

Enhanced STD Surveillance Network (SSuN)

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SUPPORTING STATEMENT A

Reinstatement with Change

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- **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 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 (interviews) for a random sample of patients diagnosed with gonorrhea, persons diagnosed early syphilis with neuro/ocular manifestations in each of the funded jurisdictions, and sentinel surveillance in STD clinics.
- **Subpopulation:** Men and women diagnosed and reported with gonorrhea, men and women diagnosed with early 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, incidence and prevalence of STDs by patient characteristics, and monitor prescribing recommended treatment.

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 3-year Reinstatement with change of the previously approved data collection entitled, “Enhanced STD Surveillance Network (SSuN)”. Enhanced SSuN is a sentinel surveillance system designed to better understand community burden of disease, to identify populations at greatest risk for STDs, and to monitor long-term health consequences of STDs. Revisions to this submission include, removal of facility-based surveillance in family planning clinics, the addition of 11 interview questions to the gonorrhea population component, 8 new data elements to the facility component, and the addition of an enhanced surveillance activity to monitor adverse health outcomes of early syphilis cases with neurologic and/or ocular manifestations. The following revisions were made to the OMB-approved project 0920-1072: (For detailed description, see **ATTACHMENT 3**)

- Addition of high priority topics to the interview template for gonorrhea patients: Questions were added to improve data collection of three priority emerging issues related to STD/HIV risk and prevention: Pre-Exposure Prophylaxis (PrEP), specific symptoms to allow estimation of proportion of cases identified through general STD screening versus those tested diagnostically based on clinically relevant symptoms, and assessment of prescription opioid and injection drug use.
- Addition of high priority topics to the data abstracted from STD clinic patients: Data elements were added to improve data collection of three priority issues related to STD/HIV risk and prevention: PrEP, assessment of prescription opioid and injection drug use, and delivery of expedited partner therapy (EPT).
- Deletion of 108 family planning clinics from facility-based surveillance: Our experience in the nearly 3 years of data collection has demonstrated the inability to extract critical data elements from these type of facilities.
- Measurement improvements including new skip patterns in the interview template were introduced for better flow and cognitive ease.
- The addition of a population-based activity to conduct surveillance on patients diagnosed with early syphilis who report neurologic and/or ocular manifestations. Reported rates of syphilis have been increasing in the US since 2001 with an estimated 18.0% increase in the rate of primary and secondary syphilis in 2016 compared with 2015 (2016 is the latest data available). Concomitantly the proportion of early syphilis cases reporting neurologic and/or ocular manifestations has also been increasing with clusters of ocular syphilis cases being reported in several US jurisdictions. At present, there are significant gaps in the surveillance of early syphilis cases with neurologic and/or ocular manifestations and there is a need to engage in systematic surveillance to estimate the proportion of cases with neurologic and/or ocular manifestations and to monitor whether there has in fact been a rise in the proportion of early syphilis cases with neurologic and/or ocular symptoms over time.

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, and other essential epidemiologic and health care information on persons diagnosed with STDs. Second, the amount of information received by CDC and available for national analysis is limited. 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. Third, case reporting provides little to no information for understanding key populations at risk. Lastly, data are needed to better understand gaps and opportunities in sexual health services that can lead to effective policy actions and resource allocation for optimizing public health activities.

The need for an enhanced and sentinel STD surveillance system is aligned with priorities of the Division of STD and Prevention (DSTDP), the National Center for HIV, Hepatitis, STD and Tuberculosis and Prevention (NCHHSTP) as well as CDC. They include the following:

- (1) Focus on DSTDP programmatic priorities of population-level sexual health, adolescents and young adults, gonorrhea resistance, and preventing adverse consequences of STDs, including ocular and neuro syphilis,
- (2) Supports program collaboration and service integration as well as prevention through healthcare initiatives and,
- (3) Addresses changes in health IT infrastructure and healthcare delivery system. Stakeholders for data collected from the active surveillance programs funded by The Enhanced STD Surveillance Network include STD program managers and other public health personnel, policy makers, health care providers, and the general population.

