

**Supporting Statement
For OMB Information Collection Request**

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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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0920-1072**

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

This is a Reinstatement with change request for the currently approved enhanced STD Surveillance Network (SSuN)- OMB# 0920-1072, expiration date 06/30/2018.

Enhanced SSuN is 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 (e.g., mapping) and interpretation of disease information. Enhanced SSuN activities will utilize two distinct surveillance strategies to collect information: STD clinic-based surveillance and population-based STD surveillance, as outlined below.

Facility-based STD surveillance:

The respondents providing the information for enhanced SSuN's STD clinic-based surveillance are (1) the STD clinic data managers at the facilities/networks and (2) the data managers at the 10 enhanced SSuN collaborating sentinel surveillance sites (Table B.1.A). Within these 10 collaborating sites there are 30 STD clinics that collectively report data from approximately 132,000 patient visits per year (Table B.1.A). All patient visits to the participating STD clinics will be included in the project and reported to CDC by the collaborating sites. 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 will abstract routinely collected data from electronic medical records and transmit to SSuN project staff at the local level.

Table B.1.A

Collaborating sentinel surveillance jurisdictions	Participating STD Clinics	Total No. of Clinic Data Managers abstracting data	Estimated # STD patient visits/year
Baltimore City Health Department	Druid, Eastern	1	9,000
California Department of Public Health	Antelope Valley, Central, Curtis Tucker, Hollywood-Wilshire, Monrovia, North Hollywood, Pomona, Ruth Temple, Simms Mann, South Torrance, Whittier	1	17,000
Florida Department of Health	Miami-Dade STD Clinic	1	8,000
Massachusetts Department of	Massachusetts STD clinic (Fenway)	1	900

Public Health			
Minnesota Department of Health	Red Door	1	10,000
Multnomah County Health Department	Multnomah STD Clinic	1	5,000
New York City Department of Health & Mental Hygiene	Central Harlem, Manhattanville, Corona, Fort Greene, Jamaica, Chelsea, Crown Heights, Morrisania,	1	50,000
Philadelphia Department of Public Health	Philadelphia Health Clinic # 1, Philadelphia Health Clinic # 5	1	14,000
San Francisco Department of Public Health	SF City STD Clinic	1	11,000
Washington State Department of Health	Harborview STD Clinic	1	7,000
Totals	30 facilities	10	132,000

Population-based gonorrhea surveillance:

The respondents providing the information for enhanced SSuN's gonorrhea population-based surveillance are (1) the data managers at the 10 enhanced SSuN collaborating sentinel surveillance sites (Table B.1.A) and (2) persons identified as having gonorrhea by case report in the 10 state or municipal health departments participating in enhanced SSuN. From the latter group, a sample of patients will be chosen for interview by systematic random sampling (Table B.1.B). Within these 10 collaborating sites there is an estimated population of more than 90 million people (U.S. Census Bureau 2017, Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2016). In 2016 there were 129,434 gonorrhea case reports from this population, representing approximately 27.6% of the national gonorrhea case reports in that year. Health departments will approach randomly-selected persons reported with gonorrhea and request their participation for interview.

Table B.1.B

Collaborating sentinel surveillance sites	Total # of gonorrhea	# of interviews completed
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	case reports in 2016	for enhanced SSuN
1 Baltimore City Health Department	3451	340
2 California Department of Public Health	53645	1425
3 Florida Department of Health	24165	740
4 Massachusetts Department of Public Health	4254	450
5 Minnesota Department of Health	1959	250
6 Multnomah County Health Department	3934	396
7 New York City Department of Health & Mental Hygiene	18828	471
8 Philadelphia Department of Public Health	6876	490
9 San Francisco Department of Public Health	4803	375
10 Washington State Department of Health	7519	555
Totals	129,434	5492

Minimum sample size for subgroup analysis for gonorrhea population-based activities

For the population-based portion of enhanced SSuN, each of the 10 collaborating jurisdictions conducted a total of 5,492 interviews in 2016 with persons infected with gonorrhea. 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 data 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.

Population-based neuro/ocular/otic syphilis surveillance:

The respondents providing the information for enhanced SSuN's syphilis surveillance activity are (1) the data managers at the 10 enhanced SSuN collaborating sentinel surveillance sites (Table B.1.C) and (2) persons identified by routine case reporting in the 10 state or municipal health departments participating in enhanced SSuN as having symptoms consistent with neurologic, ocular or otic involvement in their infection. This represents a small subset of all reported early syphilis cases. Within these 10 collaborating sites there is an estimated population of more than 90 million people (U.S. Census Bureau 2017, Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2016). In 2016 there were 25,353 gonorrhea case reports from this population. Health departments will screen early syphilis case reports, contact providers for additional clinical and treatment for all cases with symptoms of interest (estimated at 507 total cases) and request the patient's participation in an initial interview and follow-up at three months following treatment.

No sampling methodology is proposed for this activity; a complete census of syphilis cases reporting symptoms of interest will be recruited for enhanced investigations.

Table B.1.C

Collaborating sentinel surveillance sites	Total # of early syphilis case reports in 2016	Estimate # of interviews completed for enhanced SSuN
1 Baltimore City Health Department	432	10
2 California Department of Public Health	9896	198
3 Florida Department of Health	5040	101
4 Massachusetts Department of Public Health	1037	20
5 Minnesota Department of Health	577	11
6 Multnomah County Health Department	307	7
7 New York City Department of Health & Mental Hygiene	4948	99
8 Philadelphia Department of Public Health	932	18
9 San Francisco Department of Public Health	1163	23
10 Washington State Department of Health	1021	20
Totals	25,353	507

2. Procedures for the Collection of Information

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.

