

Information Collection Request

Request for Reinstatement with change

Monitoring Breastfeeding-Related Maternity Care-US Hospitals

OMB Control No. 0920-0743

Supporting Statement: Part A

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September 27, 2018

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Goal of the study: To gather information about breastfeeding-related maternity care practices in hospitals providing intrapartum care in the United States and Territories, and to analyze trends and changes in these breastfeeding-related maternity practices over time.

Intended use of the resulting data: The resulting data is to provide timely and specific, action-oriented information (facility-specific Benchmark Reports) to participating hospitals in the United States and Territories, and to provide aggregated state data to a wide spectrum of state-level stakeholders (state-specific State Reports). Data are used by CDC and state health departments to inform programmatic activities and by hospitals to improve breastfeeding-related maternity care practices. Aggregate national data are posted on the CDC website for use by the general public and the data are used to answer questions raised by independent researchers, as requested.

Methods to be used to collect: This is a national census of hospitals routinely providing maternity care in the United States and Territories. Data are collected via a Web-based survey, which assesses five domains of breastfeeding-related maternity care.

The subpopulation to be studied: Hospitals in the United States and Territories that have provided maternity care in the previous year are eligible to participate. Participation in the study is completely voluntary, and data provided in the mPINC survey are at the hospital-level, related to the organization's practices and policies across the population receiving maternity care.

How data will be analyzed: The mPINC survey data will be analyzed using standard descriptive statistics (e.g., means, frequencies, crosstabs). Given the census design (i.e., surveying all hospitals), statistical significance testing of differences is not warranted. Beginning in 2020, trend analyses using data from multiple survey years collected beginning in 2018, will be completed as well.

Monitoring Breastfeeding-Related Maternity Care-US Hospitals

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

In this Information Collection Request (ICR), the Centers for Disease Control and Prevention (CDC) requests a Reinstatement with change approval from the Office of Management and Budget (OMB) to conduct in 2018 and 2020 follow-up surveys of the national Maternity Practices in Infant Nutrition and Care (“mPINC”) survey. The Reinstatement with change request is based on previous experience with administration of a baseline mPINC survey in 2007 and follow-up surveys in 2009, 2011, 2013, and 2015. OMB approval is requested for three years.

There is substantial evidence on the social,¹ economic,^{2,3} and health benefits of breastfeeding for both the mother⁴⁻⁶ and infant^{7,8} as well as for society in general.⁹⁻¹¹ A Cochrane review found that institutional changes in maternity care practices effectively increased breastfeeding initiation and duration rates.¹² Birth facilities that have achieved designation as part of the World Health Organization/UNICEF *Baby-Friendly Hospital Initiative* (BFHI)¹³ typically experience an increase in breastfeeding rates.¹⁴ In addition, DiGirolamo et al.¹⁵ found a relationship between the number of the *Ten Steps to Successful Breastfeeding (Ten Steps)* in place at a birth facility and a mother’s breastfeeding success, finding mothers that experienced none of the *Ten Steps* during their stay were eight times as likely to stop breastfeeding before 6 weeks as those who experienced six steps.

Breastfeeding is inextricably related to mothers’ birth experiences and establishing breastfeeding is time-sensitive, thus experiences in those first hours and days of life while in the hospital significantly influence feeding throughout infancy. Mothers who are not able to establish breastfeeding well during the hospital stay face substantial risk of not being able to be breastfed successfully later on. In most cases, however, these experiences reflect routine practices at the hospital level, and new mothers rarely request care different from that offered them by health professionals.

In order to better understand national maternity practices and the change in those practices over time, CDC began in 2003, at the request of experts in the maternal-child health field, developing the national Maternity Practices in Infant Nutrition and Care survey. In 2007, OMB approved an initial ICR, *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) to administer a baseline and two-year follow-up survey to maternity facilities and disseminate findings back to those facilities that participated. The initial survey in 2007 established baseline measures of hospitals’ practices across the United States and Territories and the extent to which these practices vary by state. In 2009, OMB approved a Revision ICR submission that included CDC’s response to OMB’s request for a report of baseline findings to be provided prior to conducting the planned two-year follow-up survey in 2009 (OMB Control Number 0920-0743, expiration date 10/31/2010). OMB additionally approved a Revision ICR to field a 2011 survey (OMB Control Number 0920-0743, expiration date 12/31/2011) and surveys in 2013 and 2015 (OMB Control Number 0920-0743, expiration date 9/30/2016).

Approval from OMB to consistently administer the mPINC survey every two years has allowed

CDC to be fully responsive to maternity facilities and other stakeholders in addressing their needs for biennial census data as well as to examine changes in maternity care practices over time. Response rates for all survey years have attained or exceeded 82 percent, reflecting hospitals' strong interest in participating in the mPINC survey and their increasing recognition of the survey's value to their work. Additionally, information from the surveys will help inform hospitals, state public health departments, and CDC programs as well as independent researchers.

