Assessment and Monitoring of Breastfeeding-Related Maternity Care Practices in Intrapartum Care Facilities in the United States and Territories

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

The Maternal and Child Nutrition Branch of the Division of Nutrition and Physical Activity of the Centers for Disease Control and Prevention (CDC) proposes to design, implement, and analyze an initial and a follow-up survey of practices related to breastfeeding at intrapartum care facilities. The surveys are being designed and implemented through a contract with Battelle Centers for Public Health Research and Evaluation. The first survey is proposed for administration in 2007. It will establish a baseline measure of breastfeeding-related maternity care practices at intrapartum care facilities across the United States and Territories and the extent to which practices vary by state. The second survey is proposed for administration in 2009. It will examine changes in practices over time. Information from the surveys will help inform intrapartum care facilities, state public health departments, and CDC programs.

There is substantial evidence on the social,[1] economic[2,3] and health benefits of breastfeeding for both the mother[4,5] and infant[6,7] as well as for society in general.[8] Yet breastfeeding initiation rates and duration in the United States did not achieve Healthy People 2010 objectives and significant disparities continue to exist between African American and white women in breastfeeding rates.[9] The Healthy People 2010 objectives are to increase the proportion of mothers who breastfeed in the early postpartum period from 64% (1998 estimate) to 75%, the proportion who breastfeed their babies through 6 months of age from 29% to 50%, and to increase from 16% to 25% the proportion of mothers who breastfeed to 1 year of age. A goal for all three points in time is to decrease the wide disparities in breastfeeding initiation and duration between African American and white women. In addition to ethnic and racial disparities, there is evidence of significant variation in breastfeeding rates across states. For example, the lowest state breastfeeding initiation rate in 2004 was 46.1 percent in Mississippi and the highest was 88.0 percent in Alaska.[10]

The maternity care experience exerts unique influence on both breastfeeding initiation and later infant feeding behavior. In the United States, nearly all infants are born in a hospital or free-standing birth center, and even though their stay is typically very short, events during this time have a lasting meaning. Correspondingly, the hospital stay is known to be a critical period for the establishment of breastfeeding.

Many of the experiences of mothers and newborns in the hospital and practices in place there affect how likely breastfeeding is to be established. In most cases, however, these experiences reflect routine practices at the facility level, and new mothers rarely request care different from that offered them by health professionals. Prenatal education on breastfeeding can affect a mother's decision to even consider it as a feeding option. Medications and procedures administered to the mother during labor affect the infant's behavior at the time of birth, which in turn affects the infant's ability to suckle in an organized and effective manner at the breast. Infants who are put to the breast within the first few hours after birth continue breastfeeding longer than those whose first breastfeeding is delayed. Mothers who room-in with their infants will have many more opportunities to practice breastfeeding because of the infant's proximity.

Breastfeeding is an extremely time-sensitive relationship. Experiences with breastfeeding in the first hours and days of life significantly influence an infant's later feeding. Because of its inextricable relationship with the birth experience, breastfeeding must be established during the maternity hospital stay, not postponed until the infant goes home.

A Cochrane review[11] found that institutional changes in maternity care practices effectively increased breastfeeding initiation and duration rates. Birth facilities that have achieved designation as part of the World Health Organization/UNICEF *Baby Friendly Hospital Initiative* (BFHI)[12] typically experience an increase in breastfeeding rates.[13] In addition, DiGirolamo et al.[14] found a relationship between the number of *Baby Friendly* steps (included in the *Ten Steps to Successful Breastfeeding* of BFHI) in place at a birth facility and a mother's breastfeeding success. The authors found that mothers experiencing none of the *Ten Steps to Successful Breastfeeding* required for BFHI designation during their stay were eight times as likely to stop breastfeeding before 6 weeks as those experiencing five steps.

Authority for CDC to collect this data is granted by Section 301 of the Public Health Services Act (42 U.S.C. 241) **(Appendix A)**.

A.2. Purpose and Use of Information Collection

CDC works in partnership with states to promote optimal maternal and infant health through increased breastfeeding initiation and continuation. Consistent with this mission, and with clear evidence that breastfeeding-related maternity care practices influence breastfeeding initiation and continuation, it is necessary to determine prevalence of practices and policies related to breastfeeding at intrapartum care facilities across the United States. This critical data can then be used to effectively inform state and national programs. The objective of the proposed study is to conduct a mail survey in 2007 and 2009 in all U.S. states and territories of all facilities that routinely provide maternity care services.

The proposed design of this study is a national census of facilities routinely providing maternity care based on careful review of advantages and limitations of various study designs as well as input from stakeholders and experts in evaluation of hospital maternity care practices. Three major issues necessitate a national census of facilities. They are:

- State health departments have voiced a strong desire to be able to conduct state and local level analyses to use these data to tailor public health breastfeeding interventions to their particular needs. A nationally representative sample of facilities would not allow for State-level analysis to address individual local research and policy needs. Wide variation in breastfeeding prevalence across the United States makes these needs particularly salient.
- This study includes the plan that individual facilities receive their own data back, benchmarked against other facilities. Data from other facilities will be unidentified and in aggregate form. This will enable individual facilities to take on their own issues internally. The practical utility of this option allows for rapid and localized assessment of issues that can be tackled. A sampling of facilities eliminates the possibility of this aspect of the study.

