STD Surveillance Network (SSuN)

Project Protocol

&

Implementation Guide

SSuN Cycle 4

(2019 – 2024)

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Introduction - Background

The STD Surveillance Network (SSuN) was established in 2005 to create a robust network of geographically diverse collaborating health departments with the capacity to implement a wide variety of enhanced STD surveillance activities, the flexibility to modify activities over time as trends and emergent issues demand, and the ability to use surveillance data in a timely way to inform STD prevention policy at all levels of the public health infrastructure to guide STD programmatic action.

SSuN was expanded in 2008 to include more collaborating health departments and further strengthen the human resources, data management and IT infrastructure capacity. Activities funded in 2008 included monitoring the prevalence of STDs, HIV, viral hepatitis, and risk behaviors in MSM, assessing trends in the burden of genital wart disease in patients attending STD clinics, monitoring HIV testing coverage in patients attending STD clinics, and implementing population-based enhanced gonorrhea surveillance to provide estimates of demographic and behavioral characteristics of diagnosed and reported cases.

In 2013, ten sites were funded to maintain the network's core focus on sentinel surveillance in STD clinics, expanded these sentinel surveillance activities to include patients being seen in reproductive health/family planning settings. Case-based enhanced surveillance activities were revised to include brief provider investigations to obtain important clinical and treatment information, additional look-back data from health department records and added interview questions related to care-seeking behaviors, HIV preventive services such as pre-exposure prophylaxis (PrEP) and sexual network/partnership characteristics. Revisions to data management processes with respect to data quality assurance, and collection of fully relational laboratory, provider, treatment and diagnoses datasets enhanced the utility of data across both core surveillance components of SSuN in the 2013 – 2019 funding cycle. Additionally, weighting algorithms were developed to assure timely weighted analysis of sampled cases and routine dissemination of findings.

The current cycle of SSuN (Cycle 4, 2019 - 2024) continues the network's focus on enhanced STD surveillance through three primary surveillance strategies. **Strategy A** continues sentinel surveillance activities in STD specialty clinics serving populations at risk for HIV and STDs. **Strategy B** supports enhanced, case-based surveillance among reported cases of STD (gonorrhea and adult syphilis). Additional, shorter-term, STD surveillance activities constitute **Strategy C**; these activities will vary throughout funding period and address emergent issues in STD incidence, prevalence of co-infections , immediate complications of STDs and longer-term consequences of STDs.

Collectively, these three strategies and corresponding activities constitute the core work of the network. Emphasis is added in Cycle 4 on STD-related HIV prevention opportunities; HIV-registry matching activities cross-cut Strategies A and B in Cycle 4 for reported cases and for patients being seen in STD specialty clinics. This activity is central to identifying opportunities and gaps in the HIV/STD prevention continuum and for strengthening programs, policies and research that are guided by the principles of high impact prevention (HIP).

This protocol document describes methods that funded jurisdictions will use in implementing these enhanced and sentinel surveillance strategies. Additional information on the STD Surveillance Network may be obtained by contacting CDC SSuN Project staff:

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Supported Jurisdictions - SSuN Cycle 4

The following state, county and/or city health departments successfully competed for funding under CDC-RFA-PS19-1907, STD Surveillance Network (SSuN).

Baltimore City Health Department

California Department of Public Health

Columbus Public Health/City of Columbus

Florida Department of Health

Indiana State Department of Health

New York City Department of Health and Mental Hygiene

Multnomah County Health Department

Philadelphia Department of Public Health

San Francisco Department of Public Health

Utah Department Health

Washington State Department of Health

SSuN Cycle 4 Protocol Sections:

A. Overarching Responsibilities/Activities of Collaborators
    1. Fidelity to data collection protocols
    2. Adherence to data security and confidentiality requirements
    3. Full participation in all SSuN meetings, conference calls and collaborations
    4. Participation in project evaluation and data quality assurance processes
    5. Provision of technical assistance (TA) to state and local STD programs

B. CDC Responsibilities/Activities
C. Data use guidelines
D. Memorandum of Agreement
E. Strategy A – Facility-Based Sentinel Surveillance
    i. Methods
    ii. HIV Registry Matching Requirements

F. Strategy B – Case-Based Surveillance:
    i. Gonorrhea
    ii. Adult (non-congenital) syphilis
    iii. HIV Registry Matching Requirements

G. Strategy C – Surveillance Focus Activities:
    i. *Lymphogranuloma venereum* surveillance
    ii. Enhanced chlamydia surveillance
    iii. Neuro, ocular and otic syphilis
    iv. Syndromic surveillance for ocular, neuro or otic syphilis
    v. Implementation of HL7 case reporting through NNDSS
    vi. Targeted technical assistance to PCHD recipients

H. Data Management
I. Appendices
    1. Memorandum of Understanding
    2. Data Use Proposal Template
    3. Sample Data Collection Templates
    4. Data Dictionary

A. Overarching Responsibilities/Activities of Collaborators

i. Fidelity to data collection protocols and methods
ii. Adherence to data security and confidentiality requirements
iii. Full participation in all SSuN meetings, conference calls and collaborations
iv. Participation in project evaluation and data quality assurance processes
v. Provision of technical assistance (TA) to state and local STD programs

SSuN cooperative agreement recipients are competitively chosen based on superior human resources and local health department capacity for participation in the STD Surveillance Network. SSuN jurisdictions are considered key collaborators in CDC's efforts to maintain robust, flexible and comprehensive capacity for STD surveillance in the United States. CDC expects that the legacy of high performance in SSuN will continue to generate robust, high-impact surveillance data and analytic products to inform our understanding of the epidemiology of STDs in the U.S. and to guide efforts to prevent and control sexually transmitted infections and their consequences.

Jurisdictions receiving funding under CDC-RFA-PS19-1907 are required to participate in the implementation, maintenance and evaluation of sentinel and enhanced surveillance activities as requirements of their cooperative agreement; continued funding is contingent on maintaining outstanding levels of performance across all funded strategies and activities.

All SSuN collaborators are required to complete the project Memorandum of Agreement (MOA; see section D and Appendix 1) governing shared expectations for recipient conduct, collaboration and participation in analyses and dissemination of SSuN findings.

i. Fidelity to data collection protocols and methods:

SSuN protocols and data collection methods have been developed over multiple cooperative agreement cycles to maximize the efficiency and utility of these important surveillance activities and to assure valid, reliable, timely and useful results. CDC expects that SSuN collaborators will adhere to all protocols for data collection with regard to collecting required data elements, data

collection methods, data cleaning and quality assurance, formatting and routine, secure transport of data to CDC in a timely fashion according to agreed schedules.

