NCBDDD)
Cc: Boyle, Coleen (CDC/ONDIEH/NCBDDD); Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Smith, Kimberly E. (CDC/ONDIEH/NCBDDD)
Subject: ControlledCorres_ASD and hyperbili_04292014_2

Hopefully final version with a couple of typos corrected.

Thanks,

Cindy

From: Christie del Castillo-Hegyi (b)(6)
Sent: Friday, March 28, 2014 7:22 AM
To: CDC Speakers Bureau
Subject: Hypothesis about the rising prevalence of autism from a physician, scientist and mother of an autistic child

Hello,

Please read and forward to the CDC director.

Thank you for your consideration.

Christie del Castillo-Hegyi, MD

(b)(6)

(b)(6)



April 28, 2014

Christie del Castillo-Hegyi, M.D.

(b)(6)

Dear Dr. Del Castillo-Hegyi:

On behalf of Dr. Frieden, thank you for your letter sharing your family's experience. We recognize your commitment to your son's health and the health of all infants. You raise important questions about current guidance to exclusively breastfeed, neonatal hyperbilirubinemia, and increasing numbers of children with autism spectrum disorder (ASD) – and possible connections among these factors. The Centers for Disease Control and Prevention (CDC) is always interested in insights from astute clinicians and moms such as yourself, because these insights have led to many scientific discoveries. Scientists in CDC's Division of Birth Defects and Developmental Disabilities (where our ASD activities are located) and the Division of Nutrition, Physical Activity, and Obesity (where our breastfeeding activities are located) read your letter and our response follows. Because these issues may overlap, we have laid them out in a way we hope you will find helpful. We have also included a few references at the end of this letter.

The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for about six months followed by continued breastfeeding as complementary foods are introduced until the infant is at least one year of age (AAP, 2012). Our work at CDC is focused on supporting women who breastfeed through policy and environmental approaches. We emphasize improvement in maternity care practices to support breastfeeding women as well as measures to support breastfeeding women when they return home and to their employment. During the hospital stay, breastfeeding women are encouraged to exclusively breastfeed their newborn infant unless a supplement is medically indicated. Medical indications to supplement such as an infant's weight loss of 8% to 10% accompanied by delayed lactogenesis and/or evidence of dehydration are outlined in Academy of Breastfeeding Medicine (ABM) clinical protocol for supplementary feeding in healthy term newborns (ABM, 2009). When an infant has early feeding difficulties, professional lactation support is critical to work with the mother and infant to overcome these feeding difficulties. Part of this support is monitoring for indications to supplement and working with mother when a supplement is needed; however, early feeding difficulties do not always indicate the need for a supplement. Because unnecessary supplementation can interfere with the establishment of breastfeeding and lead to a shorter duration of breastfeeding, it should be avoided. The American Academy of Pediatrics recommends hospital routines that optimize

opportunities and support for mothers to exclusively breastfeed but also acknowledges the role of pediatricians in assessing the adequacy of breastfeeding and any indication for supplementation (AAP, 2012).

Poor breastfeeding with inadequate caloric intake during the first days of life increases the risk for early neonatal jaundice. The mechanisms have been well-described and are related to developmental limitations in bilirubin metabolism and transport that are physiologically normal for newborns. The ABM has also provided a clinical protocol for management of serum bilirubin concentrations while breastfeeding, again including indications for supplementation (ABM, 2010). In addition, breastfeeding difficulty associated hypernatremia has been widely reported in the medication literature and sometimes has been associated with severe consequences. A recent population-based, prospective study in the UK (Oddie, 2013) found that severe hypernatremia in newborns was rare (about 1 in 100,000 live births) and primarily associated with breastfeeding difficulties. Short-term outcomes for these infants appear to be good; however, long-term studies are lacking.

As you have learned by looking through the scientific literature, there have been several studies assessing the possible association of jaundice and ASD. In 2011, a systematic review and meta-analysis of eleven studies showed a pooled risk estimate of 1.43 which was statistically significant (Amin et al., 2011). This finding of a 43% increase was seen in studies where the majority of infants were born at term. The authors noted a limitation that this finding is based on observational studies which can only show an association between factors and cannot prove causality. However, such a review may be the stimulus for more research.

While feeding problems in children with ASD have been documented in several studies, the possible association between breastfeeding difficulties and ASD has been less studied. A 2013 study from Sweden (Barnevik-Olsson, 2013) reports a significantly higher number of consultations for early regulatory problems such as feeding and sleeping difficulties among children with a later diagnosis of ASD. While it is known that older children with autism may have difficulties with eating, this study measured feeding problems reported during the first two years of life during consultations before a diagnosis of autism. Regarding breastfeeding, the practice has been found to be associated with a lesser risk for ASD and other neurological disorders, but there is some literature proposing that early difficulties with breastfeeding may be positively associated with ASD. A recent study found a higher odds of ASD with shorter durations of exclusive breastfeeding and shorter durations of any breastfeeding. The study also reported 48% higher odds for ASD with late initiation of breast-feeding (Al-Farsi, 2010). The findings in this small study need to be supported by additional studies.

A number of studies have documented various delays in motor skills as well as other neurologic problems in children with ASD (Chukoskie, 2013). It is not known if an underlying neurologic

problem such as oral motor dysfunction might predispose infants with ASD to breastfeeding difficulties that present before a diagnosis of ASD. Changes in the cerebellum which, as you know, is important for coordination and motor learning have been documented in numerous studies (Fatimi, 2012) and most recently, areas of disorganization in the neocortex have been identified in children with autism who had died (Stoner, 2014). The changes described would have occurred prenatally.

CDC is working closely with the Food and Drug Administration (FDA) to support the Infant Feeding Practices Study II, a national longitudinal study of 4,902 pregnant women and their infants, 3,033 of whom were followed through the first 12 months postpartum with nearly monthly questionnaires. The study provides detailed information about infant diet, including breast milk and infant formula, factors that contribute to infant feeding practices, infant morbidity, dietary patterns of pregnant and postpartum women, and other factors (<http://www.cdc.gov/ifps/>). A follow up study of the children at age six years was recently completed and will be released in September 2014.

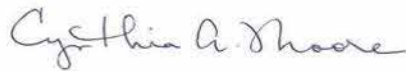
To help identify factors that may put children at risk for autism and other developmental disabilities, CDC is conducting one of the largest studies in the United States called the Study to Explore Early Development (SEED). SEED is looking at numerous risk factors for ASD such as genetic factors, environmental factors, and the interaction between genetic and environmental factors that have not been explored in other studies. SEED collects a variety of information on perinatal factors, such as preterm birth, found to increase the risk for ASD in previous studies. We collect less information on postnatal factors, such as jaundice, which also may be important. Through SEED we collect basic information on jaundice and early feeding difficulties; however, we have not collected information on breastfeeding difficulties per se. We will take a look at the information we have related to jaundice and feeding difficulties and we will also share your letter with our collaborators working on SEED through the CDC-funded Centers for Autism and Developmental Disabilities Research and Epidemiology. Your letter will stimulate discussion on what further information could be collected as part of this effort.

It's difficult to succinctly sum up where we are in the search for causes of ASD. We agree with your conclusion that the increases in ASD prevalence cannot be due to changes in the genetic make-up of the population. We know that having some genetic conditions such as Down syndrome is a strong risk factor for ASD. We also know that some environmental exposures prenatally increase the risk, and we are identifying more and more genetic variants that also appear to increase the risk – often in concert with environmental exposures. We know that some of the increase is due to better identification of children across a broad phenotype of children with ASD. We have identified a number of additional factors such as parental age, but we know there must be others.

Again, we thank you for sharing your story and motivating us to continue to explore the difficult questions. You have gone above and beyond to help your child thrive by continuing to breastfeed for 20 months. However, a mother always wants to know the “why” when her child has developmental challenges, and many times will feel guilt even in the absence of an answer. It is so distressing that the safeguards which have been put in place to help mothers successfully breastfeed did not prevent your baby’s need for ICU care shortly after birth.

To conclude, at this point in time we have found connections between difficulties in breastfeeding, jaundice and ASD, but we don’t know if there is a causal pathway or the direction of the pathway if it exists. Both promoting successful breastfeeding and finding the causes of autism will remain important public health issues for CDC. We wish your family well in the future and remain available if further questions or concerns arise.

Sincerely,



Cynthia A. Moore, M.D., Ph.D.
Director
Division on Birth Defects and
Developmental Disabilities
National Center on Birth Defects and
Developmental Disabilities
Centers for Disease Control and Prevention



Kelley S. Scanlon, Ph.D., R.D.
Lead Epidemiologist
Epidemiology and Surveillance Team
Division of Nutrition, Physical Activity, and Obesity
National Center for Chronic Disease Prevention and
Health Promotion
Centers for Disease Control and Prevention

Selected References

Academy of Breastfeeding Medicine. (2009). ABM Clinical Protocol #3: Hospital Guidelines for the Use of Supplementary Feedings in the Healthy Term Breastfed Neonate, Revised 2009. Retrieved from www.breastfeedingmadesimple.com/abm_supplementation.pdf on April 26, 2014.

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Al-Farsi YM, Al-Sharbati MM, Waly MI, et al. (2012). Effect of suboptimal breast-feeding on occurrence of autism: a case-control study. *Nutrition*. 28(7-8):e27-32.

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Amin SB, Smith T, Wang H. (2011). Is neonatal jaundice associated with autism spectrum disorders: a systematic review. *J Autism Dev Disord* 41:1455-63.

Barnevik Olsson MB, Höglund Carlsson L, Westerlund J, et al. (2013). Autism before diagnosis: crying, feeding and sleeping problems in the first two years of life. *Acta Pædiatrica*. 102:635-39.

Chukoskie L, Townsend J, Westerfield M. (2013). Motor skill in autism spectrum disorders: a subcortical view. *Int Rev Neurobiol*. 113:207-49.

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Oddie SJ, Craven V, Deakin K, et al. (2013). Severe neonatal hypernatraemia: a population based study. *Arch Dis Child Fetal Neonatal Ed*. 985:F384-7.

Stoner R, Chow ML, Boyle MP. (2014). Patches of disorganization in the neocortex of children with autism. *NEJM*. 370:1209-19.

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 2 May 2017 18:16:04 +0000
To: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Subject: FW: ControlledCorres_ASD and hyperbili_04292014_2
Attachments: ControlledCorres_ASD and hyperbili_04292014_2.docx

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Monday, May 01, 2017 10:47 AM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>
Subject: FW: ControlledCorres_ASD and hyperbili_04292014_2

Kelley asked we not forward the original email below, because it contains personal information. So please only share as needed. Kelley and Cindy Moore from Birth Defects wrote a joint response – attached. I'll forward Christie del Castillo-Hegy's response to this letter.

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, May 21, 2014 9:19 AM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: FW: ControlledCorres_ASD and hyperbili_04292014_2

Fyi - please do not forward original email from mom

From: Moore, Cynthia (CDC/ONDIEH/NCBDDD)
Sent: Tuesday, April 29, 2014 11:01 AM
To: Belser-Vega, Elizabeth (CDC/ONDIEH/NCBDDD)
Cc: Boyle, Coleen (CDC/ONDIEH/NCBDDD); Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Smith, Kimberly E. (CDC/ONDIEH/NCBDDD)
Subject: ControlledCorres_ASD and hyperbili_04292014_2

Hopefully final version with a couple of typos corrected.

Thanks,

Cindy

From: Christie del Castillo-Hegy (b)(6)
Sent: Friday, March 28, 2014 7:22 AM
To: CDC Speakers Bureau
Subject: Hypothesis about the rising prevalence of autism from a physician, scientist and mother of an autistic child

Hello,

(b)(6)

(b)(6)



April 28, 2014

Christie del Castillo-Hegyi, M.D.

(b)(6)

Dear Dr. Del Castillo-Hegyi:

On behalf of Dr. Frieden, thank you for your letter sharing your family's experience. We recognize your commitment to your son's health and the health of all infants. You raise important questions about current guidance to exclusively breastfeed, neonatal hyperbilirubinemia, and increasing numbers of children with autism spectrum disorder (ASD) – and possible connections among these factors. The Centers for Disease Control and Prevention (CDC) is always interested in insights from astute clinicians and moms such as yourself, because these insights have led to many scientific discoveries. Scientists in CDC's Division of Birth Defects and Developmental Disabilities (where our ASD activities are located) and the Division of Nutrition, Physical Activity, and Obesity (where our breastfeeding activities are located) read your letter and our response follows. Because these issues may overlap, we have laid them out in a way we hope you will find helpful. We have also included a few references at the end of this letter.

The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for about six months followed by continued breastfeeding as complementary foods are introduced until the infant is at least one year of age (AAP, 2012). Our work at CDC is focused on supporting women who breastfeed through policy and environmental approaches. We emphasize improvement in maternity care practices to support breastfeeding women as well as measures to support breastfeeding women when they return home and to their employment. During the hospital stay, breastfeeding women are encouraged to exclusively breastfeed their newborn infant unless a supplement is medically indicated. Medical indications to supplement such as an infant's weight loss of 8% to 10% accompanied by delayed lactogenesis and/or evidence of dehydration are outlined in Academy of Breastfeeding Medicine (ABM) clinical protocol for supplementary feeding in healthy term newborns (ABM, 2009). When an infant has early feeding difficulties, professional lactation support is critical to work with the mother and infant to overcome these feeding difficulties. Part of this support is monitoring for indications to supplement and working with mother when a supplement is needed; however, early feeding difficulties do not always indicate the need for a supplement. Because unnecessary supplementation can interfere with the establishment of breastfeeding and lead to a shorter duration of breastfeeding, it should be avoided. The American Academy of Pediatrics recommends hospital routines that optimize

opportunities and support for mothers to exclusively breastfeed but also acknowledges the role of pediatricians in assessing the adequacy of breastfeeding and any indication for supplementation (AAP, 2012).

Poor breastfeeding with inadequate caloric intake during the first days of life increases the risk for early neonatal jaundice. The mechanisms have been well-described and are related to developmental limitations in bilirubin metabolism and transport that are physiologically normal for newborns. The ABM has also provided a clinical protocol for management of serum bilirubin concentrations while breastfeeding, again including indications for supplementation (ABM, 2010). In addition, breastfeeding difficulty associated hypernatremia has been widely reported in the medication literature and sometimes has been associated with severe consequences. A recent population-based, prospective study in the UK (Oddie, 2013) found that severe hypernatremia in newborns was rare (about 1 in 100,000 live births) and primarily associated with breastfeeding difficulties. Short-term outcomes for these infants appear to be good; however, long-term studies are lacking.

As you have learned by looking through the scientific literature, there have been several studies assessing the possible association of jaundice and ASD. In 2011, a systematic review and meta-analysis of eleven studies showed a pooled risk estimate of 1.43 which was statistically significant (Amin et al., 2011). This finding of a 43% increase was seen in studies where the majority of infants were born at term. The authors noted a limitation that this finding is based on observational studies which can only show an association between factors and cannot prove causality. However, such a review may be the stimulus for more research.

While feeding problems in children with ASD have been documented in several studies, the possible association between breastfeeding difficulties and ASD has been less studied. A 2013 study from Sweden (Barnevik-Olsson, 2013) reports a significantly higher number of consultations for early regulatory problems such as feeding and sleeping difficulties among children with a later diagnosis of ASD. While it is known that older children with autism may have difficulties with eating, this study measured feeding problems reported during the first two years of life during consultations before a diagnosis of autism. Regarding breastfeeding, the practice has been found to be associated with a lesser risk for ASD and other neurological disorders, but there is some literature proposing that early difficulties with breastfeeding may be positively associated with ASD. A recent study found a higher odds of ASD with shorter durations of exclusive breastfeeding and shorter durations of any breastfeeding. The study also reported 48% higher odds for ASD with late initiation of breast-feeding (Al-Farsi, 2010). The findings in this small study need to be supported by additional studies.

A number of studies have documented various delays in motor skills as well as other neurologic problems in children with ASD (Chukoskie, 2013). It is not known if an underlying neurologic

problem such as oral motor dysfunction might predispose infants with ASD to breastfeeding difficulties that present before a diagnosis of ASD. Changes in the cerebellum which, as you know, is important for coordination and motor learning have been documented in numerous studies (Fatimi, 2012) and most recently, areas of disorganization in the neocortex have been identified in children with autism who had died (Stoner, 2014). The changes described would have occurred prenatally.

CDC is working closely with the Food and Drug Administration (FDA) to support the Infant Feeding Practices Study II, a national longitudinal study of 4,902 pregnant women and their infants, 3,033 of whom were followed through the first 12 months postpartum with nearly monthly questionnaires. The study provides detailed information about infant diet, including breast milk and infant formula, factors that contribute to infant feeding practices, infant morbidity, dietary patterns of pregnant and postpartum women, and other factors (<http://www.cdc.gov/ifps/>). A follow up study of the children at age six years was recently completed and will be released in September 2014.

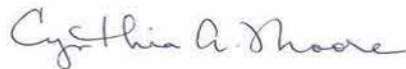
To help identify factors that may put children at risk for autism and other developmental disabilities, CDC is conducting one of the largest studies in the United States called the Study to Explore Early Development (SEED). SEED is looking at numerous risk factors for ASD such as genetic factors, environmental factors, and the interaction between genetic and environmental factors that have not been explored in other studies. SEED collects a variety of information on perinatal factors, such as preterm birth, found to increase the risk for ASD in previous studies. We collect less information on postnatal factors, such as jaundice, which also may be important. Through SEED we collect basic information on jaundice and early feeding difficulties; however, we have not collected information on breastfeeding difficulties per se. We will take a look at the information we have related to jaundice and feeding difficulties and we will also share your letter with our collaborators working on SEED through the CDC-funded Centers for Autism and Developmental Disabilities Research and Epidemiology. Your letter will stimulate discussion on what further information could be collected as part of this effort.

It's difficult to succinctly sum up where we are in the search for causes of ASD. We agree with your conclusion that the increases in ASD prevalence cannot be due to changes in the genetic make-up of the population. We know that having some genetic conditions such as Down syndrome is a strong risk factor for ASD. We also know that some environmental exposures prenatally increase the risk, and we are identifying more and more genetic variants that also appear to increase the risk – often in concert with environmental exposures. We know that some of the increase is due to better identification of children across a broad phenotype of children with ASD. We have identified a number of additional factors such as parental age, but we know there must be others.

Again, we thank you for sharing your story and motivating us to continue to explore the difficult questions. You have gone above and beyond to help your child thrive by continuing to breastfeed for 20 months. However, a mother always wants to know the “why” when her child has developmental challenges, and many times will feel guilt even in the absence of an answer. It is so distressing that the safeguards which have been put in place to help mothers successfully breastfeed did not prevent your baby’s need for ICU care shortly after birth.

To conclude, at this point in time we have found connections between difficulties in breastfeeding, jaundice and ASD, but we don’t know if there is a causal pathway or the direction of the pathway if it exists. Both promoting successful breastfeeding and finding the causes of autism will remain important public health issues for CDC. We wish your family well in the future and remain available if further questions or concerns arise.

Sincerely,



Cynthia A. Moore, M.D., Ph.D.
Director
Division on Birth Defects and
Developmental Disabilities
National Center on Birth Defects and
Developmental Disabilities
Centers for Disease Control and Prevention



Kelley S. Scanlon, Ph.D., R.D.
Lead Epidemiologist
Epidemiology and Surveillance Team
Division of Nutrition, Physical Activity, and Obesity
National Center for Chronic Disease Prevention and
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Stoner R, Chow ML, Boyle MP. (2014). Patches of disorganization in the neocortex of children with autism. *NEJM*. 370:1209-19.

From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 13 Jul 2017 17:24:44 +0000
To: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Subject: FW: DEADLINE EXTENDED: Sign On by Fri, July 21: REVISED Open Letter to Fed Is Best Foundation

Click on the link to see the content of the letter. This is to keep you up to date.

From: office@usbreastfeeding.org [mailto:office@usbreastfeeding.org]
Sent: Thursday, July 13, 2017 1:12 PM
To: MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Subject: DEADLINE EXTENDED: Sign On by Fri, July 21: REVISED Open Letter to Fed Is Best Foundation

*****apologies for cross-posting*****

DEADLINE EXTENDED: Sign On by Fri, July 21: REVISED Open Letter to Fed Is Best Foundation

[COMPLETE THE SIGN ON FORM](#)
[READ THE REVISED LETTER](#)

Dear Member Organization Primary/Poll Contacts,

Thank you to the 30+ organizations who have signed on to the Open Letter to the Fed Is Best Foundation. We already have a broad and diverse group of organizations represented.

Since we sent the original sign-on invitation, we have received some very constructive expert feedback which has led us to revise the letter slightly – specifically in its tone, but not its substance. Please read the [revised Open Letter](#).

Given this development, **we have extended the deadline for sign-ons to next Friday, July 21.**

For those organizations that **HAVE** already signed on, we plan to include your organization's name on the Open Letter ***unless*** we hear from you by Friday, July 21, that you would like to be removed. To "opt-out" please contact Adrianna Logalbo, Managing Director at 1,000 Days, by email (Adrianna@thousanddays.org) or phone (202-969-4125).

For those organizations that **HAVE NOT** yet signed on, [you can still do so on the form](#).

As a reminder: all national, state, and local USBC member and partner organizations are invited to sign on to the Open Letter. See original invitation below for additional background and details.

Thank you again for your support.

From: USBC Headquarters
Sent: Friday, June 23, 2017 8:14 AM
Subject: Sign On by Fri, July 7: Open Letter to Fed Is Best Foundation

*****apologies for cross-posting*****

SIGN ON BY FRIDAY, JULY 7: OPEN LETTER TO FOUNDERS OF FED IS BEST FOUNDATION

[COMPLETE THE SIGN ON FORM](#)

[READ THE LETTER](#)

Dear Member Organization Primary/Poll Contacts,

There is growing concern in the "First Food Field" about the Fed Is Best (FIB) Foundation's increasingly aggressive efforts to undermine mothers' confidence in breastfeeding. Over the past several months, FIB has engaged in what could be characterized as a well-orchestrated disinformation campaign aiming to raise doubts about the safety of exclusive breastfeeding. Their messages attempt to draw links between the practice of exclusive breastfeeding by parents, as well as its education and promotion by health care providers, and the tragic deaths and injuries of babies.

FIB uses fear-based messaging and imagery to put out a false narrative that mothers who exclusively breastfeed might be inadvertently putting their babies' health at risk. FIB has a large and growing following on Facebook and recently managed to garner national media coverage of a story it had been promoting to its network that linked breastfeeding to a specific infant's death in California in 2012. (If you were not previously aware of these stories, [see this document with several links to new clippings](#).) Furthermore, FIB advocates and surrogates have engaged in increasingly aggressive rhetoric directed at organizations involved in breastfeeding education and support, including WHO, UNICEF, the Academy of Breastfeeding Medicine, and Baby-Friendly USA.

Out of concern for how FIB is undermining our collective efforts to support families to reach their breastfeeding goals, several organizations have been in joint discussions about organizing a response, both before and after the USBC-hosted Media Networking Call on this topic on April 24. In consultation with a number of partners, USBC member organization 1,000 Days has **developed an "[Open Letter](#)" to invite FIB's co-founders to engage in a constructive dialogue** about their concerns with representatives from the field. This approach gives FIB the benefit of the doubt, assuming that they share our goal of working collaboratively to improve the health and well-being of our nation's families.

All national, state, and local USBC member and partner organizations are invited to sign-on to this letter (deadline Friday, July 7). It is our hope to gather sign-ons from a broad and diverse group of organizations working to strengthen supports for families across all sectors of society.

We believe that a coordinated response will be particularly impactful and send a much-needed message to FIB and its supporters that we are committed to working with all interested stakeholders to ensure that families have access to the timely and skilled care they need. It will also convey our concerns that FIB's messaging and tactics are problematic and ultimately diverting attention from addressing the underlying issue—the lack of adequate postpartum support.

To confirm the process, we will send the letter to the FIB co-founders first, and subsequently post it publicly. We cannot predict how FIB will respond – they will either go on the attack or accept the invitation to a meeting. The organizing partners are planning for both scenarios and will report out on the results to all organizations that sign on.

The [sign on form](#) also asks if you would be interested/willing to have a representative of your organization at the meeting with FIB, if such a meeting occurs. Note that, due to the likelihood of a large number of signers and the limitations of structuring such a meeting in a way that maximizes diplomacy, we will not be able to accommodate **all** interested parties.

If you have questions, please don't hesitate to be in touch with Adrianna Logalbo, Managing Director at 1,000 Days, by email (b)(6) or phone (b)(6)

Thank you in advance for your support.

***Note:** This message is being sent to the Primary/Poll Contacts for the national USBC member organizations and state breastfeeding coalitions, as well as the Advocacy & Media Contacts for national member and partner organizations.*

United States Breastfeeding Committee (USBC)

4044 N Lincoln Ave, # 288

Chicago, IL 60618

Phone: 773/359-1549

Fax: 773/313-3498

office@usbreastfeeding.org

www.usbreastfeeding.org

***Note:** You are on this distribution list because you are currently set as Primary/Poll Contact on your USBC Member Organization's Group Profile in the USBC website. If you need help updating these contacts, please e-mail office@usbreastfeeding.org.*

From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 26 Jul 2017 18:35:00 +0000
To: Joan Meek
Subject: FW: DEADLINE EXTENDED: Sign On by Fri, July 21: REVISED Open Letter to Fed Is Best Foundation
Attachments: 2017-07-xx FIB Open Letter - revised.pdf

Hey Joan,

Great talking with you today. Since the revised letter was distributed by USBC, I'm assuming you've seen it.

Jennifer

From: office@usbreastfeeding.org [<mailto:office@usbreastfeeding.org>]
Sent: Thursday, July 13, 2017 1:12 PM
To: MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Subject: DEADLINE EXTENDED: Sign On by Fri, July 21: REVISED Open Letter to Fed Is Best Foundation

*****apologies for cross-posting*****

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July xx, 2017

Dear Dr. Castillo-Hegy and Ms. Segrave-Daly:

We write to you as fellow advocates for the health and well-being of infants and their families. We believe that we share a common goal—to ensure that every baby gets the strongest start to life. It is in that spirit that we extend an invitation to you to discuss the concerns that you and your organization, the Fed Is Best Foundation, have raised with respect to our nation's infant feeding recommendations and associated health care practices.

We believe the ground we have in common is far greater than the areas where we may have disagreement. For the sake of all children, mothers and families, we therefore seek ways to unite in a shared vision rather than engaging in divisive messaging. For example, we all agree that the health of the baby is the ultimate goal, that infant feeding is a highly personal decision, that the mother should be fully informed of her options in making this decision, that nobody has the right to impose their beliefs or values on another, and that no infant, mother, or family should suffer as a result of ineffective support or care practices. We also agree that many physicians and other health care providers need improved training and education to ensure their competency to properly diagnose and address infant feeding issues, and that improved continuity of care is needed to enable new mothers to access timely, integrated, and continuous care throughout the prenatal and postpartum periods.

That's a lot of common ground to build on.

Where we seem to disagree is on the root cause behind the tragic stories that Fed Is Best has recently highlighted. That is where we would hope to engage in some honest and constructive dialogue to find shared messaging focused on providing the accurate and unbiased information families need to make their personal infant feeding decisions, along with the appropriate care and support they need to implement those decisions.

We believe that we can be most effective in serving moms and babies when we attack the root causes of problems, rather than each other. For this reason, we invite you to meet with us to talk about your concerns and discuss ways we can work together to ensure that no family has to endure the pain and heartbreak of a baby who doesn't get the nutrition they need to thrive. We hope that you will take us up on our offer and look forward to receiving your response.

Sincerely,

From: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 23 Mar 2017 09:32:07 -0400
To: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: Dr. Bass response
Attachments: OADS_Bass_response data run.docx, in hospital deaths.xlsx

From: Cox, Shanna (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, March 23, 2017 9:07 AM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Cc: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) ; Foster, Sarah (CDC/ONDIEH/NCCDPHP) ; Parks Brown, Sharyn (CDC/ONDIEH/NCCDPHP) ; Olson, Christine (CDC/ONDIEH/NCCDPHP)
Subject: FW: Dr. Bass response

FYI per your comments (b)(5)
(b)(5)

Shanna

From: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, March 23, 2017 8:54 AM
To: Cox, Shanna (CDC/ONDIEH/NCCDPHP) <cio8@cdc.gov>; Briss, Peter (CDC/ONDIEH/NCCDPHP) <pxb5@cdc.gov>; Foster, Sarah (CDC/ONDIEH/NCCDPHP) <sjf4@cdc.gov>
Subject: RE: Dr. Bass response

Thanks. see a couple of comments in response. Glad this is wrapping up.

From: Cox, Shanna (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, March 22, 2017 11:20 AM
To: Briss, Peter (CDC/ONDIEH/NCCDPHP) <pxb5@cdc.gov>; Foster, Sarah (CDC/ONDIEH/NCCDPHP) <sjf4@cdc.gov>; Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>
Subject: RE: Dr. Bass response

See response to OADS comment

Thanks for shepherding this through Peter

Shanna

From: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, March 22, 2017 10:50 AM

To: Foster, Sarah (CDC/ONDIEH/NCCDPHP) <sjf4@cdc.gov>; Cox, Shanna (CDC/ONDIEH/NCCDPHP) <cio8@cdc.gov>; Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>
Subject: RE: Dr. Bass response

Janelle, looping you in as I intended the first time.

Peter A. Briss, MD, MPH
Director, Office of Medicine and Science
Medical Director

National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

770-488-5410
pbriss@cdc.gov

From: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, March 22, 2017 10:40 AM
To: Foster, Sarah (CDC/ONDIEH/NCCDPHP) <sjf4@cdc.gov>; Cox, Shanna (CDC/ONDIEH/NCCDPHP) <cio8@cdc.gov>
Subject: FW: Dr. Bass response

(b)(5) How do you folks feel about this version?

Peter A. Briss, MD, MPH
Director, Office of Medicine and Science
Medical Director

National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

770-488-5410
pbriss@cdc.gov

From: Cono, Joanne (CDC/OD/OADS)
Sent: Wednesday, March 22, 2017 9:51 AM
To: Briss, Peter (CDC/ONDIEH/NCCDPHP) <pxb5@cdc.gov>
Subject: RE: Dr. Bass response

Hi Peter,

Patty and I have looked closely at the data and last letter. Here is our suggested revision with a few questions. I've provided just a clean copy, because the track changes version was quite confusing. Please feel free to mark it up. As "outsiders," to this topic we may have inadvertently misstated some things or over-reached, so please don't hesitate to set us straight.

Thanks again for the super nice and thorough data provided too. Sorry this has been such an effort for many. Hopefully, we'll be as responsive as possible.

Joanne

From: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Sent: Monday, March 20, 2017 10:11 AM
To: Cono, Joanne (CDC/OD/OADS) <bzc6@cdc.gov>
Subject: Re: Dr. Bass response

Any further news?

Sent from my BlackBerry 10 smartphone.

From: Cono, Joanne (CDC/OD/OADS)
Sent: Wednesday, March 15, 2017 12:31 PM
To: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Cc: Foster, Sarah (CDC/ONDIEH/NCCDPHP); Cox, Shanna (CDC/ONDIEH/NCCDPHP)
Subject: RE: Dr. Bass response

Thanks to you all and DRH for quickly pulling this together. I'll be back in touch.

Joanne

From: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, March 15, 2017 10:44 AM
To: Cono, Joanne (CDC/OD/OADS) <bzc6@cdc.gov>
Cc: Foster, Sarah (CDC/ONDIEH/NCCDPHP) <sjf4@cdc.gov>; Cox, Shanna (CDC/ONDIEH/NCCDPHP) <cio8@cdc.gov>
Subject: FW: Dr. Bass response

Thanks to DRH for pulling together [REDACTED] (b)(5)

[REDACTED] (b)(5)

Please let us know if you need anything else.

PB

Peter A. Briss, MD, MPH
Director, Office of Medicine and Science
Medical Director
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

770-488-5410
pbriss@cdc.gov

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(b)(5)

From: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 2 May 2017 07:56:14 -0400
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Cc: Gunn, Janelle P. (CDC/DDNID/NCCDPHP/DNPAO); DNPAO/Health Policy Team (CDC); Torres, Monica (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: DUE 5/4: Draft for the Castillo Response for Folder 2384430
Attachments: RESPONSE REQUIRED: Topic: Dangers of the Baby-Frien, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t05C6tK:ref], 2379661 Baby-Friendly Initiative, Fed is Best, Christie del Castillo-Heg....docx

Hi Cria,

I wanted you to be aware of this request. Since Janelle is going to be traveling Tues-Thurs, I will help craft a response and will share with you before it goes forward. Janelle will share any materials that she's developed before she leaves.

Thanks.

Karen

From: DNPAO/Health Policy Team (CDC)
Sent: Monday, May 01, 2017 12:46 PM
To: Bosso, Eileen T. (CDC/ONDIEH/NCCDPHP) <guz3@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Subject: FW: DUE 5/4: Draft for the Castillo Response for Folder 2384430

From: Johnson, Margaret Sarti (CDC/ONDIEH/NCCDPHP)
Sent: Monday, May 1, 2017 12:45:44 PM (UTC-05:00) Eastern Time (US & Canada)
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); DNPAO/Health Policy Team (CDC)
Cc: Johnson, Abigail P. (CDC/ONDIEH/NCCDPHP); Johnson, Margaret Sarti (CDC/ONDIEH/NCCDPHP)
Subject: DUE 5/4: Draft for the Castillo Response for Folder 2384430

Hello Janelle,

I'm sending the attached draft response and the original email for the Castillo request. The draft response uses verbiage from (b)(5) Peter reviewed and (b)(5)

(b)(5)

Please review, revise as necessary and send back to me by COB Thursday May 4th.

Thanks and let me know if you have any questions,
Margaret

From: Dean, Contessa J. (CDC/OD/OCS)

Sent: Monday, May 01, 2017 11:59 AM

To: Johnson, Margaret Sarti (CDC/ONDIEH/NCCDPHP) <kcy3@cdc.gov>; Johnson, Abigail P. (CDC/ONDIEH/NCCDPHP) <vmh3@cdc.gov>

Subject: Draft for the Castillo Response for Folder 2384430

Importance: High

Attached is the incoming and draft response for the Castillo letter. We prepared the draft using language from (b)(5) This is a Direct Reply for NCCDPHP, and you can edit as you see fit and send out under the signature of who NCCDPHP thinks is appropriate. Please send me a copy of the final to close out the folder.

From: Reply Needed from CDC
Sent: Tue, 4 Apr 2017 12:07:32 +0000
To: DIRECTOR'S INCOMING (CDC)
Subject: RESPONSE REQUIRED: Topic: Dangers of the Baby-Frien, Priority: Medium,
Mode: Email [ref:_00DU0YCBU._500t05C6tK:ref]

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

This inquiry is being escalated because as per A-Z, anything regarding Dr. Frieden is to be escalated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-INFO Correspondence Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain.

Thank you,
K.C.

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Email -----

From : null

To : cdcinfo@cdc.gov

Date : 2017-03-30 01:27:59

Subject : CDC-INFO: Inquiry

Subject: Dangers of the Baby-Friendly Hospital Initiative

From: Clinician

Email Address: christie@fedisbest.org

Your Question: Dear Dr. Friedan,

I am one of the Co-Founders of the Fed is Best Foundation, emergency physician and former newborn brain injury scientist, Dr. Christie del Castillo-Hegyi. You may have heard of the starvation death of Landon Johnson that occurred because of the management of a Baby-Friendly hospital. Since the beginning of my campaign 2 years ago, we have received tens of thousands newborn hospitalization and starvation stories from insufficient exclusive breastfeeding. Starvation-related complications are happening to thousands of newborns a day who are exhibiting obvious signs of starvation including non-stop crying and nursing even while they are in the hospital, as Landon did before he suffered from cardiac arrest from hypernatremic dehydration. These complications are in fact the leading causes of newborn hospitalizations in the world. This Fed is Best petition is attached along with comments/stories left by parents and health professionals. Please read the petition. We are preparing to propose legislation to protect newborns from the dangers of the Baby-Friendly Hospital Initiative and we hope you will address the safety concerns of thousands of parents represented by the Foundation.

https://drive.google.com/open?id=0B0_MbXCqYazzcUNXbEN10ThzeE0

Comments from petitioners:

https://drive.google.com/open?id=0B0_MbXCqYazzS1NFZXRnUjh5cEk

Respectfully,

Christie del Castillo-Hegyi, M.D.
Co-Founder, Fed is Best Foundation

Optional Information

Name: Christie del Castillo-Hegyi, M.D.
Title: Emergency Physician, Infant Feeding Advocate
Organization: The Fed is Best Foundation
Phone: (b)(6)

Other Email: christie@fedisbest.org
Address: christie@fedisbest.org

(b)(5)

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 4 May 2017 09:18:03 -0400
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Subject: FW: DUE 5/4: Draft for the Castillo Response for Folder 2384430
Attachments: 2379661 Baby-Friendly Initiative Fed is Best Christie del Castillo-Heg....docx

FYI.

From: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, May 03, 2017 8:58 PM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Cc: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Subject: FW: DUE 5/4: Draft for the Castillo Response for Folder 2384430

Hi Janelle,

Here is the final. Should this be from Ruth? The email says that this is "a Direct Reply for NCCDPHP and we can send out under the signature of who NCCDPHP thinks is appropriate." Let me know what you think.

Thanks.

Karen

From: Johnson, Margaret Sarti (CDC/ONDIEH/NCCDPHP)
Sent: Monday, May 01, 2017 12:46 PM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>; DNPAO/Health Policy Team (CDC) <DNPAOPolicy@cdc.gov>
Cc: Johnson, Abigail P. (CDC/ONDIEH/NCCDPHP) <vmh3@cdc.gov>; Johnson, Margaret Sarti (CDC/ONDIEH/NCCDPHP) <kcy3@cdc.gov>
Subject: DUE 5/4: Draft for the Castillo Response for Folder 2384430

Hello Janelle,

I'm sending the attached draft response and the original email for the Castillo request. The draft response uses verbiage from (b)(5) Peter reviewed and (b)(5)

(b)(5)

Please review, revise as necessary and send back to me by COB Thursday May 4th.

Thanks and let me know if you have any questions,

Margaret

From: Dean, Contessa J. (CDC/OD/OCS)

Sent: Monday, May 01, 2017 11:59 AM

To: Johnson, Margaret Sarti (CDC/ONDIEH/NCCDPHP) <kcy3@cdc.gov>; Johnson, Abigail P. (CDC/ONDIEH/NCCDPHP) <vmh3@cdc.gov>

Subject: Draft for the Castillo Response for Folder 2384430

Importance: High

Attached is the incoming and draft response for the Castillo letter. We prepared the draft using language from (b)(5) This is a Direct Reply for NCCDPHP, and you can edit as you see fit and send out under the signature of who NCCDPHP thinks is appropriate. Please send me a copy of the final to close out the folder.

(b)(5)

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Fri, 16 Sep 2016 09:42:15 -0400
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP); Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP); Murphy, Paulette (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Subject: FW: Email from Kelley to Trish 9/27/15

Found the final version Kelley sent to Trish about specific changes requested for the GEC. I'll be printing and bringing copies this afternoon, but wanted all to have for their records.

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Monday, December 07, 2015 12:40 PM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; Murphy, Paulette (CDC/ONDIEH/NCCDPHP) <pem1@cdc.gov>
Subject: FW: summary of our call on November 19

For your records
I am also preparing a letter to AAP CEO, which I will share once finalized.

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Friday, November 27, 2015 1:08 PM
To: 'Trish MacEnroe' (b)(6)
Subject: summary of our call on November 19

Dear Trish:

Thank you for talking with us last Thursday on very short notice to discuss Baby-Friendly practices and the guidance provided on your website. As I mentioned to you on the call, the chair of a pediatrics department at a US hospital contacted CDC leadership about CDC's endorsement of Baby-Friendly with concerns regarding the safe implementation of Baby-Friendly recommended practices to prevent unintended and devastating outcomes such as sudden unexpected postnatal collapse (SUPC) and falls in the hospital maternity ward. I want to be certain that Baby-Friendly USA is doing everything possible to clarify your priority on the safety of mothers and infants.

To summarize our call last Thursday, I want to request that the safety procedures be clarified and made more prominent in the Guidelines and Evaluation Criteria (GEC) on your website. Some hospitals are implementing the *Ten Steps to Successful Breastfeeding* without or prior to going through the extensive training that is required for Baby-Friendly designation, and they are using your GEC document to do so. I also think it is important to clarify in the GEC a practice that is mentioned but not part of the evaluation criteria for Baby-Friendly designation, specifically skin-to-skin contact beyond the immediate post-partum period. Clarification of the practices and the safety procedures in the GEC will also ensure that all training on implementation is consistent in emphasizing infant safety and the practices evaluated for designation.

Below I list some specific areas of clarification we discussed with you on the call:

Step 4 of the *Ten Steps to Successful Breastfeeding* is “Help mothers initiate breastfeeding within one hour of birth.” Placing mothers and infant in skin-to-skin (STS) contact immediately after birth and until completion of the first feeding unless there is a medically justifiable reason for delayed contact is included in step 4. This is the evidence based practice that Baby-Friendly USA evaluates hospitals on for designation. While it is clear in the GEC that the criteria for evaluation is on this immediate STS contact, it is not clear why the GEC includes an earlier sentence about encouraging STS contact throughout the hospital stay. This is not part of Step 4 and is not part of the evaluation criteria for Baby-Friendly designation. Therefore I suggest this sentence be removed from the GEC or that the document explain what is intended by this sentence. For example, if it is meant to encourage mother-infant closeness to promote breastfeeding, then it is best to state this. Otherwise, there is a risk that unsupervised STS is taking place in the maternity ward, which could put some infants at risk. Further, you have explained on the phone and in the training materials developed for EMPOWER coaches that I reviewed that the immediate STS is always under the supervision of hospital staff. Please also clarify this in the GEC so that hospitals implementing Step 4 on their own without the required training are clear that the mother and newborn infant should not be left alone during the STS contact immediately after birth until completion of the first feeding. Lastly, it is important to clarify in the GEC as is clearly stated in training materials that “uninterrupted” STS does not mean that a health care provider is not actively monitoring the infant’s activity, color, and vital signs during STS. If an infant shows signs of distress, then the STS process should be interrupted. As stated in your materials, safety is the first priority of Baby-Friendly.

Step 7 of the *Ten Steps to Successful Breastfeeding* is “Practice rooming-in – allow mothers and infants to remain together twenty-four hours a day.” Rooming-in is the standard for mother-baby care for healthy, full term infants unless there are medical reasons for separation. I know that Baby Friendly USA does not recommend bed sharing of mother and infant but it would be helpful to clearly state this in the GEC. Most (14/18) of the cases of infant death or near death in recent paper published in the Journal of Perinatology (Thach 2014) occurred when the mother and infant fell asleep together in the maternity ward, often while breastfeeding. Without a clear statement about bed sharing in the GEC, there may be misinterpretation of Baby Friendly’s position on this practice. Every effort should be made to prevent mothers from falling asleep with their newborn infant in the bed. Additionally, efforts also need to be implemented by hospitals to prevent falls. It would be helpful to include guidance to prevent falls in the GEC. Finally, you clearly acknowledge that rooming-in would not be practiced if there are medical reasons for separation but it would be helpful to emphasize in the GEC the importance of using clinical judgement to assess factors that may contraindicate rooming-in for a mother and infant.

I realize you have been revising the GEC for release in April 2016. CDC encourages you to make some of the above revisions sooner so that the information is available to those downloading the GEC. We would appreciate a follow up conversation with you about the process used in making revisions to the GEC.

I am very supportive of the ideas you shared with us on the call: 1) examination of all training programs used by hospitals to implement the Ten Steps to assess the quality of the trainings; 2) increasing the number of hours of required training so that safe sleep training is more prominently included in the training of hospital staff; 3) providing periodic webinars emphasizing the safety of implementing the Ten Steps; and 4) considering other content areas for training such as training parents on soothing babies. I also look forward to viewing your upcoming webinar series, titled “Implementing Baby Friendly Steps in a Safe and Friendly Manner.”

Thanks for your continued support of mothers and babies,

Kelley

Kelley S. Scanlon, PhD RD
Chief, Nutrition Branch
Division of Nutrition, Physical Activity, and Obesity,
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Email kscanlon@cdc.gov

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 26 Oct 2016 00:12:12 +0000
To: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Subject: FW: EMPower All-Hospital Webinar Recording- Making Baby Friendly Baby Safe
Attachments: Safe Sleep and Skin-to-Skin Care in the Neonatal.pptx

From: Cynthia Klein (b)(6)
Sent: Friday, October 14, 2016 12:42 PM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; Murphy, Paulette (CDC/ONDIEH/NCCDPHP) <pem1@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP) <rnf2@cdc.gov>; Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>
Subject: FW: EMPower All-Hospital Webinar Recording- Making Baby Friendly Baby Safe

Hi Daurice, Rafa, Paulette, Carol, Cria and Jennifer,

Attached you will find the .ppt slides from Dr. Goldsmith's EMPower All-Hospital presentation yesterday – Making Baby Friendly Baby Safe.

Also, the link to the webinar recording can be found [here](#). The recording started early so you will need to advance to 8:05 for the beginning of the presentation.

If you have any questions, please let me know.

Thanks,

Cynthia

Cynthia Klein, PhD | Principal Associate | Abt Associates
2200 Century Parkway, Suite 950 | Atlanta, GA 30345
O (b)(5) C: (b)(6) www.abtassociates.com



From: EMPower
Sent: Friday, October 14, 2016 11:56 AM
Subject: All-Hospital Webinar Recording- Making Baby Friendly Baby Safe



Dear EMPower Hospitals,

Thank you for joining us yesterday for Dr. Jay Goldsmith's presentation on *"Making Baby Friendly Baby Safe"*. To access yesterday's webinar, please use the link below. The presentation begins at the 8:05 recording mark. Additionally, please see attachments for webinar slides and for Dr. Goldsmith's AAP clinical report.

Webinar recording:

<https://abtassociates.webex.com/abtassociates/lst.php?RCID=da5c1260c810a865c112dbcae70ecc34>

Baby Friendly USA Safety Webinar referenced by Dr. Goldsmith:

<https://attendee.gotowebinar.com/recording/289258797253942786>

All the best,

The EMPower Breastfeeding Team

www.EMPowerBreastfeeding.org

This message may contain privileged and confidential information intended solely for the addressee. Please do not read, disseminate or copy it unless you are the intended recipient. If this message has been received in error, we kindly ask that you notify the sender immediately by return email and delete all copies of the message from your system.

Making “Baby Friendly” Baby Safe




*smith, M.D. Tulane University New
s, LA goldsmith.jay@gmail.com*



Unlike this group, I have no conflicts of interest to disclose!!!

} "Health care systems should ensure that maternity care practices provide education and counseling on breastfeeding. Hospitals should become more “baby-friendly,” by taking steps like those recommended by the UNICEF/WHO’s Baby-Friendly Hospital Initiative.” Regina A. Benjamin, MD, MBA
US Surgeon General (2009–2013)



Case

- } 3410 gm AGA term male born by SVD at 1546 hours to 30 y.o. g7 p1 mother in Level 1 hospital Mother had balanced translocation of chromosome 15 and multiple losses PROM x 3 days → pitocin induction Apgars 6/9 Allowed to breast feed in LDRP in first hour

Case

} Assessed by RN x2 during “bonding period,”
the last time at 1647 (born at 1546)1655:
found by RN to be gray, apneic, bradycardic in
mother’s armsRushed to nursery and CPR
startedMD arrived at 1700 and successfully
intubatedUnable to place peripheral ivFirst
gasp and HR at 1729Neonatologist at 1737

Case

- } Successful resuscitation and baby moved to Level 3 for cooling
Now has significant developmental delays and CPLitigation claims inadequate monitoring during “bonding period” and resuscitation beneath the standard of care

The Problem

- } Skin-to-skin care, rooming in; promotion of breastfeeding in hospitalsWHO Ten Steps to Successful BreastfeedingSSC and RI have evidence of enhanced outcomes
BUTSafety concernsSUPCFallsUnrecognized medical problems in newborn

Definitions

- } Skin-to-skin Care Placing naked infant in direct contact with mother with the ventral skin of the baby touching the ventral skin of the caregiver Recommended immediately following birth for 1 hour; also later in infancy Delay painful procedures (Vit K, eye treatment) Provided for all “well” term newborns (c-sections) Late preterm may also “benefit”, but are at increased risk of early morbidities



Photo courtesy of Keri Duckett Photography

Definitions

- } Rooming-in Mothers and infants to remain together 24 hours/day while in hospital Applies to term and late preterm (>35 weeks) Procedures performed at the bedside Mothers may nap, shower or leave the room with the expectation that staff will monitor the newborn at “routine intervals” Mothers encouraged to use call bell for assistance

Evidence Supporting SSC & RI

- } Extensive research on SSCImmediately after birth stabilizes newborn temp, prevents hypothermiaStabilized blood glucose, decreases crying, better CR stabilityDecreases pain from proceduresIn preterms, improves neurobehavioral maturation, gi adaptation, better sleep patters, better growthDecreases maternal stress, decreases depression, decreases postpartum hemorrhage (!)Improves breastfeeding (reduced formula use)



Evidence Supporting SSC & RI

- } Research on RI improves patient satisfaction
- Better outcomes including dyads with NAS
- Provides better security against abduction
- Leads to decreased infant abandonment
- Supports cue based feeding
- Decreases hyperbilirubinemia
- Increases likelihood of breastfeeding to 6 months




Breastfeeding and the Use of Human Milk

Pediatrics, March 2012

- } Policy Statement (Section on Breastfeeding) Reaffirmed recommendation of exclusive breastfeeding for first 6 months of life Protective effect of breastfeeding against: Asthma, eczema, atopic dermatitis, gi infections, lower respiratory tract infections, O.M.

Breastfeeding and the Use of Human Milk

- } SIDS reduced by $>1/3$ in breastfed babies
15–30% decrease in adolescent and adult obesity in breastfed vs. non-breastfed infants
Pediatricians encouraged to promote breastfeeding to mothers and for hospitals to accommodate and stimulate breastfeeding during the birth hospitalization.
- 

Hospital Routines

- } AAP Sample Hospital Breastfeeding Policy
Adopts WHO/UNICEF principles on
breastfeeding (1991) Revise hospital policies
that interfere with early skin-to-skin
contact or limit time infant can spend with
mother, eliminate human milk substitutes
and pacifier use AAP endorsed Ten Steps
Program (2009)

The Ten Steps to Successful Breastfeeding are:

Have a written breastfeeding policy that is routinely communicated to all health care staff. Train all health care staff in the skills necessary to implement this policy. Inform all pregnant women about the benefits and management of breastfeeding. Help mothers initiate breastfeeding within one hour of birth. Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants. Give infants no food or drink other than breast-milk, unless medically indicated. Practice rooming in – allow mothers and infants to remain together 24 hours a day. Encourage breastfeeding on demand. Give no pacifiers or artificial nipples

Ten Steps Program

- } Adherence to program demonstrated to:
Increase rates of breastfeeding initiation, duration and exclusivity
Implementation of 5 postpartum practices have been shown to:
Increase breastfeeding duration (regardless of SE status)
Increase breastfeeding in 1st hour after birth
Increase exclusive breastfeeding
Increase avoidance of pacifiers

“Baby Friendly” Hospitals

- } Baby Friendly Hospital Initiative (BFHI) launched in 1991 Based on WHO/UNICEF Ten Steps Program (1991) and Innocenti Declaration (1990) “Baby Friendly USA”, certifying body (the “Golden Bow”) First hospital certified in 1996 September 2016: 375 certified hospitals (700 more applications in process); these hospitals deliver 18.5% of babies in US ($\approx 740,000$)

Safety Concerns re: immediate STS care

- } Contraindications to immediate STS care
 - Baby requiring positive pressure ventilation in DR
 - Low Apgar scores (< 7 at 5 minutes)
 - Cord pH < 7.0 or BD > -12
 - Baby < 37 weeks gestation
- Concerns re lack of standardization in care
- Lapses of observation by staff
- Lack of education of staff in potential dangers

Unintended Consequences of Current Breastfeeding Initiatives

- } Concerns re: SUPC, co-sleeping, leaving mother-baby unattended in first hours of life, fallsAdvocates against “overly rigid insistence” on following 10 STEPSConcerns regarding advice against pacifiers which have protective effect against SIDS

Definition of SUPC

- } Potentially fatal event in otherwise healthy-appearing term newborn
British definition: >35 weeks gestation
Well at birth (normal 5 minute Apgar)
Collapses unexpectedly requiring CPR
Dies, goes to NICU or develops encephalopathy
Other medical conditions (sepsis, cardiac, etc.) ruled out

Incidence of SUPC

- } Depends on definition used
If brief resolved unexplained event (BRUE) included, low risk and probably benign
Then incidence much higher
Serious SUPC requiring medical CPR
2.6 to 133 cases/100,000 live births
Kernicterus estimated at 1–2/100,000 live births

SUPC of Newborn Infants: A Review of Cases, Definitions, Risks and Preventive Measures

- } Reviewed all published reports of SUPC in first postnatal week (398) Wide ranging estimates of incidence: 2.6 to 133/100,000 births 1/2 died; 1/2 CNS sequelae No etiology found in 153 of 233 deaths 1/3 of cases in first 2 hours; 1/3 between 24 hours and 1/3 between 1 and 7 days

SUPC of Newborn Infants: A Review of Cases, Definitions, Risks and Preventive Measures

- } Recommendations to reduce SUPC
Systematic information to parents re: airway patency
Parent education re: supine position, bed-sharing, soft bedding, head covering, etc.
Appropriate surveillance of newborn in first hours
Supervision of STS with education
Positioning infant to avoid mechanical airway obstruction

Reports of deaths and ALTEs in early neonatal period associated with STS contact

- } Unexpected postnatal collapse of presumably health newborns
Etiology of arrests unknown
Are these events consistent with “Triple Risk Model”?
Intrinsic vulnerability of infant (blunted CO₂ response)
Critical developmental period (e.g. post-delivery stress or sedation)
Exogenous stressor (e.g. prone position, nose in breast, covers over face, hyperthermia, etc.)

Apparent life-threatening events in presumably healthy newborns during early STS contact

Andres V et al, *Pediatrics*, 2011

- } 6 cases of ALTEs in DR during 1st 2 hours of life
- All healthy infants, on mother during early STS contact
- Mother and infant not observed
- Suggested surveillance during early STS

Sudden deaths and severe ALTEs in term infants within 24 hours of birth

Poets A et al, *Pediatrics*, 2011

- } Report of cases in Germany in 2009 of unexplained SUD after 10 min Apgar ≥ 8 43 cases reported, 17 met entry criteria Incidence 2.6/100,000 live births 7 deaths, 6 abnormal CNS at discharge 9 events in first 2 hours of life; 12 babies lying on mother's chest and abdomen 7 noticed by HP while mother was awake!!

Deaths and near deaths of healthy newborn infants while bed sharing on maternity wards

Thach BT, *J Perinatol*, 2014

- } Evaluate bed sharing programs on maternity wards
- Survey MEs for deaths of healthy newborns while bed sharing
- 15 deaths, 3 near deaths reported
- Accidental suffocation deemed most likely cause of incidents
- Suggests education of mothers and more efficient monitoring during STS contact

Sudden unexplained early neonatal death or collapse: a national surveillance study

- } National 3 year surveillance study:
AustraliaSUEND or ALTEs reported at 0.05–0.38/1000 live births; identified 48 cases26 babies who collapsed found on carer's chest“First postnatal day is a vulnerable period” Development and implementation of safe sleep guidelines needed

Lutz et al. 2016 Pediatr Res

Falls

- } Mothers (or fathers) may become dizzy, faint or unable to hold infant
- Maternal fatigue, drug administration may increase risk
- Mother with baby in bed may fall asleep and baby roll to floor

Oregon Patient Safety Review

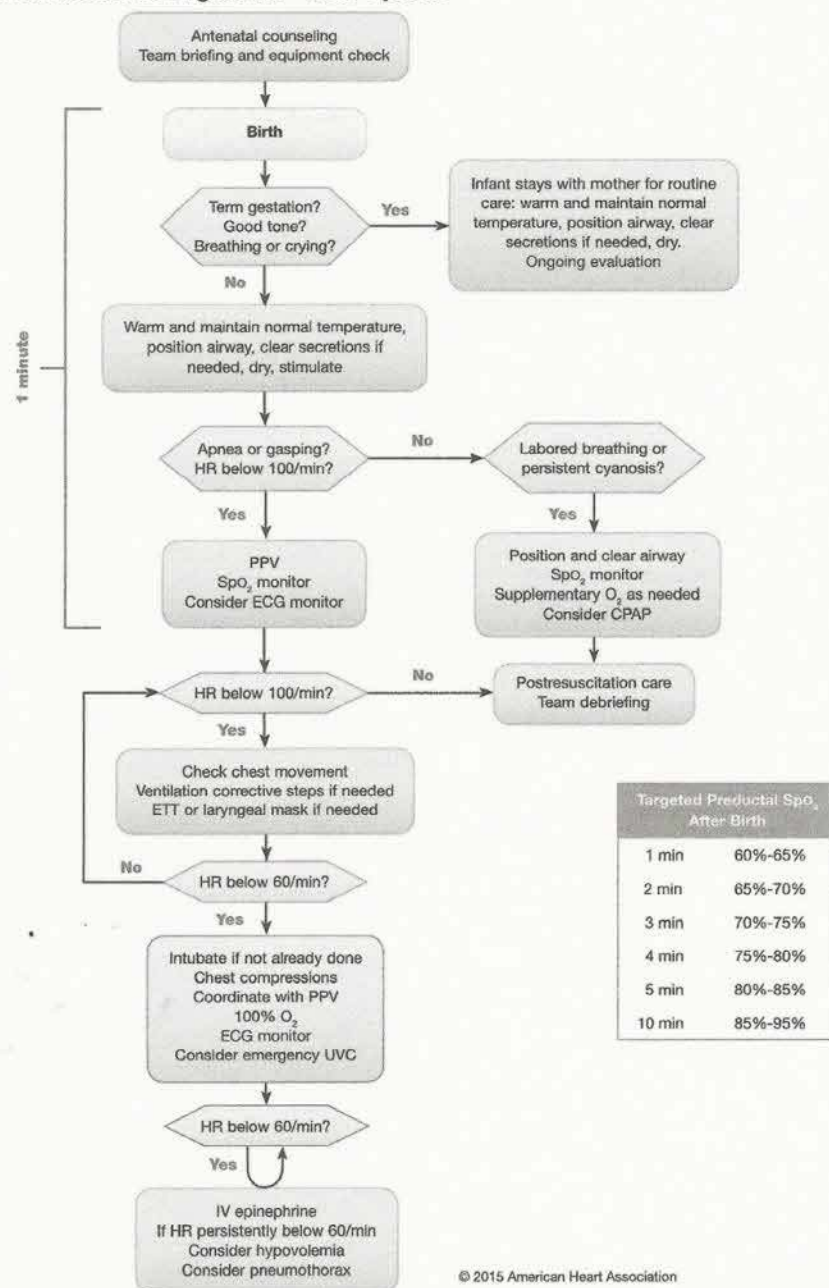
- } 7 hospitals part of one health system
22,866 births: 9 cases of infant falls
Incidence of 3.94 falls per 10,000 births (2006–2007)
Increase from previous review (1.6/100,000 births) for unknown reasons

AAP Policies in place

- } Discourage bed-sharing (Task Force On SIDS, Pediatrics, 2011) NRP, 7th edition (2016):
baby who requires PPV requires post-resuscitation care (implies monitoring)



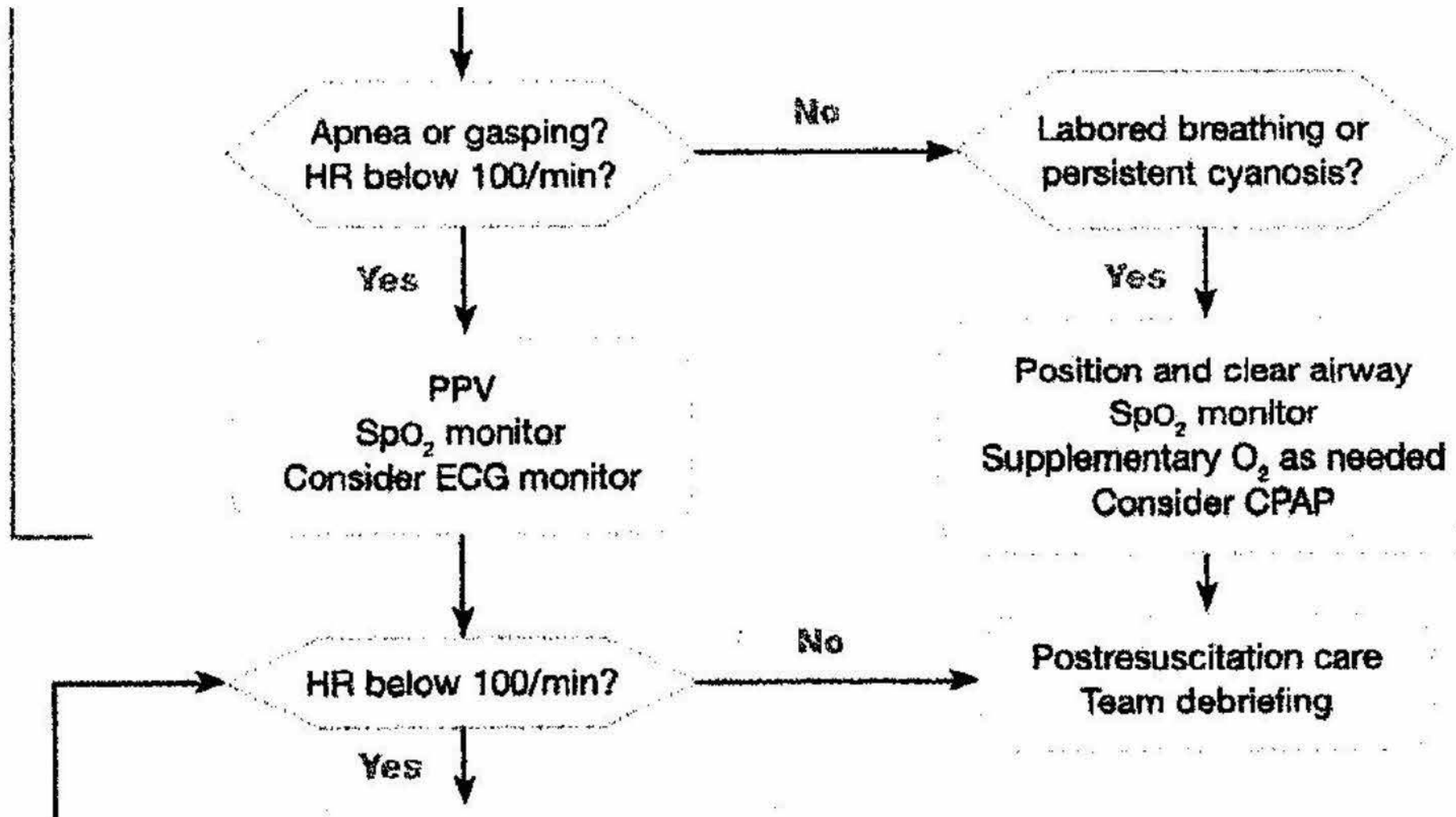
Neonatal Resuscitation Algorithm—2015 Update



© 2015 American Heart Association

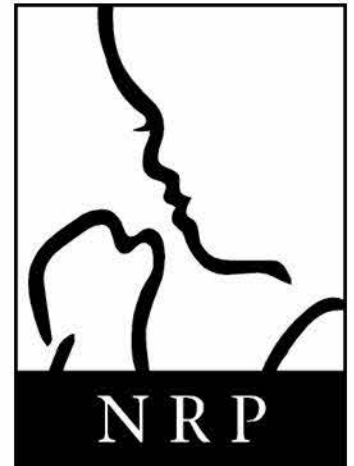
Figure 1
Neonatal Resuscitation Algorithm—2015 Update.

Neonatal Resuscitation Algorithm – 2016 Update



Post Resuscitation Care:

NRP 7th Edition, 2016



“Babies who required supplemental oxygen or PPV after delivery will need close assessment.

They.....should be evaluated frequently during the immediate newborn period...Many will require admission to a nursery environment where continuous cardio-respiratory monitoring is available and vital signs can be measured frequently.”

Making the first days of life safer: time for a new protocol?

Paviotti G et al, J Perinatol, 2014

- } Developed protocol to:
 - Promote safe mother–infant bonding
 - Establish successful early breastfeeding
 - Correct risk factors for SUTC
- Protocol concentrates on maternal education, frequent assessments, discouraging bed–sharing, STS only when mother awake, not leaving mother alone in first hours after birth

Infant Safety

- } Mother post delivery exhaustion Mother may have had opioids, MgSO₄, other depressant/sedating medications Monitoring by hospital personnel (who?) or family (untrained, father also fatigued) Danger of SUPC or fall

Balance safe sleep and skin-to-skin care/breastfeeding initiation

- } Trained observer during first 1–2 hoursLimit bonding in compromised infantIncreased maternal education re: bedsharing

Procedure for immediate postnatal STS

- } Delivery of term infant
Dry, stimulate, assess
If stable place STS with cord attached, clamp cord after one minute
Cover head with cap (optional) and place prewarmed blankets to cover body, leaving face exposed
Assess 1 and 5 minute Apgar scores
Replace wet blankets and cap with dry warm ones
Assist and support to breastfeed

Risk stratification for STS care

- } High risk situations include: PPV (resuscitation) Low Apgar scores Late preterm Difficult delivery Mother receiving opioids, MgSO₄ Excessively sleepy mother IUGR/LGA/IDM baby

Additional safety measures

- } Stabilize ambient temperature
- Use of appropriate lighting
- Facilitating unobstructed view of baby's face
- Additional support persons may augment but NOT replace staff monitoring
- Education of staff in SUPC including safe positioning of baby

Components of safe positioning during STS

- } Infant's face can be seen
- Head in sniffing position
- Nose and mouth are not covered
- Head turned to one side
- Neck is straight, not bent
- Shoulders and chest face mother
- Legs flexed
- Back covered with blankets
- Monitored continuously by staff in delivery area
- Infant placed in bassinet when mother wants to sleep

Safety Concerns When Rooming-In

- } Similar concerns to STSMother falling asleep with baby in bed leading to SUPC or fallMother may be unstable due to exhaustion, medication effects; may not be able to ambulate safelyRelatively unstudied compared to falls of neurologically impaired, post surgical cases or elderly

British study on rooming-in safety

- } 64 mother–infant dyads
 - Sleep in stand alone bassinet, side–car bassinet or mother’s bed
 - Breastfeeding more frequent in bed–sharing and side–car
 - No adverse events, but video monitoring identified more safety issues with bed–sharing
 - Authors concluded side–car provided best opportunity for breastfeeding and safest conditions

Randomly Allocated Postnatal Unit Bassinets



Control, standard rooming-in with
a stand-alone bassinet. to the bed.

Intervention, side-car bassinet attached

Improve safety with rooming-in

- } AWHONN: no more than 3 maternal–infant dyads to 1 RN Nursing extenders may augment care and monitoring Education of mothers and families on risks of bed sharing Safe sleep practices for babies modeled and taught (firm surface, back to sleep, sleep alone)

Suggestions for rooming-in

- } Use a patient safety contract
- Monitor mothers according to risk assessment
- Use fall assessment tools
- Implement maternal egress testing
- Review mother–infant equipment (bed rails, call bells, resuscitation equipment)
- Educate staff re: prevention of infant falls
- Use risk assessment tools to avoid hazards of rooming-in and STS practices

Transitioning to home and safe sleep beyond discharge

- } Anticipatory guidance re:
breastfeeding and sleep safety
Follow AAP recommendations on smoking,
pacifier introduction, use of alcohol,
bed sharing, sleep positioning
Post discharge support for breastfeeding



Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns

Lori Feldman-Winter, MD, MPH, FAAP, Jay P. Goldsmith, MD, FAAP, COMMITTEE ON FETUS
AND NEWBORN, TASK FORCE ON SUDDEN INFANT DEATH SYNDROME

} Combined effort of COFN and Task Force on
SIDS Published in Pediatrics, September 2016

AAP “Clinical Report”: Characteristics

- } Informs the pediatrician in the clinical setting/best practices, state of the art medicineBased on literature review & data analysisCan be a stand-alone documentDOES NOT include recommendations (only suggestions)

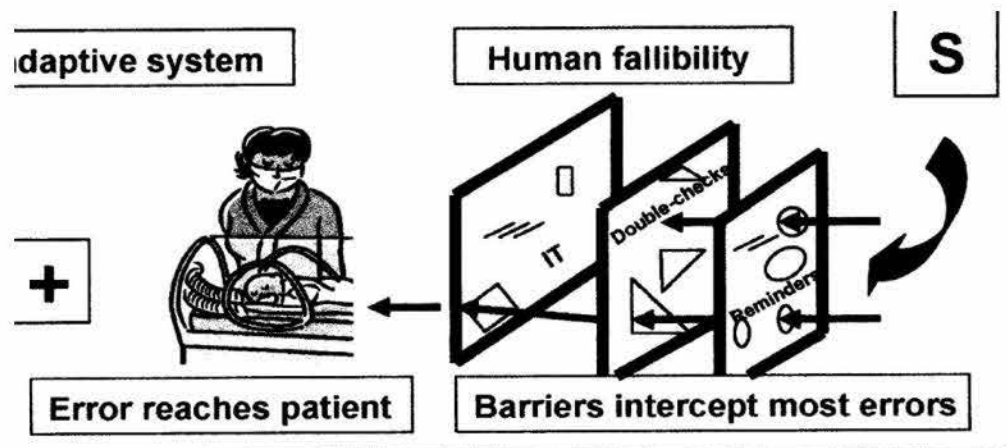
AAP Safe Sleep Suggestions

- } Use patient safety contract (focus on high risk)
- Monitor mothers according to risk assessment
- Use fall assessment tools
- Implement maternal egress testing, especially if mother using medications
- Review mother–infant equipment (bed–rails, call bells, etc.)
- Publicize information on fall prevention
- Use risk assessment tools to avoid hazards of STS and rooming in practices

Baby Friendly Safety Webinar:

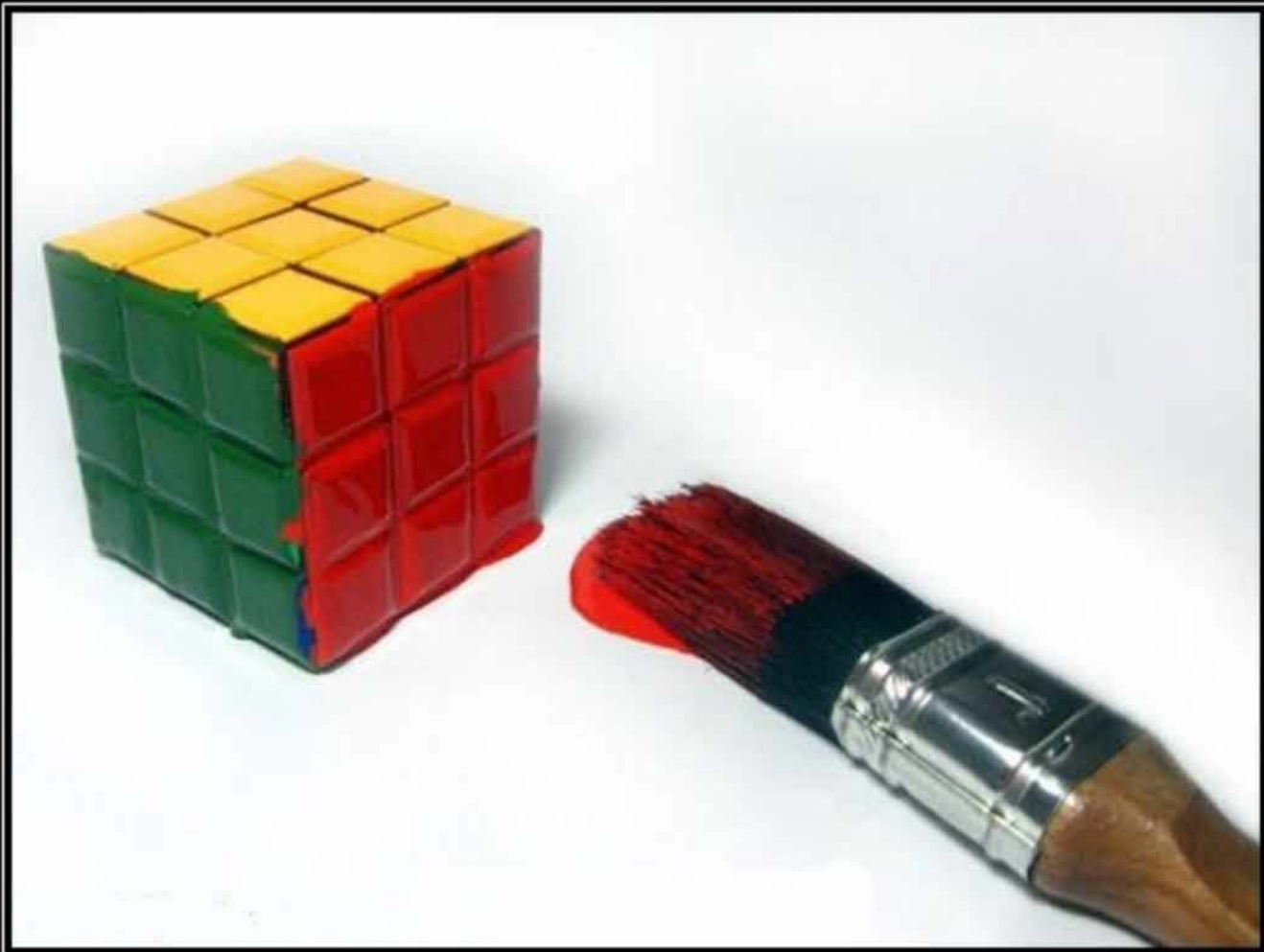
Safety First, Step 4

- Example of late preterm infant with hypoglycemia
 - OM Swiss cheese analogy on how untoward effects of STS could have been avoided with appropriate preparations and interventions
- <https://attendee.gotowebinar.com/recording/289258797253942786>



Case Denouement

- } Multiple expert depositions taken for both sides
Defense claimed no protocol required full time staff in mother's room (arrest occurred after 1 hour of age)
Defense claimed resuscitation met standard for Level 1 hospital
Defendant hospital settled for undisclosed amount prior to start of trial



There are solutions:
even to the hardest problems

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 1 Aug 2017 15:29:39 +0000
To: Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP)
Subject: FW: FIBWG Agenda - August 3
Attachments: FIBWG Discussion_Aug 2017_short.docx

From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Sent: Tuesday, August 1, 2017 9:38 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Olson, Christine (CDC/ONDIEH/NCCDPHP) <cco7@cdc.gov>
Subject: FW: FIBWG Agenda - August 3

Cria and Christine,

I haven't heard back re: the attached proposal. I know Christine is out of the office tomorrow so I'd like to get talking points, etc. finalized today.

Thanks, Jennifer

From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Sent: Friday, July 28, 2017 10:16 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Olson, Christine (CDC/ONDIEH/NCCDPHP) <cco7@cdc.gov>
Subject: FW: FIBWG Agenda - August 3

Hey-

Based on Carol's outline below, I have modified and updated the agenda used for our cross-division meeting. Please review to see if I've 1) missed anything or 2) need to modify something.

Much thanks, Jennifer

From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Friday, July 28, 2017 8:17 AM
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>
Cc: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: RE: FIBWG Agenda - August 3

Hi Jennifer

I put a lot of time on this topic because I thought it would generate a lot of discussion – not just around (b)(5) but also around the need for us, as the FIBWG to communicate regularly on big areas like this.

Here is more or less what I envisioned – not in this order, but main topics to bring up:

(b)(5)

(b)(5)

I actually was not even envisioning slides – but they might be useful if you want to have sort of an outline of the “journey” through this topic, and to list the major things we did. Sometimes slides get in the way. If you want to have some slides, let’s make sure we take a laptop with us.

We might want to let people know to go ahead and ask questions along the way, since it is supposed to be a discussion more than a formal presentation. I forget that not everyone is deeply into this like we are, so might need clarification. I think that if we are okay sharing an internal document it would be fine – like the one we put together in preparation for what we were going to put on the web.

Don’t put a lot of extra time into this – if it ends up being only an hour, that is fine. We never give enough time for around the table updates as it is. And we sometimes take a little extra time getting started. Keep in mind it is a work group, not a formal meeting or conference – more about sharing and communicating, and getting us working together.

Word of caution. (b)(6) if present, will ask a lot of questions – (b)(6)
(b)(6)

Cria, we need to talk about what our updates for this group will be – different than USBC – our funding plans, our getting into ECN ...

From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Sent: Friday, July 28, 2017 6:46 AM
To: MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Subject: RE: FIBWG Agenda - August 3
Importance: High

Hey Carol-

Hope you had a great trip!

I saw where we were slotted for 1.5 hrs to present/discuss (b)(5). I am working with Cria and Christine to pull together this information. Can you provide guidance on exactly how you envision this time being spent? Formal presentation with slides vs. discussion only? Do we need to prepare handouts, etc?

Thanks for the insight.
Sincerely, Jennifer

From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, July 20, 2017 8:37 AM
Subject: FIBWG Agenda - August 3

Good morning everyone

I am going to be sending you an appointment for the Federal Interagency Breastfeeding Work Group, so that you can block your calendar and accept or decline the invitation. I am attaching the Agenda here, but will also include with the appointment.

Of note. It is important for us to know who will be attending the meeting. Sharon Adamo will be compiling a list of names for the purpose of building entry and needs to submit these at least 48 hours ahead of the meeting day. FYI, the meeting will be held at 5600 Fishers Lane (Parklawn Building), in Rockville.

Please let Sharon and/or me know if you have any questions. Carol

Carol A. MacGowan, MPH, RDN, LD
Acting Deputy Branch Chief
Nutrition Branch
DNPAO/NCCDPHP/CCHP/CDC
Desk Phone: (770) 488-5626
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4770 Buford Highway, NE
Mailstop K-77
Atlanta, GA 30341-3717
cmacgowan@cdc.gov
www.cdc.gov

(b)(5)

From: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Tue, 19 Feb 2019 19:48:07 +0000
To: Petersen, Ruth (CDC/DDNID/NCCDPHP/DNPAO); Flores-Ayala, Calixto Rafael (CDC/DDNID/NCCDPHP/DNPAO); Janelle Gunn (bfy2@cdc.gov); Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) (dbg6@cdc.gov); Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: Follow-up Newborn SUPC/SUID
Attachments: Quick_Safety_Issue_40_2018_Newborn_falls_drops.pdf, PC-06.pdf

From: Briss, Peter (CDC/DDNID/NCCDPHP/OD) <pxb5@cdc.gov>
Sent: Tuesday, February 19, 2019 2:31 PM
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>; Shapiro-Mendoza, Carrie K. (CDC/DDNID/NCCDPHP/DRH) <ayn9@cdc.gov>; Kaufmann, Rachel (CDC/DDNID/NCCDPHP/OD) <rbk8@cdc.gov>; Cucchi, Sean (CDC/DDNID/NCCDPHP/OD) <axz7@cdc.gov>
Subject: FW: Follow-up Newborn SUPC/SUID

Just FYI.

PB

From: Bass, Joel L., M.D. (b)(6)
Sent: Tuesday, February 19, 2019 11:57 AM
To: Briss, Peter (CDC/DDNID/NCCDPHP/OD) <pxb5@cdc.gov>; Cono, Joanne (CDC/DDPHSS/OS/OD) <bzc6@cdc.gov>
Cc: Kleinman, Ronald E., M.D. <RKLEINMAN@mgh.harvard.edu>; Gartley, Hilda Tina, M.D. (b)(6)
Subject: RE: Follow-up Newborn SUPC/SUID

Dear Dr Briss & Dr. Cono, Thanks for your response, We are pleased that the CDC has responded positively to our suggestion to incorporate safe sleep messages into the mPinc score. If possible we would appreciate a copy of the new version you mentioned.

We do remain concerned that the CDC web page on hospital support for breastfeeding : <https://www.cdc.gov/vitalsigns/breastfeeding/index.html> continues to promote baby-friendly designation, as the BFUSA organization while maintaining that it promotes safety, has not actually modified its designation criteria to reflect the safety issues now recognized by the WHO and the AAP and continues to promote unsafe practices which are associated with both sudden unexpected postnatal collapse and newborn falls. As the CDC is a leading voice for public health in the US, I think it must provide consistency in its recommendations, which is not compatible with current Baby-Friendly USA designation criteria.

In addition, the Joint Commission has now recognized the serious nature of these problems and has sent out an advisory on preventing newborn falls and a new perinatal measure (PC-06) on Unexpected Complications in Term Newborns which includes unexpected death and other complications related to overzealous implementation of Baby-Friendly designation practices.

Thanks again for responding to our communications. We would be happy to speak in greater detail on these issues if you think it would be helpful

Joel L Bass MD
Tina Gartley MD
Ronald Kleinman MD

From: Briss, Peter (CDC/DDNID/NCCDPHP/OD) <pxb5@cdc.gov>
Sent: Tuesday, February 05, 2019 8:29 PM
To: Bass, Joel L., M.D. (b)(6)
Subject: RE: Follow-up Newborn SUPC/SUID

External Email - Use Caution

Dear Dr. Bass,

Thank you for your continued work to ensure that hospital practices to support breastfeeding are implemented safely. Our work on breastfeeding and safe sleep is coordinated to support these goals. Specifically, our recommendations for safe sleep are aligned with the AAP's recommendations to reduce SIDS and other sleep-related infant deaths as well as NIH's Safe to Sleep campaign.

CDC's National Vital Statistics System conducts ongoing surveillance of infant mortality in the U.S. We are also committed to continuing surveillance of sudden unexpected infant death (SUID) rates, by age at death, which is important to identify new risk factors for SUID and track progress towards reducing SUID mortality. CDC supports SUID surveillance in 22 states and jurisdictions through its SUID Case Registry, covering one-third of all SUID cases. The SUID Case Registry aims to improve the information collected about these tragic events so that participating states and jurisdictions can develop strategies to prevent future deaths.

In addition, we continue to strive to ensure that hospital practices to support breastfeeding are implemented safely. To monitor how hospitals are addressing the safety of their practices, we added several new questions to the mPINC survey; this completely revised mPINC survey is currently being fielded. Specifically, we now ask hospitals questions about monitoring of the mother-infant dyad during the first few hours after birth, teaching safe sleep practices, and policies addressing staff competencies and training related to safety in maternity care.

CDC takes the health and safety of infants seriously. We appreciate your continuing attention to these important issues.

Peter Briss
Medical Director
National Center for Chronic Disease Prevention and Health Promotion
pbriss@cdc.gov
770-488-5401

From: Bass, Joel L., M.D. (b)(6)
Sent: Monday, December 17, 2018 9:54 AM
To: Cono, Joanne (CDC/DDPHSS/OS/OD) <bzc6@cdc.gov>
Cc: Briss, Peter (CDC/DDNID/NCCDPHP/OD) <pxb5@cdc.gov>; Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Gartley, Hilda Tina, M.D. (b)(6) Kleinman, Ronald E., M.D. <RKLEINMAN@mgh.harvard.edu>
Subject: RE: Follow-up Newborn SUPC/SUID

Dear Dr. Cono,

We are writing to give you an update on our research concerning sudden unexpected postnatal collapse (SUPC). As you know we have expressed concerns about the relationship of the Baby Friendly (BF) designation process and its potential to contribute to these events as well as to other sentinel events including newborn falls in the hospital. Since we last communicated there have been a number of significant developments. The issue of early newborn falls is now well recognized, and The Joint Commission has issued a circular warning about this problem (attached).

As deaths due to SUPC correspond to the CDC definition of sudden unexpected infant death (SUID) we have been able to utilize the CDC Wonder data base to further explore the potential extent of this problem. Reviewing 20 years of US data we have been able to document an important trend. While SUID in the post neonatal time-period has decreased substantially, it has remained unchanged in the newborn period. From 1995 through 2014 there have been 8869 SUIDs in newborns, including 2593 deaths in the first six days of life and 1317 on the first day of life. I am attaching a recent publication in the Journal of Pediatrics describing and analyzing this finding in detail, including the likely contribution of SUPC. Of note skin-to-skin care is now considered a well-recognized major contributing factor for SUPC by the American Academy of Pediatrics. This is of great significance, as continuing this practice beyond the immediate post birth time-period, when close observation is no longer likely, is promoted by BF USA designation criteria. I am also including a reply to a letter about our article which includes a figure demonstrating a remarkable parallel between national percentages of BF designation and the corresponding national SUPC incidence rates.

Subsequent to publication, this article was selected for review in the Journal of Pediatrics Best Evidence section and a commentary was written by the CDC SUID epidemiologist Dr. Shapiro-Mendoza. In her analysis, in which she noted the importance of our findings, she was able to include Apgar scores on a 1-year sample documenting that those cases fully complied with the definition of SUPC. We think this is important because in the past, on behalf of the CDC, Dr. Briss has maintained in his last communication (5/1/17) that the CDC has found no evidence of any trend of concern regarding SUPC or any evidence of a relationship of SUID to BF practices.

Of note the World Health Organization has issued a revised BF evidence document. In this revision they emphasized the imperative to avoid intellectual bias in their process and specifically excluded decision making participation for individuals closely involved with professional BF designation activities. The new evidence validates the concerns we have brought to your attention including the risk for SUPC raised by the American Academy of Pediatrics and by national public health organizations worldwide. The WHO has also made an important shift in emphasis and now supports individual approaches to implementing the 10 steps in a manner that suits local circumstances rather than the BF designation process.

We were recently asked by the editors of JAMA Pediatrics to write a guideline synopsis of the new WHO evidence which we have also included for your review. As a result of this new evidence we are hoping that the CDC will reconsider its position promoting universal BF Designation in the US and consider aligning with the current WHO suggestion to no longer promote universal BF designation in favor of individual approaches to breastfeeding support. In addition, integrating NIH safe sleep concepts with breastfeeding support should also be a CDC priority and incorporated into the mPINC scores, in order to help prevent both neonatal and post-neonatal SUID.

We would be happy to discuss any of these issues with you in greater detail.

Joel L Bass MD
Tina Gartley MD
Ronald Kleinman MD

From: Cono, Joanne (CDC/OD/OADS) <bzc6@cdc.gov>
Sent: Friday, February 03, 2017 5:33 PM
To: Bass, Joel L., M.D. (b)(6)
Subject: Follow-up

Dear Dr. Bass,

Though it is very late in the day, I wanted to acknowledge your phone message of yesterday, and also receipt of your communication to Dr. Briss earlier in the week. Thank you for sharing your most recent work on SUPC in newborns. We will take a closer look and be back in touch soon.

Best regards,
Joanne

*Joanne Cono, MD, ScM
Director, Office of Science Quality
Office of the Associate Director for Science
Centers for Disease Control and Prevention
Phone: 404-639-4621
Email: jcono@cdc.gov*

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Preventing newborn falls and drops

Issue:

Inpatient falls have been well studied in the adult population, and there is a large body of research on fall prevention and cost reduction.¹ Conversely, there is little attention to falls in the newborn population, although it has been estimated that 600 to 1,600 newborns in the United States experience an in-hospital fall every year.² Infant falls can escalate into conditions of serious harm to the newborn as well as emotional distress to parents and caregivers.³

What defines a newborn fall or drop?

The Agency for Healthcare Research and Quality (AHRQ) defines a fall as: An unplanned descent to the floor with or without injury to the patient.⁴ The National Database for Nursing Quality Indicators (NDNQI) defines both newborn falls and newborn drops. A newborn fall is “a sudden, unintentional descent, with or without injury to the patient that results in the patient coming to rest on the floor, on or against another surface, on another person or object.” A newborn drop is defined as “a fall in which a baby being held or carried by a health care professional, parent, family member, or visitor falls or slips from that person’s hands, arms, lap, etc. This can occur when a child is being transferred from one person to another. The fall is counted regardless of the surface on which the child lands and regardless of whether or not the fall resulted in injury.”⁵ Current literature supports that this patient safety concern, defined as a newborn fall or a newborn drop, are synonymous; organizations should follow the same patient safety analysis process for both a fall and a drop.

Risk factors for newborn falls drops

The literature supports that the most prevalent maternal risk factors associated with newborn falls and drops include:

- Cesarean birth
- Use of pain medication within four hours
- Second or third postpartum night, specifically around midnight to early morning hours
- Breastfeeding

Numerous maternal infant units promote exclusive breastfeeding as the ideal method of infant feeding in the first six months of life. To help facilitate early attachment between the mother and her newborn, skin-to-skin care is recommended. There is good evidence that normal term newborns who are placed skin to skin with their mothers immediately after birth make the transition from fetal to newborn life with greater respiratory, temperature, and glucose stability and significantly less crying indicating decreased stress.⁶

We also know that while breastfeeding, oxytocin is released from the pituitary gland; while this hormone allows for let down and milk ejection, it also may cause sleepiness in the new mother. The important goal of early skin-to-skin contact, frequent maternal infant interactions, and the promotion of breastfeeding can lead to increased risk of a newborn fall or drop.

Safety actions to consider:

Understanding the potential increased risk of newborn falls and drops is a challenge in today’s fast paced health care environment. Utilizing principles of high reliability, including preoccupation with failure, a health care system should consider developing a process to help prevent newborn falls and drop for all infants under their care, including:

- Developing an assessment tool to indicate those at increased risk for a newborn fall. This tool will promote common language and a shared mental model among the health care team, and act as a cognitive aid to staff so all are performing assessment in a similar manner.

(Cont.)

- Educating parents based on assessment. Those at highest risk should be counseled on the risks for newborn falls and drops and the need to call for help when feeling tired or sleepy. All parents should be cautioned against falling asleep with their newborn in the bed or co-sleeping with their newborn.
- Rounding hourly by staff so mothers or other caregivers noted to be drowsy can be assisted to place their newborn in a bassinet.
- Promoting maternal rest.
- Developing signage for the patient room or a crib card to reinforce the increased risk of infant falls and the importance of placing the infant in a bassinet when the mother is sleepy or after the mother receives pain medications.
- Developing a standardized reporting and debriefing tool in the event of an infant fall. A standard tool will help capture important data to better understanding risk and environment when the event occurred and the result in consistent post-fall care to the newborn.
- In the event of a fall, providing emotional support to the family or caregiver who may suffer as a second victim in this event.

Resources:

1. Galuska L. Prevention of in-hospital newborn falls. *Nursing for Women's Health*, 2011;15(1):59-61.
2. Helsey L., et al. Addressing In-hospital "falls" of newborn infants. *The Joint Commission Journal on Quality and Patient Safety*, 2010;36(7),327-333.
3. Wallace S. (2014). Balancing family bonding with newborn safety. *Pennsylvania Patient Safety Advisory*, 2014;11(3).
4. Agency for Healthcare Research and Quality. [Overview](#). Content last reviewed January 2013. Agency for Healthcare Research and Quality, Rockville, MD.
5. National Database of Nursing Quality Indicators (NDNQI). 2016. Guidelines for Data Collection and Submission on Patient Falls. Press Ganey, Overland Park, KS. Pages 2-3.
6. Philips R. Uninterrupted skin to skin contact immediately after birth. *Medscape*, 2013;13(2):67-72.

Note: This is not an all-inclusive list.

Other resources from The Joint Commission:

The Joint Commission. *Sentinel Event Alert* Issue 55: [Preventing falls and fall-related injuries in health care facilities](#). Sept. 28, 2015.

The Joint Commission. *Quick Safety* Issue 39: [Supporting second victims](#). Jan. 22, 2018



Legal disclaimer: This material is meant as an information piece only; it is not a standard or a *Sentinel Event Alert*. The intent of *Quick Safety* is to raise awareness and to be helpful to Joint Commission-accredited organizations. The information in this publication is derived from actual events that occur in health care.



APPROVED: New Perinatal Care Performance Measure

Effective January 1, 2019, The Joint Commission will require data collection for a new Perinatal Care (PC) performance measure in addition to the five currently required (see table below) for accredited hospitals with at least 300 live births per year and for all hospitals seeking Perinatal Care certification.

The new measure, **PC-06 Unexpected Complications in Term Newborns**, identifies the percentage of infants with unexpected newborn complications among full-term newborns with no preexisting conditions. The most important childbirth outcome for families is bringing home a healthy baby. While there have been measures developed to assess clinical practices and outcomes in preterm infants, there is a lack of metrics that assess the health outcomes of term infants who represent more than 90% of all births. The new measure is designed to address this gap and gauge adverse outcomes resulting in severe or moderate morbidity in otherwise healthy term infants without preexisting conditions.

Importantly, this metric also serves as a balancing measure for other maternal measures such as NTSV (Nulliparous, Term, Singleton, Vertex) cesarean rates and early elective delivery rates. The purpose of a balancing measure is to guard against any unanticipated or unintended consequences of quality improvement activities for these measures. The denominator excludes most serious fetal conditions that are “preexisting” (present before labor), including prematurity, multiple gestations, poor fetal growth, congenital malformations, genetic disorders, other specified fetal and maternal conditions, and infants exposed to maternal drug use in utero. The final denominator population consists of babies who are expected to do well following labor and delivery and go home routinely with their mothers.¹

Specifications for the new measure will be detailed in the [Specifications Manual for Joint Commission National Quality Measures](#), Version 2018B, available in early August. Questions about these measures may be sent via the [Performance Measurement Network Q&A Forum](#). **P**

2019 MEASURES FOR PERINATAL CARE

PC-01: Elective Delivery	Patients with elective vaginal deliveries or elective cesarean sections at ≥ 37 and < 39 weeks of gestation completed
PC-02: Cesarean Birth	Nulliparous women with a term, singleton baby in a vertex position delivered by cesarean birth
PC-03: Antenatal Steroids	Patients at risk of preterm delivery at ≥ 24 and < 34 weeks gestation receiving antenatal steroids prior to delivering preterm newborns
PC-04: Health Care–Associated Bloodstream Infections in Newborns	Staphylococcal and gram negative septicemias or bacteremias in high-risk newborns

PC-05: Exclusive Breast Milk Feeding	Exclusive breast milk feeding during the newborn's entire hospitalization
PC-06: Unexpected Complications in Term Newborns	The percentage of infants with unexpected newborn complications among full-term newborns with no preexisting conditions

Reference

1. California Maternal Quality Care Collaborative (CMQCC). [Unexpected Complications in Term Newborns](#). Accessed Jul 16, 2018.



Specifications Manual for Joint Commission National Quality Measures (v2018B)

[Home](#) » [Perinatal Care \(PC\)](#) » PC-06[Print this page](#)

Release Notes:
 Measure Information Form
 Version 2018B

Measure Information Form

Measure Set: [Perinatal Care\(PC\)](#)

Set Measure ID: PC-06

Set Measure ID	Performance Measure Name
PC-06.0	Unexpected Complications in Term Newborns - Overall Rate
PC-06.1	Unexpected Complications in Term Newborns - Severe Rate
PC-06.2	Unexpected Complications in Term Newborns - Moderate Rate

Performance Measure Name: Unexpected Complications in Term Newborns**Description:** The percent of infants with unexpected newborn complications among full term newborns with no preexisting conditions.

Severe complications include neonatal death, transfer to another hospital for higher level of care, severe birth injuries such as intracranial hemorrhage or nerve injury, neurologic damage, severe respiratory and infectious complications such as sepsis.

Moderate complications include diagnoses or procedures that raise concern but at a lower level than the list for severe e.g. use of CPAP or bone fracture. Examples include less severe respiratory complications e.g. Transient Tachypnea of the Newborn, or infections with a longer length of stay not including sepsis, infants who have a prolonged length of stay of over 5 days.

Rationale: The most important childbirth outcome for families is bringing home a healthy baby. While there have been measures developed to assess clinical practices and outcomes in preterm infants, there is a lack of metrics that assess the health outcomes of term infants who represent over 90% of all births. This measure addresses this gap and gauges adverse outcomes resulting in severe or moderate morbidity in otherwise healthy term infants without preexisting conditions. Importantly, this metric also serves as a balancing measure for other maternal measures such as NTSV Cesarean rates and early elective delivery rates. The purpose of a balancing measure is to guard against any unanticipated or unintended consequences of quality improvement activities for these measures.

Type of Measure: Outcome**Improvement Noted As:** Decrease in the rate**Numerator Statement:** Newborns with severe complications and moderate complications.**Included Populations:****Severe Complications:**

- Death
- Transfer to a another acute care facility
- ICD-10-CM Principal Diagnosis Code, ICD-10-CM Other Diagnosis Codes, ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for Severe Morbidities as defined in Appendix A, Tables:
 - 11.36 Severe Birth Trauma
 - 11.37 Severe Hypoxia/Asphyxia
 - 11.38 Severe Shock and Resuscitation
 - 11.39 Neonatal Severe Respiratory Complications
 - 11.40 Neonatal Severe Infection
 - 11.41 Neonatal Severe Neurological Complications
 - 11.42 Severe Shock and Resuscitation Procedures
 - 11.43 Neonatal Severe Respiratory Procedures

- 11.44 Neonatal Severe Neurological Procedures
- Patients with Length of Stay greater than 4 days AND an ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for Sepsis as defined in Appendix A, Table 11.45 Neonatal Severe Septicemia

Moderate Complications:

- ICD-10-CM Principal Diagnosis Code, ICD-10-CM Other Diagnosis Codes, ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for moderate complications as defined in Appendix A, Tables:
 - 11.46 Moderate Birth Trauma
 - 11.47 Moderate Respiratory Complications
 - 11.48 Moderate Respiratory Complications Procedures
- ICD-10-CM Principal Diagnosis Code for single liveborn newborn as defined in Appendix A, Table 11.20.2 Single Liveborn Newborn-Vaginal AND Length of Stay greater than 2 days
OR
ICD-10-CM Principal Diagnosis Code for single liveborn newborn as defined in Appendix A, Table 11.20.3 Single Liveborn Newborn-Cesarean AND Length of Stay greater than 4 days
AND ANY
ICD-10-CM Principal Diagnosis Code, ICD-10-CM Other Diagnosis Codes, ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for moderate complications as defined in Appendix A, Tables:
 - 11.49 Moderate Birth Trauma with LOS
 - 11.50 Moderate Respiratory Complications with LOS
 - 11.51 Moderate Neurological Complications with LOS Procedures
 - 11.52 Moderate Respiratory Complications with LOS Procedures
 - 11.53 Moderate Infection with LOS
- Patients with Length of Stay greater than 5 days and NO ICD-10-CM Principal Diagnosis Code, ICD-10-CM Other Diagnosis Codes, ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for jaundice or social indications as defined in Appendix A, Tables:
 - 11.33 Neonatal Jaundice
 - 11.34 Phototherapy
 - 11.35 Social Indications

Excluded Populations: None**Data Elements:**

- [Admission Date](#)
- [Discharge Date](#)
- [Discharge Disposition](#)
- [ICD-10-CM Other Diagnosis Codes](#)
- [ICD-10-CM Principal Diagnosis Code](#)
- [ICD-10-PCS Other Procedure Codes](#)
- [ICD-10-PCS Principal Procedure Code](#)

Denominator Statement: Liveborn single term newborns over 2500 gm in birth weight.**Included Populations:** Single liveborn newborns with ICD-10-CM Principal Diagnosis Code for single liveborn newborn as defined in Appendix A, Table Number 11.20.1: Single Liveborn Newborn**Excluded Populations:**

- Patients who are not born in the hospital or are part of multiple gestation pregnancies, with no ICD-10-CM Principal Diagnosis Code for single liveborn newborn as defined in Appendix A, Table Number 11.20.1: Single Liveborn Newborn
- ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for birth weight <= 2500g as defined in Appendix A, Table 11.12, 11.13, 11.14, 11.15 or 11.16 OR Birth Weight <= 2500g
- Patients who are not term or with < 37 weeks gestation completed
- ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for congenital malformations and genetic diseases as defined in Appendix A, Table 11.30 Congenital Malformations
- ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for pre-existing fetal conditions as defined in Appendix A, Table 11.31 Fetal Conditions
- ICD-10-CM Principal Diagnosis Code or ICD-10-CM Other Diagnosis Codes for maternal drug use exposure in-utero as defined in Appendix A, Table 11.32 Maternal Drug Use

Data Elements:

- [Birth Weight](#)
- [Birthdate](#)

- [ICD-10-CM Other Diagnosis Codes](#)
- [ICD-10-CM Principal Diagnosis Code](#)
- [ICD-10-PCS Other Procedure Codes](#)
- [ICD-10-PCS Principal Procedure Code](#)
- [Term Newborn](#)

Risk Adjustment: No.

Data Collection Approach: Retrospective data sources for required data elements include administrative data and medical records.

Data Accuracy: Variation may exist in the assignment of ICD-10 codes; therefore, coding practices may require evaluation to ensure consistency.

Measure Analysis Suggestions: In order to identify areas for improvement, hospitals may want to review results based on specific ICD-10 codes or patient populations. Data could then be analyzed further to determine specific patterns or trends to help reduce unexpected newborn complications.

Sampling: No.

Data Reported As: Aggregate rate generated from count data reported as a rate per 1000 livebirths.

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- "Unexpected Complications in Term Newborns." California Maternal Quality Care Collaborative (CMQCC), 2018, www.cmqcc.org/focus-areas/quality-metrics/unexpected-complications-term-newborns.

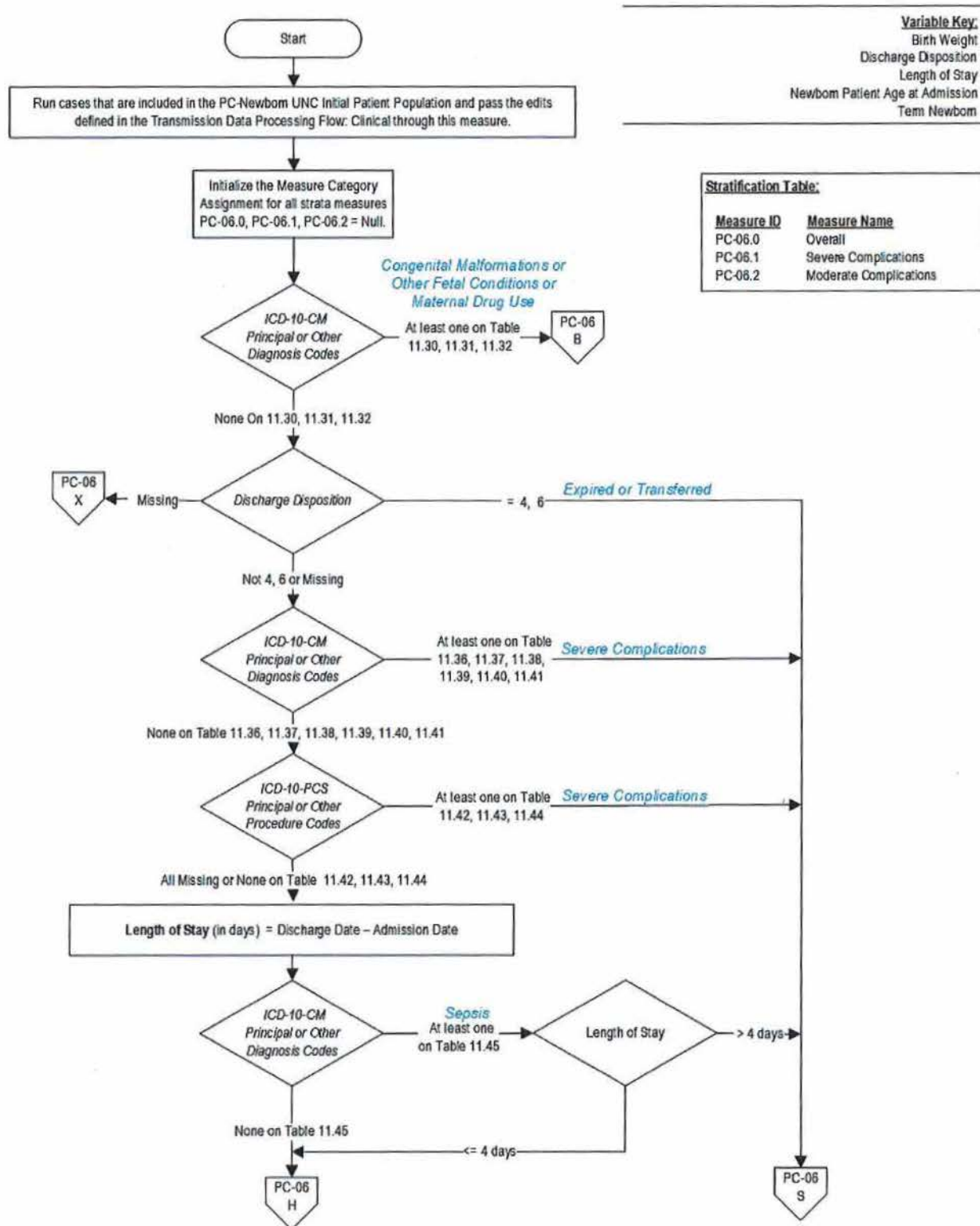
Original Performance Measure Source / Developer:
California Maternal Quality Care Collaborative

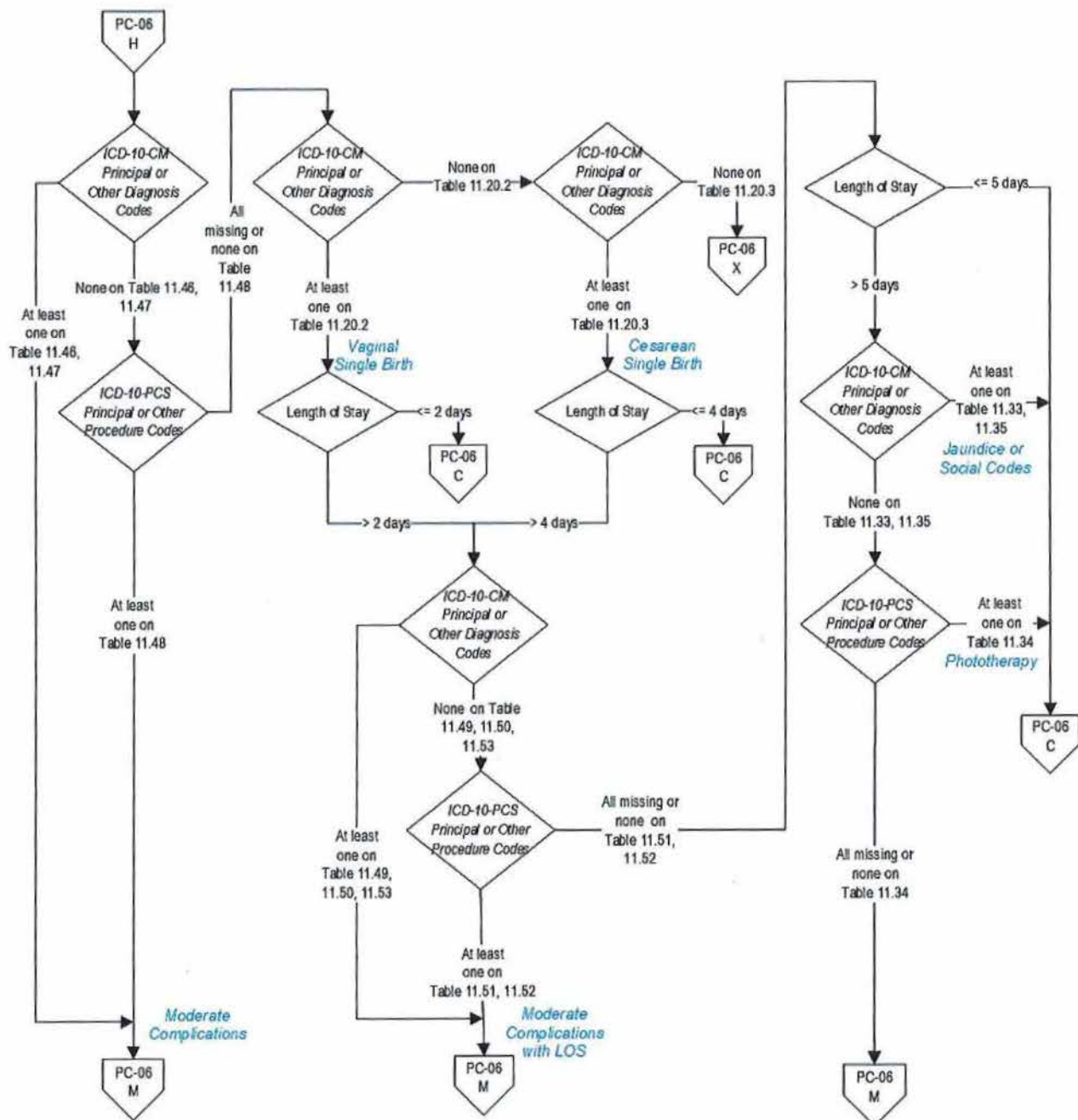
Measure Algorithm:

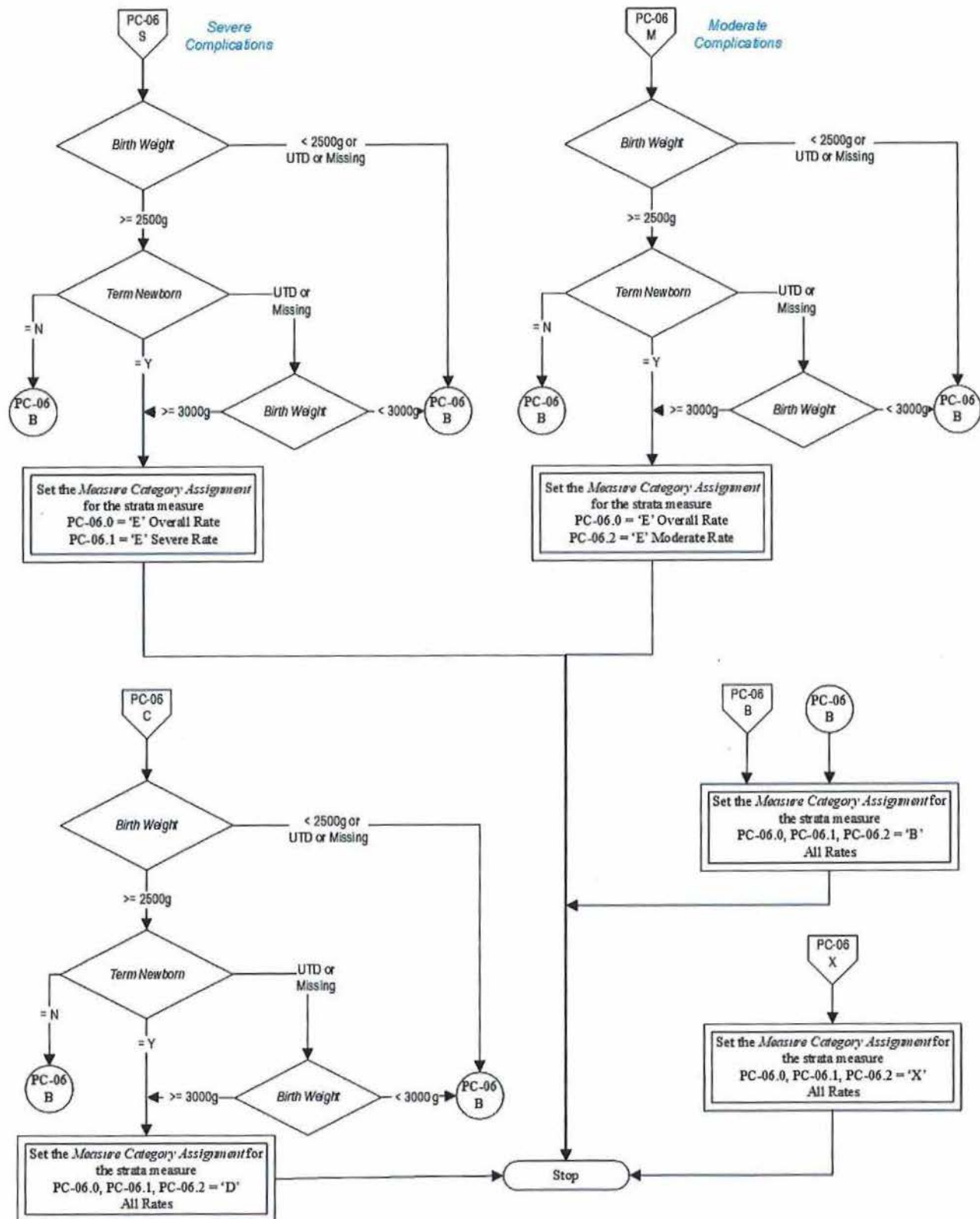
PC-06: Unexpected Complications in Term Newborns

Numerator: Newborns with severe complications and moderate complications.

Denominator: Liveborn single term newborns over 2500 gm in birth weight.







Specification's Manual for Joint Commission National Quality Measures (v2018B)
Discharges 01-01-19 (1Q19) through 06-30-19 (2Q19)

Measure Information Form PC-06

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Questions? [Ask Question to Joint Commission staff](#)

From: Olson, Christine (CDC/DDNID/NCCDPHP/DRH)
Sent: Fri, 7 Dec 2018 13:30:13 -0500
To: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO); Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: following up from meeting about safe newborn positioning
Attachments: 2013 SUPC of Newborn Infants _ a Review of Cases_Definitions_Risks_and Preventive Measures_HERLENIUS.pdf, friedman2015_breastfeeding and delivery room neonatal collapse.pdf, Kellams Moon Colson Hauck _ Pediatrics Oct 2017 _ TodaysBaby Quality Improvement_Safe Sleep Teaching and Role Modeling in 8 US Maternity Units.pdf, Lipke _ AJMCN Oct 2017 _ Newborn Safety Bundle to Prevent Falls and Promote Safe Sleep.pdf, Feldman-Winter CHAMPS webinar 2-15-2017 response to Bass JAMA editorial.pdf, Unintended Consequences of Current Breastfeeding Initiatives _ jamapediatrics_Bass_ Oct 2016.pdf, Sustained skin to skin AWHONN.pdf, Thach _ 2014_Deaths and near deaths of healthy newborn infants while bed sharing on maternity wards.pdf, JC March 2018 _ Quick_Safety_Issue_40_2018_Newborn_falls_drops.pdf, SUPC Rodriguez NeoReviews 2017 e717.full.pdf

FYI

From: Olson, Christine (CDC/DDNID/NCCDPHP/DRH)
Sent: Friday, November 30, 2018 3:34 PM
To: Anne Santa-Donato (b)(6); Elizabeth Rochin (b)(6)
Cc: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>; Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO) <zcn6@cdc.gov>
Subject: following up from meeting about safe newborn positioning

Dear Anne and Elizabeth,

It was such a pleasure to meet both of you in person! I'm very glad that worked out this week. I'm attaching some of the articles I mentioned as well as the JC statement on newborn falls that came out earlier this year. I'm also including two of my colleagues in the Division of Nutrition, Physical Activity, and Obesity who work in the area of infant nutrition/breastfeeding – Drs.Cria Perrine and Jennifer Nelson. We're all very invested in trying to make meaningful improvements in this area and work very collaboratively with each other and with a lot of the same external partners, including the AAP contacts (Mike Goodstein and Joe Hageman) and ACOG contact (Alison Stuebe) I mentioned. I think with your thoughtful input on this topic and the other folks who are very interested and positioned with the national organizations, we can hopefully move this effort forward. We'd look forward to following up with you in January, or even sooner if time permits.

Again, I felt very fortunate that our paths were so easy to cross here in Atlanta this week! I hope you have a smooth and safe trip home and a good weekend.

Best,
Christine

List of attached documents:

- 1) Herlenius article on SUPC – good overview

- 2) Friedman case report on two cases of infants with neonatal collapse while nursing
- 3) Kellams QI Toolkit on Modeling Safe Sleep for Parents and Providers in Maternity Wards
- 4) Lipke Newborn Safety Bundle to Prevent Falls and Promote Safe Sleep
- 5) Feldman-Winter CHAMPS webinar response to Bass JAMA Peds editorial
- 6) Bass JAMA Peds editorial – Unintended Consequences
- 7) AWHONN Practice Brief on Skin to Skin
- 8) Thach Deaths and near deaths of healthy newborn infants while bed sharing on maternity wards
- 9) Joint Commission statement (March 2018) on newborn falls
- 10) Video produced by Northshore (IL) “An Acute Event in a Newborn” – this was the education piece I mentioned that was developed with one of the IL PQC OBs

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Sudden Unexpected Postnatal Collapse of Newborn Infants: A Review of Cases, Definitions, Risks, and Preventive Measures

Eric Herlenius · Pierre Kuhn

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Abstract This study aimed to review available published reports concerning sudden unexpected postnatal collapse (SUPC) of apparently healthy infants within the first days of postnatal life, establish a structured presentation and delineate recommendations for preventive measures. All published reports of SUPC cases were retrospectively analyzed, and three not previously published SUPC cases at Karolinska University Hospital were detailed to exemplify the varying presentations and outcomes of SUPC. We found 398 published cases of SUPC occurring during first postnatal week. Estimated incidence of the SUPC of a presumably healthy infant after birth differs widely, ranging from 2.6 cases to 133 cases/100,000. However, definition, inclusion, and exclusion criteria vary substantially between reports. Our summary indicates that reported SUPC occurs more frequently than expected from recent surveys. About half of the infants die, and of the remaining survivors, half have neurological sequela. Of the 233 cases of sudden unexpected

death described, no etiology was found in 153 cases. When a defined time for the SUPC event is described, approximately one third of reported events occur during the first 2 h, between 2 and 24 h and between 1 and 7 days after birth, respectively. Adequate education of caregivers and appropriate surveillance during the first days of newborns should enable us to save hundreds of lives.

Keywords Sudden unexpected postnatal collapse · Prone · Hypoxia · Birth asphyxia · Adenosine · Prostaglandin · Cardiorespiratory control

Abbreviations

SUPC	Sudden unexpected postnatal collapse
eSIDS	Early sudden infant death syndrome
ALTE	Apparent life threatening event
SUDI	Sudden unexpected death in infancy
SUEND	Sudden unexpected early neonatal death
BE	Base excess
EEG	Electroencephalography
CPAP	Continuous positive airway pressure
HIE	Hypoxic ischemic encephalopathy
TTN	Transient tachypnea of the newborn
PFO	Patent foramen ovale
ICD	International Classification of Disease
PDA	Patent ductus arteriosus
PGE ₂	Prostaglandin E2
mPGES-1	Microsomal prostaglandin E synthase-1
SSC	Safe early skin-to-skin care

Sudden unexpected postnatal collapse (SUPC) of healthy infants within the first days after birth is a rare event but consequences are often catastrophic. Sudden apparent life-threatening events and deaths may occur during the first postnatal week and happens more frequently than indicated in recent national surveys limited to events within the first 24 h. Three new SUPC cases are described to illustrate the varying presentation, outcome as well as possible etiologies and testable hypotheses. Healthy newborns, especially during skin-to-skin contact in prone position, should be supervised during the first hours of postnatal life without interfering with the mother–child bonding to prevent SUPC.

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Introduction

Sudden unexpected postnatal collapse (SUPC) of apparently healthy term or near-term infants within the first days of life is rare but can have catastrophic consequences. About 5 %

of unexpected infant deaths during the first year of life occur during the first postnatal week [1].

SUPC includes both severe apparent life-threatening event (ALTE) and sudden unexpected death in infancy (SUDI) occurring within the first postnatal week. Sudden unexpected early neonatal death (SUEND) in the first week of life shares features with SUDI but is not included as SUDI, which is limited to postperinatal deaths (1 week–1 year). As SUPC is unexpected, infants with well-known risk factors, e.g., prematurity (<35 week gestation), perinatal asphyxia, or congenital malformations are not included in published reports as they are classified as “expected” neonatal deaths or ALTE events [1].

Even if considered rare, consequences are serious with death in half of the cases and remaining disability in a majority of the cases reported [2–4]. Polberger and Svenningsen [5] described, in a regional and a population-based study, sudden cardiovascular collapse, occurring between 6 and 100 h after birth, in infants considered healthy at birth. Here, the incidence of early neonatal sudden unexpected death and severe early-ALTE was established as 12 and 35 cases per 100,000 live births, respectively [5].

Recent national surveys from the UK and Germany have used different criteria for inclusion; SUPC is defined as occurring within the first 24 postnatal hours and excluding (Germany) respectively including (UK) identified and possibly preventable causes [3, 6]. Both these national surveys report an incidence of about 3 cases/100,000 infants. However, recently published guidelines for investigations of SUPC include infants with sudden unexpected collapse during *the first week of life* [7]. These “Guidelines for the investigations of newborn infants who suffer a sudden and unexpected postnatal collapse in the first week of life” mentions 14 published reports concerning SUPC [7]. However, not all publications concerning SUPC are included; neither have a summary of existing SUPC reports and their respective definition of and inclusion criteria for SUPC been done or published.

Thus, we performed an exhaustive literature review of SUPC cases to do a structured presentation of definitions, inclusions, gestational age, and postnatal time of occurrence in published cases. We also describe new cases of SUPC to illustrate and highlight some varying presentations and outcomes. Finally, in view of all the presented data, we summarize preventive measures that might save hundreds of lives.

Methods

Scopus, Web of Science, and Medline databases were searched to retrieve and analyze published SUPC cases and reports concerning early SUDI, early neonatal sudden unexpected death, SUEND, and early ALTE occurring during the first

postnatal days in presumably healthy term and near term newborns. The selection criteria of the published articles were derived from the general guidelines for systematic reviews [8, 9]. All the terms comprised in “SUPC,” “SUDI,” “SUEND,” “ALTE,” and the terms “newborn infant” or “neonate” were used as MeSH terms for the research process. All references of retrieved articles were cross-searched.

We used the recent definition of a SUPC event established in “The guidelines for the investigation of newborn infants who suffer a sudden and unexpected postnatal collapse” [7]. We thus included infants born >35 weeks gestational age, with 10 min Apgar of >7, considered healthy who collapsed suddenly and unexpectedly within the first postnatal week [7, 10, 11].

We excluded cases that occurred after the first week of life and only retained articles in which minimal neonatal data were available. All articles with an English language title were analyzed. Non-English articles in French or Spanish were analyzed with the help of native language scientist in the research group (Drs. Kuhn and Perez, respectively). Unpublished studies were excluded.

We then determined which type of study (case report, site, regional study, or population survey) and which inclusion and exclusion criteria (gestational age, postnatal age, underlying conditions, outcome, as well as risk and associated factors) were reported. All cases including those where a possible etiology to the SUPC event was found during autopsy or after clinical investigations in survivors were eligible. Inquiries regarding inclusion and exclusion criteria were addressed to Drs. Christian and Anette Poets regarding the two German national inquiries [3, 12].

In order to illustrate the varying presentations and outcomes of this condition, an examination of three cases of SUPC occurring in presumably healthy newborns at the Karolinska University Hospital-Solna, Stockholm, Sweden, not previously reported, was performed. Characteristics of mothers and infants perinatal, postpartum, events and subsequent investigations, and outcome data at discharge and at 1 year of age follow-up were recorded and analyzed.

The study was performed in accordance with European Community guidelines and approved by the regional hospital research ethics committee.

Results

Review of Published Cases

We found 400 published cases of SUPC occurring during first postnatal week. Two cases were excluded due to insufficient neonatal data available. These 2 cases were described in two articles investigating possible pathologies of SUDI. One article refers only to one case of a female newborn where SUPC occurred at 2 days of life, in a cohort of infants in whom an

anomaly of the pulmonary artery was found [13]. The other excluded article retrospectively reviews autopsies of neonatal SUDI cases occurring before 28 days of life, to look for brain lesions, and reports only one case of death that occurred in the first week of life, when “the infant was still in the neonatal ward,” but with no other perinatal information described [14]. Tables 1 and 2 give an overview of the remaining 398 cases of SUPC reported in 26 different studies. Table 1 lists reports that have early neonatal sudden unexpected deaths as inclusion criteria, and Table 2 lists SUPC studies where both SUDI/SUEND and ALTE during initial hours to days of life are included.

Most publications are case reports, but regional cohorts as well as national surveys exist. Estimated incidence of SUPC vary between 1.6 to 133/100,000 live born infants, excluding congenital malformations and preterm infants born before gestational week 35 (<38). However, interpretations must be made with caution as the inclusion criteria differ widely. Some studies only include SIDS, unexplained deaths occurring <2 h [15–17], while other reports include early-unexpected ALTE events during first week of life also when a plausible etiology is found after postevent investigations [18, 19].

We have summarized in Table 3 the reports where time of SUPC event is described. A third of reported cases occur during the first two hours of life ($n=106$, 33 %). This summary is biased, as different postnatal age exclusion criteria have been used. For example, only 8 out of 26 studies included cases occurring between the third and seventh postnatal day. Nonetheless, Table 3 gives a systematic overview of the different cases, studies, and postnatal age exclusion criteria used. Notably, among the 11 studies that include SUPC occurring within 72 h of postnatal age, about half of SUPC cases occur <24 h and between 24–72 h postnatal age respectively [84 and 73 cases out of 157 SUPC reported, in these studies (54 and 46 %)].

Illustrative Cases

Three different cases of SUPC are described with varying presentations and outcomes. All three events occurred during skin-to-skin contact in prone position.

Case 1 A boy born at gestational age 41 weeks, 3,683 g, cardiotocogram variable decelerations and thin meconium present during last minutes of, an otherwise uneventful, vaginal delivery. He was hypotonic at 1 min age, Apgar score 7, but rapidly recovered with rosy color good responsiveness and breathing movements with Apgar score 9 at 5 min and 10 at 10 min. Due to umbilical cord artery pH 7.0, base excess (BE)-15 (mmol/L), and metabolic acidosis, he received a bolus dose of Tribonate® 15 mL and 10 % glucose 5 mL and supplemental oxygen during initial

15 min. At 20 min, he was alert, responsive with good saturation, also without supplemental oxygen. He was presumed to be healthy and placed prone on the mother’s chest for skin-to-skin contact. He was seen, still in prone position, and considered healthy by midwife as well as pediatrician at 80 min postnatal age, 2130 hours in the evening. At 100 min (2150 hours), he was discovered cyanotic, hypotonic, without breathing movements or pulse by midwife. Immediate and extensive resuscitation commenced including cardiac compression and intubation. Blood gas minutes after event revealed pH 6.71, $p\text{CO}_2$ of 15, $p\text{O}_2$ of 11, and BE of -21 (mmol/L). Adrenaline injection and Tribonate® boluses were given, and after 7 min, he had >100 heartbeats/minute and subsequently normalized oxygen saturation and blood gases. He was placed on mechanical ventilation after 30 min of resuscitation due to absence of spontaneous breathing movements. Generalized seizures begun at 180 min postnatal age and were stabilized with phenobarbital. Brain cerebral function monitoring exhibited burst suppression pattern. Lumbar puncture performed 18 h after collapse revealed clear cerebrospinal fluid. Due to isoelectric EEG and hypoxic-ischemic encephalopathy (HIE) grade III, he was detached from mechanical ventilation after parental consent and subsequently died at 23 h of age. Extended investigations including autopsy did not reveal any malformations, infections, or sign of prenatal events that could explain the sudden collapse and early death of this infant, an early SIDS.

Case 2 A girl born at gestational age 40 weeks and 5 days, 3,455 g by normal primiparous vaginal delivery. Her Apgar scores were 9, 10, and 10 at 1, 5, and 10 min of age, with normal adequate postnatal examinations and behavior. She started breastfeeding under midwife supervision. She was hungry, and supplemental milk was given with two normal blood glucose controls <23 h postnatal age. At 24 h postnatal age, 1330 hours in the afternoon, while in prone breastfeeding position, the mother discovered her daughter motionless, cyanotic without breathing movements. Immediate resuscitation with vigorous stimulation led to rapid, within minute, recovery of spontaneous breathing and normal color and tonus and responsiveness after some two to three additional minutes. A full investigation for possible sepsis was performed, including blood, urine, and cerebrospinal fluid (CSF) cultures. All results were negative including brain ultrasound. After 24 h extra surveillance at the neonatal intensive care unit and four-dose antibiotic treatment, until blood and CSF cultures were negative, the girl was considered healthy. Follow-up and outcome were normal.

Case 3 A boy, first twin, born at gestational age week 36 and 3 days. He was delivered after a planned cesarean

Table 1 Sudden unexpected neonatal death (SUEND) during the first week of postnatal life

Reference SUEND	Study	N	Number of births	Estimated incidence	Included GA	Included PNA	Plausible etiology	Out come death (%)	Outcome pathologic	Outcome full recovery	Year	Primipara	Position
Polberger and Svenningsen [5]	Populat-based	16	133,110	12/100,000	≥w38	6–100 h	6/16 ^a	100	NA	NA	1977–1979	NA	NR
Dehan et al. [10]	Hospital based	31	NR	36/100,000	≥w36	≤7 days	25/31 ^d	100	NA	NA	1985–1991		
Obonai et al. [27]	Case report	9 ^a	NA	NA	≥w36	≤10 days ^a	7/9 ^e	100	NA	NA	NR	NR	NR
Espagne et al. [15]	Case report	2	NA	NA	≥w37	<2 h	1/2 ^f	100	NA	NA	2003?	NA	2/2 Prone
Inwald et al. [45]	Case report	3 ^b	NA	NA	≥w36	<7 days	3/3 ^g	100	NA	NA	2001–2003	NR	NA
Weber et al. [1]	Case report	55	NA	NA	≥w35	<7 days	32/55 ^h	100	NA	NA	1996–2005	NR	13/19 coved
Leow and Platt [11]	Regional study	30	828648	3.5/100,000	≥w35	<7 days	5/28 ⁱ	100	NA	NA	1983–2007	8/8	8/30 die at breast

coved co-bedding with parents, NA not applicable, NR not reported, GA gestational age, PNA post natal age

^a One of 10 cases reported occurred at 10 days postnatal age and is excluded here

^b Seven cases of enterovirus myocarditis presenting with sudden unexpected collapse, three within the first postnatal week

^c GBS infection ($n=4$), anemia ($n=2$)

^d Perinatal anoxia, generally associated with massive amniotic inhalation (16 cases) and maternal-fetal infection (9 cases)

^e Mild gliosis in medulla oblongata cardiorespiratory control regions ($n=7$)

^f Possible *Candida albicans* septicemia, no autopsy performed

^g Enterovirus myocarditis

^h Congenital heart malformations ($n=11$), infection ($n=9$), pulmonary hypertension ($n=6$) and metabolic disorder ($n=3$)

ⁱ Metabolic defects ($n=5$)

Table 2 Sudden unexpected postnatal collapse (SUPC) during the first week of postnatal life

Reference SUPC	Study	N	Number of births	Estimated incidence	Included GA	Included PNA	Plausible etiology	Outcome death (%)	Outcome pathologic	Outcome full recovery	Year	Primipara	Position
Polberger and Svenningsen [5]	Regional study	13	20,123	50/100,000	≥w38	6–100 h	6/13, ^b 46 %	7/13, 54 %	4/13, 31 %	2/13, 15 %	1977–1984	NR	NR
Burchfield and Rawlings [46]	Single center	10	NA	NA	≥w37	15–86 h	0	5/10, 50 %	4/5, 40 %	1/10, 10 %	NR	NR	NR
Rodriguez-Alarcon et al. [21]	Single center	29	107,263	27/100,000	≥w37	<72 h	0	20/29, 69 %	NA	9/29, 31 %	1975–1991	NR	29/29 prone
Grylack and Williams [18]	Single center	20	~15,000	133/100,000	≥w37	<72 h	8/20, ^c 40 %	0	NR	20/20?	1993–1995	NR	NR
Kuhn et al. [38]	Case report	2	NA	NA	>w37	<2 h	0	1/2, 50 %	1/2, 50 %	0	1999	2/2, 100 %	2/2 prone
Gatti et al. [16]	Case report	6	NA	NA	≥w36	≤2 h	0	5/6, ^d 83 %	5/6, 83 %	1/6, 16 %	1996–2003	6/6, 100 %	6/6 prone
Toker-Maimon et al. [47]	Case report	2	NA	NA	≥w37	<2 h	0	0	1/2, 50 %	1/2, 50 %	2005?	2/2, 100 %	2/2 prone
Hays et al. [24]	Case report	11	NA	NA	≥w38	<2 h	0	4/11, 36 %	1/11, 9 %	6/11, 55 %	2000–2005	7/8, 88 %	11/11 prone
Aboudiab et al. [48]	Case report	2	~3,000	NA	≥w37	<2 h	0	0	0	2/2	2006	NR	2/2 prone
Branger et al. [49]	Case report	11	~28,6000	3.9/100,000	≥w37	<7 days	0	7/11, 64 %	0	4/11, 36 %	2001–2006	5/10, 50 %	2/4 prone; 5/8 StS
Foran et al. [22]	Case report	12	NA	NA	≥w36	<72 h	4/12, ^d 33 %	7/12, 58 %	0 at 2 years	5/12, 42 %	1993–2006	9/12, 75 %	6/12 breast+2 cobed
Nakamura and Sano [50]	Case report	1	NA	NA	≥w38	70 min	0	0	0	1/1	NR	NR	1/1 prone at breast
Dageville et al. [17]	Regional study	2	62,968	3.2/100,000	≥w36	<2 h	0	0/2, 0 %	1/2, 50 %	1/2, 50 %	2006–2007	1/2, 50 %	2/2 prone
Peters et al. [4]	Single center	5	12,362	40/100,000	≥w36	<12 h	0	4/5, ^h 80 %	1/5, 20 %	0	2004–2006	5/5, 100 %	2 prone +2 cobed
Schrewe et al. [51]	Single center	1	NA	NA	>w37	20 min	0	0	0	1/1	2009	1/1	1 prone
Rodriguez-Alarcon et al. [23]	Regional study	5	90,780	5.5/100,000	≥w36	<2 h	0	NR	NR	NR	1992–2008	NR	NR
Rodriguez-Alarcon et al. [23]	Regional study	8	10,804	74/100,000	≥w36	<2 h	0	1/8, 12 %	1/8, 12 %	6/8, 75 %	2008–2010	6/8, 75 %	8/8 prone
Andres et al. [2]	Case report	6	~180,000	3.4/100,000	>w36	<2 h	0	3/6, 50 %	0	3/6, 50 %	2004–2007	4/6, 67 %	6/6 prone and StS
Poets et al. [3]	National survey	17	665,126	2.6/100,000	≥w37	<24 h	NA	7/17, 41 %	6/17, 35 %	4/17, 24 %	2009	13/17, 76 %	12/17 prone/side
Poets et al. [12]	National survey	17 ^a	NR	NR	≥w35	<24 h	3/14, ^e 18 %	NR	NR	NR	2010	12/14, 86 %	12/14 prone
Becher et al. [6]	Nationa survey	45	858,466	5/100,000	≥w37	<12 h	15/45, ^f 33 %	12/45, 27 %	8/45, 18 %	25/45, 56 %	2008–2009	33/45, 77 %	24/30 breast/StS
Tsao et al. [19]	Regional study	17	~90,000	19/100,000	≥w37	<7 days	6/17, ^g 35%	7/17, 41 %	7/17, 41 %	3/17, 18 %	2001–2005	12/17, 71 %	5/13 side/cobed

cobed cobedding with parents, StS skin-to-skin, NA not applicable, NR not reported, GA gestational age, PNA post natal age

^a Inclusion only of the cases not published in Poets et al. [3]

^b Infection ($n=4$), anemia ($n=2$)

^c Airway obstruction ($n=2$), patent foramen ovale and/or patent ductus arteriosus ($n=3$), neurological abnormalities ($n=3$; PVL, IVH, and structural abnormality with seizures)

^d PPHN persistent pulmonary hypertension of the newborn ($n=3$), respiratory distress syndrome ($n=1$)

^e PPHN ($n=1$), infection ($n=2$)

^f Bacterial pneumonia ($n=5$), cardiac malformation ($n=2$), metabolic disorder ($n=2$), meconium aspiration syndrome ($n=2$), anemia ($n=1$), congenital diaphragmatic hernia ($n=1$)

^g Infection ($n=2$), hypocalcemia ($n=2$), cardiomyopathy ($n=1$), urea-cycle disorder ($n=1$), the cases with associated possible dehydration ($n=7$; >5 % bodyweight loss<48 h) are not included

^h Death within 3 weeks (11 day, 20 day, 21 h, 47 h) and one infant died at 80 months age

section that was performed due to a risk for preeclampsia development in a primiparous mother and because both twins were in breech position. A proportional healthy boy, 2.48 kg and 49 cm length was delivered with Apgar 9, 10, and 10 at 1, 5, and 10 min of age and umbilical cord artery pH 7.3, and BE of -2 (mmol/L). He exhibited good sucking reflexes and started breastfeeding immediately and had normal blood-glucose levels and normal postnatal weight loss during first day. Due to tachypnea (60–72 breaths/min) and saturation levels between 80 and 90 %, he received supplementary O₂ (30 %) via continuous positive airway pressure (CPAP). Several pediatric checkups were made during the first 24 h with normal CRP level ($< \text{mg/L}$) and clinical status except a breathing frequency around 60–70/min. Due to tachypnea, infectious workup and lung X-ray were performed, and he was diagnosed as having a mild transient tachypnea of the newborn (TTN). At 35 h postnatal age, (2330 hours at night), the midwife saw him breastfeeding in prone position. The midwife then noted that he suddenly became pale, hypotonic, and apneic. Bag and mask resuscitation were initiated, and cardiac compression commenced as no pulse could be detected. After 2 min, he remained apneic, pale and unresponsive, and had bradycardia (about 100 beats/min). Blood-gas showed pH 6.98 and BE of -15 (mmol/L), and he received NaCl-bolus (10 mL/kg), Tribonate[®] 8 mL, and supplementary oxygen. Some minutes later, gasping began. Subsequently, he commenced breathing with normal saturation under supplementary oxygen, but had an elevated lactate (10 mmol/L). As he was still pale with decreased peripheral circulation, blood culture, infection samples were taken before intravenous antibiotics with ongoing surveillance at the neonatal intensive care unit. Infectious and metabolic investigations were all normal.

