**Assessment and Monitoring of**

**Breastfeeding-Related Maternity Care Practices in**

**Intrapartum Care Facilities in the United States and Territories**

OMB Control No. 0920-0743

**Request for Reinstatement with Changes**

**Supporting Statement: Part B**

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Appendix I IRB Approval Letter**B. Collections of Information Employing Statistical Methods.**

**B.1. Respondent Universe and Sampling Methods**

The methodology, content, and administration of the 2013 and 2015 national survey of Maternity Practices in Infant Nutrition and Care (mPINC) will match those used in 2007, 2009, and 2011. The study population will include all facilities in the United States and Territories that routinely provided maternity care in the previous year (hospitals and free-standing birth centers, referred to in this document generally as ‘hospitals’ or ‘facilities’). Facilities will be identified using information from the American Association of Birth Centers (AABC) and the American Hospital Association (AHA) Annual Survey of Hospitals. A brief screening call to all hospitals and birth centers with ≥1 registered maternity bed will assess eligibility for participation in the future waves of the survey, identify additional locations, and identify the appropriate point of contact (contact person) in each. Hospitals that will be invited to participate in the survey include hospitals that participated in previous waves and those that were invited but did not participate in the previous waves, as well as those that have become eligible since the most recent mPINC survey. This will allow CDC to effectively monitor current practices across the U.S. and to provide customized assessment reports to the broadest range of public health partners.

Although a nationally representative sample was considered, CDC determined after consideration of extensive comment and insight from experts in the areas examined through this survey that sampling data would not allow CDC to be fully responsive to our partners’ needs as it would not allow for state- and local-level analyses to address individual local programmatic and research needs, which were expressed as top priorities by state health department experts, academic researchers, and quality improvement experts who were part of an expert panel convened to discuss issues surrounding the design of the survey (see **Appendix D – Expert Panel Meeting Final Report – October 2003**).

A national census is the only design that will allow states to individually tailor their efforts to increase progress toward meeting their public health breastfeeding goals. The census design is especially important for small states and states with few hospitals.

The wide disparities in breastfeeding rates across U.S. states highlight the need for individual, state-level data to be available for local analyses. Further evidence on attitudes towards breastfeeding across the United States reveals significant geographic differences in barriers to breastfeeding,[[1]](#endnote-1) which are likely manifested in maternity care practices related to breastfeeding as well.

Furthermore, results from the previous waves of the mPINC surveys support a census methodology (see **Appendix C-5**). An analysis of the 2007 mPINC data published in a CDC Morbidity and Mortality Weekly Report showed differences in facility practices by state and geographic region in maternity care practices and differences between types of hospitals. Mean total scores reflective of maternity care practices related to infant nutrition ranged from 48/100 in Arkansas to 81/100 in New Hampshire and Vermont. Data from mPINC 2007 and 2009 served as the basis for the August 2011 Vital Signs (**Appendix C-3**). This report examined 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). This report showed that only 3.5% of hospitals were fully implementing the Ten Steps to Successful Breastfeeding. The report also described variations in practices implemented by region and by facility size.

The survey will be administered to all hospitals and free-standing birth centers in the U.S. and Territories that provide intrapartum care. To identify these facilities, we will obtain the most recent American Hospital Association’s Annual survey of Hospitals to identify all hospitals that have registered obstetric beds or at least one birth; all non-hospital based birth centers will be identified through the American Association of Birth Centers (AABC). Our calculation of 3,856 respondents (3597 hospitals and 259 birth centers) for the screening call is based on our experience with the 2011 mPINC survey. We then estimate that approximately 14.4% of those screened will not be eligible to participate in the survey due to having not provided routine maternity care in the previous year. Estimates described in **Table B.1** are based on our experience with the 2011 mPINC survey.

**Table B.1. Estimated Annualized Respondents for 2013 and 2015 data collection cycles, by Data Collection Instrument**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Form Name | Number of Respondents in 2013 | Number of Respondents in 2015 | Total Number of Respondents | Annualized Number of Respondents |
| Screening Telephone Call Part A (partial) | 3,856 | 3,856 | 7,712 | 2,570 |
| Screening Telephone Call Part B (complete) | 3,301 | 3,301 | 6,602 | 2,200 |
| mPINC Facility Survey | 2,738 | 2,738 | 5,476 | 1,825 |

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

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

We obtained a response rate of 82 percent to the maternity care practices surveys administered in 2007 and 2009, and a response rate of 83% in 2011.

**B.2. Procedures for the Collection of Information**

This section describes information collection procedures. The discussion is divided into two subsections: (1) data collection procedures, and (2) quality control procedures.

