

**Enhanced STD Surveillance Network (SSuN)
Revision**

**OMB No. 0920-1072
Exp. 09/30/2021**

SUPPORTING STATEMENT A

March 24, 2020

Contact Information

Mark R Stenger, Lead Science Officer
Centers of Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of STD Prevention- Surveillance and Data Management
STD Surveillance Branch
1600 Clifton Rd., MS E-02
Atlanta, GA 30329
Phone: 404-639-6136
Fax: 404-639-8610
Email: mstenger@cdc.gov

A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of Information Collection

3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities

6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
11. Institutional Review Board (IRB) and Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
14. Annualized Cost to the Federal Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions

EXHIBITS

- Exhibit 12.A Estimated Annualized Burden Hours
Exhibit 12.B Estimated Annualized Burden Costs
Exhibit 14.A Estimated Annualized Costs to the Government

LIST OF ATTACHMENTS

- 1 Section 301 of the Public Health Service Act
- 2 60-Day Federal Register Notice
- 3 Summary of Revisions
- 4 Enhanced SSuN Protocol
- 5 Enhanced SSuN Data Elements
- 6 List of enhanced SSuN Collaborators
- 7 Enhanced SSuN Publications
- 8 Interview Template for Gonorrhea and Early Syphilis Patients
- 9 CDC Project Determination
- 10 Table of Potentially Sensitive Question
- 11 Privacy Impact Assessment (PIA)

- **Goal:** The enhanced STD Surveillance Network (SSuN) is a supplemental surveillance project designed to : 1) provide supplemental information on case reports of sexually transmitted diseases (STDs) of interest; 2) monitor STD and HIV screening, incidence, prevalence, and health care access in populations seeking STD clinic services, 3) provide timely surveillance and epidemiologic data on persons diagnosed with gonorrhea to direct public health STD prevention and control efforts, 4) monitor STD treatment and prevention services practices, and 5) monitor selected adverse health outcomes of STDs.
- **Intended Use:** To better interpret trends in reported case incidence, assess burden of disease by population characteristics, monitor and evaluate adherence to STD/HIV screening recommendations and treatment guidelines, and to respond to issues such as co-morbidities and decreasing antibiotic susceptibility.
- **Methods:** SSuN activities will utilize two distinct surveillance strategies to collect information: Enhanced investigation (record searches and patient interviews) for a random sample of patients diagnosed with gonorrhea, registry matching and treatment ascertainment for adult syphilis cases, and, sentinel surveillance in STD clinics in each of the funded jurisdictions.
- **Subpopulation:** Men and women diagnosed and reported with gonorrhea, men and women diagnosed with syphilis and men and women seeking care at STD clinics.
- **Analysis:** Descriptive statistics and multivariable analyses to assess STD prevalence and trends by patient characteristics, geography, social determinants and provider type. Data collected from the facility component will be analyzed descriptively to evaluate STD/HIV testing and co-infection, incidence and prevalence of STDs by patient characteristics, and monitor prescribing of recommended treatments.

A. JUSTIFICATION

A. 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests a revision of the previously approved data collection entitled, “Enhanced STD Surveillance Network (SSuN)”. Enhanced SSuN is a sentinel surveillance system designed to provide information to better understand community burden of disease, identify populations at greatest risk for STDs, and to monitor long-term health consequences of STDs, including the risk of HIV infection. Revisions to this submission include, addition of an HIV registry matching activity for reported syphilis cases and persons seeking care in STD clinics, addition of a patient survey activity in collaborating STD clinics, update to list of collaborating health departments to reflect new funding cycle (Attachment 6), reduction in the number of STD clinics providing data, removal of 115 data elements associated with retired ocular syphilis surveillance activity and addition of data elements (Attachment 5) to capture HIV registry results, patient clinic surveys and to better characterize treatment for reported gonorrhea and syphilis cases. The following revisions are proposed to the currently approved project (OMB# 0920-1072). For a detailed description of revisions and changes, see **ATTACHMENT 3**.

- Removal of all 115 data elements associated with an early syphilis surveillance activity (activity has met the stated objectives and is being retired).
- Addition of an HIV surveillance registry matching activity to monitor HIV-coinfection among patients presenting for care in collaborating STD clinics and this activity among diagnosed and reported syphilis and gonorrhea cases.
- Addition of a periodic, anonymous, self-administered patient survey in collaborating STD clinics (**ATTACHMENT 8**) with 54 associated data elements (**ATTACHMENT 3, ATTACHMENT 5**).
- Expansion of response codes for test types, results, treatments, and dosages to capture additional syphilis and HIV-related laboratory tests, results and treatments (**ATTACHMENT 3, Tables 2A and 3A**).
- Addition of 20 data elements (**ATTACHMENT 3, ATTACHMENT 5**) to gonorrhea patient interviews to better characterize STI-related symptoms and STD-related high impact HIV prevention outcomes (**ATTACHMENT 8**).
- Addition of 19 data elements to be abstracted from STD clinic medical record systems for additional STI-related patient symptoms and STD-related high impact HIV prevention outcomes and one (1) data element associated with remnant chlamydia-positive specimens to be tested for the presence of lymphogranuloma venereum (LGV) variants. (**ATTACHMENT 3, ATTACHMENT 5**).