The limitations of national case report data and the need to meet the division, center and agency goals led to the development of enhanced SSuN. Through enhanced SSuN, CDC works 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.

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 objective of enhanced SSuN is to 1) enhance STD surveillance data, to inform a more comprehensive understanding of epidemiologic trends and determinants of STDs of interest, and 2) monitor public health program impact and provide a more robust evidence base for directing public health action. The explicit ability to identify STD risk behaviors among these populations at risk, otherwise unavailable through national case report data, is a unique and defining feature of enhanced SSuN.

At the national level, data from enhanced SSuN are used to document the need for prevention resources and interventions targeting persons at highest risk of STD infection. 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 recommendations, providing the infrastructure for identifying emerging sequelae of STDs, such as ocular/neurologic syphilis, and for ascertaining behavioral characteristics among these populations, such as opioid use, that may influence STD 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 HIV prevention interventions such as PrEP. Enhanced SSuN is the only source of this information among persons diagnosed with acute STDs, a population specifically targeted for PrEP.

Data from the facility component of enhanced SSuN are also used to ascertain patient-level provision of treatment and recommended STD screening tests, including concurrent HIV testing, and screening for STDs across 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 and use of these services are used to evaluate local prevention services for people at risk for STDs.

Without enhanced SSuN, behavioral data are limited to 1) case surveillance, which only 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. The latter are not likely to have enhanced SSuN's large population size, or geographic diversity. Not having enhanced SSuN data adversely affects the ability to monitor the STD epidemic both locally and nationally.

The overall strategy of enhanced SSuN utilizes two distinct components that conceptually are grouped into two primary categories reflecting the core network functions: population-based STD surveillance and sentinel facility-based STD surveillance (**ATTACHMENT 4**).

Population-based STD surveillance:

The population-based component contains two activities. The focus of the first activity centers around obtaining complete demographic, behavioral and clinical information on a probability sample of gonorrhea cases (up to 10% of total gonorrhea morbidity) reported to participating health departments through routine case notifications (**ATTACHMENT 5**). 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 will be uniformly employed across jurisdictions. Health department staff will 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 as well as 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). All laboratory data associated with the patient and specific episode of gonorrhea are obtained and documented for provisions for multiple tests across multiple anatomic sites. Wherever available, negative laboratory results will also be

included in the enhanced SSuN to demonstrate screening practices. Patient-level investigations/interviews among gonorrhea cases are conducted either by phone or in-person with at least 3 documented attempts to contact each patient. Sites are encouraged to develop locally focused protocol documents and/or data collection instruments for investigators, provide adequate training to local investigators conducting patient contact and to address local human subject's requirements. Where not otherwise formally required, brief verbal informed consent is obtained from patients prior to eliciting information; consent requirements are documented in local protocols.

The second activity focuses on obtaining complete demographic, behavioral and clinical information on early syphilis cases who report ocular/ neurologic symptoms (**ATTACHMENT 5**). Early syphilis cases are reported to participating health departments through routine partner services or provider reporting. Jurisdictions routinely conduct partner investigations for patients with early (primary, secondary, and early latent) syphilis through Disease Intervention Specialists (DIS). These partner investigations ascertain some demographic, behavioral, and clinical information relevant to the syphilis diagnosis, including information about ocular and/or neurologic symptoms. However, additional data elements will be collected through patient interviews that will include additional standardized screening questions to those who report symptoms for a more complete assessment of ocular/ neurologic involvement, including the full spectrum of eye, ear, and neurologic symptoms (**ATTACHMENT 5**). In addition, a follow-up evaluation with the diagnosing or reporting provider will be conducted to ascertain additional information about physical exam findings, laboratory tests results, including cerebrospinal fluid (CSF) results, and prescribed (type and duration) treatment if not present in the original case or laboratory report. These evaluations can be either by direct contact with providers (phone) or through other methods such as secure fax-back, mail or other means as long as privacy of patient information can be strictly maintained. Lastly, early syphilis cases reporting neurologic and/or ocular symptoms will be re-contacted at approximately three months following prescribed treatment to ascertain whether initial symptoms have resolved. The three month follow-up patient-level investigations/interviews are conducted either by phone or in-person with at least 3 documented attempts to contact each patient. Sites are encouraged to provide adequate training to investigators conducting patient contact and to address local human subject's requirements. Where not otherwise formally required, brief verbal informed consent should be obtained from patients prior to eliciting information; consent requirements should be documented in local protocols.

