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

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**Request for Revision**

## Supporting Statement: Part A

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## Introduction

In this Revision ICR, CDC requests one additional year of OMB approval to conduct the mPINC survey again in 2011. In 2007, CDC submitted an ICR for *Assessment and Monitoring of Breastfeeding-Related Maternity Care Practices in Intrapartum Care Facilities in the United States and Territories* (OMB Control Number 0920-0743, expiration date 7/31/2009). The ICR requested administration of a baseline survey in 2007 and a follow-up survey in 2009. The survey instrument is called the Maternity Practices in Infant Care and Nutrition ("mPINC") Survey.

At the time of initial OMB approval, CDC was approved to administer the 2007 survey and disseminate findings back to respondents. OMB requested that CDC submit a report to OMB prior to administration of the 2009 survey.

The requested report of 2007 findings is included as Appendix C in this ICR. The report provides a brief background about the survey, a summary of data and activities that resulted from the 2007 collection, examples of types of feedback CDC has received since fielding the survey and related reports, and the role of the 2007 survey in planning for the 2009 follow-up survey.

OMB approved a Revision to conduct the mPINC survey again in 2009 (OMB Control Number 0920-0743, expiration date 10/31/2010).

This Revision ICR, which requests approval to conduct the 2011 mPINC survey, eliminates the proposed Results Report Pre-testing activity described in the Revision ICR for the 2009 mPINC survey. There are no changes to the facility screening activity, the estimated number of respondents for the mPINC survey, or the estimated burden per response for the survey.

## A. Justification

### A.1. Circumstances Making the Collection of Information Necessary

The Nutrition Branch of the Division of Nutrition, Physical Activity, and Obesity of the Centers for Disease Control and Prevention (CDC) proposes to conduct a planned follow-up survey of practices at intrapartum care facilities related to breastfeeding. The initial survey was administered in 2007. It established 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 survey was administered again in 2009; subsequent biennial surveys will examine changes in practices over time. Information from the surveys will help inform intrapartum care facilities, state public health departments, and CDC programs. The surveys were designed in collaboration with and are being implemented through a contract with Battelle Centers for Public Health Research and Evaluation.

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 persist 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 2007 was 52.5 percent in Mississippi and the highest was 89.8 percent in Utah.[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.

Maternity care practices related to breastfeeding are changing across the United States, and the rate of change in these practices has increased substantially in the past few years. Prior to administration of the first mPINC survey in 2007, the largest annual increase in number of births at hospitals and birth centers in the United States that have been designated as part of the UNICEF/WHO Baby Friendly Hospital Initiative was 8% (the Baby Friendly Hospital Initiative promotes maternity care practices that have been shown to increase breastfeeding initiation and continuation). In the first year following the first mPINC survey, the number of US births at such facilities increased by 48.5%, and the number of births at BFHI facilities has more than doubled since the first mPINC survey. 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.

In April, 2010, the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations) adopted a new perinatal core measure set that includes lactation practices as part of its overall assessment of hospitals. The exclusive breast milk feeding measure (PC 5) was derived from the quality measure endorsed by the National Quality Forum in October 2008, measuring breastfeeding at the time of hospital discharge. Public reporting of exclusive breastfeeding rates at hospital discharge in California has led to improvements statewide. In addition, congressional interest in improving maternity care practices has been mounting.

CDC thus requests OMB approval to conduct a planned follow-up survey in 2011 of Maternity Practices in Infant Nutrition and Care (mPINC) matching the survey methodology of the prior surveys. 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)**.

**Privacy Impact Assessment**

Overview of the Data Collection System

Facilities that provide maternity care services in the United States and Territories will be invited to participate in the 2011 mPINC survey. A brief screening interview will be conducted by telephone to confirm each facility's eligibility and contact information (see **Appendix G-1,** Telephone Screening Interview for Hospitals, and **Appendix G-2**, Telephone Screening Interview for Birth Centers). Each eligible facility will receive a survey packet by mail (see **Appendix H-1**, 2011 mPINC Survey for Hospitals, and **Appendix H-2**, 2011 mPINC Survey for Birth Centers). Facilities may respond by completing the hardcopy survey form or a web-based electronic survey.