- The broad diversity between maternity care facilities in the United States makes it problematic to identify and recruit facilities that could legitimately be considered to be representative of other facilities.

The 2007 survey will establish a baseline measure of the extent to which intrapartum care facilities engage in the specific practices related to successful breastfeeding promotion. The second survey in 2009 will examine changes in practices over time. Specifically, the goals of the study are to:

- Examine the variation in breastfeeding-related maternity care practices across and between 50 States and Territories and by other intrapartum care facility characteristics such as size and type of ownership;
- Describe the characteristics of those facilities that are implementing maternity care practices more and less conducive to promoting breastfeeding initiation and continuation;
- Provide feedback to CDC, State health departments, and intrapartum care facilities to inform programs and practices.

Without this research, the CDC and state public health departments have little information regarding the extent to which intrapartum care facilities are implementing specific breastfeeding-related maternity care practices.

Data collected and analyzed can be used by facilities as a benchmark to see how they are performing relative to other similar facilities, by state health departments and public health and policy officials to optimize allocation of resources to promote breastfeeding practices, to evaluate interventions at the state, or national level, and to identify barriers to meeting Healthy People 2010 objectives. Data can also be used by researchers to better understand the relationships between intrapartum care facility characteristics, maternity-care practices, state level factors, and breastfeeding initiation and continuation rates.

A.3. Use of Information Technology and Burden Reduction

A computer assisted telephone interviewing (CATI) system will be used to screen facilities selected for possible inclusion in the study. The purpose of the telephone call is four-fold: (1) to verify that the facility provided maternity care in the previous calendar year, (2) to determine the most appropriate respondent at the facility (3) to obtain further survey respondent contact information, and (4) to determine if the facility provides maternity care at other locations, and, if so, to obtain contact information for the other sites. Use of the CATI will reduce the burden to the respondent since it normally reduces the amount of time necessary to complete a screening interview and captures the data more accurately.

Once the appropriate respondent has been identified, there will be two options for completing the survey. A web-based system will be developed to allow respondents the option of completing the survey electronically. Data will be downloaded electronically from the web-based system. For those respondents without the resources to fill out a web-based survey, a hard copy will be available. The pages of the hard-copy surveys will be separated and scanned for data entry. Both options are designed to minimize burden to the respondent and obtain data as efficiently as possible. Both methods allow establishment of an infrastructure for subsequent data collection waves.

A.4. Efforts to Identify Duplication and Use of Similar Information

Although a few small studies have been conducted in individual states,[15,16,17] it is currently not possible to assess and monitor breastfeeding-related maternity care practices across the United States and territories. This type of information is not captured via birth certificate data, nor is it captured by the CDC Pregnancy Risk Assessment Monitoring System (PRAMS) or any other federal survey capturing hospital practices or women's experiences during the intrapartum period. To our knowledge, no other existing surveillance system captures facility practice information in maternity care settings.

In October, 2003, CDC convened an expert panel comprised of the researchers who conducted the previous, state-level studies as well as other researchers with specific experience in surveillance and monitoring of maternity care practices related to breastfeeding. The expert panel reviewed existing research and available data, identified current research, evaluation, and public health programmatic needs, various methodologies for a national assessment of breastfeeding-related maternity care practices at hospitals, and possible barriers to data collection. Attendees agreed that the monitoring system needs to be a recurring national census of facilities routinely providing maternity care.

In October, 2004, CDC convened another meeting of experts to discuss the draft survey instrument and implementation of the survey. As part of the discussion, experts again reviewed existing data sources and other studies that were underway and agreed both that no similar data collection system exists, and the need for such data is high.

A.5. Impact on Small Businesses or Other Small Entities

Since the study population will include all hospitals and free-standing childbearing centers in the United States and territories, it will include some small businesses. Extensive effort has been made to minimize the burden of the survey on small businesses. In designing the survey instrument, the number of questions has been held to the minimum necessary for addressing the objectives of the study. Skip patterns built into the survey will allow small hospitals and birthing centers to answer only the sections that apply to their specific conditions, thereby reducing the burden on these small businesses. For example, questions on surgical births (Cesarean sections) and neonatal intensive care can be skipped by facilities that do not perform surgical births or provide neonatal intensive care. Many smaller facilities that fall into this category, thus these facilities will have less response burden and fewer items to which they need respond.

The use of the CATI screening instrument and offering two options for completing the survey, a web-based option and a hard copy option, will also reduce the burden on participating small businesses. Small businesses such as free-standing childbearing centers represent approximately one half of one percent of the entire study population.

A.6. Consequences of Collecting the Information Less Frequently

We plan to administer an initial survey in 2007. This will be the first of an ongoing systematic data collection for the continued assessment of breastfeeding-related maternity care practices. We plan to administer a second round in 2009 to examine changes in practices over time.

Changes in maternity care practices related to breastfeeding occur relatively rapidly. In many cases these changes occur as a result of a single person's decision. While annual assessment of facilities is desirable, to lessen the burden on respondents, biannual assessment will be adequate to characterize the major issues of concern without losing point-in-time data. Assessment less than every 2 years will not be able to fully capture these changes as they occur, making analyses and public health program planning less accurate and effective. Documentation of these changes over time will allow for more careful program planning and more efficient use of hospital funds to improve maternity care practices.