CDC staff will work with funded collaborators to provide for reasonable local flexibility in implementing specific activities, where necessary, to reflect local public health contexts and conditions – while assuring comparability of data across all funded areas. SSuN Science Officers, Project Officers and Subject Matter Experts (SMEs) will also work with collaborators to identify and address relevant training and/or technical assistance needs to assure success of local activities. All SSuN collaborators contribute de-identified record and case-level clinical, disease surveillance, behavioral, laboratory and other public health-related observations to aggregate national project datasets; the accuracy, validity and reliability of these data depend critically on the comparability of methods across funded sites as well as a commitment on the part of SSuN collaborators to due diligence in data collection, data cleaning and quality assurance.

ii. Adherence to data security and confidentiality requirements:

SSuN-funded jurisdictions are public health departments, and from this perspective are not considered covered entities under HIPAA regulation:

> *"Without individual authorization, a covered entity may disclose protected health information to a public health authority that is legally authorized to collect or receive the information for the purposes of preventing or controlling disease, injury, disability including, but not limited to reporting of disease...and conducting public health surveillance…" (MMWR, 2003).*

Yet SSuN values the principles embodied in these patient-level protections and strives to establish and maintain the highest level of performance in protecting the confidentiality and security of all information. Patient-level data transmitted to CDC must not contain personal identifiers such as name, social security number, date-of-birth, street address, or medical record number. Unique, non-personally identified event and patient IDs are critical for the success of SSuN and specifically permit longitudinal monitoring of unique persons in Strategies A & B. To do this reliably, the unique identifiers associated with individual patients and related health events must be maintained over the full course of the cooperative agreement and must be static and immutable over the project period. Moreover, because identifiers assigned to uniquely identify

persons are transmitted to CDC, these IDs must not contain elements of the above listed personal identifiers. All unique identifiers for patients and events must be developed and maintained locally and may be (or may not, depending on state/local practice) the same IDs used in local surveillance data management systems or electronic health records as locally determined.

Human Subjects Protections

The Associate Director for Science (ADS) of the National Center for Hepatitis, HIV, STD and TB Prevention (NCHHSTP), reviews SSuN protocols. A Determination of Non-Research has been obtained for SSuN Cycle 4 activities. SSuN activities continue to be exempted from CDC Institutional Review Board (IRB) review because they constitute public health surveillance – a disease control activity – and do not represent research activities. No incentives are provided directly to patients for participating in SSuN activities, nor should any actual or perceived consequences devolve to patients for non-participation or refusal. Post-award, all collaborating health departments must assess their local requirements for similar determinations. Where necessary, local IRB non-research exemptions or waivers should be procured, with the understanding that any additional local requirements for patient consent must be carefully balanced against public health surveillance needs and should not be burdensome to the extent of precluding the jurisdiction's full participation in SSuN activities or significantly compromising compliance with CDC-approved protocols.

Confidentiality

To protect the confidentiality of all SSuN data, state and local surveillance program staff agree to abide by standards embodied in, and documented by, the "*Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action",* available here: http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf.

Funded jurisdictions are required to obtain a statement from their jurisdiction's Overall Responsible Party (ORP) for HIV surveillance to document compliance as part of the award process and must obtain annual re-certification as part of annual project reporting. All names,

street addresses, social security numbers, telephone numbers, or any other specific identifying information maintained at the local level must be securely stored and be appropriately redacted before transporting records to CDC. Data transmitted to CDC will contain only required geographic information (county, state and census tract) as well as other demographic, clinical, and behavioral data elements specified in SSuN protocols.

All record-level data transmitted to CDC by collaborators must be transported using encrypted, secure transport methods approved by CDC (e.g., SAMS). Data stored at CDC is maintained on secure servers with multi-layered access restrictions. SSuN data archived at CDC are available only to staff in the Division of STD Prevention (DSTDP) on an "as needed" basis. SSuN surveillance data, as with all national STD surveillance records, are governed by strict data re-release policies; disclosure of any information that could be used to directly or indirectly identify any individual on whom a record is maintained is strictly prohibited.

iii. Full participation in all SSuN meetings, conference calls and collaborations:

SSuN collaborators are expected to take an active role with CDC and with their SSuN colleagues from other sites, and to fully participate in individual and group discussions and scheduled gatherings. The purpose of these meetings, conference calls and individual site consultations is to assure that SSuN activities are implemented according to protocols, provide a regular forum to discuss emergent issues in STD surveillance, address site-specific issues and collaborate in analyses and dissemination of SSuN findings. SSuN collaborators may also be occasionally called upon to serve as surveillance consultants to the Division of STD Prevention for expertise on issues involving emergent and/or long-standing problems in STD surveillance at the local and national level.

iv. Participation in project evaluation and data quality assurance processes:

SSuN staff at CDC will provide recipients with SAS data structures, format libraries and SAS syntax for edit checking and data quality assurance for all required datasets that must be applied prior to transmitting data to CDC. These tools should be used by funded sites to assure that all data

quality, structure and format issues are addressed – and corrections made – before data are transmitted to CDC. Additional quality assurance processes will be deployed at CDC before data are merged into the national datasets. SSuN collaborators are expected to actively participate in data quality assurance processes and to collaborate with CDC staff in addressing any and all deficiencies identified in datasets submitted to CDC.

Periodically, CDC may request that collaborators participate in initiatives designed to evaluate SSuN activities, provide additional information about the effectiveness or efficiency of SSuN surveillance methods and to provide quantitative or qualitative information to CDC for future planning purposes. SSuN recipients are expected to collaborate with their CDC colleagues in these important evaluation activities.

v. Provision of technical assistance to state and local STD programs:

SSuN collaborators are expected to provide technical assistance on surveillance methods and best practices to the state, county and local STD/HIV programs in their jurisdiction as part of routine SSuN activities. SSuN collaborators are a rich source of information and surveillance expertise and should proactively make themselves available to their local colleagues to improve the overall quality of STD surveillance data, especially those data routinely reported to CDC through the National Notifiable Disease Surveillance System (NNDSS). SSuN collaborators are asked to develop formal, written processes to share lessons-learned locally and provide for data sharing with HIV and STD surveillance programs to assure that SSuN data are used supplement the completeness of existing STD and HIV case data reported to CDC. Additionally, SSuN data should be used to enhance the quality of STD epidemiology reports developed and disseminated locally to guide STD prevention and control efforts funded under PS19-1901, Prevention and Control for Health Departments (STD-PCHD).

SSuN jurisdictions may also elect to propose funding under SSuN Strategy C to provide targeted technical assistance to other jurisdictions in their region implementing enhanced and core STD surveillance strategies funded under STD-PCHD. Such technical assistance will be identified and delivered in collaboration with CDC's PCHD Prevention Specialists, and will be fully documented and evaluated as an integral part of this SSuN Strategy C focus activity.

B. CDC Responsibilities/Activities

Collaborators in the STD Surveillance Network are funded through a Cooperative Agreement rather than a grant mechanism in recognition of the substantial involvement of CDC in the development of activities, protocols and priorities for the network – consistent with the broader goals of the Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Division of STD Prevention. Substantial involvement by the SSuN Science Officer, SMEs, Project Officer and other CDC collaborators includes:

- Coordination and dissemination of protocols for SSuN activities
- Facilitation of routine SSuN communications
- Coordination of conference calls and annual collaborator's meeting(s)
- Provision of infrastructure for secure transport of data to CDC
- Provision of technical assistance, including SAS licensure and SAS training (limited)
- Monitoring of recipient progress toward achieving SSuN outcomes, including recipient implementation of data quality assurance processes
- Management of SSuN data warehouse or other CDC central data stores to support data provisioning for collaborative analyses
- Provision of guidance and technical assistance (where requested and/or identified by CDC) essential to implementation of activities in compliance with protocols
- Summary and aggregate reporting to CDC leadership and external stakeholders
- Ensuring that analyses and dissemination of site-specific findings from SSuN surveillance activities are conducted collaboratively by both CDC and appropriate colleagues at participating sites
- Providing laboratory services for STD surveillance focus activities funded under Strategy C
- Facilitating discussions with SSuN recipients to identify emerging trends/issues in STDs/HIV and sexual health, STD surveillance technologies and methods and other issues that merit further investigation
- Coordinating development, dissemination and approval of proposals for multi-site SSuN analytic projects
- Assisting co-authors and lead authors in the development of multi-site SSuN manuscripts
- Facilitating CDC clearance for manuscripts and presentations based on multi-site SSuN findings

- Working with SSuN recipients to assure that all activities, at both the awardee and CDC level, adhere to NHHSTP data security and confidentiality guidelines

Project Coordination and Performance Monitoring

The SSuN Project Officer will work with each recipient to implement routine performance monitoring processes. CDC will provide periodic annotated progress reports to collaborators that will summarize key performance metrics for the project overall and serve as the basis for comparison of these same metrics across individual sites.

