5 Data Collection

5.1 Data Sources

PRAMS data are derived from three sources: birth certificate data, operational data, and questionnaire data. All three sources of data are combined to create a final, weighted PRAMS analysis data set. An analysis data set cannot be produced unless all three sources of data are in place.

- 5.1a Birth Certificate Data. Birth certificates are essential to PRAMS data collection for several reasons. First, they provide the sampling frame from which births are stratified and then randomly selected for PRAMS surveillance. Second, birth certificate information is used to weight PRAMS survey data so that it is representative of the population. Third, birth certificates serve as a source of demographic and clinical information about the sampled mother and the infant.
- 5.1b Operational Data. PRAMS operational data are generated by customized tracking software to assist the Project Coordinator and the Data Manager in PRAMS activities. Operational data are used to calculate response rates and to monitor the quality of operations. They are also used for analysis of PRAMS survey methodology. For a more complete description of the PRAMS Integrated Data Collection System (PIDS) software's capabilities, see Section 5.5b and Appendix A.
- 5.1c Questionnaire Data. Self-reported data are collected by mail, web, and by telephone. The PRAMS questionnaire serves as the principal source of maternal behavioral information for the time before, during, and after the mother's most recent pregnancy. More detailed information regarding the PRAMS questionnaire is provided in Section 5.4.

5.2 Methodology

5.2a Achieving Adequate Response Rates. Response rates are crucial to the quality of a surveillance system such as PRAMS, and consequently, to the ability to produce valid scientific analyses. The goal of PRAMS surveillance activities is to obtain completed interviews for 100% of sampled women. Starting with the 2007 data, the minimum acceptable overall weighted response rate for analysis of PRAMS data is 65%. Furthermore a stratum-specific response rate of 65% or higher is required to conduct stratum-specific analyses for each sampling stratum. For

previous data years the minimum acceptable weighted response rate was 70%. Because of nonresponse, actual sample sizes for PRAMS must be larger than those needed to achieve a given level of precision in epidemiologic measurements. Larger sample sizes reduce the random component of error in estimates obtained from PRAMS. However, increasing sample sizes does not compensate for response bias. Nonrandom or systematic error from response bias can only be reduced by improving response rates.

In PRAMS, one of the components of the analysis weights adjusts for nonresponse patterns because response rates vary among strata. However, weights may not adequately compensate for low response rates. The nonresponse weight assumes that the average of the answers of the respondents within a particular stratum and response category under consideration is the same as the average of the answers for the nonrespondents in that stratum and response category. Whereas this assumption seems reasonable for strata with response rates of 65% or higher, it becomes increasingly implausible for strata with lower response rates. For strata with response rates below 50%, this assumption is unjustified.

- 5.2b The Tailored Design Method. Studies of survey methodology have established specific techniques that can be used to increase response rates. The principles and practices of the mixed-mode survey methodology incorporated in PRAMS are based primarily on the Tailored Design Method (TDM). Don Dillman has developed and refined this methodology based on years of research. As stated in Section 4.3c, Dillman served as a consultant to PRAMS during its initial development. He is the author of Mail and internet surveys: the Tailored Design Method¹, a follow-up to his book Mail and telephone surveys: the Total Design Method². The key features of the Tailored Design Method, listed below, have been demonstrated to improve response rates to mail surveys.
 - i. Make multiple and varied contacts. Each contact should offer a unique appeal to complete the survey. Using different types of contacts and different messages increases the likelihood of appealing to a broader group of women, and thus, of increasing the response rates.
 - *ii. Provide a token incentive.* While financial incentives are most effective, they are not possible for some surveys. Other token

¹ Dillman DA (2000). *Mail and internet surveys: the tailored design method.* John Wiley & Sons, Inc.

² Dillman DA (1978). *Mail and telephone surveys: the total design method*. New York: Wiley-Interscience.

incentives should be used in those cases. Research has consistently shown that incentives, even small incentives, are more effective than rewards to increase response rates. Note: Although this may have been true at the time of Dillman's publications, recommendations on incentives and rewards have evolved over time as the survey climate has changed. Please refer to Section 5.6b ix for an updated discussion of incentives and rewards.

- iii. Develop a "respondent-friendly" questionnaire. The questions and instructions should be straightforward and easily understood. This not only increases the likelihood that the person will complete the questionnaire, it also increases the likelihood that valid responses will be provided.
- *iv. Provide return envelopes with first-class stamps.* The use of first-class stamps on return envelopes has been shown to increase response rates by 2%-4%. (Note that the use of first-class stamps on the outgoing mail package has no effect on response rates.)
- v. Personalize all correspondence. Letters should be addressed to an individual versus a generic title (i.e., Dear Ms. Smith versus Dear Mother).

As suggested by the name, the specific components of the Tailored Design Method can be tailored to address the needs of any particular survey. Each of these features will be discussed in more detail throughout this chapter.

5.3 Mixed-Mode Surveillance

PRAMS surveillance combines three modes of data collection: mail, web, and telephone. Because of the advantages of mail surveillance, particularly cost and (in the case of PRAMS) ready access to mailing addresses, this mode is used as the primary form of data collection. Up to three self-administered surveys are mailed to sampled women. The option to complete the survey online is offered during the mailings and runs concurrently with the mail phase. As younger women are increasingly connected to the internet through tablets, laptops, and cell phones, this mode may be more appealing than mail or telephone. Women who do not respond to the mailings or complete the survey online are followed up by telephone and encouraged to complete a telephone interview. Telephone follow-up for mail and web nonrespondents adds substantially to the number of completed questionnaires that PRAMS states are able to obtain. Aggregate data from 38 PRAMS states for 2011 show that telephone follow-up increased the overall response rate by an average of 14%, with a range of 3% to 22%. In

addition, the greatest impact in response rates is observed among hard-to-reach populations.

The combination of multiple contacts and mixed data collection modes has proven effective in increasing response rates in many populations. The specific modes selected for PRAMS complement one another to maximize response rates while minimizing cost. The advantages and disadvantages of each mode are discussed here.

5.3a Advantages and Disadvantages of Mail Surveillance.

i. Advantages.

- Data collection by mail is often less expensive than other data collection techniques. Hiring and training interviewers requires more resources than mailing self-administered questionnaires.
- Mail questionnaires prevent interviewer bias. When a face-toface or telephone interviewer varies the way a question is asked, bias and variability are introduced. Because there are no interviewers in a mail survey, this source of bias is avoided.
- Mail questionnaires may reduce response bias. Respondents may be more likely to answer difficult, unpleasant, or sensitive questions honestly if the questions are posed on paper rather than in person.
- Mailing addresses are readily available from the birth certificates that serve as the PRAMS sampling frame. We assume that the majority of addresses supplied on the birth certificates are correct. PRAMS experience has found that about 7% of mailed questionnaires are returned undelivered. It is often possible to identify alternate addresses for these cases or to identify telephone numbers for telephone follow-up.

ii. Disadvantages.

- Mail surveys tend to have a lower response rate than either telephone surveys or in-person interviews. It is easier not to respond to a mail survey than it is to refuse to respond by telephone or in person.
- Literacy or visual impairment may be issues that prevent some women from responding to a self-administered survey.

 Researchers cannot be sure of the identity of the respondent (i.e., that the sampled woman is the person actually filling out the questionnaire).

5.3b Advantages and Disadvantages of Telephone Surveillance.

i. Advantages.

- Telephone interviews tend to yield higher response rates than mailed surveys.
- Telephone interviews provide an opportunity for women with low levels of literacy to participate.
- Telephone interviews are less expensive and require fewer staff than contacting women for face-to-face interviews.

ii. Disadvantages.

- Interviewer bias may be introduced if questions are asked differently between interviewers or if the same interviewer varies the way questions are asked between interviews.
- In contacting individuals by telephone, several barriers exist that may introduce response bias:
 - o Some individuals, usually those in low-income households, do not have telephones or service may be disconnected.
 - o For those women who do have telephones, locating working numbers may be difficult. Telephone numbers are not normally available from birth certificates, and access to up-to-date sources of telephone numbers may be difficult.
 - Many women are using cell phones exclusively (no LAN lines in the home), and there is no directory available to access these numbers.
 - o Individuals with unpublished numbers and individuals who have the ability to screen incoming calls (or filter them thru Privacy Director) may be difficult to contact. Both of these situations have become more common in recent years. These are often attempts to minimize unwanted intrusions by telemarketers, and

they may negatively impact the ability of PRAMS interviewers to reach women.

5.3c Advantages and Disadvantages of Web Surveillance.

i. Advantages.

