International Formula Council Comments on the
Proposed CDC Project *Assessment and Monitoring of Breastfeeding-Related Maternity Care Practices in Intra-Partum Care Facility in the United States and Territories New National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC)*
June 9, 2006

The International Formula Council (IFC)* offers the following comments on the four topics mentioned in the April 10, 2006, Federal Register [71 FR 18101]:

(a) **"Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility."**

IFC Comment: As stated in the proposed survey, "CDC is interested in your facility's policies and practices regarding infant feeding. Your responses to the survey will guide CDC and other organizations in developing programs and practice guidelines." However, the survey focuses almost entirely on breastfeeding. No questions are asked on what guidance/information is given to formula feeding mothers or how staff is trained to provide information on formula feeding. Even the Healthy People 2010 goals (set at 75% of mothers initiate breastfeeding in the hospital) acknowledge that up to 25% of newborns will be fed a breast milk alternative. If this survey will form the basis for practice guidelines, information on *all* infant feeding practices should be included.

Demographic information about the various hospital populations will be important in interpreting the survey results, as breastfeeding rates can be significantly influenced by such variables. While it assumed that demographic information would be collected on the hospital patient populations, the methodology did not define any specific demographic variables, which could limit use and interpretation of the data.

A second concern is that this survey, while yielding information on hospital practices, will not provide practical information on how to overcome two of the largest barriers to breastfeeding in the US: lack of workplace support for breastfeeding mothers and the availability of free infant formula through the WIC program.

CDC Response: This is a survey that assesses hospital maternity care practices that have been shown in controlled intervention trials to be associated with increased rates of breastfeeding exclusivity and continuation (Merten et al., Pediatrics 2005; Kramer et al., JAMA 2001).

Demographic information about the various hospital populations will be obtained from the American Hospital Association's Annual Survey of Hospitals, from HRSA's Area Resource File, and from Census data. We assessed the possibility of collecting this information from the hospitals during the pretest of the survey instrument and determined that it would not be feasible.

We agree that there are multiple barriers to breastfeeding in the United States. The proposed assessment and monitoring project is one of many initiatives to address these issues. We are concurrently working in several arenas including multiple complementary initiatives to improve workplace support for breastfeeding mothers, dissemination of information about the evidence supporting breastfeeding interventions in multiple settings, improving the breadth and depth of breastfeeding support in the WIC program, and expanding utilization of breastfeeding data . However, this does not imply that maternity practices are not also an important component of

* The IFC is an international association of manufacturers and marketers of formulated nutrition products (e.g., infant formulas and adult nutritionals) whose members are predominantly based in North America. IFC members are: Mead Johnson Nutritionals; Nestlé USA, Inc., Nutrition Division; PBM Products; Ross Products Division, Abbott Laboratories; Solus Products; and Wyeth Nutrition.

breastfeeding support. Hospital practices have been shown to influence breastfeeding exclusivity and continuation.

(b) **"The accuracy of the agency's estimate of the burden of the proposed collection of information."**

IFC Comment: A national census design is a cumbersome model and was reportedly selected because it was the only design that "will allow states to individually tailor their efforts to increase progress toward meeting their public health breastfeeding goals." However, hospitals practices are not a major barrier to increased breastfeeding rates in the United States. In the last ten years, hospital breastfeeding initiation rates have increased. Most US mothers (77 percent) report they made the decision about what to first feed their newborn baby before giving birth. And mothers overwhelmingly know that breastfeeding is best for babies (almost 9 out of 10 women--85 percent) say breastfeeding is "healthier for the child." Other methods to help states increase breastfeeding rates by reducing true barriers may be more productive than a hospital survey.

CDC Response: Hospital practices are a known barrier to breastfeeding initiation (DiGirolamo et al., Health Education and Behavior, 2005). Indeed, despite widespread understanding of the benefits of breastfeeding, many mothers' desire to breastfeed cannot be fulfilled due to institutional barriers to breastfeeding experienced in the maternity care setting. A national census design is necessary so that individual communities can tailor their efforts to promote breastfeeding initiation, exclusivity, and continuation. Wide variation between individual hospitals makes generalization of findings from one hospital to another problematic; and small states especially would not be able to use aggregate data.

Benchmark reports will be provided back to each hospital to identify those areas in which they are not performing as well as other hospitals. This would be of limited use if done only for a sample. Furthermore, state health departments and breastfeeding coalitions need data on hospitals in their state in order to effect changes – national data will not be helpful for this.

