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

Generic Information Collection Request under OMB #0920-0840

Section A: Supporting Statement

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- **Goals of the study:** The goal of this qualitative 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. We will 1) document women associated with congenital syphilis (CS) cases (case mothers) recollections of and perspectives about their pregnancy and prenatal care experience, 2) attempt to identify potential protective or supportive factors that would facilitate care and reduce the risk of CS, and 3) identify strategies to reach vulnerable women and increase awareness of the risks of CS during pregnancy.
- **Intended use:** Findings from the interviews will help increase STD program capacity to reach women at risk for congenital syphilis (CS), and will prevent CS cases by identifying strategies for improving outreach and education to women at risk for CS.
- **Methods to be used to collect data:** Data will be collected from sixty (60) semi-structured, 90-minute long, in-person qualitative interviews using a timeline elicitation method.
- **The subpopulation to be studied:** Data will be collected from case mothers in three CDC-funded jurisdictions: the states of California and Florida and the metropolitan statistical area (MSA) of Chicago.The number of interviews to be conducted in each site will be based on weighted averages related to disease burden, but will be approximately 20 per location.
- **How data will be analyzed:** Qualitative coding and thematic analysis of 60 in-depth interview transcripts using computer-assisted qualitative data analysis software Nvivo 11.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of STD Prevention, (DSTDP) requests OMB approval for a qualitative extramural research study entitled,
"Pathways: Qualitative Interviews with Post-Partum Women Associated with Congenital Syphilis Cases (Case Mothers)" in three CDC-funded jurisdictions: the states of California and Florida and the metropolitan statistical area (MSA) of Chicago, under "Formative Research and Tool Development" Generic Clearance OMB #0920-0840 (expires 1/31/2019). CDC will sponsor this data collection activity. Data collection will be carried out by CDC's cooperative agreement partner, Association of State and Territorial Health Officials (ASTHO).

If syphilis is not appropriately treated in pregnant women, it can lead to stillbirth, death of an infant after birth, or serious medical complications for the infant. Our proposed data collection has the potential to address a critical knowledge gap, gathering first-hand information through in-depth interviews from women whose babies were affected by congenital syphilis, also known as case mothers. In 2017, CDC issued an official Call to Action to combat rising rates of syphilis, including congenital syphilis, in the US, making this data collection a Division priority. The data from this project will build sexually transmitted disease (STD) program capacity to prevent perinatal transmission of syphilis by working with state and local partners.

Specifically, we ask information on these women's living situation, sources of support, factors that affect frequency and timing of prenatal care, and factors that influenced inadequate treatment for syphilis. Asking these questions of the individuals directly affected via in-depth interviews helps illuminate their decision making processes, who was involved in decision making, factors considered before making decisions, what could have changed the decision, and how women feel about the decisions they made. The information we collect will help identify barriers and missed opportunities throughout the care continuum. Our partner state and local STD programs can use this information to develop strategies to improve their programming around congenital syphilis. Without speaking to women directly, STD programs can only infer this information second-handedly from case reports, surveillance, and medical records, which is often incomplete and not readily available. The purpose of this qualitative study is to better understand and document the experiences and perspectives of CS case mothers. A case of CS occurs when a pregnant woman with untreated syphilis passes the infection to her fetus in utero. CS case mothers are identified as associated with a case according to the CDC

surveillance definition based on maternal and/or infant criteria (2016 Surveillance Report). The majority of CS cases are prevented through routine screening and treatment of pregnant women during prenatal care.

In recent years, syphilis cases have surged in the US, and after a period of decline, CS has rebounded. CS cases increased every year between 2012 and 2016. In 2016, there were 628 cases of CS, including 41 syphilitic stillbirths, with the highest rates reported from the West (25.6 cases per 100,000 live births) and South (17.8 cases per 100,000 live births) compared to the national rate of 15.7 cases per 100,000 live births (2016 Surveillance Report). The vast majority of CS cases are concentrated in a small number of states and in a small number of counties within states.

A substantial proportion of CS case mothers lack timely and adequate prenatal care. In 2014, there were 458 cases of CS reported in the US. More than a fifth (21.8%) of women associated with these cases did not receive any prenatal care at all. More than two-thirds (68.6%) of women received some prenatal care, but were inadequately treated, or untreated, for syphilis (Bowen et al 2015). There are insufficient data to ascertain how many prenatal visits these women actually had, or when during pregnancy these visits occurred, but Su et al (2015) reported that only 14% of women associated with CS cases from 1999-2013 had 10 or more prenatal care visits.

