# Supporting Statement B
# For OMB Information Collection Revision Request

## OMB No. 0920-1072

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## Enhanced STD Surveillance Network (SSuN)

**Supported by:**
**Department of Health and Human Services**
**Centers for Disease Control and Prevention**
**National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention**
**Division of STD Prevention**

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**Enhanced STD Surveillance Network**
**0920-1072**

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## B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

### B.1. Respondent Universe and Sampling Methods

This is a revision request with changes for the currently approved enhanced STD Surveillance Network (SSuN) - OMB# 0920-1072, expiration date 06/30/2021.

Enhanced SSuN is a currently a network of 10 collaborating surveillance jurisdictions in the United States serving as a platform to identify STD trends, monitor STD epidemiology and evaluate the effectiveness of public health interventions through active surveillance collection, reporting, analysis, visualization and interpretation of disease information. Eleven (11) jurisdictions will participate in a fourth 5-year funding cycle beginning September 30, 2019 (**ATTACHMENT 6**). Enhanced SSuN utilizes two distinct surveillance strategies to collect information: STD clinic-based sentinel surveillance (Strategy A) and case-based enhanced STD surveillance (Strategy B), as outlined below.

*Strategy A: Facility-based STD surveillance:*

The respondents providing the information for enhanced SSuN's STD clinic-based sentinel surveillance are; (1) data managers at collaborating STD clinical facilities, and, (2) data managers at the 11 participating city, county and state health departments (Table B.1.A). Within these 11 collaborating sites there are 16 STD clinics that will report data from approximately 145,000 patient-visits per year (Table B.1.A). All patient visits to the participating STD clinics are abstracted for the project, recoded per protocol by data mangers and reported to CDC by the collaborating health departments. As part of routine patient care, information on demographics, limited behavioral risk factors, and details about the clinical encounter (e.g., signs and physical exam findings, diagnoses, laboratory tests and treatment) are collected by clinic staff and entered into the patient's health record. Clinic staff abstract these routinely collected data elements from existing electronic medical records and securely transmit de-identified records to SSuN project staff at the local level.

Table B.1.A

| Collaborating jurisdictions, Cycle 4, 2019 - 2014 | Participating STD Clinics | Total No. of Clinic Data Managers abstracting data | Estimated # STD patient visits/year |
|---|---|---|---|
| Baltimore City Health Department | Druid Clinic, Eastern Clinic | 1 | 10,000 |
| California Department of Public Health | 17th Street Testing, Treatment, and Care Clinic (Orange County) | 1 | 8691 |
| Florida Department of Health | Miami-Dade STD Clinic, Escambia STD Clinic (Pensacola) and Leon County STD Clinic (Tallahassee) | 1 | 15,000 |

| | | | |
|---|---|---|---|
| City of Columbus Public Health | CPH Sexual Health Clinic (Columbus, OH) | 1 | 9,200 |
| Indiana Department of Health | Bell Flower Clinic | 1 | 10,000 |
| Multnomah County Health Department | Multnomah County STD Clinic | 1 | 5,384 |
| New York City Department of Health & Mental Hygiene | Fort Greene Sexual Health Clinic, Riverside Sexual Health Clinic | 1 | 25,384 |
| Philadelphia Department of Public Health | Philadelphia Health Center # 1, Philadelphia Health Center # 5 | 1 | 21,000 |
| San Francisco Department of Public Health | SF City STD Clinic | 1 | 17,107 |
| Utah Department of Public Health | Salt Lake County STD/HIV Clinic | 1 | 6,160 |
| Washington State Department of Health | Harborview STD Clinic | 1 | 12,000 |
| **Totals** | **16 facilities** | **11** | **145,300** |