**B.2.A. Data Collection Procedures**

A computer assisted telephone interviewing (CATI) system will be used to screen hospitals selected for possible inclusion in the study. A screening telephone call (see **Appendix G**, Telephone Screening Interview Script) will be made to all facilities identified from the most recent American Hospital Association’s (AHA) Annual Survey of Hospitals and the American Association of Birth Centers list (AABC) as having provided maternity care in the past year. The purpose of the screening 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 to whom the survey will be sent to for that hospital, (3) to obtain contact information about the contact person 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. The only personal information that is requested or collected about the contact person as part of the mPINC survey is their name and contact information, for purposes of routing the survey to the hospital. This person’s function and responsibility related to the mPINC survey is limited to receiving the survey (either via email or mail). This contact person is not required to be the person who fills out the survey on behalf of the hospital, nor is this person required to be the person who actually submits the survey back to the CDC contractor (or via the survey website).

During the screening telephone call, an e-mail address for the identified facility contact person will be collected, if available. For those who provide an e-mail address, the web-based response option will be offered first to increase the number of hospitals that submit the survey electronically. Promotion of the web-based option in 2011 resulted in 56% of hospitals submitting the survey electronically which was a 31 and 37 percentage point increase in the survey web response compared to the 2007 and 2009 mPINC surveys, respectively. A survey administration protocol similar to the 2007 and 2009 mPINC surveys will be used for hospital contacts without an e-mail address provided. Survey administration steps include the following:

**Table B.2. Survey Administration Steps**

|  |  |  |  |
| --- | --- | --- | --- |
| Administration step | E-mail address provided | No e-mail address provided | Appendix reference |
| Step 1 – Immediately following telephone screening | Send initial e-mail invitation to individual identified during screening call (contact person) that includes the e-mail invitation cover letter and a link for accessing the mPINC web survey. | Send survey packet via express mail to contact person that includes cover letter on CDC letterhead providing options of either completing a hard copy survey or a web-based version, survey questionnaire with ID label, and pre-paid business reply envelope. | Appendix H, H-1, and H-2 |
| Step 2 – Reminder contact two weeks after initial contact | Send an e-mail reminder that includes the e-mail reminder cover letter and a link for accessing the mPINC web survey. | Send a reminder letter via first class mail. | Appendix H-3 and H-4 |
| Step 3 – Non-response contact four weeks after initial contact for those who have not completed the survey | Send a survey packet via express mail that includes a non-response cover letter, survey questionnaire with ID label, and pre-paid business reply envelope. | Same as Step 3 for e-mail address provided | Appendix H-5 |
| Step 4 – Follow-up telephone call six weeks after initial contact for those who have not completed the survey | Call the contact person to encourage him/her to complete the survey. Resend the e-mail invitation if requested. | Call the contact person to encourage him/her to complete the survey. Resend the survey packet via express mail if requested. | Appendix H-6 |

The e-mail and hardcopy cover letters will be on CDC letterhead (an electronic CDC header is used for e-mail messages) and emphasize the importance of the study. The hardcopy cover letter provides options of either completing the enclosed hard copy of the survey or a web-based version by following the instructions, including a username and password, provided in the letter. The e-mail and hardcopy cover letters will provide the name and toll-free telephone number of a staff member to call with questions about the study. The letters will also include the name and telephone number of a person to call with questions regarding Human Subjects protection.

Surveys will be sent continuously over a two to three-month period. The contractor will track all returned surveys in the computer system upon receipt. As outlined above in Table B.2, two weeks after the initial invitation, a reminder e-mail/letter will be sent to each facility contact person to encourage survey completion. The e-mail/letter (see **Appendix H-3 and H-4**, Thank You/Reminder (paper letter/e-mail letter)) will include a toll-free number that can be called if the facility contact person has any questions about completing the survey or needs to have another copy of the survey e-mailed/mailed. Four weeks after sending the initial invitation, a survey packet via express mail will be sent to the contact person at all non-respondent facilities. The non-response mailing will include a different cover letter (see **Appendix** **H-5**), Non-Responder Follow-Up (paper letter)) emphasizing the importance of the study. A follow-up phone call will be made to the contact person at all non-respondent facilities six weeks after the initial invitation (see **Appendix H-6**, Non-Responder Reminder Call Telephone Script). This call will serve as a final reminder to complete the survey and provide an opportunity to answer any questions that may be delaying survey completion.

**B.2.B. Quality Control Procedures**

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

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

An emphasis on quality will continue with data editing and data entry. A mail paper and pencil instrument (PAPI) will be sent in the survey package if an e-mail address is not available for the identified facility contact contact person or if the facility has not completed the survey four weeks after receiving the initial survey invitation. To reduce data entry errors, Battelle (current contractor) programmers have developed quality control checks for the entry of hardcopy surveys. Additionally a random 10% of hardcopy surveys will be selected for quality control purposes and the hardcopy surveys will be compared against the data entered into the mPINC web survey application. A web-based survey option will also be available in order to provide faster survey response time and availability of data as well as high quality data since control checks are built in. Both methods allow us to establish an infrastructure for subsequent data collection waves.