Maternity care practices related to breastfeeding are changing across the United States. CDC is developing recommendations to promote and support this change. As of July, 2005, 50 hospitals and birth centers in the United States have been designated as part of the UNICEF/WHO Baby Friendly Hospital Initiative to promote maternity care practices that have been shown to increase breastfeeding initiation and continuation. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recently began including lactation practices as part of its overall assessments of hospitals. In addition, on May 18, 2005, United States Senator Tom Harkin introduced a bill (S.1074) to improve the health of Americans and reduce health care costs by reorienting the Nation's health care system toward prevention, wellness, and self care. Section 105 of the legislation includes establishing a 'Baby-Friendly Hospital Initiative' and a certification process for hospitals that promote maternity care practices conducive to breastfeeding initiation.

The goal of this work is to not only establish CDC's national system for monitoring practices related to breastfeeding at intrapartum care facilities on a bi-annual basis, but to ensure the longevity of the system and provide meaningful results to CDC, intrapartum care facilities, and States. In the long term, development and implementation of a national surveillance system will help inform programs to achieve Healthy People 2010 objectives and reduce disparities in breastfeeding initiation and duration.

There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This study complies fully with the guidelines of 5 CFR 1320.5. No exceptions to the guidelines are required.

A.8. Comments in Response to Federal Register Notice and Efforts to Consult Outside the Agency

A. CDC published a notice soliciting public comment on the proposed information collection in the Federal Register on April 10, 2006 (Vol 71, No. 68, pp. 18101-18102). A copy is attached **(Appendix B)**. One inquiry was received for a copy of the draft methodology along with the hospital survey. Those materials were provided to the requester **(Appendix C-1)**. One inquiry was received requesting consideration of adjustments to the survey instrument. Responses to these requests were provided to the requester **(Appendix C-2)**.

B. A panel of experts in evaluation of hospital maternity care practices in the United States met in Orlando, Florida, on October 30 and 31, 2003 to discuss the future of assessment and monitoring of maternity care practices related to breastfeeding. CDC convened the meeting specifically to identify current research, surveillance, and public health program needs, discuss various monitoring methodologies, identify barriers to data collection, and explore future possibilities for national assessment and monitoring. This was the first such meeting bringing together diverse experts from across the country to help shape a national system of monitoring breastfeeding-related maternity care. The outcome of this expert panel meeting was a strong recommendation on the part of meeting participants to establish an ongoing national census of maternity care practices related to breastfeeding among all facilities that routinely provide maternity care services. The final report of this meeting is attached **(Appendix D).**

A draft survey was developed based on the recommendations of the Expert Panel at the October 2003 meeting and survey instruments used in past studies, such as the FDA Infant Feeding Practices Study (IFPS), the Maternity Center Association Listening to Mothers Survey, and the Pregnancy Risk Assessment Monitoring System (PRAMS). The surveys used to collect state-level data in states such as California, Pennsylvania, Colorado, Oregon, New Jersey, and New York were also reviewed.

A follow-up meeting with experts was held in Boston, Massachusetts, on October 21, 2004, to discuss the draft survey instrument. Discussion included: (1) feedback on the survey plan; (2) general discussion of the draft survey instrument; (3) question by question observations on the draft survey instrument.

Persons consulted at the two expert panel meetings are listed in Table A.8.A:

Table A.8.A Non-CDC Experts Consulted

Date Consulted	Name, Title, Phone Number	Agency, Location, Email Address
2003	Elizabeth Adams, PhD Assistant Professor Food Science and Human Nutrition 970-491-6535	Colorado State University Fort Collins, CO lizadams@CAHS.Colostate.edu
2003	Mary Applegate, MD, MPH Medical Director 518-473-4439	Bureau of Women's Health NY State Dept of Health Albany, NY msa04@health.state.ny.us
ongoing	Karin Cadwell, PhD Director (508) 888-8044	Healthy Children/Baby Friendly USA East Sandwich, MA karin@healthychildren.cc
ongoing	Andrea Crivelli-Kovach, PhD Director of Community Health 215-572-4014	Arcadia University Glenside, PA kovach@ARCADIA.EDU
ongoing	Eugene Declercq, MBA, PhD Professor (617) 638-7795	Boston U. Sch of Public Health Boston, MA declercq@bu.edu

Date Consulted	Name, Title, Phone Number	Agency, Location, Email Address
2003	Jennifer Dellaport, RD, MPH WIC Breastfeeding Promotion Coordinator 303-692-2462	Colorado Dept of Public Health & Environment Denver, CO
2003	Ann DiGirolamo, PhD, MPH Research Assistant Professor 404-727-9814 adigiro@sph.emory.edu	Rollins School of Public Health at Emory University Atlanta, GA Jennifer.Dellaport@state.co.us
2003	Anne Merewood, MA, IBCLC Director, Research Breastfeeding Center 617-414-6455	Boston Medical Center Boston, MA Anne.Merewood@bmc.org
2003	Barbara Philipp, MD Associate Professor of Pediatrics 617-414-4233	Boston Medical Center Boston, MA bobbi.philipp@bmc.org
ongoing	Ken Rosenberg, PhD PRAMS Project Director 503-731-4507	Oregon Department of Human Services Ken.D.Rosenberg@state.or.us
2003	Laurie Tiffin, MS, RD Chief-Breastfeeding Promotion Unit WIC Supplemental Nutrition Branch 916-928-8526	California Department of Health Services Sacramento, CA LTiffin@dhs.ca.gov
ongoing	Cindy Turner-Maffei, MA, IBCLC National Coordinator 508-888-8092	Baby-Friendly USA East Sandwich, MA cturner@babyfriendlyusa.org

A.9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be made to the respondents.