- Web data collection is less expensive than other data collection techniques. There is no staff time required to administer the interviews or key in the survey responses. There are no additional costs such as postage or telephone lines.
- Web questionnaires prevent interviewer bias. When a face-toface or telephone interviewer varies the way a question is asked, bias and variability are introduced. Because there are no interviewers in a web survey, this source of bias is avoided.
- Web questionnaires may reduce response bias. Respondents may be more likely to answer difficult, unpleasant, or sensitive questions honestly if the questions are posed online rather than in person.
- Web surveys offer the respondent the convenience of completing the survey whenever they want and do not require any follow-up effort like returning a mail survey.

ii. Disadvantages.

- Web surveys may not increase overall response rates, but just pull in respondents that would have completed a survey by mail or telephone.
- Literacy or visual impairment may be issues that prevent some women from responding to a web survey, as might computer literacy or comfort level with computers.
- Researchers cannot be sure of the identity of the respondent (i.e., that the sampled woman is the person actually filling out the questionnaire).
- Some women may not have access to the Internet and will be unable to complete a web survey.

5.4 Data Collection Instruments

5.4a Historical Development of the PRAMS Questionnaire.

The PRAMS questionnaire has been revised several times throughout the life of the project. In all cases, the development of the questionnaire has been a collaborative process between participating states and CDC. Potential topics and questions are identified and researched by staff in the states, staff in the Division of Reproductive Health at CDC, or in some cases, by other maternal and child health colleagues.

The questionnaire consists of core questions, which are included on all states' surveys. In addition, states may add additional questions that address topics of interest. For the first two phases of the survey, each state developed its own questions (state-developed questions) to add to the survey. Beginning with the Phase 3 survey, a set of standard questions was developed. States are able to choose questions from the standard set when selecting questions for their state-specific sections of the survey. They can also use state-developed questions, those they have developed on their own. Thus, the state-specific section of the questionnaire can now include two types of questions: standard or state-developed.

The first questionnaire, known as the Phase 1 questionnaire, was in the field from fall 1988 to summer 1990. The Phase 2 questionnaire was in the field from fall 1990 through 1995. Beginning in 1994, a comprehensive evaluation and revision of the questionnaire was undertaken, and the resulting Phase 3 questionnaire was in the field from fall 1995 through 1999. While selected questions were retained, revised, added, or deleted during each revision, the basic structure of the questionnaire remained the same. Each state used all core questions, which followed a chronological order through the pregnancy and early infancy of the baby. These were followed by state-added questions (standard or state-developed), which again followed a chronological order.

Another comprehensive revision was undertaken in 1999. In addition to evaluating and revising the content of the questionnaire, the questionnaire structure also underwent a major revision. Based on current survey research, the Phase 4 questionnaire was arranged in two-column format, with well-placed instructions to help respondents move through the questionnaire appropriately. Also new in the Phase 4 questionnaire was the integration of core and standard questions. Where appropriate,

standard questions that relate to core topics appeared with the core questions. Standard questions on topics not covered in the core, as well as all state-developed questions, remained in a separate section at the end of the survey. The resulting Phase 4 questionnaire went into the field with 2000 births.

In 2001, an optional "mini-revision" was offered for the first time. States were given the opportunity to make limited changes to their Phase 4 questionnaires. The scope of the revision was limited to a maximum of six standard or state-developed questions. New questions could be added, and questions could be revised or dropped only if the state had at least two years of data. Eleven states chose to participate in this "mini-revision," and their revised Phase 4 surveys were placed in the field in 2002.

Periodic reviews and revisions of the PRAMS questionnaire are an important part of maintaining data quality and usefulness. At the end of 2002, the evaluation of the Phase 4 questionnaire began. As before, the revision was a collaborative process between PRAMS states and CDC. Existing questions were evaluated and revised as necessary, new topics were explored, and new standard questions were solicited from maternal and child health colleagues. For Phases 5 and 6, the content of the core changed slightly, and several new standard questions were developed and tested thoroughly. States still had the option of inserting selected standard questions within the core section, but many standards and all state-developed questions were placed at the back of the questionnaire. CDC PRAMS developed guidelines on the order of the state-selected questions. Implementation of the Phase 5 questionnaire occurred in 2004, implementation of the Phase 6 questionnaire occurred in 2009, and the Phase 7 questionnaire was implemented in 2012.

During Phase 6, supplemental survey questions about the Pandemic Influenza A (H1N1) and seasonal influenza were implemented from December 2009-December 2010. Thirty-one states added 12 questions to their PRAMS surveys on receipt of H1N1 and seasonal flu shots during the 2009 and 2010 flu season (September 2009 – May 2010 births). The questions were developed with input from the CDC's Immunization Program. Because the questions were added after the Phase 6 survey was printed and fielded, the new questions were printed on a separate page and attached to the last page of the survey booklet. The additional questions were read at the end of the regular survey to phone respondents. An updated and revised supplemental about seasonal flu continued to be appended to the mail and phone surveys beginning in December 2010; this was revised in December 2011. Core questions about flu were added to the Phase 7 survey, and use of a flu supplement was discontinued when Phase 7 was implemented in August 2012.

Beginning in 2016, the Phase 8 questionnaire will be formatted for web administration and made available online. All future revisions of the questionnaire will include a web version. Phase 8 questions added access to dental care, E-cigarettes, electronic cigarettes and other products, baby safe sleep practices, and disaster preparation questions.

- **5.4b Criteria for Selection of Questions.** The following criteria are used to determine the content areas of the questionnaire:
 - The usefulness of the information to develop and target specific interventions to reduce infant morbidity and mortality.
 - The likelihood that valid information can be collected from the mother two to six months after delivery.
 - The estimated prevalence of the behavior, attitude, or experience.
 - The strength of the association between the behavior, attitude, or experience, and infant morbidity and mortality.
 - The availability of state-level information from other data sources.
 - The importance of the information as a covariate for the association between the behavior, attitude, or experience, and infant morbidity and mortality.
 - The likelihood that sensitive information can be elicited from the mother.
 - The state's need for the information for the 2020 health objectives or other program needs.

5.4c Types of Questions on the PRAMS Questionnaire.

- i. Core Questions. The core questions are used by all states and provide data that can be used for comparisons of maternal behaviors between the states. Core questions include (but are not limited to) the following topics:
 - Insurance coverage
 - Preconception health and care
 - Contraception
 - Pregnancy intention

- Perinatal substance use (alcohol and tobacco).
- Prenatal care (content andtiming,)
- Infant sleep environment
- Mental Health
- Household income
- Breastfeeding
- HIV testing
- ii. Standard Questions. Standard questions are often reflective of topics of interest to a majority of PRAMS states, and these questions can be used to provide comparisons among states that choose them. Standard questions may be developed by CDC, PRAMS states, or other maternal and child health colleagues, and they are pretested and field tested by CDC. The use of standard questions simplifies and speeds up the question revision process at the state level since they are finalized and tested by CDC. Standard questions include (but are not limited to) the following topics:
 - Prenatal care (barriers, satisfaction)
 - Assisted reproductive technology
 - Workplace leave
 - Psychosocial stressors
 - Social support and services
 - House and household characteristics
 - Infant health care
 - Baby friendly hospital practices
 - Injury prevention
 - Physical activity
 - Oral health
- iii. State-Developed Questions. States have the opportunity to supplement the standard questions they select with questions that address additional issues of particular importance to their individual states. State-developed questions are developed and pretested by the state, and are incorporated into the state-specific portion of the questionnaire.
- 5.4d Development of Questions. Question development and testing is a field unto itself. Extensive literature is available on the subject, and CDC can provide references upon request. Some basic principles of question development are discussed here. It will be helpful to keep these principles in mind when developing new questions for the PRAMS questionnaire.

- i. Question Structure. For self-administered surveys, open-ended questions can be problematic. First, they are more likely to be left unanswered. Second, it is difficult to get a complete answer because no interviewer is available to probe for more information or for a better understanding of the respondent's initial answer.
 - In general, closed-ended questions are a better choice for a self-administered questionnaire such as PRAMS. Because the response options of interest are printed on the questionnaire, it is easier to get a thorough response than if the question structure forced the respondent to search her memory for all relevant responses. This is particularly true for the many questions on PRAMS that ask a respondent to identify reasons for engaging in a particular behavior (e.g., reasons for not using birth control).
- ii. Question Wording. The wording of a question can impact the way in which a respondent answers. To increase the likelihood that the respondent can understand the question and provide a valid response, keep in mind the following:
 - Use simple, easily understood words.
 - Be direct and to the point.
 - Be specific. For example, if the question is specific to a certain time period, state that explicitly (e.g., "In the last three months of your most recent pregnancy...").
 - Use a neutral tone to prevent "leading" the respondent toward one response versus another.
 - Provide simple, short instructions as necessary (e.g., "Check all that apply" or "Check one answer.")
 - Be sure that every respondent can answer the question. If a
 question does not apply to a group of respondents, a filter question
 should precede it so that group can skip the question (e.g., "Did you
 ever breastfeed or pump breast milk to feed your new baby after
 delivery?").

