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

Revision

OMB Control No. 0920-0743

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Supporting Statement A

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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 are to provide timely and specific, action-oriented information (hospital-specific mPINC Hospital Reports) to participating hospitals in the United States and territories, and to provide aggregated national and state data to a wide spectrum of national and state-level stakeholders (mPINC National Results Report and state-specific mPINC 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 and policies. Aggregate national and state reports 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 secure Web-based survey, which assesses specific 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 survey 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). Given the census design (i.e., surveying all eligible hospitals), statistical significance testing of differences is not warranted. Beginning in 2022, trend analyses using data from multiple survey years collected beginning in 2018, will be completed as well.

JUSTIFICATION SUMMARY

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

In this Information Collection Request (ICR), the Centers for Disease Control and Prevention (CDC) request approval of a Revision from the Office of Management and Budget (OMB) to conduct 2022 and 2024 follow-up surveys of the national Maternity Practices in Infant Nutrition and Care (mPINC) survey. The Revision request is based on previous experience with administration of a baseline mPINC survey in 2007 and follow-up surveys in 2009, 2011, 2013, 2015, and the administration of revised mPINC surveys in 2018 and 2020. OMB approval is requested for three years to conduct the 2022 and 2024 mPINC surveys.

There is substantial evidence on the social,[1] economic,[2, 3] and health benefits of breastfeeding for both the mother[4-6] 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*) a mother experienced during the birth hospitalization and her 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 the 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 breastfeed successfully. 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 these practices over time, CDC began in 2003, at the request of experts in the maternal-child health field, developing the national mPINC 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 participating facilities. The initial survey in 2007 established baseline measures of breastfeeding supportive maternity practices across the United States and territories and the extent to which these practices varied 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), surveys in

2013 and 2015 (OMB Control Number 0920-0743, expiration date 9/30/2016), and 2018 and 2020 (OMB Control Number 0920-0743, expiration date 10/31/2021).

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 need for biennial census data as well as to examine changes in maternity care practices over time. Response rates for past survey years (2007-2018) have attained or exceeded 70 percent, reflecting hospitals' strong interest in participating in the mPINC survey and their increasing recognition of the survey's value to their work. Additionally, data from the survey can be used by hospital leadership to improve breastfeeding-related maternity care practices and aggregate data can be used by state public health departments and CDC to inform programmatic activities. Data are also used to answer questions raised by independent researchers, as requested.

Thus, CDC requests OMB approval to conduct planned mPINC surveys in 2022 and 2024 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** Public Health Service Act [42 U.S.C. 241]).

A2. 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 monitor 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 United States and territories, and trends in these practices were analyzed through 2015. In 2018 the mPINC survey items were redesigned and subsequent survey years will allow for analysis of trends, identifying new or on-going priority needs and opportunities for collaboration and improvement.

This Revision ICR includes a sample of recent documents illustrating the variety of ways CDC strives to ensure full use 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** (CDC Survey Website) provides an overview of the dedicated website CDC created for hospitals responding to the mPINC survey, state partners, researchers, and other interested stakeholders. The website is updated as needed and provides links to the national and state reports. The mPINC Hospital Report is the customized information and technical report that CDC creates and provides to every maternity hospital that participates in the mPINC survey. An example of the 2018 Hospital Report is shown in **Attachment 3b** (2018 mPINC Hospital Report). CDC has published studies based on mPINC data in the Morbidity and Mortality Weekly Report[16-20], and researchers use the data to gain a better understanding of the relationships between hospital characteristics, maternity-care practices, state level factors, and breastfeeding initiation and continuation rates.

In 2020 CDC researchers published a manuscript describing how the mPINC survey has been used for surveillance, quality improvement, and research and its value as a tool for hospitals, organizations, governments, and researchers to improve breastfeeding support provided to mothers and infants[21].

To facilitate completion of the questionnaire, hospital respondents will be able to access a page with answers to frequently asked questions, and an example is included in **Attachment 3c**. Screenshots of the mPINC 2022 survey are in **Attachment 3d**.