A.10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this application and has determined that the Privacy Act is not applicable. Respondents are hospital and non-hospital facilities that provide maternity care services. Although one or more contact persons will be identified for each responding facility, the contact person will not provide any identifiable information about himself or herself. Based on their role, the contact person will provide information about the respondent facility's practices related to infant nutrition and breastfeeding education. The contact person's name and contact information will be destroyed after individualized facility reports have been generated and sent back to facilities with aggregate results reports.

CDC determined this project to be non-human subject research as the project collects information about practices and policies in hospitals and birthing centers and does not collect data about individuals. (**Appendix E)**

A contractor, the Battelle Centers for Public Health Research and Evaluation, will be responsible

for screening contacts with respondents and for collecting response data on behalf of CDC. Battelle personnel assigned to this project will be required to sign a confidentiality agreement. Great care will be taken to treat the survey data in a confidential manner.

The contractor will assign a unique study identifier code to each respondent facility. Although the survey packet containing the questionnaire will be addressed to the named contact person, the completed survey returned to the contractor, as well as the electronic data files containing the survey response data, will be identified only by the study identifier code and will not include names or direct identifiers. Data base files linking facility names with identification numbers will be kept separate from survey response data. Once the data collection has been completed, all names, addresses, and telephone numbers of contact persons will be destroyed, however, facility names will be kept in order to be able to create linkage with other studies and for further analysis by state health departments who may need to identify and target hospitals with particular practices. Facilities will be informed that data may be released for additional approved research purposes.

Respondents who choose to submit response data electronically will be given a password for access to the contractor's website. All data submitted to the contractor's web site will travel via secure data sockets and will be stored in a database behind the contractor's server firewall. Project files will be password protected and access will be limited to authorized project staff. Completed questionnaires submitted in hardcopy format will be stored in locked file cabinets.

No names, facility names, or personal identifying information will be used in any published reports of this study. CDC plans to present all survey reports and findings in aggregate so individual facility responses cannot be identified. Data will be treated in a confidential manner, unless disclosure is otherwise required by law.

A.11. Justification for Sensitive Questions

Topics typically considered to be of a sensitive nature include personal sexual practices, alcohol or drug use, religious beliefs or affiliations, immigration status, and employment history. No questions regarding these topics or any other topic of a sensitive nature will be asked in this survey. We do not anticipate that the respondent facilities will consider any of the questions about facility practices to be sensitive, however, the data de-identification processes described above have been implemented as further safeguards to respondent privacy.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.A. Estimate of Burden Hours

The total number of respondents for both years 2007 and 2009 (respondents to the screening call and to the mail survey) is estimated to be 16,188. Using the most recent data from the American Hospital Association's (AHA) annual survey of hospitals, we estimate there will be 4,375 respondents to each screening call. We base these estimates on using AHA data from 2000, with an assumption that 25% of facilities may have satellite facilities and an assumption that approximately 15% of those screened will be ineligible to participate in the survey due to not having maternity beds. These assumptions would result in a total of 3,719 eligible for the mail

survey. We plan to administer the screening instrument to the director of maternity care who will identify the person in their facility who can best complete the mail survey.

The total burden hours for both survey years 2007 and 2009 for screening and survey administration are 4,450. The approximate annualized burden for this three-year project is 1,484 hours.

Table A.12.A. Estimated Annualized Burden Hours

Questionnaire/ Respondents	Number of Respondents	Frequency of Responses/ Respondent	Average Time per Response (in hours)	Annual Burden (in hours)
Screening call/ facilities that have at least one registered maternity bed (2006)	1458	1	5/60	122
Mail survey/ facilities providing maternity care in the past calendar year (2006)	1240	1	30/60	620
Screening call/ facilities that have at least one registered maternity bed (2008)	1458	1	5/60	122
Mail survey/ facilities providing maternity care in the past calendar year (2008)	1240	1	30/60	620
Total	**5396**			**1484**

A.12.B. Estimated Annualized Cost to Respondents

The approximate annualized burden is 1484 hours. The burden estimate is based on pretests along with CDC's experience with surveys with similar administration protocols and lengths. The screening instrument and the survey will most likely be administered to Registered Nurses who will be answering the survey on behalf of their facility (hospital or birthing center). The hourly wage rate is based on statistics from the U. S. Department of Labor, Bureau of Labor Statistics.[18] An annual increase of 5% is added to the wage rate of $25.96 for Registered Nurses in the United States posted for the year 2003.

Table A.12.B. Estimated Annualized Cost to Respondents

Type of Respondent	Questionnaire/ Respondents	Number of Respondents	Frequency of Responses/ Respondent	Average Burden per Response (in hours)	Total Burden (in hrs)	Hourly Wage Rate	Annual Respondent Cost
Nurses (2006 Survey)	Screening call/ facilities that have at least one registered maternity bed	1458	1	5/60	122	$28.62	$3492.00
Nurses (2006 Survey)	Mail survey/ facilities providing maternity care in the past calendar year	1240	1	30/60	620	$28.62	$17,744.00
Nurses (2008 Survey)	Screening call/ facilities that have at least one registered maternity bed	1458	1	5/60	122	$31.55	$3849.00
Nurses (2008 Survey)	Mail survey/ facilities providing maternity care in the past calendar year	1240	1	30/60	620	$31.55	$19,561.00
	Total	**5396**			**1484**		**$44,646.00**

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

The data collection entails no additional costs to respondents or record keepers.