The Question Appraisal System (QAS-99), originally developed for the Behavioral Risk Factor Surveillance System (BRFSS), provides a systematic method for evaluating newly developed questions. The QAS-99 is available on the **PRAMS SharePoint site**, and states are encouraged to use it before pretesting state-developed questions.

5.4e Pretesting the PRAMS Questions. It is critical to pretest questions before they are placed on the questionnaire. This is true whether the question is newly developed for PRAMS or whether it has been used in another setting (e.g., with another population or with another mode of administration). Pretesting questions often uncovers potential problems that the researcher may not have anticipated. It is much better to discover and correct these problems before one or more years of unusable data are collected. CDC conducts two types of pretesting on newly developed or modified English and Spanish questions; cognitive interviewing and field testing.

Cognitive interviewing. Pretesting PRAMS core, standard, and state-developed questions involves the use of cognitive techniques such as those utilized in CDC's National Center for Health Statistics (NCHS) Questionnaire Design Research Laboratory (QDRL). The respondent must be able to appropriately interpret the question, retrieve relevant information, evaluate the information retrieved, and formulate a response to the question in order to provide a valid response. Unlike traditional field-testing, the cognitive approach involves extensive probing to gain information about how individuals interpret questions and formulate responses. This technique improves the question structure to resemble the way people structure information in their memory, thereby improving questionnaire validity. Revisions to the questions are made based upon the findings of the cognitive interviews.

Beginning with the development of the Phase 3 questionnaire, NCHS/QDRL has pretested the core and standard questions using the cognitive techniques described above. A pretest summary of the current questionnaire is available upon request from CDC.

Hawaii must conduct appropriate pretests on any new or revised state-developed questions that are under consideration for the survey. Questions must be tested for both mail and telephone administration and in both English and Spanish (if applicable). A total sample of 20-25 postpartum women of various sociodemographic backgrounds (i.e., race/ethnicity, education, age) is recommended. Any revisions that are made as a result of initial pretests should undergo additional pretesting. Materials to guide Hawaii staff in these cognitive interviewing techniques are available on PRAMS SharePoint site; CDC staff is available to discuss these techniques upon request.

5.4f Field Testing the PRAMS Questionnaire. Following the cognitive interview pretests, CDC conducts field tests of core and standard questions. This provides an opportunity to ensure that revisions made

based on the cognitive testing results are appropriate. Approximately 20-25 women of various sociodemographic backgrounds (i.e., race/ethnicity, education, age) are included in the testing. Respondents are provided with a letter (or oral information for interviewer-administered format) that assures that participation is voluntary and that all responses are anonymous. Field tests are typically carried out in health department clinics and over the telephone to allow testing of both the mail and telephone versions of the survey. Field and usability testing of the web questionnaire is conducted to test the user experience with the online interface. Further, field tests are conducted in both English and Spanish.

Protocol Development Task

In **Appendix C**, describe the **pretests (cognitive interviews or field testing)** for state-developed questions, including descriptions of the participants, locations, and results. For those states that conduct surveillance in both English and Spanish, state-developed questions will require testing by the state in both languages. For all states, state-developed questions will require testing by the state in both mail and telephone formats.

Because each state questionnaire is different based on the selection of standard and state specific questions, the final step in the testing process is for states to conduct a flow assessment of the final questionnaire. For this step, Hawaii may use a convenience sample (coworkers, friends, family, etc.) of postpartum women to test its full questionnaire with all standard and state-developed questions inserted appropriately. This provides an opportunity to ensure that the questionnaire flows smoothly as a whole and that the proper skip instructions are in place throughout the questionnaire. Again, the mail, web, and telephone versions of the survey are tested, as well as English and Spanish versions (if applicable).

Protocol Development Task

In **Appendix C**, describe the testing procedures for the **flow assessment** of the Hawaii questionnaire, including descriptions of the participants, locations, and results. For those states that conduct surveillance in both English and Spanish, the Hawaii questionnaire will require testing by the state in both languages. For

all states, the Hawaii questionnaire will require testing by the state in mail, web, and telephone formats.

5.4g Rationale for Topics on PRAMS Questionnaire. Specific data and analytic needs should always determine selection of topics and questions. To ensure that the selection of a question is justifiable and will result in useful data, each PRAMS question is accompanied by a rationale for its inclusion in the questionnaire. These rationales describe the basis or justification for the question, as well as plans for how information from the question will be used. Rationales for the core questions are located in Appendix D. Rationales for the state-developed and standard questions chosen by <STATE> are located in Appendix E.

Protocol Development Task

In **Appendix E**, provide a rationale for each standard and state-developed question chosen by your state.

- 5.4h Mode of Questionnaire Administration. Survey methodology emphasizes the importance of using the appropriate questionnaire format for the mode in which the respondent will complete the questionnaire. Because PRAMS employs three modes of data collection, three types of questionnaires are required.
 - i. Format of Self-Administered Mail Questionnaire. The self-administered mail questionnaire is designed so that the respondent can read and fill out the questionnaire without the presence of an interviewer. All instructions and skips are clearly noted in the booklet so that the respondent can complete the questionnaire on her own.

Because the appearance of the questionnaire can influence response rates, it should appear inviting, interesting, and not too long or too difficult to complete. The self-administered questionnaire is restricted to 14 pages. The questionnaire is printed in booklet form on $8\frac{1}{2}$ " x 7" pages. Questions are printed on the front and back of each booklet page to increase the number of questions without affecting the perceived size of the questionnaire. A blank page at the end of the questionnaire booklet is reserved for any additional comments the mother may wish to make.

The booklet cover is reserved for the study name, the sponsoring organization, and an eye-catching logo. The name, address, and telephone number (1-800 number if available) of the state health department are printed on the questionnaire in case the addressed return envelope is lost. The issue date or edition number may be printed on the back cover.

ii. Format of Interviewer-Administered Telephone Questionnaire. The interviewer-administered questionnaire contains the same questions as the self-administered questionnaire. For telephone follow-up, however, the questions must be reformatted as necessary for oral administration. The interviewer-administered questionnaire includes prompts and instructions for the interviewer that are not read aloud to the respondent. The interviewer-administered questionnaire format ensures that all interviewers deliver questions and instructions uniformly and consistently with the mail questionnaire.

Beginning in 2006, CDC PRAMS began using a standardized Computer Assisted Telephone Interviewing (CATI) system. In 2012, PIDS replaced all the various software systems used to support PRAMS, including the WebCATI system. PIDS is designed to assist with telephone interviewer-administered questionnaires. PIDS allows the interviewer to administer the questionnaire and enter data into an electronic database while the interview is being conducted.

Each state's telephone module in PIDS is programmed with the telephone script for the interviewer to read as an introduction to the mother. The introduction provides the mother with all information she needs to provide informed consent; this is the same information that is presented in the mail cover letters. The hard copy telephone questionnaire is used to program the PIDS system to incorporate the appropriate questions, instructions, flow and skip patterns. In addition, the PIDS system records the date, time, and result of each call.

iii. Format of Self-Administered Web Questionnaire. The self-administered web questionnaire is designed so that the respondent can read and fill out the questionnaire without the presence of an interviewer. All instructions are clearly noted on the screen so that the respondent can complete the questionnaire on her own. In these respects the wording of the web version is similar to the mail version. Skip patterns are built in to the system, as in the telephone version, so the respondent is seamlessly guided to the next appropriate question. Error/warning messages will appear if an out-of-range value is entered or if a question is left blank so the respondent may correct her entries.

The web screens will include appropriate introductions, informed consent, some brief navigation instructions, and then the survey screens. Formatting of the web survey will match as closely as possible to the formatting of the mail survey.

Protocol Development Task

Specify whether your state uses web data collection.

Hawaii PRAMS will implement the web option as part of the data collection upon receipt of DOH IRB approval when the mode of data collection becomes available. The use of the web option will be conservative in that it may be introduced with the second or third mailing. The operational results of the web option will be evaluated in order to determine whether the web option assisted the program or not. Should the evaluation illustrate negative effect on data collection or response rates, the program will drop the web option.

5.4i Translations of Questionnaires. The PRAMS questionnaire is available in English and Spanish. States with a large Hispanic population may choose to utilize the Spanish questionnaire. Formatting and appearance are the same in both languages. CDC translates the PRAMS questionnaire (mail, web, and telephone versions) as well as all accompanying materials (question-and-answer brochure, etc.) into Spanish. Translations of the questionnaires by a single source ensure consistency of question content across all states and populations, and translations of questionnaires by other sources are prohibited for Spanish or any other languages.