Sentinel facility-based STD surveillance:

The second core component of enhanced SSuN is the sentinel facility-based surveillance where visit-level clinical, diagnosis, laboratory and treatment data are collected from patients attending participating categorical STD clinics (**ATTACHMENT 5**). Categorical STD clinics, for the purposes of this project, are defined as clinical facilities whose main purpose is to provide STD-related services. Transmission of the data is primarily performed by abstraction of routinely collected information from existing electronic medical records by clinic data managers that will then be sent to funded local/state health departments. For both clinic-based and population-based STD surveillance activities, funded jurisdictions are expected to maintain rigorous procedures to assure the quality and validity of data before submitting to CDC. They will also complete data verification, recode and appropriately structure the data to facilitate merging into the national

enhanced SSuN datasets. In collaboration with data managers in each jurisdiction, CDC will prepare syntax for data validation that will provide for appropriate quality assurance. Jurisdictions will apply these validation checks and fix the offending records prior to transmission. Locally prepared SAS datasets used for validation and transmission to CDC will not include patients' names, date of birth, phone number, mailing address or medical record numbers. Enhanced STD surveillance network records from STD clinics will be assigned a unique patient identifier (patient ID) and a unique event identification number for each visit; a unique patient ID code will be assigned in the enhanced population component by the corresponding state/local health department. CDC will only receive the unique identifier and will not have the ability to back-convert the Patient ID to a medical record number. Sites will send data through the CDCs secure data network (SAMS), or equivalent, using specified encryption methods on a monthly basis (alternating between the population and facility data files). CDC agrees to accept and securely store these data, accessible only to enhanced SSuN project staff. Enhanced STD surveillance network data will not be integrated into other datasets maintained by CDC and will at all times be stored on secure servers with fully restricted access.

Both components of enhanced SSuN are designed to integrate traditional 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 success of the network, enhanced SSuN awardees employ substantively comparable strategies to implement enhanced SSuN activities in their jurisdictions. This will assure that enhanced SSuN functions at the national level in a way that is consistent with the principles and attributes of all robust disease surveillance systems.

The information collection described in this request is funded through a cooperative agreement with state and local health departments (CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments). The five-year funding announcement PS13-1306 was published February 14, 2013. From 2013 to 2018, 10 jurisdictions were awarded to participate in enhanced SSuN. See **ATTACHMENT 6** for a list of enhanced SSuN collaborators.

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 has also been included in CDC's annual STD Surveillance Report, which garnered 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 was used for an analysis on HIV diagnoses among HIV-uninfected MSM who are repeatedly tested for HIV. Findings included 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 presented at the 2015 National HIV Prevention Conference and received media attention for greater efforts to promote HIV prevention strategies to uninfected MSM attending STD clinics. Finally, data from the facility component was used to examine how well pelvic inflammatory disease (PID) diagnosis and treatment practices in STD clinic settings follow CDC-recommended guidelines. The findings were that approximately 70% of the patients met the CDC treatment case definition for PID, and about two thirds were treated with a CDC-recommended outpatient regimen, underscoring the need for continued efforts to optimize quality of care and adherence to current guidance for PID management given the anticipated expertise of providers in these settings. The results were published in 2015 in Sexually Transmitted Diseases. See **ATTACHMENT 7** for additional citations of SSuN publications.

Enhanced SSuN methods have been replicated by other non-enhanced SSuN jurisdictions, vetted by external and internal researchers and have undergone internal validation by CDC colleagues as well as local and state health department collaborators. For example, CDC and our SSuN collaborators meet annually for a principal investigators meeting to discuss methodological issues and lessons learned in the preceding year.