A.14 Annualized Cost to the Government

This study will take approximately 3 years to complete (see Estimated Timeline – Table A.16.1). The estimated total cost to the government is $966,083. The CDC costs are estimated as follows: Salary $67,000; Fringe (25 %); Travel $6200; Administration $5,000. The estimated cost of the Battelle contract (CDC 200-2001-00121, Task Order # 0013) is $871,133 which covers the cost of survey administration, distribution and collection, data entry, coding and cleaning and data analysis. Therefore, the annualized cost to the government is $322,028.

Table A.14. Estimated Annualized Cost to the Government

Type of Cost	Annualized Amount	
Contractual Costs	$290,378	
Salaries	$27,917	(includes fringe)
Travel	$2,067	
General and Administrative	$1,667	
Annualized cost-Government	$322,028	

Note we are seeking three year approval for this project.

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

A.16.A. Project Time Schedule

Table A.16.A. Project Time Schedule

Activity	Schedule (months after OMB clearance)
First Survey Iteration	
Identify facilities to be surveyed	Month 1-2
Conduct screening telephone calls	Month 1-4
Conduct mail survey	Month 2-8
Data coding, entry, and cleaning	Month 2-9
Data analysis	Month 9-10
Final reports, manuscripts, web-benchmarking	Month 9-12
Second Survey Iteration	
Identify facilities to be surveyed	Month 25-26
Conduct screening telephone calls	Month 25-28
Conduct mail survey	Month 26-32
Data coding, entry, and cleaning	Month 26-33
Data analysis	Month 33-34
Final reports, manuscripts, web-benchmarking	Month 33-36

A.16.B. Publication Plan

Upon completion of the data analysis, a separate technical report will be prepared for each facility and each state. These reports will be provided to recipients via paper copy and made available on a password-accessible website to protect the confidentiality of individual facility data. These technical reports will summarize the results of the data analysis. Each report will describe the objectives of the study, methods of survey administration (including the response rates to the survey), and analysis results. The results of the study will also be disseminated to various stakeholders through the publication of manuscripts in peer-reviewed journals.

A.16.C. Analysis Plan

A.16.C.1. Calculation of Sampling Weights

Due to conducting a census of all facilities providing maternity care in all States and Territories, weighting of the survey data need only be performed to reduce bias due to patterns of non-response. If non-response is low, or non-differential, the analyses will be unweighted.

To adjust for non-response we will use sample weighting class adjustments. The variables that are the best candidates for the formation of weighting classes are those variables that are: (1) available for respondents as well as non-respondents; (2) highly correlated with the survey variables; and (3) highly correlated with the likelihood of non-response. Variables available for the non-response analysis will be limited to geographic location, variables obtained through the screening telephone interview (e.g. number of satellite clinics), and variables available from the American Hospital Association's Annual Survey of Hospitals (e.g. ownership type, number of obstetric beds, births).

These weights will be applied to all analyses described below if necessary. By using weights to adjust for non-response we will obtain estimates that will be unbiased and generalizable to hospitals providing maternity care.

For most analyses, the unit of analysis will be the facilities. However, for some analyses, it will also be of interest to estimate the number of births in the country experiencing different feeding related practices. For these analyses, the tables will be weighted by the number of births in the facility in the previous year.

A.16.C.2. Data Analysis

The survey data will be analyzed using standard univariate and bivariate descriptive statistics (e.g. means, frequencies, crosstabs) and multivariate analyses. The following types of variables will be examined:

Hospital/birthing center practices: Practices include staff training regarding breastfeeding-related maternity care practices, prenatal classes that include breastfeeding instruction, routine newborn procedures, breastfeeding instruction and lactation support, infant supplementation and feeding schedules, rooming-in, and information provided at discharge.

Hospital/birthing center policy: These variables include whether the hospital has a written policy or policies that promotes and supports maternity care practices related to breastfeeding, content of the policy, and how staff are informed about the policy, staff training, and personnel.

Hospital/birthing center characteristics: These variables include total number of live births in the past year, total number of obstetric beds, staffing, number of deliveries by cesarean-section, teaching hospital, ownership, breastfeeding rates, geographic location of hospital including urban or rural and state.

Indicator variables will be constructed using multiple survey questions to reflect the extent to which hospitals and birthing centers have policies and practices associated with breastfeeding initiation and continuation (see Table A.16.C.2. for example of possible indicator variables mapped to survey questions). For each indicator variable, we will create a score from 0 to 100, with higher scores reflecting more consistent application or more positive policies and practices.