Thus, CDC requests OMB approval to conduct planned mPINC surveys in 2018 and 2020 closely matching the methodology of the prior surveys. Authority for CDC to collect this information is granted by Section 301 of the Public Health Services Act (42 U.S.C. 241)

(Attachment 1 Authorizing Legislation).

2. Purpose and Use of the Information Collection

CDC works 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 better understand hospital practices related to breastfeeding across the United States. These critical data are used to effectively inform state and national programs. The initial mPINC survey, conducted in 2007, established baseline measures of the prevalence of specific practices related to breastfeeding in maternity care facilities across the U.S. and Territories. From this baseline all subsequent data allow analysis of trends, changes, priority needs, and opportunities for collaboration and improvement.

This Reinstatement with change ICR includes a sample of documents illustrating the variety of ways CDC strives to ensure full utilization of the data provided by participating maternity hospitals and support for partners and other stakeholders' ability to examine their own data to determine how best to improve their maternity care practices related to breastfeeding.

Attachment 3a (Summary 2007-2015 Surveys) synthesizes for OMB the overarching main findings from the first five mPINC surveys (**Attachment 3b OMB Results Report—2007**).

Attachment 3c (CDC Survey Website) provides an overview of the dedicated website CDC created for facilities responding to the mPINC survey, state partners, researchers, and other interested stakeholders, including detailed web tables presenting frequency data on all mPINC score indicators, allowing broad access to the rich data available from the survey. The website will be updated as needed (e.g., with new information about scoring). **Attachments 3d, 3e, 3f, 3g, and 3h** include the **Benchmark Report** samples from 2007, 2009, 2011, 2013, and 2015.

This is the customized information and data report that CDC creates and provides to every maternity hospital that participates in the mPINC survey. **Attachments 3i, 3j, 3k, and 3l** are publications from CDC's **Morbidity and Mortality Weekly Report** based on mPINC data.

Attachment 3i describes breastfeeding-related maternity practices at hospitals and birth centers from the 2007 survey. **Attachment 3j** describes hospital practices to support breastfeeding in the United States based on the 2007 and 2009 surveys. **Attachment 3k** examines racial disparities in access to maternity care practices that support breastfeeding using data from the 2011 survey.

Finally, **Attachment 3l** describes improvements in maternity care policies and practices that support breastfeeding in the United States from the mPINC 2007-2013 surveys. **Attachment 3m** provides screenshots of the mPINC facility survey taken March 12, 2018. To facilitate

completion of the questionnaire respondents will be able to access a page with answers to frequently asked questions, and an example is included in **Attachment 3n**.

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. The percent of U.S. births at facilities with the UNICEF/WHO *Baby-Friendly Hospital Initiative* (BFHI) designation was 1.8% in 2007,¹⁶ increased to 6.2% in 2012, and further increased to 18.3% of US births in 2016.^{17, 18}

The objective of the proposed ICR is to continue gathering information about hospitals' maternity care practices related to breastfeeding and analyze trends and changes by continuing the established pattern for follow-up surveys of all eligible hospitals in 2018 and 2020 in all U.S. states and territories. The design of this study remains a national census of hospitals 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. Since the initial launch of the mPINC surveys in 2007, several major issues have highlighted the necessity of a continued national census. They are:

- Baby-Friendly USA is the independent non-profit organization responsible for the BFHI in the U.S. In 2011, Baby-Friendly USA expanded the scope of data they require from hospitals, including the facility's current hospital-specific total mPINC score.
- State health departments have voiced a strong need to be able to conduct state- and local-level analyses of the mPINC data to tailor public health breastfeeding interventions to their particular needs. A national census design allows for state-level analysis to address individual local research and policy needs. Variation in maternity practices and in breastfeeding prevalence across the United States makes these needs particularly salient.
- The mPINC survey provides individual hospitals with their own data, benchmarked against aggregate data (national, statewide, and all facilities nationwide that have a similar number of annual births) from other facilities. Many hospitals see the benefit in using their mPINC Benchmark Report to understand baseline maternity practices, to make changes need to improve the quality of care they provide, and to earn the Baby-Friendly designation.
- The broad diversity among maternity care hospitals in the United States and lack of generalizability between them makes it problematic to identify and recruit hospitals that could legitimately be considered to be representative of other hospitals.

Since implementing the first mPINC survey in 2007, the national census design has enabled CDC to provide timely and specific, action-oriented data to hospitals nationwide as well as to a wide spectrum of state-level stakeholders. This has spurred substantive and valuable changes at the hospital and state level.