*Strategy B: Case-based enhanced gonorrhea and syphilis surveillance:*

The respondents for SSuN's case-based enhanced surveillance are; (1) data managers at the 11 collaborating city, county and state health departments (Table B.1.A), and, (2) persons identified as having gonorrhea by routine public health case reporting in the participating jurisdictions. From the universe of persons reported with gonorrhea, a probability sample of patients is selected for enhanced investigations. Enhanced case investigations include look-back investigations using existing department of health disease registries, clinical information from diagnosing providers and patient interviews. The initial sample size is variable by protocol but include at least 10% of all reported cases (Table B.1.B). Within these 11 collaborating sites there is an estimated population of 91,332,000 people (U.S. Census Bureau 2019, Annual

Estimates of the Resident Population: April 1, 2010 to July 1, 2018). In 2017 there were there were 173,605 gonorrhea cases reported among this population, representing approximately 27% of the national gonorrhea case reports in that year. Following standardized protocols, trained health department staff approach randomly-selected persons reported with gonorrhea to request their participation in the enhanced surveillance interview. Interview completion rates in SSuN have historically varied between 40 and 60% of all sampled cases and efforts are ongoing to maximize response rates.

Table B.1.B

| Collaborating sentinel surveillance sites | Estimated # of gonorrhea case reports in 2017 | Estimate of interviews to be completed 10/2019 – 9/2020 |
|---|---|---|
| 1. Baltimore City Health Department | 4,231 | 250 |
| 2. California Department of Public Health | 69,573 | 1,500 |
| 3. Florida Department of Health | 31,683 | 1,500 |
| 4. Columbus Health Department | 5,197 | 300 |
| 5. Indiana Department of Health | 11,835 | 500 |
| 6. Multnomah County Health Department | 2,086 | 450 |
| 7. New York City Department of Health & Mental Hygiene | 23,497 | 1200 |
| 8. Philadelphia Department of Public Health | 7,288 | 500 |
| 9. San Francisco Department of Public Health | 5,775 | 300 |
| 10. Utah Dept. of Public Health | 2,543 | 300 |
| 11. Washington State Department of Health | 9,915 | 580 |
| Totals | 173,605 | 7,380 |

*Minimum sample size for subgroup analysis for case-based enhanced gonorrhea surveillance activities*

For the case-based investigations, 11 collaborating jurisdictions will conducted a total of 7,380 interviews with persons infected with gonorrhea (Table B.1.B). The interviews are conducted with persons who are randomly selected out of the total number of gonorrhea case-reports received by each site.

Through a verbal consent process, selected patients are contacted for interview. Data collected from the interview includes basic demographics, medical history, high-risk sexual behaviors, drug use behaviors and care-seeking experiences. The questionnaires comply with OMB standards on race and ethnicity. Local/state health department staff abstract pertinent information from paper or electronic forms and enter it into the local project's electronic database, perform quality assurance and transmit de-identified date to CDC. These methods result in a representative sample of patients diagnosed with gonorrhea at the project area level

and significantly improve ascertainment of critically important information often missing from routine case reporting such as the race, Hispanic ethnicity, gender of sex partners of the patient, anatomic site(s) of infection, clinical care experience and HIV co-morbidity. More complete ascertainment of these data allows for more accurate calculation of the burden of disease across populations and contributes to a more complete understanding of inequalities and identification of disproportionately affected populations. Currently, there are no systems in place that easily identify groups of people with higher burdens of gonorrhea.

To improve the capacity of national, state, and local STD programs to detect, monitor, and respond rapidly to trends in STDs and to improve the health of populations disproportionately affected by STDs and other related diseases and conditions, an understanding of the epidemiology of GC is fundamental. Design weights are calculated separately for each collaborating jurisdiction based on the effective sample fraction for the participating jurisdiction. Post-stratification weights are also calculated to adjust for observed non-response at the jurisdiction level by sex and age allowing for weighted analysis at the individual site and overall project levels.