Echocardiography revealed an atrial–septal defect (7 mm) and a patent ductus arteriosus (PDA, 3 mm) at 48 h postnatal age. PDA remained until day 4 before spontaneously closing during the subsequent days. He received CPAP with air until 60 h postnatal age, discontinued with adequate blood saturation levels. He was irritable, and brain ultrasound at days 2 and 3 revealed an HIE grade 1. No seizures and normal electroencephalogram. The persistent foramen ovale (PFO) diminished from 7 to 3–4 mm during a week and was not present at 5-month follow-up. During cardiovascular recordings and tilt test [20], he exhibited an immature but not pathological cardiovascular response. His twin brother also had a similar, but less pronounced, immature cardiovascular response. This immature response remained at examination at 3 and 7 months but was normal at 12-month follow-up. Normal neuromotor development and no sequela were detected at 12-month follow-up. Cases 1 and 2 occurred 2001 and case 3 in 2010. These cases illustrate the varying outcome and presentation of SUPC that occurs in the delivery wards and in the available literature. However, a systematic review of

all the SUPC events reported during 2001 until 2010 at the Karolinska University hospitals has not yet been performed.

Discussion

Based on our exhaustive review of previous published case reports, regional studies, and national surveys of SUPC, several questions emerge and can be addressed. When discussing them, we will use data coming from our three described cases that illustrate the broad spectrum of SUPC: case 1, SUDI-early SIDS < 2 h postnatal age; case 2, ALTE at 24 h postnatal age, with good outcome and no etiology found; and finally, case 3, an ALTE event during second postnatal day with possible etiologies, TTN, persistent foramen ovale, and immature cardiorespiratory control. All occurred unexpectedly during skin-to-skin contact in prone position.

How Often Do SUPC in Healthy Newborns Occur?

Reports have used varying inclusion and exclusion criteria for SUPC requiring caution when comparing estimations of incidence. The definitions of when (gestational age $> \text{week } 35$ or $> \text{week } 38$) and onset of (< 2 , < 12 , < 24 , < 72 h or within 7 days after birth) unexpected collapses of apparent healthy infants occur differ between published reports, i.e. [2, 3, 6, 12, 21, 22] (Table 1). Single center reports an incidence of 27–40 SUPC cases per 100,000 births, but inclusion have been < 12 and < 72 h postnatal age, respectively [4, 21]. Several case reports from French maternity wards exist, and two estimate incidence to be 3.2–3.6/100,000 [2, 17]. Reports from Spain describe an incidence between 5.5 and 74/100,000 [21, 23]. However, these French and Spanish studies have only included cases occurring within 2 h after birth [2, 16, 17, 23, 24]. Recent national surveys from the UK and Germany have used yet another time criteria for inclusion; SUPC is defined as occurring within the first 24 postnatal hours [3, 6]. Both these national surveys report an incidence of about 3 cases/100,000 infants (2.6 and 3.5/100,000, respectively). Notably, the German study excluded SUPC where an explanation could be found, while the English study included these, possibly preventable, SUPC cases in its report [3, 6]. However, recent guidelines for investigations of SUPC include infants with sudden unexpected collapse during the first postnatal week [7]. Moreover, in the reports that include also infants of postnatal age < 3 or < 7 days, roughly half of SUPC cases that are reported occur after 24 h (Table 3). Thus, excluding SUPC cases that occur after 24 h in reports will underestimate the incidence of sudden unexpected postnatal collapses in presumably healthy babies.

In addition, several clusters of cases have been described [4, 21, 23]. Most publications and authors indicate that the

Table 3 Reported postnatal age of sudden unexpected postnatal collapse (SUPC)

Reference	Number of infants	Included PN age	<2 h	2–24 h	24–72 h	4–7 days
Polberger and Svenningsen [5]	13 ^b	6–100 h	NA	1	9	3
Burchfield and Rawlings [46]	10	15–86 h	NA	4	6	1
Dehan et al. [10]	31	≤7 days	1	14	11	5
Rodriguez-Alarcon et al. [21]	29	≤72 h	9	8	12	NA
Grylack and Williams [18]	20	≤72 h	0	10	10	NA
Obonai et al. [27]	9 ^c	≤10 days	0	3	5	1
Kuhn et al. [38]	2	≤2 h	2	NA	NA	NA
Gatti et al. [16]	6	≤2 h	6	0	NA	NA
Espagne et al. [15]	2	≤2 h	2	NA	NA	NA
Inwald et al. [45]	3	≤7 days	0	0	0	3
Toker-Maimon et al. [47]	2	≤2 h	2	NA	NA	NA
Aboudiab et al. [48]	2	≤2 h	2	NA	NA	NA
Branger et al. [49]	11	≤7 days	4	4	1	1
Foran et al. [22]	12	≤3 days	7	4	1	NA
Dageville et al. [17]	2	≤2 h	2	NA	NA	NA
Nakamura and Sano [50]	1	≤2 h	1	NA	NA	NA
Peters et al. [4]	5	≤12 h	3	2	NA	NA
Schrewe et al. [51]	1	≤2 h	1	NA	NA	NA
Rodriguez-Alarcon et al. [23]	5	≤2 h	5	NA	NA	NA
Rodriguez-Alarcon et al. [23]	8	≤2 h	8	NA	NA	NA
Andres et al. [2]	6	≤2 h	6	NA	NA	NA
Poets et al. [3]	17	≤24 h	9	8	NA	NA
Leow and Platt [11]	30	≤7 days	3	4	10	13
Becher et al. [6]	45	≤12 h	29	16	NA	NA
Tsao et al. [19]	17	≤7 days	1	7	8	1
Poets et al. ^a [12]	17	≤24 h	17	NA	NA	
Total	306	0–7 days	103,	85,	73,	28,
Percentage of reported cases			36 %	29 %	24 %	9 %

Note that only 11 and 8 out of 26 studies provide data for events beyond 24 and 72 h, respectively. The 11 studies that include SUPC events <72 h report 73 cases out of 157 cases that occur between 24 and 72 h

PN postnatal, NA not applicable

^a Inclusion only of the cases not published in Poets et al. [3]

^b only partial data coming from one substudy where postnatal age at event were described.

^c Excluding 1 SUDI case at 10 days.

number of reported SUPC cases is lower than what occurs in the wards and only reflects the most critical events [3]. Events with rapid and favorable outcome could easily be missed in large surveys [2]. One recent retrospective study indicates that the prevalence of early SUDI has not changed in northwest England during 35 years and is considered rare (3.5 SUDI/100,000) [11]. In contrast to the UK survey and report, Rodriguez-Alarcon et al. [23], in their regional study, show a significant increase in SUPC (ALTE as well as SUDI) since December 2008. They associate the increased SUPC incidence with altered routines in maternity wards and encouragement of early skin-to-skin contact but without adequate surveillance.

We have, in a separate report, investigated the prevalence of SUPC in three Stockholm University Hospitals examining some 68,000 births during 2.5 years, between January 2010 and July 2012. In this regional cohort study, the SUPC incidence is about half of the recent Spanish report but, nonetheless, nearly tenfold higher than in the UK and German national surveys (Pejovic and Herlenius, unpublished results). SUPC were vigorous stimulation enabled recovery are included in reports by Andres et al. (2 of 6 infants) [2] and Grylack et al. (20 infants) [18], but these cases are only mentioned in other studies and not included in some calculations of SUPC incidence, i.e., Poets et al. [12].

A consensus for coding unexpected postnatal collapse in ICD 10 has not yet been established. We think that also the early apparent life-threatening events occurring in newborn where vigorous stimulation, with or without positive pressure ventilation, should be included in the SUPC definition [7], as our cases 2 and 3 illustrate. If these, and other, unexpected collapses leading to sudden cyanotic infants had been discovered later, the consequences could have been more serious. These infants often need additional surveillance after resuscitation. Moreover, surviving cases outside of the hospital would have been classified as ALTE, and *all* SUPC cases should undergo structured investigations for possible preventable causes of the collapse [7]. In our case 3, a combination of underlying, possible causative factors, associated to the SUPC event, were found (PFO, PDA, TTN, and immature cardiorespiratory control). This allowed adequate therapeutic interventions, surveillance, and follow-up with good outcome.

Our summary of published reports indicates that even if still rare and with varying reported incidences, SUPC might occur more frequently than indicated in recent surveys. Even the lowest incidence numbers, if extrapolated on the 5 million annual births in the European Union, would result in some 500 SUPC cases and 150 newborn unexpected deaths yearly. Most of them are likely preventable.

Known and Preventable Etiologies to SUPC

Weber et al., in their review of autopsies performed over a 10-year period, revealed an underlying cause of the SUPC leading to early SUDI in 58 % of the 55 infants examined. All were born after gestational week 35 and died unexpectedly during the first postnatal week. Congenital heart malformations ($n=11$) and infections ($n=9$) were the leading causes of events, leading to sudden unexpected deaths, both potentially preventable with an early discovery (Tables 1 and 4). Sudden and unexpected death can occur in newborns with metabolic fatty organic acid (FAO) disorders [25]. A significant proportion of patients with an FAO disorder experience hypoglycemia within the first 72 h after birth and exhibit warning signals before a potential collapse [26]. Nonetheless, some of the SUDI described ($n=10$) were due to metabolic disorders (Tables 1, 2, and 4) [6]. Most of the known disorders that are involved in the explained SUPC cases induce signs and warning signals in the infants before the collapse (Table 4). These collapses could be prevented with adequate surveillance and therapeutic support.

Birth and Attenuation of Brainstem Cardiorespiratory Control

Even if several of the unexpected deaths can be explained after autopsy [1], 153 described SUPC cases leading to

Table 4 Potentially preventable SUPC etiologies

Etiology to SUPC event	<i>N</i>	Reference
Infection	26	[5, 6, 10, 12, 15, 19, 45]
Cardiac disorder	18	[5, 6, 10, 19]
PPHN respiratory disorder	14	[6, 10, 12, 22]
Metabolic defects	10	[1, 6, 11, 19]
Anemia	3	[5, 6]

death remain unexplained (Tables 1 and 2) and have been classified as early SIDS. The present case 1 had a metabolic acidosis at birth, but recovered rapidly, and was presumed to be healthy before unexpectedly collapsing without an etiology was found in spite of extensive, clinical laboratory, and autopsy investigations.

A mild gliosis in brainstem areas involved in cardiorespiratory control was found in seven of nine cases reexamined by Obonai et al. [27]. They suggest that impaired cardiorespiratory control due to hypoxic ischemic insults occurring several days before death could contribute to these SUPC cases. A white matter gliosis was also found in 10 out of 16 unexplained SUDI cases, occurring mostly between days 8 and 28 of life [14]. However, these authors hypothesized that these lesions suggest that these infants could have experienced a previous prenatal or early postnatal central nervous system insult, thus making them vulnerable for known SIDS risk factors such as bed sharing. Our case 3 had an immature cardiorespiratory control and persistent pulmonary hypertension of the newborn. A planned cesarean section, before onset of spontaneous delivery, will lack the catecholamine surge induced by normal delivery and increase respiratory morbidity (odds ratios 2–4) [28]. The immature cardiorespiratory control, exemplified in our case 3, is in accordance with this as well as previous report where about half of the early ALTE cases examined had apneas >15 s and desaturations <85 % with four infants exhibiting bradycardias (heart rate <80 beats/min for more than 5 s) implying immature cardiorespiratory control [18]. We speculate that dysfunctional or immature brainstem cardiorespiratory control is involved in some of the unexplained SUPC cases.

The transition from fetal to extra-uterine life could make the newborn more vulnerable during the first hours of life. Before birth, the fetal brain microenvironment contains high levels of the neuromodulators adenosine and prostaglandin that both exert inhibition of the fetal movements, decrease metabolic rate, energy turnover, and thus protect the brain when oxygen and energy resources might be scarce, i.e., during birth. In fact, birth is a “hypoxic” and stressful event [29].

The healthy newborn baby is aroused and awake the first hour after birth and starts continuous breathing movements after the first gasps of air. Factors like squeezing and squashing

of the fetus, increased sensory input, and cooling are important. There is also a noradrenaline surge in the human brain, and high level of plasma catecholamines is detected after birth [29]. Moreover, a rapid decrease in the inhibitory neuromodulator adenosine in the brain occurs, as partial pressure of oxygen in arterial blood rapidly increases after birth, and contributes to the increased activity in the newborn infant compared with the fetus [30]. The initial arousal of the newborn is followed by a period of diminished responsiveness to external stimuli [31] and increased vagal tone [32].

At birth, high levels of PGE₂ are present in human term infants and neonates [33]. This is especially true during third stage of labor [34]. Hypoxia, per se, rapidly induces an increase in microsomal prostaglandin E synthase-1 activity and a subsequent brainstem-specific release of PGE₂ with a depression of brainstem respiratory centers, e.g., see Fig. 1b in Hofstetter et al. [35]. This is consistent with evidence that anoxia induces PGE₂ production in mice cortex and prostaglandin H synthase-2 messenger RNA expression in the piglet brain [36]. PGE₂ is thus involved in the acute hypoxic response, also recently shown by us [35, 37]. Actually, PGE levels in plasma are 20-fold higher in newborns than in 5–8-week-old infants and declines rapidly during the first postnatal week [33]. Moreover, elevated levels of prostaglandin in the cerebrospinal fluid are present during the first 24 h after birth especially after birth asphyxia (Björk, Leifsdottir, Saha, and Herlenius, unpublished results). Presently, we can only speculate if these elevated levels of prostaglandin contribute to the postnatal irresponsiveness that begins some hour after birth and contribute to the SUPC occurring within the first hours after birth. This is a testable hypothesis, and we are currently examining the role of eicosanoids in autonomic control and SUPC during the first days of postnatal life [30].

Well-Identified Risk Factors for SUPC

A majority of events occur within 2 h of birth, often at the time of the first breastfeeding attempt [6, 12] (Table 3). Moreover, most of cases reported, where information is available, occur in prone position, i.e., [21, 23, 38], during skin-to-skin contact with their mothers (Table 1). In fact, SUPC is associated with prone position/skin-to-skin/cobedding in 74 % (152 out of 207 cases; Tables 1 and 2). This in agreement with Poets et al. who, based on their 31 cases and 93 “controls,” estimated an odds ratio of 6.4 for SUPC to occur in prone or “potentially asphyxiating position” when an identified cause could not be identified [12]. Moreover, SUDI occurring in the first month of life is associated with bed sharing [14].

All the present three cases occurred in newborns to primiparous mothers during skin-to-skin contact, which is

consistent with previous reports. Prone position, first breastfeeding attempt, cobedding, mother in episiotomy position, a primiparous mother, and parents left alone with baby during first hours after birth have been identified as risk factors for SUPC or early SIDS in several recent publications [2, 4, 12, 17, 24, 39, 40].

SUPC-SIDS Analogous Mechanisms and Risk Factors?

The current concept of SIDS is based on the “triple-risk” hypothesis of an underlying genetic or developmental predisposition in combination with an external trigger acting synergistically at a vulnerable developmental period [41]. Nevertheless, despite recognition of possible generic mechanisms and epidemiological risk factors, the exact mechanism(s) of death is still unclear. The occurrence of an alveolar septal collapse in the neonatal lung has been shown to induce severe hypoxemia and to be involved in some early SUDI cases [42]. This possible biomechanical mechanism has been hypothesized to explain the association of the known risk factors for SUDI such as cosleeping, prematurity, prone sleeping position, overwrapping, overheating, and maternal smoking and possibly also be involved in some SUPC events.

Although deaths in the first week of life are often not included in SIDS datasets, the current and other summaries of SUPC cases and risk factors [1, 12] suggest that similar processes to SIDS may account for about half of all sudden unexpected deaths of apparently previously healthy infants in the first week of life [1]. In ALTE, the role of central respiratory control immaturity is established, and the same risk factors as for SIDS are apparent, at least during the first 24 h of life [43].

Recommendations that all newborn infants should be placed in supine position within the first few hours after birth are emphasized in the reports of SUPC and in the guidelines to reduce the risk of SIDS [44].

Recommendations to Promote and Implement to Reduce SUPC

Different preventive measures and organizations of care have been strongly recommended by the majority of authors. Regardless of SUPC’s etiology, the most important point underlined by most authors as well as in the current report is to maintain unobtrusively, but continuously, a secure surveillance of the newborn during his first hours and days of life. Barriers to this during night/weekend times or periods of overwork in busy units should not be disregarded and should be taken into account using quality process audit in each center. The three targets on which perinatal healthcare teams could focus to protect otherwise

healthy newborns, are (1) safe early skin-to-skin care (SSC) in the delivery room, (2) safe breastfeeding establishment in the

first days of life, and (3) secure positioning of the infant during sleep. Some tools to reach them are summarized in Box 1.

- Systematic information of the parents about signs of infant's well-being and the need to maintain an adequate supervision ensuring upper airway patency of the newborn infant.
- Parental education to use the recommended supine position and to avoid, already from first hours of life, recognized risk factors for SIDS (co-bedding or bed-sharing, prone sleeping in soft bedding, face down and head covering) (43, 44)
- Appropriate non-obtrusive surveillance of the newborn's clinical condition by caregivers aware of the possibility of SUPC and continuous clinical supervision of mothers at risk (primiparous, alone and exhausted).
- Medical supervision to discuss the opportunity of SSC, in case of pathological conditions of the mother (sedative treatment, infection) or the newborn (difficult adaptation, mild respiratory distress, suspicion of infection).
- Position the infant supine to avoid mechanical airway obstruction or a possibly asphyxiating position[44].

Risk Reduction Strategies to Prevent Sudden Unexpected Postnatal Collapses

The impact of the implementation of these recommendations should be evaluated, and they could also help prevent further cases occurring in otherwise healthy infants. Moreover, the early recognition of an underlying disease could allow therapeutic intervention and improvement of long-term outcome.

Even if SUPC is a rare entity, an adequate surveillance of the infants, during their first hours (and days) of life, should enable us to save hundreds of newborn lives annually.

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Conflict of interest The authors declare that they have no conflict of interest.

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Breastfeeding and Delivery Room Neonatal Collapse

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Abstract

Sudden unexpected neonatal collapse in the delivery room is a rare occurrence in healthy term infants. Upper airway obstruction may occur from improper positioning of the newborn even while breastfeeding. Such occlusion may have dire consequences if not recognized immediately. We report 2 healthy term neonates who suffered respiratory arrest while in the mother's arms and attempting breastfeeding. In each case, rapid response by the delivery room nurse averted tragedy. Metabolic and infectious evaluations were unremarkable. Both babies have been well on subsequent examinations. We conclude that proper education of mothers and safe positioning of neonates is critical during the initiation of breastfeeding.

Keywords

breastfeeding, neonatal collapse, neonatal respiratory arrest, neonatal suffocation

Background

Respiratory arrest occurring in healthy full-term infants immediately after birth is a very rarely reported event. Factors that may lead to neonatal apnea include metabolic diseases, including inborn errors of metabolism; drug-induced, whether illicit or iatrogenic, central nervous system anomalies; and neonatal depression resulting from labor or the birthing process. Mechanical suffocation is an uncommon cause and is usually due to oronasal obstruction in a crib or a result of a plastic bag.¹ As such, most such cases usually occur in the home, long after discharge from the maternity suite. Neonatal suffocation in the hospital is a very rare occurrence, with an estimated frequency of 2.6 to 5 per 100 000 live births.^{2–5}

Whereas initial descriptions of such events were limited to small case series and were principally from Europe, the appearance in the literature of more frequent reports seems to indicate an increasing incidence.^{2–9} Many of the reported instances in the United States have occurred on the postpartum floors, rather than in the delivery room; these have been associated with bed sharing and may have resulted from maternal suffocation of her newborn.¹⁰ We document 2 cases of healthy neonates born after uneventful pregnancies and discovered by the labor floor nurse to be in respiratory arrest while breastfeeding within the first 90 minutes of life.

Case Report I

The first patient was a 41 4/7-week gestation baby boy who was delivered from a 42-year-old grand multipara (Para 8 0 7 8), who received routine prenatal care. The mother had an

uneventful pregnancy and normal standard prenatal laboratory values except for a positive group B *streptococcus* (GBS) culture. The mother had an uncomplicated vaginal delivery without analgesia or anesthesia and was adequately treated for GBS. The baby emerged vigorous with an Apgar score of 9 at 1 and 5 minutes; birth weight was 3650 g. The mother, who had large pendulous breasts, opted to breastfeed her child. At 60 minutes of life, the neonatology team was called emergently by the labor floor nurse, after she found the baby limp and cyanotic with no respiratory effort; the infant was lying in the mother's arms, pressed underneath the breast. The baby received positive pressure ventilation and was intubated but did not require chest compressions or epinephrine administration. The heart rate immediately improved to greater than 100 beats per minute when the airway was re-established and maintained. The initial blood pH was 7.16 with a base excess of –16 and lactic acid concentration of 13 mmol/L. The metabolic acidosis rapidly improved, as did the initial hypotonia. An electroencephalogram and brain magnetic resonance imaging were normal, as were evaluations for infection, cardiac anomalies, and metabolic

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diseases. The baby was discharged home at the end of his first week of life without any obvious neurologic abnormalities.

Case Report 2

The second patient was a 40-week gestation baby girl who was delivered from a 34-year-old nullipara. The mother received routine prenatal care and had an uneventful pregnancy and normal standard prenatal laboratory values except for a positive GBS culture. The mother had a continuous epidural anesthetic in labor and received adequate prophylaxis for GBS. The baby had an unremarkable fetal heart monitor tracing in labor and was delivered by low forceps for maternal exhaustion. The baby emerged vigorous with an Apgar score of 9 at 1 and 5 minutes; birth weight was 2920 g. Standard postpartum delivery room care was provided. At 90 minutes of life, the neonatal intensive care unit team was called emergently by the obstetric nurse who found the baby in a prone position, pressed against the mother's chest and nestled underneath her breast, limp and cyanotic with no respiratory effort. The mother was talking on her cellular phone while breastfeeding and was oblivious to the situation. The baby received positive pressure ventilation and was intubated but did not require chest compressions or epinephrine administration. The heart rate improved to greater than 100 beats per minute when the airway was established and maintained. The initial blood pH was 7.17, base excess -17 , and lactic acid concentration of 11 mmol/L. The metabolic acidosis rapidly resolved. The patient was extubated on the second day of life and breastfeeding was reinitiated. Infectious, cardiac, neurologic, and metabolic causes were ruled out. The patient was discharged home on her sixth day of life and has been well on follow-up evaluations.

Discussion

In healthy newborns, an acute life-threatening event in the immediate peripartum period during breastfeeding is an extremely rare occurrence.²⁻⁹ Although there have been reports of neonatal suffocation resulting from breastfeeding in the immediate period following delivery, many of these complications were on the postpartum floor or in association with administration of narcotics for maternal analgesia.²⁻¹⁰ A majority of the situations that occurred after discharge from the labor floor were either during breastfeeding episodes or in association with bed sharing where the mother fell asleep with the baby, possibly suffocating the infant^{10,11}; 1 report described suffocation of the baby of a drowsy mother who had a protracted labor course following an extended prodromal labor and required cesarean delivery.¹² In that case, the mother received narcotics for postoperative analgesia and had fallen asleep while nursing. There are several reports of airway obstruction during breastfeeding that have occurred in otherwise healthy infants during the immediate

puerperium, and indeed many of these situations occurred within the first 2 hours of life.^{2,3,5-9,13,14} Our 2 cases are unusual in that they happened in the birthing room in the immediate postpartum period during the initial bonding and breastfeeding events within 90 minutes of birth. They both occurred under similar circumstances; however, in our patients, the outcome was less devastating than described in the literature. Herlenius and Kuhn¹³ reported that in their investigation of almost 400 babies with sudden unexpected postnatal collapse (SUPC), almost half died, and of the survivors, half had neurologic compromise. In many previous reports, the infants' faces were covered in prone position while on the mother's abdomen, breast, or neck during the initiation of breastfeeding and were all unsupervised. Although mechanical suffocation is generally considered the cause of neonatal collapse in most such patients, other theories for neonatal cardiopulmonary arrest have been proposed. Toker-Maimon et al¹⁴ suggested that increased vagal tone during nursing may be a contributing factor.

In view of the absence of other explanations, and as a result of the position in which the newborns were discovered, we believe that in our neonates, upper airway obstruction was indeed the cause of respiratory arrest. In our first case, we believe that improper positioning under the pendulous breasts resulted in this occlusion and suffocation. In our second case, the mother's arm position, while talking on her cell phone, likely caused similar airway obstruction. In both cases, the mother was oblivious to jeopardy in which the baby was placed. Pejovic and Herlenius⁹ also reported on cell phone use as a potentially incriminating factor in 3 cases. It is likely that as smart phones become more integrated into our lives, this problem will become more prevalent. In many of the reported cases, SUPC occurred following a first delivery, suggesting that inappropriate positioning of the infant during breastfeeding was the cause of the respiratory arrest. However, the first of our presented patients was a grand multipara and was experienced in lactation. Nonetheless, the occurrence of suffocation emphasizes a need for supervision and caution with the initiation of newborn breastfeeding even with seasoned mothers. Although both of our patients were born to group B *streptococcus* culture positive mothers, we believe that this was a coincidence in view of the negative infectious evaluations of the neonates and treatment as per standard Centers for Disease Control protocol.¹⁵

The American Academy of Pediatrics recommends initiating skin-to-skin contact and breastfeeding immediately after birth.¹⁶ Although we whole-heartedly agree with this recommendation, we believe that there is a need for close supervision of the mothers and instruction on positioning, especially when the mother is primiparous. Instructions regarding proper positioning should include those recommended for sleeping, breastfeeding, and other bonding opportunities.¹⁷ Following delivery, our nurses instruct and assist all mothers during the initiation of lactation. Such instruction begins in the birthing rooms and includes proper techniques, positioning, and

alertness; this includes caution when using cell phones or conversing with others. As a result of these 2 events, we have modified our protocol to extend the observation period and monitor more frequently the mother–child interactions.

Conclusion

Neonatal collapse during breastfeeding is a rare but dangerous occurrence, often with dire sequelae. New mothers should be instructed on proper positioning and technique and be observed during bonding and initial feedings. Increased vigilance and limited distractions during breastfeeding and bed sharing will help to eliminate this problem.

Declaration of Conflicting Interests

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Today's Baby Quality Improvement: Safe Sleep Teaching and Role Modeling in 8 US Maternity Units

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BACKGROUND AND OBJECTIVES: Nursing education and role modeling can increase adherence to safe sleep practices. Eight US hospital maternity units with variable baseline approaches to education participated in a national multicenter nursing quality improvement (QI) intervention to promote safe sleep practices. The goals at participating maternity units were to (1) increase the rate of mothers who reported receiving safe sleep information from nurses to $\geq 90\%$ and (2) increase the rates of infants observed sleeping supine in a safe environment to $\geq 90\%$.

METHODS: A safe sleep QI toolkit, designed for and provided to all sites, included an educational curriculum and tools to use for staff and parent education. Local teams implemented safe sleep education using the tools as plan-do-study-act cycles. After each cycle, audits assessing maternal report of nursing education on safe sleep and inpatient infant sleep position and environment were performed.

RESULTS: The QI interventions lasted a median of 160 days (range, 101–273). Mothers reported receiving information on 4 primary safe sleep topics 72% to 95% of the time (a 24%–57% increase over the baseline). Additionally, 93% of infants were observed in a supine sleep position, and 88% of infants were observed in a safe sleep environment (a 24% and 33% increase over baseline, respectively). These rates were sustained up to 12 months later.

CONCLUSIONS: Implementation of a multisite QI intervention for safe sleep parenting education and role modeling led to increased knowledge of and compliance with safe sleep practices during postpartum hospitalization.

Annually, ~3500 infants die suddenly and unexpectedly during sleep in the United States, despite the successful Back to Sleep campaign of the 1990s that halved the sudden infant death syndrome rate.¹ Adherence to supine sleep recommendations has plateaued since 2001,² and public health efforts have not resulted in significant decreases in soft bedding use and bed-sharing.^{3,4} Advice and role modeling to caregivers by health care providers during the postpartum hospital stay are associated with greater caregiver

adherence to the American Academy of Pediatrics (AAP) safe sleep recommendations.^{5,6}

Most US births occur in a hospital setting, which affords an ideal opportunity to model and provide education about safe sleep practice for caretakers. Although nurses interface most frequently with parents in the postpartum setting and have tremendous impact on infant care practices after discharge,^{5,7} there is inconsistent in-hospital adherence to safe sleep practices.^{8,9}

abstract



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We therefore developed a quality improvement (QI) intervention for safe sleep education as part of a multicenter trial for promoting AAP safe sleep recommendations. In this article, we describe the strategies used to improve safe sleep education and role modeling at 8 US maternity units and the extent to which participating maternity units achieved the goals of $\geq 90\%$ maternal-reported, in-hospital safe sleep education on sleep position: an environment without objects, room-sharing (but not bed-sharing), pacifier use after established breastfeeding, and $\geq 90\%$ of infants with observed safe sleep practices (supine in a separate sleep environment [ie, crib or bassinette] free of other objects).

METHODS

Context

The Social Media and Risk Reduction Training (SMART) study is a multicenter, randomized controlled trial of 2 interventions aimed at promoting safe sleep practices. In 1 intervention, hospital staff provided QI education in maternity units on either safe sleep ($n = 8$) or breastfeeding ($n = 8$) practices. The hospitals in the safe sleep QI program were evaluated in this analysis. At baseline, these hospitals had variable approaches for the delivery of safe sleep education and modeling practices to parents. Members of the SMART study team visited and provided initial training and tools on enrollment. However, the 8 hospitals implemented the QI independently, with minimal interaction among hospitals. Therefore, the participating hospitals were not part of a QI collaborative but rather completed nearly simultaneous QI projects using a common set of tools.

The Intervention: Hospital QI Teams

Study investigators conducted a study enrollment visit lasting 2 to 3

hours at each participating hospital to introduce the TodaysBaby Safe Sleep Toolkit, instruction manual, and data collection tools and procedures. Each hospital identified a site “champion” (usually a nurse manager or nurse educator) who provided educational material about safe sleep to maternity nursing staff, emphasizing their role in role modeling and education for parents and visiting family members. Physician and nursing team members could receive part 4 Maintenance of Certification credits or continuing education units, respectively, if they met participation requirements. The study team provided technical assistance, but otherwise, the local teams operated independently. Study investigators held 1 conference call with representatives from each hospital, during which they could ask questions, troubleshoot common concerns, and share strategies to overcome barriers. To increase the feasibility of more widespread implementation in the future, we standardized implementation of the QI intervention as much as possible; therefore, no other study team support was provided to sites during the active QI phase.

The Intervention: Development of the Safe Sleep Toolkit

Guiding principles in the development of the toolkit were ease of implementation and cost-effective use across a variety of locations and settings. Study investigators developed the Safe Sleep Nursing Education Toolkit using (1) existing tools, including the National Institutes of Health Safe Infant Sleep Curriculum for Nurses¹⁰ and the 2011 AAP safe sleep recommendations¹¹; (2) previous epidemiologic research about barriers to adherence to safe sleep practices (such as concerns about choking if supine)^{1,12–18}; (3) qualitative data from nursing leadership at the participating maternity units identifying successful

materials, venues, and strategies used in previous QI projects on their units; (4) qualitative data from focus groups with maternity staff at Yale University and the University of Virginia to identify facilitators and barriers to providing safe sleep education to parents; and (5) consultation with an advertising agency with expertise in branding and social marketing to provide insight into the designing and scripting of educational materials for nursing staff to deliver to families. The tools were designed to be a “campaign” rather than a traditional “educational initiative.” The campaign name, “TodaysBaby,” and logo were used on all materials (Supplemental Fig 6).

The toolkit materials emphasized that infant sleep practices be modeled and taught by nursing staff and provided strategies for addressing known barriers to adherence. Elements included sleep position, the absence of other objects in the sleep environment, room-sharing without bed-sharing, and the introduction of a pacifier for sleep once breastfeeding is established. The final toolkit included the following: (1) PowerPoint slides providing a brief review of the plan-do-study-act (PDSA) cycle methodology¹⁹ and key safe sleep messages for nursing staff; (2) posters calling attention to the QI campaign and the need to deliver key messages; (3) pocket-sized cards that nurses could use when counseling parents about safe sleep; (4) sample letters that could be sent to hospital leadership, QI officers, and pediatric and obstetrical providers to raise awareness about the QI campaign and highlight the AAP recommendations; (5) a sample hospital policy on safe sleep that could be adapted for each hospital; and (6) a secure SMART study Web site with safe sleep resources, answers to frequently asked questions about infant safe sleep, and the ability to track QI progress.

The Intervention: Site QI Activities

QI activities occurred between July 2014 and July 2015. Each hospital initiated its QI intervention on a rolling basis. The baseline data at each hospital were collected at a single point in time, ~2 weeks before beginning the QI intervention, to allow time for planning the first cycle's intervention. Hospitals used PDSA cycles¹⁹ as the cornerstone of their QI initiatives. On the basis of audit results after each cycle, each team decided on changes for their next cycle. Hospitals were encouraged to individualize their approaches on the basis of needs and previous successful strategies (eg, e-mail reminders, team huddle updates, and presentations at staff meetings). Maternal education was expected to be completed during the postpartum hospital stay.

Measures and Audits (Study of Interventions)

The main outcomes included (1) reports by mothers of receiving safe sleep information from nursing staff and (2) observations of infants sleeping in a supine position and in a safe sleep environment. By using identical measures for each hospital, outcomes were assessed by unannounced audits of postpartum mothers and sleeping infants on the maternity unit before discharge. Mothers were asked if nurses advised them on safe sleep practices, including (a) placing the infant on his or her back for sleep, (b) not placing anything in the bassinet or crib other than the infant, (c) sharing the room but not the bed with the infant, and (d) offering a pacifier at sleep time once breastfeeding is established. Sleeping infants were observed for sleep position (supine versus other) and safe sleep environment, standardly defined as the following: absence of objects

(other than a thin swaddle blanket or light cotton blanket tucked snugly on 3 sides, below the level of the infant's neck) and sleep location (alone in bassinet, not bed-sharing with sleeping adult).

Each hospital designated 1 to 2 QI team members (nurses, educators, or other staff members) to conduct unannounced audits; they were trained by study investigators and used standardized, structured, web-based data reporting forms. Audits of 10 mothers and 10 infants were conducted at baseline, at the end of each PDSA cycle (approximately every 2–3 weeks), and approximately monthly after completion of the site's QI intervention. The number of observations and audits was selected to allow for rapid PDSA cycles²⁰ without creating an undue burden on staff. The final audit at each site consisted of 20 maternal interviews and 20 infant observations. For each audit, staff approached 10 mothers, using a systematic sampling strategy (eg, first 10 sleeping infants, odd-numbered rooms) of their choosing that was consistently applied. The sampling strategy and time of day (day or night shift) for the audit was determined by each individual hospital QI team. The forms captured the local interventions used in each PDSA cycle and the audit results. Team progress tracked over time (and compared with the de-identified progress of other participating hospitals) was displayed and easily accessible on the study Web site. On completion of the QI intervention, the teams were asked to give their feedback regarding the impact and effectiveness of integrating project activities into nursing workflow via a written 2-page questionnaire and/or verbally by phone with a member of the study team. The questions were compiled by the study team

and included items such as the unit's experience of whether efficiency, patient care, or workflow were impacted negatively, which resources were most helpful and least helpful, and any changes they would suggest for other hospitals planning to implement the QI.

We estimated that it would take 3 to 4 months to complete the QI intervention but that the length of the campaign would vary for each hospital to achieve the goal of $\geq 90\%$ compliance with all outcome measures. During the QI intervention, certain outcome measures (usually maternal report of nursing education on pacifier use) did not reach 90% compliance. In this case, the decision to end the local QI work was made jointly between the local hospital and the research team when it was mutually felt that further improvement was unlikely with the current resources. Once the QI intervention was considered completed, the hospitals entered "maintenance mode," in which they were instructed to continue with the changes they had implemented to date but not to implement anything new; sites completed the standardized audit approximately monthly to monitor their results over time.

Analysis

The interventions during each PDSA cycle were categorized as the following: staff awareness about the QI intervention and key messages, staff education on the evidence behind safe sleep, unit policy changes, and parent education (Table 1). The main outcomes among all participating hospitals were analyzed at baseline ("time 0") and after PDSA cycles (2–3 week intervals) for 6 months by using run charts. We compared site-specific data regarding main outcomes at baseline and

TABLE 1 Interventions Used During PDSA Cycles Among Participating Hospitals

	Hospitals Used ≥ 1 Time Out of Max of 8 Hospitals, n (%)
Increase staff awareness	
TodaysBaby poster for nurses ^a	8 (100%)
Verbal review during shift change team huddles	7 (87.5%)
Verbal review during staff meetings	7 (87.5%)
Staff e-mail blast	5 (62.5%)
Announcement letters ^a	3 (37.5%)
Presentation and/or posting of campaign results	2 (25.0%)
Staff education	
Computer-based staff education	3 (37.5%)
Competency checklist and staff demonstration with manager and one-on-one teaching	3 (37.5%)
Mandatory in-service or skills day	1 (12.5%)
Staff policy	
Incorporated safe sleep teaching into discharge process	3 (37.5%)
Modified existing policies ^a	4 (50.0%)
Removed contradictory messages	5 (62.5%)
Family education about safe sleep	
TodaysBaby laminated cards ^a	7 (87.5%)
Posters and/or bulletin boards visible to families	5 (62.5%)
Written education materials provided	3 (37.5%)
Incorporated education in a discharge class	3 (37.5%)
Incorporated education into local news or hospital magazine	1 (12.5%)

Max, maximum.

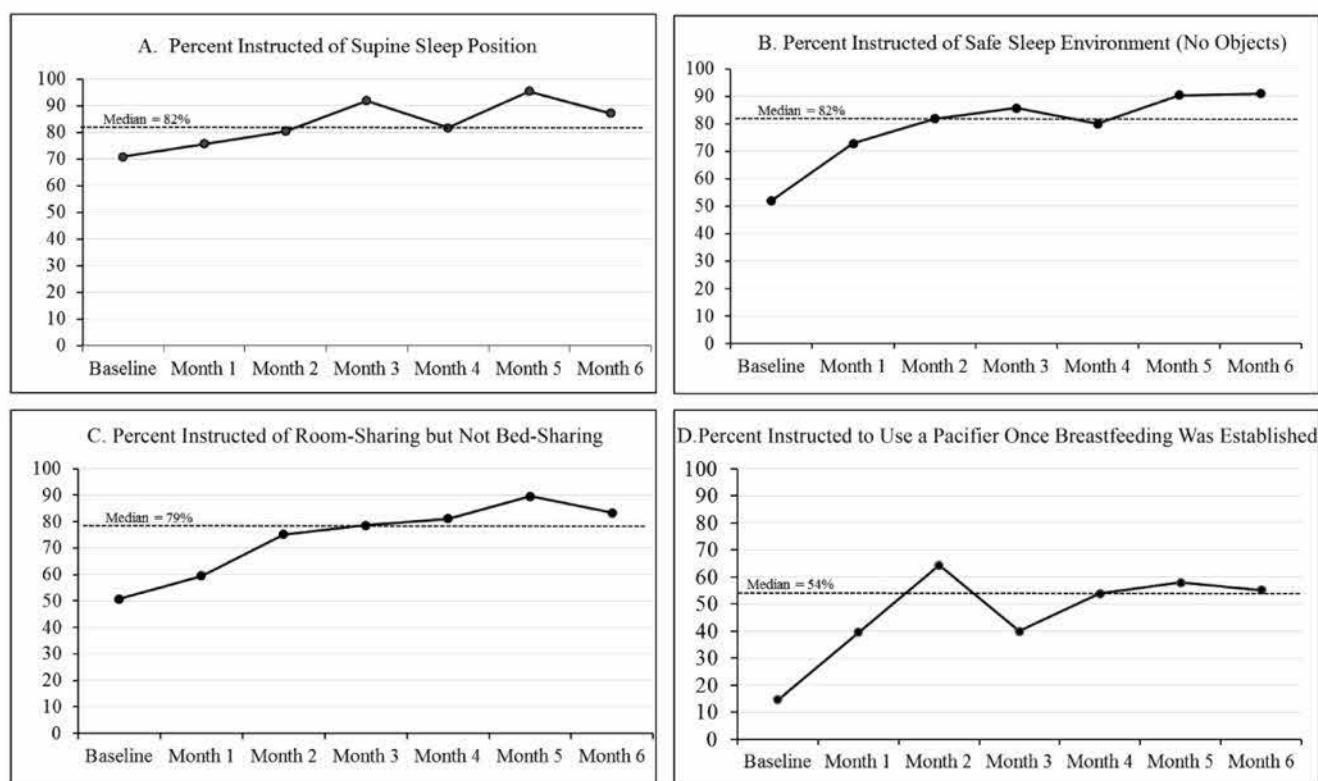
^a Provided by the research team.

after the QI intervention. Average aggregate rates for each month were calculated on the basis of any data that were submitted by teams within a given month (Figs 1 and 2). During the maintenance mode, rates of outcomes were calculated at ~4, 6, and 12 months postcompletion of the QI intervention to track sustainability (Figs 3 and 4).

The written and/or verbal feedback from the teams on completion of the QI intervention were reviewed by the study team, and dominant themes were identified and compiled to assist in informing the possibility of implementation at future sites.

Ethical Considerations

Each site was instructed to provide their routine care and education for other aspects of

**FIGURE 1**

TodaysBaby safe sleep QI hospital run charts of maternal report of receipt of instruction in 4 key safe sleep education messages among 8 participating hospitals. Hospitals performed audits on 10 mothers at each time point. Data points represent the average of all hospitals at monthly time points.

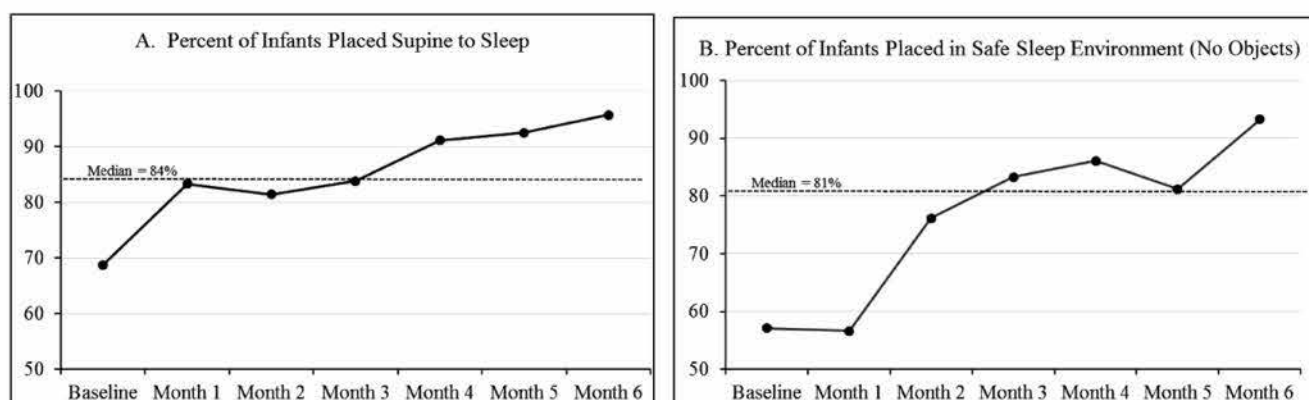


FIGURE 2 Today'sBaby safe sleep QI hospital run charts of infants placed in a (A) supine sleep position and (B) a safe sleep environment (no objects in the crib) among 8 participating hospitals. Hospitals performed audits on 10 infants at each time point. Data points represent the average of all hospitals at monthly time points.

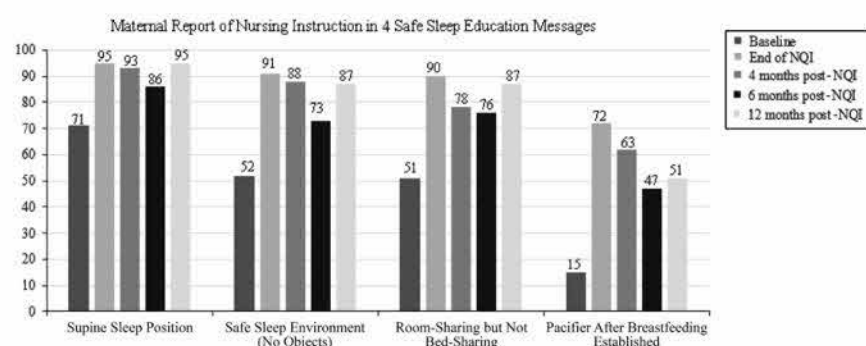


FIGURE 3 Today'sBaby safe sleep QI averaged percent of maternal report of receipt of nursing instruction in 4 safe sleep education messages among 8 participating hospitals. Data are shown at baseline, at the end of the QI time period, and at 4, 6, and 12 months post-QI. NQI, nursing QI.

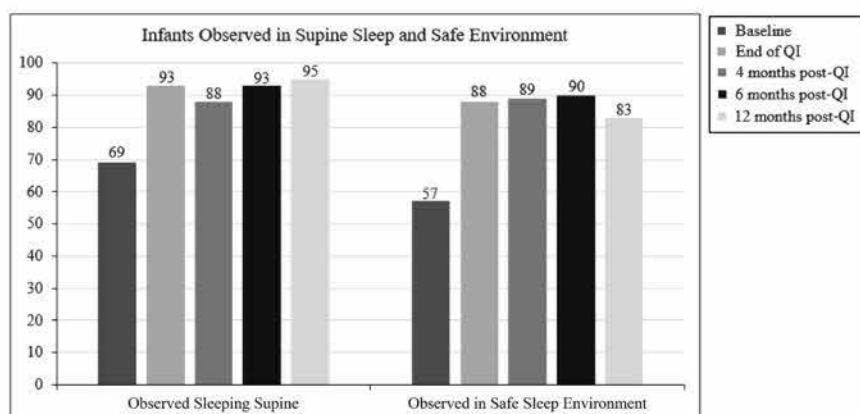


FIGURE 4 Today'sBaby safe sleep QI averaged percent of infants placed in a supine sleep position and placed in a safe sleep environment with no objects among 8 participating hospitals. Data are shown at baseline, at the end of the QI time period, and at 4, 6, and 12 months post-QI.

maternal education and infant care in addition to the safe sleep education and role modeling targeted by the campaign. The

institutional review board at each participating hospital approved the QI campaign as part of the larger SMART study.

RESULTS

Characteristics of the Sites

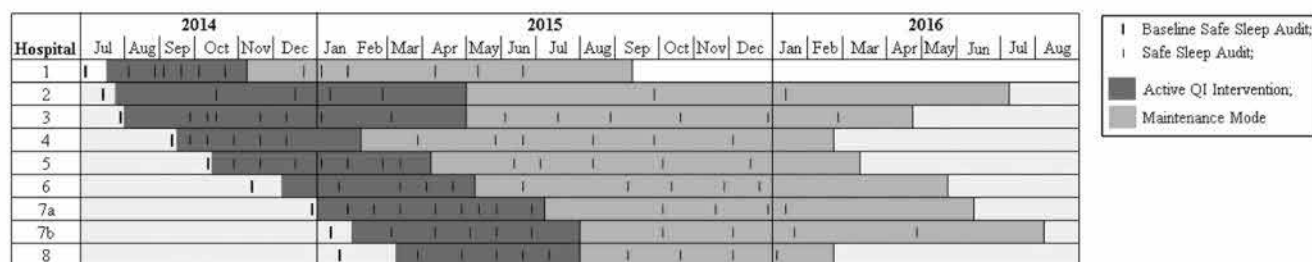
Characteristics of the 8 hospitals are shown in Table 2. One hospital (hospital 7) consisted of 2 campuses that completed separate QI interventions. These campuses are represented separately when the timing of active QI work versus the maintenance mode are presented (Fig 5) because the QI intervention started and stopped at different times at each site. However, the results from these 2 campuses are presented as 1 hospital (Tables 1 and 3, Figs 1–4). Hospitals were chosen from 4 different US regions. Six sites were urban, 2 were suburban, and 1 was rural. Six had >2000 deliveries (range, 1229–4376) in the QI period of July 2014 to July 2015. One hospital was designated “Baby-Friendly,” and 3 were in the initial designation process.

Intervention Over Time

In Fig 5, we show the timeline for each site's enrollment and audits. Hospitals spent a median of 24.1 (range, 14.4–39.0) weeks completing the QI intervention. The maintenance mode for each site was a median of 51.6 (range, 29.3–61.4) weeks. Each team completed a median of 6 (range, 5–9) PDSA cycles. Each audit was completed over a median of 3 days

TABLE 2 Characteristics of Participating TodaysBaby Safe Sleep QI Hospitals

Hospital	US Region	Annual Births From July 2014 to July 2015	Urban or Rural Classification	Non-Hispanic African American, %	Hispanic, %	Private Insurance, %	Baby-Friendly Status From July 2014 to July 2015
1	South Atlantic	2249	Urban	49	4	39	Designation in process
2	Northeast	1229	Urban	70	25	34	Designation in process
3	South Atlantic	3300	Urban	10	60	25	No
4	Northeast	4130	Urban	8	30	43	No
5	West	1604	Suburban	14	67	2	Baby-Friendly
6	West	4376	Rural	3	65	20	No
7a	West South	2152	Suburban	36	3	50	No
7b	Central	1477	Urban	25	6	25	No
8	West South Central	3390	Urban	8	40	53	Designation in process

**FIGURE 5**

Timeline for hospital enrollment, baseline and PDSA audits, and maintenance mode.

TABLE 3 Outcomes of SMART Study at Baseline and at the End of the QI Initiative

Hospital	Maternal Report of Receipt of Instructions								Infant Observations			
	Supine Position, %		No Objects, %		Room-Sharing, %		Pacifier, %		Supine Position, %		No Objects, %	
	Baseline	End	Baseline	End	Baseline	End	Baseline	End	Baseline	End	Baseline	End
1	30	100	30	100	30	100	0	100	60	50	30	80
2	100	100	100	100	80	100	10	80	90	100	70	90
3	90	100	70	100	100	100	30	70	90	100	90	100
4	40	90	30	90	60	80	10	10	80	90	10	80
5	80	90	20	90	20	80	0	70	40	90	60	100
6	90	100	40	100	0	90	0	90	60	100	40	100
7	80	90	80	90	60	90	40	70	85	100	95	100
8	50	90	40	80	50	80	20	40	40	100	60	80

Percentages represent the median proportion of hospitals with indicated outcomes.

(range, 0–60 days). Each hospital completed a median of 14 audits (range, 9–16).

The QI teams at each site (which included bedside nurses, nurse managers, and physicians) chose interventions for PDSA cycles based on perceived needs and the effectiveness of previous cycles. The interventions used in PDSA cycles and the percent of sites using each intervention are listed in Table 1. The most common strategy was the posting of TodaysBaby posters for nursing staff (used at all 8

hospitals), followed by nursing use of TodaysBaby pocket-size resource cards, huddle announcements, and staff meetings (each used by 7 hospitals). Five hospitals used staff e-mail blasts, removed contradictory messages from policies and education materials, and displayed posters and bulletin boards visible to families. We are unable to formally assess whether particular interventions had greater or lesser impact with only 8 hospitals completing their QI interventions in varied combinations.

Outcomes

Aggregated data of the main outcomes are shown in Figs 1 and 2. Mothers' reports of receipt of nursing education on safe sleep practices (Fig 1) and observations of infants in a safe sleep position and environment (Fig 2) increased by >20 percentage points during the QI intervention. In general, hospital units that had low baseline percentages of adherence with the outcome measures attained similarly high percentages after the QI intervention as those with higher baseline percentages (Table 3).

Overall, each individual hospital had a median increase of 30% (range, 10%–50%) across the 6 measures. Maintenance mode data demonstrated that improvements were maintained, with the exception of maternal report of nursing education regarding pacifier use (Figs 3 and 4).

Contextual Elements

Communication was minimal among the sites during the QI campaign, with the exception of the aforementioned conference call. This collaborative discussion was well received and helpful, especially for hospitals that were earlier in their QI intervention. The barriers discussed on the call included physician engagement, reviewing with physicians the evidence base for the recommendations, the need for scripting for nursing staff to answer common questions from families, and carving out staff time for the audits.

Because each unit implemented different interventions and different combinations of interventions, it is not possible to discern if any particular intervention was more effective than the others. However, in both qualitative interviews and the concluding survey, teams reported that reminders at huddles and staff meetings, the TodaysBaby pocket-sized cards used to teach parents, and individual crib cards (1 site created these for their own use) were the most useful strategies. In general, there was enthusiasm for the PDSA cycle methodology. Many sites endorsed the importance of having a champion. The hospitals reported that the toolkits were easy to use, they liked the branding and the scripting, and all of the tools were helpful to some degree. It was important for each hospital to be able to creatively tailor the approach for their site. In addition, hospitals commented that it was helpful to view their progress in comparison with the other participating hospitals

on the study Web site. Although there were some initial concerns regarding the amount of time it would take and whether they could free up staff to perform the audits, all sites indicated that the audits were not time consuming (<30 minutes per cycle). Teams were surprised to discover that often some of the “other” items in the cribs (eg, thermometers, bulb syringes) were related to infant care. Most said that they would not change anything, but 2 sites mentioned that they would have liked more help with data collection, and 1 site said that they would have liked their PDSA cycles to be a little longer than the suggested 2 weeks.

DISCUSSION

Implementation of a nursing-focused safe sleep toolkit using QI methodology was feasible among 8 US maternity units and led to rapid improvement of adherence to AAP-recommended safe sleep practices during postpartum hospitalization, with over 90% of infants observed to be sleeping in the supine position and almost 90% of infants observed to be in a safe sleep environment. These improvements were sustained for 12 months after the QI intervention. This intervention was successful with minimal training in QI methodology and safe sleep practices provided by the study team among a diverse set of maternity units.

These results are consistent with results from studies in other hospital settings where QI methodology has been an effective strategy to increase adherence to infant safe sleep practices.^{21–23} As in the current study, the use of safe sleep toolkits that include education tools for nurses to deliver to families have also been successfully used in the NICU.^{24,25} In recent studies conducted in maternity units, researchers have demonstrated that bundled interventions using nurse modeling, parents viewing a DVD,

and either nurses or parents signing a commitment or acknowledgment of the fact that education improved adherence to safe sleep practices at the time of discharge and at 4 months.^{26,27}

This project was unique in that it was designed to be a comprehensive campaign, and each site could select resources and strategies from the toolkit to tailor their PDSA cycles on the basis of specific needs. The introduction and overview could be viewed online or presented in a webinar format, and the toolkit and materials could be downloaded as needed by each facility. Hospitals could identify champions and form teams on their own. Frequently asked questions and helpful resources were readily available online.

The only measure that did not reach the $\geq 90\%$ target was the report of receipt of nursing advice to use a pacifier during sleep once breastfeeding has been established. Lower reporting of receiving advice about pacifiers may be due to residual confusion regarding the AAP recommendations to introduce pacifiers as a part of safe sleep and sudden infant death syndrome risk reduction¹¹ and the recent push to implement the Baby-Friendly Ten Steps, which discourage the introduction of pacifiers until breastfeeding is well established.^{28,29} For future implementation, greater emphasis on this recommendation with careful explanation may be needed to encourage appropriate pacifier use as a risk reduction strategy.

It is important to ascertain whether gains attained during the birth hospitalization are sustained postdischarge. The role modeling of safe sleep practices by hospital personnel is associated with greater caregiver adherence at home^{5,6} because it establishes or reinforces the importance of the safe sleep practices.¹⁵ There are few studies in which researchers evaluated longer-term effects of QI initiatives such

as this, and discussing these effects are beyond the scope of this article. However, incremental benefits may be hard to demonstrate given that many hospitals have high baseline levels of adherence. Additional studies will be needed to determine the optimal timing and content needed for sustained increases in adherence.

The QI intervention was designed before the updated AAP policy statement in 2016,¹¹ and therefore it is possible that the updated safe sleep recommendations could have required a change in the toolkit. However, the 4 safe sleep recommendations included in the QI campaign were unchanged in the 2016 AAP policy statement, making the QI campaign consistent with current AAP guidelines.

We did not formally assess each hospital's baseline educational practices, although most did report having safe sleep brochures available. However, units with low baseline percentages of adherence with the outcome measures attained similarly high percentages after the QI intervention as those with higher baseline percentages.

Participating teams were engaged in the larger SMART study, suggesting that they were committed to the

success of the safe sleep intervention. They also received basic training and support from the study team. However, individual hospital-level data on unit-specific barriers were not collected. Future maternity hospitals aiming to adopt the intervention may differ in level of engagement and resources, and there may be different barriers.

Teams collected their data at different times, depending on the rate of their PDSA cycles, so data were grouped by monthly intervals for 6 months. This provided only 7 data points (including the baseline), which was insufficient to create statistical process control charts, which would enable the creation of confidence limits around the outcomes. Individual hospitals wishing to implement this intervention would be able to decide for themselves an appropriate end point.

CONCLUSIONS

Adherence to infant safe sleep practices (including supine position and proper sleep location) in the first months of life remains suboptimal. Safe sleep education and role modeling for parents in the postpartum hospital setting are variable but represent an opportunity for intervention. The implementation of a simple, nursing-based safe

sleep education toolkit using basic QI methodology among a diverse group of maternity units led to rapid and sustained improvements in safe sleep education and practices. This intervention has the potential for widespread adoption that may contribute to reduction in sleep-related infant deaths.

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ABBREVIATIONS

AAP: American Academy of Pediatrics
PDSA: plan-do-study-act
QI: quality improvement
SMART: Social Media and Risk Reduction Training

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TodaysBaby Quality Improvement: Safe Sleep Teaching and Role Modeling in 8 US Maternity Units

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Newborn Safety Bundle to Prevent Falls and Promote Safe Sleep

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and Christopher Kowal, DNP, RN, CCRN-CSC

Abstract

Purpose: At our Baby-Friendly USA hospital, with at least 80% of mothers breastfeeding and rooming-in, it is not uncommon for mothers to fall asleep in their hospital bed while feeding. The aim of this study was to develop a newborn infant safety bundle and evaluate its efficacy in helping reduce unsafe sleep situations while simultaneously preventing newborn falls.

Study Design and Method: Data were collected in March 2015 using an infant at risk-to-fall instrument prior to nurses initiating the newborn infant safety bundle. The bundle included: (a) a parent safety agreement; (b) education, teach-back, and role modeling of safe sleep practices; and (c) implementation of a reporting and debriefing system for infant falls. All new mothers were eligible for inclusion. Data were collected over a random month every quarter for four quarters (through June 2016).

Results: Fourteen percent ($n = 23$) of babies born at the hospital in March 2015 were found to be exposed to risk-to-fall situations; over half of their mothers were found asleep and still holding the baby. Following bundle implementation, identified unsafe sleep situations during June 2015 to June 2016 have trended down with no reports of an infant fall through May 2017.

Clinical Implications: Increasing parental awareness, understanding, and participation in safe sleep practice creates and maintains a safer infant environment in the hospital setting.

Key words: Infant falls; Infant risk-reduction bundle; Infant safety bundle; Newborn falls; Safe sleep; Safety strategies.

Improving and sustaining newborn infant safety in acute care mother-baby clinical units and beyond, including safe sleep and newborn falls reduction, have become a priority focus in the United States. The American Academy of Pediatrics (AAP) Task Force on Sudden Infant Death Syndrome (2016) recommends room sharing without bed sharing during the postpartum hospitalization and after discharge

home to minimize risk of sudden infant death syndrome. Recommendations about safe sleep for newborns in the acute care setting are focused on skin-to-skin care and rooming-in (Feldman-Winter, Goldsmith, AAP Committee on Fetus and Newborn, & AAP Task Force on Sudden Infant Death Syndrome, 2016). Baby-Friendly USA (2012) hospitals are challenged with maintaining best practices: (a) early introduction of

skin-skin contact after birth; (b) keeping mother and baby together (rooming-in) throughout the acute care birthing stay; and (c) striving for greater than 80% breastfeeding rates (World Health Organization, 2016).

It is not uncommon for a mother to fall asleep in her hospital bed while feeding her newborn. This situation increases risk of adverse outcomes such as sudden unexpected postnatal collapse and near-miss events or deaths related to sleep, suffocation, and falls from the mother's hospital bed (Feldman-Winter et al., 2016; Simpson, 2017). Galuska (2011) reports typical infant risk-to-fall maternal indicators including breastfeeding, cesarean birth, use of opioid pain relief within the last 4 hours, and the phenomenon of emotional/physiologic maternal exhaustion second or third night postpartum (especially between midnight and early morning [9:00 a.m.]) (Monson, Henry, Lambert, Schmutz, & Christensen, 2008). Slogar, Gargiulo, and Bodrock (2013) reinforce earlier findings of maternal risks resulting in infant falls: (a) increased levels of maternal fatigue; (b) any episode of nighttime feeding; and (c) prior near-miss occurrence experienced where nurses find the mother either falling asleep with or asleep already while holding her infant. Further research suggests leaving babies alone to

room-in with sleep-deprived parents during the first hours postpartum may result in accidental adverse outcomes (Wallace, 2014). Although nurses may educate mothers and families about the risks of bed sharing, falling asleep while breastfeeding, and during skin-to-skin care, nurses should be readily available to safely place newborns close to mother but in their own separate sleep area when mothers fall asleep with her newborn (Feldman-Winter et al., 2016). According to Wallace (2015) in the *Pennsylvania Patient Safety Advisory*, 55% of infant falls were infants falling from a sleeping parent's arms, with more than half of these events occurring between midnight and 7:00 a.m.

Newborn falls are underreported and may occur more frequently than what has been documented (Teuten, Bolger, & Paul, 2015). Reasons for lack of parental reporting include

fear of reprisal from healthcare professionals, apprehension of being negatively judged (re: poor parenting skills), and fear of social service involvement (Teuten et al.). Between 600 and 1,600 infant falls per year occur in the United States (Helsley, McDonald, & Stewart, 2010). Even falls from low levels of height can cause significant trauma and head injury to the newborn (Ruddick, Platt, & Lazaro, 2010). Infant falls can escalate into conditions of serious harm to the newborn as well as severe emotional distress for parents and caregivers (Wallace, 2014). Infant falls in the acute care setting can create multiple legal and financial implications for hospitals.

The literature is sparse with historical publications discussing near-miss opportunities, risk, and prevalence of occurrence of falls among newborns in U.S. hospitals (Feldman-Winter et al., 2016).

Recently, greater attention to infant safety is emerging in professional literature (Simpson, 2017; Slogar et al., 2013). Similarly, acute care hospitals and many ambulatory care centers are now focusing on fall-prevention strategies for all patient populations: paying specific attention to the phenomenon of newborn fall safety.

To promote newborn safety in the acute care setting, Simpson (2015) suggests the following practice strategies: (a) Assess the individual needs of each mother, considering her level of pain, fatigue, support, medication status, and her understanding of infant safety practices. (b) Encourage mothers to room-in with their baby while avoiding making the hesitant or resistant mother feel guilty. (c) Assign one nurse to three (mother-baby) couplets. This is the current staffing recommendation (Association of Women's Health, Obstetric, and Neonatal Nurses, 2010) and should be maintained particularly during the night hours, as mothers often need a great deal of assistance breastfeeding especially at nighttime (when they are most tired). (d) Encourage hospitalized mothers to call for assistance when tired, exhausted, or need help placing their infant in the bassinet.

Evidence is emerging on a more accurate prevalence of newborn falls in the immediate, acute care, postpartum periods. Similarly, the clinical leadership team for maternity units are challenged with balancing mother-baby attachment time, encouragement and management of improved breastfeeding practices, and providing education to all parents during their brief, postpartum hospital stay. As a result, more innovative infant safety programs are being developed across the United States. Galuska (2011) developed a universal newborn fall-prevention program focusing on parent education, commitment pledge to infant safety, use of infant safety signage, and maternal rest promotion in busy and often loud units.

Figure 1. Infant at Risk-to-Fall Instrument

Infant at Risk-to-Fall Form	
Date: _____	Time: _____ MR Number: _____
Location of Infant: _____	
In arms of sleeping adult:	
<input type="checkbox"/> Mother <input type="checkbox"/> Other _____ <input type="checkbox"/> Mother's bed <input type="checkbox"/> Chair or cot <input type="checkbox"/> Unsupervised on bed or chair <input type="checkbox"/> Crowded room/pathway: _____ <input type="checkbox"/> Other: _____	
Mother's bed:	
Locked:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Position:	<input type="checkbox"/> Low <input type="checkbox"/> Other _____
Side-rails:	<input type="checkbox"/> Up <input type="checkbox"/> Down
Was anyone else in the room with the mother? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Other comments to describe unsafe situation for infant (use other side if more space is needed): _____	

Newborn Infant Safety Bundle

In 2005, our facility adopted a patient safety improvement program for physicians, midwives, and nurses. After successful completion, we obtained advanced certification in the same program in 2007. We continue the practice of consistent global staff education; safety and emergency drills; CHAT (current communication, history, assessment, treatment) huddles; and debriefing sessions built into daily, standard delivery of maternity care.

The team expanded this safety program and developed a Sudden Infant Death Syndrome (SIDS) educational campaign (McMullen, Lipke, & LeMura, 2009). This included: (a) use of an online SIDS teaching tool; (b) placement of an educational “Steps-to-Home” crib card at the newborn’s bedside; (c) implementation of a “No Co-sleeping for Multiples” intervention; (d) use of sleep sack swaddling in the unit (parents also received one to take home); and (e) use of more safety-specific, infant discharge instructions (St. Joseph’s Health [SJH], 2012, 2015). Since program implementation, nursing role-modeling safe sleep practice and providing parental education on the topic of SIDS prevention have greatly improved.

Our team was confident we had a robust safety practice for mothers and infants. However, in 2014, two infants experienced a fall. In each case, the mother fell asleep with her baby in her arms. A taskforce was created to analyze the events and develop an infant safety bundle to further reduce risk and the number of infant falls. Real-time, unsafe sleep situations and risk factor exemplars were gathered, establishing a baseline before any new and improved safety bundle practices were implemented. Colleagues developed an infant risk-to-fall evaluation form for staff to complete if an unsafe sleep situation is witnessed (Figure 1) (SJH, 2015).

Figure 2. Infant Safety Bundle

Maternal risk factors

- Epidural analgesia/anesthesia
- Cesarean birth
- High level of fatigue
- Second or third postpartum night
- Recent opioid or sedative use

Parent safety agreements

- Parental form with safety risks and education on keeping baby safe while in the hospital
- Parents sign agreement after nurse reviews the agreement with the parents

Safety interventions for parents and visitors

- Safety bulletin boards on Mother–Baby unit
- Crib cards for safe sleep on every baby crib
- Nurses role model safe sleep practices
- Nurses round every 1–2 hours minimum
- Patient doors are left unlatched at night for nurses to check on infant
- Nurses instruct mothers to call the nurse when ready to feed their baby

Reporting and debriefing system for infant falls

- Contact neonatal provider if an infant fall occurs
- Event report generated and sent to risk management
- Team debriefing after an infant fall

Purpose

The purpose of this study was to evaluate the efficacy of the infant safety bundle in reducing and preventing unsafe sleep conditions and infant falls in our maternal–child units. Clinical colleagues felt optimistic that if risk-reduction strategies to prevent infant falls were included in current safe sleep practices, nurses could improve outcomes. The project was approved by the organization’s institutional review board.

Study Design and Methods

An observational, descriptive safety study was designed for nurses to assess environmental conditions and personal behaviors and interactions between adult parents and newborns in the postpartum acute care setting. Demographic information about mothers was not included. Data about unsafe sleep situations were collected. Infants less than a week old who were patients on our postpartum units and infants in the neonatal intensive care unit were included in the study. Nurses and other team members were made aware of the study’s intent, instrument, and data collection timeframe. Preprogram (baseline) data

were collected in March 2015 prior to beginning the study. Data were collected during a randomly chosen month per quarter (June 2015–June 2016) using an evaluation instrument developed by the hospital’s clinical taskforce based on unsafe sleep situations reported in the literature (Figure 1). For example, a baby should sleep in their own safe sleep place; anything other would be considered unsafe unless the infant was asleep in the arms of an awake and alert adult (Feldman-Winter et al., 2016). If the mother was asleep with the baby in her arms or in an unsafe sleep space, then this would be a reported unsafe sleep situation. Collection months were selected each quarter through simple random sampling. All postpartum parents ($N = 832$ births) were eligible for recruitment and study inclusion. If an unsafe sleep situation was identified, nurses were instructed to evaluate and document it and then educate parents, family, and friends about findings; with inclusion of appropriate, subsequent remediation and quality documentation.

Bundle components (Figure 2) included use of parental safety agreements with the caregiver team and a

list of safety interventions for parents and visitors. Education with role modeling on safe sleep practice came next, and awareness on reporting and debriefing after an infant fall followed (SJH, 2015).

The safety program used maternal risk factors attributed to newborn falls identified in the literature: cesarean birth, extreme fatigue, second or third postpartum night, and recent opioid or sedative use (Ainsworth, Summerlin-Long, & Mog, 2016; Galuska, 2011; Kassa, Moon, & Colvin, 2016; Matteson, Henderson-Williams, & Nelson, 2013). Epidural anesthesia was added as a risk factor because it was currently in the “risk-to-fall” criteria for our hospital fall bundle (SJH, 2015). Although breastfeeding was listed as a potential risk factor contributing to newborn falls, as a Baby-Friendly USA (Baby-Friendly USA, Inc., 2012) hospital, it was encouraged with appropriate safety recommendations.

A parental–newborn safety agreement adapted from Providence Health & Services perinatal departments (Helsley et al., 2010; Providence Health & Services, 2012) was used to instruct mothers, fathers, and home caregivers of the risks for newborn falls in the hospital and at home. The agreement summarizes

the protocols to keep infants safe in the acute care setting as well as providing education required for care early-on in the home. Our *Steps-to-Home* crib card focuses on safe sleep practices and newborn care that parents should follow in the hospital and at home (SJH, 2015).

In the event of an infant fall, multiple steps are taken immediately by the team. First, they inform the manager and contact a neonatal intensive care unit provider while protecting and assessing the infant. Next, a patient safety event report is completed and submitted. Immediately following the event, a postfall debriefing occurs, and involved clinical team members are given the opportunity to come together and communicate their feelings about the occurrence as well as the mother’s assessed risk status (SJH, 2015).

Shortly into the launch of the infant safety bundle, another infant fall was reported in June 2015. Our nursing team wanted to create the safest environment, so instructions were given to mothers to call the nurse for physical presence during feedings at any time of day or night. Nurses conducted more frequent parent–newborn bedside rounds (every 1–2 hours at minimum), and patient’s room doors were not latched

shut, so the nurse could quietly check on parent and baby even while asleep (SJH, 2015).

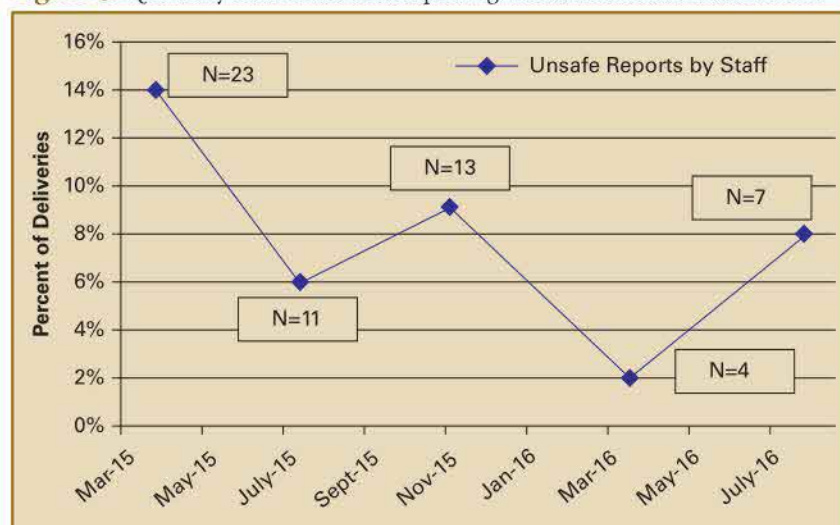
Results

Preprogram data collected in March 2015 produced 23 risk evaluations. These represented 14% ($n = 23$) of the month’s total births ($n = 169$), with over half of them being mothers who were found asleep while still holding their baby. Over the next 12 months, there was a reduction in the number of episodic findings during the study timeframe (Figure 3).

There are approximately 2,000 births at our hospital each year. In 2014, we had two infant falls and in 2015, one infant fall. As of May 2017, there were no further infant falls on their mother–baby units. The number of identified unsafe sleep situations from June 2015 to June 2016 has trended downward since bundle implementation. As of June 2016, the infant safety bundle has been integrated as a standard of best clinical practice and embraced by the nursing practice culture in all mother–baby clinical units within our system. Nurses continue to identify, report, and educate parents about unsafe sleep situations as part of their routine practice. Our maternal–child safety program committee receives reports on all adverse and near-miss situations. This process for reporting near-miss episodes in care allows clinicians to account for unsafe sleep scenarios, should they occur.

We found some parents who refused to sign the safety agreement because they felt that by signing the form, an infant fall would become their fault. We identified this as an opportunity for nursing education, as it was reported some nurses were simply presenting the form to parents to sign without offering the education. We reeducated nurses, so they could better explain the significance of the safety agreement to the parent before asking them to sign. Parents needed to understand that the safety agreement was intended to

Figure 3. Quarterly Data Collection Reporting of Unsafe Situations for Infants



be a partnership between the parent and staff to help keep the newborn safe. We also wanted nurses to recognize that the parent and other caregivers needed to have the information presented to them in a non-threatening way. Beginning with a caring but structured parental communication, we helped build a team approach to creating a safer environment for the infant.

Clinical Nursing Implications

Parents should be encouraged to report any infant fall situation during their postpartum hospitalization without the worrying about repercussion. Although parents may be willing to comply with the concept of safe infant sleep practices, there is always a risk they may fall asleep unknowingly in the postpartum, acute care phase due to extreme exhaustion experienced during childbirth (Monson et al., 2008). It is understood that parents have best intentions for their newborn, but inherent risk factors with childbirth may increase risk for an infant to fall or be placed in an unsafe sleep position. Nurses accept responsibility to discuss and educate parents about any identified potential action-behavior situations. This can be challenging as parents may feel ashamed, upset, afraid, or even annoyed at the nurse who requests to place the infant in the bassinet if mom and dad are falling asleep in bed. Bed sharing is always a personal choice, no matter how much parental guidance is bestowed. Maternal-baby nurses must balance infant safety, safe sleep practices, and risk-reduction strategies to prevent an infant fall, at the same time they help the parents learn about normal newborn care and promote attachment. Role-modeling safe sleep and falls-prevention strategies for parents can have a great impact on routines at home. Nurses can help create a caring, healing, and learning environment for parents so

Suggested Clinical Nursing Implications

- Implementation of a newborn safety bundle to promote safe sleep and minimize risk of falls in the acute care setting may decrease risk of adverse accidental outcomes.
- Nurses conduct more frequent parent-newborn bedside rounds (every 1–2 hours at minimum), and patient's room doors are not latched shut, so the nurse can quietly check on parent and baby even while asleep.
- Instructions are given to mothers to call the nurse for physical presence during infant feedings at any time of day or night.
- Use of role-playing and face-to-face counseling by mother-baby nurses can create a caring and learning environment for parents so safety practices learned while in the hospital continue at home after discharge from the hospital.

they may continue safe newborn practices after discharge.

Development, implementation, and evaluation of a newborn safety program requires a team to achieve success. Our team began a safety initiative over 12 years ago, and learned the value of highlighting efforts to promote infant safety using evidence-based practices. We appreciate the value of frontline clinical team members' engagement in program development, process management and improvement, and evaluation audits to remove barriers and help cultivate changes in nursing practice. Parents and frontline colleagues working together creates a safe environment for protecting our smallest patients from harm. As a Magnet™-designated (American Nurses Credentialing Center, 2017) facility with Baby-Friendly USA (2012) designation, we found fluid communication, strong team dynamics, and bundled practice strategies help shape best practice into a program of caring.

Safe sleep practices for mothers, fathers, and family members are role-modeled so at home the family can emulate what they have experienced in the hospital setting. As the body of evidence on infant falls grows, our safety strategies may need to be modified. Practice changes take time. Many maternal-child nurses have been providing care in

the same way they have for many years. It is challenging to change how things have always been done: whether according to tradition or rote memory from past practice. The first steps to improving infant safety are to find innovative ways to convince clinicians that old practice needs to change. As more recent scientific findings are incorporated into evidence-based practice, it will help reinforce their value and benefit when nurses are explaining safety practices to parents. Future evidence on newborn infant safety will be added to our clinical practice as it becomes available. ❖

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VIEWPOINT

Unintended Consequences of Current Breastfeeding Initiatives

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Promoting and supporting breastfeeding during the postpartum period has been an important and appropriate priority for maternity units in recent years. The Ten Steps to Successful Breastfeeding of the Baby-Friendly Hospital Initiative have been implemented by an increasing number of hospitals as the standard of care for optimally supporting breastfeeding from birth to hospital discharge.¹ As some or all of these steps are increasingly being promoted as standard of care by government agencies (eg, the Centers for Disease Control and Prevention) and by The Joint Commission, it is important to be certain that the basis for the recommendations has been documented in reproducible scientific studies and that the benefits of the practices recommended outweigh the risks. Unfortunately, there is now emerging evidence that full compliance with the 10 steps of the initiative may inadvertently be promoting potentially hazardous practices and/or having counterproductive outcomes.

The wording of the 10 steps themselves may not suggest a potential for risk. However, the specific guidelines for Baby-Friendly designation provide the cause for concern. For example, to comply with step 4 (help mothers initiate breastfeeding within 1 hour of birth), the guidelines state that all mothers should have continuous skin-to-skin contact with their baby immediately after birth until completion of the first feeding and that skin-to-skin contact should also be encouraged throughout the hospital stay,¹ a time period when direct continuous observation by medical care professionals is not likely to occur. Although a recent Cochrane Review provides evidence for the benefits of skin-to-skin care for healthy full-term and late preterm infants for the first hour after birth, it also stipulates that mother and baby not be left unattended while skin-to-skin care takes place during this early period.² Reports of sudden unexpected postnatal collapse (SUPC) in association with the skin-to-skin practice, published over the past several years, have focused attention on the importance of this caveat.³

Reports of SUPC include both severe apparent life-threatening events (recently referred to as brief resolved unexplained events) and sudden unexpected death in infancy occurring within the first postnatal week of life.³ A comprehensive review of this issue identified 400 case reports in the literature, mostly occurring during skin-to-skin care, with one-third of the events occurring in the first 2 hours after birth and the remainder in the subsequent week of life.³ The review reported death in half of the cases and persistent disability in the majority of survivors. European rates of SUPC varied from 2.6 to 74 cases per 100 000 births, with higher rates related to the length of the inclusion period and infant care practices related to prone sleeping

and co-bedding.³ Furthermore, a recent publication from the American Academy of Pediatrics observed that lawsuits have surfaced in US hospitals attributed to unexpected respiratory arrest in apparently healthy newborns during early skin-to-skin care and cautioned that this practice needs to be balanced with the need to implement safe sleep practices with monitoring of infants during skin-to-skin care unless direct observation takes place.⁴

While breastfeeding exclusivity (step 6) and 24-hour rooming in (step 7) have demonstrated benefits in the postpartum period, these practices may also engender risk. An overly rigid insistence on these steps in order to comply with Baby-Friendly Hospital Initiative criteria may inadvertently result in a potentially exhausted or sedated postpartum mother being persuaded to feed her infant while she is in bed overnight, when she is not physically able to do so safely. This may result in prone positioning and co-sleeping on a soft warm surface in direct contradiction to the Safe Sleep Recommendations of the National Institutes of Health. In addition, co-sleeping also poses a risk for a newborn falling out of the mother's bed in the hospital, which can have serious consequences.⁵ There is also the possibility that unsafe sleep practices modeled in the hospital may continue at home.⁶

The justification for breastfeeding exclusivity is based on a 1998 World Health Organization review of the evidence for the 10 steps.⁷ However, that review included evidence that when supplementation was given for a medical indication, there was no adverse effect on the duration of breastfeeding. It also concluded, based on the available evidence, that it was not clear to what extent supplementation in other circumstances was a marker of breastfeeding difficulty rather than an actual cause of breastfeeding failure.

Another issue of concern is the ban on pacifier use (step 9). Compliance requires that mothers be educated repeatedly that pacifiers may interfere with the development of optimal breastfeeding.¹ Because there is strong evidence that pacifiers may have a protective effect against sudden infant death syndrome (SIDS), the American Academy of Pediatrics has suggested avoidance of pacifiers only until breastfeeding is established at approximately 3 to 4 weeks of age.⁸ Because a substantial number of SUPC events occur during the first week of life,³ this recommendation to proscribe the use of pacifiers is difficult to defend based on risk.

Preventing the unintended serious outcomes from these practices has been made more challenging by the emphasis on breastfeeding exclusivity in the perinatal measures recently promulgated by The Joint Commission. Measure PC-05 requires documentation of the

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reasons for not exclusively breastfeeding, with no allowable exceptions for newborn conditions. In addition, the Centers for Disease Control and Prevention actively promotes the "10 Steps" and Baby-Friendly designation, and monitors "10 Steps" compliance in the United States. In Massachusetts, the recently enacted Massachusetts Health Quality Measure 3A requires increasing rates of breastfeeding exclusivity, with soon to be implemented financial implications.

In an effort to explore the potential effect of these initiatives, we reviewed data from the Massachusetts Department of Public Health Registry of Vital Records and Statistics concerning statewide rates of sudden unexplained infant deaths among newborns. This includes *International Classification of Diseases* codes R95 (SIDS), R99 (undetermined cause and manner), W75 (accidental suffocation), and W84 (unspecified threat to breathing). While SIDS in the first month of life is generally considered an uncommon event, in Massachusetts (2004-2013), 14% of the cases of SIDS occurred in the first 28 days of life. Of note, 8 (22.2%) of the cases of SIDS among newborns and 20 (35.1%) of the newborn sudden unex-

plained infant deaths occurred in the first 5 days of life, suggesting that the concerns raised in the recent American Academy of Pediatrics report⁴ may be more common than previously recognized.

In 2011, the Office of the Surgeon General issued a call to action to support breastfeeding that proposed the accelerated implementation of the Baby-Friendly Hospital Initiative in the United States.⁹ Considering the available evidence, that recommendation should be reconsidered. If government and accreditation agencies wish to encourage and support breastfeeding, their focus should shift from monitoring Baby-Friendly practices and breastfeeding exclusivity to monitoring breastfeeding initiation rates coupled with evidence of lactation support both during and after the hospital stay. More attention should also be placed on ensuring compliance with established safe sleep programs, emphasizing the need to integrate safe sleep practices with breastfeeding. Hospitals should direct their efforts toward implementing practices that will promote breastfeeding safely, the common goal of both private and public groups with an interest in these issues.

ARTICLE INFORMATION

Correction: This article was corrected on January 30, 2017, to add Conflict of Interest Disclosures that were missing.

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Immediate and Sustained Skin-to-Skin Contact for the Healthy Term Newborn After Birth: AWHONN Practice Brief Number 5

An official practice brief from the Association of Women's Health, Obstetric and Neonatal Nurses

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The information herein is designed to aid nurses in providing evidence-based care to women and newborns. These recommendations should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Recommendations

The following recommendations represent the consensus of the AWHONN Power of Touch Scientific Advisory Panel. Although AWHONN recommends skin-to-skin contact for preterm infants in other resources, the focus of the literature review for this practice brief was full-term, healthy newborns.

- All stable infants greater than 37 weeks and 0 days gestation born by vaginal or cesarean birth should be placed in immediate skin-to-skin contact for at least the first hour of life or until the first breastfeeding is completed.
- All mothers of stable infants greater than 37 weeks and 0 days gestation should be offered the option of skin-to-skin contact during painful neonatal procedures, such as vaccinations and blood sampling, whenever possible.
- All parents of healthy infants greater than 37 weeks and 0 days gestation should be encouraged to have frequent, uninterrupted skin-to-skin contact with their newborns while in the hospital and after discharge.

benefits of immediate skin-to-skin contact after birth for the newborn include improved thermoregulation and cardiopulmonary stabilization (Beiravand et al., 2014; Srivastava, Gupta, Bhatnagar, & Dutta 2014; Takahashi, Tamakoshi, Matsushima, & Kawabe, 2011). Full-term newborns who have immediate and sustained skin-to-skin contact with mothers also demonstrate short- and long-term improvements in feeding, such as shorter time to first successful breastfeed, better suckling at the breast, and overall longer duration of breastfeeding (Bramson et al., 2010; Mahmood, Jamal, & Khan, 2011; Srivastava et al., 2014). Erlandsson et al. (2007) compared full-term neonates born by cesarean and placed on their fathers' chests to those placed in cots. Those held on their fathers' chests stopped crying, became calmer, and reached a drowsy state more quickly than those placed in cots.

Skin-to-Skin Contact

Skin-to-skin contact is described as holding the unclothed, diapered newborn on the mother's or caretaker's bare chest, usually in an upright position (Jefferies & Canadian Paediatric Society, Fetus and Newborn Committee, 2012; Moore, Anderson, Bergman, & Dowswell, 2012). Skin-to-skin contact has also been referred to as kangaroo care.

Skin-to-Skin Contact for Full-Term Infants

Although there are many positive effects of skin-to-skin contact for healthy, term newborns, this method of care is not routinely practiced in all obstetric settings, especially for neonates born by cesarean (Beiravand, Valizadeh, Hosseinabadi, & Pournia, 2014; Erlandsson, Dsilna, Fagerberg, & Christensson, 2007). The initial

During routine care practices, full-term, healthy infants are exposed to some interventions that are considered painful, including heel lance procedures for blood sampling and intramuscular injections. Skin-to-skin contact has been shown to reduce the responses of newborns to painful stimuli, including a decrease in facial grimace, heart rate, and crying time when compared to those who were not in skin-to-skin contact during the same procedures (Gray, Watt, & Blass, 2000; Kostandy, Anderson, & Good, 2013; Liu, Zhao, & Li, 2015).

In addition to the benefits of skin-to-skin contact for the newborn, there are many benefits for the mother. For mothers who choose to breastfeed, earlier and longer sessions of skin-to-skin contact support exclusive and extended breastfeeding (Bramson et al., 2010; Marín Gabriel et al., 2010;

Mikiel-Kostyra, Mazur, & Boltruszko, 2002). Skin-to-skin contact can reduce symptoms of depression and physiological stress in the postpartum period (Bigelow, Power, MacLellan-Peters, Alex, & McDonald, 2012), increase feelings of bonding and attachment (Stevens, Schmied, Burns, & Dahlen, 2014), and improve mothers' confidence in their ability to breastfeed (Aghdas, Talat, & Sepideh, 2014).

Timing of Skin-to-Skin Contact

Uninterrupted skin-to-skin contact should be encouraged for at least the first hour of life after birth and until the first breastfeeding is completed as long as the mother and newborn remain stable. If desired, skin-to-skin contact can be extended to the first two to three hours of life if the mother and infant remain stable. Routine care practices should ideally be delayed until the initial skin-to-skin session is completed. Although the evidence remains inconclusive about how long infants should remain in skin-to-skin contact, improved breastfeeding outcomes have been reported with sessions as short as 20 minutes in duration (Mikiel-Kostyra, 2002). Most researchers recommend sessions lasting at least one to two hours and as long as five hours per day for the first week of life (Bigelow et al., 2012; Bramson et al., 2010; Suzuki, 2013).

Safety Measures

AWHONN recommends that an appropriately trained health care professional (e.g., registered nurse, midwife, nurse practitioner, physician) be in attendance for all immediate skin-to-skin sessions during the first two hours of life and that the infant and mother be observed frequently during this time. While most researchers suggest that there are no risks to the mother or newborn during skin-to-skin sessions (Moore et al., 2012; Kostandy et al., 2013), there are case reports of sudden, unexpected postnatal collapse of healthy term infants who were positioned prone during skin-to-skin contact (Ludington-Hoe & Morgan, 2014; Pejovic & Herlenius, 2013). There is no agreed upon definition of sudden, unexpected infant collapse in the literature. However, Pejovic & Herlenius (2013) described it as an incident in which a healthy, previously vigorous infant with Apgar scores of 8 suddenly becomes apneic, which necessitates medical intervention and often resuscitation measures.

Health care professionals should be trained how to manage skin-to-skin contact in obstetric and

postpartum settings. This training should include proper positioning, maternal and newborn safety measures, and physiologic indicators that should be monitored during immediate and ongoing skin-to-skin contact (Stevens et al., 2014). Although the use of neonatal assessment tools to monitor infants in skin-to-skin contact have been suggested, such as respiratory effort, activity, perfusion, position (Ludington-Hoe & Morgan, 2014), no assessment tools have been validated at this time. Parents should be educated on proper positioning for the parent and newborn and how to avoid distractions during skin-to-skin sessions.

Infant Massage Therapy

Currently, insufficient data exists upon which to base recommendations for routine infant massage therapy during the hospitalization period immediately after birth. However, some researchers found that infant massage therapy performed on stable infants of greater than 37 weeks gestation resulted in increased stooling and decreased bilirubin levels (Chen, Sadakata, Ishida, Sekizuka, & Sayam, 2011; Dalili, Sheikh, Shariat, & Haghazarian, 2016; Lin, Yang, Cheng, & Yen, 2015), improved sleep patterns (Ferber, Laudon, Kuint, Weller, & Zisapel, 2002), and enhanced growth and development (Field et al., 2004). Before routine recommendations can be made for infant massage therapy, more research is needed in this population.

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ORIGINAL ARTICLE

Deaths and near deaths of healthy newborn infants while bed sharing on maternity wards

BT Thach

OBJECTIVE: Our aim was to evaluate programs promoting bed sharing on maternity wards and determining ways to reduce these risks.

STUDY DESIGN: Members of the National Association of Medical Examiners were contacted requesting information on deaths of healthy infants while bed sharing on maternity wards.

RESULT: Fifteen deaths and three near deaths are reported. One or more factors that increase the risk of bed sharing were present in all cases. Accidental suffocation was deemed the most likely cause of these incidents.

CONCLUSION: Cases of infant deaths and near deaths while bed sharing on maternity wards are under reported. The 'Baby Friendly' (BF) initiative in maternity hospitals to promote breastfeeding is endorsed by the American Academy of Pediatrics and the US Center for Disease Control and Prevention. The BF initiative encourages prolonged skin-to-skin contact and bed sharing. Education of mothers and more efficient monitoring should significantly reduce the risk of maternity ward bed sharing.

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Keywords: infant deaths; skin-to-skin; bed sharing; maternity wards

INTRODUCTION

Although bed sharing with infants is well known to be hazardous, deaths and near deaths of newborn infants while bed sharing in hospitals in the United States have received little attention aside from a recent brief report of a single death and two near deaths.¹ In the recent past, similar deaths and near deaths have been reported in Europe and Britain.^{2–11} The incidence of these events is reported to be as high as 4/1000 live births.¹² These events occurred within the first 24 h of birth during 'skin-to-skin' contact between mother and infant, a practice promoted by the 'Baby Friendly' (BF) initiative endorsed by United Nations Children's Fund, BF, USA and the US Center for Disease Control and Prevention to support breastfeeding.^{13–17} We report 15 deaths and 3 near deaths of healthy infants occurring during skin-to-skin contact or while bed sharing on maternity wards in the United States. Our findings suggest that such incidents are underreported in the United States and are preventable. We suggest ways in which close maternal infant contact to promote breast feeding may be done more safely.

METHODS

In 2011, information on deaths of healthy newborn infants while bed sharing in hospital was requested by email from members of the National Association of Medical Examiners using a listserv. Persons on the Center for Disease Control and Prevention Sudden Unexpected Infant Death listserv were also contacted. Information with identifiers deleted on 15 deaths was forwarded. Information on three near deaths of infants, although not originally requested, was forwarded to us by close colleagues and others who were aware of our interest in such cases. The information we obtained included post mortem reports, hospital records and other sources

(Table 1). This research was approved by an institutional committee for human research.

RESULTS

Data for the cases are shown in Table 2. All infants were presumed to be healthy at the time the incident occurred. The incidents occurred between 1999 and 2013. The infants mean age was 23.9 h (range = 1.15 h to 3 days). The median age was 14.75 h (\pm 5 and 45.75 h). The mother's pregnancy and delivery were minimally complicated in 10 cases (Table 2). Of the 13 cases where mother's parity was known, 7 were primipara and 6 were multipara. Apgar scores available in 16 cases were all within normal limits. Medical examiners' or physicians' diagnoses included overlaying (one case), sudden infant death syndrome (SIDS) (one case), cause of death undetermined (eight cases), accidental suffocation (five cases) and apnea of undetermined etiology (three cases). Two near deaths resulted in severe lasting brain injury.

In eight cases, the mother fell asleep while breastfeeding (Table 2). In four cases, the mother woke up from sleep but believed her infant to be sleeping when an attendant found the infant lifeless. One or more risk factors that are known or suspected (obesity and swaddling) to further increase the risk of bed sharing were present in all cases.^{17–21} These included the infants' age < 4 months in all 17 cases; maternal sedating drugs in 7 cases; cases excessive of maternal fatigue, either stated or assumed if the event occurred within 24 h of birth in 12 cases; pillows and/or other soft bedding present in 9 cases; obesity in 2 cases; maternal smoking in 2 cases; and infant swaddled in 4 cases (numbers 6, 10, 12 and 16).

Factors presumed to potentially reduce the risk of bed sharing were present in most of the cases. These included mother awake

Table 1. Information sources for cases*

Case number	Case history and post mortem report	Hospital records	Interview with medical examiner	Interview with attending physician	Interview with parent
1	+	+			
2	+	+			
3	+	+	+		
4	+	+	+		
5			+	+	
6	+	+			
7	+		+		
8	+	+	+		
9	+		+		
10	+				
11	+	+			+
12	+		+		
13	+				+
14		+		+	
15	+		+		
16	+		+		
17		+		+	
18	+	+			

*Information available.

when the death or near death occurred in 4 cases and other individuals in the room when the event occurred in 10 cases.

DISCUSSION

This study suggests that the majority or all of the deaths and near deaths reported here were preventable. In six infants, routine screens for metabolic inborn errors were reported as normal (Table 2). For these and the other infants, evidence from the scene indicated suffocation as the most likely cause of death. Therefore, it is unlikely that inherited metabolic disorders had a role in the cases reported here.

In spite of the reports from overseas, it is likely that most maternity hospital personnel and neonatologists are still unaware of the risk of suffocation during close maternal infant contact. In the three near-death cases accidental suffocation was not considered in the differential diagnosis, and in two cases (numbers 17 and 18) the mother was initially accused on totally insufficient grounds of intentionally suffocating her infant. In one of these cases (number 17), the incident was allegedly reported to a child protection agency.

In the European literature, several authors suggest the causal mechanism resulting in the fatal or near-fatal incidents is airway occlusion when the infant's face is in contact with the mother's breast or abdomen.^{2,9} In our study, eight infants were 'on the breast' when discovered. Occlusion of an infant's airway while breastfeeding has been previously reported as a cause of death.^{22,23} Relief from obstruction depends on the mother's responses and/or the infant's neck extension reflex initiated by airway occlusion.²⁴ Breastfeeding in a recumbent position may increase the risk of airway obstruction if the infant's attempt to withdraw from the breast is blocked by the mother's hand or arm.

The incidents reported here are probably a substantial underestimate of such occurrences in past years. We did not request information on near deaths. The three cases reported here were brought to our attention by individuals aware of our interest in such cases. Previous reports of near deaths were nearly twice that of reports of actual deaths.⁹ Furthermore, in four instances information on deaths were not reported to us by National Association of Medical Examiners members but were brought to

our attention by parents or others. In four additional deaths, information was requested but this was not made available to us. In order to know the true incidence of such deaths and near deaths, we feel that in the future reporting to a public health agency should be mandatory as is already the case for other adverse in-hospital events.

Whereas previous reports have been concerned with adverse incidents during the first 24 h of life, the present study indicates that infants are at risk for death or injury throughout the hospital stay. A stated aim of BF USA is to 'help mothers initiate breastfeeding within one hour of birth'.¹⁴ To facilitate this, the American Academy of Pediatrics recommends direct skin-to-skin contact with mothers immediately after delivery and as much as possible throughout the post-partum period.^{15,25} BF USA advises that infants and mothers share a room continuously and that infants be breast fed on demand without restricting the duration of the feeding and with a minimum of 10–12 feedings in 24 h.¹⁴ In addition United Nations Children's Fund encourages in-hospital bed sharing.²⁶ These recommendations will likely result in bed sharing for prolonged periods of time, particularly for mothers who have had cesarean sections or others, who do not wish to leave their beds frequently to breastfeed.

Some professionals see minimal risks in bed sharing, with few exceptions, and this may explain a nurse not taking time to remove the infant from the mother's bed after being requested to do so (case number 10).^{27,28} One hundred fifty hospitals in the United States are already certified 'BF,' and reportedly many more are seeking to become certified (<http://www.babyfriendlyusa.org/find-facilities>). The American Academy of Pediatrics and the Center for Disease Control and Prevention have taken steps to increase the number of BF hospitals in the United States.^{14–17} This stems from the findings that skin-to-skin contact has been shown to be beneficial for mother–infant bonding, and the BF approach reportedly increases breastfeeding rates after hospital discharge.^{29,30}

An important question is: can in-hospital bed sharing be done safely? The presence of other individuals in the room could reduce the risk, but in 10 instances resulting in death or near death other individuals were present. In three of the present cases, the room was dark or dimly lit. This was likely in many of the other cases, a situation hindering the ability to assess the infant's wellbeing. In addition, the finding that in four cases the mother was awake at the time of the incident indicates that wakefulness is not completely protective. It has been previously reported that in 20% of death and near deaths, the mother was awake when the incident occurred.¹⁰ In the United States, breastfeeding during bed sharing is regarded as safe so long as the mother is awake and the United Nations Children's Fund UK BF initiatives concurs with this.^{18,30} The present and prior reports clearly show this is not the case during the immediate post-partum period. Frequent bed checks by nurses at 5–10 min intervals is advocated in the BF literature, but as deaths or injury can occur in a few minutes, such checks would have to become nearly continuous to entirely prevent death or injury.¹³

We have several suggestions to increase the safety of infants on maternity wards. First, hospital personnel and expectant parents should be made aware of potential hazards of skin-to-skin and bed-sharing practices. Mothers should be taught to assess breathing, skin color and response to stimuli in their infants, and when in close contact there should be sufficient light in the room to allow assessment. When a mother is in close contact with her infant, one-on-one supervision of infant and mother should be undertaken by a person trained to monitor the infant's wellbeing as well as the mother's wakefulness. In many cases, nurses will be unavailable for these duties. A previous recommendation is that close surveillance is needed especially during the first 2 h after delivery; however, the present findings indicate that close supervision is needed throughout the hospital stay when infants

Table 2. Case histories and relevant data

Case number	Case summary	Diagnosis	Week gestation	Apgar score	Gender	Maternal age	Maternal parity	Inborn error score	Age event occur	Infant < 3 months	Excessive fatigue	Sedating drugs +	Soft bedding/pillows swaddled	Obesity/Lg Breast	Maternal smoking
1	Infant co-sleeping between parents on a standard bed. Father had a pillow on his stomach and placed infant on top of it. Infant found lifeless on its side facing father's back.	Undetermined	40	9.9	M	16	P		19 h	+	+	+	+		
2	Infant breastfeeding in mother's bed. Mother awoke 1 h later and found infant wedged under her breast.	Accidental suffocation	40	8.9	F	25	M		3 Days	+		+			+
3	Infant breastfeeding in mother's bed. Mother fell asleep and 20 min later she finds baby 'blue and not breathing.'	SIDS	37 ^{3/9}	9.9	M	19	M		45 h	+					+
4	Breastfeeding in hospital room, fell asleep 5 to 10 min, infant found cyanotic with mouth on nipple. Partially resuscitated. Survived 12 days then taken off life support.	Undetermined	38 ^{6/7}	8.9	M		P		1 Day	+	+	+	+		
5	Infant breastfeeding in hospital bed. Nurse found mother asleep with infant wedged under 'large pendulous' breast and axilla.	Accidental suffocation							2 Days	+				+	
6	Swaddled infant fell asleep on pillow while breastfeeding. Then mother fell into a 'deep sleep'. 15 min later, mother passed baby to grandmother who found baby limp and not breathing.	Undetermined	37 ^{2/7}	8.9	F	30	M	+	3 Days	+		+	+		
7	Mother fell asleep with infant beside her in bed. Later mother awoke and found infant lifeless. Mother fears 'she might have rolled over on her baby'.	Asphyxia accidental overlay	40	6.9	F				24 h	+	+				
8	Mother pretreated during labor with antibiotics for prolonged rupture of membranes and positive group B <i>Streptococcus</i> . After breastfeeding, she did not return infant to crib because infant 'was congested.' She fell asleep, 2 h and 30 min later nurse finds baby 'latched on' to breast but 'blue and floppy.'	Sudden unexplained infant death	42 ^{1/7}		F	42	M	+	32 h	+	+		+		
9	Mother had C-section due to hypertension and pre-eclampsia treated with MgSO ₄ . Mother said to be 'intellectually challenged,' and 'obese and large breasted.' Mother breastfeeding when infant 'became quiet' and unresponsive. Mother believed baby had gone to sleep, 5 min later mother calls nurse who finds the baby lifeless.	Accidental suffocation	38 ^{4/7}	9.9	F	21	P		5 h	+	+	+		+	
10	Labor was complicated by prolonged rupture of membranes and positive group Strep B <i>Streptococcus</i> treated during labor with IV antibiotics. Labor lasted 30 h. Mother stated 'she had never been so tired in (her) life.' Mother asked the nurse to take the baby to the nursery so she could sleep. Nurse said she might not have time to. Mother then breast fed briefly and fell asleep with her infant latched on to the breast. She awoke in the darkened room believing her swaddled infant to be sleeping. Neither parents noted whether baby was breathing or not. Father laid baby supine in bassinet for 90 mins. Father awoke and the infant found lifeless.	Undetermined	41	9.9	M	29	P		8 h	+	+	+	+		
11	Labor complicated by prolonged rupture of membranes and positive group Strep B <i>Streptococcus</i> and prolonged labor (24 h). Treated with IV antibiotics. Mother complaining of 'extreme exhaustion' breast fed her infant lying on its side on a pillow with the baby rolled toward her. Nurse entered room and found lifeless infant lying beneath her sleeping mother.	Overlay		7.9	F	26	P		5 h	+	+		+		

Table 2. (Continued)

Case number	Case summary	Diagnosis	Week gestation	Apgar score	Gender	Maternal age	Maternal parity	Inborn error score	Age event occur	Infant < 3 months	Excessive fatigue	Sedating drugs +	Soft bedding/pillows swaddled	Obesity/Lg Breast	Maternal smoking
12	Mother fell asleep while breast feeding. 45 min later, mother awoke in the dimly lit room and found the infant unresponsive lying next to her facing her breast. Believing infant to be sleeping she called the nurse to take baby to nursery. Nurse discovered the infant flaccid and cyanotic.	Undetermined	35 ^{4/7}		M	23		+	2 Days	+			+		+
13	Mother fell asleep 7 h after C-section with infant nursing on her breast. Mother awoke 13 min later and found her infant cyanotic and limp still on her breast.	Undetermined		6.9	M	41	M		7 h	+	+	+			
14	Nurse entered mother's dimly lit room. Awake mother reports infant just breastfed vigorously for 20 min but is now limp and assumes she is now sleeping. Nurse finds the infant grey and not breathing and begins CPR. Infant survives but with severe permanent brain damage. Extensive medical evaluation fails to reveal cause of the infants collapse. Father in the room at the time of the incident. A friend was also in the room.	Clinical Dx-apnea of undetermined etiology	40	9.9		28	P		2.3 h	+	+	+			
15	Labor complicated by maternal fever. Both mother and baby treated with prophylactic antibiotics. After breast feeding, the mother placed her infant between her and the father in a 'tiny' fold out sofa bed. At some point, the mother then placed the infant behind her and continued talking with the father. After some min, she turned over to check her infant and found him cold and unresponsive. Both parents were noted to be obese.	Compression asphyxia	39	8.9	M		M	+	10.5 h	+	+		+	+	
16	Infant noted to be 'grunting' immediately after delivery and as a precaution was taken to the NICU where he was kept briefly, evaluated and returned to the mother's room after the grunting subsided. A blood culture was obtained. Mother was propped on her side using rolled towels and pillows for breast feeding her infant after which she fell asleep. She awoke, found the infant's head cool and placed a hat on its head. Mother then noted face to be 'partially blue' and called for a nurse who found the infant to be deceased. Father was present in the room.	Probable positional asphyxia	40					+	5.5 h	+	+		+		
17	Mother was breast feeding her infant in the delivery room lying supine on delivery bed. Father at mother's side. About 2 h after delivery, the mother noticed that the baby's chest was not moving and called the nurse who found the infant to be apneic and cyanotic and began CPR with intratracheal intubation and mechanical ventilation. Extubated on arrival at the NICU. Normal neurological exam 3 days later	Clinical DX-apnea of undetermined etiology +	40						2 h	+	+				
18	Maternal pregnancy and delivery were uncomplicated. Soon after delivery the infant was given to the mother for 'skin-to-skin' contact. Minutes later, he was observed to be successfully breast feeding. Then about an hour later, a nurse found him lifeless lying on his mother's chest with his face into her chest and shoulder. He was successfully resuscitated but suffered severe, lasting brain injury.	Clinical DX-apnea of undetermined etiology +	39	6.9	M		P	+	1.15 h	+	+				

Abbreviations: F, female; M, male; NICU, neonatal intensive care unit; SIDS, sudden infant death syndrome. Fatigue stated or assumed if event occurred within 24 h of delivery.
+ Clinical diagnosis.

are in close contact with their mothers. In some cases, dedicated relatives or friends might perform this function. An alternative approach would be to electronically monitor infants (heart rate or arterial saturation) with alarms referred to the nursing station to avoid disturbing parents with false alarms. This would offer considerable protection for infants in close physical contact with mothers.

In summary, the BF initiative is an important public health program benefiting infants in many ways, including reducing the incidence of childhood obesity.^{16,17} However, any extensive health program needs to be monitored for adverse effects and modified accordingly.

CONFLICT OF INTEREST

The author declare no conflict of interest.

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Preventing newborn falls and drops

Issue:

Inpatient falls have been well studied in the adult population, and there is a large body of research on fall prevention and cost reduction.¹ Conversely, there is little attention to falls in the newborn population, although it has been estimated that 600 to 1,600 newborns in the United States experience an in-hospital fall every year.² Infant falls can escalate into conditions of serious harm to the newborn as well as emotional distress to parents and caregivers.³

What defines a newborn fall or drop?

The Agency for Healthcare Research and Quality (AHRQ) defines a fall as: An unplanned descent to the floor with or without injury to the patient.⁴ The National Database for Nursing Quality Indicators (NDNQI) defines both newborn falls and newborn drops. A newborn fall is “a sudden, unintentional descent, with or without injury to the patient that results in the patient coming to rest on the floor, on or against another surface, on another person or object.” A newborn drop is defined as “a fall in which a baby being held or carried by a health care professional, parent, family member, or visitor falls or slips from that person’s hands, arms, lap, etc. This can occur when a child is being transferred from one person to another. The fall is counted regardless of the surface on which the child lands and regardless of whether or not the fall resulted in injury.”⁵ Current literature supports that this patient safety concern, defined as a newborn fall or a newborn drop, are synonymous; organizations should follow the same patient safety analysis process for both a fall and a drop.

Risk factors for newborn falls drops

The literature supports that the most prevalent maternal risk factors associated with newborn falls and drops include:

- Cesarean birth
- Use of pain medication within four hours
- Second or third postpartum night, specifically around midnight to early morning hours
- Breastfeeding

Numerous maternal infant units promote exclusive breastfeeding as the ideal method of infant feeding in the first six months of life. To help facilitate early attachment between the mother and her newborn, skin-to-skin care is recommended. There is good evidence that normal term newborns who are placed skin to skin with their mothers immediately after birth make the transition from fetal to newborn life with greater respiratory, temperature, and glucose stability and significantly less crying indicating decreased stress.⁶

We also know that while breastfeeding, oxytocin is released from the pituitary gland; while this hormone allows for let down and milk ejection, it also may cause sleepiness in the new mother. The important goal of early skin-to-skin contact, frequent maternal infant interactions, and the promotion of breastfeeding can lead to increased risk of a newborn fall or drop.

Safety actions to consider:

Understanding the potential increased risk of newborn falls and drops is a challenge in today’s fast paced health care environment. Utilizing principles of high reliability, including preoccupation with failure, a health care system should consider developing a process to help prevent newborn falls and drop for all infants under their care, including:

- Developing an assessment tool to indicate those at increased risk for a newborn fall. This tool will promote common language and a shared mental model among the health care team, and act as a cognitive aid to staff so all are performing assessment in a similar manner.

(Cont.)

- Educating parents based on assessment. Those at highest risk should be counseled on the risks for newborn falls and drops and the need to call for help when feeling tired or sleepy. All parents should be cautioned against falling asleep with their newborn in the bed or co-sleeping with their newborn.
- Rounding hourly by staff so mothers or other caregivers noted to be drowsy can be assisted to place their newborn in a bassinet.
- Promoting maternal rest.
- Developing signage for the patient room or a crib card to reinforce the increased risk of infant falls and the importance of placing the infant in a bassinet when the mother is sleepy or after the mother receives pain medications.
- Developing a standardized reporting and debriefing tool in the event of an infant fall. A standard tool will help capture important data to better understanding risk and environment when the event occurred and the result in consistent post-fall care to the newborn.
- In the event of a fall, providing emotional support to the family or caregiver who may suffer as a second victim in this event.

Resources:

1. Galuska L. Prevention of in-hospital newborn falls. *Nursing for Women's Health*, 2011;15(1):59-61.
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Note: This is not an all-inclusive list.

Other resources from The Joint Commission:

The Joint Commission. *Sentinel Event Alert* Issue 55: [Preventing falls and fall-related injuries in health care facilities](#). Sept. 28, 2015.

The Joint Commission. *Quick Safety* Issue 39: [Supporting second victims](#). Jan. 22, 2018



Legal disclaimer: This material is meant as an information piece only; it is not a standard or a *Sentinel Event Alert*. The intent of *Quick Safety* is to raise awareness and to be helpful to Joint Commission-accredited organizations. The information in this publication is derived from actual events that occur in health care.

An Acute Event in a Newborn

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Please view the video of a newborn with an acute event.



Video 1. [Click here to view the video.](#)

The most likely diagnosis for the infant in this video is a(n):

- A. Sudden unexpected postnatal collapse
- B. Brief resolved unexplained event
- C. Ductal-dependent congenital heart lesion
- D. Severe combined immune deficiency
- E. Inborn error of metabolism

CRITIQUE

Case

The 3-kg female infant described in this case was born at 39 weeks' gestation to a 31-year-old gravida 2, para 2 woman via spontaneous vaginal delivery. Prenatal maternal laboratory testing revealed blood type A positive with unremarkable serologic findings. Rupture of membranes occurred 7 hours before delivery and the amniotic fluid was clear. The infant emerged active and had an Apgar score of 9 at 1 and 5 minutes after birth. The infant was then placed skin to skin with her mother. Subsequently, the infant was breastfed and fell asleep in her mother's arms. Within 2 hours, the nurse found the infant to be limp and cyanotic. A full resuscitation was initiated with positive pressure ventilation and chest compressions, and the infant underwent intubation. An umbilical venous catheter was placed and 2 doses of epinephrine were administered. However, after 20 minutes of cardiopulmonary resuscitation, the infant remained asystolic so resuscitative efforts were stopped and the infant was pronounced dead. A postmortem examination and case review was unrevealing about underlying infectious, metabolic, or structural etiologies. A diagnosis of sudden unexpected postnatal collapse was rendered.

AUTHOR DISCLOSURE Drs Rodriguez, Pellerite, Hughes, Wild, Joseph, and Hageman have disclosed no financial relationships relevant to this article. This commentary does not contain a discussion of an unapproved/investigative use of a commercial product/device.



Video 2. [Click here to view the video.](#)

Sudden Unexpected Postnatal Collapse

A “new” clinical entity has been characterized in the European, Australian, and United States literature, which has been called by various names including sudden unexpected postnatal collapse (SUPC). (1)(2)(3)(4)(5)(6) This sudden collapse occurs in apparently healthy term newborns soon after birth, commonly during initial skin-to-skin contact or the initial breastfeeding session. (1)(2)(7) Video 1 depicts a simulated case of SUPC in a postpartum department.

Diagnostic criteria and risk factors for SUPC are detailed in Tables 1 and 2, respectively. The true incidence of SUPC is not known because there is wide variation in the definition. For example, inclusion and exclusion criteria in published reports range from:

- A gestational age of more than 35 weeks or 38 weeks (8)
- Onset of the event before 2, 12, 24, or 72 hours of postnatal life, or within the first 7 days after birth (8)
- The presence or absence of an underlying pathologic condition (1)

Also, infants who experience SUPC but respond favorably to resuscitation (near misses) are often not included in published reports. Given the lack of consensus in definition

and no International Classification of Diseases 10 coding to report “unexpected postnatal collapse,” it is likely that the true incidence of SUPC is underreported.

International data show an incidence of 0.026 to 0.05 per 1,000 live births. (3) In Australia, the reported incidence is 0.05 per 1,000 live births >37 weeks’ gestation per year. (3) A twofold difference in the reported incidence in Australia, compared with New South Wales (0.1/1,000 live births) suggests reluctance on the part of clinicians to report cases. (3) Failure to investigate cases by autopsy leaves parents uninformed about the cause of death and without relevant information that may affect future pregnancies. (3)

Based on published literature, the median age at SUPC occurrence is 70 minutes after birth, for infants *without* an underlying pathology. (1) For infants *with* an underlying condition (as detailed in Table 2) the median age at SUPC is 195 minutes after birth. (1) Approximately one-third of cases occur in the first 2 hours after birth (often during the first breastfeeding session), one-third occur between 2 and 24 hours of age, and one-third between 1 and 7 days postnatally. (8)

Previously known risk factors include primiparous mother, maternal analgesia, prone position of infant during skin-to-skin contact, first breastfeeding session, and mothers falling asleep while breastfeeding. (3) In a recent report, up to 53% (24/45) of cases were attributed to airway obstruction associated with breastfeeding, skin-to-skin contact, or prone positioning. (1) More recent evidence suggests that there are many additional risk factors, as detailed in Table 2.

Comparing Clinical Entities

In 2016, the American Academy of Pediatrics (AAP) published a clinical practice guideline to reclassify the clinical entity of apparent life-threatening event (ALTE) as brief resolved unexplained event (BRUE) in an effort to more accurately label often self-limited events, and to offer evidence-based guidance for minimizing unnecessary medical evaluation of those patients deemed to have a low risk for serious adverse outcomes. (9) BRUE is defined as a brief, resolved event observed by a caregiver in a child younger than 1 year with at least 1 of the following features:

- cyanosis or pallor
- absent, decreased, or irregular breathing
- marked change in tone
- altered responsiveness

A diagnosis of low-risk BRUE is made only in well-appearing infants after no explanation for the event can be identified on history and physical examination. If an infant is categorized as low risk, as evidenced by being more than 60 days of age, born ≥32 weeks of gestation, with a postmenstrual age >45 weeks’ gestation, the absence of cardiopulmonary resuscitation by

TABLE 1. **Diagnostic Criteria for Sudden Unexpected Postnatal Collapse**

• ≥37 weeks’ gestation at birth
• Apgar score ≥8 at 5 minutes of postnatal age
• Collapse within 12 hours of birth in hospital
• Required resuscitation after collapse with positive pressure ventilation
• Died or received ongoing intensive care

Modified from Becher et al, 2012. (1)

TABLE 2. Risk Factors for Sudden Unexpected Postnatal Collapse

MATERNAL	PERINATAL	NEONATAL	ENVIRONMENTAL/ SITUATIONAL
Primiparous status	Prenatal compromise	Prone position of the infant while mother supine	Breastfeeding (especially first attempt)
Maternal opiate analgesia	Passage of meconium in utero	Infant fatigue	Unobserved skin-to-skin care with infant prone or side-lying on mother's chest
Regional or general anesthesia within 8 hours of event	Need for extensive neonatal resuscitation after delivery	Late preterm or preterm infant deemed safe to be left in the delivery room	Mother in supine position during skin-to-skin contact
Magnesium sulfate administration during labor	Delivery via cesarean section	Accidental suffocation due to occluded airway	Parental distraction (including use of smartphones)
Maternal body mass index >25 kg/m ²	Need for extensive repair after vaginal delivery	Underlying conditions, including:	Fatigued parents
Large breasts		• Cardiac disease (HLHS, interrupted aortic arch)	Mother left alone with neonate
Maternal fatigue/falling asleep during breastfeeding		• Pulmonary disease (PPHN)	
		• Infection (pneumonia, sepsis)	
		• Inborn error of metabolism (congenital lactic acidemia, urea cycle defect)	
		• Otolaryngology (prolapsed epiglottis with laryngomalacia)	

HLHS=hypoplastic left heart syndrome; PPHN=persistent pulmonary hypertension of the newborn.

medical providers, and with a first-time event that lasted less than 1 minute, then they may not require further evaluation or hospitalization. (9) High-risk BRUEs and additional evaluation of some low-risk BRUEs are left to clinical judgment.

As awareness of perinatal infant collapse has developed, the nomenclature continues to evolve. In keeping with prior existing terminology, severe apparent life-threatening event (s-ALTE) and unexplained sudden infant death were terms first used in a German case series to distinguish between surviving and deceased term infants who received assisted breaths or chest compressions due to cyanosis, pallor, or unconsciousness when less than 24 hours old, having had a 10-minute Apgar score greater than or equal to 8. (2) Currently, the term SUPC consists of more concise clinical inclusion criteria, while uniting surviving and deceased infants under the same label. Infants must be ≥ 37 weeks' gestation, with a 5-minute Apgar score greater than or equal to 8, presenting with collapse within 12 hours of birth in a hospital, and requiring resuscitation with positive pressure ventilation. (1)

SUPC involves cardiorespiratory collapse that leads to ongoing intensive care or death, and thus, is fundamentally different from a BRUE, which is a resolved event in a well-

appearing infant. Some characteristics of SUPC are similar to potential characteristics of a high-risk BRUE. Similar to SUPC, a high-risk BRUE does not fulfill low-risk criteria, may last over 1 minute, and/or occur in an infant less than 60 days old, and/or require resuscitation. SUPC is similar to high-risk BRUE in that underlying predisposing conditions can often be identified, such as accidental suffocation, underlying cardiac disease, pulmonary disease, pneumonia, sepsis, inborn errors of metabolism, or airway abnormalities. (1)(9)

Prevention

The numerous benefits of early skin-to-skin contact and breastfeeding, for both mother and infant, are undisputed. To optimize health outcomes, clinicians must facilitate these sessions in the early postpartum period, yet promote a safe environment for the infant/mother dyad. Current recommendations support continuous "rooming in" of newborn infants with their mothers, from the time of delivery until hospital discharge. Yet, there is also increasing awareness that healthy "well-appearing" infants are at risk for SUPC. (1)(2)(3)(8)(10)(11) The peak incidence of SUPC is within the first 2 hours after birth, (2) typically, the time when the

mother first places the newborn skin to skin and also breastfeeds for the first time. Although many risk factors have been identified (Table 2), prone positioning, first-time mother, unsupervised first attempt at breastfeeding, and parental distraction, including smartphones, appear to be primary among them. (8)(10)(11) In a recent report involving 26 cases of SUPC, 15 of the infants were positioned prone during skin-to-skin contact, 18 were born to primiparous mothers, 13 occurred during unsupervised breastfeeding within the first 2 hours after birth, and 3 cases occurred during maternal use of a cellular smartphone. (10) Some of these (situational) risk factors are easily modifiable. Although SUPC events are relatively rare, the clinical outcomes for these infants are devastating, with many infants dying either at the time of the event or after a prolonged hospital course. (1) (2)(3)(10) Those who survive are at risk for hypoxic-ischemic encephalopathy, which is often severe, with seizures occurring as early as 6 hours after the period of asphyxia. (10) Despite prompt hypothermia treatment, SUPC survivors may suffer severe neurodevelopmental disabilities. (1)(10)(12)

With increased awareness of SUPC, some authors have proposed clinical guidelines for prevention. For example, Davanzo et al (11) proposed a nursing guideline for monitoring at-risk infants during the first 2 hours after birth, a high-risk period for SUPC. In addition to increased surveillance of the infant during this critical postpartum transitional period, *parental education is key to prevention*.

Physicians and nurses play a pivotal role in SUPC prevention by counseling parents during the immediate postpartum period. However, it is important that the education be provided in a manner that does not frighten parents and discourage breastfeeding/skin-to-skin sessions.

The teaching should focus on the following:

- Proper positioning of the infant to maintain upper airway patency
- “Distraction-free” breastfeeding and skin-to-skin contact
- Emphasis should be placed on “no distractions” (ie, no use of smartphone by mother) during sessions of skin-to-skin contact and/or breastfeeding
- Parents must also be cognizant that maternal fatigue is common. They must be taught that if the mother is overly fatigued, and without additional help, the infant should be placed back to sleep in the bassinet so that the mother does not risk falling asleep while holding the infant.

By increasing awareness of SUPC, better identifying infants who are at risk, and providing counseling to parents in the immediate postpartum period, future cases of this devastating phenomenon may be prevented. Please view Video 2, showing a physician counseling a mother in the immediate postpartum period.

CORRECT RESPONSE

A. Sudden unexpected postnatal collapse

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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Fri, 12 May 2017 16:20:56 -0400
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP); Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP)
Subject: FW: Following up on our collective effort

See highlighted section below

From: Kimberly Seals Allers (b)(6)
Sent: Friday, May 12, 2017 4:04 PM
To: Stuebe, Alison M <alison_stuebe@med.unc.edu>; (b)(6)
(b)(6) Jodine Chase <(b)(6)>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; (b)(6) Angela Malloy
(b)(6) Arissa Palmer (b)(6) Bettina Forbes
(b)(6) Camie Goldhammer
(b)(6) Christine Staricka (b)(6) Celine Malanum
(b)(6) Dallas Gilpin (b)(6) Fiona Lang-Sharpe
(GOLD LEARNING) (b)(6) Info - Healthy Children Project
<info@centerforbreastfeeding.org>; Iona Macnab (b)(6) Leslie Lytle
(b)(6) Kristin Rowe-Finkbeiner (b)(6) Katrina Pavlik
(b)(6) Paige Smith <phsmith@uncg.edu>; Sarah Hung
(b)(6) Sili Recio (b)(6) Stephanie Sosnowski (b)(6)
(b)(6) Tina Sherman (b)(6) Trish MacEnroe (b)(6)
(b)(6) Kinkini Banerjee (b)(6)
Cc: Sullivan, Lucy (b)(6) Adrianna Logalbo (b)(6)
Amanda Medlock (b)(6)
Subject: Following up on our collective effort

Dear friends and partners,

As we head into Mother's Day weekend, I wanted to thank all of you for the hard work you do for mothers and babies every day! That includes the incredible support in recent weeks in speaking up and setting the record straight that breastfeeding saves lives. We will continue to speak out against misinformation.

I also greatly appreciate the feedback many of you have already provided – both directly to me and through our brief survey. If you have not yet shared your feedback, please feel free to answer [this brief 4 question survey](#) so we can learn what worked for you, what did not work, and how we can improve going forward.

I wanted to reach out to assure you that seeming silence is not a sign of inactivity. As we've mentioned from the outset, our initial collective action around my and Lucy's blogs was just a first step in a much-needed and ongoing effort to ensure the facts about breastfeeding win-out over misinformation, divisiveness and fear. We are re-assessing and strategizing the best next step and expect to report fully back to you all very soon.

As we monitor the messaging coming out of Fed is Best and some new developments, we are organizing around several opportunities, including:

- Expert input around the sources Fed is Best is citing and the “facts” they are promoting
- A “breastfeeding saves lives” campaign to highlight the stories of women who have positive breastfeeding stories (an antidote to FIB stories about the dangers of exclusive breastfeeding)
- A joint action for all partners and allies to participate in, such as an open-letter inviting FIB to an honest conversation about the underlying issues facing new mothers

I will be sure to keep you up to date as this work progresses. In the meantime, please feel free to let me know if you have any questions or ideas.

Onward,
Kimberly

--

Kimberly Seals Allers
Journalist | Author | Speaker | Consultant
Director, First Food Friendly Community Initiative ([3FCI](#))
www.KimberlySealsAllers.com
O: (b)(6) M: (b)(6)
@iamKSealsAllers | @MochaManual

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 30 Aug 2017 17:33:05 +0000
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP); Olson, Christine (CDC/ONDIEH/NCCDPHP)
Subject: FW: FYI Fed is Best response to our request for meeting
Attachments: 2017-8-21 FIB Response to 1000 Days.pdf

From: Petersen, Ruth (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, August 30, 2017 1:14 PM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>; OConnor, Ann E. (CDC/ONDIEH/NCCDPHP) <fxy8@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>; Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP) <rnf2@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Cc: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: FW: FYI Fed is Best response to our request for meeting

FYI

*Ruth Petersen, MD, MPH
Director
Division of Nutrition, Physical Activity, and Obesity
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention*

*Email: rpetersen@cdc.gov
Phone 770.488.6001 Mobile 404.353.8474*

From: Lucy Sullivan (b)(6)
Sent: Wednesday, August 30, 2017 1:07 PM
To: Petersen, Ruth (CDC/ONDIEH/NCCDPHP) <rip0@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: FYI Fed is Best response to our request for meeting

Dear Ruth and Cria,

I hope this note finds you well.

I wanted you to all be aware of the letter we received (attached) from the Fed is Best Foundation in response to the letter that we sent them on behalf of over 60 organizations requesting to meet to discuss their views on infant feeding.

Please let me know if you have any questions.
Lucy

Lucy M. Sullivan | Executive Director



1020 19th Street NW, Suite 250 | Washington, DC 20036
Direct: (b)(6) www.ThousandDays.org | @1000Days

For scheduling requests, please contact Amanda Medlock: amanda@thousanddays.org 202-969-4142



THE
FED IS BEST
FOUNDATION

August 21, 2017

Ms. Lucy Martinez Sullivan
Executive Director
1,000 Days
1020 19th St NW, Suite 250
Washington, DC 20036

Dear Ms. Sullivan:

Thank you for reaching out to The Fed is Best Foundation. As you are aware, we are a non-profit organization of medical, nursing, lactation, public health, and advocacy professionals dedicated to improving public health education and neonatal patient safety in both the inpatient and outpatient settings. Our organizational focus is on the promotion of safe, science- and research-based breastfeeding and infant monitoring practices to help reduce the incidence of hypoglycemia, hyperbilirubinemia, hypernatremic dehydration, and failure to thrive due to preventable insufficient milk intake. In addition, we also provide educational resources and support to families who have experienced these negative outcomes. At this time, our core panel of medical and scientific advisors is in the process of developing a comprehensive patient safety and quality improvement report which will include The Foundation's official recommendations for providers, hospitals, parents, and policy makers. We will be happy to provide copies of this report to all of your respective organizations when it becomes available.

Sincerely,

Jody-Segrave Daly, MS, RN, IBCLC
Co-Founder

Christie del Castillo-Hegy, MD
Co-Founder

From: MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Fri, 15 Nov 2019 12:25:01 +0000
To: Flores-Ayala, Calixto Rafael (CDC/DDNID/NCCDPHP/DNPAO);Gunn, Janelle P. (CDC/DDNID/NCCDPHP/DNPAO)
Cc: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: FYI
Attachments: Outcomes from CDC Report Card_Bass_Gartley_Kleinman.pdf
Importance: High

Hi Rafa and Janelle

Sharing the email from Catherine Sullivan from the Carolina Global Breastfeeding Institute (CGBI). CGBI was a sub-contractor of Abt, for the two EMPOWER projects. You have seen the article, but I wanted you to see the email re. media coverage of Bass' article, as a heads up.

From: Grossniklaus, Daurice (CDC/DDNID/NCCDPHP/DNPAO) <dtg3@cdc.gov>
Sent: Thursday, November 14, 2019 4:50 PM
To: MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO) <dvx2@cdc.gov>; Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>
Subject: FW: FYI
Importance: High

I assume you have seen this, but if not...

From: Sullivan, Catherine Sposito <Catherine_Sullivan@unc.edu>
Sent: Thursday, November 14, 2019 4:02 PM
To: Cynthia Klein (b)(6); Grossniklaus, Daurice (CDC/DDNID/NCCDPHP/DNPAO) <dtg3@cdc.gov>
Subject: FYI
Importance: High

Good afternoon. I hope you are both doing well. The attached article is getting a lot of traction on social media due to Fed is Best sharing it with sensational headlines. We have been inundated with hospital calls/emails. We do not plan to publish a response as we generally do not respond to upheaval on social media. We are sharing the response from Baby Friendly USA . Bartick et al. have an article that will come out in the next week or so that is supportive of the Ten Steps. Melissa presented at APHA. You have probably seen the derogatory article but since they mention EMPOWER I thought I should send just in case you haven't read through it.

Best,
Catherine

Catherine S. Sullivan, MPH, RD, LDN, IBCLC, FAND
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Outcomes from the Centers for Disease Control and Prevention 2018 Breastfeeding Report Card: Public Policy Implications

Joel L. Bass, MD¹, Tina Gartley, MD¹, and Ronald Kleinman, MD²

Objectives To compare the impact of Baby-Friendly designation vs rates of in-hospital breastfeeding initiation on breastfeeding outcomes at 3, 6, and 12 months postdischarge.

Study design Breastfeeding outcome data from the 2018 Centers for Disease Control (CDC) Breastfeeding Report Card were used as a basis for determining outcomes from the corresponding 2015 birth cohort. Linear regression models were used to determine the strength of association of breastfeeding initiation and Baby-Friendly hospital penetrance and attainment of postdischarge breastfeeding rates. All hospital births from all 50 states, 3 territories, and the District of Columbia were included in the study.

Results Statewide breastfeeding initiation rates were positively associated with targeted breastfeeding outcomes. Similar associations were not found for Baby-Friendly hospital designation penetrance.

Conclusions To attain the Healthy People 2020 breastfeeding objectives, future public policy initiatives should consider the interaction of population demographics, individual hospital programs, and public health strategies used to support breastfeeding in states reporting high breastfeeding initiation rates. (*J Pediatr* 2019; ■:1-6).

See editorial, p ●●● and
related article, p ●●●

In 2011 the Surgeon General of the US issued a call for action for maternity care practices throughout the US to support breastfeeding.¹ The active involvement of the Centers for Disease Control (CDC) in this activity was reviewed that same year in a Morbidity and Mortality Weekly Report.² As breastfeeding was thought to be associated with lower rates of childhood obesity, the CDC involvement in hospital practices to support breastfeeding was predicated on the assumption that this would be a way to reduce the increasing prevalence of childhood obesity. The report makes reference to the CDC annual Breastfeeding Report Card which provides state specific data on breastfeeding outcomes after discharge and includes World Health Organization (WHO) Baby-Friendly Hospital Initiative (BFHI) designation rates.³ The Breastfeeding Report Card provides annual reports from 2007 through 2014 and biennial reports from 2014. The following analysis is based on outcome data from the 2018 report.³

As a result of active CDC promotion of Baby-Friendly designation,⁴ the 2018 Breastfeeding Report Card provides a unique opportunity to compare the impact of Baby-Friendly designation with breastfeeding initiation and to clarify those public policy initiatives most likely to result in better breastfeeding outcomes after discharge. This is particularly important considering recent concerns about adverse neonatal sentinel events associated with some of the prescribed compliance requirements of Baby-Friendly designation,⁵⁻⁸ and a CDC publication,⁹ and a US Preventive Services Task Force report,¹⁰ which called into question the efficacy of Baby-Friendly designation in meeting its breastfeeding objectives.