Protocol Development Task

Specify whether your state uses Spanish questionnaires in addition to the English questionnaires.

Hawaii PRAMS does not use Spanish questionnaires.

Protocol Development Task

In practice, there may be several versions of the same questionnaire in one state. Questionnaires may be available in two languages (English and Spanish). Different questionnaires may be available for adults and minors (if physical abuse questions must be removed from minors' surveys; see **Section 10.3** for more information). To avoid confusion when assembling the mailing packets, most

states choose to vary the colors of the questionnaire booklet covers. For instance, the cover of all self-administered questionnaire booklets in English should be a different color than self-administered booklets in Spanish. It may be beneficial to vary the colors of the different phases of questionnaires as well. Describe the covers for each type of questionnaire here.

Hawaii PRAMS Questionnaire Booklet Cover History

Hawai uses a different design and/or color scheme for each phase. The questionnaire is done in English only and used for all participants. These are the colors used for the questionnaire.

1999 Pilot Surveillance and Phase II

2000-2001 Phase III

Dark Red

2002-2003 Phase IV

Purple

2004-2005 Phase V

Dark Blue Green

Very Light Peach

Peach

2012-2016 Phase VII Mint
2017-2018 Phase VIII Beige
2019-2020 Continuation Phase VIII Light Blue
2020-2021 Continuation Phase VIII Lavender

5.5 General Data Collection Procedures

5.5a Timing and Contacts. While a well-designed questionnaire is crucial for obtaining accurate and reliable data, the questionnaire design itself is but one of several factors contributing to a person's decision to respond to a questionnaire. It is the data collection procedures themselves that have the biggest impact on response rates. One of the key components to Dillman's approach to survey research is to make numerous and varied contacts, which has been demonstrated to increase response rates. PRAMS utilizes the following set of contacts based on the TDM approach. Each contact described below is required for PRAMS data collection unless noted as recommended. Recommended contacts are strongly encouraged and are consistent with Dillman's recommendations. Copies of each letter can be found in Appendix F; copies of the telephone introductions can be found in Appendix G; copies of the web introductory screens can be found in Appendix BB.

Research on mixed mode surveys including a web component have found that offering too many options for survey completion up front results in respondent paralysis and may ultimately lower response rates.⁴ It may

better to offer a single option initially, and introduce other options later in the data collection cycle. However, studies on mixed-mode surveys specific to the PRAMS population are not available, and PRAMS states may need to experiment to find out the most effective way to introduce the web survey. A conservative approach is to introduce the web option with the tickler or second mailing. An aggressive approach is to offer the web option in the preletter before offering the mail survey. Also, statements mentioning that a phone interview can be conducted upon request should not be included in the mailing where the web option is introduced.

It is imperative to conduct methodological experiments to determine the optimal time to introduce the web option. If it is determined that the timing of the web option does not have an impact on response rates, then states can choose when they prefer to introduce the web option. Once introduced, it will be mentioned in all subsequent mailings. Once the telephone follow-up begins, the web option will not be actively discussed with respondents, but only offered if a respondent specifically requests it.

Protocol Development Task

Specify the mailing where the web option will be introduced. Provide results of any operational experiments conducted on the introduction of the web option to justify your selection or provide a rationale for your choice.

Hawaii PRAMS will implement the web option as part of the data collection upon receipt of DOH IRB approval when the mode of data collection becomes available. The use of the web option will be conservative in that it may be introduced with the second or third mailing. The operational results of the web option will be evaluated in order to determine whether the web option assisted the program or not. Should the evaluation illustrate negative effect on data collection or response rates, the program will drop the web option.

i. Preletter. This is a brief letter that is sent a few days to one week in advance of the questionnaire. It informs the woman that a survey is forthcoming while providing only minimum detail about the project itself.

Optional: The preletter can be used to introduce the option of completing the survey online for states using the web mode and provide the URL and passcode for accessing the web survey. A QR scan code is also provided for users with mobile devices.

- ii. First Questionnaire Mailing. The questionnaire is sent with a cover letter that describes the project. Other appropriate materials (e.g., informed consent document, incentive, question-and-answer brochure, resource list, calendar, return envelope) are included as well. If the web option is introduced in an earlier mailing, the web option is again offered along with the URL and passcode for access to the web survey. A QR scan code is also provided for users with mobile devices.
- iii. Tickler (Reminder Letter). This letter is sent to nonrespondents 7 to 10 days after the questionnaire to remind the woman to complete the questionnaire and to offer thanks in case she has already replied. A postcard is inappropriate for PRAMS surveillance because the contents of a postcard are not private.

Optional: The tickler can be used to introduce the option of completing the survey online for states using the web mode and provide the URL and passcode for accessing the web survey. If the web option is introduced in an earlier mailing, the web option is again offered along with the URL and passcode for access to the web survey. A QR scan code is also provided for users with mobile devices.

iv. Second Questionnaire Mailing. Another questionnaire is mailed one to two weeks after the tickler. A cover letter informs the person that the previous questionnaire has not been returned and includes a stronger appeal for participation. Research does not support the inclusion of another incentive in this mailing packet. However, the informed consent document, question-and-answer brochure, resource list, calendar, and return envelope should be included with this mailing.

Optional: The cover letter in this mailing can introduce the option of completing the survey online for states using the web mode and provide the URL and passcode for accessing the web survey. If the web option is introduced in an earlier mailing, the web option is again offered along with the URL and passcode for access to the web survey. A QR scan code is also provided for users with mobile devices.

v. Third Questionnaire Mailing One to two weeks after the second questionnaire is mailed, a third and final questionnaire is mailed to the person. A cover letter informs the person that the previous questionnaire has not been returned and includes a stronger appeal for participation. If the web option is introduced in an earlier mailing, the web option is again offered along with the URL and passcode for access to the web survey. A QR scan code is also provided for users with mobile devices.

Research does not support the inclusion of another incentive in this mailing packet. However, the informed consent document, question-and-answer brochure, resource list, calendar, and return envelope should be included with this mailing.

- vi. Alternate Mailing (recommended). In the event of an undelivered or returned mailing, an Alternate Mailing can be sent. An alternate mailing will contain the same information that was included in the Mail One Packet. States are required to label an alternate mailing in the operations tracking software, PIDS, and also indicate where alternate mailings will be sent in their regular mailing schedule (See section 5.5a, Protocol Development Task Box). The web option will be offered in all alternate mailings.
- vii. Telephone Follow-up. Seven to fourteen days after the final mailing, telephone calls are initiated with any mail nonrespondents. Multiple telephone calls are made in an attempt to reach the mother and persuade her to complete a telephone interview.

The timing and nature of the mail and telephone contacts and mention of the web option is designed to elicit the best response rates possible. The operations tracking software, PIDS, assists in setting and managing the contact schedule.

The box below contains the recommended time frames for each mail and phone activity. Any additional mailings outside of the recommended schedule for all contacts are prohibited. To maintain data integrity, the entire data collection period should not exceed 95 days. Most women are sampled at two to three months after delivery. Assuming that most women are sampled during this time period, a data collection period of 95 days means that the infants are up to six months old when data collection ceases. Because of concerns about recall bias, CDC recommends that questionnaires be completed within six months after delivery, and no questionnaires completed after nine months of delivery will be accepted. With timely sampling procedures and timely implementation of data collection procedures, very few, if any, questionnaires will be completed beyond six months of the infant's date of birth.

Protocol Development Task

Below is the recommended schedule for all contacts. "Day 1" in the schedule refers to the day that the preletter is mailed. Subsequent tasks are performed on the scheduled days as the batch progresses.

After reviewing the recommendations below, specify the schedule (i.e., the specific day) that your state will use to conduct PRAMS surveillance activities.

Action	Recommended Time FrameHAWAII Sched	ule
1. Mail preletter	Day 1	Day 1
2. Mail first questionnaire	3-7 days after preletter	Day 8
3. Alternate 1		
4. Mail tickler	7-10 days after first questionnaire	Day _21_
5. Mail second questionnaire	e 7-14 days after tickler	Day _33_
6. Alternate 2		
7. Mail third questionnaire	7-14 days after second questionnaire	Day _52_
8. Alternate 3		
9. Initiate telephone calls	7-14 days after third questionnaire	Day _60_
10. End data collection	21-35 days after initiating phone	Day _95_

5.5b Tracking Software - PRAMS Integrated Data System (PIDS). The operations tracking software, PIDS, assists in tracking all aspects of data collection. As soon as a monthly sample is drawn from Vital Records, the tracking information in the CONTACT.DAT file (see Section 6.5c) is electronically imported into the tracking software. At that point, the contact procedures described above begin. The tracking software is designed to assist with the mail and telephone schedule. The timing between mailings and the duration of the telephone follow-up period are programmed into the tracking software according to the schedule identified above. The software then prompts the user regarding the dates activities are scheduled.