- Provision of mPINC data has prompted concrete action from state health departments, statewide breastfeeding coalitions, and other statewide partners that has since directly resulted in improved maternity care practices. Collaborations between hospitals, researchers, and state agencies are now in place in every HHS region of the U.S. Examples of state actions include:
 - Following in-depth analysis of the maternity care priorities in Massachusetts as identified by the mPINC survey, Massachusetts became the first state to launch an invitation-only statewide collaborative among the leadership of each of the major

hospitals statewide in order to improve maternity practices in their state. All participating hospitals initiated major quality improvement efforts, the number of BFHI facilities in the state doubled, and Massachusetts has since secured funding from a national non-profit foundation to continue efforts to improve breastfeeding-related maternity care.

- Coalitions from 15 states have built upon the model from Massachusetts to support and encourage hospitals to work together and learn from each other to improve care. Within each state, the approaches differ slightly, reflecting different needs and priorities, and an ability to customize the collaboration opportunities to best address the issues in a given state.
 - The Interstate Collaborative for Widespread Implementation of the *Ten Steps* was launched by the Carolina Global Breastfeeding Institute to address the need to accelerate the systematic implementation of the *Ten Steps* as essential maternity care practices associated with optimal breastfeeding. Initially a collaborative of a few states that had pioneered programs to improve maternity care across facilities using early mPINC data, this project was able to expand nationwide, thanks to recurring mPINC data and the engagement of hospitals and states as a result of the availability of these data. The short-term aims of the collaborative are to: 1) define best practices for implementation of the *Ten Steps* on a state-by-state basis through collaboration among states with active programs, and 2) develop a specific research agenda for further study of opportunities and challenges to systematized implementation of evidence-based breastfeeding support in America's hospitals.
- Participating hospitals have used their mPINC Benchmark Reports to initiate internal improvement processes and prioritize activities for staff training and recruitment.
 - The availability of detailed, hospital-level data on maternity practices and logistics has been an invaluable element of pandemic and disaster response. During the H1N1 Influenza pandemic, the mPINC data were the only available data source for detailed information about the location of the mother and the baby throughout the hospital stay and helped estimate capacity of U.S. hospitals to shift care of mothers and infants during the maternity hospital stay.

The 2018 and 2020 surveys will allow examination of changes in practices over time.

Specifically, goals of the mPINC survey are to:

- Examine point-in-time analyses of variation in breastfeeding-related maternity care practices across and between 50 States and Territories and by other hospital characteristics such as size and type of ownership.
- Examine changes in practices reported by hospitals every two years beginning in 2020, using 2018 as the baseline survey.
- Describe the characteristics of those hospitals that consistently participate in the mPINC surveys as well as of those that do not, and characteristics of hospitals 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 these practices over time.

- Provide feedback to CDC, state health departments, and hospitals to inform programs and practices.

Without this information, CDC and state health departments are unable to know the extent to which hospitals implement specific breastfeeding-related maternity care practices that have been identified as supportive based on extensive empiric evidence.

CDC will use information from the mPINC surveys to identify, document, and share information related to incremental changes in practices and care processes over time at the hospital, state, and national levels. Data are also used by researchers to better understand the relationships between hospital characteristics, maternity-care practices, state level factors, and breastfeeding initiation and continuation rates.

The planned methodology for the 2018 and 2020 national survey of Maternity Practices in Infant Nutrition and Care (mPINC) will closely match that of the previously administered mPINC surveys in 2007, 2009, 2011, 2013, and 2015.

Changes described in this Reinstatement with change include:

- Deployment of 2018 and 2020 Surveys.
- Data collection via web-survey only (no paper surveys).
- Surveying hospitals only (not birth centers).
- Requesting contact information for two individuals per facility (previously only one).
- An updated American Hospital Association (AHA) database will be acquired to identify hospitals not currently on the list for recruitment in the 2018 survey. This process will not occur for the 2020 survey, but additional hospitals identified from the new database for 2018 will be included in the 2020 survey.
- 2018 and 2020 survey content has been updated.

Birth centers will no longer be included in the survey because they frequently have optimal infant feeding-related maternity care practices, and less than 1% of US births occur at birth centers. In comparison over 98% of US births occur in hospitals. Additionally, birth center participation rates (67% in 2015) have historically been lower than hospitals (83% in 2015) and have declined over the past survey cycles from 88% in 2007 to 67% in 2015 (compared to 82% to 83%, respectively, for hospitals) suggesting that, as a tool for intervention, the survey is less useful to them. Removing birth centers will not have an impact on multi-year comparison as data from the new surveys (2018 and 2020) will not be compared to the historical survey data (2007, 2009, 2011, 2013, and 2015) since many questions have been revised. Any multi-year comparisons will only be made between the new data.

