Assessment of Gonorrhea Case Interviewing in STD Surveillance Network Sites
Generic Information Collection under OMB # 0920-0840

Section A: Supporting Statement

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- **Goals of the study:** This qualitative assessment focuses on 10 city, county and state health departments participating in Cycle III of the STD Surveillance Network (SSuN). The goal of this qualitative assessment is to identify factors contributing to variations in gonorrhea (GC) case interview completion rates across the SSuN sites. These 10 sites are funded by CDC's existing PS13-1306 cooperative agreement to address STD surveillance problems of national, state, and local interest and to better understand the epidemiology of STDs and to inform national and local STD prevention efforts.

- **Intended use:** Assessment outcomes will be communicated to SSuN staff in positions to consider and implement site-specific improvements in their GC case interviewing processes. The results are not intended to be generalized to the larger population. Assessment of the factors related to GC case interview completion will help document best practices and inform future strategies to improve GC case interviewing efforts of health departments in participating SSuN jurisdictions. The results also will provide CDC an increased understanding of the factors that contribute to effective GC case interviews provided by facilities participating in SSuN.
- **Methods to be used to collect data:** Data will be collected from a total of 50 individuals through semi-structured, qualitative in-depth interviews (IDIs).
- **Subpopulations to be studied:** We will obtain data from 30 staff (3 per SSuN site) responsible for conducting GC case interviewing (e.g., disease investigation specialist, contract workers) and 20 staff (2 per SSuN site) responsible for supervising or overseeing GC case interviewing (e.g., STD managers, SSuN site PI). These 50 staff will be selected from the 10 SSuN sites located in Baltimore, California, Florida, Massachusetts, Minnesota, Multnomah County Oregon, New York City, Philadelphia, San Francisco, and Washington.
- **How data will be analyzed:** Qualitative coding of IDI notes using computer-assisted qualitative data analysis software (e.g., NVivo).

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 assessment entitled, "Assessment of Gonorrhea Case Interviewing in STD Surveillance Network Sites" under the "Formative Research and Tool Development" (OMB#0920-0840, exp. 10/31/2021) Generic Clearance. Data collection will be carried out by an evaluation team composed of CDC DSTDP staff who will lead the evaluation design, data collection, analysis, and dissemination of evaluation results.

Gonorrhea (GC) is the second most common notifiable disease reported in the United States with over half a million cases reported in 2017[1]. GC rates continue to rise with an 18.6% increase since 2016 and a 75.2% increase since a historic low in 2009[1]. GC infections are a leading cause of pelvic inflammatory disease (PID), which can lead to tubal infertilities, ectopic pregnancy, and chronic pelvic pain in women. In addition, research has found that GC infections can facilitate the transmission of HIV[2].

In 2005, the CDC Department of STD Prevention (DSTDP) established the STD Surveillance Network (SSuN) to gather enhanced STD data from selected health departments. The information gathered from the network sites is used to better understand the epidemiology of STDs and inform national and local STD prevention efforts. DSTDP currently funds 10 jurisdictions as part of Cycle III of the SSuN cooperative agreement. As part of the cooperative agreement, the health departments associated with each jurisdiction conduct interviews with a random sample of reported GC cases to obtain additional demographic and behavioral information (e.g., age, race and Hispanic ethnicity, gender of recent sex partners, symptoms, and treatment received). The optimal rate for interview completion among the sampled GC cases is 65%. Over the past few years, jurisdictions have experienced difficulty in

completing patient interviews among sampled cases. From January 2018 to November 2018 the overall interview completion rate across all SSuN sites was 40%, with a range from 21% to 62% between sites[3]. This low completion rate, as well as the range across SSuN sites, may be explained by differences among sites in the characteristics of staff conducting the interviews (e.g. training, background, job role and responsibilities, attitude, funding), the procedure for interviewing (e.g. consent, contact information, methods, timing, documentation/tracking, callbacks), the context of the community served (e.g. clinic reputation, over sampling, attitudes, perceptions), and characteristics of patients (e.g. variation in patient characteristics of those who have complete versus incomplete interviews). A better understanding of the barriers and facilitators to conducting and completing GC interviews is essential to strengthening enhanced surveillance data that informs national and local STD prevention efforts.

2. Purpose and Use of the Information Collection

The purpose of this information collection is to identify factors contributing to variations in GC case interview completion rates across the SSuN sites. Specifically, this assessment focuses on 10 city, county and state health departments participating in Cycle III of the STD Surveillance Network (SSuN). The study will take place at the SSuN sites that volunteer to participate located in Baltimore, California, Florida, Massachusetts, Minnesota, Multnomah County Oregon, New York City, Philadelphia, San Francisco, and Washington. These 10 sites are funded by CDC's existing PS13-1306 cooperative agreement to address STD surveillance problems of national, state, and local interest and to better understand the epidemiology of STDs and to inform national and local STD prevention efforts.