Methods

We used data from the 2018 CDC Breastfeeding Report Card as the source for statistics concerning postdischarge breastfeeding outcomes. The CDC Breastfeeding Report Card uses data from the National Immunization Survey and relies on maternal recall when the children are between 19 and 35 months of age. Breastfeeding outcomes are analyzed by birth cohort (2015) rather than survey year.³ As 98.5% of births in the US in 2015 took place in hospitals,¹¹

BFHI	Baby-Friendly Hospital Initiative
CDC	Centers for Disease Control
HP2020	Healthy People 2020
SUPC	Sudden unexpected postnatal collapse
WHO	World Health Organization

From the ¹Department of Pediatrics, Newton-Wellesley Hospital, Newton, MA; and ²Department of Pediatrics, Massachusetts General Hospital, Boston, MA

R.K. has received payment for serving as a coeditor for the American Academy of Pediatrics book, *Pediatric Nutrition*, 8th edition; serves as the Vice Chair for the 2020 US Dietary Guidelines for Americans Advisory Committee, United States Dept of Agriculture/Health and Human Services; serves on the board of UNICEF New England; and has received honorarium for serving as chair of a Mead Johnson Pediatric Nutrition Iron Expert Panel meeting in 2014. The other authors declare no conflicts of interest.

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<https://doi.org/10.1016/j.jpeds.2019.08.059>

the Breastfeeding Report Card category of “Ever Breastfed” was used as an indicator for postnatal in-hospital breastfeeding initiation penetrance. The Breastfeeding Report Card statewide Baby-Friendly results are specific to the actual report card year rather than the birth cohort year. Because of the lack of a 2015 report, we used the 2016 Breastfeeding Report Card,¹² which includes both hospitals that were designated or in the final stages of Baby-Friendly designation in 2015, as the indicator for the 2015 Baby-Friendly penetrance. Baby-Friendly designation is a lengthy process, usually taking several years to complete. Thus, it was assumed that only those facilities that were well along the way to designation in 2015 would receive final designation in 2016. Inclusion of those latter facilities was, therefore, considered appropriate.

Attainment of the Healthy People 2020 (HP2020) postdischarge breastfeeding objectives³ was used as an indicator of breastfeeding success. For all 50 states, 3 territories, and the District of Columbia included in the Breastfeeding Report Card, linear regression lines were generated with R^2 and P values to evaluate the relationships between breastfeeding initiation percentages (low to high) with any breastfeeding at 6 and 12 months and exclusive breastfeeding at 3 and

6 months. Comparable regression lines were also generated for Baby-Friendly penetrance (low to high). To determine the contribution of Baby-Friendly designation participation to breastfeeding initiation, a comparison of Baby-Friendly penetrance to breastfeeding initiation was computed. To diminish the impact of the ecological fallacy (ie, errors in reaching conclusions about individual impacts when population outcomes are measured), comparisons using weighted averages based on annual births¹¹ were also made between the states with the highest Baby-Friendly births (92% Baby-Friendly penetrance) to those with the highest breastfeeding initiation rates (13.7% Baby-Friendly penetrance). Linear regression models were calculated using SAS v 9.4 (SAS Institute, Cary, North Carolina), and the regression plots were generated using Microsoft Excel (Microsoft Corporation, Redmond, WA) after confirming agreement between the SAS and Excel results.

Results

Breastfeeding initiation was significantly associated with all outcomes ($P < .0001$), including any breastfeeding at 6 and 12 months (Figure 1, A) and exclusive breastfeeding at 4

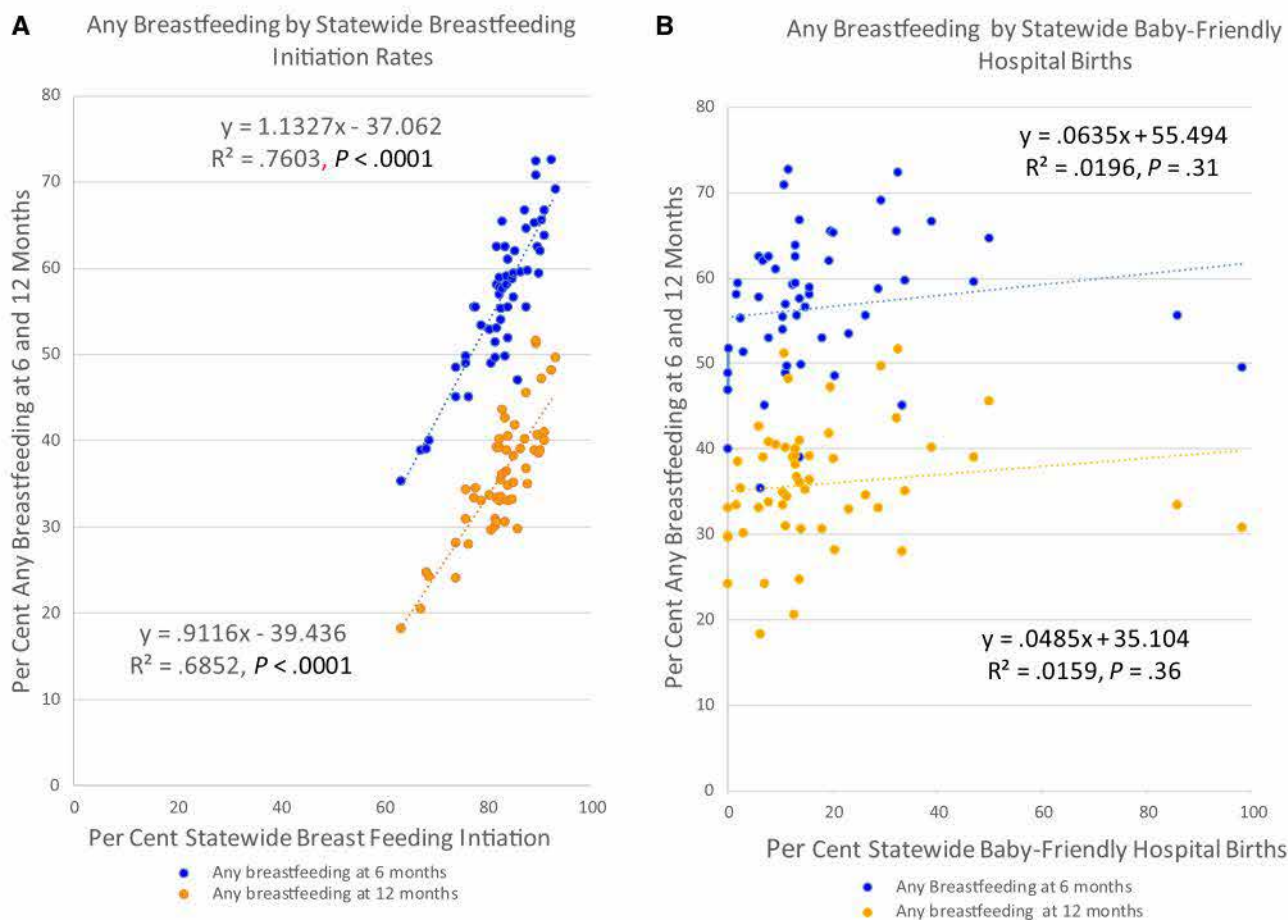


Figure 1. Any breastfeeding outcomes by statewide initiation and Baby-Friendly rates. Source: CDC Breastfeeding Report Cards 2016-2018.

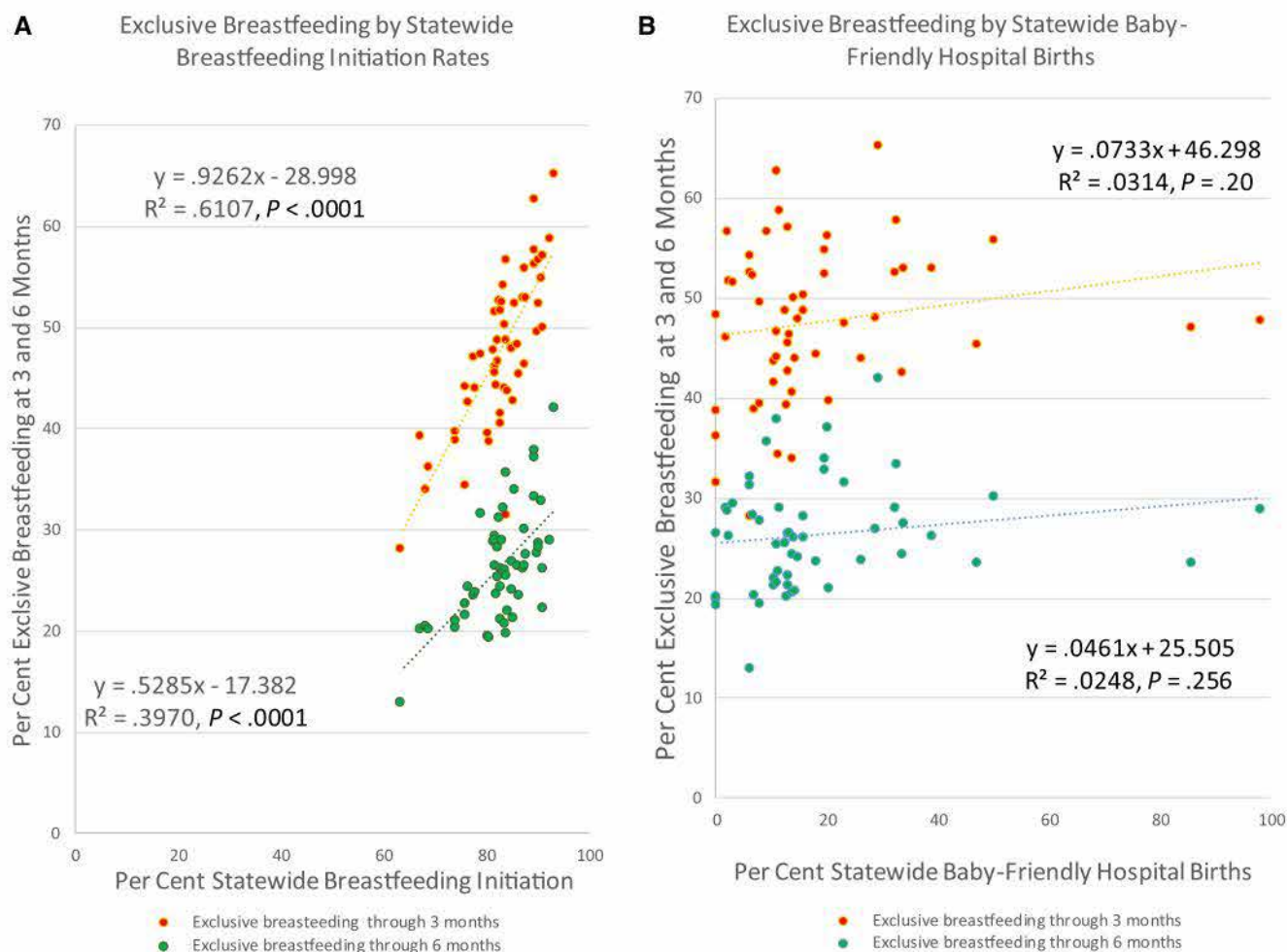


Figure 2. Exclusive breastfeeding by statewide initiation and Baby-Friendly rates. Source: CDC Breastfeeding Report Cards 2016-2018.

3 and 6 months (Figure 2, A). Baby-Friendly designation did not demonstrate a significant association with any postdischarge breastfeeding outcome (Figures 1, B and 2, B). There was no association between Baby-Friendly designation and breastfeeding initiation rates (Figure 3; available at www.jpeds.com)

Table 1 summarizes the results of the comparison of average attainment of the HP2020 Breastfeeding Objectives in the top tier groups: Baby-Friendly (85.8-98.2%, $n = 2$) and breastfeeding initiation (90-93.1%, $n = 7$). The performance of the high breastfeeding initiation group was greater in every category of outcome.

Discussion

The CDC has made a substantial commitment to promote breastfeeding in maternity services employing practices based on those recommended in the Ten Steps of the BFHI. This involved the funding of large-scale programs to implement Baby-Friendly designation throughout the US,⁴ including the 90 hospitals in the Best Fed Beginnings program (2011-

2015), a national initiative to increase breastfeeding and Baby-Friendly designation,¹³ and the 93 hospitals in the EMPOWER breastfeeding project (2014-2018), an initiative focused on maternity care practices leading to Baby-Friendly designation.¹⁴ It is largely as a result of these efforts that Baby-Friendly hospital designation penetrance in the US became substantial enough to critically evaluate the impact of the intervention using the Breastfeeding Report Card.

In a review of its 6 major public health initiatives, the CDC sought to determine whether these efforts had been “winnable battles.”⁹ Baby-Friendly designation in the US was one of the CDC efforts that had not achieved its intended objective to reduce childhood obesity. The report does note success in implementing Baby-Friendly designation in many hospitals, however, other reports also note concerns about associated neonatal sentinel events including sudden unexpected postnatal collapse (SUPC),^{8,15,16} newborn falls,^{15,17,18} and newborn dehydration and jaundice,^{19,20} which are recognized by the American Academy of Pediatrics,^{5,15} the WHO,^{16,20} The Joint Commission,^{18,21} and the CDC.^{22,23} In addition, there has been increasing recognition

Table I. CDC breastfeeding report card 2018: top tier comparisons baby-friendly vs breastfeeding initiation (ever breastfed)

State/territory	% Ever breastfed	% Breastfeeding at 6 mo	% Breastfeeding at 12 mo	% Exclusive breastfeeding through 3 mo	% Exclusive breastfeeding through 6 mo	% Live births occurring at Baby-Friendly facilities (2016)
HP2020	81.9	60.6	34.1	46.2	25.5	
Breastfeeding Objectives						
Weighted average: % high Baby-Friendly, (85.8-98.2)	79.4	52.6	32.2	47.5	26.2	92.0
Weighted average: % high initiation, (90-93.1)	91.4	67.4	43.5	55.7	27.5	13.7
High initiation vs high Baby-Friendly Δ	12.0	14.8	11.4	8.2	1.3	
High Baby-Friendly vs 2020 goals Δ	-2.5	-8.0	-2.0	1.3	0.7	
High initiation vs 2020 goals Δ	9.5	6.8	9.4	9.5	2.0	

Highest tier Baby-Friendly (n = 2): Delaware and Rhode Island

Highest tier breastfeeding initiation (n = 7): Wyoming, Idaho, Hawaii, Colorado, Maryland, Washington, and Alaska

of adverse perceptions of Baby-Friendly designation based on reports of the experiences of some mothers in Baby-Friendly designated hospitals.²⁴ This is reflected in the new WHO Baby-Friendly Guideline statement on the need to respect maternal autonomy and avoid judgmental attitudes which could infringe on the mother's dignity.¹⁶ The Breastfeeding Report Card outcomes also support the results of the recent US Preventive Services Task Force report, which demonstrated that Baby-Friendly designation was not a consistently effective intervention and that individual approaches were more successful.¹⁰

The report of the Best Fed Beginnings program suggests that the most significant contribution of increasing Baby-Friendly designation was the promotion of breastfeeding exclusivity at discharge.¹³ However, our analysis of the Breastfeeding Report Card indicates that states with substantially fewer births at Baby-Friendly facilities, and who have high breastfeeding initiation rates, have had greater success in promoting breastfeeding after discharge, a more important outcome than exclusivity during the birth hospitalization.

There is increasing recognition of the importance of updating and revising public policy initiatives as new data emerge.²⁵ The updated guidelines of the WHO, the parent organization of the BFHI, recommend significant changes, including a shift in focus from universal Baby-Friendly designation to implementing support for evidence-based breastfeeding practices through alternative approaches.²⁶ These changes may have been facilitated by the WHO policy regarding intellectual bias,¹⁶ which served to limit the role of Baby-Friendly designation advocates from policy decisions. As the Breastfeeding Report Card shows, the strength of association of breastfeeding initiation with successful later outcomes is very compelling. In addition, the temporal relationship of breastfeeding initiation to these outcomes, the dose-response evidence and the strong biologic plausibility fulfill most of the usual criteria of causality.

There are some limitations to the National Immunization Survey data source used by the Breastfeeding Report Card. In 2018, contact with potential participants was made exclu-

sively by cell phone.²⁷ Although low income families are more likely to rely exclusively on cell phones, their access to cellular service may be less reliable. In addition, the Breastfeeding Report Card does not provide specific demographic data to permit a deeper analysis and interpretation of response rates. Furthermore, breastfeeding initiation is strongly influenced by maternal intent,²⁸ which may be impacted by multiple factors including race, ethnicity, poverty, and educational level²⁹; these were data not included in the Breastfeeding Report Card. As an example, **Table II** (available at www.jpeds.com) provides a summary of these factors for the high breastfeeding initiation and Baby-Friendly states and demonstrates the heterogeneity of statewide demographics.³⁰ This highlights the complexity of the task and need to consider multiple factors to effectively establish public policy. A suggested framework for these interactions is presented in **Figure 4**. We suggest the current emphasis on universal Baby-Friendly designation should be re-evaluated, with consideration for policies that promote individualized approaches such as those successfully implemented in high breastfeeding initiation states with differing demographic characteristics.

A positive example of the impact of an individualized approach can be seen in the experience of the state of Maryland where a statewide initiative to improve hospital breastfeeding support was implemented in 2012.³¹ This initiative encouraged all birthing hospitals to become a "Maryland Best Practices Hospital" either by attaining Baby-Friendly Hospital certification or by implementing the Maryland Hospitals Breastfeeding Policy recommendations based on the BFHI Ten Steps to Successful Breastfeeding. Prior to the initiative, Maryland had not achieved any of the HP2020 objectives. By 2018, Maryland exceeded all HP2020 objectives. As only 18.2% of Maryland births in 2018 were in Baby-Friendly designated facilities, this provides additional evidence for the efficacy of a flexible approach to implementation of the BFHI Ten Step practices.

The Maryland experience also complements previous evidence that BFHI Ten Step practices implemented apart

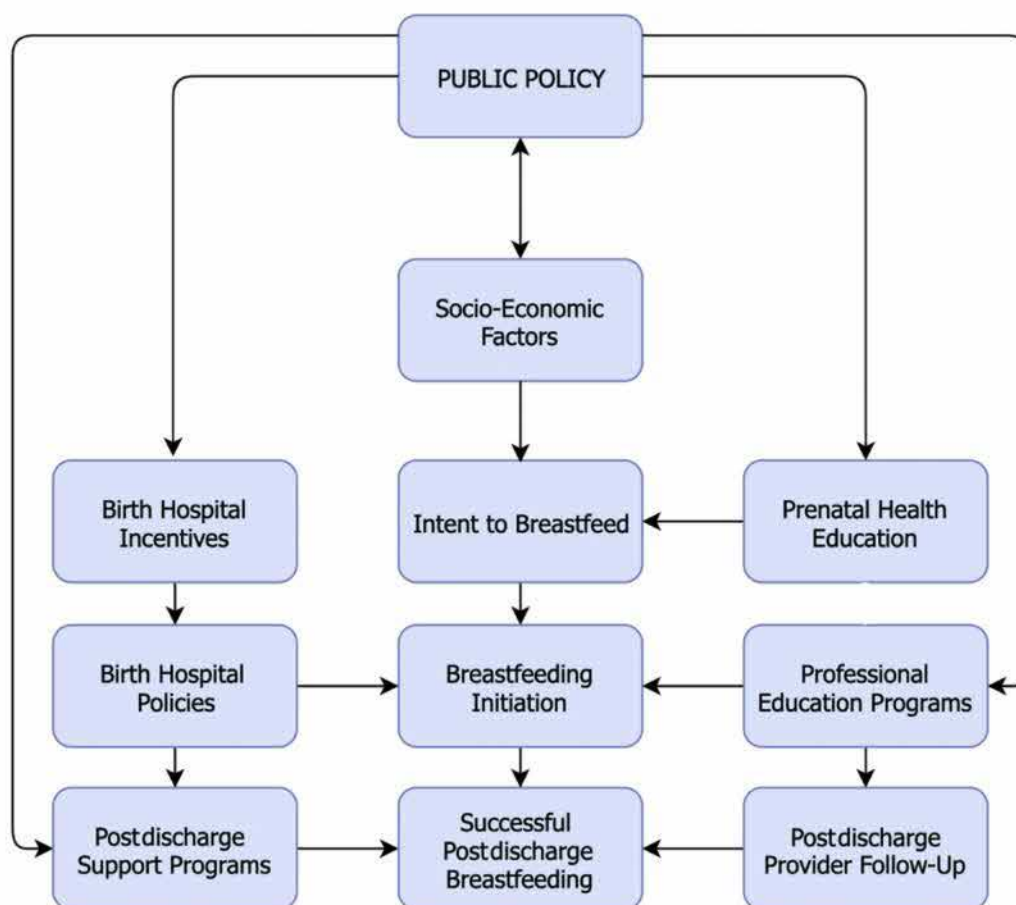


Figure 4. Framework for public policy and successful breastfeeding outcomes.

from Baby-Friendly designation may be playing a significant role in the positive HP2020 outcomes noted in the high breastfeeding initiation states.³² Future research should utilize CDC resources to help identify the specific practices used in the higher performing states and leverage their success to implement positive change and further the goals of the HP2020 breastfeeding objectives. In addition, other factors not included in those resources (eg, maternal pain medication) are worthy of further investigation.³²

The CDC has also recognized the need to prevent associated sentinel events as a component of breastfeeding support. A recent report on 20 years of CDC data on sudden unexplained deaths in newborns raised concerns about the potential extent of these events.³³ Further analysis of this data, which incorporated Apgar scores, revealed 51 cases of SUPC in 2015.²³ As part of its effort to address SUPC concerns, the CDC updated its 2018 Maternity Practices in Infant Nutrition and Care survey to include questions concerning continuous observed monitoring of newborns in the first 2 hours of life and frequent observation of high-risk mother-infant dyads (eg, after maternal sedation) to ensure safety when they are together. In addition, teaching mothers and support persons safe sleep strategies with their newborn

has been added to the survey. As breastfeeding itself has an important role to play in SIDS prevention,³⁴ integrating safe sleep with lactation support should further enhance that benefit.

In conclusion, states with high hospital breastfeeding initiation rates were associated with highly significant rates of any (6 and 12 months) and exclusive (3 and 6 months) breastfeeding rates after discharge. Baby-Friendly designation penetrance did not demonstrate any positive postdischarge breastfeeding association. To accomplish more widespread attainment of the HP2020 breastfeeding objectives, we suggest a shift in emphasis from promotion of universal Baby-Friendly designation to a more comprehensive public health approach with a focus on the interaction of population demographics, individual hospital programs, and public health strategies implemented in states with high breastfeeding initiation rates. This should also include an analysis of the impact of current hospital policies regarding the BFHI, including compliance with the International Code of Marketing Breast Milk Substitutes^{16,20} as well as methods to enhance professional education and provision of resources concerning the assessment and management of delayed lactogenesis and other problems commonly encountered in breastfeeding dyads. ■

We thank Sarah Kachan-Liu, MD, for reviewing our results, David Lyczkowski, MD, for reviewing the manuscript, and Janis Breeze, MPH, Epidemiologist, Tufts Clinical and Translational Science Institute, for assistance with the statistical analyses.

Submitted for publication May 31, 2019; last revision received Aug 28, 2019; accepted Aug 28, 2019.

Reprint requests: Joel L. Bass, MD, Department of Pediatrics, Newton-Wellesley Hospital, 2014 Washington St, Newton, MA 02462. E-mail: joelbass@comcast.net

Data Statement

Data sharing statement available at www.jpeds.com.

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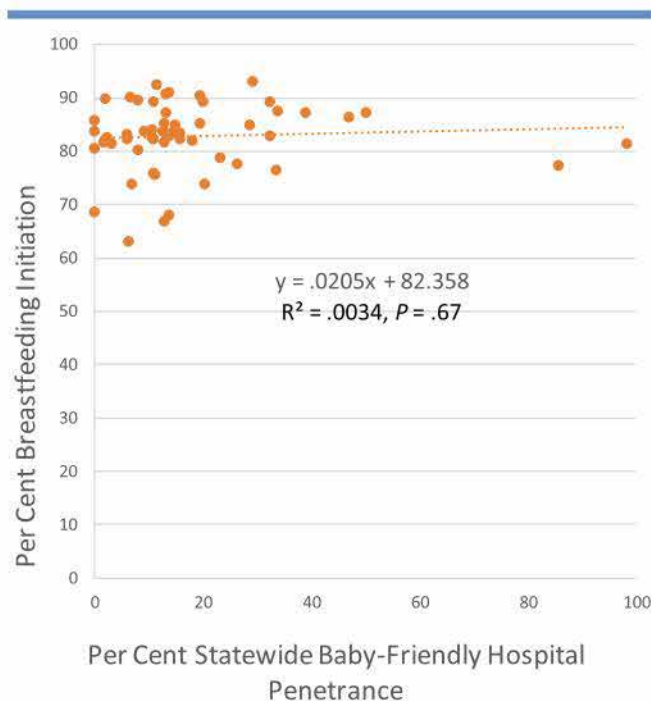


Figure 3. Breastfeeding initiation by Baby-Friendly hospital penetration. Source: CDC Breastfeeding Report Cards 2016–2018.

Table II. Comparative population demographics

State	% African American	% Hispanic or Latino	% Bachelor's degree or higher	% Persons in Poverty
US total	13.4	18.3	30.9	12.3
High breastfeeding Initiation				
Wyoming	1.3	10.1	26.7	11.3
Idaho	0.9	12.7	26.8	12.8
Hawaii	2.2	10.7	32	9.5
Colorado	4.6	21.7	21.7	10.3
Maryland	30.9	10.4	39	9.3
Washington	4.3	12.9	34.5	11
Alaska	3.8	7.2	29	11.1
High Baby-Friendly penetration				
Delaware	23	9.5	31	13.9
Rhode Island	8.4	15.9	33	11.6

Source: US Census Bureau Quick Facts: United States, 2018

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 22 Aug 2016 10:23:50 -0400
To: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO); Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO); Murphy, Paulette (CDC/ONDIEH/NCCDPHP)
Subject: FW: F/Up-team meeting
Attachments: Implementation of the Ten Steps to Successful Breastfeeding Saves Lives.pdf, Unintended Consequences of Current Breastfeeding Initiatives.pdf
Importance: High

All,

FYI- Dr. Bass referenced the 2010 GEC (reference #1). The updated 2016 GEC were posted (soft launch at the end of June 2016) in early July 2016.

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Subject: F/Up-team meeting
Importance: High

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VIEWPOINT

Implementation of the Ten Steps to Successful Breastfeeding Saves Lives

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Lawrence Noble, MD

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Viewpoint

The Baby-Friendly Hospital Initiative (BFHI), developed in 1991 by the World Health Organization and the United Nations Children's Fund to improve maternity care practices and breastfeeding rates, has been implemented globally in more than 152 countries. The core tenets of the BFHI are the Ten Steps to Successful Breastfeeding, which have been endorsed by the American Academy of Pediatrics. A recent meta-analysis of studies evaluating the BFHI found that implementation of the BFHI increased exclusive breastfeeding by 49% (95% CI, 33%-68%) and any breastfeeding by 66% (95% CI, 34%-107%).¹ The meta-analysis reviewed 29 studies that found that the BFHI and its elements of hospital support increased breastfeeding in the first hour (relative risk = 1.11; 95% CI, 1.06-1.16), 51 studies that found that it increased exclusive breastfeeding in the first 5 months (relative risk = 1.46; 95% CI, 1.37-1.56), and 47 studies that found that it increased any breastfeeding in the first 6 months (relative risk = 1.40; 95% CI, 1.30-1.52).

For optimal child health and development, the American Academy of Pediatrics recommends exclusive breastfeeding for about the first 6 months of life, followed by continuation of breastfeeding for at least the first year of life.² Increased duration and exclusivity of breastfeeding are most closely linked to improved maternal and child health outcomes. An analysis of the effect of 90% of infants being exclusively breastfed for 6 months revealed that 911 infant deaths could be saved in the United States, most secondary to decreased sudden infant death syndrome.³ A recent meta-analysis revealed that improved breastfeeding globally would annually save 823 000 deaths in children younger than 5 years and 20 000 breast cancer-related deaths in women.⁴ In addition, it found that breastfeeding reduces morbidity and has an economic impact in improving the educational potential of children and their earnings as adults. Improved breastfeeding rates would reduce treatment costs by at least \$2.45 billion annually in the United States alone.¹ Breastfeeding prevents acute infectious diseases, decreases prevalence of obesity and type 2 diabetes, and promotes optimal intellectual development in children, while decreasing maternal risk of breast cancer and ovarian cancer.⁴ These compelling benefits support the premises that breastfeeding is a public health issue, breastfeeding promotion is a public health imperative, and breastfeeding support indeed saves lives.

Breastfeeding initiation occurs in the maternity facility and requires an environment that supports and encourages breastfeeding. Baby-Friendly USA is the entity that designates maternity facilities in the United States that have implemented the Ten Steps to Successful Breastfeeding and follow the World Health Organi-

zation International Code of Marketing of Breast-Milk Substitutes. Facilities go through a process of self-assessment of compliance with the Ten Steps to Successful Breastfeeding and then follow quality improvement methods, using small tests of change, to modify their policies and procedures to improve compliance. With the support of funding from the Centers for Disease Control and Prevention and in accordance with the Surgeon General's Call to Action to Support Breastfeeding, the number of births that occur in maternity facilities designated as Baby-Friendly increased from 1.79% in 2007 to 17.65% in June 2016, exceeding the Healthy People 2020 goal of 8.1%. During that same period, national rates of initiation of breastfeeding increased from 73.8% to 80%, breastfeeding at 6 months increased from 41.5% to 53.9%, and exclusive breastfeeding rates at 6 months increased from 11.3% to 21.9%, concurrent with the emphasis on implementation of Baby-Friendly practices and the assessment of Maternity Practices in Infant Nutrition and Care surveys conducted biannually by the Centers for Disease Control and Prevention.⁵

The Ten Steps to Successful Breastfeeding include development of a breastfeeding policy, education of all staff, and altering the paradigm under which maternity care is delivered. A key element involves allowing as much uninterrupted contact between the newborn and family as possible, beginning immediately after birth with skin-to-skin care and followed by continuous rooming in throughout the hospital stay. A meta-analysis of 34 randomized trials with 2177 participants revealed that early postpartum skin-to-skin contact increased breastfeeding rates, with no clear negative outcomes.⁶ In addition, skin-to-skin contact decreases hypothermia, hypoglycemia, and crying and promotes cardiorespiratory stability, especially in the late-preterm newborn. One study found that rooming in increased exclusive breastfeeding during the first few days of life.⁷

Sudden unexpected postnatal collapse is a rare but potentially fatal event in otherwise healthy-appearing term newborns. Mothers are naturally exhausted and are at risk for falling asleep and/or dropping their newborn, especially after cesarean deliveries. The mother-infant dyad needs careful observation during the postpartum period, whether the mother is giving skin-to-skin care, breastfeeding, bottle feeding, or even just holding her infant. This is true whether the infant is rooming in or is sent to the mother for feedings. If the mother is sleepy, the infant should be moved to a separate sleep surface next to the mother's bed. This can be done by hospital staff or by support persons.

While pacifier use has been recommended as a means to decrease the risk of sudden infant death

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syndrome, a meta-analysis of 21 trials found that the use of pacifiers was associated with shortened duration of both exclusive and any breastfeeding.⁸ The American Academy of Pediatrics has recommended that pacifier use be restricted for healthy, term newborns until breastfeeding has been well established, to promote a good maternal milk supply and to eliminate potential risk of nipple confusion, especially during the first few weeks of life when sudden infant death syndrome is less common.²

Infant safety and the prevention of sudden unexpected postnatal collapse are of paramount importance, but so are implementation of the Ten Steps to Successful Breastfeeding and designation of Baby-Friendly maternity facilities. These are not mutually

exclusive goals and both can save infant lives. Pediatricians and other health care professionals need education about how to protect, promote, and support breastfeeding. All members of the health care team should be trained to assess newborns and provide appropriate education to new parents. Neither skin-to-skin care nor rooming-in negates the requirement for trained mother-baby staff to continue to monitor newborns throughout the postpartum stay. There is a link between the BFHI, perinatal care quality, and in-hospital exclusive breastfeeding rates. Instead of abandoning the demonstrated benefits of the BFHI, promoting safe and effective assessment of babies should complement the implementation of the Ten Steps to Successful Breastfeeding.

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VIEWPOINT

Unintended Consequences of Current Breastfeeding Initiatives

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Viewpoint

Promoting and supporting breastfeeding during the postpartum period has been an important and appropriate priority for maternity units in recent years. The Ten Steps to Successful Breastfeeding of the Baby-Friendly Hospital Initiative have been implemented by an increasing number of hospitals as the standard of care for optimally supporting breastfeeding from birth to hospital discharge.¹ As some or all of these steps are increasingly being promoted as standard of care by government agencies (eg, the Centers for Disease Control and Prevention) and by The Joint Commission, it is important to be certain that the basis for the recommendations has been documented in reproducible scientific studies and that the benefits of the practices recommended outweigh the risks. Unfortunately, there is now emerging evidence that full compliance with the 10 steps of the initiative may inadvertently be promoting potentially hazardous practices and/or having counterproductive outcomes.

The wording of the 10 steps themselves may not suggest a potential for risk. However, the specific guidelines for Baby-Friendly designation provide the cause for concern. For example, to comply with step 4 (help mothers initiate breastfeeding within 1 hour of birth), the guidelines state that all mothers should have continuous skin-to-skin contact with their baby immediately after birth until completion of the first feeding and that skin-to-skin contact should also be encouraged throughout the hospital stay,¹ a time period when direct continuous observation by medical care professionals is not likely to occur. Although a recent Cochrane Review provides evidence for the benefits of skin-to-skin care for healthy full-term and late preterm infants for the first hour after birth, it also stipulates that mother and baby not be left unattended while skin-to-skin care takes place during this early period.² Reports of sudden unexpected postnatal collapse (SUPC) in association with the skin-to-skin practice, published over the past several years, have focused attention on the importance of this caveat.³

Reports of SUPC include both severe apparent life-threatening events (recently referred to as brief resolved unexplained events) and sudden unexpected death in infancy occurring within the first postnatal week of life.³ A comprehensive review of this issue identified 400 case reports in the literature, mostly occurring during skin-to-skin care, with one-third of the events occurring in the first 2 hours after birth and the remainder in the subsequent week of life.³ The review reported death in half of the cases and persistent disability in the majority of survivors. European rates of SUPC varied from 2.6 to 74 cases per 100 000 births, with higher rates related to the length of the inclusion period and infant care practices related to prone sleeping

and co-bedding.³ Furthermore, a recent publication from the American Academy of Pediatrics observed that lawsuits have surfaced in US hospitals attributed to unexpected respiratory arrest in apparently healthy newborns during early skin-to-skin care and cautioned that this practice needs to be balanced with the need to implement safe sleep practices with monitoring of infants during skin-to-skin care unless direct observation takes place.⁴

While breastfeeding exclusivity (step 6) and 24-hour rooming in (step 7) have demonstrated benefits in the postpartum period, these practices may also engender risk. An overly rigid insistence on these steps in order to comply with Baby-Friendly Hospital Initiative criteria may inadvertently result in a potentially exhausted or sedated postpartum mother being persuaded to feed her infant while she is in bed overnight, when she is not physically able to do so safely. This may result in prone positioning and co-sleeping on a soft warm surface in direct contradiction to the Safe Sleep Recommendations of the National Institutes of Health. In addition, co-sleeping also poses a risk for a newborn falling out of the mother's bed in the hospital, which can have serious consequences.⁵ There is also the possibility that unsafe sleep practices modeled in the hospital may continue at home.⁶

The justification for breastfeeding exclusivity is based on a 1998 World Health Organization review of the evidence for the 10 steps.⁷ However, that review included evidence that when supplementation was given for a medical indication, there was no adverse effect on the duration of breastfeeding. It also concluded, based on the available evidence, that it was not clear to what extent supplementation in other circumstances was a marker of breastfeeding difficulty rather than an actual cause of breastfeeding failure.

Another issue of concern is the ban on pacifier use (step 9). Compliance requires that mothers be educated repeatedly that pacifiers may interfere with the development of optimal breastfeeding.¹ Because there is strong evidence that pacifiers may have a protective effect against sudden infant death syndrome (SIDS), the American Academy of Pediatrics has suggested avoidance of pacifiers only until breastfeeding is established at approximately 3 to 4 weeks of age.⁸ Because a substantial number of SUPC events occur during the first week of life,³ this recommendation to proscribe the use of pacifiers is difficult to defend based on risk.

Preventing the unintended serious outcomes from these practices has been made more challenging by the emphasis on breastfeeding exclusivity in the perinatal measures recently promulgated by The Joint Commission. Measure PC-05 requires documentation of the

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reasons for not exclusively breastfeeding, with no allowable exceptions for newborn conditions. In addition, the Centers for Disease Control and Prevention actively promotes the "10 Steps" and Baby-Friendly designation, and monitors "10 Steps" compliance in the United States. In Massachusetts, the recently enacted Massachusetts Health Quality Measure 3A requires increasing rates of breastfeeding exclusivity, with soon to be implemented financial implications.

In an effort to explore the potential effect of these initiatives, we reviewed data from the Massachusetts Department of Public Health Registry of Vital Records and Statistics concerning statewide rates of sudden unexplained infant deaths among newborns. This includes *International Classification of Diseases* codes R95 (SIDS), R99 (undetermined cause and manner), W75 (accidental suffocation), and W84 (unspecified threat to breathing). While SIDS in the first month of life is generally considered an uncommon event, in Massachusetts (2004-2013), 14% of the cases of SIDS occurred in the first 28 days of life. Of note, 8 (22.2%) of the cases of SIDS among newborns and 20 (35.1%) of the newborn sudden unex-

plained infant deaths occurred in the first 5 days of life, suggesting that the concerns raised in the recent American Academy of Pediatrics report⁴ may be more common than previously recognized.

In 2011, the Office of the Surgeon General issued a call to action to support breastfeeding that proposed the accelerated implementation of the Baby-Friendly Hospital Initiative in the United States.⁹ Considering the available evidence, that recommendation should be reconsidered. If government and accreditation agencies wish to encourage and support breastfeeding, their focus should shift from monitoring Baby-Friendly practices and breastfeeding exclusivity to monitoring breastfeeding initiation rates coupled with evidence of lactation support both during and after the hospital stay. More attention should also be placed on ensuring compliance with established safe sleep programs, emphasizing the need to integrate safe sleep practices with breastfeeding. Hospitals should direct their efforts toward implementing practices that will promote breastfeeding safely, the common goal of both private and public groups with an interest in these issues.

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From: MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO)
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Subject: FW: GEC Release
Attachments: Baby Friendly GEC Final.pdf

I think she probably sent this to you all as well – but just in case.

From: Trish MacEnroe (b)(6)
Sent: Thursday, July 22, 2021 4:42 PM
To: MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO) <dvx2@cdc.gov>
Subject: GEC Release

Dear Carol,

I just wanted to be sure that you knew that Baby-Friendly USA's updated Guidelines and Evaluation Criteria were released today. We also plan to release the NICU materials in the next 2 – 3 weeks.

Now that the GEC are released, I will be transitioning out of my fulltime role with Baby-Friendly USA effective July 30. My heartfelt thanks for the many years of collaboration and friendship. I truly treasure our work together.

Keep up your great work.

Best,

Trish MacEnroe
Senior Policy Advisor to the CEO
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THE BABY-FRIENDLY HOSPITAL INITIATIVE

Guidelines and Evaluation Criteria

SIXTH EDITION



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The 2018 UNICEF/WHO Protecting, Promoting and Supporting Breastfeeding in Facilities Providing Maternity and Newborn Services: the revised Baby-Friendly Hospital Initiative.

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See Appendix G

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Association of Women's Health Obstetric and Neonatal Nurses (AWHONN)
United States Lactation Consultant Association (USLCA)



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INTRODUCTION

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BABY-FRIENDLY HOSPITAL INITIATIVE (BFHI) was established in 1991 by the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO). The BFHI is a global program to support the implementation of the *Ten Steps to Successful Breastfeeding (the Ten Steps)* and the *International Code of Marketing of Breast-milk Substitutes (the International Code)* in maternity facilities. "The core purpose of the BFHI is to ensure that mothers and newborns receive timely and appropriate care before and during their stay in a facility providing maternity and newborn services, to enable the establishment of optimal feeding of newborns, which promotes their health and development. Given the proven importance of breastfeeding, the BFHI protects, promotes and supports breastfeeding while enabling timely and appropriate care and feeding of newborns who are not *(yet or fully)* breastfed."¹

An important philosophy of the Initiative is that "families must receive quality and unbiased information about infant feeding. Facilities providing maternity and newborn services have a responsibility to promote breastfeeding, but they must also respect the mother's preferences and provide her with the information needed to make an informed decision about the best feeding option for her and her infant. The facility needs to support mothers to successfully feed their newborns in the manner they choose."¹

In 2015, WHO and UNICEF embarked on a process to review the most current scientific evidence pertaining to each of the Ten Steps and update the implementation guidance for the BFHI. Their goal was to reinvigorate the BFHI with the aim of worldwide adoption of the Ten Steps in all facilities providing birthing services.

The results of their work were published in two separate key documents:

GUIDELINE: *Protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services*² This is a review of the evidence for each individual step of the Ten Steps. It is NOT a review the evidence for the combined impact of multiple steps.

IMPLEMENTATION GUIDANCE: *Protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services: the revised BABY-FRIENDLY HOSPITAL INITIATIVE*¹ (2018 Implementation Guidance)

The 2018 Implementation Guidance established global standards for each of the Ten Steps while calling on nations to customize the materials to address specific national goals. BFUSA engaged in a robust process to revise the Initiative for the US. An immediate and thorough review of the two key documents was conducted. A document was developed comparing the new guidance and standards with the existing US Guidelines and Evaluation Criteria (GEC) to determine if any immediate changes could be implemented. It was determined that adjustments to the requirements for Step 9 were warranted. Therefore, revised versions of the US GEC were published in July 2018 and December 2019.

In the meantime, an expert panel consisting of individuals with widespread knowledge and experience with implementing the BFHI standards was convened for a face-to-face meeting in August 2018. Based on its review of the updated evidence, the new implementation guidance, and the comparison with the existing standards, the panel recommended revisions to customize the global guidance for applicability to the US. These revisions were incorporated into updated documents and submitted to the expert panel, the BFUSA Board of Directors, Clinical Committee and several key national professional health organizations for further input. Those organizations included: Academy of Breastfeeding Medicine, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American College of Nurse Midwives, Association of Women's Health, Obstetric and Neonatal Nurses and the United States Lactation Consultant Association.

The expert panel was reconvened in July 2019 to review the comments received in the latest review stage and assist with finalizing the guidance, standards and evaluation criteria for the US. The last component of the process was the incorporation of "Performance indicators demonstrating staff competency to implement" based on WHO and UNICEF's Competency Verification Toolkit: Ensuring Competency of Direct Care Providers to Implement the Baby-Friendly Hospital Initiative released on August 5, 2020.³

REVISIONS TO THE TEN STEPS TO SUCCESSFUL BREASTFEEDING

An important component of the effort to reinvigorate the BFHI by WHO and UNICEF was a review of the evidence for each of the Ten Steps to Successful Breastfeeding. Upon completing this task, the WHO and UNICEF then evaluated the actual wording for each Step. They concluded that the theme of each Step was appropriate but some of the phrasing needed to be changed to better align with the evidence.

Several noteworthy changes include: the incorporation of the International Code of Marketing of Breast-milk Substitutes and monitoring procedures into Step 1 and a shift in the focus of Step 2 from an emphasis on a specific number of hours of training to competency verification.

It is also worth pointing out that the steps are now divided into critical management procedures and key clinical practices. The chart to the right compares the 2018 revised version to the original 1989 Ten Steps.

TEN STEPS TO SUCCESSFUL BREASTFEEDING	
REVISED IN 2018	ORIGINAL
CRITICAL MANAGEMENT PROCEDURES 1 A. Comply fully with the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions. 1 B. Have a written infant feeding policy that is routinely communicated to staff and parents. 1 C. Establish ongoing monitoring and data-management systems. 2. Ensure that staff have sufficient knowledge, competence and skills to support breastfeeding.	1. Have a written breastfeeding policy that is routinely communicated to all health care staff. 2. Train all health care staff in the skills necessary to implement this policy. 3. Inform all pregnant women about the benefits and management of breastfeeding. 4. Help mothers initiate breastfeeding within one hour of birth. 5. Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.
KEY CLINICAL PRACTICES 3. Discuss the importance and management of breastfeeding with pregnant women and their families. 4. Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth. 5. Support mothers to initiate and maintain breastfeeding and manage common difficulties. 6. Do not provide breastfed newborns any food or fluids other than breast-milk, unless medically indicated. 7. Enable mothers and their infants to remain together and to practice rooming-in 24 hours a day. 8. Support mothers to recognize and respond to their infants' cues for feeding. 9. Counsel mothers on the use and risks of feeding bottles, artificial nipples (teats) and pacifiers. 10. Coordinate discharge so that parents and their infants have timely access to ongoing support and care.	6. Give infants no food or drink other than breast-milk, unless medically indicated. 7. Practice rooming-in — allow mothers and infants to remain together 24 hours a day. 8. Encourage breastfeeding on demand. 9. Give no pacifiers or artificial nipples to breastfeeding infants. 10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

DOCUMENT CONTENT AND FORMAT

It is the goal of BFUSA to implement a program for the US that remains as closely aligned with the global initiative as possible, while at the same time, addressing the US needs and circumstances. As such, within the Guidelines and Evaluation Criteria section, as much specific language as possible was used from the 2018 (WHO/UNICEF) Implementation Guidance. (**NOTE:** some words were changed from the European to American spelling and some small amounts of text containing guidance unrelated to US hospitals were removed in order to avoid confusion.) Where necessary, additional US language within the implementation for each step were added in *italics*.

The document is organized according to the 2018 Ten Steps to Successful Breastfeeding. It must be noted that “while each of the Ten Steps contributes to improving the support for breastfeeding, optimal impact on breastfeeding practices, and thereby on maternal and child well-being, is only achieved when all Ten Steps are implemented as a package.”¹ This entire document should be read with this point in mind.

Each step consists of the following sections:

- **THE STEP NUMBER AND NAME**
- **RATIONALE**
- **IMPLEMENTATION GUIDANCE**
- **CONSIDERATIONS FOR SAFE IMPLEMENTATION**
- **PERFORMANCE INDICATORS DEMONSTRATING STAFF COMPETENCY TO IMPLEMENT**
- **STANDARDS**
- **CRITERIA FOR EVALUATION**
- **REFERENCES ARE FOUND AT THE END OF THE DOCUMENT**

It is also important to point out that the BFHI is typically focused on the healthy term infant, however, in the US many late preterm infants are cared for on the postpartum floor. Therefore, some guidance and standards are relevant to their care. In some cases, the 2018 Implementation Guidance specifies if a standard applies to term infants or preterm infants. BFUSA felt it was more appropriate to remove the “term” and “preterm” language from the standard. Instead, the standard applies to where the mother, baby, or both are being cared for. In addition, a NICU Toolkit offering a comprehensive set of clinical practice recommendations geared towards increasing the use of breastfeeding and human milk in neonatal intensive care management has been developed.

This toolkit will be posted to www.babyfriendlyusa.org by the end of summer 2021.

DESCRIPTION OF SECTIONS INCLUDED IN EACH STEP

STEP NAME AND NUMBER: appears exactly as it is worded in the 2018 BFHI Implementation Guidance.

RATIONALE: offers insight into the purpose of the step and appears in this document exactly as it is worded in the 2018 BFHI Implementation Guidance.

IMPLEMENTATION GUIDANCE: provides critical information to support the standards which facilities should strive to achieve for all patients. This language is predominantly taken from the 2018 Implementation Guidance, with some adjustments in *italics* for applicability to the US. (**NOTE:** some words were changed from the European to American spelling and some small amounts of text containing guidance unrelated to US hospitals were removed in order to avoid confusion.)

US CONSIDERATIONS FOR SAFE IMPLEMENTATION: are suggested documents, policies, and/or protocols from either a recognized national/international medical professional organization or US governmental department, WHO or UNICEF that may assist facilities with the safe implementation of the step.

PERFORMANCE INDICATORS DEMONSTRATING STAFF COMPETENCY TO IMPLEMENT: are the knowledge, skills and attitudes that are necessary for staff to properly implement the step. They are mostly drawn from the WHO/UNICEF Competency Verification Toolkit titled “Ensuring Competency of Direct Care Providers to Implement the Baby-Friendly Hospital Initiative”, however six Performance Indicators were developed specifically for the United States.

STANDARDS: are predominantly taken from the 2018 Implementation Guidance, with some adjustments in *italics* for applicability to the US.

CRITERIA FOR EVALUATION: are the specific quantifiable measures used by Baby Friendly USA (BFUSA) assessors to determine the birthing facility’s conformity with the BFHI.

IMPORTANCE OF BREASTFEEDING

Human milk provided by direct breastfeeding is the biologically normal way to feed an infant. There are very few true contraindications to breastfeeding and scientific evidence overwhelmingly indicates that it is nutritionally superior, offers substantial immunological and health benefits, facilitates mother-baby bonding, and should be promoted and supported to ensure the best health for women and their children. Breastfeeding is the single most powerful and well-documented preventative modality available to health care providers to reduce the risk of common causes of infant morbidity. Significantly lower rates of diarrhea, otitis media, lower respiratory tract infections, Type 1 and Type 2 diabetes, childhood leukemia, necrotizing enterocolitis, and Sudden Infant Death Syndrome occur among those who were breastfed.^{4, 5} Breastfeeding also supports the healthy development of an infant’s gut microbiome⁶ and is shown to be inversely associated with overweight risk.⁷

Women who breastfeed have a lower risk of Type 2 diabetes, hypertension and breast and ovarian cancers.^{4, 8, 9} Evidence suggests that reduction in the risk of cardiovascular and other related diseases may be added to the benefits of breastfeeding for women.^{10, 11} The American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the Centers for Disease Control and Prevention, and the World Health Organization all recommend exclusive breastfeeding for about 6 months and continued breastfeeding while adding complimentary foods for one year and beyond.

Despite the significant gains made during the past few years, the initiation, duration, and exclusivity of breastfeeding continue to lag

behind the national objectives, and racial disparities persist. In 2017, approximately 84% of all women initiated breastfeeding; however, only 74% of non-Hispanic black women and 77% of women with incomes below the poverty line initiated breastfeeding.¹²

While causes of this trend are multifactorial and complex, health care practices have been shown to play a fundamental role in impacting breastfeeding initiation, exclusivity, and duration. Unsupportive practices during the perinatal period can disrupt the unique and critical link between the prenatal education and the community postpartum support provided after discharge from the birthing facility. Conversely, supportive practices positively impact breastfeeding outcomes. The Ten Steps to Successful Breastfeeding, which form the foundation of the Baby-Friendly Hospital Initiative, are a package of evidence-based practices shown to improve breastfeeding outcomes. Studies have shown that the more steps a mother reports experiencing, the more likely she is to meet her breastfeeding goals.^{13,14}

CULTURAL HUMILITY AND RESPECT: ADDRESSING THE DIVERSE NEEDS OF PATIENTS

The Guidelines and Evaluation Criteria will directly affect all birthing individuals, pregnant women, mothers, and their infants and children. The practices described in this document apply equally to parents who may not identify as “women” or “mothers”, including transgender and non-binary parents. The terms “mother” and “breastfeeding” are used throughout this document, reflecting the fact that the biological norm is female persons who give birth to infants and feed them at the breast.

However, BFUSA wants to emphasize that we are respectful and mindful of the many different family types that exist in the US in which these terms do not necessarily represent the circumstances or norms of the family. This includes, but is not limited to, situations such as surrogacy, chest-feeding, or other circumstances in which persons who give birth to infants do not identify as “women” or “mothers,” including transgender and nonbinary parents who may experience difficulty accessing culturally safe care.

We also want to highlight that different racial and ethnic groups have unique cultural norms that may affect a family’s decision-making process. Achieving equity in breastfeeding is a key objective of the BFHI. This requires that leadership create an environment that enables and supports the availability of and access to quality breastfeeding support for all patients equally. It also requires that practitioners address the needs of diverse populations through breastfeeding counselling, safeguard privacy, and respect each individual’s right to make informed and autonomous decisions.

Our expectation is that all families will be embraced and supported equally and that all patients will be provided the highest standard of individualized infant feeding care. Staff should engage in meaningful conversations with families — especially those with unique circumstances — to ensure the health professionals in charge have a clear understanding of each family’s specific wishes and fully support each family’s unique birth plan.

GUIDELINES AND EVALUATION CRITERIA FOR FACILITIES SEEKING TO ATTAIN AND SUSTAIN BABY-FRIENDLY® DESIGNATION

The Baby-Friendly USA Guidelines and Evaluation Criteria and the assessment and accreditation processes are predicated on the following tenets:

1. Well-constructed, comprehensive policies effectively guide staff to deliver evidence-based care.
2. Well-trained staff provide quality, evidence-based care.
3. Monitoring of practice is required to ensure adherence to policy and sustained standard of care.
4. The mother and her family should be protected within the health care setting from false or misleading product promotion and/or advertising which interferes with or undermines informed decisions regarding infant health care practices.
5. Facility staff should be protected from product promotion and/or advertising which may impact their professional activities and judgment.
6. Breastfeeding has been recognized by scientific authorities as the optimal method of infant feeding and should be the norm within all maternal and child health care facilities.
7. Facilities should follow the most scientifically sound, respectful, safe and effective procedural approaches to supporting breastfeeding and human lactation in the birthing environment.
8. The health care delivery environment should facilitate informed health care decisions on the part of the mother and her family. It should not be either restrictive or punitive.
9. The health care delivery environment should be culturally respectful and mindful of the diverse needs of the patients.
10. When a mother has chosen not to breastfeed, when supplementation of breastfeeding is medically indicated, or when supplementation is a decision by the breastfeeding mother (after appropriate conversations and education), it is crucial that safe and appropriate methods of formula preparation, handling, storage, and feeding are taught to the parents.
11. Recognition as a Baby-Friendly institution should have both national and international credibility and prestige, so that it is marketable to the community, increases demand, and thereby improves motivation among facilities to participate in the Initiative.
12. Participation of any facility in the U.S. BFHI is entirely voluntary and is available to any institution providing birthing services.
13. Each participating facility assumes full responsibility for assuring that its implementation of the BFHI is consistent with all of its safety protocols.

FACILITY POLICIES



Step 1 includes three critical management procedures:

STEP 1A

Application of the International Code of Marketing of Breast-milk Substitutes

STEP 1B

Development of written policies

STEP 1C

Operation of monitoring and data-management systems

Comply fully with the
International Code of
Marketing of Breast-milk
Substitutes and relevant
World Health Assembly
resolutions.

RATIONALE:

Families are most vulnerable to the marketing of breast-milk substitutes during the entire prenatal, perinatal, and postnatal period when they are making decisions about infant feeding. The WHA (*World Health Assembly*) has called upon health workers and health-care systems to comply with the International Code of Marketing of Breast-milk Substitutes^{15,16} and subsequent relevant WHA resolutions¹⁷ (the *International Code*), in order to protect families from commercial pressures and influences. Additionally, health professionals themselves need protection from commercial influences that could affect their professional activities and judgement. Compliance with the *International Code* is important for facilities providing maternity and newborn services, since the promotion of breast-milk substitutes is one of the largest undermining factors for breastfeeding.¹⁸

Companies marketing breast-milk substitutes, feeding bottles and *artificial nipples [including pacifiers]* are repeatedly found to violate the *International Code*.^{19,20} It is expected that the sales of breast-milk substitutes will continue to increase globally, which is detrimental for children's survival and well-being.^{21,22} This situation means that ongoing concerted efforts will be required to protect, promote and support breastfeeding, including in facilities providing maternity and newborn services.¹

IMPLEMENTATION GUIDANCE:

THE INTERNATIONAL CODE^{15,16} lays out clear responsibilities of healthcare systems to not promote infant formula, feeding bottles or *artificial nipples [including pacifiers]* and to not be used by manufacturers and distributors of products under the scope of the *International Code* for this purpose. This includes the provision that all facilities providing maternity and newborn services must acquire any breast-milk substitutes, feeding bottles or *artificial nipples [including pacifiers]* they require through normal procurement channels and not receive free or subsidized supplies.²³ Furthermore, staff of facilities providing maternity and newborn services should not engage in any form of promotion or permit the display of any type of advertising of breast-milk substitutes, *feeding bottles*, and/or infant feeding supplies [*pacifier promotion must meet the requirements specified in Criterion 9.2.1*] including the

display or distribution of any equipment or materials bearing the brand of manufacturers of breast-milk substitutes, or discount coupons, and they should not routinely give samples of infant formula to mothers to take home.¹

In line with the [WHO GUIDANCE ON ENDING THE INAPPROPRIATE PROMOTION OF FOODS FOR INFANTS AND YOUNG CHILDREN](#), published in 2016 and endorsed by the WHA,²⁴ health workers and health systems should avoid conflicts of interest with companies that market foods for infants and young children. Health-professional meetings should never be sponsored by industry covered by the *International Code* and industry covered by the *International Code* should not participate in parenting education.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Health professionals and institutions should avoid activities with commercial influences that could affect their professional activities and judgement. Below are a few examples:

AVOIDANCE OF CONFLICTS OF INTEREST

POTENTIAL CONFLICT	<i>Allowing companies that manufacture and/or market breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers] to sponsor and/or host trainings, events, meetings, and scientific seminars on breastfeeding.</i>
POTENTIAL HARM	<i>Associating the name of the respected health facility with a company implies facility endorsement of that company and/or its products. This may unintentionally sway health professionals to recommend products to patients that are not specific to their needs.</i>
REQUIREMENT	<i>Criterion 1A.3.1 requires that no items bear product images or product logos of companies that produce breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers] or names of products covered under the International Code unless specific to the pregnant woman's, mother's or infant's needs or conditions. Criterion 1A.4.4 calls for the facility to have a policy that describes how the facility and its staff members: do not receive support/sponsorship for events/meetings.</i>

POTENTIAL CONFLICT	<i>Health professionals attending trainings sponsored by companies that manufacture and/or market breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers].</i>
POTENTIAL HARM	<i>Receipt of meals and/or free registration to meetings creates a potential obligation to favor that company's products over other products.</i>
REQUIREMENT	<i>Criterion 1A.4.4 calls for the facility have a policy that describes how the facility and its staff members do not receive free gifts.</i>

POTENTIAL CONFLICT	<i>Receipt of awards and gifts by the staff or facility from companies that manufacture and/or market breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers].</i>
POTENTIAL HARM	<i>It associates a company's name with a respected staff member setting that staff member up as "role model" for others. This may imply the staff member's endorsement of a product or company.</i>
REQUIREMENT	<i>Criterion 1A.4.4 calls for the facility have a policy that describes how the facility and its staff members do not receive free gifts, [Examples include meals, conference fees].</i>

US CONSIDERATIONS FOR FACILITIES THAT COORDINATE WITH OUTSIDE AGENCIES THAT ALSO DISCUSS INFANT FEEDING WITH MOTHERS AND THEIR SUPPORT SYSTEMS:

*All facilities are encouraged to coordinate services with other community programs that provide counseling, support, and education on breastfeeding. Some facilities have developed processes that begin coordinating services during the birth hospitalization. While these services offer many benefits to families, hospitals should coordinate efforts to minimize interruptions to mothers during the hospital stay. This will allow maximum opportunity for mothers to recover from birth, bond with their babies and learn their feeding cues. Outside agencies interacting with mothers in the hospital setting should have sufficient training to support exclusive breastfeeding. Procedures should be established between the facility and the outside agency as to how the outside agency should respond and support the breastfeeding mother who requests formula from them while in the hospital setting. **Compliance with the International Code is essential in protecting mothers who are still making decisions about infant feeding.***

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 1A	VERIFICATION METHOD
1. List at least 3 products that are covered by the Code.	Question or case study
2. Describe at least 3 ways a direct care provider/direct care staff member protects breastfeeding in practice.	Question or case study
3. Describe at least 1 way a direct care provider/direct care staff member should respond if offered information provided by manufacturers and/or distributors of products within the scope of the Code.	Question or case study
4. Describe at least 1 type of financial or material inducement that might be offered to a direct care provider/direct care staff member by a manufacturer and/or distributor of products within the scope of the Code.	Question or case study
5. Describe at least 1 harm of a direct care provider/direct care staff member accepting financial or material inducements.	Question or case study
6. Explain at least 2 ways that the facility and any affiliated prenatal services ensure that there is no promotion of infant formula, feeding bottles, or <i>artificial nipples</i> in any part of facilities providing maternity and newborn services, or by any of the direct care providers/direct care staff.	Question or case study



THE FOLLOWING STANDARDS APPLY

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1A.1 All infant formula, feeding bottles and artificial nipples [including pacifiers] used in the facility have been purchased through normal procurement channels and not received through free or subsidized supplies.	<p>A review of records will confirm:</p> <p>Criterion 1A.1.1 A review of records [invoices and proofs of payment] indicates that infant formula, feeding bottles and artificial nipples [including pacifiers] used in the facility have been purchased at a fair market price through normal procurement channels and not received through free or subsidized supplies or rebates that drop the price below the fair market price.</p>
1A.2 Health professionals who provide prenatal, delivery and/or newborn care can explain at least two elements of the International Code.	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>Criterion 1A.2.1 At least 80% of health professionals who provide prenatal, delivery, postpartum, and/or well newborn units can explain at least two elements of the International Code.</p> <ul style="list-style-type: none"> A. Direct care nursing staff, AND B. Direct care providers with privileges
1A.3 The facility [including affiliated prenatal services] has no display of products covered under the International Code or items with logos of companies that produce breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers], or names of products covered under the International Code.	<p>A review and/or observation of items will confirm:</p> <p>Criterion 1A.3.1 A review of submitted and/or observed items in the facility [including affiliated prenatal services] will confirm that no items bear product images or product logos of companies that produce breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers] or names of products covered under the International Code unless specific to the pregnant woman's, mother's or infant's needs or conditions. (For example, information about how to safely use a needed product such as a formula or a specialty bottle would be acceptable to give to a mother or infant needing that specific product. Marketing information for such products would not be acceptable.)</p> <ul style="list-style-type: none"> A. In the affiliated prenatal clinic/service, AND B. In the birthing facility <p>continued</p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
<p>1A.3 The facility [including affiliated prenatal services] has no display of products covered under the <i>International Code</i> or items with logos of companies that produce breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers], or names of products covered under the <i>International Code</i>.</p>	<p>A review and/or observation of items will confirm:</p> <p>Criterion 1A.3.2 A review of submitted and/or observed items displayed and/or distributed to pregnant women, mothers, or staff in the facility [including affiliated prenatal services] will confirm all items are free of messages that promote or advertise breast-milk substitutes, feeding bottles, and artificial nipples or other infant feeding supplies.</p> <p>A. In the affiliated prenatal clinic/service, AND</p> <p>B. In the birthing facility</p> <p>Criterion 1A.3.3* A review of submitted and/or observed items in the facility [including affiliated prenatal services] will confirm that any items displayed or distributed to pregnant women and mothers are free of messages that promote or advertise the use of pacifiers, except safe sleep and SUIDS/SIDS risk reduction materials which must contain additional language to promote breastfeeding. [See criterion 9.2.1]</p> <p>A. In the affiliated prenatal clinic/service, AND</p> <p>B. In the birthing facility</p> <p>Observation will confirm:</p> <p>Criterion 1A.3.4 Observations will confirm that infant formula is kept out of view of patients and the general public.</p> <p>A. In the affiliated prenatal clinic/service, AND</p> <p>B. In the birthing facility</p>

CLARIFICATION: CRITERION 1A.3.3* PACIFIERS AND SUIDS/SIDS REDUCTION INFORMATION

BFUSA acknowledges the evidence pertaining to pacifier use related to SUIDS/SIDS risk reduction.²⁵ Safe sleep and SUIDS/SIDS risk reduction information is important for parents to receive during the birth hospital stay.^{26,27} This education may be compatibly provided to parents by using safe sleep materials that also promote breastfeeding. SEE STANDARD 9.2 FOR ADDITIONAL GUIDANCE.

WHO/UNICEF STANDARD	US CRITERIA FOR EVALUATION
<p>1A.4 The facility has a policy that describes how it abides by the <i>International Code</i>, including procurement of breast-milk substitutes, not accepting support or gifts from producers or distributors of products covered by the <i>International Code</i> and not giving samples of breast-milk substitutes, feeding bottles or <i>artificial nipples</i> [including pacifiers] to mothers.</p>	<p>The facility has a policy that describes how it abides by the <i>International Code</i>, including:</p> <p>Criterion 1A.4.1 How the facility procures infant feeding products.</p> <p>Criterion 1A.4.2 How the facility [including affiliated prenatal services] protects pregnant women, mothers, and their families by not allowing the receipt or distribution of:</p> <ul style="list-style-type: none"> ▪ Marketing materials ▪ Samples ▪ Gift packs ▪ Coupons <p>that include breast-milk substitutes, feeding bottles, artificial nipples, and pacifiers, or other infant feeding supplies.</p> <p>Criterion 1A.4.3 How the facility [including affiliated prenatal services] protects pregnant women, mothers and their families by preventing direct contact or indirect contact with the manufacturers and/or distributors of breast-milk substitutes, feeding bottles, artificial nipples, and pacifiers.</p> <ul style="list-style-type: none"> ▪ Direct contact [examples include providing infant feeding hotline numbers staffed by company employees/contractors] ▪ Indirect contact [examples include use of mechanisms to collect mothers' names and provide to companies/contractors through photographers and special discharge programs] <p>Criterion 1A.4.4 How the facility [including affiliated prenatal services] protects itself and its staff members from marketing by manufacturers or distributors of breast-milk substitutes, bottles, nipples, pacifiers or other infant feeding supplies, by precluding the receipt of:</p> <ul style="list-style-type: none"> ▪ Free gifts [Examples include meals, conference fees] ▪ Information that is not scientific, factual, and unbiased ▪ Materials [Examples include posters, magazines] ▪ Promotional items ▪ Equipment ▪ Money ▪ Support for breastfeeding education ▪ Support/sponsorship for events/meetings <p>All other interactions with these manufacturers/distributors are in compliance with the facility's vendor/ethics policy.</p>

Have a written infant feeding policy that is routinely communicated to staff and parents.

RATIONALE:

Policy drives practice. *Health professionals* and institutions are required to follow established policies. The clinical practices articulated in the Ten Steps need to be incorporated into facility policies, to guarantee that appropriate care is equitably provided to all mothers and babies and is not dependent on the *routines and/or* preferences of each *direct care* provider. Written policies are the vehicle for ensuring patients receive consistent, evidence-based care, and are an essential tool for *direct care* staff accountability. Policies help to sustain practices over time and communicate a standard set of expectations for all health workers.¹

IMPLEMENTATION GUIDANCE:

Facilities providing maternity and newborn services should have a clearly written breastfeeding policy that is routinely communicated to staff and parents.² A facility breastfeeding policy may stand alone as a separate document, be included in a broader infant feeding policy, or be incorporated into a number of other policy documents *or protocols*. However organized, the policy should include guidance on how each of the clinical and care practices should be implemented, to ensure that they are applied consistently to all mothers. The policy should also spell out how the management procedures should be implemented, preferably via specific processes that are institutionalized.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Orient all direct care staff and direct care providers who are impacted by the infant feeding policy as soon as possible, no later than 12 weeks post hire.

In order to have safe, effective and sustained improvement in practices, infant feeding policies in facilities providing maternity and newborn services need to cover all established standards of practice, be fully implemented and regularly communicated to direct care staff and direct care providers.² Frequency of communication to staff must occur, minimally, every 2 years.

STEP 1B

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 1A	VERIFICATION METHOD
*7. Describe at least 2 elements that are in the facility's infant feeding policy.	Question or case study
*8. Explain at least 3 ways that the infant feeding policy affects a direct care provider's/direct care staff member's work in <i>providing safe, equitable and appropriate care</i> .	Question or case study

THE FOLLOWING STANDARDS APPLY

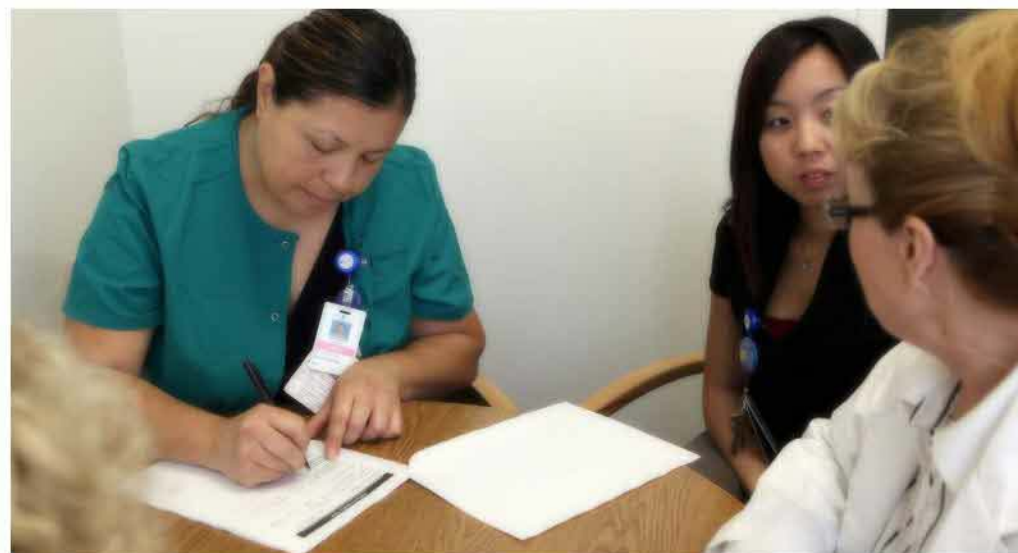
WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1B.5 The health facility has a written infant feeding policy that addresses the implementation of all eight key clinical practices of the Ten Steps, <i>International Code</i> implementation, and regular competency assessment.	<p>A review of the policy will confirm:</p> <p><i>Criterion 1B.5.1</i> The facility will have comprehensive, evidence-based, written maternity care and infant feeding policies that address all Ten Steps, protect breastfeeding, and which includes adherence to the International Code.</p>
1B.6 A review of all clinical protocols or standards related to breastfeeding and infant feeding used by the maternity services indicates that they are in line with BFHI standards and current evidence-based guidelines.	<p>A written description will confirm:</p> <p><i>Criterion 1B.6.1</i> The Director of Maternity will provide a written description of how all the clinical protocols or standards related to breastfeeding and infant feeding used by the maternity services are reviewed and aligned with BFHI standards and current evidence-based guidelines.</p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1B.7 Observations in the facility confirm that a summary of the policy is visible to pregnant women, mothers and their families.	<p>Observations will confirm:</p> <p>Criterion 1B.7.1 Observations in the facility and affiliated prenatal services confirm that The Ten Steps to Successful Breastfeeding (WHO/UNICEF revised 2018) will be visible to pregnant women, mothers and their families. The Ten Steps poster locations include the waiting room and/or admission areas of the following units:</p> <ul style="list-style-type: none"> A. Labor and delivery unit B. Postpartum unit C. Affiliated prenatal services D. Ultrasound, screening/lab, prenatal testing areas E. Newborn nursery/observation area/procedure room F. Neonatal intensive care unit G. Emergency room <p>This information will be displayed in the language(s) most commonly understood by patients.</p> <p>A review of materials will confirm:</p> <p>Criterion 1B.7.2 A review of the content of the Ten Steps posters will verify alignment to the Ten Steps Poster Guide requirements [4-D Pathway document].</p>
1B.8 Clinical staff [Health professionals] who provide prenatal, delivery and/or newborn care can explain at least two elements of the infant feeding policy that influence their role in the facility.	<p>Interviews with direct care nursing staff and direct care provider will confirm:</p> <p>Criterion 1B.8.1 At least 80% of health professionals who provide prenatal, delivery, postpartum, and/or well newborn care can explain at least two elements of the infant feeding policy that influence their role in providing safe, equitable and appropriate care. [PI 8]</p> <ul style="list-style-type: none"> A. Direct care nursing staff, AND B. Direct care providers with privileges <p>Criterion 1B.8.2 At least 80% of health professionals who provide prenatal, delivery, postpartum, and/or well newborn care will confirm that they are aware of the facility's maternity care and infant feeding policies and know where the policies are kept or posted.</p> <ul style="list-style-type: none"> A. Direct care nursing staff, AND B. Direct care providers with privileges <p>continued</p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1B.8 Clinical staff [Health professionals] who provide prenatal, delivery and/or newborn care can explain at least two elements of the infant feeding policy that influence their role in the facility.	<p>A review of materials will confirm:</p> <p>Criterion 1B.8.3 A designated health professional will provide a written description that includes a summary of how and when health professionals are made aware of the infant feeding policy including:</p> <ul style="list-style-type: none"> A. A Process and timeline to orient direct care staff and direct care providers who provide prenatal, delivery and/or newborn care in the implementation of the infant feeding policy, AND B. A Process and frequency for routine communication of all direct care staff and direct care providers who provide prenatal, delivery and/or newborn care. Considerations for routine communication may include: <ul style="list-style-type: none"> ▪ A review of high-risk/safety-related procedural steps, and/or ▪ Updates regarding revisions, and/or ▪ Review of practical skills, and/or ▪ Quality improvement efforts when monitoring data indicates one or more policy practices are not being fully adhered to.

US STANDARD	CRITERION FOR EVALUATION
1B.9 All forms of patient educational materials related to infant feeding (booklets, applications, videos, text, etc.) and a written description of the content of the education, will be made available at assessment. A review of these materials must demonstrate current evidence-based guidance, include all of the required topics listed in Appendix A, and align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding.	<p>A review of educational materials will confirm:</p> <p>Criterion 1B.9.1 Prenatal Education: All forms of patient educational materials related to infant feeding (booklets, applications, videos, text, etc.) and a written description of the content of the education provided to pregnant women during the prenatal period [including both affiliated prenatal services and in-house programs], will be made available at assessment. A review of these materials must:</p> <ul style="list-style-type: none"> A. Demonstrate current evidence-based guidance, AND B. Include all of the required topics listed in Appendix A, AND C. Align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding. <p>Criterion 1B.9.2 Postpartum Breastfeeding Education: All forms of educational materials related to infant feeding (booklets, applications, videos, text, etc.) and/or a description of the content of the education, provided to postpartum breastfeeding mothers during the birth hospitalization will be made available at assessment. A review of these materials must:</p> <ul style="list-style-type: none"> A. Demonstrate current evidence-based guidance, AND B. Include all of the required topics listed in Appendix A, AND C. Align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding. <p><i>continued</i></p>

US STANDARD	CRITERION FOR EVALUATION
<p>1B.9 All forms of patient educational materials related to infant feeding (booklets, applications, videos, text, etc.) and a written description of the content of the education, will be made available at assessment. A review of these materials must demonstrate current evidence-based guidance, include all of the required topics listed in Appendix A, and align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding.</p>	<p>A review of educational materials will confirm:</p> <p>Criterion 1B.9.3 Postpartum Infant Formula Feeding Education: All forms of educational materials related to infant feeding (booklets, applications, videos, text, etc.) and/or a description of the content of the education, provided to formula feeding mothers during the birth hospitalization will be made available at assessment. A review of these materials must:</p> <ul style="list-style-type: none"> A. Demonstrate current evidence-based guidance, AND B. Include all of the required topics listed in Appendix A, AND C. Align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding.



Establish ongoing monitoring and data-management systems.

RATIONALE:

Facilities providing maternity and newborn services need to integrate recording and monitoring of the clinical practices related to breastfeeding into their quality-improvement/monitoring systems.¹

IMPLEMENTATION GUIDANCE:

IMPLEMENTATION: *A fundamental principle of the BFHI is that monitoring of practices is required to confirm adherence to policies and evidence-based care. Indicators for facility-based monitoring of the required key clinical practices are listed in APPENDIX B: INDICATORS FOR FACILITY MONITORING KEY CLINICAL PRACTICES. The monitoring data for certain indicators will be collected from medical records and reported on the Facility Data Sheet located in the BFUSA portal. Specific guidance on numerator and denominator inclusions and exclusions are found in the instructions for each indicator on the Facility Data Sheet. Two of the indicators, early initiation of breastfeeding and exclusive breastfeeding, are considered "sentinel indicators". A sentinel indicator captures an essential element that serves as a bellwether in a complex change process. "Sentinel indicators are placed at critical points in a system map to help monitor and inform the mutually influencing relationship between the program and its context."^{28, 29} Facilities should routinely track all required indicators for each mother–infant pair. Recording of information on the indicators should be incorporated into the medical charts and extracted into relevant reports and/or dashboards.¹ The monitoring data for indicators not included on the Facility Data Sheet will be collected through audits and/or surveys, also located in the BFUSA portal.*

Each facility must form a multi-disciplinary committee, which must consist of some direct care providers and direct care staff, to guide the work towards implementation of these Guidelines and Evaluation Criteria. This committee will retain a key post-designation role which will include monitoring the required key clinical practices to ensure sustainability and should meet to review progress at least every 6 months. During concentrated periods of implementation of a practice and/or quality improvement, monthly review is needed.

The purpose of the review is to continually track the values of these indicators, to determine whether established targets are met, and, if not, plan and implement corrective actions. In addition, *mother's surveys and/or audits are to be used* for additional verification purposes or periodic checks.¹

Once acceptable levels of compliance have been achieved, the frequency of data collection on these additional indicators can be reduced, for example to annually. However, if the level of the sentinel indicators falls below 80% (or below national standards), it will be important to assess both the clinical practices and all management procedures, to determine where the *breakdown is* and what needs to be done to achieve the required standards.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Quality improvement can be defined as “systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups.”²² Sustaining practices requires facilities to build systems to monitor key clinical indicators. Key principles of sustaining safe, evidence-based practices include cyclical quality improvement methodologies, active participation of a multi-disciplinary committee, engaged administrative leaders, meeting consistently over time, and external assessment.¹

As facilities strive to achieve the metrics described in these Guidelines and Evaluation Criteria, it is important they do so while continuing to focus on providing individualized, culturally sensitive care equitably provided to all mothers and babies.

SUSTAINING PRACTICES

Objective external evaluation conducted every 5 years is essential to validate the maintenance of all Ten Steps practices

Monitoring of practices through regular collection of data facilitates early identification of problems which results in improved sustainability of each of the Ten Steps



Supportive leadership committed to providing evidence based care enables the necessary changes to improve care.

Review monitoring data to decide on processes or actions to improve care practices based on findings from audits and surveys.

STEP 1C

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 1C	VERIFICATION METHOD
*9. Explain at least 2 reasons why monitoring of hospital practices is important to ensure quality of care.	Question or case study
*10. Explain at least 2 ways practices are monitored in this facility.	Question or case study

THE FOLLOWING STANDARDS APPLY

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1C.10 The facility has a protocol for an ongoing monitoring and data-management system to comply with the eight key clinical practices.	<p>A review of the policy will confirm:</p> <p><i>Criterion 1C.10.1 A review of the infant feeding policy and any related protocols includes a description of how the facility will routinely collect and track clinical practice indicators in order to report and improve on quality of care involving the data to evaluate the 8 key clinical practice steps [Steps 3-10].</i></p>
1C.11 Clinical staff (<i>direct care providers and direct care staff</i>) at the facility meet at least every 6 months to review implementation of the system.	<p>The nursing director/manager will confirm:</p> <p><i>Criterion 1C.11.1 The Nursing Director/Manager will confirm that the multi-disciplinary committee, which must consist of some direct care providers and direct care staff, meets at least every 6 months, ideally every 3 months, for monitoring purposes that include:</i></p> <ul style="list-style-type: none"> <i>A. Analyzing the key clinical practice indicator data to determine if targets are met, AND</i> <i>B. Defining corrective actions to improve quality of care, if needed.</i> <p><i>NOTE: "During concentrated periods of quality improvement, monthly review may be needed." Facilities should consider ways to provide constructive feedback to direct care providers and direct care staff and support for practice improvement when monitoring data indicate practices are not fully implemented.</i></p>

STEP 1C

COMPETENCY ASSESSMENT— SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>1C.12 Health professionals who provide prenatal, delivery and/or newborn care will demonstrate their competence regarding the facility's monitoring systems.</p>	<p>The nursing director/manager will confirm:</p> <p>Criterion 1C.12. 1 <i>At least 80% of health professionals who provide prenatal, delivery, postpartum, and/or well newborn care will be able to explain at least 2 reasons why monitoring of hospital practices is important to ensure quality of care. [PI 9]</i></p> <ul style="list-style-type: none"> <i>A. Direct care nursing staff, AND</i> <i>B. Direct care providers with privileges</i>

Ensure that staff have sufficient knowledge, competence and skills to support breastfeeding.

RATIONALE:

Timely and appropriate care for all mothers can only be accomplished if staff have the knowledge, skills and *attitudes* to carry it out. Training of health staff enables them to develop effective skills, give consistent messages, and implement policy standards. Staff cannot be expected to implement a practice or educate a patient on a topic for which they have received no training.¹

IMPLEMENTATION GUIDANCE:

COMPETENCY REQUIREMENTS: *Health professionals who provide infant feeding services must be competent in the knowledge, skills and attitudes to implement the Ten Steps to Successful Breastfeeding.*

TABLE 1 (on the next page) provides the high-level competency framework in which 16 specific management and support competencies are organized into seven unique domains. The domains begin with critical management procedures that health professionals need to participate in to create such needed environments. Foundational skills include effective communication and counseling that transversally apply throughout clinical competencies. They then progress through the various perinatal stages along the continuum of care and services, from the prenatal period until discharge from the site of birth.³ **VERIFICATION OF THE 16 COMPETENCIES IS THE PRIMARY FOCUS ON ENSURING SAFE, EVIDENCE-BASED, COMPASSIONATE CARE.**



TABLE 1: DOMAINS AND COMPETENCIES³

DOMAINS	COMPETENCIES NECESSARY FOR IMPLEMENTING THE TEN STEPS TO SUCCESSFUL BREASTFEEDING
DOMAIN 1: Critical management procedures to Support the Ten Steps (Step 1A, 1B, and 1C)	01. Implement the Code in a health facility 02. Explain a facility's infant feeding policies and monitoring systems
DOMAIN 2: Foundational skills: communicating in a credible and effective way (All Steps)	03. Use listening and learning skills whenever engaging in a conversation with a mother 04. Use skills for building confidence and giving support whenever engaging in a conversation with a mother
DOMAIN 3: Prenatal period (Step 3)	05. Engage in antenatal conversation about breastfeeding
DOMAIN 4: Birth and immediate postpartum (Step 4)	06. Implement immediate and uninterrupted skin-to-skin 07. Facilitate breastfeeding within the first hour, according to cues
DOMAIN 5: Essential issues for a breastfeeding mother (Steps 3, 5, 6, 7, 8, 9)	08. Discuss with a mother how breastfeeding works 09. Assist mother getting her baby to latch 10. Help a mother respond to feeding cues 11. Help a mother manage milk expression
DOMAIN 6: Helping mothers and babies with special needs (Steps 5, 6, 7, 8, 9)	12. Help a mother to breastfeed a low-birth-weight or sick baby 13. Help a mother whose baby needs fluids other than breast milk 14. Help a mother who is not feeding her baby directly at the breast 15. Help a mother prevent or resolve difficulties with breastfeeding
DOMAIN 7: Care at discharge (Step 10)	16. Ensure seamless transition after discharge

PERFORMANCE INDICATORS: Performance indicators are a subset of the competencies that provide measurable guidance to evaluate each competency listed in **TABLE 1**. Each performance indicator represents only one action, so only one action verb is used.³ Performance indicators have been included in their relative steps throughout this document. Appendix C includes a comprehensive list of all performance indicators. All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *. **TABLE 2** provides an example from Domain 5, Competency 9, Assist mother getting her baby to latch.

TABLE 2: EXAMPLE: PERFORMANCE INDICATORS AND MEASURABLE ACTIONS⁴⁶

DOMAIN	COMPETENCY	PERFORMANCE INDICATORS	MEASURABLE ACTIONS
Essential issues for a breastfeeding mother	09. Assist mother getting her baby to latch	32. Evaluate a full breastfeeding session observing at least 5 points.	Observation
		33. Demonstrate at least 3 aspects of how to help a mother achieve a comfortable and safe position for breastfeeding within the first 6 hours after birth and later as needed during the hospital stay.	Observation
		34. Demonstrate how to help a mother achieve an effective and comfortable latch, noting at least 5 points.	Observation

TRAINING, ASSESSMENT, AND VERIFICATION OF COMPETENCIES: *Health professionals need to know what to explain to a mother, why it is important, how to do what is necessary and how to do it respecting the mother's concerns and circumstances. STEP 2 focuses on verification of the performance indicators [Appendix C] to ensure that health professionals are competent in supporting breastfeeding, especially during the first few days of the birth hospitalization. Ideally, the responsibility for assessing, training, and verifying the competencies of health professionals should reside with the pre-service education system [professional degree programs]. However, if this has not occurred and staff training is deficient in this area, facilities providing maternity and newborn services will need to take corrective measures to strengthen that capacity, such as by offering courses at the facility or requiring that staff to take courses elsewhere. While some material can be taught through didactic lectures (including electronic resources), some supervised clinical experience with assessing of competencies is necessary. It is important to focus not on a specific curriculum but on the knowledge and skills obtained.¹ TABLE 3 describes 2 options for implementing Step 2 competency-based training.*

TABLE 3: FACILITY OPTIONS FOR COMPETENCY-BASED TRAINING.

OPTION 1: COMPETENCY-BASED TRAINING SPECIFIC TO IDENTIFIED NEEDS	OPTION 2: COMPETENCY-BASED TRAINING FOR ALL HEALTH PROFESSIONALS
<ol style="list-style-type: none"> 1. Assess the competencies of each health professional to identify specific training needs. 2. Provide competency-based training specific to needs identified. 3. Verify each health professional is competent. 4. Remediate as needed. 	<ol style="list-style-type: none"> 1. Provide competency-based training program [internal or external] for all health professionals. 2. Verify all health professionals are competent. 3. Remediate as needed.

HEALTH PROFESSIONAL ROLES REQUIRING COMPETENCY-BASED TRAINING: *All direct care staff and direct care providers [physicians, midwives, physician's assistants, and advanced practice registered nurses] who provide education, assessment, support, intervention, assistance and/or follow-up with regards to infant feeding must have required competencies verified and completed training on identified areas needing improvement, within 6 months of hire. Typically, this will involve the following units/services including: Affiliated Prenatal Services, Labor and Delivery Unit, Postpartum Unit, Newborn Unit. **NOTE:** Steps 1-10 include unit/care-based competency and training requirements specific to staff/provider roles.*

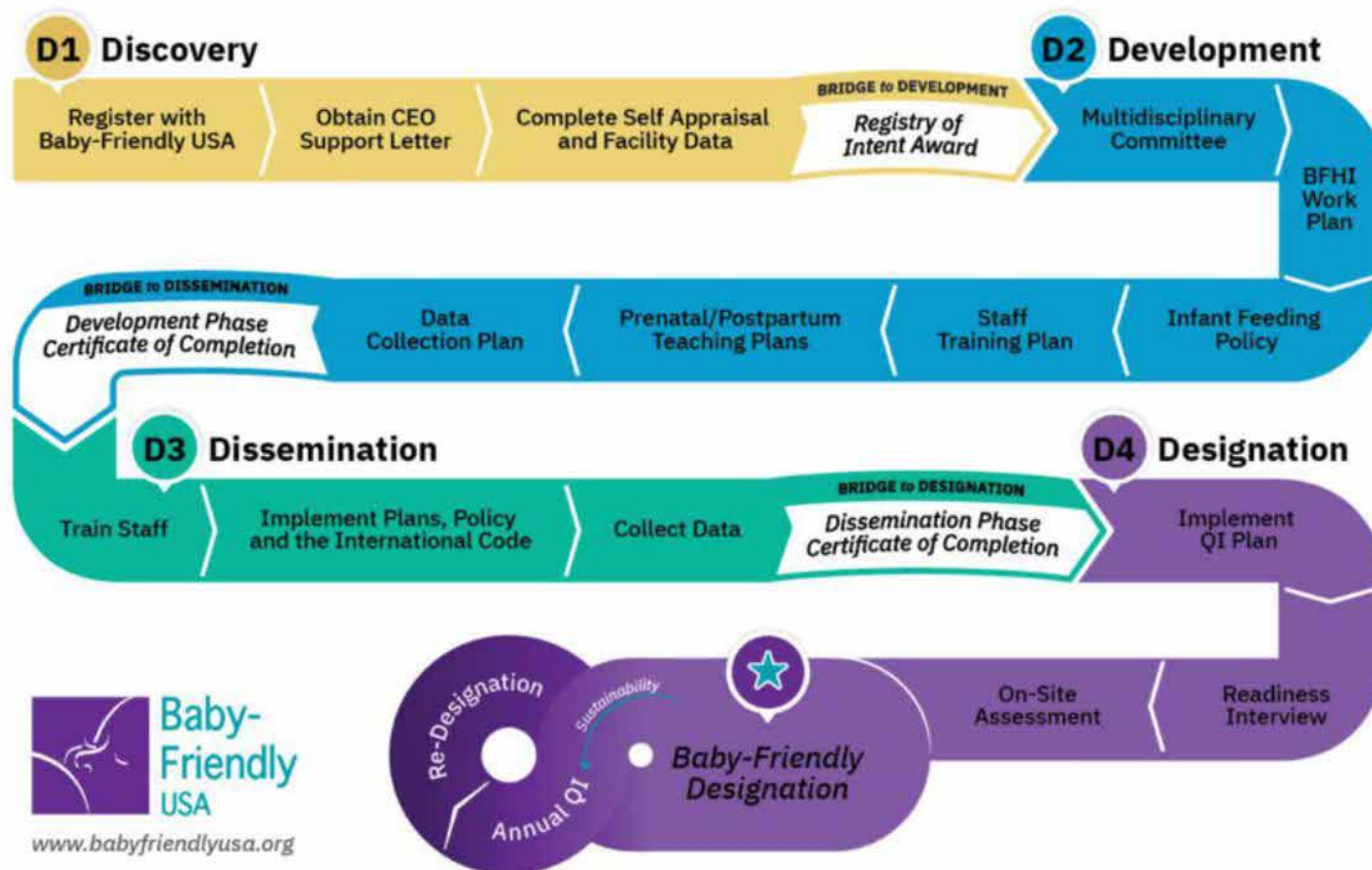
OTHER ROLES *with anticipated workplace exposure to mothers and babies should have training and competency verification in accordance with their roles. Examples of other positions that may need training include:*

- *Administrative Leaders/Managers*
- *Purchasing Agent*
- *Pharmacists*
- *Anesthesiologists*
- *Outside agencies that make inpatient visits*

US PRE-DESIGNATION, ASSESSMENT, AND POST-DESIGNATION CONSIDERATIONS

The 4-D Pathway, consisting of 4 pre-designation and 2 post-designation phases was developed to guide facilities through the designation process. Facilities have specific tasks to complete in each phase and are provided with a variety of tools and resources to assist with their implementation of the Baby-Friendly USA Guidelines and Evaluation Criteria.

The 4-D Pathway to Baby-Friendly Designation



- **D1: DISCOVERY PHASE:** *The Discovery Phase is a time for facilities to learn about the processes and requirements for becoming Baby-Friendly designated. The Discovery Phase toolkit provides a self-appraisal tool to help facilities identify which requirements are already in place and which ones still need additional work.*
- **D2: DEVELOPMENT PHASE:** *The Development Phase provides a template titled, **DIRECT CARE STAFF AND DIRECT CARE PROVIDER COMPETENCY VERIFICATION AND TRAINING PLAN** to assist facilities in developing a comprehensive plan for verifying competencies and helping health professionals gain the knowledge, skills and attitudes necessary to competently implement the facility's infant feeding policy in a safe and effective manner.*
- **D3: DISSEMINATION PHASE:** *The Dissemination Phase involves the verifying of competencies and implementation of training plans that address identified gaps in knowledge and skills, for all direct care staff and direct care providers.*
- **D4: DESIGNATION PHASE:** *The Designation Phase is the time for facilities to reverify competencies for those areas where additional training was provided.*
- **EXTERNAL ASSESSMENT:** *During the Assessment, interviews with health professionals will include facility-based direct care nursing staff and privileged direct care providers. Evaluation of performance indicators at assessment will include a selection of knowledge-based questions and skills-based demonstrations*

specific to the interviewee's role and responsibilities. Baby-Friendly USA has aligned competency-based assessment tools of health "professionals with the WHO/UNICEF Competency Verification Toolkit: Ensuring Competency of Direct Care Providers to Implement the Baby-Friendly Hospital Initiative released on August 5, 2020."

- **ANNUAL QUALITY IMPROVEMENT-SUSTAINABILITY PHASE:** *During the first-year post-designation facilities must develop an Ongoing Competency Evaluation, Training and Verification Plan similar to the one prepared during the Development Phase. (A template for this plan will be provided by Baby-Friendly USA) In-service training must take place minimally every 2 years. The facility will determine the number of hours and content of this training for each staff and provider role. Competency assessment and in-service training must also take place on specific topics when monitoring data indicates one or more practices are not being fully adhered to.*
- **RE-DESIGNATION YEAR 1 PHASE:** *Facilities entering the Re-Designation Year 1 Phase will complete assigned competency assessments and audits to ensure that practices have been sustained. If the results of either reveal practices have slipped, targeted training must be completed to address identified knowledge and/or skills gaps for each direct care provider and direct care staff member.*

US CONSIDERATION FOR SAFE IMPLEMENTATION:

Facilities are encouraged to review the American Academy of Pediatrics' "Clinical Report: Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns" for suggested safe skin-to-skin care and rooming-in practices.²⁵ Staff should receive training that supports safe implementation of these practices.

*Sufficient knowledge, skills and attitudes to support breastfeeding are essential for the provision of safe, evidence-based, compassionate care. In addition, how information is communicated is equally important. Direct care providers and staff should engage in meaningful conversations that **ENCOURAGES** the patient and family members.*

EMPATHIZE

E – Empathize while listening and engaging in the conversation.

NON-JUDGMENTAL

N – Be Non-judgmental by respecting each individual's experiences with breastfeeding, current infant feeding goals, and/or cultural and social considerations.

CONFIRM

C – Confirm you understand the specific circumstances, issues and/or concerns.

OPEN-ENDED QUESTIONS

O – Ask Open-ended questions to evaluate each person's understanding of breastfeeding, infant formula feeding and/or specific maternity care practices applicable to the conversation. For example, "What have you heard about breastfeeding?" "What do you know about infant formula?"

USE COMPETENT SKILLS

U – Use competent skills to assess any potential or current concerns or challenges.

RESPONSIVE CARE

R – Responsive care that provides anticipatory guidance [including suitable options] and/or addresses the specific concerns and circumstances.

AFFIRM

A – Affirm successes and the desire to do what is right for the baby.

GIVE EVIDENCE-BASED INFORMATION

G – Give evidenced based, scientific, unbiased, and factual information in a sensitive manner that emphasizes the protections provided by breastfeeding/maternity care practices to enable an informed decision.

EMPower

E – Empower each individual to make the decision that is right for her/his circumstances.

SUPPORT

S – Support informed decisions by providing an individualized plan that encourages a mother to have a safe, responsive, caring, and nurturing relationship with her baby.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT THE STEP	VERIFICATION METHOD
Foundational skills: communicating in a credible and effective way	
*11. Demonstrate at least 3 aspects of listening and learning skills when talking with a <i>pregnant woman/mother</i> .	Observation
*12. Demonstrate at least 3 ways to adapt communication style and content when talking with a mother.	Observation
*13. Demonstrate at least 2 ways to encourage a mother to share her views, taking time to understand and consider these views.	Observation
*14. Demonstrate at least 3 aspects of building confidence and giving support when talking with a mother.	Observation

THE FOLLOWING STANDARDS APPLY

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
2.1 Health professionals who provide <i>prenatal, delivery and/or newborn care</i> report they have received pre-service or in-service training on breastfeeding during the previous 2 years.	<p>Interviews with health professionals will confirm:</p> <p>Criterion 2.1.1 At least 80% of health professionals who provide prenatal, delivery and/or newborn care can describe what pre-service or in-service training on breastfeeding they have received during the previous 2 years.</p> <p>A. Direct care nursing staff, AND</p> <p>B. Direct care providers with privileges</p> <p>Considerations for in-service sessions may include:</p> <ul style="list-style-type: none"> Initial competency evaluation, training and verification, AND/OR Ongoing competency training and verification with a focus on changing evidence, high-risk performance indicators, and a refresher for common practical skills, AND/OR Ongoing competency training and verification with a focus on quality improvement efforts when monitoring data indicates one or more practices are not being fully adhered to.

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
2.2 Health professionals who provide prenatal, delivery and/or newborn care report receiving competency assessments in breastfeeding in the previous 2 years.	<p>Interviews with health professionals will confirm:</p> <p>Criterion 2.2.1 At least 80% of health professionals who provide prenatal, delivery and/or newborn care can describe what type of competency assessments in breastfeeding they have received during the previous 2 years.</p> <p>A. Direct care nursing staff, AND</p> <p>B. Direct care providers with privileges</p> <p>Considerations for competency assessments in breastfeeding may involve:</p> <ul style="list-style-type: none"> Initial competency assessments of performance indicators to ensure direct care staff and direct care providers have the necessary knowledge, skills, and attitudes to deliver compassionate, safe, and evidence-based care according to their defined roles and the infant feeding policy, AND/OR Ongoing competency assessments to evaluate job performance and identify gaps to sustain and ensure the delivery of consistent and safe care practices, AND/OR Ongoing competency assessments aligned with quality improvement efforts regarding specific monitoring indicators.
2.3 Health professionals who provide prenatal, delivery and/or newborn care are able to correctly answer three out of four questions on breastfeeding knowledge and skills to support breastfeeding.	<p>BFUSA external assessment will confirm:</p> <p>During the external assessment, direct care providers and direct care staff who provide prenatal, delivery and/or newborn care will be asked questions relating to performance indicators pertinent to their role in the care of patients. The specific performance indicators to be discussed are identified in each step under the heading of COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS.</p>
US STANDARD	CRITERION FOR EVALUATION
2.4 Facilities providing maternity and newborn services have the responsibility for assessing, training, and verifying the required competencies ensuring that all health professionals who provide education, assessment, support, intervention, assistance and/or follow-up with regards to infant feeding have the appropriate knowledge, skills and attitudes to provide safe, evidence-based care.	<p>A review of the competency verification and training plan will confirm:</p> <p>Criterion 2.4.1 The head of maternity services will be able to identify the health professional(s) responsible for all aspects of planning, implementing, and verifying direct care staff's and direct care provider's competencies.</p> <p>Criterion 2.4.2 A copy of the <u>Direct Care Staff and Direct Care Provider Competency Verification and Training Plan</u> [BFUSA materials] will be available for review and analysis demonstrating a comprehensive plan for assessing, training, and verifying the competencies for all required health professionals.</p>

Discuss the importance and management of breastfeeding with pregnant women and their families.

RATIONALE:

All pregnant women must have basic information about breastfeeding, in order to make informed decisions. A review of 18 qualitative studies indicated that mothers generally feel that infant feeding is not discussed enough in the *prenatal* period and that there is not enough discussion of what to expect with breastfeeding.¹⁴ Mothers want more practical information about breastfeeding.

Pregnancy is a key time to inform women about the importance of breastfeeding, support their decision-making and pave the way for their understanding of the maternity care practices that facilitate its success. Mothers also need to be informed that birth practices have a significant impact on the establishment of breastfeeding.¹

IMPLEMENTATION GUIDANCE:

Where facilities provide *prenatal care* [see the *Affiliated Prenatal Services Questionnaire in Appendix D*], pregnant women and their families should be counseled about the benefits and management of breastfeeding.² In many settings, prenatal care is predominantly provided through primary health-care clinics or by community health workers. If facilities providing maternity and newborn services do not have authority over these care providers [as defined by the *Affiliated Prenatal Services Questionnaire*], they should work with them to ensure that mothers and families are fully informed about the importance of breastfeeding and know what to expect when they deliver at the facility. In other cases, the facility directly provides prenatal care services or offers classes for pregnant women. In this case, provision of breastfeeding information and counseling is the direct responsibility of the facility.¹



Breastfeeding education should include information on the importance of breastfeeding and the risks of giving formula or other breast-milk substitutes, along with national and health-professional recommendations for infant feeding. Practical skills such as positioning and attachment, on-demand feeding, and recognizing feeding cues are a necessary component of *prenatal* counseling. Families should be presented with up-to-date information on best practices in facilities providing maternity and newborn services regarding skin-to-skin contact, initiation of breastfeeding, supplementation protocols and rooming-in. Women also need to be informed about possible challenges they might encounter (such as engorgement, or a perception of not producing enough milk) and how to address them.¹

Prenatal breastfeeding counseling must be tailored to the individual needs of the woman and her family, addressing any concerns and questions they have. This counseling needs to be sensitively given and consider the social and cultural context of each family.¹

Wherever possible, conversations on breastfeeding should begin with the first or second *prenatal* visit, so that there is time to discuss any challenges, if necessary. This is particularly important in settings where women have few *prenatal* visits and/or initiate their visits late in their pregnancy. Additionally, women who deliver prematurely may not have adequate opportunities to discuss breastfeeding if the conversations are delayed until late in pregnancy.¹

Information on breastfeeding should be provided in multiple ways. *According to the U.S. Department of Health & Human Services, over a third of adults have below basic health literacy, verbal communication as a primary teaching tool with patients is recommended.* Printed or online information that is in a language mothers understand [*usually recommended at or below a 5th grade reading level*] is one way to ensure that all relevant topics are covered. However, there is no assurance that all women will read this information, and it may not directly address the key questions they have. Interpersonal counseling, either one-on-one or in small groups, is important to allow women to discuss their feelings, doubts and questions about infant feeding.¹

The information must be provided free of conflicts of interest. As stipulated in the “Guidance on ending inappropriate promotion of foods for infants and young children”,²⁴ companies that market foods for infants and young children should not “directly or indirectly provide education to parents and other caregivers on infant and young child feeding in health facilities”.¹

Women at increased risk for preterm delivery or birth of a sick infant (e.g. pregnant adolescents, *women with* high-risk pregnancies, known congenital anomalies) must begin discussions with knowledgeable providers as soon as feasible concerning the special circumstances of feeding a premature, low-birth-weight or sick baby.^{1, 30}

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Engaging pregnant women in a conversation about creating a safe environment for both breastfeeding and sleep is extremely important as this is a time when many parents are preparing these settings. The American Academy of Pediatrics', "SIDS and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment" and the "Clinical Report: Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns", provide recommendations regarding the education that should be provided to reduce the risk of SIDS and sleep-related suffocation, asphyxia, and entrapment among infants.^{25, 26} While providing the education on safe sleep practices, mothers should gain an understanding that sleepiness is a hormonally-driven, physiological response to breastfeeding. This normal response can lead to a mother, unintentionally, falling asleep while breastfeeding. Mothers should also understand that other factors such as exhaustion, fatigue, and pain medications can make falling asleep while breastfeeding common. Families should be offered information about how to create a safe sleep environment for breastfeeding and what hazardous situations are with open, honest, non-judgmental discussions to inform their decisions.

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for all pregnant mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 3	VERIFICATION METHOD
*15. Engage in a conversation with a pregnant woman on 3 aspects of the importance of breastfeeding.	Observation
*16. Assess at least 3 aspects of a pregnant woman's knowledge about breastfeeding in order to fill the gaps and correct inaccuracies.	Observation
*17. Engage in a conversation with a pregnant woman about at least 4 care practices a mother/infant dyad will experience at the birthing facility that will support breastfeeding.	Observation
*29. Engage in a conversation with a pregnant woman regarding at least 3 reasons why effective exclusive breastfeeding is important.	Observation

THE FOLLOWING STANDARDS APPLY ONLY FOR FACILITIES WITH AFFILIATED PRENATAL SERVICES:

[See Affiliated Prenatal Services Questionnaire in Appendix D]

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
3.1 Mothers who received prenatal care at the facility report having received prenatal counseling on breastfeeding.	<p>Affiliated services: interviews with pregnant women in the third trimester who have had at least 2 visits at an affiliated prenatal service will confirm:</p> <p>Criterion 3.1.1 At least 80% of pregnant women will report that a staff member/provider at the affiliated prenatal services:</p> <p>A. Assessed their understanding of breastfeeding and the specific maternity care practices that support it, AND</p> <p>B. Entered into a meaningful conversation [see Step 2] with them on the required WHO/UNICEF prenatal conversation topics provided in Appendix A either one-on-one or in small groups, or by following up to education provided through another learning mode [videos, podcasts, texts] based on their specific needs.</p> <p>NOTE: if mothers have questions about infant formula, their issues, concerns and circumstances will be discussed on an individual basis.</p>

US CLARIFICATION: PRENATAL EDUCATION AND MEANINGFUL CONVERSATIONS

While education may be provided by a variety of different learning modes including videos, podcasts, texts, etc., meaningful prenatal breastfeeding conversations must be tailored to the individual needs of the woman and her family, addressing any concerns and questions they have. This counseling needs to be sensitively given and consider the social and cultural context of each family.¹ "The Guideline: Counseling of Women to Improve Breastfeeding Practices" states that the "aim of breastfeeding counseling is to empower women to breastfeed, while respecting their personal situations and wishes."¹⁸ As you enter into conversations with pregnant women, consider incorporating appropriate components of the following acronym, E.N.C.O.U.R.A.G.E.S as you enter into meaningful conversations [see Step 2].

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
3.2 Mothers who received prenatal care at the facility [affiliated prenatal services] are able to adequately describe what was discussed about two of the required WHO/UNICEF prenatal conversation topics provided in Appendix A.	<p>Affiliated prenatal services: interviews with pregnant women in the third trimester who have had at least 2 visits at an affiliated prenatal service will confirm:</p> <p>Criterion 3.2.1 At least 80% of pregnant women who received prenatal care at the affiliated prenatal services are able to adequately describe two topics from required WHO/UNICEF prenatal conversation topics provided in Appendix A.</p>

THE FOLLOWING STANDARDS OF CARE APPLY FOR ALL FACILITIES WITH AND WITHOUT AFFILIATED PRENATAL SERVICES:

US STANDARD	CRITERION FOR EVALUATION
3.3 All facilities should foster the development of and coordinate services with programs to promote consistent education about breastfeeding that is made available to pregnant women.	<p>A written description will confirm:</p> <p>Criterion 3.3.1 A written description will confirm how the facility has fostered the development of and coordinated services with in-house programs and/or community-based projects to promote consistent education about breastfeeding that is made available to all pregnant women.</p>

US CLARIFICATION: PRENATAL EDUCATION AND RETURNING TO WORK

Pregnant women who know they will be returning to work and/or school often ask questions about their options for continuation of breastfeeding and/or breast-milk feeding. While it is appropriate to answer these questions and to provide basic information about maintaining lactation when direct breastfeeding is not possible or desired, it is important that prenatal breastfeeding education focus on building mothers' knowledge, skills, and confidence in their ability to breastfeed. As needed, more in-depth, education on breast pumps, milk storage, and handling can be given.

Prenatal education that discusses pumping and bottle use must only be given in the context of discussing infant feeding options when mother and baby are separated [e.g., mother going back to school or work], to help mothers initiate or maintain lactation [Step 5], and to support exclusive breastfeeding. Prenatal education on pumping and bottle use must address the following points:

- Bottle use should be delayed until breastfeeding is well-established.
- Possible negative consequences of bottle use on the success of breastfeeding.

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>3.4 Health professionals who provide care to pregnant women will be competent in engaging in a prenatal conversation about breastfeeding.</p>	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 3.4.1 At least 80% of direct care nursing staff who provide labor & delivery care will be able to describe how they engage in a conversation with a pregnant woman on 2 aspects of the importance of breastfeeding. [PI 15]</p> <p>Criterion 3.4.2 At least 80% of direct care nursing staff who provide labor & delivery care will be able to describe how to assess at least 2 aspects of a pregnant woman's knowledge about breastfeeding in order to fill the gaps and correct inaccuracies. [PI 16]</p> <p>Criterion 3.4.3 At least 80% of direct care nursing staff who provide labor & delivery care will be able to describe how they engage in a conversation with a pregnant woman about at least 2 care practices a mother/infant dyad will experience at the birthing facility that will support breastfeeding. [PI 17]</p> <p>Criterion 3.4.4 At least 80% of direct care nursing staff who provide labor & delivery care will be able to describe how they engage in a conversation with a pregnant woman regarding at least 2 reasons why effective exclusive breastfeeding is important. [PI 29]</p> <p>DIRECT CARE PROVIDERS</p> <p>Criterion 3.4.5 At least 80% of direct care providers with privileges to provide care to pregnant women in the labor and delivery unit will be able to describe how they engage in a conversation with a pregnant woman on 2 aspects of the importance of breastfeeding. [PI 15]</p> <p>Criterion 3.4.6 At least 80% of direct care providers with privileges to provide care to pregnant women in the labor and delivery unit will be able to describe how to assess at least 2 aspects of a pregnant woman's knowledge about breastfeeding in order to fill the gaps and correct inaccuracies. [PI 16]</p> <p>Criterion 3.4.7 At least 80% of direct care providers with privileges to provide care to pregnant women in the labor and delivery unit will be able to describe how they engage in a conversation with a pregnant woman regarding at least 2 reasons why effective exclusive breastfeeding is important. [PI 29]</p>

Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.

RATIONALE:

Immediate skin-to-skin contact and early initiation of breastfeeding are two closely linked interventions that need to take place in tandem for optimal benefit. Immediate and uninterrupted skin-to-skin contact facilitates the newborn's natural rooting reflex that helps to imprint the behavior of looking for the breast and suckling at the breast.

Additionally, immediate skin-to-skin contact helps populate the newborn's microbiome and prevents hypothermia. Early suckling at the breast will trigger the production of breast-milk and accelerate lactogenesis. Many mothers stop breastfeeding early or believe they cannot breastfeed because of insufficient milk, so establishment of a milk supply is critically important for success with breastfeeding. In addition, early initiation of breastfeeding has been proven to reduce the risk of infant mortality.^{1, 31}

IMPLEMENTATION GUIDANCE:

Early and uninterrupted skin-to-skin contact between mothers and infants should be facilitated and encouraged as soon as possible after birth. Skin-to-skin contact is when the infant is placed prone on the mother's abdomen or chest with no clothing separating them. It is recommended that skin-to-skin contact begins immediately, regardless of method of delivery. It should be uninterrupted for at least 60 minutes ¹ or longer if the mother wishes and/or if the infant needs more time to complete a breastfeed. To clarify, immediately after birth, an infant may be on the abdomen until the cord is clamped and cut. Then the infant moves his/herself or is moved to the chest, atop the sternum.



Initiation of breastfeeding is typically a direct consequence of uninterrupted skin-to-skin contact, as it is a natural behavior for most babies to slowly squirm or crawl toward the breast *[this may take up to an hour]*. Mothers may be supported to help the baby to the breast if desired. Mothers should be helped in understanding how to support the baby and how to make sure the baby is able to self-attach and suckle at the breast. All mothers should be supported to initiate breastfeeding as soon as possible after birth, within the first hour after delivery *[unless there are medically justifiable reasons]*.^{1,2} *This first breastfeed should be allowed to continue until the baby indicates that the breastfeed is completed. This may take up to another hour. The initial period of skin-to-skin contact until completion of the first feeding may take up to 2 hours.*

It should be noted that the milk a newborn consumes immediately after birth is colostrum, which is highly nutritious and contains important antibodies and immune-active substances. The amount of colostrum a newborn will receive in the first few feedings is very small. Early suckling is important for stimulating milk production and establishing the maternal milk supply. The amount of milk ingested is a relatively unimportant factor.^{1,2} During immediate skin-to-skin contact, and for at least the first 2 hours after delivery, sensible vigilance and safety precautions should be taken so that health professionals can observe for, assess and manage any signs of distress *in infants*. Mothers who are sleepy or under the influence of anesthesia or drugs will require closer observation.¹ When mothers are not fully awake and responsive,

a health professional should accompany the mother, to prevent the baby from being hurt accidentally.

Immediate skin-to-skin care and initiation of breastfeeding is feasible following a cesarean section with local/*regional* anesthesia (epidural).³² After a cesarean section with general anesthesia, skin-to-skin contact and initiation of breastfeeding can begin when the mother is sufficiently alert to hold the infant. Mothers or infants who are medically unstable following delivery may need to delay the initiation of breastfeeding. However, even if mothers are not able to initiate breastfeeding during the first hour after birth, they should still be supported to provide skin-to-skin contact and to breastfeed as soon as they are able *(responsive and alert)*.^{1,32,33} *Routine procedures (e.g. assessment, vital signs, security steps, APGAR scoring) should be done with the infant skin-to-skin with the mother. Procedures that are painful or may require separation from skin-to-skin (e.g., eye ointment, weights, vitamin K, bathing) should be delayed until the completion of first feeding or after the initial first hour of skin-to-skin contact (if formula feeding).*¹³ *To diminish pain, where feasible, painful procedures should be conducted while in skin-to-skin contact. Procedures requiring separation of the mother and infant (bathing, for example) should be delayed until after this initial period of skin-to-skin contact and should be conducted, whenever possible, at the mother's bedside. Staff should be vigilant during this time and support mothers to look for signs that their babies are ready to feed and offer help if necessary.*

Preterm infants may be able to root, attach to the breast and suckle.³⁴ As long as the infant is stable, with no evidence of severe apnea, desaturation or bradycardia, preterm infants can start breastfeeding. However, early initiation of effective breastfeeding may be difficult for these infants if the suckling reflex is not yet established and/or the mother has not yet begun plentiful milk secretion. Early and frequent milk expression is critical to stimulating milk production and secretion for preterm infants who are not yet able to suckle. Transition to direct and exclusive breastfeeding should be the aim whenever possible³⁵ and is facilitated by prolonged skin-to-skin contact.

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Facilities are encouraged to review the "American Academy of Pediatrics' Clinical Report: Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns"²⁵ and the WHO/UNICEF "Competency Verification Tool Kit Examiners Resource"³ for suggested safe skin-to-skin care practices.

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an ')

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 4	VERIFICATION METHOD
*18. Explain at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the mother.	Question or case study
*19. Explain at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the infant.	Question or case study
20. Demonstrate at least 3 points of how to routinely implement immediate, uninterrupted and safe skin-to-skin between mother and infant, regardless of method of birth.	Observation
*21. Demonstrate at least 3 safety aspects to assess when mother and baby are skin-to-skin during the first 2 hours postpartum, regardless of method of birth.	Observation
*22. List at least 3 reasons why skin-to-skin should NOT be <i>delayed or</i> interrupted.	Question or case study
*23. Explain at least 2 reasons when skin-to-skin could be <i>delayed or</i> interrupted for medically justifiable reasons.	Question or case study
24. “WHERE APPLICABLE” Explain how to maintain skin-to-skin during transfer of mother and infant to another room or other recovery area.	Question or case study
*25. Engage in a conversation with a mother including at least 3 reasons why suckling at the breast in the first hour is important, when the baby is ready.	Observation
26. Demonstrate at least 3 aspects of safe care of the newborn in the first 2 hours post-birth.	Observation
27. Describe to a mother at least 3 pre-feeding behaviors babies show before actively sucking at the breast.	Observation

THE FOLLOWING STANDARDS APPLY:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
<p>4.1 Mothers report that their babies were placed in skin-to-skin contact with them immediately after birth and that this contact lasted 1 hour or more, unless there were documented medically justifiable reasons for delayed contact.</p>	<p>Interviews with mothers will confirm:</p> <p>Criterion 4.1.1 <i>Following a vaginal birth, at least 80% of mothers will confirm:</i></p> <ul style="list-style-type: none"> A. <i>That their infants were placed in skin-to-skin contact with them immediately after birth, unless there were documented medically justifiable reasons for delayed contact, AND</i> B. <i>The initial period of skin-to-skin contact continued uninterrupted for at least 1 hour [longer, if needed, to allow a breastfeeding infant to complete a feeding], unless there were documented medically justifiable reasons to interrupt contact.</i> <p>Criterion 4.1.2 <i>Following a cesarean birth, at least 80% of mothers will confirm:</i></p> <ul style="list-style-type: none"> A. <i>That their infants were placed in skin-to-skin contact with them when safe and feasible [minimally, following a cesarean delivery, skin-to-skin should begin in the recovery area as soon as mother is responsive and alert], unless there were documented medically justifiable reasons for delayed contact, AND</i> B. <i>The initial period of skin-to-skin contact continued uninterrupted for at least 1 hour [longer, if needed, to allow a breastfeeding infant to complete a feeding], unless there were documented medically justifiable reasons to interrupt contact.</i> <p>Criterion 4.1.3 <i>At least 80% of mothers will confirm that in the event of delayed or interrupted skin-to-skin contact for medically justifiable reasons, skin-to-skin was initiated/re-established when safe and medically feasible.</i></p> <p>Documentation:</p> <p>Criterion 4.1.4 <i>If necessary, a review of the medical record will provide documentation of skin-to-skin contact including:</i></p> <ul style="list-style-type: none"> A. <i>Time of delivery,</i> B. <i>Time skin-to-skin was implemented,</i> C. <i>Time of completion/duration of skin-to-skin contact, and</i> D. <i>Any reasons for delay/interruption of skin-to-skin contact</i> <p>Observations of births will confirm:</p> <p>Criterion 4.1.5 <i>Observations of vaginal births, if necessary and/or available, show:</i></p> <ul style="list-style-type: none"> A. <i>That infants are placed skin-to-skin with their mothers immediately after birth, unless there were medically justifiable reasons for delayed contact, AND</i> B. <i>The initial period of skin-to-skin contact continued uninterrupted for at least 1 hour [longer, if needed, to allow a breast-feeding infant to complete a feeding], unless there were medically justifiable reasons to interrupt contact.</i> <p><i>continued</i></p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
4.1 Mothers report that their babies were placed in skin-to-skin contact with them immediately after birth and that this contact lasted 1 hour or more, unless there were documented medically justifiable reasons for delayed contact.	<p>Observations of birth will confirm:</p> <p>Criterion 4.1.6 Observations of cesarean births, if necessary and/or available, show:</p> <p>A. That infants are placed in skin-to-skin contact with their mothers when safe and feasible [minimally, following a cesarean delivery, skin-to-skin should begin in the recovery area as soon as mother is responsive and alert], unless there were medically justifiable reasons for delayed contact, AND</p> <p>B. The initial period of skin-to-skin contact continued uninterrupted for at least 1 hour [longer, if needed, to allow a breastfeeding infant to complete a feeding], unless there were medically justifiable reasons to interrupt contact.</p>

U.S. CLARIFICATION: MEDICALLY JUSTIFIABLE REASONS FOR-DELAYED/INTERRUPTED SKIN-TO-SKIN CONTACT

Healthcare Professionals must use their clinical judgement. Mothers or infants that are not stable may require that immediate skin-to-skin contact be postponed. Interruptions may be necessary to address any procedure that cannot be postponed until the completion of the first feeding. In the event that a mother and/or infant are separated for medical reasons, skin-to-skin contact will be initiated as soon as the mother and infant are stabilized/reunited. Any delays or interruptions of skin-to-skin contact should be clearly documented in the medical record.

To be clear, routine procedures (e.g., assessment, vital signs, security steps, APGAR scoring) should be done with the infant skin-to-skin with the mother. Procedures that are painful or may require separation from skin-to-skin (e.g. eye ointment, weights, vitamin K, bathing) should be delayed until the completion of first feeding or after the initial first hour of skin-to-skin contact [if formula feeding].



WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
<p>4.2 Mothers report that their babies were put [supported or self-attached] to the breast within 1 hour after birth, unless there were documented medically justifiable reasons.</p> <p>NOTE: Early Initiation of Breastfeeding: According to WHO, infants should be put to the breast within 1 hour of birth. This practice gives infants the opportunity to feed at the mother's breast. Early initiation of breastfeeding does not require that the infant attached/suckled at the breast or that milk was transferred from breast to infant. It represents the practice of putting an infant in skin-to-skin contact and allowing an infant to slowly crawl toward the breast or supporting mothers to help the baby to the breast, if desired. Putting the baby to breast within the first hour is related to a number of positive outcomes including reduced mortality and exclusive breastfeeding.³⁶</p>	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 4.2.1 At least 80% of breastfeeding mothers will report that they were supported to initiate breastfeeding with their babies as soon as possible after birth, within the first one to two hours after delivery, unless there were documented medically justifiable reasons. NOTE: Supporting the initiation of breastfeeding is defined as placing the baby on the mother's chest (skin-to-skin) for breastfeeding, pointing out infant feeding readiness cues and gently coaching the mother to allow baby to move and attach to the breast.</p> <p>Criterion 4.2.2 At least 80% of breastfeeding mothers will confirm that they were encouraged to look for signs that their infants were ready to feed during this first one to two hours of contact.</p> <p>BFUSA CLARIFICATION/INTERPRETATION: BFUSA supports the practice of "putting infants to the breast" within 1 hour of birth. Due to the effect of various birth medications, some infants do not show readiness to feed until the end of the first hour and/or well into the second hour, even though they have been in uninterrupted skin-to-skin contact with their mothers. Therefore, for the purposes of evaluating the initiation of breastfeeding with a latch or attempts to latch, criterion 4.2.1 will focus on the initiation of the first feeding within the first 2 hours after birth.</p> <p>Documentation:</p> <p>Criterion 4.2.3 If necessary, a review of the medical record will provide documentation of the initiation of breastfeeding including:</p> <ul style="list-style-type: none"> A. Time of delivery B. Time of initiation of breastfeeding C. Any medically justifiable reasons for delay of initiation of breastfeeding <p>Observations of breastfeeding infants will confirm:</p> <p>Criterion 4.2.4 Observations, if necessary and/or available, confirm that breastfeeding mothers are supported to initiate breastfeeding with their infants as soon as possible after birth, within the first one to two hours after delivery, unless there are medically justifiable reasons. NOTE: Supporting the initiation of breastfeeding is defined as placing the baby on the mother's chest (immediate and uninterrupted skin-to-skin) for breastfeeding, pointing out infant feeding readiness and gently coaching the mother to allow baby to move and attach to the breast.</p> <p>Criterion 4.2.5 Observations, if necessary and/or available, show that at least 80% of breastfeeding mothers are shown how to recognize the signs that infants are ready to feed during this first hour of contact.</p>

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>4.3 Health professionals who provide labor & delivery and/or immediate newborn care will be competent to safely implement immediate and uninterrupted skin-to-skin contact and facilitate breastfeeding within the first hour, according to cues.</p>	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 4.3.1 At least 80% of direct care nursing staff who provide labor & delivery and/or immediate newborn care will be able to demonstrate or explain at least 3 points of how to routinely implement immediate, uninterrupted and safe skin-to-skin between a mother and infant regardless of method of birth. [PI 20]</p> <p>Criterion 4.3.2 At least 80% of direct care nursing staff who provide labor & delivery and/or immediate newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Demonstrating or explaining at least 3 safety aspects to assess when a mother and baby are skin-to-skin during the first 2 hours postpartum, regardless of method of birth. [PI 21] B. Demonstrating or explaining at least 3 aspects of safe care of the newborn in the first 2 hours post-birth. [PI 26] <p>Criterion 4.3.3 At least 80% of direct care nursing staff who provide labor & delivery and/or immediate newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Describing at least 2 pre-feeding behaviors babies show before actively sucking at the breast. [PI 27] B. Describing at least 2 reasons why suckling at the breast in the first hour is important, when the baby is ready. [PI 25] <p>DIRECT CARE PROVIDERS</p> <p>Criterion 4.3.4 At least 80% of direct care providers with privileges to provide labor & delivery and/or immediate newborn care will be able to list at least 2 reasons why skin-to-skin should not be delayed or interrupted. [PI 22]</p> <p>Criterion 4.3.5 At least 80% of direct care providers with privileges to provide labor & delivery and/or immediate newborn care will be able to explain at least 2 reasons when skin-to-skin could be delayed or interrupted for medically justifiable reasons. [PI 23]</p> <p>Criterion 4.3.6 At least 80% of direct care providers with privileges to provide labor & delivery and/or immediate newborn care will be able to describe at least 2 points to include in a conversation with a mother concerning why suckling at the breast in the first hour is important, when the baby is ready. [PI 25]</p>

Support mothers to initiate and maintain breastfeeding and manage common difficulties.

RATIONALE:

While breastfeeding is a natural human behavior, most mothers need practical help in learning how to breastfeed. Even experienced mothers encounter new challenges with breastfeeding a newborn. Postnatal breastfeeding counseling and support has been shown to increase rates of breastfeeding up to 6 months of age.³⁷ Early adjustments to positioning and attachment can prevent breastfeeding problems at a *future* time. Frequent coaching and support helps build maternal confidence.¹

IMPLEMENTATION GUIDANCE:

Mothers should receive practical support to enable them to initiate and maintain breastfeeding and manage common breastfeeding difficulties.² Practical support includes providing emotional and motivational support, imparting information and teaching concrete skills to enable mothers to breastfeed successfully. The stay in the facility providing maternity and newborn services is a unique opportunity to discuss and assist the mother with questions or problems related to breastfeeding and to build confidence in her ability to breastfeed.¹

All mothers should receive individualized attention, but first-time mothers and mothers who have not breastfed before will require extra support. However, even mothers who have had another child might have had a negative breastfeeding experience and need support to avoid previous problems. Mothers delivering by cesarean section and obese mothers should be given additional help with positioning and attachment.¹



A number of topics should be included in teaching mothers to breastfeed. It is essential to demonstrate good positioning and attachment at the breast, which are crucial for stimulating the production of breast-milk and ensuring that the infant receives enough milk. Direct observation of a feed is necessary to ensure that the infant is able to attach to and suckle at the breast and that milk transfer is happening. *Competent direct care staff will observe at least one feed every shift.*³⁸ Additionally, facility direct care staff need to educate mothers on the *importance of direct breastfeeding, prevention of pathologically engorged breasts, ways to ensure and maintain a good milk supply, prevention of cracked and sore nipples, and evaluation of milk intake.*¹

Mothers should be coached on how to express breast-milk as a means of maintaining lactation in the event of their being separated temporarily from their infants.² There is not sufficient evidence that one method of expression (hand expression, manual pump or electric pump) is more effective than another,³⁹ and thus any method(s) may be taught, depending on the mother's context. However, hand expression does have the advantage of being available no matter where the mother is and of allowing the mother to relieve pressure or express milk when a pump is not available *or during an emergency where there may be power outages. It is reasonable for all mothers to be taught hand expression during the birth hospitalization.* Pumps can potentially have more microbial contamination if they cannot easily be cleaned. Mothers also need to be supported for collection and storage of expressed milk.¹

Practical support for preterm, including late preterm newborns is particularly critical, in order to establish and maintain the production of breast-milk. Many mothers of preterm infants have health problems of their own and need motivation and extra support for milk expression. *Robust and older* late preterm infants are generally able to exclusively breastfeed at the breast, but are at greater risk of jaundice, hypoglycemia and feeding difficulties than full-term infants, and thus require increased vigilance.⁴⁰ Mothers of twins (multiples) also need extra support, especially for positioning and attachment.¹

Conversations with mothers should include information on the importance of direct breastfeeding. However, some mothers will make an informed decision to exclusively pump and feed their expressed breast-milk to their infants. If this is the case, they should be advised to pump and feed their infants expressed breast-milk at least 8 times in 24 hours.

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

General guidance regarding facilitating milk production and maintaining milk supply may include **(NOTE: This guidance must be individualized.)**

- **Direct breastfeeding:** Ensure good positioning and correct attachment with observable efficient suckling patterns at the breast. Practice responsive feeding with no limits on frequency and duration of feedings. Avoid non-medically indicated supplemental feeds, pacifiers, and artificial nipples.
- **Breastfeeding and formula feeding combined [Mixed-feeding - Maternal request]:** Establish exclusive direct breastfeeding for several weeks with supplementation introduced at a later date. The mother must be knowledgeable regarding the importance of expressing breast-milk after formula is introduced.
- **Temporary medically-indicated supplementation:** Supplement, when possible, at the breast. Avoid pacifiers and artificial nipples. Establish expression of breast-milk when supplements are offered.
- **Exclusively breast-milk feeding, preterm infants, and infants that cannot breastfeed due to illness or separation:** Express breast-milk regularly, at least 8 times in 24 hours, with stretches not longer than 4 hours. Mothers may describe hand expression, manual pumping or electric pumping.

- **Preterm infants, particularly those being cared for on the regular postpartum unit must receive individualized care, including close observation, due to their immaturity. These infants are less alert, have less stamina, are often hypotonic, and have greater difficulty with latch, suck and swallow.⁴¹ Mothers of late preterm infants are at a greater risk of delayed lactogenesis.⁴⁰ Management strategies to support these couplets include developing an adequate milk volume and ensuring that these infants are adequately fed.⁴⁰ Mothers should be assisted to start expressing their milk within the first 6 hours after birth [preferably within 1-2 hours after birth and completion of initial skin-to-skin contact]. In order to initiate and establish the mother's milk supply, regular expression using hand expression may be necessary to stimulate the breasts.⁴⁰ Many of these infants may not effectively transfer milk during breastfeeding, so supplementation with the mother's own milk, pasteurized donor human milk or infant formula may be necessary following attempted breastfeeds with appropriate lactation support.⁴¹**

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS

for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY

for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 5	VERIFICATION METHOD
28. Describe at least 6 essential issues that every breastfeeding mother should know or demonstrate.	Question or case study
*30. Engage in a conversation with a mother regarding 2 elements related to infant feeding patterns in the first 36 hours of life.	Observation
*31. Describe to a mother at least 4 signs of adequate transfer of milk in the first few days.	Observation
32. Evaluate a full breastfeeding session observing at least 5 points.	Observation
*33. Demonstrate at least 3 aspects of how to help a mother achieve a comfortable and safe position for breastfeeding within the first 6 hours after birth and later as needed during the hospital stay.	Observation
*34. Demonstrate how to help a mother achieve an effective and comfortable latch, noting at least 5 points.	Observation
40. Demonstrate to a mother how to hand express breast-milk, noting 8 points.	Observation
43. Help a mother achieve a comfortable and safe position for breastfeeding with her preterm, late preterm, or weak infant at the breast, noting at least 4 points.	Observation
*44. Engage in a conversation with a mother of a preterm, late preterm, or low-birth-weight infant not sucking effectively at the breast, including at least 5 points.	Observation
57. Engage in a conversation with a mother regarding at least 4 different ways to facilitate breastfeeding in order to prevent or resolve most common conditions of the lactating breasts (sore nipples, engorgement, mother who thinks she doesn't have enough milk, infants who have difficulty sucking).	Observation
*65. Describe at least 2 maternal and 2 infant risk factors associated with delayed lactogenesis II.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
5.1 Breastfeeding mothers report that someone on the <i>direct care</i> staff offered assistance with breastfeeding within 6 hours after birth.	<p>Interviews with breastfeeding [including breast-milk feeding] mothers will confirm:</p> <p>Criterion 5.1.1 At least 80% of breastfeeding [including breast-milk feeding] mothers will report that:</p> <ul style="list-style-type: none"> A. Term infants/Direct Breastfeeding: direct care staff provided additional guidance and support as needed with breastfeeding within 6 hours of birth. OR B. Exclusively expressing/Breast-milk feeding: direct care staff provided additional guidance and support with expressing their breast-milk within the first 6 hours after birth [preferably within 1–2 hours after birth and completion of initial skin-to-skin contact], unless there is a justifiable reason to delay initiation of expression. OR C. Late preterm infants/Direct Breastfeeding on the postpartum unit: direct care staff provided additional guidance and support as needed with breastfeeding and expressing their breast-milk within the first 6 hours after birth [preferable within 1–2 hours after birth and completion of the initial skin-to-skin contact], unless there is a justifiable reason to delay initiation of expression. <p>NOTE: Early adjustments to positioning and attachment within the first 6 hours following the initial breastfeeding after delivery can prevent breastfeeding problems at a future time.</p>
5.2 Breastfeeding mothers are able to demonstrate how to position their babies for breastfeeding and that the babies can suckle and transfer milk.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 5.2.1 At least 80% of breastfeeding mothers are able to demonstrate or describe:</p> <ul style="list-style-type: none"> A. Correct positioning with their babies, AND B. Correct attachment (latch) with their babies, AND C. Observable efficient suckling patterns with their babies, AND D. Audible sounds associated with the transfer of breast-milk with their babies.
5.3 Breastfeeding mothers can describe at least two ways to facilitate milk production for their infants.	<p>Interviews with breastfeeding [including breast-milk feeding] mothers will confirm:</p> <p>Criterion 5.3.1 At least 80% of breastfeeding [including breast-milk feeding] mothers can describe at least two ways to facilitate milk production and to keep up the supply for their babies.</p>
5.4 Breastfeeding mothers can describe at least two indicators of whether a breastfed baby consumes adequate milk.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 5.4.1 At least 80% of breastfeeding mothers can describe at least two indicators of whether a breastfed baby has consumed adequate milk.</p>

continued

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT: *continued*

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
5.5 Mothers of breastfed infants can correctly demonstrate or describe how to express breast-milk.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 5.5.1 At least 80% of breastfeeding mothers can correctly demonstrate or describe how to hand express breast-milk.</p>

THE FOLLOWING STANDARD APPLIES TO MOTHERS WITH INFANTS THAT ARE BEING CARED FOR IN THE NICU:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
5.6 Mothers of preterm or sick infants report having been helped to express milk within 1–2 hours after birth.	<p>Interviews with mothers who are breastfeeding or intending to do so with infants in the NICU will confirm:</p> <p>Criterion 5.6.1 At least 80% of mothers with infants in the NICU, who are breastfeeding or intending to do so, will report that they have been provided guidance and support with expressing their breast-milk within the first 6 hours after birth [preferably within 1–2 hours after birth and completion of initial skin-to-skin contact – if safe and medically feasible], unless there is a justifiable reason to delay initiation of expression.</p> <p>Criterion 5.6.2 At least 80% of mothers with infants in the NICU, who are breastfeeding or intending to do so will report that they have been provided guidance that they need to breastfeed or express their milk at least 8 times every 24 hours, with stretches not longer than 4 hours, to establish and maintain their milk supply.</p>

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>5.9 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in:</p> <ul style="list-style-type: none"> • How to assist a mother in the steps to getting her baby to latch • How to discuss with a mother how breastfeeding works • In helping a mother to breastfeed a late-preterm baby • In helping a mother prevent or resolve difficulties with breastfeeding • In helping a mother manage milk expression • In helping a mother who is not feeding her baby directly at the breast 	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 5.9.1 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will be able to describe at least 3 essential issues that every breastfeeding mother should know or demonstrate. [PI 28]</p> <p>Criterion 5.9.2 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will be able to describe to a mother at least 2 signs of adequate transfer of milk in the first few days. [PI 31]</p> <p>Criterion 5.9.3 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will be able to describe how they evaluate a full breastfeeding session observing at least 5 points. [PI 32]</p> <p>Criterion 5.9.4 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will be able to describe how they engage in a conversation with a mother of a late preterm infant rooming-in on the postpartum unit that is not sucking effectively at the breast, including at least 3 points. [PI 44]</p> <p>Criterion 5.9.5 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Demonstrate at least 3 aspects of how to help a mother achieve a comfortable and safe position for breastfeeding within the first 6 hours after birth and later as needed during the hospital stay. [PI 33] B. Help a mother achieve a comfortable and safe position for breastfeeding with her preterm, late preterm or weak infant at the breast, noting at least 3 points. [PI 43] <p>Criterion 5.9.6 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Demonstrate how to help a mother achieve an effective and comfortable latch, noting at least 3 points. [PI 34] B. Demonstrate to a mother how to hand express breast-milk to a mother, noting at least 3 points. [PI 40] <p>Criterion 5.9.7 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Engage in a conversation with a mother regarding 2 elements related to infant feeding patterns in the first 36 hours of life. [PI 30] B. Engage in a conversation with a mother regarding at least 4 different ways to facilitate breastfeeding in order to prevent or resolve most common conditions of the lactating breasts (sore nipples, engorgement, mother who thinks she doesn't have enough milk, infants who have difficulty sucking). [PI 57]

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>5.9 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in:</p> <ul style="list-style-type: none"> • How to assist a mother in the steps to getting her baby to latch • How to discuss with a mother how breastfeeding works • In helping a mother to breastfeed a late-preterm baby • In helping a mother prevent or resolve difficulties with breastfeeding • In helping a mother manage milk expression • In helping a mother who is not feeding her baby directly at the breast 	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE PROVIDERS</p> <p><i>Criterion 5.9.8 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will be able to describe how they engage in a conversation with a mother regarding 2 elements related to infant feeding patterns in the first 36 hours of life. [PI 30]</i></p> <p><i>Criterion 5.9.9 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will be able to describe to a mother at least 2 signs of adequate transfer of milk in the first few days. [PI 31]</i></p> <p><i>Criterion 5.9.10 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will be able to describe at least 2 maternal and 2 infant risk factors associated with delayed lactogenesis II. [PI 65]</i></p> <p><i>Criterion 5.9.11 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will be able to explain how they would engage in a conversation with a mother of a preterm, late preterm, or low-birth weight infant not sucking effectively at the breast, including at least 3 points. [PI 44]</i></p>

Do not provide breastfed newborns any food or fluids other than breast-milk, unless medically indicated.