Background

National STD case reporting data is the primary source for reporting, analysis, and interpretation of trends in the incidence, prevalence and societal impact of chlamydial infection, gonorrhea and syphilis in the United States and U.S. Territories. However, data derived from the case reporting system are limited and incomplete. For example, case report data often lack complete information on the race and Hispanic ethnicity, gender of sex partners, treatments prescribed and other essential epidemiologic and health care information on persons diagnosed with STDs. This

limits the amount of information received by the CDC and available for national analysis. STD case reporting is subject to reporting and analysis delays at the national level and hence understanding disease trends may not be available in a timely manner. Moreover, case reporting does not provide information critical for understanding key populations at risk. Lastly, sentinel and enhanced surveillance data are needed to better characterize gaps and opportunities in sexual health services that can lead to effective policy actions and resource allocation for optimizing public health activities.

The ongoing need for an enhanced and sentinel STD surveillance network is responsive to multiple priorities of the Division of STD and Prevention (DSTDP), the National Center for HIV, Hepatitis, STD and Tuberculosis and Prevention (NCHHSTP) as well as fully aligned with CDC's imperative to improve the nation's disease surveillance portfolio. Specific priorities addressed by this network include:

- (1) Focus on DSTDP programmatic priorities of population-level sexual health, adolescents and young adults, gonorrhea resistance, and preventing adverse consequences of STDs, including HIV infection, congenital syphilis and other maternal and reproductive health risks;
- (2) Supports program collaboration and service integration at the state and local level as well as monitoring high impact STD-related HIV prevention through healthcare initiatives, and;
- (3) Addresses changes in health IT infrastructure and evolution in the healthcare delivery system.

Limitations in national case report data, and the need to meet these longstanding division, center and agency goals led to the initial development and funding of enhanced SSuN. Through several previous funding cycles of the STD Surveillance Network, CDC has partnered with state and local health departments to obtain STD-related behavioral and clinical data from those diagnosed with gonorrhea, early syphilis and those persons seeking care at STD clinics. Stakeholders for analysis and interpretation of data collected from the active surveillance programs funded by the enhanced STD Surveillance Network (SSuN) include state and local STD program managers, public health personnel, health policymakers, health care providers, and the general population. These data have proven invaluable for supporting progress metrics the division reports to internal and external stakeholders, have directly contributed to STD prevention initiatives and led to over 20 peer-reviewed manuscripts in clinical and STD-focused journals.

The collection of STD surveillance data is regulated by Title III – General Powers and Duties of Public Health Service, Section 301 (241.) (a) (**ATTACHMENT 1**).

A. 2. Purpose and Use of Information Collection

The primary objectives of enhanced SSuN are to, 1) enhance the quality, completeness, and timeliness of STD surveillance data to inform a more comprehensive understanding of epidemiologic trends and determinants of STDs of interest, and, 2) to monitor public health program impact and provide a robust evidence base for directing public health action. The explicit capacity to identify STD risk behaviors and clinical presentation among populations at risk – data which are otherwise unavailable through national case reporting – is a unique and defining feature of enhanced SSuN.

The large and geographically diverse sample obtained through enhanced SSuN provides a valid and reliable data source for evaluating progress toward national public health goals, such as identifying priority populations for STD prevention activities, evaluating effectiveness of CDC published treatment guidelines and screening recommendations, providing the infrastructure for identifying emerging sequelae of STDs and for ascertaining behavioral characteristics among these populations that contribute to significant co-morbidities, such as opioid use and HIV infection risk. Moreover, enhanced SSuN data collection is one of the only sources of information for evaluating the uptake of important STD prevention interventions including EPT, and high impact, STD-related HIV prevention interventions such as pre- and post-exposure prophylaxis (PrEP and PEP). Moreover, enhanced SSuN is the only source of this information among persons diagnosed with acute STDs, a population specifically targeted for these evidence-based HIV-prevention interventions.

Data from the facility component of enhanced SSuN are also used to ascertain patient-level provision of the recommended treatment and STD screenings, including concurrent HIV testing, and screening for STDs across all exposed anatomic sites. SSuN provides information on the characteristics of persons receiving STD prevention services and the types of services they are accessing. Information about access to, and use of, these services are essential for evaluating and enhancing local prevention services for people at risk for STDs.

Without enhanced SSuN, behavioral data are limited to, 1) case surveillance, which collects a negligible amount of demographic and clinical information from case reports of persons diagnosed with STDs, or, 2) from small-scale, periodic or ad hoc behavioral surveys conducted by community partners. The latter efforts are not likely to have a large population size or geographic diversity that enhanced SSuN provides. The absence of SSuN data would adversely affect the ability of the public health community to monitor emergent trends in multiple STD epidemics both locally and nationally.