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

Interview data for both the patients diagnosed and reported with gonorrhea as well as those with early syphilis are locally collected and managed on password-protected encrypted computers meeting local health department security requirements. An interview template is provided only as an example for data collection (See **ATTACHMENT 8**). Collaborating jurisdictions are encouraged to develop local data collection tools improving the efficiency of data collection. All interviews will be conducted by locally trained staff.

Local jurisdictions provide training that includes instructions on how to conduct the interviews and collect data. They also assign a point person to provide supervision on the project to monitor interviewers regularly. CDC conducts periodic site visits to provide further technical assistance as well as gather feedback on the interviewing process. During our more recent principal investigator's meeting, CDC and enhanced SSuN collaborators discuss lessons-learned to identify and resolve issues related to how the interviews are conducted. Since eSSuN is not an electronic application and does not utilize any web-based software, all of the data that is collected from interviews are validated and formatted into SAS datasets. CDC data edit pre-checks are provided to the grantees as a further data quality check to ensure variables are in the correct syntax and response codes are valid. These measures coupled with technical assistance help reduce the burden on grantees conducting enhanced SSuN.

The provider investigation on the patients diagnosed and reported with early syphilis with ocular and/or neurologic manifestations can be either by direct contact with providers (phone) or through other methods such as secure fax-back, mail or other means as long as privacy of patient information can be strictly maintained. Ascertainment of the information either by phone or by form will require 10 minutes or less during one sitting, thus minimizing participant burden.

For the facility-based component, data managers at the STD clinics will electronically transmit to local/state health department/CDC batches of clinical variables every two months. These variables are available from existing electronic archived databases at the clinics. These clinical data will be stored on a secure server at CDC. The data managers at the clinics do not use paper forms, search any paper medical files, or conduct any hand abstractions of medical charts.

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

We 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 data on STD risk behavioral data from patients diagnosed and reported with gonorrhea and/or early syphilis from multiple jurisdictions or from multi-site STD clinics.

Within CDC, there is a data collection system already in place that contains similar data elements to enhanced SSuN, the Gonococcal Isolate Surveillance Project (GISP) (OMB 0920-0307, exp. 8/31/2016). However, the existing information collection system cannot be modified, used partially, nor satisfy the needs of enhanced SSuN. GISP collects data and gonococcal specimens from a sample of men attending STD clinics, measuring the ability of the specimens to resist the effects of multiple antibiotics. In an effort to avoid duplication, GISP variables have been integrated into enhanced SSuN protocols so that jurisdictions participating in both GISP and enhanced SSuN can transmit combined SSuN and GISP data, further minimizing duplication at the funded jurisdictional level.

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

No small businesses will be involved in this data collection effort. County-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, 2018). Additionally, a 1 year cost-extension for enhanced SSuN has been approved, extending the project period through September 29, 2019. Enhanced SSuN, similar to other surveillance systems, require ongoing 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 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

A 60-day notice to solicit public comments was published in the Federal Register on Thursday, March, 15, 2018, Vol. 83, No. 51 page 11532-4 (**ATTACHMENT 2a**). Thirty-seven public comments were received (**ATTACHMENT 2b**). Many of the non-substantive comments were in support to CDC's activity to reduce the burden of STD, which will in turn raise greater awareness of this ongoing efforts to reduce STD on the public and on our youth. In additions, some comments were in favor of CDC doing more with schools in the absence of sex education programs in many districts. In short, there was broad support for the proposed activities as further outlined in the attachment 2a. However, CDC received 3 other non-substantial comments were opposed to CDC spending any tax dollars on addressing STD. The responders claim that the general public should already be aware of the dangers of STD and are therefore responsible for their own plight and that any effort on CDC's part will only prove to be wasteful spending. As indicated by the attachment, most commenters listed their names in their responses. However, no one provided contact information and therefore no CDC responses were sent.