Items of Information to be Collected

The mPINC survey includes questions about facility size and other characteristics; number of staff devoted to breastfeeding support and their credentials; facility practices such as first feeding

after birth, supplemental feeding, and rooming-in; breastfeeding education and support for mothers; relevant training for facility staff; and availability of supportive facility policies.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

There is no website content directed at children under 13 years of age.

## 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. An initialsurvey was conducted in 2007, which established baseline measures of the extent to which intrapartum care facilities engage in specific practices related to successful breastfeeding promotion.

In response to OMB's Terms of Clearance for the 2007 survey, which required CDC to report on results of the 2007 information collection prior to fielding the 2009 survey, a report is included in this Revision request, in **Appendix C** (**2007 mPINC Results Report**), along with **Appendix C-1** (**CDC MMWR**), which contains a major scientific publication resulting from the information collection, **Appendix C-2 (2007 mPINC Facility Benchmark Report)**, demonstrating an example of the reporting CDC has provided back to participating facilities, and **Appendix C-3 (CDC Web Resources at www.cdc.gov/mpinc)** illustrating the online resources CDC provides to participating facilities, state partners, researchers, and other interested stakeholders.

The objective of the proposed study is to gather information about maternity care practices that are related to breastfeeding and analyze trends and changes in practices and policies by conducting a follow-up survey in 2011 in all U.S. states and territories of all facilities that routinely provide maternity care services. The 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 extensive input from stakeholders and experts in evaluation of hospital maternity care practices. From the initial launch of the mPINC surveys in 2007, three major issues have necessitated a continued national census of facilities. They are:

- State health departments have voiced a strong need 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 does 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 survey provides individual facilities with their own data, benchmarked against other facilities. Data from other facilities is only provided in aggregate groups (national, statewide, and all facilities nationwide that have a similar number of annual births). This enables 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.

Since completing the first mPINC survey in 2007, the strengths of the national census design have been obvious, and CDC's ability to address the above issues and provide timely and specific, action-oriented data to facilities nationwide as well as a wide spectrum of state-level stakeholders has spurred substantive and valuable changes at the facility and state level.

- After learning of their state results on the 2007 survey, the state of Massachusetts was the first to launch an invitation-only statewide collaborative among the leadership of each of the major hospitals statewide in order to improve practices in their state. This effort led directly to changes in all of the participating hospitals, as well as a doubling of the number of BFHI facilities in the state.
    - Eight additional states have now initiated statewide or regional quality improvement collaboratives focusing on improving maternity care practices related to breastfeeding and engaging hospital leadership in the necessary changes and improvements.
- Participating facilities have begun working with their state health department partners to improve state regulations that can better support maternity care practices related to breastfeeding, and collaborations between facilities, researchers, and state agencies have begun in every HHS region of the US.
- Participating facilities have used their benchmark reports to initiate internal improvement processes and prioritize activities for staff training and recruitment, as well as for identifying critical need areas that need to be protected in times of budget cuts.
- The availability of detailed, facility-level data on maternity practices and logistics provided invaluable insight into possible approaches to mitigate transmission of 2009 Novel H1N1 Influenza during the 2009 Novel H1N1 Influenza pandemic – the mPINC data were the only available data source in the world that could provide detailed information about the location of the mother and the baby throughout the hospital stay, as well as the capacity of US hospitals to shift the locations for care of mothers and infants during the maternity care hospitalization.

The 2011 survey will examine trends in changes in practices over time. Specifically, goals of the study are to:

- Examine the variation in breastfeeding-related maternity care practices across and between 50 States and Territories as of 2011 (point-in-time analyses) and by other intrapartum care facility characteristics such as size and type of ownership;
- Examine changes between practices reported by facilities in 2007, 2009 and 2011, including trends in facilities that participated in all three iterations of the survey as well as cross-sectional observations of change, ensuring full utilization of data from facilities that participate in the survey for the first time in 2011 and those that participate in only 2 of the 3 iterations.
- Describe the characteristics of those facilities that consistently participate in the mPINC surveys as well as of those that do not, and characteristics of facilities that consistently

implement maternity care practices more and less conducive to promoting breastfeeding initiation and continuation as well as of those that have experienced significant changes in practices over time in either direction;

- Provide feedback to CDC, State health departments, and intrapartum care facilities to inform programs and practices.