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, indicating their provision of evidence-based breastfeeding-related maternity care, was 1.8% in 2007[22], and increased to 28.2% in 2020[23].

The purpose of the revised 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 2022 and 2024 in all U.S. states and territories. The design of this survey remains a national census of hospitals routinely providing maternity care, based on careful review of advantages and limitations of various survey designs and extensive input from stakeholders and experts in evaluation of hospital maternity care practices. Several issues highlight the need for a national census of maternity hospitals, including:

- Address variation in breastfeeding rates and maternity care practices: Breastfeeding rates vary widely across U.S. states and highlight the need for state and local-level data.
    - Breastfeeding attitudes differ significantly by geography[24] and are likely manifested in maternity care practices related to breastfeeding.
    - Maternity care practices differ by state[17] and geographic region[17,18] and hospital size[18].
    - The proportion of hospitals implementing 10 practices that serve as the basis for the WHO/UNICEF Baby-Friendly Hospital Initiative, the Ten Steps to Successful Breastfeeding (Ten Steps) differ by state[20].
- State and local level data are needed: 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 and attain public health breastfeeding goals. A national census design allows for state-level analysis to address individual local research and policy needs and is especially important for small states and states with few hospitals.
- Tailored information is needed: Participating hospitals receive their hospital-specific technical report with their own data compared to aggregate data (national, regional, and hospitals with a similar number of annual births). A national census design allows for

hospital-specific data to inform quality improvement efforts. Many hospitals have used their mPINC data to understand their maternity practices, to make changes to improve the quality of care they provide, and to help them work toward earning the Baby-Friendly designation.

- Diversity is captured among maternity care provided: The broad diversity among maternity care provided by hospitals in the United States and lack of generalizability among hospitals makes it problematic to identify and recruit a sample of hospitals that could legitimately be considered representative of other hospitals. Therefore, a national census design is needed to capture the spectrum of maternity care provided.

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. Examples of state actions include:
    - There are many state-specific recognition programs designed to acknowledge hospitals for implementing a portion or all of the Ten Steps to Successful Breastfeeding, and at least five states use state-specific mPINC data to inform theses programs[21].
    - Four states have used their mPINC data to inform state-based quality improvement initiatives. An example of state-based quality improvement initiative is Healthy Tennessee Babies which developed a breastfeeding toolkit (http://healthytennesseebabies.com/toolkit.aspx) to help hospitals improve their breastfeeding practices[21].
- Participating hospitals have used their mPINC Benchmark Reports to initiate internal improvement processes and prioritize these activities[21].

The availability of detailed, hospital-level data on maternity practices and logistics has been an invaluable element of pandemic and disaster response. During the 2009 H1N1 pandemic, mPINC data about the prevalence and locations of facilities with separate newborn nurseries and/or rooming-in for mothers and infants during the birth hospitalization informed CDC's development of H1N1 guidance to help U.S. hospitals continue safely caring for mothers and infants. During the early phases of the global coronavirus disease 2019 pandemic, routine maternity care practices (e.g., maternal–infant rooming-in) were disrupted over concerns of transmission of the coronavirus from an infected mother to her newborn. A supplemental mPINC questionnaire was administered to the hospitals which completed the 2018 mPINC survey to understand how infection prevention and control practices associated with the coronavirus pandemic may have impacted breastfeeding supportive maternity care (Paperwork Reduction Act

waiver approved 6/24/2020 under Section 319 of the Public Health Service Act [42 U.S.C. 247d]). The CDC published the findings of the survey in the Morbidity and Mortality Weekly Report[25].

The 2022 and 2024 surveys will allow examination of changes in breastfeeding supportive maternity practices over time, including monitoring any on-going changes resulting from the coronavirus pandemic. Specifically, goals of the mPINC survey are to:

- Examine point-in-time analyses of variation in breastfeeding-related maternity care practices across 50 states and territories and by other hospital characteristics such as size (e.g., number of annual births).
- Examine changes in practices reported by hospitals every two years beginning in 2020, using 2018 as the baseline survey.
- Describe the characteristics of hospitals that consistently participate in the mPINC surveys and characteristics of hospitals that consistently implement maternity care practices more and less conducive to promoting breastfeeding initiation and continuation as well as 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, and state level factors.