C. Uses of SSuN Data

Data from SSuN are expected to improve local and national STD surveillance activities, contribute to STD/HIV prevention and control programs, inform local and national STD policy-making and increase understanding of the epidemiology of populations being diagnosed with STDs and trends in persons seeking STD clinical services. Results and findings from SSuN are also intended to guide other national STD surveillance projects and contribute to strengthening the human resources and technical infrastructure for state and local STD surveillance.

SSuN is a surveillance network that is, in part, intended to be representative of persons being diagnosed and reported with STDs in multiple participating geographic areas encompassing a significant proportion of all STDs reported nationally. An important outcome of SSuN is to disseminate findings in a timely and useful way. Many findings will be particularly useful at the local level; other results will be more meaningful after the data from all SSuN collaborators have been aggregated, cleaned and appropriately weighted for analysis where appropriate. SSuN recipients are expected to analyze and disseminate their site-specific data and to use local results to improve state and local surveillance reporting, inform STD-related health policy and improve STD prevention and control efforts in their jurisdiction. The principles and guidelines presented in this section are intended to assure that SSuN findings are disseminated widely and that all SSuN collaborators have opportunities to fairly participate in the process of analyzing, presenting and participating in the development of manuscripts for submission to peer-reviewed journals.

SSuN Data Uses at the Individual Site Level

SSuN recipients retain all rights and stewardship responsibilities with regard to the SSuN data collected and stored locally. Moreover, CDC data stewardship principles preclude sharing site-identified data transmitted to CDC with internal or external parties without the explicit permission of local collaborators contributing those data. Collaborators are strongly encouraged to use their local SSuN data for routine reporting, novel descriptive or statistical analyses, presentations and manuscripts submitted for publication.

CDC requests that SSuN funding be acknowledged (CDC-RFA-PS19-1907, STD Surveillance Network, SSuN) if an analysis is presented or manuscript published that includes enhanced case or clinic visit data normally transmitted to CDC as part of SSuN – or for an activity that was substantively supported by SSuN funding through Strategy C. CDC clearance is not required for site-specific data products, unless a CDC collaborator is included as a co-author. Sites are asked to share local SSuN data products with CDC for inclusion in the SSuN bibliography. Moreover, it is strongly encouraged that SSuN collaborators share their ideas and plans for local analysis and publication with their SSuN colleagues at CDC and other sites through the SSUN proposal process; there may be valuable opportunities to strengthen a single-site analysis by including multi-site data. This collegial approach will also serve to inform and inspire colleagues who may wish to conduct similar analyses and to create an environment that fosters collaboration, prevents duplication of effort and fulfils SSuN's primary mission of enhancing STD surveillance nationally.

Analysis of aggregate SSuN data (no identified site-level stratification)

SSuN Science Officer and CDC SMEs will have primary responsibility for generating reports, coordinating authorship and publication of SSuN data aggregated across sites and will summarize these data as requested by CDC leadership, in national surveillance reports, conference presentations, peer-reviewed journals and other internal and/or external publications. SSuN strongly values the insight of our funded jurisdictions and supports participatory analysis

processes designed to provide SSuN collaborators the option of participating in all aggregate analyses and data dissemination of national data. Yet CDC staff retain the prerogative to respond rapidly to requests from DSTPD leadership for presentations of aggregate SSuN data in multiple formats and/or publications without prior notice.

Reporting of aggregate SSuN data at the national level that displays no site-specific stratifications, or only present ranges across de-identified sites, will not require co-authors or individual site-level approval or be subject to local clearance processes. However, all sites providing data used in any such analyses will be formally acknowledged if representatives from that site are not otherwise included as contributing co-authors. Reasonable effort will be made to propose such analyses to the SSuN collaborators in advance and to solicit input and co-authorship for aggregate analyses. Whenever non-CDC co-authors are included in SSuN manuscripts or presentations based on aggregate data, SSuN promotes and respects adherence to local clearance requirements when appropriate based on inclusion of a co-author from that jurisdiction.

SSuN Data Stratified by Site (site-level data presented)

All analyses that include data stratified by identifiable site, with the exception of figures presented in DSTDP's annual STD Surveillance Report, will be disseminated as formal proposals to collaborators for discussion. Full participation as co-authors by SSuN collaborators is encouraged in these analytic projects, but is not required. Co-authorship for SSuN purposes is construed to include substantive involvement in planning, data management and analysis, manuscript drafting, data visualization, methodologic decisions, implication discussions and reviews of final draft products. Contribution of data by a funded SSuN jurisdiction, in the absence of substantive involvement as described above, would not generally constitute sufficient contribution to be included as a formal co-author, consistent with the guidelines of most peer-reviewed journals.

Sites contributing data to identified, site-specific data products should identify an investigator to be included in a "SSuN Working Group" designation if there are no formal co-authors from that

site. “On Behalf of the SSuN Working Group” will be the last formally acknowledged co-author on such manuscripts. Statements of approval for CDC clearance purposes are required of every co-author or “SSuN Working Group” member for abstracts submitted for presentations and for manuscripts submitted to journals for publication. We ask that all SSuN collaborators be conscientious in responding promptly to requests for clearance approvals.

Proposals for Analysis

SSuN collaborators from funded jurisdictions and investigators, science officers and fellows at CDC are all encouraged to develop proposals for analyses of SSuN data for consideration. In general, proposals for analyses will be reviewed for approval twice a year by all collaborators, at the annual collaborator’s meeting and on a mid-year all-site conference call.

Proposals for abstracts to be submitted to upcoming conferences may be reviewed more frequently, or on an ad hoc basis. Non-response after two (2) weeks will be considered tacit approval of the proposal, formally declining co-authorship and approval to use the site’s data (with formal acknowledgement as described above). There is no limit to the number of proposals that may be discussed and approved at the semi-annual meeting/conference call. However, the SSuN Science Officer will work with investigators to consolidate proposed projects if there is significant overlap between proposals. Completed abstracts for approved proposals should be distributed to collaborators not less than one (1) month prior to the conference’s abstract submission deadline; collaborators will be given a minimum of two weeks to review, provide comments/edits, decide on co-authorship and provide clearance statement (if required), with defaults for non-response as described above.

For proposals using only aggregate data (no site-specific stratification) to move forward, SSuN sites whose data are being requested will be given an opportunity to review within the time periods specified above, comment and formally elect to participate as co-authors or with acknowledgement for the contribution of data. All data use proposals will generally be approved by consensus, but may be subject to majority vote if necessary. Sites may elect to approve or disapprove of a proposal, and may decline to have their site’s data included for reasonable cause.