Information on completed and refused mail questionnaires is recorded in the tracking software on a timely basis. The software then uses this information to identify those mothers who are eligible for the next contact activity. Mothers who have responded or refused are excluded from the remaining mail and telephone contact activities. Similarly the software will track the web survey responses and exclude respondents who complete a web survey from further follow-up.

The tracking software has a mail merge function to manage each mailing; the software sorts the mothers into appropriate categories and prints the corresponding letters. Those mothers whose babies have died receive a special cover letter acknowledging the loss. In addition, for states using Spanish materials, the tracking software sorts women by Hispanic ethnicity and prints two letters for Hispanic women: one in English and one in Spanish.

The operations tracking software will also manage the mail schedule for women who have undelivered mail. These women may be taken out of the regular activity schedule while a new address is located. If a new address is not located before the end of mail phase, the woman will be automatically forwarded to telephone phase with the rest of the nonrespondents.

The operations tracking software is designed to standardize and electronically gather all telephone operational data including the call attempts, scheduling, call-related notes and final call disposition information. The automated tracking system will synchronize the mail, web, phone, and operations information. For example, woman will be automatically removed from the phone phase once a completed mail or web survey is documented in the operations tracking system. Similarly the system will track the progress of survey completion across modes. A survey that is partially completed by one mode can be completed in any other mode with the system automatically starting at the question where the previous session left off.

5.5c Dealing with Ineligible Mothers

Occasionally, staff will discover that a woman who is ineligible for PRAMS has been sampled. See **Section 4.2a** for a complete list of exclusions to the sampling frame. While it is extremely rare for an ineligible woman to be sampled, it does happen on occasion. In these cases, it is inappropriate to pursue a response. The mother should be dropped from the sample, using the operations tracking software's "Drop Mom" feature. They are not counted in the computation of response rates. The situations described below correspond to "Drop Mom" codes.

- i. Adoptive Mothers. The birth mother is the individual who is most qualified to complete the questionnaire. If the adoptive mother's name appears on the birth certificate, she should be excluded from the sample. If this situation is discovered after the sample is drawn, then the adoptive mother should be dropped from the sample. If the birth mother is sampled, then all attempts should be made to encourage her participation. As the majority of the PRAMS questions are related to the time just before and during the pregnancy, the birth mother is well qualified to answer these questions, and she will be prompted to skip any questions that are related to the health and care of the infant.
- ii. Surrogate Births. The survey should be completed by the surrogate carrier (or gestational carrier) and not by the intended mother (the woman who is raising the child). If the intended mother's name appears on the birth certificate, she should be excluded from the sample if possible. If this situation is discovered after the sample is drawn, then the intended mother should be dropped from the sample. If the surrogate carrier is sampled, then all attempts should be made to encourage her participation. As the majority of the PRAMS questions are related to the time just before and during the pregnancy, the surrogate carrier is well qualified to answer these questions, and she will be prompted to skip any questions that are related to the health and care of the infant.
- iii. Out-of-State Resident. Only births occurring within the state to residents of the state are eligible for PRAMS. If an in-state birth to a non-resident mother is discovered in the PRAMS sample, then the mother should be dropped from the sample.
- *iv.* **Still-born Infant**. Only live-born infants are eligible for PRAMS. In rare instances a live birth certificate may accidentally be filed when a fetal death actually occurred. If this situation is discovered after the sample is drawn, then the mother should be dropped from the sample.
- v. Duplicate Twin. The sampling procedures include coding that identifies and randomly selects only one infant from a multiple gestation (multiple births of order 4 and above are excluded altogether). Despite these procedures, occasionally more than one sibling from a multiple gestation is sampled. Matching twins or triplets when the birth certificates fall into separate batches is particularly challenging. If this situation is discovered, the twin/triplet(s) that should have been excluded based on the selection algorithm should be dropped from the sample. If they appear in different batches, the

- twin/triplet(s) in the later batch should be dropped since it is presumed the mother has already been contacted.
- vi. Other Ineligibles. There may be other situations where a mother should be dropped such as a duplicate birth appearing in the sample unrelated to a multiple gestation or a birth occurring out of state.
- No mother should be dropped unless she falls into one of the categories above or she meets one of the exclusion criteria described in **Section 4.2a**. In some situations it may be inappropriate to pursue a response even though the mother is eligible for PRAMS. In two such situations, deceased and incapacitated mothers, the "Drop Mom" feature is used to indicate no further follow-up for these mothers even though they are not actually dropped from the sample. They will remain in the sample and count as nonresponders to be consistent with standard definitions of nonresponse established by the survey research community. This change went into effect beginning with 2003 weighted data. Prior to this time, deceased and incapacitated mothers were completely excluded from response rate calculations.

In all other cases, a response should be pursued. Occasionally, staff will encounter an unusual situation, such as a woman who is incarcerated, who is undergoing drug/alcohol treatment, or who has moved out of the state. While these women may be more difficult to locate, they do meet the eligibility criteria for PRAMS and should *not* be dropped from the sample.

In the process of contacting eligible mothers, a mother or family member may indicate they are not interested in participating in PRAMS or request that no further contact attempts be made. Because participation in PRAMS is voluntary, these requests should be honored. These cases should be recorded as refusals and no further follow-up should be pursued.

5.6 Mail Data Collection Procedures

5.6a Presentation of Mailed Materials. Any mail sent to sampled women contains only PRAMS materials and not information regarding other state-specific maternal and child health programs or services.

The TDM stresses the importance of personalizing the survey package to distinguish it from junk mail and to emphasize the importance and legitimacy of PRAMS surveillance to the sampled mothers. Dillman has changed some of his specific recommendations for mailed materials based on research conducted since the original publication of his methodology. Based on the revised TDM, CDC recommends the following to improve mail response rates:

- Names and addresses may be printed directly on the envelopes or may be affixed with a mailing label.
- Use first-class postage (either stamps or postage meters) for outgoing mail. First-class mail is automatically forwarded for up to 90 days if the United States Postal Service (USPS) has a forwarding address. Additionally, "Address correction requested" or "Forwarding service requested" will ensure that the sender receives the new address for up to one year.
- Avoid bulk (third-class) mail because it can be held temporarily at any distribution center through which it passes (delaying delivery), it is not automatically forwarded or returned (unless return postage is guaranteed), and finally, the bulk rate stamp on the envelope is inconsistent with the personalized image being sought.
- Do not stamp messages to the recipient on the envelope (i.e., "Important materials enclosed").
- Avoid brightly colored packaging that conveys a marketing image.
 While personalization of the materials is important, we do not want the mothers to confuse the PRAMS mailings with marketing materials ("junk mail") that may be readily discarded.
- Keep up with current postal procedures that may influence the likelihood that PRAMS mail is delivered in a timely fashion (i.e., whether the use of punctuation is discouraged or whether certain areas of the envelope are reserved for postal use only).
- Use official letterhead for letters. If data collection is contracted to an outside organization, consider using health department letterhead for the preletter and indicate that an outside organization will be conducting a survey on behalf of the health department.
- Use personal salutations on letters (i.e., "Dear Ms. Smith" instead of "Dear Mother").

- For cover letters, use handwritten signatures or scanned signatures (i.e., scan an image of a signature; cut and paste the cropped image into the cover letter document). Blue ink is preferred if signatures are handwritten or there is a color printer available.
- Provide a toll-free number on each letter so that a woman may call the office if she has any questions.
- Provide a return envelope with a stamp (not a postage meter or business reply envelope). This has been demonstrated to improve response rates and to produce more timely response (which can save costs on future mailings). Note that the recommendation for the return envelope differs from the recommendation for the outgoing envelope as stated above.

In addition to the above recommendations from the TDM, the words "Pregnancy Risk Assessment Monitoring System" may not be printed on any envelopes that are mailed to women as this violates a woman's confidentiality; specifically, the word "Pregnancy" is of concern. The acronym "PRAMS" may be used, however.

Protocol Development Task

Specify the procedures that your state uses for letters and envelopes.

Hawaii uses 6 letters: preletter, mail 1, tickler, mail 2, mail 3, and reward letter. All letters are printed on the Hawaii State Department of Health stationary. Preletter, tickler and reward letters are sent out in a window develop with a metered postage stamp. Preletter includes the Q and A brochure as well. Mail 1, 2, and 3 use a plain envelope with a postage stamp and printed labels. Mail 1, 2, and 3 includes the letter, informed consent insert, questionnaire booklet (2 year calendar on the inside cover and OMB No. 0920-1273), and return paid postage envelope. In addition, mail 1 has a resource list. All envelopes have PRAMS return address on the upper left hand corner of the front. Printed label of mother's address is affixed on the front of regular envelopes.