Enhanced SSuN is a collaborative project among CDC investigators, non-CDC epidemiologists, ten state/local health departments and 30 STD clinics located around the United States. Frequent consultations between CDC and persons outside of CDC regarding the collection of data, frequency of data collection and transmission, record keeping data management, methodologic design, and data elements have taken place. This has been largely through: 1) multiple site visits to participating health departments and sentinel clinics, 2) quarterly conference calls with principal investigators/designated staff about availability of data and barriers to data collection, 3) annual meetings of enhanced SSuN co-investigators outside of CDC who are closely associated with the participating clinics (most recently March 14-15, 2017); and 4) email communications.

In the fall of 2016, the Division of STD Prevention (DSTDP) solicited feedback on enhanced SSuN activities through a division-wide planning retreat. Multiple members of each of the Division's five branches were represented at the meeting. The discussions included various topics including a review of project progress and data quality issues, as well as a discussion on how to use SSuN data methods to better meet the Division stakeholder's need.

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 is used to verify 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 forwarded to CDC as a requirement of this project. Census tract information are used 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. Information on gender, age and race/ethnicity are collected (**ATTACHMENT 5**) and transmitted to CDC 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 by the participating facility. CDC cannot use this number in the identification of individual patients seeking care in these facilities. In the population component of enhanced SSuN, the unique person ID code is assigned by the local grantee to each gonorrhea or early 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 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 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 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 population-based STD surveillance activity, state and/or local health departments contact 1) individuals diagnosed with reportable condition (either gonorrhea or early syphilis) under local public health authority to conduct disease investigations, and 2) diagnosing healthcare providers for additional information about the gonorrhea or early syphilis cases. CDC does not contact any providers or conduct any interviews with patients. The interviews are conducted by trained local health department staff in a private location 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 survey. Participants are told they may decline to participate without penalty or if they agree to participate, they may refuse to answer any of the survey questions. They are informed that the data will be used to improve STD/HIV prevention services for persons at increased risk of STD in their area, and that aggregated data may be released in published reports.

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.

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 highly sensitive, the purposes of enhanced SSuN can not 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 during established operating hours. Interviewers are trained to administer the consent script and all interview questions by reading each item verbatim, thus ensuring that all respondents receive the same information for the consent and each question. No interviews are conducted 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 can not be accomplished without their collection. Moreover, this information is routinely collected as part of the clinical care activities 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 2854 hours to 3,460 hours for the current project. The overall annual burden primarily increased because of 1) the addition of the neuro/ocular syphilis activity, and 2) additional patients diagnosed and reported with GC sampled and interviewed.

The respondents for the facility-based portion of the enhanced SSuN project are the 10 collaborating state or local health departments (**ATTACHMENT 4**). Though there is an increase in overall burden hours for the project, the burden for the clinic-based portion is decreasing because of the discontinuation of family planning clinics in the enhanced SSuN network. For this reason, the number of STD clinic managers has decreased from twenty-two to ten. STD clinic managers within the 10 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 180 burden hours (10 respondents x 6 data transmissions x 3 hours). There are minimal changes to the previously approved medical record data elements. However, the collection of data does not affect project burden hours because the data are collected through automated programs that extract the data from existing databases.

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. 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 represents the number of patients interviewed for 2016. There were 129,434 such case reports across the 10 participating enhanced SSuN jurisdictions in 2016. Each of the sites is expected to sample approximately 10% of the respondents, for 12,943 respondents. The average interview success rate in the first three years of enhanced SSuN population data collection was 35%, therefore we expect to interview approximately 5,492 respondents over a 12-month period. Because on average the interview takes approximately 10 minutes to complete, 915 hours burden hours are estimated for this activity.