RATIONALE:

Giving newborns any foods or fluids other than breast-milk in the first few days after birth interferes with the establishment of breast-milk production. Newborns' stomachs are very small and easily filled. Newborns who are fed other foods or fluids will suckle less vigorously at the breast and thus inefficiently stimulate milk production, creating a cycle of insufficient milk and supplementation that leads to breastfeeding failure. Babies who are supplemented prior to facility discharge have been found to be twice as likely to stop breastfeeding altogether in the first 6 weeks of life.¹³ In addition, foods and liquids may contain harmful bacteria and carry a risk of disease. Supplementation with artificial milk significantly alters the intestinal microflora. *Breastfeeding exclusively is necessary to establish a healthy normal microbiome.*^{1, 6}

IMPLEMENTATION GUIDANCE:

*Exclusive breastfeeding for 6 months provides the nurturing, nutrients, immune factors and energy needed for physical and neurological growth and development. Beyond 6 months, breastfeeding continues to provide energy, immune factors and high-quality nutrients that, jointly with safe and adequate complementary feeding, help prevent hunger, undernutrition and obesity. Inadequate breastfeeding practices significantly impair health, development and survival of infants, children and mothers.*¹

Mothers should be discouraged from giving any food or fluids other than breast-milk, unless medically indicated.² Very few conditions of the infant or mother preclude the



feeding of breast-milk and necessitate the use of breast-milk substitutes. The WHO/UNICEF document on “Acceptable medical reasons for use of breast-milk substitutes” describes conditions for which breastfeeding is contraindicated.⁴² In addition, some breastfed infants will require supplementation. The Academy of Breastfeeding Medicine (ABM) has laid out a clinical protocol for managing situations in which supplementation of the mother’s own milk would become necessary.⁴³ Infants should be assessed for signs of inadequate milk intake and supplemented when indicated, but routine supplementation is rarely necessary in the first few days of life. Lack of resources, staff time or knowledge is not justification for the use of early additional foods or fluids.¹ *In addition to the WHO and ABM documents, facilities are encouraged to utilize the recommendations from the Centers for Disease Control and Prevention and the American Academy of Pediatrics to develop a policy/protocol that describes the current, evidence-based medical indications for supplementation and contraindications to breastfeeding.*⁴⁴⁻⁴⁶

Mothers who intend to “mixed-feed” (a combination of both breastfeeding and feeding with breast-milk substitutes) should be counseled (*using meaningful conversation techniques– see Step 2*) on the importance of exclusive breastfeeding in the first few weeks of life, how to establish a milk supply and to ensure that the infant is able to suckle and transfer milk from the breast. Supplementation can be introduced at a later date if the mother chooses. Mothers who report they have chosen not to breastfeed should be counseled

(*using meaningful conversation techniques–see Step 2*) on the importance of breastfeeding. However, if they still do not wish to breastfeed, feeding with breast-milk substitutes will be necessary. Mothers who are feeding breast-milk substitutes, by necessity or by choice, must be taught about safe preparation and storage of formula^{47, 55, 56} and how to respond adequately to their child’s feeding cues.¹

If a breastfeeding mother requests that her infant be supplemented, direct care staff and/or direct care providers should gently engage in an appropriate meaningful conversation [see Step 2] that carefully listens to her reasons. If the mother expresses any challenges, staff/providers should provide responsive care to evaluate/assess her concerns. It is possible that she is experiencing some breastfeeding difficulties that staff may be able to support her to overcome with additional guidance. If she still wishes to supplement with infant formula, staff should empower her understanding of evidence-based information that emphasizes the protections provided by breastfeeding, the possible impact of this decision to her health, the health of her infant and to the potential success of breastfeeding. Her informed decision should be confirmed and documented in the medical record. This education is only required to be provided once during the hospital stay.

FOR INFANTS WHO ARE UNABLE TO BE FED THEIR MOTHER'S OWN MILK.

IMPLEMENTATION GUIDANCE:

Infants who cannot be fed their mother's own milk, or who need to be supplemented, especially low-birth-weight infants, including those with very low birthweight^{48,49} and other vulnerable infants, should be fed *pasteurized* donor *human* milk. If *pasteurized* donor human milk is unavailable or culturally unacceptable, breast-milk substitutes are required. In most cases, supplementation is temporary, until the newborn is capable of breastfeeding and/or the mother is available and able to breastfeed. Mothers must also be supported and encouraged to express their milk to continue stimulating production of breast-milk, and to prioritize use of their own milk, even if direct breastfeeding is challenging for a period of time.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

If a mother expresses concern about the sufficiency of her breast-milk, an infant feeding assessment is warranted.

When mothers have decided not to breastfeed their infant or supplementation is needed/requested, direct care staff should discuss various options suitable to their situation such as the choice of supplement, volume of supplemental feeding, and methods of providing supplementary feedings.

In the case of supplementation for medical reasons, the decision to supplement is a delicate one. Practitioners must carefully weigh the risks and benefits of this decision.

When a mother decides to feed formula and/or it is determined that the benefits of supplementation outweigh the risks, the recommendation should be communicated in a respectful manner that is mindful of the sense of guilt, concerns and failure the mother may experience regarding such a recommendation.

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS

for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY

for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

US CLARIFICATION: BABY-FRIENDLY USA EXCLUSIVE BREASTFEEDING STANDARDS

The WHO/UNICEF BFHI Implementation Guidance standards call for a minimum of 80% exclusive breastfeeding (either milk from their own mothers or from a human milk bank) throughout the stay at the facility.¹ It is recognized by WHO and UNICEF that lower standards may need to be set at the national or local level, with the expectation that they should be raised over time, as other aspects of breastfeeding support in the community improve.

The US Designation is NOT based on an exclusive breastfeeding rate of greater than 80%.

It is expected that the facility will regularly monitor exclusive breastfeeding rates and that rates less than 80% will show improvement over time. Designated facilities with exclusive breastfeeding rates less than 50% will be required to submit quarterly reports to BFUSA.

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 6	VERIFICATION METHOD
*29. Engage in a conversation with a mother regarding at least 3 reasons why effective exclusive breastfeeding is important.	Observation
41. Explain at least 3 aspects of appropriate storage of breast-milk.	Question or case study
42. Explain at least 3 aspects of handling of expressed breast-milk.	Question or case study
*47. List at least 2 potential contraindications to breastfeeding for a baby and 2 for a mother.	Question or case study
*48. Describe at least 4 medical indications for supplementing breastfed newborns: 2 maternal indications and 2 newborn indications, when breastfeeding is not improved following skilled assessment and management.	Question or case study
*49. Describe at least 3 risks of giving a breastfed newborn any food or fluids other than breast-milk, in the absence of medical indication.	Question or case study
*66. Describe at least 1 professional medical reference or resource for identifying medications that are safe/compatible for use during lactation.	Question or case study
*50. For those few health situations where infants cannot, or should not, be fed at the breast, describe , in order of preference, the alternatives to use.	Question or case study
*51. Engage in a conversation with a mother who intends to feed her baby formula, noting at least 3 actions to take.	Observation
52. Demonstrate at least 3 important items of safe preparation of infant formula to a mother who needs that information.	Observation
*67. Identify 3 high-risk infant populations that may warrant extra precautions to protect against severe infections associated with powdered infant formula.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
6.1 Infants receive only breast-milk (either from their own mother or from a human milk bank) throughout their stay at the facility, unless medically indicated or informed parental decision.	<p>Interviews with mothers will confirm:</p> <p>Criterion 6.1.1 At least 80% of mothers will report that:</p> <ul style="list-style-type: none"> A. Their babies have received no food or drink other than human milk (direct breastfeeding, expressed breast-milk, or pasteurized donor human milk) while in the facility, OR B. Formula has been given for a medically acceptable reason, OR C. Formula has been given in response to an informed parental request/decision. <p>Criterion 6.1.2 Of breastfeeding mothers whose infants have been given food or drink other than breast-milk, at least 80% of those who have no acceptable medical reason will report that a health professional:</p> <ul style="list-style-type: none"> A. Listened to her reasons/concerns, AND B. Responded by assessing potential and/or existing challenges specific to her concerns, and/or providing additional guidance with workable solutions, AND C. If the mother still requests a breast-milk substitutes, health professionals empowered her with an understanding of evidence-based information [scientific, unbiased, factual] that allowed her to make an informed decision for her baby including: <ul style="list-style-type: none"> ▪ Importance of exclusive breastfeeding ▪ Possible risk factors that could influence health outcomes ▪ Possible impacts to the success of breastfeeding <p>Clarification: The counseling conversation only needs to be provided once at first request.</p>

U.S. CLARIFICATION: INFORMED DECISIONS - MEANINGFUL CONVERSATIONS Mothers should feel involved in all decisions regarding their selves and their babies. Empowering mothers to make informed decisions for their selves and their babies requires that they have up-to-date evidence-based [scientific, factual, unbiased] information that emphasized the protections provided by breastfeeding along with an understanding of risk factors that could influence health outcomes. The "Guideline: Counselling of Women to Improve Breastfeeding Practices" states that the "aim of breastfeeding counseling is to empower women to breastfeed, while respecting their personal situations and wishes."⁵⁰ As you work with families, consider incorporating appropriate components of the acronym E.N.C.O.U.R.A.G.E.S. so that you enter into meaningful conversations with them [see Step 2]

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
6.2 Breastfed babies who received supplemental feeds have a documented medical indication for supplementation in their medical records.	<p>Documentation:</p> <p>Criterion 6.2.1: <i>Of breastfeeding infants who have been given food or drink other than breast-milk for medical indications, at least 80% will have the reasons for supplementation clearly documented in their medical records.</i></p> <p>Criterion 6.2.2: <i>Of breastfeeding infants who have been given food or drink other than breast-milk for parental request, at least 80% will have the reasons for supplementation and evidence of parental counseling clearly documented in their medical records.</i></p>
6.3 Mothers who have decided not to breastfeed report that the staff discussed with them the various feeding options and helped them to decide what was suitable in their situations.	<p>Interviews with mothers who have decided not to breastfeed:</p> <p>Criterion 6.3.1 <i>Of mothers who have decided not to breastfeed [requesting to feed their babies with breast-milk substitutes], at least 80% of those who have no acceptable medical reason will report that the health care staff:</i></p> <ul style="list-style-type: none"> A. Listened to their reasons/concerns, AND B. Responded by assessing potential and/or existing challenges specific to her concerns, and/or providing additional guidance with workable solutions including various feeding options, AND C. If the mothers still requested to feed their babies with breast-milk substitutes, health care staff empowered them with an understanding of evidence-based information [scientific, unbiased, factual] that allowed them to make an informed decision for their babies including: <ul style="list-style-type: none"> ▪ Importance of breastfeeding ▪ Possible risk factors that could influence health outcomes when feeding breast-milk substitutes <p>Clarification: <i>The counseling conversation only needs to be provided once at first request.</i></p>
6.4 Mothers who cannot, or have decided not to breastfeed, will report that the staff discussed with them the safe preparation, feeding and storage of breast-milk substitutes.	<p>Interviews with mothers who are feeding their infants any formula and/or plan to continue post-discharge will be able to:</p> <p>Criterion 6.4.1 <i>At least 80% of mothers who are feeding their infants any formula and plan to continue post-discharge, will be able to describe 2 appropriate steps that staff discussed with them about safe preparation, feeding and storage of formula.</i></p>

U.S. CLARIFICATION: SAFE PREPARATION, STORAGE AND FEEDING OF INFANT FORMULA *Mothers who have decided not to breastfeed, decided to “mixed-feed”, or will require supplementation with formula for their infants at the time of discharge must receive written instruction and verbal information about safe preparation, storage and feeding of formula. Staff should document completion of formula preparation instruction and feeding in the medical record. The information should be given on an individual basis only.*

Safe preparation, feeding, and storage of formula instruction must follow the recommendations of leading national and international authorities and must include:

1. *Appropriate hand hygiene*
2. *Cleaning infant feeding items [bottles, nipples, rings, caps, syringes, cups, spoons, etc.] and workspace surfaces*
3. *Appropriate and safe reconstitution of concentrated and powdered infant formulas*
4. *Accuracy of measurement of ingredients*
5. *Safe handling of formula*
6. *Proper storage of formula*
7. *Appropriate feeding methods which may include feeding on cue, frequent low volume feeds, paced bottle techniques, eye-to-eye contact, and holding the infant closely*
8. *Powdered infant formula is not sterile and may contain pathogens that can cause serious illness in infants younger than 3 months*

National and international authorities include:

- *American Academy of Pediatrics*
- *Centers for Disease Control and Prevention*
- *Food and Drug Administration*
- *United States Department of Agriculture*
- *World Health Organization*

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>6.5 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in:</p> <p><i>In helping a mother whose baby needs fluids other than breast-milk.</i></p>	<p>Interviews with Direct Care Nursing Staff and Direct Care Providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 6.5.1 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. List at least 1 potential contraindication to breastfeeding for a baby and 1 for a mother. [PI 47] B. Describe at least 2 medical indications for supplementing breastfed newborns: 1 maternal indication and 1 newborn indication, when breastfeeding is not improved following skilled assessment and management. [PI 48] <p>Criterion 6.5.2 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Engage in a conversation with a mother regarding at least 2 reasons why effective exclusive breastfeeding is important. [PI 29] B. Describe at least 2 risks of giving a breastfed newborn food or fluids other than breast-milk, in the absence of medical indications. [PI 49] <p>Criterion 6.5.3 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Engage in a conversation with a mother who intends to feed her baby formula, noting at least 3 actions. [PI 51] B. Identify 2 high-risk infant populations that may warrant extra precautions to protect against severe infections associated with powdered infant formula. [PI 67]

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>6.6 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in:</p> <p><i>In helping a mother whose baby needs fluids other than breast-milk.</i></p>	<p>DIRECT CARE PROVIDERS</p> <p>Criterion 6.6.4 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe how they engage in a conversation with a mother regarding at least 2 reasons why effective exclusive breastfeeding is important. [PI 29]</p> <p>Criterion 6.6.5 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will list at least 2 potential contraindications to breastfeeding for a baby and 2 for a mother. [PI 47]</p> <p>Criterion 6.6.6 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 4 medical indications for supplementing breastfed newborns: 2 maternal indications and 2 newborn indications, when breastfeeding is not improved following skilled assessment and management. [PI 48]</p> <p>Criterion 6.6.7 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 1 professional medical reference or resource for identifying medications that are safe/compatible for use during lactation. [PI 66]</p> <p>Criterion 6.6.8 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will identify 2 high-risk infant populations that may warrant extra precautions to protect against severe infections associated with powdered infant formula. [PI 67]</p>

Enable mothers and their infants to remain together and to practice rooming-in 24 hours a day.

RATIONALE:

Rooming-in is necessary to enable mothers to practice responsive feeding, as mothers cannot learn to recognize and respond to their infants' cues for feeding if they are separated from them. When the mother and infant are together throughout the day and night, it is easy for the mother to learn to recognize feeding cues and respond to them. This, along with the close presence of the mother to her infant, will facilitate the establishment of breastfeeding.¹

IMPLEMENTATION GUIDANCE:

Facilities providing maternity and newborn services should enable mothers and their infants to remain together and to practice rooming-in throughout the day and night.² Rooming-in involves keeping mothers and infants together in the same room, immediately after vaginal birth or cesarean section, or from the time when mothers are able to respond to their infants, until discharge. This means that mothers and infants are together throughout the day and night.¹

Postpartum units need to be designed so that there is enough space for mothers and their newborns to be together. Facility staff need to visit the *hospital room* regularly to ensure the babies are safe. Babies should only be separated from their mothers for justifiable medical and safety reasons. Minimizing disruption to breastfeeding during the stay in the facility will require health-care practices that enable a mother to breastfeed for as much, as frequently and for as long as her baby needs it.¹



When a mother is placed in a dedicated unit [recovery area and/or postpartum room] to recover from a cesarean section, the baby should be accommodated in the same room with her, close by. She will need practical support to position her baby to breastfeed, and will need help with lifting the baby from a bassinet.¹

Rooming-in may not be possible in circumstances when infants need to be moved for specialized medical care.¹ If preterm or sick infants need to be in a separate room to allow for adequate treatment and observation, efforts must be made for the mother to recuperate postpartum with her infant, or to have no restrictions for visiting her infant. Mothers should have adequate space to express milk adjacent to their infants.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

There are several factors that must be understood when mothers and infants are rooming-in together:

- *Mothers will be naturally exhausted and/or only sleep in short bursts following childbirth.²⁵*
- *Sleepiness is a normal, hormonally-driven, physiological response to breastfeeding for both mothers and infants. Unintentionally, this can lead to mothers falling asleep while breastfeeding their infants.⁵¹*
- *Following cesarean births, mothers have limited mobility and are likely to feel the effects of medications, which may cause them to be less responsive.²⁵*

Facilities are encouraged to develop processes that support staff in the safe implementation of rooming-in practices.^{25, 26, 51}

The hospital setting is the perfect place to role model safe rooming-in and to help families plan for a safe breastfeeding and sleep environment for home. It is a prime opportunity to educate mothers and families about the components of a safe environment which includes but is not limited to:

- *Mothers and infants have close but separate sleep surfaces.²⁷*
- *Infants are placed on their backs to sleep, for naps and at night.²⁷*
- *Firm flat sleep surface is used in a safety-approved crib, covered by a fitted sheet.²⁷*
- *Soft bedding and objects are avoided. Do not put pillows, blankets, sheepskins in baby's sleep area.²⁷*
- *Baby is dressed in sleep clothing. Loose blankets are not used, and baby is not over bundled.²⁷*

Mothers (and families) should be given anticipatory guidance about considering how tired they are before and during their infant's feeding so that steps can be taken to reduce risks to their infant.⁵² Facilities and staff should consider implementing the following safe rooming-in practices:

- *Monitor mothers according to their risk assessment.²⁵*
- *Review equipment, such as call bells, with mothers²⁵ and instruct them to call for help when feeling tired or sleepy.⁵¹*
- *Conduct hourly rounding to provide assistance placing infants in bassinets when mothers or caregivers appear to be drowsy or after mothers have received pain medications.⁵¹*
- *Educate families and support persons to transition newborn to the bassinet when mother is falling asleep.*
- *Promote maternal rest⁵¹ by limiting staff and visitor interruptions.*

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 7	VERIFICATION METHOD
*35. Engage in a conversation with a mother regarding 2 aspects related to the importance of rooming-in 24h/day.	Observation
68. Describe 2 aspects involved in creating a safe environment for rooming-in during the hospital stay.	Question or case study
*69. Demonstrate at least 3 safety aspects to assess when mother and baby are skin-to-skin during the postpartum hospitalization, regardless of method of birth.	Observation
*36. Explain 2 situations: 1 for the mother and 1 for the infant, when it is acceptable to separate mother and baby while in hospital.	Question or case study
45. Engage in a conversation with a mother separated from her preterm or sick infant regarding at least 2 reasons to be with her infant in the intensive care unit.	Observation

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
7.1 Mothers report that their babies stayed with them since birth, without separation lasting for more than 1 hour.	<p>Interviews with mothers will confirm:</p> <p>Criterion 7.1.1 At least 80% of mothers will report that their infants have stayed with them in the same room day and night, without separation of more than 1 hour per 24-hour period unless:</p> <ul style="list-style-type: none"> A. Medically justifiable reason for a longer separation, OR B. Safety-related reason for a longer separation, OR C. Informed decision for a longer separation [maternal request]

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
7.1 Mothers report that their babies stayed with them since birth, without separation lasting for more than 1 hour.	<p>Interviews with mothers will confirm:</p> <p>Criterion 7.1.2 At least 80% of mothers who requested their infant to be removed from the room will report the facility staff:</p> <ul style="list-style-type: none"> A. Listened to her reasons/concerns AND B. Responded by assessing potential and/or existing challenges specific to her concerns, and/or providing additional guidance with workable solutions to safely avoid the separation AND C. If the mother still requested separation, health professionals empowered her with an understanding of evidence-based information [scientific, unbiased, factual] that allowed her to make an informed decision for her baby including: <ul style="list-style-type: none"> ■ Importance of rooming-in, ■ If breastfeeding, a plan for reuniting the mother and infant as soon as the infant displays feeding cues. <p>Documentation:</p> <p>Criterion 7.1.3 Of mothers and babies that have been separated, at least 80% will have the following documented in the medical record:</p> <ul style="list-style-type: none"> A. Reason for the separation B. Location of infant C. Length of separation D. Infant feedings during separation E. Counseled on the importance of rooming-in including a plan for reuniting the mother and infant, and infant feeding. <p>NOTE: Facilities must make every effort to minimize any disruptions to breastfeeding by reuniting a mother and infant as frequently and for as long as her baby needs it.</p> <p>Criterion 7.1.4 Quality improvement question for informational purposes (not a designation criterion): Mothers will report that they felt supported with rooming and caring for her baby.</p> <ul style="list-style-type: none"> A. They received practical information AND B. Received help when needed.
7.2 Observations in the postpartum wards and well-baby observation areas confirm that mothers and babies are together or, if not, have medically justifiable reasons for being separated.	<p>Observations in the postpartum unit and newborn units will confirm:</p> <p>Criterion 7.2.1 Observations in the postpartum unit and any well-baby observation areas confirm that at least 80% of the mothers and infants are rooming-in or have a documented:</p> <ul style="list-style-type: none"> A. Medically justifiable reason for separation, OR B. Safety-related reason for separation, OR C. Informed decision for separation [maternal request]

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE NICU UNIT:

US STANDARD	US CRITERION FOR EVALUATION
7.3 Mothers of preterm or sick infants report having no restrictions and had access to their infants in the NICU whenever they wanted.	<p>Interviews with mothers who are breastfeeding or intending to do so with infants in the NICU will confirm:</p> <p>Criterion 7.3.1 At least 80% of mothers with infants in the NICU report that they have had access to their infants in the NICU whenever they wanted.</p>



COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
7.4 Health professionals who provide postpartum and/or newborn care will be competent in helping a mother to respond to her baby's feeding cues [by enabling a mother and infant to rooming-in 24 hours a day].	<p>DIRECT CARE NURSING STAFF</p> <p>Criterion 7.4.1 At least 80% of direct care nursing staff who provide postpartum, and/or newborn care will describe or demonstrate how they engage in a conversation with a mother regarding 2 aspects related to the importance of rooming-in 24h/day. [PI 35]</p> <p>Criterion 7.4.2 At least 80% of direct care nursing staff who provide postpartum, and/or newborn care will describe or demonstrate at least 2 safety aspects to assess when mother and baby are skin-to-skin during the postpartum hospitalization regardless of method of birth. [PI 69]</p> <p>Criterion 7.4.3 At least 80% of direct care nursing staff who provide postpartum, and/or newborn care will explain 2 situations: 1 for the mother and 1 for the infant, when it is acceptable to separate mother and baby while in the hospital. [PI 36]</p> <p>DIRECT CARE PROVIDER</p> <p>Criterion 7.4.4 At least 80% of direct care providers with privileges to provide postpartum and/or newborn care will describe how they engage in a conversation with a mother regarding 2 aspects related to the importance of rooming-in 24h/day. [PI 35]</p> <p>Criterion 7.4.5 At least 80% of direct care providers with privileges to provide postpartum and/or newborn care will explain 2 situations: 1 for the mother and 1 for the infant, when it is acceptable to separate mother and baby while in the hospital. [PI 36]</p>

U.S. CLARIFICATION: MEDICALLY JUSTIFIABLE OR SAFETY-RELATED REASONS FOR SEPARATION *Healthcare Professionals must use their clinical judgement.* While it is true that rooming-in is the expected practice in Baby-Friendly designated facilities, we recognize some circumstances necessitate mother-baby separation. The decision that leads to a separation is often complex involving observations, assessments, and an understanding of the individual mother-baby dyad. It is imperative in these situations that care and decisions are individualized and include the mother's participation, if possible. Facilities should have a dedicated area to provide care to infants who have a justifiable reason for separation. As a reminder, BFUSA does NOT require that facilities close their nursery.

To be clear, infants must not be separated for routine facility procedures that could be performed in the mother's room.

Support mothers to recognize and respond to their infants' cues for feeding.

RATIONALE:

Breastfeeding involves recognizing and responding to the infant's display of hunger and feeding cues and readiness to feed, as part of a nurturing relationship between the mother and infant. Responsive feeding (also called on-demand or baby-led feeding) puts no restrictions on the frequency or length of the infant's feeds, and mothers are advised to breastfeed whenever the infant is hungry or as often as the infant wants. Scheduled feeding, which prescribes a predetermined, and usually time-restricted, frequency and schedule of feeds is not recommended. It is important that mothers know that crying is a late *feeding* cue and that it is better to feed the baby earlier, since optimal positioning and attachment are more difficult when an infant is in distress.¹

IMPLEMENTATION GUIDANCE:

Mothers should be supported to practice responsive feeding as part of nurturing care.¹ Regardless of whether they breastfeed or not, mothers should be supported to recognize and respond to their infants' cues for feeding, closeness and comfort, and enabled to respond accordingly to these cues with a variety of options, during their stay at the facility providing maternity and newborn services.² Supporting mothers to respond in a variety of ways to behavioral cues for feeding, comfort or closeness enables them to build a caring, nurturing relationship with their infants and increases their confidence in themselves, in breastfeeding and in their infants' growth and development.¹



When the mother and baby are not in the same room for medical or other justifiable reasons, the facility staff need to bring the mother and infant together as often as possible, so that she can recognize feeding cues. When staff notice feeding cues, they should also bring the mother and baby together.¹

New mothers believe that it is important that they respond to their infant's feeding cues. However, mothers have reported being stressed and anxious about how to interpret their infant's needs. Postpartum conversations support families to develop an understanding of an infant's cues for feeding, comfort, or closeness. Education provided to families should increase a mother's confidence in interpreting these cues and responding in a variety of ways which might include breastfeeding, rocking, holding, walking, singing, and skin-to-skin contact.²

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

ABM Protocol #10 recommends that mothers of late preterm and early term infants on the postpartum unit should be taught to respond to their infants' cues for feeding. However, it may be necessary for mothers to wake their infants when they do not demonstrate hunger cues within 4 hours of the previous feeding. Preterm infants should be breastfed (or breast-milk fed) 8-12 times in a 24-hour period.⁴¹

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS

for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 8	VERIFICATION METHOD
*37. Describe at least 2 early feeding cues and 1 late feeding cue.	Question or case study
38. Describe at least 4 reasons why responsive feeding (also called on-demand or baby-led feeding) is important.	Question or case study
39. Describe at least 2 aspects of responsive feeding (also called on-demand or baby-led feeding) independent of feeding method.	Question or case study
46. Engage in a conversation with a mother of a preterm, late preterm or vulnerable infant (including multiple births) regarding the importance of observing at least 2 subtle signs and behavioral state shifts to determine when it is appropriate to breast-feed.	Observation
*58. Describe at least 4 elements to assess when a mother says that her infant is crying frequently.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
8.1 Breastfeeding mothers can describe at least two feeding cues.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 8.1.1 <i>At least 80% of breastfeeding mothers can describe at least 2 early feeding cues.</i></p>
8.2 Breastfeeding mothers report that they have been advised to feed their babies as often and for as long as the infant wants.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 8.2.1 <i>At least 80% of breastfeeding mothers will report that they have been advised to feed their infants as often and as long as the infants want.</i></p> <p>Criterion 8.2.2 <i>Quality improvement question for informational purposes (not a designation criterion): At least 80% of breastfeeding mothers can provide 2 acceptable responses to describe normal infant feeding patterns after the first 24 hours of life including:</i></p> <ul style="list-style-type: none"> ▪ <i>The average feeding frequency is at least 8-12 times in 24 hours,</i> ▪ <i>Infants feeding through the night and/or</i> ▪ <i>That cluster feeding is common.</i>

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>8.3 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in helping a mother to respond to her baby's feeding cues.</p>	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 8.3.1 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe at least 2 early feeding cues and 1 late feeding cue. [PI 37]</p> <p>Criterion 8.3.2 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe at least 2 reasons why responsive feeding (also called on-demand feeding) is important [PI 38]</p> <p>Criterion 8.3.3 3 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe at least 2 elements to assess when a mother says her infant is crying frequently. [PI 58]</p> <p>DIRECT CARE PROVIDER</p> <p>Criterion 8.3.4 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 2 early feeding cues and 1 late feeding cue. [PI 37]</p> <p>Criterion 8.3.4 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 2 elements to assess when a mother says her infant is crying frequently. [PI 58]</p>

Counsel mothers on the use and risks of feeding bottles, artificial nipples, and pacifiers.

RATIONALE:

Proper guidance and counseling of mothers and other family members enables them to make informed decisions on the use or avoidance of pacifiers and/or feeding bottles and *artificial nipples* until the successful establishment of breastfeeding. While WHO guidelines² do not call for absolute avoidance of feeding bottles, *artificial nipples* and pacifiers for term infants, there are a number of reasons for caution about their use, including hygiene, oral formation and recognition of feeding cues.¹

IMPLEMENTATION GUIDANCE:

If expressed milk or other feeds are medically indicated for term infants, feeding methods (*devices*) such as cups, spoons or feeding bottles and *artificial nipples* can be used during their stay at the facility.² However, it is important that staff do not become reliant on *artificial nipples* as an easy response to suckling difficulties instead of counseling mothers and enabling babies to attach babies properly and suckle effectively.¹

It is important that the facility staff ensure appropriate hygiene in the cleaning of these utensils, since they can be a breeding ground for bacteria. Facility staff should also inform mothers and family members of the hygiene risks related to inadequate cleaning of feeding utensils, so that they can make informed *decisions* on the feeding method.

The physiology of suckling at the breast is different from the physiology of suckling from a feeding bottle and an *artificial nipple*.⁵³ It is possible that the use of the feeding bottle and an *artificial nipple* could lead to breastfeeding difficulties, particularly if use is prolonged.



However, the only study on this did not demonstrate a specific carry-over effect from suckling at a feeding bottle and *an artificial nipple* to suckling at the breast.^{1, 15}

Pacifiers have long been used to soothe an upset infant. In some cases, they serve a therapeutic purpose, such as reducing pain during procedures when breastfeeding or skin-to-skin contact are not possible. *Pacifiers have also been shown to reduce the risk of SIDS, even among breastfeeding infants.* However, if pacifiers replace suckling and thus reduce the number of times an infant stimulates the mother's breast physiologically, this can lead to a reduction of maternal milk production. The use of *artificial nipples* or pacifiers may interfere with the mother's ability to recognize feeding cues. If the use of a pacifier prevents the mother from observing the infant's smacking of the lips or rooting towards the breast, she may delay feeding until the infant is crying and agitated.¹ *Therefore, recommending to parents that they delay pacifier introduction until breastfeeding is well established supports breastfeeding while reducing the risk of SIDS and helps parents understand appropriate timeframes for introducing pacifiers.*^{26, 27}

For preterm infants, evidence does demonstrate that use of feeding bottles with *artificial nipples* interferes with learning to suckle at the breast. If expressed breast-milk or other feeds are medically indicated for preterm infants, feeding methods such as cups or spoons are preferable to feeding bottles and *artificial nipples*.² On the other hand, for preterm infants who are unable to breastfeed directly, non-nutritive sucking and oral stimulation may be

beneficial until breastfeeding is established.² Non-nutritive sucking or oral stimulation involves the use of pacifiers, a gloved finger or a breast that is not yet producing milk.¹ **NOTE:** *If a preterm infant is in the room with the mother, oral stimulation should always be done by placing baby at the breast.*

There should be no promotion of feeding bottles or *artificial nipples* in any part of facilities providing maternity and newborn services, or by any of the staff. As is the case with breast-milk substitutes, these products fall within the scope of the *International Code*.^{1, 15, 16, 54} *[SEE STANDARD 9.2 FOR ADDITIONAL GUIDANCE on the promotion of pacifiers as a SIDS risk reduction measure.]*

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Hygiene is an important consideration for safe implementation of the use of bottles, nipples and pacifiers and other infant feeding items. The Centers for Disease Control and Prevention (CDC) and World Health Organization provide the steps that families should follow to clean, sanitize, and store infant feeding items. The CDC also provides steps to ensure that breast pump and breast pump parts are clean and sanitized.^{55, 56}

*Pacifiers are also recognized as a risk reduction measure for Sudden Infant Death Syndrome (SIDS). To reduce the risk of SIDS, the AAP recommends exclusive breastfeeding, breastfeeding for at least 6 months, and offering a pacifier at naptime and bedtime, once breastfeeding is well established. Infants who are not being directly breastfed can begin pacifier use as soon as desired.*²⁶

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 9	VERIFICATION METHOD
28. Describe at least 6 essential issues that every breastfeeding mother should know or demonstrate.	Question or case study
53. Demonstrate to a mother how to safely cup-feed her infant when needed, showing at least 4 points.	Observation
54. Describe to a mother at least 4 steps to feed an infant a supplement in a safe manner.	Observation
*55. Describe at least 2 alternative feeding methods other than feeding bottles.	Question or case study
56. Engage in a conversation with a mother who requests feeding bottles, <i>artificial nipples</i> , and pacifiers [soothers] without medical indication, including at least 3 points.	Observation
*59. Describe at least 4 elements of anticipatory guidance to give to a mother on calming or soothing techniques before or as alternatives to pacifiers.	Question or case study
*70. Describe when the acceptable time is for introducing a pacifier with a breast-feeding infant, with regards to SUID/SIDS reduction strategies.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
9.1 Breastfeeding mothers report that they have been taught about the risks of using feeding bottles, artificial nipples and pacifiers. ²	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 9.1.1 At least 80% of breastfeeding mothers can describe:</p> <ul style="list-style-type: none"> A. One possible impact that pacifiers might have on breastfeeding, AND B. When the acceptable time is for introducing the pacifier. <p>Criterion 9.1.2 At least 80% of breastfeeding mothers can describe one possible impact that bottles and artificial nipples might have on breastfeeding.</p> <p>Criterion 9.1.3 At least 80% of breastfeeding mothers that are unable to feed their baby directly at the breast or needed/chose additional supplementation will report:</p> <ul style="list-style-type: none"> A. Alternative feeding devices other than bottles were offered, AND B. They were informed of the potential impacts of feeding bottles on breastfeeding AND C. Will be able to describe 2 feeding techniques appropriate for the use of selected feeding device. <p>Criterion 9.1.4 At least 80% of breastfeeding mothers [including breast-milk feeding] utilizing infant feeding items [bottles, artificial nipples, rings, caps, syringes, cups, spoons, breast pump equipment, etc.] can provide 1 acceptable response about proper hygiene when cleaning these infant feeding items.</p>

SAFE SLEEP AND SIDS REDUCTION MESSAGES SHOULD BE DISTRIBUTED BY THE FACILITY AND THE FOLLOWING STANDARDS AND CRITERIA FOR EVALUATION APPLY:

RATIONALE:

BFUSA acknowledges the evidence pertaining to pacifier use related to SIDS risk reduction.²⁵ Safe sleep and SIDS risk reduction information is important for parents to receive during the birth hospital stay.^{26, 27} This education may be compatibly provided to parents by using safe sleep materials that also promote breastfeeding.

US STANDARD	US CRITERION FOR EVALUATION
9.2 Facilities distributing safe sleep materials must also provide additional verbal and written education related to breastfeeding and pacifier use to mothers.	<p>A review of education materials will confirm:</p> <p>Criterion 9.2.1 A review of materials will confirm that safe sleep and SIDS risk reduction materials that are provided to mothers also provide additional written education that includes the all of the following:</p> <ul style="list-style-type: none"> A. Pacifier use in the breastfed infant should be delayed until breastfeeding is firmly established.^{26, 27} AND B. How mothers can know that breastfeeding is firmly established (For example, milk supply has increased, infant is breastfeeding 8–12 times in 24 hours, infant is satisfied after feedings, infant is gaining weight, mother can hear baby swallowing during feeding, adequate voiding and stooling according to expected norms).AND C. Breastfeeding is associated with a reduced risk of SIDS, and the protective effect increases with breastfeeding duration and exclusivity, with the greatest protection offered by breastfeeding for at least 6 months.^{27, 57} <p>Criterion 9.2.2 Quality improvement question for informational purposes (not a designation criterion): At least 80% of mothers should be able to recall at least 2 of the following key safe sleep messages:</p> <ul style="list-style-type: none"> ■ Baby should always be placed on back to sleep. ■ Baby should sleep in an empty, approved (CPSC) crib. ■ Baby should sleep in the same room as parents for at least 6 and preferably to 12 months. ■ Parents should refrain from smoking during and after pregnancy and baby should sleep in a smoke-free environment. ■ Breastfeeding reduces the risk of SIDS. ■ Pacifier use at bedtime reduces the risk of SIDS.

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>9.3 Health professionals who provide labor and delivery, postpartum and/or newborn care will be competent in:</p> <ul style="list-style-type: none"> • How to discuss with a mother how breastfeeding works, • Helping a mother who is not feeding her baby directly at the breast. 	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 9.3.1 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe to a mother at least 4 steps to feed an infant a supplement in a safe manner. [PI 54]</p> <p>Criterion 9.3.2 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe at least 2 elements of anticipatory guidance to give to a mother on calming or soothing techniques before or as alternatives to pacifiers. [PI 59]</p> <p>Criterion 9.3.3 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe when the acceptable time is for introducing a pacifier with a breastfeeding infant with regards to SUID/SIDS reduction strategies. [PI 70]</p> <p>DIRECT CARE PROVIDER</p> <p>Criterion 9.3.4 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 2 elements of anticipatory guidance to give to a mother on calming or soothing techniques before or as alternatives to pacifiers. [PI 59]</p> <p>Criterion 9.3.5 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe when the acceptable time is for introducing a pacifier with a breastfeeding infant with regards to SUID/SIDS reduction strategies. [PI 70]</p>

Coordinate discharge so that parents and their infants have timely access to ongoing support and care.

RATIONALE:

Mothers need sustained support to continue breastfeeding. While the time in the facility providing maternity and newborn services should provide a mother with basic breastfeeding skills, it is very possible her milk supply has not been fully established until after discharge. Breastfeeding support is especially critical in the succeeding days and weeks after discharge, to identify and address early breastfeeding challenges that occur. She will encounter several different phases in her production of breast-milk, her infant's growth and her own circumstances (e.g. going back to work or school), in which she will need to apply her skills in a different way and additional support will be needed. Receiving timely support after discharge is instrumental in maintaining breastfeeding rates. Maternity facilities must know about and refer mothers to the variety of resources that exist in the community.¹

IMPLEMENTATION GUIDANCE:

As part of protecting, promoting and supporting breastfeeding, discharge from facilities providing maternity and newborn services should be planned for and coordinated, so that parents and their infants have access to ongoing support and receive appropriate care.² Each mother should be linked to lactation-support resources in the community upon discharge. Facilities need to provide appropriate referrals to ensure that mothers and babies are seen by a health worker to assess the feeding situation. *The AAP recommends that every infant should have an evaluation within 3 to 5 days of birth and within 48 to 72 hours after discharge from the hospital that includes an evaluation for feeding and jaundice. Breastfeeding newborns*



should receive formal breastfeeding evaluation, and their mothers should receive encouragement and instruction. Printed and/or online information could be useful to provide contacts for support, in case of questions, doubts or difficulties, but this should not substitute for active follow-up care by a skilled professional.¹

Facilities providing maternity and newborn services need to identify appropriate community resources for continued and consistent breastfeeding support that is culturally and socially sensitive to their needs. The facilities have a responsibility to engage with the surrounding community to enhance such resources. Community resources include primary health-care centers, community health workers, home visitors, breastfeeding clinics, nurses/midwives, lactation consultants, peer counsellors, mother-to-mother support groups, or phone lines ("hot lines"). The facility should maintain contact with the groups and individuals providing the support as much as possible and invite them to the facility where feasible.¹

Follow-up care is especially crucial for preterm and low-birth-weight babies. In these cases, the lack of a clear follow-up plan could lead to significant health hazards. Ongoing support from skilled professionals is needed.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Vulnerable Populations: Breastfeeding can be extremely challenging, especially if a mother is in a community at risk for not breastfeeding. Equity will be increased if competently skilled professionals and evidence-based breastfeeding counseling is accessible to all mothers. Populations at risk for lower rates of breastfeeding duration may include African American/Black

mothers, mothers who are young, return early to work; lack social support; mothers with mental or medical concerns; parents with social and cultural considerations; late preterm and early term infants.^{50, 58}

Knowledge of the existence of post discharge support can be instrumental in a mother's willingness to give breastfeeding a try. While breastfeeding mothers may have some particular concerns, it is critically important that support be provided to all mothers.

Continuum of care: The Academy of Breastfeeding Medicine's "Clinical Protocol #7: Model Maternity Policy Supportive of Breastfeeding" provides the following guidance:

- *Before discharge, the health care team will ensure that there is effective breastfeeding, that breastfeeding mothers are able to efficiently breastfeed their infants and that continuity of care is guaranteed, either by follow-up visits or by arranging qualified primary care providers and/or lactation specialists visits and/or support groups or peer counseling contacts.³⁸*
- *If the infant is still not latching or feeding well at the time of discharge, an individualized feeding plan will be devised and, depending on the dyad's clinical situation and resources, the infant's discharge may be delayed.³⁸*
- *Mothers identified prenatally or soon after delivery as at risk of delayed lactogenesis II will be assigned to special help as deemed appropriate. A feeding plan and close follow-up of the infant (for adequate hydration and nutrition besides help with expression) will be offered. At discharge, continuum of care will be ensured with a feeding plan and close follow-up.³⁸*

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 10	VERIFICATION METHOD
57. Engage in a conversation with a mother regarding at least 4 different ways to facilitate breastfeeding in order to prevent or resolve most common conditions of the lactating breasts (sore nipples, engorgement, mother who thinks she doesn't have enough milk, infants who have difficulty sucking).	Observation
60. Describe at least 2 locally available sources for timely infant feeding information and problem management.	Question or case study
61. Describe at least 2 ways the healthcare facility engages with community-based programs to coordinate breastfeeding messages and offer continuity of care.	Question or case study
*62. Develop individualized discharge feeding plans with a mother that includes at least 6 points.	Observation
*63. Describe to a mother at least 4 warning signs of infant undernourishment or dehydration for a mother to contact a health care professional after discharge.	Observation
*64. Describe at least 3 warning maternal signs for a mother to contact a health care professional after discharge.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
10.1 Mothers report that a staff member has informed them where they can access breastfeeding support/infant formula feeding support in their community.	<p>Interviews with mothers will confirm:</p> <p>Criterion 10.1.1 At least 80% of breastfeeding mothers [including breast-milk feeding] will report that they have been given verbal and written information on:</p> <ul style="list-style-type: none"> A. How to access breastfeeding support [support groups, peer counselors, providers, or other skilled community health services] after discharge from the facility, AND B. When to follow-up for a newborn evaluation for jaundice and feeding, AND C. Maternal/infant warning signs/symptoms of breastfeeding problems that must receive urgent evaluation and whom they should call for assistance. <p>Criterion 10.1.2 At least 80% of mothers choosing to feed their babies formula will report that they have been given verbal and written information on:</p> <ul style="list-style-type: none"> A. How to access infant formula feeding support [support groups, peer counselors, providers, or other skilled community health services] after discharge from the facility, AND B. When to follow-up for a newborn evaluation for jaundice and feeding, AND C. Maternal/infant warning signs/symptoms of breast problems and/or formula feeding concerns that must receive urgent evaluation and whom they should call for assistance. <p>NOTE: Mothers who are "mixed-feeding" their babies should receive verbal and written information appropriate to support optimal, safe infant feeding individualized to their feeding intentions.</p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
<p>10.2 The facility can demonstrate that it coordinates with community services that provide breastfeeding/infant feeding support, including clinical management and mother-to-mother support.</p>	<p>A review of documents indicates:</p> <p><i>Criterion 10.2.1 A review of documents indicates that written (printed or electronic) information is distributed to mothers before discharge on how and where mothers, regardless of feeding method, can find help on feeding their infants after returning home and includes information on what type of help is available from each source of support.</i></p> <p><i>Criterion 10.2.2 The facility provides a written description of how it fosters the establishment of and/or coordinates with mother support groups and other community services that provide breastfeeding/infant feeding support to mothers. The description includes a specific list of programs and services they fostered/coordinated with.</i></p>
COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>10.3 Health professionals who provide postpartum and/or newborn care will be competent to ensure a seamless transition after discharge.</p>	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p><i>Criterion 10.3.1 At least 80% of direct care nursing staff who provide postpartum and/or newborn care will describe the components of an individualized discharge feeding plans with a mother that includes at least 4 points. [PI 62]</i></p> <p><i>Criterion 10.3.2 At least 80% of direct care nursing staff who provide postpartum and/or newborn care will describe to a mother at least 3 warning signs of infant undernourishment or dehydration for a mother to contact a health professional after discharge. [PI 63]</i></p> <p><i>Criterion 10.3.3 At least 80% of direct care nursing staff who provide postpartum and/or newborn care will describe at least 2 maternal warning signs for a mother to contact a health care professional after discharge. [PI 64]</i></p> <p>DIRECT CARE PROVIDER</p> <p><i>Criterion 10.3.4 At least 80% of direct care providers with privileges to provide postpartum and/or newborn care will describe to a mother at least 3 warning signs of infant undernourishment or dehydration for a mother to contact a health professional after discharge. [PI 63]</i></p> <p><i>Criterion 10.3.5 At least 80% of direct care providers with privileges to provide postpartum and/or newborn care will describe at least 2 maternal warning signs for a mother to contact a health care professional after discharge. [PI 64]</i></p>

APPENDICES:

APPENDIX A: Patient Education Topics

APPENDIX B: Indicators for Facility Monitoring of Key Clinical Practices

APPENDIX C1: Performance Indicators to Measure Each Competency

APPENDIX C2: Performance Indicators Sorted by Step

APPENDIX D: Determining Affiliated Prenatal Services

APPENDIX E: Acceptable Medical Reasons for Use of Breast-Milk Substitutes

APPENDIX F: Definitions of Terms and Abbreviations Used in This Document

APPENDIX G: Expert Panel Members

APPENDIX H: Guidelines and Evaluation Criteria Clarification Statements

APPENDIX I: References

APPENDIX A: PATIENT EDUCATION TOPICS

PRENATAL CONVERSATION TOPICS INCLUDE:

WHO/UNICEF Required Prenatal Conversation Topics Include at a Minimum:

Breastfeeding

- the importance of breastfeeding *[including a discussion on the importance of direct breastfeeding, as needed]*
- global recommendations for breastfeeding including:
 - exclusive breastfeeding for the first 6 months
 - the risks of giving formula or other breast-milk substitutes
 - breastfeeding continues to be important after 6 months when other foods are given
- the basics of good positioning and attachment
- recognition of feeding cues

Birth Practices

- the importance of immediate and sustained skin-to-skin contact
- the importance of early initiation of breastfeeding
- the importance of rooming-in

US Recommended Prenatal Discussion Topics for Anticipatory Guidance include:

- non pharmacologic pain relief during labor
- creating a safe sleep environment:
 - along with the importance of rooming-in, staff should discuss how to create a safe sleep environment while rooming-in at the hospital. Narcotic-induced sleepiness, hormonally driven sleepiness *[physiology of lactation and its effects on mothers]* and fatigue are all factors that mothers should be aware of while rooming-in at the hospital.
 - risk reduction strategies for SIDS after leaving the hospital including the importance of removing suffocation hazards *[e.g., soft bedding/pillows]* from the breastfeeding environment and defining hazardous circumstances
- how to have an abundant milk supply
- how to prevent nipple soreness
- how to prevent or minimize engorgement after birth
- availability of community resources with staff properly trained to assist with breastfeeding assessment and management
- a brief conversation to discuss details about feeding a premature, low birthweight or sick baby that might need to be admitted to the NICU

POSTPARTUM BREASTFEEDING EDUCATION TOPICS INCLUDE:

- proper positioning, correct attachment, efficient suckling, and milk transfer
- ensuring a good milk supply
- criteria to assess if the infant is getting enough breast-milk including adequate intake and output for day of life
- preventative management of common problems such as engorgement, sore and cracked nipples⁵
- hand expression of breast-milk
- the importance of exclusive breastfeeding
- how to maintain exclusive breastfeeding for about 6 months
- signs/symptoms of infant feeding issues requiring referral to a qualified provider
- early feeding cues and a reminder that crying is a late cue
- no limits on how often or how long infants should be fed
- the effects of pacifiers and artificial nipples on breastfeeding and why to avoid them until lactation is established
- normal newborn feeding patterns
- collection and storage of breast-milk
- creating a safe sleep environment for breastfeeding including:
 - the physiology of lactation and its effects on the mother leading to hormonally driven sleepiness
 - the importance of removing suffocation hazards *[e.g., soft bedding/pillows]* from the breastfeeding environment
- community breastfeeding support services *[including how to access support and when to follow-up for formal evaluation]*
- maternal/infant warning signs/symptoms of breast problems and breastfeeding problems that must receive urgent evaluation *[including who they should call for assistance]*

POSTPARTUM INFANT FORMULA FEEDING EDUCATION TOPICS INCLUDE:

- safe preparation, feeding, and storage of infant formula including:
 - appropriate hand hygiene
 - cleaning infant feeding items *[bottles, nipples, rings, caps, syringes, cups, spoons, etc.]* and workspace surfaces
 - appropriate and safe reconstitution of concentrated and powdered infant formulas
 - accuracy of measurement of ingredients
 - safe handling of formula
 - proper storage of formula
 - appropriate feeding methods which may include feeding on cue, frequent low volume feeds, paced bottle techniques, eye-to-eye contact, and holding the infant closely
 - powdered infant formula is not sterile and may contain pathogens that can cause serious illness in infants younger than 3 months
- preventative steps to minimize engorgement *[if mother plans to exclusively formula feed]*
- signs/symptoms of infant feeding issues requiring referral to a qualified provider
- normal newborn feeding patterns
- creating a safe sleep environment for feeding your baby including:
 - the importance of removing suffocation hazards *[e.g., soft bedding/pillows]* from the environment
- community infant formula feeding services *[including how to access support and when to follow-up for formal evaluation]*
- maternal/infant warning signs/symptoms of breast problems and/or formula feeding concerns that must receive urgent evaluation and who they should call for assistance

APPENDIX B: INDICATORS FOR FACILITY MONITORING OF KEY CLINICAL PRACTICES

KEY CLINICAL PRACTICES	INDICATOR DEFINITION NOTE: More detailed and specific guidance on numerator/denominator inclusions/exclusions is described on the Facility Data Sheet.	TARGET	PRIMARY SOURCE	OTHER SOURCES	SUBMIT METHOD
Step 3: Discuss the importance and management of breastfeeding with pregnant women and their families.	Affiliated Prenatal Services: The percentage of mothers who received prenatal care at an affiliated prenatal service who received prenatal counseling on breastfeeding.	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
Step 4: Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.	Vaginal Delivery: <i>The percentage of infants that were placed in skin-to-skin contact with their mothers immediately after a vaginal birth and remained there uninterrupted for at least 1 hour (longer, if needed, to allow a breastfeeding infant to complete a feeding).</i>	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
	Cesarean Delivery: <i>The percentage of infants born by cesarean delivery that were placed in skin-to-skin contact with their mothers, when safe and feasible [mother is responsive and alert] and remained there uninterrupted for at least 1 hour (longer, if needed, to allow a breastfeeding infant to complete a feeding).</i>	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
	All Deliveries: <i>The percentage of infants who were supported to breastfeed as soon as possible after birth, within the first one to two hours after delivery.</i> NOTE: <i>Supporting the initiation of breastfeeding is defined as placing the baby on the mother's chest (skin-to-skin) for breastfeeding, pointing out infant feeding readiness cues and gently coaching the mother to allow baby to move and attach to the breast.</i>	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
Step 5: Support mothers to initiate and maintain breastfeeding and manage common difficulties.	<i>The percentage of breastfeeding mothers who report being taught how to position their baby for breastfeeding.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of breastfeeding mothers who report being taught how to attach their baby for breastfeeding.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of breastfeeding mothers who report being taught how to observe for expected suckling patterns.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link

APPENDIX B: INDICATORS FOR FACILITY MONITORING OF KEY CLINICAL PRACTICES

KEY CLINICAL PRACTICES	INDICATOR DEFINITION NOTE: More detailed and specific guidance on numerator/denominator inclusions/exclusions is described on the Facility Data Sheet.	TARGET	PRIMARY SOURCE	OTHER SOURCES	SUBMIT METHOD
Step 5: Support mothers to initiate and maintain breastfeeding and manage common difficulties.	<i>The percentage of breastfeeding mothers who report being taught how to listen for swallowing sounds.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of breastfeeding mothers who report being taught how to express their breast-milk by hand.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
Step 6: Do not provide breastfed newborns any food or fluids other than breast-milk, unless medically indicated.	<i>The percentage of infants who received only breast-milk throughout their stay at the facility.</i> Reminder: The US BFHI Designation Is based on implementation of clinical practices, NOT on an exclusive breastfeeding rate of ≥80%.	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
	<i>The percentage of breast-milk fed infants who received formula supplementation during their stay at the facility.</i>	≤14.2%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
	<i>The percentage of mixed-feeding and formula feeding mothers who report being taught how to safely prepare, feed and store infant formula.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
Step 7: Enable mothers and their infants to remain together and to practice rooming-in 24 hours a day.	<i>The percent of infants who stayed with their mothers both day and night, without separation of more than 1 hour per 24-hour period.</i>	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
Step 8: Support mothers to recognize and respond to their infants' cues for feeding.	<i>The percentage of mothers [regardless of feeding method] who report being taught that salivating or rooting is an early feeding cue.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of mothers [regardless of feeding method] who report being taught that the baby putting fingers or fist in or around his/her mouth is an early feeding cue.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of mothers [regardless of feeding method] who report being taught that the baby becoming more active and alert is an early feeding cue.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link

APPENDIX B: INDICATORS FOR FACILITY MONITORING OF KEY CLINICAL PRACTICES

KEY CLINICAL PRACTICES	INDICATOR DEFINITION NOTE: More detailed and specific guidance on numerator/denominator inclusions/exclusions is described on the Facility Data Sheet.	TARGET	PRIMARY SOURCE	OTHER SOURCES	SUBMIT METHOD
Step 9: Counsel mothers on the use and risks of feeding bottles, artificial nipples and pacifiers.	<i>The percentage of breastfeeding mothers who report being taught about the risks of using feeding bottles, artificial nipples and pacifiers.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of breastfeeding mothers who report being taught when an acceptable time is to introduce a pacifier.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
Step 10: Coordinate discharge so that parents and their infants have timely access to ongoing support and care.	<i>The percentage mothers [regardless of feeding method] who report being taught how to tell if their babies are getting enough.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of mothers [regardless of feeding method] who report being taught where they can access infant feeding support in the community.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an 'k')	VERIFICATION METHOD
DOMAIN 1: CRITICAL MANAGEMENT PROCEDURES TO SUPPORT THE TEN STEPS	
Competency 01. Implement the Code in a health facility (Step 1A)	
*1. List at least 3 products that are covered by the Code.	Question or case study
*2. Describe at least 3 ways a direct care provider/direct care staff protects breastfeeding in practice.	Question or case study
*3. Describe at least 1 way a direct care provider/direct care staff should respond if offered information provided by manufacturers and/or distributors of products within the scope of the Code.	Question or case study
*4. Describe at least 1 type of financial or material inducement that might be offered to a direct care provider/direct care staff by a manufacturer and/or distributor of products within the scope of the Code.	Question or case study
*5. Describe at least 1 harm of a direct care provider/direct care staff accepting financial or material inducements.	Question or case study
*6. Explain at least 2 ways that the facility ensures that there is no promotion of infant formula, feeding bottles, or teats in any part of facilities providing maternity and new-born services, or by any of the direct care staff/direct care providers.	Question or case study

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an 'k')	VERIFICATION METHOD
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DOMAIN 1: CRITICAL MANAGEMENT PROCEDURES TO SUPPORT THE TEN STEPS continued

Competency 02. Explain a facility's infant feeding policies and monitoring systems (Step 1B and 1C)

*7. Describe at least 2 elements that are in the facility's infant feeding policy.	Question or case study
*8. Explain at least 3 ways that the infant feeding policy affects a direct care provider's/direct care staff member's work in <i>providing safe, equitable and appropriate care</i> .	Question or case study
*9. Explain at least 2 reasons why monitoring of hospital practices is important to ensure quality of care.	Question or case study
*10. Explain at least 2 ways practices are monitored in this facility.	Question or case study

DOMAIN 2: FOUNDATIONAL SKILLS: COMMUNICATING IN A CREDIBLE AND EFFECTIVE WAY

Competency 03. Use listening and learning skills whenever engaging in a conversation with a mother (All Steps)

*11. Demonstrate at least 3 aspects of listening and learning skills when talking with a mother.	Observation
*12. Demonstrate at least 3 ways to adapt communication style and content when talking with a mother.	Observation

Competency 04. Use skills for building confidence and giving support whenever engaging in a conversation with a mother (All Steps)

*13. Demonstrate at least 2 ways to encourage a mother to share her views, taking time to understand and consider these views.	Observation
*14. Demonstrate at least 3 aspects of building confidence and giving support when talking with a mother.	Observation

DOMAIN 3: PRENATAL PERIOD

Competency 05. Engage in antenatal conversation about breastfeeding (Step 3)

*15. Engage in a conversation with a pregnant woman on 3 aspects of the importance of breastfeeding.	Observation
*16. Assess at least 3 aspects of a pregnant woman's knowledge about breastfeeding in order to fill the gaps and correct inaccuracies.	Observation
*17. Engage in a conversation with a pregnant woman about at least 4 care practices a mother/infant dyad will experience at the birthing facility that will support breastfeeding.	Observation

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

DOMAIN 4: BIRTH AND IMMEDIATE POSTPARTUM

Competency 06. Implement immediate and uninterrupted skin-to-skin (Step 4)

*18. **Explain** at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the mother.

Question or case study

*19. **Explain** at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the infant.

Question or case study

20. **Demonstrate** at least 3 points of how to routinely implement immediate, uninterrupted and safe skin-to-skin between mother and infant, regardless of method of birth.

Observation

*21. **Demonstrate** at least 3 safety aspects to assess when mother and baby are skin-to-skin during the first 2 hours postpartum, regardless of method of birth.

Observation

*22. **List** at least 3 reasons why skin-to-skin should NOT be interrupted.

Question or case study

*23. **Explain** at least 2 reasons when skin-to-skin could be interrupted for medically justifiable reasons.

Question or case study

24. "WHERE APPLICABLE" **Explain** how to maintain skin-to-skin during transfer of mother and infant to another room or other recovery area.

Question or case study

DOMAIN 5: ESSENTIAL ISSUES FOR A BREASTFEEDING MOTHER

Competency 07. Facilitate breastfeeding within the first hour, according to cues (Step 4)

*25. **Engage** in a conversation with a mother including at least 3 reasons why suckling at the breast in the first hour is important, when the baby is ready.

Observation

26. **Demonstrate** at least 3 aspects of safe care of the newborn in the first 2 hours post-birth.

Observation

27. **Describe** to a mother at least 3 pre-feeding behaviours babies show before actively sucking at the breast.

Observation

Competency 08. Discuss with a mother how breastfeeding works (Steps 3, 5, 6 and 9)

28. **Describe** at least 6 essential issues that every breastfeeding mother should know or demonstrate.

Question or case study

*29. **Engage** in a conversation with a mother regarding at least 3 reasons why effective exclusive breastfeeding is important.

Observation

*30. **Engage** in a conversation with a mother regarding 2 elements related to infant feeding patterns in the first 36 hours of life.

Observation

*31. **Describe** to a mother at least 4 signs of adequate transfer of milk in the first few days.

Observation

*66. **Describe** at least 1 professional medical reference or resource for identifying medications that are safe/compatible for use during lactation.

Question or case study

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

DOMAIN 5: ESSENTIAL ISSUES FOR A BREASTFEEDING MOTHER continued

Competency 09. Assist mother getting her baby to latch (Step 5)

32. **Evaluate** a full breastfeeding session observing at least 5 points.

Observation

*33. **Demonstrate** at least 3 aspects of how to help a mother achieve a comfortable and safe position for breastfeeding within the first 6 hours after birth and later as needed during the hospital stay.

Observation

*34. **Demonstrate** how to help a mother achieve an effective and comfortable latch, noting at least 5 points.

Observation

Competency 10. Help a mother respond to feeding cues (Steps 7 and 8)

*35. **Engage** in a conversation with a mother regarding 2 aspects related to the importance of rooming-in 24h/day.

Observation

*36. **Explain** 2 situations: 1 for the mother and 1 for the infant, when it is acceptable to separate mother and baby while in hospital.

Question or case study

*37. **Describe** at least 2 early feeding cues and 1 late feeding cue.

Question or case study

38. **Describe** at least 4 reasons why responsive feeding is important (also called on-demand or baby-led feeding) independent of feeding method.

Question or case study

39. **Describe** at least 2 aspects of responsive feeding (also called on-demand or baby-led feeding) independent of feeding method.

Question or case study

68. **Describe** 2 aspects involved in creating a safe environment for rooming-in during the hospital stay.

Question or case study

*69. **Demonstrate** at least 3 safety aspects to assess when mother and baby are skin-to-skin during the postpartum hospitalization, regardless of method of birth.

Observation

Competency 11. Help a mother manage milk expression (Steps 5 and 6)

40. **Demonstrate** to a mother how to hand express breast milk, noting 8 points.

Observation

41. **Explain** at least 3 aspects of appropriate storage of breast-milk.

Question or case study

42. **Explain** at least 3 aspects of handling of expressed breast-milk.

Question or case study

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

DOMAIN 6: HELPING MOTHERS AND BABIES WITH SPECIAL NEEDS

Competency 12. Help a mother to breastfeed a low-birth-weight or sick baby (Steps 5, 7 and 8)

43. **Help** a mother achieve a comfortable and safe position for breastfeeding with her preterm, late preterm, or weak infant at the breast, noting at least 4 points.
- *44. **Engage** in a conversation with a mother of a preterm, late preterm, or low-birth-weight infant not sucking effectively at the breast, including at least 5 points.
45. **Engage** in a conversation with a mother separated from her preterm or sick infant regarding at least 2 reasons to be with her infant in the intensive care unit.
46. **Engage** in a conversation with a mother of a preterm, late preterm or vulnerable infant (including multiple births) regarding the importance of observing at least 2 sub-tle signs and behavioural state shifts to determine when it is appropriate to breastfeed.

Observation

Observation

Observation

Observation

Competency 13. Help a mother whose baby needs fluids other than breast milk (Step 6)

- *47. **List** at least 2 potential contraindications to breastfeeding for a baby and 2 for a mother.
- *48. **Describe** at least 4 medical indications for supplementing breastfed newborns: 2 maternal indications and 2 newborn indications, when breastfeeding is not improved following skilled assessment and management.
- *49. **Describe** at least 3 risks of giving a breastfed newborn any food or fluids other than breast milk, in the absence of medical indication.
- *50. For those few health situations where infants cannot, or should not, be fed at the breast, **describe**, in order of preference, the alternatives to use.
- *51. **Engage** in a conversation with a mother who intends to feed her baby formula, noting at least 3 actions to take.
52. **Demonstrate** at least 3 important items of safe preparation of infant formula to a mother who needs that information.
- *67. **Identify** 3 high-risk infant populations that may warrant extra precautions to protect against severe infections associated with powdered infant formula.

Question or case study

Question or case study

Question or case study

Question or case study

Observation

Observation

Question or case study

Competency 14. Help a mother who is not feeding her baby directly at the breast (Step 9)

53. **Demonstrate** to a mother how to safely cup-feed her infant when needed, showing at least 4 points.
54. **Describe** to a mother at least 4 steps to feed an infant a supplement in a safe manner.
- *55. **Describe** at least 2 alternative feeding methods other than feeding bottles.
56. **Engage** in a conversation with a mother who requests feeding bottles, teats, pacifiers and soothers without medical indication, including at least 3 points.

Observation

Observation

Question or case study

Observation

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)	VERIFICATION METHOD
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DOMAIN 6: HELPING MOTHERS AND BABIES WITH SPECIAL NEEDS continued

Competency 15. Help a mother prevent or resolve difficulties with breastfeeding (Steps 5, 8, 9 and 10)

57. **Engage** in a conversation with a mother regarding at least 4 different ways to facilitate breastfeeding in order to prevent or resolve most common conditions of the lactating breasts (sore nipples, engorgement, mother who thinks she doesn't have enough milk, infants who have difficulty sucking).

Observation

*58. **Describe** at least 4 elements to assess when a mother says that her infant is crying frequently.

Question or case study

*59. **Describe** at least 4 elements of anticipatory guidance to give to a mother on calming or soothing techniques before or as alternatives to pacifiers.

Question or case study

*70. **Describe** when the acceptable time is for introducing a pacifier with a breastfeeding infant, with regards to SUID/SIDS reduction strategies.

Question or case study

*65. **Describe** at least 2 maternal and 2 infant risk factors associated with delayed lactogenesis II.

Question or case study

DOMAIN 7: CARE AT DISCHARGE

Competency 16. Ensure seamless transition after discharge (Step 10)

60. **Describe** at least 2 locally available sources for timely infant feeding information and problem management.

Question or case study

61. **Describe** at least 2 ways the healthcare facility engages with community-based programs to coordinate breastfeeding messages and offer continuity of care.

Question or case study

*62. **Develop** individualized discharge feeding plans with a mother that includes at least 6 points.

Observation

*63. **Describe** to a mother at least 4 warning signs of infant undernourishment or dehydration for a mother to contact a health care professional after discharge.

Observation

*64. **Describe** at least 3 warning maternal signs for a mother to contact a health care professional after discharge.

Question or case study

APPENDIX C2: PERFORMANCE INDICATORS TO MEASURE COMPETENCY - SORTED BY STEP

TEN STEPS TO SUCCESSFUL BREASTFEEDING (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

STEP 1A. COMPLY FULLY WITH THE INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES AND RELEVANT WORLD HEALTH ASSEMBLY RESOLUTIONS. (COMPETENCY 01)

*1. List at least 3 products that are covered by the Code.	Question or case study
*2. Describe at least 3 ways a direct care provider/direct care staff protects breastfeeding in practice.	Question or case study
*3. Describe at least 1 way a direct care provider/direct care staff should respond if offered information provided by manufacturers and/or distributors of products within the scope of the Code.	Question or case study
*4. Describe at least 1 type of financial or material inducement that might be offered to a direct care provider/direct care staff by a manufacturer and/or distributor of products within the scope of the Code.	Question or case study
*5. Describe at least 1 harm of a direct care provider/direct care staff accepting financial or material inducements.	Question or case study
*6. Explain at least 2 ways that the facility ensures that there is no promotion of infant formula, feeding bottles, or teats in any part of facilities providing maternity and newborn services, or by any of the direct care providers.	Question or case study

STEP 1B. HAVE A WRITTEN INFANT FEEDING POLICY THAT IS ROUTINELY COMMUNICATED TO STAFF AND PARENTS. (COMPETENCY 02)

*7. Describe at least 2 elements that are in the facility's infant feeding policy.	Question or case study
*8. Explain at least 3 ways that the infant feeding policy affects a direct care provider's/direct care staff member's work in <i>providing safe, equitable and appropriate care</i> .	Question or case study

STEP 1C. ESTABLISH ONGOING MONITORING AND DATA-MANAGEMENT SYSTEMS. (COMPETENCY 02)

*9. Explain at least 2 reasons why monitoring of hospital practices is important to ensure quality of care.	Question or case study
*10. Explain at least 2 ways practices are monitored in this facility.	Question or case study

STEP 2. ENSURE THAT STAFF HAVE SUFFICIENT KNOWLEDGE, COMPETENCE AND SKILLS TO SUPPORT BREASTFEEDING. (FOUNDATIONAL SKILLS APPLYING TO ALL STEPS. (COMPETENCY 03 AND 04)

*11. Demonstrate at least 3 aspects of listening and learning skills when talking with a mother.	Observation
*12. Demonstrate at least 3 ways to adapt communication style and content when talking with a mother.	Observation
*13. Demonstrate at least 2 ways to encourage a mother to share her views, taking time to understand and consider these views.	Observation
*14. Demonstrate at least 3 aspects of building confidence and giving support when talking with a mother.	Observation

APPENDIX C2: PERFORMANCE INDICATORS TO MEASURE COMPETENCY - SORTED BY STEP

TEN STEPS TO SUCCESSFUL BREASTFEEDING (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

STEP 3. DISCUSS THE IMPORTANCE AND MANAGEMENT OF BREASTFEEDING WITH PREGNANT WOMEN AND THEIR FAMILIES. (COMPETENCY 05 AND 08)

- | | |
|---|-------------|
| *15. Engage in a conversation with a pregnant woman on 3 aspects of the importance of breastfeeding. | Observation |
| *16. Assess at least 3 aspects of a pregnant woman's knowledge about breastfeeding in order to fill the gaps and correct inaccuracies. | Observation |
| *17. Engage in a conversation with a pregnant woman about at least 4 care practices a mother/infant dyad will experience at the birthing facility that will support breastfeeding. | Observation |
| *29. Engage in a conversation with a mother regarding at least 3 reasons why effective exclusive breastfeeding is important. | Observation |

STEP 4. FACILITATE IMMEDIATE AND UNINTERRUPTED SKIN-TO-SKIN CONTACT AND SUPPORT MOTHERS TO INITIATE BREASTFEEDING AS SOON AS POSSIBLE AFTER BIRTH. (COMPETENCY 06 AND 07)

- | | |
|---|------------------------|
| *18. Explain at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the mother. | Question or case study |
| *19. Explain at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the infant. | Question or case study |
| 20. Demonstrate at least 3 points of how to routinely implement immediate, uninterrupted and safe skin-to-skin between mother and infant, regardless of method of birth. | Observation |
| *21. Demonstrate at least 3 safety aspects to assess when mother and baby are skin-to-skin during the first 2 hours postpartum, regardless of method of birth. | Observation |
| *22. List at least 3 reasons why skin-to-skin should NOT be interrupted. | Question or case study |
| *23. Explain at least 2 reasons when skin-to-skin could be interrupted for medically justifiable reasons. | Question or case study |
| 24. "WHERE APPLICABLE" Explain how to maintain skin-to-skin during transfer of mother and infant to another room or other recovery area. | Question or case study |
| *25. Engage in a conversation with a mother including at least 3 reasons why suckling at the breast in the first hour is important, when the baby is ready. | Observation |
| 26. Demonstrate at least 3 aspects of safe care of the newborn in the first 2 hours post-birth. | Observation |
| 27. Describe to a mother at least 3 prefeeding behaviors babies show before actively sucking at the breast. | Observation |

APPENDIX C2: PERFORMANCE INDICATORS TO MEASURE COMPETENCY - SORTED BY STEP

TEN STEPS TO SUCCESSFUL BREASTFEEDING (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

STEP 5. SUPPORT MOTHERS TO INITIATE AND MAINTAIN BREASTFEEDING AND MANAGE COMMON DIFFICULTIES. (COMPETENCY 08, 09, 11, 12 AND 15)

28. Describe at least 6 essential issues that every breastfeeding mother should know or demonstrate.	Question or case study
*30. Engage in a conversation with a mother regarding 2 elements related to infant feeding patterns in the first 36 hours of life.	Observation
*31. Describe to a mother at least 4 signs of adequate transfer of milk in the first few days.	Observation
32. Evaluate a full breastfeeding session observing at least 5 points.	Observation
*33. Demonstrate at least 3 aspects of how to help a mother achieve a comfortable and safe position for breastfeeding within the first 6 hours after birth and later as needed during the hospital stay.	Observation
*34. Demonstrate how to help a mother achieve an effective and comfortable latch, noting at least 5 points.	Observation
40. Demonstrate to a mother how to hand express breast milk, noting 8 points.	Observation
43. Help a mother achieve a comfortable and safe position for breastfeeding with her preterm, late preterm, or weak infant at the breast, noting at least 4 points.	Observation
*44. Engage in a conversation with a mother of a preterm, late preterm, or low-birth-weight infant not sucking effectively at the breast, including at least 5 points.	Observation
57. Engage in a conversation with a mother regarding at least 4 different ways to facilitate breastfeeding in order to prevent or resolve most common conditions of the lactating breasts (sore nipples, engorgement, mother who thinks she doesn't have enough milk, infants who have difficulty sucking).	Observation
*65. Describe at least 2 maternal and 2 infant risk factors associated with delayed lactogenesis II.	Question or case study

STEP 6. DO NOT PROVIDE BREASTFED NEWBORNS ANY FOOD OR FLUIDS OTHER THAN BREAST-MILK, UNLESS MEDICALLY INDICATED. (COMPETENCY 08, 11, 13.)

*29. Engage in a conversation with a mother regarding at least 3 reasons why effective exclusive breastfeeding is important.	Observation
41. Explain at least 3 aspects of appropriate storage of breast-milk.	Question or case study
42. Explain at least 3 aspects of handling of expressed breast-milk.	Question or case study
*47. List at least 2 potential contraindications to breastfeeding for a baby and 2 for a mother.	Question or case study
*48. Describe at least 4 medical indications for supplementing breastfed newborns: 2 maternal indications and 2 newborn indications, when breastfeeding is not improved following skilled assessment and management.	Question or case study
*49. Describe at least 3 risks of giving a breastfed newborn any food or fluids other than breast milk, in the absence of medical indication.	Question or case study

APPENDIX C2: PERFORMANCE INDICATORS TO MEASURE COMPETENCY - SORTED BY STEP

TEN STEPS TO SUCCESSFUL BREASTFEEDING (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

STEP 6. DO NOT PROVIDE BREASTFED NEWBORNS ANY FOOD OR FLUIDS OTHER THAN BREAST-MILK, UNLESS MEDICALLY INDICATED. (COMPETENCY 08, 09, 11, 13.) continued

66. Describe at least 1 professional medical reference or resource for identifying medications that are safe/compatible for use during lactation.	Question or case study
*50. For those few health situations where infants cannot, or should not, be fed at the breast, describe , in order of preference, the alternatives to use.	Question or case study
*51. Engage in a conversation with a mother who intends to feed her baby formula, noting at least 3 actions to take.	Observation
52. Demonstrate at least 3 important items of safe preparation of infant formula to a mother who needs that information.	Observation
*67. Identify 3 high-risk infant populations that may warrant extra precautions to protect against severe infections associated with powdered infant formula.	Question or case study

STEP 7. ENABLE MOTHERS AND THEIR INFANTS TO REMAIN TOGETHER AND TO PRACTICE ROOMING-IN 24 HOURS A DAY. (COMPETENCY 10 AND 12)

*35. Engage in a conversation with a mother regarding 2 aspects related to the importance of rooming-in 24h/day.	Observation
68. Describe 2 aspects involved in creating a safe environment for rooming-in during the hospital stay.	Question or case study
*69. Demonstrate at least 3 safety aspects to assess when mother and baby are skin-to-skin during the postpartum hospitalization, regardless of method of birth.	Observation
*36. Explain 2 situations: 1 for the mother and 1 for the infant, when it is acceptable to separate mother and baby while in hospital.	Question or case study
45. Engage in a conversation with a mother separated from her preterm or sick infant regarding at least 2 reasons to be with her infant in the intensive care unit.	Observation

STEP 8. SUPPORT MOTHERS TO RECOGNIZE AND RESPOND TO THEIR INFANTS' CUES FOR FEEDING. (COMPETENCY 10, 12 AND 15)

*37. Describe at least 2 early feeding cues and 1 late feeding cue.	Question or case study
38. Describe at least 4 reasons why responsive feeding is important (also called on-demand or baby-led feeding) independent of feeding method.	Question or case study
39. Describe at least 2 aspects of responsive feeding (also called on-demand or baby-led feeding) independent of feeding method.	Question or case study
46. Engage in a conversation with a mother of a preterm, late preterm or vulnerable infant (including multiple births) regarding the importance of observing at least 2 subtle signs and behavioral state shifts to determine when it is appropriate to breastfeed.	Observation
*58. Describe at least 4 elements to assess when a mother says that her infant is crying frequently.	Question or case study

APPENDIX C2: PERFORMANCE INDICATORS TO MEASURE COMPETENCY - SORTED BY STEP

TEN STEPS TO SUCCESSFUL BREASTFEEDING (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

STEP 9. COUNSEL MOTHERS ON THE USE AND RISKS OF FEEDING BOTTLES, ARTIFICIAL NIPPLES (TEATS) AND PACIFIERS. (COMPETENCY 14 AND 15)

53. **Demonstrate** to a mother how to safely cup-feed her infant when needed, showing at least 4 points.

Observation

54. **Describe** to a mother at least 4 steps to feed an infant a supplement in a safe manner.

Observation

*55. **Describe** at least 2 alternative feeding methods other than feeding bottles.

Question or case study

56. **Engage** in a conversation with a mother who requests feeding bottles, teats, pacifiers and soothers without medical indication, including at least 3 points.

Observation

*59. **Describe** at least 4 elements of anticipatory guidance to give to a mother on calming or soothing techniques before or as alternatives to pacifiers.

Question or case study

*70. **Describe** when the acceptable time is for introducing a pacifier with a breastfeeding infant, with regards to SUID/SIDS reduction strategies.

Question or case study

STEP 10. COORDINATE DISCHARGE SO THAT PARENTS AND THEIR INFANTS HAVE TIMELY ACCESS TO ONGOING SUPPORT AND CARE. (COMPETENCY 15 AND 16)

57. **Engage** in a conversation with a mother regarding at least 4 different ways to facilitate breastfeeding in order to prevent or resolve most common conditions of the lactating breasts (sore nipples, engorgement, mother who thinks she doesn't have enough milk, infants who have difficulty sucking).

Observation

60. **Describe** at least 2 locally available sources for timely infant feeding information and problem management.

Question or case study

61. **Describe** at least 2 ways the healthcare facility engages with community-based programs to coordinate breastfeeding messages and offer continuity of care

Question or case study

*62. **Develop** individualized discharge feeding plans with a mother that includes at least 6 points.

Observation

*63. **Describe** to a mother at least 4 warning signs of infant undernourishment or dehydration for a mother to contact a health care professional after discharge.

Observation

*64. **Describe** at least 3 warning maternal signs for a mother to contact a health care professional after discharge.

Question or case study

APPENDIX D: DETERMINING AFFILIATED PRENATAL SERVICES

AFFILIATED PRENATAL SERVICES

INTRODUCTION: It is important to accurately determine your facility's status regarding affiliation with prenatal services early in your Baby-Friendly journey.

INSTRUCTIONS: The questions below describe various situations in which BFUSA considers facilities to have affiliated prenatal services. If any of the situations below is true for your facility, you are considered to have affiliated prenatal services. Carefully consider each of the questions with your multi-disciplinary team. It is also important to consider these questions again any time your facility has a change.

The questions should be applied to all primary prenatal services that have patients who deliver at your facility. Providers who do not provide primary prenatal services, but rather are specialists who provide consultation for the patient's primary prenatal care provider, should not be included. For example, a Maternal Fetal Medicine provider who is consulted when needed but never becomes the primary provider for a woman or her infant would not be considered to be an affiliated prenatal service. A Maternal Fetal Medicine provider who acts as the patient's primary provider would be considered to be an affiliated prenatal service if one of the scenarios described in the questions below also applies.

EVOLVING STATE OF HEALTH CARE: Health care in the United States is dynamic. Facilities are merging into systems as well as buying and selling service lines. In large institutions, some structural changes may not be known by the facility's Baby-Friendly multi-disciplinary committee, yet they have a significant impact on the Baby-Friendly process. Therefore, **it is recommended that this questionnaire be completed annually by the facility and discussed with leadership by the multi-disciplinary committee.** The committee should then consider how the results will impact the implementation of Steps 1, 2, and 3, and the International Code of Marketing of Breast-milk Substitutes.

QUESTIONS:

Your facility is considered to have affiliated prenatal services if you answer "yes" to any of the following questions:

1. Are providers who deliver primary prenatal care at the prenatal service employed by the facility?
2. Are providers who deliver primary prenatal care at the prenatal service employed by the same system that employs staff at the facility?
3. Are providers who deliver primary prenatal care at the prenatal service contracted (or in another type of agreement, such as an MOU) by the facility or system to provide prenatal services on behalf of the facility?
4. Are staff who provide care or education at the prenatal service employed by the facility?
5. Are staff who provide care or education at the prenatal service employed by the same system that employs staff at the facility?
6. Are staff who provide care or education at the prenatal service contracted (or in another type of agreement, such as an MOU) by the facility or system to provide prenatal services on behalf of the facility?
7. Are prenatal services offering primary prenatal care owned by the facility or the system that owns the facility?
8. Do marketing or patient information materials imply that primary prenatal care is offered by the facility? (Consider the facility or system website, brochures and media marketing campaigns.)

APPENDIX E: ACCEPTABLE MEDICAL REASONS FOR USE OF BREAST-MILK SUBSTITUTES

Most mothers can breastfeed successfully, which includes initiating breastfeeding within the first hour of life, breastfeeding exclusively for the first 6 months, and continuing breastfeeding along with giving appropriate complimentary foods up to 2 years of age or beyond.

The facility should develop a protocol/procedure that describes the current, evidence-based contraindications to breastfeeding and medical indications for supplementation. Staff and care providers should be trained to utilize the protocol/procedure as guidance in the case of supplementation. A facility may utilize the recommendations of national and international authorities [e.g., Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), and Academy of Breastfeeding Medicine (ABM), American Academy of Pediatrics (AAP), American College of Obstetricians and Gynecologists (ACOG)] in developing this protocol/procedure. However, the facility is responsible for ensuring that its medical indications for supplementation are supported by current evidence.

APPENDIX F: DEFINITION OF TERMS AND ABBREVIATIONS USED IN THIS DOCUMENT

AFFILIATED PRENATAL SERVICES – Primary prenatal care delivered through a close formal or informal association with a birthing facility. For Baby-Friendly purposes, the affiliation is determined through completion of a questionnaire regarding specific aspects of the relationship, such as business relationship, personnel relationship, and marketing of services. *(See Appendix D)*

CAMPUS – The institution's main buildings and the physical area immediately adjacent to them, other areas and structures that are not strictly contiguous to the main buildings but are located on the same property or within 250 yards of the main buildings, and any other areas determined, on an individual case basis, to be part of the provider's campus.

CLINICAL STAFF – Includes all individuals providing direct patient care. Clinical roles often require certification or licensing. Examples include: RN, LPN, Technicians, CNA, MA, etc.

CRITERIA FOR EVALUATION – The minimum standards which must be met to achieve Baby Friendly designation.

COMPETENCY – The capability to use a set of related knowledge, skills and behaviors to successfully perform identified jobs, roles or responsibilities.³

COMPETENCY ASSESSMENT – An evaluation of an individual's ability to use a set of related knowledge, skills and behaviors to successfully perform identified jobs, roles or responsibilities.³

COMPETENCY VERIFICATION – The confirmation of an individual's ability to use a set of related knowledge, skills and behaviors to successfully perform identified jobs, roles or responsibilities.

CONFLICT OF INTEREST – Any situation where an individual or organization is in a position to derive a benefit which is at odds with the interests / purpose of their position or organization. In this context, it is most usually seen when individual members of staff enter a relationship with companies falling within the scope of the Code (the companies) in order to gain some advantage for themselves or their service.

COUNSELING – Professional guidance, advice and/or assistance provided by an individual trained in the specific topic area of concern.

CUE-BASED FEEDING — Feeding practices that are based on infant readiness indicators such as alertness, rooting, orienting toward own or caregivers' hands, pacifier, breast or bottle nipple; sucking on own hands or other objects; pacing as well as pausing when an infant's stress cues are observed.

DIRECT CARE PROVIDERS — Physicians, midwives, physician assistants, and advanced practice registered nurses who provide education, assessment, support, intervention, assistance and/or follow-up with regards to infant feeding [Including the following units: Affiliated Prenatal Services, Labor and Delivery Unit, Postpartum Unit, Newborn Unit]. Interviews with direct care providers will include providers granted privileges to provide care in labor & delivery, postpartum and well newborn units.

DIRECT CARE STAFF — All other non-Direct Care Provider health professionals who provide education, assessment, support, intervention, assistance and/or follow-up with regards to infant feeding [Including the following units: Affiliated Prenatal Services, Labor and Delivery Unit, Postpartum Unit, Newborn Unit]. Interviews with direct care staff will include facility-based direct care nursing staff providing care in labor & delivery, postpartum and well newborn units.

EDUCATION — Information about what to do and why; didactic knowledge; may be provided in classroom or electronically, individually or in group settings.

EDUCATIONAL MATERIALS — Information provided through written or electronic sources including brochures, pamphlets, posters, websites, videos, texting programs, social media, education channels, applications, and other evolving technologies.

EXCLUSIVE BREAST-MILK FEEDING — The infant receives only human milk (including direct breastfeeding, expressed breast-milk or donor

human milk) and is allowed to receive vitamins, minerals, and medicines.

FACILITY — A building or area that is used for the provision of health care services. Some health care facilities have multiple campuses. BFUSA policies require individual assessment and designation of each individual campus.

FAIR MARKET PRICE — The International Code of Marketing of Breast-milk Substitutes, and subsequently, the BFHI call for health systems to purchase infant foods and feeding supplies at a fair market value. Fair market pricing can be determined by calculating the margin of retail price the facility pays on other items available on the retail market or by using the minimum threshold price method as described in BFUSA materials.

FEEDING OPTIONS — The type of food (mother's own milk, pasteurized donor human milk, infant formula) and method of feeding (direct breast feeding, expression of milk, cup, syringe, supplemental nursing system, bottle) an infant. Feeding options may consist of a combination of foods and methods. For example, a mother may directly breastfeed sometimes and occasionally pump and feed her own milk through a cup.

GESTATIONAL AGE (INCLUDING DEFINITIONS OF PRETERM AND TERM INFANTS) — Time elapsed between the first day of the last menstrual period and the day of delivery.

Preterm infants are defined as born alive before 37 weeks of pregnancy are completed. There are sub-categories of preterm birth defined by the WHO.⁵⁹ Related groups of infants defined by ACOG⁶⁰ may be admitted to the NICU based on gestational age:

- Extremely preterm (<28 weeks)
- Very preterm (28 to <31 6/7 weeks)
- Moderate preterm (32 to 33 6/7 weeks)
- Late preterm (34 to 36 6/7 weeks)

Additionally, infants' size in relation to gestational age may relate to risk categories:

AGA = Appropriate for gestational age (► 10 and ◄ 90 percentile birth weight)

LGA = large for gestational age (► 90 percentile birth weight)

IUGR = intrauterine growth restriction

SGA = small for gestational age (◄ 10 percentile birthweight)

"Corrected Gestational Age": post-menstrual age calculated as gestational age at birth + chronological (calendar) age since birth; also sometimes called "adjusted age".

GUIDELINES – The standards of care which facilities strive to achieve for all patients.

HEALTH PROFESSIONAL – A health worker with a professional / degree, certification, diploma or license, such as but not limited to a medical practitioner, a registered nurse or midwife. Health professionals include all providers and clinical staff with policy making, supervisory, education and/or patient care responsibilities. Interviews with health professionals will include direct care nursing staff and privileged direct care providers.

HEALTH PROVIDER – A doctor, advanced practice nurse, physician assistant or midwife.

INFANT FEEDING SUPPLIES – Products used to nourish and/or deliver nourishment to a baby.

IN-SERVICE EDUCATION – Instruction provided to individuals already employed in a profession.

ITEM – An individual object or article. Examples include:

- Written educational materials, brochures/pamphlets, etc.
- Electronic sources including websites, videos, texting programs, social media, education channels, applications, and other evolving technologies.
- Posters, calendars, notepads, pens, cups, gift packs, growth charts, bassinet cards, etc.

KANGAROO MOTHER CARE (KMC) – Kangaroo Care or Kangaroo Mother Care are often used interchangeably to refer to skin-to-skin care provided by a parent of a preterm infant (or any infant in NICU). The infant is placed against the parent's naked chest in such a fashion that the infant is held upright and/or prone to maximize contact between ventral skin surfaces. The dyad is then wrapped in a blanket or other clothing to secure the infant against the parent's chest. Ideally, the infant may be held continuously (or almost continuously) in this fashion for multiple hours. Optimally, KMC begins as soon as the infant is judged ready for skin-to-skin contact or holding; sometimes part of stabilization immediately after birth.

When provided by the mother, it may allow for access to the breast for non-nutritive sucking or pre-feeding practice (nuzzling, licking, tasting drops of expressed milk) as well as direct feeding from the breast. Whether or not it includes breastfeeding, it offers benefits such as warmth/temperature regulation, respiratory support/improved oxygenation, cardiovascular stabilization, glucose homeostasis and immune support through colonization with normal flora. Maximal benefits are obtained with continuous or sustained KMC.

LOGO – An emblem, picture or symbol by means of which a company or product is identified.

MOU – Memorandum of Understanding is a formal written agreement between two or more parties.

NEONATAL UNIT (NICU) – Space designated and used for specialized patient care and consultation, monitoring and medical/nursing interventions. May include designated areas in maternity/postpartum units or pediatric units where infants are admitted. *Levels of neonatal care are designated:*⁶¹

LEVEL I: Well newborn nursery: for term or stable late-preterm (35–37 week gestation) infants, or for stabilization of ill or more preterm infants

LEVEL II: Special care nursery: Level I capabilities plus care for ≥ 32 week gestation, ≥ 1500 gram, moderately ill or convalescing infants, possibly requiring brief respiratory support, and/or stabilization of more preterm or ill infants

LEVEL III: NICU: Level II capabilities plus comprehensive care for infants ≥ 32 weeks and ≥ 1500 grams, including sustained life support, full range of respiratory support and advanced imaging services

LEVEL IV: Regional NICU: Level III capabilities plus surgical services, medical and surgical subspecialists, pediatric anesthesiologists, transport and outreach education.

NON-CLINICAL STAFF – Facility employees and/or contractors who interact with patients but provide no medical care. Examples: Administrative Assistants, Unit Secretaries, etc.

PACIFIER – An artificial nipple/teat-shaped device for non-nutritive sucking, also called a dummy or soother. (Limited use to decrease pain during procedures when the infant cannot be safely held or breastfed is acceptable.)

PERFORMANCE INDICATOR – Measures of a direct care provider and direct care staff's competence to protect, promote and support breastfeeding in a facility providing maternity and newborn services.

POLICY – An enforceable document that guides staff in the delivery of care. At the facility level, this may include policies, practice guidelines and protocols.

PRE-SERVICE EDUCATION – Instruction designed to enable individuals to acquire the knowledge and skills required to enter a profession.

PROMOTE – To employ any method of directly or indirectly encouraging a person, a health facility, or any other entity to purchase or use a designated product whether or not there is reference to a brand name.

SAMPLE – A small part or quantity intended to show what the whole is like.

SKILLED PROFESSIONAL – an individual with specialized training and a demonstrated ability to provide assessment, education, intervention, and follow-up in a specific field.

SKIN-TO-SKIN CONTACT (STS) – Contact between the newborn infant and its mother. (In the case of incapacitation of the mother, another adult, such as the infant's father or grandparent, may hold the infant skin-to-skin.) After birth, the infant is placed naked against the mother's naked ventral surface. The infant and mother are then covered with a warm blanket, keeping the infant's head uncovered. The infant may wear a diaper and/or a hat, but no other clothing should be between the mother's and infant's bodies. STS should continue, uninterrupted, until completion of the first feeding, or at least one hour if the mother is not breastfeeding. STS should be encouraged beyond the first hours and into the first days after birth and beyond.

SPONSOR – An individual or organization that pays some or all of the costs involved in staging an event in return for advertising.

STANDARD – The established requirement for delivery of evidenced-based care.

SUPPLEMENTATION – Additional feeding(s) provided to a breastfed infant. Options for supplementation include expressed breast-milk, pasteurized donor human milk, and appropriate breast-milk substitutes. The method of providing supplementary feedings may include supplemental nursing systems at the breast, cup feeding, spoon or dropper feeding, finger feeding, syringe feeding or bottle feeding.

TRAINING – Applying and/or acquiring knowledge and learning how to perform a specific skill, task, or behavior: typically requires simulation, clinical skills practice, counseling, role play and/or competency verification.

AAP	American Academy of Pediatrics
AAFP	American Academy of Family Physicians
ABM	Academy of Breastfeeding Medicine
ACNM	American College of Nurse Midwives
ACOG	American College of Obstetricians and Gynecologists
AWHONN	Association of Women's Health Obstetrical and Neonatal Nurses
BFHI	Baby-Friendly Hospital Initiative
BFUSA	Baby-Friendly USA Inc.
CDC	Centers for Disease Control and Prevention
KMC	Kangaroo Mother Care
NICU	Neonatal Intensive Care Unit
STS	Skin-to-skin contact
UNICEF	United Nations Children's Fund
USLCA	United States Lactation Consultant Association
WHA	World Health Assembly
WHO	World Health Organization

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APPENDIX H: GUIDELINES AND EVALUATION CRITERIA CLARIFICATION STATEMENTS

None at this time. We use this section to address issues that emerge between planned updates to the GEC.

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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 19 Oct 2016 14:49:56 +0000
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) (dbg6@cdc.gov)
Cc: Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP); Murphy, Paulette (CDC/ONDIEH/NCCDPHP)
Subject: FW: Hypothesis the Rising Prevalence of Autism - Response
Attachments: ControlledCorres_ASD and hyperbili_04292014_2.docx, RE: Advice on response to inquiry about inadequate breastfeeding

Correspondence with Dr. del Castillo-Hegy, who co-founded Fed is Best, and some additional follow up with AAP attached and below.

<https://fedisbest.org/>

Recent Forbes article on Fed is Best

<http://www.forbes.com/sites/kavinsenapathy/2016/09/27/beware-of-accidentally-starving-your-breastfed-newborn/#2d43df4d1d4c>

Recent HP UK counter argument

http://www.huffingtonpost.co.uk/amy-brown/why-fed-will-never-be-bes_b_12311894.html

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Sunday, February 07, 2016 9:22 PM
To: Bosso, Eileen T. (CDC/ONDIEH/NCCDPHP) <guz3@cdc.gov>
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; O'Connor, Ann E. (CDC/ONDIEH/NCCDPHP) <fxy8@cdc.gov>; Murphy, Paulette (CDC/ONDIEH/NCCDPHP) <pem1@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>
Subject: FW: Hypothesis the Rising Prevalence of Autism - Response

Hi Eileen –

Attached (and below) is the earlier correspondence with Dr. del Castillo-Hegy when she first contacted CDC regarding her concerns about milk insufficiency, hyperbilirubinemia, and autism. The inquiry was received and responded to through NCBDDD and therefore may not be in our files.

Dr. del Castillo-Hegy more recently contacted us through CDC Info regarding her concerns about exclusive breastfeeding. I understand you have these correspondences. At this time we reached out to the AAP Section on Breastfeeding to discuss the issue (email correspondence attached). I share Dr. del Castillo-Hegy's concerns regarding proper management of breastfeeding including the identification of situations when a supplementary feeding is necessary. The medical indications to supplement breastfeeding are outlined in an Academy of Breastfeeding Medicine (ABM) clinical protocol for

supplementary feeding in healthy term newborns. We need to continue our discussions with AAP on how to improve education on these medical indications.

Kelley

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Tuesday, February 02, 2016 2:20 PM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>; O'Connor, Ann E. (CDC/ONDIEH/NCCDPHP) <fxk8@cdc.gov>
Subject: FW: Hypothesis the Rising Prevalence of Autism - Response

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Monday, May 26, 2014 12:10 PM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: FW: Hypothesis the Rising Prevalence of Autism - Response

This was email back from the mom after we responded.

From: Gibbs Shields, Julie I. (CDC/ONDIEH/NCBDDD) (CTR)
Sent: Wednesday, April 30, 2014 7:06 AM
To: Moore, Cynthia (CDC/ONDIEH/NCBDDD); Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Cc: Belser-Vega, Elizabeth (CDC/ONDIEH/NCBDDD)
Subject: Hypothesis the Rising Prevalence of Autism - Response

From: Christie del Castillo-Hegyi (b)(6)
Sent: Wednesday, April 30, 2014 1:49 AM
To: Gibbs Shields, Julie I. (CDC/ONDIEH/NCBDDD) (CTR)
Subject: Re: Hypothesis the Rising Prevalence of Autism - Response

Dear Dr. Moore and Dr. Scanlon,

Thank you so much for such a thoughtful and well-researched response! I truly feel honored to have the consideration that you have given me. I am so touched and hopeful that you will find important information about autism and hopefully find within your data something that we can intervene upon through a public health effort. I am clearly not bound to my hypothesis. I would just be as happy to find out that (b)(6)

(b)(6) But I do hope we find the brain insult that happens with enough frequency to explain the rise in ASD prevalence that matches the epidemiology of the disease and leads us to causality.

If nothing else, I hope I can offer ways to making exclusive breastfeeding safer for newborns.

Having talked to many moms, I am not alone in my experience. I know moms who have breastfed non-stop for weeks looking puzzled at their hungry baby who is not gaining weight,

who have been told to simply "keep breastfeeding" or are questioned about their techniques when in fact, they simply did not have enough as evidence by the lack of any milk production while pumping. While breastfeeding is without a doubt the best thing a mother can do for her baby, I think if mothers were better educated about the possibility of there not being enough and that it is possible for their babies to become dehydrated, hypoglycemic or jaundiced due to insufficient feeding, more mothers would present earlier and prevent their babies from going to the ICU. Unfortunately, the current teaching to mothers is summed up by the following statement that was a direct quote from a lactation consultant when addressing a friend's daughter: "Your child will never learn to properly breastfeed if you give her a bottle." That mother went on to having breastfeeding difficulties because she did not produce enough, breastfed day and night for 2 weeks while her baby went hungry and did not gain weight while refusing to give a bottle and as a result, gave up breastfeeding all together. I question whether a few bottles to satisfy this baby's hunger and perhaps give this mother a break would have salvaged her breastfeeding effort. I worry that the pursuit of exclusive breastfeeding, especially before lactogenesis, may not be respecting the physiologic need of the newborn. Thousands of years of evolution has shaped a mother's urge to feed a crying baby as evidenced by the prevalence of "pre-lacteal feeding" in non-Western traditional cultures. I wonder if we are potentially interfering with an important biological protective instinct.

I wish to tell you that I would like to write the president of the AAP and include your letter with it. You offer such a complete review of the relevant information thus far. While I do not wish to interfere with your research, I would like to advocate for a patient safety initiative asking hospitals to weigh exclusively breastfed babies before and after breastfeeding while in the hospital so that mothers and health-care providers can identify the mothers who are most at risk of underfeeding after discharge. Exclusively breastfed babies are the only patients in the hospital for which we have no information about the quality and quantity of the food they receive. As you can see, if such a severe case of dehydration and hyperbilirubinemia can occur to two physicians taking home their first child, it can happen to anyone.

As for jaundice and autism, I leave that matter to your capable hands. If you ever want to hear about all the highly educated, exclusively breastfeeding moms with kids on the spectrum within my very small group of friends, I would be happy to tell you about them. I pray and hope that you find something that will save the countless future children at risk.

Thank you from the bottom of my heart,

Christie del Castillo-Hegy, M.D.

Christie del Castillo-Hegy

(b)(6)

On Apr 29, 2014, at 3:53 PM, Gibbs Shields, Julie I. (CDC/ONDIEH/NCBDDD) (CTR) wrote:

Dear Dr. del Castillo-Hegy:

In response to your email dated March 28, 2014, where you provided your hypothesis about the rising prevalence of autism, attached is a letter from Dr. Cynthia Moore and Dr. Kelley Scanlon addressing the issues outlined in your correspondence.

Regards,

Julie Gibbs Shields

*Julie Gibbs Shields, MBA
Centers for Disease Control and Prevention (CDC)
National Center on Birth Defects and Developmental Disabilities (NCBDDD)
Office of Policy, Planning and Evaluation (OPPE)
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April 28, 2014

Christie del Castillo-Hegy, M.D.
cdelcastillohegy@gmail.com
505-803-5304

Dear Dr. Del Castillo-Hegy:

On behalf of Dr. Frieden, thank you for your letter sharing your family's experience. We recognize your commitment to your son's health and the health of all infants. You raise important questions about current guidance to exclusively breastfeed, neonatal hyperbilirubinemia, and increasing numbers of children with autism spectrum disorder (ASD) – and possible connections among these factors. The Centers for Disease Control and Prevention (CDC) is always interested in insights from astute clinicians and moms such as yourself, because these insights have led to many scientific discoveries. Scientists in CDC's Division of Birth Defects and Developmental Disabilities (where our ASD activities are located) and the Division of Nutrition, Physical Activity, and Obesity (where our breastfeeding activities are located) read your letter and our response follows. Because these issues may overlap, we have laid them out in a way we hope you will find helpful. We have also included a few references at the end of this letter.

The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for about six months followed by continued breastfeeding as complementary foods are introduced until the infant is at least one year of age (AAP, 2012). Our work at CDC is focused on supporting women who breastfeed through policy and environmental approaches. We emphasize improvement in maternity care practices to support breastfeeding women as well as measures to support breastfeeding women when they return home and to their employment. During the hospital stay, breastfeeding women are encouraged to exclusively breastfeed their newborn infant unless a supplement is medically indicated. Medical indications to supplement such as an infant's weight loss of 8% to 10% accompanied by delayed lactogenesis and/or evidence of dehydration are outlined in Academy of Breastfeeding Medicine (ABM) clinical protocol for supplementary feeding in healthy term newborns (ABM, 2009). When an infant has early feeding difficulties, professional lactation support is critical to work with the mother and infant to overcome these feeding difficulties. Part of this support is monitoring for indications to supplement and working with mother when a supplement is needed; however, early feeding difficulties do not always indicate the need for a supplement. Because unnecessary supplementation can interfere with the establishment of breastfeeding and lead to a shorter duration of breastfeeding, it should be avoided. The American Academy of Pediatrics recommends hospital routines that optimize

opportunities and support for mothers to exclusively breastfeed but also acknowledges the role of pediatricians in assessing the adequacy of breastfeeding and any indication for supplementation (AAP, 2012).

Poor breastfeeding with inadequate caloric intake during the first days of life increases the risk for early neonatal jaundice. The mechanisms have been well-described and are related to developmental limitations in bilirubin metabolism and transport that are physiologically normal for newborns. The ABM has also provided a clinical protocol for management of serum bilirubin concentrations while breastfeeding, again including indications for supplementation (ABM, 2010). In addition, breastfeeding difficulty associated hypernatremia has been widely reported in the medication literature and sometimes has been associated with severe consequences. A recent population-based, prospective study in the UK (Oddie, 2013) found that severe hypernatremia in newborns was rare (about 1 in 100,000 live births) and primarily associated with breastfeeding difficulties. Short-term outcomes for these infants appear to be good; however, long-term studies are lacking.

As you have learned by looking through the scientific literature, there have been several studies assessing the possible association of jaundice and ASD. In 2011, a systematic review and meta-analysis of eleven studies showed a pooled risk estimate of 1.43 which was statistically significant (Amin et al., 2011). This finding of a 43% increase was seen in studies where the majority of infants were born at term. The authors noted a limitation that this finding is based on observational studies which can only show an association between factors and cannot prove causality. However, such a review may be the stimulus for more research.

While feeding problems in children with ASD have been documented in several studies, the possible association between breastfeeding difficulties and ASD has been less studied. A 2013 study from Sweden (Barnevik-Olsson, 2013) reports a significantly higher number of consultations for early regulatory problems such as feeding and sleeping difficulties among children with a later diagnosis of ASD. While it is known that older children with autism may have difficulties with eating, this study measured feeding problems reported during the first two years of life during consultations before a diagnosis of autism. Regarding breastfeeding, the practice has been found to be associated with a lesser risk for ASD and other neurological disorders, but there is some literature proposing that early difficulties with breastfeeding may be positively associated with ASD. A recent study found a higher odds of ASD with shorter durations of exclusive breastfeeding and shorter durations of any breastfeeding. The study also reported 48% higher odds for ASD with late initiation of breast-feeding (Al-Farsi, 2010). The findings in this small study need to be supported by additional studies.

A number of studies have documented various delays in motor skills as well as other neurologic problems in children with ASD (Chukoskie, 2013). It is not known if an underlying neurologic

problem such as oral motor dysfunction might predispose infants with ASD to breastfeeding difficulties that present before a diagnosis of ASD. Changes in the cerebellum which, as you know, is important for coordination and motor learning have been documented in numerous studies (Fatimi, 2012) and most recently, areas of disorganization in the neocortex have been identified in children with autism who had died (Stoner, 2014). The changes described would have occurred prenatally.

CDC is working closely with the Food and Drug Administration (FDA) to support the Infant Feeding Practices Study II, a national longitudinal study of 4,902 pregnant women and their infants, 3,033 of whom were followed through the first 12 months postpartum with nearly monthly questionnaires. The study provides detailed information about infant diet, including breast milk and infant formula, factors that contribute to infant feeding practices, infant morbidity, dietary patterns of pregnant and postpartum women, and other factors (<http://www.cdc.gov/ifps/>). A follow up study of the children at age six years was recently completed and will be released in September 2014.

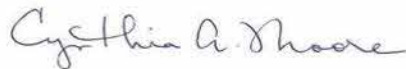
To help identify factors that may put children at risk for autism and other developmental disabilities, CDC is conducting one of the largest studies in the United States called the Study to Explore Early Development (SEED). SEED is looking at numerous risk factors for ASD such as genetic factors, environmental factors, and the interaction between genetic and environmental factors that have not been explored in other studies. SEED collects a variety of information on perinatal factors, such as preterm birth, found to increase the risk for ASD in previous studies. We collect less information on postnatal factors, such as jaundice, which also may be important. Through SEED we collect basic information on jaundice and early feeding difficulties; however, we have not collected information on breastfeeding difficulties per se. We will take a look at the information we have related to jaundice and feeding difficulties and we will also share your letter with our collaborators working on SEED through the CDC-funded Centers for Autism and Developmental Disabilities Research and Epidemiology. Your letter will stimulate discussion on what further information could be collected as part of this effort.

It's difficult to succinctly sum up where we are in the search for causes of ASD. We agree with your conclusion that the increases in ASD prevalence cannot be due to changes in the genetic make-up of the population. We know that having some genetic conditions such as Down syndrome is a strong risk factor for ASD. We also know that some environmental exposures prenatally increase the risk, and we are identifying more and more genetic variants that also appear to increase the risk – often in concert with environmental exposures. We know that some of the increase is due to better identification of children across a broad phenotype of children with ASD. We have identified a number of additional factors such as parental age, but we know there must be others.

Again, we thank you for sharing your story and motivating us to continue to explore the difficult questions. You have gone above and beyond to help your child thrive by continuing to breastfeed for 20 months. However, a mother always wants to know the “why” when her child has developmental challenges, and many times will feel guilt even in the absence of an answer. It is so distressing that the safeguards which have been put in place to help mothers successfully breastfeed did not prevent your baby’s need for ICU care shortly after birth.

To conclude, at this point in time we have found connections between difficulties in breastfeeding, jaundice and ASD, but we don’t know if there is a causal pathway or the direction of the pathway if it exists. Both promoting successful breastfeeding and finding the causes of autism will remain important public health issues for CDC. We wish your family well in the future and remain available if further questions or concerns arise.

Sincerely,



Cynthia A. Moore, M.D., Ph.D.
Director
Division on Birth Defects and
Developmental Disabilities
National Center on Birth Defects and
Developmental Disabilities
Centers for Disease Control and Prevention



Kelley S. Scanlon, Ph.D., R.D.
Lead Epidemiologist
Epidemiology and Surveillance Team
Division of Nutrition, Physical Activity, and Obesity
National Center for Chronic Disease Prevention and
Health Promotion
Centers for Disease Control and Prevention

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Stoner R, Chow ML, Boyle MP. (2014). Patches of disorganization in the neocortex of children with autism. *NEJM*. 370:1209-19.

From: Winter, Lori
Sent: Mon, 21 Dec 2015 13:50:13 -0500
To: Meek, Joan; Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR); 'Onyema-Melton, Ngozi'
Subject: RE: Advice on response to inquiry about inadequate breastfeeding

Dear Jennifer,

I concur with everything Joan has said and would add that the premise behind Safe and Healthy Beginnings tool kit and EQIPP modules was to protect continued exclusive breastfeeding while preventing hyperbilirubinemia and ensuring timely and appropriate follow up for care after leaving the delivery hospital. Elements in these guidelines are still not being followed, so before issuing new policies we need to figure out how to encourage more providers to follow what has been published. Furthermore, the hyperbilirubinemia policy is being updated and should provide additional guidance to support continued exclusive breastfeeding while preventing hyperbilirubinemia.

There are many theories about what leads to ASD, and interestingly research has demonstrated that exclusive breastfeeding is associated with a lower incidence of ASD.

I agree with the concept of a webinar to educate pediatricians on How to support continued exclusive breastfeeding.

(b)(5)

Best regards for a happy and healthy holiday,
Lori

Lori Feldman-Winter, MD, MPH
Div. Head, Adolescent Medicine
Cooper University Hospital
Professor of Pediatrics
CMSRU

From: Meek, Joan [Joan.Meek@med.fsu.edu]
Sent: Monday, December 21, 2015 12:25 PM
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR); 'Onyema-Melton, Ngozi'; Winter, Lori
Subject: RE: Advice on response to inquiry about inadequate breastfeeding

Jennifer,

Yes, I believe that the AAP has heard from the same individual. In fact, we have one pediatrician and one ER doc who routinely communicate with us about the dangers of breastfeeding and dispute all of the evidence supporting breastfeeding.

We, of course, are concerned about the babies who are discharged either not feeding well and/or who do not have close outpatient follow-up arranged. In fact, that is why all of our guidance recommends close follow-up, as do the Bright Futures materials. We do not currently have a guideline planned to address a longer hospital stay, but both the Guidelines for Perinatal Care and those on the hospital stay for the newborn, as well as discharge guidelines, mention that the baby should have feeds evaluated each shift and should have had two successful feedings prior to discharge. We also state direct breastfeeding first, expressed breast milk second or donor milk, but formula supplementation should be given as appropriate, if the baby is not feeding adequately. We do not recommend withholding supplementation, when necessary, but recommend providing better support for breastfeeding as the

first strategy.

(b)(5)

Guidance to either continue exclusive breastfeeding or supplement with formula at 15% weight loss is not appropriate without a careful evaluation of feeding pattern, milk transfer, stage of lactogenesis, specific recommendations about supplementation, and follow-up at no more than 24 hours, assuming that the patient does not appear clinically dehydrated and the baby is able to latch. Education about milk expression to use as a supplement would be recommended until regular weight gain is assured or baby is able to transfer adequate volumes of milk via direct breastfeeding.

Clearly, this is an area requiring ongoing education as we have more babies being exclusively breastfed and more Baby Friendly Hospitals. Babies born in Baby Friendly Hospitals tend to have less excessive weight loss because they tend to have earlier initiation of breastfeeding, more frequent breastfeeding and are getting better support, guidance, and follow-up. We still have education to do with the providers that are seeing all of the breastfeeding babies in follow-up. I am not sure that we need more policies to address, although we could consider this, but education about the policies and recommendations is really important. We have touched on this in previous webinars, but would you consider this as a topic for a joint webinar?

Joan

Joan Younger Meek, MD, MS, RD, FAAP, FABM, IBCLC
Associate Dean for Graduate Medical Education
Designated Institutional Official
Professor, Clinical Sciences
Florida State University College of Medicine
1115 West Call St.
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joan.meek@med.fsu.edu<mailto:joan.meek@med.fsu.edu>

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From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) [<mailto:zcn6@cdc.gov>]
Sent: Saturday, December 19, 2015 8:25 AM
To: Meek, Joan <Joan.Meek@med.fsu.edu>; 'lbwinter@umdnj.edu' <lbwinter@umdnj.edu>; 'Onyema-Melton, Ngozi' (b)(6)
Cc: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>; Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR) <yhm7@cdc.gov>
Subject: Advice on response to inquiry about inadequate breastfeeding

Greetings Joan and Lori,

We would like your advice on a response to a public inquiry regarding the potential dangers of inadequate exclusive breastfeeding (EBF) during the early postpartum period.

As background, we received an email in March 2014 via our website (CDC-Info) from a physician, hypothesizing whether jaundice among exclusively breastfed infants could explain the rising incidence of Autism Spectrum Disorder (ASD). The physician derived this hypothesis from personal experience (b)(6)

(b)(6)
(b)(6) Upon receiving this inquiry, Kelley Scanlon, CDC's Nutrition Branch Chief, and Cynthia Moore, CDC's Director for the Division on Birth and Developmental Disabilities, wrote a very thorough letter outlining the evidence that while there is a connection between breastfeeding difficulties, jaundice, and ASD that it is not known if there is a causal pathway or the direction of the pathway if it exists. In response to CDC's reply, she had some interesting ideas on how to improve patient safety for EBF infants during their birth hospitalization. She also indicated that she would be writing to AAP's president so you may have already heard from her.

Fast-forward to November 2015 when we received a second inquiry to CDC Info from the same physician, highlighting the problem of inadequate exclusive breastfeeding in the early post-partum period. She mentioned a recently published case series from Cincinnati Children's that reported on 11 term neonates who were admitted to their NICU for hypothesized breastfeeding-related hypoglycemia; of which, 5 of 6 (83%) had evidence of ischemic brain injury on MRI (article attached). She also mentioned her review of the scientific literature as well as antidotal evidence she has collected on this issue. We again sent a reply albeit shorter.

She then sent a third inquiry through CDC Info this week, voicing her concern about CDC's "lack of initiative to warn mothers of the possibility of severe disabl[ing] brain injury," resulting from inadequate EBF. She then requested that CDC issue an "urgent warning" to inform mothers of these dangers.

(b)(5) we do want to ensure providers and parents are sufficiently aware of this issue and are also aware of the indications for supplementation. As you know, hospitals need to ensure breastfeeding is going well prior to discharge. Mothers, especially those at high risk for breastfeeding problems, need to be educated about the signs of inadequate feeding and when/where to seek support for any issues. And pediatricians need to ensure adequate assessment and follow-up of EBF newborns, especially when discharged before breastfeeding is well established and before lactogenesis II (aside: Her son was assessed by his pediatrician at DOL 3 with a 15% weight loss, "appropriate" urine/stools, and mild jaundice (no bilirubin checked). She was told to either supplement or continue frequent breastfeeding).

We were wondering if AAP is working on any policy efforts related to extending the initial hospitalization for newborns and their mothers if they are having breastfeeding problems. Are there ways we could incorporate ensuring adequate EBF into patient safety initiatives in maternity care facilities (aside: she made an interesting point that EBF newborns are the only patients in a hospital for which there is no information about quality/quantity of food they receive)? Do you have any thoughts on efforts to improve patient and provider education on identification of inadequate breastfeeding and/or the need for supplementation? Do you have any other suggestions or comments?

We really appreciate your thoughts and comments regarding this issue.

Happy Holidays!

Sincerely,
Jennifer

Jennifer M. Nelson, MD, MPH
LT United States Public Health Service
Epidemic Intelligence Service Officer
CDC/NCCDPHP/DNPAO/Nutrition Branch
4770 Buford Hwy, MS F-77, Atlanta, GA 30341-3717
Ph: 770-488-5157 | Email: jmnelson@cdc.gov<<mailto:jmnelson@cdc.gov>>

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From: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Fri, 18 Dec 2015 11:32:33 -0500
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Subject: FW: Hypothesis the Rising Prevalence of Autism - Response

[Her response to Kelley's letter.](#)

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Tuesday, December 01, 2015 8:32 AM
To: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR) <yhm7@cdc.gov>
Cc: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Subject: FW: Hypothesis the Rising Prevalence of Autism - Response

[Response to our letter](#)

From: Gibbs Shields, Julie I. (CDC/ONDIEH/NCBDDD) (CTR)
Sent: Wednesday, April 30, 2014 7:06 AM
To: Moore, Cynthia (CDC/ONDIEH/NCBDDD) <cam0@cdc.gov>; Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>
Cc: Belser-Vega, Elizabeth (CDC/ONDIEH/NCBDDD) <vsx6@cdc.gov>
Subject: Hypothesis the Rising Prevalence of Autism - Response

From: Christie del Castillo-Hegyi [REDACTED] (b)(6)
Sent: Wednesday, April 30, 2014 1:49 AM
To: Gibbs Shields, Julie I. (CDC/ONDIEH/NCBDDD) (CTR)
Subject: Re: Hypothesis the Rising Prevalence of Autism - Response

Dear Dr. Moore and Dr. Scanlon,

Thank you so much for such a thoughtful and well-researched response! I truly feel honored to have the consideration that you have given me. I am so touched and hopeful that you will find important information about autism and hopefully find within your data something that we can intervene upon through a public health effort. I am clearly not bound to my hypothesis. I would just be as happy to find out that [REDACTED] (b)(6) [REDACTED] (b)(6) But I do hope we find the brain insult that happens with enough frequency to explain the rise in ASD prevalence that matches the epidemiology of the disease and leads us to causality.

If nothing else, I hope I can offer ways to making exclusive breastfeeding safer for newborns.

Having talked to many moms, I am not alone in my experience. I know moms who have breastfed non-stop for weeks looking puzzled at their hungry baby who is not gaining weight, who have been told to simply "keep breastfeeding" or are questioned about their techniques when in fact, they simply did not have enough as evidence by the lack of any milk production while pumping. While breastfeeding is without a doubt the best thing a mother can do for her baby, I think if mothers were better educated about the possibility of there not being enough and

that it is possible for their babies to become dehydrated, hypoglycemic or jaundiced due to insufficient feeding, more mothers would present earlier and prevent their babies from going to the ICU. Unfortunately, the current teaching to mothers is summed up by the following statement that was a direct quote from a lactation consultant when addressing a friend's daughter: "Your child will never learn to properly breastfeed if you give her a bottle." That mother went on to having breastfeeding difficulties because she did not produce enough, breastfed day and night for 2 weeks while her baby went hungry and did not gain weight while refusing to give a bottle and as a result, gave up breastfeeding all together. I question whether a few bottles to satisfy this baby's hunger and perhaps give this mother a break would have salvaged her breastfeeding effort. I worry that the pursuit of exclusive breastfeeding, especially before lactogenesis, may not be respecting the physiologic need of the newborn. Thousands of years of evolution has shaped a mother's urge to feed a crying baby as evidenced by the prevalence of "pre-lacteal feeding" in non-Western traditional cultures. I wonder if we are potentially interfering with an important biological protective instinct.

I wish to tell you that I would like to write the president of the AAP and include your letter with it. You offer such a complete review of the relevant information thus far. While I do not wish to interfere with your research, I would like to advocate for a patient safety initiative asking hospitals to weigh exclusively breastfed babies before and after breastfeeding while in the hospital so that mothers and health-care providers can identify the mothers who are most at risk of underfeeding after discharge. Exclusively breastfed babies are the only patients in the hospital for which we have no information about the quality and quantity of the food they receive. As you can see, if such a severe case of dehydration and hyperbilirubinemia can occur to two physicians taking home their first child, it can happen to anyone.

As for jaundice and autism, I leave that matter to your capable hands. If you ever want to hear about all the highly educated, exclusively breastfeeding moms with kids on the spectrum within my very small group of friends, I would be happy to tell you about them. I pray and hope that you find something that will save the countless future children at risk.

Thank you from the bottom of my heart,

Christie del Castillo-Hegyí, M.D.

Christie del Castillo-Hegyí

(b)(6)

On Apr 29, 2014, at 3:53 PM, Gibbs Shields, Julie I. (CDC/ONDIEH/NCBDDD) (CTR) wrote:

Dear Dr. del Castillo-Hegyí:

In response to your email dated March 28, 2014, where you provided your hypothesis about the rising prevalence of autism, attached is a letter from Dr.

Cynthia Moore and Dr. Kelley Scanlon addressing the issues outlined in your correspondence.

Regards,

Julie Gibbs Shields

*Julie Gibbs Shields, MBA
Centers for Disease Control and Prevention (CDC)
National Center on Birth Defects and Developmental Disabilities (NCBDDD)
Office of Policy, Planning and Evaluation (OPPE)
Contractor - McNeal Professional Services
404-498-0621 - Phone
404-498-3478 – Fax*

From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 8 Mar 2017 07:22:04 -0500
To: MacGowan, Carol (CDC/ONDIEH/NCCDPHP); Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Subject: FW: idea for SBIR topic

FYI...

From: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP)
Sent: Tuesday, March 07, 2017 5:20 PM
To: Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP) <rnf2@cdc.gov>; Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>; Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfi2@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Subject: FW: idea for SBIR topic

All,

Folks from the Center gave me a call today and were wondering if we might be interested in developing an SBIR to have a company address some of the safety issues related to baby friendly.

(An SBIR is money given to small business to develop innovative business solutions to problems). The money does not come from our budget but there is a competitive process to get an idea selected for posting by CDC.

(b)(5)

If you want to discuss further let me know.

(Rafa—I talked about this at OD/BC on Monday).

Deb

From: Colley Gilbert, Brenda (CDC/ONDIEH/NCCDPHP)
Sent: Friday, March 03, 2017 3:38 PM
To: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>
Subject: idea for SBIR topic

Hey Deb,

Rachel and I were talking about possible SBIR topics and had one we wanted to talk with you about. Could you give me a call please.

Thanks so much,

Brenda CG

Brenda Colley Gilbert, PhD, MSPH
Director, Extramural Research Program Operations and Services
serving NCCDPHP and NCBDDD
Centers for Disease Control and Prevention
4770 Buford Hwy NE MS F-80
Atlanta GA 30341
Phone: 770-488-6295
ERPO Phoneline: 770-488-8390

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 30 Aug 2018 15:57:21 +0000
To: Cynthia Klein (Cynthia_Klein@abtassoc.com)
Subject: FW: Important Information and Updates from Baby-Friendly USA

FYI – you may have already received this, but if not.

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, August 30, 2018 11:52 AM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>
Subject: FW: Important Information and Updates from Baby-Friendly USA

From: Trish MacEnroe (b)(6)
Sent: Wednesday, August 29, 2018 3:31 PM
To: 'Larry Grummer-Strawn' <grummerstrawnl@who.int>; 'Maaïke Arts' (b)(6) Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: FW: Important Information and Updates from Baby-Friendly USA

Dear Friends,

I just wanted to share our latest newsletter with you.

Trish

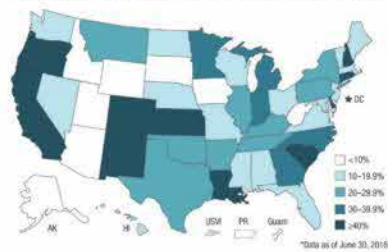


**Important Information and Updates
from Baby-Friendly USA**

[CDC Maps Widespread Baby-Friendly Growth](#)

Positive news about the Baby-Friendly Hospital Initiative continues to roll in with the CDC's release of its 2018 Breastfeeding Report Card. To understand how much progress has been made in the spread of Baby-Friendly practices across the US, all one needs to do is compare two maps. [Read More >>](#)

Percentage of Live Births at Baby-Friendly Facilities, 2018*

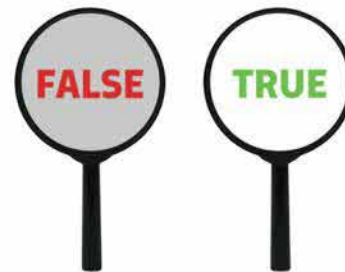


[Changing the Breastfeeding Culture in Baton Rouge](#)

In 2016, 12.6% of live births in Louisiana occurred in Baby-Friendly hospitals. In 2018, that number is 41.6%. How did this important growth occur? And how has it changed the lives of providers, parents and children in this Deep South state? For answers, we spoke with key members of the maternity team at Woman's Hospital in Baton Rouge, the largest birthing facility in Louisiana. [Read More >>](#)

[Fact Vs. Fiction: Calling Out a Misleading FIB, Part 2](#)

After BFUSA posted a statement about one of many inaccurate assertions frequently promoted by the Fed Is Best Foundation, they replied with a series of posts that are once again riddled with inaccuracies and misleading interpretations. As long as this organization continues to spread misinformation about the Baby-Friendly Hospital Initiative, we will continue to call them out. [Read More >>](#)



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UPDATED TOOLS

Updated Tools Posted to the BFUSA Portal

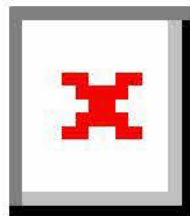
BFUSA has updated and posted several tools in the following phases in the Baby-Friendly USA portal: Development, Dissemination, Designation, Annual Quality Improvement (AQI) and Re-Designation. Please refer to the specific phases' NOTICES/ UPDATES section of the portal for detailed descriptions of the changes made. [Read More >>](#)

Baby Friendly USA | 125 Wolf Road, Suite 402, Albany, NY 12205

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From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 21 Mar 2017 16:13:12 +0000
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Subject: FW: Invitation to discuss response to 'Fed is Best'

What do you think? This is from USLCA

From: Danielle Harmon (b)(6)
Sent: Wednesday, March 15, 2017 5:23 PM
To: Stuebe, Alison M <alison_stuebe@med.unc.edu>; Trish MacEnroe (b)(6); Debi Ferrarello (b)(6); MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; winter-lori@cooperhealth.edu; joan.meek@med.fsu.edu; Marsha Walker (b)(6)
Subject: Invitation to discuss response to 'Fed is Best'

Hello all,

As we are all aware, much discussion is currently underway surrounding the Fed is Best movement. As the US based professional association for IBCLCs, we are hoping to facilitate a discussion on how we might respond. I am writing to invite your organization to participate in an initial call to discuss and create a strategy/action plan around this topic.

In an effort to streamline this initial strategy session we are asking that each of the following organizations sends one representative to the call. If you do not feel you are the appropriate person to participate, please let us know if there may be someone to fit in your place.

- ABM
- AAP SOB
- CDC
- BFHI
- NABA
- USLCA

We are asking that you respond by Friday regarding your interest and availability. If your organization is not interested in participating, please let me know and we will remove you from the list.

If you would like to participate, please complete the following Doodle Poll to help us find a time.

<http://doodle.com/poll/4fdi7c3mbd7rtwk8>

Once we have an action plan, we can then invite other organizations to sign-on in support.

We look forward to hearing from you and appreciate your willingness to participate in this critical discussion.

All the best,

Danielle

Danielle Harmon, MPH

Executive Director

United States Lactation Consultant Association

Office: (b)(6)

Cell: (b)(6)

(b)(6)

www.uslca.org



May 3-6, 2017 | San Antonio, TX

The content of this communication may not reflect the official position of USLCA.

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Fri, 14 Apr 2017 14:48:45 -0400
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP); Calixto Rafael Flores-Ayala, (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Subject: FW: Join us to set the record straight that breastfeeding saves lives
Attachments: 2017-04-12 Lucy M Sullivan Blog.docx

From: Adrianna Logalbo (b)(6)
Sent: Friday, April 14, 2017 9:59 AM
To: Stuebe, Alison M <alison_stuebe@med.unc.edu>; (b)(6)
(b)(6); Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>;
(b)(6) Angela Malloy (b)(6); Arissa
Palmer (b)(6) Bettina Forbes (b)(6)
(b)(6) Camie Goldhammer (b)(6); Celine Malanum
(b)(6); Christine Staricka (b)(6); Dallas Gilpin
(b)(6) Fiona Lang-Sharpe (GOLD LEARNING) (b)(6) Info -
Healthy Children Project <info@centerforbreastfeeding.org>; Iona Macnab (b)(6)
Jessica Martin-Weber (b)(6) Jodine Chase (b)(6)
Katrina Pavlik (b)(6) Kiddada Green (b)(6); Kristin Rowe-
Finkbeiner (b)(6) Leslie Lytle (b)(6) Paige Smith
<phsmith@uncg.edu>; Sarah Hung (b)(6) Sili Recio (b)(6) Stephanie
Sosnowski (b)(6) Tina Sherman (b)(6)
(b)(6)
Cc: Lucy Sullivan (b)(6) Kimberly Seals Allers (b)(6) Amanda
Medlock (b)(6)
Subject: RE: Join us to set the record straight that breastfeeding saves lives

Good morning everyone,

Lucy's blog is now live: <http://www.huffingtonpost.com/entry/58f0cb68e4b04cae050dc66a>

It is also attached for those that would like to post it directly to their sites.

Below is sample copy for a Facebook post - feel free to use this or tweak it as needed:

In the U.S., breastfeeding moms are expected to be their baby's sole source of nutrition while also working, running their household, and somehow finding time for rest and self-care — all with little to no societal support!

Simply put, our country's moms and babies deserve better.

1,000 Days executive director Lucy Sullivan explains the tragic consequences of our nation's lack of support and what we can do to help mothers properly, confidently and successfully breastfeed their babies.

Thank you again for your support! Please feel free to reach out with any questions.

All the best,
Adrianna

Adrianna Logalbo | Managing Director



1020 Nineteenth Street NW, Suite 250 | Washington, DC 20036
Direct: (b)(6) | www.ThousandDays.org | @1000Days

From: Adrianna Logalbo

Sent: Thursday, April 13, 2017 1:24 PM

To: 'Stuebe, Alison M' <alison_stuebe@med.unc.edu>; (b)(6)

(b)(6)

'hgk3@cdc.gov' <hgk3@cdc.gov>; (b)(6)

(b)(6) 'Angela Malloy' (b)(6) 'Arisa

Palmer' (b)(6) >; 'Bettina Forbes' (b)(6)

(b)(6); 'Camie Goldhammer' (b)(6)

'Celine Malanum' (b)(6) 'Christine Staricka' (b)(6)

'Dallas Gilpin' (b)(6) 'Fiona Lang-Sharpe (GOLD LEARNING)'

(b)(6) 'Info - Healthy Children Project' <info@centerforbreastfeeding.org>; 'Iona

Macnab' (b)(6) 'Jessica Martin-Weber' (b)(6) 'Jodine Chase'

(b)(6) 'Katrina Pavlik' (b)(6) 'Kiddada Green'

(b)(6) 'Kristin Rowe-Finkbeiner' (b)(6) 'Leslie Lytle'

(b)(6) 'Paige Smith' <phsmith@uncg.edu>; 'Sarah Hung'

(b)(6) 'Sili Recio' (b)(6) 'Stephanie Sosnowski' (b)(6)

(b)(6) 'Tina Sherman' (b)(6)

(b)(6)

Cc: Lucy Sullivan (b)(6) 'Kimberly Seals Allers' (b)(6) Amanda

Medlock (b)(6)

Subject: RE: Join us to set the record straight that breastfeeding saves lives

Hello everyone,

Thank you all for your support yesterday and today as we've pushed Kimberly's blog far and wide. There has been a lot of traction online and - as many of you have seen - response from FIB co-founders and supporters, in particular on the [ABM Facebook post](#).

If you're able, we would encourage you to comment on the ABM post with a simple statement of support, such as: *Thank you for posting this story OR I stand with ABM in sharing this post.*

Lucy Sullivan's blog will go live tomorrow morning on Huffington Post and the 1,000 Days website. I will send out the links along with a sample Facebook post so you can cross promote to your networks.

For those that are interested and able to post the blog directly to their websites, the word doc is attached. Please feel free to get it up and out beginning at 10:00am tomorrow.

Feel free to reach out to me or Kimberly with any questions. And thank you again for your support!

All the best,
Adrianna

Adrianna Logalbo | Managing Director



1020 Nineteenth Street NW, Suite 250 | Washington, DC 20036
Direct: (b)(6) | www.ThousandDays.org | @1000Days

From: Adrianna Logalbo

Sent: Wednesday, April 12, 2017 5:00 PM

To: 'Stuebe, Alison M' <alison_stuebe@med.unc.edu> (b)(6)

(b)(6); (b)(6)

'hgk3@cdc.gov' <hgk3@cdc.gov> (b)(6)

(b)(6); Angela Malloy (b)(6); Arissa Palmer

(b)(6); Bettina Forbes (b)(6) Camie

Goldhammer (b)(6); Celine Malanum (b)(6)

Christine Staricka (b)(6); Dallas Gilpin (b)(6) Fiona Lang-

Sharpe (GOLD LEARNING) (b)(6); Info - Healthy Children Project

<info@centerforbreastfeeding.org>; Iona Macnab (b)(6); Jessica Martin-Weber

(b)(6) Jodine Chase (b)(6) Katrina Pavlik

(b)(6); Kiddada Green (b)(6) Kristin Rowe-Finkbeiner

(b)(6); Leslie Lytle (b)(6) Paige Smith <phsmith@uncg.edu>;

Sarah Hung (b)(6) Sili Recio (b)(6) Stephanie Sosnowski

(b)(6); Tina Sherman (b)(6)

Cc: Lucy Sullivan (b)(6) 'Kimberly Seals Allers' (b)(6) Amanda

Medlock (b)(6)

Subject: FWD: Join us to set the record straight that breastfeeding saves lives

Dear Colleagues,

Please join us as we work to set the record straight that breastfeeding saves lives.