This project utilizes two distinct surveillance methodologies that are conceptually grouped into two primary strategies, reflecting the core network functions: Strategy A includes sentinel surveillance in key clinical settings, and, Strategy B enhances the utility of case-based surveillance through comprehensive investigations of a representative sample of reported cases and improvements in the completeness of vital, on-going case-based information such as patient demographics, clinical characteristics and treatments prescribed across the full range of healthcare settings. These strategies are fully described in project protocols and are rigorously implemented across all collaborating health departments (**ATTACHMENT 4**).

Strategy A: Sentinel Surveillance in STD Clinics:

Strategy A includes sentinel facility-based surveillance in STD clinics where visit-level clinical, diagnosis, laboratory and treatment data (**ATTACHMENT 5**) are collected from patients attending participating specialty STD clinics (**Table B.1.A**). Specialty STD clinics, for the purposes of this project, are defined as clinical facilities whose main, advertised and actual purpose is to provide STD-related health services such as testing, diagnoses and treatment of sexually transmitted diseases. Data collection is primarily accomplished through automated abstraction of routinely collected clinical information from existing electronic medical records

by clinic data managers. These data are securely transmitted to funded local/state health departments for recoding, HIV registry matching, de-identification and secure transmission to CDC using specified data formats. Funded jurisdictions are required by protocol to maintain rigorous procedures to assure the quality and validity of data before submitting to the CDC. Recoding and compliance with strict data structure standards assures that data from multiple facilities can be seamlessly merged into national SSuN datasets at CDC for aggregate analysis and reporting. CDC supplies syntax and programming to local collaborators for data validation and appropriate quality assurance. Jurisdictions apply these validation checks and correct record-level errors or issues prior to transmission to CDC.

Records transmitted to CDC do not include patient names, dates of birth, phone numbers, mailing addresses or medical record numbers, in compliance with protocols. Patient records from STD clinics are however, assigned a non-name based unique patient identifier (patient ID) and a unique event number is assigned for each visit; CDC only receives the unique, non-name-based identifier and does not have the ability to re-identify patients from information contained in the records. Health departments send data through CDCs secure data network (SAMS) using specified encryption methods on a monthly basis (alternating between Strategy A and B data files). CDC accepts validates and securely stores these data, which are accessible only to enhanced SSuN project staff on a need to know basis. Enhanced STD surveillance network data are not integrated into other datasets maintained by CDC and are at all times stored on secure servers with fully restricted access.

Important healthcare services are provided at STD clinics that protect the reproductive and sexual health of men and women, prevent STD transmission in the community, and prevent HIV transmission. These services include STD testing and treatment, STD partner services, counseling, HIV testing and linkage to care for those who are HIV-infected, and STD and HIV prevention activities for the community. Previous studies have found that patients prefer to be treated at STD clinics for several reasons, including confidentiality concerns and the convenience of this venue with its expert STD care. As part of this project revision, SSuN clinic collaborators will deploy a brief, anonymous, patient self-administered survey (**ATTACHMENT 8**) as part of patient registration. Surveys will be administered for sequentially presenting patients during a limited timeframe sufficient to collect 350 surveys from one clinic in each of the 11 collaborating health departments (for a total of 3,850 surveys annually). These data will be used to better understand the characteristics of persons who utilize STD clinics by providing aggregate information not routinely collected in electronic medical records, such as their health insurance status and their reasons for selecting this venue rather than other types of venues. This information will also provide key insights into best methods to assure that public STD clinics appropriately serve their intended patient populations.

Strategy B, Case-based Enhanced STD surveillance:

The case-based enhanced surveillance component of SSuN focuses on obtaining complete demographic, behavioral and clinical information on a probability sample of gonorrhea cases (with minimum sample fractions of 10% of total gonorrhea morbidity) reported to participating health departments through routine case notifications and more complete ascertainment of HIV

co-infection and treatment status of gonorrhea and syphilis cases (**ATTACHMENT 5, ATTACHMENT 8**).

Gonorrhea cases must be reported within 60 days of specimen collection and must have resided in the jurisdiction at the time of the diagnosis to be eligible for sampling. Sampling methodologies are uniformly implemented across the funded health departments to assure a true probability sample of cases for enhanced investigation. Health department staff review sampled records against existing health department disease and laboratory registries to determine if the sampled case (i.e., patient diagnosed and reported with gonorrhea) has previously been reported to the department of health for any notifiable disease of interest (STDs, HIV, TB, viral hepatitis, etc.), document any recent history of STDs, and provide additional clinical information that is available through routine provider case reporting. Previous diagnoses occurring within 365 days of the specimen collection date/diagnosis date of their current GC diagnoses will be documented and included in the enhanced SSuN record; this allows determining whether the record represents a ‘duplicate record’ (defined as a GC diagnosis within 30 days of the specimen collection date/diagnosis date of a previously reported record for the same anatomic site) or whether the current case indicates a potential treatment failure (critical to monitor emergence of antimicrobial resistance).

Patient-level investigations among sampled gonorrhea cases are conducted either by phone or in person, with at least 4 documented attempts to contact each sampled patient. Sites are encouraged to develop locally relevant protocol materials and/or data collection instruments based on templates provided by CDC (**ATTACHMENT 8**). Moreover, all funded health departments are required to provide adequate training to local investigators conducting patient contact, and to address all applicable local human subjects requirements. Where not otherwise formally required, informal verbal informed consent is obtained from patients prior to eliciting information in the same fashion as routine partner management activities conducted by the health department; consent requirements are documented in local protocols.