Without this information, the CDC and state public health departments have no information about the extent to which intrapartum care facilities implement specific breastfeeding-related maternity care practices that have been identified as supportive based on extensive empiric evidence.

CDC will use information from the 2011 survey to identify, document, and share information related to incremental changes in practices and care processes over time at the facility, state, and national levels. 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.

**Privacy Impact Assessment Information**

As with the prior surveys in 2007 and 2009, a major goal of the follow-up survey in 2011 is to provide direct feedback to facilities and to be fully responsive to their needs for information and technical assistance. Following completion of the 2011 survey, CDC will again provide facilities with feedback. **Appendix C-2** (**2007 mPINC Facility Benchmark Report**) is an example of the feedback provided to respondents; and **Appendix C-3** (**CDC Web Resources**) includes a description of web-based resources that are currently available to respondents and the public on CDC's website that is dedicated to the mPINC survey. Following completion of the 2011 survey, CDC will expand on the information provided at this dedicated website by reporting on progress on quality improvement efforts captured from mPINC surveys from 2007 through 2011.

The mPINC survey requests the minimum amount of information necessary to conduct the planned analyses and to provide meaningful, individualized feedback reports to facilities which can be used for program evaluation and improvement.

The mPINC survey requests contact information for a contact person at each responding facility. The contact person provides information about organizational policies and practices. No personal information is requested, and no effect on personal privacy is anticipated due to participation in the 2011 mPINC survey.

## 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, using a web-based system from which each respondent's data are downloaded electronically, or a paper survey, including a self-addressed envelope in which the respondent sends back the completed survey. Upon receipt at Battelle, the pages of the paper surveys are 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 support an ongoing infrastructure for subsequent data collection waves.

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

Although a few small studies were conducted in individual states prior to the 2007 mPINC Survey,[15,16,17] the CDC mPINC Survey is the only national source of information that provides facility-specific data for the vast majority of facilities in each state 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 this type of facility-level practice information in U.S. 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.

Since beginning to plan and implement the 2007 survey, CDC has continued to communicate with external experts and sought to identify other data sources. Since fielding the 2007 survey, researchers have begun to identify CDC as their expected source for this kind of information.

## 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 may 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 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

An initial survey was administered in 2007. This was the first of an ongoing systematic data collection for the continued assessment of breastfeeding-related maternity care practices. The second round was administered in 2009, which created the first opportunity to examine changes in practices over time in addition to providing vital point-in-time assessments of practices nationwide. We plan to administer a third round in 2011 to identify current point-in-time assessments of practices nationwide, as well as to improve our ability to support facilities' improvement efforts as we further enhance our analytic opportunities to examine changes in practices over time. A further and vitally important role of administering and reporting on the 2011 survey is to maintain relationships and expected services among our partners. The positive response to mPINC reporting has made it clear that our partners have come to expect from CDC in the form of their own data benchmarked to peer facilities as well as their state's data benchmarked to facilities across the nation.

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.

The goal of this work is to not only to assess the feasibility of establishing 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 May 10, 2010 (Vol. 75, No. 89, pp. 25862-25863). A copy of the notice is attached **(Appendix B-1)**. CDC received 14 public comments in response to this Notice, including comments from organizations that represent large numbers of professionals. The majority of comments were extremely supportive of continuing the voluntary mPINC data collection, with one exception. One comment was received about the trade-off between maintaining the privacy of the point of contact for the survey, and the need to ensure broad input from appropriate staff within each responding facility. CDC appreciates this concern and is very sensitive to it, as described in **Appendix D (Expert Panel Meeting Final Report – October 2003)**. Consideration of this and many other important issues in the design of the mPINC survey has resulted in our decision to maintain the data collection plan at this time. **Appendix B-2** provides a summary of public comments and CDC's responses.