As you know, a disinformation campaign designed to cause fear, uncertainty and doubt among new parents regarding breastfeeding is emerging. As such, we have teamed up with Kimberly Seals Allers to promote a few pieces of content to push back on some of the claims that we have seen circulating in the press. We hope you will join us in this effort.

Kimberly's first blog post is now live.

You can find it [here](#) (and attached).

Please feel free to post this to your website and/or cross promote it on social media.

Thank you to everyone who has already done so today - we're seeing a lot of great traction online.

If helpful, below is sample copy for a Facebook post to link to the blog:

The science behind the benefits of exclusive breastfeeding is clear - it saves countless lives and improves the health of both mom and baby. What is also clear is the urgent need for expert and reliable support for nursing moms and babies before, during and after leaving the hospital. Breastfeeding advocate Kimberly Seals Allers explains the lessons our society must learn from the tragic story of a mother's loss and why we must stop setting up America's breastfeeding moms to fail.

We welcome thoughtful and respectful discussion on this topic.

We have also developed [several responses](#) to comments that we *might* receive on Facebook. These are crafted from 1,000 Days' perspective, but hopefully the language will be helpful for you if needed.

1,000 Days will be posting a blog (authored by Lucy Sullivan) on FRIDAY morning, which I will send to you via email so you can post it to your website and/or cross promote it on Friday as well.

You are of course welcome to share your own comments/perspectives on this issue. If you choose to do so, here are a few suggestions (as Kimberly outlined below):

- Don't attack the messenger, redirect the message.
- Don't get caught up in the details of any specific incident but focus on the systemic barriers.
- As you post Kimberly's and/or my blog – or your own – you can invite thoughtful and respectful conversation from your community. However, if you receive comments that are disrespectful you can always turn off the comments on your blog or hide or block users on Facebook.

As Kimberly said, we know this will be a long fight to ensure the facts about breastfeeding win-out over misinformation and divisiveness. We are taking just the first small steps this week, and hope you will join us. Please feel free to reach out to us with any questions or ideas.

Thank you,
Adrianna Logalbo and Lucy Sullivan

Adrianna Logalbo | Managing Director



1020 Nineteenth Street NW, Suite 250 | Washington, DC 20036
Direct: (b)(6) www.ThousandDays.org | @1000Days

From: (b)(6)

Date: Tuesday, April 11, 2017 at 5:44 PM

To: (b)(6)

(b)(6), Kiddada Green (b)(6) Jessica Martin-Weber
(b)(6), Angela Malloy (b)(6) Jodine
Chase (b)(6) Arissa Palmer (b)(6)
Christine Staricka (b)(6), Celine Malanum
(b)(6) Tina Sherman (b)(6) Kristin Rowe-
Finkbeiner (b)(6) Camie Goldhammer (b)(6)
Iona Macnab (b)(6), Leslie Lytle (b)(6) Dallas Gilpin
(b)(6) (b)(6) Info - Healthy
Children Project (b)(6), Katrina Pavlik
(b)(6), Paige Smith <phsmith@uncg.edu>, "Fiona Lang-Sharpe
(GOLD LEARNING)" (b)(6), Stephanie Sosnowski (b)(6)
(b)(6) Sili Recio (b)(6)
(b)(6)
Adrianna Logalbo (b)(6) Amanda Medlock
(b)(6)

Subject: Please join us STARTING TOMORROW to set the record straight that breastfeeding saves lives

Dear friends and partners,

As we're sure you are aware, the Fed is Best (FIB) organization has undertaken a well-orchestrated disinformation campaign designed to cause fear, uncertainty and doubt among new parents and their narrative is getting picked up by national media. One blog post in March has been covered in major outlets from the Washington Post to USA Today to Parents magazine, with sensational headlines that point to breastfeeding as the cause of infant deaths.

We know this to be not only false, but irresponsible. So we're speaking up and we hope you will join 1,000 Days and myself, starting tomorrow, in a coordinated effort to support the facts about breastfeeding.

While it may not be prudent to respond to every negative story about breastfeeding, inflammatory and sensational headlines and organizations that look to use scare tactics and fear mongering are an emerging threat to the mothers and babies we serve and to the decades of collective work to promote breastfeeding for the health of moms and babies. These stories are not just read by moms but by policy makers and legislators, and can be used to discredit our efforts.

As advocates we can and should set the record straight that breastfeeding saves lives.

I've been working with 1,000 Days to produce several pieces of content to push back on some of FIB's claims around the dangers of exclusive breastfeeding and BFHI.

Attached you will find my first blog post on this topic - **please feel free to post this to your website and/or cross promote it on social media (it will be on my [website](#) as well by 10 am) TOMORROW, Wednesday, April 10th.**

The coordinated effort will include 2 additional posts and I will be following up later in the week with the blog from Lucy Sullivan, Executive Director of 1,000 Days, as well. The plan would be to post the attached blog tomorrow, Wednesday, then Lucy's blog on Friday with another blog post from me early next week.

We will also follow up with some suggested Facebook posts and general suggestions about addressing comments on social media--so keep your eyes open for a follow up email.

Please feel free to develop your own response for others to share. As a broad messaging strategy do not get caught up in the details of any incident but seek to point to the systemic barriers or "fails" that occurred, if responding at all.

I know 1,000 Days is working with the U.S. Breastfeeding Committee to convene a call among partners and allies to discuss additional tactics for a collective response going forward.

In the meantime, please feel free to let me or Lucy know if you have any questions. We know this will be a long fight to ensure the facts about breastfeeding win-out over misinformation and divisiveness. We hope you will join us this week as we take the first step.

Together we can!!

Best,
Kimberly

--

Kimberly Seals Allers
Journalist | Author | Speaker | Consultant
Director, First Food Friendly Community Initiative ([3FCI](#))
www.KimberlySealsAllers.com

O (b)(6) M (b)(6)
@iamKSealsAllers | @MochaManual

The Real National Scandal of Newborn Deaths, and Why Support for Breastfeeding Moms Matters

Each year in the United States, over 23,000 infants die before their first birthday. As a nation, we currently have a [higher infant mortality](#) rate than 25 of the world's wealthiest 29 countries. The deaths of so many babies is a national tragedy and should be a national scandal—but it isn't.

Many of these infant deaths—particularly those that occur after the newborn period—are preventable. And one of the most powerful ways we can prevent this horrible loss of young life is to ensure that mothers are able to breastfeed successfully and for as long as possible.

This is because breastfeeding saves lives. It protects babies from life-threatening infections and illnesses as well as conditions such as Sudden Infant Death Syndrome (SIDS)—one of the leading causes of infant mortality in the U.S. In fact, *not* breastfeeding carries a huge price tag, measured in the health and lives of mothers and babies.

Last year, in a [groundbreaking study](#) in the world-renowned medical journal *The Lancet*, researchers estimated that globally over 800,000 lives of children could be saved annually through better breastfeeding practices. It also found that breastfeeding could save 20,000 women each year from dying from breast cancer. Here in the U.S., a [recent study notes](#) that for every 597 women who optimally breastfeed, one maternal or infant death is prevented. [Researchers have also found a strong correlation between decreased infant mortality](#) from SIDS, lower respiratory tract infections (LRTI), and necrotizing enterocolitis (NEC) and increased rates of breastfeeding. Moreover, given that the [majority of infant deaths in the U.S. are linked to preterm birth](#), ensuring these vulnerable premature newborns have access to breast milk can help save lives because of its unrivaled power to fuel growth and brain development. Because of this, the [American Academy of Pediatrics](#) recommends that all preterm infants receive pasteurized human donor milk rather than infant formula as the preferred alternative if a mother's breast milk is not available.

But some of the recent stories in the news and articles spreading through social media appear to paint quite the opposite picture about breastfeeding—that somehow breastfeeding is potentially dangerous to babies and that the "pressure to breastfeed" is the reason behind some babies getting sick or even, in a handful of cases, dying.

This is misleading and wrong. Many babies get sick and die in the U.S. before their first birthday because as a country we don't do enough to support mothers to breastfeed and properly care for their children. The reality is that we are failing our nation's babies because we are failing our nation's mothers.

In our society, a mother must balance the desire to breastfeed with a lack of support and resources to do so. This has little to do with a woman's own supply and everything to do with the context in which she lives. The pressure to breastfeed exists because society expects a mother to be her infant's sole source of nutrition while also working, managing a household,

caring for other family members, and finding time to get adequate rest and self-care. These demands are unfair and unreasonable.

Many women who want to breastfeed have to contend with numerous other barriers: unsupportive hospital practices and workplace policies including a lack of any kind of paid parental leave; an overall lack of qualified help when it comes to breastfeeding; and often, incorrect medical advice because many physicians and other health professionals are not trained in or have limited knowledge of lactation and infant feeding. America's mothers are also constantly being bombarded by messages that inspire fear, uncertainty and doubt in their ability to breastfeed and cause them to question their choice. And mothers are surrounded by these messages—in hospitals and doctors' offices, at stores, in their Facebook feeds and inboxes and even in their mommy support groups. All of this combined can leave a woman feeling that breastfeeding is perhaps not worth the trouble, or worse, that it is potentially dangerous.

As a society, we have to do more to give mothers the support they need to properly, confidently, and successfully breastfeed their babies. For starters, we at 1,000 Days, along with many other organizations, are pushing for a national paid family leave program to ensure that all mothers in the U.S. have access to time off to care for their babies. We're also working alongside partners such as the [U.S. Breastfeeding Committee](#) to ensure that all health insurance plans in the U.S. cover lactation counseling and breastfeeding support and supplies. In addition, organizations like the [Academy of Breastfeeding Medicine](#) are calling for better training for physicians, nurses and other health care professionals in lactation management and to know when it is appropriate and necessary to supplement newborns—ideally with donor breast milk or with formula if breast milk is not available.

Downplaying the importance of breastfeeding is doing infants and mothers a grave disservice, particularly when breastfeeding can help reduce the unacceptably high rate of infant mortality in our country. That's why all of us can play an important role in calling out the manipulative and misleading marketing of infant formula as well as disinformation campaigns designed to stoke fears, undermine women's confidence to breastfeed, play into a mother's guilt, and blame-and-shame groups that work to promote breastfeeding.

We owe it mothers to do better. We also owe it to the thousands of babies who get sick or die each year in the U.S. because they do not have the opportunity to fully benefit from mother's milk. This is the national scandal that we need to be attacking—rather than attacking breastfeeding and those who work to make breastfeeding more possible for more mothers and babies.

Lucy Martinez Sullivan is the Executive Director of 1,000 Days, the leading advocacy organization working in the U.S. and around the world to improve nutrition and ensure women and children have the healthiest first 1,000 days. Learn more at www.thousanddays.org and follow Lucy on Twitter @lucymsullivan

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 13 Apr 2017 06:43:25 -0400
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP); Calixto Rafael Flores-Ayala, (CDC/ONDIEH/NCCDPHP); Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP); Olson, Christine (CDC/ONDIEH/NCCDPHP)
Subject: FW: Join us to set the record straight that breastfeeding saves lives
Attachments: FiB Response Post 1 .docx

FYI

From: Adrianna Logalbo (b)(6)
Sent: Wednesday, April 12, 2017 5:00 PM
To: Stuebe, Alison M <alison_stuebe@med.unc.edu>; (b)(6)
(b)(6) Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>;
(b)(6) Angela Malloy (b)(6) Arissa
Palmer (b)(6) Bettina Forbes (b)(6)
(b)(6) Camie Goldhammer (b)(6) Celine Malanum
(b)(6); Christine Staricka (b)(6) Dallas Gilpin
(b)(6); Fiona Lang-Sharpe (GOLD LEARNING) (b)(6); Info -
Healthy Children Project (b)(6); Iona Macnab (b)(6)
Jessica Martin-Weber (b)(6); Jodine Chase (b)(6)
Katrina Pavlik (b)(6) Kiddada Green (b)(6) Kristin Rowe-
Finkbeiner (b)(6); Leslie Lytle (b)(6) Paige Smith
<phsmith@uncg.edu>; Sarah Hung (b)(6); Sili Recio (b)(6); Stephanie
Sosnowski (b)(6); Tina Sherman (b)(6)
(b)(6)
Cc: Lucy Sullivan (b)(6); Kimberly Seals Allers (b)(6) Amanda
Medlock (b)(6)
Subject: FWD: Join us to set the record straight that breastfeeding saves lives

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(b)(6) Sili Recio (b)(6)
(b)(6)
Adrianna Logalbo (b)(6) Amanda Medlock
(b)(6)

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Together we can!!

Best,
Kimberly

--

Kimberly Seals Allers
Journalist | Author | Speaker | Consultant
Director, First Food Friendly Community Initiative ([3FCI](#))
www.KimberlySealsAllers.com

O: (b)(6) M: (b)(6)
@iamKSealsAllers | @MochaManual

Setting the Record Straight: Breastfeeding Saves Lives, Doesn't Cost Lives.
Getting beyond the headlines to the truth about recent stories of "breastfeeding-related deaths."

By Kimberly Seals Allers

Losing a child is a tragedy. As the Internet buzzed recently with the story of Jillian Johnson and the death of her son Landon, our hearts ached. Every mother, every human, feels her pain. Often, the best you can glean from any tragedy are important lessons learned. While it may seem easiest to blame breastfeeding or the Baby Friendly Hospital Initiative, as the click-generating headlines and story promoters simplistically suggest, that would not give the issue proper justice. If the true end goal is to ensure that no mother has a similar experience to what the Johnson family endured, then it is important to consider all the factors that contributed to that tragic loss and how we respond to that loss. We owe baby Landon that much.

Most importantly, we must not allow the media or any organization's desire to sensationalize a rare occurrence turn into a dangerous, broad-based message that exclusive breastfeeding kills. That is categorically untrue and extremely irresponsible. In fact, decades of global research proves that exclusive breastfeeding consistently saves lives. The World Health Organization reports that over 800,000 babies could be saved worldwide by increasing breastfeeding rates, preventing 13% of all deaths under age five. The Baby Friendly Hospital initiative served over 788,000 births in 2016 alone, providing evidence-based care with positive outcomes. (Note: The Johnson family has not revealed the name of the hospital so it cannot be confirmed that it was indeed a BFHI certified hospital).

Take for example, seat belts. We know seat belts save lives, by and large, yet we also know that people can still die in a car accident while wearing a seat belt. But it would be short sighted to demonize seat belts in general for the specific incidences where unique circumstances meant a seat belt failed to prevent death. We would not condemn all seat belt use, attack seat belt users or criticize all public health campaigns designed to encourage their use, would we?

Yes, Jillian's story as a rare occurrence must be told. These stories shock us to see the gaps and do better. But we can't just stand by while sensational headlines and questionable motives trap us into an equally dangerous matrix of fear, divisiveness and emotional manipulation that foolishly paints a broad stroke over an acute complication when decades of scientific evidence proves that breastfeeding—when properly supported—saves countless babies and improves infant and maternal health.

Now for two important acknowledgments: First, we must acknowledge that not all mothers can successfully exclusively breastfeed. While the percent of women who cannot breastfeed due to biological factors is rather small, lactation is impacted by psychological factors such as anxiety and stress and these are mounting in our society leading to increases in incidences of insufficient milk supply.

Second, we have to acknowledge that most physicians simply do not know enough about lactation medicine and we have to start facilitating and demanding that they receive more evidence-based education about a biological norm. Again, we don't know for sure that Landon was delivered at a certified Baby Friendly Hospital (although that hasn't stopped the story promoters from blaming BFHI). But perhaps that is more to the point—that all families, regardless of where they deliver deserve physicians and nurses, who are properly trained and certified in lactation science, so they can effectively educate parents to manage breastfeeding, particularly in the early days and weeks after birth. This includes avoiding "one size fits all"

breastfeeding advice and being sure to educate parents on the warning signs of a sick infant, beyond counting diapers. That knowledge also includes understanding medical conditions that can impact milk supply including having a C-section, as Jillian did, and certain health conditions such as the hormonal disorder that Jillian had. Physicians need to better understand lactation and lactation failures.

It is also important to note that the Johnson family tragedy happened five years ago. And much has changed in five years. Think of how far we've come in cancer treatment, mobile phone technology and even food labeling transparency in the past five years. Meanwhile, contrary to some published reports, BFHI guidelines have always allowed for supplementation when medically justifiable, such as with an infant like Landon who was in distress prior to the emergency C-section. BFHI guidelines also stipulate that a mother's educated, informed choice for supplementation will not be denied. [See: Baby-Friendly USA. "Guidelines and Evaluation Criteria for Facilities Seeking Baby-Friendly Designation." Guideline 6.1, p 18-19, Albany, NY: Baby-Friendly USA, 2016]. In other words, no mother who takes in all the facts and still chooses formula will be denied formula. Period. Point blank.

But there is a critical difference between supporting formula use when medically necessary and undermining breastfeeding among all women, all the time, with insidious marketing schemes including back-door, multi-million dollar payments to hospitals for formula marketing rights. The former requires physician knowledge and close monitoring of a specific infant to recommend supplementation as needed. The latter attempts to broadly trip up all mothers before they even start. One requires surgical skill and precision the other just swings a machete. Similarly, using broad-based scare tactics, horror stories and media manipulation to frighten all mothers is equally reckless. The health of mothers and babies is at stake.

However, one of the most painful parts of reading Jillian's story, for me, is the sense of responsibility that weighed heavy upon her shoulders. Too often in these experiences we hear of mothers who said they read everything, went to classes, etc, only to be let down by the enormity of motherhood and the realities of breastfeeding. This perpetuates the dangerous thinking that it is up to mothers alone to successfully breastfeed or self-diagnose breastfeeding problems. It's so terribly easy for a patriarchal culture to put all the responsibility on mothers and not chase the real culprits behind why breastfeeding is often so difficult, particularly in the early days. No holding hospital physicians to task for missing early warning signs. No question of how many International Board Certified Lactation Consultants were employed by the hospital to provide sufficient support. No mention of federal and state laws that allow for a 96-hour minimum stay after a C-section birth. No asking about the importance of prompt follow-up home visits (a standard in the UK and most European countries) or where was the social support of other mothers or relatives who could possibly raise alarms. This is what is most dangerous to us all—the isolation of breastfeeding and the burden mothers are told they must bear alone. It is absolutely unacceptable.

But so is fear mongering.

And parading horror stories and graphic images of sick infants to market your agenda.

Which brings me to a very brief word about The Fed is Best Foundation. I'm all in for sharing stories—even at times, tragic ones—they jar us into seeing how we fail mothers so we can ensure it doesn't happen again. I am opposed to shaming formula feeders. As a first time mom, my baby was given formula in the NICU. And I refuse to subscribe to the breast vs. bottle wars—that's a concept pushed by marketing propaganda because it drives profits. All mothers simply want the best for their baby. But I'm deeply concerned by the aggressive and mean-

spirited comments posted by the founders on blogs and social media. People are being viciously attacked or blocked simply for expressing counter opinions and sharing important facts. There's high school-ish name calling that's downright nasty (please stand by and watch this comments section) and other tactics clearly designed to silence and control women. Is this the best way forward? Adopting tactics of aggression and using cyber bullying is not the modus operandi of a well-intentioned education campaign that merely seeks to caution mothers. With so much at stake, we owe it to our babies and ourselves to question the true intent here.

Succumbing to scare-tactics without carefully considering the systemic failures and all the facts, including examining those who are peddling it, won't get any of us anywhere in making true changes to the system that failed the Johnson family. That would simply be yet another tragedy.

Kimberly Seals Allers is an award-winning journalist and nationally recognized infant health advocate. Her fifth book, *The Big Letdown—How Medicine, Big Business and Feminism Undermine Breastfeeding* was released in January by St. Martin's Press. Learn more at www.KimberlySealsAllers.com and follow her on Twitter @iamKSealsAllers.

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 22 Jun 2017 11:55:20 -0400
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP); Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR); Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP); Lore, Diane (CDC/ONDIEH/NCCDPHP) (CTR)
Subject: FW: JOIN US: Monday June 26th to promote #FactsNotFear on breastfeeding
Attachments: Facts Not Fear Blog Post - Final.pdf

From: Kimberly Seals Allers (b)(6)
Sent: Thursday, June 22, 2017 11:51 AM
To: Alison M <alison_stuebe@med.unc.edu>; (b)(6)
(b)(6) Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>;
(b)(6) Angela Malloy (b)(6) Arissa Palmer (b)(6); Bettina Forbes (b)(6); Camie Goldhammer (b)(6) Celine Malanum (b)(6) Christine Staricka (b)(6); Dallas Gilpin (b)(6) Fiona Lang-Sharpe (GOLD LEARNING) (b)(6); Info - Healthy Children Project <info@centerforbreastfeeding.org>; Iona Macnab (b)(6) Jessica Martin-Weber (b)(6) odine Chase (b)(6) Katrina Pavlik (b)(6); Kristin Rowe-Finkbeiner (b)(6) Leslie Lytle (b)(6) Paige Smith <phsmith@uncg.edu>; Sarah Hung (b)(6) Sili Recio (b)(6); Stephanie Sosnowski (b)(6) Tina Sherman (b)(6) Trish MacEnroe (b)(6) Lucy Sullivan (b)(6) Amanda Medlock (b)(6) (b)(6) Marion Rice (b)(6) Ginger Gorrell (b)(6)
Subject: JOIN US: Monday June 26th to promote #FactsNotFear on breastfeeding

Dear friends,

Back in April we kicked off a [coordinated effort](#) to set the record straight on breastfeeding in response to the disinformation campaign organized by the Fed Is Best Foundation. With your support, we took a stand for the truth and showed our collective strength as allies.

When we started that effort, we knew that it would be an ongoing one. Fed Is Best (FIB) continues to spread misinformation and lies about breastfeeding, and most reprehensibly is using fear as their primary tool to target families.

As such, 1,000 Days and I come to you today with a new opportunity to speak up and speak out on the importance of breastfeeding.

On Monday, June 26 - we will launch #FactsNotFear - a campaign to highlight that mothers and families deserve FACTS, not fear-mongering.

In this effort, we will avoid getting into a back and forth of scientific evidence of breastmilk, etc., and instead focus only on the tactic of using fear to make a point.

The mini-campaign will kick-off with a blog post and several social graphics (which we will send to you on before Monday).

Here's what you can do:

1. Read the attached blog and let me know if you have any questions
2. On Monday, June 26 - post the blog to your website and/or share on Facebook and Twitter
3. Use the social graphics provided to get the message out that moms and families deserve #FactsNotFear (we will provide suggested copy as well)

Please feel free to contact me with any questions. I look forward to our continued work together to ensure the facts about breastfeeding win-out over misinformation and divisiveness. Together we can!

All the best,
Kimberly

--

Kimberly Seals Allers
Journalist | Author | Speaker | Consultant
Director, First Food Friendly Community Initiative ([3FCI](#))
www.KimberlySealsAllers.com

C: (b)(6) M: (b)(6)
@iamKSealsAllers | @MochaManual

Facts Not Fear: Protecting the One Place Where Fear Does Not Belong.
By Kimberly Seals Allers

We live in a world of fear. From the recent terrorist attacks in England to last year's Orlando nightclub massacre. We have seen how the fear of outsiders has sparked powerful political movements around the world. As a frequent business traveler I sense my own anxiety as I sit on planes and trains, and as a mother I know the feeling that sweeps over me whenever I receive an incoming phone call from my children's school.

Yes, we live in times of fear and anxiety—much of which is beyond our control.

But there is one place where fear should not exist. There is one area, where, as women and mothers, that we should insist that fear not enter—that is in the precious act of feeding our babies. From the time they are first placed in our arms, we are anxious that we will do our best. Yes, we are nervous that we will make mistakes. But we should not be made to dread our ability to mother—particularly when it comes to feeding our infants—one of our very first tasks.

That's why a recent spate of fear-based marketing, particularly from the Fed Is Best Foundation, stoking fears that exclusive breastfeeding kills babies is both erroneous and irresponsible. But it is also the type of insidious marketing that preys on a mother's existing insecurities that should make all women concerned. If the only way Fed Is Best can make its point is by sensationalizing infant deaths and undermining our confidence in our bodies—then maybe their point needs to be carefully considered.

Or, as women, we insist that they make it with valid facts and sans the fear mongering.

Let's face it, women are sold fear and anxiety as a marketing tool every day. In fact, the strategy, officially known in business circles as FUD—fear, uncertainty and doubt—was designed by an IBM executive decades ago to persuade buyers to feel “safe” with IBM products rather than risk a crash, virus or server disruption. By the early 90's it was generalized to refer to any kind of misinformation used as a competitive weapon.

Today, weaponizing fear takes many forms. We fear our faces aren't pretty enough, so we buy cosmetics. We worry that our body isn't the right “type” so we are sold diet plans and surgical procedures. We are told our hair isn't shiny, bouncy or thick enough so we are sold multitudinous hair products. And then we are told to fear that our bodies may not properly do what they are biologically made to do, and we are sold infant formula.

The truth is, our bodies were uniquely made to feed the infants we create. Decades of scientific research proves that formula is nutritionally inferior to breastmilk. Admittedly, societal pressures, structural barriers such as a lack of paid maternity leave, and physicians who receive little to no training in lactation science in medical school, make it very difficult for some women to fulfill their biological norm. Many women who want to breastfeed find undereducated physicians and nurses and limited post-natal support—particularly in the early days after discharge. We have much to overcome.

To be clear, infant formula is necessary. When a mother's own breastmilk or human donor milk is not available, then infant formula is an important third option that can, at times, save lives. However, women should come to that decision fully informed, not because of marketing efforts

designed to incite distrust in their own bodies or threatened with the fear of the death of their infant.

It's no secret that, especially in the Western world, women already fear they will have insufficient milk. For some, this fear can become a self-fulfilling prophecy because fear and anxiety can literally limit lactation by stifling the letdown reflex that stimulates the milk glands. Feeding into this insecurity by promoting early formula supplementation "just in case" has been a go-to move by the formula industry for years.

As far back as the 1940s, the manufacturers of Borden KLIM evaporated milk ran a radio jingle in the Congo that stoked mother's fears over insufficient milk. The song went:

The Child is going to die
Because the mother's milk has given out
Mama o Mama the child cries
If you want your child to get well
Give it KLIM milk

So when Fed Is Best frequently promotes eerily similar headlines claiming, "One bottle would have saved my baby"—it seems to make early supplementation innocuous, while deploying a similar tactic used to spur sales of infant formula. The insidious message is that your breast cannot be trusted but a bottle can—this type of marketing should concern all women.

Instead of fear, we should demand the facts about why physicians and nurses don't have more education to properly identify lactation dysfunction or failure. We should demand knowledge about other options to increase milk output such as hand expression, which can extract more milk than a pump. If formula must be used, it should be administered as a temporary bridge until a mother's supply is established, not a breastfeeding killer for mothers who want to nurse. And we should demand standard home visitation immediately after discharge, as is the practice in the UK and other European countries.

Ultimately, women deserve facts not fear. Women have a right to guilt-free, confidence-building information and support. And it's time that we demand it of everyone—including, and especially, from those claiming to support mothers. We cannot stand by while Fed Is Best insists that fear is best.

From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 14 Nov 2017 13:33:37 +0000
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP); Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Subject: FW: Lessons to Learn from Fed is Best – Women's Health Today

I don't know if you get updates from Praeclarus Press, where this blog is housed. I think it is worth reading

Lessons to Learn from Fed is Best – Women's Health Today
<https://womenshealthtoday.blog/2017/11/04/lessons-to-learn-from-fed-is-best/>

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 25 May 2017 20:51:43 +0000
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP); Olson, Christine (CDC/ONDIEH/NCCDPHP)
Subject: FW: Letter response to Dr. Ruth Petersen.docx
Attachments: Letter response to Dr. Ruth Petersen.docx

From: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Sent: Tuesday, May 23, 2017 2:37 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Subject: Fwd: Letter response to Dr. Ruth Petersen.docx

From: Fed Is Best.org <christie@fedisbest.org>
Date: May 23, 2017 at 1:26:08 PM EDT
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>, Petersen, Ruth (CDC/ONDIEH/NCCDPHP) <rip0@cdc.gov>
Cc: Julie Tibbets (b)(6), Jody Segrave-Daly (b)(6)
Subject: Letter response to Dr. Ruth Petersen.docx

Dear Dr. Petersen,

Thank you so much for your response. Enclosed is a letter detailing the collaboration we would like to establish with the CDC with regard to developing guidelines for safe infant feeding and educating the public on the prevention of complications related to underfeeding.

Sincerely,

Christie del Castillo-Hegyí, M.D.
Co-Founder, Fed is Best Foundation

Jody Segrave-Daly, RN, IBCLC
Co-Founder, Fed is Best Foundation



May 18, 2017

VIA E-MAIL (rip0@cdc.gov)

Ruth Petersen, MD, MPH
Director
Division of Nutrition, Physical Activity and Obesity
National Center of Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

Dear Dr. Petersen,

Our Foundation is so appreciative of your response and your Center's commitment to supporting breastfeeding and newborn safety. The public health concerns of our Foundation's mission extend not only to the care of babies who are discharged but also to newborn babies in the hospital setting where inadequate monitoring for signs and symptoms of hunger begins and where public health education currently falls short. We agree that breastfeeding and the promotion and protection of infant safety are complementary public health objectives, but the literature linked below is just a sampling of what the current public health outcomes are for babies born in the United States under the protocols you reference from the Academy of Breastfeeding Medicine, the American Academy of Pediatrics, and also from the World Health Organization's Baby-Friendly Hospital Initiative guidelines (1991) that over 400 hospitals across the country administer:

- [Early Weight Loss Nomograms for Exclusively Breastfed Newborns](#)
- [Study of Asymptomatic Hypoglycemia in Full Term Exclusively Breastfed Neonates in First 48 Hours of Life](#)
- [Association Between Transient Newborn Hypoglycemia and Fourth-Grade Achievement Test Proficiency: A Population-Based Study](#)
- [Rehospitalization for neonatal dehydration: a nested case-control study](#)
- [Hypoglycemia is associated with increased risk for brain injury and adverse neurodevelopmental outcome in neonates at risk for encephalopathy](#)

I would sincerely appreciate the opportunity to discuss with you, either by video conference or phone, the gaps our Foundation has identified with the Baby-Friendly Hospital Initiative protocol as well as with the Academy of Breastfeeding Medicine and American Academy of Pediatrics breastfeeding guidelines and where your Center might consider research work or updates to [existing CDC breastfeeding public health information](#). As a breastfeeding complications and newborn brain injury investigator, I have been investigating the impacts of these policies on preventable complications and injuries to newborns that are associated with underfeeding.

Our Foundation's mission is to help bring about reform to current protocols, guidelines, and public health information based on the peer-reviewed literature and science of newborn brain injury. Current thresholds for supplementation take newborn babies past what is safe for newborn brain development and information about [the warning signs of hunger](#) is not included in current protocols or new parent materials. I recently discussed my concerns about the safety of current protocols in an episode of [the Doctor Show](#) where I appeared with Jillian Johnson, the brave mother of Landon Johnson who died of preventable hypernatremic dehydration 12 hours after discharge from a Baby-Friendly Initiative certified hospital. The [Washington Post](#) recently covered the Johnson's story.

As a leading national organization responsible for the protection of the public, the Foundation looks to your Centers for leadership on increasing public health education around newborn nutritional needs and monitoring for signs of hunger that lead to preventable medical complications and injuries associated with underfeeding. We also look to your Centers for leadership on outreach to the World Health Organization, the American Academy of Pediatrics, and the Academy of Breastfeeding Medicine on how their protocols and guidelines can be updated to close the public health education gap to make breastfeeding promotion safer for all newborns.

The national public health focus on achieving high rates of exclusive breastfeeding at discharge has inadvertently overtaken education around feeding needs and the medical conditions and dangers to which underfeeding too often leads. I believe it would be helpful to have experts in neonatology, newborn nutrition, starvation physiology, and neonatal brain injury convened to discuss the science of newborn brain development and research data and findings surrounding breastfeeding and jaundice, hypoglycemia, and dehydration. We seek a collaborative relationship with the CDC and look forward to continuing this dialogue with you. We are free to arrange a call or videoconference in the weeks ahead, so please let me know your availability.

We look forward to hearing from you and other experts who can provide thought leadership and increase public health education around promoting safe newborn and infant feeding.

Respectfully,

Christie del Castillo-Hegyí, M.D.
Co-Founder, the Fed is Best Foundation

cc: Janelle Gunn (bfy2@cdc.gov), Associate Director for Policy, Partnerships, and Communications, CDC

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 15 Aug 2017 20:54:11 -0400
To: Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP); Petersen, Ruth (CDC/ONDIEH/NCCDPHP)
Subject: FW: Letter to Fed Is Best
Attachments: 2017-08-15-Joint-Letter-to-FIB-Fndtn.pdf

Trying to resend because the attachment didn't seem to come through for some people.

From: Trish MacEnroe (b)(6)
Sent: Tuesday, August 15, 2017 1:12 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: Letter to Fed Is Best

Hi Cria,

I am assuming you have already seen the attached letter to FIB or at least have been told about it. It was emailed to FIB at noon today. All of us sent copies of it to our "membership". BFUSA sent a copy of it to all 4-D Pathway hospitals as well as to designated hospitals.

Or organizations have distribution plans as well. We are all gearing up for their response.

Trish MacEnroe
Executive Director
Baby-Friendly USA, Inc.
125 Wolf Rd., Suite 402
Albany, NY 12205

(b)(6) (p)
(f)

www.babyfriendlyusa.org

August 15, 2017

Dr. Christie del Castillo-Hegyí
Ms. B. Jody Segrave-Daly
Fed Is Best Foundation
PO Box 241736
Little Rock, AR 72223

Dear Dr. Castillo-Hegyí and Ms. Segrave-Daly:

We write to you as fellow advocates for the health and well-being of infants and their families. We believe that we share a common goal—to ensure that every baby gets the strongest start to life. It is in that spirit that we extend an invitation to you to discuss the concerns that you and your organization, the Fed Is Best Foundation, have raised with respect to our nation's infant feeding recommendations and associated health care practices.

We believe the ground we have in common is far greater than the areas where we may have disagreement. For the sake of all children, mothers and families, we therefore seek ways to unite in a shared vision rather than engaging in divisive messaging. For example, we all agree that the health of the baby is the ultimate goal, that infant feeding is a highly personal decision, that the mother should be fully informed of her options in making this decision, that nobody has the right to impose their beliefs or values on another, and that no infant, mother, or family should suffer as a result of ineffective support or care practices. We also agree that many physicians and other health care providers need improved training and education to ensure the competency to properly diagnose and address infant feeding issues, and that improved continuity of care is needed to enable new mothers to access timely, integrated, and continuous care throughout the prenatal and postpartum periods.

That's a lot of common ground to build on.

Where we seem to disagree is on the root cause behind the tragic stories that Fed Is Best has recently highlighted. That is where we would hope to engage in some honest and constructive dialogue to find shared messaging focused on providing the accurate and unbiased information families need to make their personal infant feeding decisions, along with the appropriate care and support they need to implement those decisions.

We believe that we can be most effective in serving moms and babies when we attack the root causes of problems, rather than each other. For this reason, we invite you to meet with us to talk about your concerns and discuss ways we can work together to ensure that no family has to endure the pain and heartbreak of a baby who doesn't get the nutrition they need to thrive. We hope that you will take us up on our offer and look forward to receiving your response.

Sincerely,

1,000 Days

Academy of Breastfeeding Medicine
Alabama Breastfeeding Committee
American Association of Birth Centers
American Breastfeeding Institute
American Samoa Breast Feeding Coalition
Arkansas Breastfeeding Coalition, Inc.
Baby Cafe USA
Baby-Friendly USA, Inc.
Best for Babes Foundation
Breastfeeding Task Force of Nevada
California Breastfeeding Coalition
California WIC Association
Childbirth and Postpartum Professional Association
Eastern Kentucky Breastfeeding Coalition
Georgia Breastfeeding Coalition
Healthy Children Project, Inc.
Indiana Breastfeeding Coalition
International Board of Lactation Consultant Examiners
International Childbirth Education Association
Kansas Breastfeeding Coalition, Inc.
La Leche League USA
Louisiana Breastfeeding Coalition
Macomb County Breastfeeding Coalition
Massachusetts Breastfeeding Coalition
Michigan Breastfeeding Network
The Milk Mob
Mom2Mom Global
MomsRising
Mothers' Milk Bank
Mothers' Milk Bank Northeast
National Alliance for Breastfeeding Advocacy
National WIC Association
Nebraska Breastfeeding Coalition
New Hampshire Breastfeeding Task Force
New Mexico Breastfeeding Task Force
New York Statewide Breastfeeding Coalition, Inc.
NYC Breastfeeding Leadership Council, Inc.
Ohio Breastfeeding Alliance
Reaching Our Sisters Everywhere, Inc.
Rhode Island Breastfeeding Coalition
Texas Breastfeeding Coalition
United States Lactation Consultant Association
Vermont Breastfeeding Network

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 26 Jun 2017 14:18:00 +0000
To: (b)(6)
Subject: FW: Meeting Confirmation: Safe Sleep, Skin-to-Skin Care, and Breastfeeding - AAP Clinical Report

From: Ngozi Onyema-Melton (b)(6)
Sent: Monday, June 26, 2017 10:17 AM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>
Subject: Meeting Confirmation: Safe Sleep, Skin-to-Skin Care, and Breastfeeding - AAP Clinical Report

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



Safe Sleep, Skin-to-Skin Care, and Breastfeeding - AAP Clinical Report

Dear Daurice Grossniklaus,

Your registration for this meeting has been confirmed. All of the information you need to join the meeting is below.

Login

[Join Meeting](#)

(b)(6)

Streaming audio available through your computer.

Or you can call in to listen to the audio via your phone



U.S. & Canada: (b)(6)

U.S. Toll: (b)(6)

[List of global toll-free numbers](#)



Access Code: (b)(6)

Meeting Description:

Details

Date: Mon, Jun 26, 2017
Time: 02:00 PM EDT
Duration: 1 hour
Host(s): Ngozi Onyema-Melton
Share: [f](#) [in](#) [t](#)

Add to your Calendar



[Outlook Calendar](#)



[Lotus Notes Calendar](#)



[Google Calendar](#)

Test Your Computer

[Test your computer](#) for compatibility prior to the meeting.

Presenter Information

Lori Feldman-Winter, MD, MPH, FAAP

Skin-to-skin care (SSC) and rooming-in have become common practice in the newborn period for healthy newborns with the implementation of maternity care practices that support breastfeeding as delineated in the World Health Organization's "Ten Steps to Successful Breastfeeding." In this webinar, Dr Feldman-Winter, discusses components of the AAP clinical report, [Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns](#), SIDS prevention and breastfeeding promotion. Ms MacEnroe will discuss the Safety Audit Tool developed by Baby-Friendly, USA.

Participants will be able to:

1. Delineate components of the AAP Clinical Report: Safe Sleep and Skin-to-Skin Care in the Neonatal Period for the Healthy Newborn *and* the SIDS and other Sleep Related Deaths Policy and Technical Report.
2. Identify issues from each statement that affect the breastfeeding dyad.
3. Define and adopt practices that support simultaneous implementation of the Ten Steps to Successful Breastfeeding and safe sleep guidelines.



Professor of Pediatrics at Cooper Medical School of Rowan University

AAP Task Force on Sudden Infant Death Syndrome

Trish MacEnroe, CDN, CLC



Executive Director
Baby-Friendly, USA

For technical support:
Email: help@readytalk.com Web: [Conferencing Support](#)

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From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 26 Jun 2017 18:35:55 +0000
To: Olson, Christine (CDC/ONDIEH/NCCDPHP)
Subject: FW: Meeting Confirmation: Safe Sleep, Skin-to-Skin Care, and Breastfeeding - AAP Clinical Report

Hey- Not sure if you were aware of this (sorry, if not). It's being recorded. You should def. listen.
Jennifer

From: Ngozi Onyema-Melton (b)(6)
Sent: Monday, June 26, 2017 11:59 AM
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>
Subject: Meeting Confirmation: Safe Sleep, Skin-to-Skin Care, and Breastfeeding - AAP Clinical Report

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



Safe Sleep, Skin-to-Skin Care, and Breastfeeding - AAP Clinical Report

Dear Jennifer Nelson,

Your registration for this meeting has been confirmed. All of the information you need to join the meeting is below.

Login

[Join Meeting](#)

(b)(6)

Streaming audio available through your computer.

Or you can call in to listen to the audio via your phone



U.S. & Canada: (b)(6)

U.S. Toll: (b)(6)

[List of global toll-free numbers](#)

Details

Date: Mon, Jun 26, 2017

Time: 02:00 PM EDT

Duration: 1 hour

Host(s): Ngozi Onyema-Melton

Share: [f](#) [in](#) [t](#)

Add to your Calendar



[Outlook Calendar](#)



[Lotus Notes Calendar](#)



[Google Calendar](#)

Test Your Computer

[Test your computer](#) for compatibility prior to the meeting.

Presenter Information

Lori Feldman-Winter, MD, MPH,
FAAP



Access Code: (b)(6)

Meeting Description:

Skin-to-skin care (SSC) and rooming-in have become common practice in the newborn period for healthy newborns with the implementation of maternity care practices that support breastfeeding as delineated in the World Health Organization's "Ten Steps to Successful Breastfeeding." In this webinar, Dr Feldman-Winter, discusses components of the AAP clinical report, [*Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns*](#), SIDS prevention and breastfeeding promotion. Ms MacEnroe will discuss the Safety Audit Tool developed by Baby-Friendly, USA.

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2. Identify issues from each statement that affect the breastfeeding dyad.
3. Define and adopt practices that support simultaneous implementation of the Ten Steps to Successful Breastfeeding and safe sleep guidelines.



Professor of Pediatrics at
Cooper Medical School of
Rowan University
AAP Task Force on Sudden
Infant Death Syndrome

Trish MacEnroe, CDN, CLC



Executive Director
Baby-Friendly, USA

For technical support:

Email: help@readytalk.com Web: [Conferencing Support](#)

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From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 11 May 2017 14:02:07 -0400
To: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Subject: FW: Meeting Request from Fed is Best Foundation
Attachments: 37151871_1.pdf, ATT00001.htm

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Friday, April 28, 2017 3:46 PM
To: Calixto Rafael Flores-Ayala, (CDC/ONDIEH/NCCDPHP) <rnf2@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Cc: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>; Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfi2@cdc.gov>
Subject: FW: Meeting Request from Fed is Best Foundation

This is the original letter to which I just forwarded AAP and March of Dimes thoughts. Janelle and I talked; I want to review the literature mentioned and possibly discuss with some AAP colleagues before we decide on how to respond.

Chloe has pulled all of the papers cited, and they are saved here:
\\cdc.gov\project\CCHP_NCCD_DNPAO\4_NB\Infant_Feeding_Team\Literature_reviews\Fed is Best

From: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Sent: Friday, April 28, 2017 2:03 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: FW: Meeting Request from Fed is Best Foundation

Will touch base with you later...

From: Johnson, Abigail P. (CDC/ONDIEH/NCCDPHP)
Sent: Friday, April 28, 2017 12:20 PM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfi2@cdc.gov>
Cc: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>; DNPAO/Health Policy Team (CDC) <DNPAOPolicy@cdc.gov>; Merkle, Sarah (CDC/ONDIEH/NCCDPHP) <zrp0@cdc.gov>
Subject: FW: Meeting Request from Fed is Best Foundation

Hi Janelle,

Please see the attached meeting request from a pro bono law firm representing the Fed is Best Foundation. The Foundation would like to meet with CDC to discuss exclusive breastfeeding and potential newborn complications from underfeeding. The request was initially sent to Injury and Birth Defects, but the concerns raised align more closely with DNPAO's activities.

The Foundation is proposing a meeting to discuss:

(1) What research projects, if any, does CDC have underway to monitor injuries that result

from inadequate feeding in newborns?

(2) What available grant programs does CDC have that may provide funding for such research?

(3) What updates, if any, does CDC have planned to its website on Breastfeeding Guidelines and Recommendations?

(4) What plans does the CDC have to educate new parents on the prevention of injuries associated with insufficient breast milk intake?

(5) What authorities is CDC lacking, if any, to be able to proactively conduct data collection and surveillance on newborn injuries and medical complications associated with inadequate feeding after birth?

They have also reached out to a number of agencies and organizations to discuss this topic including NICHD, AAP, March of Dimes, ACOG and WHO.

Please let me know if Ruth is interested in scheduling a meeting or teleconference. Happy to discuss if you have any questions.

Thanks,
Abbey

From: Walker, Misha (Nikki) (CDC/ONDIEH/NCBDDD)
Sent: Thursday, April 27, 2017 3:35 PM
To: Sayer, Janna (CDC/OD/OCS) <krn3@cdc.gov>
Cc: Chaney, Sascha (CDC/ONDIEH/NCBDDD) <zpo7@cdc.gov>
Subject: FW: Meeting Request
Importance: High

Hi Janna –

We are hoping we can route this to you/IMAC for follow-up with Julie (below) and Chronic. We haven't heard back from Chronic as of yet and want to make sure CDC is responsive to the requestor. This topic is not something either of our Centers (Birth Defects or Injury) are involved in but Chronic has an infant nutrition program through DNPAO that has a focus on breastfeeding.

Let me know if IMAC can facilitate.

Thanks!

nikki

From: Boyle, Coleen (CDC/ONDIEH/NCBDDD)
Sent: Tuesday, April 25, 2017 5:49 AM
To: Bauer, Ursula (CDC/ONDIEH/NCCDPHP) <iws8@cdc.gov>; Shelton, Dana (CDC/ONDIEH/NCCDPHP) <dzs8@cdc.gov>
Cc: Dulin, Stephanie M. (CDC/ONDIEH/NCBDDD) <smd3@cdc.gov>; Houry, Debra E.

(CDC/ONDIEH/NCIPC) <vjz7@cdc.gov>

Subject: Fwd: Meeting Request

Hi Ursula and Dana: This request seems more appropriate for your infant nutrition/breastfeeding group than our Centers. Ok to have the f/u come from them? Thx Coleen

Sent from my iPad

Begin forwarded message:

From: "Tibbets, Julie" (b)(6)

Date: April 24, 2017 at 5:31:27 PM EDT

To: "'vjz7@cdc.gov'" <vjz7@cdc.gov>, "Boyle, Coleen (CDC/ONDIEH/NCBDDD) (cab3@cdc.gov)" <cab3@cdc.gov>, "'vjz7@cdc.gov'" <vjz7@cdc.gov>, "Boyle, Coleen (CDC/ONDIEH/NCBDDD) (cab3@cdc.gov)" <cab3@cdc.gov>

Cc: 'Fed Is Best.org' <christie@fedisbest.org>, 'Fed Is Best.org' <christie@fedisbest.org>, "B. Jody Segrave-Daly" (b)(6)

Subject: Meeting Request

Dear Drs. Boyle and Houry,

I am representing the Fed Is Best Foundation in its public health education and awareness mission regarding the preventable public health risks that result from jaundice, hypoglycemia, and dehydration in newborns on account of underfeeding in the early hours and days of life. We have provided an overview of some of the key literature in the attached and note the work that both of your Centers have done in the past regarding injury and disease prevention in similar areas. We hope to begin a dialogue with your Centers about the work you are doing related to breastfeeding and newborn nutritional needs for the prevention of brain injuries and other medical complications.

A few years ago, our law firm was proud to work with a coalition of the American Academy of Pediatrics, March of Dimes, Spina Bifida Association, and Gruma Corporation (a large producer of Hispanic foods) to utilize CDC's research work on folic acid intake to petition FDA to amend its food additive regulations to permit folic acid addition to corn masa flour to help lower the incidence of spina bifida and neural tube defects in Hispanic newborns. We are again working to build a public health coalition with outreach to the American Academy of Pediatrics, March of Dimes, and others for the important public health education mission the Foundation has established to raise awareness and reduce the staggering incidence of *preventable* infant injuries associated with inadequate milk or formula intake. In the tens of thousands of stories the Foundation has received since its founding, too often we hear from new parents that if they "had only known" that more milk or formula would have prevented life-long injuries and cognitive delays their children now face, that they would have acted differently.

We look forward to talking with your Centers about how your current or future projects and research work can help further public health education and awareness and result in meaningful change for infants and parents.

Please let us know your availability in the near-term to schedule a meeting or teleconference with the Co-Founders of the Foundation and me.

Sincerely,

Julie K. Tibbets
Partner, Alston & Bird LLP
950 F Street, NW
Washington, DC 20004

(b)(6)

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ALSTON & BIRD

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Fax: 202-654-4944
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Julie K. Tibbets

Direct Dial: 202-239-3444

Email: (b)(6)

April 24, 2017

VIA E-MAIL (Original by USPS)

Coleen Boyle, PhD, MSHyg
Director, National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

Debra Houry, MD, MPH
Director, National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

Re: Prevention of Newborn Brain Injuries and Medical Complications
Associated with Underfeeding

Dear Drs. Boyle and Houry:

I am writing on behalf of my client, the Fed is Best Foundation, to request a teleconference or in-person meeting with your Centers to discuss the work your Centers are doing on disability and injury prevention relative to the Foundation's mission of raising public health education and awareness to preventable newborn injuries due to underfeeding in the early days of life. The most recent data shows alarming trends in infant feeding, namely a rise in re-hospitalizations for feeding complications in exclusively breastfed newborns who do not receive enough breast milk in their first days of life, including increasing rates of jaundice, hypoglycemia, and dehydration, which can threaten a newborn's brain and lead to other preventable medical complications and health care costs. While mothers and health professionals are taught that it is rare to have insufficient breast milk, inadequate breast milk production affects at least 1 in 5 women in the first days of an infant's life. Without enough milk, infants can starve in those first days, and starvation can cause brain injury leading to preventable cognitive and developmental delays and an increased risk of seizure disorders. While the Academy of Breastfeeding Medicine highlights "starvation jaundice" in its newborn breastfeeding protocol, there is currently a dangerous lack of public health education and awareness amongst new parents and health care professionals alike as to the warning signs of hunger in a newborn that are risk factors for preventable brain injury and medical complications. We would like to understand the research and surveillance work your Centers are doing in this regard and discuss potential updates to the Centers' Guidelines and Recommendations on breastfeeding.

The data reported in the peer-reviewed medical literature and the Academy of Breastfeeding Medicine's protocol are clear:

- 10% of vaginally-delivered and 25% of cesarean-delivered exclusively breastfed (EBF) babies [lose excessive weight in the first days of life](#).^[i]
- 10-18% of babies experience "starvation jaundice" [from insufficient milk intake](#), according to the [Academy of Breastfeeding Medicine jaundice protocol](#), a fact to which no breastfeeding or new parent educational manual alert new parents.^[ii]
- 10% of EBF babies undergoing current breastfeeding protocols experience levels of hypoglycemia (low blood sugar), [which can be associated with developmental complications](#).^[iii]
- 10% of well-monitored exclusively breastfed babies undergoing the World Health Organization's Baby-Friendly Hospital Initiative protocol [develop hypoglycemia of less than 40 mg/dL within the first 48 hours](#). This incidence is reported as 23% in babies born to first-time mothers.^[iv]
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- A [glucose of less than 46 mg/dL](#) within the first 24 hours of life has been associated with a 3.7-fold increased risk of brain injury on MRI and a 4.8-fold increased odds of lower motor, cognitive and language scores at 1 year of age.^[vi]
- Cognitive impairment can have life-long effects as evidenced by a [study of 1395 newborns](#) showing that newborns who develop transient hypoglycemia of less than 40 mg/dL had a 50% reduction in passing their fourth-grade proficiency test in literacy and math. Even a glucose less than 45 mg/dL resulted in a 38% reduction in passing the literacy test.^[vii]
- The current standard of care [tolerates a glucose between 40 and 45 mg/dL](#) within the first 4 hours of life when there is no evidence that neurons have greater tolerance for hypoglycemia in the first hours than they do at any other time.^[viii]
- Exclusive breastfeeding at discharge has been associated with an [11-fold higher risk of rehospitalization](#) for underfeeding and dehydration.^[ix]

Based on these data and *tens of thousands of stories* the Foundation has received from parents all across the country since it was founded, these data are significant when you consider that more and more babies today are exclusively breastfed at birth due to the proven health benefits of breastfeeding. With around 4 million births per year and the trend of exclusive breastfeeding on the rise, the number of newborns suffering from jaundice, hypoglycemia, dehydration and the medical complications that can follow is staggering. This is particularly the case when I recall the work I did with Gruma Corporation, the American Academy of Pediatrics, and the March of Dimes a few years ago in reliance on CDC research and modeling data for folic acid consumption with the fortification of corn masa flour. The incidence of spina bifida (~1,500 births per year) today is a tiny fraction of the number of infants who suffer preventable medical complications, including brain injuries or worse, by a lack of monitoring by health care professionals and awareness by new parents of the signs of newborn hunger and the serious health risks hunger can pose in the first days of life.

The Foundation is developing public health education and awareness materials such as its “HUNGRY” flyer which advises new parents of the signs of hunger to monitor their babies for in order to avoid preventable brain injuries or medical complications:



Recent data trends show a concerning rise in hospitalizations of exclusively breastfed newborns. This is due to feeding complications from insufficient breast milk intake, including jaundice, hypoglycemia, and dehydration- which can threaten a newborn's brain.

Know the signs to look for when your newborn baby is HUNGRY, in the first days of life and watch your baby for:

- H** Hypoglycemia (low blood sugar) jittery hands, low body temperature, inconsolable and high-pitched crying, turning blue and seizures
- U** Unsatisfied nursing, lasting longer than 30 minutes and occurring more frequently than every 2 hours, crying despite continuous breastfeeding
- N** Not waking for feeding every 3 hours, difficult to arouse and very sleepy while attempting to breastfeed, limpness, lethargy
- G** Growth or weight loss exceeding 4% in the first 24 hours and 7% at any time, which increases risk of hospitalization for jaundice
- R** Reduced wet and dirty diaper counts (no wet diapers in 6 hours), and/or red brick dust on diapers
- Y** Yellowing of the skin or eyes, known as jaundice

If you see the signs that your baby is HUNGRY, seek medical assistance from your pediatrician immediately and supplement your baby. Don't wait until it's too late.

For more resources about how to safely breastfeed your newborn baby, click on parent resources at: <https://fedisbest.org/resources-for-parents/feeding-plan/>

The Fed is Best Foundation is a registered 501(c)(3) tax-exempt non-profit organization believes that babies should never go hungry and mothers should be supported in choosing clinically safe feeding options for their babies, whether breast milk, formula, or a combination of both.

The Foundation is volunteer-led by health care professionals who are dedicating their spare time to spreading the word to new parents and other health care professionals about these preventable dangers and the risk factors for which parents and health care professionals can monitor. The Foundation does not accept any donations from those with a commercial interest in the breastfeeding or formula industries and Alston & Bird LLP's representation of the Foundation is pro bono. At this time, the Foundation does not have the reach that the CDC, professional associations, and major health foundations have to ensure public education awareness around the signs of newborn hunger, the dangers for which to monitor, and the importance of ensuring adequate nutrition to avoid preventable injuries and medical complications. As such, the Foundation is reaching out to CDC and separately to the National Institute of Child Health and Human Development, the American Academy of Pediatrics, the March of Dimes, the American College of Obstetricians and Gynecologists, the American College of Nurse Midwives, the Gates Foundation, and the World Health Organization, whose Baby-Friendly Hospital Initiative

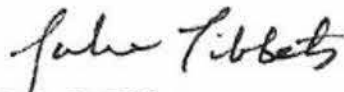
guidelines on breastfeeding have not been updated since 1991 despite a wealth of peer-reviewed data that has been published since that time.

We would like to discuss the following with the CDC:

- (1) What research projects, if any, does CDC have underway to monitor injuries that result from inadequate feeding in newborns?
- (2) What available grant programs does CDC have that may provide funding for such research?
- (3) What updates, if any, does CDC have planned to its website on Breastfeeding Guidelines and Recommendations?
- (4) What plans does the CDC have to educate new parents on the prevention of injuries associated with insufficient breast milk intake?
- (5) What authorities is CDC lacking, if any, to be able to proactively conduct data collection and surveillance on newborn injuries and medical complications associated with inadequate feeding after birth?

We look forward to partnering with your Centers to ensure responsible public health education reaches new parents and health care professionals so that infants in the U.S. avoid preventable injuries and medical complications associated with inadequate feeding after birth. Our team is generally available the week of May 1, 2017 to schedule a call with your teams and can provide a briefing package ahead of that meeting. I look forward to learning more about the research projects, guideline development, and educational activities your Centers may have underway.

Sincerely,



Julie K. Tibbets
Partner

cc: Christie del Castillo-Hegyi, M.D., Board Certified Emergency Physician, Newborn Brain Injury and Breastfeeding Complications Researcher, Co-Founder, Fed is Best Foundation

B. Jody Segrave-Daly, Registered Nurse, International Board Certified Lactation Consultant (IBCLC), Newborn Nursery and Newborn Intensive Care Unit Nurse, Co-Founder, Fed is Best Foundation

[i] Valerie J. Flaherman, MD, MPH, et al., Early Weight Loss Nomograms for Exclusively Breastfed Newborns, *Pediatrics*, 2015 Jan; 135(1): e16–e23. [ii] ABM Clinical Protocol #22: Guidelines for Management of Jaundice in the Breastfeeding Infant Equal to or Greater Than 35 Weeks' Gestation, The Academy of Breastfeeding Medicine Protocol Committee, *Breastfeeding Medicine*, Vol. 5(2):87-93. [iii] Purnima Samayam, et al., Study of Asymptomatic Hypoglycemia in Full Term Exclusively Breastfed Neonates in First 48 Hours of Life, *J Clin Diagn Res*. 2015 Sep; 9(9): SC07–SC10. [iv] *Id.* [v] Dewey KG, et al., Risk factors for suboptimal infant breastfeeding behavior, delayed onset of lactation, and excess neonatal weight loss, *Pediatrics*, 2003 Sep;112(3 Pt 1):607-19. vi] Emily W.Y. Tam et al., Hypoglycemia is associated with increased risk for brain injury and adverse neurodevelopmental outcome in neonates at risk for encephalopathy, *J Pediatr.*, 2012 Jul; 161(1): 88–93. [vii] Jeffrey R. Kaiser, MD, MA et al., Newborn Hypoglycemia and Fourth-Grade Achievement Test Proficiency: A Population-Based Study, *JAMA Pediatr.*, 2015;169(10):913-921. [viii] Postnatal Glucose Homeostasis in Late-Preterm and Term Infants, Committee on Fetus and Newborn, *Pediatrics*, 2011;127:575–579. [ix] Escobar GJ, et al., Rehospitalization for neonatal dehydration: a nested case-control study, *Arch Pediatr Adolesc Med.*, 2002 Feb;156(2):155-61.

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Fri, 28 Apr 2017 19:38:45 +0000
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Subject: FW: Meeting Request from Fed is Best Foundation
Attachments: 37151871_1.pdf, ATT00001.htm

Here is the original letter. Chloe pulled the papers cited and saved in a folder under Literature Reviews in our Team Folder. Not urgent, but I would like to make sure we've reviewed.

From: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Sent: Friday, April 28, 2017 2:03 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: FW: Meeting Request from Fed is Best Foundation

Will touch base with you later...

From: Johnson, Abigail P. (CDC/ONDIEH/NCCDPHP)
Sent: Friday, April 28, 2017 12:20 PM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>
Cc: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>; DNPAO/Health Policy Team (CDC) <DNPAOPolicy@cdc.gov>; Merkle, Sarah (CDC/ONDIEH/NCCDPHP) <zrp0@cdc.gov>
Subject: FW: Meeting Request from Fed is Best Foundation

Hi Janelle,

Please see the attached meeting request from a pro bono law firm representing the Fed is Best Foundation. The Foundation would like to meet with CDC to discuss exclusive breastfeeding and potential newborn complications from underfeeding. The request was initially sent to Injury and Birth Defects, but the concerns raised align more closely with DNPAO's activities.

The Foundation is proposing a meeting to discuss:

- (1) What research projects, if any, does CDC have underway to monitor injuries that result from inadequate feeding in newborns?
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They have also reached out to a number of agencies and organizations to discuss this topic including NICHD, AAP, March of Dimes, ACOG and WHO.

Please let me know if Ruth is interested in scheduling a meeting or teleconference. Happy to discuss if you have any questions.

Thanks,
Abbey

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Sent: Thursday, April 27, 2017 3:35 PM
To: Sayer, Janna (CDC/OD/OCS) <knn3@cdc.gov>
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Date: April 24, 2017 at 5:31:27 PM EDT
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<cab3@cdc.gov>, ""vjz7@cdc.gov"" <vjz7@cdc.gov>, "Boyle, Coleen (CDC/ONDIEH/NCBDDD)
(cab3@cdc.gov)" <cab3@cdc.gov>

Cc: 'Fed Is Best.org' <christie@fedisbest.org>, 'Fed Is Best.org' <christie@fedisbest.org>, "B. Jody
Segrave-Daly" [REDACTED] (b)(6)

Subject: Meeting Request

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Julie K. Tibbets
Partner, Alston & Bird LLP
950 F Street, NW
Washington, DC 20004

[REDACTED] (b)(6)

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202-239-3300
Fax: 202-654-4944
www.alston.com

Julie K. Tibbets

Direct Dial: 202-239-3444

Email: (b)(6)

April 24, 2017

VIA E-MAIL (Original by USPS)

Coleen Boyle, PhD, MSHyg
Director, National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

Debra Houry, MD, MPH
Director, National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
1600 Clifton Road
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Re: Prevention of Newborn Brain Injuries and Medical Complications
Associated with Underfeeding

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- Cognitive impairment can have life-long effects as evidenced by a [study of 1395 newborns](#) showing that newborns who develop transient hypoglycemia of less than 40 mg/dL had a 50% reduction in passing their fourth-grade proficiency test in literacy and math. Even a glucose less than 45 mg/dL resulted in a 38% reduction in passing the literacy test.^[vii]
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Based on these data and *tens of thousands of stories* the Foundation has received from parents all across the country since it was founded, these data are significant when you consider that more and more babies today are exclusively breastfed at birth due to the proven health benefits of breastfeeding. With around 4 million births per year and the trend of exclusive breastfeeding on the rise, the number of newborns suffering from jaundice, hypoglycemia, dehydration and the medical complications that can follow is staggering. This is particularly the case when I recall the work I did with Gruma Corporation, the American Academy of Pediatrics, and the March of Dimes a few years ago in reliance on CDC research and modeling data for folic acid consumption with the fortification of corn masa flour. The incidence of spina bifida (~1,500 births per year) today is a tiny fraction of the number of infants who suffer preventable medical complications, including brain injuries or worse, by a lack of monitoring by health care professionals and awareness by new parents of the signs of newborn hunger and the serious health risks hunger can pose in the first days of life.

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- G** Growth or weight loss exceeding 4% in the first 24 hours and 7% at any time, which increases risk of hospitalization for jaundice
- R** Reduced wet and dirty diaper counts (no wet diapers in 6 hours), and/or red brick dust on diapers
- Y** Yellowing of the skin or eyes, known as jaundice

If you see the signs that your baby is HUNGRY, seek medical assistance from your pediatrician immediately and supplement your baby. Don't wait until it's too late.

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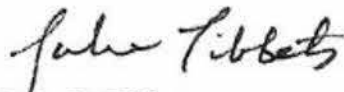
guidelines on breastfeeding have not been updated since 1991 despite a wealth of peer-reviewed data that has been published since that time.

We would like to discuss the following with the CDC:

- (1) What research projects, if any, does CDC have underway to monitor injuries that result from inadequate feeding in newborns?
- (2) What available grant programs does CDC have that may provide funding for such research?
- (3) What updates, if any, does CDC have planned to its website on Breastfeeding Guidelines and Recommendations?
- (4) What plans does the CDC have to educate new parents on the prevention of injuries associated with insufficient breast milk intake?
- (5) What authorities is CDC lacking, if any, to be able to proactively conduct data collection and surveillance on newborn injuries and medical complications associated with inadequate feeding after birth?

We look forward to partnering with your Centers to ensure responsible public health education reaches new parents and health care professionals so that infants in the U.S. avoid preventable injuries and medical complications associated with inadequate feeding after birth. Our team is generally available the week of May 1, 2017 to schedule a call with your teams and can provide a briefing package ahead of that meeting. I look forward to learning more about the research projects, guideline development, and educational activities your Centers may have underway.

Sincerely,



Julie K. Tibbets
Partner

cc: Christie del Castillo-Hegyi, M.D., Board Certified Emergency Physician, Newborn Brain Injury and Breastfeeding Complications Researcher, Co-Founder, Fed is Best Foundation

B. Jody Segrave-Daly, Registered Nurse, International Board Certified Lactation Consultant (IBCLC), Newborn Nursery and Newborn Intensive Care Unit Nurse, Co-Founder, Fed is Best Foundation

[i] Valerie J. Flaherman, MD, MPH, et al., Early Weight Loss Nomograms for Exclusively Breastfed Newborns, *Pediatrics*, 2015 Jan; 135(1): e16–e23. [ii] ABM Clinical Protocol #22: Guidelines for Management of Jaundice in the Breastfeeding Infant Equal to or Greater Than 35 Weeks' Gestation, The Academy of Breastfeeding Medicine Protocol Committee, *Breastfeeding Medicine*, Vol. 5(2):87-93. [iii] Purnima Samayam, et al., Study of Asymptomatic Hypoglycemia in Full Term Exclusively Breastfed Neonates in First 48 Hours of Life, *J Clin Diagn Res*. 2015 Sep; 9(9): SC07–SC10. [iv] *Id.* [v] Dewey KG, et al., Risk factors for suboptimal infant breastfeeding behavior, delayed onset of lactation, and excess neonatal weight loss, *Pediatrics*, 2003 Sep; 112(3 Pt 1):607-19. vi] Emily W.Y. Tam et al., Hypoglycemia is associated with increased risk for brain injury and adverse neurodevelopmental outcome in neonates at risk for encephalopathy, *J Pediatr.*, 2012 Jul; 161(1): 88–93. [vii] Jeffrey R. Kaiser, MD, MA et al., Newborn Hypoglycemia and Fourth-Grade Achievement Test Proficiency: A Population-Based Study, *JAMA Pediatr.*, 2015;169(10):913-921. [viii] Postnatal Glucose Homeostasis in Late-Preterm and Term Infants, Committee on Fetus and Newborn, *Pediatrics*, 2011;127:575–579. [ix] Escobar GJ, et al., Rehospitalization for neonatal dehydration: a nested case-control study, *Arch Pediatr Adolesc Med.*, 2002 Feb;156(2):155-61.

From: Borda, Ashley (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Wed, 7 Sep 2016 12:44:43 -0400
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO); Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO)
Cc: Betts, Kristen (CDC/ONDIEH/NCCDPHP)
Subject: FW: MI-Normal-Healthline-Baby-Friendly Hospital Initiative - JAMA Viewpoint interview questions/answers
Attachments: Implementation of the Ten Steps to Successful Breastfeeding Saves Lives.pdf, Unintended Consequences of Current Breastfeeding Initiatives.pdf, QA_BFHI safety responses.docx
Importance: High

Hi Cria and Jennifer,

Can you let me know when you are back in the office? I am going to run and grab lunch real quick but am coming right back!

There is a bit of confusion in SCT regarding where these responses came from. We are wondering if:

- a. Did anyone from OADC reach out to you directly for these responses?
- b. Are they accurate?
- c. Can we attempt to put them through clearance, as the reporter's deadline is today. (Not likely going to happen but want to try since this original e-mailed confused me last week (re: who wrote these answers) AND I did not see his deadline until today ☹)

Ashley

From: Blankenship, Anita (CDC/ONDIEH/NCCDPHP)
Sent: Friday, September 02, 2016 5:16 PM
To: Curtis, A Brittany (CDC/ONDIEH/NCCDPHP) <gnk2@cdc.gov>; Bryant, Pamela (CDC/ONDIEH/NCCDPHP) <hei0@cdc.gov>; Betts, Kristen (CDC/ONDIEH/NCCDPHP) <dei0@cdc.gov>; Borda, Ashley (CDC/ONDIEH/NCCDPHP) (CTR) <WRG5@cdc.gov>
Subject: RE: MI-Normal-Healthline-Baby-Friendly Hospital Initiative - JAMA Viewpoint interview questions/answers

Hi all

Kristen and Ashley are aware of this study and worked with the breastfeeding SME's for talking points in case any questions came up during BF report card interviews. The responses to the reporter's questions will need to go through OADC for clearance.

- When did Sudden Unexpected Postnatal Collapse (SUPC) first become apparent among medical centers that have adopted the Ten Steps to Successful Breastfeeding?
- Has the CDC and the Federal government been keeping statistics on SUPC and the Baby Friendly Hospital Initiative, since the Initiative was developed in the 1990s?
- Can you give me the most important statistics?
- Does CDC work with HHS on these kinds of medical problems? How?

- In the JAMA Pediatrics Viewpoint article, the authors wrote that "it is important to be certain that the basis for the recommendations has been documented in reproducible scientific studies and that the benefits of the practices recommended outweigh the risks."
--Were the Ten Steps arrived at in that scientific manner? --

Attached are the talking points.

Best,

Anita

From: Buckner, Amesheia (CDC/OD/OADC)
Sent: Friday, September 02, 2016 4:52 PM
To: Curtis, A Brittany (CDC/ONDIEH/NCCDPHP) <gnk2@cdc.gov>; Bryant, Pamela (CDC/ONDIEH/NCCDPHP) <hei0@cdc.gov>
Cc: Blankenship, Anita (CDC/ONDIEH/NCCDPHP) <aob4@cdc.gov>
Subject: FW: MI-Normal-Healthline-Baby-Friendly Hospital Initiative

Please see the below of for next week.

Amesheia Buckner, MBA | Health Communication Specialist
CDC News Media Branch
Office: 404-639-3150 | Email: ynp5@cdc.gov

From: Iverson, Dontae (CDC/OD/OADC) (CTR)
Sent: Friday, September 02, 2016 4:44 PM
To: Buckner, Amesheia (CDC/OD/OADC) <ynp5@cdc.gov>
Subject: MI-Normal-Healthline-Baby-Friendly Hospital Initiative

Reporter's Name: Patrick Keefe

Media Outlet: Healthline

Status: New

Deadline: 09/07/2016 12:00PM

Phone: (b)(6)

Cell: (b)(6)

E-Mail: (b)(6)

Note:

Questions for CDC: I am a contributing writer for the well-regarded health-and-medical website Healthline, based in San Francisco, and am working on an article based on the August 22 JAMA

Pediatrics Viewpoint article by Dr. Joel Bass of the Newton-Wellesley Hospital, titled "The Unintended Consequences of Current Breastfeeding Initiatives." I have a list of questions below that I would like to have answered by a physician or other expert at CDC. May I ask your help? My deadline to deliver the article to my editors is Friday, September 9. So, if possible, I would like to hear back from someone by Wednesday, September 7. Since everyone is over-scheduled these days, it's always easier if I e-mail a list of questions. That gives everyone the convenience and flexibility to answer at their leisure. I always suggest that the best approach is to simply write the answers in a conversational style. The typical Healthline reader is a 30-year-old mother who's reading information on a mobile device. She's college-educated and is looking for solid, reliable information written in clear, accessible English. So, it's Healthline's job to make sure we translate complicated topics to give those readers information on health and medical topics that are crucial to their lives. FYI, here is the link to one of my recent Healthline stories, about the effect of western diets on obesity in China: <http://www.healthline.com/health-news/western-diets-making-people-obese-around-world> Some background: I am an accomplished newspaper and magazine journalist -- daily newspapers in the San Francisco Bay Area, and national magazines in New York City, including Money and Fortune, and Time's Magazine Development Group. I've also written extensively for the publications of NYU Polytechnic Institute in New York City and for North Shore-Long Island Jewish Health System (now Northwell). My work has appeared in numerous media, including The New York Times and Newsday, and on CNN.com. Questions: --When did Sudden Unexpected Postnatal Collapse (SUPC) first become apparent among medical centers that have adopted the Ten Steps to Successful Breastfeeding? --Has the CDC and the Federal government been keeping statistics on SUPC and the Baby Friendly Hospital Initiative, since the Initiative was developed in the 1990s? --Can you give me the most important statistics? --Does CDC work with HHS on these kinds of medical problems? How? --In the JAMA Pediatrics Viewpoint article, the authors wrote that "it is important to be certain that the basis for the recommendations has been documented in reproducible scientific studies and that the benefits of the practices recommended outweigh the risks." --Were the "Ten Steps" arrived at in that scientific manner? --When a discovery such as SUPC occurs, what involvement does CDC have in addressing it? I would be very grateful for your help. Thank you very much, Patrick Keeffe

Information Provided by CDC:

[View Inquiry Details](#)

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VIEWPOINT

Implementation of the Ten Steps to Successful Breastfeeding Saves Lives

Joan Younger Meek, MD

Department of Clinical Sciences, Florida State University College of Medicine, Tallahassee.

Lawrence Noble, MD

Department of Pediatrics, Icahn School of Medicine at Mount Sinai, New York, New York.



Viewpoint

The Baby-Friendly Hospital Initiative (BFHI), developed in 1991 by the World Health Organization and the United Nations Children's Fund to improve maternity care practices and breastfeeding rates, has been implemented globally in more than 152 countries. The core tenets of the BFHI are the Ten Steps to Successful Breastfeeding, which have been endorsed by the American Academy of Pediatrics. A recent meta-analysis of studies evaluating the BFHI found that implementation of the BFHI increased exclusive breastfeeding by 49% (95% CI, 33%-68%) and any breastfeeding by 66% (95% CI, 34%-107%).¹ The meta-analysis reviewed 29 studies that found that the BFHI and its elements of hospital support increased breastfeeding in the first hour (relative risk = 1.11; 95% CI, 1.06-1.16), 51 studies that found that it increased exclusive breastfeeding in the first 5 months (relative risk = 1.46; 95% CI, 1.37-1.56), and 47 studies that found that it increased any breastfeeding in the first 6 months (relative risk = 1.40; 95% CI, 1.30-1.52).

For optimal child health and development, the American Academy of Pediatrics recommends exclusive breastfeeding for about the first 6 months of life, followed by continuation of breastfeeding for at least the first year of life.² Increased duration and exclusivity of breastfeeding are most closely linked to improved maternal and child health outcomes. An analysis of the effect of 90% of infants being exclusively breastfed for 6 months revealed that 911 infant deaths could be saved in the United States, most secondary to decreased sudden infant death syndrome.³ A recent meta-analysis revealed that improved breastfeeding globally would annually save 823 000 deaths in children younger than 5 years and 20 000 breast cancer-related deaths in women.⁴ In addition, it found that breastfeeding reduces morbidity and has an economic impact in improving the educational potential of children and their earnings as adults. Improved breastfeeding rates would reduce treatment costs by at least \$2.45 billion annually in the United States alone.¹ Breastfeeding prevents acute infectious diseases, decreases prevalence of obesity and type 2 diabetes, and promotes optimal intellectual development in children, while decreasing maternal risk of breast cancer and ovarian cancer.⁴ These compelling benefits support the premises that breastfeeding is a public health issue, breastfeeding promotion is a public health imperative, and breastfeeding support indeed saves lives.

Breastfeeding initiation occurs in the maternity facility and requires an environment that supports and encourages breastfeeding. Baby-Friendly USA is the entity that designates maternity facilities in the United States that have implemented the Ten Steps to Successful Breastfeeding and follow the World Health Organi-

zation International Code of Marketing of Breast-Milk Substitutes. Facilities go through a process of self-assessment of compliance with the Ten Steps to Successful Breastfeeding and then follow quality improvement methods, using small tests of change, to modify their policies and procedures to improve compliance. With the support of funding from the Centers for Disease Control and Prevention and in accordance with the Surgeon General's Call to Action to Support Breastfeeding, the number of births that occur in maternity facilities designated as Baby-Friendly increased from 1.79% in 2007 to 17.65% in June 2016, exceeding the Healthy People 2020 goal of 8.1%. During that same period, national rates of initiation of breastfeeding increased from 73.8% to 80%, breastfeeding at 6 months increased from 41.5% to 53.9%, and exclusive breastfeeding rates at 6 months increased from 11.3% to 21.9%, concurrent with the emphasis on implementation of Baby-Friendly practices and the assessment of Maternity Practices in Infant Nutrition and Care surveys conducted biannually by the Centers for Disease Control and Prevention.⁵

The Ten Steps to Successful Breastfeeding include development of a breastfeeding policy, education of all staff, and altering the paradigm under which maternity care is delivered. A key element involves allowing as much uninterrupted contact between the newborn and family as possible, beginning immediately after birth with skin-to-skin care and followed by continuous rooming in throughout the hospital stay. A meta-analysis of 34 randomized trials with 2177 participants revealed that early postpartum skin-to-skin contact increased breastfeeding rates, with no clear negative outcomes.⁶ In addition, skin-to-skin contact decreases hypothermia, hypoglycemia, and crying and promotes cardiorespiratory stability, especially in the late-preterm newborn. One study found that rooming in increased exclusive breastfeeding during the first few days of life.⁷

Sudden unexpected postnatal collapse is a rare but potentially fatal event in otherwise healthy-appearing term newborns. Mothers are naturally exhausted and are at risk for falling asleep and/or dropping their newborn, especially after cesarean deliveries. The mother-infant dyad needs careful observation during the postpartum period, whether the mother is giving skin-to-skin care, breastfeeding, bottle feeding, or even just holding her infant. This is true whether the infant is rooming in or is sent to the mother for feedings. If the mother is sleepy, the infant should be moved to a separate sleep surface next to the mother's bed. This can be done by hospital staff or by support persons.

While pacifier use has been recommended as a means to decrease the risk of sudden infant death

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syndrome, a meta-analysis of 21 trials found that the use of pacifiers was associated with shortened duration of both exclusive and any breastfeeding.⁸ The American Academy of Pediatrics has recommended that pacifier use be restricted for healthy, term newborns until breastfeeding has been well established, to promote a good maternal milk supply and to eliminate potential risk of nipple confusion, especially during the first few weeks of life when sudden infant death syndrome is less common.²

Infant safety and the prevention of sudden unexpected postnatal collapse are of paramount importance, but so are implementation of the Ten Steps to Successful Breastfeeding and designation of Baby-Friendly maternity facilities. These are not mutually

exclusive goals and both can save infant lives. Pediatricians and other health care professionals need education about how to protect, promote, and support breastfeeding. All members of the health care team should be trained to assess newborns and provide appropriate education to new parents. Neither skin-to-skin care nor rooming-in negates the requirement for trained mother-baby staff to continue to monitor newborns throughout the postpartum stay. There is a link between the BFHI, perinatal care quality, and in-hospital exclusive breastfeeding rates. Instead of abandoning the demonstrated benefits of the BFHI, promoting safe and effective assessment of babies should complement the implementation of the Ten Steps to Successful Breastfeeding.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: None reported.

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7. Jaafar SH, Lee KS, Ho JJ. Separate care for new mother and infant versus rooming-in for increasing the duration of breastfeeding. *Cochrane Database Syst Rev*. 2012;(9):CD006641.
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VIEWPOINT

Unintended Consequences of Current Breastfeeding Initiatives

Joel L. Bass, MD

Department of Pediatrics, Newton-Wellesley Hospital, Newton, Massachusetts.

Tina Gartley, MD

Department of Pediatrics, Newton-Wellesley Hospital, Newton, Massachusetts.

Ronald Kleinman, MD

Department of Pediatrics, Massachusetts General Hospital, Boston.



Viewpoint

Promoting and supporting breastfeeding during the postpartum period has been an important and appropriate priority for maternity units in recent years. The Ten Steps to Successful Breastfeeding of the Baby-Friendly Hospital Initiative have been implemented by an increasing number of hospitals as the standard of care for optimally supporting breastfeeding from birth to hospital discharge.¹ As some or all of these steps are increasingly being promoted as standard of care by government agencies (eg, the Centers for Disease Control and Prevention) and by The Joint Commission, it is important to be certain that the basis for the recommendations has been documented in reproducible scientific studies and that the benefits of the practices recommended outweigh the risks. Unfortunately, there is now emerging evidence that full compliance with the 10 steps of the initiative may inadvertently be promoting potentially hazardous practices and/or having counterproductive outcomes.

The wording of the 10 steps themselves may not suggest a potential for risk. However, the specific guidelines for Baby-Friendly designation provide the cause for concern. For example, to comply with step 4 (help mothers initiate breastfeeding within 1 hour of birth), the guidelines state that all mothers should have continuous skin-to-skin contact with their baby immediately after birth until completion of the first feeding and that skin-to-skin contact should also be encouraged throughout the hospital stay,¹ a time period when direct continuous observation by medical care professionals is not likely to occur. Although a recent Cochrane Review provides evidence for the benefits of skin-to-skin care for healthy full-term and late preterm infants for the first hour after birth, it also stipulates that mother and baby not be left unattended while skin-to-skin care takes place during this early period.² Reports of sudden unexpected postnatal collapse (SUPC) in association with the skin-to-skin practice, published over the past several years, have focused attention on the importance of this caveat.³

Reports of SUPC include both severe apparent life-threatening events (recently referred to as brief resolved unexplained events) and sudden unexpected death in infancy occurring within the first postnatal week of life.³ A comprehensive review of this issue identified 400 case reports in the literature, mostly occurring during skin-to-skin care, with one-third of the events occurring in the first 2 hours after birth and the remainder in the subsequent week of life.³ The review reported death in half of the cases and persistent disability in the majority of survivors. European rates of SUPC varied from 2.6 to 74 cases per 100 000 births, with higher rates related to the length of the inclusion period and infant care practices related to prone sleeping

and co-bedding.³ Furthermore, a recent publication from the American Academy of Pediatrics observed that lawsuits have surfaced in US hospitals attributed to unexpected respiratory arrest in apparently healthy newborns during early skin-to-skin care and cautioned that this practice needs to be balanced with the need to implement safe sleep practices with monitoring of infants during skin-to-skin care unless direct observation takes place.⁴

While breastfeeding exclusivity (step 6) and 24-hour rooming in (step 7) have demonstrated benefits in the postpartum period, these practices may also engender risk. An overly rigid insistence on these steps in order to comply with Baby-Friendly Hospital Initiative criteria may inadvertently result in a potentially exhausted or sedated postpartum mother being persuaded to feed her infant while she is in bed overnight, when she is not physically able to do so safely. This may result in prone positioning and co-sleeping on a soft warm surface in direct contradiction to the Safe Sleep Recommendations of the National Institutes of Health. In addition, co-sleeping also poses a risk for a newborn falling out of the mother's bed in the hospital, which can have serious consequences.⁵ There is also the possibility that unsafe sleep practices modeled in the hospital may continue at home.⁶

The justification for breastfeeding exclusivity is based on a 1998 World Health Organization review of the evidence for the 10 steps.⁷ However, that review included evidence that when supplementation was given for a medical indication, there was no adverse effect on the duration of breastfeeding. It also concluded, based on the available evidence, that it was not clear to what extent supplementation in other circumstances was a marker of breastfeeding difficulty rather than an actual cause of breastfeeding failure.

Another issue of concern is the ban on pacifier use (step 9). Compliance requires that mothers be educated repeatedly that pacifiers may interfere with the development of optimal breastfeeding.¹ Because there is strong evidence that pacifiers may have a protective effect against sudden infant death syndrome (SIDS), the American Academy of Pediatrics has suggested avoidance of pacifiers only until breastfeeding is established at approximately 3 to 4 weeks of age.⁸ Because a substantial number of SUPC events occur during the first week of life,³ this recommendation to proscribe the use of pacifiers is difficult to defend based on risk.

Preventing the unintended serious outcomes from these practices has been made more challenging by the emphasis on breastfeeding exclusivity in the perinatal measures recently promulgated by The Joint Commission. Measure PC-05 requires documentation of the

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reasons for not exclusively breastfeeding, with no allowable exceptions for newborn conditions. In addition, the Centers for Disease Control and Prevention actively promotes the "10 Steps" and Baby-Friendly designation, and monitors "10 Steps" compliance in the United States. In Massachusetts, the recently enacted Massachusetts Health Quality Measure 3A requires increasing rates of breastfeeding exclusivity, with soon to be implemented financial implications.

In an effort to explore the potential effect of these initiatives, we reviewed data from the Massachusetts Department of Public Health Registry of Vital Records and Statistics concerning statewide rates of sudden unexplained infant deaths among newborns. This includes *International Classification of Diseases* codes R95 (SIDS), R99 (undetermined cause and manner), W75 (accidental suffocation), and W84 (unspecified threat to breathing). While SIDS in the first month of life is generally considered an uncommon event, in Massachusetts (2004-2013), 14% of the cases of SIDS occurred in the first 28 days of life. Of note, 8 (22.2%) of the cases of SIDS among newborns and 20 (35.1%) of the newborn sudden unex-

plained infant deaths occurred in the first 5 days of life, suggesting that the concerns raised in the recent American Academy of Pediatrics report⁴ may be more common than previously recognized.

In 2011, the Office of the Surgeon General issued a call to action to support breastfeeding that proposed the accelerated implementation of the Baby-Friendly Hospital Initiative in the United States.⁹ Considering the available evidence, that recommendation should be reconsidered. If government and accreditation agencies wish to encourage and support breastfeeding, their focus should shift from monitoring Baby-Friendly practices and breastfeeding exclusivity to monitoring breastfeeding initiation rates coupled with evidence of lactation support both during and after the hospital stay. More attention should also be placed on ensuring compliance with established safe sleep programs, emphasizing the need to integrate safe sleep practices with breastfeeding. Hospitals should direct their efforts toward implementing practices that will promote breastfeeding safely, the common goal of both private and public groups with an interest in these issues.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: None reported.

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(b)(5)

From: Boundy, Ellen (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Fri, 1 Oct 2021 16:50:18 +0000
To: MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: mPINC State Reports status
Attachments: Marks_GaPQC_October2021.pptx

Hi Carol,

Kristin will be pre-recording a presentation on mPINC 2020 for the GA Perinatal Quality Collaborative, which will be held on Oct 15, but she needs record next week. It sounds like the comms team is not positive whether or not the state reports will be posted on our webpage by Oct 15. I did present some of the national data on the USBC call, but wanted to check whether you think it's okay if Kristin shares the GA-specific data if their report may not be posted by then. I think it would be very much of interest to this audience to see their state info, but just wanted to hear your thoughts before I respond to Kristin.

Thanks,
Ellen

From: Marks, Kristin Jean (CDC/DDNID/NCCDPHP/DNPAO) <kma8@cdc.gov>
Sent: Friday, October 1, 2021 12:16 PM
To: Boundy, Ellen (CDC/DDNID/NCCDPHP/DNPAO) <lwz9@cdc.gov>
Cc: Anstey, Erica Hesch (CDC/DDNID/NCCDPHP/DNPAO) (CTR) <yhm7@cdc.gov>
Subject: FW: mPINC State Reports status

Hi Ellen,

Below is the most recent update from Rachel on the mPINC state reports and the website. Seems like October 15th is not guaranteed.

I've attached my slides so you can see what I was planning to present. If we don't want to share 2020 state data before it hits the website, I think slides

(b)(5)

(b)(5)

Happy to talk more about this on Monday afternoon!

Thanks,
Kristin

From: Robb, Rachel (CDC/DDNID/NCCDPHP/DNPAO) <wqp8@cdc.gov>
Sent: Friday, October 1, 2021 11:40 AM
To: Marks, Kristin Jean (CDC/DDNID/NCCDPHP/DNPAO) <kma8@cdc.gov>
Cc: Anstey, Erica Hesch (CDC/DDNID/NCCDPHP/DNPAO) (CTR) <yhm7@cdc.gov>
Subject: RE: mPINC State Reports status

Hi Kristin,

I talked to Sarah on the web team and she thinks that we shouldn't promise that it will be up by 10/15. Curtis is still working on the food service guidelines toolkit, which is a big lift. We expect he'll be able to start the mPINC reports next week, but, especially with the holiday, we can't guarantee that he'll be done by the 15th.

There was another presentation recently in which we were told that we could share the data as a "sneak peak" in advance of the web release. I'll leave that up to your team to decide if that is the right thing to do for this situation.

Sorry! If I hear any updates, I'll keep you posted.

Rachel

From: Marks, Kristin Jean (CDC/DDNID/NCCDPHP/DNPAO) <kma8@cdc.gov>
Sent: Friday, October 1, 2021 10:57 AM
To: Robb, Rachel (CDC/DDNID/NCCDPHP/DNPAO) <wqp8@cdc.gov>
Cc: Anstey, Erica Hesch (CDC/DDNID/NCCDPHP/DNPAO) (CTR) <yhm7@cdc.gov>
Subject: RE: mPINC State Reports status

Hi Rachel,

It's nice to meet you! Like Erica said, I'm the new EIS officer on the MITN team.

Do you have an update on when the mPINC state reports might be up on the website? I am planning to record my presentation in the middle of next week and want to know what I can include.

Thanks, and have a great weekend!
Kristin

From: Anstey, Erica Hesch (CDC/DDNID/NCCDPHP/DNPAO) (CTR) <yhm7@cdc.gov>
Sent: Wednesday, September 29, 2021 11:08 AM
To: Robb, Rachel (CDC/DDNID/NCCDPHP/DNPAO) <wqp8@cdc.gov>
Cc: Marks, Kristin Jean (CDC/DDNID/NCCDPHP/DNPAO) <kma8@cdc.gov>
Subject: mPINC State Reports status

Hey Rachel-

Our EIS fellow, Kristin, is doing a presentation with the GA Perinatal Quality Collaborative on 10/15, but she needs to record it by 10/8. Do you think we can for sure have the mPINC State Reports up on the website by 10/15? It would be nice if she could use the 2020 data in her presentation.

Thanks,
Erica

Erica H. Anstey, PhD, MA, CLC
(Pronouns: she, her, hers)
Program Coordinator and Breastfeeding Specialist

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Maternal, Infant, and Toddler Nutrition Team
[Division of Nutrition, Physical Activity, and Obesity](#) (DNPAO)
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
Centers for Disease Control and Prevention (CDC)
770.488.5041 (office) | eanstey@cdc.gov

[Chat with Erica on MS Teams](#)

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From: Kahin, Sahra A. (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Thu, 12 Aug 2021 15:19:10 +0000
To: Grossniklaus, Daurice (CDC/DDNID/NCCDPHP/DNPAO); O'Connor, Lauren (CDC/DDNID/NCCDPHP/DNPAO) (CTR); Ayers, Diane G. (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: mPINC Webinar?
Attachments: Nelson_mPINC Breastfeeding Networking call_clean.pdf

FYI

From: Kahin, Sahra A. (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Thursday, August 12, 2021 11:18 AM
To: Carol MacGowan (dvx2@cdc.gov) <dvx2@cdc.gov>; Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>
Subject: mPINC Webinar?

Hey Cria and Carol,

I was wondering if there is interest/availability from the Nutrition Branch in doing a webinar this fall/winter for mPINC similar to what Jennifer did several years ago (see attached)? I remember it was such a valuable call to state's and hospitals at the time (over 100 participants- I think we actually overwhelmed the call in line at the time). I'm thinking the audience this time would be the same (state and local health departments as well as hospitals). For our recent AAP webinar, we shared the flyer on the CDC BF and mPINC lists. Turnout was about 150 participants. Let me know what you think.

Take care,

Sahra A. Kahin, MA, MPH
(Pronouns: she/her/hers)
Health Scientist
Program Development and Evaluation Branch
Division of Nutrition, Physical Activity and Obesity
Centers for Disease Control and Prevention
4770 Buford Hwy, NE
MS S107-5
Atlanta, GA 30341
Email: skahin@cdc.gov

Using mPINC as a Tool for Improvement



Jennifer M. Nelson, MD, MPH

Medical Epidemiologist
Centers for Disease Control and Prevention

Breastfeeding Networking Call
December 5, 2016

mPINC Survey

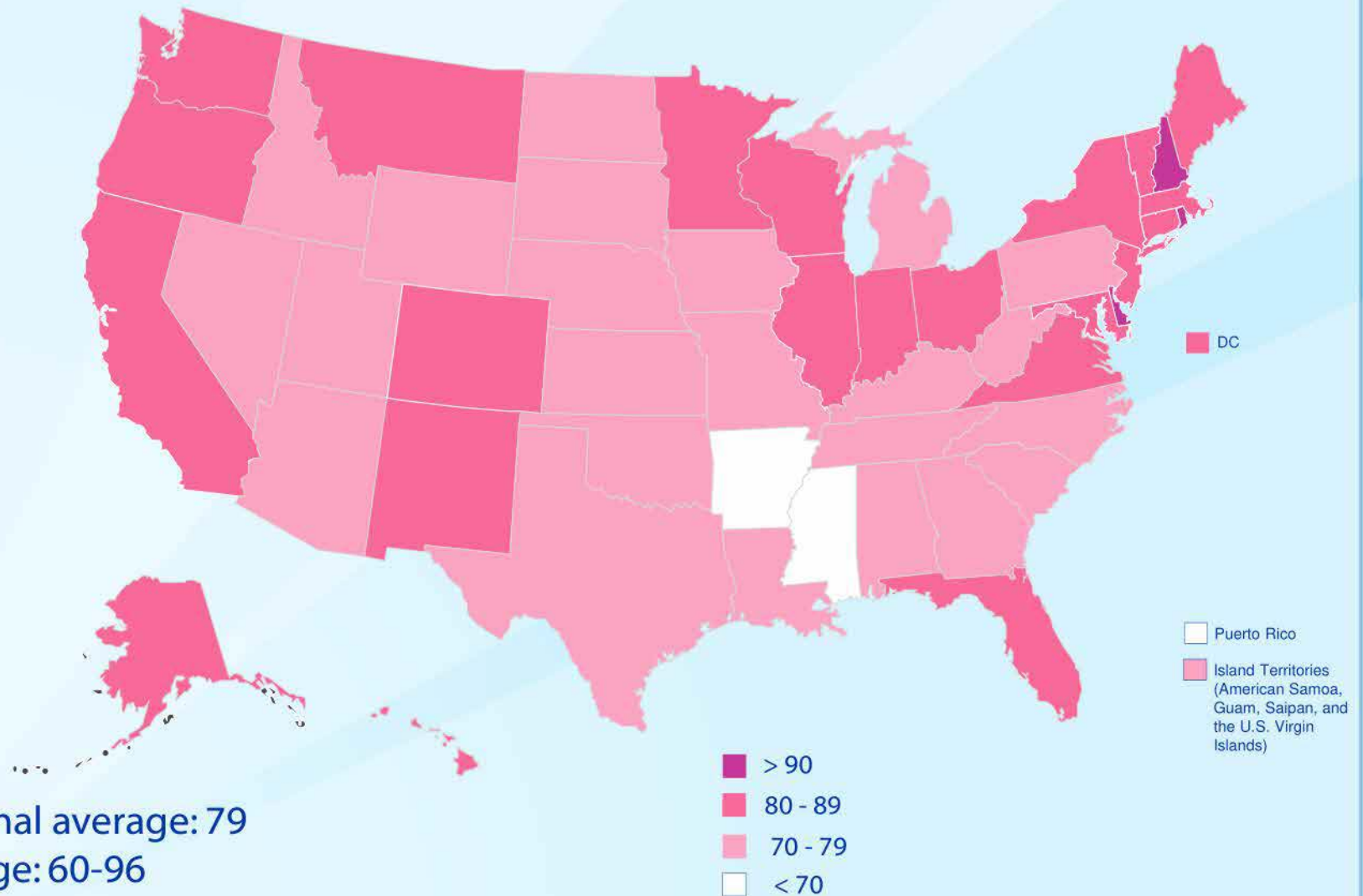
- **Launched in 2007**
 - Administered every 2 years
- **Census of all hospitals and birth centers**
- **Breastfeeding-related maternity care practices and policies**
- **Key informant**
- **Response rate >80%**
- **Benchmark report**
 - Total Score
 - 7 domain sub-scores



Average Total mPINC Scores, 2007-2015

Year	Total Score
2007	63
2009	65
2011	70
2013	75
2015	79

Total mPINC Score, by state, 2015



Hospitals in our state have many barriers in implementing evidence-based maternity care.....resistant doctors, formula supplementation, skin-to-skin care in the operating room....just to name a few.

How can we improve our overall mPINC score?

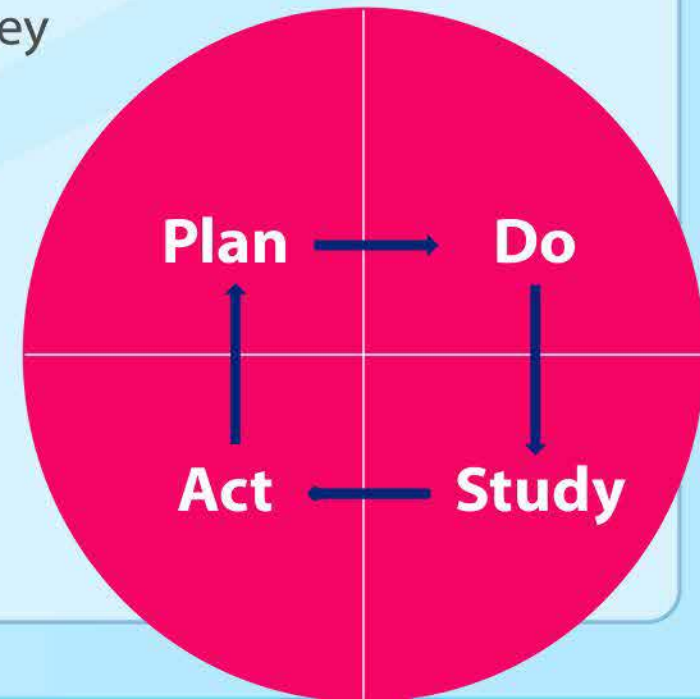


Hospital A: Safety-Net Hospital

- **Medically underserved population**
 - 25-35% uninsured; 40-60% underinsured
 - Average annual income: <\$15,000
 - 96% Hispanic and Spanish-speaking
 - 69% nulliparous
 - Additional risk factors
- **Safety-net hospital**
 - Remote location
 - Challenge to acquire physician and nurse resources
 - 5,000 births (pre-2008) → 3,500 births (2012)
 - “decrease in admissions was an administrator’s nightmare”
- **Total mPINC score**
 - 65 (2011) → 92 (2013)
 - How??

Hospital A: Solution

- **Maternal-Child Nurse Managers**
 - Sought and acquired knowledge on Baby-Friendly Hospital Initiative (BFHI) and mPINC survey
 - Memberships to lactation organizations obtained
 - Obtained ideas and information
 - Utilized BFHI Guidelines and mPINC survey
 - External benchmarks and defined data collection processes
- **Plan-Do-Study-Act (PDSA) model**



Hospital A: Selected Challenges

▪ Staff Training

- Trained 443 individuals and verified 5,035 hours of training
- Established on-going process for training and education
- Beyond required 20 hours to develop own experts

▪ Newborn Hypoglycemia Protocol

- Worked with pediatric team
- All newborns → routine only for at-risk or symptomatic newborns
 - Reduced glucose testing for 46% of newborns

▪ Non-breast milk products

- *Los dos* ("the two")
- Nurse education
- Maternal choice form
- Chart review for nursing/physician documentation
- Electronically linking formula distribution to individual staff

Hospital A: Results

- **Vaginal deliveries**
 - 97% had skin-to-skin contact
 - 92% received breast milk as first feed
 - 95% mother-infants transferred together
- **Stable C-sections**
 - 40% were couplets
 - 90% had skin-to-skin contact
 - 83% received breast milk as first feed
 - 91% mother-infants transferred together
- **Exclusive Breastfeeding rates**
 - 16% (2012) → 42% (2015)
- **Total mPINC score**
 - 65 (2011) → 92 (2013)

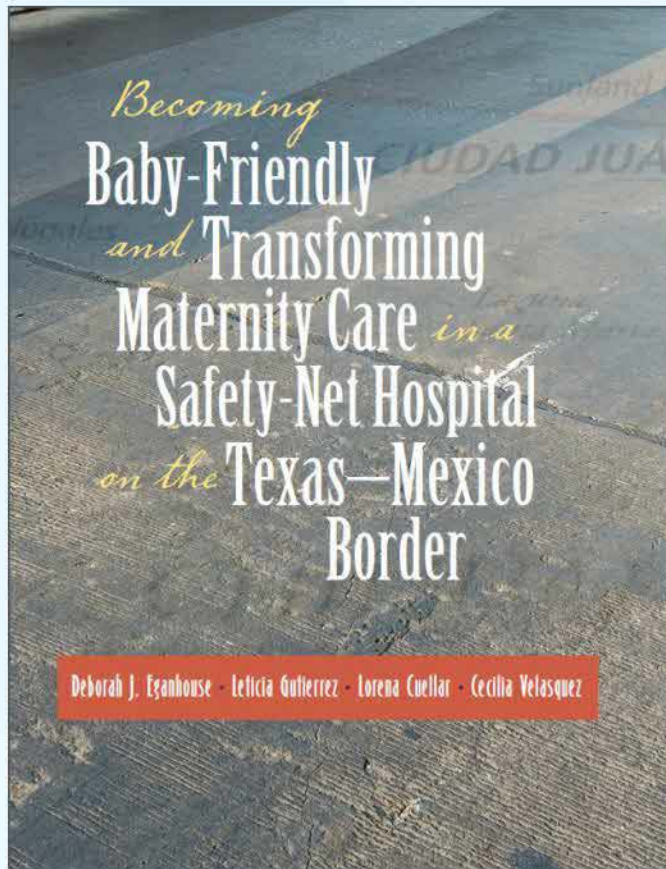
Hospital A: Keys to success

- **“A change process that was driven by nurse leaders with the authority, motivation, and resources to move practice forward”**
- **Having 3 nurses pass the IBCLC exam**
 - Strong message of success to the entire nursing staff
- **Data collection plan critical for early and ongoing success**
 - Multi-team process
 - Each unit leader played a role in data collection
 - Customized form to capture BFHI and mPINC data elements
 - Initiated in L&D, used for patient hand-off
 - Data abstracted daily, analyzed monthly



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“.....the mPINC survey provided external benchmarks used to guide the transformation of our maternity care and to define our data collection processes.”

Eganhouse, DJ, et al. Becoming Baby-Friendly and Transforming Maternity Care in a Safety-Net Hospital on the Texas-Mexico Border. Nurs Womens Health. 2016;20(4):378-90.

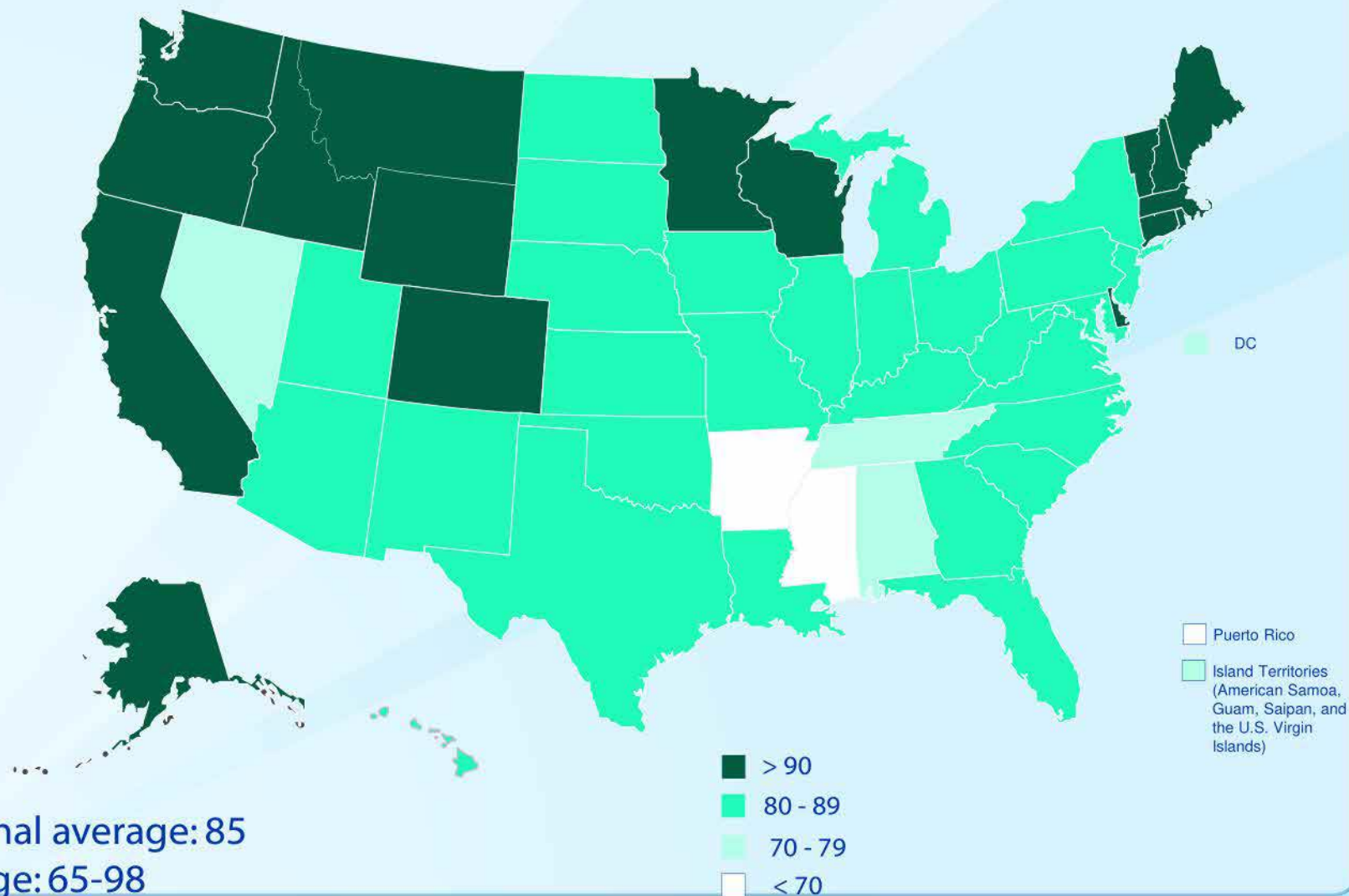
mPINC Sub-Scores



Average Labor & Delivery Care Sub-Scores, 2007-2015

Year	Total Score
2007	59
2009	63
2011	70
2013	80
2015	85

Labor & Delivery Care mPINC Sub-score, by state, 2015



National average: 85

Range: 65-98



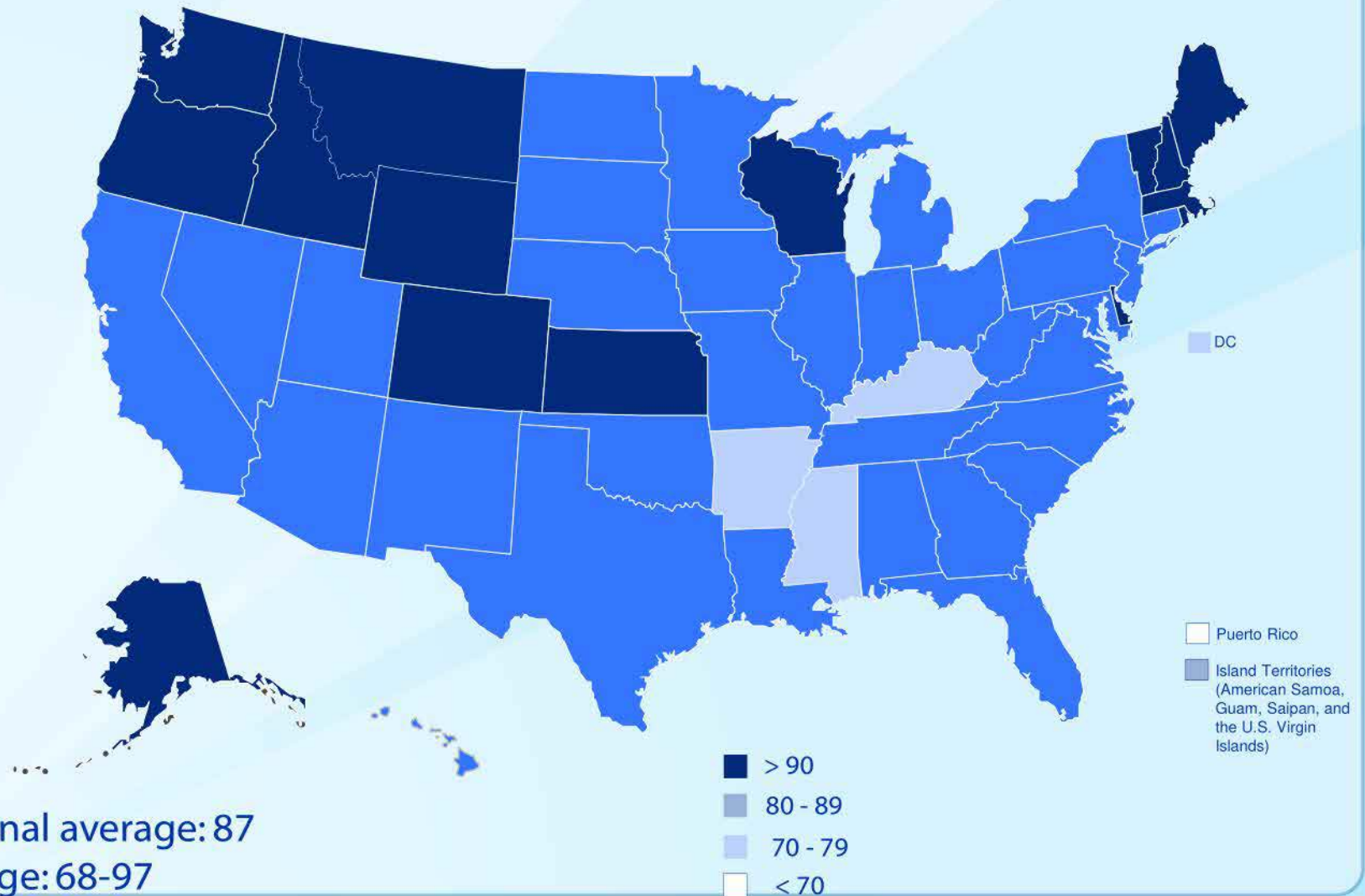
The Iowa Experience: Increasing Access to Breastfeeding Friendly Hospitals

- **Iowa's Labor & Delivery Care sub-score: 50 (2007) → 85 (2015)**
 - Skin-to-skin (Cesarean births): 16% → 73%
 - Procedures performed skin-in-skin: 9% → 41%
- **Iowa Department of Public Health**
 - Targeted rural hospitals with large proportion of Medicaid births
 - Met with key stakeholders
 - Reviewed policies and mPINC results
 - Hosted training (*6 Steps 4 Success*)
 - Additional efforts in 4-5 hospitals annually
 - Rural location with large proportion of Medicaid births
 - mPINC score less than state average
 - Assistance in reviewing mPINC results
 - Determine opportunities for improvement
 - Develop improvement plan for ≥ 2 dimensions of care

Average Feeding of Breastfed Infants Sub-Scores, 2007-2015

Year	Total Score
2007	76
2009	78
2011	81
2013	84
2015	86

Feeding of Breastfed Infants mPINC Sub-score, by state, 2015



California County- and Region-specific Benchmark Reports

Maternity Practices in Infant Nutrition and Care (mPINC) Survey, 2013 Alameda County Benchmark Report

Alameda County Overview



- 8 Birthing Hospitals
- 7 Hospitals (88%) Participated in mPINC Survey in 2013

Breastfeeding Statistics for Participating Hospitals

- Average Any Breastfeeding: 96%
- Average Exclusive Breastfeeding: 76%

Establishing maternity practices supportive of breastfeeding in California hospitals will help meet Healthy People 2020 breastfeeding objectives and improve maternal and child health.

For assistance with breastfeeding promotion efforts visit the CDPH, Breastfeeding and Healthy Living web-site at: <http://cdph.ca.gov/breastfeeding>

For further information about the mPINC Survey visit www.cdc.gov/imzinc



California Composite Quality Practice (Total mPINC) Score*: 83

Alameda County Composite Quality Practice (Total mPINC) Score*: 83

mPINC Dimension of Care	County Sub-scale Score*	State Sub-scale Score*	Ideal Response to mPINC Survey Question	Percent of Facilities with Ideal Response (N = 7)
Labor and Delivery Care	94	86	Initial skin-to-skin contact is w/in 1 hr (vaginal births)	100
			Initial skin-to-skin contact is w/in 2 hr (cesarean births)	71
			Initial breastfeeding opportunity is w/in 1 hr (vaginal births)	71
			Initial breastfeeding opportunity is w/in 2 hr (cesarean births)	71
			Routine procedures are performed skin-to-skin	86
Feeding of Breastfed Infants	94	86	Initial feeding is breast milk (vaginal births)	100
			Initial feeding is breast milk (cesarean births)	100
			Supplemental feedings to breastfeeding infants are rare	29
			Water and glucose water are not used	100
Breastfeeding Assistance	92	92	Infant feeding decision is documented	100
			Staff provide breastfeeding advice & instructions	86
			Patients are taught breastfeeding cues	86
			Patients are taught not to limit sucking time	57
			Staff directly observe & assess breastfeeding	86
			Standard feeding assessment tool is used	100
Contact Between Mother and Infant	85	90	Pacifiers are rarely provided to breastfeeding infants	71
			Mother-infant pairs are not separated for postpartum transition	86
			Most mother-infant pairs room-in at night	83
			Most mother-infant pairs are not separated during the hospital stay	57
			Infant procedures, assessment and care are in the patient room	17
Facility Discharge Care	74	74	Non-rooming-in infants are brought to mothers at night for feeding	100
			Staff provide appropriate discharge planning (referrals & other multi-modal support)	29
			Discharge packs containing product marketing infant formula samples are not given to breastfeeding patients	100
Staff Training	56	72	New staff receive appropriate breastfeeding education	29
			Current staff receive appropriate breastfeeding education	0
			Most staff received breastfeeding education in the past year	29
			Annual assessment of staff competency in breastfeeding management & support	57
Structural & Organizational Aspects of Care Delivery	88	84	Breastfeeding policy includes all 10 model policy elements	57
			In-service training	57
			Prenatal breastfeeding classes	86
			Asking about mothers' feeding plans	86
			Initiating breastfeeding within 60 minutes (vaginal) or after recovery (cesarean)	100
			Showing mothers how to express milk and maintain lactation	100
			Giving only breast milk to breastfeeding infants	100
			Rooming-in 24 hours/day	100
			Breastfeeding on-demand and duration/frequency of feedings	100
			Pacifier use by breastfed infants	86
			Referral of mothers to appropriate breastfeeding resources	86
			Breastfeeding policy is communicated effectively	86
			Facility documents infant feeding in patient population	100
			Facility provides breastfeeding support to employees	100
			Facility does not receive infant formula free of charge	43
			Breastfeeding is included in prenatal patient education	86
			Facility has a designated staff member responsible for coordination of lactation care	100

* The Centers for Disease Control and Prevention (CDC) administered the mPINC Survey of all U.S. maternity care facilities in 2013. Scores were calculated for each survey item, then item scores were averaged to create a score for each of the 7 dimensions of care ("subscores"). Averages of the subscore scores were used to create a Composite Quality Practice or "Total mPINC" score. Possible scores ranged from 0-100, with higher scores denoting better maternity care practices. Facilities may not have responded to all individual mPINC survey questions; "ideal response" rates exclude facilities with missing data for a given survey item.

Breastfeeding Statistics for Participating Hospitals

- Average Any Breastfeeding: 96%
- Average Exclusive Breastfeeding: 76%

YouTube Search

Today's Topic

usbc
United States Breastfeeding
COMMITTEE
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*Using mPINC Data to Support
Breastfeeding Quality
Improvement Efforts in
California*

4:16 / 55:20

CDC-USBC Bi-Monthly Coalitions Webinars: Using
mPINC Data to Support Breastfeeding
(12/08/2015)

usbc USBreastfeeding
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57 views

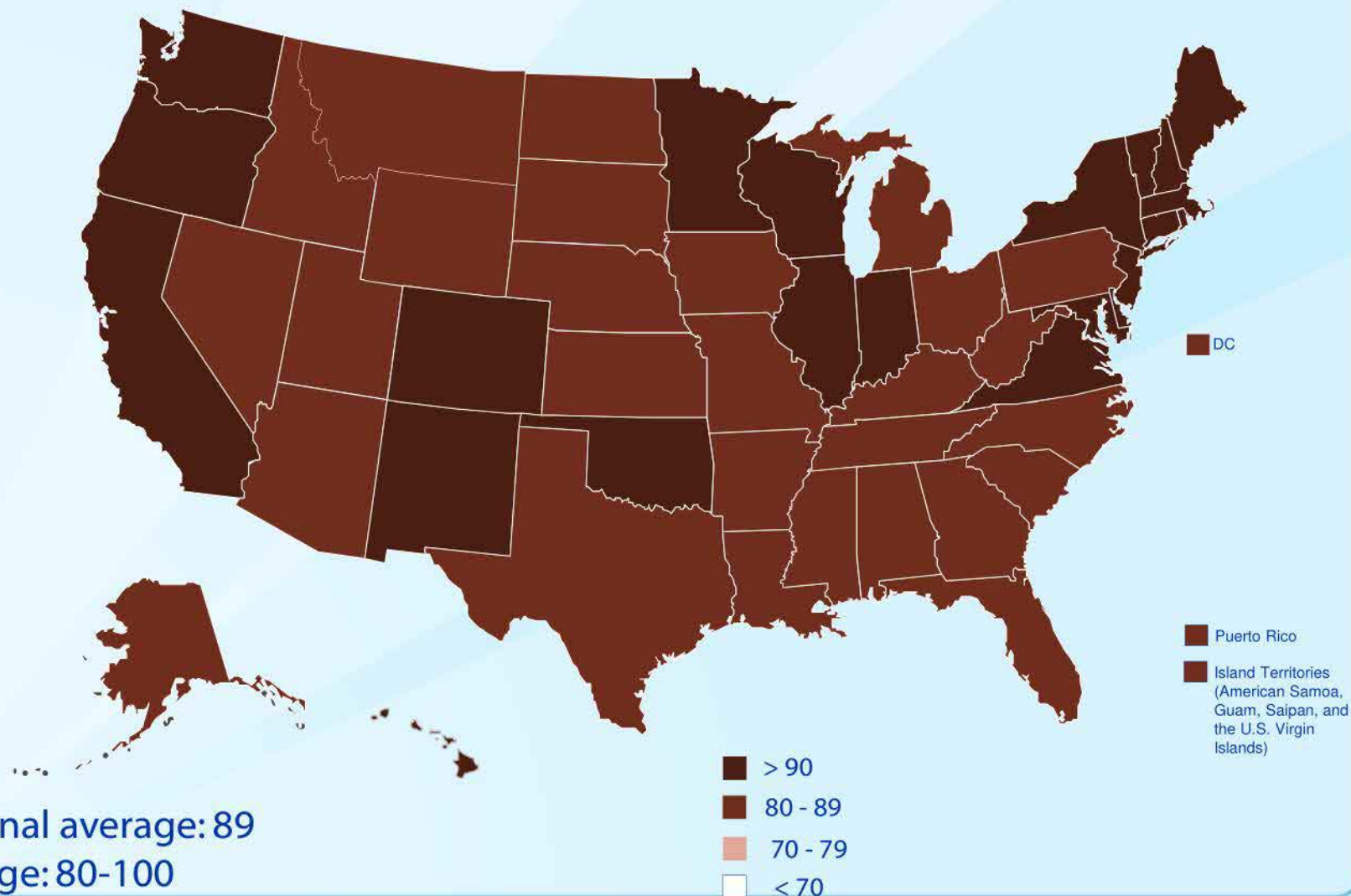
+ Add to ↗ Share ... More

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Average Breastfeeding Assistance Sub-Scores, 2007-2015

Year	Total Score
2007	79
2009	81
2011	84
2013	86
2015	89

Breastfeeding Assistance mPINC Sub-score, by state, 2015





Massachusetts

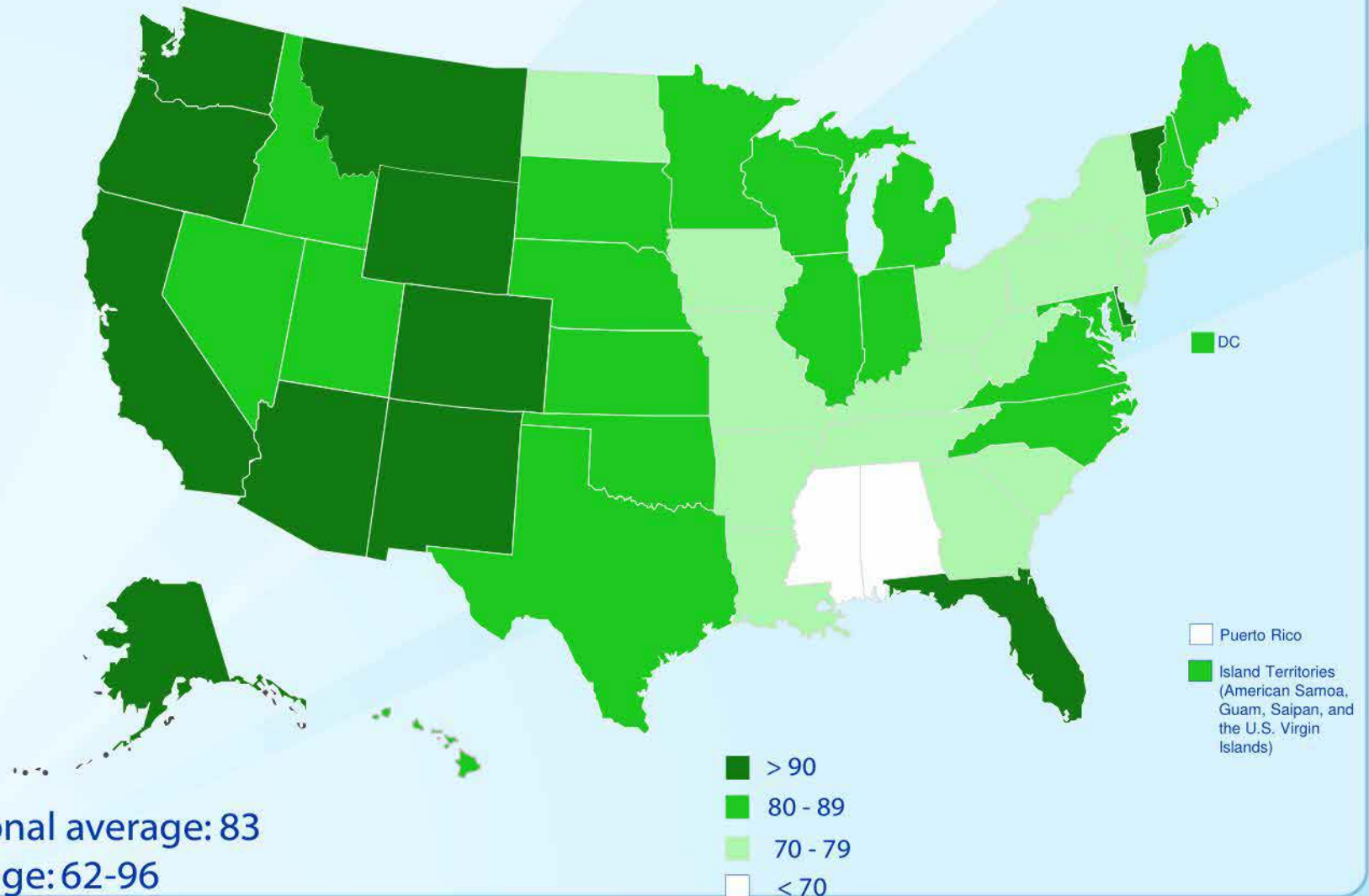
- **MA's Breastfeeding Assistance Sub-score: 86 (2007) → 95 (2015)**
 - Using standard assessment tool: 68% → 93%
 - Rarely providing pacifiers: 35% → 74%
- **Massachusetts Baby-Friendly Collaborative**
 - 4 facilities applying for Baby-Friendly designation
 - Goal: to assist hospitals in achieving the Ten Steps by sharing information, ideas, support, and encouragement
 - Summarized recommendations and specific actions taken
 - "Use existing tools to make small steps that really count"
 - Keep pacifiers in a locked medication system

“The mPINC survey offers an important opportunity for gathering internal stakeholders to **complete the survey together** and discuss what practices could be improved as well as **brainstorm ways to change** those practices in terms of attaining specific score gains for changed practices. It can serve as the **missing catalyst** to unite staff to improve performance on a **specific goal** tied to 1 or 2 questions on the mPINC survey.”

Average Mother-Infant Contact Sub-Scores, 2007-2015

Year	Total Score
2007	67
2009	71
2011	74
2013	79
2015	83

Mother-Infant Contact mPINC Sub-score, by state, 2015



Working for Equity in Breastfeeding in the Maternity Services of Puerto Rican Hospitals

Yvette Piovanetti, Cindy Calderon, Gisela Castaner
2015 AAP conference abstract (Washington, DC)



■ Puerto Rico (PR) Mother-Baby Summits

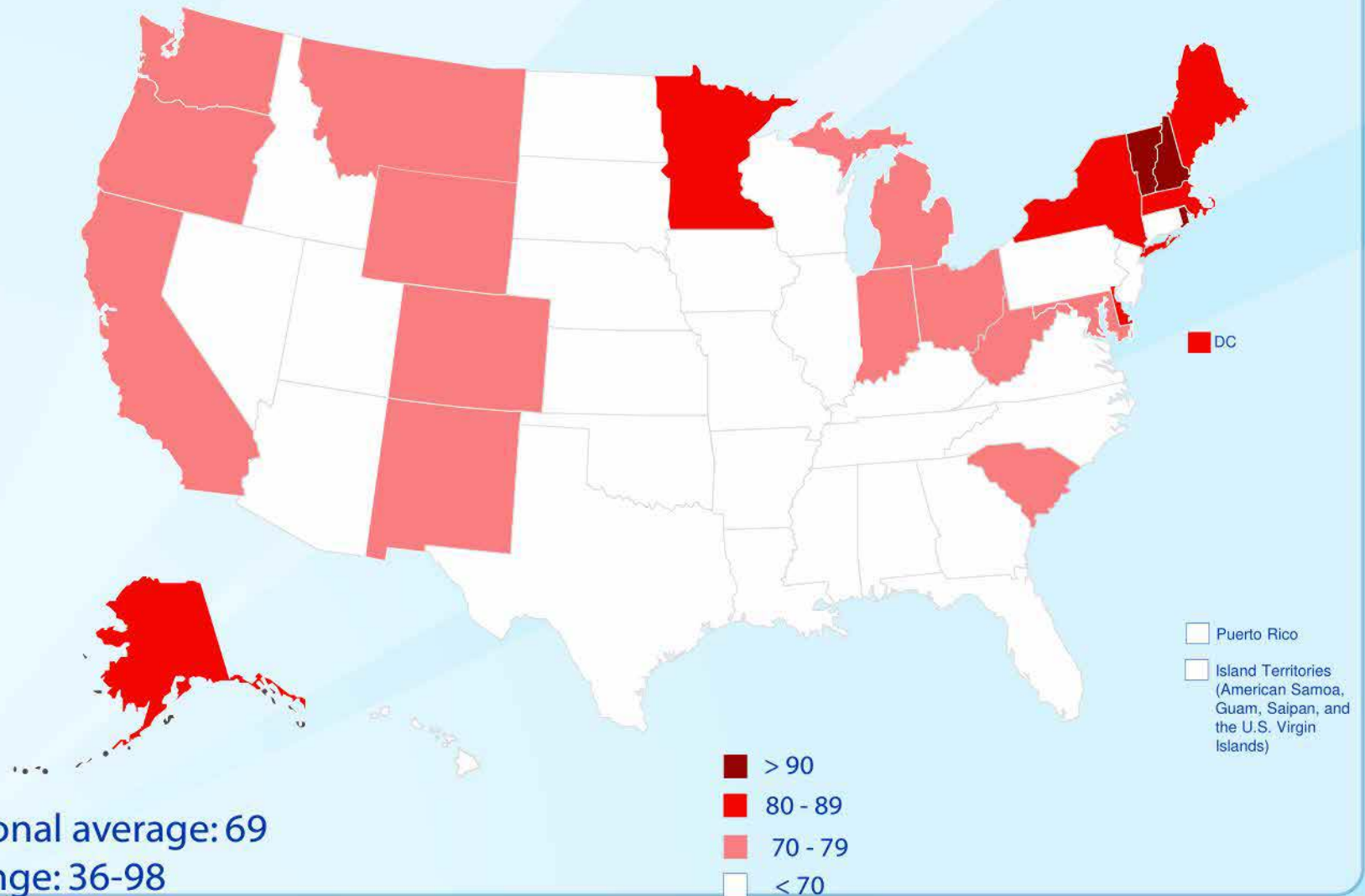
- Breastfeeding Coalition of the PR Health Department
- 67% of hospitals represented
- Goals:
 - Encourage mPINC participation
 - Encourage improved maternity care practices

	Initial Assessment	12-month Follow-up
mPINC Participation	8 hospitals (<30%)	12 hospitals (42%)
Breastfeeding policy	85%	94%
Rooming-in offered	75%	95%

Average Discharge Care Sub-Scores, 2007-2015

Year	Total Score
2007	40
2009	43
2011	49
2013	62
2015	68

Discharge Care mPINC Sub-score, by state, 2015



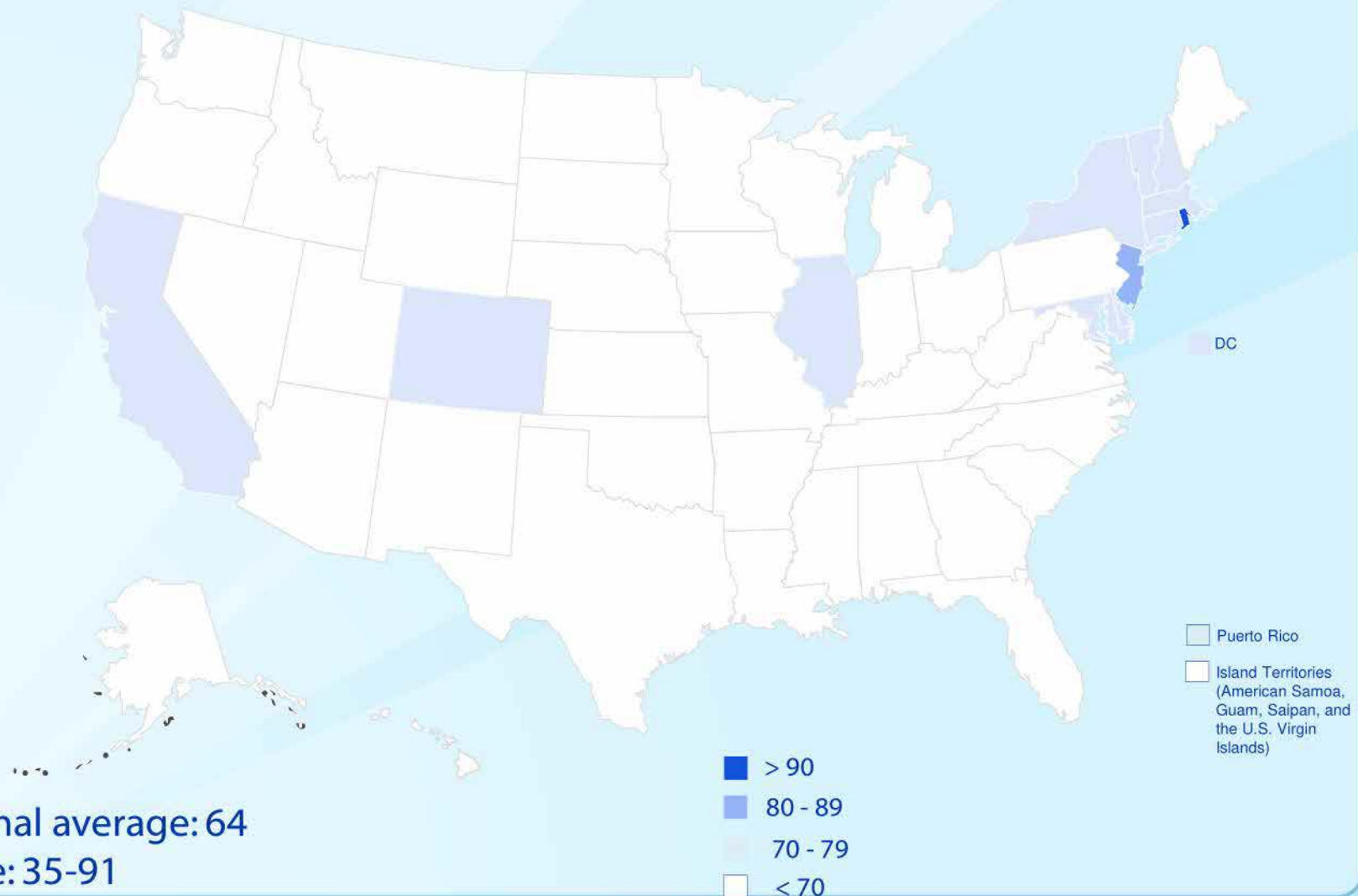
Percentage of Hospitals Distributing Infant Formula Discharge Packs, mPINC 2007-2015

	% of hospitals distributing packs					% point change
	2007	2009	2011	2013	2015	(2007-2015)
Total	72.6	65.8	54.5	31.6	21.3	-51.3

Average Staff Training Sub-Scores, 2007-2015

Year	Total Score
2007	51
2009	51
2011	57
2013	62
2015	64

Staff Training Sub-score, by state, 2015



Tennessee Breastfeeding Tool Kit

- Staff Training Sub-score: 47 (2007) → 63 (2015)



Tuesday, November 22, 2016

Share this page:

[Toolkit Home](#) [LBD](#) [Breastfed Infants](#) [BF Assistance](#) [Early Contact](#) [Discharge](#) [Training](#) [Care Delivery](#) [Misc.](#)



Welcome to the TN Breastfeeding Toolkit!

We're glad you're here. On this site, you'll find a collection of the resources from around the web that are intended to help a hospital or birthing center improve their breastfeeding practices. We realize, though, that improving something as broad and complicated as "all breastfeeding practices" can be difficult, and perhaps a bit intimidating. Well, of this toolkit. We've categorized the resources by mPINC domain and subdomain (along with a "miscellaneous" section), all to help you find the specific resources the areas in which your institution can improve. In this manner, your hospital or birthing center can start to take small, concrete steps toward bettering the mPINC score (for information on mPINC, see link at bottom of page), becoming BabyFriendly, improving breastfeeding practices, and - hopefully - enhancing the health and wellness of infants. Click the button below if you'd like an example of how to use your mPINC score to guide you to the most useful parts of the toolkit. Or, if you'd just like to get some of the links above!