5.6b Contents of the First Questionnaire Mailing Packet. The following items are included in the first questionnaire mailing packet. All materials included in the mailing packet are also available in Spanish. If your state is

using Spanish materials, the Hispanic women in the sample will receive two copies of everything: one copy in English and one copy in Spanish. Maternal Hispanic ethnicity is identified from the birth certificate.

- i. Questionnaire Booklet (see Appendix H). A label with the identification (study) number, the batch number, and the type of mailing is attached to the back cover of each questionnaire. The operations tracking software is equipped with an Avery Label feature. This feature can produce a modifiable label so that other requested options (such as a space for writing the date the completed survey is received) may be printed and placed on the label as well.
- ii. Standardized Cover Letter (see Appendix F). The cover letter for a mailed survey serves several functions:
 - Explain the purpose of PRAMS.
 - Direct the woman to the informed consent document.
 - Encourage the woman's participation by:
 - o Emphasizing the importance of her individual experiences, and
 - o Stating that she may help to improve the health of mothers and babies by sharing those experiences.
 - Describe the participation incentive or reward.
 - Explain the procedures for completing and returning the questionnaire.
- iii. Informed Consent Document (see Appendix I). All elements of informed consent are provided on the informed consent document. See Section 10.2 for a list of the required elements of informed consent. In the event that CDC's IRB requires changes to the informed consent document, it should be printed as a separate document, and not printed directly on the questionnaire booklet.
- iv. Self-addressed Return Envelope With Postage Affixed. As mentioned previously, the use of a stamp (versus postage meter or business reply envelope) has been demonstrated to improve response rates and to produce more timely response (which can save costs on future mailings).

- v. Question-and-Answer Brochure (see Appendix J). A question-and-answer brochure is included in the mail packet to provide additional information about PRAMS. The text of the brochure was designed at the sixth-grade reading level and employs appeals used in the health education literature to encourage people to participate in the survey. The format of the brochure may be state-specific. Topics addressed in the question and answer brochure reflect questions commonly asked by mothers, such as: How was I chosen to participate in PRAMS? Is it really important that I answer these questions? Will my answers be kept private?
- vi. Calendar as a Memory Aide (see Appendix K). A three-year calendar is mailed with the questionnaire to use as a memory aid for recollection of important dates related to pregnancy and delivery that are asked about in the questionnaire.
- vii. Resource List (see Appendix L). Because of concerns that some questions could prompt women to request help from PRAMS staff, a resource list is provided in the mailing packet. This list has a variety of hotline numbers that women can call for assistance if they need it. PRAMS staff are prohibited from providing services or counseling to sampled women, which violates research responsibilities. If a woman does request help for any problem, she should be directed to the resource list. PRAMS staff must remember that they are forbidden to suggest that a woman needs help for any problem (e.g., physical abuse, substance use) if she has not directly asked for it.

viii.OMB# Form Approved and Expiration Date. To be included in survey on page 2 bottom of cover page or as an insert.

- **iX. Card for Multiple Births (recommended).** For mothers of multiple births, is helpful to insert a separate card that states that "Some of the questions are about mothers and some of the questions are about babies. For the questions about babies, please answer for Baby _____." This card is intended to reinforce that the mother should be answering only for the selected baby.
 - viii. Participation Incentives or Rewards. A participation incentive is something that is included with the questionnaire when it is mailed to each woman in the sample. A reward is something that is given to the respondent after a completed questionnaire is received.

Research has shown that incentives are much more effective than rewards in increasing response rates, even if the incentive has a smaller cash value than the reward. While financial incentives are most effective, material incentives (e.g., picture frames, magnets, pens)

work well also, and they are generally easier to administer by government organizations. The incentive should not introduce bias by including public health messages that might influence how a mother responds to the survey. For example, the item should not include messages about smoke free environments, benefits of breast feeding or the best infant sleep position. These materials would, however, be appropriate as a reward.

Over the years, the effectiveness of using incentives and rewards of nominal value has changed. In the 1980's and 1990's the literature indicated nominal amounts were sufficient to encourage respondents and previous PRAMS state experiences confirmed this was true. More recently, however, nominal values are no longer proving to be effective. Operations experiments suggest the higher the value the greater the resulting response rates. States have had to increase the value of incentives and rewards to have an impact. For example, states have employed methods such as offering both an incentive and reward and increasing the value of the incentive to maintain historic levels of response (Example: \$5 → \$20 subway fare card).

Regardless of the value of the incentive, it does need to be appropriate for the sponsoring organization, and useful or appealing to the sample of women. Ideally, one incentive should be used for all women, with the exception of women in the PRAMS sample have lost their infants due to death or other circumstances. CDC recommends using an incentive that is sensitive to these women. If a state selects an incentive that is geared toward the infant, an alternate incentive should be chosen for those women whose babies have died.

Recent research has shown that people have different inherent predispositions to respond based on the saliency of the topic, length of survey, and their own attitude/tolerance towards surveys. If these things could be measured then incentives could be targeted for different population groups; for example a higher incentive amount could be given to the less compliant and little or no incentive to the most compliant to maximize response and minimize operational expenses. 1,2 It has also been noted that targeted incentives to get the hardest to reach respondents can greatly improve nonresponse bias, since these individuals tend to respond differently than more compliant respondents. There is some debate in the literature regarding the ethical principles of targeted incentives or rewards³ and CDC recommends that PRAMS projects considering the use of incentives or rewards of unequal value submit their revised state protocol to a local IRB for review and approval.

While incentives are more effective than rewards, some PRAMS states have chosen to use rewards. The above principles apply to rewards as well. States may choose to include description or a list of the rewards available in the mailing.

Examples of PRAMS participation incentives and rewards include prepaid long-distance calling cards, postage stamps, gift certificates for local retailers, sachets, picture frames, baby bibs, coupons for certified birth certificates, and participation in a cash reward raffle.

Protocol Development Task

Specify whether your state uses an incentive or reward. Describe the type of incentive or reward your state uses, the rationale for its selection, and the method of administration. If a different incentive or reward is required for women whose babies have died, describe that as well.

Hawaii PRAMS uses \$20 gift cards for reward. The same gift cards are sent to women without distinction for dead or live birth. Gift cards are mailed with a thank you letter once mothers complete their survey. PIDS is used in tracking mailing of reward gift cards.

Gift Card:

Foodland Gift \$20 Cards: Oahu, Maui, Big Island

Amazon \$20 Cards: Kauai, Lanai, Molokai, Out of State

5.6c Contents of the Second and Third Questionnaire Mailing Packets. The items listed in Sections 5.5b.i-viii are included in the second and third questionnaire mailing packets. An incentive is not included in these subsequent mailings because research has shown that additional incentives do not affect response rates. An additional paragraph

incentives do not affect response rates. An additional paragraph introducing the web survey option and providing the URL and passcode for the web survey can be included in the cover letter of the second and third mailing. Like the first questionnaire packet, the Hispanic women in the sample will receive two copies of everything: one copy in English and one copy in Spanish.

5.6d Procedures for Stuffing the Questionnaire Mailing Packets. This task is rarely given deliberate consideration. However, Dillman stresses the importance of arranging the materials carefully so that all materials will come out of the envelope together. The goal is to prevent anything from getting inadvertently left in the envelope. Furthermore, the appealing aspect of each enclosure should be apparent upon initial review. The

following recommendations are based on Dillman's research into mailing 8.5" x 7" survey booklets with standard business envelopes.

- *i.* Fold questionnaire vertically with the front cover on the outside.
- *ii.* Place the incentive (size permitting) on top of the survey. (Incentive is included only with the first questionnaire packet.)
- *iii.* Place the informed consent document, question-and-answer brochure, calendar, and resource list (size permitting) underneath the survey.
- iv. Place return envelope underneath these materials.
- v. Place all of these on the middle one-third of the cover letter.
- vi. Fold the bottom one-third of the cover letter over these items.
- vii. Fold the top one-third of the cover letter down.
- viii. Card for multiple infants

With these procedures, everything can be easily inserted into, and more importantly, removed from the envelope.

Protocol Development Task

Your state's procedures may vary somewhat from the above recommendations, depending on the size of your materials and envelopes. Describe the procedures that your state will use to stuff the questionnaire mailing packets here.

Hawaii PRAMS contracts Rutgers to perform the mailing operations using the Department of Health (DOH) letterhead and PRAMS Q and A brochure. Preletter includes DOH letterhead and Q and A brochure which are automatically stuffed by the folding machine. Mail 1, 2, and 3 have DOH letterhead, informed consent, and return envelope which are stuffed manually, in addition to survey which is manually stuffed. A resource list is inserted into mail 1. Tickler has only the DOH letterhead which is automatically stuff by folding machine. An identification number label is attached to the back cover of the questionnaire booklet. A master list is used to cross check the name on the envelope, the letter (different letters sent for each mailing), and the questionnaire booklet for every 10th envelope. Dead baby letters are checked with the appropriate mothers. Reward letter is processed by the DOH PRAMS Program has DOH letterhead, which is automatically stuffed by the folding machine, and gift card, which is manually stuffed.