For proposals using site-specific data (site-identified stratifications presented) to move forward, all SSuN sites will be given an opportunity to review and comment within the time periods specified above. All sites contributing data must identify one co-author for participation, either as a formal co-author or by inclusion in the "SSuN Working Group" designation. Sites may decline to permit the use of their data for multi-site analyses but must provide rationale for such decisions. *Concurrent plans for a substantively similar site-level analysis by SSuN collaborators will generally not be considered a robust rationale for failing to permit use of their national SSuN data or for declining to participate in an approved SSuN multi-site analysis*.

Occasionally, analyses may be proposed using longitudinal data from sites that are not currently participating in SSuN, in addition to currently funded sites continuing from previous cycles. Efforts will be made to contact previously participating PIs for co-authorship and approval; current collaborators may also participate as co-authors for any such analyses with consensus of the sites contributing data.

Proposals for multi-site analyses from investigators that are not SSuN-funded collaborators (local interns, academic partners, etc.) must be sponsored by the Principal Investigator (PI) of the site from which the proposal is submitted and must have the sponsorship of at least one CDC SSuN Science officer or SME; if approved through normal processes by the SSuN collaborators group, the proposing site's PI will take responsibility for assuring full adherence to all appropriate data security and confidentiality requirements.

In many cases, preliminary data may be needed to assess the merits or feasibility of a given analysis. CDC project staff will work with investigators to conduct preliminary data exploration on the national SSuN data repository resulting in simple frequency tables and/or crosstabs to help inform the proposal; these data/tables will accompany the proposal distributed for review. All submitted proposals and any included preliminary data visualizations should be considered internal, privileged and confidential documents.

Proposals should address how the analysis will be used for public health purposes and the specific objective, data to be used (data elements, time frame), methods of analysis and briefly address the specific assumptions and how missing data may be dealt with. Collaborators will be provided

with pending proposals at least two (2) working weeks prior to the PI meeting or mid-year conference call. Non-response after two (2) weeks will be considered tacit approval of the proposal, declining of co-authorship and approval to use the site's data with formal acknowledgement. A sample proposal form is included as Appendix 2.

Access to Analytic Data

SSuN project collaborators from funded jurisdictions and investigators, SSuN Science Officers, SMEs, and colleagues or fellows from other divisions or centers at CDC are all encouraged to develop proposals for analyses of SSuN data for consideration. SSuN staff will assist with simple exploratory crosstabs in the proposal development stage if requested. However, full access to analytic data will be provided contingent on approval of proposals; only data elements pertinent to the proposed analysis will be shared and only records for the time periods proposed in the analysis. Any SSuN data shared with external partners as part of an approved analysis proposal will be securely transported to the site sponsoring the analysis, with agreement that SSuN data will be afforded the highest level of protection at the receiving site, with limited access only for the purposes approved in the initial proposal and only by persons identified in the proposal. Sites agree to securely destroy (wipe) SSuN datasets after all analytic needs are fulfilled and further, agree that no secondary release of record-level data is permitted. Any publication requiring inclusion of full datasets as part of the publication process must be referred to the SSuN Science Officer prior to the transfer of any SSuN datasets to 3rd parties. In general, such uses will not be permitted.

D. SSuN Memorandum of Agreement

Health department collaborators funded for SSuN Cycle 4 activities will be required to complete a Memorandum of Agreement with CDC governing the jurisdiction's intention to provide required data, adhere to SSuN protocols for data collection and to fully participate in SSuN collaborations as described in the cooperative agreement and this protocol document. A duly executed copy of this MOA should be completed and forwarded to CDC within one month post award. A template MOA is provided as Appendix 1.

E. Strategy A – STD Clinic-Based Sentinel Surveillance Activities

Purpose and Scope

Cycle 4 of SSuN builds on previous experience in enhanced facility-based surveillance from Cycles 1, 2, and 3. The primary objectives of Strategy A are; 1) monitoring trends in people seeking care in STD clinics, and, 2) monitoring STD-related HIV prevention opportunities among persons seeking care in STD clinics. The primary purpose of this protocol is to provide a consistent method for SSuN recipients to use in conducting sentinel surveillance in STD clinics. Collection of data from these settings should produce high-quality, timely facility-based surveillance and epidemiologic data to direct public health STD prevention and control efforts, and improve the understanding of STD & HIV preventive services and intervention opportunities in STD-specific clinical settings. State and local STD surveillance programs have a history of strong collaborations with local STD clinics in their jurisdictions. Because SSuN data are critically dependent on the quality of data, state and local STD surveillance programs are encouraged to optimize strategies to ensure data completeness.

Methods

Population of Inference

The population of inference for the facility-based component of SSuN includes all clinic patients presenting for care and/or STD preventive services in participating STD clinics.

Definition of STD clinics

STD clinics are operationally defined as any clinical facility providing timely comprehensive, confidential and culturally sensitive STD care as the facility's primary function. Clinics need not be stand alone and may be integrated into broader practice settings. However, the selected facility must have a specifically identifiable STD clinic and have the ability to identify and extract records from their electronic health records system for patients specifically seeking STD clinical services separately from any broader patient population. Additionally, at least one of the proposed STD clinic sites must meet the volume requirement of at least 5,000 visits per year and

provide active management of (or documented referral to) pre-exposure prophylaxis (PrEP)/post-exposure prophylaxis (PEP) for eligible patients.

Data Management

Participating grantees will collaborate with selected STD clinical site(s) to obtain visit-level clinical information, including all data elements specified in this protocol, for all patients who receive STD and/or sexual health services in participating STD clinics. Required data elements and the appropriate response coding for clinic records are included as Appendix 4. Data transmission will be at the interval of every other month for the duration of the project period.

Data abstracted will include patients demographic, behavioral and clinical information collected during all visit encounters. The clinical information collected will be primarily related to the diagnosis of STD/HIV related conditions, provision of preventive care, treatment prescribed, and laboratory records (tests and results).

Data abstraction will be performed to create the following five files:

- Visit: SAS file containing visit-level records and include routinely obtained patient demographics (e.g., age, sex, gender identity, race, etc.) behavioral (e.g., gender of sexual partners, drug use, etc.), and clinical (e.g., symptomatic status, recent HIV testing and results, use of PrEP/PEP, etc.) data associated with all visits.
- Diagnosis: SAS file containing visit-level records that contain routinely obtained diagnosis records associated with all STD clinic visits (e.g., pelvic inflammatory disease, chlamydia, non-gonococcal urethritis, muco-purulent cervicitis, etc.)
- Laboratory: SAS file containing visit-level records that contain routinely obtained STD-related and pregnancy, if applicable, laboratory records performed that are associated with all STD clinic visits.
- Treatment: SAS file containing visit-level records that contain routinely prescribed STD-related treatment records associated with all STD clinic visits.

- Metadata- SAS file containing information on facility-level characteristics for each participating clinic or network of clinics (e.g., type of clinic, policies on STD screening, billing)

Visit level records of patients from STD clinics will include a unique patient identifier (patient ID) to ensure multiple visits by the same patient are captured and longitudinal tracking can be done over the course of the cooperative agreement. This patient ID must be included as part of each visit record. If applicable, it is strongly encouraged to use the same unique identifier for an individual patient if there exists multiple participating STD clinics within a network in a single jurisdiction. Each clinic encounter will also be assigned a unique event identification (event ID) number for each visit. The non-name-based unique patient and event ID, should be assigned by either the state or local health department or the sentinel facility, and 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 and/or local health department. CDC cannot use this number in the identification of individual patients seeking care in these facilities. Records for all visits containing a unique patient ID and a unique event ID, will be used to link all STD-related diagnoses, laboratory (including HIV) tests and results, and treatments given that are captured in related SAS files. Each jurisdiction will also be identified by a unique site code and every clinical facility will have its own unique facility ID code, both of which will be prepopulated by CDC.