Tennessee Department of Health

Partnering with communities and providers to increase breastfeeding awareness and support.

Using the Toolkit



The mPINC Survey and mPINC Domains

Want to know more about the CDC's mPINC survey? Click on the link below!

Learn More

Learn More



Your Turn!

Have any suggestions about how the toolkit can be improved? We'd love to hear them.

Leave a Comment

<http://www.healthytennesseebabies.com/toolkit.aspx>

[Toolkit Home](#) [LBD](#) [Breastfed Infants](#) [BF Assistance](#) [Early Contact](#) [Discharge](#) [Training](#) [Care Delivery](#) [Misc.](#)



Staff Training

Preparation of New Staff : Continuing Education : Competency Assessment

Preparation of New Staff and Continuing Education
Practical and Educational

[ABM Breastfeeding and Substance Abuse Protocols](#)



[ABM Galactagogue Protocol](#)



[ABM Mastitis Protocol](#)



[ABM Hypoglycemia Protocol](#)



Source: ABM

Description: Various ABM Protocols concerning important breastfeeding-related situations.

Date of Access: October 2015

[AAP Staff Education Toolkit](#)

Source: AAP

Description: A collection of PPT presentations - complete with script -targeted toward staff concerning breastfeeding benefits, support, and common problems.

Date of Access: October 2015



[CDPH Hospital Training Toolkit](#)

Source: CDPH/WIC

Description: A sample collection of PPT, handouts, worksheets, and scripts meant to be presented to the interdisciplinary team in charge of improving breastfeeding practices within a hospital.

Date of Access: October 2015



Competency Assessment
Practical

[Core Competencies for Professionals](#)

Source: USBC

Description: A checklist of competencies all providers should have in regard to breastfeeding knowledge and practice.

Date of Publication: 2010



[Practical Skills Review Sheet](#)

Source: AAP

Description: Checklist of necessary skills a provider needs in order to instruct mothers in how to breastfeed.

Date of Access: October 2015



[Assessing Midwives' Breastfeeding Knowledge](#)

Source: *International Breastfeeding Journal*

Description: Academic paper examining the use of a questionnaire used to assess breastfeeding knowledge. Also includes a copy of the questionnaire and answer sheet.

Date of Publication: 2008

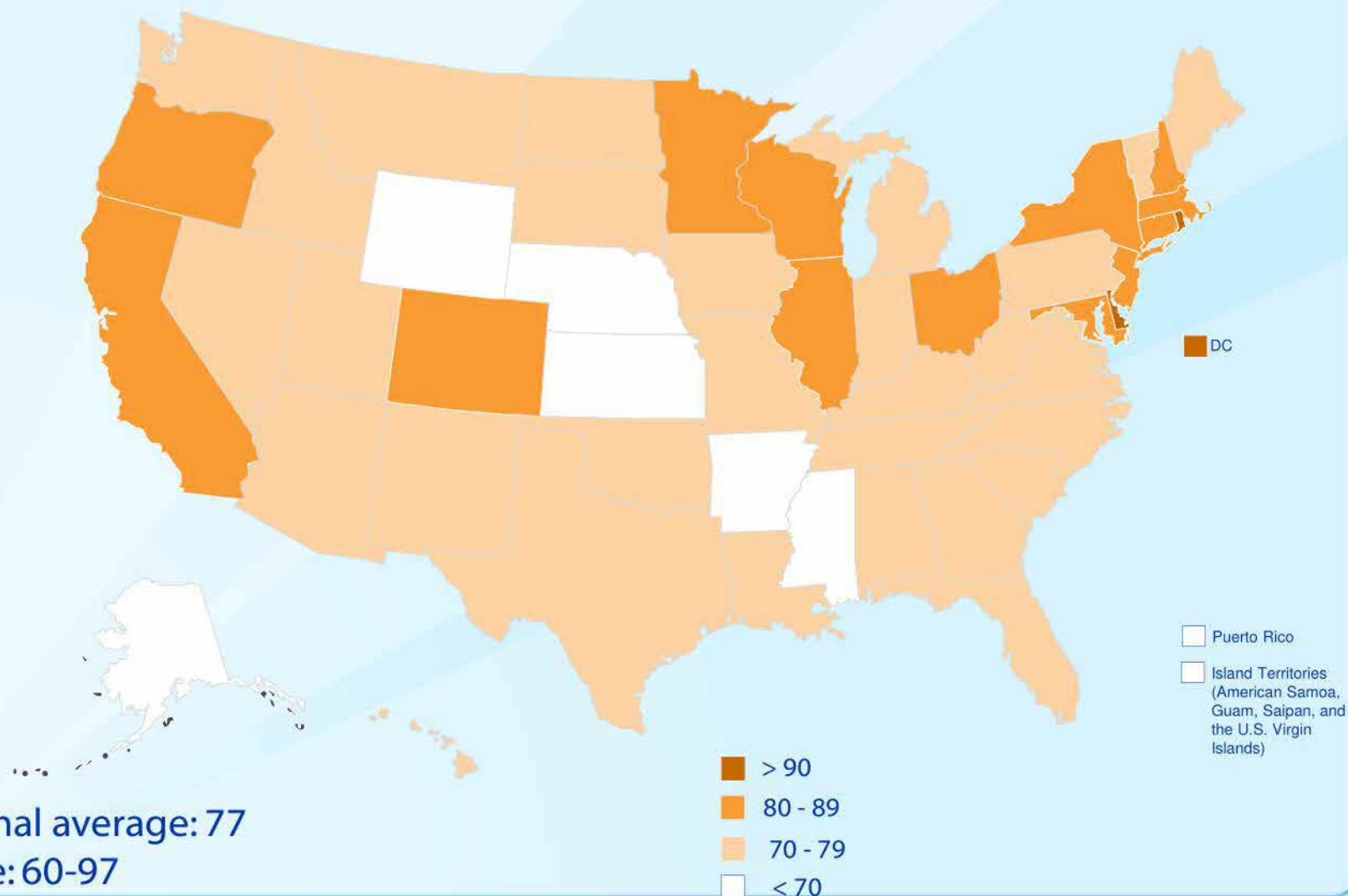


Average Structural & Organizational Aspects of Care Delivery Sub-Scores, 2007-2015

Year	Total Score
2007	66
2009	69
2011	71
2013	74
2015	77

Structure & Organizational Aspects of Care Delivery

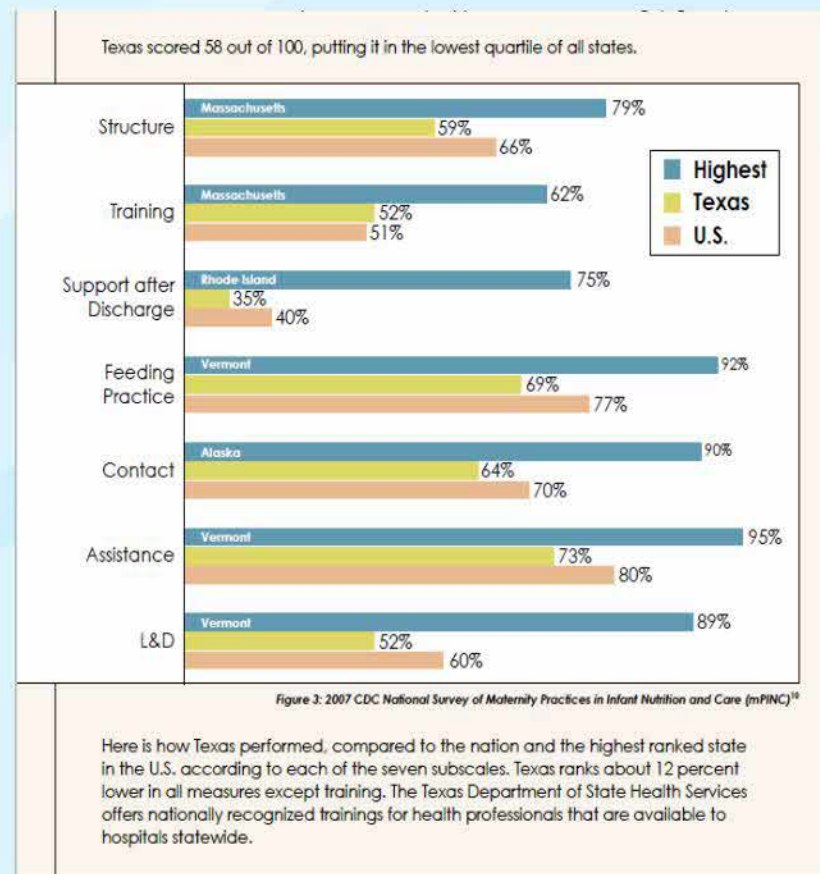
Sub-score, by state, 2015



Texas Ten Step: How Texas Hospitals Can Reduce Obesity Through Breastfeeding Policy

- Structure Sub-Score: 59 (2007) → 71 (2015)

- Model policy: 7% → 32%



2015 mPINC data availability

■ Hospital-specific Benchmark Reports

- Hard copies mailed to:
 - Hospital Administrator/CEO
 - Director of Obstetrics
 - Director of Pediatrics
 - Director of Quality Improvement
 - Mother-Baby Nurse Manager
 - Survey recipient
- Questions: mpinc@cdc.gov

■ State-specific Reports

- Emailed to state-level organizations and others
- Available: https://www.cdc.gov/breastfeeding/data/mpinc/state_reports.html

■ National Web Tables

- Available: <https://www.cdc.gov/breastfeeding/data/mpinc/results-tables.htm>

Conclusion

- **Hospital practices are improving**
 - Total and subscores increasing
- **Continued areas for improvement**
 - Staff Training
 - Structural and Organizational Aspects of Care
- **Future directions**
 - Completely revised questionnaire
 - Web only
 - Target 2018 launch

Maternity Practices in Infant Nutrition and Care Bench Mark Reports



National Center for Chronic Disease Prevention and Health Promotion
Division of Nutrition, Physical Activity, and Obesity

<http://bit.ly/2bgA14F>

For more information please contact: jmnelson@cdc.gov

1600 Clifton Road NE, Atlanta, GA 30333

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

National Center for Chronic Disease Prevention and Health Promotion

Division Nutrition, Physical Activity, and Obesity

Photo credit: <http://pediatric-house-calls.djmed.net/breastfeeding-human-milk/>



From: Li, Ruowei (Rosie) (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 11 Oct 2017 12:41:31 -0400
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO);Grossniklaus, Daurice (CDC/DDNID/NCCDPHP/DNPAO);Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO);Anstey, Erica Hesch (CDC/DDNID/NCCDPHP/DNPAO) (CTR);MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO);Flores-Ayala, Calixto Rafael (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: Online consultation for Implementation Guidance for the Baby-friendly Hospital Initiative
Attachments: Operationalization of the BFHI.pdf

WHO's new guidance for BFHI is now open for comments.

From: ESTEVEZ, Diana [mailto:estevezd@who.int]
Sent: Wednesday, October 11, 2017 6:15 PM
Cc: Grummer-Strawn, Laurence ; (b)(6) MURIEL, Jo-ann Rivera
Subject: Online consultation for Implementation Guidance for the Baby-friendly Hospital Initiative

Dear BFHI Congress 2016 participants,

It is an honor to share with you the Online consultation for Implementation Guidance for the Baby-friendly Hospital Initiative (BFHI) which is being conducted by WHO and UNICEF in order to solicit comments on revised guidance for the BFHI. The consultation is open from 11-24 October 2017.

This document, "**Protection, Promotion, and Support of Breastfeeding in Facilities Providing Maternity and Newborn Services: The Revised Baby-friendly Hospital Initiative 2017**" describes a revised set of the Ten Steps to Successful Breastfeeding and recommends strategies to implement the steps in all countries worldwide. Your comments will be taken into consideration in finalizing the document prior to publication and dissemination.

Interested parties are encouraged to provide comments on one or more of the five chapters of the document as well as overarching comments by completing the online form at:

<http://www.who.int/nutrition/events/consultation-protection-promotion-support-breastfeeding/en>.

Please send any questions on the online consultation process to nutrition@who.int.

If you know of others who would wish to comment on the document, please feel free to forward this email with the attachment and link. We thank you for your comments and suggestions to this draft.

Background

Since 1991, WHO and UNICEF have led the Baby-friendly Hospital Initiative (BFHI) to support maternity care facilities worldwide to improve the quality of care for infant feeding. Based on the Ten Steps to Successful Breastfeeding, the BFHI aims to protect, promote, and support breastfeeding in all facilities that provide maternity and newborn services, worldwide.

Almost all countries in the world have implemented the BFHI at some point in time. However, coverage within most countries has remained low. As of 2017, WHO estimated that only about 10% of babies in the world were born in a facility currently designated as Baby-friendly. Many countries have struggled to sustain the initiative over time.

WHO developed new guidelines on the Ten Steps in 2017 based on systematic evidence reviews on each of the steps. The guidelines were written by an external Guideline Development Group following standard WHO procedures. The guidelines are finalized and will be published in November 2017. These guidelines form the basis for the revised Ten Steps. To assist countries in assuring that all facilities adopt the revised Ten Steps in a sustainable way, WHO and UNICEF have developed revised guidance on implementing the Baby-friendly Hospital Initiative, with the aim to increase coverage and sustainability. WHO and UNICEF are inviting public to comment on the proposed new guidance.

Looking forward to your participation.

Best wishes,

Diana G. Estevez, MSc

Consultant | Department of Nutrition for Health and Development

World Health Organization | 20 Avenue Appia | CH1211 Geneva 27, Switzerland

email: estevezd@who.int | website: www.who.int/nutrition

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(b)(5)

(b)(5)

From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 11 May 2017 11:57:17 +0000
To: Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP)
Subject: FW: please provide input Rafa's presentation EMPower learning session
Attachments: EMPower learning session May 2017_draft.pptx
Importance: High

I haven't looked at these yet, but go ahead and see what you think.

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, May 10, 2017 12:12 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Subject: please provide input Rafa's presentation EMPower learning session
Importance: High

Carol and Cria,
Will you please review and see if you think the content is appropriate for Rafa's presentation on Tuesday for the EMPower learning collaborative? I don't know that the slides are necessary, but I am not sure of his presentation style. (b)(5)

Please let me know:
if you agree with the content – if not please offer suggestions
If you think that Rafa needs slides or can we give him a script that he can put in his own words?

If you think we need slides, I can try to find some images, but if you have suggestions, I will appreciate it

If we agree to use slides, I would like to submit them to Cynthia by noon on Monday so that they are ready for Tuesday morning.

Finally I wanted to give you a heads up, a Carol please share this info with Rafa, Cynthia and I have

(b)(5)

Cynthia wanted to give Carol and Rafa a heads up that Trish/ Lora Elston are going to talk about the BFUSA designation process and the new FMV guidelines in the opening session. Also, Trish mentioned that the Fed is Best folks were on the TV show "The Doctors" yesterday morning so we're watching to make sure this doesn't bubble up again. (b)(5)

(b)(5)

I am going to sign off now for the day, but if possible, please provide input so that I can finalize tomorrow.

Thanks,
Daurice

(b)(5)

(b)(5)

(b)(5)

(b)(5)

From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 10 May 2017 19:56:08 +0000
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Subject: FW: please provide input Rafa's presentation EMPower learning session
Attachments: EMPower learning session May 2017_draft.pptx
Importance: High

I will ask when we talk sometime Thursday – a question about the slides.

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, May 10, 2017 12:12 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Subject: please provide input Rafa's presentation EMPower learning session
Importance: High

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if you agree with the content – if not please offer suggestions
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(b)(6)

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(b)(6)

I am going to sign off now for the day, but if possible, please provide input so that I can finalize tomorrow.

Thanks,
Daurice

(b)(5)

(b)(5)

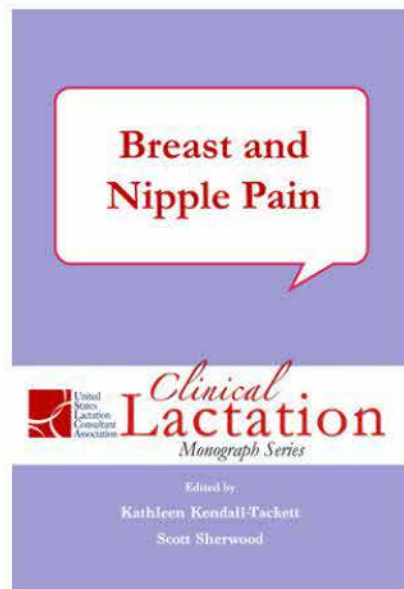
(b)(5)

(b)(5)

From: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Wed, 8 Nov 2017 11:35:22 -0500
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP); Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Cc: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Subject: FW: Praeclarus Press- Nipple Pain and Blog Post.

Just sharing this article – see link below.

From: Praeclarus Press [mailto:Praeclarus_Press@mail.vresp.com]
Sent: Tuesday, November 07, 2017 10:55 AM
To: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR)
Subject: Praeclarus Press- Nipple Pain and Blog Post.



Hey Everyone,

We hope you are doing well. The temperature is starting to drop and we've got our winter jackets out in Texas. Like last week, we are offering an issue from our *Clinical Lactation Monograph* series at half price. *Breast and Nipple Pain* is without a doubt one of our most popular titles to date. For one week, you can get it for **\$7.00 a copy**. Remember, bulk discounts still apply so if you have an event coming up or a library to stock, now is the time.

[Get your copy here.](#)

Also, we have a brand new article on Women's Health Today by our editor-in-chief, Kathleen Kendall-Tackett. The article is titled [***Lessons to Learn from Fed is Best.***](#) The article discusses what issues might be fueling anti-breastfeeding sentiment and what we can do to improve. Check it out [here.](#)

Have a lovely day.

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Amarillo, Texas 79114
US



[Read](#) the VerticalResponse marketing policy.



From: Li, Ruowei (Rosie) (CDC/DDNID/NCCDPHP)
Sent: Thu, 25 Oct 2018 09:28:47 -0400
To: Grossniklaus, Daurice (CDC/DDNID/NCCDPHP)
Subject: FW: Question for group on ROI
Attachments: image001.png

From: Jegier, Briana <jegierb@dyc.edu>
Sent: Wednesday, October 24, 2018 11:05 PM
To: Li, Ruowei (Rosie) (CDC/DDNID/NCCDPHP) <ril6@cdc.gov>
Cc: Perrine, Cria G. (CDC/DDNID/NCCDPHP) <hgk3@cdc.gov>; Grossniklaus, Daurice (CDC/DDNID/NCCDPHP) <dtg3@cdc.gov>; Nelson, Jennifer M. (CDC/DDNID/NCCDPHP) <zcn6@cdc.gov>
Subject: Re: Question for group on ROI

Dear Rosie,

Yes I can work on something for this to address the question.

Briana

Sent from my iPhone

On Oct 24, 2018, at 4:49 PM, Li, Ruowei (Rosie) (CDC/DDNID/NCCDPHP) <ril6@cdc.gov> wrote:

Hey Briana;

Please see the question below. Can you provide a brief update of your project that we can share with Becky?

Thanks and take care,

Rosie

From: Mannel, Rebecca L. (HSC) <Rebecca-Mannel@ouhsc.edu>
Sent: Wednesday, October 24, 2018 3:38 PM
To: Kahin, Sahra A. (CDC/DDNID/NCCDPHP) <xfz9@cdc.gov>
Cc: MacGowan, Carol (CDC/DDNID/NCCDPHP) <dvx2@cdc.gov>; Oklahoma Breastfeeding Resource Center (HSC) <OBRC@ouhsc.edu>
Subject: RE: Question for group on ROI

Hi Sahra, I'm checking in on the ROI conversation from last year. Any recent news from CDC on this report?

We have had 2 Oklahoma hospitals withdraw from their Baby-Friendly journey within the past year, one just let us know this week. Both were in Dissemination. Are you hearing this kind of issue from any other states? I'm concerned that our friends at Fed is Best are having some impact.

Thanks, Becky

Becky Mannel, MPH, IBCLC, FILCA
Director, Oklahoma Breastfeeding Resource Center
Clinical Assistant Professor, Department of OB/GYN
Adjunct Clinical Assistant Professor, Department of Pediatrics
University of Oklahoma Health Sciences Center
920 Stanton L Young Blvd, WP 2236
Oklahoma City, OK 73104
Rebecca-mannel@ouhsc.edu
www.ouhsc.edu/breastfeeding
Office: 405-271-4350
Fax: 405-271-8547
<image001.png>

From: CDC Breastfeeding Programs <CDC-BREASTFEEDING-PROGRAMS@LISTSERV.CDC.GOV>
On Behalf Of Kahin, Sahra A. (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, July 26, 2017 1:05 PM
To: CDC-BREASTFEEDING-PROGRAMS@LISTSERV.CDC.GOV
Subject: Re: Question for group on ROI

Good morning everyone,

Thanks for the recent in depth conversation regarding return on investment (ROI) for Baby-Friendly Hospital designation and identifying the need and value of a Business Case for Baby-Friendly Hospitals. I've shared parts of this conversation with our division leadership and parts have been shared with Trish MacEnroe at Baby-Friendly USA.

I wanted to share that CDC is currently working on a 2-year project which aims to build the evidence for the economic benefits of implementing the Baby-Friendly Hospital Initiative (BFHI) to support and promote breastfeeding. It will consist of a small series of case studies with a variety of US maternity care hospitals that are either Baby-Friendly designated or on the pathway to become designated. A report summarizing the overall health care cost savings per \$1 invested in BFHI across these case hospitals and the strategies used in the hospital with the—

lowest cost of implementing BFHI with the largest increase on breastfeeding rates will be produced

Feel free to email me with additional questions or comments (skahin@cdc.gov).

Thanks,
Sahra

From: Genevieve Colvin [REDACTED] (b)(6)
Sent: Tuesday, July 25, 2017 11:47 AM
To: CDC Breastfeeding Programs <CDC-BREASTFEEDING-PROGRAMS@LISTSERV.CDC.GOV>
Cc: Kahin, Sahra A. (CDC/ONDIEH/NCCDPHP) <xfz9@cdc.gov>
Subject: RE: Question for group on ROI

So in looking at this excellent NY strategy – there are still substantial missing pieces. JC during the stay is not a good measure of health care support for breastfeeding. It is a snapshot in time. The recent ARHQ report on breastfeeding defines that it is a multi-modal approach across the lifespan of a pregnancy, childbirth and postpartum period that moves the needle on breastfeeding success.

The VBP arrangement still does not adequately account for the need for better prenatal assessments/education/interventions and TIMELY postpartum follow up for breastfeeding newborns. Where is the measure set for Ex. Breastfeeding at 30 days PP?

Part of the problem is that NCQA only has TWO HEDIS measures for Maternal care– Was the mother seen in the first trimester and was the mother seen for post partum f/u within 6 weeks of delivery. For the infant there is one measure, which is like 8 or 10 visits in the first 2 years of life of the infant, plus a bunch on vaccination. Right now – we measure what is the most costly upfront to the health care system, not what reduces costs over time.

If you want to move the needle on ex. Breastfeeding, then make the Payers (health plans or NCQA) be measured by the breastfeeding outcomes, which will then cause the providers who are paid by the payers to change practice.

From: CDC Breastfeeding Programs [<mailto:CDC-BREASTFEEDING-PROGRAMS@LISTSERV.CDC.GOV>] **On Behalf Of** Sherry, Cherylee (MDH)
Sent: Monday, July 24, 2017 3:46 PM
To: CDC-BREASTFEEDING-PROGRAMS@LISTSERV.CDC.GOV
Subject: Re: Question for group on ROI

Greetings,

Part of the discussion I have read has been on “fee-for-service” reimbursement and a transition is occurring- the reimbursement is moving from fee-for-service to value-based care. Another

thought could be that CDC and/or BFUSA work with states and CMS to ensure that Breastfeeding quality of care measures are part of a maternity measure set for Medicaid and other health plan shared saving arrangements. This would mean that in order to get full reimbursement, the hospitals and/or clinics would have to achieve these measures for reimbursement or shared savings.

An example is New York State who has a breastfeeding measure in their measure set. CDC could offer a webinar on the reimbursement transition, steps for states, and NYS case study about how to get a breastfeeding measure into the measure set (if it hasn't already been offered). I have attached a recent fact sheet from New York State's Department of Health: Maternity Care Value Based Payment Arrangement. *This fact sheet has been prepared to assist payers and providers to more thoroughly understand New York State Medicaid's Maternity Care Value Based Payment (VBP) Arrangement. It provides an overview of the Arrangement including a summary of the components of care, the underlying episodes of care, and the recommended quality measures.* You will notice that in the appendix on page 12, they do have a Pay for Performance (P4P) measure- Percentage of Babies Who Were Exclusively Fed with Breast Milk During Stay. The Joint Commission is the steward of this measure and it is an NQF measure so it has been thoroughly vetted. In Minnesota, this same measure is part of the MN Medicaid Child Core Set Measures.

If the hospital has already added up the costs- training, supplies, direct patient education and counseling, etc, then that information should be shared with the whoever is negotiating the P4P or shared savings arrangement on behalf of the hospital so that there is enough \$\$\$ available to support breastfeeding support activities.

An example of a Value-Base P4P without a breastfeeding measure is Integrated Healthcare in California http://www.iha.org/sites/default/files/resources/my_2017_measure_set.pdf Even California's Medicaid Core Measure Set and Supplemental Measure Set does not have a breastfeeding measure <http://www.iha.org/sites/default/files/files/page/supplemental-measure-set.pdf>

In addition, CDC and BFUSA could advocate for exclusive breastfeeding measure(s) after hospital stay and it could be part of a Pay for Performance incentive. More advocacy is needed and those who support breastfeeding may want to go through the process to get on a measure set advisory group in their state if there is one. -cherylee

Cherylee Sherry, MPH, MCHES®

Healthy Systems Supervisor | OSHII, Healthy Systems Unit

Minnesota Department of Health

Office: 651-201-3769

From: CDC Breastfeeding Programs [<mailto:CDC-BREASTFEEDING-PROGRAMS@LISTSERV.CDC.GOV>] **On Behalf Of** Lea Minton

Sent: Monday, July 24, 2017 1:08 PM

To: CDC-BREASTFEEDING-PROGRAMS@LISTSERV.CDC.GOV

Subject: Re: Question for group on ROI

Hi Sahra and group,

Yes I agree we need a business case for Baby Friendly Hospitals.

I know at ours that it's a loss. We aren't able to get reimbursed for the lactation visits while they are in-patient so it's added staff, and in situations where the mom goes home and the baby is in our nursery we can't bill for the lactation services provided to the infant because we were told "you can't bill for education to an infant, they don't receive education."

Further, all the supplies we have - more breast pumps, kits, dish soap, hydrogels, syringes, nipple shields, SNS systems- none of that is provided at a charge to the patient; it's not scanned. The formula we buy at market value is not charged either of course because that's "food", so it's not scanned. Whereas hospitals who get formula for free aren't taking that hit and they generally don't have the staffing and supplies that Baby Friendly do -or at least to the same level.

Plus the purchasing of supplies like Medications and Mothers' Milk textbook q 2 years and all the extra printing/xeroxing we have to have to provide patients, along with the additional training hours time of our entire hospital staff. Then the annual fees for maintaining your certification plus the hours for annual audits, etc.

We are proud to be a Baby Friendly hospital, but I hear all the time about how much it costs us. And I don't think it's right that there isn't a financial guide for making it work. Much less a look at truly what the costs can be on a hospital.

Last, there's the issue to address of papers that have come out saying Baby Friendly hospitals may not be so Baby Friendly when we look at outcomes. In reading these my take on it is that there is a lack of a standard of specific training practices that need to be in place for staff who are going Baby Friendly. This also results in increased costs. For example- not all of our IBCLC staff were trained in oral exams and ability to assess tongue function for tight labial or lingual frenulums. So depending on who was on for the day a dyad may or may not be at increased risk for breastfeeding success and the baby may be at increased risk for significant weight loss and readmission for hyperbilirubinemia, while putting the mom at increased risk for depression. Also if the staff doesn't know the S&S to alert the IBCLC, it may either be missed, OR as often happens both the RN and the Peds given conflicting info from the IBCLC and we end up with a worse issue than intended.

It's not just a staff training financial issue, it's a loss to the hospital financially as well because we don't get reimbursed for re-admissions after discharge for our babies and moms (sometimes coming back for surgery for breast abscesses).

The financial impact is extensive in my opinion and has been grossly neglected. It's good business for BFUSA but that has not specifically been reciprocated with the hospitals. I don't disagree it's the right thing to do; and since it is I think the right thing for the company making money off of these mandates is to ensure the livelihood of their clients (hospitals & birth centers).

Thank you,
Le'a

Sent with Aloha:)

On Jul 24, 2017, at 6:43 AM, Brenda Bandy <(b)(6)> wrote:

Attached is the only research on this topic of which I am aware. It found *"the incremental institutional impact [of Baby-Friendly] on costs per delivery is somewhere between 2.3% and 3.7% in the initial year, but decreases to just over 1.2% (most likely case) in year 5."* The analysis is old (2009) and uses the old BFUSA "steps" rather than the "D-phases". This analysis, or one like it, needs to be updated.

I agree – we need a *"Business Case for Baby-Friendly Hospitals"* to share with hospitals. I have suggested this to BFUSA and they are interested in providing advocates with the tools they need to support BFHI.

Brenda Bandy, IBCLC
Executive Director
Kansas Breastfeeding Coalition
3005 Cherry Hill, Manhattan, KS 66503
(b)(6)

Twitter: @KSBreastfeeding
www.facebook.com/ksbreastfeeding
www.KSBreastfeeding.org

Join our work to create a landscape of breastfeeding support across Kansas: <http://ksbreastfeeding.org/join/>

From: CDC Breastfeeding Programs [<mailto:CDC-BREASTFEEDING-PROGRAMS@LISTSERV.CDC.GOV>] **On Behalf Of** Kahin, Sahra A. (CDC/ONDIEH/NCCDPHP)
Sent: Monday, July 24, 2017 11:28 AM
To: CDC-BREASTFEEDING-PROGRAMS@LISTSERV.CDC.GOV
Subject: Question for group on ROI

Hey everyone,

Happy Monday. Question for the listserv from a state. Please reply to the group if you have any experience on this topic:

As we work to promote the Baby Friendly Hospital designation, we are often asked by hospitals about Return on Investment (ROI) for becoming Baby Friendly. I have done research online and haven't come up with much. I don't know if other states encounter this question or if it would make a good topic for a webinar, just something that I would like to be able to answer better.

(When replying to this post, you will be prompted to confirm your message. Simply reply with an "OK" and leave the rest of the email blank- your message will be sent to the group).

Sahra A. Kahin, MA, MPH
Health Scientist
Program Development and Evaluation Branch
Division of Nutrition, Physical Activity and Obesity
Centers for Disease Control and Prevention
4770 Buford Hwy, NE
MS F-77
Atlanta, GA 30341
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<Baby_Friendly_Cost_Analysis.pdf>

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From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 28 Feb 2017 11:47:13 -0500
To: Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP); Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Subject: FW: References

FYI.....

From: Arlene Toole (b)(6)
Sent: Tuesday, February 28, 2017 11:12 AM
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>
Subject: RE: References

Dr. Nelson,
Our meeting will be tomorrow, Wednesday, March 1 @ 8:00am.
The call in number is (b)(6) and the passcode is (b)(6)

These are the comments made by Dr. Fitzgerald and some of our members:

1. It is more difficult to examine the baby in the mother's room due to insufficient lighting. Some discoloration of the skin might be missed.
2. Pacifiers help to calm the baby when certain procedures are being done and we need to calm the baby to assist with a more accurate test.
3. Hospitals are not able to accept free formula for the babies that are not breastfed.
4. Many of the smaller hospitals do not wish to become Baby Friendly because of the additional cost involved in purchasing this formula or formula supplies.
5. High cost to the hospital of applying to Baby Friendly.

Talk to you tomorrow!
Arlene

From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) [<mailto:zcn6@cdc.gov>]
Sent: Tuesday, February 28, 2017 11:09 AM
To: Arlene Toole (b)(6)
Subject: RE: References

Yes, please send to this one. Thanks, Jennifer

From: Arlene Toole (b)(6)
Sent: Tuesday, February 28, 2017 11:07 AM
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>
Subject: RE: References

Thanks, I have the one from the JHL. I emailed Ngozi to see if she could get the other one.

Did you get my earlier email? I sent it to your yahoo email. Do you want me to send it to this one?
Arlene.

From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) [<mailto:zcn6@cdc.gov>]

Sent: Tuesday, February 28, 2017 10:35 AM

To: Arlene Toole <(b)(6)>

Subject: References

Hey Arlene,

Please find the reference that I mentioned below. I'm sure there are probably others.

Eganhouse, DJ, et al. Becoming Baby-Friendly and Transforming Maternity Care in a Safety-Net Hospital on the Texas-Mexico Border. Nurs Womens Health. 2016;20(4):378-90.

Bartick, M, et al. The Massachusetts Baby-Friendly Collaborative: Lessons Learned From an Innovation to Foster Implementation of Best Practices. J Hum Lact. 2010;26(4):405-11.

Sincerely, Jennifer

Jennifer M. Nelson, MD, MPH, FAAP
LCDR, U.S. Public Health Service
Infant Feeding Team/Nutrition Branch/CDC

From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 30 Nov 2017 20:14:13 +0000
To: Murphy, Paulette (CDC/ONDIEH/NCCDPHP)
Subject: FW: Request to JAMA Peds

May want to be in the loop on this one. You should take a look at what Melissa Bartick wrote as well (link is below). There will be another one coming soon, from Rafael Perez-Escamilla.

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, November 30, 2017 3:06 PM
To: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>; Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfi2@cdc.gov>; Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP) <rnf2@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>; Olson, Christine (CDC/ONDIEH/NCCDPHP) <cco7@cdc.gov>; Cox, Shanna (CDC/ONDIEH/NCCDPHP) <cio8@cdc.gov>; Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>
Subject: FW: Request to JAMA Peds

FYI

From: Trish MacEnroe (b)(6)
Sent: Thursday, November 30, 2017 2:57 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: FW: Request to JAMA Peds

Hi Cria,

FYI – I just sent this to JAMA-Peds. Just wanted to keep you in the loop.
Trish

From: Trish MacEnroe (b)(6)
Sent: Thursday, November 30, 2017 2:31 PM
To: 'Frederick Rivara' <fpr@uw.edu>
Subject: Request to JAMA Peds

Frederick P. Rivara, MD, MPH
Editor
JAMA-Pediatrics

Dear Dr. Rivara,

New information has come to light demonstrating that the authors of an article published by JAMA-Pediatrics (on-line August 2016) knowingly misrepresented the data they used to support their viewpoint. This, along with the fact that one of the authors, Ronald Kleinman, MD, was subsequently discovered to have an undisclosed conflict of interest, now compels us to request you to withdraw the article titled [“Unintended Consequences of Current Breastfeeding Initiatives,”](#) [1] and rebuke the authors. We also request that you publish the work of Melissa Bartick, MD that illustrates the manner in

which the authors misused the data. (https://www.huffingtonpost.com/entry/influential-article-against-baby-friendly-is-based_us_5a199e42e4b0bf1467a846cb)

In their article, Joel Bass, MD and colleagues take aim at the safety of the Baby-Friendly Hospital Initiative (BFHI). Their speculations and misuse of the data to build their arguments is unconscionable. The article has done significant harm. It triggered a firestorm of on-line articles with sensational headlines geared towards frightening practitioners and families away from the BFHI. I am sad to report that, subsequently, we have had a number of hospitals withdraw from the program.

The BFHI is a vital resource for our nation to meet some of its most important health goals; increasing the initiation, duration and exclusivity of breastfeeding. As you know, the evidence is solid; breastfeeding confers significant health benefits to both the mother and infant and the more of the *Ten Steps to Successful Breastfeeding* (the basis of the BFHI) experienced by a mother, the more likely she is to reach her breastfeeding goals [2].

Baby-Friendly USA appreciates honest, transparent discussions regarding the impacts of the BFHI. Our intent is for all patients to receive the best possible, evidence-based care delivered safely and in a culturally sensitive manner. Inputs on ways we can improve are always welcome. However, we cannot tolerate speculation and assertions of harm made on incorrect interpretation of data, most especially, when it is intentional. Since it is your vision to be "the most respected source of information for investigators, providers, and policy makers seeking the highest-quality evidence to guide decision making", we are counting on you to honor our request.

Thank you for your consideration.

Sincerely,

Trish MacEnroe
Executive Director

References

- [1 J. Bass, T. Gartley and R. Kleinman, "Unintended Consequences of Current Breastfeeding Initiatives,"] *JAMA Pediatrics*, 2016.
- [2 R. Pérez-Escamilla, J. Martinez and S. Segura-Pérez, "Impact of the Baby-friendly Hospital Initiative] on Breastfeeding and Child Health Outcomes: A Systematic Review. doi: /mcn.12294.," *Maternal Child Nutrition*, 2016.

Trish MacEnroe
Executive Director
Baby-Friendly USA, Inc.
125 Wolf Rd., Suite 402
Albany, NY 12205

(b)(6) (p)

(b)(6) (f)
www.babyfriendlyusa.org

From: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Thu, 24 Jun 2021 20:08:16 +0000
To: Boundy, Ellen (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: Research Connection
Attachments: BFM-2021-0050.R2_Proof_fl.pdf

Do you want to follow-up with her? I'm assuming the "minor tweaks" are referring to (b)(5)
(b)(5)

Of note, she's published on the mPINC data before.

From: Julie Patterson (b)(6)
Sent: Thursday, June 24, 2021 1:15 PM
To: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO) <zcn6@cdc.gov>
Subject: Research Connection

Hello Dr. Nelson,

I hope that you are doing well! I wanted to reach out as it seems like our research interests seem to align. I wanted share my latest research publication with you on differences in exclusive breastfeeding and access to BFHI hospitals across geographic locations identified as low, medium and highly deprived using the Area deprivation Index. I can only share the author accepted version. The published version can be found online https://www.liebertpub.com/doi/10.1089/bfm.2021.0050?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

I also have some ideas/thoughts on how we could strengthen our ability to understand the impact of maternity care practices on EBF rates with minor tweaks to the current survey mechanisms. The suggestions I have may have already been considered by the CDC, but I thought it might be worth sharing in the event that they have not been discussed.

If you ever have time to connect about our mutual research interests and/or if you see potential for a research collaboration, please let me know.

Thank you again for all you do!

Take care,

Julie

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Title: Differences in Exclusive Breastfeeding Rates in US hospitals according to Baby-Friendly
Hospital Initiative designation and Area Deprivation Index category

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Abstract:

Background: Disparities in breastfeeding persist placing a greater burden of disease on non-Hispanic Black and Hispanic women and infants. Targeted implementation of the Baby-Friendly Hospital Initiative (BFHI) in areas at risk for poor breastfeeding outcomes has been shown to improve disparities in breastfeeding. The Area Deprivation Index (ADI), a measure of the relative socioeconomic disadvantage of a neighborhood, may be useful in exploring the accessibility of BFHI hospitals in highly deprived areas and the differences in Exclusive Breastfeeding Rates (EBF) in hospitals with and without the BFHI designation across deprivation categories.

Objective: To evaluate the geographical distribution of BFHI and non-BFHI hospitals across ADI categories and explore the differences in EBF rates in BFHI and non-BFHI hospitals across ADI categories.

Methods: Hospital EBF rates obtained from the Joint Commission included 414 BFHI and 1,532 non-BFHI hospitals. State ADI rank scores were determined for each hospital's census block group. Descriptive statistics were used to describe the geographic distribution of BFHI hospitals across three ADI categories (low, medium, and high). EBF rates across ADI categories and BFHI designations were compared using multi-way ANOVA.

Results: The distribution of BFHI was similar across all ADI categories, ranging from 18 to 24%. EBF rates were 4.9% lower in highly deprived areas compared to areas with lower deprivation ($p < 0.01$). BFHI was associated with significantly higher EBF rates across all ADI categories (6.9%-11.2%, $p < 0.01$)

Conclusion: ADI may be a useful tool for targeting the implementation of BFHI in hospitals in highly deprived areas to reduce breastfeeding disparities.

Article:

Introduction:

Equitable access to evidence-based breastfeeding support practices is an urgent public health issue and valuable investment in the health of a nation.¹ In addition to the enormous benefits of breastfeeding for the infant, there are significant maternal health and economic benefits of breastfeeding.^{2,3} However, disparities in breastfeeding rates limit how much those benefits are

extended across all women and infants.⁴ This is concerning, as exclusively breastfeeding for less than 6 months, is associated with a greater burden of morbidity and mortality among non-Hispanic Black and Hispanic populations compared to the non-Hispanic white population.⁴ Ensuring infants have access to a form of nutrition that reduces the risk of morbidity and mortality should be a basic human right.⁵ Unfortunately barriers to breastfeeding, such as those identified in the health care setting,⁶ prevent the benefits of breastmilk and breastfeeding from being fully realized. Ensuring that breastfeeding protection, promotion and support reaches vulnerable populations is essential to improve health equity. Such efforts require an understanding of which types of interventions and delivery mechanisms are best suited to meet the needs of minority and low-income populations.⁷

To address inequities in breastfeeding outcomes, ecological frameworks such as the Community Energy Balance (CEB) framework are valuable for identifying cultural and contextual influences that enable women to engage in the practice of breastfeeding.⁸ A goal within this framework is to intervene in the environment with community level approaches, such as policies and procedures, to improve health outcomes.⁸ Engagement in health behaviors, such as breastfeeding, are influenced by historical experiences, racial and ethnic demographic characteristics, and structural and sociocultural influences.⁸ According to Centers for Disease Control and Prevention (CDC) data on babies born in the United States between 2010 and 2017, “exclusive” breastfeeding (EBF) and “any” breastfeeding (ABF) are lower for mothers who have low income, are unmarried, or have lower educational attainment.⁹ While there has been a positive increase in breastfeeding rates across all racial and ethnic groups during this timeframe, EBF rates continue to be higher for the non-Hispanic white and Asian populations compared to the African American and Hispanic populations.⁹

Hospitals offer an opportunity to improve breastfeeding outcomes in the communities they serve through implementation of strong breastfeeding policies and procedures. The Baby-Friendly Hospital Initiative (BFHI), which is based on implementation of the *Ten Steps to Successful Breastfeeding*¹⁰ and compliance with the *International Code of Marketing of Breast-Milk Substitutes*¹¹, improves breastfeeding support in the hospital and community setting and, in turn, has been well established as positively impacting EBF rates and ABF duration after hospital discharge.¹² Recent studies in the US found implementation of the BFHI increased breastfeeding initiation and exclusivity,^{13,14} and reduced racial inequities in breastfeeding outcomes in the

hospital.¹⁴ A study by Jung et al. found participants in the Women Infant and Children (WIC) program had increased odds of ABF and EBF at 1 and 3 months when mothers were exposed to two or more BFHI practices.¹⁵ In addition, significant increases in ABF and EBF over time in this population corresponded with a significant increase in the number of BFHI hospitals or hospitals in the BFHI pathway within a large metropolitan area.¹⁵ Another study found for every one unit increase in WIC participants perception of exposure to the *Ten Steps to Successful Breastfeeding* was associated with a 43% increase in the odds of EBF upon discharge.¹⁶ Research on a dose-response relationship between the number of BFHI practices mothers experience and breastfeeding duration, suggests the need for strong implementation of BFHI practices.¹⁷ However, in a recent ecological analysis of state-level data, Bass and colleagues (2020) found that “Baby-Friendly hospital penetrance” at the state level was not associated with state-wide breastfeeding outcomes.¹⁸ Therefore, a need exists to explore hospital level data on national scale in the US that takes into account community attributes, such as socio-economic indicators- to evaluate the relationship between BFHI and EBF.

According to data from Baby-Friendly USA, the US national authority and accrediting body on the BFHI program,¹⁹ there has been a 211% increase in the number of BFHI designated hospitals in the last 5 years.²⁰ While commendable, it is unknown whether this increase changed the availability of BFHI hospitals in communities that serve individuals who are at higher risk for poor breastfeeding outcomes. Evaluating availability of BFHI hospitals in neighborhoods with limited resources and examining differences in EBF rates between BFHI and non-BFHI hospitals may be a useful strategy to focus efforts in these areas that will most efficiently reduce disparities in breastfeeding rates.

One strategy for exploring mothers’ access to BFHI hospitals in low resource areas is to use the Area Deprivation Index (ADI). The ADI was developed by clustering 17 socioeconomic census block group variables from the American Community Survey together.²¹ The elements included in the ADI score are educational attainment of the population, employment status, housing-quality, family income, access to transportation and poverty indicators.²² Recently, the ADI for census block groups became publicly available through the Neighborhood Atlas.^{23,24} The Neighborhood Atlas was developed by the University of Wisconsin and these data are updated annually with the release of the five-year American Community Survey data.²⁴ Internal validation is conducted evaluating the loadings generated by the new data, as well as the

geographic output to evaluate stability over time. Studies that have used ADI found that individuals living in areas with a higher deprivation index have poor health outcomes.^{22,25} With respect to EBF outcomes, a higher neighborhood disadvantage index has been associated with lower EBF rates specifically among the Black, Hispanic and Asian populations.²⁶ Using ADI in research can help identify population needs in a given health care community.^{25,27} Additionally, ADI has been used to evaluate the availability of evidence-based interventions across areas with low to high ADI scores.²⁸ The CDC has shown the use of zip-code level data as a valuable tool for exploring the availability of hospitals with high engagement in maternity care practices that support breastfeeding in underserved communities.²⁹ The Neighborhood Atlas allows researchers to explore zip code data in a more meaningful way, as it includes a broader range of socioeconomic variables important to address health inequities. Utilizing the ADI to target evidence-based interventions in areas at risk for poor breastfeeding outcomes may be a promising and important strategy to improve breastfeeding outcomes.

Objective:

The objective of this study was to (1) evaluate the geographical distribution of BFHI and non-BFHI hospitals across ADI categories and (2) explore the differences in EBF rates in BFHI and non-BFHI hospitals across all ADI categories.

Methods:

The data for this study were obtained from three sources: (1) the Joint Commission;³⁰ (2) the Neighborhood Atlas® ADI State Rank Data;²⁴ and (3) Baby-Friendly USA.²⁰ The Joint Commission, a leading hospital accreditation agency, collects data on hospitals EBF rates as part of the Perinatal Care Exclusive Breastfeeding standard (PC-05) for the hospitals they certify. In 2016, this standard was revised, which increased the number of hospitals reporting their EBF rates within this hospital performance data set.³¹ These publicly available data are reported as an aggregated “Exclusive Breast Milk Feeding” rate from a sample of eligible infants within the hospital population and expressed as a proportion.³² The Joint Commission defined EBF as “a newborn receiving only breast milk and no other liquid or solids except for drops or syrups consisting of vitamins, minerals or medicines.”³² Data extracted on EBF rates from the Joint Commission was from July 1, 2018 - June 30, 2019.³⁰ This sample excluded infants: (a) admitted into the Neonatal Intensive Care Unit (NICU), (b) diagnosed with galactosemia, (c) requiring parenteral nutrition, (d) died, (e) had a hospital stay greater than 120 days, (f) were transferred to

another hospital, or (g) were not term or with < 37 weeks' gestation completed.³² Data extracted from the Joint Commission Data Mart included EBF rates for 1,946 hospitals located across all US states and territories.³⁰ Cross-sectional data on hospitals' BFHI status was obtained from Baby-Friendly USA at two time points: April 1, 2014, and March 10, 2020.²⁰ On April 1, 2014, there were 172 BFHI designated hospitals in the US, of which 170 were matched by address to the Joint Commission data set. As of March 10, 2020, there were 605 BFHI designated hospitals in the US, of which 414 hospitals were matched to the Joint Commission data set. Using these cross-sectional time points, the following four categories were created: (1) hospitals that were BFHI for ≤ 5 years, (2) hospitals that were BFHI for > 5 years, (3) hospitals that lost their BFHI designation in the last 5 years, and (4) hospitals that never had BFHI designation. Hospitals were categorized based on the number of days they had been designated BFHI since March 10, 2020. Hospitals who had been BFHI for ≤ 1825 days were defined as "BFHI hospital for ≤ 5 years." Hospitals who held their designation for > 1825 days were defined as "BFHI hospital for > 5 years." Hospitals that had been recognized as having their BFHI designation according to cross sectional data obtained from Baby-Friendly USA on April 1, 2014 but not recognized as BFHI designated per Baby-Friendly USA as of March 10, 2020 were defined as "Hospitals that lost BFHI designation in last 5 years." Finally, hospitals that were not recognized as having BFHI designation as of March 10, 2020 were defined as "Hospitals never designated BFHI."

The ADI is based on 17 data elements from the 2011-2015 American Community Survey used to create a socioeconomic indicator for the neighborhood surrounding each hospital.²¹ The neighborhood surrounding the hospital was used as a proxy for the population of patients served by each hospital. While many factors influence patients' use of health services, research has shown individuals with low income and those who identify as Black and Hispanic are more likely to give birth at their local hospital.³³ This may be related to transportation limitations reported as a barrier to prenatal care among this population,³⁴ which suggests the need to utilize health care services closest to home. The State ADI rank values were determined for each hospital's census block group.²⁴ Of the 1946 hospitals in the data set, the ADI was applied to 1,820 hospitals. There were 126 hospitals that did not have an ADI due to missing data necessary to calculate the ADI rank value. The State ADI rank represents deciles from 1 to 10 for each individual state, with 1 representing the lowest level of deprivation and 10 representing the most deprivation in the state.²⁴ Research has established that individuals living in neighborhoods with

an ADI above 8 experience the most deprivation, which has been linked to adverse health outcomes.²¹ Therefore, we defined ADI categories 8, 9 and 10 as “high deprivation,” then equally split the remaining 7 categories into “low deprivation” (ADI state rank value 1-3) and “medium deprivation” (ADI state rank value 4-7). We explored different groupings of ADI rank values into categories, but results were fundamentally equivalent regardless of grouping (data not shown). To explore differences in EBF rates across ADI categories, hospitals’ BFHI status as of March 10, 2020 (BFHI or non-BFHI), according to Baby-Friendly, USA²⁰ was used.

This study was certified as not human subjects research by Northern Illinois University institutional review board.

Statistical Analysis:

Using hospital locations, a nation-wide map was generated that indicated State ADI rank category and BFHI status. A cross-tabulated summary table was created, breaking down hospitals according to ADI rank category and BFHI categories. A multi-way ANOVA model was fit with EBF rate as the response that included effects for State ADI rank categories, BFHI designation, and their interaction. Pairwise comparisons of means were made via the Tukey multiple comparisons method. The ANOVA model was fit and checked graphically for adherence to the necessary assumptions. Normality of the residuals was checked using a normal Q-Q plot, and constant variance and model fit were checked using a residuals versus fitted value plot. Both assumptions were found to be adequately met. Data analysis was performed using the R statistical package (version 3.6.1), using RStudio Software (version 1.2.5001) as an interface.

Results:

The distribution of BFHI and non-BFHI hospitals across the continental US by State ADI categories are displayed in Figure 1. BFHI hospitals are located in all US states and territories; however, BFHI hospitals located in Hawaii and Alaska and the US territories were not displayed. BFHI and non-BFHI hospitals are concentrated in geographic areas with higher population densities, such as the East Coast and California. Figure 2 displays a closer view of BFHI and non-BFHI hospitals across ADI categories in California, Ohio and the Southeast region of the US. There are 204 hospitals in California included in our data set, of which 81 (40%) are BFHI. Of the 73 hospitals located in high ADI areas in California, 31 (42%) are BFHI. There are 71

hospitals in Ohio that are included in our data set, 12 (17%) are BFHI. Among the 26 hospitals located in high ADI areas in Ohio, 3 (12%) are BFHI.

Of the 414 BFHI hospitals in the data set, 273 (65.9%) achieved their BFHI designation in the last 5 years. Table 1 describes cross-sectional data representing the distribution of BFHI and non-BFHI hospitals and the change in their designation over the last 5 years across socioeconomic areas categorized as low, medium and highly deprived using the State ADI rank value. BFHI hospitals with a state rank ADI value ($n=377$) were distributed approximately equally across low (24.0%), medium (18.3%) and highly (20.6%) deprived areas. Of the hospitals with an ADI value that were BFHI for ≤ 5 years ($n=247$), 35.6% were in low deprivation areas, 33.6% were in medium deprivation areas, and 30.7% were in highly deprived areas. While there was an overall net increase in BFHI hospitals in the last 5 years, it is important to note that 28 hospitals lost their BFHI designation within this period of time.

Table 2 summarizes the estimated mean EBF rate in BFHI and non-BFHI hospitals across state ADI categories. The mean EBF rate in non-BFHI hospitals was 4.9% higher in low deprivation areas compared to high deprivation areas ($p<0.001$). In BFHI hospitals, the EBF rates were 5.5% higher in low deprivation areas compared to high deprivation areas, although this was not statistically significant, likely due to small sample sizes ($p=0.1351$). EBF rates across all ADI categories were 6.9% ($p<0.01$) to 11.2% ($p<0.001$) higher in BFHI hospitals compared to non-BFHI hospitals.

Discussion:

To the authors' knowledge, this is the first study to evaluate the distribution of BFHI hospitals and non-BFHI hospitals across the US in areas identified as low, medium and highly deprived using the State ADI. In 2001, a study by Merewood et al. evaluated the geographic location of the BFHI designated hospitals across the US.³⁵ At that time there was a total of 32 BFHI designated hospital, located predominantly in the Pacific region. Since then the number of BFHI hospitals in the US has grown substantially, especially over the last five years.²⁰ This study found the distribution of hospitals serving populations characterized as low, medium and highly deprived was about equal, with 20.6% of BFHI hospitals serving highly deprived populations. Increasing mothers access to BFHI hospitals may be an important public health strategy to address disparities in breastfeeding outcomes.³⁶ To scale up BFHI hospitals in the US, the

Becoming Baby Friendly toolbox has been developed.³⁷ The Becoming Baby Friendly toolkit includes an index to assess national readiness to scale up breastfeeding programs and provides an evidence-based approach to improve EBF rates nationally.³⁷

When evaluating the change in the number of BFHI hospitals across ADI categories between April 2014 and March 2020, the percent change in BFHI hospitals was slightly greater in hospitals serving low and medium deprivation areas (a 231% increase and a 197% increase, respectively) compared to hospitals serving highly deprived populations (a 152% increase). This may be due to persistent obstacles in implementing BFHI in hospitals serving high risk populations.³⁸ Despite this, several examples of hospitals and programs that have been able to overcome these challenges exist, providing evidence that increased implementation of BFHI in hospitals located in high deprivation areas is feasible.^{13,14,39,40} For example, a collaboration between key public health organizations, a large insurance provider, community stakeholders and hospitals located in a region with historically low breastfeeding were successful at increasing the number of BFHI hospitals that area.¹⁴ Another positive example was the use of a systemwide approach to facilitating the implementation of BFHI in 13 federal hospitals that serve disadvantaged impoverished populations with a high medical need.⁴¹ This study demonstrated a 100% success rate in helping hospitals achieve BFHI status.⁴¹ Other facilitators that could be considered as helping increase the number of BFHI hospitals include evidence-based policies and practices and increased mandates from hospital accreditation agencies, like the Joint Commission.⁴² Data on the number of BFHI hospitals in California, specifically those hospitals in high deprivation areas, may reflect the benefit of state legislation that requires birthing hospitals adopt BFHI or an evidence-based alternative by 2025.⁴³

While there has been a marked increase in the number of BFHI hospitals in the last 5 years, 28 hospitals in our dataset had lost their BFHI designation. BFHI hospitals maintain their accreditation with Baby-Friendly USA over a 5-year period.¹⁹ Within the 5-year accreditation period, hospitals complete annual quality improvement measures in years 1-3, followed by a re-designation phase in years 4-5, and finally, an on-site assessment.¹⁹ Given this strong sustainability model, implementation research on why certain hospitals have been unsuccessful in maintaining their designation should be explored to prevent hospitals from losing their BFHI designation status.

With respect to exploring differences in EBF rates across ADI categories, this study revealed that EBF rates decreased as the level of deprivation increased for both BFHI and non-BFHI hospitals. This is consistent with the Centers for Disease Control and Prevention data that indicate lower breastfeeding rates among women with lower socioeconomic status.⁹ Patterson et al. also found that EBF rates in BFHI and non-BFHI hospitals were negatively associated with individuals who had lower educational attainment, those who experienced poverty, and those who identified as African American or Hispanic,⁴⁴ demographics that are more prevalent in high deprivation areas.⁴⁵ The benefit of BFHI was relatively consistent across all demographic groups studied.⁴⁶

This study also revealed that the mean EBF rates across all State ADI categories were higher in BFHI hospitals compared to non-BFHI hospitals, indicating that BFHI benefited mothers' EBF rates regardless of ADI categories. Similarly, a separate study found EBF rates were higher in BFHI hospitals compared to non-BFHI hospitals regardless of race/ethnicity, educational attainment, or income.⁴⁴ Compliance with BFHI practices has been shown to decrease racial and/or ethnic inequalities with breastfeeding initiation and EBF rates.¹⁴ In addition, targeted implementation of BFHI in geographic areas with historically low breastfeeding rates positively impacted EBF rates and improved access to high quality breastfeeding care by increasing the number of BFHI hospitals in a given region.^{13,14}

A major strength of our study is that it provides a clear illustration of the call to action described by Perez-Escamilla et al. regarding the use of publicly available data to inform breastfeeding policy.⁴⁷ Another strength of this project is that it included a large nationally representative sample of hospitals that used a standardized definition of exclusive breastfeeding. The ADI was used to characterize and rank the socioeconomic deprivation of a hospital's neighborhood to understand access to high quality breastfeeding care across ADI categories. While ADI does not contain all of the information that would explain the variability in EBF, it may be a useful tool to target evidence-based interventions in areas that are at high risk for poor breastfeeding outcomes. A limitation of this study is that EBF may underestimate the effects of BFHI as increases in any breastfeeding increase before EBF rates when hospitals are in the process of making changes to improve breastfeeding support. Another limitation of this study was that census block group data were used as a proxy for the population delivering at a given

hospital. Finally, this study did not include the number of births per hospital. According to Baby Friendly USA, approximately 1 million (28.24%) births in the US occur in BFHI designated hospitals.²⁰ Without knowing the size of each hospital in our data set, we were not able to assess how many of these births occurred in BFHI designated hospitals in geographic areas ranked as low, medium or highly deprived using the ADI. Future studies should obtain patient-specific data to calculate the ADI of the population served by each hospital in addition to including other variables not represented by ADI. While this study is generalizable to the US, other countries that use an area-based deprivation index may benefit from applying this instrument to evaluate access to BFHI hospitals and the impact the BFHI designation has on breastfeeding outcomes across area deprivation indices.

Conclusion:

Disparities in breastfeeding rates persist and hospitals offer an environment to focus efforts on implementing BFHI to promote mothers' engagement in breastfeeding. Research has shown implementation of BFHI hospitals in geographic areas with historically low breastfeeding rates is feasible. In this study utilizing a US national sample of hospitals, we found that BFHI hospitals were distributed about equally in areas identified as low, medium and highly deprived. Furthermore, while EBF rates were lower in hospitals serving highly deprived populations compared to areas with lower deprivation, BFHI benefited mothers' EBF rates across ADI categories. The ADI may be a useful tool to scale up BFHI designated programs in areas identified as highly deprived to most efficiently reduce disparities in breastfeeding rates.

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Author Contributions:

JA Patterson conceptualized and designed the study, analyzed the data, drafted the manuscript and reviewed and revised the manuscript. NS Keuler designed the study, analyzed data, reviewed and revised the manuscript. WR Buckingham designed the study, determined the Area Deprivation Index for each hospital, created the figures and reviewed and revised the manuscript.

Author Disclosure Statement:

JA Patterson, NS Keuler and WR Buckingham have no conflicts of interest to disclose.

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Table 1: The distribution of hospitals by Baby-Friendly Hospital Initiative (BFHI) designation and change in BFHI status over the last 5 years across low, medium and high deprivation areas based on State Area Deprivation Index (ADI) categories.

ADI Categories	BFHI hospital for ≤5 years	BFHI hospital for >5 years	Total BFHI hospitals (%)	Hospitals that lost BFHI designation in last 5 years	Hospitals never designated BFHI	Total non- BFHI hospitals (%)	Total hospitals
Low Deprivation (ADI value 1-3)	88	38	126 (24.0)	8	392	400 (76.0)	526
Medium Deprivation (ADI value 4-7)	83	42	125 (18.3)	13	544	557 (81.7)	682
High Deprivation (ADI value 8-10)	76	50	126 (20.6)	4	482	486 (79.4)	612
NA ^a	26	11	37 (29.4)	3	86	89 (70.6)	126

^aNA=Hospitals located in geographic areas that do not have data required to calculate the ADI value.

Table 2: Estimated mean (%) Exclusive Breastfeeding Rates (EBF) in Baby-Friendly Hospital Initiative (BFHI) designated hospitals and non-BFHI hospitals located in low, medium and high deprivation areas based on State Area Deprivation Index (ADI) categories				
ADI Categories	Estimated mean EBF rate in BFHI hospitals (%)	Estimated mean EBF rate in non-BFHI (%)	Difference in estimated mean EBF rate between BFHI and non-BFHI hospitals (95% CI)	Difference in EBF between BFHI and Non-BFHI (p-value)
Low Deprivation (ADI Value 1-3)	57.8%	50.3%	7.6% (4.0-11.2)	<0.01
Medium Deprivation (ADI value 4-7)	58.5%	47.2%	11.2% (7.7-14.7)	<0.0001
High Deprivation (ADI value 8-10)	52.3%	45.4%	6.9% (3.4-10.4)	<0.01
*p-value represents the results from the multi-way ANOVA for the difference in EBF rates in hospitals located in low, medium and highly deprived areas using categories for the State ADI				

Figure 1: Baby-Friendly Hospital Initiative (BFHI) designated and non-BFHI hospitals across State Area Deprivation Index (ADI) categories in the continental US.

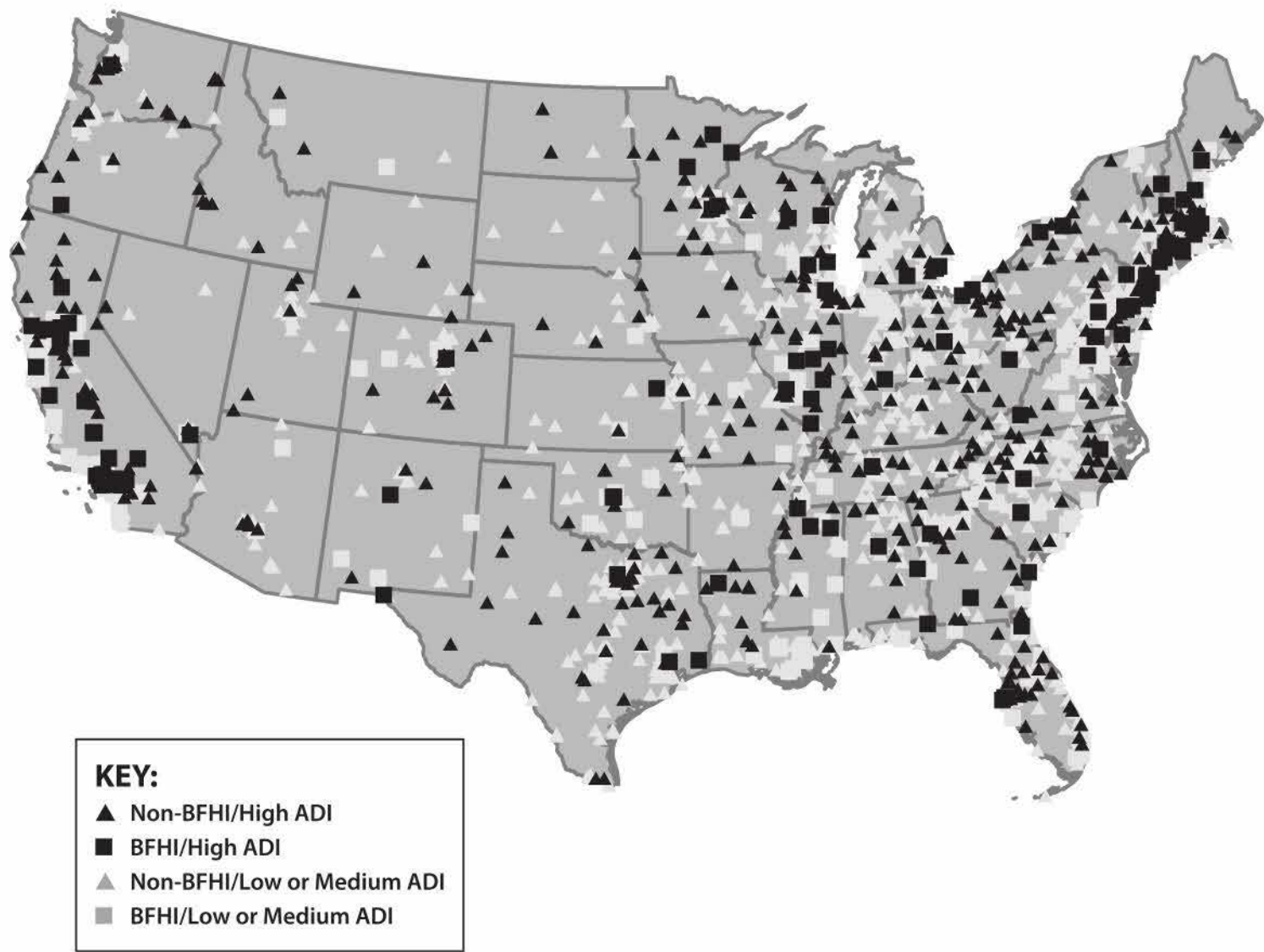


Figure 2: Baby-Friendly Hospital Initiative (BFHI) designated and non- BFHI hospitals across State Area Deprivation Index (ADI) categories in California, Ohio and the Southeast region of the US.

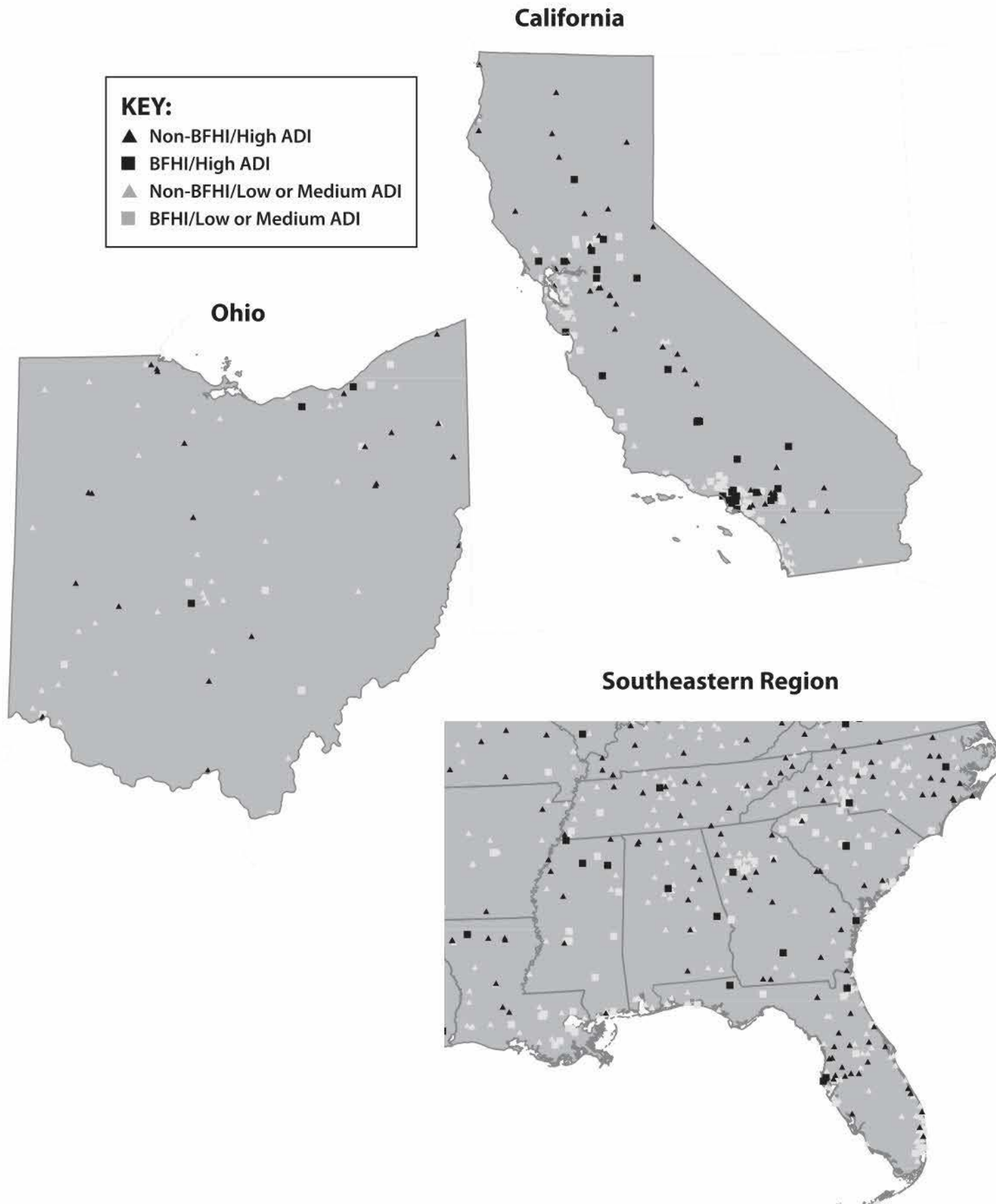


Figure 1: Baby-Friendly Hospital Initiative (BFHI) designated and non-BFHI hospitals across State Area Deprivation Index (ADI) categories in the continental US.

- Key:
- ▲ Non-BFHI/High ADI
 - BFHI/High ADI
 - ▲ Non-BFHI/Low or Medium ADI
 - BFHI/Low or Medium ADI

Figure 2: Baby-Friendly Hospital Initiative (BFHI) designated and non-BFHI hospitals across State Area Deprivation Index (ADI) categories in California, Ohio, and the Southeast region of the US.

- Key:
- ▲ Non-BFHI/High ADI
 - BFHI/High ADI
 - ▲ Non-BFHI/Low or Medium ADI
 - BFHI/Low or Medium ADI

From: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Fri, 18 Dec 2015 11:30:48 -0500
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Subject: FW: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t01wjAA:ref]

Our response to the first most recent request.

From: Mucciaccio, Francesca (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, December 03, 2015 4:33 PM
To: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR) <yhm7@cdc.gov>
Cc: DNPAO Info (CDC) <DNPAOInfo@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Robinson, Desir'ee (CDC/ONDIEH/NCCDPHP) <flz9@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t01wjAA:ref]

*Erica, not Anstey. Shows where my brain is this time of day!

From: Mucciaccio, Francesca (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, December 03, 2015 4:32 PM
To: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR)
Cc: DNPAO Info (CDC); Perrine, Cria G. (CDC/ONDIEH/NCCDPHP); Robinson, Desir'ee (CDC/ONDIEH/NCCDPHP)
Subject: RE: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t01wjAA:ref]

Thank you so much for drafting a response, Anstey! We will send out through CDC Info tomorrow when Desiree is back in office.

Best,

Francesca

From: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Thursday, December 03, 2015 8:13 AM
To: Robinson, Desir'ee (CDC/ONDIEH/NCCDPHP)
Cc: DNPAO Info (CDC); Scanlon, Kelley (CDC/ONDIEH/NCCDPHP); Perrine, Cria G. (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP); Shealy, Katherine (CDC/ONDIEH/NCCDPHP); Mucciaccio, Francesca (CDC/ONDIEH/NCCDPHP); DNPAO/Health Policy Team (CDC)
Subject: RE: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t01wjAA:ref]

Just adding Francesca and the DNPAO Healthy Policy box so we are all on the same page. See our response below. Kelley and I are planning to investigate the available literature on this further and

confer with some experts in the field. We will keep you all posted. Please let me know if you have any questions or concerns.

Thanks,
Erica

Erica H. Anstey, PhD, MA, CLC
McKing Consulting Corporation
CDC/ONDIEH/NCCDPHP/DNPAO

Nutrition Branch, MS: F-77
4770 Buford Highway, N.E.
Atlanta, Georgia 30341-3717

Phone: [770-488-5041](tel:770-488-5041)
Fax: [770-488-5369](tel:770-488-5369)
Email: yhm7@cdc.gov

From: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Thursday, December 03, 2015 8:02 AM
To: Robinson, Desir'ee (CDC/ONDIEH/NCCDPHP) <flz9@cdc.gov>
Cc: DNPAO Info (CDC) <DNPAOInfo@cdc.gov>; Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; Shealy, Katherine (CDC/ONDIEH/NCCDPHP) <srk3@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t01wjAA:ref]

Hi Desiree,
Here is our response for the moment. Thanks!
Erica

Dear Dr. del Castillo-Hegy,

On behalf of Dr. Friedan, we appreciate your continued dedication to improve monitoring and safe practices for exclusively breastfed babies. Thank you for informing us about the recent case study published in Hospital Pediatrics journal and for providing the link to your video presentation on the research related to ischemic brain injury due to inadequate nutrition. Your email has prompted us to review these materials and seek out consultations with experts in the field in an effort to gather the best information to inform the promotion of safe breastfeeding support practices. We share your passion for ensuring that all babies receive the critical nutrition needed to have the best start in life.

Thank you again,
Erica Anstey, PhD

From: Robinson, Desir'ee (CDC/ONDIEH/NCCDPHP)
Sent: Monday, November 30, 2015 4:47 PM
To: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR) <yhm7@cdc.gov>
Cc: DNPAO Info (CDC) <DNPAOInfo@cdc.gov>
Subject: FW: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email
[ref:_00DU0YCBU._500t01wjAA:ref]

Hi Erica,

This inquiry came through the DNPAO policy channels. I know we don't typically review external content but I may be worth a view given the specific nature of the information presented. Please let me know your thoughts.

Desiree

----- Original Email -----

Date :2015-11-04 06:01:13

Subject :CDC-INFO: Inquiry

Subject: Ischemic brain injury in underfed exclusively breastfed newborns

From: Clinician

Email Address: (b)(6)

Your Question: Dear Dr. Friedan,

I have been campaigning for over a year for greater monitoring and safer practices in the care of exclusively breastfed babies. The Hospital Pediatrics Journal just published a report of 11 healthy term mostly exclusively breastfed babies that developed lethargy, seizures and apnea from critically low hypoglycemia who had extensive ischemic brain injury to a third to almost all their brain. I have been researching the scientific literature and collected the postpartum breastfeeding stories of hundreds of mothers for 9 month now and this is happening frequently because mothers are sent home before the onset of milk production, their baby's glucose are rarely checked and they are discouraged from supplementing on their own, even if it can save a child from hypoglycemic brain injury. Please respond to this message. I have a video presentation summarizing my research on YouTube that I have prepared for health providers and parents.

<https://youtu.be/monS77c0uHI>

Christie del Castillo-Hegyi, M. D.

Optional Information

Name: Christie del Castillo-Hegyi
Title: Emergency Physician

Organization:

Phone: (b)(6)

Other Email: (b)(6)

Address: (b)(6)

From: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 21 Dec 2015 23:15:07 -0500
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t022cb4:ref]

Here it is.... Response back to Dr. Castillo-Hegyí
Ok – last email I hope!

From: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Monday, December 21, 2015 8:41 AM
To: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP) <kxs5@cdc.gov>; Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>
Subject: FW: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t022cb4:ref]

Whoops- forgot to Cc you.

From: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR)
Sent: Monday, December 21, 2015 8:41 AM
To: DNPAO Info (CDC) <DNPAOInfo@cdc.gov>; Robinson, Desir'ee (CDC/ONDIEH/NCCDPHP) <flz9@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t022cb4:ref]

Hi Desiree,
Here is our response this time. Just for your own knowledge, we have been discussing this issue, are looking into the research, and have begun conversations with some folks at AAP. Thank you!

Hello Dr. Christie del Castillo-Hegyí, M. D.,

We appreciate your interest and concern about this most important topic. Your email has prompted us to consult with additional experts in the field. Our experts will not hesitate to reach out to you should we have any additional questions. Thank you again for bringing this issue to our attention.

From: Robinson, Desir'ee (CDC/ONDIEH/NCCDPHP) **On Behalf Of** DNPAO Info (CDC)
Sent: Monday, December 14, 2015 11:46 AM
To: Anstey, Erica Hesch (CDC/ONDIEH/NCCDPHP) (CTR) <yhm7@cdc.gov>
Subject: FW: RESPONSE REQUIRED: Topic: Ischemic Brain Injury, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t022cb4:ref]

Hi Erica,

Highlighted below is a follow-up response from Dr. Christie del Castillo-Hegyi after our response to her initial inquiry. [REDACTED] (b)(5)

[REDACTED] (b)(5)

Let me know your thoughts.

----- Original Email -----

From : null
To : cdcinfo@cdc.gov
Date : 2015-12-13 13:17:18
Subject : CDC-INFO: Inquiry

Subject: Ischemic brain injury in breastfed newborns

From: Clinician

Email Address: [REDACTED] (b)(6)

Your Question: Dear Dr. Friedan:

I have received the email from the DNPOA and am concerned about the lack of initiative to warn mothers of the possibility of severe disable brain injury occurring in their exclusively breastfed babies who may accidentally not receive enough milk, especially if discharged by 48 hours. I would expect the CDC to issue an urgent warning to mothers because this is happening to hundreds every single day, given that 22% of mothers don't produce sufficient milk before 72 hours. Please let me know your plans to inform the public while the details of newborn feeding protocols are worked out. I do not think this is a matter that can afford slow deliberation as a newborn may be disabled every single day a warning is not issued.

Optional Information

Name: Christie del Castillo-Hegyi, M. D.
Title: Emergency Physician
Organization:
Phone: [REDACTED] (b)(6)
Other Email:
Address: [REDACTED] (b)(6)

From: Murphy, Paulette (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 29 Aug 2016 10:49:17 -0400
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Cc: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Subject: FW: response to articles available on line

Just wanted you to be aware of these updates to Baby Friendly's site. We had a lengthy conversation with them Wednesday where we reiterated our concerns about their Guideline and Evaluation Criteria.

P

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Sent: Sunday, August 28, 2016 7:39 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Murphy, Paulette (CDC/ONDIEH/NCCDPHP) <pem1@cdc.gov>
Subject: response to articles available on line

All,

In case you are not aware, I wanted to alert you that BFUSA updated their Guidelines and Evaluation Criteria webpage

<https://www.babyfriendlyusa.org/get-started/the-guidelines-evaluation-criteria> (see new text below) and added a link to their official response to the JAMA Pediatrics articles
file:///C:/Users/dgross2/Downloads/BFUSA_Response-BassGartleyKleinmanArticle.pdf

NEW TEXT ADDED TO GUIDELINES AND EVALUATION CRITERIA webpage:

The *Guidelines and Evaluation Criteria* are the most important tool to guide the work of hospitals through the Baby-Friendly designation process.

Recently there was an article published in JAMA-Pediatrics which has triggered some discussion in blogs and other media about the safety of the Baby-Friendly Hospital Initiative (BFHI) and the practice of mothers and infants remaining together throughout the hospital stay. [Click here](#) to read Baby-Friendly USA's response. Another article published in JAMA in the same issue points to how these practices save lives. [Click here](#) to access the article by Drs. Meek and Noble titled [Implementation of the Ten Steps to Successful Breastfeeding Saves Lives](#).

The AAP has also released a Clinical Report on [Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns](#). It offers sound recommendations for the safe implementation of these practices and well-vetted references. [Click here](#) to access the report.

Baby-Friendly USA released updated "**Guidelines and Evaluation Criteria for Facilities Seeking Baby-Friendly Designation**" (2016 Revision). As indicated by the title, it includes both the **Guidelines** facilities would need to follow to achieve full Baby-Friendly status and **Evaluation Criteria** that clearly spell out the minimum standards that a facility must achieve in order to become Baby-Friendly designated.

From: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 1 May 2017 10:35:48 -0400
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: responses request - CDC Info

Do you have other correspondence from del Castillo-Hegyí in your records?

From: DNPAO Comm Team (CDC)
Sent: Monday, May 01, 2017 9:52 AM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>
Subject: Re: responses request - CDC Info

Hi Janelle, I checked our archive of responses for "Fed is Best" and did not find anything, however we have one question from Dr. Castillo-Hegyí, see below.

Question	Response
<p>To :cdcinfo@cdc.gov Date :2015-11-04 06:01:13 Subject :CDC-INFO: Inquiry Subject: Ischemic brain injury in underfed exclusively breastfed newborns</p> <p>Email Address: (b)(6) Your Question: Dear Dr. Friedan,</p> <p>I have been campaigning for over a year for greater monitoring and safer practices in the care of exclusively breastfed babies. The Hospital Pediatrics Journal just published a report of 11 healthy term mostly exclusively breastfed babies that developed lethargy, seizures and apnea from critically low hypoglycemia who had extensive ischemic brain injury to a third to almost all their brain. I have been researching the scientific literature and collected the postpartum breastfeeding stories of hundreds of mothers for 9 month now and this is happening frequently because mothers are sent home before the onset of milk production, their baby's glucose are rarely checked and they are discouraged from supplementing on their own, even if it can save a child from hypoglycemic brain injury. Please respond to this message. I have a video presentation summarizing my research on YouTube that I have prepared for health providers and</p>	<p>Hello Christie del Castillo-Hegyí,</p> <p>CDC appreciates your continued dedication to improve monitoring and safe practices for exclusively breastfed babies. Thank you for informing us about the recent case study published in Hospital Pediatrics journal and for providing the link to your video presentation on the research related to ischemic brain injury due to inadequate nutrition. Your email has prompted us to review these materials and seek out consultations with experts in the field in an effort to gather the best information to inform the promotion of safe breastfeeding support practices. We share your passion for ensuring that all babies receive the critical nutrition needed to have the best start in life.</p> <p>Kindly,</p> <p>DNPAO INFO</p>

parents.

<https://youtu.be/monS77c0uHI>

Christie del Castillo-Hegy, M. D.

DNPAO Strategic Communications Team (Nicole)

E-mail: dnpaocommteam@cdc.gov

From: DNPAO Comm Team (CDC)
Sent: Monday, May 1, 2017 9:48:33 AM
To: Curtis, A Brittany (CDC/ONDIEH/NCCDPHP)
Subject: Re: responses request - CDC Info

Wonderful, that worked! Thank you so much!!

DNPAO Strategic Communications Team (Nicole)

E-mail: dnpaocommteam@cdc.gov

From: Curtis, A Brittany (CDC/ONDIEH/NCCDPHP)
Sent: Monday, May 1, 2017 9:47 AM
To: DNPAO Comm Team (CDC)
Subject: RE: responses request - CDC Info

Hi, Nicole—Ashley had asked me to remove the old CDC-Info site, so that's why you're not seeing it. Glad I only hid it instead. ☺ Try now.

Brittany Curtis

Phone: 770-488-5423

BB: 404-263-5401

Teleworking: Mondays, Thursdays & every other Wednesday

From: DNPAO Comm Team (CDC)
Sent: Monday, May 01, 2017 9:44 AM
To: Curtis, A Brittany (CDC/ONDIEH/NCCDPHP) <gnk2@cdc.gov>
Subject: Fw: responses request - CDC Info
Importance: High

Brittany -I was only able to find one in the CDC Info Mail Box -I tried checking the old CDC Info tracker on SharePoint but I do not have access. Can you grant me access quickly or check for the below request?
Thank you,

DNPAO Strategic Communications Team (Nicole)

E-mail: dnpaocommteam@cdc.gov

From: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP)

Sent: Sunday, April 30, 2017 3:16 PM

To: DNPAO Comm Team (CDC)

Subject: responses request - CDC Info

Hi – can you please pull for me any past incoming and associated responses from to Dr. del Castillo-Hegy or Fed is Best? I need Monday morning please. (b)(5)

Thanks-Janelle

Janelle Peralez Gunn

Associate Director for Policy, Partnerships and Communications

Division of Nutrition, Physical Activity and Obesity

Centers for Disease Control and Prevention

P: 770-488-8231, M: 404-429-3633

E: bfy2@cdc.gov

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 1 Mar 2018 16:02:55 +0000
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Subject: FW: Review of evidence regarding early breastfeeding complications

FYI

From: Abrams, Steven [mailto:sabrams@austin.utexas.edu]
Sent: Thursday, March 1, 2018 10:59 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Meek, Joan <Joan.Meek@med.fsu.edu>
Cc: Debra L. Burrowes (b)(6) Onyema-Melton, Ngozi
(b)(6) Spire, Paul (b)(6)
Subject: Re: Review of evidence regarding early breastfeeding complications

Cria:

As I understand, the Committee on Fetus and Newborn has proposed a statement related to these issues. Recently, in a call with them, SoBr and CON we decided that all three groups should work on this together and that there would be an updated plan for the statement. I have not heard anything since then but perhaps Paul or Debra know more.

As you also know, the DGAC process has begun for 2020 and a series of B/24 questions posed. It does not appear that this issue is covered by the proposed questions.

Regards

Steve

From: "Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)" <hgk3@cdc.gov>
Date: Thursday, March 1, 2018 at 8:17 AM
To: Steve Abrams <sabrams@austin.utexas.edu>, "Meek, Joan" <Joan.Meek@med.fsu.edu>
Cc: "Burrowes, Debra" (b)(6) "Onyema-Melton, Ngozi" (b)(6)
Subject: Review of evidence regarding early breastfeeding complications

Hi Steve and Joan, are either the CON or SoBr working on or planning a review of the evidence behind some of the claims being made by Fed-is-Best? Steve, I know at the last CON meeting you said AAP needed to figure out what its role in this discussion was going to be. The Global Breastfeeding Collective (GBC), led by WHO and UNICEF, recently established several subgroups, one of which is the Evidence Working Group. The purpose of this group is to review evidence and develop position statements/talking points on controversial issues, emerging science, or policy positions taken by the Collective. I am a member of this working group, and we had our first call this week. The group discussed that reviewing some of the evidence around the claims being made by Fed-is-Best would be appropriate for this group. However, we know other groups may also be doing some of this, and we don't want to duplicate efforts. I believe ABM is working on a response to the specific statements FIB made about their new clinical protocol regarding supplementation in the hospital setting. I believe

ACOG may also be working on some reviews, so will reach out to them as well. It would be very helpful to know what, if anything, AAP plans specifically around review and interpretation of the data and clinical claims being made.

Another question the group had was just anecdotally whether physicians were perceiving an increase in neonatal dehydration, jaundice, or readmissions for conditions related to breastfeeding challenges?

Best,
Cria

Cria Perrine, PhD
CDR, US Public Health Service
Lead, Infant Feeding Team
Division of Nutrition, Physical Activity, and Obesity
Centers for Disease Control and Prevention
☎ Phone: 770.488.5183 | ✉ Email: cperrine@cdc.gov

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 9 May 2017 15:07:48 +0000
To: Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP)
Subject: FW: REVIEW: Response to Fed is Best - DUE 5/4
Attachments: RESPONSE REQUIRED: Topic: Dangers of the Baby-Frien, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500t05C6tK:ref], 2379661 Baby-Friendly Initiative Fed is Best Christie del Castillo-Heg....docx

From: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, May 04, 2017 9:22 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>
Subject: FW: REVIEW: Response to Fed is Best - DUE 5/4

Do you guys have the guidelines that I can send to Deb?

From: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>
Date: May 4, 2017 at 9:18:37 AM EDT
To: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Subject: FW: REVIEW: Response to Fed is Best - DUE 5/4

Karen,

Quick question.

(b)(5)

From: Petersen, Ruth (CDC/ONDIEH/NCCDPHP)
Sent: Thursday, May 04, 2017 9:04 AM
To: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>
Subject: FW: REVIEW: Response to Fed is Best - DUE 5/4

Electronic version

*Ruth Petersen, MD, MPH
Director
Division of Nutrition, Physical Activity, and Obesity
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention*

Email: rpetersen@cdc.gov

Phone 770.488.6001 Mobile 404.353.8474

From: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)

Sent: Thursday, May 04, 2017 7:43 AM

To: Petersen, Ruth (CDC/ONDIEH/NCCDPHP) <rip0@cdc.gov>

Cc: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>; DNPAO/Health Policy Team (CDC) <DNPAOPolicy@cdc.gov>

Subject: REVIEW: Response to Fed is Best - DUE 5/4

Hi Ruth,

Please see the attached response to the Fed is Best Foundation. The Center references a response that CDC OD had drafted, (b)(5) I have attached a response for your review and have cleared this with Janelle and Cria.

Let me know if you have any comments. We need to send to the Center by COB today.

Thanks.

Karen

From: Johnson, Margaret Sarti (CDC/ONDIEH/NCCDPHP)

Sent: Monday, May 01, 2017 12:46 PM

To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfy2@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>; DNPAO/Health Policy Team (CDC) <DNPAOPolicy@cdc.gov>

Cc: Johnson, Abigail P. (CDC/ONDIEH/NCCDPHP) <vmh3@cdc.gov>; Johnson, Margaret Sarti (CDC/ONDIEH/NCCDPHP) <kcy3@cdc.gov>

Subject: DUE 5/4: Draft for the Castillo Response for Folder 2384430

Hello Janelle,

I'm sending the attached draft response and the original email for the Castillo request. The draft response uses verbiage from (b)(5) Peter reviewed and (b)(5)

(b)(5)

Please review, revise as necessary and send back to me by COB Thursday May 4th.

Thanks and let me know if you have any questions,
Margaret

From: Dean, Contessa J. (CDC/OD/OCS)

Sent: Monday, May 01, 2017 11:59 AM

To: Johnson, Margaret Sarti (CDC/ONDIEH/NCCDPHP) <kcy3@cdc.gov>; Johnson, Abigail P. (CDC/ONDIEH/NCCDPHP) <vmh3@cdc.gov>

Subject: Draft for the Castillo Response for Folder 2384430

Importance: High

Attached is the incoming and draft response for the Castillo letter. We prepared the draft using language from (b)(5). This is a Direct Reply for NCCDPHP, and you can edit as you see fit and send out under the signature of who NCCDPHP thinks is appropriate. Please send me a copy of the final to close out the folder.

From: Reply Needed from CDC
Sent: Tue, 4 Apr 2017 12:07:32 +0000
To: DIRECTOR'S INCOMING (CDC)
Subject: RESPONSE REQUIRED: Topic: Dangers of the Baby-Frien, Priority: Medium,
Mode: Email [ref:_00DU0YCBU._500t05C6tK:ref]

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

This inquiry is being escalated because as per A-Z, anything regarding Dr. Frieden is to be escalated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-INFO Correspondence Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain.

Thank you,
K.C.

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Email -----

From : null

To : cdcinfo@cdc.gov

Date : 2017-03-30 01:27:59

Subject : CDC-INFO: Inquiry

Subject: Dangers of the Baby-Friendly Hospital Initiative

From: Clinician

Email Address: christie@fedisbest.org

Your Question: Dear Dr. Friedan,

I am one of the Co-Founders of the Fed is Best Foundation, emergency physician and former newborn brain injury scientist, Dr. Christie del Castillo-Hegyi. You may have heard of the starvation death of Landon Johnson that occurred because of the management of a Baby-Friendly hospital. Since the beginning of my campaign 2 years ago, we have received tens of thousands newborn hospitalization and starvation stories from insufficient exclusive breastfeeding. Starvation-related complications are happening to thousands of newborns a day who are exhibiting obvious signs of starvation including non-stop crying and nursing even while they are in the hospital, as Landon did before he suffered from cardiac arrest from hypernatremic dehydration. These complications are in fact the leading causes of newborn hospitalizations in the world. This Fed is Best petition is attached along with comments/stories left by parents and health professionals. Please read the petition. We are preparing to propose legislation to protect newborns from the dangers of the Baby-Friendly Hospital Initiative and we hope you will address the safety concerns of thousands of parents represented by the Foundation.

https://drive.google.com/open?id=0B0_MbXCqYazzcUNXbEN10ThzeE0

Comments from petitioners:

https://drive.google.com/open?id=0B0_MbXCqYazzS1NFZXRnUjh5cEk

Respectfully,

Christie del Castillo-Hegyi, M.D.
Co-Founder, Fed is Best Foundation

Optional Information

Name: Christie del Castillo-Hegyi, M.D.
Title: Emergency Physician, Infant Feeding Advocate
Organization: The Fed is Best Foundation
Phone: (b)(6)

Other Email: christie@fedisbest.org
Address: christie@fedisbest.org

(b)(5)

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 23 Jan 2018 21:35:53 -0500
To: Flores-Ayala, Calixto Rafael (CDC/DDNID/NCCDPHP/DNPAO);MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO);Seymour, Jennifer (Jenna) (CDC/DDNID/NCCDPHP/DNPAO);Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO);Voetsch, Karen P. (CDC/DDNID/NCIPC/DOP)
Subject: FW: Slides from call last week
Attachments: BFUSA-CDC-180119.pptx

From: Trish MacEnroe (b)(6)
Sent: Tuesday, January 23, 2018 9:21 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Subject: RE: Slides from call last week

Hi Cria,

Please see attached. Sorry, I meant to send them right out after the meeting.

Also, when you have a chance, could you send me Jenna's email. I promised to send her the WHA briefing materials.

Thanks so much.
Trish

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) [<mailto:hgk3@cdc.gov>]
Sent: Tuesday, January 23, 2018 8:30 PM
To: Trish MacEnroe (b)(6)
Subject: Slides from call last week

Hi Trish, I believe you said you would share your slides from our call last week. I would like to share them with Karen since she wasn't able to join our call.

Cria

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From: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Wed, 4 Aug 2021 15:18:30 +0000
To: Bosso, Eileen T. (CDC/DDNID/NCCDPHP/DNPAO); MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO); McKinstry, Joya (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: Status update - CDC projects
Attachments: CDC_Final_Report_Summary.docx

From: Jegier, Briana <jegierb@dyc.edu>
Sent: Friday, September 25, 2020 2:47 PM
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>
Cc: MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO) <dvx2@cdc.gov>; Flores-Ayala, Calixto Rafael (CDC/DDNID/NCCDPHP/DNPAO) <rnf2@cdc.gov>
Subject: Re: Status update - CDC projects

Dear All,

Please find attached the executive summary for this IPA project. I have truly appreciated this work and all of the flexibility afforded me over the period. It has been a very rough couple of years but this has been a labor of love throughout and I hope it is useful.

Kind regards,

Briana

On Aug 31, 2020, at 6:25 PM, Jegier, Briana <jegierb@dyc.edu> wrote:

Dear Cria,

I am just sending an update that we are on schedule for this to be to you by the end of this week. I met with Sam from Vizient to just re-review the data one more time before calling it final. I and he appreciate all your support.

Kind regards,
Briana

On Aug 20, 2020, at 1:07 PM, Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov> wrote:

Thank you Briana. I understand if the SUPC data are not publishable. We went into the project knowing that was a likely possibility, but nonfindings/information on the utility of the data source for trying to answer the questions are still valuable for us to know.

Cria

From: Jegier, Briana <jegierb@dyc.edu>

Sent: Tuesday, August 18, 2020 4:30 PM

To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>

Cc: MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO) <dvx2@cdc.gov>; Flores-Ayala, Calixto Rafael (CDC/DDNID/NCCDPHP/DNPAO) <rnf2@cdc.gov>

Subject: Re: Status update - CDC projects

Dear Cria,

Thank you for your email. I hope you and yours are well also. I will be sending everything to you over the course of the next two weeks. I have 2 manuscripts (BFHI cost, BFHI readmission) and one more white paper style (the SUPC evaluation). I don't think the SUPC is publishable to be truthful though we have looked at various iteration and options. It just won't meet that standard (b)(5)

(b)(5)

I will be following up a few times in the coming week with documents. Thank you for being patient with me through what has been a rather trying 12 months.

Kind regards,
Briana

On Aug 18, 2020, at 10:30 AM, Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov> wrote:

Hi Briana, I hope you and your family are well. I know these are challenging times with the COVID-19 pandemic, and many of us have additional responsibilities with children at home, but I want to follow up on the projects you were working on for CDC. We currently don't have anything concrete to show for the funding. We are expecting write ups of the analyses for the BFHI cost study and the hospital readmission/SUPC work. If you cannot write these up for a publication, we would at least like them in report form that we can use.

Cria

From: Jegier, Briana <jegierb@dyc.edu>

Sent: Wednesday, January 15, 2020 3:22 PM

To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>

Subject: Re: Status update

Hi Cria,

Happy new year! I apologize for all the craziness and delays. To be realistic, I will promise to have drafts to you by the end of the month. It has been a very tumultuous couple of months. I am finally not in hole and should be able to have everything back out soon.

Hope all is well,
Briana

On Jan 8, 2020, at 10:29 AM, Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov> wrote:

Hi Briana, happy new year. Can you provide a status update on the various papers for the projects we've supported? We really would like to see this move forward.

Cria

From: Jegier, Briana <jegierb@dyc.edu>
Sent: Thursday, November 7, 2019 8:30 PM
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>
Cc: Li, Ruowei (Rosie) (CDC/DDNID/NCCDPHP/DNPAO) <ril6@cdc.gov>
Subject: Re: Status update

Hi Cria and Rosie,

I just wanted to give you an update. I came home from APHA to learn

(b)(6)

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With all of this, I just will not be able to head to work tomorrow and thus get at my computer. I will send the papers as soon as I can.

I'm sorry for the additional delay.

Briana

On Nov 5, 2019, at 8:18 PM, Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov> wrote:

Thanks for your email Briana. I hope your presentation at APHA goes well and we look forward to seeing everything.

Cria

From: Jegier, Briana <jegierb@dyc.edu>
Sent: Tuesday, November 5, 2019 11:44 AM
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hgk3@cdc.gov>
Cc: Li, Ruowei (Rosie) (CDC/DDNID/NCCDPHP/DNPAO) <ril6@cdc.gov>
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Hi Cria,

I am so sorry, I missed your previous email.

I will have it to all by the end of the week. I am at APHA through Thursday and am working on a few updates now. I honestly just missed a sending in August. My apologies.

Regards,
Briana

Sent from my iPhone

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From: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Tuesday, October 8, 2019 9:21 AM
To: Briana Jegier (jegierb@dyc.edu) <jegierb@dyc.edu>
Cc: Li, Ruowei (Rosie) (CDC/DDNID/NCCDPHP/DNPAO) <ril6@cdc.gov>
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Cria

Cria Perrine, PhD
Commander, US Public Health Service
Team Lead, Maternal, Infant, and Toddler Nutrition Team
Division of Nutrition, Physical Activity, and Obesity

Centers for Disease Control and Prevention
770.488.5183 (o) | 678.429.4210 (m)
cperrine@cdc.gov

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From: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Fri, 2 Oct 2020 18:20:56 +0000
To: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: Status update - CDC projects
Attachments: CDC_Final_Report_Summary.docx

I'm not sure if we're actually going to get paper drafts or not. I shared this with Rosie as well. Please read through when you have time and see if there are any ideas of follow up for projects that this inspires.

From: Jegier, Briana <jegierb@dyc.edu>
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Cria Perrine, PhD
Commander, US Public Health Service
Team Lead, Maternal, Infant, and Toddler Nutrition Team
Division of Nutrition, Physical Activity, and Obesity

Centers for Disease Control and Prevention
770.488.5183 (o) | 678.429.4210 (m)
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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 10 Nov 2016 10:14:10 -0500
To: Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); Black, Erin (CDC/ONDIEH/NCCDPHP)
Cc: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Subject: FW: Staying Abreast: Weekly Wednesday Wire

This is the United States Breastfeeding Committee's weekly newsletter. See [highlighted section](#), which describes the new page on safety on BF USA's website.

From: office=usbreastfeeding.org@mail.salsalabs.net
[mailto:office=usbreastfeeding.org@mail.salsalabs.net] **On Behalf Of** U.S. Breastfeeding Committee
Sent: Thursday, November 10, 2016 1:21 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: Staying Abreast: Weekly Wednesday Wire



STAYING ABREAST

Published by the United States Breastfeeding Committee

Please note: Inclusion of an item in this e-newsletter does NOT imply endorsement or support of such item by the United States Breastfeeding Committee, unless specifically noted.

Weekly Wednesday Wire: November 9, 2016

Federal News

Infant Formula Labeling Guidance, from FDA

The U.S. Food and Drug Administration has [issued guidance for the labeling of infant formula](#) to support industry in helping infant formula manufacturers and distributors comply with certain labeling requirements for infant formula products. This guidance clarifies requirements pertaining to statements of identity; "exempt" infant formula; nutrient content claims; health claims and qualified health claims; labeling requirements, including directions for preparation and use, pictograms, use-by dates, water statement and symbol, warning statements, and physician's recommendation; and general labeling requirements, including intervening material, foreign language and

religious symbols, statements intended for specific religious needs, and allergen statements.

Trauma Recovery Program Award, from SAMHSA

The Substance Abuse and Mental Health Services Administration has [awarded up to a total of \\$278 million](#) over the next five years for programs that help people and communities recover from, and build resiliency from trauma. Grant award recipients originate in 28 states and the District of Columbia

Grantee Success Stories, from CDC/TFAH

The Centers for Disease Control and Prevention and Trust for America's Health have released [updated success stories](#) that highlight the progress made through the Racial and Ethnic Approaches to Community Health (REACH) program, aimed at improving the health and wellness of racial and ethnic groups across the United States. In communities across the country, REACH is making a difference by improving access to nutritious foods, enhancing places for physical activity, and preventing tobacco use among those most impacted by chronic disease.

Member News

Children's Food Marketing Twitter Chat, from Various

Join the Rudd Center for Food Policy and Obesity, 1,000 Days, Nacersano Baby, and National WIC Association on Friday, November 11, at 1 p.m. ET for a #SaludTues Twitter chat entitled, "Is Your Baby's Food What It's Cracked Up to Be." The conversation will focus on marketing techniques and nutritional quality of children's food and beverages. According to a [new report from the Rudd Center](#), marketing for baby and toddler food, infant formula and toddler milk, and nutritional supplements often contradicts expert guidance. Targeting Latino parents with products containing added sugars is especially problematic, due to higher rates of overweight and obesity among Latino children. In addition to the #SaludTues hashtag, participants are encouraged to use the hashtags #BabyFood, #AddedSugar, and #LatinoHealth.

Safety of Baby-Friendly Practices, from BFUSA

Baby-Friendly USA has published a [new webpage on the safety of Baby-Friendly practices](#). The page contains information about safe sleep, pacifiers, rooming-in, and skin to skin care.

Partner News

Data Tools to Improve Health, from NLC

Join the National League of Cities on Tuesday, December 6, from 1-2 p.m. ET for a web forum entitled, "[Health Data for City Leaders: Where to Find It, How to Use It, and Why It's Important](#)." The web forum will discuss ways cities can use data more efficiently to improve the health and well-being of all communities. Experts from Data Across Sectors for Health and Community Commons will share data tools and resources to support efforts to build a Culture of Health.

Global Report on Infant and Young Child Feeding, from UNICEF

The United Nations Children's Fund has released a new global report, [First Hour of Life: Making the case for improved infant and young child feeding everywhere](#), providing a global status update on infant and young child feeding practices and putting forth recommendations for improving them. The report is divided into two parts: Part I focuses on breastfeeding and Part II looks at complementary feeding practices. Each part reviews the most recent evidence on infant and young child feeding practices and provides updated global and regional estimates and trends, where available, as well as disaggregated analyses.

Maternity Facility Recommendations, from WHO

The World Health Organization has convened the [second meeting of the WHO Guideline Development Group – Nutrition Actions 2016-2018](#) to update recommendations on breastfeeding in maternity facilities. This group, together with other WHO expert advisory panels and a multi-disciplinary team of experts, will formulate final draft recommendations on newborn and infant nutrition, taking into account existing evidence as well as diverse values and preferences, costs and feasibility.

News from the Field

Adherence to Recommendations in Advertisements, from *Children*

The journal *Children* has published an article titled, "[Compliance of Parenting Magazines Advertisements with American Academy of Pediatrics Recommendations](#)." The study examined 3218 advertisements from the two parenting magazines with highest circulation in the United States. The authors compared each advertisement for a product for use by children, against all the published recommendations of the American Academy of Pediatrics (AAP) on topics such as toy safety, helmet use, age-defined choking hazards, infant sleep safety, and others. Nearly one in six (15.7%) of the advertisements contained example(s) of non-adherence to AAP recommendations.

Study of Pumping Information Sought Online, from *Children*

The journal *Children* has published an article entitled, "[Mothers' Use of Social Media to Inform Their Practices for Pumping and Providing Pumped Human Milk to Their Infants](#)." The researchers conducted a qualitative, longitudinal, and cross-sectional analysis of data provided by a cohort of women within an online discussion forum. The study investigated how the number and nature of questions changed over time by examining questions women asked about pumping across five themes: choosing and purchasing pumps, storing and preparing pumped human milk, strategies for and difficulties with pumping, integrating pumping into work, and stopping pumping.

Collective Impact Connection

Trend Mapping Tool, from Tamarack Institute

The Tamarack Institute has released "[Most Significant Change](#)," a monitoring and evaluation tool designed to synthesize qualitative data into outcomes. The process involves collecting stories from the field and systematically analyzing them to monitor progress and impact. An evaluation expert is not needed to use this method.

News & Views

Forbes: "[Working Moms Need A Real Option To Breastfeed After Maternity Leave](#)"

Breastfeeding Medicine (ABM blog): "[Evidence is Clear: Baby-Friendly Hospital Initiative Increases Breastfeeding Rates in the US and Closes Breastfeeding Disparities](#)"

The Lunch Tray: "[FDA Seeks to Rein in Unsubstantiated Claims for Infant Formula](#)"

People: "[Breastfeeding Mom Asked to Leave TEDWomen Conference Due to No-Baby Policy](#)"

About Staying Abreast: Weekly Wednesday Wire

The USBC e-Newsletter, *Staying Abreast*, is published in a weekly news brief format, called the *Weekly Wednesday Wire*. Past issues are [archived on the USBC website](#).

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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Thu, 24 Aug 2017 11:39:53 +0000
To: Sowers, Alexandra (CDC/ONDIEH/NCCDPHP) (CTR); Elliott, Nicole (CDC/ONDIEH/NCCDPHP)
Cc: Betts, Kristen (CDC/ONDIEH/NCCDPHP)
Subject: FW: Staying Abreast: Weekly Wednesday Wire

Thought you'd want to see how USBC used the Gov-D newsletter (3rd item down). Thanks to you both for getting this linked for them to be able to use. This newsletter goes to all 40+ member organizations of USBC and state breastfeeding coalitions.

From: office=usbreastfeeding.org@mail.salsalabs.net
[mailto:office=usbreastfeeding.org@mail.salsalabs.net] **On Behalf Of** U.S. Breastfeeding Committee
Sent: Thursday, August 24, 2017 4:32 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>
Subject: Staying Abreast: Weekly Wednesday Wire



STAYING ABREAST
Published by the United States Breastfeeding Committee

Please note: Inclusion of an item in this e-newsletter does NOT imply endorsement or support of such item by the United States Breastfeeding Committee, unless specifically noted.

Weekly Wednesday Wire: August 23, 2017

Federal News

Secretary's Advisory Committee Meeting on Healthy People 2030, from HHS

The Department of Health and Human Services has announced that the [fifth meeting of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030](#) will take place on Wednesday, September 6, and Thursday, September 7. Individuals must pre-register to attend the meeting. The Committee will discuss the development of the Nation's health promotion and disease prevention objectives, discuss proposed recommendations and updates from each of the Committee's subcommittees, and hear oral testimony from the public on the proposed

Healthy People 2030 framework. There will be an opportunity for members of the public and stakeholders to deliver two minutes of oral public comments regarding the proposed Healthy People 2030 vision, mission, overarching goals, foundational principles, and plan of action. Individuals interested in delivering oral public comments must register their intention and submit a written copy of their oral testimony no later than Wednesday, August 30.

Healthy People 2030 Public Comment Period Open, from HHS

The Department of Health and Human Services has opened an online [public comment period for Healthy People 2030](#). The Healthy People team is requesting comments on the proposed framework for Healthy People 2030, which refers to the Healthy People 2030 vision, mission, foundational principles, plan of action, and overarching goals. Both individuals and organizations are invited to submit comments on the proposed framework. The public comment period ends Friday, September 29.

National Breastfeeding Month Bulletin, from CDC

The Centers for Disease Control and Prevention have released a [National Breastfeeding Month bulletin](#). The bulletin highlights this year's National Breastfeeding Month theme—*Charting the Course Together*—and presents new data on breastfeeding rates. Among babies born in 2014, breastfeeding initiation exceeded the Healthy People 2020 (HP2020) target of 81.9% and is now 82.5%. Breastfeeding at 6 months increased 3.5 percentage points and is now 55.3%. Exclusive breastfeeding through 3 months exceeded the HP2020 target of 46.2% and is now 46.6%. In addition, data is now available for three U.S. territories: Puerto Rico, Guam, and the U.S. Virgin Islands. The bulletin also speaks to the work that still needs to be done to close the racial breastfeeding disparities.

Printable Breastfeeding Resources, from NLM

The National Library of Medicine has released HealthReach, a national collaborative partnership to create quality multilingual, multicultural public health information for those working with or providing care to individuals with limited English proficiency. The resource features printable handouts as well as video and audio resources. Handouts include [Breastfeeding Basics](#), [Breastfeeding Problems](#), [Getting Started Breastfeeding Your Baby](#), and [Pumping and Storing Breast Milk](#).

Public Health Grand Rounds Recording on Workplace Health, from CDC

The Centers for Disease Control and Prevention have released a recording of the August session of Public Health Grand Rounds, entitled "[New Frontiers in Workplace Health](#)." The webinar addresses comprehensive integrated approaches, best practices, and the role state health departments have in the support of workplace health and safety. The session highlighted CDC's new "[Workplace Health Resource Center](#)," a one-stop website for reliable and easy to use resources for employers and employees.

National Public Health Improvement Initiative Compendium, from CDC

The Centers for Disease Control and Prevention have released "[Advancing Public Health: The Story of the National Public Health Improvement Initiative](#)," a compendium that describes the successes and outcomes of the [National Public Health Improvement Initiative](#) (NPHII). This initiative represented an unprecedented opportunity for the CDC to support state, tribal, local, and territorial public health departments in building their performance capacity for more efficient and effective program and service delivery. The compendium contains stories about the activities undertaken by each funded health department.

Member News

Open Letter to Request Meeting w/ Fed Is Best Foundation, from 1,000 Days & ROSE

On August 15, on behalf of over 40 signing organizations, 1,000 Days sent [an open letter](#) requesting a meeting with the co-founders of the Fed Is Best Foundation. Fed Is Best has engaged in a public campaign that draws links between the recommended practice of exclusive breastfeeding—as well as its education and promotion by health care providers—and the tragic deaths and injuries of babies. On August 22, Reaching Our Sisters Everywhere sent an updated version of the letter, now with over 60 signing organizations. The [sign on form](#) has been reopened indefinitely, to accommodate organizations that wish to sign on as the word spreads further.

#IPumpedHere Petition Delivery Video, from MomsRising

MomsRising has [released a video](#) highlighting the delivery of stories, photos, and petition signatures gathered during the #IPumpedHere campaign to Members of Congress. The campaign aims to improve workplace support for

breastfeeding moms.

Partner News

NAPPSS-IIN Announcement, from NICHQ

The National Institute for Children's Health Quality has announced that they will lead a five year national initiative aimed at making infant safe sleep and breastfeeding the national norm. The [National Action Partnership to Promote Safe Sleep Improvement and Innovation Network](#) (NAPPSS-IIN) engages champions within the systems that intersect with infant caregivers and families at risk to disseminate infant safe sleep and breastfeeding messages. Participants will develop and test a small set of evidence-based practices, known as a safety bundle, and guide implementation and refinement of the bundle across sectors to improve the likelihood that infant caregivers and families receive consistent, evidence-based instruction about safe sleep and breastfeeding.

Statement on Racial Healing, from WKKF

The W.K. Kellogg Foundation has released a [statement on racial healing](#) from its president and CEO. The statement calls for a new approach that penetrates the full consciousness of our society, draws in all communities, and focuses on racial healing and truth-telling. WKKF supports racial justice healing through the Truth, Racial Healing & Transformation framework.

New Funding Approaches to Support Multi-Sector Initiatives, from TFAH and Monitor Deloitte

Trust for America's Health and *Monitor Deloitte* have released a paper entitled, "[Supporting Healthy Communities: How Rethinking the Funding Approach Can Break Down Silos and Promote Health and Health Equity](#)." The paper discusses the Healthy Communities Funding Hub model, which offers a way to bridge a gap in many communities where there is no existing infrastructure for sustainably funding multi-sector and multi-funding-stream efforts to improve health. The hubs would be place-based organizations bringing together funding from federal, state, local, and philanthropic sources across the many sectors that affect health. Each hub would serve as a trusted intermediary and formal financial manager, equipped with the necessary financial capacities to coordinate health improvement funds, and

be a single point of financial accountability to stakeholders.

Paid Leave and Preventive Care Report, from CLASP

The Center for Law and Social Policy has released a publication entitled, "[Paid Leave Necessary for an Ounce of Prevention](#)." The paper discusses the importance of paid leave for improving public health by allowing time for preventive care and highlights research showing that access to paid maternity leave leads to higher breastfeeding rates. Many workplaces do not provide paid leave and no federal paid leave laws exist. As a result, millions of Americans cannot obtain preventive care that could produce cost savings and better public health outcomes over the long term.

Preventive Health Data by Congressional District, from TFAH

Trust for America's Health has released an updated version of "[Special Analysis: How Healthy Is Your Congressional District?](#)" The report provides a one-year snapshot of seven preventive health measures for each Congressional District and for each state and the District of Columbia. It uses data from the Centers for Disease Control and Prevention's 2015 Behavioral Risk Factor Surveillance System. Several descriptive charts and maps are available, including a listing of the range of healthiest to least healthy Congressional districts.

News from the Field

Breastfeeding Education In Residency Article, from *Breastfeeding Medicine*

The journal *Breastfeeding Medicine* has published a paper entitled, "[Breastfeeding Education and Support Services Provided to Family Medicine and Obstetrics–Gynecology Residents](#)." A cross-sectional study was conducted using a web-based survey emailed to program directors of family medicine and obstetrics–gynecology residency programs in the United States to investigate breastfeeding education and support services provided to family medicine and obstetrics–gynecology residents in the United States. The results were compared with a 2011 study of pediatric residents. A median of 23 hours of breastfeeding education is provided to obstetrics–gynecology residents (4-year program) and 8 hours provided to family medicine residents (3-year program). In comparison, pediatric programs reported a median of 9 hours. The most commonly used settings included lectures with faculty and lactation consultants, similar to the pediatric study.

Researchers concluded that better educating residents in prenatal and perinatal specialties may increase breastfeeding rates.

New Formula Marketing Code, from Hong Kong

The government of Hong Kong has issued a [voluntary code of marketing of formula milk and related products](#). The HK Code aims to contribute to the provision of safe and adequate nutrition for infants and young children by protecting breastfeeding and ensuring the proper use of designated products, on the basis of adequate and unbiased information and through appropriate marketing. Drafted by the Taskforce on Hong Kong Code of Marketing of Breastmilk Substitutes, the Code offers guidance for manufacturers and distributors on marketing to the public, in health care facilities, and to health workers.

Health and Early Childhood Care and Education, from NASEM

Join the National Academies of Sciences, Engineering, and Medicine's Roundtable on Population Health Improvement on Thursday, September 14, for [a one-day workshop](#) that explores the intersection of health and early childhood care and education (ECE), two key social determinants of health. The workshop will provide a brief overview of the science, including effective interventions, programs, and practices that can be supported by health and ECE sectors.

Equity in Multisector Community Health Partnerships Workshop Proceedings, from NASEM

The National Academies of Sciences, Engineering, and Medicine have released, "[Exploring Equity in Multisector Community Health Partnerships: Proceedings of a Workshop](#)." The workshop explored multisector community health partnerships that engage residents, reduce health disparities, and improve health and well-being. Speakers shared strategies that they have learned make partnerships effective and described the challenges that residents and other stakeholders have had to overcome in order to create change in their communities. The workshop included demonstrations of interactive activities used to engage a diversity of residents in developing, leading, and sustaining equitable community partnerships.

Research on Continuous Support During Childbirth, from CDSR

The Cochrane Database of Systematic Reviews has released research findings in an article entitled, "[Continuous support for women during childbirth](#)." The primary objective was to assess the effects, on women and

their babies, of continuous, one-to-one intrapartum support compared with usual care, in any setting. Women allocated to continuous support were more likely to have a spontaneous vaginal birth and less likely to report negative ratings of or feelings about their childbirth experience and to use any intrapartum analgesia. In addition, their labors were shorter, they were less likely to have a caesarean birth or instrumental vaginal birth, regional analgesia, or a baby with a low five-minute Apgar score. There was no apparent impact on other intrapartum interventions, maternal or neonatal complications, such as admission to special care nursery, and exclusive or any breastfeeding at any time point.

State/Community News

New Protections for Pregnant and Breastfeeding Workers, from Massachusetts

Governor Charlie Baker of Massachusetts has signed the Massachusetts Pregnant Workers Fairness Act into law. The legislation will prohibit workplace and hiring discrimination related to pregnancy or a condition related to pregnancy, including lactation, and require employers to provide reasonable accommodations for expectant and new mothers in the workplace. [Read the press release.](#)

Assessment of School District Support for Breastfeeding Employees, from Kansas

The Kansas Breastfeeding Coalition has published a report entitled, "[Statewide Baseline Assessment of Kansas School Districts' Support for Breastfeeding Employees](#)." The coalition worked in partnership with the Kansas Department of Health and Environment and the Kansas State Department of Education to assess school districts' employment practices with regard to support of their breastfeeding employees. The assessment examined policies, scheduling of employees to allow time for milk expression breaks, accommodations in district buildings for milk expression breaks, and education of co-workers about the importance of supporting breastfeeding employees.

Collective Impact Connection

Learning From Organizing, from Collective Impact Forum

The Collective Impact Forum has released a blog post entitled, "[What Can Collective Impact Learn from Organizing?](#)." The article explores three lessons collective impact practitioners can learn from community organizers. While community organizing and collective impact are distinct change strategies, with quite different approaches and contexts in which they make sense, the themes addressed in the post can help strengthen the way we apply collective impact as an approach to achieving social change.

News & Views

The New York Times: "[Working to Close the Breast-Feeding Gap](#)"

The Huffington Post: "[How Governments Are Failing Breastfeeding Moms](#)"

Medium: "[No One Breastfeeds Alone: Alive & Thrive's Successful Model](#)"

The National Academy of Medicine: "[The Interplay of Community Trauma, Diet, and Physical Activity](#)"

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From: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Wed, 4 Dec 2019 13:13:17 +0000
To: Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) (dbg6@cdc.gov)
Subject: FW: The Journal of Pediatrics Articles in Press E-mail Alert - December 4, 2019

From: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO) <zcn6@cdc.gov>
Sent: Wednesday, December 4, 2019 6:46 AM
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO) <hkg3@cdc.gov>; Grossniklaus, Daurice (CDC/DDNID/NCCDPHP/DNPAO) <dtg3@cdc.gov>; Anstey, Erica Hesch (CDC/DDNID/NCCDPHP/DNPAO) (CTR) <yhm7@cdc.gov>
Cc: Flores-Ayala, Calixto Rafael (CDC/DDNID/NCCDPHP/DNPAO) <rnf2@cdc.gov>; MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO) <dvx2@cdc.gov>
Subject: FW: The Journal of Pediatrics Articles in Press E-mail Alert - December 4, 2019

All,

The editorial that accompanies the Bass et al. and Bartick et al. articles has been published.

Sincerely,
Jennifer

[Breastfeeding, Baby-Friendly, and Safety: Getting the Balance Right](#)
Robin H. Steinhorn

From: Elsevier Journal Alerts <journals@notification.elsevier.com>
Sent: Wednesday, December 4, 2019 3:08 AM
To: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO) <zcn6@cdc.gov>
Subject: The Journal of Pediatrics Articles in Press E-mail Alert - December 4, 2019

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[Cardiometabolic Health and Carotid-Femoral Pulse Wave Velocity in Children: A Systematic Review and Regression](#)

Lee Stoner, Anna Kucharska-Newton, Michelle L. Meyer

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Shani Ma, So Yung Choi, Hyeong Jun Ahn, Andrea M. Siu, Marian E. Melish, Andras Bratincsak

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Robin H. Steinhorn

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From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 17 Nov 2015 12:54:25 +0000
To: Scanlon, Kelley (CDC/ONDIEH/NCCDPHP)
Subject: FW: Tickets still available for this FRIDAY and NEW December seminar open!

FYI – notice the topic of the seminar – safe S2S

From: BreastfeedLA Seminars [mailto:info@breastfeedla.org]
Sent: Monday, November 16, 2015 5:26 PM
To: MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>
Subject: Tickets still available for this FRIDAY and NEW December seminar open!





BreastfeedLA

November 16, 2015



Continuing Education 2015

Do you need to know more about skin-to-skin safety, rock-solid discharge feeding plans, support groups, or formula supplementation for the breastfed baby?

If you can answer "yes" to any part of this question, join us this coming Friday in Burbank for our next seminar!

A seat is waiting for YOU: **register**
TODAY!



Baby-Friendly Hospitals: Keeping the Safety Net Strong

Friday, November 20, 2015

9:00 am - 4:00 pm

Providence St. Joseph Medical
Center
Burbank, CA



Faculty:

Susan Aldana, IBCLC BreastfeedLA

Réka Morvay, MA, IBCLC BreastfeedLA and Inland Empire Breastfeeding Coalition

Denise Parker, IBCLC Kaiser Permanente Baldwin Park

Aida Simonian, MSN, RNC-NIC, SCM, SRN Chief Executive Officer, Pac/Lac

Topics include:

Skin to Skin Safety: Reducing the Risk of Sudden Unexpected Infant Collapse

The 10 Steps: How To Fully Implement Them As a Breastfeeding Safety Net

Formula Use and the Baby-Friendly Hospital

Building An Effective Support Group: A Key to Increasing Breastfeeding Exclusivity and Duration

[Register](#) | [Download Brochure](#)

When Milk Supply is Challenged: Strategies for Treatment and Counseling



Wednesday, December 9, 2015
9:00 am - 4:00 pm
Henry Mayo Newhall Hospital
Valencia, CA

Faculty:

Lisa Marasco, MA, IBCLC, FILCA

Author, Researcher, and WIC of Santa Barbara County

Mei-Ling Schwartz, MPH

Director of Physician Education, Health Education, and Staff Development, Kaiser Permanente

Topics include:

Breastfeeding on the Insulin Dysregulation Spectrum

Deciphering the Lactation Curve: Lessons in Breastfeeding Physics from the Dairy Industry

Motivational Interviewing: Counseling the Breastfeeding Mother Facing Challenges

Guided Practice: Honing Your Motivational Interviewing Skills

[Register](#) | [Download Brochure](#)

Thank YOU for being a part of BreastfeedLA!

Our programs, which teach about and advocate for the health and well being of babies and families, are made possible through the generosity of our supporters.

Please join others who are committed to removing barriers to successful breastfeeding for all mothers and babies in Greater Los Angeles and become a Friend of BreastfeedLA with a donation of \$10 or more per month.

With your support, we can create a healthier LA for every baby!



Donate TODAY!

Sincerely,

Jessica Claire, IBCLC
jclaire@breastfeedla.org
Education Coordinator
BreastfeedLA

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Breastfeeding Task Force of Greater Los Angeles | 2851 W. 120th St. Suite
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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 26 Jun 2017 14:31:40 -0400
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP); Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP); Seymour, Jennifer (Jenna) (CDC/ONDIEH/NCCDPHP)
Subject: FW: Today is the day!! #FactsNotFear Kicks Off to Protect Breastfeeding!
Attachments: FactsNotFear Social Media Guide_FINAL.docx, Facts Not Fear Blog Post - Final.pdf

From: Kimberly Seals Allers (b)(6)
Sent: Monday, June 26, 2017 9:05 AM
Subject: Today is the day!! #FactsNotFear Kicks Off to Protect Breastfeeding!

Dear friends,

Join us TODAY as we kick-off #FactsNotFear to highlight that mothers deserve the facts - not fear-mongering - with respect to breastfeeding.

Back in April we kicked off a [coordinated effort](#) to set the record straight on breastfeeding in response to the disinformation campaign organized by the Fed Is Best Foundation. With your support, we took a stand for the truth and showed our collective strength as allies.

When we started that effort, we knew that it would be an ongoing one. Fed Is Best (FIB) continues to spread misinformation and lies about breastfeeding, and most reprehensibly is using fear as their primary tool to target families.

As mentioned, together with 1,000 Days I have posted a [new blog](#): **"Facts Not Fear: Protecting the One Place Where Fear Does Not Belong."** We have also developed some suggested social media posts and graphics for both [Facebook](#) and [Twitter](#).

Here are two ways to promote #FactsNotFear starting today:

1. Post the blog to your website and/or share it on Facebook and Twitter
2. Use the social graphics provided in the above links to get the message out that moms and families deserve #FactsNotFear

We have developed a brief social media guide (attached and below). Please do not hesitate to reach out to me with any questions or ideas.

Thank you for your ongoing support. Together, we will!

All the best,
Kimberly

#FactsNotFear Campaign: Social Media Toolkit

Objective: To highlight that mothers and families deserve FACTS, not fear-mongering, when it comes to breastfeeding.

Timing: Monday, June 26

Hashtag: #FactsNotFear

Blog Post URL: <https://thousanddays.org/facts-not-fear> (live on Monday morning)

Please feel free to incorporate the following social copy, graphics and GIF in your promotion of the #FactsNotFear campaign.

SAMPLE FACEBOOK POSTS

Yes, we live in times of fear and anxiety – much of which is beyond our control. But there's one place where we, as women and mothers, should insist that fear NOT enter – the precious act of feeding our babies. Instead, we must demand:

- FACTS about why there's a lack of societal breastfeeding support and education
- FACTS about ways for moms to safely and successfully increase breastmilk supply
- FACTS about supplement options for moms working to establish their breastmilk supply

Women deserve #FactsNotFear.

Women who wish to breastfeed have a right to guilt-free, confidence-building information and support.

And it's time that we DEMAND it of everyone – including, and especially, from those claiming to support mothers.

We cannot stand by while others insist that fear is best.

#FactsNotFear

When it comes to breastfeeding, women deserve #FactsNotFear.

Check out @KimberlySealsAllers' latest blog that makes the case for why we should question those who use fear to make their point and demand the facts.

SAMPLE TWEETS:

In a world full of fear, there's a place it should NOT exist – the act of feeding our babies. We deserve #FactsNotFear

RT if you agree: Women have a right to guilt-free, confidence-building info & support
#FactsNotFear

Author & advocate @iamKSealsAllers makes the case why women deserve the facts when it comes to breastfeeding. #FactsNotFear

SAMPLE GRAPHICS & GIF:

Facebook: <http://bit.ly/2tyGUF1>

Twitter: <http://bit.ly/2rHVn0n>

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Kimberly Seals Allers

Advocate | Writer | Consultant

Director, First Food Friendly Community Initiative ([3FCI](#))

www.KimberlySealsAllers.com

O (b)(6) | M (b)(6)

@iamKSealsAllers | @MochaManual

#FactsNotFear Campaign: Social Media Toolkit

Objective: To highlight that mothers and families deserve FACTS, not fear-mongering when it comes to breastfeeding.

Timing: Monday, June 26

Hashtag: #FactsNotFear

Blog Post URL: <https://thousanddays.org/facts-not-fear> (live on Monday morning)

Please feel free to incorporate the following social copy, graphics and GIF in your promotion of the #FactsNotFear campaign.

Sample Facebook Posts:

- Yes, we live in times of fear and anxiety – much of which is beyond our control.

But there's one place where we, as women and mothers, should insist that fear NOT enter – the precious act of feeding our babies. Instead, we must demand:

- ✓ FACTS about why there's a lack of societal breastfeeding support and education
- ✓ FACTS about ways for moms to safely and successfully increase breastmilk supply
- ✓ FACTS about supplement options for moms working to establish their breastmilk supply

Women deserve #FactsNotFear.

- Women who wish to breastfeed have a right to guilt-free, confidence-building information and support.

And it's time that we DEMAND it of everyone – including, and especially, from those claiming to support mothers.

We cannot stand by while others insist that fear is best.

#FactsNotFear

- When it comes to breastfeeding, women deserve #FactsNotFear.

Check out @KimberlySealsAllers' latest blog that makes the case for why we should question those who use fear to make their point and demand the facts.

Sample Tweets:

- In a world full of fear, there's a place it should NOT exist – the act of feeding our babies. We deserve #FactsNotFear
- RT if you agree: Women have a right to guilt-free, confidence-building info & support #FactsNotFear
- Author & advocate @iamKSealsAllers makes the case why women deserve the facts when it comes to breastfeeding. #FactsNotFear

Sample Graphics & GIF:

- Facebook: <http://bit.ly/2tyGUFI>
- Twitter: <http://bit.ly/2rHVn0n>

Facts Not Fear: Protecting the One Place Where Fear Does Not Belong.
By Kimberly Seals Allers

We live in a world of fear. From the recent terrorist attacks in England to last year's Orlando nightclub massacre. We have seen how the fear of outsiders has sparked powerful political movements around the world. As a frequent business traveler I sense my own anxiety as I sit on planes and trains, and as a mother I know the feeling that sweeps over me whenever I receive an incoming phone call from my children's school.

Yes, we live in times of fear and anxiety—much of which is beyond our control.

But there is one place where fear should not exist. There is one area, where, as women and mothers, that we should insist that fear not enter—that is in the precious act of feeding our babies. From the time they are first placed in our arms, we are anxious that we will do our best. Yes, we are nervous that we will make mistakes. But we should not be made to dread our ability to mother—particularly when it comes to feeding our infants—one of our very first tasks.

That's why a recent spate of fear-based marketing, particularly from the Fed Is Best Foundation, stoking fears that exclusive breastfeeding kills babies is both erroneous and irresponsible. But it is also the type of insidious marketing that preys on a mother's existing insecurities that should make all women concerned. If the only way Fed Is Best can make its point is by sensationalizing infant deaths and undermining our confidence in our bodies—then maybe their point needs to be carefully considered.

Or, as women, we insist that they make it with valid facts and sans the fear mongering.

Let's face it, women are sold fear and anxiety as a marketing tool every day. In fact, the strategy, officially known in business circles as FUD—fear, uncertainty and doubt—was designed by an IBM executive decades ago to persuade buyers to feel “safe” with IBM products rather than risk a crash, virus or server disruption. By the early 90's it was generalized to refer to any kind of misinformation used as a competitive weapon.

Today, weaponizing fear takes many forms. We fear our faces aren't pretty enough, so we buy cosmetics. We worry that our body isn't the right “type” so we are sold diet plans and surgical procedures. We are told our hair isn't shiny, bouncy or thick enough so we are sold multitudinous hair products. And then we are told to fear that our bodies may not properly do what they are biologically made to do, and we are sold infant formula.

The truth is, our bodies were uniquely made to feed the infants we create. Decades of scientific research proves that formula is nutritionally inferior to breastmilk. Admittedly, societal pressures, structural barriers such as a lack of paid maternity leave, and physicians who receive little to no training in lactation science in medical school, make it very difficult for some women to fulfill their biological norm. Many women who want to breastfeed find undereducated physicians and nurses and limited post-natal support—particularly in the early days after discharge. We have much to overcome.

To be clear, infant formula is necessary. When a mother's own breastmilk or human donor milk is not available, then infant formula is an important third option that can, at times, save lives. However, women should come to that decision fully informed, not because of marketing efforts

designed to incite distrust in their own bodies or threatened with the fear of the death of their infant.

It's no secret that, especially in the Western world, women already fear they will have insufficient milk. For some, this fear can become a self-fulfilling prophecy because fear and anxiety can literally limit lactation by stifling the letdown reflex that stimulates the milk glands. Feeding into this insecurity by promoting early formula supplementation "just in case" has been a go-to move by the formula industry for years.

As far back as the 1940s, the manufacturers of Borden KLIM evaporated milk ran a radio jingle in the Congo that stoked mother's fears over insufficient milk. The song went:

The Child is going to die
Because the mother's milk has given out
Mama o Mama the child cries
If you want your child to get well
Give it KLIM milk

So when Fed Is Best frequently promotes eerily similar headlines claiming, "One bottle would have saved my baby"—it seems to make early supplementation innocuous, while deploying a similar tactic used to spur sales of infant formula. The insidious message is that your breast cannot be trusted but a bottle can—this type of marketing should concern all women.

Instead of fear, we should demand the facts about why physicians and nurses don't have more education to properly identify lactation dysfunction or failure. We should demand knowledge about other options to increase milk output such as hand expression, which can extract more milk than a pump. If formula must be used, it should be administered as a temporary bridge until a mother's supply is established, not a breastfeeding killer for mothers who want to nurse. And we should demand standard home visitation immediately after discharge, as is the practice in the UK and other European countries.

Ultimately, women deserve facts not fear. Women have a right to guilt-free, confidence-building information and support. And it's time that we demand it of everyone—including, and especially, from those claiming to support mothers. We cannot stand by while Fed Is Best insists that fear is best.

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 21 Sep 2016 11:05:20 +0000
To: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Subject: FW: Two quick updates

Carol -

Oct 4, 2 – 3 pm works for Allison. Do you want to reach out to her about the specifics? Please let me know how you would like to proceed.

Thanks,
Daurice

From: Cynthia Klein (b)(6)
Sent: Tuesday, September 20, 2016 4:50 PM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>
Subject: RE: Two quick updates

That works. Here's Allison's email address to coordinate specifics. I know she is interested to learn about any expectations for prep work that she'll need to do.

(b)(6)

Thanks,

Cynthia

Cynthia Klein, PhD
Principal Associate
Abt Associates

(b)(6)

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) [<mailto:dtg3@cdc.gov>]
Sent: Tuesday, September 20, 2016 4:08 PM
To: Cynthia Klein
Subject: RE: Two quick updates

How about Oct 4, 2 – 3 pm?

From: Cynthia Klein (b)(6)
Sent: Tuesday, September 20, 2016 12:52 PM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>
Subject: RE: Two quick updates

Hi Daurice,

Allison is out at all-day meetings on the 26th and 27th. Is there another date that might work?

Cynthia

Cynthia Klein, PhD
Principal Associate
Abt Associates

(b)(6)

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) [<mailto:dtg3@cdc.gov>]
Sent: Tuesday, September 20, 2016 12:22 PM
To: Cynthia Klein
Subject: RE: Two quick updates

Cynthia,
Could you please check about this date and time. If not available, then we will try to figure out other options.
9/27 at 2-3 pm?
Thanks,
Daurice

From: Cynthia Klein (b)(6)
Sent: Tuesday, September 20, 2016 8:51 AM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>
Subject: RE: Two quick updates

Glad to see this go up and we'll make sure to pass on to the rest of our team. Thanks.