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

Over the past 20 years, Battelle (the current contractor) has developed procedures that have been successfully used to achieve response rates of 70 to 80% to surveys of hospitals and other health care facilities. Multiple methods studies, reviews, and meta-analyses have been conducted to determine which factors lead to an increase in response rates in mail surveys. Preliminary notification, multiple follow-ups with hospitals, use of express mail, personalization techniques, sponsorship or endorsement, length of questionnaires, and individualized feedback to respondents, have shown positive effects on response rates.[[2]](#endnote-2)

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

The survey invitation will be personally addressed to the contact person who was identified as being most knowledgeable about breastfeeding-related maternity care practices during the screening telephone call. Since the name and e-mail and/or physical address of the individual will be confirmed before the questionnaire is sent, we can send the questionnaires by e-mail or express mail directly to the contact person thereby assuring fast, accurate delivery. The contact person will be given the name and toll-free telephone number to call if they have questions regarding the study. A reminder e-mail or letter will be used to encourage non-respondent facilities to complete and return the survey as will a non-response survey mailing with a new cover letter and hardcopy survey, and a final phone-call.

Response rates will be reported at each stage, i.e., the response rate from the initial mailing, the reminder, and non-response mailing. Once data collection has been completed, we will conduct a non-response analysis and assess whether it is necessary to adjust for non-response by weighting the survey data.

The response rates for all three of the previous waves were extraordinarily high, at 82 to 83%. Data from the previous waves were used to create personalized, facility-level reports for each responding facility that were confidential to their facility, and customized state-level reports for key decision-makers (state health departments, health professional and hospital administrator organizations, medical boards, etc.). Personalized, facility-level reports also provided an incentive for participants to participate in the previous mPINC surveys. We have received extensive positive feedback from hospitals and states about the usefulness of the reports and encouragement to repeat the survey to evaluate the effectiveness of actions at the facility and state levels based on information obtained from the previous mPINC surveys.

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

In developing the initial mPINC survey questionnaire, we sought input regarding the appropriateness and logic of the survey questions from a panel of experts and practitioners similar to the individuals who will be asked to complete the survey. Most of these experts have conducted surveys on breastfeeding related hospital practices before, so the procedures have generally been tested in single states or communities. Experienced survey operations staff formatted the survey questionnaire for ease of completion, as well as to facilitate coding and data entry. In 2005, while awaiting initial OMB clearance (obtained in 2007), the survey questionnaire was pre-tested in-person and over the telephone at nine hospitals in the Seattle, Atlanta, Indianapolis, and Albuquerque metropolitan areas representing urban, rural, small, large, teaching, and non-teaching hospitals, and birthing centers. The purpose of the pretest was to obtain an estimate of respondent burden, as well as to obtain comments and advice about the format, comprehensibility, ease of response and relevance of individual questions, feasibility of web-based survey response option, and to identify the most appropriate person at the facility to recieve the survey.

The pretest protocol began with calling a hospital and determining the contact person to whom to send the survey. We sought the following information:

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

Modifications to the survey questions and format were made based on comments received during pre-testing. The same survey instrument was used in the 2009 and 2011 mPINC administration and will be used in the 2013 and 2015 mPINC administration with minor modifications (see **Appendix H**, Facility Survey Instrument 2013 and 2015 mPINC Surveys). Each facility that participated in the previous waves received an individualized mPINC Facility Benchmark Report (see **Appendix C-2, C-4, and C-6** for examples). CDC is also developing mechanisms to provide information to hospitals that participated in the previous survey administrations about changes between the two survey administrations. Data from the previous surveys have been aggregated at the state level for reporting to a wide array of partners/stakeholders in each state, including state health department leadership, health professional and hospital associations, and state Medicaid agencies. With possible expansion to include reporting on changes between previous surveys similar results reporting is planned for the 2013 and 2015 surveys.

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

Paulette E. Murphy, MLIS, of the CDC Nutrition Branch is the Contracting Officer’s Technical Representative (COTR) for the study, and has overall responsibility for overseeing the design, conduct, and analysis of the study. Ms. Murphy will also approve and receive all contract deliverables. Telephone: 770-488-5849; electronic mail address PEM1@CDC.GOV.

The survey instrument, sampling and data collection procedures, and analysis plan were originally designed in collaboration with researchers at Battelle Center for Analytics and Public Health (CAPH). Battelle will conduct data collection and will perform data analysis for the 2013 mPINC survey, in consultation with CDC. The 2015 mPINC survey contract has not yet been awarded.

Jaime Liesmann Dohack, MS, RD has overall technical and financial responsibility for the study at Battelle. Ms. Liesmann Dohack will direct the overall data collection and analysis effort. She will also be responsible for writing the project reports. Telephone: (314) 993-5234 ext. 109; electronic mail address [dohackj@BATTELLE.ORG](mailto:CohenJ@BATTELLE.ORG).

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