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<br>Assistant Professor<br>Food Science and Human Nutrition<br>970-491-6535 | Colorado State University<br>Fort Collins, CO<br>lizadams@CAHS.Colostate.edu |
| 2003 | Mary Applegate, MD, MPH<br>Medical Director<br>518-473-4439 | Bureau of Women's Health<br>NY State Dept of Health<br>Albany, NY<br>msa04@health.state.ny.us |
| ongoing | Karin Cadwell, PhD<br>Director<br>(508) 888-8044 | Healthy Children/Baby Friendly USA<br>East Sandwich, MA<br>karin@healthychildren.cc |
| ongoing | Andrea Crivelli-Kovach, PhD<br>Director of Community Health<br>215-572-4014 | Arcadia University<br>Glenside, PA<br>kovach@ARCADIA.EDU |
| ongoing | Eugene Declercq, MBA, PhD<br>Professor<br>(617) 638-7795 | Boston U. Sch of Public Health<br>Boston, MA<br>declercq@bu.edu |
| ongoing | Jennifer Dellaport, RD, MPH<br>WIC Breastfeeding Promotion Coordinator<br>303-692-2462 | Colorado Dept of Public Health & Environment<br>Denver, CO |
| 2003 | Ann DiGirolamo, PhD, MPH<br>Research Assistant Professor<br>404-727-9814<br>adigiro@sph.emory.edu | Rollins School of Public Health at Emory University<br>Atlanta, GA<br>Jennifer.Dellaport@state.co.us |
| 2003 | Anne Merewood, MA, IBCLC<br>Director, Research Breastfeeding Center<br>617-414-6455 | Boston Medical Center<br>Boston, MA<br>Anne.Merewood@bmc.org |
| 2003 | Barbara Philipp, MD<br>Associate Professor of Pediatrics<br>617-414-4233 | Boston Medical Center<br>Boston, MA<br>bobbi.philipp@bmc.org |
| ongoing | Ken Rosenberg, PhD<br>PRAMS Project Director<br>503-731-4507 | Oregon Department of Human Services<br>Ken.D.Rosenberg@state.or.us |
| 2003 | Laurie Tiffin, MS, RD<br>Chief-Breastfeeding Promotion Unit<br>WIC Supplemental Nutrition Branch<br>916-928-8526 | California Department of Health Services<br>Sacramento, CA<br>LTiffin@dhs.ca.gov |
| ongoing | Cindy Turner-Maffei, MA, IBCLC<br>National Coordinator<br>508-888-8092 | Baby-Friendly USA<br>East Sandwich, MA<br>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

A. Privacy Act Determination. This Information Collection Request has been reviewed by staff in CDC's Information Collection Review Office, who determined that the Privacy Act is not applicable. Respondents are hospital and non-hospital facilities that provide maternity care services. The following information in identifiable form (IIF) will be collected from one or more contact persons at each responding facility: name, job title, telephone number, email address, and mailing/FedEx address. The information is needed to facilitate routing of the mPINC survey to the appropriate facility representative. 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 will not provide any identifiable personal information about himself or herself. 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.

   This project is considered to be non-human subject research as it collects information about practices and policies in hospitals and birthing centers and does not collect data about individuals. The project does not involve the collection of information from human subjects. IRB approval is not required.

B. Safeguards. 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. Great care will be taken to treat the survey data in a secure manner. Battelle staff receive extensive training in data management and security.

   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 secure manner, unless disclosure is otherwise required by law.

C. Consent. Each facility will receive a cover letter (**Appendix I**) that provides an overview of the project and requests the facility's participation.

D. Voluntary Nature of Response. Participation in the mPINC survey is completely voluntary. Facilities are advised of the voluntary nature of response in the cover letter (**Appendix I**).

## 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

Potential respondents will be screened by telephone call. Using the most recent data from the American Hospital Association's (AHA) annual survey of hospitals, we estimate there will be a total of 4,089 respondents (3,897 hospitals and 192 birth centers) contacted for initial screening calls (see **Appendix G-1**, **Telephone Screening Interview for Hospitals**, and **Appendix G-2**, **Telephone Screening Interview for Birth Centers**). We plan to administer the screening instrument to the director of maternity care at each facility, who will identify the person in their facility who can best complete the mPINC survey.