The visit file will serve as the 'parent' record as it serves as the record of the actual clinical encounter. Each visit (parent) record must include the patient ID, event ID, site ID, facility ID and visit date variables in correct values; null values will not be accepted for these variables. These key variables will be used to link records from the diagnosis, treatment and laboratory files. All records from these 3 files that do not link to a parent record are considered 'orphan' records. These records should be reconciled at the local level before transmission of data to the CDC. Facility-based characteristics included in the metadata file will be collaboratively defined by SSuN collaborators post-award but should up updated yearly. Funded jurisdictions are expected to maintain rigorous procedures to assure the quality and validity of data before submitting to CDC,

including but not limited to, completing data verification, recoding and appropriately structuring the data to facilitate merging into the national enhanced SSuN datasets.

Automated SAS edit checks will be provided by CDC and used to in order to assure high quality data are being collected. Jurisdictions should apply these validation checks and fix the offending records prior to transmission.

Patient Surveys

In addition to implementing visit-level data abstraction in STD clinics, recipients are expected to implement periodic, brief patient surveys in STD clinics participating in SSuN Strategy A. These surveys, conducted in collaboration with CDC staff, will aid in 1) gaining a better understand of the access and utilization patterns of people who seek health services in STD clinics and 2) assessing information not routinely captured in the clinic health record. At least one (1) survey must occur in the first funding year with a minimum recruitment of 350 consecutive patient/respondents. In years 2-5, we anticipate multiple surveys per year, each with a minimum of 350 consecutive patients/respondents per survey. SSuN recipients may chose when in the budget year to implement their survey(s), based on local considerations, but must allow sufficient time to complete the required 350 surveys by the end of the budget year. CDC survey protocols and survey questions may vary from year to year, allowing for emergent issues to be investigated in a timely fashion.

Although recipients may propose paper-based or technology-assisted data collection methods, the design must allow capture of voluntary, self-reported responses from all patients seen consecutively during the survey administration interval. Patients should respond to the survey prior to receipt of their clinical services (e.g., in the registration area/waiting room). Conducting these periodic patient surveys can also provide the opportunity, if needed, for jurisdictions to include supplemental questions related to issues of specific interest at the discretion of the individual jurisdiction. However, this supplemental information would not be transmitted to CDC.

Patient duplication during the survey period is allowed, but only a single survey should be administered/collected per clinic visit. It is preferred, though not required, that survey data be

linked to the associated SSuN patient visit record through appropriate identifiers where feasible (unique visit ID, medical record number, patient name, etc.). Jurisdictions may propose to pilot various methods to link with clinical records in the first year. Recipients with multiple STD specialty clinic sites contributing data to SSuN Strategy A should consider survey administration in higher-volume clinics (>5,000 visits per year) and may propose rotating between participating clinics with this volume annually as needed to fully represent the jurisdiction's STD specialty clinic population. Data entry of survey data (if needed based on local methods proposed) will be accomplished at the STD clinic site, or may be aggregated at the recipient's health department for central data entry.

HIV registry matching

In this cycle of SSuN, recipients will be required to collaborate with selected STD clinical facilities to conduct eHARS (or similar official, comprehensive HIV case registry) matching of clinic patients (regardless of diagnoses) seeking care. Collaborating STD clinics are expected to provide patient identifiers (e.g., first and last name, date of birth, social security number, race, sex, etc.). The choice of identifiers to use in matching records is up to the recipient but in general, variables with the greatest specificity should be used. The matching process will strictly be performed at the recipient level; CDC will not conduct these matches nor receive patient identifiers. Although jurisdictions will propose methods specific to their jurisdiction (e.g., software, matching methodology), the expectation is that matching will be automated and tuned for maximum efficiency. The details of this process, including the frequency of matching, will be finalized post award.

All patient records should have a disposition for result of HIV registry match. In cases where there is uncertainty or matching discrepancies are noted, a manual review of the matching variables is strongly suggested. For patients that are matched to a record in the HIV registry, recipients are asked to abstract patient-level data on the date of earliest indication of HIV infection and documented mode of transmission in the HIV registry. This information will be populated in the visit file (specific to patient's visit record). In addition, recipients are required to obtain all HIV diagnostic and HIV laboratory data that are available in the HIV registry for matched patients,

including the earliest recorded initial HIV–positive diagnostic test date, HIV viral load date(s)/result(s) and CD4+ date(s)/result(s) with specimen collection dates on or subsequent to October 1st, 2018.

It is highly recommended that recipients collaborate with their CDC-funded HIV Surveillance units to address reciprocal information sharing to assure that desired patient demographics, sexual orientation, gender identify, HIV testing and or treatment are available to CDC-funded HIV surveillance unit staff for related evaluations and to enhance the completeness of HIV case surveillance data. There is no requirement for data abstracted from the HIV registry to be shared back to clinical facilities for the purpose of patient-level interventions or public health actions. However, if jurisdictions choose to develop processes by which to share data back with clinical partners SSuN would have no objections otherwise.