The planned methodology for the 2022 and 2024 mPINC survey will closely match that of the previously administered mPINC surveys in 2007, 2009, 2011, 2013, 2015, 2018, and 2020. The planned methodology includes contacting all hospitals in the United States and territories that provide maternity care services to invite participation in the mPINC survey, conducting a brief screening interview by telephone to confirm each hospital's eligibility and contact information (see **Attachment 4a**, Screening Call Script-Part A; **Attachment 4b,** Screening Call Script-Part B), sending each eligible hospital a survey cover letter (**Attachment 5a**, Survey cover letter paper; **Attachment 5b,** Survey cover letter email) that provides an overview of the project and invites the hospital's participation. The purpose of the survey and information about the protection of the privacy and confidentiality of information is included on the mPINC survey instrument (**Attachment 5c** mPINC Hospital Survey) and in follow up contacts (**Attachment 5d** Reminder (paper); **Attachment 5e** Reminder (email); **Attachment 5f,** Reminder Telephone Call Script).

Changes described in this Revision include:

- Deployment of 2022 and 2024 mPINC hospital surveys.
- Acquire an updated American Hospital Association (AHA) database to identify hospitals not currently on the list for recruitment. This process will occur for the 2022 survey but not for the 2024 survey. Additional hospitals identified from the new database for 2022 will be included in the 2024 survey.
- No collection of information about other hospital locations (satellite hospitals) during eligibility screening.
- Revision of 2022 and 2024 survey items to streamline the survey and ensure survey questions are consistent with implementation guidance from professional and public health organizations.
- Electronic distribution of hospital reports to participating hospitals.

A3. Use of Improved Information Technology and Burden Reduction

For the 2022 and 2024 surveys, a computer assisted telephone interviewing (CATI) system will be used to screen hospitals identified as potential respondents to the mPINC survey. The purpose of the telephone screening call is to: 1) verify that the hospital provided maternity care in the previous calendar year, 2) determine the most appropriate contact person(s) for that hospital, and 3) obtain business contact information about the contact person identified. Use of the CATI may reduce 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, improve data quality and efficiency by obtaining data entered directly by the hospital into the system. This web-based system is designed to support an ongoing infrastructure for subsequent data collection cycles.

A4. Efforts to Identify Duplication and Use of Similar Information

The CDC mPINC survey is the only national source of information that provides hospital-specific data for the vast majority of hospitals 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 national system captures this type of hospital-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 experts 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 implementing 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.

A5. 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 hospitals to answer only the sections that apply to the types of care they provide, thereby reducing the burden on hospitals. 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 hospitals may fall into this category, thus these hospitals will have less response burden and fewer items to which they need to respond. Additionally, the use of secure, online CATI screening instrument and web-based survey reduces the burden on participating small businesses.

According to the U.S. small business administration, a medical and surgical hospital is considered a small business if they have less than $41.5 million in receipts annually[26]. For the 2022 and 2024 survey administration, we estimate that the proportion of hospitals included in this survey that meet the criteria of being a small business will be nominal.

A6. 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. The mPINC survey was revised in 2018 and beginning in 2022 subsequent data will allow analysis of trends so that hospitals, partners, and stakeholders can use this information to identify priority needs and opportunities for collaboration and improvement. During summer 2020, hospitals implemented a number of practices intended to balance evidence-based maternity care with measures to prevent and control SARS-COV-2, the virus that causes coronavirus disease. Because of the pandemic, hospitals reported in-person lactation support decreased and mothers and babies were discharged

from the hospital less than 48 hours after birth. Monitoring hospital practices every two years continues to be important to assess the impact of these pandemic related infection control and prevention practices on maternity care, breastfeeding rates, and infant health[25]. These data will help CDC, partners, and stakeholders understand what types of technical assistance and resources may be needed to help hospitals continue to support breastfeeding in the context of the evolving nature of the 2019 coronavirus pandemic, future pandemics, or other emergencies.

