

**Supporting Statement
For OMB Information Collection Revision Request**

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STI Surveillance Network (SSuN)

**Supported by:
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Centers for Disease Control and Prevention
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Division of STI Prevention**

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Enhanced STI Surveillance Network

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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 STISTI Surveillance Network (SSuN) - OMB# 0920-1072, expiration date 09/30/2026.

The STI Surveillance Network is a network of 15 collaborating surveillance jurisdictions in the United States serving as a surveillance infrastructure providing information to characterize STI trends, refine understanding of STI epidemiology, monitor emergent/re-emergent health issues (mpox, etc.) and evaluate the effectiveness of public health interventions through active data collection, reporting, analysis, visualization, and interpretation of disease information. Fifteen (15) jurisdictions are participating in this 5-year funding cycle, which began September 30, 2024 (**ATTACHMENT 6**). SSuN utilizes two distinct surveillance strategies to collect information: STI clinic-based sentinel surveillance (Strategy A – 12 funded jurisdictions) and case-based enhanced STI surveillance (Strategy B – 12 funded jurisdictions), as outlined below.

Strategy A: Facility-based STI surveillance:

The respondents providing the information for SSuN's STI clinic-based sentinel surveillance are (1) data managers at collaborating STI clinical facilities, and, (2) data managers at the 12 participating city, county and state health departments (Table B.1.A). Within these 12 collaborating sites there are 16 STI clinics that currently report data from approximately 139,000 patient-visits per year (Table B.1.A). All patient visits to the participating STI clinics are abstracted for the project, recoded per protocol by data managers and reported to CDC by the clinic or 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 –5, 2024-2029	Participating STI Clinics	Total No. of Clinic Data Managers abstracting data	Estimated # STI patient visits/year
Baltimore City Health Department	Druid Clinic, Eastern Clinic	1	12,500
California Department of Public Health	17th Street Testing, Treatment, and Care Clinic (Orange County)	1	10,000
Florida Department of Health	Miami-Dade STI Clinic, Escambia STI Clinic (Pensacola) and Leon County STI Clinic (Tallahassee)	1	15,000

Colorado Department of Health and Environment	Denver Sexual Health Clinic	1	10,000
City of Columbus Public Health	CPH Sexual Health Clinic (Columbus, OH)	1	6,300
Washington DC Department of Health	DC Health and Wellness Center	1	7,200
Indiana Department of Health	Bell Flower Clinic	1	13,000
Massachusetts Department of Public Health	Massachusetts General Health Sexual Health Clinic	1	5,900
New York City Department of Health & Mental Hygiene	Fort Greene Sexual Health Clinic, Morissania Sexual Health Clinic	1	24,100
Philadelphia Department of Public Health	Philadelphia Health Center # 1	1	14,000
San Francisco Department of Public Health	SF City STI Clinic	1	11,000
Washington State Department of Health	Public Health – Seattle & King County (PHSKC) Sexual Health Clinic (SHC)	1	10,000
Totals			139,000

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 or syphilis by routine public health case reporting in the participating jurisdictions. From the universe of persons reported with gonorrhea, a probability sample 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 7% of all reported cases (Table B.1.B). Within these 11 collaborating sites there is an estimated population of 108,864,348 people (U.S. Census Bureau 2023, Annual Estimates of the Resident Population: April 1, 2020 to July 1, 2023). In 2023 there were 187,883 gonorrhea cases reported among this population, representing approximately 31.2% of the national gonorrhea case reports. Following standardized protocols, trained health department staff contact randomly selected cases reported with gonorrhea to request their participation in the enhanced surveillance interview. Interview completion rates in SSuN have historically varied between 35 and 60% of all sampled cases; efforts are ongoing to maximize response rates.