**2. Procedures for the Collection of Information**

*Strategy A - Facility-based STD surveillance:*

Clinic staff at each facility or network of facilities at participating enhanced SSuN sites abstract and electronically transmit clinical data from (1) all patients visiting participating STD clinics at the state and local health jurisdictions. Data are de-identified and recoded by health departments and then uploaded on a bi-monthly basis by trained local data managers at collaborating site to a CDC-designed and operated secure access management system (SAMS). None of the data transmitted to CDC contains any identifiable information. Data are stored and maintained at CDC by a data manager in the Surveillance and Data Management Branch of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

Data elements collected in this facility-based STD surveillance include patient demographics, limited behavioral risk factors associated with STDs, clinical history and physical exam findings, STD laboratory test and results, STD diagnoses, and treatment (see data elements attachment). These data elements were developed collaboratively and agreed upon by members of enhanced SSuN. Participation in enhanced SSuN does not require the collection of data elements that are not already collected as part of routine care at collaborating facilities. Completeness of reporting and the quality of data submitted will be monitored by CDC on a monthly basis. Site visits, regular communication with CDC, data quality checks and technical assistance will also provide opportunities for evaluation and troubleshooting of these processes.

*Strategy B - Population-based gonorrhea surveillance:*
A random sample of persons with gonorrhea reported to the health department are interviewed by trained state/local health department staff and included in enhanced SSuN population-based STD surveillance. These persons are a probability sample subset of all persons diagnosed with gonorrhea and reported to a health department within collaborating sites.

As a gonorrhea case report is received by the local health department, it is assigned a random number (e.g. from 0 to 1) by local officials. If the random number assigned to a particular case is below a set threshold value for the site (the threshold values vary from one site to another depending on how many case reports a particular site receives in a year and interviewer capacity availability but sample sizes are generally 10% of all reported cases), the case is referred to investigators for follow-up investigations and a patient interview is attempted. Funded jurisdictions use this randomization method per protocol to identify cases and complete interviews. CDC does not receive information in identifiable form for any cases and does not participate in any way in the contact of cases for interview.

Among sampled cases, a minimum of 4 contact attempts are made by trained interviewers within 30 days of receipt of their case report to complete a telephone or in-person interview. Interviewers follow protocols to collect information on demographics, STD clinical history, and behavioral risk factors associated with STDs (see data elements attachment). Funded jurisdictions develop their own local data collection instruments, in compliance with protocols, to elicit case-specific information from diagnosing providers. Jurisdictions employ data collection method(s) that work best in their project area such as conducting phone interviews with a computer-assisted data entry capability or use printed interview forms. Field experience and pilot testing confirms that patient interview are conducted in approximately 10 minutes.

Interview data are maintained in secure data systems by the collaborating jurisdictions. These data are routinely verified by trained data management staff using CDC-provided edit check programs. On a bi-monthly basis, data are securely transferred to CDC by trained data managers at collaborating sites using CDC's secure access management system (SAMS). At CDC, data are stored and maintained by a data manager in the Surveillance and Data Management Branch (Division of STD and Prevention/ National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention). Completeness of reporting and data quality are actively monitored by CDC on a routine basis. Site visits, regular communication with CDC, data quality checks and technical assistance also provide opportunities for evaluation and troubleshooting of these processes.

Data on race and ethnicity is collected in compliance with the two-question format described in the 1997 Office of Management and Budget's Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, also known as Statistical Policy Directive 15. Validated questions, or widely recognized best practices, were used for all other data collection activities.

*Strategy B - Syphilis Case Surveillance:*
Routine case reports for persons diagnosed with syphilis infection will be extracted from local disease surveillance data management systems. Data elements associated with treatment, laboratory testing and HIV co-infection (based on registry matching) maintained locally, but not otherwise reported to CDC through NNDSS, will be reformatted, records de-identified following SSuN protocols, and case records reported every two months to CDC in combined datasets along with all gonorrhea case and investigation data.

## 3. Methods to Maximize Response Rates and Deal with Nonresponse

*Strategy A - Facility-based STD surveillance:*

Facility data for enhanced SSuN are extracted from data collected as a routine part of all STD facility encounters in the participating clinics. The challenge of non-response is not applicable for this activity because the data elements are extracted according to a pre-determined protocol for all patients presenting for care at the facility and submitted to CDC through the existing secure data network.