For women who obtain some amount of prenatal care, delays in recognizing and diagnosing pregnancy, along with an insufficient number or poor timing of prenatal care visits during the pregnancy, can shorten the window of opportunity for diagnosing and effectively treating syphilis infections. Disruption of the timeline for routine screening and timely treatment of syphilis in pregnant women can result in a pregnant woman with syphilis transmitting the infection to her infant in utero, resulting in a case of congenital syphilis.

There are many psychosocial and behavioral factors that prevent or delay women's use of prenatal care services including unplanned or unwanted pregnancy; denial or concealment of the pregnancy; lack of awareness of a pregnancy; unawareness of or lack of belief in the importance and timeliness of prenatal care; and mental health, substance abuse, or other emotional, family or personal problems. In addition, women experience situational factors such as difficulty finding transportation or child care that prevent them from getting regular care during pregnancy (Braveman, et al. 2000; Feijen-de Jong, et al. 2011; Goldenberg, et al. 1992; Johnson, et al. 2011; Phillippi 2009). Structural and health systems factors that affect prenatal care include lack of insurance coverage, late enrollment in insurance or Medicaid, and the cost of co-pays (Egerter, et al. 2002; Nothnagle, et al. 2000; Rittenhouse, et al. 2003; Weir, et al. 2011).

There are also missed opportunities within the health system to screen and treat pregnant women for syphilis. CDC recommends serological screening for syphilis of all pregnant women during the first prenatal care visit. Women who live in high syphilis morbidity areas, or who are at risk for obtaining suboptimal prenantal care, should be rescreened early in the third trimester and at delivery. While 46 states have laws requiring at least one screening test during pregnancy, only 12 states require screening in the third trimester. Screening in both the first and third trimesters allows providers to monitor the effectiveness of treatment and the patient's response. However, states requiring additional screening are not necessarily states with the highest morbidity (Hollier, et al. 2003). There are also missed opportunities when pregnant women who may be at high risk for syphilis are not screened in emergency room settings (Warner, et al. 2001).

2. Purpose and Use of the Information Collection

The purpose of this information collection is to conduct in-depth interviews 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. We will 1) document women associated with congenital syphilis (CS) cases (case mothers) recollections of and perspectives about their pregnancy and prenatal care experience, 2) attempt to identify potential protective or supportive factors that would facilitate care and reduce the risk of CS, and 3) identify strategies to reach vulnerable women and increase awareness of the risks of CS during pregnancy.

The planned study design 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 three sites. Unlike 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. We will use qualitative, in-depth interviews to collect data for this study (**Attachment 5a**). The in-depth interviews will primarily include open-ended questions with some closed-ended questions designed to elicit information on participants' pregnancy, prenatal care, and syphilis diagnosis experiences related to those events. Key variables to be explored through the

interviews are described in Exhibit 2.1 below. All data collection instruments have been approved by the

CDC Institutional Review Board (**Attachment 6**). CDC, in partnership with partner staff, will identify and develop appropriate dissemination opportunities for these findings. The results of this study are not generalizable to the larger population. Information collected will be used to revise, augment or finalize communication campaign platforms and systems.

CDC will not be drawing any inferences from this data. This data is not generalizable. CDC will share its final report with OMB.

Exhibit 2.1: Overview of Key Variables

Case Moms (Attachment 5a)
• Demographics • Experiences of Pregnancy Diagnoses • Prenatal Care during 1St, 2nd, and 3rd Trimester • Syphilis Diagnosis • Post Pregnancy Experiences

3. Use of Improved Information Technology and Burden Reduction

Trained qualitative interviewers subcontracted by ASTHO will conduct individual in-depth interviews at a time and location that is convenient to the selected respondents. Body language and facial cues are critical to understand where additional probing may be needed or should stop, and telephone or web interviews limit the interviewer's ability to read both. Thus, the contractor will conduct the individual, in-depth interviews (IDIs) in person. After asking for and receiving permission from the respondent, the contractor will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the respondent (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the respondent.

4. Efforts to Identify Duplication and Use of Similar Information

The interviews will collect key information that the Agency believes is not captured elsewhere. The Agency believes no other data collection effort has been conducted or has been planned to collect similar information for these populations. CDC conducted a review of similar studies prior to the issuance of the cooperative agreement, and determined that this study is collecting unique information

from the populations. Therefore, our study requires the collection of this new primary data. There would be no reason for another Federal Agency to conduct a similar study.

5. Impact on Small Businesses or Other Small Entities

This study will collaborate with local health departments in three CDC-funded jurisdictions: the states of California and Florida and the metropolitan statistical area (MSA) of Chicago to aid in recruiting potential respondents by identifying eligible potential respondents through their routine and regularly occurring activities and referring them to the study. We do not anticipate substantial burden.