3. Use of Improved Information Technology and Burden Reduction

For the 2018 and 2020 surveys, a computer assisted telephone interviewing (CATI) system is used to screen hospitals identified as potential respondents to the mPINC survey. The purpose of the telephone call is four-fold: (1) to verify that the hospital provided maternity care in the previous calendar year, (2) to determine the most appropriate contact person(s) for that hospital, (3) to obtain contact information about the contact person(s) identified, and (4) to determine if the hospital provides maternity care at other locations, and, if so, to obtain contact information for the other sites. Use of the CATI reduces the burden to the contact person since it normally reduces the amount of time necessary to complete a screening interview and captures the data more accurately.

The hospital will complete the survey using a web-based system from which each hospital's data are electronically submitted via a secure server directly to the contractor. Use of the web-based system will minimize burden and obtain data in the most efficient way possible and is designed to support an ongoing infrastructure for subsequent data collection cycles.

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,¹⁹⁻²¹ 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 or any other federal survey capturing hospital practices or women's experiences during the intrapartum period. To our knowledge, no other existing 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 survey needed 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 that no similar data collection system existed, 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, hospitals, state health departments, researchers, and other stakeholders have come to identify CDC as their expected source for this kind of information.

5. Impact on Small Businesses or Other Small Entities

Since the survey population includes all hospitals 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 survey. Skip patterns built into the survey allow small hospitals to answer only the sections that apply to the types of care they provide, thereby reducing the burden on these facilities. For example, questions on surgical births (Cesarean sections) and neonatal intensive care are skipped by those 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 to respond. Additionally, the use of the CATI screening instrument and web-based survey completion tool reduces the burden on participating small businesses.

The elimination of birth centers from the sample is expected to drastically reduce the number of small businesses impacted by this survey. According to the U.S. small business administration, a hospital is considered a small business if they have less than \$38.5 million in receipts annually.²² We estimate that the proportion of hospitals included in this study that meet the criteria of being a small business will be nominal.

6. Consequences of Collecting the Information Less Frequently

The initial survey in 2007 was the first of an ongoing, systematic data collection for the continued assessment of breastfeeding-related maternity care practices. Administration of the 2009, 2011, 2013, and 2015 surveys provided new assessments of practices nationwide and allowed opportunities to examine changes in practices over time. A further and vitally important role of administering and reporting on the 2011, 2013, and 2015 surveys was 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 their own data benchmarked against peer facilities as well as their state's data benchmarked to facilities across the nation. Biennial data from this survey have now become integral elements of activities and initiatives by government partners at the Federal and State levels as well as national and community partner organizations and clinical and public health stakeholders alike. These partners and stakeholders now rely on these data because they are predictable, reliable, and well-suited to unifying communication and analysis of activities across multiple audiences.

Changes in maternity care practices related to breastfeeding occur moderately rapidly. While our partners would prefer annual assessment of hospitals' practices, CDC has thus far determined biennial assessment to be adequate to characterize the major issues of concern without excessive loss of point-in-time data, in order to minimize the burden as much as possible on survey respondent facilities. Assessment less frequently than every 2 years would not be able to fully capture practice changes as they occur in real time, making public health program planning more difficult.

The goal of this work is to not only to continue biennial assessment of hospital practices related to breastfeeding as part of CDC's national system for monitoring, but to fully utilize the data gathered to date and provide meaningful results to participating hospitals, CDC, states, and other stakeholders.

Less frequent collection of these data would disrupt not only CDC's work to improve maternity practices related to breastfeeding but that of partners across the U.S. as well, inadvertently undermining their ability to carry out their intended and funded activities.

There are no legal obstacles to reduce the burden.

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 requested.

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

A 60-day Federal Register Notice was published in the *Federal Register* on November 22, 2017, Docket No. CDC-2017-0086, Vol. 82, No. 224, p. 55609-55611 (3 pages), see **Attachment 2a**. CDC received 12 unique responses, including individuals and organizations that are outside of CDC. For a summary of the public comments, see **Attachment 2b**. Within these 12 unique responses, one respondent did not include comments and one response included comments that were out of scope, thus there were 10 responses with substantive comments. There were no comments expressing concerns or suggestions related to participant burden.

The 10 responses with public comments were supportive of the mPINC survey. From these 10 responses, there were four suggestions related to the survey methodology and one comment that offered a suggestion related to the scoring of the survey. The CDC response and how it plans to address these are summarized in **Attachment 2b**.

CDC benefits from ongoing exchange, dialogue, and coordination among all federal agencies whose work involves infant feeding. In response to the Surgeon General's 2011 *Call to Action to Support Breastfeeding*, the Interagency Federal Breastfeeding Workgroup was established and holds regular meetings to discuss and collaborate on issues related to breastfeeding support. Discussion of the mPINC survey is a consistent priority to meet shared and related information needs. Relevant staff from the following federal departments are members: U.S. Department of Agriculture, U.S. Department of Defense, U.S. Department of Health and Human Services, and U.S. Department of Labor.

