

Attachment 16—Opioid Call-Back Survey Methods

Background:

Pregnancy is a uniquely vulnerable period for the devastating effects of opioid misuse and overdose due to the impact on the health of both the mother and infant. Between 1998 and 2011, there has been a 127% increase in the prevalence of opioid abuse or dependence during pregnancy resulting in increased maternal morbidity and mortality¹. From 2004 and 2013 the impact of crisis on infant health has also been documented by the significant increase in neonatal intensive care unit admissions of infants with neonatal abstinence syndrome². We aim to improve the ability of states to detect and prevent maternal opioid misuse and overdoses by documenting and addressing opioid use during, and after pregnancy. The call-back survey will support enhanced, rapid surveillance to provide data that can be used to understand community needs, policy gaps, and to identify best practices to reduce maternal opioid misuse and overdose deaths.

References:

1. Maeda A, Bateman BT, Clancy CR, Creanga AA, Leffert LR. Opioid abuse and dependence during pregnancy: temporal trends and obstetrical outcomes. *Anesthesiology* 2014;121:1158–65.
2. Hedegaard H, Warner M, Miniño AM. Drug Overdose Deaths in the United States, 1999–2016. Hyattsville, MD: National Center for Health Statistics; 2017. NCHS Data Brief, No. 294

Statement of Goals:

The purpose of the opioid call-back survey is to build on the existing methodology from CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) to implement rapid surveillance of maternal behaviors and experiences related to use of prescription pain relievers and other opioids during pregnancy (Prescription and Illicit Opioid Supplement, Attachment 10c) , with more intensive follow-up in states with the highest burden of opioid-related hospitalizations and overdose deaths. The currently planned call back survey will targeted to areas with a high burden of opioid overdose deaths and include topics such as opioid misuse and access to medication assisted therapy, experiences with respectful care, postpartum care, rapid repeat pregnancy, infant feeding practices, infant health and social services such as well child visit attendance, home visitation, developmental delays, and social supports. Data from this effort will can be used to understand community needs and policy gaps, subsequently informing state health departments, clinical providers, CDC, and other federal agencies.

Sampling:

Participating states in the planned opioid call back survey include Kentucky, Louisiana, Massachusetts, Missouri, Utah and West Virginia. Each participating state will design a

sampling plan to oversample women in areas of the state where there is high risk of exposure to opioid use by pregnant women and/or their family members or community. Identification of high-risk areas is determined by each state using relevant available data sources, such as reporting of overdose hospitalizations, overdose deaths, and neonatal abstinence syndrome incidence. Indicators used to select the oversample must be available to the state on the birth certificate file for PRAMS sampling. It is desirable for the sampling plan to be in place for the duration of the 2019 birth year.

Steps to identify the opioid stratum in each state are outlined below:

Identifying the counties to oversample

- 1) Identify the opioid burden (best estimate of the percentage of opioid users among new mothers) in the counties in the state using the data sources available
- 2) Rank the counties from highest burden to lowest burden
- 3) Select the top ranking counties that it takes to make up 30% of state birth population; these counties will be combined to create opioid oversample stratum
- 4) Decide if there will be additional strata oversampled, in addition to the opioid oversample stratum

Data Collection Methodology:

- 1) Beginning in April 2019, each site will implement a new sampling strategy to oversample women in areas where there is high-risk/high-burden of exposure to opioid use as described above.
- 2) The opioid supplement questions will be implemented for all women in the sample, and regular PRAMS protocol data collection procedures will be followed.
- 3) A courtesy card should be included with each survey mailing (**Attachments 13a-13d**) to alert women to the fact that they will be re-contacted when their baby is approximately 9 months old:
 - a. This card should request the mother's contact information; it is often helpful to also ask for the name and contact information (address or phone) of someone who would be able to locate the mother. States should decide on most appropriate method to track contact information cards in order to associate it to the correct mother.
 - b. The card will also include a check box for mothers to "opt out" of participating in future surveys. If a mother checks this box, she would not be re-contacted, regardless of her participation on the regular PRAMS survey and/or opioid supplement.

- c. If a mother does not fill out the card, but complete a PRAMS survey, it is okay to re-contact her for the call-back survey.

All women who are respondents to the regular PRAMS survey will be re-contacted for the call-back survey, regardless of their answers to the opioid supplement questions, and even if they did not answer any of the opioid supplement questions. The only exception is if they opted-out of further contact by either mail or phone.

Starting in October 2019, respondents will be called by telephone on or shortly after the date of their baby's 9-month birthday. Each woman will be followed-up until she responds or refuses, or until the date of her baby's 10-month birthday. Telephone operations will be conducted as per the standard PRAMS protocol. The only exception is that given the shortened follow-up time, interviewers will make a maximum of 10 call attempts per working number.

The call-back survey will be implemented with a minimum of 5 batches from April to August 2019. States have the option to continue data collection for additional months while the opioid oversampling strategy is implemented.

Data management:

As with all PRAMS data collection activities, call-back survey activities will be accommodated in PIDS. States may elect to develop additional tracking forms outside of the system, but that is not required.

Training Requirements:

CDC will provide state PRAMS staff with training on use of any new features developed to track women for the call-back survey in PIDS.

Additional phone interviewer time will also be needed. Any newly hired phone interviewers will receive standard PRAMS training from the state PRAMS staff, including Human Subjects Training, and training on using the PIDS CATI/phone module using existing PIDS training materials and documentation.

All interviewers, including current PRAMS interviewers, will receive refresher telephone training to cover topics related to confidentiality, sensitivity related to substance use disorder, and crisis management for which training materials will be provided by CDC. Other special training may also be provided if deemed necessary by the state.

Timeline:

The timeline for the PRAMS Opioid Call-Back survey is outlined below.

Timeline	Activity
September 2018	Project funding awarded.
October 2018 – March 2019	Identify high-risk geographic area and create modified state-wide sampling strategy to oversample the target area. Once modified, the sampling strategy will remain in place during the entire year (2019 births). Submit modified sampling plan to CDC PRAMS statistician for review and approval. Complete state protocol modification, including incorporation of modified sampling, updating consent forms to re-contact women 9-months after their delivery, and methodology for conducting 9-month call-back survey. Print supplemental questions, modify of any contracts for enhanced operations, submit protocol to IRB, and test data collection software.
April 2019	Opioid questionnaire supplement data collection begins with inclusion of the new courtesy card alerting women to the call-back and providing the chance to opt out.
May 2019 – August 2019	Hire and train staff, or modify existing telephone contracts, to prepare for initiation of 9-month call-back survey.
October 2019 – March 2020	Conduct telephone call-back survey with April – August batches, as babies in each batch reach their 9-month birthday. Continue call-back until babies from all 5 batches are 9 months old. Begin working on analysis plan for 9-month call-back survey data.
March 2020 – April 2020	Complete development of preliminary 9-month call-back survey analysis plan. Receive 5-month dataset from CDC. Begin data analysis and publish initial findings.