Figure 1: Example of Jurisdiction-Level HIV Match Process Flow

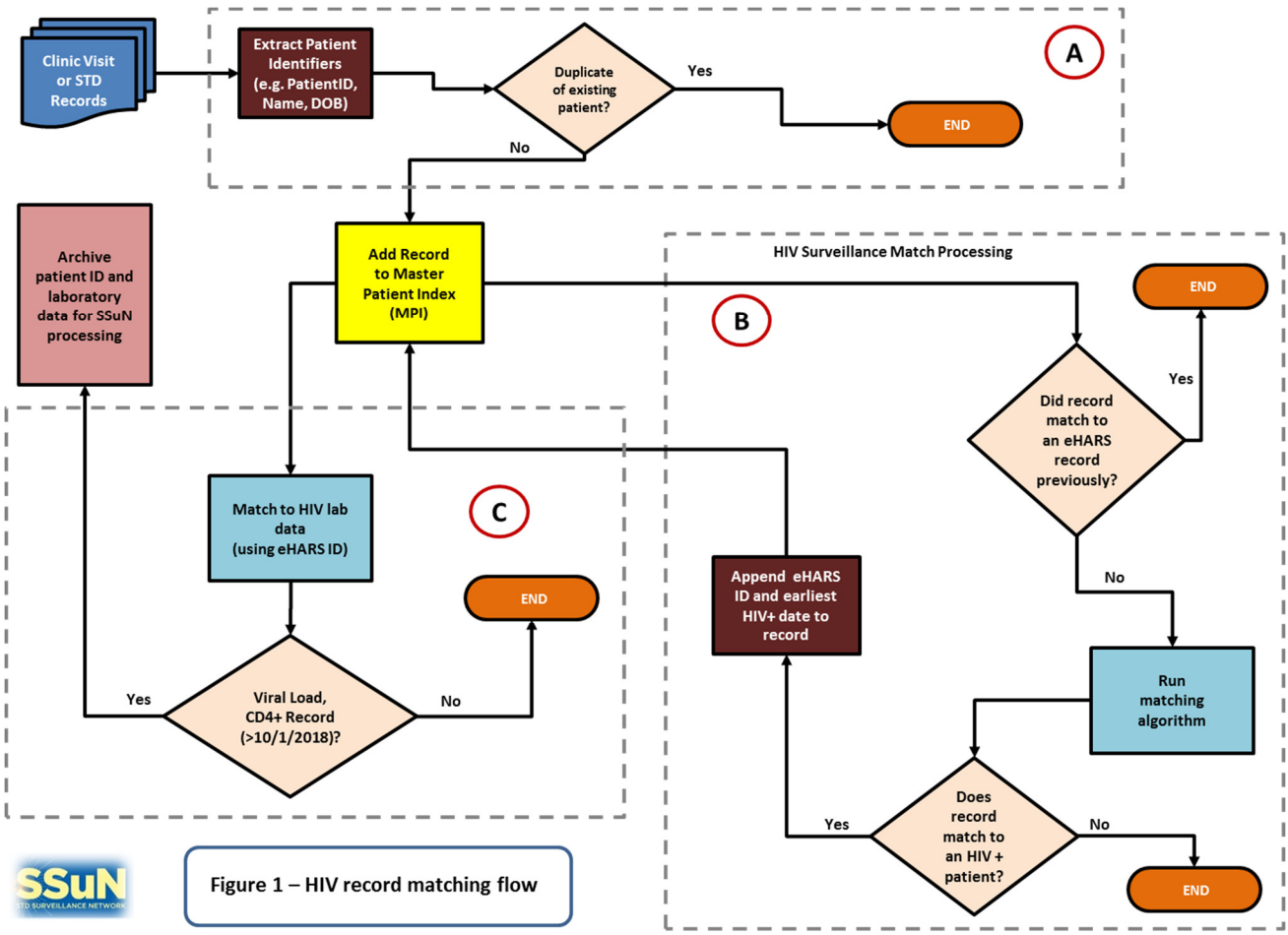


Figure 1 – HIV record matching flow

It is suggested that jurisdictions develop and maintain a separate patient index file for all patients for matched cases at the recipient's health department to obviate the need to rerun the patient through a matching algorithm. However, if a previously matched patient presents to a participating STD clinic for subsequent visits, the patient's HIV laboratory (VL/CD4+) will need to be updated based on the date of each additional clinic visit.

Data matching or linking records between data sources can be an important means of strengthening STD and HIV surveillance data, including identifying co-infections, improving the completeness of existing databases, and guiding public health program activities. Grantees will be able to assess their local burden of co-infection among reported STD cases and patients presenting for STD care in STD clinics. Matches will also enable CDC to do the following:

- Evaluate HIV status among STD clinic patients diagnosed with or at risk for STDs and to stratify by behavioral risk, diagnosing provider characteristics, geography and demographics
- Understand the proportion of STD clinic patients diagnosed with or at risk for STDs who are HIV-negative and eligible for and receiving PrEP/PEP (at time of STD diagnosis) and to stratify these outcomes by multiple demographic, behavioral and healthcare factors
- Understand the proportion of STD clinic HIV-positive patients diagnosed with or at risk for STDs who are HIV-positive and in HIV-primary care, on ART and virally suppressed and to stratify these outcomes by multiple demographic, behavioral and healthcare factors
- Provide relevant patient-level and aggregate information at the recipient level to assist local HIV surveillance/prevention units to resolve selected NRR/NIR cases, better monitor HIV care status and prevalence patterns, and to better understand gaps in and opportunities for promotion and uptake of HIV prevention interventions.

F. Strategy B – Enhanced Case-based Population Surveillance SSuN

Purpose and Scope

Enhanced data collection on all reported cases of gonorrhea and adult syphilis (all stages) provides a valuable supplement to national case notifications allowing assessment of key surveillance data quality measures. Collection of HIV registry matching provides information valuable for assessing progress toward HIV prevention goals and gaps in HIV preventive services among persons diagnosed with STDs. Additional patient and provider data obtained on a representative sample of gonorrhea cases allows for valid estimation of case characteristics often missing or not present in routine cases reporting.

Cycle 4 of SSuN builds on previous experience in enhanced case-based surveillance and recipients are required to implement 6 primary Strategy B activities:

a. Extraction, cleaning and recoding a full census of gonorrhea and adult syphilis cases to a case dataset with enhanced data elements including case and patient deduplication indicators,
b. Conducting look-back investigations on all reported cases of gonorrhea and adult syphilis, including matching with HIV registry and aggregating all HIV/STD-related laboratory observations associated with cases in a separate, related laboratory dataset linked to the case records by unique event and patient IDs,
c. Selection of a random sample from this universe of reported cases of gonorrhea,
d. Brief provider investigations on cases selected in the random sample (beginning with gonorrhea in year one) to obtain relevant clinical and STD treatment information,
e. Enhanced patient investigations of gonorrhea cases selected in the random sample.
f. Technical assistance within the STD program within their jurisdiction to improve overall STD surveillance data quality, use of SSuN data to inform local STD epidemiology and disease prevention and control.

Methods

Generating a Random Sample of Cases

Collaborating health departments will develop the capacity to generate a random sample of all cases of nationally notifiable STDs within the first three months of funding. The most effective way to achieve this result is to modify local STD surveillance data management systems to incorporate this functionality by creating a system variable associated with individual records of confirmed cases/events. This variable should be populated with the results of a random number generator (generally a system function that randomly generates number between 0 and 1.0) which runs only once at the time the case is entered into their system, regardless of whether the record is created automatically based on incoming laboratory data or manually based on review of internal or external case or laboratory reports. Random number functions are available in SQL, Oracle and most other database platforms.

A useful analogy is that as each case is entered into the system, dice are rolled and the result frozen for that unique case; the 'dice' should not be rolled again once the initial result is recorded. The variable or data element containing this 'frozen' random number must be permanently stored in the underlying case/event records and available for export for use in constructing SSuN datasets and for directing subsequent SSuN case investigations. Because this random number is generated uniquely for each individual record, it is irrelevant whether subsequent investigations determine that the case/event is a duplicate or if the case/event is out-of-jurisdiction.

Each system will have unique characteristics from the programming/development perspective, but the end result must be a random number permanently associated with each unique case or event record that can be used to select a sample for enhanced investigation regardless of any subsequent disposition of that specific record.

Using Random Numbers to Assign Sample Status

Once a random number is associated with individual cases/events, this number will be used to assign a sample indicator based on the desired sample fraction for cases of interest to SSuN (which includes all gonorrhea, adult syphilis and also for chlamydia cases if the jurisdiction

participates in the chlamydia focus investigation). This can be done either internally in the local STD surveillance data management system or externally using SAS, SQL or other software.

For example, if a sample fraction of 30% is desired for gonorrhea cases, and the random number generator returns a value of between 0 and 1.0, all records with a value between 0 and 0.3 should be selected, and the sample indicator (P1_RandSamp) assigned a value of 1. For records with values > 0.3, the sample indicator should be assigned a value of 0. All records with a sample indicator =1 constitute a 30% random sample.