CDC has a history of consulting with non-CDC experts on breastfeeding, surveillance, and public health program needs related to breastfeeding supportive maternity care practices. In 2003, the CDC brought together diverse experts to hear their perspectives on a national system of monitoring breastfeeding-related maternity care. The CDC decided to establish an ongoing assessment and monitoring of maternity care practices related to breastfeeding among all U.S. facilities that routinely provide maternity care services, see report **Attachment 4a**. This led to first mPINC survey administration in 2007.

CDC continues to consult with non-CDC experts in the content areas specific to the mPINC survey related to survey administration, content, utility, and potential improvements. On July 1 and 2, 2014, CDC consulted with non-CDC experts to obtain their views on CDC's mPINC survey (**Attachment 4b**). These individuals had expertise and experience in one or more of the following areas: clinical and public health medical care, nursing care, and lactation management and support, maternal and child health epidemiology, state public health program implementation, quality improvement, hospital accreditation and certification processes, and participation in and utilization of the mPINC survey. These experts provided their views to CDC on the availability of data, frequency of data collection, clarity of instructions, reporting and

reporting formats, and data elements to be reported. Table A.8 lists the non-CDC experts consulted since 2014 about the mPINC survey.

Experts from outside the CDC were consulted in 2015 and 2016 to provide input on selected data elements during the questionnaire and methodology revision process. In August, 2016, CDC held listening session at a national meeting which provided an opportunity to comment on the availability of data, survey administration, reporting format, and data elements. State breastfeeding coalition leaders and other stakeholders described their mPINC data report content, framing, format, and audience priorities, identified useful components of existing reports, and suggested new reporting formats. They find the existing mPINC Benchmark Reports valuable and useful as well as the State Reports to be user-friendly and useful. Going forward, state breastfeeding coalition leaders and other public stakeholders would like to be able to do more with the mPINC data already available to them, and would like access to unformatted data they could more easily adapt and use as needed. They would like reports in the future to retain data elements with item-level details, want hospitals to continue receiving Benchmark Reports, and want to continue having a new State Report for each survey year. They suggested that new, simplified reports would be useful to them in order to communicate with others who are unfamiliar with mPINC in particular or even breastfeeding and maternity care practices in general.

Table 8. Non-CDC Experts Consulted

Date Consulted	Name, Title	Agency, Location	E-mail	Phone Number
2014	Tina Cardarelli, IBCLC State Breastfeeding Coordinator	Indiana Perinatal Network Indianapolis, IN	tcardarelli@indianaperinatal.org	317-518-5146
2014	Tricia Cassi, BSS, IBCLC WIC State Breastfeeding Coordinator	Vermont Department of Health — WIC Burlington, VT	Tricia.Cassi@vermont.gov	802-652-4177
2014	Sylvia Edwards, RN, MS, APRN, IBCLC, RLC Advanced Nursing and Lactation Services Coordinator	University of Alabama Birmingham Hospital Birmingham, AL	sjedwards@uabmc.edu	205-996-7351
2014, 2016	Lori Feldman-Winter, MD, MPH Head of Adolescent Medicine Division Professor of Pediatrics	Children's Regional Hospital at Cooper Camden, NJ	Winter-Lori@CooperHealth.edu	856-968-9576
2014	Cinny Kittle Director of Health Improvement Initiatives	West Virginia Hospital Association Charleston, WV	ckittle@wvha.org	304-344-9744
2014, 2016	Trish MacEnroe Executive Director	Baby-Friendly USA, Inc. Albany, NY	tmacenroe@babyfriendlyusa.org	518-621-7982
2014, 2015	Rebecca Mannel, BS, IBCLC, FILCA Director of Lactation Services	University of Oklahoma Health Sciences Center Oklahoma City, OK	rebecca-mannel@ouhsc.edu	405-271-4350
2014	Anne Merewood, PhD, MPH, IBCLC Associate Professor of Pediatrics Boston University School of Medicine	Boston University School of Medicine Boston, MA	Anne.Merewood@bmc.org	617-414-7902
2014	Celeste Milton, MPH, BSN, RN Associate Project Director	The Joint Commission Oakbrook Terrace, IL	Currently Retired	Currently Retired
2014	Marianne Neifert, MD, FAAP Clinical Professor of Pediatrics	University of Colorado Denver School of Medicine Denver, CO	info@dr-mom.com	303-841-0205
2014	Carina Saraiva, MPH Research Scientist California Department of Public Health	California Department of Public Health Sacramento, CA	Carina.Saraiva@cdph.ca.gov	916-650-0333

9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be made to the survey respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This ICR has been reviewed by staff in CDC's National Center for Chronic Disease Prevention and Health Promotion, who determined that the Privacy Act is not applicable. (see **Attachment 10**, Privacy Impact Assessment)

Because the mPINC survey is administered to hospitals and not to individuals, all of the data provided in the mPINC survey are at the hospital level, related to organizational practices across the entire population under that hospital's care. The items of information to be collected are facility size and other characteristics; number of staff devoted to breastfeeding support and the types of lactation care providers; facility practices; the nature of breastfeeding education and support the health care facility makes available to mothers; staff training; and prevalence of specific facility policies that have been elsewhere identified as influential for breastfeeding and maternal and infant health.