The respondents for the syphilis population-based portion of the enhanced SSuN are individuals identified through routine disease reporting requirements by state or municipal health departments as having an early syphilis diagnosis. Annualized estimates of respondent burden provided below represents the number of patients interviewed for 2016. There were 25,353 such case reports across the 10 participating enhanced SSuN jurisdictions in 2016. Jurisdictions routinely prioritize these patients for partner services and are asked about neurologic and ocular involvement. Studies estimate that 2% of all early syphilis cases will report neurologic and ocular complications, corresponding to 507 respondents with a diagnosis of early syphilis in our enhanced SSuN jurisdictions. We are expecting to interview 80% of 507 patients or 406 respondents. The 406 respondents will provide 1 response each that will take approximately 10 minutes for a total of 68 burden hours.

For the early syphilis population-based activity, health department staff will obtain additional clinical information from the diagnosing healthcare provider on the patients that are interviewed (i.e., 406 respondents). This additional information pertains to ascertainment of clinical signs, testing performed and laboratory results, and prescribing type and duration of treatment and are collected through phone, fax-back form or mail. We estimated the completion of the additional clinical information will take 10 minutes, bringing the annual burden for this activity to 68 hours.

Syphilis cases reporting neurologic and/or ocular symptoms are re-contacted at approximately three months following prescribed treatment to ascertain whether initial symptoms have resolved. Assuming our interview success rate for follow-up interviews will be approximately 50%, the total burden for this activity will be 17 hours.

Each of the 10 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 10 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 2,280 burden hours (10 respondents x 12 data transmissions x 19 hours).

A12a. 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)	10	6	3	180
General Public – Adults (persons diagnosed and reported with gonorrhea or early syphilis)	Interview (ATT 8)	5492	1	10/60	915
Diagnosing Provider	Data for early syphilis cases (ATT 8)	406	1	10/60	68
General Public – Adults (persons with early syphilis who were reported with neurologic/ ocular manifestations)	3 month follow-up telephone Interview (ATT 8)	203	1	5/60	17
Data Managers: 10 local/state health department	Data cleaning/ validation/reformatting	10	12	19	2,280
Total	3,460

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 \$43.28. The majority of the patient respondents will be of lower socioeconomic status. If employed, the majority are likely to be in service-related industries with an estimated average hourly wage of \$13.00. It is estimated that the respondents

completing the fax back form for facility investigations will be medical records and health information technicians with an hourly wage of \$19.95.

Note: The hourly rate was determined by using information obtained from the US Department of Labor, Bureau of Labor Statistics: <http://www.bls.gov/cps/cpsaat39.htm>

Type of Respondent	No of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Clinic data manager	10	180	\$29.88	\$5,378
Data Administrator at health department	10	2280	\$43.28	\$98,667
Patients diagnosed with gonorrhea and/or early syphilis	5492	915	\$13.00	\$11,895
Medical Record Technician at diagnosing healthcare provider	406	68	\$19.95	\$1,357
Three month follow- up interview among patients diagnosed with early syphilis w/ ocular/neurologic manifestations	203	17	\$13.00	\$221
Total		3,460		\$117,518

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 \$3,054,367. The cost of this project for the three years is estimated to be \$9,163,101. 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 the Federal Government	Enhanced SSuN – Personnel	\$351,137
	Epidemiologist-14 1 100% \$118,263	
	Epidemiologist-12 1 100% \$84,162	
	Data Analyst-14 1 50% \$62,610	
	Data Analyst-13 1 75% \$86,102	
	Cooperative agreement funds to 10 project areas	\$2,637,280
Contractor and Other Expenses	Contracted Project Coordinator (1) 50%	\$35,950
	Travel (site visits)	\$30,000
	Meetings	\$0
	TOTAL COST TO THE GOVERNMENT	\$3,054,367

*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/2016/general-schedule/>.