Interview data will be gathered from a total of 50 persons. These include 30 staff (3 per SSuN site) responsible for conducting GC case interviewing (e.g., disease investigation specialist, contract workers) and 20 staff (2 per SSuN site) responsible for supervising or overseeing GC case interviewing (e.g., STD managers, SSuN site PI).

The qualitative data collected through this study will be used to inform policies and practices of the SSuN sites included in the evaluation. CDC DSTDP and sites participating in SSuN may use findings to address barriers and implement strategies to improve completion of GC case interviews and develop a plan of action to address key recommendations. The results also will provide CDC an increased understanding of the factors that contribute to effective GC case interviewing provided by SSuN sites in different geographic locations. As this is Cycle III and DSTDP is planning for Cycle IV, this assessment may help CDC/DSTDP identify programmatic changes and provide guidance related to GC case interviewing as a SSuN activity. These results will be communicated to relevant SSuN site personnel in a position to use the results to further strengthen their GC interviewing practices. CDC/DSTDP will disseminate the information through presentation at a SSuN site recipient meeting or distribution of an evaluation report. Subsequent presentation of this evaluation and any program changes that may result from the evaluation may also be shared with other STD control partners and may occur at a scientific meeting or be presented in a scientific manuscript..

The 30 SSuN site staff and 20 SSuN site supervisors will be recruited for in-depth interviews (IDIs) across all ten sites. An initial concept for the evaluation plan was presented to SSuN jurisdiction principal investigators (PIs) during the November 2018 quarterly conference call. Follow-up communication with PIs will occur following agency clearance approvals via email and telephone to assess interest and gather additional information to identify eligible staff to participate. PIs will provide the initial gateway to approach staff for participation. CDC/DSTDP staff involved with this assessment will identify eligible staff through SSuN site PIs and by examining personnel lists. These staff will include individuals responsible for completing GC case interviewing (e.g., disease investigation specialist, contract workers (MPH students)) and individuals responsible for supervising or overseeing

GC case interviewing (e.g., STD managers, SSuN site PI). Once project clearances have been obtained, we will request name and contact information for all staff on the list, and will use that list to recruit participants and invite them for an interview. Participation in this assessment will not impact staff job performance, and there is no requirement for the 50 staff members and supervisors to participate in this assessment as a function of their job performance. No screening tool is needed for staff participants because they will be purposively recruited based on the roles they play in the 10 SSuN sites. (For additional details on how we protect the identities of study participants, see the Protection of the Privacy and Confidentiality of Information Provided by Respondents section included below in this document.)

Eligible staff who choose to participate in the assessment will be scheduled for an interview. At the beginning of each interview with staff and before any data collection starts, the DSTDP team will review the assessment procedures with each participant. Participants will be asked to complete an informed consent form **(Attachment 1**). The wording of these forms has been reviewed and approved by the CDC IRB (**Attachment 3**). CDC IRB protocol approval was received April 4, 2019.

We will use two semi-structured qualitative interview guides to collect information for this assessment, one for SSuN site staff, and the other for SSuN site supervisors (**Attachments 2a-b)**. Both types of interviews include open-ended questions. For the participants, the interview guide begins with a series of open-ended questions that elicit descriptive characteristics of the respondent, including the role they have within the SSuN site (**Attachment 2a-2b**). In addition staff will be interviewed regarding their job background related to GC case interviewing, interviewing procedures and processes, and the context of the community where GC case interviews are conducted. Interview questions will examine staff characteristics (i.e., training, job background, and responsibilities), attitudes and perceptions towards interviewing, interview processes and procedures, and community context (e.g., health department reputation, over-sampling).

Key variables to be explored through the participant interviews are described in Exhibit 2.1 below. All data collection instruments have been approved by the CDC IRB **(Attachment 3)**.