*Strategy B - Case-based Enhanced Gonorrhea Surveillance:*

The revised project will employ the same methods to maximize response rates and to address nonresponse as was previously described for the approved project. For the revised activity, trained project staff will continue to employ telephone or in-person interviewing. Protocols for maximizing the likelihood of a successful interview with patients vary by site, but a minimum of four attempts to contact selected patients are made in all sites and additional sources of patient contact information will be used, such as provider emergency contact information, state licensing data and/or social services registries.

Participants are informed that the interview is voluntary and refusal to participate accrues no risk or harm. Project staff are also encouraged to offer evening and weekend interview hours to maximize the convenience of participation for the patient. The response rate for the proposed project is expected to be the same as or better than the most recent enhanced SSuN response rate for gonorrhea diagnosed persons. Nevertheless, the goal of enhanced SSuN is to interview > 50% of eligible persons sampled.

If local health departments offer additional partner management services for patients with gonorrhea, patients are referred to these services regardless of participation in the enhanced investigations.

*Assessing Non-Response Bias*

The same procedures for assessing non-response bias that are currently used for enhanced SSuN population surveillance will be used for the revised activity. Predictors with statistically significant effects will be used in the development of weight adjustment classes. Along with selection probabilities (based on the sampling design), non-response or post-stratification weights are calculated to increase the generalizability of results to the entire universe of patients diagnosed with gonorrhea. No weighting criteria or response biases are applicable to syphilis case data as the full census of reported cases are represented in the data set.

In the analysis of non-response that was completed for the current enhanced SSuN cycle (2013-2018), the most significant predictors of patient response were jurisdiction and gender. The ability to assess and adjust for nonresponse in case-based enhanced gonorrhea investigations is a strength of this surveillance project. Interview success rates are monitored through on-going data reports generated bimonthly from the data submitted to CDC and provided back to collaborating jurisdictions during monthly conference calls. Technical assistance is available to jurisdictions encountering difficulties in maintaining acceptable interview response rates.

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

*Strategy A - Facility-based STD surveillance:*

Enhanced SSuN will collect the results of multiple diagnostic tests, clinical procedures, and laboratory tests such as bacterial culture, gram stain, wet mount, nucleic acid amplification tests, pregnancy test, rapid HIV test, ELISA, Western blot. The information received for this project reports the results carried out by the collaborating facilities as part of the routine clinical care of their patients.

*Strategy B - Population-based gonorrhea surveillance:*

Beginning in early 2013, CDC began an evaluation of the gonorrhea interview template instrument that included consultation with external stakeholders, including grantees, subject matter experts, and colleagues from other federal agencies. The evaluation focused on examination of the relevance, coherence, and scientific contribution of interview questions. In addition, questions from Behavioral Risk Factor Surveillance System (BRFSS), California Health Survey and other ongoing, or previous CDC surveillance projects were considered. Local staff extensively tested the skip patterns and responses using a paper version of the interview instrument prior to initial implementation. Experience in the field confirms that interviews take approximately 10 minutes to complete.

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

The following individual was consulted on statistical aspects:

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Individuals Collecting and/or Analyzing Data

CDC is not directly engaged with human subjects during data collection. However, CDC Project Staff listed below will monitor investigation success rates by health department staff, and analyze the data.

CDC Project Staff
All CDC project staff can be reached at the following address and phone number:
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Revised enhanced SSuN Awardees:

1. Baltimore City Health Department
2. California Department of Public Health
3. City of Columbus Public Health
4. Florida Department of Health
5. Indiana State Health Department
6. Multnomah County Health Department
7. New York City Department of Health and Mental Hygiene
8. Philadelphia Department of Public Health
9. San Francisco Department of Public Health
10. Utah Department of Public Health
11. Washington State Department of Health