6. Consequences of Collecting the Information Less Frequently

The present study will provide the primary qualitative data needed to understand perspectives of CS case mothers regarding their pregnancy and prenatal care experiences, interactions with the health system, and syphilis diagnoses. If this evaluation were not conducted, it would not be possible to identify barriers and facilitators of timely syphilis screening and treatment among pregnant women as well as linkages between STD programs and partners who provide care to vulnerable pregnant women. The length of data collection is 2-4 months and data will only be collected once.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection effort does not involve any special circumstances.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

8a. For sub-collection requests under a generic approval, Federal Register Notices are not required and none were published. A 60-Day Federal Register Notice for the generic clearance 0920-0840 was published on 06/25/2015, Vol. 80 No. 122, pages 36540-36542, exp. 01/31/2019.
In addition, the following partnering staff at ASTHO and local Health Departments were consulted for the development of this study. There were no unresolved issues associated with the consultation process. Aside from the official 60-day public comment period for the Generic data collection, there were no other public contacts or opportunities for public comment on this information collection.
8b. ASTHO consultant on this project include:

Geetika Nadkarni, MPH Director, Infectious Diseases

(571) 527-3164 | Association of State and Territorial Health Officials
National Headquarters: 2231 Crystal Drive, Suite 450, Arlington, VA 22202
Regional Office: 600 Peachtree Street NE, Suite 1000, Atlanta, GA 30308

9. Explanation of Any Payment or Gift to Respondents

Interview respondents will each receive a $60 token of appreciation in the form of a Visa gift card. Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates, and the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses (Abreu & Winters 1999; Shettle 1999). Additionally, offering tokens of appreciation is cost-efficient, decreasing cost to the government by reducing the number of contact attempts necessary to gain participation when no token of appreciation is offered (Bricker 2014).

Remuneration has been used in other HIV/STD-related CDC data collection efforts, such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Testing Brief Messages for BLMSM Study (OMB 0920-14SY under 0920-0840, exp. 1/31/2019), which included high risk populations and had a similar length of time for completing the client interview as in this proposed research. In all of these other projects, tokens of appreciation were used to help increase participation rates.

Participating in a 90-minute in-depth interview requires a considerable investment of personal time and potential for inconvenience to the respondent. Women who volunteer to participate in this research do so at the significant cost of their own time, transportation, lost wages, and need for childcare.

The $60 proposed token of appreciation is commensurate with government-wide practices, which include a $40 token of appreciation for a one-hour, up to $75 for a 90 – 120 min. in-depth interview, designed to include needs associated with traveling to a facility (e.g., gas, parking, taxi, day care needs). Groth (2010) stated when applied in a reasonable manner, financial incentives are not an unjust inducement to participation and are an approach that acknowledges participants for their time and effort. Financial incentives can contribute to minority participation without using coercion (Halpern et al., 2004). In fact, payment affirms participants' value and the importance of their participation (Russell et al., 2000). It can also equalize the burden placed on participants in terms of time and cost to participation (Russell et al., 2000).

The $60 amount is also consistent with other tokens of appreciation used in CDC-sponsored HIV/STD data collection efforts, using similar methodologies, and targeting similar vulnerable and at-risk

populations; including the “Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the
United States” (OMB 0920-1091, exp. 09/30/2021), “National HIV Behavioral Surveillance” (OMB 0920-0770, exp. 5/31/2014) and the “Testing Brief Messages for BLMSM Study” (OMB 0920-14SY under 0920-0840, exp. 1/31/2019).

Research has shown offering tokens of appreciation is cost-efficient, decreasing cost to the government by increasing participation and reducing the number of contact attempts necessary to gain participation compared to data collections where no token of appreciation is offered (Church, 1993; Singer et al., 2008; Bricker 2014).Although they effect of incentives on response rates and non-response bias are used to primarily characterize quantitative data collections (i.e. surveys); offering monetary tokens of appreciation for qualitative research, such as in-depth interviews, is a common and encouraged practice used to increase higher levels of engagement, increase recruitment time, limit “no shows”, and lower overall project costs in qualitative research (Hagglund 2017) .

CDC-IRB approved this incentive amount and did not consider it too high or coercive considering the population, amount of time required, and the sensitive nature of the topics discussed in the interview. Data quality depends on being able to recruit engaged respondents who are willing to spend time and share their perspectives with the interviewer. The study team feels that anything less than $60 is likely to hamper recruitment and would not be reflective of the level of appreciation warranted by the respondent’s contribution to the study aims.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCHHSTP PRA Coordinator has reviewed this project and determined the Privacy Act does not apply since personally identifiable information (PII) will not be transmitted to the CDC.