Exhibit 2.1: Overview of Key Variables

Staff (Att. 2a)	Supervisors (Att. 2b)
• Staff role at health department (SSuN site) • Staff training related to GC case interviewing • Health department procedures for interviewing a GC case • Staff process for interviewing a GC case • Staff perspectives on what facilitates or hinders GC case interview completion • Staff attitudes and perspectives towards GC case interviewing • Staff perspectives on the community context surrounding GC case interviewing	• Supervisor role at health department (SSuN site) • Staff training related to GC case interviewing • Health department procedures for interviewing a GC case • Supervisor perspective of staff process for interviewing a GC case • Supervisor perspectives on what facilitates or hinders GC case interview completion • Supervisor attitudes and perspectives towards GC case interviewing and perspective of staff attitudes • Supervisor perspectives on the community context surrounding GC case interviewing

3. Use of Improved Information Technology and Burden Reduction

The DSTDP team will conduct individual IDIs in person at each participating SSuN site. Telephone interviews or visual remote interviews (such as web or Skype interviews) are not a good vehicle for developing the necessary rapport between interviewer and client participant for a successful qualitative interview. 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 DSTDP team will conduct the individual IDIs in person.

A member of the DSTDP team will invite staff to participate, either by telephone or by email. No staff screening tool is needed with potential staff respondents because they will be invited based on their job roles within the SSuN site (for example, staff responsible for completing GC case interviewing or supervising or overseeing GC case interviewing). When possible, the DSTDP team will conduct face-to-face interviews with the staff participants. However, this may not always be possible because of busy work schedules for the staff. In those situations, some program staff may be conducted by phone instead of face-to-face.

Participating staff will all be asked to provide a signed consent form prior to doing the interview (**Attachment 1**). The consent form has been reviewed and approved by the CDC IRB **(Attachment 3)**. After asking for and receiving signed consent forms from the participant, the contracting team will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the participant (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the participant.

4. Efforts to Identify Duplication and Use of Similar Information

This evaluation is an effort to assess the activities of the SSuN jurisdictions involved in SSuN Cycle III as this is a distinct activity of the network. This assessment will gather information about factors contributing to variations in GC case interview completion rates across 10 city, county and state health departments participating in Cycle III of SSuN. Because variation among SSuN health department sites for GC case interviewing are currently not well understood, descriptive, qualitative data are needed to allow the identification of the full range of practices, barriers, and facilitators involved. Thus, we will

conduct qualitative semi-structured interviews (up to 60 minutes) with staff at the volunteer health departments. Assessment of the factors related to GC case interview completion will help document facilitators and barriers and may assist in improving program outcomes.

We are not aware of any previous studies that have collected information on factors that influence GC case interview completion. To the Agency's knowledge, the current proposed information collection will be the first study to examine these issues. The results obtained from the proposed assessment will provide unique, novel, and useful information that can be used to inform policies and practices of the SSuN sites included in the evaluation. There is no other existing network of this kind, to our knowledge, and there is no indication that this level of activity would occur elsewhere or by another agency.

Thus, the Agency believes this proposed information collection is not captured elsewhere, and that no other data collection effort has been conducted or has been planned to collect similar information for this population in these jurisdictions. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate these research questions.

5. Impact on Small Businesses or Other Small Entities

This information collection does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

This will be a one-time information collection from sites participating in SSuN Cycle III. This information collection will provide the primary qualitative data needed to understand the facilitators and barriers to effective GC case interviewing and interview completion in individual SSuN sites. If this case study were not conducted, it would not be possible to form an in-depth contextual understanding of factors that may affect the success of SSuN sites providing GC case interviews in their respective jurisdictions. Collecting this type of jurisdiction-specific information is important, as it will allow us to provide feedback to SSuN sites and other public health stakeholders that is relevant for improving GC case interviews conducted by the SSuN sits. The total length of data collection is 3-4 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

A 60 day FRN notice to solicit public comments was published for the Generic umbrella collection (0920-0840) in the Federal Register on 04/23/2018, Volume 83, Number 78, Page Number 17663-17664. No public comments were received.

In addition, an initial concept for the evaluation plan was presented to SSuN jurisdiction principal investigators (PIs) during the November 2018 quarterly conference call. Follow-up communication with PIs will occur following agency clearance approvals via email and telephone to assess interest to participate. There were no unresolved issues associated with this initial concept process.

9. Explanation of Any Payment or Gift to Respondents

Interview participants will not receive token of appreciation funds. No incentives will be provided. Health department staff will not be compensated for their participation in the evaluation as interviews can be accomplished during normal business hours and pertain to their work as health professionals.

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

The CDC Privacy Officer has assessed this package for applicability of 5 U.S.C. § 552a, and determined that the Privacy Act does apply to the overall information collection. CDC has completed a Privacy Impact Assessment of the data system used by the DSTDP team (**Attachment 4**).

Participants will be invited to provide their contact information (name, phone, email), in order to schedule the in-depth interview. This contact information will be hand written on paper, and not be computerized on a form. When not in active use, the papers containing the contact information will be stored in locked cabinets separate from other study data at the CDC/DSTDP team office. These papers with the participant's contact information will be destroyed after the interview is completed and the interview data have been fully transcribed and verified for accuracy.

