Pathways: Qualitative Interviews with Post-Partum Women Associated with Congenital Syphilis Cases (Case Mothers)

Generic Information Collection Request under OMB #0920-0840

Section B: Supporting Statement

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EXHIBITS

1. Respondent Universe and Sampling Methods

The population of this study is congential syphillis (CS) case mothers, defined as women associated with a CS case in the years 2015, 2016, or 2017. CS cases are identified by maternal or infant criteria, based on the CDC surveillance definition and reported by the state/city health department to the Division of STD Prevention (STD Surveillance Report 2016). Recruitment is targeted at cases which have been previously identified and reported per surveillance reporting guidelines and procedures.

Sampling Methods

We will use purposive, targeted sampling to recruit 60 case mothers to participate in an interview from all women identified as CS case mothers in 2015, 2016, or 2017 in the states of California and Florida and the metropolitan statistical area (MSA) of ChicagoUnlike probability sampling, the goal of purposive sampling is not to achieve objectivity in the selection of the sample or to necessarily attempt to make statistical inferences from the sample being studied to the wider population of interest. Instead, researchers following a qualitative research design that includes purposive sampling tend to be interested in the intricacies of the sample being studied. Thus, with purposive sampling, there are strong theoretical reasons for the chosen cases to be included in the sample. In this case, the purposive sampling of CS case mothers allows us to respond to the stated research objectives.

CS case mothers have been previously identified by local and state health authorities as meeting the infant or maternal criteria for CS. In short, the criteria are clinical signs and symptoms in the infant; identification via laboratory criteria; or, untreated or inadequately treated syphilis in the mother at the time of delivery regardless of signs and symptoms in the infant (2016 STD Surveillance Report Page 130-131). All women identified as cases in 2015, 2016, or 2017 in the three sites are potentially eligible to participate in an interview. Women who are documented as having obtained some prenatal care will be recruited as well as women who have no documentation of prenatal care.

Sampling Plan CS Case Mothers

Up to 60 in-depth qualitative interviews will be conducted with 2015-2017 CS case mothers across at least three jurisdictions with high numbers of congenital syphilis cases.

Qualitative interviews will allow case mothers to convey, in their own words, their perspectives on their pregnancy and prenatal care experience, their syphilis diagnosis, and the subsequent negative birth outcome. The goal of this project is to better understand and identify factors that result in deviations

from the “ideal” pregnancy narrative, as well as factors that are protective, supportive, or that appear to facilitate access to and use of timely and adequate prenatal care and syphilis diagnosis and treatment during pregnancy. Interviews will explore case mothers’ knowledge and understanding about giving birth to an infant with congenital syphilis, and elicit their perspectives on what could have helped prevent a negative birth outcome.

Using appropriate elicitation (e.g., timeline, life event) techniques, interviews will focus on the period from 30 days prior to diagnosis of pregnancy until 30 days after delivery of the infant. Interviews will be structured to explore specific points during the course of the pregnancy and prenatal care continuum for missed opportunities and potential intervention points.

Case mothers inclusion criteria:

Eligible participants will be:

- 18 years or older
- Female
- English-Speaking
- Carried or gave birth to the infant identified as having congenital syphilis
- Identified as meeting CS case definition in one of the 3 sites during the years of 2015, 2016 or 2017

Case mothers exclusion criteria:
Participants will be excluded from the study if they are:

- 17 years or younger
- Did not carry or give birth to the infant identified as having congenital syphilis
- Unable to converse easily in English
- Do not meet case definition of a CS case in 2015, 2016 or 2017

Although pregnant women may be approached to participate in the project, their current pregnancy status will neither bar them from participation nor will they be targeted for participation. All information collected will pertain to the pregnancy for which they were associated with a case of CS; as such, their current pregnancy status is incidental.

Recruitment of CS Case Mothers

The Role of Partnering Health Departments

CS case mothers will be recruited from CS cases that have been investigated and reported to CDC based on maternal and/or infant criteria in the 3 sites in 2015, 2016, or 2017. State and local health departments will already have identifying and contact information on case mothers obtained during the

CS case investigations. These investigations are typically carried out by STD program disease investigation specialists (DIS) or public health nurses; information is documented both in DIS case investigation files and also in case report forms submitted to CDC, though the latter does not include personally identifiable information (PII). This information is retained by state and local health departments and periodically subject to review. Retained information includes information regarding aspects of the pregnancy such as the pregnancy outcome (live birth or stillbirth), receipt of prenatal care during pregnancy, syphilis testing and treatment dates, etc. The state and local health departments will work together to develop a list of potential participants from case records, and will make initial contact with case mothers to let them know about the interview study, using the approved recruiting script (**Attachment 3a**). Case mothers will be informed about the study and about the token of appreciation and asked if their contact information can be given to the interviewer. If case mothers provide verbal consent over the phone, the contact member from the local health department will document this consent on the recruitment script form (**Attachment 3a**), and then provide their name and contact information (email address and phone) to the interviewer. ASTHO-contracted interviewers at each site will follow up to set up an appointment to conduct the interview (**Attachment 3c**). Health department staff will monitor the ultimate disposition of each case mother contacted for recruitment (**Attachment 3b**). Each case mother contacted will be assigned a participant identification number which will be stored in a linked data file containing only the participant's name, identification number, and agreement to participate; this data file will be used to ensure that case mothers are not contacted again if they decline participation. In a separate data file, information will be recorded to note if a participant agreed to participate and, if they did agree, if an interview was conducted. This file will also include two pieces of information taken from case investigation notes: birth outcomes and receipt of prenatal care during pregnancy. This information will be provided to the project team in aggregate form at the completion of the project. Aggregate data will not contain any PII. If recruitment challenges occur, ASTHO will work with CDC staff to determine the best course of action.