(c) **"Ways to enhance the quality, utility, and clarity of the information to be collected."**

IFC Comment: The data collected from this survey are largely subjective, based on the views, beliefs, and estimations of the individuals answering the survey. There should be specific employee(s) (titles) identified at the facility to complete the survey, because it is unlikely all questions can be answered accurately by one person. Additionally, there may be wide variability in the results, depending on the position, qualifications, and views of who answers the survey, unless better instructions as to who should complete the survey are provided. This should also enable more accurate comparisons between institutions. Finally, the questions that involve estimates of percentages are very difficult to accurately answer.

It is also likely that when the survey is instituted again in 2 years, a different employee at the institution may answer the questions, making year-to-year comparisons less reliable.

CDC Response: Survey pre-testing verified that this was an appropriate survey design and that respondents were able to provide consistent percentages. The data collection protocol specifies identifying a similar respondent from each hospital through an initial screening telephone call. There is a place on the survey to indicate the title and role of the people who completed the survey. This information will be used in preliminary analyses to determine if responses varied by type of respondent. We acknowledge that there will be staff turnover, but that is anticipated in any institutional survey and will not render year to year comparisons invalid.

(d) **"Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology."**

IFC Comment: An online survey, as suggested in the methodology, may help reduce burden of data collection.

CDC Response: We agree and as mentioned in the methodology section there will be an online version of the survey.

In addition, below are some general and specific comments on the survey instrument, which we believe would improve the quality of the survey.

General IFC Comments on the Survey

- Is this proposed survey similar to other CDC tools for developing policy?

  CDC Response: This survey is similar to other CDC tools for developing policy. Battelle was chosen in part to be the contractor because of demonstrated expertise in this type of survey assessing practices and policies at health care facilities.

- Does the CDC write hospital policy? Is the CDC the right governmental body to conduct this assessment?

  CDC Response: CDC is seen as a source of expertise for development of hospital policy—individual hospitals develop their policies based on multiple factors, including expertise and data from CDC. Examples include Universal Precautions, Pandemic Flu, Nosocomial Infections, etc. Specific to women's and infants' health and maternity care practices, CDC is recognized as the scientific expert agency for health promotion and disease prevention during this critical time. Examples include recommendations for prevention of iron deficiency in pregnancy, the CDC Pregnancy Risk Assessment and Monitoring System (PRAMS), prevention of transmission of Group B Strep, PMTCT, fetal monitoring, administration of medications during pregnancy and breastfeeding, and recommendations for preconceptional care.

- It is not explained in the Federal Register notice why the assessment is to be repeated every two years.

  CDC Response: The survey will be repeated every two years to assess changes at the individual facilities and at the state and federal levels. Annual assessment would have been too burdensome on the respondents.

- What is the basis for selection of experts used in developing the survey instrument?

  CDC Response: *Experts were chosen from an expert panel convened by CDC in 2003 on the assessment and monitoring of maternity care practices related to breastfeeding in the United States. The experts represented health departments from different states, WIC programs, non profit organizations, and academic researchers. All of the selected experts had specific expertise in gathering data related to maternal and institutional breastfeeding-related maternity care practices at either the state or local level.*

- The survey will likely take longer than the proposed allotted time of 30 minutes to complete, and a relatively high percentage of participants will "drop out" prior to completion. Therefore, unless the order of the questions are rotated, the questions at the end of the survey may receive inaccurate responses due to responder fatigue.

  CDC Response: Order of survey items is based on pre-testing and cognitive testing of the items. Pre-testing also verified that respondents were engaged throughout the process. The estimate of allotted time came from specific pre-testing of the instrument to determine the length of time needed to adequately complete the survey.

- If the hospital has other priorities established upon receipt of the survey, it is unlikely to be completed in the requested timeframe due to other priorities.

  CDC Response: We pre-tested the survey to ensure a minimum burden to the respondents and to ensure that the topic was of sufficient importance that it would be high on a priority list. The survey administration protocol includes specific steps to ensure as high a response rate as possible. This protocol is modeled in part on the protocol of PRAMS.

IFC Comments Regarding Individual Survey Questions

A1. **"Are prenatal classes offered at your hospital, either by hospital staff or contracted personnel?"**
This question should be expanded, as the follow-up questions currently are specific only to breastfeeding. For example, if the answer is "Yes", respondents should be asked, "Is safe and appropriate formula feeding covered as part of the class content?" as well as, "Does the hospital have a policy for support of mothers who, for whatever reason, choose to not follow breastfeeding recommendations?"