A further and vitally important role of administering and reporting on surveys 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 that CDC will compare their own data to peer hospitals as well as their state's data compared to hospitals across the nation. Biennial data from this survey have now become integral elements of activities and initiatives by national and community partner organizations and clinical and public health stakeholders. These partners and stakeholders now rely on mPINC 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 evolve over time. 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 and minimize the burden as much as possible on survey respondent hospitals. Assessment less frequently than every two 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.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This survey complies fully with the guidelines of 5 CFR 1320.5. No exceptions to the guidelines are requested.

A8. Comments in Response to Federal Register Notice and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE

A 60-day Federal Register Notice was published in the *Federal Register* on March 19, 2021, Docket No. CDC-2021-0024, vol. 86, No. 52, pp. 14919-14921 (**Attachment 2a**, 60-day Federal

Register Notice). CDC received one non-substantive comment and one substantive comment. The public comments and the CDC response is provided in **Attachment 2b,** Summary Public Comments.

Part B. CONSULTATION

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 Federal Interagency 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 across multiple federal agencies. 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 including

- 2003: CDC brought together diverse experts to provide input on the survey design. CDC determined a census of maternity care facilities was needed.
- 2014: Non-CDC experts provided feedback on the availability of data, frequency of data collection, clarity of instructions, reporting and reporting formats, and data elements to be reported.
- 2016: Non-CDC stakeholders provided feedback on the availability of data, survey administration, reporting format, and data elements.
- 2018-2020: Non-CDC experts provided feedback on selected data elements during the questionnaire and methodology revision process.

Table A1 lists the non-CDC experts consulted since 2018 about the mPINC survey.

Date Consulted	Name	Title	Affiliation	Phone	E-mail	Role
OUTSIDE CONSULTANTS						
2018	Trish MacEnroe	Executive Director	Baby-Friendly USA, Inc. Albany, NY	518-621-7982	tmacenroe@babyfriendlyusa.org	Subject Matter Expert: Survey items related to written hospital policy
ACADEMIC INSTITUTIONS						
2018, 2019	Lori Feldman-Winter, MD, MPH	Head of Adolescent Medicine Division Professor of Pediatrics	Children's Regional Hospital at Cooper Camden, NJ Cooper University Hospital, Three Cooper Plaza Suite 309, Camden, New Jersey	856-968-9576	Winter-Lori@CooperHealth.edu	Subject Matter Expert: mPINC survey (2018); scoring and reporting (2019); infant safe sleep (2019)
2019	Stephen Patrick, MD, MPH, MS	Director, Center for Child Health Policy Associate Professor of Pediatrics and Health Policy Division of Neonatology	Vanderbilt University School of Medicine 2525 West End Ave. Suite 1200 Nashville, TN 37203	615-322-3475	stephen.patrick@vanderbilt.edu	Subject Matter Expert: Survey items related to Neonatal Abstinence Syndrome (NAS)
2020	Alison Stuebe, MD, MSc	Professor Department of Maternal and Child Health Distinguished Scholar in Infant and Young Child Feeding Department of Maternal and Child Health Professor Department of Obstetrics and Gynecology	Division of Maternal-Fetal Medicine 3010 Old Clinic Building CB #7516 Chapel Hill, NC 27599	919-966-1601	astuebe@med.unc.edu	Subject Matter Expert: Maternity care in the context of opioid use disorder
2019	Catherine Sullivan, MPH, RD, LDN, IBCLC, FAND	Director, Assistant Professor	Carolina Global Breastfeeding Institute, UNC-Chapel Hill, CB#7445, 422B Rosenau Hall, Chapel Hill, NC 27599-7445	919-843-4118	catherine_sullivan@unc.edu	Subject Matter Expert: Scoring and reporting

Table A1. External Consultations

Table A2 lists the CDC experts consulted about the mPINC survey since 2018.