Table A.16.C.2. Examples of Indicator Variables

Indicator Variable	BFHI Step	Measurement	Hospital Survey Item	
Mother's prenatal instruction	3	Extent to which all pregnant women are informed about the benefits and management of breastfeeding	A1 A2, A3	Breastfeeding education Feeding plans
Initiating breastfeeding after vaginal birth	4	Extent to which mother is helped to initiate breastfeeding within half an hour of birth	A4 A5 A6 A7	Skin-to-skin contact Newborn procedures Infant first put to breast First feeding
Initiating breastfeeding after surgical (c-section) birth	4	Extent to which mother is helped initiate breastfeeding within 2 hours of birth	A9 A10 A11	Skin-to-skin contact Infant first put to breast First feeding
Breastfeeding instruction	5	Extent to which mothers are shown how to breastfeed, and how to maintain lactation even if they should be separated from their infants	A12 A15 A16	Breastfeeding techniques Assessment Type of assessment
Supplementation	6	Extent to which newborn infants are given no food or drink other than breast milk, unless medically indicated	A18 A19	Reason for supplementation Type of supplementation
Rooming-In	7	Extent to which hospital or birthing center practices rooming-in, allowing mother and infants to remain together, 24 hours a day	A23 A24 A26 A28	Separation during transition Night placement Reasons for separation Hours rooming-in
Feeding schedules	8	Extent to which breastfeeding on demand is encouraged	A13 A14 A25	Signs of hunger Length of sucking Night feedings
Pacifiers	9	Extent to which no additional teats or pacifiers are given to breastfeeding infants	A20	Use of pacifiers

Indicator Variable	BFHI Step	Measurement	Hospital Survey Item	
Hospital discharge	10	Extent to which hospital or birthing center fosters the establishment of breastfeeding support groups and refers mothers to them on discharge from the hospital or clinic	A29 A30	Discharge packs Post-discharge support
Staff instruction & Personnel	2	Extent to which all health care staff are trained in skills necessary to implement hospital breastfeeding policy	B1,B2, B3,B4, B6 B5 B8 B9 B10	Breastfeeding education Competency assessment Lactation coordinator Lactation FTE Availability of assistance
Hospital policy	1	Extent to which hospitals or birthing centers have a written breastfeeding policy that is routinely communicated to all health care staff and that contains key practices related to breastfeeding initiation and continuation	B11 B12 B13	Written policy Content of policy Staff informed about policy
Hospital Characteristics	n/a	Basic demographic variables used to categorize facility	A8 A17 A21 A22 A27 A31 A32 A33 B7 B14 C1,C2, C3,C4, C5,C6, C7,C8	Prevalence of surgical births Prevalence of supplementing Receipt of free infant formula Presence of newborn nursery Average length of stay Highest level of infant care Use of donor human milk Milk used for NICU feedings Types of care providers Employee support Basic demographics

A.16.D. Table Shells

All Table Shells are located in **Appendix F**.

Benchmarking analyses

Each facility participating in the study will receive an analysis of its own scores on these indicators compared to other facilities of a similar type. An example of such a report is shown in Table Shell 1.

Univariate analyses

Univariate distributions and summary statistics will be generated to describe hospital or birthing center characteristics across the U.S. This is an essential first step in describing the sample and generalizing the findings to the respondent universe.

Univariate analyses will be conducted on items in the remaining sections of the questionnaire and constructed indicator variables in order to describe hospital and birthing center maternity care practices and policies related to breastfeeding. Table Shells 2 through 5 present table shells as examples of univariate analyses.

To summarize the scores across U.S. hospitals, we will examine mean scores as well as a percent distribution of scores deemed to be low, medium or high based on pre-defined cutoffs. See Table Shell 4 for an example.

For each indicator, reports will be generated to compare maternity care facilities by state and region. For example, Table Shell 5. shows such a table for the first three indicators.

Bivariate analyses

Bivariate analyses will be conducted to: 1) obtain hospital or birthing center subgroup percentages or means on survey measures, 2) test for subgroup differences on those measures, and 3) test for associations between hospital or birthing center characteristics and practice and policy measures. In planning and conducting these analyses, hospital or birthing center (e.g. number of births, cesarean section rates) can be referred to as independent variables. Practice (e.g. 24-hour rooming-in, medical record documentation of intention to breastfeed), and policy (e.g. having a formal written policy or policies on breastfeeding) can be referred to as dependent variables. Table Shell 6 shows an example of a bivariate analysis looking at the content of hospital policy. Table Shell 7 shows an example of a bivariate analysis looking at the number of births and indicators of breastfeeding-related maternity care practices.

Table Shell 8 presents a shell table example showing a cross-classification of geographic location of hospital by extent of training provided to new maternity care nurses. Similar tables will be produced for other hospital or birthing center characteristics (independent variables) crossed by hospital or birthing center maternity care practices and policies. It is of particular interest to determine whether response distributions for these dependent measures are similar or dissimilar for the various types of hospitals or birthing centers.

Trend analyses

Univariate and bivariate analyses will also be carried out after the second iteration of the survey to evaluate changes in hospital and birthing center practices over time. For hospitals that respond to the survey at both iterations, their report will include a comparison to scores given at

the first iteration to show where there have been improvements. National reports will examine trends overall and broken down by facility type and location.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption from display of expiration date is requested.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to certification are sought.

B. Collections of Information Employing Statistical Methods.

B.1. Respondent Universe and Sampling Methods

The study population will include all facilities in the United States and Territories that routinely provided maternity care in the previous year. A nationally representative sample was considered but researchers from state health departments who were part of an expert panel convened to discuss breastfeeding practices expressed serious concerns that a nationally representative sample would limit practical utility of resultant data. Sampling data will not allow for state- and local-level analyses to address individual local programmatic, research and policy needs. A national census is the only design that will allow states to individually tailor their efforts to increase progress toward meeting their public health breastfeeding goals. The census design is especially important for small states and states with few hospitals.