We will inform respondents that their responses will be kept private to the extent permitted by the law. Names will be stripped from transcripts of interviews before transcripts are transmitted to CDC. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the research team. Terms of the CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected. Accordingly, individuals’ data will be kept private and protected to the extent permitted by law.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval:

This study has been reviewed and approved by the CDC Institutional Review Board IRB (**Attachment 6**).

All project staff, contracted interviewers, including state and local health departments site personnel were included in and approved by CDC's IRB, on June 7, 2018. All project staff received a copy of CDC's approved IRB protocol for this project. Each local site had the option to go through their own local IRB or defer to CDC's IRB, because the CDC-level review was inclusive of all the sites. Florida and California elected to defer to CDCs IRB, Chicago went through the additional layer of their own local IRB, using the CDC approved protocol package and received approval October 26, 2018.

Sensitive Questions:

This study is an initiative aimed to inform the development of strategies to prevent and reduce congenital syphilis transmission and promote sexual health among women at high risk for syphilis. As such, our information collection entails measurement of sensitive syphilis diagnosis-related information. All contracting staff will be trained to provide respondents with city-specific hotlines for STD-care related and mental health care organizations as needed. We will inform all participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

Exhibits 12.1 and **12.2** provide details about how the estimates of burden hours and costs were calculated. We calculated the overall burden per respondent by multiplying the frequency of response by the time to complete each data collection item. All women referred to the project by the local health departments will meet eligibility for the study, so they will not be screened. Eligible women will be contacted for recruitment by health department staff. We estimate that approximately 100 eligible women will be contacted per each of the three sites, for a total of 300 women contacted. The recruitment script (Att. 3a) and follow on interview scheduling script for those women who agree to participate (Att 3c) are expected to take a total of 5 minutes each. The in-depth interviews (Att. 5a) for case moms is expected to take a total of 90 minutes (1.5 hour) each. The total number of burden hours is120.

12A. **Estimated Annualized Burden Hours**

Exhibit 12.2: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Recruitment Script(Att. 3a)	300	1	5/60	25
General Public-Adults	Interview Scheduling Script (Att. 3c)	60	1	5/60	5
General Public-Adults	Interview Guide (Att. 5a)	60	1	1.5	90
				Total	**120**

12B. **Estimated Annualized Burden Costs**

The annualized costs to the respondents are described in **Exhibit 12.3**. The United States Bureau of Labor Statistics' employment and wages estimates from May,2016 (http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this GenIC request. The total estimated cost of the burden to respondents is approximately $2,863.20. This cost represents the total burden hours of general respondents multiplied by the average hourly wage rate ($23.86).

Exhibit 12.3: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	Recruitment Script (Att. 3a)	25	$23.86	$596.50
General Public-Adults	Interview Scheduling Script (Att. 3c)	5	$23.86	$119.30
General Public-Adults	Interview Guide (Att. 5a)	90	$23.86	$2,147.40
				Total $2,863.20

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents for participating in this survey.

14. Annualized Cost to the Federal Government

The estimated annualized cost to carry out the data collection activities is $197,060.90. This estimate includes the cost of recruitment, screening, conducting the interviews, analysis and reporting, as well as the total cost of the tokens of appreciation ($60 per completed interview, for a total of $3,600).

Exhibit 14.4: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs

		(dollars)
Direct Costs to the Federal Government	CDC Co-Project Lead (GS-13 0.20 FTE)	$20,258.80
	CDC Scientist (GS-13, 0.10 FTE)	$10,079.40
	CDC Health Scientist (GS-13, 0.10 FTE)	$10,079.40
	CDC Health Scientist (GS-11, 0.10 FTE)	$6,643.30
	Subtotal, Direct Costs	**$47,060.90**
CoAg Costs	**Annual Cooperative Agreement (NNPHI #** CDC-RFA-OT13-1302**)**	**$150,000**
	TOTAL COST TO THE GOVERNMENT	**$197,060.90**

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics of respondents collected in the first part of the interview (e.g., city, age, education, employment status). Data collection will occur between Aug-Oct 2018, analyses will be carried out in Oct-Dec 2018, and the final data set and report will be submitted in January 2019. The project timeline is detailed in **exhibit 16.1**.

Exhibit 16.5: Project Time Schedule

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol, IRB and PD approvals	Oct 2017- May 2018
OMB Submission	Jun 2018
Recruitment	After OMB Approval
Data Collection	1-3 months after OMB Approval
Data analysis finalized and report drafted	4-6 months after OMB Approval
Final data set and final report submitted to CDC	7 months after OMB Approval

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names, other PII, and locations will be removed) qualitative database for this study along with the corresponding data documentation. This database will be made publicly available within 30 months of the end of data collection, if the final de-identified data are of sufficient quality and usefulness. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

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