In addition to enhanced surveillance for gonorrhea cases, all adult syphilis cases will also be extracted from the health department’s existing STD surveillance system. While no additional investigations will be conducted on syphilis cases through SSuN, considerable public health follow-up is routinely conducted for all early syphilis cases. For SSuN purposes, these records will include local unique patient IDs, documented HIV co-infection status and treatment information which are not otherwise reported to CDC through national case reporting. Laboratory records associated with reported cases of gonorrhea and syphilis are also obtained, allowing for documentation of testing across multiple anatomic sites and for validating staging of reported syphilis cases (**ATTACHMENT 5**). Wherever available, negative laboratory results are also included in enhanced SSuN data to demonstrate provider adherence to recommended screening practices.

Both strategies of enhanced SSuN are designed to integrate with traditional case surveillance methods to produce high-quality, timely surveillance and epidemiologic data to direct public health STD prevention and control efforts, better understand community burden of disease, identify syndemic patterns and population at greatest risk and monitor long-term health consequences of STDs. To assure comparability of activities and data across funded jurisdictions

and maximize the potential utility of the network, enhanced SSuN recipients are required to follow common protocols (**ATTACHMENT 4**) in implementing enhanced SSuN activities in their jurisdictions. This rigor assures that the project functions at the national level in a way that is consistent with the principles and attributes of all robust and reliable disease surveillance systems.

As with all other CDC surveillance activities, the revised information collection described in this request is funded through cooperative agreement with state and local health departments. The five-year Notice of Funding Opportunity CDC-RFA-PS19-1907 was published February 15, 2019. Eleven (11) jurisdictions were competitively selected to participate in Cycle 4 of enhanced SSuN for the project period 9/30/2019 through 9/29/2024. See **ATTACHMENT 6** for a list of collaborators for this cooperative agreement.

The usefulness of enhanced SSuN data are demonstrated by the amount of national press that enhanced SSuN analyses have received. For example, data from the population component of the current enhanced SSuN and the previous SSuN cycles has been presented at international conferences and published in peer-reviewed journals demonstrating a significant and ongoing increase in the burden of gonorrhea among men who have sex with men (MSM). These data generated coverage from the general press in the U.S. as well as public health reporting from several international media outlets. Data from enhanced SSuN population component is also included in CDC's annual STD Surveillance Reports, which garner considerable domestic coverage, including findings related to the estimated proportion of gonorrhea cases attributable to MSM as well as heterosexual populations. Data from the enhanced SSuN STD facility component has been used for analyses on HIV diagnoses among HIV-uninfected MSM who are repeatedly tested for HIV. Previous findings include an overall incidence of new HIV diagnosis of 3.1 / 100 person years, approximately 25 times higher than what is observed in heterosexual men and women. Findings were also presented at the 2018 National HIV Prevention Conference showing that symptomatic case rates are increasing dramatically among MSM, providing evidence that gonorrhea incidence continues to increase among this group. See **ATTACHMENT 7** for additional citations of SSuN publications.

Enhanced SSuN methods have been replicated by other non-funded jurisdictions, vetted by external and internal researchers and have undergone internal validation by CDC colleagues as well as local and state health department collaborators. CDC and SSuN collaborators meet annually for a principal investigators meeting to discuss methodological issues and lessons learned in the preceding year; the current request for revisions is a direct result of changing national priorities and a full, collaborative assessment of SSuN methods and data outcomes.

A. 3. Use of Improved Information Technology and Burden Reduction

Interview and survey data are locally collected and managed using applications running on password-protected encrypted computers meeting local health department security requirements. Interview and survey templates are provided for collaborators as a guide for developing applications for data collection (See **ATTACHMENT 8**). Collaborating jurisdictions are encouraged to develop local data collection tools and methods that maximize the efficiency of

data collection. All patient interviews are conducted by locally trained staff using relevant public health standards for maintaining the security and confidentiality of all information collected.

Local collaborators provide training that includes instructions on how to initiate patient contact, establish rapport, conduct the interview and manage data generated. They also assign key project staff to provide supervision and to monitor interviewers regularly. CDC conducts periodic site visits to provide technical assistance as well as gather feedback on the interviewing process. Since SSuN does not provide electronic applications, and does not utilize web-based or other software, all data collected from clinic, case and patient interviews are validated and formatted into SAS datasets at the local level. CDC provides data structures, data formats and syntax for edit pre-checks to the grantees to assure data quality. These measures, coupled with ongoing technical assistance, help reduce the burden on grantees conducting enhanced SSuN.

For the STD clinic-based component of SSuN, data managers at the STD clinics electronically abstract relevant data elements from their electronic medical records systems and securely transmit these data to local/state health department. Health department collaborators recode, format and conduct data quality assurance before securely transmitting to CDC. Data managers at the clinics do not use paper forms, search any paper medical files, or conduct manual abstractions of medical charts.