Based on our experience with the 2007 and 2009 administrations of the mPINC survey, we then estimate that approximately 20% of those screened will not be eligible to participate in the survey due to having not provided routine maternity care in the previous year. Approximately 3,281 eligible facilities will be invited to participate in the survey (3,143 hospitals and 138 birth centers). We estimate that 2,568 hospitals will complete the hospital version of the survey (see **Appendix H-1**, **2011 mPINC Survey for Hospitals**), and 122 birth centers will complete the birth center version of the survey (see **Appendix H-2**, **2011 mPINC Survey for Birth Centers**).

The total estimated burden to respondents is 1,686 hours, including screening (341 hours) and survey completion (1,345 hours).

Table A.12.A. Estimated Annualized Burden Hours

| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|---|---|---|---|---|---|
| Hospitals | Telephone Screening Interview for Hospitals | 3,897 | 1 | 5/60 | 325 |
| | 2011 mPINC Survey for Hospitals | 2,568 | 1 | 30/60 | 1,284 |
| Birth Centers | Telephone Screening Interview for Birth Centers | 192 | 1 | 5/60 | 16 |
| | 2011 mPINC Survey for Birth Centers | 122 | 1 | 30/60 | 61 |
| | | | | Total | 1,686 |

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

The screening instrument and the survey will most likely be completed by Registered Nurses who will be answering the survey on behalf of their facility (hospital or birthing center). The hourly wage rate of $31.55 is based on statistics from the U. S. Department of Labor, Bureau of Labor Statistics.[18] The total estimated cost to respondents is $53,194.

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

| Type of Respondents | Form Name | Number of Respondents | Number of Responses per Respondent | Average Hourly Wage | Total Burden (in hours) | Total Cost to Respondents |
|---|---|---|---|---|---|---|
| Hospitals | Telephone Screening Interview for Hospitals | 3,897 | 1 | $31.55 | 325 | $10,254 |
| | 2011 mPINC Survey for Hospitals | 2,568 | 1 | $31.55 | 1,284 | $40,510 |
| Birth Centers | Telephone Screening Interview for Birth Centers | 192 | 1 | $31.55 | 16 | $505 |
| | 2011 mPINC Survey for Birth Centers | 122 | 1 | $31.55 | 61 | $1,925 |
| | | | | | Total | $53,194 |

## 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

The 2011 survey and study will take approximately eighteen months to complete (see Estimated Timeline – Table A.16.1) with reporting and benchmarking occurring in the last six months following data collection. The estimated total cost to the government is $439,336. The CDC costs are estimated as follows: Salary $36,000; Fringe (25 %); Travel $2000; Administration $1,500. The estimated cost of the Battelle contract (CDC Contract No. 200-2008-27956, Task Order # 2010-06) is $399,836 which covers the cost of survey administration, distribution and collection, data entry, coding and cleaning, data analysis, and reporting and benchmarking for the 2011 survey. The annualized cost to the government is $439,336.

**Table A.14. Estimated Annualized Cost to the Government**

| Type of Cost | Annualized Amount |
|---|---|
| Contractual Costs | $399,836 |
| CDC Salaries | $36,000 (includes fringe) |
| Travel | $2,000 |
| General and Administrative | $1,500 |
| Total Annualized Cost to the Government | $439,336 |

## A.15 Explanation for Program Changes or Adjustments

This Revision ICR, which requests approval to conduct the 2011 mPINC survey, eliminates the proposed Results Report Pre-testing activity described in the Revision ICR for the 2009 mPINC survey. There are no changes to the facility screening activity, the estimated number of respondents for the mPINC survey, or the estimated burden per response for the survey.

Facilities that will be invited to participate in the 2011 survey include facilities that: participated in 2007 or 2009, were invited but did not participate in 2007 or 2009, and have become eligible since 2009. This will allow CDC to effectively monitor current practices across the U.S. and to provide customized assessment reports to the broadest range of public health partners.

As with the initial surveys in 2007 and 2009, a major goal of the follow-up survey in 2011 is to provide direct feedback to facilities and to be fully responsive to their needs for information and technical assistance. Following completion of the 2011 survey, CDC will again provide facilities with feedback and will expand on this feedback by reporting on progress on their quality improvement efforts since 2009. Based on the 2009 reports, CDC will identify, document, and share information related to incremental changes in practices and care processes over time at the facility, state, and national levels.