CDC Response: Instruction provided to mothers on appropriate formula feeding is not directly related to the goals of this assessment. The scope of the survey is breastfeeding and factors related specifically to breastfeeding, because that is within the scope of CDC's purview. FDA is the agency that is responsible for the assessment of safe and appropriate preparation of infant formula. Further, FDA and CDC are currently collaborating on an Infant Feeding Practices Study that will gather in-depth information about mothers' experiences with infant formula preparation both in-hospital and throughout the first year of the infant's life. Gathering information about provision of this type of instruction to mothers prior to the availability of the IFPS data could potentially result in redundant and burdensome data collection.

A3. **"If a mother indicates she wants to breastfeed, is her decision recorded on a hospital record? *(either hers or her infant's hospital record)*"**
Since the survey is about infant feeding practices, the question should be expanded to include all options, for example, "Is the mother's infant feeding decision recorded on a hospital record?"

CDC Response: We agree with comment A3. and have revised the question to read 'Is the mother's infant feeding decision recorded on a hospital record? (either hers or her infant's hospital record)".

A5. **"Are routine newborn procedures (e.g. Apgar, cord clamping, foot printing) after uncomplicated vaginal births done while the mother is holding the healthy full-term infant skin-to-skin?"**
Are such procedures done when mothers are holding their infants without skin-to-skin contact?

CDC Response: We are interested in the impact of these procedures on breastfeeding. The evidence clearly indicates that skin-to-skin is the critical factor, rather than a clothed mother holding a clothed infant.

A6. **"Approximately what percentages of healthy full-term breastfed infants are put to the breast for the first time during the specified period after delivery for uncomplicated vaginal births?"**
The survey should include the following questions, similar to that above: "Approximately what percentages of healthy term infants not breastfed are fed during the specified time? Are there any special feeding instructions given for first feedings of infant formula (e.g., first feeding is ½ strength?"

CDC Response: The scope of the survey is breastfeeding and factors related specifically to breastfeeding.

A7. **"Approximately what percentage of healthy full-term breastfed infants are given the following as a first feeding after uncomplicated vaginal births?"**
This question seems to pertain to all infants, not only breastfed infants.

CDC Response: The scope of the survey is breastfeeding and factors related specifically to breastfeeding.

A9. **"Approximately how many mothers (regardless of feeding method) are encouraged to hold their healthy full-term infants skin-to-skin for at least 30 minutes within two hours after delivery for uncomplicated cesarean births?"**
What is the measure of "encouraged"? A single mention? How often is encouragement given, and under what conditions is encouragement discontinued? Should this question be repeated for times other than the two hours after delivery?

CDC Response: This question doesn't need to be repeated for other times, a) because that would add to the burden on respondents and b) because we're concerned about delaying that skin-to-skin contact. Since the item specifically asks about "uncomplicated cesarean births," it is beyond the scope of the survey to ask under what conditions encouragement is discontinued. The scope of this survey is to measure routine practice within a maternity care facility. This item is specifically designed to measure the respondent's perception of their own behavior in the given situation (management of mother baby dyads within the first two hours after uncomplicated cesarean births).

A10. **"Approximately what percentages of healthy full-term breastfed infants are put to the breast for the first time during the specified period after delivery for uncomplicated cesarean sections?"**
This question seems to pertain to all infants, not only breastfed infants.

CDC Response: The scope of the survey is breastfeeding and factors related specifically to breastfeeding. It is not pertinent to ask about the time until the infant is first put to the breast if the infant is not breastfed.

A11. **"Approximately what percentage of healthy full-term breastfed infants are given the following as a first feeding after uncomplicated cesarean section births?"**
This question seems to pertain to all infants, not only breastfed infants.

CDC Response: The scope of the survey is breastfeeding and factors related specifically to breastfeeding.

A12. **"Of mothers who are breastfeeding, or intend to breastfeed approximately how many do you teach breastfeeding techniques (e.g. comfortable positioning, holding infant, how to express milk, assessing the effectiveness of breastfeeding)?"**
How is intention assessed?

CDC Response: The purpose of this question is not to assess intention. The question assesses whether hospital staff teach breastfeeding techniques to women they think are or are going to breastfeed.