A. 4. Efforts to Identify Duplication and Use of Similar Information

CDC reviewed currently-funded programs and did not identify potential areas of duplication. We are not aware of any department or agency that rigorously or systematically collects or maintains this type of data on STD behavioral risk, treatment, clinical observations and treatment for patients diagnosed and reported with gonorrhea and/or adult syphilis from multiple jurisdictions or patient census data from multiple STD clinics.

Within CDC, there are data collection systems already in place that contains similar data elements to enhanced SSuN, the Gonococcal Isolate Surveillance Project (GISP) (OMB 0920-0307, exp. 8/31/2016) and the National Electronic Disease Surveillance System (NNDSS). However, the existing information collection systems cannot be modified, used partially, nor fully satisfy the needs of enhanced SSuN. GISP collects data and gonococcal specimens from a limited sample of men attending STD clinics, measuring the ability of the specimens to resist the effects of multiple antibiotics, and NNDSS collects minimal case information for persons diagnosed with gonorrhea and syphilis, though the limitation of this case reporting infrastructure is one of the primary drivers for the creation of an enhanced STD Surveillance Network.

A. 5. Impact on Small Businesses or Other Small Entities

No small businesses are or will be involved in this data collection effort. County or city-level health departments may be minimally impacted by data collection activities through contractual arrangements with state health departments participating in eSSuN. Staff time and effort is reimbursed as routine disease investigation in these counties per pre-existing arrangements with their state health departments. Clinic-level data management staff in participating STD clinics

are county health department employees, university employees (where the clinic has accreditation) or state-funded through other STD program funds; contractual agreements with collaborating health departments reimburse these entities for data extraction activities.

A. 6. Consequences of Collecting the Information Less Frequently

Enhanced SSuN data collection activities are planned to continue through the end of the cooperative agreement (ending on September 29th, 2024). Enhanced SSuN, similar to other surveillance systems, requires ongoing, longitudinal data collection to monitor trends and allow for rapid identification of changes in disease transmission. If these data are not available, CDC, state, and local health departments will not have the necessary tools to make data-based decisions regarding national prevention program planning, resource allocation and planning. Data for the enhanced SSuN project is transmitted every month (alternating between the population and facility components) in order to balance the need for timely information and the need to minimize the burden on collaborating clinics and health departments.

A. 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

None of the special circumstances in the guidelines of 5 CFR 1320.5 applies.

A. 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60 day Federal Register Notice on Friday, October 25, 2019, Vol. 84, No. 207, page. 57432. No comments were received during the 60-day Federal Notice period.

A. 9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents.

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

The Privacy Officer for CDC / ATSDR has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act applies to this information collection. Personally identifiable information (PII) is being collected. A Privacy Impact Assessment was completed and approved in 2018 (**ATTACHMENT 11**). The applicable system of records notice (SORN) is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC.

Reporting of gonorrhea or syphilis case report data is required under state laws and regulations for notifiable disease reporting. These data are reported without consent of the individual by health care providers and laboratories to state or local health departments or through abstraction of medical records by health department personnel. Data are reported voluntarily by state and local health departments to CDC and these activities are supported through cooperative

agreements. Although identifiable patient-level case report data are collected by local health departments the case report data are de-identified before they are transmitted to CDC.

The personally identifiable information (PII) that is collected at the local level includes the patient's name, contact information (including street address and phone number), gender, race/ethnicity and date of birth to facilitate patient investigations. PII is used for 3 purposes: (1) the address is used to verify that the patient resides in the participating jurisdiction and to complete routine case investigations, (2) the name and date of birth are used to verify the patient's identity for informed consent, and (3) the contact information, including telephone number is used to contact the patient for interview as well as re-contacting the patient for follow-up. These PII are maintained independent of data collected through the course of eSSuN interviews. None of the patient identifiers, such as patient names, medical record numbers, home address or zip codes, or birthdates, are included in records securely transmitted to CDC as a requirement of this project. Census tract information is used only in the aggregate to identify health disparities in treatment, clinical outcomes and access to care based on distance from resident census tract to provider location, or based on population characteristics of place to identify social determinants of health. Information on gender, age, and race/ethnicity are collected (**ATTACHMENT 5**) and transmitted to CDC in national case reporting and through enhanced SSuN because STDs disproportionately impact racial/ethnic and other minorities.

In the data sent to CDC, respondents are identified only by a unique patient ID code. The non-name-based unique patient ID, assigned by either the state or local health department, or the sentinel facility, is created solely for the purposes of surveillance and is not itself a medical record number. The unique patient ID code for the STD clinic patients are assigned and maintained only by the participating facility. CDC cannot use this number in the identification of individual patients seeking care in these facilities. In the case-based component of enhanced SSuN, the unique person ID code is assigned by the local grantee to each gonorrhea or syphilis case using data on case reports submitted by providers/ laboratories pursuant to local reporting regulations. These records can only be re-identified at the local level. Data is encrypted and transmitted via the CDC's Secure Access Management System (SAMS). At CDC, enhanced SSuN data are maintained on secure servers behind the CDC firewall. Password-protected access is required and directory-specific user access rights are assigned by a CDC data steward. Restricted access to STD data is provided to DSTDP/CDC scientists, researchers, and program managers. CDC will work with collaborating sites to design a plan to destroy site-specific enhanced SSuN data files after data analyses are completed.