Table B.1.B

Collaborating sentinel surveillance sites	Population 2023	Gonorrhea cases reported in 2023	Interviews completed 2023
1. Baltimore City Health Department	565,239	4,387	93
2. California Department of Public Health	39,198,693	67,879	741
3. Florida Department of Health	22,904,868	46,654	849
4. Chicago Department of Public Health	2,670,000	12,382	Was not funded for 2023
5. Columbus Health Department	1,500,000	4,969	222
6. Massachusetts Department of Public Health	7,066,568		Was not funded for 2023
7. Michigan Department of Health	10,083,356		Was not funded for 2023
8. New York City Department of Health & Mental Hygiene	8,300,000	33,304	1,214
9. Philadelphia Department of Public Health	1,570,000	8,561	72
10. Tennessee Department of Public Health	7,148,304		Was not funded for 2023
11. Washington State Department of Health	7,857,320	9,747	343
Totals	108,864,348	187,883	3,534

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

Through an informal verbal consent process consistent with local disease investigation processes, selected patients are contacted for interview. Data collected from the interview includes basic demographics, medical history, high-risk sexual behaviors, drug use behaviors and preventive services accessed. The questionnaires comply with OMB standards on collection of race and ethnicity as well as recent guidance of the collection of sex and sexual orientation. Local/state health department manage these data in their 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, sex of sex partners, sexual orientation of the patient, anatomic site(s) of infection, preventive services experience, and HIV co-morbidity. More complete ascertainment of these data allows for accurate assessment of the differential burden of disease across important populations and facilitates identification of disproportionately affected populations. Currently, there are no systems in place that easily identify critical sub-populations with higher burdens of gonorrhea.

A more comprehensive understanding of the epidemiology of gonorrhea and syphilis is fundamental to improve the capacity of national, state, and local STI programs to detect, monitor, and respond rapidly to trends in STIs and to improve the health of populations disproportionately affected by STIs and other related diseases and conditions. Record level design weights are calculated separately for each collaborating jurisdiction based on the effective county-level 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 group allowing for weighted analysis at the individual site and overall project levels allowing for estimating case characteristics fully representative of the universe of all reported cases in the collaborating jurisdictions.

2. Procedures for the Collection of Information

Strategy A - Facility-based STI surveillance:

Clinic staff at each facility or network of facilities at participating SSuN sites electronically extract and transmit clinical data for (1) all patients visiting participating STI clinics at the state and local health jurisdictions (2) all associated laboratory observations, (3) diagnoses received and (4) treatments dispensed or prescribed. All patients are also matched locally against the local jurisdictions HIV surveillance registry to determine HIV coinfection. Data are de-identified and recoded by health departments or clinic staff and uploaded on a bi-monthly basis by trained local data managers to a CDC-operated secure access management system (SAMS). None of the data transmitted to CDC contain any identifiable information. Data are stored and maintained at CDC by a data manager in the Surveillance and Data Science Branch of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

Data elements collected in facility-based STI sentinel surveillance include patient demographics, behavioral risk factors associated with STIs, clinical history and physical exam findings, STI

laboratory test and results, STI diagnoses, and treatment (see **ATTACHMENT 5**). These data elements were developed collaboratively and agreed upon by members of enhanced SSuN and informed with input from CDC staff. Participation in SSuN does not require the collection of data elements beyond what would ordinarily be collected during routine care at collaborating facilities. Completeness of reporting and the quality of data submitted is monitored by CDC monthly. Site visits, regular communication with CDC, data quality checks and technical assistance also provide opportunities for evaluation and troubleshooting of these processes.

Additionally, participating clinics are required to implement periodic, brief anonymous patient surveys. These surveys, conducted in collaboration with CDC staff, are designed to gain a better understanding of patients' utilization of prevention services available at the clinics. The clinic survey designed for this cycle is focused on Doxycycline Post-exposure Prophylaxis (Doxy PEP). The survey should be administered to all presenting patients until the target sample size is reached. The survey should be completed by patients after clinic check-in but prior to receiving clinical care. Target number of surveys for each clinic will depend on clinic volume and be decided upon in collaboration with CDC for a total of 3,000 surveys across all participating jurisdictions. Clinics can choose administer the survey on paper, in-person, or via tablets or other electronic devices. Because the main purpose of this survey is to assess awareness, attitudes, and utilization of Doxy PEP in persons attending STI clinics, the survey will only be administered to men who report sexual contact with another man (MSM) in the past 12 months. This is because current CDCs guidelines for Doxy PEP recommend Doxy PEP for MSM with a history of STIs. As such, the survey contains two screening questions to determine whether patients are eligible to complete the survey that will take <15 seconds to answer; the target of 3,000 surveys is only intended to include surveys partially or fully complete by MSM respondents.