The wide disparities in breastfeeding rates across U.S. States highlight the need for individual, state-level data to be available for local analyses. Further evidence on attitudes towards breastfeeding across the United States reveals significant geographic differences in barriers to breastfeeding,[19] which are likely manifested in maternity care practices related to breastfeeding as well.

The sampling frame will be all hospitals providing maternity care as indicated in the most current American Hospital Association's (AHA) Annual Survey of Hospitals database as having at least one registered obstetric bed in the previous year; and all non-hospital based birth centers identified through the National Association of Childbirth Centers Directory of Birthing Centers.

The survey will be administered to all hospitals and free-standing birth centers in the U.S. and Territories that provide intrapartum care. The survey will be administered in 2007 and again in 2009. To identify these facilities, we will obtain the most recent American Hospital Association's annual survey of hospitals to identify all hospitals that have registered maternity beds or that have an associated birthing center. Our calculation of 4,375 respondents for the screening call is based on a preliminary analysis of AHA data from the year 2000, plus an assumption that up to 25% of facilities in AHA may have satellite facilities that provide intrapartum care plus non-hospital birthing centers identified through the National Association of Birthing Centers and state health departments. We then assume that approximately 15% of those screened will not be eligible to participate in the survey due to not having maternity beds.

Table B.1. Estimated Size of the Respondent Universe in Survey Iterations 1 and 2

	Survey Iteration 1	Survey Iteration 2
Total number of hospitals and childbirth centers in the sampling frame/Number to be pre-screened by telephone	4375	4375
Estimated number ineligible for the survey during screening call	656	656
Estimated total eligible for the survey	3719	3719

To minimize possible bias from nonresponse and to maximize statistical power, the study aims to achieve a response rate of at least 75%. In surveying the universe of eligible facilities, the only source of sampling error is nonresponse. Therefore, our estimated standard error includes the following finite population correction factor:

Standard error=SQRT ((nonresponse rate)*(standard deviation)^2/(no. of surveys in analysis))

B.2. Procedures for the Collection of Information

This section describes data information collection procedures. The discussion is divided into three subsections: (1) pre-test procedures (2) data collection procedures and (3) quality control procedures.

B.2.A. Pre-test Procedures

The draft survey questionnaire was pre-tested in-person and over the telephone at nine facilities in Washington, Georgia, Indiana, Connecticut, and New Mexico representing urban, rural, small, large, private, public, HMO, teaching, and non-teaching hospitals, and birth centers. The pretest protocol began with calling a hospital and determining the proper person to whom to send the survey. We sought the following information:

- Appropriateness of the cover letter
- Who the best person would be to ask for in a pre-screening call to hospital/best way to identify multiple campuses that provide maternity care practices
- How long survey took to fill out/length of survey
- What information sources needed to be consulted (databases or other personnel) to complete survey
- Does hospital require permission to fill out survey
- Would respondent consider filling out by web-based option? If not, what are barriers
- Comprehensibility of questions/ write notes in margin

- Any other comments about survey

B.2.B. Data Collection Procedures

A computer assisted telephone interviewing (CATI) system **(Appendix G)** will be used to screen facilities selected for possible inclusion in the study. A screening telephone call will be made to all facilities identified from the American Hospital Association's Annual Survey of Hospitals (AHA) and the National Association of Childbearing Centers (NACC) as having provided maternity care in the past year. The purpose of the screening call is to (1) confirm that the hospital or birthing center provided maternity care in the previous year, (2) to identify possible satellite clinics providing maternity care, and (3) to identify survey respondent in each of the facilities.

A survey packet will then be sent via express mail to the individual identified during the screening call. The packet will include (1) the survey questionnaire **(Appendix H)** with an ID number pre-printed on it, (2) a personal cover letter on CDC letterhead **(Appendix I)** emphasizing the importance of the study and providing options of either completing hard copy of survey or a web-based version, and (3) a postage-paid return envelope. The letter will provide the name and toll-free telephone number of a staff member to call with questions about the study. The letter will also include the name and telephone number of a person to call with questions regarding Human Subjects protection.

Surveys will be sent continuously over a one-month period. Battelle will track all returned surveys in the computer system upon receipt. Within two weeks of the initial mailing, a thank-you/reminder postcard will be sent to each respondent to encourage survey completion. The postcard **(Appendix J)** will include a toll-free number that can be called if respondent has any questions about completing the survey or needs to have another copy of the survey mailed. Three weeks after the sending the postcard reminder, a second mailing of the survey packet via express mail will be sent to non-respondents. The second mailing will include a different cover letter **(Appendix K)** emphasizing the importance of the study. A follow-up phone call will be made to all non-respondents three weeks after the second mailing. This call will serve as a final reminder to complete the survey and provide an opportunity to answer any questions that may be delaying survey completion.

B.2.C. Quality Control Procedures

Beginning with study initiation and continuing through all phases of data collection and analysis, steps will be taken to ensure that the data collected are of the highest quality possible. All project staff will be trained to understand the purpose, sponsorship, background, objectives, and importance of the project, as well as their specific role and activities on the study. In training project staff, we will emphasize the steps that will be taken to protect the confidentiality of the data that are collected. Completed survey questionnaires will be stored in locked file cabinets. All project files will be password protected and access to the files will be limited to authorized project staff.