## 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 |
|---|---|
| Identify facilities to be surveyed | Early Summer 2011 |
| Conduct screening telephone calls | Late Summer 2011 |
| Conduct mail survey | Late Summer/Fall 2011 |
| Data coding, entry, and cleaning | Winter 2011 |
| Data analysis | Spring 2012 |
| Final reports, manuscripts, benchmarking | Spring/Summer 2012 |

### A.16.B. Publication Plan

As with the 2007 and 2009 surveys, upon completion of the data analysis, a separate technical report will be prepared for each facility and each state. 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. See **Appendix C-2** for an example facility benchmarking report based on the actual 2007 reports. 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. The extremely high response rate to the 2007 and 2009 surveys makes weighting of 2011 data unlikely to be necessary.

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. Trend analyses utilizing data from both the 2009 and the 2011 survey data will be completed as well. The following types of variables are examples of data that 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. 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.

See **Appendix E** for the algorithm used for scoring the 2007 and 2009 surveys. Because this is a repeat of the 2009 survey, this is also the planned scoring algorithm for the 2011 survey.

### A.16.D. Table Shells

Selected table shells are located in **Appendix F**.

*Benchmarking analyses*

For each indicator, reports will be generated to compare maternity care facilities by state and region.

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 **Appendix A-2**.

*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.

*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.

Bivariate analyses will also be conducted to examine the variation in facility scores by facility characteristics such as having a level 3 neonatal intensive care unit, being a teaching facility, and geography (state and region). Facility scores are categorized based on pre-defined cut-offs as low, medium, or high overall and by maternity care dimension. Table Shells 1 and 6 present table shells as examples of bivariate analyses of facility scores. Table Shells 2-5 present table shells as examples of bivariate analyses of the first dimension of maternity care—labor and delivery—presented in Table Shell 1. These tables will be repeated for all of the other dimensions of maternity care.

*Trend analyses*

Univariate and bivariate analyses will also be carried out to evaluate changes in hospital and birthing center practices over time. For hospitals that responded to previous iterations of the surveys, their report will include a comparison of scores given in each year of participation 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.

## List of Appendices

Appendix A Authorizing Legislation

Appendix B-1 60 Day Federal Register Notice

Appendix B-2 Summary of Public Comments and CDC's Response

Appendix C 2007 mPINC Results Report

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[1] Kuzela AL, Stifter CA, Worobey J. Breastfeeding and mother-infant interactions. J Reprod Infant Psychol 1990; 8: 185-194.

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[11] Fairbank L, O'Meara S. Renfrew MJ, Woolridge M, Snowden AJ, Lister-Sharp D. A systematic review to evaluate the effectiveness of interventions to promote the initiation of breastfeeding. Health Technology Assessment 2000;4(25):1-171.

[12] World Health Organization/UNICEF. Protecting, Promoting and Supporting Breastfeeding:

Appendix C-1 CDC MMWR: Breastfeeding-related maternity practices at hospitals and birth centers—United States, 2007. June 13, 2008

Appendix C-2 2007 mPINC Facility Benchmark Report

Appendix C-3 CDC Web Resources at www.cdc.gov/mpinc

Appendix D Expert Panel Meeting Final Report – October 2003

Appendix E mPINC Survey Scoring Algorithm

Appendix F Table Shells

Appendix G-1 Telephone Screening Interview – Hospitals

Appendix G-2 Telephone Screening Interview – Birth Centers

Appendix H-1 2011 mPINC Survey for Hospitals

Appendix H-2 2011 mPINC Survey for Birth Centers

Appendix I Cover Letter

Appendix J Thank You/Reminder Postcard

Appendix K Non-Responders Follow-Up Letter

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The Special Role of Maternity Services. A joint WHO/UNICEF statement. Geneva: World Health Organization, 1989.

[13] Philipp BL, Merewood A, Miller LW, et al. Baby Friendly Hospital Initiative improves breastfeeding initiation rates in a U.S. hospital setting. Pediatrics 2001;108(3):677-81.

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[15] Kovach, AC, Hospital breastfeeding policies in the Philadelphia area: a comparison with the ten steps to successful breastfeeding. Birth. 1997 Mar;24(1):41-8.

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[18]

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