Strategy B - Population-based enhanced surveillance:

A random sample of persons with gonorrhea reported to the health department is selected, contact attempted, and brief patient interviews conducted by trained state/local health department staff.

As a gonorrhea case report or laboratory result is received by the local health department, it is assigned a random number between 0 and 1 by local staff. This number is then used to draw a probability sample of cases for enhanced investigations. Sample sizes vary between funded sites but generally include 4 - 10% of all reported cases. Cases in this random sample are referred to investigators for follow-up investigations and a patient interview is attempted. Funded jurisdictions use this randomization method, per consensus protocols, to identify cases and complete interviews. All identifiable information is held locally in compliance with state/local disease reporting regulations; CDC does not receive any information for cases investigated and CDC does not participate in any way in the contact of cases for interview.

Among sampled cases, a minimum of 4 contact attempts to complete a telephone or in-person interview is made by trained interviewers within 30 days of receipt of their case report. Interviewers follow protocols to collect information on demographics, STI clinical history, and behavioral risk factors associated with STIs (see **ATTACHMENT 5**). Funded jurisdictions develop their own local data collection instruments, in compliance with protocols, to elicit case-

specific information from diagnosing providers. Jurisdictions employ local 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 interviews take approximately 10 minutes for patients to complete.

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 Science 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. All gonorrhea and syphilis cases are also matched locally against the local jurisdictions HIV surveillance registry to determine HIV coinfection.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Strategy A - Facility-based STI surveillance:

Facility data for SSuN are extracted from information collected in electronic health records as a routine part of all STI 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.

The clinic patient survey will be offered to each presenting patient until the agreed upon target number of surveys completed by MSM is achieved. Patients will be informed their participation is voluntary and that their decision to participate will not affect clinical care.

Strategy B - Case-based Enhanced Gonorrhea Surveillance:

This project requires compliance with protocols (see **ATTACHMENT 4**) for multiple contact attempts, outreach to diagnosing providers for current contact information and evening/weekend contact attempts to maximize response rates. Trained project staff routinely employ telephone or in-person interviewing and may also incorporate SMS messaging to recruit patients. Specific 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. Additional sources of patient contact information are also used, such as provider emergency contact information, state licensing data and/or social services registries to reduce loss to follow-up.

Participants are informed that the interview is voluntary and that refusal to participate or respond to specific questions accrues no risk or harm. The response rate varies between funded jurisdictions

but has historically been between 35% - 70% of all randomly sampled cases. The project goal is to interview >60% of eligible persons sampled for an effective overall sample of at least 2% of all reported cases. If local health departments offer additional partner management, treatment or additional preventive services to patients, referrals to these services are provided regardless of participation in the enhanced case investigations.

Assessing Non-Response Bias

Non-response bias is routinely assessed by comparing characteristics of respondents with complete investigations to those initially sampled. Corrective actions are implemented if response bias of greater than 2% is noted by either sex or age. Similarly, selection bias is assessed by regularly comparing the random sample against the universe of reported cases. No oversampling of cases is permitted, and the project goal is a true probability sample of all reported gonorrhea and syphilis cases. Along with selection probabilities, which can vary within and between collaborating jurisdictions, (design weights), non-response or post-stratification weights are calculated by sex and by age through iterative raking (to within 2% of marginal totals) to increase the generalizability of results to the entire universe of patients diagnosed with gonorrhea.

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 STI surveillance:

SSuN collects 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 enhanced case surveillance:

CDC conducted an evaluation of the patient interview templates and instruments 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, including End the HIV Epidemic (EHE) initiatives. 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 Subject Matter Expert was consulted on the initial project design of sampling, weighting, and statistical analysis of data:

Jaeyoung Hong, PhD
Statistician
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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 monitor investigation success rates by health department staff and analyze the data.

CDC Project Staff
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Current SSuN Awardees:

1. Baltimore City Health Department
2. California Department of Public Health
3. Chicago Department of Public Health
4. Colorado Department of Health and Environment
5. City of Columbus Public Health
6. Washington DC Department of Health
7. Florida Department of Health
8. Indiana State Health Department
9. Massachusetts Department of Public Health
10. Michigan Department of Health and Human Services
11. New York City Department of Health and Mental Hygiene
12. Philadelphia Department of Public Health
13. San Francisco Department of Public Health
14. Tennessee Department of Health
15. Washington State Department of Health