Written informed consent is not required at any of the STD clinics for the collection of de-identified electronic clinical data elements routinely maintained in archived databases at the clinics. This is deemed to be of minimal risk and the data collection could not be conducted with written informed consent. The data transmittals to CDC do not have any personal identifiers (patient names, initials, date of birth, contact information, or medical record numbers). Patients are identified in the database only by a unique patient ID code and CDC does not receive any information that could be used to personally identify any data records.

For the case-based STD surveillance activity, state and/or local health departments contact 1) individuals diagnosed with gonorrhea under local public health authority to conduct disease investigations, and, 2) diagnosing healthcare providers for additional information about the gonorrhea cases. CDC does not directly contact any providers or conduct interviews with patients. The interviews are conducted by trained local health department staff in a private location or by phone where the questions and responses cannot be overheard by others. Individuals being contacted for interviews are verbally consented over the phone or in person prior to the administration of the interview. Participants are informed that they may decline to participate without penalty, or if they agree to participate, they may refuse to answer any of the interview questions. They are informed that the data are used to improve STD/HIV prevention services for persons at increased risk of STD in their area, and that only aggregated data may be released in published reports. Similarly, clinic patients provided an anonymous survey at registration for their visit may decline to fill out any information without penalty or impact on their clinic visit.

The surveillance and data management branch (SDMB/DSTDP/CDC), is charged with the responsibility of maintaining the privacy, security, and scientific integrity of all enhanced SSuN databases. The CDC project data managers are designated as custodians of the SSuN data files, and are responsible for observance of all conditions of use, and for establishment and maintenance of security arrangements to prevent unauthorized use. Access to the data is strictly limited to key members of the SDMB who are integral officers and collaborators of the study in the performance of their assigned duties. The enhanced SSuN Project Officer(s) and/or SDMB data stewards are responsible for granting access to SSuN data by other CDC staff in DSTDP as needed. The enhanced SSuN principal collaborators are promptly notified of any CDC personnel changes that affect access to the data for the project. All CDC staff with data access have completed, and remain current with, the annual Health and Human Services Information Security Awareness Training. A record of the completion of security training for all CDC staff is maintained by the CDC Information Technology Services Office (ITSO). CDC may retain enhanced SSuN data as long as the data are protected as described herein. CDC will annually review the need for the data with SSuN principal collaborators and shall destroy all copies of the data if it is determined that no further analyses will be conducted. An Assurance of Confidentiality is being sought for eSSuN activities to govern all access to and use of eSSuN data.

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

The approved Project Determination Form (**ATTACHMENT 9**) indicates that because the project is a routine disease surveillance activity, the protocol is exempt from review by CDC's IRB.

The collection of information about STDs itself is sensitive because of stigma associated with STD/HIV infection (**ATTACHMENT 10**). In addition, the modes of transmission of STDs (through sexual contact) and contributing risk factors necessitate the collection of sensitive data, including sexual practices, drug use, and HIV status. In keeping with the purpose of this data collection, other sensitive data are collected about specific behaviors, experiences or conditions that have been shown to be associated with STD infection. For enhanced eSSuN, this includes the collection of STD and HIV testing and diagnoses, gender and HIV status of most recent sexual partners. Collection of these data will be used to understand barriers to STD care and treatment, and the impact of behaviors and health conditions on the clinical course of STD/HIV disease. These data are also used to enhance STD prevention programs designed to reduce high-risk behaviors in persons most likely to transmit STD/HIV, in understanding sexual network dynamics and for modeling STD transmission and prevention interventions. Data on health insurance status and type are also collected. However, no portion of a social security number or medical identifier associated with insurance status/type is collected or transmitted. Census tract information is collected for the purposes of spatial analysis of the data to understand the geographic distribution of disease and risk.

Although the information requested from STD clinic patients and interviewed participants is sensitive, the purposes of enhanced SSuN cannot be accomplished without their collection. Collection of the data are used to understand barriers to engaging in protective behaviors and to using STD prevention services. These data are also used to enhance STD prevention programs designed to reduce high-risk behaviors in persons most likely to acquire or transmit STD/HIV. The context in which interview questions are asked help to overcome their potential sensitivity. There are several steps taken in enhanced SSuN to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

- Most questions allow for responses of “don’t know” or “refuse to answer.”
- Consent scripts make it clear that the survey is sponsored by CDC and the local health department and that the information will be put to important uses.
- The interview questions are carefully organized to lead smoothly from one topic to another.
- Transitions are clear to respondents and the need for the information explained.
- Assurance about the privacy of the information are reiterated.

All interviews are conducted by trained local/state health department staff in a private location or by phone at times convenient to patients. Interviewers are trained to administer informal consent; all interview questions are administered by reading each item verbatim in compliance with protocols, ensuring that all respondents receive the same information for informal consent and with respect to each question. Interviews are not attempted without the verbal consent of the respondent.