Consider that it may be desirable to have different sample fractions in different counties (or other geographic units) based on available resources for follow-up or to balance workloads based on morbidity levels. The same random number can be used, but the geographic unit would be incorporated into the assignment of the sample indicator. For example; given three counties with local IDs of 01, 02 & 03, and desired sample fractions of 10%, 20% and 50% , the sample indicator would be assigned this way using SAS code:

P1_RandSamp=0;

If county=01 and (0 LE RandomNumber LE 0.1) then P1_RandSamp=1;

If county=02 and (0 LE RandomNumber LE 0.2) then P1_RandSamp =1;

If county=03 and (0 LE RandomNumber LE 0.5) then P1_RandSamp =1;

Note that this schema can be deployed using a macro that could get the fraction and county data from an external source such as an excel workbook or other source to provide greater flexibility in changing the sample fraction over time, by geographic area or by disease. SSuN recipients are encouraged to develop and deploy flexible means of sampling cases wherever possible.

a. The 'universe' for assigning a random number will include ALL cases of laboratory confirmed gonorrhea, chlamydia and adult syphilis cases diagnosed and reported from ALL public and private sources within the geographic boundaries of the collaborating jurisdiction.
b. Records should be individually assigned a random number at the time they are received into the jurisdiction's STD data management system (or batched in a timely manner daily,

or at a minimum, weekly if randomization is performed external to STD data management system) such that all records meeting the sampling criteria based on information contained in the report (provider located in jurisdiction, laboratory confirmed diagnosis of CT, GC or adult syphilis) are assigned a random number.

c. The 'sample' is assigned by comparing the random number to a predetermined sample fraction based on the disease and geography (as locally determined, see above). A sample variable (P1_RandSamp) with values of 0 and 1 should be assigned to determine disposition of the record.
d. For initial SSuN Strategy B activities, follow-up of cases in the random sample of cases will be restricted to gonorrhea
e. A sufficient volume of records should be included in the resulting random samples to fulfil stated project objectives:
    i. for jurisdictions with >50,000 gonorrhea cases reported in 2018, the minimum acceptable target for completed patient interviews is 2.5% of all reported cases;
    ii. for jurisdictions with 30,000 - 50,000 gonorrhea cases reported in 2018, the minimum acceptable target for completed patient interviews is 3.0% of all reported cases;
    iii. for jurisdictions with 10,000 - 30,000 gonorrhea cases reported in 2018, the minimum acceptable target for completed patient interviews is 3.5% of all reported cases;
    iv. for jurisdictions with <10,000 cases reported in 2018, the minimum acceptable target for completed patient interviews is 4% of all reported cases;
    v. patient interview completion rate will be calculated as the ratio of completed interviews to the number of cases in the sample;
    vi. **interview completion rate target for SSuN investigations is 65%.**

f. "Completed" patient interviews refer to complete or substantially complete (partial), patient interview. An interview will be considered as 'partial' if complete demographic and gender/number of sex partner information is obtained but other information is

refused or the interview terminated prematurely. However, every effort must be made to complete all data elements on the patient interview; periodic recipient performance reviews will include assessments of missing or incomplete patient-reported data elements.

g. Jurisdictions will conduct routine and frequent (e.g. quarterly) quality assurance activities to assess the representativeness of their samples by disease, with particular attention to equal probability of sampling by patient characteristics (at a minimum by sex, age, and geographic region within jurisdictions and source of report).
h. Jurisdictions will assure that appropriate data are available on the universe of all reported cases to calculate valid stratification and non-response weights for their sampled cases.

Extraction of Case, Laboratory, Treatment and Provider Records to SSuN Datasets

Gonorrhea and adult syphilis 'records' are defined to include provider case reports, laboratory records or any other original source documents as appropriate given the specific surveillance infrastructure in funded jurisdictions. Data for all reported adult syphilis and gonorrhea cases will be extracted, recoded and formatted for inclusion in SSuN datasets. Each record must contain a unique 'event' ID and a unique, static patient ID. Patient ID's must uniquely represent a single individual and must be static (i.e., must remain the same throughout the project period for any given individual, unique patient to allow for tracking repeat and co-infection). Required data elements and the appropriate response coding for case records are included as Appendix 4.

All laboratory data associated with gonorrhea and adult syphilis cases are to be extracted, reformatted and assembled into a separate, related dataset related to the case data through unique IDs. Required data elements and the appropriate response coding for laboratory records are included as Appendix 4.

Unique provider records associated with reported cases of gonorrhea and adult syphilis will be extracted and assembled into a separate, related dataset, updated twice annually. Records will be linked to case records with unique provider number. Required data elements and the appropriate response coding for provider records are included as Appendix 4.

Case-level Look-Back Investigations (All gonorrhea and adult syphilis cases)

At a minimum, case records for gonorrhea and adult syphilis will be compared with existing disease and laboratory registries to determine if the patient of record has previously been reported (ever reported) to the department of health for GC, CT, Syphilis, viral hepatitis or TB diagnoses occurring within 365 days of the specimen collection date/diagnosis date of current GC diagnosis. This should be documented and included in the appropriate data elements the SSuN record. If multiple diagnoses are found, only the most recent previous diagnosis needs to be retained for the SSuN record. It should also be determined at this time whether the record represents a 'duplicate case record', which is defined as a GC diagnosis (or for syphilis cases, a syphilis diagnosis similarly staged) within the previous 30 days; if record is a duplicate of existing report, this should be documented and included in the SSuN record as P1_CaseDup=1. For duplicate cases/records, earliest report date and specimen collection date (used to determine duplicate status) should be documented in the appropriate SSuN data elements.

Provider Investigations (All gonorrhea cases in the random sample)

Case records that meet the following criteria should be referred to brief provider investigations.

- Record represents case of confirmed gonorrhea case and is not a duplicate of a previously reported case
- Diagnosing provider/facility is ascertained and is within funded jurisdiction
- Patient determined to reside within jurisdiction at the time of diagnosis
- Case falls within the random sample

For these investigations, the diagnosing provider is contacted to provide additional information about clinical characteristics, treatment(s) prescribed, the specific care setting and demographics of the patient. These investigations can be conducted and completed either by direct contact with providers (phone) or through other methods such as secure fax, mail or other means as long as confidentiality of patient information is strictly maintained. Provider investigations also provide an opportunity to obtain more recent contact information necessary for completing patient investigations, especially if this information is missing from initial laboratory or case

reports. SSuN recipients must institute quality assurance and follow-up procedures to assure the highest possible completion rate for provider investigations, including tracking investigation status and periodic re-contact to assure provider completion.

Patient/Case Investigations (All gonorrhea cases in the random sample)

Criteria for referral to patient investigations (patient interview) will include:

- Record represents case of confirmed gonorrhea and is not a duplicate of a previously reported case
- Patient determined to reside within jurisdiction at the time of diagnosis
- Initial case report or notification was received by health department within 60 days of the diagnosis (or specimen collection) date

Patient-level investigations/interviews may be conducted either by phone or in-person with *a minimum of four (4)* documented attempts at various times (evenings/weekends, etc.) and using a range of methods (SMS, phone calls, mail, etc.) to contact each patient referred for investigation. Sites are required to develop local protocols and data collection instruments (paper and/or electronic) for investigators, provide adequate training for conducting direct patient contact and to address local human subject's requirements as necessary.

All reasonable attempts must be made to obtain reliable contact information for cases eligible for patient interviews. Methods for obtaining contact information for patients may include vital record searches, registry searches, direct provider contact, social media (following local health department conventions), driver's license and/or vehicle registration registries if available.