A management information system will be developed to monitor data collection activities. The database will store all background data known about each facility. In addition, the database will contain the dates of screening and follow-up telephone calls, the dates that questionnaires and other survey materials are mailed, and the dates that completed questionnaires are received. Mailing labels and personalized letters will be generated from this system. Follow-up mailing dates will then be computed by the tracking system to ensure timely mailing of necessary and appropriate follow-up materials. The management information system will also be used to

generate weekly reports summarizing the status of data collection activity through the data collection period.

An emphasis on quality will continue with data editing and data entry. A mail paper and pencil instrument (PAPI) will be sent in the survey package. To reduce data entry errors, scannable survey will be used. Battelle programmers will develop quality control checks for the scannable surveys. A web based survey option will also be available in order to provide faster survey response time and availability of data as well as high quality data since control checks are built in. Both methods allow us to establish an infrastructure for subsequent data collection waves.

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B.3. Methods to Maximize Response Rates and Deal with Nonresponse

Over the past 20 years, Battelle has developed procedures that have been successfully used to achieve response rates of 70 to 80% to surveys of hospitals and other health care facilities. Multiple methods studies, reviews, and meta-analyses have been conducted to determine which factors lead to an increase in response rates in mail surveys. Preliminary notification, multiple follow-ups with respondents, use of express mail, personalization techniques, sponsorship or endorsement, and length of questionnaires have shown positive effects on response rates.[20]

Battelle discussed with CDC, the Expert Panel, and facility respondents during pre-testing the content of the letter to accompany the survey packet, including sponsorship by CDC. The cover letter, which will stress the importance of the study, will be signed by Dr. Laurence Grummer-Strawn, Chief of CDC's Maternal and Child Nutrition Branch.

The survey packet will be personally addressed to the person who was identified as being most knowledgeable about breastfeeding-related maternity care practices during the screening telephone call. Since the name and address of the individual will be confirmed before the questionnaire is sent, we can send the questionnaires by express mail directly to the respondent thereby assuring fast, accurate delivery. Respondents will be given the name and toll-free telephone number to call if they have questions regarding the study. A postcard reminder will be

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used to encourage non-respondents to complete and return the survey as will a second survey mailing with a new cover letter, and a final phone-call.

Response rates will be reported at each stage, i.e. the response rate from the initial mailing, the second mailing and the additional response rate following the postcard reminder. Once data collection has been completed, we will conduct a non-response analysis and adjust for non-response by weighting the survey data.

B.4. Tests of Procedures or Methods to be Undertaken

In developing the survey questionnaire, we sought input regarding the appropriateness and logic of the survey questions from a panel of experts and practitioners similar to the individuals who will be asked to complete the survey. Most of these experts have conducted surveys on breastfeeding related hospital practices before,Error: Reference source not found,Error: Reference source not found,Error: Reference source not found so the procedures have generally been tested in single states or communities. Experienced survey operations staff formatted the survey questionnaire for ease of completion, as well as to facilitate coding and data entry. Prior to requesting OMB clearance, the draft survey questionnaire was pre-tested in-person and over the telephone at nine facilities in the Seattle, Atlanta, Indianapolis, and Albuquerque metropolitan areas representing urban, rural, small, large, teaching, and non-teaching hospitals, and birthing centers. The purpose of the pretest was to obtain an estimate of respondent burden, as well as to obtain comments and advice about the format, comprehensibility, ease of response and relevance of individual questions, feasibility of web-based survey response option, and to identify the most appropriate person at the facility to fill in the survey. Modifications to the survey questions and format were made based on comments received during pre-testing.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Paulette E. Murphy, MLIS, of the Maternal and Child Nutrition Branch is the Technical Monitor for the study, and has overall responsibility for overseeing the design, conduct, and analysis of the study. Ms. Murphy will also approve and receive all contract deliverables. Telephone: 770-488-5849.

The survey instrument, sampling and data collection procedures, and analysis plan were designed in collaboration with researchers at Battelle Centers for Public Health Research and Evaluation (CPHRE) under contract No. 200-2001-00121, Task order No. 0013 with the Center for Disease Control and Prevention. Battelle will conduct data collection and will perform data analysis, in consultation with CDC.

Diane L. Manninen, PhD, has overall technical and financial responsibility for the study at Battelle and led the Battelle effort to design this protocol. Dr. Manninen will direct the overall data collection and analysis effort. She will also be responsible for writing the project reports. Telephone: (206) 528-3140.

Other personnel involved in design of the protocol and data collection instruments are:

Laurence M. Grummer-Strawn, PhD
Chief, Maternal and Child Nutrition Branch, Division of Nutrition and Physical Activity, CDC
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Brenda Cox, PhD
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[pre-screening call, survey implementation, tracking database development], Tel: 206-528-3138

David Sommers
Battelle, Associate Director Programming
[web-based response option software development; benchmarking software development], Tel: 206-528-3117

Eileen Miles, MPH
Battelle, Health Researcher
[Expert panel and pre-test coordination, CDC coordination, OMB Preparation], Tel: 770-451-0882

Mary Kay Dugan, MA
Battelle, Senior Health Research Scientist
[protocol development, survey instrument design, benchmarking], Te: 206-528-3142

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List of Appendices

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References