Date Consulted	Name	Title	Affiliation	Phone	E-mail	Role
2019	Kristie Clarke (Elizabeth Ailes, Kathleen Krause)	Medical Epidemiologist	Division of Birth Defects and Infant Disorders	404-718-6551	vhz9@cdc.gov	Subject Matter Expert: Neonatal Abstinence Syndrome (NAS) survey items
2020	Zsakeba Henderson	Medical Officer	Division of Reproductive Health	770-488-6003	bwc5@cdc.gov	Subject Matter Expert: NAS survey items
2019	Jean Ko	Team Lead	Division of Reproductive Health	404-997-9382 (Mon) and 770-488-6083 (Tues-Fri)	fob1@cdc.gov	Subject Matter Expert: NAS survey items
2019	Christine Olson	Team Lead	Division of Reproductive Health	770.488.6243	cco7@cdc.gov	Subject Matter Expert: Infant safe sleep survey items

Table A2. Consultations within CDC

A9. Explanation of Any Payment or Gift to Respondents

No monetary or non-monetary incentives will be provided.

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by the NCCDPHP Information System Security Officer and the CDC Privacy Officer. The Privacy Impact Assessment (Attachment 6a) and the Privacy Narrative Form (Attachment 6b) are attached. The Privacy Act does not apply.

Because the mPINC survey is administered to hospitals and not to individuals, all 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 hospital size and other characteristics; maternity care and infant feeding practices; the nature of breastfeeding education and support the health care facility makes available to mothers; training of maternity staff; and prevalence of specific hospital policies that have been identified as influential for breastfeeding and maternal and infant health.

Through the screening process, a contact person at each participating hospital is identified as the survey recipient. Minimal information in identifiable form (IIF) is collected from this contact person and is used as a means to invite participation, deliver login instructions for completing the survey using the web-based system, distribute the Hospital Report, and inform the contact person about survey related opportunities. The IIF collected is business contact information including

name, position, telephone number, official hospital e-mail address, and mailing/FedEx address. CDC collects no data to allow identification of the individual(s) who completes 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.

The 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.

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 and are password protected. Access to the project files at the contractor site is limited to authorized project staff.

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 survey. 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.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

CDC has determined that this project does not constitute research with human subjects (**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 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.

A12. Estimates of Annualized Burden Hours and Costs

Estimates of Annualized Burden Hours

Respondents are hospitals that offer maternity care. We base all estimates on numbers of hospitals contacted, burden hours, and costs on our data and experience fielding the mPINC survey in 2018. Table A12A summarizes estimated annualized burden hours and costs for two cycles of data collection in 2022 and 2024, annualized over the three years of the current clearance request.

Potential respondent hospitals will be screened to confirm eligibility (**Attachment 4a** Screening Call Script-Part A and **Attachment 4b** Screening Call Script-Part B). There were 3,152 hospitals on the 2018 facility list. We estimate that approximately 3,152 hospitals will participate in initial screening lasting one minute or less (**Attachment 4a** Screening Call Script-Part A). 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 3,152 hospitals, an estimated 87.9% (2,771) will 1complete the screening process (additional burden of four minutes per respondent; **Attachment 4b** Screening Call Script-Part B). We then anticipate that 70% (1,940) of the 2,771 that completed the screening process will respond to the survey itself (**Attachment 5c**, mPINC Hospital Survey). This estimate is based on the 2018 survey response rate of 70%.

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., (3,152 respondents for Part A * 2 cycles)/3 years of OMB coverage). The 3,152 responding to Part A was annualized to 2,101; the 2,771 responding to Part B was annualized to 1,847; and the 1,940 completing the survey was annualized to 1,293. Annualized numbers were rounded to the nearest whole number. The burden for each mPINC Hospital Survey is 30 minutes. The total estimated annualized burden hours are 805, as summarized below in Table A12A.

Table A12A: Estimated Annualized Burden (Hours)

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Maternity Hospitals	Screening Call Script Part A	2,101	1	1/60	35
Maternity Hospitals	Screening Call Script Part B	1,847	1	4/60	123
Maternity Hospitals	mPINC Hospital Survey	1,293	1	30/60	647
Total					805

Estimated Annualized Burden Costs

We estimate the total annualized cost to respondents to be $29,978.20, as summarized below in Table A12B. We anticipate that staff responding to the Screening Telephone Call and returning the Hospital Survey on behalf of their hospital 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 $37.24[27].