Through the screening process, a contact person at each participating hospital is contacted. Minimal information in identifiable form (IIF) is collected from this contact person solely as a means to route delivery of login instructions for completing the survey using the web-based system and the Benchmark Report to that hospital. The IIF collected is: name, title, telephone number, e-mail address, and mailing/FedEx address. CDC collects no data to allow identification of the individual(s) who actually complete the web-based survey for a given hospital. Although piloting revealed that this often is the 'point person,' this is not necessarily the case. As such, the IIF for each hospital's contact person has no analytic or empiric value in connection to that hospital's data. It is therefore maintained securely for routing purposes only, and is kept separate from all analytic files.

A contractor (currently Battelle) screens eligible hospitals and gathers hospitals' data on behalf of CDC. Care is taken to treat the survey data in a secure manner. Contractor staff receive training in data management and security.

All hospitals in the United States and Territories that provide maternity care services are invited to participate in the mPINC survey. A brief screening interview is conducted by telephone to confirm each hospital's eligibility and contact information (see **Attachment 5**, Screening Call Script). Each hospital receives a survey cover letter (cover letter paper: **Attachment 6a**, cover letter e-mail: **Attachment 6b**) that provides an overview of the project and requests the hospital's participation. This information is reiterated at the beginning of the actual survey instrument (**Attachment 6c** mPINC Facility Survey) and in follow up contacts (Reminder (paper): **Attachment 6d**, Reminder (e-mail): **Attachment 6e**, Non-responder follow-up: **Attachment 6f**, Non-responder script: **Attachment 6g**).

The contractor assigns a unique study identifier code to each respondent hospital. Although the web link to the survey is sent to the contact person at that hospital, the completed survey (electronic data files containing the survey response data) is identified only by the study identifier code and does not include any names or IIF. Hospitals are informed that data may be used for additional approved research purposes.

Hospitals are given a password for access to the contractor's website. All data submitted to the contractor's website travels via secure data sockets and is stored in a database behind the contractor's server firewall. Project files containing survey data are transferred to CDC using secure file exchange or are password protected and access at the contractor site is limited to

authorized project staff. Completed hard copy, paper questionnaires will be returned to the survey recipient as we are no longer accepting paper questionnaires. The returned survey will be accompanied by a letter providing the web link to the survey, and when an e-mail address is also available for the recipient, we will also send an e-mail acknowledging receipt of the paper survey and directing the recipient to the web survey (Returned surveys paper: **Attachment 6h** and Returned surveys e-mail: **Attachment 6i**). There is no website content directed at children under 13 years of age.

No IIF or hospital names are ever used in any published reports of this study. CDC presents all survey reports and findings in aggregate so individual hospitals' responses cannot be identified. Data are treated in a secure manner, unless disclosure is otherwise required by law.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This information collection request has received IRB approval. A copy of the IRB approval letter is included as **Attachment 7**.

No questions regarding topics that are typically considered to be of a sensitive nature or any other topic of a sensitive nature will be asked in this survey. 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.

We do not anticipate that the respondent hospitals will consider any of the questions about hospital practices to be sensitive, and no hospital has yet raised this concern in any of the previous iterations of the survey; however, the processes described above have been implemented as further safeguards to survey recipient privacy.

12. Estimates of Annualized Burden Hours and Costs

Estimate of Annualized Burden Hours

Respondents are hospitals that offer maternity care. We base all estimates of numbers of facilities contacted, burden hours, and costs on our data and experiences from fielding the mPINC survey in 2007, 2009, 2011, 2013, and 2015. Table 12a summarizes estimated annualized burden hours for two cycles of data collection in 2018 and 2020, annualized over the three years of the current clearance request.

Potential respondent hospitals will be screened to confirm eligibility (see **Attachment 5**, Screening Call Script). There were 2,928 hospitals on the 2015 facility list; therefore, we estimate that approximately 2,928 hospitals will participate in initial screening lasting one minute or less (see Part A of the instrument). We believe this to be a conservative estimate because, although new hospitals may be added to the list, some hospitals will close or be consolidated, and while we attempt to reach every hospital, not every hospital completes the screening. Of these 2,928 hospitals, an estimated 85.62% (2,507) will be found to be eligible, and will complete the screening process (additional burden of four minutes per respondent; see Part B of the instrument). We then anticipate that 85% (2,131) of the 2,507 that completed Part A will respond to the survey itself. Past surveys have observed 81-83% response rate, so this estimate errs on a higher response rate.