Cynthia Klein, PhD
Principal Associate
Abt Associates

(b)(6)

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) [<mailto:dtg3@cdc.gov>]
Sent: Tuesday, September 20, 2016 8:00 AM
To: Cynthia Klein
Subject: RE: Two quick updates

Cynthia,

Thanks, I will let Carol know and ask her to send you the details. In case you have not seen the new page related to safety on the BFUSA website, so here is the link <https://www.babyfriendlyusa.org/get-started/the-guidelines-evaluation-criteria/safety-of-baby-friendly-practices>.

Daurice

From: Cynthia Klein (b)(6)
Sent: Friday, September 16, 2016 4:33 PM
To: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>
Subject: Two quick updates

Hi Daurice,

Good to catch up with you this week...a couple of follow-up items below from our meeting.

1. Allison would be happy to participate as a QI expert on the workgroup call Carol is coordinating assuming she doesn't have any other commitments at that time/date. If you can send along the details once available, I can send to Allison and she can Carol can coordinate from there. She's excited about the opportunity!
2. As for the other meeting this week, we couldn't find a time to connect while in Atlanta but we're setting up a time to talk next week.

Hope you have (had) a nice weekend!

Cynthia

Cynthia Klein, PhD | Principal Associate | Abt Associates
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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Fri, 29 Sep 2017 18:12:47 +0000
To: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP); Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Cc: Carol MacGowan (dvx2@cdc.gov)
Subject: FW: Update from Baby-Friendly USA

FYI. Trish mentioned this on a call with Carol and I yesterday.

From: Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP)
Sent: Friday, September 29, 2017 1:16 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP) <rnf2@cdc.gov>
Subject: FW: Update from Baby-Friendly USA

All,
I was forwarded this message. I assume you are aware, but just in case.
Daurice

Baby-Friendly usa

The gold standard of care



Dear Friend of Baby-Friendly USA,

It has been a month-and-a half since Baby-Friendly USA and 40 other organizations sent an open letter to the leaders of the Fed Is Best (FIB) Foundation requesting a meeting. As we stated in the letter, our intent was to initiate a constructive dialogue in the hopes that we could “unite in a shared vision rather than engaging in divisive messaging.” We wanted to believe that our common goal of ensuring that every baby gets the best start in life could enable us to unify in clear, consistent, evidenced-based messaging to parents and parents-to-be.

We shared that letter with all US hospitals enrolled in the Baby-Friendly Hospital Initiative (BFHI) on August 15. You can read the letter [here](#).

We are disappointed to inform you that, as of this date, FIB has responded only with contentious rhetoric and has not accepted our invitation to meet.

At the same time, we have also learned that FIB has continued its divisive crusade by launching a campaign that urges mothers to complain to hospitals and The Joint Commission about the early care they have received related to infant feeding. We want you to be aware of this campaign because some of you may receive (or may have already received) a personalized version of the FIB form letter and we want you to be informed about the original source. You can read the form letter [here](#).

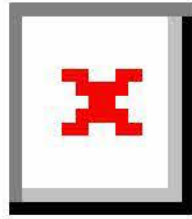
The BFHI has enabled tremendous progress in lactation support since its inception over two decades ago. Across our great nation, we have seen maternity wards transform from places historically infused with enormous influence from formula companies and default infant feeding practices that undermined breastfeeding, to environments in which evidenced-based care is provided, education is free from commercial interests, all infant feeding options are possible, and individual preferences are respected. We need to build on this progress and strive to meet Baby-Friendly metrics by continuing to ensure each family receives the individualized care and support that is most responsive to their needs.

Culture change is not easy and we have worked hard to find the proper balance on behalf of mothers and babies everywhere. I am very proud to say that, together, we have accomplished a very important achievement – the extraction of formula company influence from the first critical days of an infant's life, thus enabling true freedom for every mother to choose her preferred feeding method.

Despite these challenges to the mission of the BFHI by this organization that is using strategies to undermine mothers confidence in their ability to breastfeed similar to those used by the formula companies, we stand united with hospitals and the breastfeeding community and will continue to push forward. Our offer to meet with FIB remains open and we hope we will find the common ground we seek for all mothers and babies.

Sincerely,

Trish MacEnroe
Executive Director



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From: Hamner, Heather (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Tue, 5 Oct 2021 19:10:40 +0000
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO); MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO)
Cc: McGowan, Andrea (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: updated breastfeeding history
Attachments: Breastfeeding History _9.29AM.xlsx

A BIG thank you to Andrea for developing this summary of breastfeeding history. Sharing with you both for future reference.

Thanks,
Heather

Heather C. Hamner, PhD, MS, MPH
Health Scientist
Maternal, Infant, and Toddler Nutrition Team
Division of Nutrition, Physical Activity, and Obesity
Centers for Disease Control and Prevention
Phone: 404-498-3868 Email: hfc2@cdc.gov

What	Year	Description	Category	Major Players	Impact	Equity
Baby Friendly Hospital Initiative	1991	Global effort to promote and protect breastfeeding by implementing WHO's ten steps to successful breastfeeding	Hospital Efforts	CDC National Institute for Children's Health Baby Friendly USA UNICEF	In 2011, 100 US hospitals were baby friendly, impacting 6.2% of births in the US Provided coaching to 90 hospitals on applying the model for improvement to maternity care in pursuit of baby friendly designation	Through standardization of the "baby friendly designation," they are ensuring that all facilities have high standards of care, thus improving care in an equitable way for the locations serviced
Best Fed Beginnings	2011-2015	Nationwide quality improvement initiative to help hospitals improve maternity care and increase # of baby friendly designated hospitals. Some of the problems of this one stemmed from really trying to accelerate the pace for baby friendly designations. Empower focused on a similar approach with a different mechanism and different players. Focus on baby friendly designation.	Hospital Efforts	CDC Baby Friendly USA USBC National Institute for Children's Health Quality	72 out of 90 hospitals received this designation, doubling the number of baby friendly hospitals in the US 72 of the 94 participating hospitals successfully achieved Baby-Friendly designation. This added Baby-Friendly designated hospitals in two states without baby-friendly designated hospitals, including five hospitals in Arkansas and three in West Virginia.	see above
EMPower Breastfeeding: Enhancing Maternity Practices	2014-2018	Implementation of the evidence-based maternity care practices leading to designation as Baby Friendly based on WHO's ten steps. Three year program building on lessons learned in the BFB course. Helped hospitals become baby friendly designated. Increased focus on safety and prevention of SIDS. Focus on baby friendly designation. The focus was building capacity of hospital-based maternity staff by providing 5 hours of skills competency training on safe implementation of evidence-based maternity practices that support breastfeeding. Training and technical assistance to advance the capacity of hospital staff to implement the practices. Includes digital tools and training guides. Safe implementation of 10 steps. focused on training and technical assistance to help hospitals train staff with underlying lens of hospital safety.	Hospital Efforts	CDC Carolina Global Breastfeeding Institute Abt Associates	81 of the 85 participating hospitals reached the goal of training 80% of their maternity staff, and many trained more than 90% of their staff. At the conclusion of the project, 3,626 maternity staff received 5 hours of competency training for a total of 18,130 hours.	see above
EMPower training	2017-2019	Quality improvement aimed at improving evidence-based maternity care practices supportive of optimal infant nutrition through skills-based competency training and ongoing technical assistance	Hospital Efforts	CDC Carolina Global Breastfeeding Institute Abt Associates		see above
EMPower Best Practices	2020-2024	Training compliant with WHO's Ten Steps and Baby Friendly USA requirements. Skills based competency training to help maternity staff improve breastfeeding support for culturally diverse populations the hospital serves. Focused on a similar safety lens as previous iterations, while adding cultural component * Cultural diversity curriculum was more integrated	Hospital Efforts	Abt Associates UNC Global Breastfeeding Institute and Population Health Improvement Partners CDC	In enrollment/ recruitment phase. Impact yet to be measured.	Focuses on priority populations. There are existing differences in how maternity practices were provided in southern states based on race/ethnicity. We need to improve our communication skills in these populations to ensure equitable and culturally competent care

Please refer to this link to see preferred terms for at risk and underserved populations: https://www.cdc.gov/healthcommunication/P-referred_Terms.html

What	Year	Description	Category	Major Players	Impact	Equity
Racial and Ethnic approaches to Community Health (REACH)	1999-present	National program administered by the CDC to reduce racial and ethnic health disparities. Goals include planning and executing local, culturally appropriate programs to address a wide range of health issues including breastfeeding initiatives	State and local programs	CDC States and local communities	2020: 29/31 states 2021: 33/36 REACH Recipients are working on breastfeeding strategies All are working on breastfeeding continuity of care. We received additional funding to fund 5 more states	Goal of funding is to address specific priority populations/communities. This includes: * racial and ethnic groups: Black or African American, Hispanic or Latino, American Indian, and Natives of Hawaii, other Pacific Islands and Alaska
Nutrition, Physical Activity, and Obesity (NPAO) Program's Cooperative Agreement (Breastfeeding Supplement), CDC-RFA-DP08-050501PPHF12	2012-2013	Funding was awarded to 6 states for the purpose of implementing innovative projects addressing community level support, for the purpose of informing our work. This resulted in the publication of a special supplement to the Journal of Human Lactation (November 1, 2015) describing the projects and their impact. Supplement to former SPAN program	State and local programs	CDC States and Local Communities	Special Issue on a CDC Initiative to Improve Community-Based Support for Breastfeeding. This supplement influenced the development of the Blueprint and NACCHO's continuity of care work. It is supplemental funding to 805 recipients	*no clear equity focus
Funding of National Association of County and City Health Officials (NACCHO)	2014 to present	Funded to work with communities, to implement strategies to increase access to support for breastfeeding. In 2021, as a culmination of this work, NACCHO has published the Continuity of Care Blueprint to continue to guide this work. They have goals of reducing breastfeeding disparities in breastfeeding.	State and local programs	CDC NACCHO REACH Grantees	Two rounds of funding: 2014-2018: In 2014, NACCHO, in partnership with the Centers for Disease Control and Prevention's Division of Nutrition, Physical Activity, and Obesity (DNPAO), implemented the Reducing Disparities in Breastfeeding through Peer and Professional Support project to increase breastfeeding rates among African American and underserved populations. The effort supported implementation of community-level peer and professional breastfeeding support programs at 72 local health departments (LHDs), community-based organizations (CBOs), and local hospitals in 32 states and territories. Grantees provided direct community-level breastfeeding support. Lessons learned from this funding cycle led to the publication of several articles in the Journal of Human Lactation and influenced the development of the Continuity of Care Blueprint. 2018-present: NACCHO actively supports local approaches to chest/breastfeeding protection, promotion, and support. NACCHO is currently implementing the Reducing Breastfeeding Disparities through Continuity of Care project to develop a national Continuity of Care (COC) blueprint with national partners, provide targeted technical assistance to CDC REACH grantees in COC, and funding Continuity of Care community partnership activities. In 2021, NACCHO created the Continuity of Care Blueprint. NACCHO has also launched a Request for Applications (RFA) entitled Implementing the Continuity of Care in Breastfeeding Support: A Blueprint for Communities. Eligible applicants include local health departments and community-based organizations working with oppressed communities with historically low rates of	working with priority populations that to improve outcomes and reduce disparities
Funding of Association of State and Territorial Health Officials (ASTHO)	2014 to present	Since 2014, CDC has funded ASTHO and APHN to provide training, technical assistance to state departments of health, to increase their capacity to provide guidance and support for breastfeeding programs at the state and local level.	State and local programs	CDC ASTHO APHN	Two rounds of funding: 2014-2018: supported 18 states and district of Columbia in implementing and improving strategies to increase breastfeeding initiation and duration rates. Toolkit focused on hospital policies and practices, peer and professional support, and encouraging breastfeeding friendly worksites. 2018 to present: assist current SPAN program recipients in increasing their capacity for breastfeeding programs in three key areas: * increase practices supportive of breastfeeding in birthing facilities, provide access to professional and peer support for breastfeeding, ensure workplace compliance with the federal lactation accommodation law 2020 innovation grant: funding 9 states in strategies to advance state-level breastfeeding and health equity through innovative strategies	* innovation grants focus on health equity of priority populations to reduce health disparities
State Physical Activity and Nutrition (SPAN)	2018 to present	CDC funds implementation of evidence based strategies at state and local levels to improve nutrition and physical activity. Required to address one of the following breastfeeding practices: Maternity care practices in birthing facilities, continuity of care/community support, workplace compliance with the federal lactation accommodation law	State and local programs	CDC States and local communities	2020: 16/16 states 2021: 16/16 are working on breastfeeding initiatives Strategy counts: *Maternity care practices in birthing facilities 10/16 *Continuity of care/community support: 14/16 *workplace compliance with the federal lactation accommodation law: 9/16	Applicants for this funding have to describe how it will address health disparities- no specific focus on health equity and this isn't asked again in their work plan
Other funding outside of DNPAO : Community transformation grants (CTG) Communities putting prevention to work (CPPW)	CTG (2011-2014) CPPW (2009)	CTG: helped communities design and carry out local programs that prevent chronic diseases such as obesity, diabetes and heart disease as well as breastfeeding CPPW: funded 50 communities on prevention based efforts that might have touched on breastfeeding *both housed in DCH/NCCDPHP	Local communities	CDC State and Local Communities		

What	Year	Description	Category	Major Players	Equity
Healthy People 2020	2020	Included various breastfeeding related topics as indicators. This has served to create awareness and support for progress on these indicators. MICH-21.1: Increase the proportion of infants who are ever breastfed MICH-21.2: Increase the proportion of infants who are breastfed at 6 months MICH-21.3: Increase the proportion of infants who are breastfed at 1 year MICH-21.4: Increase the proportion of infants who are breastfed exclusively through 3 months MICH-21.5: Increase the proportion of infants who are breastfed exclusively through 6 months MICH-22: Increase the proportion of employers that have worksite lactation support programs MICH-23: Reduce the proportion of breastfed newborns who receive formula supplementation within the first 2 days of life MICH-24: Increase the proportion of live births that occur in facilities that provide recommended care for lactating mothers and their babies	Surveillance and research	CDC	Equity focus in some of the goals - "obtaining highest level of health for all"
Healthy People 2030	2030	included breastfeeding in their objectives. This has served to create awareness and support for progress on these indicators. *Increase the proportion of infants who are breastfed exclusively through age 6 months — MICH 15 *Increase the proportion of infants who are breastfed at 1 year — MICH 16	Surveillance and research	CDC	Equity focus in some of the goals - "obtaining highest level of health for all"
National Immunization Survey	2001 present	Breastfeeding questions were added to NIS to gather information on breastfeeding rates at both national and state levels by birth year. All respondents with children ages 19-35 months are included Survey administered to every facility in the US and territories that routinely provided maternity care services to evaluate *Survey was administered to hospitals and birth centers from 2007-2015. Starting in 2018, it was only administered to hospitals.	Surveillance and Research	CDC	data can be used to identify priority populations for intervention efforts equity in the sense that all hospitals are held to the same standards and data can help elevate level of care equitably.
mPINC	2007 to present	Private proprietary national marketing survey collecting health related opinions of men and women aged 18 or older. Questions about public opinion on breastfeeding.	Surveillance and Research	CDC Batelle	
SummerStyles	1999	a longitudinal study that followed about 2,000 mother-infant pairs from the third trimester of pregnancy throughout the first year of life to study a variety of infant feeding practices.	Surveillance and Research	CDC	data can be used to identify priority populations for intervention efforts
IFPS II	2005-2007	study among mothers and children who participated in the IFPSII to characterize the health, development and dietary patterns of these children at 6 years of age	Surveillance and Research	FDA CDC	see above
6 Year Follow-up	2012	longitudinal study that will follow about 2,500 mothers and children from birth through 24 months of age. This study will assess feeding practices and related health outcomes during a critical period of child development.	Surveillance and Research	FDA CDC	see above
IFPS III Breastfeeding Report Cards	Anticipated 2021 2007	Reports state level mPINC metrics to help provide trends and areas needed for improvement on the state level for hospital practices	Surveillance and Research	FDA CDC NIH USDA	see above
			Surveillance and Research	CDC	see above

What	Description
	<p>infrastructure and support for work being done through constellations on multiple aspects of breastfeeding.</p> <p>Constellations are led by different organizations and include members from organizations and agencies throughout the United States</p>
United States Breastfeeding Committee (USBC)	<p>US.</p> <p>example of federal agencies coming together regularly to share information with one another and coordinate efforts.</p>
Federal Interagency Breastfeeding Workgroup	<p>increase the availability and accessibility of medical provider education and training related to breastfeeding.</p> <p>This project included a Project Advisory Committee of 11 different organizations.</p>
American Academy of Pediatrics	

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Wed, 2 Aug 2017 14:05:03 +0000
To: Flores-Ayala, Calixto Rafael (CDC/ONDIEH/NCCDPHP)
Subject: FW: Updated- FBFWG agenda/talking points
Attachments: FBFWG Discussion_Aug 2017_long.docx

FYI

From: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Sent: Wednesday, August 2, 2017 9:51 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Olson, Christine (CDC/ONDIEH/NCCDPHP) <cco7@cdc.gov>
Subject: Updated- FBFWG agenda/talking points

All-

I have modified the agenda based on your comments and added a few talking points. I will print 3 copies for us. Additionally, I have 1 copy of the Bass article and 1 copy of the 7 replies. If they want more, I was thinking they could be photocopied there.

As far as distribution of material, I am fine with whatever but will propose the below as the main discussant:

1a (SUPC): Jennifer
1b (Fed is Best): Cria
2 a-c: Christine
2d-f: Cria/Jennifer
3: All

Jennifer

Jennifer M. Nelson, MD, MPH, FAAP
LCDR United States Public Health Service
CDC/NCCDPHP/DNPAO/Nutrition Branch
4770 Buford Hwy, MS F-77, Atlanta, GA 30341-3717
Ph: 770-488-5157 | Email: jmnelson@cdc.gov

(b)(5)

From: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO)
Sent: Fri, 13 Dec 2019 17:15:25 +0000
To: Nelson, Jennifer M. (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FW: What's new for 'breastfeeding' in PubMed

Supporting Breastfeeding Mothers During Dermatology Residency-Challenges and Best Practices.

Epigenetics: Linking Early Postnatal Nutrition to Obesity Programming?

Parental Concerns about Newborn Feeding Post Hospital Discharge.

Lactation-Specific Certifications: A Comparison of Independently Accredited Credentials.

Limitations of Workplace Lactation Support: The Case for DC WIC Recipients.

Effects of Dextrose Gel in Newborns at Risk for Neonatal Hypoglycemia in a Baby-Friendly Hospital.

Breastfeeding, Baby-Friendly, and Safety: Getting the Balance Right.

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Subject: FW: WHO/UNICEF Breastfeeding Collective Evidence Working Group
Attachments: Why the 2017 Revision of Academy of Breastfeeding Medicine Supplementation Guidelines Make the Baby-Friendly Hospital Initiative Unsafe.pdf

FYI

From: Michele Griswold (b)(6)
Sent: Monday, October 30, 2017 11:22 AM
To: Elizabeth Zehner <EZehner@hki.org>; Parry, Kathy <kathyparry@unc.edu>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Maaïke Arts (b)(6)
Cc: Grummer-Strawn, Laurence <grummerstrawnl@who.int>; France Begir (b)(6); Irum Taqi (b)(6)
Subject: WHO/UNICEF Breastfeeding Collective Evidence Working Group

Hello everyone,

Thank you once again for volunteering to participate in the WHO/UNICEF Breastfeeding Collective Evidence Working Group. I was able to speak with Larry and Irum a few days ago to discuss the activities of this group. I would like to set up a conference call to discuss the expectations listed in the Terms of Reference (TOR) and to settle on some preliminary next steps. I will be sending a doodle poll shortly to try to find a time that we are all available.

One specific area identified by the TOR is to identify scientific issues surrounding current controversies. As you are all aware, the new operational guidelines of BFHI will launch soon. As expected, the [Fed Is Best](#) group is getting a fair amount of press expressing opposition. This is one key area for us to be aware of and to have discussion sooner than later. FIB has issued a report surrounding their evidence claims on exclusive breastfeeding in the first few days following birth. It is on the website but I have attached it here for you to take a look.

We can begin to discuss this report through email until we can schedule a meeting. It is uncertain whether or not a response from the Collective is warranted but the sooner we understand the oppositional claims, the better. I suspect that our individual organizations will also be concerned about the press from FIB.

I look forward to your thoughts and to scheduling our first call.

Many thanks again,

Michele

Michele Griswold, PhD, MPH, RN, IBCLC

President, International Lactation Consultant Association
Board Liaison, Advocacy Committee and Global Collaboration Committee
michelegriswold@ilca.org



Why the 2017 Revision of Academy of Breastfeeding Medicine Supplementation Guidelines Make the Baby-Friendly Hospital Initiative Unsafe

by Christie del Castillo-Hegyi, M.D., Co-Founder of the Fed is Best Foundation

On September 22, 2017, senior members of the Fed is Best Foundation met with the top officials of the World Health Organization (WHO) Breastfeeding Program. We learned that the WHO has never studied the complications of the WHO Ten Steps to Successful Breastfeeding and the Baby-Friendly Hospital Initiative (BFHI). We learned they have no studies commissioned to monitor the complications. Despite being presented data on how unsafe and frankly illegal allowing newborns to fast for days in order to exclusively breastfeed is, they declined our offer to help make the guidelines safer and more ethical. We learned that they have known about the risks of brain injury from exclusive breastfeeding and yet refuse to inform the public and health professionals. We learned that their provision for preventing brain injury consisted of telling health professionals to look out for "convulsions, lethargy and being unable to feed," which are late signs of newborn brain injury. As a result, the WHO Ten Steps and the BFHI has created to an epidemic of infant feeding complications, hospitalization, brain injury and disability in the developed and developing world. This constitutes one of the largest and most egregious violations of patient and human rights in the history of public health and medicine. They have asked for comments from the public regarding their draft revision of the breastfeeding guidelines, which make no changes to the recommendation, "give infants no food or drink other than breastmilk unless medically indicated," while providing patients no information on the risks of avoiding supplementation. This is the official response of the Fed is Best Foundation to their request.

The Academy of Breastfeeding Medicine (ABM) recently published a [revision of their supplementation protocol](#), which provides the criteria of the WHO's BFHI to protect exclusive breastfeeding rates at discharge while providing guidelines for "medically-indicated" supplementation to prevent the known brain-threatening complications of underfeeding exclusively breastfed (EBF) newborns. The updated version of the guidelines unfortunately does not protect exclusively breastfed newborns from these complications as they in fact allow newborns to go past what is developmentally safe. They provide inadequate monitoring and prevention of hypoglycemia (low blood glucose), hyperbilirubinemia (excessive jaundice) and hypernatremia (high sodium from severe dehydration) and wait until late signs that herald the onset of brain injury to occur before testing for the conditions. They fail to fulfill the basic ethical obligation required of physicians and health care professionals to provide balanced and honest information on the common and serious complications associated with exclusive breastfeeding of newborns before copious milk production (lactogenesis II). In addition, many of the assumptions made by the ABM guidelines are based on logical fallacies that plague breastfeeding medicine. The entire system of feeding is based on the belief that babies can wait to be fully fed for days without consequence to their brain and vital organs and that supplementation is the cause of lactation failure rather than a reflection of a mother's biological

tendency to produce less milk and need to supplement. Unfortunately, it is not evident that experts in neonatal and pediatric neurology, neonatology nor pediatric endocrinology have been consulted in producing these guidelines as they appear to ignore the basic tenets of those disciplines. By denying much of the basic science of neonatal feeding and brain physiology, the ABM guidelines and the Baby-Friendly Hospital Initiative, which uses their guidelines, are operating blind to the dangerous conditions they allow newborns to be exposed to for the purpose of increasing rates of exclusive breastfeeding at discharge.

The Most Unsafe Aspects of the 2017 ABM Supplementation Criteria

1. The guidelines operate with no awareness of the caloric content of colostrum nor the caloric requirements of newborns to prevent starvation and serious injury to the brain and vital organs.
2. The ABM guidelines exclude healthy, term appropriately-sized exclusively breastfed newborns from being monitored for brain-threatening hypoglycemia when the scientific literature shows they are in fact at high risk for developing it.
3. The ABM guidelines allow newborns with hypoglycemia as low as 40-45 mg/dL to remain uncorrected with IV glucose and supplementation despite the known risks of brain injury and reduced long-term academic achievement associated with those glucose levels. Their hypoglycemia guidelines even suggest that a glucose as low as 28 mg/dL may be tolerable within the first 2 hours of life.
4. They state that 10% weight loss is not an automatic cause of supplementation without providing any research on what weight loss is in fact safe for a newborn. They allow a weight loss of 8-10% and suggest allowing greater than 10% weight loss at the same time that other research shows that brain-threatening complications occur by 7% weight loss. The guidelines require a newborn to exhibit signs of "*significant dehydration* including *high sodium [hyponatremia]*, *poor feeding and lethargy*" to be supplemented, which are late signs of newborn starvation and brain injury.
5. The threshold for supplementation to treat hyperbilirubinemia increases a child's risk for brain injury and developmental disability.
6. The ABM protocol and the BFHI guidelines recommend informing mothers of the risks of formula supplementation while making no mention of the risks of underfeeding, brain injury and disability from avoiding supplementation, a significant part of the protocol. Mothers are typically sent home before they have adequate milk supply to prevent feeding complications and are given no advice on how supplementation can prevent brain injury. For babies who are underfed, parents often find them lethargic or underweight, possibly brain-injured needing emergent hospitalization shortly after discharge.
7. Even when babies develop brain-threatening complications that meet their criteria for "medical indication" for supplementation, they recommend restricted feeding volumes meant to emulate exclusive colostrum feeding, even when those restricted volumes are what typically lead to the child's starvation-related complications.

The guidelines operate with no awareness of the caloric content of colostrum nor the caloric requirements of newborns to prevent starvation and serious injury to the brain and vital organs.

The ABM guidelines suggest that even if a mother has scant colostrum and suspects that it is insufficient to feed her one-day-old newborn, supplementation is not indicated.

"Careful attention to an infant's early feeding cues, keeping the infant safely skin-to-skin with mother when she is awake, gently rousing the infant to attempt frequent breastfeeds, and **teaching the mother hand expression of drops of colostrum, may be more appropriate than automatic supplementation after 6, 8, 12, or even 24 hours.**"[\[1\]](#)

The guidelines arbitrarily believe that exclusively breastfed newborns can sustain up to 24 hours of being fed "drops" of colostrum before they experience starvation physiology and the associated brain injury without any way to monitor which baby will develop these complications, i.e. glucose monitoring. In fact, lactation consultants are commonly taught that it is acceptable for a healthy, term appropriately-sized newborns to go without a drop of milk for a full 24 hours without any data on safety. It appears that the ABM may not be aware of the number of calories contained in those drops of colostrum and how many calories are required to keep a newborn from starving and developing brain injury. The number of calories required to prevent newborn starvation is their basal metabolic rate, which is the number of calories required to keep all their living cells alive, including brain cells, over 24 hours. This daily caloric requirement is [100-120 Cal/kg/day](#).[\[2\]](#) This is the same requirement for every newborn whether they are breastfed or formula-fed from the first day of life throughout the newborn period. The protocol operates with no awareness of this caloric requirement nor the [caloric content of the colostrum, which is 54 Cal/dL](#), which is in fact lower than the caloric content of mature breast milk (66-77 Cal/dL) and formula (66 Cal/dL), despite the widely perpetuated myth that it in fact has more calories.[\[3\]](#) The guidelines therefore operate with no awareness of the caloric yield of an average mother's colostrum and arbitrarily declares virtually all colostrum to be enough without scientific evidence. In fact, the [average mother](#) produces about 55 mL of colostrum on the 1st day, then 185 mL on the 2nd day and 380 mL on the 3rd day.[\[4\]](#) This provides about 10%, then 33% then 66% of a 3 kg (6.5 lb) newborn's daily caloric requirement, not meeting the full requirement until day 4 of life (see figures below).

[caption id="attachment_4931" align="alignnone" width="960"]

Caloric Needs of Newborns to Ensure Cell Survival

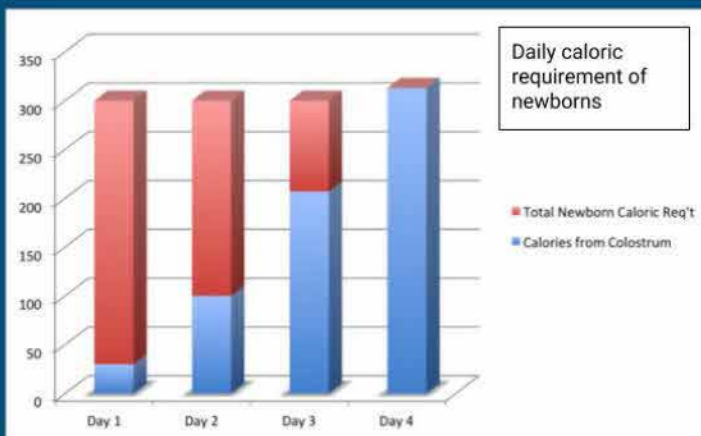
Day of life	Average daily colostrum production ¹¹	Calories provided by colostrum	Daily 3 kg newborn caloric req't
Day 1	56 mL/day	30 Cal	300 Cal
Day 2	185 mL/day	100 Cal	300 Cal
Day 3	383 mL/day	207 Cal	300 Cal
Day 4	580 mL/day	313 Cal	300 Cal

Also the approximate acceptable volumes of colostrum feeding per the BFHI / ABM guidelines¹²

Figure 1. The average daily caloric yield of colostrum vs. the daily caloric requirement of a 3 kg (6.5 lb) newborn[/caption]

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When colostrum/milk meets the newborn caloric need



Only on the fourth day does an "average" mother produce sufficient milk to meet the full caloric need of a 3 kg newborn.

Figure 2. The average daily caloric yield of colostrum requires an exclusively breastfed newborn to fast for 3 days until a mother's milk comes in. [/caption]

This means that an average exclusively breastfed newborn is in fact fasting for first 3 days of life, which is the reason why they lose weight. It is also the reason why they cry and breastfeed non-stop and why mothers typically express concern about their babies not receiving enough milk in those first few days. The ABM states that small feedings as small as [2 mL per feed is sufficient](#) to feed a one-day old newborn citing outdated and incorrect data that the one-day-old newborn stomach is 5-7 mL when in fact it is [20 mL+ by ultrasound and autopsy studies](#) with an even larger capacity considering that the stomach empties into the intestines during feeds.[1,5] A ten-fold growth in stomach size and cellular metabolism over the course of 2-3 days is anatomically and physiologically impossible yet the BFHI has taught this to parents and health professionals while again providing no scientific evidence. In reality, only the newborn knows how depleted they are of calories and how many calories they require to prevent starvation. Newborns who are freely offered milk are known to easily take 30-60 mL per feeding regardless of the type of milk they receive every 2-3 hours, even on the first day of life, while rarely allowing themselves to lose greater than 7-8% of their birth weight when given free access to milk.[6] 30-60 mL feedings every 2-3 hours meets the full daily caloric requirement of most newborns of [2.7 oz/lb or 6 oz/kg](#), which is determined by the metabolism of their living cells, *not the volume of colostrum their mother happens to produce*. [2] If a mother's colostrum volume is lower than average or her child has higher metabolic needs or has trouble extracting milk, her exclusively breastfed newborn will lose weight more rapidly. The fasting conditions imposed by the protocol quickly leads to catabolism, weight loss, extreme hunger and thirst in newborns and can lead to the starvation-related complications of hyperbilirubinemia, hyponatremia, dehydration and hypoglycemia if the child's nutritional requirements are not met by the mother's colostrum. The sooner her copious milk production arrives, the sooner her newborn is rescued from this fasting state. If a mother's milk comes late (which happens to [22% of all mothers](#) and [42% of first-time mothers](#)) or comes in insufficient quantities, her baby is exposed to the brain-threatening complications of starvation if not supplemented.[7,8]

Normalizing Newborn Hunger and Distress

As a newborn's glucose reserves decline, a newborn will exhibit distress through non-stop crying and nursing when breastfeeding is the only source of calories and fluid provided. These signs typically found in exclusively breastfed newborns by the second night of life is so common that the breastfeeding industry calls it, ["The Second Night Syndrome."](#) the second night of fasting where babies are experiencing severe hunger and thirst while they still have enough reserve energy to cry.[9]

[caption id="attachment_5085" align="alignnone" width="2048"]



Figure 3. Patient information on the Second Night Syndrome from Lutheran Children's Hospital. [/caption]

The Baby-Friendly Hospital Initiative, through the ABM guidelines, up until this recent revision published after the widely publicized death of an exclusively breastfed newborn at a Baby-Friendly hospital, has taught health professionals and mothers that fussing and constantly nursing for hours are *not* reasons or supplementation.[\[1,10\]](#) These hours of fussing and nursing are obvious signs of hunger and distress present before the development of brain-threatening levels of hypoglycemia, dehydration and jaundice.[\[11,12,13\]](#) The 2017 guidelines made revisions to this section given that fussing and "constantly feeding for several hours" leading to maternal fatigue and newborn lethargy have led to newborn starvation-related complications, hospitalizations and rare deaths from severe dehydration and accidental suffocation.[\[14,15\]](#)

[caption id="attachment_5882" align="aligncenter" width="333"]

and breastfeeding management may be necessary, but supplementation is NOT INDICATED, including:

1. The sleepy infant with fewer than eight to 12 feedings in the first 24–48 hours with less than 7% weight loss and no signs of illness
 - Newborns are normally sleepy after an initial approximately 2-hour alert period after birth.^{27,28} They then have variable sleep–wake cycles, with an additional one or two wakeful periods in the next 10 hours whether fed or not.²⁷
 - Careful attention to an infant's early feeding cues, and gently rousing the infant to attempt breastfeeding every 2–3 hours is more appropriate than automatic supplementation after 6, 8, 12, or even 24 hours.
 - The general rule in the first week is: "an awake baby is a hungry baby!"
 - Increased skin-on-skin time can encourage more frequent feeding.
2. The healthy, term, appropriate for gestational age infant with bilirubin levels less than 18 mg/dL (mol/L) after 72 hours of age when the baby is feeding well and stooling adequately and weight loss is less than 7%²⁹
3. The infant who is fussy at night or constantly feeding for several hours
4. The tired or sleeping mother

Figure 4. Academy

Breastfeeding Medicine 2009 for when supplementation is NOT indicated. "Constantly feeding for several hours" leading to a "tired or sleeping mother" have led to newborn hospitalizations and deaths from accidental starvation and suffocation.[/caption]

[caption id="attachment_5884" align="alignnone" width="319"]

2. The infant who is fussy at night or constantly feeding for several hours
 - Cluster feeding (several short feeds close together) is normal newborn behavior, but should warrant a feeding evaluation to observe the infant's behavior at the breast³⁵ and the comfort of the mother to ensure that the infant is latched deeply and effectively.
 - Some fussy infants are in pain that should be addressed.

Figure 5. 2017 ABM BFHI

guidelines revision on when supplementation is NOT indicated. "Constantly feeding for several hours" is still included as a reason to NOT supplement. However, cluster feeding has been

defined as several short feeds and now they recommend evaluation of infant behavior at the breast and latch before recommending supplementation. Fussy infants are noted to possibly be in pain but not noted to possibly be hungry.[/caption]

For decades, the Baby-Friendly Hospital Initiative has actively taught health professionals through their in-hospital training that this non-stop "fussing" and nursing is the *biological norm* and that it is to be tolerated as a *necessary step in getting a mother's milk to come in* on the misguided premise that making a newborn subsist on a fraction of their caloric requirement through exclusive colostrum feeding is a requirement for successful breastfeeding. [16] Therefore a newborn's only way to communicate distress through crying is no longer biologically protective because his mother and health professionals are told that the crying does not mean hunger or that breast milk is insufficient. In reality, if a mother's breasts do not produce sufficient milk to rescue the child from their fasting state, the child will develop dehydration, hypoglycemia, hyperbilirubinemia and [hyponatremia](#), which can cause injury to the brain and vital organs.[17,18,19] While a mother is told that the signs of hunger and starvation are normal, she is not told about the risks of the brain-threatening complications of starvation if her child does not in fact receive enough milk.[20] Once the child is sufficiently depleted of calories and fluid, the child will stop crying and may in fact look sleepy and satisfied to sleep-deprived parents or well-meaning health professionals, when in fact, the child is experiencing abnormal brain function from these abnormalities.[21] [Within hours, if a child does not receive sufficient milk, the child will become lethargic and unresponsive and soon thereafter, vitals signs will begin to fail.](#)[22] By the time a child is lethargic or unresponsive, the scientific literature has shown that they have already likely sustained devastating levels of brain injury that lead to long-term disability.[23] These complications would have been prevented had the mother been told the whole truth about the risks of exclusively breastfeeding newborns, the signs of starvation and its consequences.

The Baby-Friendly Hospital Initiative's policy to hide these common and dangerous complications of early exclusive breastfeeding hospitalizes thousands of babies a year in the U.S. alone, and millions more in the rest of the world, complications that can result in long-term developmental disability that cannot be reversed once the child reaches a critical threshold.[24,25]

[caption id="attachment_5593" align="alignnone" width="960"]

Causes of Readmissions, N = 5308 (17.9/1000 WBN Discharges) (Utah)	
Cause	N (%)
Feeding problems*	2170 (40.9)
Jaundice*	1873 (35.3)
Respiratory distress	1753 (33)
Rule out sepsis	1193 (22.5)
Infection	1124 (21.2)

Early Readmission of Newborns in a Large Healthcare System. Pediatrics May 2013, Volume 131(5)

*The leading causes of newborn readmissions in the U.S. are complications from insufficient feeding due to early exclusive breastfeeding.¹⁵

18

Figure 6. Data from a large Utah Healthcare System showing the leading causes of newborn readmissions were for feeding complications and jaundice.[26][caption][caption id="attachment_5594" align="alignnone" width="960"]

Leading Causes of Neonatal Readmission

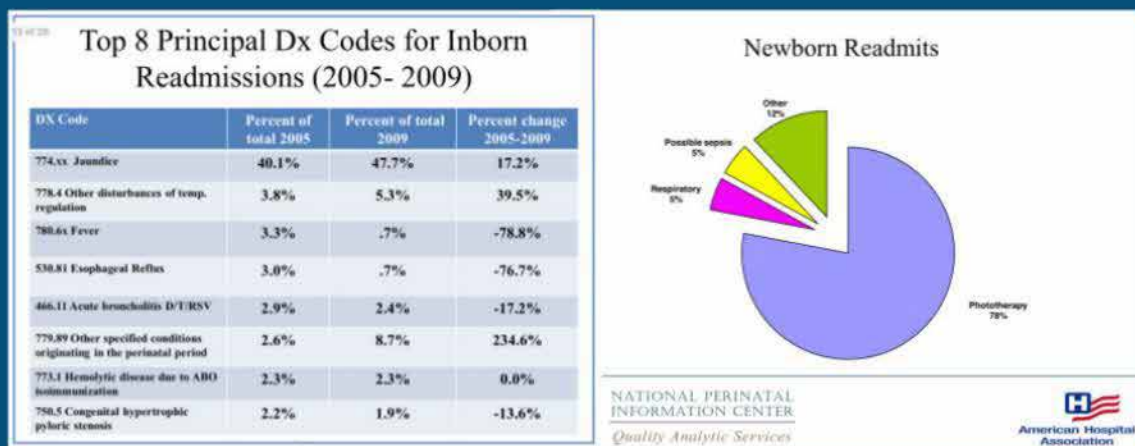


Figure 7. Data from the American Hospital Association showing the leading cause of neonatal readmissions were for jaundice and that among all neonatal readmitted patients, 78% received phototherapy.[27][caption]

One large Baby-Friendly Hospital system, the Northern California Kaiser Permanente hospital system, recently reported that 14% of previously healthy, term exclusively breastfed newborns lost excessive weight of greater than 10% (10% of vaginally-delivered and 25% of cesarean-delivered babies) and that 10.1% of the 103,000 babies born in the hospital required hospitalization for phototherapy to treat jaundice, the leading complication of exclusive breastfeeding.[28, 29] When the majority of jaundice (approximately 86%) is caused by what is known as starvation jaundice, which the ABM estimates occurs to 10-18% of U.S. exclusively breastfed newborns, these are unacceptably high complication rates.[30,31] Nearly 100% of starvation jaundice can be prevented by common sense and ad-lib supplementation. The scientific literature has shown that markers of brain injury are already present in the blood of babies who qualify for phototherapy according to the widely used American Academy of Pediatrics guidelines.[32,33] When virtually all of those babies are crying and nursing non-stop for milk before they develop excessive jaundice and weight loss, the protocol is not only unsafe, *it is barbaric*.

The Baby-Friendly Hospital Initiative is based on the inconclusive belief that the ideal, most advantageous form of feeding for *all babies* is what Western breastfeeding advocates have idealized as absolute exclusive breastfeeding from birth, when in fact the historical world breastfeeding data shows that breastfeeding mothers, even in the most remote locations of the world, near-universally supplemented breastfeeding, particularly in the first days of life to prevent starvation and death. Pre-BFHI data showed that doctors in the developing world also understood this important physiology as they supplemented breastfeeding to prevent the complications of dehydration, hypoglycemia and jaundice, which now are among the leading causes of newborn hospitalizations in the world.[71]

[caption id="attachment_5887" align="alignnone" width="960"]

High Breastfeeding Rates Despite Supplementation

Country (Survey date)	Prelacteal Feeding	Median BF Duration	BF @ 1 year / 2 year
Vietnam (1997)	Nearly 100% ³²	16.7 months	80.2% / 23.3%
India (1992-1993)	87.9% ³³ , 99% ³⁴	24.4 months	87.5% / 67.5%
Gambia (2000, earliest)	98% ³⁵	No data	96.8% / 53.9%
Nigeria (1990)	Nearly 100% ³⁶	19.5 months	86.4% / 42.9%
S. Africa (1998)	57% mix-fed; 47.1% PLF ³⁷	16 months	66.6% / 30.4%
Bangladesh (1993-94)	90% ³⁸	>36 months	95.5% / 86.5%
Pakistan (1990-91)	Nearly 100% ³⁹	19.9 months	78.2% / 51.7%

From the WHO Global Data Bank on Infant and Young Child Feeding⁴⁰

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Figure 8. Pre-lacteal feeding was used near-universally by breastfeeding mothers before the WHO guidelines to prevent starvation-related complications in the first days of life. Despite that, babies were commonly breastfed to 1-2 years of age.[34-43][caption id="attachment_5888" align="alignnone" width="960"]

Why was prelacteal feeding common?

- Most common answer from breastfeeding mothers is “not enough milk”
- 2002 Study of 1100 healthcare workers in Kaduna, Nigeria⁴¹
 - 68.2% of doctors, 70.2% of nurses gave prelacteal feeds
 - Nurses gave prelacteal feeds for “perceived” milk insufficiency
 - Doctors gave prelacteal feeds to prevent dehydration, hypoglycemia and neonatal jaundice

*Eur J Clin Nutr. 2002 Aug;56(8):729-34.

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Figure 9. Pre-lacteal feeding or supplementation before full breast milk production were commonly used by mothers and nurses because breast milk was not enough. Doctors gave

these supplemental feeds to prevent dehydration, hypoglycemia and jaundice, the most common complications of early exclusive breastfeeding.[71][[/caption]

Supplementation of breastfeeding was accomplished with the milk of wet nurses, domesticated animals and sugar water. We *evolved* to supplement because it was advantageous to our species' survival for a mother to listen to her baby's crying and want to feed alternatives to breast milk when it is clearly not enough. Before the WHO guidelines, there was no need for lactation consultants, bilirubin testing, follow-up visits or scales to ensure safety in breastfeeding. The ability of the mother to detect and prevent hunger and starvation by listening to a baby's cry and supplement when needed was all that was required to protect virtually all babies when breast milk was insufficient so long as safe alternative milk was available. So contrary to the teaching of the BFHI and its supporting organizations, mothers supplemented not because of lack of education, but because of *the primal instinct to prevent starvation, suffering and death* when it was apparent that breast milk was not enough, commonly found in the first days of life. The entire purpose of the Baby-Friendly protocol is to prevent this critically protective phenomenon from occurring. **When a child's brain requires uninterrupted delivery of fuel and fluid to prevent brain injury, teaching mothers the untested theory that a newborn baby can fast for 3-5 days while waiting for a mother's milk to arrive is the most unsafe health policy that has ever been written in the history of public health.**

[caption id="attachment_1900" align="alignnone" width="4288"]



Figure 10. Jaundiced newborns requiring phototherapy in Vietnam. Provided by Firefly. [44]

Hospitalizations for newborn jaundice have risen steadily since the 1991 introduction of the Baby-Friendly Hospital Initiative. 1.1 million newborns a year develop severe jaundice (>20 mg/dL), the majority caused by "dehydration" or underfeeding from early exclusive breastfeeding.[24,30] 114,000 of those newborns will die from their severe jaundice, the majority in resource-poor countries with insufficient health care resources to monitor the complications of exclusive breastfeeding. As a result excessive jaundice or hyperbilirubinemia, the majority from dehydration related to exclusively breastfeeding, is now the leading cause of newborn hospitalization and perinatal disability in the world.[25][caption]

Sadly, our modern-day version of breastfeeding, which focuses on *exclusive* breastfeeding rather than safe and adequate feeding, commonly results in the need for hospitalization for the brain-threatening complications of underfeeding both in the developed and developing world. These include the complications of hyperbilirubinemia (jaundice), dehydration, excessive weight loss, hypernatremia, hypoglycemia and failure to thrive. All these hospitalizations could be prevented if mothers were given honest and complete information on the risks of exclusive breastfeeding and allowed to respond to their instincts to supplement their underfed babies, **as mothers have been doing for millennia**. It appears that the World Health Organization and the supporting organizations (ABM, BFHI, etc.) have produced no research to prove that the vast majority of mothers have the perfect milk supply to breastfeed exclusively from birth to six months nor have they researched the number of calories colostrum provides or the number of calories a newborn needs to prevent starvation and brain injury as none of that data exists anywhere in the ABM, BFHI or WHO documents. Many of the components of the WHO's Ten Steps and the BFHI protocol produced by the ABM suffer from serious gaps in scientific data and it is having [very real impact on the lives of millions of babies and their families](#).

The ABM guidelines exclude healthy, term appropriately-sized exclusively breastfed newborns as not "at risk" for hypoglycemia when the scientific literature shows they are in fact at high risk.

'Small quantities of colostrum are appropriate for the size of a newborn's stomach, to prevent hypoglycemia in a healthy, term, appropriate for gestational age infant'[1]

The calculated caloric yield of exclusive colostrum feeding makes the above statement written by the ABM an incorrect and impossible statement. A child who receives a fraction of their caloric requirement though exclusive colostrum feeding for days while burning extra calories from hours of crying and nursing tolerated by the Baby-Friendly protocol is necessarily going to become hypoglycemic. In fact a recent study published from the U.K.'s National Health Service data showed that exclusive breastfeeding is an independent variable that predicts hospitalization for neonatal hypoglycemia.[45]

In a recent study of healthy, term well-latched exclusively breastfed (EBF) newborns strictly following the BFHI protocol showed that 10% experience hypoglycemia < 40 mg/dL by 6 hours

of life when screened for 48 hours, the most affected being first-born babies, affecting 23%.[46] Babies are commonly born depleted of calories as they are often born to fasted mothers and can experience stressful deliveries that deplete their caloric reserve further. In addition, an average mother's colostrum does not actually meet their full caloric requirement (see Figures 1 and 2). In fact, in a study of newborns *without symptoms* universally screened within 3 hours of life for low blood sugar or hypoglycemia, a marker of depleted caloric reserve, 19% developed developmentally deleterious low glucose levels of < 45 mg/dL and 10% developed glucoses < 40 mg/dL, including healthy, term, appropriately-sized newborns.[47] A glucose of < 45 mg/dL in these babies with no symptoms despite aggressive correction was associated with 38% *declines in passing the standardized test in literacy at 10 years of age*. This same study showed that a glucose of < 40 mg/dL was associated with **50% declines in passing the literacy and math test..**

[caption id="attachment_5090" align="alignnone" width="2047"]

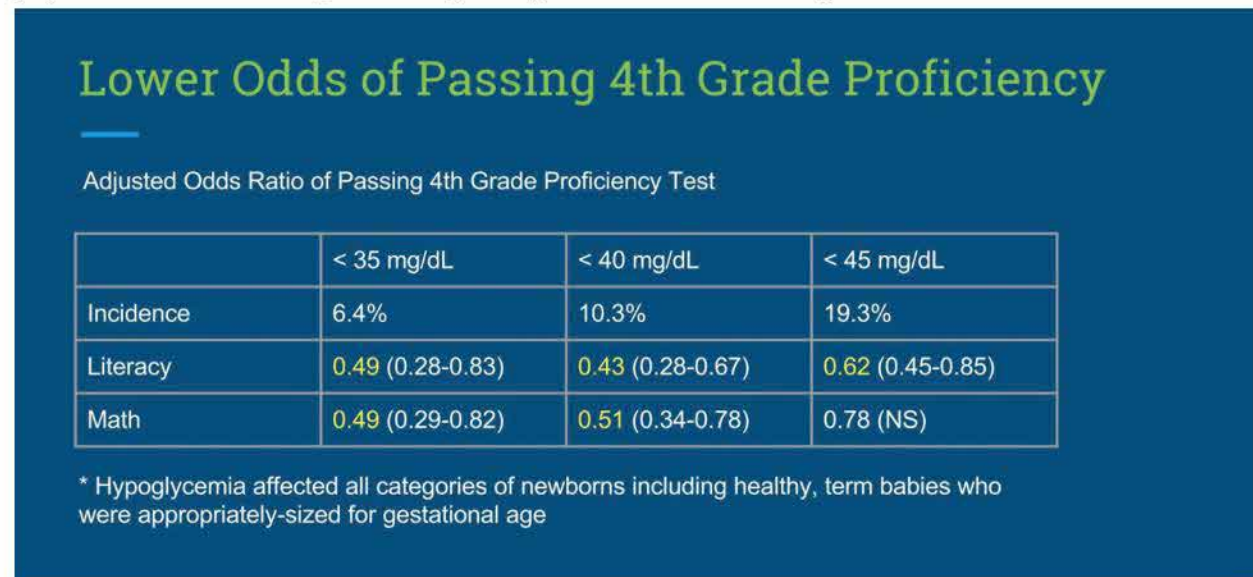


Figure 11. Decreased rates of passing 4th grade (10-year-old) literacy and math tests among hypoglycemic newborns **with symptoms** and relative incidences of hypoglycemia among universally-screened newborns without symptoms.[47][/caption]

At this time, the Baby-Friendly protocol has normalized the signs of newborn fasting and starvation while providing no glucose monitoring to protect the least-fed newborns, putting them at risk of hypoglycemic brain injury.[49,50] Despite scientific evidence that healthy, term exclusively breastfed newborns are at risk of hypoglycemic brain injury, the BFHI has chosen to ignore the evidence because glucose correction, which often requires supplementation, threatens the primary goal of the BFHI, which is to achieve high exclusive breastfeeding rates at discharge. Currently, the only time the starvation-related complication of hypoglycemia is diagnosed is when newborns are already lethargic enough to be evaluated for it. According to [mother-baby nurses and pediatricians from Baby-Friendly hospitals who write their grievances](#) to The Fed is Best Foundation, finding inconsolable as well as lethargic hypoglycemic,

jaundiced and dehydrated exclusively breastfed newborns in their mother-baby units and shortly after discharge are routine occurrences. By the time they develop lethargy, seizures or other vital sign abnormalities, the most current scientific literature has shown that they have likely already developed irreversible brain injury, which can lead to permanently lowered academic achievement and disability, even if aggressively corrected.[23,47] Allowing newborns to fast while ignoring their crying and weight loss as signs of starvation without glucose monitoring is unsafe and gambles with a child's life, health and future potential. **Furthermore, it is a violation of a newborn baby's human rights.**[48]

At this time, the standard of care allows at least 10% of healthy EBF newborns to be exposed to hypoglycemia that will reduce their lifetime academic achievement because they receive no glucose monitoring and therefore no protection from this dangerous condition until it is too late.[49] They may go days experiencing hypoglycemic brain injury while waiting for their mother's milk to arrive in the hospital and at home until they are finally hypoglycemic enough to exhibit lethargy or seizures. This recent data on the long-term outcomes of babies who experience hypoglycemia in the first hours of life appears to be absent from the ABM guidelines.[1,49]

Furthermore, even if a child is rapidly diagnosed with hypoglycemia with a bedside glucose monitor, they require laboratory confirmation to allow supplementation.[1,49] **When hypoglycemia kills thousands of brain cells within minutes of diagnosis, to allow a child's glucose to remain uncorrected for the 30 minutes minimum it takes to confirm hypoglycemia with a laboratory test, the policy exposes newborns to lifelong disability that can easily be prevented or minimized with immediate correction.** A newborn can easily lose their vital signs from hypoglycemia within this time frame. The belief that supplementation with formula is more dangerous than hypoglycemia is misguided, unsafe and negligent.

The ABM guidelines allow newborns with hypoglycemia as low as 40-45 mg/dL to remain uncorrected with IV glucose and supplementation despite the known risks of brain injury and reduced long-term academic achievement associated with those glucose levels. They suggest glucose levels as low as 28 mg/dl may also be acceptable.

According to the 2017 ABM guidelines indications to supplement:

"Asymptomatic hypoglycemia, documented by laboratory blood glucose measurement (not bedside screening methods) that is unresponsive to appropriate frequent breastfeeding [defined in the ABM Hypoglycemia guidelines as <40 mg/dL]. Note that 40% dextrose gel applied to the side of the infant's cheek is effective in increasing blood glucose levels in this scenario and improves the rate of exclusive breastfeeding after discharge with no evidence of adverse effects. Symptomatic infants or infants with glucose <1.4 mmol/L (<25 mg/dL) in the first 4 hours or <2.0 mmol/L (<35 mg/dL) after 4 hours should be treated with intravenous glucose." [1]

The ABM Hypoglycemia Protocol suggests that hypoglycemia as low as 28 mg/dL in the first 2 hours may not require correction:[49]

"...given the known lower plasma glucose levels in healthy term breastfed infants as compared with formula-fed infants, the low thresholds [for hypoglycemia] for exclusively breastfed infants might even be lower. Table 1 gives recommendations for this timed threshold approach."

TABLE 1. POPULATION LOW THRESHOLDS:
PLASMA GLUCOSE LEVEL⁴⁰

<i>Hour(s) after birth</i>	<i>$\leq 5^{\text{th}}$ percentile plasma glucose level</i>
1–2 (nadir)	28 mg/dL (1.6 mmol/L)
3–47	40 mg/dL (2.2/mmol/L)
48–72	48 mg/dL (2.7 mmol/L)

Figure 12: Suggested acceptable levels of hypoglycemia for breastfed newborns increase the risk of permanent brain injury and lower academic achievement.[hypoglycemia guidelines]

The ABM has chosen to prioritize the EBF at discharge rate over the safety of the newborn and newborn brain by lowering the threshold considered to be dangerously low blood glucose to levels that have been documented to result in brain injury and lower academic achievement. A hypoglycemia threshold of 40 and 28 mg/dL have been shown to result in permanently lower long-term academic success in babies without symptoms when universally screened by 3 hours of life even with rapid correction.[47,49] Allowing any patient to have an uncorrected glucose to the levels suggested by the ABM when there is adequate evidence that it can result in brain injury and long-term cognitive declines is negligence by nearly every standard of medicine and unnecessarily exposes newborns to brain injury that no parent would consent to if given information on the risks.

The ABM supplementation guidelines also suggest that oral dextrose is sufficient to correct hypoglycemia when stabilization of hypoglycemia typically requires ad lib supplementation of milk, either formula or safe, tested donor milk as well as IV glucose.[1] Babies with significant hypoglycemia are depleted of caloric reserve and will not only need enough calories to meet the minimum metabolic need but also enough glucose, protein and fat to restore the fuel reserves that were depleted from the fasting conditions commonly found after delivery and during early exclusive breastfeeding. Furthermore, if an already starved newborn is developing excessive

jaundice, the protein and fat in milk are required to remove bilirubin, which would not be provided by oral dextrose.[33,52]

Unless the ABM believes that exclusive breastfeeding at discharge is more important than a child's long-term cognitive potential, we advise they change these recommendations immediately. In fact, the most educated experts in hypoglycemia, the Pediatric Endocrine Society, recommends a glucose of no lower than 50 mg/dL in the first 48 hours and no lower than 60 mg/dL thereafter.[52] The brain begins to signal the body to increased glucose levels between 50 and 60 mg/dL in order to protect itself from injury. Since injury to the brain has devastating effects to a child's future potential, *the brain's preference should be honored*. In fact keeping a child's glucose as far away from the hypoglycemic threshold within the normal range is the most important way we can protect the newborn brain. We do that by making sure a newborn is adequately fed. **Nature has designed a nearly perfect mechanism for ensuring that the brain experiences no interruptions in fuel delivery--a newborn's cry and a mother's instinct to feed her child in whatever way she can to prevent her child from suffering hunger and thirst.** The entire purpose of the BFHI protocol is to prevent this protective phenomenon from occurring and it has harmed and hospitalized millions of babies for the 26 years it has defined the standard of care.

They state that 10% weight loss is not an automatic cause of supplementation without providing any research on what weight loss is in fact safe for a newborn. The threshold for supplementation requires a newborn to exhibit signs of *significant dehydration* including *high sodium, poor feeding and lethargy*.

According to the 2017 ABM guidelines on supplementation:

Indications NOT TO SUPPLEMENT:

"The infant who is fussy at night or constantly feeding for several hours. Cluster feeding (several short feeds close together) is normal newborn behavior, but should warrant a feeding evaluation to observe the infant's behavior at the breast and the comfort of the mother to ensure that the infant is latched deeply and effectively. Some fussy infants are in pain that should be addressed."

"Weight loss of $\pm 8-10\%$ (day 5 [120 hours] or later), or weight loss greater than 75th percentile for age. 1. Although weight loss in the range of 8–10% may be within normal limits if all else is going well and the physical examination is normal, it is an indication for careful assessment and possible breastfeeding assistance. Weight loss in excess of this may be an indication of inadequate milk transfer or low milk production, but a thorough evaluation is required before automatically ordering supplementation."

Indications for possible supplementation include:

"Clinical or laboratory evidence of significant dehydration (e.g., high sodium, poor feeding, lethargy, etc.) that is not improved after skilled assessment and proper management of breastfeeding."[1]

All three brain-injuring complications of hypoglycemia, hypernatremia and hyperbilirubinemia have been documented to occur before 10% weight loss.[53,54,55] In fact, they seem to be unaware that the original research done that established 10% weight loss as "normal" and presumably "safe" was done on 7 exclusively breastfed newborns showing the *maximum* weight loss experienced was 10%.[56] A study this small would not be sufficient to prove "safety" of 10% weight loss. This study failed to report on the glucose, sodium or bilirubin levels of those babies and failed to perform evaluation of long-term neurological outcomes to see if any of them experienced brain injury from the fasting conditions of early exclusive breastfeeding. No research since has been done using standardized developmental testing to prove that 10% weight loss is in fact safe. In fact the only such research on the neurological outcomes of babies who lost > 12%, while showing no differences in the overall developmental score between dehydrated and non-dehydrated newborns, the study did show evidence of increased rates of developmental delay in the dehydrated babies developing lower fine motor coordination, higher parental concerns for speech delay, shyness, allergies and disabilities.[57]

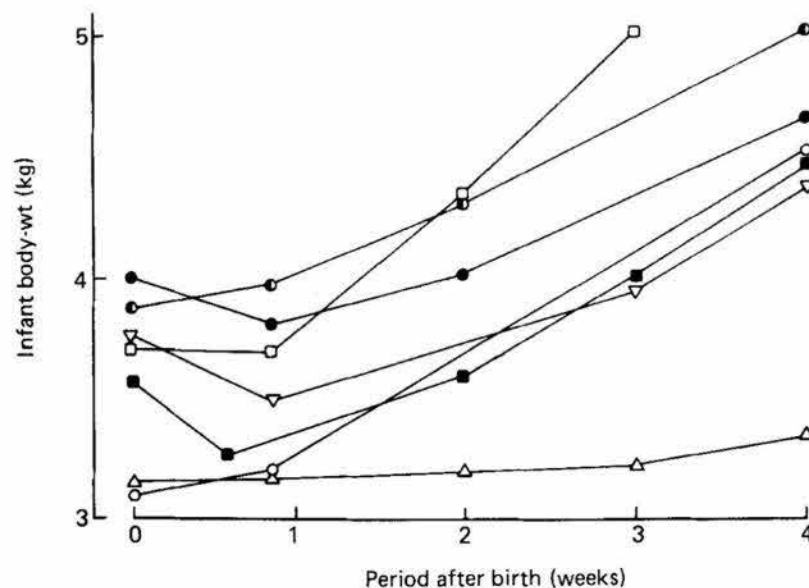


Fig. 4. The body-weight (kg) of the infants of seven mothers (A₁(○), A₂(●), A₄(■), A₆(□), A₈(◐), A₁₁(△), A₁₂(▽)) from birth of infant to 4 weeks post-partum.

Figure 13. Weight loss patterns of 7 exclusively breastfed babies that originally established the 10% weight loss threshold as "safe."[/caption][57]

They stipulate that 10% weight loss is not an automatic cause of supplementation suggesting that a clinician's assessment on breastfeeding latch and newborn behavior would be sufficient to rule out brain injury and determine whether it is safe to withhold supplementation. **In fact,**

neonatal hypoglycemic brain injury can progress with absolutely no external signs except for frequent crying and nursing for hours currently tolerated by the Baby-Friendly protocol. The first sign of hypoglycemia that may be detected by a health professional is extreme sleepiness (lethargy) or not waking for feeding by which time they may have experienced hours to days of hypoglycemic brain injury. By the time they are symptomatic, the most recent articles on hypoglycemic brain injury in underfed exclusively breastfed newborns suggests that it is too late.[23] Therefore, relying on clinical exam as the screen for newborn brain injury is unreliable because a child who looks quiet, sleepy and satisfied at 10% weight loss can in fact be *encephalopathic* (i.e. exhibiting abnormal brain function) from brain injury. The only way one can truly determine whether a *fasting* exclusively colostrum-fed newborn is safe from brain injury is by **monitoring glucose, bilirubin and sodium levels and ensuring that a child remains satisfied by their feedings.** This comes with the caveat that a starving hypoglycemic newborn will go from inconsolable to quiet once they have developed abnormal brain function and that this could be mistaken for satisfaction and successful breastfeeding. The signs of infant starvation that are present before the development of lethargy are listed as reason NOT to supplement, including fussing or crying and hours of nursing. Crying despite nursing and prolonged nursing > 30 minutes every 1-2 hours are signs of insufficient feeding and these babies are actively communicating hunger and distress to their mothers. Allowing newborns to cry for milk when their mothers cannot produce enough for hours to days is a dangerous and [common practice in Baby-Friendly hospitals](#). [1]

At this time, the scientific literature has shown that exclusively breastfed newborns can develop developmentally unsafe levels of bilirubin and hyponatremia by a weight loss percent of 7%, which became the updated maximum recommended weight loss of the American Academy of Pediatrics in their 2013 breastfeeding guidelines.

More than 50% of babies experiencing hyponatremia of > 150 mEq/dL have abnormal development by 12 months of age and 95% of hyponatremia of > 145 mEq/dL occurs by 7% weight loss.[58,59] In addition, developing 4% weight loss by 24 hours and 7% weight loss by 48 hours predicts the development of high bilirubin of > 15 mg/dl, which has been shown in multiple studies to increase the risk of developmental disabilities.[60-65] According to the largest study of weight loss patterns of exclusively breastfed newborns (or nomogram) from a large Baby-Friendly hospital system, which included over 100,000 babies, more than half of all exclusively breastfed newborns experience greater than 7% weight loss,[66] **which means more than half are at risk for developmentally unsafe hyperbilirubinemia or hyponatremia.**[28] The ABM refers to the recently developed [Newborn Weight Loss Tool](#), which is a useful tool to pick up excessive or accelerated weight loss in an exclusively breastfed newborn.[66] The ABM suggests an arbitrary threshold of > 75% percentile weight loss for age on this nomogram as "excessive" weight loss when we in fact have no data from that research at what percentile weight loss newborns are experiencing developmentally deleterious conditions that result in brain injury. The data is not tied to information on newborn bilirubin, sodium or glucose levels nor long-term neurological outcomes. We have no way of telling whether the threat of brain injury begins at the 75th or 50th or 85th percentile. In fact, it is not

possible for science and statistics to know the precise moment when an individual child goes from hungry to starving and brain injured as that threshold is different for every baby. Since every child is born with different caloric reserve, percent weight loss is in fact an imprecise way of detecting and preventing starvation. **Only the baby knows how close they are to empty and the data on the incidence of newborn hypoglycemia suggests that they can reach "empty" at any weight loss percent.**[24,46,47] The recent article documenting brain injury from hypoglycemia showed that hypoglycemia in healthy, term exclusively breastfed newborns occurred at ANY weight loss, from 0-16%.[23] **The most sensitive system that nature has created to detect and prevent starvation is the cry of a newborn and the maternal instinct to feed her baby to prevent distress. When that instinct is suppressed by policies aimed at preventing supplementation, the least-fed exclusively breastfed babies will cross the starvation threshold and can be found lethargic from caloric and fluid deprivation.** The consequences of crossing that threshold is permanent and devastating to that child and family.

The threshold for supplementation to treat hyperbilirubinemia or jaundice increases a child's risk for brain injury and developmental disability

From the 2017 ABM Supplementation Protocol:

Indications for supplementation:

- i. Jaundice of the newborn associated with poor breast milk intake despite appropriate intervention. This characteristically begins at 2–5 days and is marked by ongoing weight loss, limited stooling and voiding with uric acid crystals ["red brick dust" in diapers].
- ii. Breast milk jaundice when levels reach 340–425 $\mu\text{mol/L}$ (20–25 mg/dL) in an otherwise thriving infant and where a diagnostic and/or therapeutic interruption of breastfeeding may be under consideration. First line diagnostic management should include laboratory evaluation, instead of interruption of breastfeeding."[1]

From the ABM Jaundice protocol:

Supplementation with expressed breast milk, banked human milk, or formula (in that order of preference) should be limited to infants with at least one of the following:

- i. A clear indication of inadequate intake as defined **by weight loss in excess of 10%** after attempts to correct breastfeeding problems.
- ii. **Failure in milk production or transfer adjusted for duration of breastfeeding** and documented by pre- and post feeding weights after attempts to increase milk production and milk transfer.
- iii. Evidence of dehydration defined by significant alterations in serum electrolytes, especially **hypernatremia**, and/or clinical evidence of **significant dehydration (poor skin turgor, sunken fontanelle, dry mouth, etc.)**.[32]

A newborn child has to be starving to meet medical indication for supplementation according to the ABM guidelines. Furthermore, the guidelines allow a newborn to reach a bilirubin of 20-25 mg/dL in cases of breast milk jaundice before supplementation is offered when the

peer-reviewed literature on newborn hyperbilirubinemia bilirubin levels has shown increased levels of markers of brain injury present in the blood by a bilirubin level of greater than 17 mg/dL, which accelerates at a bilirubin of 19 mg/dL.[67,69] In fact, bilirubin levels of above 15 mg/dL has been used as the cut-off for moderate hyperbilirubinemia and has been shown to increase the risk of multiple long-term developmental disabilities including ADHD, seizure disorders, cerebral palsy, long-term declines in academic achievement and abnormalities in language, motor, sensory, behavioral and cognitive development associated with Bilirubin-Induced Neurological Disorder (BIND).[60-65] Allowing a child's bilirubin to reach a level of 20 mg/dL is unsafe as the hyperbilirubinemia literature has not differentiated between newborns who experience breast milk jaundice versus starvation jaundice. In fact, a 30-year follow-up study on severely jaundiced newborns showed that newborns with bilirubin above 19.9 mg/dL showed that 45% of those newborns had long-term neurobehavioral problems, had higher rates of ADHD, difficulty with math and reading, inability to complete high school and college, joblessness and alcoholism compared to non-jaundiced newborns.[70] The ABM has again ignored the scientific data in order to protect its primary objective, achieving high EBF rates at discharge, a quality marker which, in itself, has inconclusive benefit to long-term breastfeeding success, while having known harms to exclusively breastfed newborns.

The ABM protocol and the BFHI guidelines recommends informing mothers of the risks of formula supplementation while excluding discussion of the risks of brain injury and disability from avoiding supplementation.

"Hospitals should strongly consider formulating and instituting policies to require a medical provider's order when supplements are medically indicated and informed consent of the mother when supplements are not medically indicated. It is the responsibility of the healthcare provider to fully inform parents of the benefits and risks of supplementation, document parental decisions, and support the parents after they have made a decision."[1]

The guidelines thoroughly inform mothers of the risks of formula based on conflicting data riddled with confounding variables and make no mention of the brain- and life-threatening complications associated with early exclusive breastfeeding in order to gain compliance from mothers. In fact, the ABM does not even discuss the risks brain injury and disability from avoidance of supplementation in their own document intended to inform health providers.[1] Therefore, health professionals, particularly those with less medical training, are left to enforce the guidelines oblivious to the risks of leaving a crying exclusively breastfed newborn underfed. **Similarly, by hiding the risks of avoiding supplementation and only discussing the risks of formula, mothers are coerced to accept the risks of the Baby-Friendly protocol by agreeing to exclusively breastfeed.** They are left with no information on the signs of newborn starvation, which are normalized by the protocol, and no awareness of the increased risk of brain injury caused by avoiding supplementation when attempting to exclusively breastfeed until the complications occur to their babies. Health providers are ethically mandated to provide complete information on risks associated with health decisions, regardless of how rare, so that a patient may have full autonomy to decide for their child in order to reduce risk of harm. The risks

of early exclusive breastfeeding are well-known and make up the leading causes of newborn hospitalizations, which health professionals have been witnessing for decades.[24-28] These health professionals are commonly reprimanded for defying the Baby-Friendly rules when they offer supplementation even if it can save a child from suffering and from hospitalization. They literally have to wait for the complications to occur. **For a child to suffer complications and permanent injury due to underfeeding in our modern era, even in the most privileged of settings, is a catastrophic evolution of infant feeding and is an *abomination of modern medicine*.**

Even babies that meet medical indication for supplementation are given restricted feedings meant to emulate what limited calories are provided by colostrum *not* the metabolic requirements of the newborn to prevent and correct starvation.

Even when a newborn meets medical indication for supplementation, a point at which a newborn is at risk for brain injury if not freely supplemented, the ABM's focus is still on restricting formula feeding so that breastfed infants get as little formula as possible, even if that formula can save their brain and life. The calories allotted by what they consider as "normal" feeding volumes provide as little as 4 to 66% of a 3 kg newborn's daily caloric requirement the first 3 days of life.[1]

[caption id="attachment_5885" align="alignnone" width="332"]

**TABLE 2. AVERAGE REPORTED INTAKES OF COLOSTRUM
BY HEALTHY, TERM BREASTFED INFANTS**

<i>Time (hours)</i>	<i>Intake (mL/feed)</i>
First 24	2–10
24–48	5–15
48–72	15–30
72–96	30–60

Figure 14. Recommended volumes of supplementation for when medical indication for supplementation exists. Medical indication occurs when a newborn become depleted of calories and fluid and are experiencing life-threatening metabolic abnormalities consistent with starvation. This "normal" intake provides 4-66% of an average 3 kg newborn's caloric requirement (based on the know caloric content of colostrum of 54 Cal/100 mL) and therefore will perpetuate and worsen a newborn's fasting state. [/caption]

They recommend these same volumes for already starved newborns even if those volumes led to the starvation-related complications the newborn developed. So for babies who are already experiencing brain-threatening complications that could be quickly reversed with ad lib feeding, if health professionals follow the guidelines for formula supplementation volumes, they are in fact perpetuating the fasting physiology that resulted in the complications. It appears that no one

at the ABM looked at how many calories colostrum actually feeds a child and therefore they are unable to consider that colostrum may not in fact be enough for the majority of newborns. Because they are unable to consider the possibility that they were incorrect in their estimation of colostrum, which nearly all experienced breastfeeding mothers in the developing world felt was insufficient [72] before the La Leche League and the WHO declared it as "enough," exclusively breastfed babies are enduring days of hunger and thirst in hospitals and at home while the least-fed are experiencing life-long disability and even death.

1.1 million newborns a year experience severe jaundice, one of the leading causes of preventable long-term disability in the world, the majority caused by underfeeding.[25] 114,000 newborns die from that severe jaundice every year.[26] The majority occur in South Asia and Sub-Saharan Africa where few hospital services exist to monitor and treat hyperbilirubinemia in exclusively breastfed newborns, which was previously prevented by mother-led supplementation. The Baby-Friendly protocol in settings where breastfeeding is the only viable option for infant feeding and breastfeeding rates are already high has done nothing to promote breastfeeding. It has only made it more *perilous* by teaching mothers that there is no such thing as not enough breast milk and no consequences to allowing a child to wait to be fully fed.

In conclusion

The Fed is Best Foundation is appalled by the lack of concern that the WHO has shown for the millions of newborns and infants that have been hospitalized for jaundice, dehydration, hypoglycemia and failure to thrive, many of whom have suffered permanent declines in cognitive development, disability and death. It is shameful that a health organization would prioritize their policy over human lives and withhold information from parents that can save their child's life and future. (The full account of this meeting reported [here](#).)

We hope that health professionals and parents all over the world reject and protest the WHO's recommendation to prioritize exclusive breastfeeding over infant safety and instead support and encourage Safe Breastfeeding. Safe Breastfeeding is the breastfeeding that generations of mothers practiced before the WHO BFHI. Safe Breastfeeding prioritized feeding over *exclusivity* in breastfeeding. Safe Breastfeeding fed babies breast milk to the best of each mother's ability then supplemented freely until every baby was satisfied to prevent suffering and harm. Safe Breastfeeding breastfed and supplemented generations of babies and allowed them to reach their full potential by making sure their body and brains were fed enough calories and fluid to remain intact. Safe Breastfeeding did not exclude babies of mothers with insufficient breast milk from reaching their full potential because they could be protected from starvation as well. Safe Breastfeeding mostly required common sense and compassion along with a little wisdom passed on from experienced parents on breastfeeding and recognizing a hungry baby. Before the BFHI, breastfeeding did not require millions of dollars in breastfeeding goods and services, laboratory monitoring, office visits, phototherapy or neonatal ICUs to make it safe because exclusive breastfeeding was not the goal. **Having a safely fed baby was the goal.** At one point, mothers knew the dangers of infant starvation as every living creature has known from the

dawn of time. The BFHI has erased that knowledge from the collective knowledge of breastfeeding mothers and continues to do so every day that it spreads across the globe. In the developed and developing world, the least-fed exclusively breastfed babies continue to suffer serious harm because the WHO has chosen to hide the realities of starvation to promote its objective of making formula the enemy of infant feeding. **Meanwhile, mothers and their babies are left defenseless against the true threat to a newborn's health and future potential, hunger and thirst.**

Celebrate Safe Breastfeeding and all Safe Infant Feeding as all safe infant feeding sustains life and preserves human potential. Support every mother to feed her child the best way she can as *only she and her baby can know.*

#FedisBest

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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 17 Oct 2017 13:05:22 +0000
To: Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP)
Subject: FW: "Fed is Best" Sign for sale Targeting Baby Friendly
Attachments: FIB door sign[2305843009214334265].png

From: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Sent: Tuesday, October 17, 2017 9:03 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Subject: FW: "Fed is Best" Sign for sale Targeting Baby Friendly

A former colleague of mine, who works in a hospital system, got an email promoting this sign.



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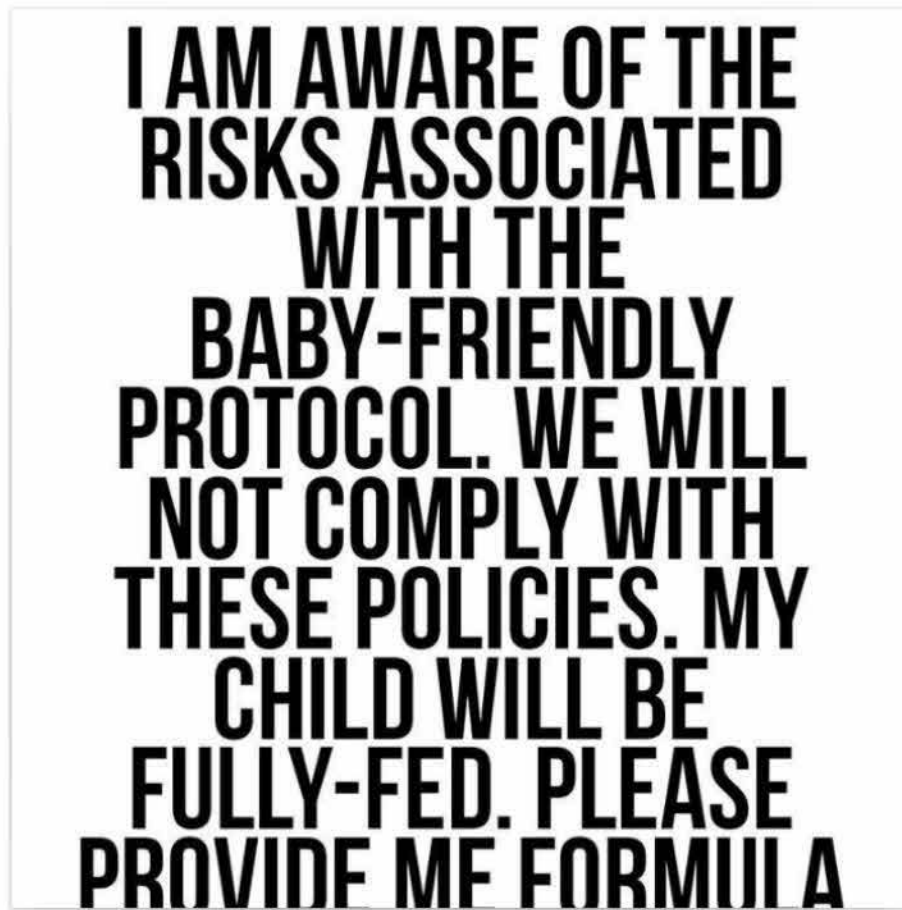
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FULLY-FED. PLEASE
PROVIDE ME FORMULA**

Fed is Best Shield Hospital Door Signs

\$5.00

Sold by Fed is Best Foundation

Buy



From: Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 30 Jan 2017 17:50:29 -0500
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Cc: MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Subject: FW:
Attachments: AAP News STS Safety.pdf, BF Bass Reply JAMAPeds.pdf

fyi

From: Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Sent: Monday, January 30, 2017 5:41 PM
To: MacGowan, Carol (CDC/ONDIEH/NCCDPHP) <dvx2@cdc.gov>; Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP) <rnf2@cdc.gov>; Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP) <zcn6@cdc.gov>; Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP) <dtg3@cdc.gov>
Cc: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfi2@cdc.gov>; Torres, Monica (CDC/ONDIEH/NCCDPHP) <enz2@cdc.gov>; Galuska, Deborah A. (CDC/ONDIEH/NCCDPHP) <dbg6@cdc.gov>
Subject: FW:

Hi everyone,

See the inquiry below from Dr. Bass. Can you start drafting a response?

Thanks.

Karen

From: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Sent: Monday, January 30, 2017 5:37 PM
To: Gunn, Janelle P. (CDC/ONDIEH/NCCDPHP) <bfi2@cdc.gov>; Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Subject: Fw:

fyi, can you guys get started on a response?

From: Bass, Joel L.,M.D. (b)(6)
Sent: Monday, January 30, 2017 4:58 PM
To: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Cc: Cono, Joanne (CDC/OD/OADS)
Subject: RE:

Peter... Since this last email, we have published a commentary in AAP News advising on the issues raised in the AAP Clinical report on skin to skin care. Also in response to correspondence from Baby-Friendly

advocates who commented on our Viewpoint, we have published data on the National Statistics on SUID deaths in the US in the neonatal period, compiled from the CDC Wonder On-Line data base. I have summarized the results in the table below:

	SUID for US infants 2003-2013					
	0-1 hr	0-23 hr	1-6 d	0-6 d	7-27 d	0-27 d
SUID "n" total	301	666	755	1421	3730	5151
SUID "n"/Year	27	61	69	129	339	468

I am certain the CDC would now agree that this a national problem that must be addressed expeditiously. Of particular note, as I mentioned in the AAP News Commentary, the states with the highest percentage of births at Baby-Friendly Hospitals (taken from the CDC Breastfeeding report Card) were not attaining the Healthy People 2020 goals, while those states with the highest initiation rates (not exclusivity) consistently attained those goals. This information is quite consistent with the recent USPTF JAMA report which showed that there was a lack of consistent evidence that system level interventions, including the Baby-Friendly initiative improved breast feeding outcomes.

I hope the CDC will now be willing to move forward on this issue and recommend alternative safe and effective approaches to support breastfeeding which will not contribute to sentinel events (SUPC and Falls).

I would be happy to meet with the CDC leadership to discuss this in greater detail.

Joel

Joel L Bass MD

Chair, Department of Pediatrics

Newton-Wellesley Hospital

Professor of Pediatrics, Part-time

Harvard Medical School

From: Bass, Joel L.,M.D.

Sent: Tuesday, September 27, 2016 3:35 PM

To: 'Briss, Peter (CDC/ONDIEH/NCCDPHP)'

Subject: RE:

Dear Peter... I appreciate your message below and interest in continuing our ongoing dialogue about this important issue. A few points I think require clarification: It's important to recognize that, as we mentioned in our publication, the problem is not with the 10 Steps per se but with the Baby Friendly (BF) method of documenting compliance with the steps. Only the pacifier ban is inherently problematic.

It's also important to recognize that the recent AAP report you mention was prepared prior to the population-based data from Massachusetts which we published and will now be interpreted within that

context. The AAP report describes in even greater detail all of the safety hazards which we have previously brought to your attention. Of particular note, the report points out the following critical issues: The BF hospital initiative encourages continued skin-to-skin care (SSC) throughout the hospital stay while rooming in (e2) and none of the checklists or procedures developed have been proven to reduce the risk or prevent the associated sentinel events (e4). I also think it is very important for your colleagues at the CDC to pay detailed attention to the Swedish study quoted in AAP report demonstrating the severe consequences of widespread adoption of SSC beyond the first hours of life. The posting of the link to the AAP report on the BF webpage in no way addresses the need to incorporate the safety issue into the actual BF Guidelines and Criteria as requested by the CDC last year. The new 2016 guidelines remain unchanged and do not in any way include parental or provider education of risks associated with some of these practices and retains their standard generic safety disclaimer which the CDC deemed unacceptable last year.

Regarding the issue of data collection you mentioned, while SUPC has been recognized for a number of years by our European colleagues, it is a relatively new diagnostic entity in the US and as there are no existing ICD 10 codes the CDC epidemiologists will need to seek out this information using the diagnostic codes for SUID. It's important to keep in mind that SUPC includes an equal number of survivors (many with significant impairment). FYI We have been able to apply the four ICD 10 codes which were used in Massachusetts to the CDC Wonder data base and have confirmed that the national data is very similar to our state data. Over a 7 year period (2007-2013) there were on average 341 SUID deaths/year in the first month of life including 70/yr within the first 6 days of life and 16/year in the first day of life. We are in the process of performing a detailed analysis of this data, and I would like to extend an offer to the CDC epidemiologists to collaborate on this effort, as we have considerable experience in understanding the data not only from an epidemiologic perspective but from a clinical one as well.

Although the CDC was certainly not initially aware of these safety hazards when it undertook active promotion of BF certification in the US, at this point, now that the AAP has confirmed the nature of risk of newborn death and injury associated with some of these practices, coupled with the emerging evidence from population-based data which points to a problem of unquestionable national significance, I hope that the CDC will now take decisive action in addressing this issue. Rather than continuing to encourage hospitals in United States to engage in practices that may expose healthy newborns to unnecessary risk, the CDC should now encourage alternate effective ways to promote breastfeeding safely. To put this in perspective, in 2001, when 90 cases of kernicterus were identified over a 17 year period, the CDC took bold action that resulted in the condition being designated a "never" event. The same type of leadership is now required.

Joel L Bass MD

Chair, Department of Pediatrics

Newton-Wellesley Hospital

Professor of Pediatrics, Part-time

Harvard Medical School

From: Briss, Peter (CDC/ONDIEH/NCCDPHP) [<mailto:pxb5@cdc.gov>]

Sent: Monday, September 26, 2016 11:01 AM

To: Bass, Joel L., M.D.

Subject:

Dear Joel,

I wanted to share some additional information with you regarding our efforts to respond to your concerns about safety in implementing the Ten Steps to Successful Breastfeeding.

Last week, Baby Friendly USA updated language on their Guidelines and Evaluation Criteria webpage that includes specific information about enhancing safety of baby friendly practices.

<https://www.babyfriendlyusa.org/get-started/the-guidelines-evaluation-criteria/safety-of-baby-friendly-practices>. The webpage links to AAP protocols and guidelines regarding infant stability and care prior to encouraging skin to skin contact and also links to the recently published AAP Guidelines on safe sleep and skin to skin practices.

In addition, our epidemiologists within the National Center for Chronic Disease Prevention and Health Promotion are researching whether there are national and state datasets that may be helpful in examining trends in SUPC and/or SUID. We have also contacted several partners, including the Joint Commission, to identify other potential sources of data.

We understand that you are communicating with the Massachusetts Department of Health and we would be interested in hearing about any data or analysis that can better document this issue.

Again, we share your interest in promoting breastfeeding safely and want to assure you that we are working hard to address the concerns that you raise.

Peter

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Commentary, News Articles, Fetus/Newborn Infant, Sleep Medicine

Commentary: Safety issues with skin-to-skin care must be acknowledged

by Joel L. Bass M.D., FAAP; Tina Gartley M.D., FAAP

The recent AAP clinical report *Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns* (<http://bit.ly/2cKSXck>) represents a significant contribution to our understanding of the importance of safe sleep in the early days of life and to practices that contribute to the risk of newborn falls in the hospital.

The report reviews the evidence supporting skin-to-skin care (SSC) and rooming-in, while addressing safety issues that need to be considered regarding both practices. The association of these practices with newborn sentinel events has been well-described in Europe and now is being recognized increasingly in the U.S.

Sudden unexplained postnatal collapse (SUPC) is a serious event in otherwise healthy term newborns resulting in death in about half the babies and significant impairment in many survivors (Herlenius E, Kuhn P. *Transl Stroke Res.* 2013;4:236-247). The events often happen during SSC.

The AAP report also sheds light on the serious issue of newborn falls in the hospital related to maternal sleeping during bed-sharing. The common link between SUPC events and newborn hospital falls is their association with mother-baby co-sleeping in the prone position.

The potential relationship of SUPC to compliance with breastfeeding practices related to the Baby Friendly Hospital Initiative (BFHI) recently was discussed in a review of hospital deaths of newborns while bed-sharing using data from the National Association of Medical Examiners (Thach BT. *J Perinatol.* 2013;34:275-279). A 2013 article in *AAP News* expressed similar concerns and suggested a need to integrate safe sleep policies with SSC (<http://www.aappublications.org/content/34/11/22>).

Although the AAP report described the SUPC events as rare, we published population-based data from Massachusetts just prior to the report's release documenting 57 deaths over 10 years attributed to sudden unexplained infant deaths in the first month of life. Twenty of the deaths occurred in the first five days of life (Bass JL, et al. *JAMA Pediatr.* 2016;170:923-924).

As Massachusetts represents 1.8% of U.S. births, one could reasonably project that the likely number of cases nationally would be cause for great concern. To put this in perspective, in response to 90 cases of kernicterus over 17 years (*MMWR Morb Mortal Wkly Rep.* 2001;50:491-494), the Centers for Disease Control and Prevention (CDC) took steps that resulted in kernicterus being considered a "never" event.

In light of these data, application of recommendations in the AAP report requires thoughtful evaluation of the risks and benefits of current breastfeeding practices. SSC generally is considered beneficial for preterm newborns well beyond the initial hours of birth. Safety concerns are mitigated by monitoring available in neonatal intensive care units. For healthy term newborns, efficacy has been demonstrated only immediately after birth and during painful procedures when most hospitals can closely monitor the newborn.

The same cannot be said for SSC beyond the immediate newborn period, as close observation may not be available 24 hours a day on postpartum units, and prone sleeping may continue at home unobserved. This is a particularly important issue for hospitals complying with the BFHI which, as the report notes, encourages SSC throughout the hospital stay while rooming-in.

The potential impact of widespread SSC can be appreciated from the Swedish experience cited in the AAP report (Pejovic NJ, Herlenius E. *Acta Paediatr.* 2013;102:680-688). In response to a cluster of events over a 30-month period in Stockholm, the records of 26 survivors of SUPC were reviewed. Investigators found that half of



Commentary, News Articles, Fetus/Newborn Infant, Sleep Medicine

the events occurred beyond the first two hours of life, four were treated with rapid hypothermia and two required mechanical ventilation.

The authors state that the SUPC rate in Sweden is 10 times the expected rate of the U.K. or Germany, which they associated with widespread adoption of SSC in their units. Of note, Sweden is the only European country reported to have 100% of hospitals with BFHI designation (<http://bit.ly/2dOG5EF>); rates in the U.K. and Germany are 17% and 4%, respectively.

Given that experience, hospitals will need to decide whether to encourage late SSC. For those that choose to do so, as the AAP report indicates that late SSC has not been specifically studied in full-term infants and no procedure has yet been shown to prevent associated sentinel events, parents must be informed of potential risks and hospitals must be equipped to manage adverse events expeditiously. Even hospitals that do not encourage late SSC must educate and safely support parents who initiate it on their own.

Concerns have been raised that this heightened awareness of safety issues could result in modification of practices that may conflict with BFHI designation guidelines and prove counterproductive to breastfeeding success. Fortunately, this is not a binary choice.

Data from the 2016 CDC Breastfeeding Report Card show that the 12 states with the highest breastfeeding initiation rates (86.6%-94.4%) almost always attained or exceeded all four Healthy People 2020 Objectives targets for breastfeeding duration despite low ranges (2%-38%) of BFHI designation. In contrast, neither of the high range BFHI states (85.8%-98.3%) attained a similar level of performance, mostly falling below targets. Clearly, there is more than one pathway to achieve successful breastfeeding outcomes.

In summary, the Academy again has shown leadership in placing the well-being of children as its top priority. While it is always difficult to change direction, this compelling new information will greatly enhance our ability to support breastfeeding safely.

Dr. Bass is department chair and Dr. Gartley is a hospitalist at Newton-Wellesley Hospital Department of Pediatrics.

Related Content

- [AAP News story "Updated safe sleep guidance warns against using soft bedding, sofa sleeping"](#)

Letters

COMMENT & RESPONSE

In Reply We appreciate the comments from the respondents about concerns we expressed regarding the Baby-Friendly Hospital Initiative (BFHI) in our Viewpoint.¹ They question our conclusions about the relationship between the BFHI guidelines encouraging skin-to-skin care beyond the first hours of life, in-hospital breastfeeding exclusivity, and pacifier restriction with an increased risk for sudden unexpected postnatal collapse and newborn falls. These relationships are supported by evidence-based citations in the recently published American Academy of Pediatrics clinical guideline² and our subsequent commentary.³ In addition, the recent US Preventive Services Task Force report on Primary Care Interventions to Support Breastfeeding⁴ concluded there is a lack of consistent evidence that demonstrates system-level interventions, including the BFHI, improve breastfeeding outcomes. The accompanying editorial by Flaherman⁵ offers further insight into issues raised with the BFHI and provides additional evidence substantiating our Viewpoint.¹ Walker's criticism of pacifier use has been definitively refuted by this evidence.⁵ We share Flaherman's concern that pacifier restriction might be ethically problematic.

Gartner et al comment that, under the BFHI Guidelines and Criteria, mothers are fully informed of the benefits of breastfeeding and supportive practices. The criteria do mandate that mothers be informed about these issues whenever they request a breastmilk substitute, nursery care, or pacifier. However, they do not require that mothers also be informed of the important safety risks of late skin-to-skin care identified in the American Academy of Pediatrics guideline² or of the established benefit that a pacifier confers to prevent sudden infant death syndrome,⁵ very significant omissions.

Philipp describes impressive success implementing the BFHI in a safety-net hospital with a very low initial breastfeeding initiation rate. However, as the US Preventive Services Task Force report demonstrated,⁴ the same results have not been shown for other populations, and enhancement of individual lactation support efforts might have proven equally effective.

Wasser et al discuss using sidecar bassinets, which are currently under development, as a safety improvement for postpartum rooms. Properly designed, these might help prevent some falls. However, the devices do not reduce the risk of the mother falling asleep with newborn inadvertently in the prone position. In any case, current safe practice can only be initiated with presently available equipment.

Boyd et al state that they were unable to document any deaths from sudden infant death syndrome before 28 days of life in New York City between 2012 and 2014 when they implemented BFHI designation in several facilities. This is not surprising given their reported rate of sudden infant death syndrome of 3.6 in 100 000 live births and that their intervention

took place in only 8 birthing facilities in a city that has 50 hospitals with maternity services. Submitting the same *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* codes cited by Boyd et al to the Centers for Disease Control and Prevention Wonder Online Data Base,⁶ we were able to ascertain there were 31 sudden unexpected infant deaths at less than 28 days of age in New York City between 2007 and 2013.

Ferrarello characterizes sudden infant death syndrome in newborns as "exceedingly rare," a position that other respondents also implied. While our Viewpoint reported population-based data only from Massachusetts,¹ national data on sudden unexpected infant death for US infants for 2003 to 2013⁶ reveal that during that interval, there were 5152 sudden unexpected infant death cases in the first 27 days of life including 1421 in the first 6 days, of which 666 occurred on the first day of life. Annually, there were a mean 468 deaths attributed to sudden unexpected infant death in the first month of life, of which 129 occurred in the first 6 days. These compelling data provide a perspective on the potential magnitude and significance of this problem, which, as we stated in our Viewpoint,¹ should encourage government and regulatory agencies, as well as concerned breastfeeding advocates, to focus on alternative effective strategies^{3,5} to promote breastfeeding safely.

Finally, it has come to our attention that one of us did not include relevant conflict of interest disclosures in the original Viewpoint. As the Viewpoint addresses nutrition, we should have indicated the following: "Dr Kleinman reports having had received payment for serving as an editor for the American Academy of Pediatrics book, *Pediatric Nutrition*, 7th edition, and an honorarium for serving as chair of the Mead Johnson Pediatric Nutrition Iron Expert Panel." We regret this omission and have asked that the article be corrected online to include this information.

Joel L. Bass, MD

Tina Gartley, MD

Ronald E. Kleinman, MD

Author Affiliations: Harvard Medical School, Boston, Massachusetts (Bass, Gartley, Kleinman); Department of Pediatrics, Newton-Wellesley Hospital, Newton, Massachusetts (Bass, Gartley); Massachusetts General Hospital, Boston (Kleinman).

Corresponding Author: Joel L. Bass, MD, Department of Pediatrics, Newton-Wellesley Hospital, 2014 Washington St, Newton, MA 02462 (jbass@partners.org).

Published Online: January 30, 2017. doi:10.1001/jamapediatrics.2016.4795

Conflict of Interest Disclosures: Dr Kleinman reports having had received payment for serving as an editor for the American Academy of Pediatrics book, *Pediatric Nutrition*, 7th edition, and an honorarium for serving as chair of the Mead Johnson Pediatric Nutrition Iron Expert Panel.

1. Bass JL, Gartley T, Kleinman R. Unintended consequences of current breastfeeding initiatives. *JAMA Pediatr*. 2016;170(10):923-924.

2. Feldman-Winter L, Goldsmith JP; Committee on Fetus and Newborn; Task Force on Sudden Infant Death Syndrome. Safe sleep and skin-to-skin care in the neonatal period for healthy term newborns. *Pediatrics*. 2016;138(3):e20161889.
3. Bass JL, Gartley T. Safety issues with skin-to-skin care must be acknowledged. AAP News. October 24, 2016. <http://www.aappublications.org/news/2016/10/24/SleepCommentary102416>. Accessed December 28, 2016.
4. Patnode CD, Henninger ML, Senger CA, Perdue LA, Whitlock EP. Primary care interventions to support breastfeeding: updated evidence report and systematic review for the US Preventive Services Task Force [published correction appears in *JAMA*. 2016;316(20):2155]. *JAMA*. 2016;316(16):1694-1705.
5. Flaherman V, Von Kohorn I. Interventions intended to support breastfeeding: updated assessment of benefits and harms. *JAMA*. 2016;316(16):1685-1687. doi:10.1001/jama.2016.15083
6. United States Department of Health and Human Services (US DHHS), Centers of Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), Division of Vital Statistics (DVS). Linked Birth / Infant Death Records 2003-2006 and 2007-2013, as compiled from data provided by 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program, on CDC WONDER On-Line Database. <https://wonder.cdc.gov/lbd-current.html>. Accessed November 3, 2016.

From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Tue, 27 Sep 2016 17:55:53 -0400
To: Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP); Murphy, Paulette (CDC/ONDIEH/NCCDPHP); Nelson, Jennifer M. (CDC/ONDIEH/NCCDPHP); Grossniklaus, Daurice (CDC/ONDIEH/NCCDPHP); MacGowan, Carol (CDC/ONDIEH/NCCDPHP)
Subject: Fw:

[Fyi. Will touch base with you all tomorrow with my thoughts on analysis.](#)

From: Briss, Peter (CDC/ONDIEH/NCCDPHP) <pxb5@cdc.gov>
Sent: Tuesday, September 27, 2016 4:31 PM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP); Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP)
Subject: Fw:

[Sent from my BlackBerry 10 smartphone.](#)

From: Bass, Joel L., M.D. (b)(6)
Sent: Tuesday, September 27, 2016 3:35 PM
To: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Subject: RE:

Dear Peter... I appreciate your message below and interest in continuing our ongoing dialogue about this important issue. A few points I think require clarification: It's important to recognize that, as we mentioned in our publication, the problem is not with the 10 Steps per se but with the Baby Friendly (BF) method of documenting compliance with the steps. Only the pacifier ban is inherently problematic. It's also important to recognize that the recent AAP report you mention was prepared prior to the population-based data from Massachusetts which we published and will now be interpreted within that context. The AAP report describes in even greater detail all of the safety hazards which we have previously brought to your attention. Of particular note, the report points out the following critical issues: The BF hospital initiative encourages continued skin-to-skin care (SSC) throughout the hospital stay while rooming in (e2) and none of the checklists or procedures developed have been proven to reduce the risk or prevent the associated sentinel events (e4). I also think it is very important for your colleagues at the CDC to pay detailed attention to the Swedish study quoted in AAP report demonstrating the severe consequences of widespread adoption of SSC beyond the first hours of life. The posting of the link to the AAP report on the BF webpage in no way addresses the need to incorporate the safety issue into the actual BF Guidelines and Criteria as requested by the CDC last year. The new 2016 guidelines remain unchanged and do not in any way include parental or provider education of risks associated with some of these practices and retains their standard generic safety disclaimer which the CDC deemed unacceptable last year.

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CDC epidemiologists to collaborate on this effort, as we have considerable experience in understanding the data not only from an epidemiologic perspective but from a clinical one as well.

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*Joel L Bass MD
Chair, Department of Pediatrics
Newton-Wellesley Hospital
Professor of Pediatrics, Part-time
Harvard Medical School*

From: Briss, Peter (CDC/ONDIEH/NCCDPHP) [mailto:pxb5@cdc.gov]

Sent: Monday, September 26, 2016 11:01 AM

To: Bass, Joel L., M.D.

Subject:

Dear Joel,

I wanted to share some additional information with you regarding our efforts to respond to your concerns about safety in implementing the Ten Steps to Successful Breastfeeding.

Last week, Baby Friendly USA updated language on their Guidelines and Evaluation Criteria webpage that includes specific information about enhancing safety of baby friendly practices.

<https://www.babyfriendlyusa.org/get-started/the-guidelines-evaluation-criteria/safety-of-baby-friendly-practices>. The webpage links to AAP protocols and guidelines regarding infant stability and care prior to encouraging skin to skin contact and also links to the recently published AAP Guidelines on safe sleep and skin to skin practices.

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We understand that you are communicating with the Massachusetts Department of Health and we would be interested in hearing about any data or analysis that can better document this issue.

Again, we share your interest in promoting breastfeeding safely and want to assure you that we are working hard to address the concerns that you raise.

Peter

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From: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP)
Sent: Mon, 26 Sep 2016 15:35:18 +0000
To: Murphy, Paulette (CDC/ONDIEH/NCCDPHP); Flores-Ayala, Rafael C. (CDC/ONDIEH/NCCDPHP)
Subject: FW:

From: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Sent: Monday, September 26, 2016 11:02 AM
To: Perrine, Cria G. (CDC/ONDIEH/NCCDPHP) <hgk3@cdc.gov>; Voetsch, Karen P. (CDC/ONDIEH/NCCDPHP) <kmp9@cdc.gov>
Subject: FW:

fyi

From: Briss, Peter (CDC/ONDIEH/NCCDPHP)
Sent: Monday, September 26, 2016 11:01 AM
To: 'JBASS@PARTNERS.ORG' <(b)(6)>
Subject:

Dear Joel,

I wanted to share some additional information with you regarding our efforts to respond to your concerns about safety in implementing the Ten Steps to Successful Breastfeeding.

Last week, Baby Friendly USA updated language on their Guidelines and Evaluation Criteria webpage that includes specific information about enhancing safety of baby friendly practices. <https://www.babyfriendlyusa.org/get-started/the-guidelines-evaluation-criteria/safety-of-baby-friendly-practices>. The webpage links to AAP protocols and guidelines regarding infant stability and care prior to encouraging skin to skin contact and also links to the recently published AAP Guidelines on safe sleep and skin to skin practices.

In addition, our epidemiologists within the National Center for Chronic Disease Prevention and Health Promotion are researching whether there are national and state datasets that may be helpful in examining trends in SUPC and/or SUID. We have also contacted several partners, including the Joint Commission, to identify other potential sources of data.

We understand that you are communicating with the Massachusetts Department of Health and we would be interested in hearing about any data or analysis that can better document this issue.

Again, we share your interest in promoting breastfeeding safely and want to assure you that we are working hard to address the concerns that you raise.

Peter

From: Anstey, Erica Hesch (CDC/DDNID/NCCDPHP/DNPAO) (CTR)
Sent: Wed, 16 Jan 2019 10:45:16 -0500
To: Perrine, Cria G. (CDC/DDNID/NCCDPHP/DNPAO); MacGowan, Carol (CDC/DDNID/NCCDPHP/DNPAO)
Subject: FYI

https://fedisbest.org/information-for-hospitals-ensuring-safety-for-breastfed-newborns/hospitals-that-have-relinquished-their-baby-friendly-status-since-2016/?fbclid=IwAR1CVXPUEaNucf-t0kdGboomEf4YuShVtrd5OmRlz19x1Br_94uPOBfaWpl

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From: Trish MacEnroe
Sent: Thu, 22 Jul 2021 20:42:42 +0000
To: Grossniklaus, Daurice (CDC/DDNID/NCCDPHP/DNPAO)
Subject: GEC release
Attachments: Baby Friendly GEC Final.pdf

Dear Daurice,

I just wanted to be sure that you knew that Baby-Friendly USA's updated Guidelines and Evaluation Criteria were released today. We also plan to release the NICU materials in the next 2 – 3 weeks.

Now that the GEC are released, I will be transitioning out of my fulltime role with Baby-Friendly USA effective July 30. My heartfelt thanks for the many years of collaboration and friendship. I truly treasure our work together.

Keep up your great work.

Best,

Trish MacEnroe
Senior Policy Advisor to the CEO
Baby-Friendly USA, Inc.
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(b)(6) (p)
(f)

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THE BABY-FRIENDLY HOSPITAL INITIATIVE

Guidelines and Evaluation Criteria

SIXTH EDITION



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The 2018 UNICEF/WHO Protecting, Promoting and Supporting Breastfeeding in Facilities Providing Maternity and Newborn Services: the revised Baby-Friendly Hospital Initiative.

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babyfriendlyusa.org

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See Appendix G

We would also like to express our deep gratitude to the following professional organizations for their thoughtful review and comments:

Academy of Breastfeeding Medicine (ABM)
American Academy of Family Physicians (AAFP)
American Academy of Pediatrics (AAP)
American College of Nurse Midwives (ACNM)
American College of Obstetricians and Gynecologists (ACOG)
Association of Women's Health Obstetric and Neonatal Nurses (AWHONN)
United States Lactation Consultant Association (USLCA)



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INTRODUCTION

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BABY-FRIENDLY HOSPITAL INITIATIVE (BFHI) was established in 1991 by the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO). The BFHI is a global program to support the implementation of the *Ten Steps to Successful Breastfeeding (the Ten Steps)* and the *International Code of Marketing of Breast-milk Substitutes (the International Code)* in maternity facilities. "The core purpose of the BFHI is to ensure that mothers and newborns receive timely and appropriate care before and during their stay in a facility providing maternity and newborn services, to enable the establishment of optimal feeding of newborns, which promotes their health and development. Given the proven importance of breastfeeding, the BFHI protects, promotes and supports breastfeeding while enabling timely and appropriate care and feeding of newborns who are not *(yet or fully)* breastfed."¹

An important philosophy of the Initiative is that "families must receive quality and unbiased information about infant feeding. Facilities providing maternity and newborn services have a responsibility to promote breastfeeding, but they must also respect the mother's preferences and provide her with the information needed to make an informed decision about the best feeding option for her and her infant. The facility needs to support mothers to successfully feed their newborns in the manner they choose."¹

In 2015, WHO and UNICEF embarked on a process to review the most current scientific evidence pertaining to each of the Ten Steps and update the implementation guidance for the BFHI. Their goal was to reinvigorate the BFHI with the aim of worldwide adoption of the Ten Steps in all facilities providing birthing services.

The results of their work were published in two separate key documents:

GUIDELINE: *Protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services*² This is a review of the evidence for each individual step of the Ten Steps. It is NOT a review the evidence for the combined impact of multiple steps.

IMPLEMENTATION GUIDANCE: *Protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services: the revised BABY-FRIENDLY HOSPITAL INITIATIVE*¹ (2018 Implementation Guidance)

The 2018 Implementation Guidance established global standards for each of the Ten Steps while calling on nations to customize the materials to address specific national goals. BFUSA engaged in a robust process to revise the Initiative for the US. An immediate and thorough review of the two key documents was conducted. A document was developed comparing the new guidance and standards with the existing US Guidelines and Evaluation Criteria (GEC) to determine if any immediate changes could be implemented. It was determined that adjustments to the requirements for Step 9 were warranted. Therefore, revised versions of the US GEC were published in July 2018 and December 2019.

In the meantime, an expert panel consisting of individuals with widespread knowledge and experience with implementing the BFHI standards was convened for a face-to-face meeting in August 2018. Based on its review of the updated evidence, the new implementation guidance, and the comparison with the existing standards, the panel recommended revisions to customize the global guidance for applicability to the US. These revisions were incorporated into updated documents and submitted to the expert panel, the BFUSA Board of Directors, Clinical Committee and several key national professional health organizations for further input. Those organizations included: Academy of Breastfeeding Medicine, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American College of Nurse Midwives, Association of Women's Health, Obstetric and Neonatal Nurses and the United States Lactation Consultant Association.

The expert panel was reconvened in July 2019 to review the comments received in the latest review stage and assist with finalizing the guidance, standards and evaluation criteria for the US. The last component of the process was the incorporation of "Performance indicators demonstrating staff competency to implement" based on WHO and UNICEF's Competency Verification Toolkit: Ensuring Competency of Direct Care Providers to Implement the Baby-Friendly Hospital Initiative released on August 5, 2020.³

REVISIONS TO THE TEN STEPS TO SUCCESSFUL BREASTFEEDING

An important component of the effort to reinvigorate the BFHI by WHO and UNICEF was a review of the evidence for each of the Ten Steps to Successful Breastfeeding. Upon completing this task, the WHO and UNICEF then evaluated the actual wording for each Step. They concluded that the theme of each Step was appropriate but some of the phrasing needed to be changed to better align with the evidence.

Several noteworthy changes include: the incorporation of the International Code of Marketing of Breast-milk Substitutes and monitoring procedures into Step 1 and a shift in the focus of Step 2 from an emphasis on a specific number of hours of training to competency verification.

It is also worth pointing out that the steps are now divided into critical management procedures and key clinical practices. The chart to the right compares the 2018 revised version to the original 1989 Ten Steps.

TEN STEPS TO SUCCESSFUL BREASTFEEDING	
REVISED IN 2018	ORIGINAL
CRITICAL MANAGEMENT PROCEDURES 1 A. Comply fully with the International Code of Marketing of Breast-milk Substitutes and relevant World Health Assembly resolutions. 1 B. Have a written infant feeding policy that is routinely communicated to staff and parents. 1 C. Establish ongoing monitoring and data-management systems. 2. Ensure that staff have sufficient knowledge, competence and skills to support breastfeeding.	1. Have a written breastfeeding policy that is routinely communicated to all health care staff. 2. Train all health care staff in the skills necessary to implement this policy. 3. Inform all pregnant women about the benefits and management of breastfeeding. 4. Help mothers initiate breastfeeding within one hour of birth. 5. Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.
KEY CLINICAL PRACTICES 3. Discuss the importance and management of breast-feeding with pregnant women and their families. 4. Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth. 5. Support mothers to initiate and maintain breastfeeding and manage common difficulties. 6. Do not provide breastfed newborns any food or fluids other than breast-milk, unless medically indicated. 7. Enable mothers and their infants to remain together and to practice rooming-in 24 hours a day. 8. Support mothers to recognize and respond to their infants' cues for feeding. 9. Counsel mothers on the use and risks of feeding bottles, artificial nipples (teats) and pacifiers. 10. Coordinate discharge so that parents and their infants have timely access to ongoing support and care.	6. Give infants no food or drink other than breast-milk, unless medically indicated. 7. Practice rooming-in — allow mothers and infants to remain together 24 hours a day. 8. Encourage breastfeeding on demand. 9. Give no pacifiers or artificial nipples to breastfeeding infants. 10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

DOCUMENT CONTENT AND FORMAT

It is the goal of BFUSA to implement a program for the US that remains as closely aligned with the global initiative as possible, while at the same time, addressing the US needs and circumstances. As such, within the Guidelines and Evaluation Criteria section, as much specific language as possible was used from the 2018 (WHO/UNICEF) Implementation Guidance. (**NOTE:** some words were changed from the European to American spelling and some small amounts of text containing guidance unrelated to US hospitals were removed in order to avoid confusion.) Where necessary, additional US language within the implementation for each step were added in *italics*.

The document is organized according to the 2018 Ten Steps to Successful Breastfeeding. It must be noted that “while each of the Ten Steps contributes to improving the support for breastfeeding, optimal impact on breastfeeding practices, and thereby on maternal and child well-being, is only achieved when all Ten Steps are implemented as a package.”¹ This entire document should be read with this point in mind.

Each step consists of the following sections:

- **THE STEP NUMBER AND NAME**
- **RATIONALE**
- **IMPLEMENTATION GUIDANCE**
- **CONSIDERATIONS FOR SAFE IMPLEMENTATION**
- **PERFORMANCE INDICATORS DEMONSTRATING STAFF COMPETENCY TO IMPLEMENT**
- **STANDARDS**
- **CRITERIA FOR EVALUATION**
- **REFERENCES ARE FOUND AT THE END OF THE DOCUMENT**

It is also important to point out that the BFHI is typically focused on the healthy term infant, however, in the US many late preterm infants are cared for on the postpartum floor. Therefore, some guidance and standards are relevant to their care. In some cases, the 2018 Implementation Guidance specifies if a standard applies to term infants or preterm infants. BFUSA felt it was more appropriate to remove the “term” and “preterm” language from the standard. Instead, the standard applies to where the mother, baby, or both are being cared for. In addition, a NICU Toolkit offering a comprehensive set of clinical practice recommendations geared towards increasing the use of breastfeeding and human milk in neonatal intensive care management has been developed.

This toolkit will be posted to www.babyfriendlyusa.org by the end of summer 2021.

DESCRIPTION OF SECTIONS INCLUDED IN EACH STEP

STEP NAME AND NUMBER: appears exactly as it is worded in the 2018 BFHI Implementation Guidance.

RATIONALE: offers insight into the purpose of the step and appears in this document exactly as it is worded in the 2018 BFHI Implementation Guidance.

IMPLEMENTATION GUIDANCE: provides critical information to support the standards which facilities should strive to achieve for all patients. This language is predominantly taken from the 2018 Implementation Guidance, with some adjustments in *italics* for applicability to the US. (**NOTE:** some words were changed from the European to American spelling and some small amounts of text containing guidance unrelated to US hospitals were removed in order to avoid confusion.)

US CONSIDERATIONS FOR SAFE IMPLEMENTATION: are suggested documents, policies, and/or protocols from either a recognized national/international medical professional organization or US governmental department, WHO or UNICEF that may assist facilities with the safe implementation of the step.

PERFORMANCE INDICATORS DEMONSTRATING STAFF COMPETENCY TO IMPLEMENT: are the knowledge, skills and attitudes that are necessary for staff to properly implement the step. They are mostly drawn from the WHO/UNICEF Competency Verification Toolkit titled “Ensuring Competency of Direct Care Providers to Implement the Baby-Friendly Hospital Initiative”, however six Performance Indicators were developed specifically for the United States.

STANDARDS: are predominantly taken from the 2018 Implementation Guidance, with some adjustments in *italics* for applicability to the US.

CRITERIA FOR EVALUATION: are the specific quantifiable measures used by Baby Friendly USA (BFUSA) assessors to determine the birthing facility’s conformity with the BFHI.

IMPORTANCE OF BREASTFEEDING

Human milk provided by direct breastfeeding is the biologically normal way to feed an infant. There are very few true contraindications to breastfeeding and scientific evidence overwhelmingly indicates that it is nutritionally superior, offers substantial immunological and health benefits, facilitates mother-baby bonding, and should be promoted and supported to ensure the best health for women and their children. Breastfeeding is the single most powerful and well-documented preventative modality available to health care providers to reduce the risk of common causes of infant morbidity. Significantly lower rates of diarrhea, otitis media, lower respiratory tract infections, Type 1 and Type 2 diabetes, childhood leukemia, necrotizing enterocolitis, and Sudden Infant Death Syndrome occur among those who were breastfed.^{4, 5} Breastfeeding also supports the healthy development of an infant’s gut microbiome⁶ and is shown to be inversely associated with overweight risk.⁷

Women who breastfeed have a lower risk of Type 2 diabetes, hypertension and breast and ovarian cancers.^{4, 8, 9} Evidence suggests that reduction in the risk of cardiovascular and other related diseases may be added to the benefits of breastfeeding for women.^{10, 11} The American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the Centers for Disease Control and Prevention, and the World Health Organization all recommend exclusive breastfeeding for about 6 months and continued breastfeeding while adding complimentary foods for one year and beyond.

Despite the significant gains made during the past few years, the initiation, duration, and exclusivity of breastfeeding continue to lag

behind the national objectives, and racial disparities persist. In 2017, approximately 84% of all women initiated breastfeeding; however, only 74% of non-Hispanic black women and 77% of women with incomes below the poverty line initiated breastfeeding.¹²

While causes of this trend are multifactorial and complex, health care practices have been shown to play a fundamental role in impacting breastfeeding initiation, exclusivity, and duration. Unsupportive practices during the perinatal period can disrupt the unique and critical link between the prenatal education and the community postpartum support provided after discharge from the birthing facility. Conversely, supportive practices positively impact breastfeeding outcomes. The Ten Steps to Successful Breastfeeding, which form the foundation of the Baby-Friendly Hospital Initiative, are a package of evidence-based practices shown to improve breastfeeding outcomes. Studies have shown that the more steps a mother reports experiencing, the more likely she is to meet her breastfeeding goals.^{13,14}

CULTURAL HUMILITY AND RESPECT: ADDRESSING THE DIVERSE NEEDS OF PATIENTS

The Guidelines and Evaluation Criteria will directly affect all birthing individuals, pregnant women, mothers, and their infants and children. The practices described in this document apply equally to parents who may not identify as “women” or “mothers”, including transgender and non-binary parents. The terms “mother” and “breastfeeding” are used throughout this document, reflecting the fact that the biological norm is female persons who give birth to infants and feed them at the breast.

However, BFUSA wants to emphasize that we are respectful and mindful of the many different family types that exist in the US in which these terms do not necessarily represent the circumstances or norms of the family. This includes, but is not limited to, situations such as surrogacy, chest-feeding, or other circumstances in which persons who give birth to infants do not identify as “women” or “mothers,” including transgender and nonbinary parents who may experience difficulty accessing culturally safe care.

We also want to highlight that different racial and ethnic groups have unique cultural norms that may affect a family’s decision-making process. Achieving equity in breastfeeding is a key objective of the BFHI. This requires that leadership create an environment that enables and supports the availability of and access to quality breastfeeding support for all patients equally. It also requires that practitioners address the needs of diverse populations through breastfeeding counselling, safeguard privacy, and respect each individual’s right to make informed and autonomous decisions.

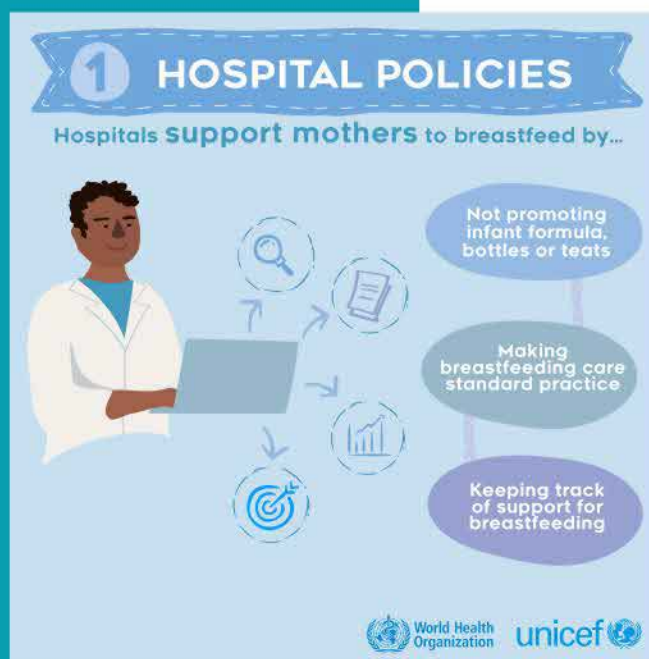
Our expectation is that all families will be embraced and supported equally and that all patients will be provided the highest standard of individualized infant feeding care. Staff should engage in meaningful conversations with families — especially those with unique circumstances — to ensure the health professionals in charge have a clear understanding of each family’s specific wishes and fully support each family’s unique birth plan.

GUIDELINES AND EVALUATION CRITERIA FOR FACILITIES SEEKING TO ATTAIN AND SUSTAIN BABY-FRIENDLY® DESIGNATION

The Baby-Friendly USA Guidelines and Evaluation Criteria and the assessment and accreditation processes are predicated on the following tenets:

1. Well-constructed, comprehensive policies effectively guide staff to deliver evidence-based care.
2. Well-trained staff provide quality, evidence-based care.
3. Monitoring of practice is required to ensure adherence to policy and sustained standard of care.
4. The mother and her family should be protected within the health care setting from false or misleading product promotion and/or advertising which interferes with or undermines informed decisions regarding infant health care practices.
5. Facility staff should be protected from product promotion and/or advertising which may impact their professional activities and judgment.
6. Breastfeeding has been recognized by scientific authorities as the optimal method of infant feeding and should be the norm within all maternal and child health care facilities.
7. Facilities should follow the most scientifically sound, respectful, safe and effective procedural approaches to supporting breastfeeding and human lactation in the birthing environment.
8. The health care delivery environment should facilitate informed health care decisions on the part of the mother and her family. It should not be either restrictive or punitive.
9. The health care delivery environment should be culturally respectful and mindful of the diverse needs of the patients.
10. When a mother has chosen not to breastfeed, when supplementation of breastfeeding is medically indicated, or when supplementation is a decision by the breastfeeding mother (after appropriate conversations and education), it is crucial that safe and appropriate methods of formula preparation, handling, storage, and feeding are taught to the parents.
11. Recognition as a Baby-Friendly institution should have both national and international credibility and prestige, so that it is marketable to the community, increases demand, and thereby improves motivation among facilities to participate in the Initiative.
12. Participation of any facility in the U.S. BFHI is entirely voluntary and is available to any institution providing birthing services.
13. Each participating facility assumes full responsibility for assuring that its implementation of the BFHI is consistent with all of its safety protocols.

FACILITY POLICIES



Step 1 includes three critical management procedures:

STEP 1A

Application of the International Code of Marketing of Breast-milk Substitutes

STEP 1B

Development of written policies

STEP 1C

Operation of monitoring and data-management systems

Comply fully with the
International Code of
Marketing of Breast-milk
Substitutes and relevant
World Health Assembly
resolutions.

RATIONALE:

Families are most vulnerable to the marketing of breast-milk substitutes during the entire prenatal, perinatal, and postnatal period when they are making decisions about infant feeding. The WHA (*World Health Assembly*) has called upon health workers and health-care systems to comply with the International Code of Marketing of Breast-milk Substitutes^{15,16} and subsequent relevant WHA resolutions¹⁷ (the *International Code*), in order to protect families from commercial pressures and influences. Additionally, health professionals themselves need protection from commercial influences that could affect their professional activities and judgement. Compliance with the *International Code* is important for facilities providing maternity and newborn services, since the promotion of breast-milk substitutes is one of the largest undermining factors for breastfeeding.¹⁸

Companies marketing breast-milk substitutes, feeding bottles and *artificial nipples [including pacifiers]* are repeatedly found to violate the *International Code*.^{19,20} It is expected that the sales of breast-milk substitutes will continue to increase globally, which is detrimental for children's survival and well-being.^{21,22} This situation means that ongoing concerted efforts will be required to protect, promote and support breastfeeding, including in facilities providing maternity and newborn services.¹

IMPLEMENTATION GUIDANCE:

THE INTERNATIONAL CODE^{15,16} lays out clear responsibilities of healthcare systems to not promote infant formula, feeding bottles or *artificial nipples [including pacifiers]* and to not be used by manufacturers and distributors of products under the scope of the *International Code* for this purpose. This includes the provision that all facilities providing maternity and newborn services must acquire any breast-milk substitutes, feeding bottles or *artificial nipples [including pacifiers]* they require through normal procurement channels and not receive free or subsidized supplies.²³ Furthermore, staff of facilities providing maternity and newborn services should not engage in any form of promotion or permit the display of any type of advertising of breast-milk substitutes, *feeding bottles*, and/or infant feeding supplies [*pacifier promotion must meet the requirements specified in Criterion 9.2.1*] including the

display or distribution of any equipment or materials bearing the brand of manufacturers of breast-milk substitutes, or discount coupons, and they should not routinely give samples of infant formula to mothers to take home.¹

In line with the [WHO GUIDANCE ON ENDING THE INAPPROPRIATE PROMOTION OF FOODS FOR INFANTS AND YOUNG CHILDREN](#), published in 2016 and endorsed by the WHA,²⁴ health workers and health systems should avoid conflicts of interest with companies that market foods for infants and young children. Health-professional meetings should never be sponsored by industry covered by the *International Code* and industry covered by the *International Code* should not participate in parenting education.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Health professionals and institutions should avoid activities with commercial influences that could affect their professional activities and judgement. Below are a few examples:

AVOIDANCE OF CONFLICTS OF INTEREST

POTENTIAL CONFLICT	<i>Allowing companies that manufacture and/or market breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers] to sponsor and/or host trainings, events, meetings, and scientific seminars on breastfeeding.</i>
POTENTIAL HARM	<i>Associating the name of the respected health facility with a company implies facility endorsement of that company and/or its products. This may unintentionally sway health professionals to recommend products to patients that are not specific to their needs.</i>
REQUIREMENT	<i>Criterion 1A.3.1 requires that no items bear product images or product logos of companies that produce breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers] or names of products covered under the International Code unless specific to the pregnant woman's, mother's or infant's needs or conditions. Criterion 1A.4.4 calls for the facility to have a policy that describes how the facility and its staff members: do not receive support/sponsorship for events/meetings.</i>

POTENTIAL CONFLICT	<i>Health professionals attending trainings sponsored by companies that manufacture and/or market breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers].</i>
POTENTIAL HARM	<i>Receipt of meals and/or free registration to meetings creates a potential obligation to favor that company's products over other products.</i>
REQUIREMENT	<i>Criterion 1A.4.4 calls for the facility have a policy that describes how the facility and its staff members do not receive free gifts.</i>

POTENTIAL CONFLICT	<i>Receipt of awards and gifts by the staff or facility from companies that manufacture and/or market breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers].</i>
POTENTIAL HARM	<i>It associates a company's name with a respected staff member setting that staff member up as "role model" for others. This may imply the staff member's endorsement of a product or company.</i>
REQUIREMENT	<i>Criterion 1A.4.4 calls for the facility have a policy that describes how the facility and its staff members do not receive free gifts, [Examples include meals, conference fees].</i>

US CONSIDERATIONS FOR FACILITIES THAT COORDINATE WITH OUTSIDE AGENCIES THAT ALSO DISCUSS INFANT FEEDING WITH MOTHERS AND THEIR SUPPORT SYSTEMS:

*All facilities are encouraged to coordinate services with other community programs that provide counseling, support, and education on breastfeeding. Some facilities have developed processes that begin coordinating services during the birth hospitalization. While these services offer many benefits to families, hospitals should coordinate efforts to minimize interruptions to mothers during the hospital stay. This will allow maximum opportunity for mothers to recover from birth, bond with their babies and learn their feeding cues. Outside agencies interacting with mothers in the hospital setting should have sufficient training to support exclusive breastfeeding. Procedures should be established between the facility and the outside agency as to how the outside agency should respond and support the breastfeeding mother who requests formula from them while in the hospital setting. **Compliance with the International Code is essential in protecting mothers who are still making decisions about infant feeding.***

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 1A	VERIFICATION METHOD
1. List at least 3 products that are covered by the Code.	Question or case study
2. Describe at least 3 ways a direct care provider/direct care staff member protects breastfeeding in practice.	Question or case study
3. Describe at least 1 way a direct care provider/direct care staff member should respond if offered information provided by manufacturers and/or distributors of products within the scope of the Code.	Question or case study
4. Describe at least 1 type of financial or material inducement that might be offered to a direct care provider/direct care staff member by a manufacturer and/or distributor of products within the scope of the Code.	Question or case study
5. Describe at least 1 harm of a direct care provider/direct care staff member accepting financial or material inducements.	Question or case study
6. Explain at least 2 ways that the facility and any affiliated prenatal services ensure that there is no promotion of infant formula, feeding bottles, or <i>artificial nipples</i> in any part of facilities providing maternity and newborn services, or by any of the direct care providers/direct care staff.	Question or case study



THE FOLLOWING STANDARDS APPLY

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1A.1 All infant formula, feeding bottles and artificial nipples [including pacifiers] used in the facility have been purchased through normal procurement channels and not received through free or subsidized supplies.	<p>A review of records will confirm:</p> <p>Criterion 1A.1.1 A review of records [invoices and proofs of payment] indicates that infant formula, feeding bottles and artificial nipples [including pacifiers] used in the facility have been purchased at a fair market price through normal procurement channels and not received through free or subsidized supplies or rebates that drop the price below the fair market price.</p>
1A.2 Health professionals who provide prenatal, delivery and/or newborn care can explain at least two elements of the International Code.	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>Criterion 1A.2.1 At least 80% of health professionals who provide prenatal, delivery, postpartum, and/or well newborn units can explain at least two elements of the International Code.</p> <ul style="list-style-type: none"> A. Direct care nursing staff, AND B. Direct care providers with privileges
1A.3 The facility [including affiliated prenatal services] has no display of products covered under the International Code or items with logos of companies that produce breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers], or names of products covered under the International Code.	<p>A review and/or observation of items will confirm:</p> <p>Criterion 1A.3.1 A review of submitted and/or observed items in the facility [including affiliated prenatal services] will confirm that no items bear product images or product logos of companies that produce breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers] or names of products covered under the International Code unless specific to the pregnant woman's, mother's or infant's needs or conditions. (For example, information about how to safely use a needed product such as a formula or a specialty bottle would be acceptable to give to a mother or infant needing that specific product. Marketing information for such products would not be acceptable.)</p> <ul style="list-style-type: none"> A. In the affiliated prenatal clinic/service, AND B. In the birthing facility <p>continued</p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
<p>1A.3 The facility [including affiliated prenatal services] has no display of products covered under the <i>International Code</i> or items with logos of companies that produce breast-milk substitutes, feeding bottles and artificial nipples [including pacifiers], or names of products covered under the <i>International Code</i>.</p>	<p>A review and/or observation of items will confirm:</p> <p>Criterion 1A.3.2 A review of submitted and/or observed items displayed and/or distributed to pregnant women, mothers, or staff in the facility [including affiliated prenatal services] will confirm all items are free of messages that promote or advertise breast-milk substitutes, feeding bottles, and artificial nipples or other infant feeding supplies.</p> <p>A. In the affiliated prenatal clinic/service, AND</p> <p>B. In the birthing facility</p> <p>Criterion 1A.3.3* A review of submitted and/or observed items in the facility [including affiliated prenatal services] will confirm that any items displayed or distributed to pregnant women and mothers are free of messages that promote or advertise the use of pacifiers, except safe sleep and SUIDS/SIDS risk reduction materials which must contain additional language to promote breastfeeding. [See criterion 9.2.1]</p> <p>A. In the affiliated prenatal clinic/service, AND</p> <p>B. In the birthing facility</p> <p>Observation will confirm:</p> <p>Criterion 1A.3.4 Observations will confirm that infant formula is kept out of view of patients and the general public.</p> <p>A. In the affiliated prenatal clinic/service, AND</p> <p>B. In the birthing facility</p>

CLARIFICATION: CRITERION 1A.3.3* PACIFIERS AND SUIDS/SIDS REDUCTION INFORMATION

BFUSA acknowledges the evidence pertaining to pacifier use related to SUIDS/SIDS risk reduction.²⁵ Safe sleep and SUIDS/SIDS risk reduction information is important for parents to receive during the birth hospital stay.^{26,27} This education may be compatibly provided to parents by using safe sleep materials that also promote breastfeeding. SEE STANDARD 9.2 FOR ADDITIONAL GUIDANCE.

WHO/UNICEF STANDARD	US CRITERIA FOR EVALUATION
<p>1A.4 The facility has a policy that describes how it abides by the <i>International Code</i>, including procurement of breast-milk substitutes, not accepting support or gifts from producers or distributors of products covered by the <i>International Code</i> and not giving samples of breast-milk substitutes, feeding bottles or <i>artificial nipples</i> [including pacifiers] to mothers.</p>	<p>The facility has a policy that describes how it abides by the <i>International Code</i>, including:</p> <p>Criterion 1A.4.1 How the facility procures infant feeding products.</p> <p>Criterion 1A.4.2 How the facility [including affiliated prenatal services] protects pregnant women, mothers, and their families by not allowing the receipt or distribution of:</p> <ul style="list-style-type: none"> ▪ Marketing materials ▪ Samples ▪ Gift packs ▪ Coupons <p>that include breast-milk substitutes, feeding bottles, artificial nipples, and pacifiers, or other infant feeding supplies.</p> <p>Criterion 1A.4.3 How the facility [including affiliated prenatal services] protects pregnant women, mothers and their families by preventing direct contact or indirect contact with the manufacturers and/or distributors of breast-milk substitutes, feeding bottles, artificial nipples, and pacifiers.</p> <ul style="list-style-type: none"> ▪ Direct contact [examples include providing infant feeding hotline numbers staffed by company employees/contractors] ▪ Indirect contact [examples include use of mechanisms to collect mothers' names and provide to companies/contractors through photographers and special discharge programs] <p>Criterion 1A.4.4 How the facility [including affiliated prenatal services] protects itself and its staff members from marketing by manufacturers or distributors of breast-milk substitutes, bottles, nipples, pacifiers or other infant feeding supplies, by precluding the receipt of:</p> <ul style="list-style-type: none"> ▪ Free gifts [Examples include meals, conference fees] ▪ Information that is not scientific, factual, and unbiased ▪ Materials [Examples include posters, magazines] ▪ Promotional items ▪ Equipment ▪ Money ▪ Support for breastfeeding education ▪ Support/sponsorship for events/meetings <p>All other interactions with these manufacturers/distributors are in compliance with the facility's vendor/ethics policy.</p>

Have a written infant feeding policy that is routinely communicated to staff and parents.

RATIONALE:

Policy drives practice. *Health professionals* and institutions are required to follow established policies. The clinical practices articulated in the Ten Steps need to be incorporated into facility policies, to guarantee that appropriate care is equitably provided to all mothers and babies and is not dependent on the *routines and/or* preferences of each *direct care* provider. Written policies are the vehicle for ensuring patients receive consistent, evidence-based care, and are an essential tool for *direct care* staff accountability. Policies help to sustain practices over time and communicate a standard set of expectations for all health workers.¹

IMPLEMENTATION GUIDANCE:

Facilities providing maternity and newborn services should have a clearly written breastfeeding policy that is routinely communicated to staff and parents.² A facility breastfeeding policy may stand alone as a separate document, be included in a broader infant feeding policy, or be incorporated into a number of other policy documents *or protocols*. However organized, the policy should include guidance on how each of the clinical and care practices should be implemented, to ensure that they are applied consistently to all mothers. The policy should also spell out how the management procedures should be implemented, preferably via specific processes that are institutionalized.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Orient all direct care staff and direct care providers who are impacted by the infant feeding policy as soon as possible, no later than 12 weeks post hire.

In order to have safe, effective and sustained improvement in practices, infant feeding policies in facilities providing maternity and newborn services need to cover all established standards of practice, be fully implemented and regularly communicated to direct care staff and direct care providers.² Frequency of communication to staff must occur, minimally, every 2 years.