At the beginning of the in-depth interview, a member of the DSTDP team will review the purpose of the study with the participant and answer any questions they might have. The participant will be asked to provide signed informed consent (**Attachment 1**). This includes permission to audio record the interview. After the consent process is finished, the interview will begin. Only project staff will have access to the records, study documents, and data.

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

IRB Approval

This study has been reviewed and approved by the CDC IRB **(Attachment 3)**.

Sensitive Questions

This is an assessment to identify factors that facilitate or hinder effective GC case interviewing and interview completion in individual SSuN sites. This assessment involves no more than minimal risk to participants, as the probability and magnitude of harm or discomfort anticipated in the evaluation are not greater in and of themselves than those ordinarily encountered in daily life. At most, participating in these discussions may cause participants to think more about their behavior at work, and they may feel uncomfortable if they realize that they could have conducted GC case interviewing more effectively in the past. Staff completing GC case interviews at the volunteer sites will be interviewed regarding their job background related to GC case interviewing, interviewing procedures and processes, and the context of the community where GC case interviews are conducted. Interview questions will examine staff characteristics (i.e., training, job background, and responsibilities), attitudes and perceptions towards interviewing, interview processes and procedures, and community context (e.g., health department reputation, over-sampling). We will inform all participants that they may skip any question or stop interviews at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

This data collection will include 50 individuals (30 staff responsible for completing GC case interviewing and 20 staff responsible for supervising or overseeing GC case interviewing). The staff and

supervisor interviews **(Attachment 2a-2b)** will take 60 minutes to complete and will be administered once.

Exhibits 12.1 and 12.2 provide further details about how the estimates of burden hours and costs were calculated. The estimated annualized burden is 50 hours.

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 (hours)	Total Burden Hours
Health Department-Staff	Staff Interview (Att. 2a)	30	1	1	30
Health Department-Supervisors	Supervisor Interview (Att. 2b)	20	1	1	20
				Total	**50**

12B. **Estimated Annualized Burden Costs**

The annualized costs to the participants are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from April 5, 2019 (https://www.bls.gov/news.release/empsit.t19.htm) were used to estimate the hourly wage rate for "education and health services" provided by the general public for the purpose of this GenIC request. The total estimated cost of the burden to participants is approximately $1,372.50. This cost represents the total burden hours of general participants multiplied by the average hourly wage rate $27.45.

Exhibit 12.3: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Health Department-Staff	Staff Interview (Att. 2a)	30	$27.45	$823.50
Health Department-Supervisors	Supervisor Interview (Att. 2b)	20	$27.45	$549.00
				Total $1,372.50

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

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

14. Annualized Cost to the Federal Government

Exhibit 14.1 provides the annualized cost to the government, which totals $ 39,905.95 using the 2019 Atlanta locality salary schedule. Managing the project, collecting and analyzing the data, and generating assorted reports will require the expertise of three CDC staff.

Exhibit 14.4: Annualized Cost to the Government (2019 scale)

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs	CDC, Principal Investigator (GS-13, 56.61 hr /125 hrs)	$7,076.25
	CDC Scientist (GS-14, 59.86 hr / 55 hrs)	$3,292.30
	CDC Scientist (GS-11, 32.41 hr / 140 hrs)	$4,537.40
	Travel (2 staff to 10 sites, 1, 250.00 per trip)	$25,000.00
	Subtotal, Direct Costs	**$14,905.95**
	TOTAL COST TO THE GOVERNMENT	**$ 39,905.95**

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

Data collection will occur between May-August 2019, analyses will be carried out in August-September 2019, and the final data set and report will be submitted in March 2020. 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	October 2018 – January 2019; CDC IRB protocol approval was received April 4, 2019
OMB Submission	April 2019
Recruitment	1 months after OMB Approval (May 2019)
Data Collection	1-4 months after OMB Approval (May-August 2019)
Data analysis finalized	4-5 months after OMB Approval (August-September 2019)
Draft report and final report written	6-8 months after OMB approval (October-December 2019)
Final report disseminated	9-12 months after OMB Approval (January-March 2020)

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

References

1. CDC. Sexually transmitted disease surveillance 2017. U.S. Department of Health & Human Services.
2. Fleming, D.R., Wasserheit, J.N. From epidemiological synergy to public health policy and practice: The contribution of other sexually transmitted diseases to sexual transmission of HIV infection. Sex Transm Infect 1999; 75(1): 3-17.
3. Stenger, M. Reported cases, sample fraction and completion rate, SSuN sites 2018 table. (unpublished data)