Table A12B: Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	Total Annual Burden Hours	Average Hourly Wage Rate	Total Respondent Labor Cost
Registered Nurses	Screening Call Script Part A	2,101	35	$37.24	$1,303.40
Registered Nurses	Screening Call Script Part B	1,847	123	$37.24	$4,580.52
Registered Nurses	mPINC Hospital Survey	1,293	647	$37.24	$24,094.28
Total					$29,978.20

A13. Estimate of Other Total Annual Cost Burden to Respondents and Record Keepers

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

A14. Annualized Cost to the Federal Government

The surveys were designed in collaboration with Battelle. Battelle is contracted (Order No. 200-2017-F-93801) to implement the 2022 mPINC survey and may implement the 2024 mPINC survey, dependent upon the execution of an Option Period – Optional Task. The execution of an Option Period – Optional Task is at the discretion of the Government when exercised through a modification with review and approval by CDC.

Each cycle of data collection and analysis takes approximately eighteen months to complete (see Estimated Timeline – Table A16) with reporting occurring in the last three to six months following data collection. The estimated annualized cost to the government to conduct two biennial surveys including administration and reporting is $444,163.37. The annualized CDC costs are estimated as follows: Salary $109,536.70. The cost of the Battelle contract for the 2022 survey is $503,978.00 and for the 2024 survey is $499,902.00. Contracts cover the cost of survey administration, data collection, coding and data cleaning, and reporting.

Table A14A. Estimated Annualized Federal Government Cost Distribution

	Annualized Cost
Federal Staff	$109,536.70
GS-13 or equivalent at 65% FTE, $50,970.40	
GS-13 or equivalent at 45% FTE, $35,400.30	
GS-14 or equivalent(s) at 25% FTE, $23,166.00	
Contractor Cost	$334,626.67
Total Cost to the Federal Government	$444,163.37

A15. Explanation for Program Changes or Adjustments

This Revision ICR reflects a reduction in the number of hospitals taking part in the survey (70% response rate, mPINC 2018 survey) resulting in an annualized reduction of 50 burden hours for a total of 805 burden hours.

The current OMB approval covers two cycles of data collection in 2018 and 2020 (OMB No. 0920-0743, exp. 10/31/2021). In this Revision ICR, we request OMB approval to support two cycles of data collection in 2022 and 2024. There is no change to the estimated burden per response for survey completion (30 minutes).

Based on our experience in 2018, we estimate that 3,152 hospitals will participate in screening during each data collection cycles in 2022 and 2024.

The planned methodology for the 2022 and 2024 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 changes to survey content for the 2022 and 2024 surveys based on experience in fielding the 2018 and 2020 surveys. The revised CDC mPINC hospital survey instrument for 2022 and 2024 is in **Attachment 5c**.

Changes described in this Revision include:

- Deployment of 2022 and 2024 Surveys.
- Acquire an updated American Hospital Association (AHA) database to identify hospitals not currently on the list for recruitment. This process will occur for the 2022 but not occur for the 2024 survey. Additional hospitals identified from the AHA database for 2022 will be included in the 2024 survey.
- Do not collect information about other hospital locations (satellite hospitals) during screening.
- Revision of 2022 and 2024 survey items to streamline data collection and better align survey questions with current professional and public health guidance related to breastfeeding supportive maternity care.
- Distribute Hospital Reports to participating hospitals by email.

