2018 Congenital Syphilis Study

Generic Information Collection Request under OMB #0920-0840

Supporting Statement B

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This data collection does not involve statistical methods.

1. Respondent Universe and Sampling Methods

Participants will be recruited in Kern County, CA and East Baton Rouge Parish, LA. Prenatal care providers and high-risk pregnant women will be recruited from local hospitals or clinics specializing in prenatal and infant care (such as the Women's Hospital in East Baton Rouge Parish or the Women's Services Department of the Dignity Health system in Kern County). The qualitative study will involve up to 20 in-depth interviews (IDIs) and up to 8 focus group discussions (FGDs).

In-Depth Interviews (IDI)

IDI participants: IDIs will be conducted with up to 20 prenatal care providers, 10 providers at each site. Different types of prenatal providers will be recruited, including:

a. Obstetricians/gynecologists (OB/GYN)
b. Family practice doctors (family physicians)
c. Maternal-fetal medicine (MFM) specialists
d. Certified nurse-midwives (CNMs)
e. Family nurse practitioners (FNPs) / women's health nurse practitioner (WHNPs)

Eligibility criteria for IDI participants includes: (1) Prenatal care provider (including any type described above) that has worked in either Kern County, CA or East Baton Rouge Parish, LA for at least 6 months; (2) Currently working directly with high-risk pregnant women (at least half of their patients); (3) Having a phone or some other way of being contacted; and (4) Consenting to involvement in the study.

Focus Group Discussions (FGD)

Up to 8 FGDs will be conducted in total, with 4 FGDs being done at each site. Each FGD will include 6-10 participants, thus a total of up to approximately 80 FGD participants will be enrolled, ~40 per site.

FGD participants: Focus groups will involve pregnant women at "high risk" for being infected with syphilis and thus at high risk for mother-to-child transmission of syphilis. Kern County, California and East Baton Rouge Parish, Louisiana are two of the most hard-hit, high-morbidity syphilis counties in the United States. Thus, pregnant women living in these two areas are considered to be high-risk (for both acquisition and transmission of syphilis). Minimum eligibility criteria for FGD participants includes: (1) Adult women (18 years and older) living in either Kern County, CA or Baton Rouge Parish/County, LA for at least 6 months; (2) Currently pregnant; (3) Having a phone or some other way of being contacted; (4) Consenting to involvement in study; and (5) English or Spanish speaking.

Snowball Sampling: Participants will also be recruited via snowball sampling, whereby participants who are recruited/informed about the study will be asked to pass on study contact details and a participant information sheet or flyer to pregnant women they know who fulfill the inclusion criteria. This way, pregnant women receiving services at any of the recruitment sites can talk about the study with friends and family and participants can be recruited as a result of word of mouth.

2. Procedures for the Collection of Information

All data collection activities will be conducted by the locally appointed research team which will consist of two skilled and experienced qualitative researchers. Methods will include up to 20 in-depth interviews (IDIs) with prenatal care providers working in Kern County, California and Baton Rouge County, Louisiana (up to 10 IDIs per county). Interviews will focus on understanding provider knowledge, awareness, and comfort in talking to women about congenital syphilis; attitudes and practices regarding testing; and information-seeking behaviors. Additionally, we propose to conduct 8 focus groups with high-risk pregnant women (6-10 women per focus group, up to 4 focus groups per county). Focus groups will assess general attitudes and practices regarding prenatal care; knowledge and awareness about congenital syphilis; information-seeking behaviors; and types of health-messaging that resonate with them. FGDs will allow for discussion of general themes, including awareness of sexually transmitted infections, challenges in accessing healthcare while pregnant and how these might be

overcome, and ideas for ways that health messaging can best resonate with them. Focus groups will be led by a moderator and notes will be taken by an assistant who will tape each session (with all participants' consent). All discussions will be structured by use of a guide and will last 1-2 hours.

Only individuals 18 years and old will be involved in the proposed study. Written consent will be obtained for the proposed qualitative research. All participants will be asked their consent to audio record interviews or focus groups. Participants will be asked to give their consent to be audio recorded, and will provide oral consent if they agree to be audio recorded. If they do not consent to be audio recorded, they will be informed that they will still be able to participate in the study. Consent forms will be written in simple language at a fourth-grade reading level. Details of study participation will be described in the consent form and explained verbally. If a potential participant decides he/she does not wish to participate, his/her decision will be honored regardless of how well the study information is comprehended. A copy of the consent form, which includes a description of the study, will be provided to all participants and includes telephone numbers of the PI where participants can call with questions or concerns. Only qualified personnel will consent subjects.

The following data collection instruments will be used in this study:
Eligibility Screeners for Prenatal Care Providers and Pregnant Women: Eligibility screeners will be utilized to identify eligible respondents and take approximately 10 minutes to complete (**Attachment 5a and 6a**). If eligible, participants will be contacted to schedule a follow up interview/participation in the focus group.

In-Depth Interviews: All interviews will be conducted by study staff using an interview guide for prenatal care providers and a separate interview guide for pregnant women. (**Attachments 5b and 6b**). Study staff will perform the transcription of all audio-recordings and maintain all transcripts on password protected/encrypted laptops.

Data Analysis

Interview and focus group notes will be transcribed and imported into QSR NVivo V10 or analyzed through identification of recurrent themes following Crabtree and Miller's 5 step "interpretive process". Transcripts will be read to identify common themes, codes will be developed and ~10% of data will be double coded and inter-rater reliability assessed. Coded text will be extracted and organized and read to

identify emergent themes. A sequential, empirically-informed approach will be used to synthesize findings to develop recommendations to better inform congenital syphilis outreach and prevention efforts. Recommendations will be developed to specifically address culturally appropriate and acceptable ways to provide outreach to high-risk pregnant women and effectively engaging them in the use of needed congenital syphilis -related prenatal care services.

Specific steps will be followed:

- Step 1: Use qualitative data from interviews and focus groups to develop a summary of findings.
- Step 2: Work with all partners (at UC San Diego and Tulane University) to synthesize qualitative findings to develop a set of recommendations for effective outreach and engagement.
- Step 3: Present key findings and recommendations to the March of Dimes and obtain additional suggestions for refinement.
- Step 4: With the support of March of Dimes and CDC, develop findings into scientific manuscripts or reports for dissemination to populations of interest.

Consent documents and data collection tools will be retained in locked filing cabinets in the PI's office at UC San Diego or Tulane University, and will only be accessible to senior investigators or designated staff. All participants will be identified by study ID numbers only. Participants' names will not be included on study materials. A master list of participant names linked with study IDs will be kept in a password-protected computer file. All computer records will be protected by standard measures that limit data access to authorized personnel, and will be identifiable only by participants' IDs. Digitally-recorded qualitative data will be stored on a secure password protected server following interview; followed by the deletion of the original audio file. Transcription and data analysis will be done through secure password-protected server. All of these procedures will be adhered to in the proposed study.

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 all participants.
- A token of appreciation of $25, in the form of a gift card will be provided to focus group participants upon completion of the focus groups. Prenatal care providers will receive a $50 token of appreciation in the form of a gift card upon the completion of the interviews.

4. Tests of Procedures or Methods to be Undertaken

Our research team includes experts with experience conducting research with community partners, and qualitative research, including screening and interview development and testing.

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

Exhibit B5.1 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 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 (**Attachment 7**). 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.

Exhibit B5.1: Statistical Consultants

Team Member	Organization	Email
Lori Elmore	CDC	Lge7@cdc.gov
Jennifer Ludovic	CDC	Bmp8@cdc.gov
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