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 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), the case is contacted for interview. If the random number assigned to a case is above the threshold number for that site, the case is not contacted for interview. Each site uses this randomization method 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.

Cases that fall within the sample are contacted within 60 days of receipt of their case report by trained interviewers working at local health departments to complete a telephone or in-person interview. Interviewers collect information on demographics, STD clinical history, and behavioral risk factors associated with STDs (see data elements attachment). Funded jurisdictions should develop data collection instruments to elicit case-specific information from diagnosing providers consistent with national SSuN protocols. Each jurisdiction may employ

whatever data collection method(s) work best in their project area. The entire interview lasts for approximately 10 minutes on average. Data elements were developed collaboratively by enhanced SSuN participating sites and CDC.

Interview data are maintained in electronic format by the collaborating jurisdictions. Data are routinely verified by trained data management personnel using CDC-designed edit check programs. On a bi-monthly basis, data are uploaded by trained data managers at collaborating sites to a CDC-designed and operated secure access management system (SAMS). At CDC, data are stored and maintained by a data manager in the Statistics and Data Management Branch (Division of STD and Prevention/ National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention). Completeness of reporting and the quality of data submitted is actively monitored by CDC on a routine basis. Site visits, regular communication with CDC, data quality checks and technical assistance will 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.

Population-based Neuro/Ocular/Otic Syphilis Surveillance:

Routine case reports for persons diagnosed with early syphilis infection received by the health department are reviewed by state/local health department staff; all enhanced SSuN jurisdictions routinely conduct disease control investigations on all early syphilis cases as part of normal public health activities. Of these cases reported with symptoms of neurologic or ocular involvement are referred for enhanced eSSuN surveillance. These persons constitute a subset of all persons diagnosed with syphilis and reported to a health department within collaborating sites. The full census of this subset of patients will be investigated. Trained staff contact reporting providers and obtain clinical and treatment information in addition to the standard disease-staging information generally required as routine public health follow-up for early syphilis cases.

Cases with neurologic, ocular or otic involvement are interviewed to assess additional information regarding the nature, duration and severity of these symptoms. The entire interview lasts for approximately 10 minutes on average. Data elements were developed collaboratively by enhanced SSuN participating sites and CDC. Funded jurisdictions should develop data collection instruments to elicit case-specific information consistent with national SSuN protocols. Each jurisdiction may employ whatever data collection tool works best in their project area. A brief telephone 3 month follow-up interview (5-minutes or less) will be conducted among these patients to determine resolution or persistence of symptoms following appropriate treatment for syphilis.

Interview data are maintained in electronic format by the collaborating jurisdictions. Data are routinely verified by trained data management personnel using CDC-designed edit check programs. On a bi-monthly basis, data are uploaded by trained data managers at collaborating sites to a CDC-designed and operated secure access management system (SAMS). At CDC, data are stored and maintained by a data manager in the Statistics and Data

Management Branch of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Completeness of reporting and the quality of data submitted is actively monitored by CDC on a routine basis. Site visits, regular communication with CDC, data quality checks and technical assistance will also provide opportunities for evaluation and troubleshooting of these processes.

Data on race and ethnicity is collected from all patients 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.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Facility-based STD surveillance:

Facility data for enhanced SSuN are extracted from data collected as a routine part of all STD facility encounters. 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.

Population-based Gonorrhea surveillance and Ocular/Neuro Syphilis Surveillance:

The proposed project will employ the same methods to maximize response rates and to address nonresponse as was previously approved for the project. For the proposed 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 three attempts to contact selected patients are made in all sites. Participants are informed participation in the interview is voluntary and refusal to participate is at no risk or harm to them. Project staff will also be encouraged to offer evening and weekend interview hours to maximize the convenience of participation. 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 accordingly. All early syphilis cases are routinely offered partner management and disease prevention interventions as part of standard public health practice.

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 proposed 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 data will factor into calculation of analytic weights so as to increase the generalizability of results to the universe of patients diagnosed with gonorrhea or early syphilis.

Weights will be developed based on the assessment of non-response bias. In the analysis of non-response that was completed for the enhanced SSuN cycle (2013-2018), the most significant predictors of patient response were jurisdiction, and gender. The ability to assess and adjust for

nonresponse is a strength of our project that may compensate for lower than desired response rates.

Interview success rates will be monitored through on-going data reports generated bimonthly from the data submitted to CDC. The project area staff and CDC will use the data in these reports to identify problems with interview success.

4. Test of Procedures or Methods to be Undertaken

Facility-based STD surveillance:

Enhanced SSuN will collect the results of multiple diagnostic tests, clinical procedures, and laboratory methods 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.

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.

Population-based early syphilis surveillance:

The neuro/ocular/otic syphilis interview template was developed by CDC syphilis subject matter experts in collaboration with epidemiologists and disease intervention specialists in the participating jurisdictions. Local staff extensively tested responses using a paper version of the interview instrument prior to initial implementation. Experience in the field confirms that the initial interview takes approximately 10 minutes to complete and the follow-up interview routinely takes less than five minutes.

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 below will monitor interview 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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Current enhanced SSuN Awardees:

1. Baltimore City Health Department
2. California Department of Public Health
3. Florida Department of Health
4. Massachusetts Department of Public Health
5. Minnesota Department of Health
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. Washington State Department of Health