A16. Plans for Tabulation and Publication and Project Time Schedule

Table A16. Estimated Time Schedule for Project Activities

Activity	Timeline
2022 Survey	
Identify hospitals to be surveyed	1 month after OMB approval
Conduct screening telephone calls	2 months after OMB approval
Conduct survey	2-8 months after OMB approval
Data coding, entry, and cleaning	9 months after OMB approval
Data analysis	10 months after OMB approval
Create and distribute hospital reports	10-12 months after OMB approval
2024 Survey	
Identify hospitals to be surveyed	24 months after OMB approval
Conduct screening telephone calls	26 months after OMB approval
Conduct survey	26-32 months after OMB approval
Data coding, entry, and cleaning	33months after OMB approval
Data analysis	34 months after OMB approval
Create and distribute hospital reports	34-36 months after OMB approval

As with prior surveys, upon completion of the data analysis, a separate technical report is prepared for each hospital (**Attachment 3b**), each state (State mPINC Report), and the nation (National mPINC Report). The results of the survey are also disseminated to stakeholders through the CDC mPINC website, publication of manuscripts in peer-reviewed journals, conference presentations, webinars, research briefs, and web-based papers.

For most analyses, the unit of analysis will be the hospital. The survey data may be analyzed using standard univariate and bivariate descriptive statistics (e.g., means, frequencies) 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.

The algorithm used for scoring the 2018 and 2020 mPINC surveys is provided in **Attachment 8**. A similar scoring algorithm will be used for the 2022 and 2024 surveys taking into account changes in the survey items. The domains to be included in the scoring for the 2022 and 2024 surveys are: 1) Immediate postpartum care, 2) Rooming-in, 3) Feeding practices, 4) Feeding

education, 5) Discharge support, and 6) Institutional management.

Each hospital participating in the survey receives an analysis of its scores on composite indicators compared to hospitals of a similar size and those in the same region and across the nation. An example of the 2018 Hospital Report is provided in **Attachment 3b**.

Univariate distributions and summary statistics are generated to describe hospital characteristics across the United States. 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, hospital type) 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.

Beginning in 2022 univariate and bivariate analyses will be carried out to evaluate changes in hospital practices over time using data from the mPINC 2018 survey as a baseline. For hospitals that participate in multiple survey cycles, a comparison of scores and/or subscores given in each year of participation can be done to show where there have been improvements. National and state reports can also be used to examine trends.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption from display of expiration date is requested.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to certification are sought.

REFERENCES

1. Kuzela ALS, C.A.; Worobey, J. Breastfeeding and mother-infant interactions. *J Reprod Infant Psychol*. 1990;8:185-194.
2. Cohen R, Mrtek MB, Mrtek RG. Comparison of maternal absenteeism and infant illness rates among breast-feeding and formula-feeding women in two corporations. *Am J Health Promot*. 1995;10(2):148-153.
3. Montgomery DL, Splett PL. Economic benefit of breast-feeding infants enrolled in WIC. *J Am Diet Assoc*. 1997;97(4):379-385.
4. Binns C, Lee M, Low WY. The Long-Term Public Health Benefits of Breastfeeding. *Asia Pac J Public Health*. 2016;28(1):7-14.
5. Labbok MH. Health sequelae of breastfeeding for the mother. *Clin Perinatol*. 1999;26(2):491-503, viii-ix.
6. Swinburn BA, Caterson I, Seidell JC, James WP. Diet, nutrition and the prevention of excess weight gain and obesity. *Public Health Nutr*. 2004;7(1A):123-146.
7. Chen A, Rogan WJ. Breastfeeding and the risk of postneonatal death in the United States. *Pediatrics*. 2004;113(5):e435-439.
8. Howie PW, Forsyth JS, Ogston SA, Clark A, Florey CD. Protective effect of breast feeding against infection. *BMJ*. 1990;300(6716):11-16.
9. Lowe NK. The Surgeon General's call to action to support breastfeeding. *J Obstet Gynecol Neonatal Nurs*. 2011;40(4):387-389.
10. Office of Women's Health. HHS Bluepring for Action on Breastfeeding. In: Services US Department of Health and Human Services, editor. Washington, D.C.2000.
11. Victora CG, Bahl R, Barros AJ, Franca GV, Horton S, Krasevec J, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *Lancet*. 2016;387(10017):475-490.
12. Fairbank L, O'Meara S, Renfrew MJ, Woolridge M, Sowden AJ, Lister-Sharp D. A systematic review to evaluate the effectiveness of interventions to promote the initiation of breastfeeding. *Health Technol Assess*. 2000;4(25):1-171.
13. World Health Organization/UNICEF. Protecting, Promoting, and Supporting Breastfeeding: The Special Role of Maternity Services.https://apps.who.int/nutrition/bfhi/en/index.html. 1989. Accessed: July 1, 2021.
14. Philipp BL, Merewood A, Miller LW, Chawla N, Murphy-Smith MM, Gomes JS, et al. Baby-friendly hospital initiative improves breastfeeding initiation rates in a US hospital setting. *Pediatrics*. 2001;108(3):677-681.