A13. **"Approximately how many mothers of breastfed infants are taught to recognize and respond to first signs of baby's hunger?"**
Why is this a question only for mothers of breastfed infants?

CDC Response: We agree with comment A13. and have revised the question to read "Approximately how many mothers are taught to recognize and respond to first signs of baby's hunger?".

A14. **"How often do maternity care staff routinely advise breastfeeding women to limit the length of suckling at each feeding (e.g. nurse for 5, 10, or 15 minutes on each breast)?"**
This question is ambiguous or redundant. If they advise rarely, it may not constitute a routine.

CDC Response: We agree with this observation and have reworded the items to read "How often do maternity care staff advise breastfeeding women to limit the length of suckling at each feeding?" as we are hoping to assess routine practice.

A15. **"Of mothers who are breastfeeding, approximately how many mother-baby couples are observed and assessed by staff for breastfeeding effectiveness during the maternity care hospital stay?"**
The survey should include the following questions, similar to that above: "Do mothers limit the opportunities for observations? Does staff state expectation that observations will be conducted?"

CDC Response: This item is assessing prevalence of an existing standard of nursing care.

A17. **"Approximately what percentage of healthy full-term breastfed infants are supplemented with something other than breast milk? (*Please provide your best estimate if your hospital does not formally track this information.*)"**
This question seems to pertain to all infants, not only breastfed infants.

CDC Response: The scope of the survey is breastfeeding and factors related specifically to breastfeeding.

A18. **"Of the healthy full-term breastfed infants who are supplemented with infant formula, what percentage are supplemented for the following reasons?"**
The IFC's understanding is that some hospitals routinely feed infant formula at night to avoid disturbing the mother. This is not necessarily a doctor's order, a nurse's recommendation, or a mother's choice; it can be a hospital practice or policy. Therefore, to the extent that breastfeeding babies are receiving formula, the IFC questions whether the reasons listed are accurate. The IFC suggests the survey include the following questions, similar to that above: "Of the healthy full-term formula fed infants, what percentage are fed formula for the following reasons? What percentage of all infants has some medical or physiological reason for not breastfeeding? What are the most common reasons?"

CDC Response: We agree that there are multiple reasons. We developed the responses in consultation with hospitals and pre-tested the response categories in a range of hospitals with low and high breastfeeding rates. We initially had response categories that included medical and physiological reasons for supplementation but found during the pre-testing that respondents could not answer this question. We will include a response category 'Other, please specify' to capture other reasons.

A19. **"Are healthy full-term breastfed infants <u>who are supplemented</u> ever given the following types of supplementary feedings?"**
This question seems broad and the reasons are not clearly explained.

<u>CDC Response</u>: Due to the nature of the survey, it does not make sense to include explanations of the response options listed.

A21. **"Does your hospital receive free infant formula?"**
Will the respondent be likely to know the answer to this question?

<u>CDC Response</u>: Pre-testing indicated a clear understanding by respondents of the purchasing of infant formula.

A29. **"Are discharge packs/bags containing infant formula samples given to breastfeeding mothers?"**
Why is this question focused on only infant formula? Mothers obtain information and samples of many other items. A description of the full content of the discharge bags (i.e., diapers, coupons, other information, toys, accessories, etc.) would be more informative.

<u>CDC Response</u>: The scope of the survey is breastfeeding and factors related specifically to breastfeeding. Discharge packs containing infant formula samples have been shown to affect breastfeeding patterns (Howard et al., Obstetrics and Gynecology, 2000).

A30. **"What support does your hospital routinely (most of the time) offer to breastfeeding mothers at discharge?"**

	Yes	No	Not Sure
a. Postpartum telephone call by hospital staff	❑	❑	❑
b. Telephone number for patient to call	❑	❑	❑
c. Postpartum follow-up visit at hospital after discharge	❑	❑	❑
d. Home follow-up visit after discharge	❑	❑	❑
e. Referral to hospital-based breastfeeding support group	❑	❑	❑
f. Referral to other breastfeeding support groups	❑	❑	❑
g. Referral to lactation consultant/specialist	❑	❑	❑
h. Referral to WIC (for those eligible)	❑	❑	❑
i. Referral to an outpatient lactation clinic	❑	❑	❑
j. List of resources for breastfeeding help	❑	❑	❑
k. Breastfeeding assessment sheet	❑	❑	❑
l. Other *(please specify)* _____			

It would be helpful to know what percentage of breastfeeding mothers utilize these services and what these services cost the hospital. An additional question that would be helpful is, "In addition, what support does your hospital routinely offer to formula feeding mothers at discharge?" The questions related to breastfeeding should be removed (e, f, g, i, k, remove "breastfeeding" from j) based on the assumption that formula-feeding mothers cannot reverse their decision and initiate breastfeeding after discharge. Also add questions, "What percentage of non-breastfeeding mothers utilize the above services?" and "What do these services cost the hospital?"