To annualize these estimates, the number of hospitals that respond for one cycle were multiplied by the two cycles and divided by the three years of OMB coverage [e.g., (2,928 respondents for Part A * 2 cycles)/3 years of OMB coverage]. The 2, 928 responding to Part A was annualized to 1, 952; the 2,507 responding to Part B was annualized to 1,672; and the 2,131 completing the survey was annualized to 1,421 (see **Attachment 6c**, mPINC Facility Survey). Annualized numbers were rounded to the nearest whole number. The burden for each Facility Survey is 30 minutes. The total estimated annualized burden hours are 855.

Table 12a. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours
Maternity Hospital	Screening Call Script Part A	1,952	1	1/60	33
	Screening Call Script Part B	1,672	1	4/60	111
	mPINC Facility Survey	1,421	1	30/60	711
Total					855

Estimated Annualized Burden Costs

We estimate the total annualized cost to respondents to be \$27,744.75. We anticipate that staff responding to the Screening Telephone Call and returning the Facility Survey on behalf of their facility will be Registered Nurses or equivalent general medical and surgical hospital employees. The U. S. Department of Labor, Bureau of Labor Statistics estimates their average hourly wage rate at \$32.45 (see **Table 12b.** for detailed information).²³

Table 12b. Annualized Cost to Respondents

Type of Respondents	Form Name	Number of Respondents	Total Burden (in Hours)	Average Hourly Wage	Total Cost
Maternity Hospital	Screening Call Script Part A	1,952	33	\$32.45	\$1,070.85
	Screening Call Script Part B	1,672	111	\$32.45	\$3,601.95
	mPINC Facility Survey	1,421	711	\$32.45	\$23,071.95

Total					\$27,744.75
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13. Estimate of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to the Federal Government

The surveys were designed in collaboration with Battelle. Battelle will implement the 2018 mPINC survey through a contract with CDC (CDC Contract No. 200-2014-F-59969, Option 2), and Battelle will implement the 2020 mPINC survey through a contract with CDC ((CDC Contract No. 200-2017-F-93801, Core Task).

Each cycle of data collection and analysis takes approximately eighteen months to complete (see Estimated Timeline – Table A.16) with reporting and benchmarking occurring in the last six months following data collection. The estimated annualized cost to the government to conduct two biennial surveys including administration, reporting, and benchmarking is \$539,543.92. The annualized CDC costs are estimated as follows: Salary \$117,552.00; Fringe (\$29,388.00; at 25%); and General and Administration \$1,590. The cost of the Battelle contract (CDC Contract No. 200-2014-F-59969, Option 2) for the 2018 survey is \$586,978 which covers the cost of survey administration, distribution and collection, data entry, coding and cleaning, data analysis, and reporting and benchmarking. The cost of the Battelle contract (CDC Contract No. 200-2017-F-93801, Core Task) for the 2020 survey is \$501,249.00 which covers the cost of survey administration, distribution and collection, data entry, coding and cleaning, data analysis, and reporting and benchmarking.

Table 14. Estimated Annualized Federal Government Cost Distribution

Government Personnel	Percent Time Commitment	Hour Time Commitment	Hourly Basic Rate	Annualized Total
GS-13 or equivalent	60	1,245	\$40.50	\$50,423
GS-13 or equivalent	40	835	\$40.50	\$33,818
GS-13 or equivalent	10	208	\$40.50	\$8,424
GS-14 or equivalent(s)	25	520	\$47.86	\$24,887
Subtotal, Government Personnel				\$117,552
Fringe Benefits (25%), Government Personnel				\$29,388
Subtotal, Government Personnel + Fringe				\$146,940
General and Administration				\$1,590
Annualized Contract Costs				\$362,742
Total Annualized Costs				\$511,272
				-

15. Explanation for Program Changes or Adjustments

This Reinstatement with change ICR reflects a reduction in the number of respondents and an annualized reduction of 248 burden hours (from the estimate for 2013-2015 to the estimate for

2018-2020). Reductions are primarily due to the elimination of birth centers from the sample.

The previous OMB approval covered two cycles of data collection in 2013 and 2015 (OMB No. 0920-0743, exp. 9/30/2016). In the current Reinstatement with change ICR, we request OMB approval to support two cycles of data collection in 2018 and 2020. There is no change to the estimated burden per response (30 minutes).

In 2013 and 2015 we estimated that 3,856 facilities would participate in the screening process. Birth centers will be removed for the 2018 and 2020 mPINC surveys. Therefore, we estimate that 2,928 hospitals will participate in screening during each data collection cycles in 2018 and 2020.