State whether the web login information will be incorporated into the cover letter or printed on a separate card to be included with the mailing packet.

Hawaii PRAMS will implement the web option as part of data collection upon receipt of DOH IRB approval when the mode of data collection becomes available. The use of the web option will be conservative in that it may be introduced with the second or third mailing. The operational results of the web option will be evaluated in order to determine whether the web option assisted the program or not. Should the evaluation showed up negative effect on data collection or response rates, the program will drop the web option.

- **5.6e Quality Assurance Stuffing Envelopes.** Because of a number of factors, it is important to make sure that the right materials are in the right envelopes. These factors include:
 - *i.* The mother's name appears on the envelope and in the letter. These must match.
 - *ii.* The questionnaire has an identification number. The number on the questionnaire must match with the name on the envelope and letter.
 - *iii.* Different letters are sent with each mailing. The proper letter must be mailed with the proper activity (preletter, mail 1, tickler, mail 2, mail 3).
 - *iv.* For any given questionnaire mailing, different letters may be sent to different women.
 - Women whose babies have died receive different letters than women whose babies have not died.
 - In some states, minors receive different letters than adults (due to physical abuse reporting requirements).
 - In states using Spanish materials, Spanish and English letters are sent to Hispanic women. Only English letters are sent to non-Hispanic women.
 - v. In some states, minors receive different surveys than adults (due to physical abuse reporting requirements). Care must be taken to ensure that the surveys without the abuse questions are sent to minors, and that surveys with the abuse questions are sent to adults.

When stuffing envelopes, staff should spot-check every 10th envelope to make sure that the appropriate materials are being placed in that envelope. All of the above items should be checked. The operations tracking software can assist with this process.

5.6f Special Cases That Require Further Follow-Up.

- *i.* Incomplete or Illegible Responses. Questionnaires that are returned illegible or incomplete (<75% complete) must be followed up by telephone if possible. In PIDS, partially completed mail surveys may be selectively moved over to the phone data collection queue for follow-up once the mail responses have been entered. Survey data is saved to a common data file, so all previously entered data is pre-populated in the Phone interview survey form for that record. States may choose whether to follow up on incomplete questionnaires that are at least 75% complete by selecting the case and marking it as Complete to end data collection or moving it to the phone queue to pursue phone follow-up.
- ii. Undelivered or Returned Mail. Mailings may be returned by the postal service if mothers have moved and left no forwarding address, the address does not exist, or the address contains insufficient information. A second mailing attempt is usually made to the same address from which mail has been returned. Names and addresses on returned pieces of mail are researched to determine an alternate mailing address. The operations tracking software assists with the handling of undelivered mailings by first generating a list of all mothers for which a mailing was returned undelivered. If alternate addresses are identified, they are entered into the tracking software, and the software automatically schedules mailings to those addresses. Usually, the letter included in the first mailing is sent with mailings to alternate addresses during the alternate phase of data collection. Once the telephone follow-up phase begins, all mailing attempts are discontinued.

Some approaches for identifying addresses include:

- Verifying whether the original address is valid using the ZIP+4 on-line service from the US Postal Service. This feature will determine

whether an address is valid or whether it might be missing information such as an apartment number.

- Verifying that the address was entered correctly from the birth certificate.
- Searching telephone directories for the mother's and father's names.
- Searching Medicaid, WIC, or other state-maintained health department databases, such as high-risk infant screening programs, newborn metabolic screening programs, SIDS, and birth defects.
- Searching reverse directories to identify the names of residents listed for the address on the certificate as well as neighbors of this address and calling them for contact information. Remember not to reveal the nature of the survey to anyone you may talk to for this purpose.
- Searching motor vehicle registration records.
- Searching voter registration or other local government records.

Protocol Development Task

List the sources your state will use to find addresses for undelivered mail and describe any special procedures necessary to use each source (i.e., required permission).

The phone phase is used to search for updated addresses for undelivered mail if a mom is contacted by phone or from the postal return address label which may refer a new address. Web search engines like www.anywho.com or www.whitepages.com is used to search for new addresses.

5.7 Telephone Data Collection Procedures

5.7a Search for Telephone Numbers. Telephone follow-up begins after the last questionnaire has been mailed. While mailing addresses are available from the birth certificate, the same is not true for telephone numbers (with the exception of very few states). Therefore, PRAMS staff must conduct a comprehensive search for telephone numbers for the women who did not respond (or refuse) during the mail phase.

The operations tracking software generates a worksheet for each mother who is entering "phone phase." The worksheet can be modified by the state, but generally includes the mother's full and maiden name, the father's full name (when available), the mother's address, and the mother's county of residence (when available) to assist with the search. A wide variety of sources may be searched for telephone numbers. These sources include, but are not limited to:

- Directory assistance
- Medicaid, WIC, or other state-maintained databases, such as high-risk infant screening programs, newborn metabolic screening programs, SIDS, and birth defects
- Internet databases
- Motor vehicle registration records
- Voter registration or other local government records

While many different options exist for locating numbers, most states have a few primary sources on which they rely. The best sources tend to be health department databases. Access to these databases often varies by state, but obtaining access to these types of databases should definitely be explored.

Sources should be searched by the mother's last and maiden name and by the father's last name when available. It is not always possible to know if a listing is correct. For instance, there may be more than one listing that matches the name being searched or people may use initials rather than first names. Any number that could potentially be a match should be used. It may be easier to search one or two sources at a time. If no number is found, or if a number is determined to be incorrect after calling, further attempts to locate a good number should be pursued from remaining sources.

Protocol Development Task

List the sources your state will use to find telephone numbers for telephone follow-up and describe any special procedures necessary to use each source (i.e., required permission).

Hawaii's source to find telephone numbers is through the Hawaii Newborn Metabolic Screening (HNMS) Program, Children's With Special Health Needs Branch (CSHNB) program in the Family Health Services Division. The research statistician of the program match demographic information of the birth certificate sample file with the information from their databases and generate an updated list of telephone numbers for the Hawaii PRAMS Program Coordinator.

Hawaii Tel-Com directory assistance is used for missing, incorrect, and non-working telephone numbers not found through other means. Web search engines like www.anywho.com or www.whitepages.com is also used to find numbers.

5.7b Preparing the Interviewers. Telephone interviewers should be thoroughly trained before they begin work on PRAMS. CDC provides training materials; see Section 3.9b for more information. Telephone interviewers should have good interviewing skills, be familiar with PRAMS data collection procedures (mail and telephone), and have a general knowledge of the PRAMS project in order to answer questions a mother may ask. PRAMS telephone interviewers must also be trained on the CATI system.

Because interviewers will have contact with a woman's family or friends when they call a household, they should be prepared to maintain confidentiality and protect the mother's privacy. See **Section 10.4** for more information. In addition, CDC recommends the placement of signs around the interviewers' workstations to remind them about confidentiality when talking with a woman's family or friends.

5.7c Making Telephone Calls and Recording Dispositions. The telephone calling period extends from three to five weeks. PIDS has the capability to schedule phone calls and track appointments. In addition, interviewers can manually select a mother to call. In the event that more than one number is located for a particular woman, PIDS will keep multiple numbers active until one has been identified as the best number. Fifteen call attempts should be made to each viable telephone number before giving up. Interviewers should make over fifteen call attempts only if they have a strong lead or a scheduled appointment to call a mother back. To increase the likelihood of reaching a mother, calls are staggered over different times of the day and different days of the week. Calls should be made in the evenings and on weekends in addition to regular business hours. Dates, times, and dispositions of all calls are recorded into the PIDS system when the calls are completed. For more information on call

dispositions, see the PRAMS Interviewer Training Manual and the PIDS User Guide.

Protocol Development Task

Describe your state's schedule for conducting telephone calls, including the days of the week and the hours of the day when calls will be made. To ensure that women are reached, evening and weekend hours must be included in the schedule. Use the following as an example:

Hawaii PRAMS Telephone Schedule

Day Time

Weekday morning 10:00 a.m. – 12 noon Weekday afternoon 1:00 p.m. – 3 p.m. Weekends 10:00 a.m-3:00 p.m.

.

5.7d Computer-Assisted Telephone Interviews using PIDS. This is now the standard approach for PRAMS telephone follow-up which includes recording survey responses, comments, and operations information pertaining to the call attempts and completed interviews. CDC will no longer accept telephone interview data collected by any other data entry or commercial software.