The enhanced SSuN data collection also include sensitive information relating to gender of sex partners, HIV status, number and characteristics of recent sex partners, anatomic sites of exposure, and alcohol and drug use. Although this information requested is sensitive, the primary purposes of enhanced SSuN cannot be accomplished without their collection. Moreover, this information is routinely collected as part of the clinical care for the patients seen in STD clinics. Collection of these data will be used to understand barriers to STD care and treatment, and the impact of behaviors and health conditions on the clinical course of STD/HIV disease. These data are also used to enhance STD prevention programs designed to reduce high-risk behaviors in persons most likely to transmit STD/HIV, in understanding sexual network dynamics and for modeling STD transmission and prevention interventions. All participants are assured that the information will be used only in the aggregate and only for the purposes of this project and will be kept private to the extent allowable by law.

A. 12. Estimates of Annualized Burden Hours and Costs

The estimate of annualized burden hours increased from 3,479 hours to 5,863 hours for the revision of the current project. The overall annual burden primarily increased because of 1) the addition of the STD clinic patient survey, 2) increase in annual number of patients diagnosed and reported with GC, with a consequent increase in sampled and interviewed cases, 3) increase in the number of collaborating health department from 10 to 11 (**ATTACHMENT 6**), and, 4) addition of an HIV registry matching component for both sentinel and enhanced case-based surveillance activities.

The respondents for the facility-based portion of the enhanced SSuN project are the 11 collaborating state or local health departments (**ATTACHMENT 6**). Though there is a reduction in the number of STD clinics contributing data (**Table B.1.A**), the number of STD clinic managers increases from 10 to 11 reflecting the increase in the number of collaborating health departments. STD clinic managers within the 11 project areas are responsible for abstracting line-listed STD clinic visit data (all patient visits of STD clinics) from their facility database and providing those data queries to the project's data manager at the local level. Since the data are transmitted every other month, this reflects 264 burden hours (11 respondents x 6 data transmissions x 4 hours). There are minimal changes proposed to the previously approved medical record data elements. However, the number of data elements does not affect project burden hours because the data are collected through automated programs that extract the data from existing databases, the increase in the burden hours per response from 3 to 4 reflects additional data quality assurance and recoding efforts.

The respondents for the gonorrhea population-based portion of the enhanced SSuN are individuals identified by state or municipal health departments as having a gonorrhea case report submitted by a provider or laboratory as required by local reporting regulations. Because the number of respondents can vary depending on the number of cases diagnosed and reported within the jurisdiction, the annualized estimates of respondent burden provided below represent the number of cases reported for 2017. There were 173,623 case reports across the 11 participating enhanced SSuN jurisdictions. Each of the sites is expected to sample approximately 10% of the respondents, for 17,362 respondents. The average interview success rate in the first three years of enhanced SSuN population data collection was 42.5%, therefore we expect to interview approximately 7,380 respondents over a the initial 12-month period. Because on average the interview takes approximately 10 minutes to complete, 1,230 hours burden hours are estimated for this activity.

Each of the 11 local/state health department data managers will be responsible for any recoding and/or data validation necessary to produce correctly formatted datasets. Every month, alternating between facility and population-based activities, the 11 collaborating jurisdictions provide clean, validated datasets to CDC (transmission to CDC via SAMS every two months), with cumulative data back to the beginning of each calendar year. That reflects 3,168 burden hours (11 respondents x 12 data transmissions x 24 hours). An additional burden of 880 hours are needed to perform required HIV registry matching every 3 months (11 x 4 x 20).

A.12a. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Data manager at Sentinel STD clinics	Record Abstraction (ATT 5)	11	6	4	264
General Public – Adults (persons diagnosed and reported with gonorrhea)	Interview (ATT 8)	7,380	1	10/60	1,230
General Public – Adults, STD Clinic Patients	STD Clinic Survey (ATT 8)	3,850	1	5/60	321
Data Managers: 11 local/state health department	HIV registry matching (ATT5)	11	4	20	880
Data Managers: 11 local/state health department	Data cleaning/ validation/reformatting and data transmission for Strategies A & B (ATT5)	11	12	24	3,168
Total					5,863

Estimated Annualized Burden Hours and Costs

Table A.12.B Annualized Cost to Respondents

The table (A.12.B) below presents the estimated annualized burden costs. The data managers at the clinics have an average hourly wage of \$29.88 and the database administrators at the health department have an hourly wage of \$31.69. The majority of the patient respondents will be of lower socioeconomic status. If employed, the majority are likely to be in service-related industries or para-professionals with an estimated average hourly wage of \$17.96.

Note: The hourly rate was determined by using information obtained from the US Department of Labor, Bureau of Labor Statistics: <https://www.bls.gov/oes/current/oes191041.htm>, <https://www.dol.gov/whd/minwage/mw-consolidated.htm>, <https://www.bls.gov/news.release/empst.t19.htm>

Type of Respondent	No of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Clinic data manager	11	264	\$29.88	\$7,889
Data Administrator at health department	11	3,168	\$31.69	\$100,393
Patients diagnosed with gonorrhea	7,380	1,230	\$17.96	\$22,091
Patients in STD Clinics	3,850	321	\$17.96	\$5,765
Total		5,863		\$136,138

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

There are no other costs to respondents associated with this proposed collection of information.