The planned methodology for the 2018 and 2020 surveys closely matches that of the previously administered mPINC surveys. As noted, there is no change to the estimated burden per response for participating in the mPINC survey (30 minutes). There are substantive changes to survey content for the 2018 and 2020 surveys to reflect changes in maternity care practices over the past decade. The revised mPINC facility survey instrument for 2018 and 2020 is included in **Attachment 6c**, mPINC Facility Survey.

Changes described in this Reinstatement with change include:

- Deployment of 2018 and 2020 Surveys.
- Data collection via web-survey only (no paper surveys).
- Surveying hospitals only (not birth). Because the 2018 and 2020 mPINC surveys will not include birth centers, the number of facilities included is anticipated to be lower than past mPINC surveys. The anticipated number of hospitals on the list for 2018 and 2020 is 2,928 and we anticipate that approximately 2,131 hospitals will complete the survey. On an annualized basis, this translates to 1,952 hospitals on the list per year and 1,451 completed surveys per year during the 3-year period of OMB coverage.
- Requesting contact information for two individuals per facility (previously only one).
- An updated American Hospital Association (AHA) database will be acquired to identify hospitals not currently on the list for recruitment in the 2018 survey. This process will not occur for the 2020 survey, but additional hospitals identified from the new database for 2018 will be included in the 2020 survey.
- 2018 and 2020 survey content has been updated.

16. Plans for Tabulation and Publication and Project Time Schedule

Table 16. Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
<i>2018 Survey</i>	
Identify hospitals to be surveyed	Fall 2018
Conduct screening telephone calls	Winter 2019
Conduct survey	Spring 2019
Data coding, entry, and cleaning	Summer 2019
Data analysis	Fall 2019

Create and distribute final reports, manuscripts, benchmarking	Winter 2020
<i>2020 Survey</i>	
Identify hospitals to be surveyed	Fall 2020
Conduct screening telephone calls	Winter 2021
Conduct survey	Spring 2021
Data coding, entry, and cleaning	Summer 2021
Data analysis	Fall 2021
Create and distribute final reports, manuscripts, benchmarking	Winter 2022

As with prior surveys, upon completion of the data analysis, a separate technical report (facility Benchmark Report) is prepared for each hospital and each state. Each report describes the objectives of the study, methods of survey administration (including the response rates to the survey), and analysis results. (See **Attachment 3h** for the most recent facility benchmarking report). The results of the survey are also disseminated to stakeholders through the publication of manuscripts in peer-reviewed journals.

As a census of all hospitals 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 prior surveys makes weighting of new data unlikely to be necessary.

If it is 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, number of births). These weights will be applied to all analyses described below if necessary.

For most analyses, the unit of analysis will be the hospital. 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 hospital in the previous year.

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 multiple surveys, when available, will be completed as well. The following types of variables are examples of data that will be examined, include hospital practices (e.g., routine newborn procedures), policies, and characteristics (e.g., teaching status).

Composite indicator variables will be constructed using multiple survey questions to reflect the extent to which hospitals have policies and practices associated with breastfeeding initiation and continuation. For each composite 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 **Attachment 8** for the algorithm used for scoring the 2015 mPINC survey. A similar scoring algorithm will be created for the 2018 and 2020 surveys, taking into account changes in the survey. The domains to be included for the 2018 and 2020 surveys are 1) Labor and delivery care; 2) Feeding of breastfed infant; 3) Breastfeeding assistance; 4) Mother/infant contact; and, 5) Discharge care.

Selected table shells are in **Attachment 9**.

For each composite indicator, Benchmark Reports are generated to compare maternity care facilities by state and region. Each hospital participating in the study receives an analysis of its own scores on these indicators compared to others of a similar type. Examples of such reports are shown in **Attachments 3d, 3e, 3f, 3g and 3h**.

Univariate distributions and summary statistics are generated to describe hospital 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 are conducted on items in the remaining sections of the questionnaire and constructed indicator variables in order to describe hospital maternity care practices and policies related to breastfeeding.

Bivariate analyses are conducted to: 1) obtain hospital subgroup percentages or means on survey measures, 2) test for subgroup differences on those measures, and 3) test for associations between hospital characteristics and practice and policy measures. In planning and conducting these analyses, hospital characteristics (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 are also conducted to examine the variation in hospital scores by hospital characteristics such as having a level 3 neonatal intensive care unit, being a teaching hospital, and geography (state and region). Table Shells 1 and 6 are examples of bivariate analyses of facility scores. Table Shells 2-5 are examples of bivariate analyses of the first dimension of maternity care – labor and delivery. These tables are repeated for all of the other dimensions of maternity care.

Beginning in 2020, univariate and bivariate analyses will be carried out to evaluate changes in hospital practices over time the mPINC 2018 survey as a baseline. For hospitals that responded to previous iterations of the surveys, a comparison of scores given in each year of participation can be done to show where there have been improvements. National reports will examine trends overall and broken down by facility type and location.

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

No exemption from display of expiration date is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to certification are sought.

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