Health department staff at the state and local levels will not participate in interviews or collect data beyond participant disposition as a part of this project. Their role is limited to recruitment, in part to help protect the PII of CS case mothers who choose not to participate in the project. No state or local health department or its staff will receive financial support as a part of this project.

2. Procedures for the Collection of Information

The ASTHO-contracted interviewers at the three sites will work with a common qualitative interview protocol and elicitation approach developed by CDC in collaboration with its partners. Face-to-face

interviews, which will be conducted by trained, contracted qualitative interviewers, will take approximately 90 minutes and will be digitally recorded and transcribed for the purposes of qualitative data analysis. Interviews will be conducted in a quiet location agreed upon by the interviewer and participant, conducive to private conversation and recording.

Visual, paper-based timelines (e.g., flip chart paper) will be created as part of the interview, and collected and treated as data for analysis purposes. Names will not appear on paper timelines, recorded interviews, or any other project-related materials. Each participant will be assigned a unique code to protect confidentiality; all data sources will be labeled with this unique code. At the end of the interview, participants will receive a $60 Visa gift card as a token of appreciation. Participants will be reminded during consent that all answers are voluntary, that they may choose to not answer any question, and that they will receive the $60 token of appreciation without regard to their participation in the interview or whether or not they choose to answer any question (**Attachment 4**).

Qualitative Interview Guide

We will use a semi-structured qualitative interview guide **(Attachment 5a)** in conjunction with timeline elicitation methods to conduct the interviews. Interviews will focus on the period from roughly 30 days prior to diagnosis of pregnancy until 30 days after completion of the pregnancy. Visual timeline methods will be used in conjunction with semi-structured interviews to augment and complement traditional qualitative data collection. In a timeline approach, the interviewer and participant work together to create a graphic visualization of the participant's life events, arranged chronologically, with some indication of the significance or importance of particular events for the participant in relation to the research topic (Kolar 2015, Berends 2011). They can be particularly useful when discussing sensitive topics because they enhance rapport and allow the participant to contextualize and share information in a way that makes sense to them.

Interviewers will use the semi-structured guide to explore participants' pregnancy, prenatal care, and syphilis diagnosis experiences related to those events. The timeline will allow the interviewer to move back and forth among periods or events and to probe for more information about life events, both positive and negative, that may have had an impact on the participant. Visual data (timelines) will be collected at the end of the interview and photographed to create an electronic version for purposes of data analysis.

3. Methods to Maximize Response Rates and Deal with No Response

We will use the following procedures to maximize cooperation and to achieve the desired response rate:

- All recruitment materials indicate the voluntary nature of the study and participation is due in part to interest in the study and participation from CS Case Mothers.
- CS case mothers will be recruited from CS cases that have been investigated and reported to CDC based on maternal and/or infant criteria in the three sites in 2015, 2016, or 2017.
- A token of appreciation of $60, in the form of a visa gift card, will be provided to respondents upon completion of the interview.

4. Tests of Procedures or Methods to be Undertaken

Our research team includes experts with experience conducting research with special populations and qualitative research, including screening and interview development and testing. ASTHO staff will conduct pretesting of the screening tool and interviews on at least three mock respondents to assess question wording, skip patterns, question sensitivity, and overall flow of the interview and to estimate response burden for each respondent. Non-CDC members of the research team will be responsible for recruiting respondents and collecting the data in the three cities as well as for generating transcripts that contain no PII.

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

Exhibit 5.1 below lists the project team members who were consulted on the aspects of research design and those who will be collecting and analyzing the data. Please note: The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC Project Determination and local IRB reviews; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The data are primarily qualitative in nature and will be analyzed accordingly.

The CDC staff will be non-engaged in the direct collection of information; CDC staff will neither collect data from nor interact with research respondents. Data will be collected by members of partner project staff listed. No individual identifiers will be linkable to collected data, and no individually identifiable private information will be shared with or accessible by CDC staff. All members of the research team will work together to analyze the data and generate reports containing summaries of the findings.

Exhibit 5.1: Statistical Consultants

Team Member	Organization	Email
Monique Carry	CDC	Kju8@cdc.gov
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