A.14. Annualized Cost to the Federal Government

The annualized cost to the government is \$3,686,832. The cost of this project for the three years is estimated to be \$11,060,496. The annualized cost is summarized in Exhibit 14.A.

A14a. Estimates of Annualized Costs to the Federal Government*

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to	Enhanced SSuN – Personnel	

the Federal Government*	Epidemiologist-14	1	100%	\$135,955
	Epidemiologist-12	1	50%	\$44,454
	Public Hlth Advisor-13	1	100%	\$105,719
	Data Analyst-14	1	50%	\$62,465
	Data Analyst-13	1	75%	\$79,289
	Cooperative agreement funds to 11 project areas			\$3,187,000
Contractor and Other Expenses	Contracted Project Coordinator (1) 50%			\$35,950
	Travel (site visits)			\$36,000
	Meetings			\$0
	TOTAL ANNUAL COST TO THE GOVERNMENT			\$3,686,832

*Salary estimates were obtained from the US Office of Personnel Management salary scale at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2019/general-schedule/>

The personnel related to the enhanced SSuN data collection include 1 Lead Science Officer project officers (epidemiologists) at the GS-12 and 14 levels, GS-13 and GS-14 level public health analyst, and a project manager. Travel is related to providing technical assistance and conducting site visits. Examples of meetings that are held include the principal investigator's meeting that will be held in government space at no cost.

The information collection described in this request are funded through cooperative agreements with state and local health departments (CDC-RFA-PS13-1306). CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments. Data for Enhanced STD surveillance network are compiled by staff in local health departments and sent via a secure network (SAMS). Data managers at CDC receive data from the data managers at the local health departments, track the progress of the data, and distribute bimonthly monitoring reports to health department staff. CDC process all data sent from local health departments to produce clean, final datasets for use by CDC and/or the health departments. Enhanced SSuN epidemiologists have responsibility for analyzing the final data set and work with enhanced SSuN data analysts to create data tables to be displayed in STD surveillance reports and other products.

A.15. Explanation for Program Changes or Adjustments


The total annualized burden will change from 3,479 hours to 5,863. Specifically, the changes in the estimates of burden are accounted for by the following:

- Change in the number of funded sites from 10 to 11 (**ATTACHMENT 6**),
- Addition of an HIV registry matching requirement (**ATTACHMENT 4**),
- Incremental increase in the number of reported gonorrhea cases in all funded sites and concomitant increase in the number of cases sampled and patients interviewed (**ATTACHMENT 4**),
- Addition of case data extraction for reported syphilis cases (**ATTACHMENT 4**).

A.16. Plans for Tabulation and Publication and Project Time Schedule

Data from enhanced SSuN continues to inform STD prevention and to inform a more comprehensive understanding of trends and determinants of STDs of interest, monitor public health program impact and provide a more robust evidence base for directing public health action. CDC regularly publishes an annual STD surveillance report using SSuN data collected. For instance, the 2017 data collection cycle results were published in September 2018 (for example, see <https://www.cdc.gov/std/stats16/STD-Surveillance-2017-print.pdf>). Analyses of these data are also distributed to the participating jurisdictions through monthly reports as well as through presentations of annual summary data presented at the enhanced SSuN annual principal investigators meeting.

These data have also been distributed through presentation at local, national and international conferences, publication in peer-reviewed journals. Local communities will continue to be informed of enhanced SSuN findings through multiple conduits of information. National data results will be released through national publications (**ATTACHMENT 7**) and presentations at conferences. Local data results will be reported back to the communities through means such as local publications, presentations to local STD prevention and community planning bodies and at local conferences and workshops.


 End of Cooperative Agreement PS13-1306, Beginning of PS19-1907

1 st	2 nd	3 rd	4 th	1 st	2 nd	3 rd	4 th	1 st	2 nd	3 rd	4 th
-----------------	-----------------	-----------------	-----------------	-----------------	-----------------	-----------------	-----------------	-----------------	-----------------	-----------------	-----------------

CDC analyses will focus on the following key objectives in our next 3 year OMB cycle:

- Enhanced understanding of the intersection of HIV and other STDs.
- Evaluate PrEP (Pre-Exposure Prophylaxis- the use of anti-HIV medication that keeps HIV negative people from becoming infected) uptake among HIV uninfected men who have sex with men attending STD clinics.
- Evaluation of PrEP and EPT (Expedited Partner Therapy- the practice of treating sex partners of patients diagnosed with gonorrhea by providing prescriptions or medications to the patient to take to his/her partner without the healthcare provider first examining the partner) among persons diagnosed and reported with gonorrhea from all provider settings.
- Understanding barriers to care among persons diagnosed and reported with gonorrhea.
- Document opioid use on those persons diagnosed and reported with gonorrhea.
- Document HIV co-infection status, trends and incidence among persons diagnosed and reported with gonorrhea and syphilis and persons presenting for care in STD clinics.

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

The OMB expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.