The personnel related to the enhanced SSuN data collection include 2 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 2854 hours to 3,460. Specifically, the changes in the estimates of burden are accounted for by the following:

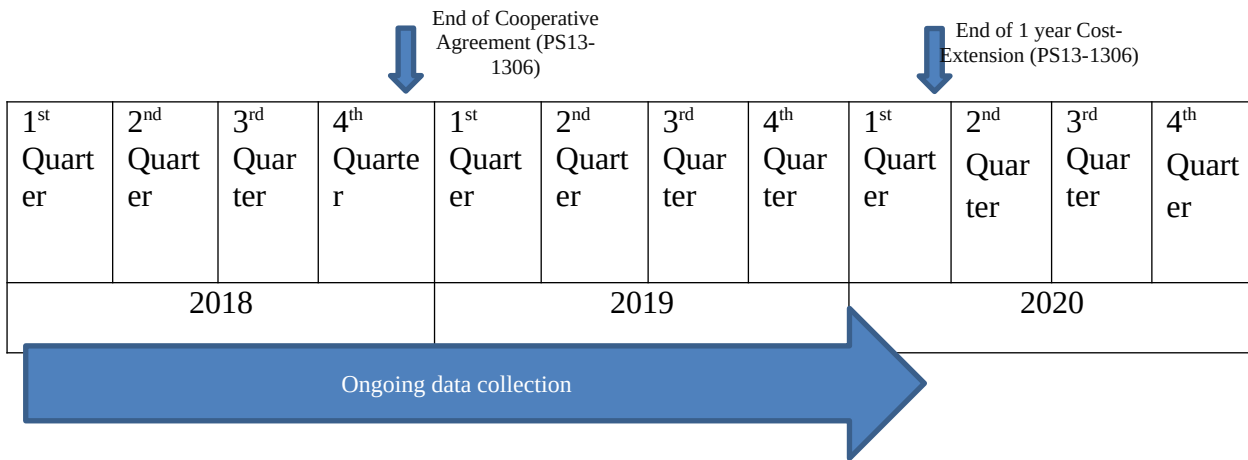
- Family planning clinics have been removed from the facility-based activity so the number of clinic data managers decreased from 22 to 10. Our experience in the 3 years of data collection has shown us that the ability to extract data elements from these type of facilities was limited. In some cases, local/state health departments had not had previous working relationships with these healthcare facilities, resulting in a fair amount of negotiations in terms of the transmission of certain data elements. In addition, these facilities have considerably lower STD morbidity than categorical STD clinics. For these reasons we saw the addition of these clinics as less useful and prefer to concentrate data collection from STD clinics.
- Ten STD clinic data elements were added and 2 STD clinic data elements were removed for a net of 8 new data elements. Because these data elements are collected through routine clinical care and extracted from an existing database there should be minimal burden to add these elements to the sequel (or equivalent) scripts used to pull the data (For detailed description, see **ATTACHMENT 3**).
- Addition of high priority topics to the previously approved interview instrument template: 11 additional questions were added to improve data collection of three priority emerging issues related to STD risk and prevention: Pre-Exposure Prophylaxis (PrEP), expedited partner therapy, opioid use and abuse (For detailed description, see **ATTACHMENT 3**).

- Addition of a high priority activity that centers around ocular/ neurologic manifestations in early syphilis cases. Reported rates of syphilis have been increasing in the US since 2001 with an estimated 19.0% increase in the rate of primary and secondary syphilis in 2015 compared with 2014. Concomitantly the proportion of early syphilis cases reporting neurologic and/or ocular manifestations has also been increasing with clusters of ocular syphilis cases being reported in certain jurisdictions. At present, there are significant gaps in the surveillance of early syphilis cases with neurologic and/or ocular manifestations and there is a need to engage in systematic surveillance to estimate the proportion of cases with neurologic and/or ocular manifestations and to monitor whether there has in fact been a rise in the proportion of syphilis cases with neurologic and/or ocular symptoms over time.

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 2016 data collection cycle results were published in September 2017 (for example, see <https://www.cdc.gov/std/stats16/STD-Surveillance-2016-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 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.



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.
- Determining 1) the frequency and type of neurologic and/or ocular symptoms and signs in early syphilis, 2) current practices for screening and/or testing for neurologic and/or ocular syphilis, and 3) the rate of neurologic and/or ocular symptom resolution within 3 months following appropriate treatment among early syphilis cases reporting neurologic or ocular manifestations of syphilis.
- 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.

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.