STEP 1B

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 1A	VERIFICATION METHOD
*7. Describe at least 2 elements that are in the facility's infant feeding policy.	Question or case study
*8. Explain at least 3 ways that the infant feeding policy affects a direct care provider's/direct care staff member's work in <i>providing safe, equitable and appropriate care</i> .	Question or case study

THE FOLLOWING STANDARDS APPLY

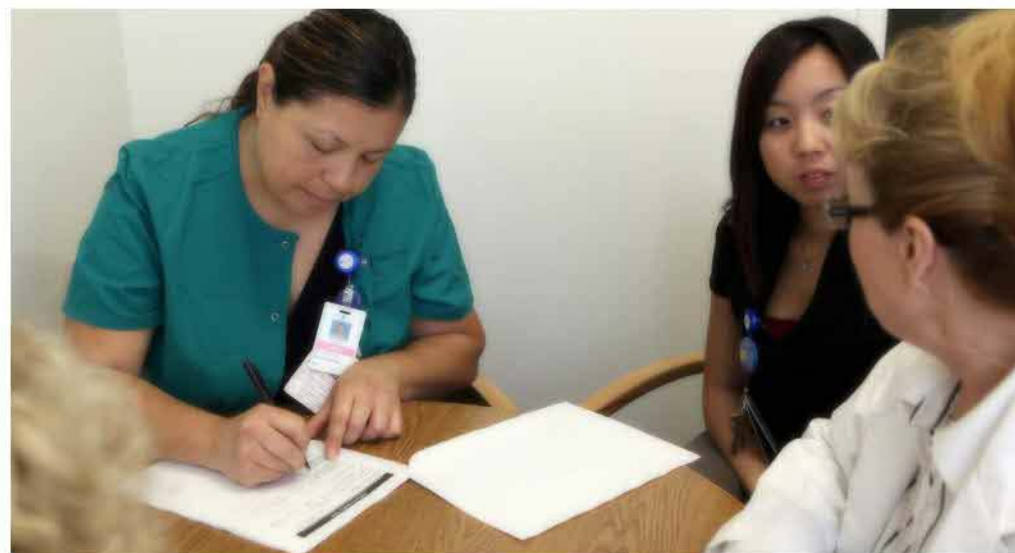
WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1B.5 The health facility has a written infant feeding policy that addresses the implementation of all eight key clinical practices of the Ten Steps, <i>International Code</i> implementation, and regular competency assessment.	<p>A review of the policy will confirm:</p> <p><i>Criterion 1B.5.1</i> The facility will have comprehensive, evidence-based, written maternity care and infant feeding policies that address all Ten Steps, protect breastfeeding, and which includes adherence to the International Code.</p>
1B.6 A review of all clinical protocols or standards related to breastfeeding and infant feeding used by the maternity services indicates that they are in line with BFHI standards and current evidence-based guidelines.	<p>A written description will confirm:</p> <p><i>Criterion 1B.6.1</i> The Director of Maternity will provide a written description of how all the clinical protocols or standards related to breastfeeding and infant feeding used by the maternity services are reviewed and aligned with BFHI standards and current evidence-based guidelines.</p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1B.7 Observations in the facility confirm that a summary of the policy is visible to pregnant women, mothers and their families.	<p>Observations will confirm:</p> <p>Criterion 1B.7.1 Observations in the facility and affiliated prenatal services confirm that The Ten Steps to Successful Breastfeeding (WHO/UNICEF revised 2018) will be visible to pregnant women, mothers and their families. The Ten Steps poster locations include the waiting room and/or admission areas of the following units:</p> <ul style="list-style-type: none"> A. Labor and delivery unit B. Postpartum unit C. Affiliated prenatal services D. Ultrasound, screening/lab, prenatal testing areas E. Newborn nursery/observation area/procedure room F. Neonatal intensive care unit G. Emergency room <p>This information will be displayed in the language(s) most commonly understood by patients.</p> <p>A review of materials will confirm:</p> <p>Criterion 1B.7.2 A review of the content of the Ten Steps posters will verify alignment to the Ten Steps Poster Guide requirements [4-D Pathway document].</p>
1B.8 Clinical staff [Health professionals] who provide prenatal, delivery and/or newborn care can explain at least two elements of the infant feeding policy that influence their role in the facility.	<p>Interviews with direct care nursing staff and direct care provider will confirm:</p> <p>Criterion 1B.8.1 At least 80% of health professionals who provide prenatal, delivery, postpartum, and/or well newborn care can explain at least two elements of the infant feeding policy that influence their role in providing safe, equitable and appropriate care. [PI 8]</p> <ul style="list-style-type: none"> A. Direct care nursing staff, AND B. Direct care providers with privileges <p>Criterion 1B.8.2 At least 80% of health professionals who provide prenatal, delivery, postpartum, and/or well newborn care will confirm that they are aware of the facility's maternity care and infant feeding policies and know where the policies are kept or posted.</p> <ul style="list-style-type: none"> A. Direct care nursing staff, AND B. Direct care providers with privileges <p>continued</p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1B.8 Clinical staff [Health professionals] who provide prenatal, delivery and/or newborn care can explain at least two elements of the infant feeding policy that influence their role in the facility.	<p>A review of materials will confirm:</p> <p>Criterion 1B.8.3 A designated health professional will provide a written description that includes a summary of how and when health professionals are made aware of the infant feeding policy including:</p> <ul style="list-style-type: none"> A. A Process and timeline to orient direct care staff and direct care providers who provide prenatal, delivery and/or newborn care in the implementation of the infant feeding policy, AND B. A Process and frequency for routine communication of all direct care staff and direct care providers who provide prenatal, delivery and/or newborn care. Considerations for routine communication may include: <ul style="list-style-type: none"> ▪ A review of high-risk/safety-related procedural steps, and/or ▪ Updates regarding revisions, and/or ▪ Review of practical skills, and/or ▪ Quality improvement efforts when monitoring data indicates one or more policy practices are not being fully adhered to.

US STANDARD	CRITERION FOR EVALUATION
1B.9 All forms of patient educational materials related to infant feeding (booklets, applications, videos, text, etc.) and a written description of the content of the education, will be made available at assessment. A review of these materials must demonstrate current evidence-based guidance, include all of the required topics listed in Appendix A, and align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding.	<p>A review of educational materials will confirm:</p> <p>Criterion 1B.9.1 Prenatal Education: All forms of patient educational materials related to infant feeding (booklets, applications, videos, text, etc.) and a written description of the content of the education provided to pregnant women during the prenatal period [including both affiliated prenatal services and in-house programs], will be made available at assessment. A review of these materials must:</p> <ul style="list-style-type: none"> A. Demonstrate current evidence-based guidance, AND B. Include all of the required topics listed in Appendix A, AND C. Align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding. <p>Criterion 1B.9.2 Postpartum Breastfeeding Education: All forms of educational materials related to infant feeding (booklets, applications, videos, text, etc.) and/or a description of the content of the education, provided to postpartum breastfeeding mothers during the birth hospitalization will be made available at assessment. A review of these materials must:</p> <ul style="list-style-type: none"> A. Demonstrate current evidence-based guidance, AND B. Include all of the required topics listed in Appendix A, AND C. Align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding. <p><i>continued</i></p>

US STANDARD	CRITERION FOR EVALUATION
<p>1B.9 All forms of patient educational materials related to infant feeding (booklets, applications, videos, text, etc.) and a written description of the content of the education, will be made available at assessment. A review of these materials must demonstrate current evidence-based guidance, include all of the required topics listed in Appendix A, and align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding.</p>	<p>A review of educational materials will confirm:</p> <p>Criterion 1B.9.3 Postpartum Infant Formula Feeding Education: All forms of educational materials related to infant feeding (booklets, applications, videos, text, etc.) and/or a description of the content of the education, provided to formula feeding mothers during the birth hospitalization will be made available at assessment. A review of these materials must:</p> <ul style="list-style-type: none"> A. Demonstrate current evidence-based guidance, AND B. Include all of the required topics listed in Appendix A, AND C. Align with both the facility's infant feeding policy and the Ten Steps to Successful Breastfeeding.



Establish ongoing monitoring and data-management systems.

RATIONALE:

Facilities providing maternity and newborn services need to integrate recording and monitoring of the clinical practices related to breastfeeding into their quality-improvement/monitoring systems.¹

IMPLEMENTATION GUIDANCE:

IMPLEMENTATION: *A fundamental principle of the BFHI is that monitoring of practices is required to confirm adherence to policies and evidence-based care. Indicators for facility-based monitoring of the required key clinical practices are listed in APPENDIX B: INDICATORS FOR FACILITY MONITORING KEY CLINICAL PRACTICES. The monitoring data for certain indicators will be collected from medical records and reported on the Facility Data Sheet located in the BFUSA portal. Specific guidance on numerator and denominator inclusions and exclusions are found in the instructions for each indicator on the Facility Data Sheet. Two of the indicators, early initiation of breastfeeding and exclusive breastfeeding, are considered "sentinel indicators". A sentinel indicator captures an essential element that serves as a bellwether in a complex change process. "Sentinel indicators are placed at critical points in a system map to help monitor and inform the mutually influencing relationship between the program and its context."^{28, 29} Facilities should routinely track all required indicators for each mother–infant pair. Recording of information on the indicators should be incorporated into the medical charts and extracted into relevant reports and/or dashboards.¹ The monitoring data for indicators not included on the Facility Data Sheet will be collected through audits and/or surveys, also located in the BFUSA portal.*

Each facility must form a multi-disciplinary committee, which must consist of some direct care providers and direct care staff, to guide the work towards implementation of these Guidelines and Evaluation Criteria. This committee will retain a key post-designation role which will include monitoring the required key clinical practices to ensure sustainability and should meet to review progress at least every 6 months. During concentrated periods of implementation of a practice and/or quality improvement, monthly review is needed.

The purpose of the review is to continually track the values of these indicators, to determine whether established targets are met, and, if not, plan and implement corrective actions. In addition, *mother's surveys and/or audits are to be used* for additional verification purposes or periodic checks.¹

Once acceptable levels of compliance have been achieved, the frequency of data collection on these additional indicators can be reduced, for example to annually. However, if the level of the sentinel indicators falls below 80% (or below national standards), it will be important to assess both the clinical practices and all management procedures, to determine where the *breakdown is* and what needs to be done to achieve the required standards.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Quality improvement can be defined as “systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups.”²² Sustaining practices requires facilities to build systems to monitor key clinical indicators. Key principles of sustaining safe, evidence-based practices include cyclical quality improvement methodologies, active participation of a multi-disciplinary committee, engaged administrative leaders, meeting consistently over time, and external assessment.¹

As facilities strive to achieve the metrics described in these Guidelines and Evaluation Criteria, it is important they do so while continuing to focus on providing individualized, culturally sensitive care equitably provided to all mothers and babies.

SUSTAINING PRACTICES

Objective external evaluation conducted every 5 years is essential to validate the maintenance of all Ten Steps practices

Monitoring of practices through regular collection of data facilitates early identification of problems which results in improved sustainability of each of the Ten Steps



Supportive leadership committed to providing evidence based care enables the necessary changes to improve care.

Review monitoring data to decide on processes or actions to improve care practices based on findings from audits and surveys.

STEP 1C

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 1C	VERIFICATION METHOD
*9. Explain at least 2 reasons why monitoring of hospital practices is important to ensure quality of care.	Question or case study
*10. Explain at least 2 ways practices are monitored in this facility.	Question or case study

THE FOLLOWING STANDARDS APPLY

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
1C.10 The facility has a protocol for an ongoing monitoring and data-management system to comply with the eight key clinical practices.	<p>A review of the policy will confirm:</p> <p><i>Criterion 1C.10.1 A review of the infant feeding policy and any related protocols includes a description of how the facility will routinely collect and track clinical practice indicators in order to report and improve on quality of care involving the data to evaluate the 8 key clinical practice steps [Steps 3-10].</i></p>
1C.11 Clinical staff (<i>direct care providers and direct care staff</i>) at the facility meet at least every 6 months to review implementation of the system.	<p>The nursing director/manager will confirm:</p> <p><i>Criterion 1C.11.1 The Nursing Director/Manager will confirm that the multi-disciplinary committee, which must consist of some direct care providers and direct care staff, meets at least every 6 months, ideally every 3 months, for monitoring purposes that include:</i></p> <ul style="list-style-type: none"> <i>A. Analyzing the key clinical practice indicator data to determine if targets are met, AND</i> <i>B. Defining corrective actions to improve quality of care, if needed.</i> <p><i>NOTE: "During concentrated periods of quality improvement, monthly review may be needed." Facilities should consider ways to provide constructive feedback to direct care providers and direct care staff and support for practice improvement when monitoring data indicate practices are not fully implemented.</i></p>

STEP 1C

COMPETENCY ASSESSMENT— SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>1C.12 Health professionals who provide prenatal, delivery and/or newborn care will demonstrate their competence regarding the facility's monitoring systems.</p>	<p>The nursing director/manager will confirm:</p> <p>Criterion 1C.12. 1 <i>At least 80% of health professionals who provide prenatal, delivery, postpartum, and/or well newborn care will be able to explain at least 2 reasons why monitoring of hospital practices is important to ensure quality of care. [PI 9]</i></p> <ul style="list-style-type: none"> <i>A. Direct care nursing staff, AND</i> <i>B. Direct care providers with privileges</i>

Ensure that staff have sufficient knowledge, competence and skills to support breastfeeding.

RATIONALE:

Timely and appropriate care for all mothers can only be accomplished if staff have the knowledge, skills and *attitudes* to carry it out. Training of health staff enables them to develop effective skills, give consistent messages, and implement policy standards. Staff cannot be expected to implement a practice or educate a patient on a topic for which they have received no training.¹

IMPLEMENTATION GUIDANCE:

COMPETENCY REQUIREMENTS: *Health professionals who provide infant feeding services must be competent in the knowledge, skills and attitudes to implement the Ten Steps to Successful Breastfeeding.*

TABLE 1 (on the next page) provides the high-level competency framework in which 16 specific management and support competencies are organized into seven unique domains. The domains begin with critical management procedures that health professionals need to participate in to create such needed environments. Foundational skills include effective communication and counseling that transversally apply throughout clinical competencies. They then progress through the various perinatal stages along the continuum of care and services, from the prenatal period until discharge from the site of birth.³ **VERIFICATION OF THE 16 COMPETENCIES IS THE PRIMARY FOCUS ON ENSURING SAFE, EVIDENCE-BASED, COMPASSIONATE CARE.**



TABLE 1: DOMAINS AND COMPETENCIES³

DOMAINS	COMPETENCIES NECESSARY FOR IMPLEMENTING THE TEN STEPS TO SUCCESSFUL BREASTFEEDING
DOMAIN 1: Critical management procedures to Support the Ten Steps (Step 1A, 1B, and 1C)	01. Implement the Code in a health facility 02. Explain a facility's infant feeding policies and monitoring systems
DOMAIN 2: Foundational skills: communicating in a credible and effective way (All Steps)	03. Use listening and learning skills whenever engaging in a conversation with a mother 04. Use skills for building confidence and giving support whenever engaging in a conversation with a mother
DOMAIN 3: Prenatal period (Step 3)	05. Engage in antenatal conversation about breastfeeding
DOMAIN 4: Birth and immediate postpartum (Step 4)	06. Implement immediate and uninterrupted skin-to-skin 07. Facilitate breastfeeding within the first hour, according to cues
DOMAIN 5: Essential issues for a breastfeeding mother (Steps 3, 5, 6, 7, 8, 9)	08. Discuss with a mother how breastfeeding works 09. Assist mother getting her baby to latch 10. Help a mother respond to feeding cues 11. Help a mother manage milk expression
DOMAIN 6: Helping mothers and babies with special needs (Steps 5, 6, 7, 8, 9)	12. Help a mother to breastfeed a low-birth-weight or sick baby 13. Help a mother whose baby needs fluids other than breast milk 14. Help a mother who is not feeding her baby directly at the breast 15. Help a mother prevent or resolve difficulties with breastfeeding
DOMAIN 7: Care at discharge (Step 10)	16. Ensure seamless transition after discharge

PERFORMANCE INDICATORS: Performance indicators are a subset of the competencies that provide measurable guidance to evaluate each competency listed in **TABLE 1**. Each performance indicator represents only one action, so only one action verb is used.³ Performance indicators have been included in their relative steps throughout this document. Appendix C includes a comprehensive list of all performance indicators. All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *. **TABLE 2** provides an example from Domain 5, Competency 9, Assist mother getting her baby to latch.

TABLE 2: EXAMPLE: PERFORMANCE INDICATORS AND MEASURABLE ACTIONS⁴⁶

DOMAIN	COMPETENCY	PERFORMANCE INDICATORS	MEASURABLE ACTIONS
Essential issues for a breastfeeding mother	09. Assist mother getting her baby to latch	32. Evaluate a full breastfeeding session observing at least 5 points.	Observation
		33. Demonstrate at least 3 aspects of how to help a mother achieve a comfortable and safe position for breastfeeding within the first 6 hours after birth and later as needed during the hospital stay.	Observation
		34. Demonstrate how to help a mother achieve an effective and comfortable latch, noting at least 5 points.	Observation

TRAINING, ASSESSMENT, AND VERIFICATION OF COMPETENCIES: *Health professionals need to know what to explain to a mother, why it is important, how to do what is necessary and how to do it respecting the mother's concerns and circumstances. STEP 2 focuses on verification of the performance indicators [Appendix C] to ensure that health professionals are competent in supporting breastfeeding, especially during the first few days of the birth hospitalization. Ideally, the responsibility for assessing, training, and verifying the competencies of health professionals should reside with the pre-service education system [professional degree programs]. However, if this has not occurred and staff training is deficient in this area, facilities providing maternity and newborn services will need to take corrective measures to strengthen that capacity, such as by offering courses at the facility or requiring that staff to take courses elsewhere. While some material can be taught through didactic lectures (including electronic resources), some supervised clinical experience with assessing of competencies is necessary. It is important to focus not on a specific curriculum but on the knowledge and skills obtained.¹ TABLE 3 describes 2 options for implementing Step 2 competency-based training.*

TABLE 3: FACILITY OPTIONS FOR COMPETENCY-BASED TRAINING.

OPTION 1: COMPETENCY-BASED TRAINING SPECIFIC TO IDENTIFIED NEEDS	OPTION 2: COMPETENCY-BASED TRAINING FOR ALL HEALTH PROFESSIONALS
<ol style="list-style-type: none"> 1. Assess the competencies of each health professional to identify specific training needs. 2. Provide competency-based training specific to needs identified. 3. Verify each health professional is competent. 4. Remediate as needed. 	<ol style="list-style-type: none"> 1. Provide competency-based training program [internal or external] for all health professionals. 2. Verify all health professionals are competent. 3. Remediate as needed.

HEALTH PROFESSIONAL ROLES REQUIRING COMPETENCY-BASED TRAINING: *All direct care staff and direct care providers [physicians, midwives, physician's assistants, and advanced practice registered nurses] who provide education, assessment, support, intervention, assistance and/or follow-up with regards to infant feeding must have required competencies verified and completed training on identified areas needing improvement, within 6 months of hire. Typically, this will involve the following units/services including: Affiliated Prenatal Services, Labor and Delivery Unit, Postpartum Unit, Newborn Unit. **NOTE:** Steps 1-10 include unit/care-based competency and training requirements specific to staff/provider roles.*

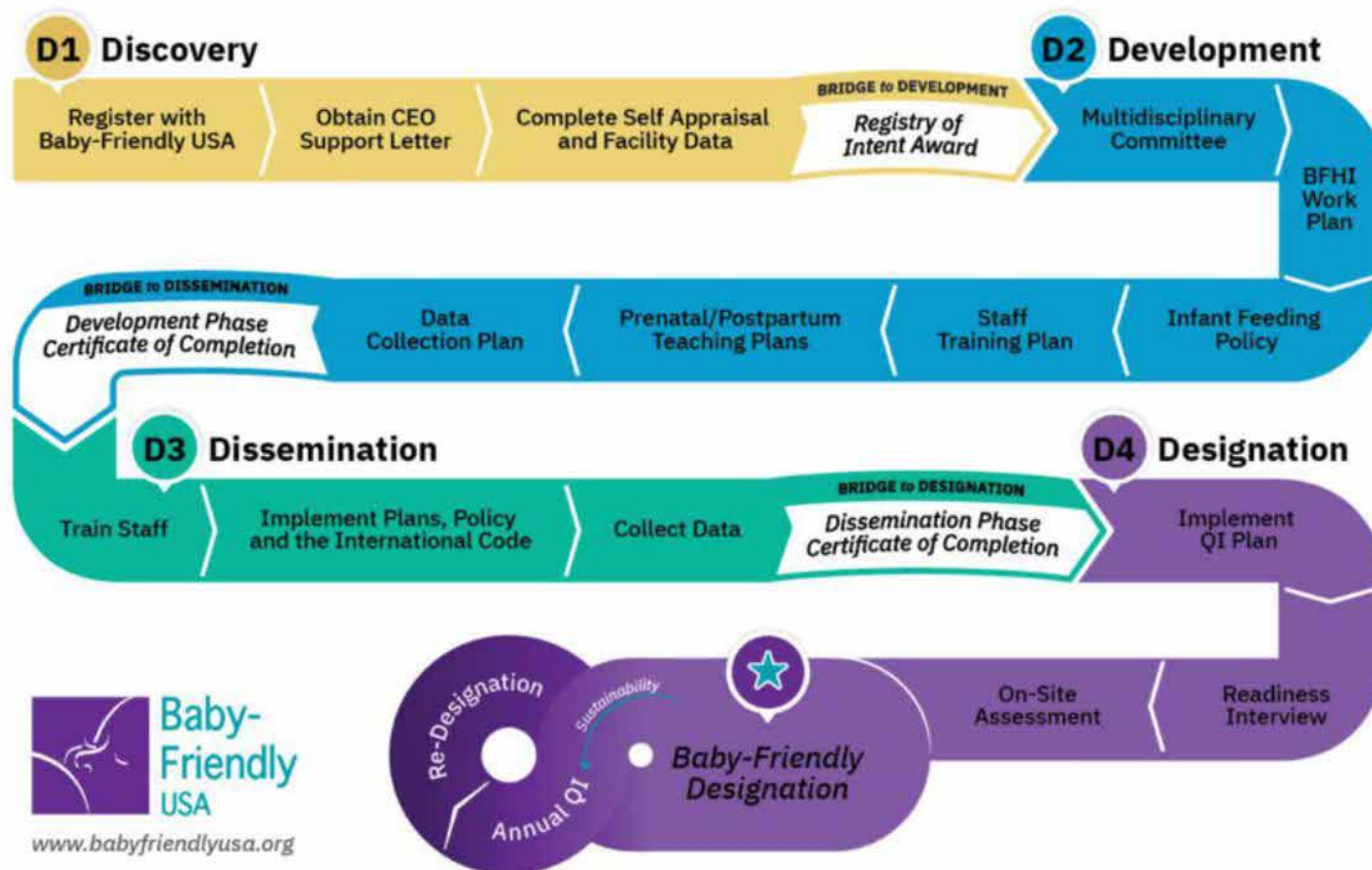
OTHER ROLES *with anticipated workplace exposure to mothers and babies should have training and competency verification in accordance with their roles. Examples of other positions that may need training include:*

- *Administrative Leaders/Managers*
- *Purchasing Agent*
- *Pharmacists*
- *Anesthesiologists*
- *Outside agencies that make inpatient visits*

US PRE-DESIGNATION, ASSESSMENT, AND POST-DESIGNATION CONSIDERATIONS

The 4-D Pathway, consisting of 4 pre-designation and 2 post-designation phases was developed to guide facilities through the designation process. Facilities have specific tasks to complete in each phase and are provided with a variety of tools and resources to assist with their implementation of the Baby-Friendly USA Guidelines and Evaluation Criteria.

The 4-D Pathway to Baby-Friendly Designation



- **D1: DISCOVERY PHASE:** *The Discovery Phase is a time for facilities to learn about the processes and requirements for becoming Baby-Friendly designated. The Discovery Phase toolkit provides a self-appraisal tool to help facilities identify which requirements are already in place and which ones still need additional work.*
- **D2: DEVELOPMENT PHASE:** *The Development Phase provides a template titled, **DIRECT CARE STAFF AND DIRECT CARE PROVIDER COMPETENCY VERIFICATION AND TRAINING PLAN** to assist facilities in developing a comprehensive plan for verifying competencies and helping health professionals gain the knowledge, skills and attitudes necessary to competently implement the facility's infant feeding policy in a safe and effective manner.*
- **D3: DISSEMINATION PHASE:** *The Dissemination Phase involves the verifying of competencies and implementation of training plans that address identified gaps in knowledge and skills, for all direct care staff and direct care providers.*
- **D4: DESIGNATION PHASE:** *The Designation Phase is the time for facilities to reverify competencies for those areas where additional training was provided.*
- **EXTERNAL ASSESSMENT:** *During the Assessment, interviews with health professionals will include facility-based direct care nursing staff and privileged direct care providers. Evaluation of performance indicators at assessment will include a selection of knowledge-based questions and skills-based demonstrations*

specific to the interviewee's role and responsibilities. Baby-Friendly USA has aligned competency-based assessment tools of health "professionals with the WHO/UNICEF Competency Verification Toolkit: Ensuring Competency of Direct Care Providers to Implement the Baby-Friendly Hospital Initiative released on August 5, 2020."

- **ANNUAL QUALITY IMPROVEMENT-SUSTAINABILITY PHASE:** *During the first-year post-designation facilities must develop an Ongoing Competency Evaluation, Training and Verification Plan similar to the one prepared during the Development Phase. (A template for this plan will be provided by Baby-Friendly USA) In-service training must take place minimally every 2 years. The facility will determine the number of hours and content of this training for each staff and provider role. Competency assessment and in-service training must also take place on specific topics when monitoring data indicates one or more practices are not being fully adhered to.*
- **RE-DESIGNATION YEAR 1 PHASE:** *Facilities entering the Re-Designation Year 1 Phase will complete assigned competency assessments and audits to ensure that practices have been sustained. If the results of either reveal practices have slipped, targeted training must be completed to address identified knowledge and/or skills gaps for each direct care provider and direct care staff member.*

US CONSIDERATION FOR SAFE IMPLEMENTATION:

Facilities are encouraged to review the American Academy of Pediatrics' "Clinical Report: Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns" for suggested safe skin-to-skin care and rooming-in practices.²⁵ Staff should receive training that supports safe implementation of these practices.

Sufficient knowledge, skills and attitudes to support breastfeeding are essential for the provision of safe, evidence-based, compassionate care. In addition, how information is communicated is equally important. Direct care providers and staff should engage in meaningful conversations that **ENCOURAGES** the patient and family members.

E MPATHIZE

E – Empathize while listening and engaging in the conversation.

N ON-JUDGMENTAL

N – Be Non-judgmental by respecting each individual's experiences with breastfeeding, current infant feeding goals, and/or cultural and social considerations.

C ONFIRM

C – Confirm you understand the specific circumstances, issues and/or concerns.

O PEN-ENDED QUESTIONS

O – Ask Open-ended questions to evaluate each person's understanding of breastfeeding, infant formula feeding and/or specific maternity care practices applicable to the conversation. For example, "What have you heard about breastfeeding?" "What do you know about infant formula?"

U SE COMPETENT SKILLS

U – Use competent skills to assess any potential or current concerns or challenges.

R ESPONSIVE CARE

R – Responsive care that provides anticipatory guidance [including suitable options] and/or addresses the specific concerns and circumstances.

A FFIRM

A – Affirm successes and the desire to do what is right for the baby.

G IVE EVIDENCE-BASED INFORMATION

G – Give evidenced based, scientific, unbiased, and factual information in a sensitive manner that emphasizes the protections provided by breastfeeding/maternity care practices to enable an informed decision.

E MPOWER

E – Empower each individual to make the decision that is right for her/his circumstances.

S UPPORT

S – Support informed decisions by providing an individualized plan that encourages a mother to have a safe, responsive, caring, and nurturing relationship with her baby.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT THE STEP	VERIFICATION METHOD
Foundational skills: communicating in a credible and effective way	
*11. Demonstrate at least 3 aspects of listening and learning skills when talking with a <i>pregnant woman/mother</i> .	Observation
*12. Demonstrate at least 3 ways to adapt communication style and content when talking with a mother.	Observation
*13. Demonstrate at least 2 ways to encourage a mother to share her views, taking time to understand and consider these views.	Observation
*14. Demonstrate at least 3 aspects of building confidence and giving support when talking with a mother.	Observation

THE FOLLOWING STANDARDS APPLY

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
2.1 Health professionals who provide <i>prenatal, delivery and/or newborn care</i> report they have received pre-service or in-service training on breastfeeding during the previous 2 years.	<p>Interviews with health professionals will confirm:</p> <p>Criterion 2.1.1 At least 80% of health professionals who provide prenatal, delivery and/or newborn care can describe what pre-service or in-service training on breastfeeding they have received during the previous 2 years.</p> <p>A. Direct care nursing staff, AND</p> <p>B. Direct care providers with privileges</p> <p>Considerations for in-service sessions may include:</p> <ul style="list-style-type: none"> Initial competency evaluation, training and verification, AND/OR Ongoing competency training and verification with a focus on changing evidence, high-risk performance indicators, and a refresher for common practical skills, AND/OR Ongoing competency training and verification with a focus on quality improvement efforts when monitoring data indicates one or more practices are not being fully adhered to.

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
2.2 Health professionals who provide prenatal, delivery and/or newborn care report receiving competency assessments in breastfeeding in the previous 2 years.	<p>Interviews with health professionals will confirm:</p> <p>Criterion 2.2.1 At least 80% of health professionals who provide prenatal, delivery and/or newborn care can describe what type of competency assessments in breastfeeding they have received during the previous 2 years.</p> <p>A. Direct care nursing staff, AND</p> <p>B. Direct care providers with privileges</p> <p>Considerations for competency assessments in breastfeeding may involve:</p> <ul style="list-style-type: none"> Initial competency assessments of performance indicators to ensure direct care staff and direct care providers have the necessary knowledge, skills, and attitudes to deliver compassionate, safe, and evidence-based care according to their defined roles and the infant feeding policy, AND/OR Ongoing competency assessments to evaluate job performance and identify gaps to sustain and ensure the delivery of consistent and safe care practices, AND/OR Ongoing competency assessments aligned with quality improvement efforts regarding specific monitoring indicators.
2.3 Health professionals who provide prenatal, delivery and/or newborn care are able to correctly answer three out of four questions on breastfeeding knowledge and skills to support breastfeeding.	<p>BFUSA external assessment will confirm:</p> <p>During the external assessment, direct care providers and direct care staff who provide prenatal, delivery and/or newborn care will be asked questions relating to performance indicators pertinent to their role in the care of patients. The specific performance indicators to be discussed are identified in each step under the heading of COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS.</p>
US STANDARD	CRITERION FOR EVALUATION
2.4 Facilities providing maternity and newborn services have the responsibility for assessing, training, and verifying the required competencies ensuring that all health professionals who provide education, assessment, support, intervention, assistance and/or follow-up with regards to infant feeding have the appropriate knowledge, skills and attitudes to provide safe, evidence-based care.	<p>A review of the competency verification and training plan will confirm:</p> <p>Criterion 2.4.1 The head of maternity services will be able to identify the health professional(s) responsible for all aspects of planning, implementing, and verifying direct care staff's and direct care provider's competencies.</p> <p>Criterion 2.4.2 A copy of the <u>Direct Care Staff and Direct Care Provider Competency Verification and Training Plan</u> [BFUSA materials] will be available for review and analysis demonstrating a comprehensive plan for assessing, training, and verifying the competencies for all required health professionals.</p>

Discuss the importance and management of breastfeeding with pregnant women and their families.

RATIONALE:

All pregnant women must have basic information about breastfeeding, in order to make informed decisions. A review of 18 qualitative studies indicated that mothers generally feel that infant feeding is not discussed enough in the *prenatal* period and that there is not enough discussion of what to expect with breastfeeding.¹⁴ Mothers want more practical information about breastfeeding.

Pregnancy is a key time to inform women about the importance of breastfeeding, support their decision-making and pave the way for their understanding of the maternity care practices that facilitate its success. Mothers also need to be informed that birth practices have a significant impact on the establishment of breastfeeding.¹

IMPLEMENTATION GUIDANCE:

Where facilities provide *prenatal care* [see the *Affiliated Prenatal Services Questionnaire in Appendix D*], pregnant women and their families should be counseled about the benefits and management of breastfeeding.² In many settings, prenatal care is predominantly provided through primary health-care clinics or by community health workers. If facilities providing maternity and newborn services do not have authority over these care providers [as defined by the *Affiliated Prenatal Services Questionnaire*], they should work with them to ensure that mothers and families are fully informed about the importance of breastfeeding and know what to expect when they deliver at the facility. In other cases, the facility directly provides prenatal care services or offers classes for pregnant women. In this case, provision of breastfeeding information and counseling is the direct responsibility of the facility.¹



Breastfeeding education should include information on the importance of breastfeeding and the risks of giving formula or other breast-milk substitutes, along with national and health-professional recommendations for infant feeding. Practical skills such as positioning and attachment, on-demand feeding, and recognizing feeding cues are a necessary component of *prenatal* counseling. Families should be presented with up-to-date information on best practices in facilities providing maternity and newborn services regarding skin-to-skin contact, initiation of breastfeeding, supplementation protocols and rooming-in. Women also need to be informed about possible challenges they might encounter (such as engorgement, or a perception of not producing enough milk) and how to address them.¹

Prenatal breastfeeding counseling must be tailored to the individual needs of the woman and her family, addressing any concerns and questions they have. This counseling needs to be sensitively given and consider the social and cultural context of each family.¹

Wherever possible, conversations on breastfeeding should begin with the first or second *prenatal* visit, so that there is time to discuss any challenges, if necessary. This is particularly important in settings where women have few *prenatal* visits and/or initiate their visits late in their pregnancy. Additionally, women who deliver prematurely may not have adequate opportunities to discuss breastfeeding if the conversations are delayed until late in pregnancy.¹

Information on breastfeeding should be provided in multiple ways. *According to the U.S. Department of Health & Human Services, over a third of adults have below basic health literacy, verbal communication as a primary teaching tool with patients is recommended.* Printed or online information that is in a language mothers understand [*usually recommended at or below a 5th grade reading level*] is one way to ensure that all relevant topics are covered. However, there is no assurance that all women will read this information, and it may not directly address the key questions they have. Interpersonal counseling, either one-on-one or in small groups, is important to allow women to discuss their feelings, doubts and questions about infant feeding.¹

The information must be provided free of conflicts of interest. As stipulated in the “Guidance on ending inappropriate promotion of foods for infants and young children”,²⁴ companies that market foods for infants and young children should not “directly or indirectly provide education to parents and other caregivers on infant and young child feeding in health facilities”.¹

Women at increased risk for preterm delivery or birth of a sick infant (e.g. pregnant adolescents, *women with* high-risk pregnancies, known congenital anomalies) must begin discussions with knowledgeable providers as soon as feasible concerning the special circumstances of feeding a premature, low-birth-weight or sick baby.^{1, 30}

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Engaging pregnant women in a conversation about creating a safe environment for both breastfeeding and sleep is extremely important as this is a time when many parents are preparing these settings. The American Academy of Pediatrics', "SIDS and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment" and the "Clinical Report: Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns", provide recommendations regarding the education that should be provided to reduce the risk of SIDS and sleep-related suffocation, asphyxia, and entrapment among infants.^{25, 26} While providing the education on safe sleep practices, mothers should gain an understanding that sleepiness is a hormonally-driven, physiological response to breastfeeding. This normal response can lead to a mother, unintentionally, falling asleep while breastfeeding. Mothers should also understand that other factors such as exhaustion, fatigue, and pain medications can make falling asleep while breastfeeding common. Families should be offered information about how to create a safe sleep environment for breastfeeding and what hazardous situations are with open, honest, non-judgmental discussions to inform their decisions.

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for all pregnant mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 3	VERIFICATION METHOD
*15. Engage in a conversation with a pregnant woman on 3 aspects of the importance of breastfeeding.	Observation
*16. Assess at least 3 aspects of a pregnant woman's knowledge about breastfeeding in order to fill the gaps and correct inaccuracies.	Observation
*17. Engage in a conversation with a pregnant woman about at least 4 care practices a mother/infant dyad will experience at the birthing facility that will support breastfeeding.	Observation
*29. Engage in a conversation with a pregnant woman regarding at least 3 reasons why effective exclusive breastfeeding is important.	Observation

THE FOLLOWING STANDARDS APPLY ONLY FOR FACILITIES WITH AFFILIATED PRENATAL SERVICES:

[See Affiliated Prenatal Services Questionnaire in Appendix D]

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
3.1 Mothers who received prenatal care at the facility report having received prenatal counseling on breastfeeding.	<p>Affiliated services: interviews with pregnant women in the third trimester who have had at least 2 visits at an affiliated prenatal service will confirm:</p> <p>Criterion 3.1.1 At least 80% of pregnant women will report that a staff member/provider at the affiliated prenatal services:</p> <p>A. Assessed their understanding of breastfeeding and the specific maternity care practices that support it, AND</p> <p>B. Entered into a meaningful conversation [see Step 2] with them on the required WHO/UNICEF prenatal conversation topics provided in Appendix A either one-on-one or in small groups, or by following up to education provided through another learning mode [videos, podcasts, texts] based on their specific needs.</p> <p>NOTE: if mothers have questions about infant formula, their issues, concerns and circumstances will be discussed on an individual basis.</p>

US CLARIFICATION: PRENATAL EDUCATION AND MEANINGFUL CONVERSATIONS

While education may be provided by a variety of different learning modes including videos, podcasts, texts, etc., meaningful prenatal breastfeeding conversations must be tailored to the individual needs of the woman and her family, addressing any concerns and questions they have. This counseling needs to be sensitively given and consider the social and cultural context of each family.¹ "The Guideline: Counseling of Women to Improve Breastfeeding Practices" states that the "aim of breastfeeding counseling is to empower women to breastfeed, while respecting their personal situations and wishes."¹⁸ As you enter into conversations with pregnant women, consider incorporating appropriate components of the following acronym, E.N.C.O.U.R.A.G.E.S as you enter into meaningful conversations [see Step 2].

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
3.2 Mothers who received prenatal care at the facility [affiliated prenatal services] are able to adequately describe what was discussed about two of the required WHO/UNICEF prenatal conversation topics provided in Appendix A.	<p>Affiliated prenatal services: interviews with pregnant women in the third trimester who have had at least 2 visits at an affiliated prenatal service will confirm:</p> <p>Criterion 3.2.1 At least 80% of pregnant women who received prenatal care at the affiliated prenatal services are able to adequately describe two topics from required WHO/UNICEF prenatal conversation topics provided in Appendix A.</p>

THE FOLLOWING STANDARDS OF CARE APPLY FOR ALL FACILITIES WITH AND WITHOUT AFFILIATED PRENATAL SERVICES:

US STANDARD	CRITERION FOR EVALUATION
3.3 All facilities should foster the development of and coordinate services with programs to promote consistent education about breastfeeding that is made available to pregnant women.	<p>A written description will confirm:</p> <p>Criterion 3.3.1 A written description will confirm how the facility has fostered the development of and coordinated services with in-house programs and/or community-based projects to promote consistent education about breastfeeding that is made available to all pregnant women.</p>

US CLARIFICATION: PRENATAL EDUCATION AND RETURNING TO WORK

Pregnant women who know they will be returning to work and/or school often ask questions about their options for continuation of breastfeeding and/or breast-milk feeding. While it is appropriate to answer these questions and to provide basic information about maintaining lactation when direct breastfeeding is not possible or desired, it is important that prenatal breastfeeding education focus on building mothers' knowledge, skills, and confidence in their ability to breastfeed. As needed, more in-depth, education on breast pumps, milk storage, and handling can be given.

Prenatal education that discusses pumping and bottle use must only be given in the context of discussing infant feeding options when mother and baby are separated [e.g., mother going back to school or work], to help mothers initiate or maintain lactation [Step 5], and to support exclusive breastfeeding. Prenatal education on pumping and bottle use must address the following points:

- Bottle use should be delayed until breastfeeding is well-established.
- Possible negative consequences of bottle use on the success of breastfeeding.

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>3.4 Health professionals who provide care to pregnant women will be competent in engaging in a prenatal conversation about breastfeeding.</p>	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 3.4.1 At least 80% of direct care nursing staff who provide labor & delivery care will be able to describe how they engage in a conversation with a pregnant woman on 2 aspects of the importance of breastfeeding. [PI 15]</p> <p>Criterion 3.4.2 At least 80% of direct care nursing staff who provide labor & delivery care will be able to describe how to assess at least 2 aspects of a pregnant woman's knowledge about breastfeeding in order to fill the gaps and correct inaccuracies. [PI 16]</p> <p>Criterion 3.4.3 At least 80% of direct care nursing staff who provide labor & delivery care will be able to describe how they engage in a conversation with a pregnant woman about at least 2 care practices a mother/infant dyad will experience at the birthing facility that will support breastfeeding. [PI 17]</p> <p>Criterion 3.4.4 At least 80% of direct care nursing staff who provide labor & delivery care will be able to describe how they engage in a conversation with a pregnant woman regarding at least 2 reasons why effective exclusive breastfeeding is important. [PI 29]</p> <p>DIRECT CARE PROVIDERS</p> <p>Criterion 3.4.5 At least 80% of direct care providers with privileges to provide care to pregnant women in the labor and delivery unit will be able to describe how they engage in a conversation with a pregnant woman on 2 aspects of the importance of breastfeeding. [PI 15]</p> <p>Criterion 3.4.6 At least 80% of direct care providers with privileges to provide care to pregnant women in the labor and delivery unit will be able to describe how to assess at least 2 aspects of a pregnant woman's knowledge about breastfeeding in order to fill the gaps and correct inaccuracies. [PI 16]</p> <p>Criterion 3.4.7 At least 80% of direct care providers with privileges to provide care to pregnant women in the labor and delivery unit will be able to describe how they engage in a conversation with a pregnant woman regarding at least 2 reasons why effective exclusive breastfeeding is important. [PI 29]</p>

Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.

RATIONALE:

Immediate skin-to-skin contact and early initiation of breastfeeding are two closely linked interventions that need to take place in tandem for optimal benefit. Immediate and uninterrupted skin-to-skin contact facilitates the newborn's natural rooting reflex that helps to imprint the behavior of looking for the breast and suckling at the breast.

Additionally, immediate skin-to-skin contact helps populate the newborn's microbiome and prevents hypothermia. Early suckling at the breast will trigger the production of breast-milk and accelerate lactogenesis. Many mothers stop breastfeeding early or believe they cannot breastfeed because of insufficient milk, so establishment of a milk supply is critically important for success with breastfeeding. In addition, early initiation of breastfeeding has been proven to reduce the risk of infant mortality.^{1, 31}

IMPLEMENTATION GUIDANCE:

Early and uninterrupted skin-to-skin contact between mothers and infants should be facilitated and encouraged as soon as possible after birth. Skin-to-skin contact is when the infant is placed prone on the mother's abdomen or chest with no clothing separating them. It is recommended that skin-to-skin contact begins immediately, regardless of method of delivery. It should be uninterrupted for at least 60 minutes ¹ or longer if the mother wishes and/or if the infant needs more time to complete a breastfeed. To clarify, immediately after birth, an infant may be on the abdomen until the cord is clamped and cut. Then the infant moves his/herself or is moved to the chest, atop the sternum.



Initiation of breastfeeding is typically a direct consequence of uninterrupted skin-to-skin contact, as it is a natural behavior for most babies to slowly squirm or crawl toward the breast *[this may take up to an hour]*. Mothers may be supported to help the baby to the breast if desired. Mothers should be helped in understanding how to support the baby and how to make sure the baby is able to self-attach and suckle at the breast. All mothers should be supported to initiate breastfeeding as soon as possible after birth, within the first hour after delivery *[unless there are medically justifiable reasons]*.^{1,2} *This first breastfeed should be allowed to continue until the baby indicates that the breastfeed is completed. This may take up to another hour. The initial period of skin-to-skin contact until completion of the first feeding may take up to 2 hours.*

It should be noted that the milk a newborn consumes immediately after birth is colostrum, which is highly nutritious and contains important antibodies and immune-active substances. The amount of colostrum a newborn will receive in the first few feedings is very small. Early suckling is important for stimulating milk production and establishing the maternal milk supply. The amount of milk ingested is a relatively unimportant factor.^{1,2} During immediate skin-to-skin contact, and for at least the first 2 hours after delivery, sensible vigilance and safety precautions should be taken so that health professionals can observe for, assess and manage any signs of distress *in infants*. Mothers who are sleepy or under the influence of anesthesia or drugs will require closer observation.¹ When mothers are not fully awake and responsive,

a health professional should accompany the mother, to prevent the baby from being hurt accidentally.

Immediate skin-to-skin care and initiation of breastfeeding is feasible following a cesarean section with local/*regional* anesthesia (epidural).³² After a cesarean section with general anesthesia, skin-to-skin contact and initiation of breastfeeding can begin when the mother is sufficiently alert to hold the infant. Mothers or infants who are medically unstable following delivery may need to delay the initiation of breastfeeding. However, even if mothers are not able to initiate breastfeeding during the first hour after birth, they should still be supported to provide skin-to-skin contact and to breastfeed as soon as they are able (*responsive and alert*).^{1,32,33} *Routine procedures (e.g. assessment, vital signs, security steps, APGAR scoring) should be done with the infant skin-to-skin with the mother. Procedures that are painful or may require separation from skin-to-skin (e.g., eye ointment, weights, vitamin K, bathing) should be delayed until the completion of first feeding or after the initial first hour of skin-to-skin contact (if formula feeding).*¹³ *To diminish pain, where feasible, painful procedures should be conducted while in skin-to-skin contact. Procedures requiring separation of the mother and infant (bathing, for example) should be delayed until after this initial period of skin-to-skin contact and should be conducted, whenever possible, at the mother's bedside. Staff should be vigilant during this time and support mothers to look for signs that their babies are ready to feed and offer help if necessary.*

Preterm infants may be able to root, attach to the breast and suckle.³⁴ As long as the infant is stable, with no evidence of severe apnea, desaturation or bradycardia, preterm infants can start breastfeeding. However, early initiation of effective breastfeeding may be difficult for these infants if the suckling reflex is not yet established and/or the mother has not yet begun plentiful milk secretion. Early and frequent milk expression is critical to stimulating milk production and secretion for preterm infants who are not yet able to suckle. Transition to direct and exclusive breastfeeding should be the aim whenever possible³⁵ and is facilitated by prolonged skin-to-skin contact.

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Facilities are encouraged to review the "American Academy of Pediatrics' Clinical Report: Safe Sleep and Skin-to-Skin Care in the Neonatal Period for Healthy Term Newborns"²⁵ and the WHO/UNICEF "Competency Verification Tool Kit Examiners Resource"³ for suggested safe skin-to-skin care practices.

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 4	VERIFICATION METHOD
*18. Explain at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the mother.	Question or case study
*19. Explain at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the infant.	Question or case study
20. Demonstrate at least 3 points of how to routinely implement immediate, uninterrupted and safe skin-to-skin between mother and infant, regardless of method of birth.	Observation
*21. Demonstrate at least 3 safety aspects to assess when mother and baby are skin-to-skin during the first 2 hours postpartum, regardless of method of birth.	Observation
*22. List at least 3 reasons why skin-to-skin should NOT be <i>delayed or</i> interrupted.	Question or case study
*23. Explain at least 2 reasons when skin-to-skin could be <i>delayed or</i> interrupted for medically justifiable reasons.	Question or case study
24. “WHERE APPLICABLE” Explain how to maintain skin-to-skin during transfer of mother and infant to another room or other recovery area.	Question or case study
*25. Engage in a conversation with a mother including at least 3 reasons why suckling at the breast in the first hour is important, when the baby is ready.	Observation
26. Demonstrate at least 3 aspects of safe care of the newborn in the first 2 hours post-birth.	Observation
27. Describe to a mother at least 3 pre-feeding behaviors babies show before actively sucking at the breast.	Observation

THE FOLLOWING STANDARDS APPLY:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
<p>4.1 Mothers report that their babies were placed in skin-to-skin contact with them immediately after birth and that this contact lasted 1 hour or more, unless there were documented medically justifiable reasons for delayed contact.</p>	<p>Interviews with mothers will confirm:</p> <p>Criterion 4.1.1 <i>Following a vaginal birth, at least 80% of mothers will confirm:</i></p> <ul style="list-style-type: none"> A. <i>That their infants were placed in skin-to-skin contact with them immediately after birth, unless there were documented medically justifiable reasons for delayed contact, AND</i> B. <i>The initial period of skin-to-skin contact continued uninterrupted for at least 1 hour [longer, if needed, to allow a breastfeeding infant to complete a feeding], unless there were documented medically justifiable reasons to interrupt contact.</i> <p>Criterion 4.1.2 <i>Following a cesarean birth, at least 80% of mothers will confirm:</i></p> <ul style="list-style-type: none"> A. <i>That their infants were placed in skin-to-skin contact with them when safe and feasible [minimally, following a cesarean delivery, skin-to-skin should begin in the recovery area as soon as mother is responsive and alert], unless there were documented medically justifiable reasons for delayed contact, AND</i> B. <i>The initial period of skin-to-skin contact continued uninterrupted for at least 1 hour [longer, if needed, to allow a breastfeeding infant to complete a feeding], unless there were documented medically justifiable reasons to interrupt contact.</i> <p>Criterion 4.1.3 <i>At least 80% of mothers will confirm that in the event of delayed or interrupted skin-to-skin contact for medically justifiable reasons, skin-to-skin was initiated/re-established when safe and medically feasible.</i></p> <p>Documentation:</p> <p>Criterion 4.1.4 <i>If necessary, a review of the medical record will provide documentation of skin-to-skin contact including:</i></p> <ul style="list-style-type: none"> A. <i>Time of delivery,</i> B. <i>Time skin-to-skin was implemented,</i> C. <i>Time of completion/duration of skin-to-skin contact, and</i> D. <i>Any reasons for delay/interruption of skin-to-skin contact</i> <p>Observations of births will confirm:</p> <p>Criterion 4.1.5 <i>Observations of vaginal births, if necessary and/or available, show:</i></p> <ul style="list-style-type: none"> A. <i>That infants are placed skin-to-skin with their mothers immediately after birth, unless there were medically justifiable reasons for delayed contact, AND</i> B. <i>The initial period of skin-to-skin contact continued uninterrupted for at least 1 hour [longer, if needed, to allow a breast-feeding infant to complete a feeding], unless there were medically justifiable reasons to interrupt contact.</i> <p><i>continued</i></p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
4.1 Mothers report that their babies were placed in skin-to-skin contact with them immediately after birth and that this contact lasted 1 hour or more, unless there were documented medically justifiable reasons for delayed contact.	<p>Observations of birth will confirm:</p> <p>Criterion 4.1.6 Observations of cesarean births, if necessary and/or available, show:</p> <p>A. That infants are placed in skin-to-skin contact with their mothers when safe and feasible [minimally, following a cesarean delivery, skin-to-skin should begin in the recovery area as soon as mother is responsive and alert], unless there were medically justifiable reasons for delayed contact, AND</p> <p>B. The initial period of skin-to-skin contact continued uninterrupted for at least 1 hour [longer, if needed, to allow a breastfeeding infant to complete a feeding], unless there were medically justifiable reasons to interrupt contact.</p>

U.S. CLARIFICATION: MEDICALLY JUSTIFIABLE REASONS FOR-DELAYED/INTERRUPTED SKIN-TO-SKIN CONTACT

Healthcare Professionals must use their clinical judgement. Mothers or infants that are not stable may require that immediate skin-to-skin contact be postponed. Interruptions may be necessary to address any procedure that cannot be postponed until the completion of the first feeding. In the event that a mother and/or infant are separated for medical reasons, skin-to-skin contact will be initiated as soon as the mother and infant are stabilized/reunited. Any delays or interruptions of skin-to-skin contact should be clearly documented in the medical record.

To be clear, routine procedures (e.g., assessment, vital signs, security steps, APGAR scoring) should be done with the infant skin-to-skin with the mother. Procedures that are painful or may require separation from skin-to-skin (e.g. eye ointment, weights, vitamin K, bathing) should be delayed until the completion of first feeding or after the initial first hour of skin-to-skin contact [if formula feeding].



WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
<p>4.2 Mothers report that their babies were put [supported or self-attached] to the breast within 1 hour after birth, unless there were documented medically justifiable reasons.</p> <p>NOTE: Early Initiation of Breastfeeding: According to WHO, infants should be put to the breast within 1 hour of birth. This practice gives infants the opportunity to feed at the mother's breast. Early initiation of breastfeeding does not require that the infant attached/suckled at the breast or that milk was transferred from breast to infant. It represents the practice of putting an infant in skin-to-skin contact and allowing an infant to slowly crawl toward the breast or supporting mothers to help the baby to the breast, if desired. Putting the baby to breast within the first hour is related to a number of positive outcomes including reduced mortality and exclusive breastfeeding.³⁶</p>	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 4.2.1 At least 80% of breastfeeding mothers will report that they were supported to initiate breastfeeding with their babies as soon as possible after birth, within the first one to two hours after delivery, unless there were documented medically justifiable reasons. NOTE: Supporting the initiation of breastfeeding is defined as placing the baby on the mother's chest (skin-to-skin) for breastfeeding, pointing out infant feeding readiness cues and gently coaching the mother to allow baby to move and attach to the breast.</p> <p>Criterion 4.2.2 At least 80% of breastfeeding mothers will confirm that they were encouraged to look for signs that their infants were ready to feed during this first one to two hours of contact.</p> <p>BFUSA CLARIFICATION/INTERPRETATION: BFUSA supports the practice of "putting infants to the breast" within 1 hour of birth. Due to the effect of various birth medications, some infants do not show readiness to feed until the end of the first hour and/or well into the second hour, even though they have been in uninterrupted skin-to-skin contact with their mothers. Therefore, for the purposes of evaluating the initiation of breastfeeding with a latch or attempts to latch, criterion 4.2.1 will focus on the initiation of the first feeding within the first 2 hours after birth.</p> <p>Documentation:</p> <p>Criterion 4.2.3 If necessary, a review of the medical record will provide documentation of the initiation of breastfeeding including:</p> <ul style="list-style-type: none"> A. Time of delivery B. Time of initiation of breastfeeding C. Any medically justifiable reasons for delay of initiation of breastfeeding <p>Observations of breastfeeding infants will confirm:</p> <p>Criterion 4.2.4 Observations, if necessary and/or available, confirm that breastfeeding mothers are supported to initiate breastfeeding with their infants as soon as possible after birth, within the first one to two hours after delivery, unless there are medically justifiable reasons. NOTE: Supporting the initiation of breastfeeding is defined as placing the baby on the mother's chest (immediate and uninterrupted skin-to-skin) for breastfeeding, pointing out infant feeding readiness and gently coaching the mother to allow baby to move and attach to the breast.</p> <p>Criterion 4.2.5 Observations, if necessary and/or available, show that at least 80% of breastfeeding mothers are shown how to recognize the signs that infants are ready to feed during this first hour of contact.</p>

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>4.3 Health professionals who provide labor & delivery and/or immediate newborn care will be competent to safely implement immediate and uninterrupted skin-to-skin contact and facilitate breastfeeding within the first hour, according to cues.</p>	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 4.3.1 At least 80% of direct care nursing staff who provide labor & delivery and/or immediate newborn care will be able to demonstrate or explain at least 3 points of how to routinely implement immediate, uninterrupted and safe skin-to-skin between a mother and infant regardless of method of birth. [PI 20]</p> <p>Criterion 4.3.2 At least 80% of direct care nursing staff who provide labor & delivery and/or immediate newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Demonstrating or explaining at least 3 safety aspects to assess when a mother and baby are skin-to-skin during the first 2 hours postpartum, regardless of method of birth. [PI 21] B. Demonstrating or explaining at least 3 aspects of safe care of the newborn in the first 2 hours post-birth. [PI 26] <p>Criterion 4.3.3 At least 80% of direct care nursing staff who provide labor & delivery and/or immediate newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Describing at least 2 pre-feeding behaviors babies show before actively sucking at the breast. [PI 27] B. Describing at least 2 reasons why suckling at the breast in the first hour is important, when the baby is ready. [PI 25] <p>DIRECT CARE PROVIDERS</p> <p>Criterion 4.3.4 At least 80% of direct care providers with privileges to provide labor & delivery and/or immediate newborn care will be able to list at least 2 reasons why skin-to-skin should not be delayed or interrupted. [PI 22]</p> <p>Criterion 4.3.5 At least 80% of direct care providers with privileges to provide labor & delivery and/or immediate newborn care will be able to explain at least 2 reasons when skin-to-skin could be delayed or interrupted for medically justifiable reasons. [PI 23]</p> <p>Criterion 4.3.6 At least 80% of direct care providers with privileges to provide labor & delivery and/or immediate newborn care will be able to describe at least 2 points to include in a conversation with a mother concerning why suckling at the breast in the first hour is important, when the baby is ready. [PI 25]</p>

Support mothers to initiate and maintain breastfeeding and manage common difficulties.

RATIONALE:

While breastfeeding is a natural human behavior, most mothers need practical help in learning how to breastfeed. Even experienced mothers encounter new challenges with breastfeeding a newborn. Postnatal breastfeeding counseling and support has been shown to increase rates of breastfeeding up to 6 months of age.³⁷ Early adjustments to positioning and attachment can prevent breastfeeding problems at a *future* time. Frequent coaching and support helps build maternal confidence.¹

IMPLEMENTATION GUIDANCE:

Mothers should receive practical support to enable them to initiate and maintain breastfeeding and manage common breastfeeding difficulties.² Practical support includes providing emotional and motivational support, imparting information and teaching concrete skills to enable mothers to breastfeed successfully. The stay in the facility providing maternity and newborn services is a unique opportunity to discuss and assist the mother with questions or problems related to breastfeeding and to build confidence in her ability to breastfeed.¹

All mothers should receive individualized attention, but first-time mothers and mothers who have not breastfed before will require extra support. However, even mothers who have had another child might have had a negative breastfeeding experience and need support to avoid previous problems. Mothers delivering by cesarean section and obese mothers should be given additional help with positioning and attachment.¹



A number of topics should be included in teaching mothers to breastfeed. It is essential to demonstrate good positioning and attachment at the breast, which are crucial for stimulating the production of breast-milk and ensuring that the infant receives enough milk. Direct observation of a feed is necessary to ensure that the infant is able to attach to and suckle at the breast and that milk transfer is happening. *Competent direct care staff will observe at least one feed every shift.*³⁸ Additionally, facility direct care staff need to educate mothers on the *importance of direct breastfeeding, prevention of pathologically engorged breasts, ways to ensure and maintain a good milk supply, prevention of cracked and sore nipples, and evaluation of milk intake.*¹

Mothers should be coached on how to express breast-milk as a means of maintaining lactation in the event of their being separated temporarily from their infants.² There is not sufficient evidence that one method of expression (hand expression, manual pump or electric pump) is more effective than another,³⁹ and thus any method(s) may be taught, depending on the mother's context. However, hand expression does have the advantage of being available no matter where the mother is and of allowing the mother to relieve pressure or express milk when a pump is not available *or during an emergency where there may be power outages. It is reasonable for all mothers to be taught hand expression during the birth hospitalization.* Pumps can potentially have more microbial contamination if they cannot easily be cleaned. Mothers also need to be supported for collection and storage of expressed milk.¹

Practical support for preterm, including late preterm newborns is particularly critical, in order to establish and maintain the production of breast-milk. Many mothers of preterm infants have health problems of their own and need motivation and extra support for milk expression. *Robust and older* late preterm infants are generally able to exclusively breastfeed at the breast, but are at greater risk of jaundice, hypoglycemia and feeding difficulties than full-term infants, and thus require increased vigilance.⁴⁰ Mothers of twins (multiples) also need extra support, especially for positioning and attachment.¹

Conversations with mothers should include information on the importance of direct breastfeeding. However, some mothers will make an informed decision to exclusively pump and feed their expressed breast-milk to their infants. If this is the case, they should be advised to pump and feed their infants expressed breast-milk at least 8 times in 24 hours.

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

General guidance regarding facilitating milk production and maintaining milk supply may include **(NOTE: This guidance must be individualized.)**

- **Direct breastfeeding:** Ensure good positioning and correct attachment with observable efficient suckling patterns at the breast. Practice responsive feeding with no limits on frequency and duration of feedings. Avoid non-medically indicated supplemental feeds, pacifiers, and artificial nipples.
- **Breastfeeding and formula feeding combined [Mixed-feeding - Maternal request]:** Establish exclusive direct breastfeeding for several weeks with supplementation introduced at a later date. The mother must be knowledgeable regarding the importance of expressing breast-milk after formula is introduced.
- **Temporary medically-indicated supplementation:** Supplement, when possible, at the breast. Avoid pacifiers and artificial nipples. Establish expression of breast-milk when supplements are offered.
- **Exclusively breast-milk feeding, preterm infants, and infants that cannot breastfeed due to illness or separation:** Express breast-milk regularly, at least 8 times in 24 hours, with stretches not longer than 4 hours. Mothers may describe hand expression, manual pumping or electric pumping.

- **Preterm infants, particularly those being cared for on the regular postpartum unit must receive individualized care, including close observation, due to their immaturity. These infants are less alert, have less stamina, are often hypotonic, and have greater difficulty with latch, suck and swallow.⁴¹ Mothers of late preterm infants are at a greater risk of delayed lactogenesis.⁴⁰ Management strategies to support these couplets include developing an adequate milk volume and ensuring that these infants are adequately fed.⁴⁰ Mothers should be assisted to start expressing their milk within the first 6 hours after birth [preferably within 1-2 hours after birth and completion of initial skin-to-skin contact]. In order to initiate and establish the mother's milk supply, regular expression using hand expression may be necessary to stimulate the breasts.⁴⁰ Many of these infants may not effectively transfer milk during breastfeeding, so supplementation with the mother's own milk, pasteurized donor human milk or infant formula may be necessary following attempted breastfeeds with appropriate lactation support.⁴¹**

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS

for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY

for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 5	VERIFICATION METHOD
28. Describe at least 6 essential issues that every breastfeeding mother should know or demonstrate.	Question or case study
*30. Engage in a conversation with a mother regarding 2 elements related to infant feeding patterns in the first 36 hours of life.	Observation
*31. Describe to a mother at least 4 signs of adequate transfer of milk in the first few days.	Observation
32. Evaluate a full breastfeeding session observing at least 5 points.	Observation
*33. Demonstrate at least 3 aspects of how to help a mother achieve a comfortable and safe position for breastfeeding within the first 6 hours after birth and later as needed during the hospital stay.	Observation
*34. Demonstrate how to help a mother achieve an effective and comfortable latch, noting at least 5 points.	Observation
40. Demonstrate to a mother how to hand express breast-milk, noting 8 points.	Observation
43. Help a mother achieve a comfortable and safe position for breastfeeding with her preterm, late preterm, or weak infant at the breast, noting at least 4 points.	Observation
*44. Engage in a conversation with a mother of a preterm, late preterm, or low-birth-weight infant not sucking effectively at the breast, including at least 5 points.	Observation
57. Engage in a conversation with a mother regarding at least 4 different ways to facilitate breastfeeding in order to prevent or resolve most common conditions of the lactating breasts (sore nipples, engorgement, mother who thinks she doesn't have enough milk, infants who have difficulty sucking).	Observation
*65. Describe at least 2 maternal and 2 infant risk factors associated with delayed lactogenesis II.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
5.1 Breastfeeding mothers report that someone on the <i>direct care</i> staff offered assistance with breastfeeding within 6 hours after birth.	<p>Interviews with breastfeeding [including breast-milk feeding] mothers will confirm:</p> <p>Criterion 5.1.1 At least 80% of breastfeeding [including breast-milk feeding] mothers will report that:</p> <ul style="list-style-type: none"> A. Term infants/Direct Breastfeeding: direct care staff provided additional guidance and support as needed with breastfeeding within 6 hours of birth. OR B. Exclusively expressing/Breast-milk feeding: direct care staff provided additional guidance and support with expressing their breast-milk within the first 6 hours after birth [preferably within 1–2 hours after birth and completion of initial skin-to-skin contact], unless there is a justifiable reason to delay initiation of expression. OR C. Late preterm infants/Direct Breastfeeding on the postpartum unit: direct care staff provided additional guidance and support as needed with breastfeeding and expressing their breast-milk within the first 6 hours after birth [preferable within 1–2 hours after birth and completion of the initial skin-to-skin contact], unless there is a justifiable reason to delay initiation of expression. <p>NOTE: Early adjustments to positioning and attachment within the first 6 hours following the initial breastfeeding after delivery can prevent breastfeeding problems at a future time.</p>
5.2 Breastfeeding mothers are able to demonstrate how to position their babies for breastfeeding and that the babies can suckle and transfer milk.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 5.2.1 At least 80% of breastfeeding mothers are able to demonstrate or describe:</p> <ul style="list-style-type: none"> A. Correct positioning with their babies, AND B. Correct attachment (latch) with their babies, AND C. Observable efficient suckling patterns with their babies, AND D. Audible sounds associated with the transfer of breast-milk with their babies.
5.3 Breastfeeding mothers can describe at least two ways to facilitate milk production for their infants.	<p>Interviews with breastfeeding [including breast-milk feeding] mothers will confirm:</p> <p>Criterion 5.3.1 At least 80% of breastfeeding [including breast-milk feeding] mothers can describe at least two ways to facilitate milk production and to keep up the supply for their babies.</p>
5.4 Breastfeeding mothers can describe at least two indicators of whether a breastfed baby consumes adequate milk.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 5.4.1 At least 80% of breastfeeding mothers can describe at least two indicators of whether a breastfed baby has consumed adequate milk.</p>

continued

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT: *continued*

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
5.5 Mothers of breastfed infants can correctly demonstrate or describe how to express breast-milk.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 5.5.1 At least 80% of breastfeeding mothers can correctly demonstrate or describe how to hand express breast-milk.</p>

THE FOLLOWING STANDARD APPLIES TO MOTHERS WITH INFANTS THAT ARE BEING CARED FOR IN THE NICU:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
5.6 Mothers of preterm or sick infants report having been helped to express milk within 1–2 hours after birth.	<p>Interviews with mothers who are breastfeeding or intending to do so with infants in the NICU will confirm:</p> <p>Criterion 5.6.1 At least 80% of mothers with infants in the NICU, who are breastfeeding or intending to do so, will report that they have been provided guidance and support with expressing their breast-milk within the first 6 hours after birth [preferably within 1–2 hours after birth and completion of initial skin-to-skin contact – if safe and medically feasible], unless there is a justifiable reason to delay initiation of expression.</p> <p>Criterion 5.6.2 At least 80% of mothers with infants in the NICU, who are breastfeeding or intending to do so will report that they have been provided guidance that they need to breastfeed or express their milk at least 8 times every 24 hours, with stretches not longer than 4 hours, to establish and maintain their milk supply.</p>

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>5.9 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in:</p> <ul style="list-style-type: none"> • How to assist a mother in the steps to getting her baby to latch • How to discuss with a mother how breastfeeding works • In helping a mother to breastfeed a late-preterm baby • In helping a mother prevent or resolve difficulties with breastfeeding • In helping a mother manage milk expression • In helping a mother who is not feeding her baby directly at the breast 	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 5.9.1 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will be able to describe at least 3 essential issues that every breastfeeding mother should know or demonstrate. [PI 28]</p> <p>Criterion 5.9.2 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will be able to describe to a mother at least 2 signs of adequate transfer of milk in the first few days. [PI 31]</p> <p>Criterion 5.9.3 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will be able to describe how they evaluate a full breastfeeding session observing at least 5 points. [PI 32]</p> <p>Criterion 5.9.4 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will be able to describe how they engage in a conversation with a mother of a late preterm infant rooming-in on the postpartum unit that is not sucking effectively at the breast, including at least 3 points. [PI 44]</p> <p>Criterion 5.9.5 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Demonstrate at least 3 aspects of how to help a mother achieve a comfortable and safe position for breastfeeding within the first 6 hours after birth and later as needed during the hospital stay. [PI 33] B. Help a mother achieve a comfortable and safe position for breastfeeding with her preterm, late preterm or weak infant at the breast, noting at least 3 points. [PI 43] <p>Criterion 5.9.6 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Demonstrate how to help a mother achieve an effective and comfortable latch, noting at least 3 points. [PI 34] B. Demonstrate to a mother how to hand express breast-milk to a mother, noting at least 3 points. [PI 40] <p>Criterion 5.9.7 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Engage in a conversation with a mother regarding 2 elements related to infant feeding patterns in the first 36 hours of life. [PI 30] B. Engage in a conversation with a mother regarding at least 4 different ways to facilitate breastfeeding in order to prevent or resolve most common conditions of the lactating breasts (sore nipples, engorgement, mother who thinks she doesn't have enough milk, infants who have difficulty sucking). [PI 57]

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>5.9 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in:</p> <ul style="list-style-type: none"> • How to assist a mother in the steps to getting her baby to latch • How to discuss with a mother how breastfeeding works • In helping a mother to breastfeed a late-preterm baby • In helping a mother prevent or resolve difficulties with breastfeeding • In helping a mother manage milk expression • In helping a mother who is not feeding her baby directly at the breast 	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE PROVIDERS</p> <p><i>Criterion 5.9.8 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will be able to describe how they engage in a conversation with a mother regarding 2 elements related to infant feeding patterns in the first 36 hours of life. [PI 30]</i></p> <p><i>Criterion 5.9.9 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will be able to describe to a mother at least 2 signs of adequate transfer of milk in the first few days. [PI 31]</i></p> <p><i>Criterion 5.9.10 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will be able to describe at least 2 maternal and 2 infant risk factors associated with delayed lactogenesis II. [PI 65]</i></p> <p><i>Criterion 5.9.11 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will be able to explain how they would engage in a conversation with a mother of a preterm, late preterm, or low-birth weight infant not sucking effectively at the breast, including at least 3 points. [PI 44]</i></p>

Do not provide breastfed newborns any food or fluids other than breast-milk, unless medically indicated.

RATIONALE:

Giving newborns any foods or fluids other than breast-milk in the first few days after birth interferes with the establishment of breast-milk production. Newborns' stomachs are very small and easily filled. Newborns who are fed other foods or fluids will suckle less vigorously at the breast and thus inefficiently stimulate milk production, creating a cycle of insufficient milk and supplementation that leads to breastfeeding failure. Babies who are supplemented prior to facility discharge have been found to be twice as likely to stop breastfeeding altogether in the first 6 weeks of life.¹³ In addition, foods and liquids may contain harmful bacteria and carry a risk of disease. Supplementation with artificial milk significantly alters the intestinal microflora. *Breastfeeding exclusively is necessary to establish a healthy normal microbiome.*^{1, 6}

IMPLEMENTATION GUIDANCE:

*Exclusive breastfeeding for 6 months provides the nurturing, nutrients, immune factors and energy needed for physical and neurological growth and development. Beyond 6 months, breastfeeding continues to provide energy, immune factors and high-quality nutrients that, jointly with safe and adequate complementary feeding, help prevent hunger, undernutrition and obesity. Inadequate breastfeeding practices significantly impair health, development and survival of infants, children and mothers.*¹

Mothers should be discouraged from giving any food or fluids other than breast-milk, unless medically indicated.² Very few conditions of the infant or mother preclude the



feeding of breast-milk and necessitate the use of breast-milk substitutes. The WHO/UNICEF document on “Acceptable medical reasons for use of breast-milk substitutes” describes conditions for which breastfeeding is contraindicated.⁴² In addition, some breastfed infants will require supplementation. The Academy of Breastfeeding Medicine (ABM) has laid out a clinical protocol for managing situations in which supplementation of the mother’s own milk would become necessary.⁴³ Infants should be assessed for signs of inadequate milk intake and supplemented when indicated, but routine supplementation is rarely necessary in the first few days of life. Lack of resources, staff time or knowledge is not justification for the use of early additional foods or fluids.¹ *In addition to the WHO and ABM documents, facilities are encouraged to utilize the recommendations from the Centers for Disease Control and Prevention and the American Academy of Pediatrics to develop a policy/protocol that describes the current, evidence-based medical indications for supplementation and contraindications to breastfeeding.*⁴⁴⁻⁴⁶

Mothers who intend to “mixed-feed” (a combination of both breastfeeding and feeding with breast-milk substitutes) should be counseled (*using meaningful conversation techniques– see Step 2*) on the importance of exclusive breastfeeding in the first few weeks of life, how to establish a milk supply and to ensure that the infant is able to suckle and transfer milk from the breast. Supplementation can be introduced at a later date if the mother chooses. Mothers who report they have chosen not to breastfeed should be counseled

(*using meaningful conversation techniques–see Step 2*) on the importance of breastfeeding. However, if they still do not wish to breastfeed, feeding with breast-milk substitutes will be necessary. Mothers who are feeding breast-milk substitutes, by necessity or by choice, must be taught about safe preparation and storage of formula^{47, 55, 56} and how to respond adequately to their child’s feeding cues.¹

If a breastfeeding mother requests that her infant be supplemented, direct care staff and/or direct care providers should gently engage in an appropriate meaningful conversation [see Step 2] that carefully listens to her reasons. If the mother expresses any challenges, staff/providers should provide responsive care to evaluate/assess her concerns. It is possible that she is experiencing some breastfeeding difficulties that staff may be able to support her to overcome with additional guidance. If she still wishes to supplement with infant formula, staff should empower her understanding of evidence-based information that emphasizes the protections provided by breastfeeding, the possible impact of this decision to her health, the health of her infant and to the potential success of breastfeeding. Her informed decision should be confirmed and documented in the medical record. This education is only required to be provided once during the hospital stay.

FOR INFANTS WHO ARE UNABLE TO BE FED THEIR MOTHER'S OWN MILK.

IMPLEMENTATION GUIDANCE:

Infants who cannot be fed their mother's own milk, or who need to be supplemented, especially low-birth-weight infants, including those with very low birthweight^{48,49} and other vulnerable infants, should be fed *pasteurized* donor *human* milk. If *pasteurized* donor human milk is unavailable or culturally unacceptable, breast-milk substitutes are required. In most cases, supplementation is temporary, until the newborn is capable of breastfeeding and/or the mother is available and able to breastfeed. Mothers must also be supported and encouraged to express their milk to continue stimulating production of breast-milk, and to prioritize use of their own milk, even if direct breastfeeding is challenging for a period of time.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

If a mother expresses concern about the sufficiency of her breast-milk, an infant feeding assessment is warranted.

When mothers have decided not to breastfeed their infant or supplementation is needed/requested, direct care staff should discuss various options suitable to their situation such as the choice of supplement, volume of supplemental feeding, and methods of providing supplementary feedings.

In the case of supplementation for medical reasons, the decision to supplement is a delicate one. Practitioners must carefully weigh the risks and benefits of this decision.

When a mother decides to feed formula and/or it is determined that the benefits of supplementation outweigh the risks, the recommendation should be communicated in a respectful manner that is mindful of the sense of guilt, concerns and failure the mother may experience regarding such a recommendation.

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS

for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY

for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

US CLARIFICATION: BABY-FRIENDLY USA EXCLUSIVE BREASTFEEDING STANDARDS

The WHO/UNICEF BFHI Implementation Guidance standards call for a minimum of 80% exclusive breastfeeding (either milk from their own mothers or from a human milk bank) throughout the stay at the facility.¹ It is recognized by WHO and UNICEF that lower standards may need to be set at the national or local level, with the expectation that they should be raised over time, as other aspects of breastfeeding support in the community improve.

The US Designation is NOT based on an exclusive breastfeeding rate of greater than 80%.

It is expected that the facility will regularly monitor exclusive breastfeeding rates and that rates less than 80% will show improvement over time. Designated facilities with exclusive breastfeeding rates less than 50% will be required to submit quarterly reports to BFUSA.

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 6	VERIFICATION METHOD
*29. Engage in a conversation with a mother regarding at least 3 reasons why effective exclusive breastfeeding is important.	Observation
41. Explain at least 3 aspects of appropriate storage of breast-milk.	Question or case study
42. Explain at least 3 aspects of handling of expressed breast-milk.	Question or case study
*47. List at least 2 potential contraindications to breastfeeding for a baby and 2 for a mother.	Question or case study
*48. Describe at least 4 medical indications for supplementing breastfed newborns: 2 maternal indications and 2 newborn indications, when breastfeeding is not improved following skilled assessment and management.	Question or case study
*49. Describe at least 3 risks of giving a breastfed newborn any food or fluids other than breast-milk, in the absence of medical indication.	Question or case study
*66. Describe at least 1 professional medical reference or resource for identifying medications that are safe/compatible for use during lactation.	Question or case study
*50. For those few health situations where infants cannot, or should not, be fed at the breast, describe , in order of preference, the alternatives to use.	Question or case study
*51. Engage in a conversation with a mother who intends to feed her baby formula, noting at least 3 actions to take.	Observation
52. Demonstrate at least 3 important items of safe preparation of infant formula to a mother who needs that information.	Observation
*67. Identify 3 high-risk infant populations that may warrant extra precautions to protect against severe infections associated with powdered infant formula.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
6.1 Infants receive only breast-milk (either from their own mother or from a human milk bank) throughout their stay at the facility, unless medically indicated or informed parental decision.	<p>Interviews with mothers will confirm:</p> <p>Criterion 6.1.1 At least 80% of mothers will report that:</p> <ul style="list-style-type: none"> A. Their babies have received no food or drink other than human milk (direct breastfeeding, expressed breast-milk, or pasteurized donor human milk) while in the facility, OR B. Formula has been given for a medically acceptable reason, OR C. Formula has been given in response to an informed parental request/decision. <p>Criterion 6.1.2 Of breastfeeding mothers whose infants have been given food or drink other than breast-milk, at least 80% of those who have no acceptable medical reason will report that a health professional:</p> <ul style="list-style-type: none"> A. Listened to her reasons/concerns, AND B. Responded by assessing potential and/or existing challenges specific to her concerns, and/or providing additional guidance with workable solutions, AND C. If the mother still requests a breast-milk substitutes, health professionals empowered her with an understanding of evidence-based information [scientific, unbiased, factual] that allowed her to make an informed decision for her baby including: <ul style="list-style-type: none"> ▪ Importance of exclusive breastfeeding ▪ Possible risk factors that could influence health outcomes ▪ Possible impacts to the success of breastfeeding <p>Clarification: The counseling conversation only needs to be provided once at first request.</p>

U.S. CLARIFICATION: INFORMED DECISIONS - MEANINGFUL CONVERSATIONS Mothers should feel involved in all decisions regarding their selves and their babies. Empowering mothers to make informed decisions for their selves and their babies requires that they have up-to-date evidence-based [scientific, factual, unbiased] information that emphasized the protections provided by breastfeeding along with an understanding of risk factors that could influence health outcomes. The "Guideline: Counselling of Women to Improve Breastfeeding Practices" states that the "aim of breastfeeding counseling is to empower women to breastfeed, while respecting their personal situations and wishes."⁵⁰ As you work with families, consider incorporating appropriate components of the acronym E.N.C.O.U.R.A.G.E.S. so that you enter into meaningful conversations with them [see Step 2]

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
6.2 Breastfed babies who received supplemental feeds have a documented medical indication for supplementation in their medical records.	<p>Documentation:</p> <p>Criterion 6.2.1: <i>Of breastfeeding infants who have been given food or drink other than breast-milk for medical indications, at least 80% will have the reasons for supplementation clearly documented in their medical records.</i></p> <p>Criterion 6.2.2: <i>Of breastfeeding infants who have been given food or drink other than breast-milk for parental request, at least 80% will have the reasons for supplementation and evidence of parental counseling clearly documented in their medical records.</i></p>
6.3 Mothers who have decided not to breastfeed report that the staff discussed with them the various feeding options and helped them to decide what was suitable in their situations.	<p>Interviews with mothers who have decided not to breastfeed:</p> <p>Criterion 6.3.1 <i>Of mothers who have decided not to breastfeed [requesting to feed their babies with breast-milk substitutes], at least 80% of those who have no acceptable medical reason will report that the health care staff:</i></p> <ul style="list-style-type: none"> A. Listened to their reasons/concerns, AND B. Responded by assessing potential and/or existing challenges specific to her concerns, and/or providing additional guidance with workable solutions including various feeding options, AND C. If the mothers still requested to feed their babies with breast-milk substitutes, health care staff empowered them with an understanding of evidence-based information [scientific, unbiased, factual] that allowed them to make an informed decision for their babies including: <ul style="list-style-type: none"> ▪ Importance of breastfeeding ▪ Possible risk factors that could influence health outcomes when feeding breast-milk substitutes <p>Clarification: <i>The counseling conversation only needs to be provided once at first request.</i></p>
6.4 Mothers who cannot, or have decided not to breastfeed, will report that the staff discussed with them the safe preparation, feeding and storage of breast-milk substitutes.	<p>Interviews with mothers who are feeding their infants any formula and/or plan to continue post-discharge will be able to:</p> <p>Criterion 6.4.1 <i>At least 80% of mothers who are feeding their infants any formula and plan to continue post-discharge, will be able to describe 2 appropriate steps that staff discussed with them about safe preparation, feeding and storage of formula.</i></p>

U.S. CLARIFICATION: SAFE PREPARATION, STORAGE AND FEEDING OF INFANT FORMULA *Mothers who have decided not to breastfeed, decided to “mixed-feed”, or will require supplementation with formula for their infants at the time of discharge must receive written instruction and verbal information about safe preparation, storage and feeding of formula. Staff should document completion of formula preparation instruction and feeding in the medical record. The information should be given on an individual basis only.*

Safe preparation, feeding, and storage of formula instruction must follow the recommendations of leading national and international authorities and must include:

- 1. Appropriate hand hygiene*
- 2. Cleaning infant feeding items [bottles, nipples, rings, caps, syringes, cups, spoons, etc.] and workspace surfaces*
- 3. Appropriate and safe reconstitution of concentrated and powdered infant formulas*
- 4. Accuracy of measurement of ingredients*
- 5. Safe handling of formula*
- 6. Proper storage of formula*
- 7. Appropriate feeding methods which may include feeding on cue, frequent low volume feeds, paced bottle techniques, eye-to-eye contact, and holding the infant closely*
- 8. Powdered infant formula is not sterile and may contain pathogens that can cause serious illness in infants younger than 3 months*

National and international authorities include:

- *American Academy of Pediatrics*
- *Centers for Disease Control and Prevention*
- *Food and Drug Administration*
- *United States Department of Agriculture*
- *World Health Organization*

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>6.5 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in:</p> <p><i>In helping a mother whose baby needs fluids other than breast-milk.</i></p>	<p>Interviews with Direct Care Nursing Staff and Direct Care Providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 6.5.1 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. List at least 1 potential contraindication to breastfeeding for a baby and 1 for a mother. [PI 47] B. Describe at least 2 medical indications for supplementing breastfed newborns: 1 maternal indication and 1 newborn indication, when breastfeeding is not improved following skilled assessment and management. [PI 48] <p>Criterion 6.5.2 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Engage in a conversation with a mother regarding at least 2 reasons why effective exclusive breastfeeding is important. [PI 29] B. Describe at least 2 risks of giving a breastfed newborn food or fluids other than breast-milk, in the absence of medical indications. [PI 49] <p>Criterion 6.5.3 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will correctly respond to 1 of the randomly selected performance indicators listed below:</p> <ul style="list-style-type: none"> A. Engage in a conversation with a mother who intends to feed her baby formula, noting at least 3 actions. [PI 51] B. Identify 2 high-risk infant populations that may warrant extra precautions to protect against severe infections associated with powdered infant formula. [PI 67]

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>6.6 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in:</p> <p><i>In helping a mother whose baby needs fluids other than breast-milk.</i></p>	<p>DIRECT CARE PROVIDERS</p> <p>Criterion 6.6.4 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe how they engage in a conversation with a mother regarding at least 2 reasons why effective exclusive breastfeeding is important. [PI 29]</p> <p>Criterion 6.6.5 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will list at least 2 potential contraindications to breastfeeding for a baby and 2 for a mother. [PI 47]</p> <p>Criterion 6.6.6 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 4 medical indications for supplementing breastfed newborns: 2 maternal indications and 2 newborn indications, when breastfeeding is not improved following skilled assessment and management. [PI 48]</p> <p>Criterion 6.6.7 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 1 professional medical reference or resource for identifying medications that are safe/compatible for use during lactation. [PI 66]</p> <p>Criterion 6.6.8 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will identify 2 high-risk infant populations that may warrant extra precautions to protect against severe infections associated with powdered infant formula. [PI 67]</p>

Enable mothers and their infants to remain together and to practice rooming-in 24 hours a day.

RATIONALE:

Rooming-in is necessary to enable mothers to practice responsive feeding, as mothers cannot learn to recognize and respond to their infants' cues for feeding if they are separated from them. When the mother and infant are together throughout the day and night, it is easy for the mother to learn to recognize feeding cues and respond to them. This, along with the close presence of the mother to her infant, will facilitate the establishment of breastfeeding.¹

IMPLEMENTATION GUIDANCE:

Facilities providing maternity and newborn services should enable mothers and their infants to remain together and to practice rooming-in throughout the day and night.² Rooming-in involves keeping mothers and infants together in the same room, immediately after vaginal birth or cesarean section, or from the time when mothers are able to respond to their infants, until discharge. This means that mothers and infants are together throughout the day and night.¹

Postpartum units need to be designed so that there is enough space for mothers and their newborns to be together. Facility staff need to visit the *hospital room* regularly to ensure the babies are safe. Babies should only be separated from their mothers for justifiable medical and safety reasons. Minimizing disruption to breastfeeding during the stay in the facility will require health-care practices that enable a mother to breastfeed for as much, as frequently and for as long as her baby needs it.¹



When a mother is placed in a dedicated unit [recovery area and/or postpartum room] to recover from a cesarean section, the baby should be accommodated in the same room with her, close by. She will need practical support to position her baby to breastfeed, and will need help with lifting the baby from a bassinet.¹

Rooming-in may not be possible in circumstances when infants need to be moved for specialized medical care.¹ If preterm or sick infants need to be in a separate room to allow for adequate treatment and observation, efforts must be made for the mother to recuperate postpartum with her infant, or to have no restrictions for visiting her infant. Mothers should have adequate space to express milk adjacent to their infants.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

There are several factors that must be understood when mothers and infants are rooming-in together:

- *Mothers will be naturally exhausted and/or only sleep in short bursts following childbirth.²⁵*
- *Sleepiness is a normal, hormonally-driven, physiological response to breastfeeding for both mothers and infants. Unintentionally, this can lead to mothers falling asleep while breastfeeding their infants.⁵¹*
- *Following cesarean births, mothers have limited mobility and are likely to feel the effects of medications, which may cause them to be less responsive.²⁵*

Facilities are encouraged to develop processes that support staff in the safe implementation of rooming-in practices.^{25, 26, 51}

The hospital setting is the perfect place to role model safe rooming-in and to help families plan for a safe breastfeeding and sleep environment for home. It is a prime opportunity to educate mothers and families about the components of a safe environment which includes but is not limited to:

- *Mothers and infants have close but separate sleep surfaces.²⁷*
- *Infants are placed on their backs to sleep, for naps and at night.²⁷*
- *Firm flat sleep surface is used in a safety-approved crib, covered by a fitted sheet.²⁷*
- *Soft bedding and objects are avoided. Do not put pillows, blankets, sheepskins in baby's sleep area.²⁷*
- *Baby is dressed in sleep clothing. Loose blankets are not used, and baby is not over bundled.²⁷*

Mothers (and families) should be given anticipatory guidance about considering how tired they are before and during their infant's feeding so that steps can be taken to reduce risks to their infant.⁵² Facilities and staff should consider implementing the following safe rooming-in practices:

- *Monitor mothers according to their risk assessment.²⁵*
- *Review equipment, such as call bells, with mothers²⁵ and instruct them to call for help when feeling tired or sleepy.⁵¹*
- *Conduct hourly rounding to provide assistance placing infants in bassinets when mothers or caregivers appear to be drowsy or after mothers have received pain medications.⁵¹*
- *Educate families and support persons to transition newborn to the bassinet when mother is falling asleep.*
- *Promote maternal rest⁵¹ by limiting staff and visitor interruptions.*

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 7	VERIFICATION METHOD
*35. Engage in a conversation with a mother regarding 2 aspects related to the importance of rooming-in 24h/day.	Observation
68. Describe 2 aspects involved in creating a safe environment for rooming-in during the hospital stay.	Question or case study
*69. Demonstrate at least 3 safety aspects to assess when mother and baby are skin-to-skin during the postpartum hospitalization, regardless of method of birth.	Observation
*36. Explain 2 situations: 1 for the mother and 1 for the infant, when it is acceptable to separate mother and baby while in hospital.	Question or case study
45. Engage in a conversation with a mother separated from her preterm or sick infant regarding at least 2 reasons to be with her infant in the intensive care unit.	Observation

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
7.1 Mothers report that their babies stayed with them since birth, without separation lasting for more than 1 hour.	<p>Interviews with mothers will confirm:</p> <p>Criterion 7.1.1 At least 80% of mothers will report that their infants have stayed with them in the same room day and night, without separation of more than 1 hour per 24-hour period unless:</p> <ul style="list-style-type: none"> A. Medically justifiable reason for a longer separation, OR B. Safety-related reason for a longer separation, OR C. Informed decision for a longer separation [maternal request]

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
7.1 Mothers report that their babies stayed with them since birth, without separation lasting for more than 1 hour.	<p>Interviews with mothers will confirm:</p> <p>Criterion 7.1.2 At least 80% of mothers who requested their infant to be removed from the room will report the facility staff:</p> <ul style="list-style-type: none"> A. Listened to her reasons/concerns AND B. Responded by assessing potential and/or existing challenges specific to her concerns, and/or providing additional guidance with workable solutions to safely avoid the separation AND C. If the mother still requested separation, health professionals empowered her with an understanding of evidence-based information [scientific, unbiased, factual] that allowed her to make an informed decision for her baby including: <ul style="list-style-type: none"> ■ Importance of rooming-in, ■ If breastfeeding, a plan for reuniting the mother and infant as soon as the infant displays feeding cues. <p>Documentation:</p> <p>Criterion 7.1.3 Of mothers and babies that have been separated, at least 80% will have the following documented in the medical record:</p> <ul style="list-style-type: none"> A. Reason for the separation B. Location of infant C. Length of separation D. Infant feedings during separation E. Counseled on the importance of rooming-in including a plan for reuniting the mother and infant, and infant feeding. <p>NOTE: Facilities must make every effort to minimize any disruptions to breastfeeding by reuniting a mother and infant as frequently and for as long as her baby needs it.</p> <p>Criterion 7.1.4 Quality improvement question for informational purposes (not a designation criterion): Mothers will report that they felt supported with rooming and caring for her baby.</p> <ul style="list-style-type: none"> A. They received practical information AND B. Received help when needed.
7.2 Observations in the postpartum wards and well-baby observation areas confirm that mothers and babies are together or, if not, have medically justifiable reasons for being separated.	<p>Observations in the postpartum unit and newborn units will confirm:</p> <p>Criterion 7.2.1 Observations in the postpartum unit and any well-baby observation areas confirm that at least 80% of the mothers and infants are rooming-in or have a documented:</p> <ul style="list-style-type: none"> A. Medically justifiable reason for separation, OR B. Safety-related reason for separation, OR C. Informed decision for separation [maternal request]

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE NICU UNIT:

US STANDARD	US CRITERION FOR EVALUATION
7.3 Mothers of preterm or sick infants report having no restrictions and had access to their infants in the NICU whenever they wanted.	<p>Interviews with mothers who are breastfeeding or intending to do so with infants in the NICU will confirm:</p> <p>Criterion 7.3.1 At least 80% of mothers with infants in the NICU report that they have had access to their infants in the NICU whenever they wanted.</p>



COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
7.4 Health professionals who provide postpartum and/or newborn care will be competent in helping a mother to respond to her baby's feeding cues [by enabling a mother and infant to rooming-in 24 hours a day].	<p>DIRECT CARE NURSING STAFF</p> <p>Criterion 7.4.1 At least 80% of direct care nursing staff who provide postpartum, and/or newborn care will describe or demonstrate how they engage in a conversation with a mother regarding 2 aspects related to the importance of rooming-in 24h/day. [PI 35]</p> <p>Criterion 7.4.2 At least 80% of direct care nursing staff who provide postpartum, and/or newborn care will describe or demonstrate at least 2 safety aspects to assess when mother and baby are skin-to-skin during the postpartum hospitalization regardless of method of birth. [PI 69]</p> <p>Criterion 7.4.3 At least 80% of direct care nursing staff who provide postpartum, and/or newborn care will explain 2 situations: 1 for the mother and 1 for the infant, when it is acceptable to separate mother and baby while in the hospital. [PI 36]</p> <p>DIRECT CARE PROVIDER</p> <p>Criterion 7.4.4 At least 80% of direct care providers with privileges to provide postpartum and/or newborn care will describe how they engage in a conversation with a mother regarding 2 aspects related to the importance of rooming-in 24h/day. [PI 35]</p> <p>Criterion 7.4.5 At least 80% of direct care providers with privileges to provide postpartum and/or newborn care will explain 2 situations: 1 for the mother and 1 for the infant, when it is acceptable to separate mother and baby while in the hospital. [PI 36]</p>

U.S. CLARIFICATION: MEDICALLY JUSTIFIABLE OR SAFETY-RELATED REASONS FOR SEPARATION *Healthcare Professionals must use their clinical judgement.* While it is true that rooming-in is the expected practice in Baby-Friendly designated facilities, we recognize some circumstances necessitate mother-baby separation. The decision that leads to a separation is often complex involving observations, assessments, and an understanding of the individual mother-baby dyad. It is imperative in these situations that care and decisions are individualized and include the mother's participation, if possible. Facilities should have a dedicated area to provide care to infants who have a justifiable reason for separation. As a reminder, BFUSA does NOT require that facilities close their nursery.

To be clear, infants must not be separated for routine facility procedures that could be performed in the mother's room.

Support mothers to recognize and respond to their infants' cues for feeding.

RATIONALE:

Breastfeeding involves recognizing and responding to the infant's display of hunger and feeding cues and readiness to feed, as part of a nurturing relationship between the mother and infant. Responsive feeding (also called on-demand or baby-led feeding) puts no restrictions on the frequency or length of the infant's feeds, and mothers are advised to breastfeed whenever the infant is hungry or as often as the infant wants. Scheduled feeding, which prescribes a predetermined, and usually time-restricted, frequency and schedule of feeds is not recommended. It is important that mothers know that crying is a late *feeding* cue and that it is better to feed the baby earlier, since optimal positioning and attachment are more difficult when an infant is in distress.¹

IMPLEMENTATION GUIDANCE:

Mothers should be supported to practice responsive feeding as part of nurturing care.¹ Regardless of whether they breastfeed or not, mothers should be supported to recognize and respond to their infants' cues for feeding, closeness and comfort, and enabled to respond accordingly to these cues with a variety of options, during their stay at the facility providing maternity and newborn services.² Supporting mothers to respond in a variety of ways to behavioral cues for feeding, comfort or closeness enables them to build a caring, nurturing relationship with their infants and increases their confidence in themselves, in breastfeeding and in their infants' growth and development.¹



When the mother and baby are not in the same room for medical or other justifiable reasons, the facility staff need to bring the mother and infant together as often as possible, so that she can recognize feeding cues. When staff notice feeding cues, they should also bring the mother and baby together.¹

New mothers believe that it is important that they respond to their infant's feeding cues. However, mothers have reported being stressed and anxious about how to interpret their infant's needs. Postpartum conversations support families to develop an understanding of an infant's cues for feeding, comfort, or closeness. Education provided to families should increase a mother's confidence in interpreting these cues and responding in a variety of ways which might include breastfeeding, rocking, holding, walking, singing, and skin-to-skin contact.²

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

ABM Protocol #10 recommends that mothers of late preterm and early term infants on the postpartum unit should be taught to respond to their infants' cues for feeding. However, it may be necessary for mothers to wake their infants when they do not demonstrate hunger cues within 4 hours of the previous feeding. Preterm infants should be breastfed (or breast-milk fed) 8-12 times in a 24-hour period.⁴¹

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS

for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 8	VERIFICATION METHOD
*37. Describe at least 2 early feeding cues and 1 late feeding cue.	Question or case study
38. Describe at least 4 reasons why responsive feeding (also called on-demand or baby-led feeding) is important.	Question or case study
39. Describe at least 2 aspects of responsive feeding (also called on-demand or baby-led feeding) independent of feeding method.	Question or case study
46. Engage in a conversation with a mother of a preterm, late preterm or vulnerable infant (including multiple births) regarding the importance of observing at least 2 subtle signs and behavioral state shifts to determine when it is appropriate to breast-feed.	Observation
*58. Describe at least 4 elements to assess when a mother says that her infant is crying frequently.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
8.1 Breastfeeding mothers can describe at least two feeding cues.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 8.1.1 <i>At least 80% of breastfeeding mothers can describe at least 2 early feeding cues.</i></p>
8.2 Breastfeeding mothers report that they have been advised to feed their babies as often and for as long as the infant wants.	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 8.2.1 <i>At least 80% of breastfeeding mothers will report that they have been advised to feed their infants as often and as long as the infants want.</i></p> <p>Criterion 8.2.2 <i>Quality improvement question for informational purposes (not a designation criterion): At least 80% of breastfeeding mothers can provide 2 acceptable responses to describe normal infant feeding patterns after the first 24 hours of life including:</i></p> <ul style="list-style-type: none"> ▪ <i>The average feeding frequency is at least 8-12 times in 24 hours,</i> ▪ <i>Infants feeding through the night and/or</i> ▪ <i>That cluster feeding is common.</i>

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>8.3 Health professionals who provide labor & delivery, postpartum and/or newborn care will be competent in helping a mother to respond to her baby's feeding cues.</p>	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 8.3.1 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe at least 2 early feeding cues and 1 late feeding cue. [PI 37]</p> <p>Criterion 8.3.2 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe at least 2 reasons why responsive feeding (also called on-demand feeding) is important [PI 38]</p> <p>Criterion 8.3.3 3 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe at least 2 elements to assess when a mother says her infant is crying frequently. [PI 58]</p> <p>DIRECT CARE PROVIDER</p> <p>Criterion 8.3.4 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 2 early feeding cues and 1 late feeding cue. [PI 37]</p> <p>Criterion 8.3.4 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 2 elements to assess when a mother says her infant is crying frequently. [PI 58]</p>

Counsel mothers on the use and risks of feeding bottles, artificial nipples, and pacifiers.

RATIONALE:

Proper guidance and counseling of mothers and other family members enables them to make informed decisions on the use or avoidance of pacifiers and/or feeding bottles and *artificial nipples* until the successful establishment of breastfeeding. While WHO guidelines² do not call for absolute avoidance of feeding bottles, *artificial nipples* and pacifiers for term infants, there are a number of reasons for caution about their use, including hygiene, oral formation and recognition of feeding cues.¹

IMPLEMENTATION GUIDANCE:

If expressed milk or other feeds are medically indicated for term infants, feeding methods (*devices*) such as cups, spoons or feeding bottles and *artificial nipples* can be used during their stay at the facility.² However, it is important that staff do not become reliant on *artificial nipples* as an easy response to suckling difficulties instead of counseling mothers and enabling babies to attach babies properly and suckle effectively.¹

It is important that the facility staff ensure appropriate hygiene in the cleaning of these utensils, since they can be a breeding ground for bacteria. Facility staff should also inform mothers and family members of the hygiene risks related to inadequate cleaning of feeding utensils, so that they can make informed *decisions* on the feeding method.

The physiology of suckling at the breast is different from the physiology of suckling from a feeding bottle and an *artificial nipple*.⁵³ It is possible that the use of the feeding bottle and an *artificial nipple* could lead to breastfeeding difficulties, particularly if use is prolonged.



However, the only study on this did not demonstrate a specific carry-over effect from suckling at a feeding bottle and *an artificial nipple* to suckling at the breast.^{1, 15}

Pacifiers have long been used to soothe an upset infant. In some cases, they serve a therapeutic purpose, such as reducing pain during procedures when breastfeeding or skin-to-skin contact are not possible. *Pacifiers have also been shown to reduce the risk of SIDS, even among breastfeeding infants.* However, if pacifiers replace suckling and thus reduce the number of times an infant stimulates the mother's breast physiologically, this can lead to a reduction of maternal milk production. The use of *artificial nipples* or pacifiers may interfere with the mother's ability to recognize feeding cues. If the use of a pacifier prevents the mother from observing the infant's smacking of the lips or rooting towards the breast, she may delay feeding until the infant is crying and agitated.¹ *Therefore, recommending to parents that they delay pacifier introduction until breastfeeding is well established supports breastfeeding while reducing the risk of SIDS and helps parents understand appropriate timeframes for introducing pacifiers.*^{26, 27}

For preterm infants, evidence does demonstrate that use of feeding bottles with *artificial nipples* interferes with learning to suckle at the breast. If expressed breast-milk or other feeds are medically indicated for preterm infants, feeding methods such as cups or spoons are preferable to feeding bottles and *artificial nipples*.² On the other hand, for preterm infants who are unable to breastfeed directly, non-nutritive sucking and oral stimulation may be

beneficial until breastfeeding is established.² Non-nutritive sucking or oral stimulation involves the use of pacifiers, a gloved finger or a breast that is not yet producing milk.¹ **NOTE:** *If a preterm infant is in the room with the mother, oral stimulation should always be done by placing baby at the breast.*

There should be no promotion of feeding bottles or *artificial nipples* in any part of facilities providing maternity and newborn services, or by any of the staff. As is the case with breast-milk substitutes, these products fall within the scope of the *International Code*.^{1, 15, 16, 54} *[SEE STANDARD 9.2 FOR ADDITIONAL GUIDANCE on the promotion of pacifiers as a SIDS risk reduction measure.]*

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Hygiene is an important consideration for safe implementation of the use of bottles, nipples and pacifiers and other infant feeding items. The Centers for Disease Control and Prevention (CDC) and World Health Organization provide the steps that families should follow to clean, sanitize, and store infant feeding items. The CDC also provides steps to ensure that breast pump and breast pump parts are clean and sanitized.^{55, 56}

*Pacifiers are also recognized as a risk reduction measure for Sudden Infant Death Syndrome (SIDS). To reduce the risk of SIDS, the AAP recommends exclusive breastfeeding, breastfeeding for at least 6 months, and offering a pacifier at naptime and bedtime, once breastfeeding is well established. Infants who are not being directly breastfed can begin pacifier use as soon as desired.*²⁶

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 9	VERIFICATION METHOD
28. Describe at least 6 essential issues that every breastfeeding mother should know or demonstrate.	Question or case study
53. Demonstrate to a mother how to safely cup-feed her infant when needed, showing at least 4 points.	Observation
54. Describe to a mother at least 4 steps to feed an infant a supplement in a safe manner.	Observation
*55. Describe at least 2 alternative feeding methods other than feeding bottles.	Question or case study
56. Engage in a conversation with a mother who requests feeding bottles, <i>artificial nipples</i> , and pacifiers [soothers] without medical indication, including at least 3 points.	Observation
*59. Describe at least 4 elements of anticipatory guidance to give to a mother on calming or soothing techniques before or as alternatives to pacifiers.	Question or case study
*70. Describe when the acceptable time is for introducing a pacifier with a breast-feeding infant, with regards to SUID/SIDS reduction strategies.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
9.1 Breastfeeding mothers report that they have been taught about the risks of using feeding bottles, artificial nipples and pacifiers. ²	<p>Interviews with breastfeeding mothers will confirm:</p> <p>Criterion 9.1.1 At least 80% of breastfeeding mothers can describe:</p> <ul style="list-style-type: none"> A. One possible impact that pacifiers might have on breastfeeding, AND B. When the acceptable time is for introducing the pacifier. <p>Criterion 9.1.2 At least 80% of breastfeeding mothers can describe one possible impact that bottles and artificial nipples might have on breastfeeding.</p> <p>Criterion 9.1.3 At least 80% of breastfeeding mothers that are unable to feed their baby directly at the breast or needed/chose additional supplementation will report:</p> <ul style="list-style-type: none"> A. Alternative feeding devices other than bottles were offered, AND B. They were informed of the potential impacts of feeding bottles on breastfeeding AND C. Will be able to describe 2 feeding techniques appropriate for the use of selected feeding device. <p>Criterion 9.1.4 At least 80% of breastfeeding mothers [including breast-milk feeding] utilizing infant feeding items [bottles, artificial nipples, rings, caps, syringes, cups, spoons, breast pump equipment, etc.] can provide 1 acceptable response about proper hygiene when cleaning these infant feeding items.</p>

SAFE SLEEP AND SIDS REDUCTION MESSAGES SHOULD BE DISTRIBUTED BY THE FACILITY AND THE FOLLOWING STANDARDS AND CRITERIA FOR EVALUATION APPLY:

RATIONALE:

BFUSA acknowledges the evidence pertaining to pacifier use related to SIDS risk reduction.²⁵ Safe sleep and SIDS risk reduction information is important for parents to receive during the birth hospital stay.^{26, 27} This education may be compatibly provided to parents by using safe sleep materials that also promote breastfeeding.

US STANDARD	US CRITERION FOR EVALUATION
9.2 Facilities distributing safe sleep materials must also provide additional verbal and written education related to breastfeeding and pacifier use to mothers.	<p>A review of education materials will confirm:</p> <p>Criterion 9.2.1 A review of materials will confirm that safe sleep and SIDS risk reduction materials that are provided to mothers also provide additional written education that includes the all of the following:</p> <ul style="list-style-type: none"> A. Pacifier use in the breastfed infant should be delayed until breastfeeding is firmly established.^{26, 27} AND B. How mothers can know that breastfeeding is firmly established (For example, milk supply has increased, infant is breastfeeding 8–12 times in 24 hours, infant is satisfied after feedings, infant is gaining weight, mother can hear baby swallowing during feeding, adequate voiding and stooling according to expected norms).AND C. Breastfeeding is associated with a reduced risk of SIDS, and the protective effect increases with breastfeeding duration and exclusivity, with the greatest protection offered by breastfeeding for at least 6 months.^{27, 57} <p>Criterion 9.2.2 Quality improvement question for informational purposes (not a designation criterion): At least 80% of mothers should be able to recall at least 2 of the following key safe sleep messages:</p> <ul style="list-style-type: none"> ■ Baby should always be placed on back to sleep. ■ Baby should sleep in an empty, approved (CPSC) crib. ■ Baby should sleep in the same room as parents for at least 6 and preferably to 12 months. ■ Parents should refrain from smoking during and after pregnancy and baby should sleep in a smoke-free environment. ■ Breastfeeding reduces the risk of SIDS. ■ Pacifier use at bedtime reduces the risk of SIDS.

COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>9.3 Health professionals who provide labor and delivery, postpartum and/or newborn care will be competent in:</p> <ul style="list-style-type: none"> • How to discuss with a mother how breastfeeding works, • Helping a mother who is not feeding her baby directly at the breast. 	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p>Criterion 9.3.1 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe to a mother at least 4 steps to feed an infant a supplement in a safe manner. [PI 54]</p> <p>Criterion 9.3.2 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe at least 2 elements of anticipatory guidance to give to a mother on calming or soothing techniques before or as alternatives to pacifiers. [PI 59]</p> <p>Criterion 9.3.3 At least 80% of direct care nursing staff who provide labor & delivery, postpartum, and/or newborn care will describe when the acceptable time is for introducing a pacifier with a breastfeeding infant with regards to SUID/SIDS reduction strategies. [PI 70]</p> <p>DIRECT CARE PROVIDER</p> <p>Criterion 9.3.4 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe at least 2 elements of anticipatory guidance to give to a mother on calming or soothing techniques before or as alternatives to pacifiers. [PI 59]</p> <p>Criterion 9.3.5 At least 80% of direct care providers with privileges to provide labor & delivery, postpartum and/or newborn care will describe when the acceptable time is for introducing a pacifier with a breastfeeding infant with regards to SUID/SIDS reduction strategies. [PI 70]</p>

Coordinate discharge so that parents and their infants have timely access to ongoing support and care.

RATIONALE:

Mothers need sustained support to continue breastfeeding. While the time in the facility providing maternity and newborn services should provide a mother with basic breastfeeding skills, it is very possible her milk supply has not been fully established until after discharge. Breastfeeding support is especially critical in the succeeding days and weeks after discharge, to identify and address early breastfeeding challenges that occur. She will encounter several different phases in her production of breast-milk, her infant's growth and her own circumstances (e.g. going back to work or school), in which she will need to apply her skills in a different way and additional support will be needed. Receiving timely support after discharge is instrumental in maintaining breastfeeding rates. Maternity facilities must know about and refer mothers to the variety of resources that exist in the community.¹

IMPLEMENTATION GUIDANCE:

As part of protecting, promoting and supporting breastfeeding, discharge from facilities providing maternity and newborn services should be planned for and coordinated, so that parents and their infants have access to ongoing support and receive appropriate care.² Each mother should be linked to lactation-support resources in the community upon discharge. Facilities need to provide appropriate referrals to ensure that mothers and babies are seen by a health worker to assess the feeding situation. *The AAP recommends that every infant should have an evaluation within 3 to 5 days of birth and within 48 to 72 hours after discharge from the hospital that includes an evaluation for feeding and jaundice. Breastfeeding newborns*



should receive formal breastfeeding evaluation, and their mothers should receive encouragement and instruction. Printed and/or online information could be useful to provide contacts for support, in case of questions, doubts or difficulties, but this should not substitute for active follow-up care by a skilled professional.¹

Facilities providing maternity and newborn services need to identify appropriate community resources for continued and consistent breastfeeding support that is culturally and socially sensitive to their needs. The facilities have a responsibility to engage with the surrounding community to enhance such resources. Community resources include primary health-care centers, community health workers, home visitors, breastfeeding clinics, nurses/midwives, lactation consultants, peer counsellors, mother-to-mother support groups, or phone lines ("hot lines"). The facility should maintain contact with the groups and individuals providing the support as much as possible and invite them to the facility where feasible.¹

Follow-up care is especially crucial for preterm and low-birth-weight babies. In these cases, the lack of a clear follow-up plan could lead to significant health hazards. Ongoing support from skilled professionals is needed.¹

US CONSIDERATIONS FOR SAFE IMPLEMENTATION:

Vulnerable Populations: Breastfeeding can be extremely challenging, especially if a mother is in a community at risk for not breastfeeding. Equity will be increased if competently skilled professionals and evidence-based breastfeeding counseling is accessible to all mothers. Populations at risk for lower rates of breastfeeding duration may include African American/Black

mothers, mothers who are young, return early to work; lack social support; mothers with mental or medical concerns; parents with social and cultural considerations; late preterm and early term infants.^{50, 58}

Knowledge of the existence of post discharge support can be instrumental in a mother's willingness to give breastfeeding a try. While breastfeeding mothers may have some particular concerns, it is critically important that support be provided to all mothers.

Continuum of care: The Academy of Breastfeeding Medicine's "Clinical Protocol #7: Model Maternity Policy Supportive of Breastfeeding" provides the following guidance:

- *Before discharge, the health care team will ensure that there is effective breastfeeding, that breastfeeding mothers are able to efficiently breastfeed their infants and that continuity of care is guaranteed, either by follow-up visits or by arranging qualified primary care providers and/or lactation specialists visits and/or support groups or peer counseling contacts.³⁸*
- *If the infant is still not latching or feeding well at the time of discharge, an individualized feeding plan will be devised and, depending on the dyad's clinical situation and resources, the infant's discharge may be delayed.³⁸*
- *Mothers identified prenatally or soon after delivery as at risk of delayed lactogenesis II will be assigned to special help as deemed appropriate. A feeding plan and close follow-up of the infant (for adequate hydration and nutrition besides help with expression) will be offered. At discharge, continuum of care will be ensured with a feeding plan and close follow-up.³⁸*

REFER TO APPENDIX A: PATIENT EDUCATION TOPICS for the comprehensive list of all required education topics for postpartum mothers.

REFER TO APPENDIX C: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY for the comprehensive list of required knowledge, skills, and attitudes. (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

WHO/UNICEF PERFORMANCE INDICATORS DEMONSTRATING COMPETENCY TO IMPLEMENT STEP 10	VERIFICATION METHOD
57. Engage in a conversation with a mother regarding at least 4 different ways to facilitate breastfeeding in order to prevent or resolve most common conditions of the lactating breasts (sore nipples, engorgement, mother who thinks she doesn't have enough milk, infants who have difficulty sucking).	Observation
60. Describe at least 2 locally available sources for timely infant feeding information and problem management.	Question or case study
61. Describe at least 2 ways the healthcare facility engages with community-based programs to coordinate breastfeeding messages and offer continuity of care.	Question or case study
*62. Develop individualized discharge feeding plans with a mother that includes at least 6 points.	Observation
*63. Describe to a mother at least 4 warning signs of infant undernourishment or dehydration for a mother to contact a health care professional after discharge.	Observation
*64. Describe at least 3 warning maternal signs for a mother to contact a health care professional after discharge.	Question or case study

THE FOLLOWING STANDARDS APPLY TO MOTHERS AND INFANTS BEING CARED FOR ON THE POSTPARTUM UNIT:

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
10.1 Mothers report that a staff member has informed them where they can access breastfeeding support/infant formula feeding support in their community.	<p>Interviews with mothers will confirm:</p> <p>Criterion 10.1.1 At least 80% of breastfeeding mothers [including breast-milk feeding] will report that they have been given verbal and written information on:</p> <ul style="list-style-type: none"> A. How to access breastfeeding support [support groups, peer counselors, providers, or other skilled community health services] after discharge from the facility, AND B. When to follow-up for a newborn evaluation for jaundice and feeding, AND C. Maternal/infant warning signs/symptoms of breastfeeding problems that must receive urgent evaluation and whom they should call for assistance. <p>Criterion 10.1.2 At least 80% of mothers choosing to feed their babies formula will report that they have been given verbal and written information on:</p> <ul style="list-style-type: none"> A. How to access infant formula feeding support [support groups, peer counselors, providers, or other skilled community health services] after discharge from the facility, AND B. When to follow-up for a newborn evaluation for jaundice and feeding, AND C. Maternal/infant warning signs/symptoms of breast problems and/or formula feeding concerns that must receive urgent evaluation and whom they should call for assistance. <p>NOTE: Mothers who are "mixed-feeding" their babies should receive verbal and written information appropriate to support optimal, safe infant feeding individualized to their feeding intentions.</p>

WHO/UNICEF STANDARD	US CRITERION FOR EVALUATION
<p>10.2 The facility can demonstrate that it coordinates with community services that provide breastfeeding/infant feeding support, including clinical management and mother-to-mother support.</p>	<p>A review of documents indicates:</p> <p><i>Criterion 10.2.1 A review of documents indicates that written (printed or electronic) information is distributed to mothers before discharge on how and where mothers, regardless of feeding method, can find help on feeding their infants after returning home and includes information on what type of help is available from each source of support.</i></p> <p><i>Criterion 10.2.2 The facility provides a written description of how it fosters the establishment of and/or coordinates with mother support groups and other community services that provide breastfeeding/infant feeding support to mothers. The description includes a specific list of programs and services they fostered/coordinated with.</i></p>
COMPETENCY ASSESSMENT-SELECTED PERFORMANCE INDICATORS	US CRITERION FOR EVALUATION
<p>10.3 Health professionals who provide postpartum and/or newborn care will be competent to ensure a seamless transition after discharge.</p>	<p>Interviews with direct care nursing staff and direct care providers will confirm:</p> <p>DIRECT CARE NURSING STAFF</p> <p><i>Criterion 10.3.1 At least 80% of direct care nursing staff who provide postpartum and/or newborn care will describe the components of an individualized discharge feeding plans with a mother that includes at least 4 points. [PI 62]</i></p> <p><i>Criterion 10.3.2 At least 80% of direct care nursing staff who provide postpartum and/or newborn care will describe to a mother at least 3 warning signs of infant undernourishment or dehydration for a mother to contact a health professional after discharge. [PI 63]</i></p> <p><i>Criterion 10.3.3 At least 80% of direct care nursing staff who provide postpartum and/or newborn care will describe at least 2 maternal warning signs for a mother to contact a health care professional after discharge. [PI 64]</i></p> <p>DIRECT CARE PROVIDER</p> <p><i>Criterion 10.3.4 At least 80% of direct care providers with privileges to provide postpartum and/or newborn care will describe to a mother at least 3 warning signs of infant undernourishment or dehydration for a mother to contact a health professional after discharge. [PI 63]</i></p> <p><i>Criterion 10.3.5 At least 80% of direct care providers with privileges to provide postpartum and/or newborn care will describe at least 2 maternal warning signs for a mother to contact a health care professional after discharge. [PI 64]</i></p>

APPENDICES:

APPENDIX A: Patient Education Topics

APPENDIX B: Indicators for Facility Monitoring of Key Clinical Practices

APPENDIX C1: Performance Indicators to Measure Each Competency

APPENDIX C2: Performance Indicators Sorted by Step

APPENDIX D: Determining Affiliated Prenatal Services

APPENDIX E: Acceptable Medical Reasons for Use of Breast-Milk Substitutes

APPENDIX F: Definitions of Terms and Abbreviations Used in This Document

APPENDIX G: Expert Panel Members

APPENDIX H: Guidelines and Evaluation Criteria Clarification Statements

APPENDIX I: References

APPENDIX A: PATIENT EDUCATION TOPICS

PRENATAL CONVERSATION TOPICS INCLUDE:

WHO/UNICEF Required Prenatal Conversation Topics Include at a Minimum:

Breastfeeding

- the importance of breastfeeding *[including a discussion on the importance of direct breastfeeding, as needed]*
- global recommendations for breastfeeding including:
 - exclusive breastfeeding for the first 6 months
 - the risks of giving formula or other breast-milk substitutes
 - breastfeeding continues to be important after 6 months when other foods are given
- the basics of good positioning and attachment
- recognition of feeding cues

Birth Practices

- the importance of immediate and sustained skin-to-skin contact
- the importance of early initiation of breastfeeding
- the importance of rooming-in

US Recommended Prenatal Discussion Topics for Anticipatory Guidance include:

- non pharmacologic pain relief during labor
- creating a safe sleep environment:
 - along with the importance of rooming-in, staff should discuss how to create a safe sleep environment while rooming-in at the hospital. Narcotic-induced sleepiness, hormonally driven sleepiness *[physiology of lactation and its effects on mothers]* and fatigue are all factors that mothers should be aware of while rooming-in at the hospital.
 - risk reduction strategies for SIDS after leaving the hospital including the importance of removing suffocation hazards *(e.g., soft bedding/pillows)* from the breastfeeding environment and defining hazardous circumstances
- how to have an abundant milk supply
- how to prevent nipple soreness
- how to prevent or minimize engorgement after birth
- availability of community resources with staff properly trained to assist with breastfeeding assessment and management
- a brief conversation to discuss details about feeding a premature, low birthweight or sick baby that might need to be admitted to the NICU

POSTPARTUM BREASTFEEDING EDUCATION TOPICS INCLUDE:

- proper positioning, correct attachment, efficient suckling, and milk transfer
- ensuring a good milk supply
- criteria to assess if the infant is getting enough breast-milk including adequate intake and output for day of life
- preventative management of common problems such as engorgement, sore and cracked nipples⁵
- hand expression of breast-milk
- the importance of exclusive breastfeeding
- how to maintain exclusive breastfeeding for about 6 months
- signs/symptoms of infant feeding issues requiring referral to a qualified provider
- early feeding cues and a reminder that crying is a late cue
- no limits on how often or how long infants should be fed
- the effects of pacifiers and artificial nipples on breastfeeding and why to avoid them until lactation is established
- normal newborn feeding patterns
- collection and storage of breast-milk
- creating a safe sleep environment for breastfeeding including:
 - the physiology of lactation and its effects on the mother leading to hormonally driven sleepiness
 - the importance of removing suffocation hazards *(e.g., soft bedding/pillows)* from the breastfeeding environment
- community breastfeeding support services *[including how to access support and when to follow-up for formal evaluation]*
- maternal/infant warning signs/symptoms of breast problems and breastfeeding problems that must receive urgent evaluation *[including who they should call for assistance]*

POSTPARTUM INFANT FORMULA FEEDING EDUCATION TOPICS INCLUDE:

- safe preparation, feeding, and storage of infant formula including:
 - appropriate hand hygiene
 - cleaning infant feeding items *[bottles, nipples, rings, caps, syringes, cups, spoons, etc.]* and workspace surfaces
 - appropriate and safe reconstitution of concentrated and powdered infant formulas
 - accuracy of measurement of ingredients
 - safe handling of formula
 - proper storage of formula
 - appropriate feeding methods which may include feeding on cue, frequent low volume feeds, paced bottle techniques, eye-to-eye contact, and holding the infant closely
 - powdered infant formula is not sterile and may contain pathogens that can cause serious illness in infants younger than 3 months
- preventative steps to minimize engorgement *[if mother plans to exclusively formula feed]*
- signs/symptoms of infant feeding issues requiring referral to a qualified provider
- normal newborn feeding patterns
- creating a safe sleep environment for feeding your baby including:
 - the importance of removing suffocation hazards *(e.g., soft bedding/pillows)* from the environment
- community infant formula feeding services *[including how to access support and when to follow-up for formal evaluation]*
- maternal/infant warning signs/symptoms of breast problems and/or formula feeding concerns that must receive urgent evaluation and who they should call for assistance

APPENDIX B: INDICATORS FOR FACILITY MONITORING OF KEY CLINICAL PRACTICES

KEY CLINICAL PRACTICES	INDICATOR DEFINITION NOTE: More detailed and specific guidance on numerator/denominator inclusions/exclusions is described on the Facility Data Sheet.	TARGET	PRIMARY SOURCE	OTHER SOURCES	SUBMIT METHOD
Step 3: Discuss the importance and management of breastfeeding with pregnant women and their families.	Affiliated Prenatal Services: The percentage of mothers who received prenatal care at an affiliated prenatal service who received prenatal counseling on breastfeeding.	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
Step 4: Facilitate immediate and uninterrupted skin-to-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.	Vaginal Delivery: <i>The percentage of infants that were placed in skin-to-skin contact with their mothers immediately after a vaginal birth and remained there uninterrupted for at least 1 hour (longer, if needed, to allow a breastfeeding infant to complete a feeding).</i>	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
	Cesarean Delivery: <i>The percentage of infants born by cesarean delivery that were placed in skin-to-skin contact with their mothers, when safe and feasible [mother is responsive and alert] and remained there uninterrupted for at least 1 hour (longer, if needed, to allow a breastfeeding infant to complete a feeding).</i>	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
	All Deliveries: <i>The percentage of infants who were supported to breastfeed as soon as possible after birth, within the first one to two hours after delivery.</i> NOTE: <i>Supporting the initiation of breastfeeding is defined as placing the baby on the mother's chest (skin-to-skin) for breastfeeding, pointing out infant feeding readiness cues and gently coaching the mother to allow baby to move and attach to the breast.</i>	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
Step 5: Support mothers to initiate and maintain breastfeeding and manage common difficulties.	<i>The percentage of breastfeeding mothers who report being taught how to position their baby for breastfeeding.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of breastfeeding mothers who report being taught how to attach their baby for breastfeeding.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of breastfeeding mothers who report being taught how to observe for expected suckling patterns.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link

APPENDIX B: INDICATORS FOR FACILITY MONITORING OF KEY CLINICAL PRACTICES

KEY CLINICAL PRACTICES	INDICATOR DEFINITION NOTE: More detailed and specific guidance on numerator/denominator inclusions/exclusions is described on the Facility Data Sheet.	TARGET	PRIMARY SOURCE	OTHER SOURCES	SUBMIT METHOD
Step 5: Support mothers to initiate and maintain breastfeeding and manage common difficulties.	<i>The percentage of breastfeeding mothers who report being taught how to listen for swallowing sounds.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of breastfeeding mothers who report being taught how to express their breast-milk by hand.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
Step 6: Do not provide breastfed newborns any food or fluids other than breast-milk, unless medically indicated.	<i>The percentage of infants who received only breast-milk throughout their stay at the facility.</i> Reminder: The US BFHI Designation Is based on implementation of clinical practices, NOT on an exclusive breastfeeding rate of ≥80%.	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
	<i>The percentage of breast-milk fed infants who received formula supplementation during their stay at the facility.</i>	≤14.2%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
	<i>The percentage of mixed-feeding and formula feeding mothers who report being taught how to safely prepare, feed and store infant formula.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
Step 7: Enable mothers and their infants to remain together and to practice rooming-in 24 hours a day.	<i>The percent of infants who stayed with their mothers both day and night, without separation of more than 1 hour per 24-hour period.</i>	≥80%	Clinical records	Mothers Survey and/or Audits	Facility Data Sheet Mothers Survey Report Form or Link
Step 8: Support mothers to recognize and respond to their infants' cues for feeding.	<i>The percentage of mothers [regardless of feeding method] who report being taught that salivating or rooting is an early feeding cue.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of mothers [regardless of feeding method] who report being taught that the baby putting fingers or fist in or around his/her mouth is an early feeding cue.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of mothers [regardless of feeding method] who report being taught that the baby becoming more active and alert is an early feeding cue.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link

APPENDIX B: INDICATORS FOR FACILITY MONITORING OF KEY CLINICAL PRACTICES

KEY CLINICAL PRACTICES	INDICATOR DEFINITION NOTE: More detailed and specific guidance on numerator/denominator inclusions/exclusions is described on the Facility Data Sheet.	TARGET	PRIMARY SOURCE	OTHER SOURCES	SUBMIT METHOD
Step 9: Counsel mothers on the use and risks of feeding bottles, artificial nipples and pacifiers.	<i>The percentage of breastfeeding mothers who report being taught about the risks of using feeding bottles, artificial nipples and pacifiers.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of breastfeeding mothers who report being taught when an acceptable time is to introduce a pacifier.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
Step 10: Coordinate discharge so that parents and their infants have timely access to ongoing support and care.	<i>The percentage mothers [regardless of feeding method] who report being taught how to tell if their babies are getting enough.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link
	<i>The percentage of mothers [regardless of feeding method] who report being taught where they can access infant feeding support in the community.</i>	≥80%	Mothers Survey	Audits	Mothers Survey Report form or Link

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an 'k')	VERIFICATION METHOD
DOMAIN 1: CRITICAL MANAGEMENT PROCEDURES TO SUPPORT THE TEN STEPS	
Competency 01. Implement the Code in a health facility (Step 1A)	
*1. List at least 3 products that are covered by the Code.	Question or case study
*2. Describe at least 3 ways a direct care provider/direct care staff protects breastfeeding in practice.	Question or case study
*3. Describe at least 1 way a direct care provider/direct care staff should respond if offered information provided by manufacturers and/or distributors of products within the scope of the Code.	Question or case study
*4. Describe at least 1 type of financial or material inducement that might be offered to a direct care provider/direct care staff by a manufacturer and/or distributor of products within the scope of the Code.	Question or case study
*5. Describe at least 1 harm of a direct care provider/direct care staff accepting financial or material inducements.	Question or case study
*6. Explain at least 2 ways that the facility ensures that there is no promotion of infant formula, feeding bottles, or teats in any part of facilities providing maternity and new-born services, or by any of the direct care staff/direct care providers.	Question or case study

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an 'k')

VERIFICATION METHOD

DOMAIN 1: CRITICAL MANAGEMENT PROCEDURES TO SUPPORT THE TEN STEPS continued

Competency 02. Explain a facility's infant feeding policies and monitoring systems (Step 1B and 1C)

*7. **Describe** at least 2 elements that are in the facility's infant feeding policy.

Question or case study

*8. **Explain** at least 3 ways that the infant feeding policy affects a direct care provider's/direct care staff member's work in *providing safe, equitable and appropriate care*.

Question or case study

*9. **Explain** at least 2 reasons why monitoring of hospital practices is important to ensure quality of care.

Question or case study

*10. **Explain** at least 2 ways practices are monitored in this facility.

Question or case study

DOMAIN 2: FOUNDATIONAL SKILLS: COMMUNICATING IN A CREDIBLE AND EFFECTIVE WAY

Competency 03. Use listening and learning skills whenever engaging in a conversation with a mother (All Steps)

*11. **Demonstrate** at least 3 aspects of listening and learning skills when talking with a mother.

Observation

*12. **Demonstrate** at least 3 ways to adapt communication style and content when talking with a mother.

Observation

Competency 04. Use skills for building confidence and giving support whenever engaging in a conversation with a mother (All Steps)

*13. **Demonstrate** at least 2 ways to encourage a mother to share her views, taking time to understand and consider these views.

Observation

*14. **Demonstrate** at least 3 aspects of building confidence and giving support when talking with a mother.

Observation

DOMAIN 3: PRENATAL PERIOD

Competency 05. Engage in antenatal conversation about breastfeeding (Step 3)

*15. **Engage** in a conversation with a pregnant woman on 3 aspects of the importance of breastfeeding.

Observation

*16. **Assess** at least 3 aspects of a pregnant woman's knowledge about breastfeeding in order to fill the gaps and correct inaccuracies.

Observation

*17. **Engage** in a conversation with a pregnant woman about at least 4 care practices a mother/infant dyad will experience at the birthing facility that will support breastfeeding.

Observation

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

DOMAIN 4: BIRTH AND IMMEDIATE POSTPARTUM

Competency 06. Implement immediate and uninterrupted skin-to-skin (Step 4)

*18. **Explain** at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the mother.

Question or case study

*19. **Explain** at least 3 reasons why immediate and uninterrupted skin-to-skin is important for the infant.

Question or case study

20. **Demonstrate** at least 3 points of how to routinely implement immediate, uninterrupted and safe skin-to-skin between mother and infant, regardless of method of birth.

Observation

*21. **Demonstrate** at least 3 safety aspects to assess when mother and baby are skin-to-skin during the first 2 hours postpartum, regardless of method of birth.

Observation

*22. **List** at least 3 reasons why skin-to-skin should NOT be interrupted.

Question or case study

*23. **Explain** at least 2 reasons when skin-to-skin could be interrupted for medically justifiable reasons.

Question or case study

24. "WHERE APPLICABLE" **Explain** how to maintain skin-to-skin during transfer of mother and infant to another room or other recovery area.

Question or case study

DOMAIN 5: ESSENTIAL ISSUES FOR A BREASTFEEDING MOTHER

Competency 07. Facilitate breastfeeding within the first hour, according to cues (Step 4)

*25. **Engage** in a conversation with a mother including at least 3 reasons why suckling at the breast in the first hour is important, when the baby is ready.

Observation

26. **Demonstrate** at least 3 aspects of safe care of the newborn in the first 2 hours post-birth.

Observation

27. **Describe** to a mother at least 3 pre-feeding behaviours babies show before actively sucking at the breast.

Observation

Competency 08. Discuss with a mother how breastfeeding works (Steps 3, 5, 6 and 9)

28. **Describe** at least 6 essential issues that every breastfeeding mother should know or demonstrate.

Question or case study

*29. **Engage** in a conversation with a mother regarding at least 3 reasons why effective exclusive breastfeeding is important.

Observation

*30. **Engage** in a conversation with a mother regarding 2 elements related to infant feeding patterns in the first 36 hours of life.

Observation

*31. **Describe** to a mother at least 4 signs of adequate transfer of milk in the first few days.

Observation

*66. **Describe** at least 1 professional medical reference or resource for identifying medications that are safe/compatible for use during lactation.

Question or case study

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an 'k')	VERIFICATION METHOD
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DOMAIN 5: ESSENTIAL ISSUES FOR A BREASTFEEDING MOTHER continued

Competency 09. Assist mother getting her baby to latch (Step 5)

32. Evaluate a full breastfeeding session observing at least 5 points.	Observation
*33. Demonstrate at least 3 aspects of how to help a mother achieve a comfortable and safe position for breastfeeding within the first 6 hours after birth and later as needed during the hospital stay.	Observation
*34. Demonstrate how to help a mother achieve an effective and comfortable latch, noting at least 5 points.	Observation

Competency 10. Help a mother respond to feeding cues (Steps 7 and 8)

*35. Engage in a conversation with a mother regarding 2 aspects related to the importance of rooming-in 24h/day.	Observation
*36. Explain 2 situations: 1 for the mother and 1 for the infant, when it is acceptable to separate mother and baby while in hospital.	Question or case study
*37. Describe at least 2 early feeding cues and 1 late feeding cue.	Question or case study
38. Describe at least 4 reasons why responsive feeding is important (also called on-demand or baby-led feeding) independent of feeding method.	Question or case study
39. Describe at least 2 aspects of responsive feeding (also called on-demand or baby-led feeding) independent of feeding method.	Question or case study
68. Describe 2 aspects involved in creating a safe environment for rooming-in during the hospital stay.	Question or case study
*69. Demonstrate at least 3 safety aspects to assess when mother and baby are skin-to-skin during the postpartum hospitalization, regardless of method of birth.	Observation

Competency 11. Help a mother manage milk expression (Steps 5 and 6)

40. Demonstrate to a mother how to hand express breast milk, noting 8 points.	Observation
41. Explain at least 3 aspects of appropriate storage of breast-milk.	Question or case study
42. Explain at least 3 aspects of handling of expressed breast-milk.	Question or case study

APPENDIX C1: PERFORMANCE INDICATORS TO MEASURE EACH COMPETENCY – SORTED BY DOMAIN/COMPETENCY

DOMAINS, COMPETENCIES AND PERFORMANCE INDICATORS (All performance indicators apply to direct care staff. Specific performance indicators for which knowledge competency applies to direct care providers are marked with an *)

VERIFICATION METHOD

DOMAIN 6: HELPING MOTHERS AND BABIES WITH SPECIAL NEEDS

Competency 12. Help a mother to breastfeed a low-birth-weight or sick baby (Steps 5, 7 and 8)

43. **Help** a mother achieve a comfortable and safe position for breastfeeding with her preterm, late preterm, or weak infant at the breast, noting at least 4 points.
- *44. **Engage** in a conversation with a mother of a preterm, late preterm, or low-birth-weight infant not sucking effectively at the breast, including at least 5 points.
45. **Engage** in a conversation with a mother separated from her preterm or sick infant regarding at least 2 reasons to be with her infant in the intensive care unit.
46. **Engage** in a conversation with a mother of a preterm, late preterm or vulnerable infant (including multiple births) regarding the importance of observing at least 2 sub-tle signs and behavioural state shifts to determine when it is appropriate to breastfeed.

Observation

Observation

Observation

Observation

Competency 13. Help a mother whose baby needs fluids other than breast milk (Step 6)

- *47. **List** at least 2 potential contraindications to breastfeeding for a baby and 2 for a mother.
- *48. **Describe** at least 4 medical indications for supplementing breastfed newborns: 2 maternal indications and 2 newborn indications, when breastfeeding is not improved following skilled assessment and management.
- *49. **Describe** at least 3 risks of giving a breastfed newborn any food or fluids other than breast milk, in the absence of medical indication.
- *50. For those few health situations where infants cannot, or should not, be fed at the breast, **describe**, in order of preference, the alternatives to use.
- *51. **Engage** in a conversation with a mother who intends to feed her baby formula, noting at least 3 actions to take.
52. **Demonstrate** at least 3 important items of safe preparation of infant formula to a mother who needs that information.
- *67. **Identify** 3 high-risk infant populations that may warrant extra precautions to protect against severe infections associated with powdered infant formula.

Question or case study

Question or case study

Question or case study

Question or case study

Observation

Observation

Question or case study

Competency 14. Help a mother who is not feeding her baby directly at the breast (Step 9)

53. **Demonstrate** to a mother how to safely cup-feed her infant when needed, showing at least 4 points.
54. **Describe** to a mother at least 4 steps to feed an infant a supplement in a safe manner.
- *55. **Describe** at least 2 alternative feeding methods other than feeding bottles.
56. **Engage** in a conversation with a mother who requests feeding bottles, teats, pacifiers and soothers without medical indication, including at least 3 points.

Observation

Observation

Question or case study

Observation