Assessment of Gonorrhea Case Interviewing in STD Surveillance Network Sites

Generic Information Collection Request under OMB #0920-0840

Section B: Supporting Statement

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**CONTACT**

Brandy L. Maddox, MPH, MCHES
Health Scientist / Principal Investigator

Centers for Disease Control and Prevention
Division of STD Prevention
1600 Clifton Road, NE, Mailstop US 12-2

Atlanta, GA 30333
Phone: 404-639-8511
E-mail: ftn6@cdc.gov

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## EXHIBITS

## 1. Respondent Universe and Sampling Methods

### Site Selection

The study will be carried out in the 10 jurisdictions participating in SSuN which include the health departments of Baltimore, California, Florida, Massachusetts, Minnesota, Multnomah County Oregon, New York City, Philadelphia, San Francisco, and Washington. These sites were selected, because these 10 sites are funded by CDC's existing PS13-1306 cooperative agreement to conduct interviews with a random sample of reported GC cases. These sites are purposively selected to document the barriers and facilitators to conducting and completing GC interviews as a related SSuN activity.

### Target Population

The purpose of this information collection is to assess the barriers and facilitators contributing to variations in GC case interview completion rates among the 10 SSuN Cycle III jurisdictions. SSuN gathers enhanced GC patient information through collaboration with the 10 jurisdictions to better understand the epidemiology of GC.

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). 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. 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.

*Inclusion criteria:*

SSuN staff participants must be

- 18 years of age or older;
- able to speak English and consent to participate;
- be responsible for conducting GC case interviewing or responsible for supervising or overseeing GC case interviewing

*Exclusion criteria:*

SSuN staff participants will be excluded from the study if they

- are unwilling or unable to provide consent;
- do not meet the other eligibility criteria.

This distribution of respondents may vary somewhat from place to place based on availability and the numbers of eligible staff at the 10 SSuN sites. This is a qualitative research study and is not designed to make comparisons between groups or to make generalizations. Probability sampling methods are not appropriate for our qualitative study purposes. Instead we will select respondents to ensure a range of experiences of staff are captured.

## 2. Procedures for the Collection of Information

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. Once project clearances have been obtained, we will request name and contact information (name, phone, email), for all staff on the list, and will use that list to recruit participants and invite them to participate and 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 contractor's office facility. 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 assessment 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 participants complete the informed consent and receive a copy of the consent for their record, the consent process is finished and the interview will begin.

For both the staff and supervisors, the DSTDP team will conduct qualitative, in-depth interviews lasting one hour, on average, to collect information for this study (**Attachments 2a-b**). Interviews will be conducted in a private setting by trained interviewers. With the respondent's permission, interviewers will digitally audio record each interview and will remind participants not to use their full names or other identifying information. The interviews will primarily include open-ended questions designed to elicit information on the factors related to GC case interview completion to help document facilitators and barriers, and their perspectives on the SSuN GC interviewing activity in their jurisdiction. Interview questions will examine staff characteristics (i.e., training, job background, responsibilities), attitudes and perceptions towards interviewing, interview processes and procedures, and community context (e.g., health department reputation, over-sampling).

Only the evaluation team will have access to data collected from the interviews. All project records, including data collection forms, consent forms, interview recordings and notes, will be maintained in an electronic file or database and stored securely on a secure CDC server with password protection. To maintain physical security, signed consent forms and data will be stored securely in a locked cabinet and/or office at the CDC in Atlanta according to record management polices established by the United States Government and as required for possible IRB. No data set file will contain any personally identifiable information from the participant; instead, a unique study ID number will be used to label each study participant's data records.

All interview audio files will be stored on the recorders; interview notes (not full transcripts) will be done in house by DSTDP team members by listening to the recording device and supplementing hand written notes to stand-alone computers that are not networked, taking care to remove any personally identifiable information (PII) that may have been transcribed accidentally. Data brought to study offices will be securely managed by securing the paper and recordings in separate locked offices, cabinets, drawers, and briefcases. Only project staff will have access to the records, study documents, and data. Electronic files will be password protected and stored on a secure server. No final interview transcript or other computerized data file will contain any personally identifiable information from the participant.

Each interview will be transcribed into an encrypted MS Word document. Transcripts and NVivo files for individual cases will be stored on and edited from a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer (without Internet access) at study offices. NVivo analysis files will be stored in on a dedicated data server. Backup files will be encrypted and maintained on flash drives securely kept under lock and key.

The DSTDP team will keep paper and audio files of the interviews as well as the completed interview guides, contact information and other project materials through the period of transcription and QA/QC processes. Participant contact information will be destroyed after completing the transcription process. All consent documents will be maintained in locked cabinets within a secured, physical space, separate from other study data, of which only key study staff have access to records. All electronic study data (transcripts without PII) will be kept in encrypted or password protected files. Analysis will be done on secure network systems or stand-alone (non-networked) password protected computers in secure locations. Study participants will only be labeled with unique numeric ID numbers in the final computerized data sets.

To protect study participant identities, CDC has completed a Privacy Impact Assessment of the data system used by the DSTDP team (**Attachment 4**).

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

CDC staff will use the following procedures to maximize cooperation and to achieve the desired high response rate:

- Participants will be identified through the SSuN site PIs who may have trusted relationships with eligible participants.
- All recruitment materials indicate the voluntary nature of the study.

### 4. Tests of Procedures or Methods to be Undertaken

An evaluation team composed of CDC DSTDP staff will lead the evaluation design, data collection, analysis, and dissemination of evaluation results. The research team includes experts with experience conducting STD research and evaluation with health departments and qualitative research, including screening and interview development and testing. 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.

## 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 the evaluation design and those who will be collecting and analyzing the data. The CDC staff are primarily responsible for the design and implementation of the evaluation, the development of the protocol and data collection instruments for CDC IRB review, collecting and analyzing data and presenting findings at meetings and in publications. All members of the DSTDP team will work together to analyze the data and generate reports containing summaries of the findings.

**Exhibit 5.1: Statistical Consultants**

| Team Member | Organization |
|---|---|
| Brandy L. Maddox | CDC/DSTDP |
| Marion Carter | CDC/DSTDP |
| Emiy Hays | CDC/DSTDP |
| Mark Stenger | CDC/DSTDP |
| Eloisa Llata | CDC/DSTDP |