<u>CDC Response</u>: While this information would be interesting, it is beyond the scope of the assessment.

A32. **"Is banked donor milk ever used in your NICU?"**
The survey should include the following questions, similar to that above: "Does your hospital have an on-site milk bank? If not, from what distance is donor milk obtained? How many mothers of LBW infants express their milk for feeding their LBW infant?"

CDC Response: While this information would be interesting, there is not enough room to include all questions. We had originally sought to collect more information on NICU practices but had to scale back the number of questions to reduce the burden on respondents.

A33. **"Among NICU infants receiving milk feedings, approximately how many are routinely provided human milk?"**
Some NICU babies are given formula and not breast milk for therapeutic reasons. Thus, the "few" or "some" vs. "many" or "most" numbers may be relatively higher in the NICU than the well-baby area for a legitimate (therapeutic) reason.

CDC Response: This item was developed based on input from NICU experts and pre-testing.

B1. **"On average, how many hours do birth attendants spend in breastfeeding education as new employees?"**
The survey should include the following question, similar to that above: "On average, how many hours do nurses spend in education on safe and appropriate formula feeding, including hygienic preparation, time from reconstitution to use, temperature of storage, and time until unused portion is discarded?"

CDC Response: Appropriate formula feeding is not relevant to the goals of the assessment. The scope of the survey is breastfeeding and factors related specifically to breastfeeding, because that is within the scope of CDC's purview. FDA is the agency that is responsible for the assessment of safe and appropriate preparation of infant formula.

B2. **"On average, how many hours do each of the following types of maternity care staff spend in breastfeeding education as new employees?"**
The survey should include the following question, similar to that above: "On average, how many hours do other health care professionals spend in education on safe and appropriate formula feeding, including hygienic preparation, time from reconstitution to use, temperature of storage, and time until unused portion is discarded?"

CDC Response: Appropriate formula feeding is not relevant to the goals of the assessment. The scope of the survey is breastfeeding and factors related specifically to breastfeeding.

B3. **"How many nurses received breastfeeding education in the past year?"**
The survey should include the following question, similar to that above: "How many received information on safe formula preparation and use?"

CDC Response: Appropriate formula feeding is not relevant to the goals of the assessment. The scope of the survey is breastfeeding and factors related specifically to breastfeeding.

B5. **"How often are nurses assessed for level of competency in breastfeeding management and support?"**
The survey should include the following questions, similar to that above: "How often are nurses assessed for competency in formula feeding instruction? How often are mothers assessed for their competency in formula reconstitution an proper formula handling?"

CDC Response: Appropriate formula feeding is not relevant to the goals of the assessment. The scope of the survey is breastfeeding and factors related specifically to breastfeeding.

B11. **"Does your hospital have a written policy addressing…**

"b. prenatal classes informing mothers of the benefits of breastfeeding
This question should follow c. The survey should include the following questions: 1) "prenatal classes informing mothers on usual problems encountered in breastfeeding;" and 2) "prenatal classes on hygienic preparation and use of formula."

"c. asking about mothers' feeding plans"
The survey should include the following questions: "do hospitals continue to give breastfeeding information and encouragement when a mother has informed that her intention is to formula feed?"

CDC Response: We appreciate the suggestion and have shortened the item to read: "b. prenatal classes informing mothers about breastfeeding.' Because the scope of the survey is breastfeeding and factors related specifically to breastfeeding we are not asking about formula. 'c' is intentionally worded neutrally and succinctly to capture the pertinent information.

B13. **"Does your hospital provide any of the following to hospital staff who are also breastfeeding mothers?**

"b. On-site child care for dependents of hospital staff
"g. Paid maternity leave (other than accrued vacation or sick leave)"
Both of these instances apply to formula feeding mothers as well.

CDC Response: We agree with comment B13. and have revised the question to read, "Does your hospital provide any of the following to hospital staff who are also mothers?".

Literature Cited

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