The PIDS system employs state-of-the art security measures to protect this information (see Appendix V for the PIDS Data Security Document).

There may be some instances where it is not practical to use PIDS for recording telephone survey data. In such situations telephone responses may be recorded on paper and keyed into the PIDS system after the interview is completed:

- In situations where a mother calls the health department and requests to complete the survey on the spot, it may not be feasible to use PIDS to conduct the interview, In this case the interview can be recorded on paper for later entry into the PIDS system.
- Another exception where pen and paper is preferred is the situation of partial mail surveys that are followed up by telephone. Only the remaining unanswered questions are asked of the mother by phone. These should be recorded on paper and then entered into the mail data entry record for that mother. Operations information

- about the phone contact should be recorded directly into operations tracking software, PIDS.
- Finally, there may be situations where an interviewer is making calls off premises and does not have access to both a phone line and an Internet connection. In this case the mother's responses can be recorded on paper for later entry into PIDS. If an interviewer is making the majority of her calls off premises, every effort should be made to provide her with equipment sufficient to access and use PIDS.

5.8 Web Data Collection Procedures

A common web address established by CDC will serve as the entry site for women from all states to complete the PRAMS web survey. The PIDS system will generate a unique passcode for each sampled mother which will serve as the passcode for access to the web survey. The web address and passcode will be provided in the cover letters of the appropriate mailing packets, as determined by each state. Once logged in, the respondent must confirm her identity before proceeding further. She will also be asked to provide an email address for ease in recontacting her if needed. All women who successfully log into the web system will be allowed to complete a survey, whether they've confirmed their name and year of birth and provided an email address or not. However, state PRAMS staff may review this information and determine whether or not to retain the responses if a mother's identity is in doubt. Respondents must actively accept the terms of the informed consent screen before proceeding to the survey questions.

Respondents who break off before completing the web survey will also have the option of entering a current phone number and current email address for future contact. This information can be used to send email reminders or conduct telephone follow-up if the web survey is not completed or only partially completed.

5.9 Quality Assurance: Telephone Interviews

Telephone interview data are vulnerable to bias from variability in the way the interviews are conducted. This bias may arise from variability between interviewers or from variability between interviews conducted by a single interviewer. Mode bias may also occur if the administration of the telephone questionnaire differs substantially from the presentation of the mail questionnaire. To prevent these biases, and to ensure that proper procedures are followed,

monitoring procedures should be implemented to assess the consistency and quality of telephone interviewing.

The person who monitors the telephone interviewers should monitor approximately 10% of the time that each interviewer is making calls. If interviews are conducted in-house, the Project Coordinator is responsible for the monitoring. If the interviews are contracted to another agency, the supervisor of the interviewing laboratory is responsible for the monitoring and the Project Coordinator should periodically monitor interviewers as well (at least quarterly). There are several options for monitoring a PIDS telephone interview. Please see **Appendix M (Telephone Interviewer Monitoring Procedures)** for further details.

5.10 Methodologic Experiments

The Tailored Design Method recognizes that individual projects may need to modify certain components of the data collection methodology to ensure maximum response rates. In PRAMS, certain components of the methodology may be altered, such as incentives, appearance of mailing packets, etc. CDC supports experimenting with different methods to understand the best way to improve response rates. By conducting an experiment, states can objectively determine whether proposed changes will have the intended effect of increasing response rates. For a full description of the experimentation procedures, as well as which components of the methodology are available for experimentation, see **Appendix N (Performing Operational Experiments)**.

5.11 Alternative Methodologies

The needs of individual projects to modify the standard PRAMS data collection methodology may extend beyond the scope of experimenting with incentives, rewards and mailing materials. The disparity in response rates among different population groups has been recognized by many states over the years, in particular in state that over sample high risk groups.

Over the course of the PRAMS project, there have been several examples of the use of alternative methodologies. The first, as described in history of PRAMS in Chapter 1, was the use of hospital based methodology in the early 1990s. When that was abandoned, primarily due to cost and lack of ability to collect data in the early postpartum period, the primary methodology of PRAMS data collection has been the mail survey with telephone follow-up.

In 2001, Colorado PRAMS was awarded funding for an enhanced project conducting a survey exclusively with African American women. The project focused primarily on intensified community engagement and outreach to the African American community, as well as targeted higher value rewards. This approach garnered only moderate success, and did not achieve the established response rate threshold at the time of 70%.

In 2006 the Yankton Sioux Tribe of South Dakota was awarded funding for a 3-year Point-in-Time survey. The project staff, based in the Northern Plains Tribal Epidemiology Center, proposed and implemented more extensive changes to the standard PRAMS methodology. The target population was exclusively American Indian women (and mothers of American Indian infants) residing on and off reservation in South Dakota and Sioux County, North Dakota. This project also employed intensified community outreach and targeted, higher value rewards. The project went a step further, while maintaining the mail, phone methodology, added a WIC clinic survey delivery component and a residential hand delivery component to the methodology to address the challenges of trying to reach American Indian women in this mobile and rural community. The project was successful in exceeding the established threshold (at the time of grant application) of 70%.

The South Dakota Tribal project provided a framework for proposing alternative methods for enhancing response rates among hard-to-reach women. This has been compiled into a template plan provided in **Appendix AA** of the protocol for other sites to follow if they would like to consider implementing alternative methods of conducting the PRAMS survey.

Protocol Development Task

Indicate here if you are employing any alternative data collection methods. Before any alternatives methods can be used, an Alternative Methods Plan must be developed, documented in the protocol, and approved by CDC PRAMS. The plan should be placed in Appendix AA. The plan must undergo CDC and local IRB review and receive approval prior to implementation. Further guidance is provided in Appendix AA.

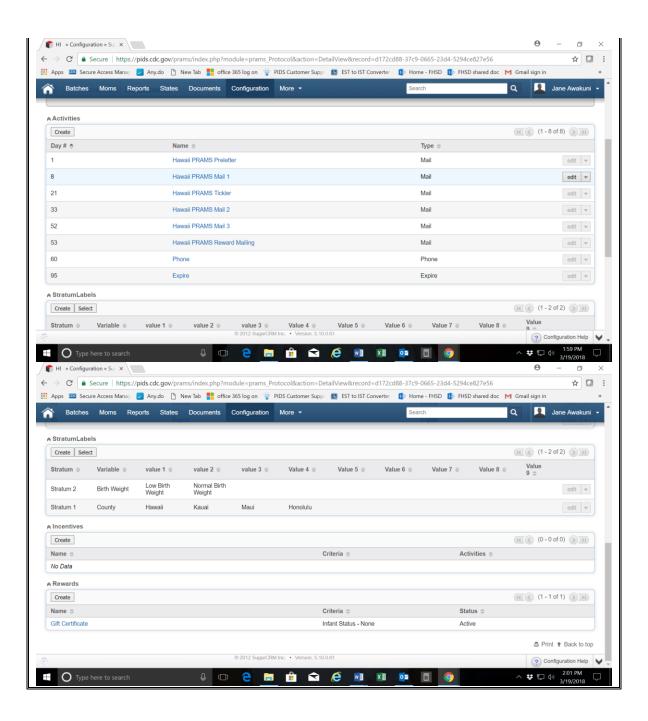
5.12 Recording and Reporting Data Collection Methodology

The State Configuration screen in PIDS shows various decisions that are important to the state-specific data collection process. This includes the stratification scheme, the incentive or reward used, the schedule of each data collection activity, experiments (if applicable), etc. The State Configuration screen in PIDS can be viewed at any time, however it only shows the current figuration, and does not maintain a record of previous configuration settings. Any time the configuration is changed, a new screenshot should be taken and stored in **Appendix O**, along with the date of the change for reference as needed.

Protocol Development Task

Place a screen shot of the State Configuration screen from PIDS from Appendix **O**. For new states, this will be created at the time of project start-up. Recreate the screenshot after any change is made to the state configuration in PIDS and add it to **Appendix O**. Be sure to document the date of the change along with the screenshot.

Screen shot of schedule updates within PIDS as of 3/21/2018.



¹ Trussell N, Lavrakas PJ. The influence of incremental increases in token cash incentive won mail survey response: Is there an optimal amount? *Public Opinion Quarterly* 2004; 68(3): 349-67.

² Zagorsky JL, Rhoton P. The effects of promised monetary incentive on attrition in a long term panel survey. *Public Opinion Quarterly* 2008; 72(3): 502-13.

³Singer, Eleanor, Robert Groves, and Amy Corning. Differential Incentives: Beliefs about Practices, Perceptions of Equity and Effects in Survey Participation. *Public Opinion Quarterly* 1999; 63:251–60.

⁴Millar MM, Dillman DA. Improving Response to Web and Mixed Mode Surveys. *Public Opinion Quarterly 2011; 75(2):249-69.*