15. DiGirolamo AM, Grummer-Strawn LM, Fein SB. Effect of maternity-care practices on breastfeeding. *Pediatrics*. 2008;122 Suppl 2:S43-49.

16. Boundy EO, Perrine CG, Nelson JM, Hamner HC. Disparities in Hospital-Reported Breast Milk Use in Neonatal Intensive Care Units-United States, 2015. MMWR Morb Mortal Wkly Rep. 2017;66(48):1313-1317. https://doi.org/10.15585/mmwr.mm6648a1

17. Centers for Disease Control and Prevention. Breastfeeding-Related Maternity Practices at Hospitals and Birth Centers-United States, 2007. MMWR Morb Mortal Wkly Rep. 2008;57(23):621-625. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5723a1.htm

18. Centers for Disease Control and Prevention. Vital Signs: Hospital Practices to Support Breastfeeding-United States, 2007 and 2009. MMWR Morb Mortal Wkly Rep. 2011;60(30):1020-1025. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6030a4.htm?s_cid=mm6030a4_w

19. Lind JN, Perrine CG, Li R, Scanlon KS, Grummer-Strawn LM. Racial Disparities in Access to Maternity Care Practices that Support Breastfeeding – United States, 2011. MMWR Morb Mortal Wkly Rep. 2014; 63(33): 725-728. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6333a2.htm

20. Perrine CG, Galuska DA, Dohack JL, Shealy KR, Murphy PE, Grummer-Strawn LM, Scanlon KS. Vital Signs: Improvement in Maternity Care Policies and Practices That Support Breastfeeding-United States, 2007-2013. MMWR Morb Mortal Wkly Rep. 2015;64(39):1112-1117. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a5.htm?s_cid=mm6439a5_w

21. Nelson JM, Grossniklaus DA, Galuska DA, Perrine CG. The mPINC survey: Impacting US maternity care practices. *Matern Child Nutr.* 2020;e13092. https://doi.org/10.1111/mcn.13092

22. Centers for Disease Control and Prevention. Breastfeeding Report Card -- United States 2007. https://www.cdc.gov/breastfeeding/pdf/2007breastfeedingreportcard.pdf. 2007. Accessed: November 19, 2020.

23. Baby-Friendly USA. Upholding the Highest Standards of Infant Feeding Care. https://www.babyfriendlyusa.org/. 2020. Accessed: November 19, 2020.

24. Li R, Fridinger F, Grummer-Strawn L. Public perceptions on breastfeeding constraints. J Hum Lact. 2002;18:227-235.

25. Perrine CG, Chiang KV, Anstey EH, Grossniklaus DA, Boundy EO, Sauber-Schatz EK, Nelson JM. Implementation of Hospital Practices Supportive of Breastfeeding in the Context of COVID-19 – United States, July 15-August 20, 2020. MMWR Morb Mortal Wkly Rep. 2020; 69(47): 1767- 1770. https://www.cdc.gov/mmwr/volumes/69/wr/mm6947a3.htm?s_cid=mm6947a3_w

26. U.S. Table of Small Business Size Standards Matched to North American Industry

Classification System Codes. https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019.pdf. 2017. Accessed: November 19, 2020.

27. U.S. Department of Labor Bureau. National Occupational Employment and Wage Estimates United States. https://www.bls.gov/oes/current/oes_nat.htm. 2019. Accessed: November 19, 2020.