Jurisdictions may also find it productive to integrate SSuN data collection into local partner management and treatment assurance protocols to prevent duplicate patient and/or provider contacts; SSuN-related data elements may be collected in the course of routine partner services as long as these data are collected in a manner consistent with SSuN protocols.

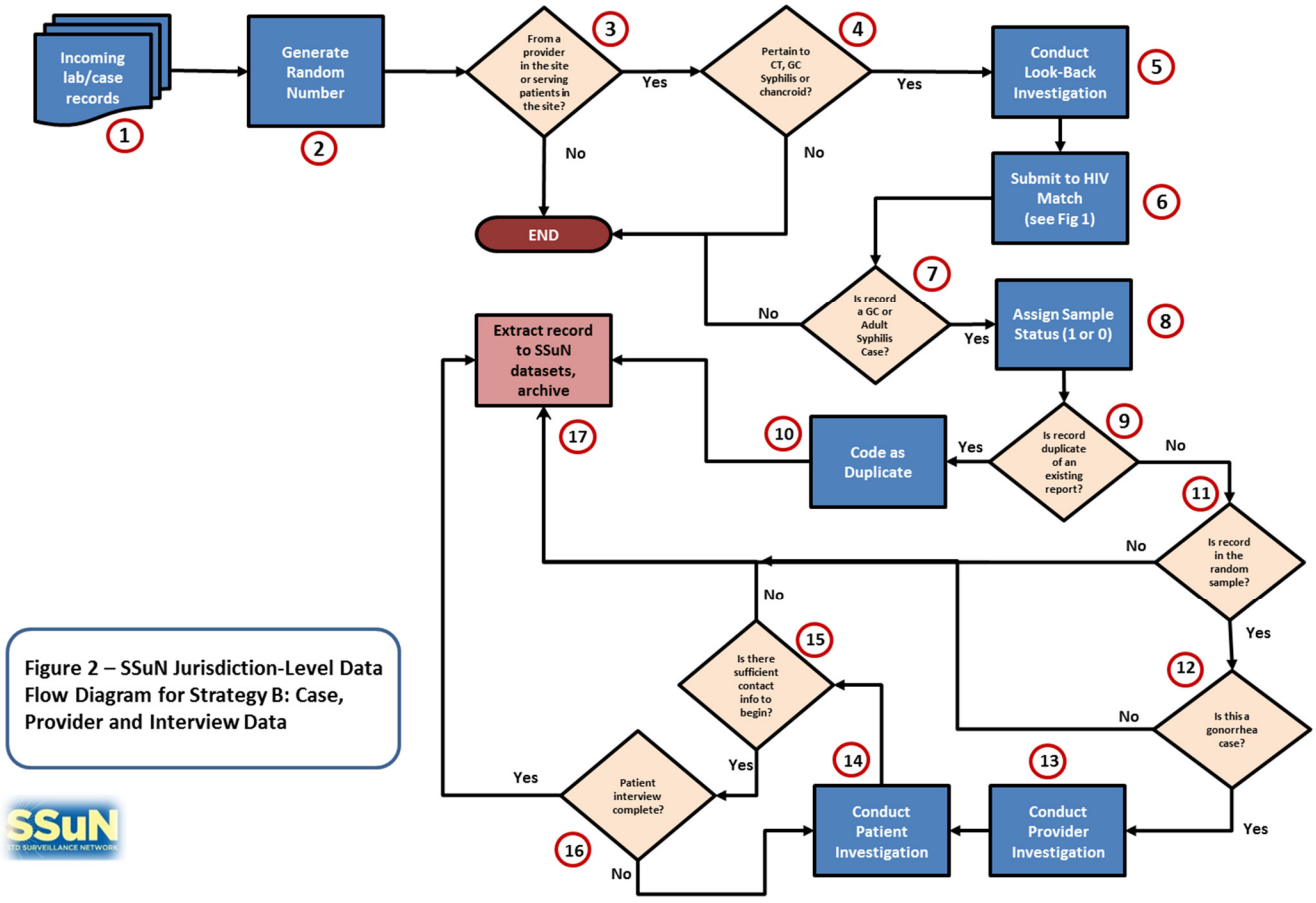
Data Management

Data obtained for the population component will come from numerous sources within the health department and will need to be locally merged, recoded and appropriately structured to facilitate merging into the national SSuN datasets. Figure 2 demonstrates a sample data flow for conducting Strategy B activities. Funded jurisdictions are expected to institute rigorous procedures to assure the quality and validity of data elements before submitting data to CDC. CDC will provide SAS data structures with variable names, lengths and types defined for all requested datasets. Local data should be transformed to conform to these data structures and include only the requested data elements, properly coded and in appropriate data formats.

Funded jurisdictions will complete data verification and validity checks on datasets prior to transmission to CDC, including consistency checks to assure that data in the record is internally rational (for example, that there are no records of males with cervical infection or pregnancy indicated for males). In collaboration with data managers in each jurisdiction, CDC will prepare syntax for data validation that will provide for the minimum data quality assurance required. Jurisdictions will apply these validation checks and fix errors in records prior to transmission. In cases where errors are repeatedly introduced from underlying, primary data sources that cannot be corrected, an "exception" file should be maintained locally and applied to the dataset before transmission to fix historical errors that recur because of the cumulative nature of SSuN data processes.

Jurisdictions will provide clean, validated datasets, alternating facility and population component data to CDC every month, such that each strategy's component data is updated with new data every two months and includes cumulative data back to the beginning of each calendar year. A final, validated annual dataset will be transmitted each year (in March) and archived to become the primary repository of that site's annual reporting. These annual datasets will serve as the basis for calculating analytic weights in the population component and should be preserved at the local level as 'frozen' data for local analytic purposes.

Figure 2: Jurisdiction-Level Record Process Flow for Strategy B Case, Provider and Patient Data



HIV Registry Matching Requirements for Strategy B

All reported cases of gonorrhea and adult syphilis (all stages) are to be matched with the jurisdictions HIV registry. For the purposes of SSuN, the jurisdiction's "HIV case registry" is a term expressly defined to mean eHARS, the CDC-provided surveillance data management system for HIV case surveillance that constitutes the universe of HIV case data officially reported to CDC. However, some jurisdictions may maintain supplemental case reporting or registry databases in synchrony with the jurisdictions official eHARS repository; these may provide similar functionality and validity for fulfilling SSuN's HIV matching requirements as long as these data are comprehensive, reflect the full geographic extent of SSuN activities within the funded jurisdiction and allow for extraction of required SSuN data elements, including HIV-related laboratory

information. Case data extracted for SSuN should be matched with the HIV registry periodically, however a minimum requirement is that matches should be performed at least twice a year, with one matching event coinciding with submission of annual, cleaned SSuN datasets (due annually in March).

Jurisdictions should coordinate with their jurisdiction's CDC-funded HIV Surveillance unit or program to conduct periodic person-based matching, mindful that both STD and HIV case registries are dynamic; new patients are added continuously as new diagnoses are reported. Previously unmatched STD patients should be re-submitted to all subsequent matches to identify subsequent HIV diagnoses/reports and to assure that complete information is available for all gonorrhea and adult syphilis cases reported throughout the full period of the SSuN cooperative agreement.

Registry matching processes (see Figure 1 above) will be performed only at the recipient level; CDC will not receive patient names or DOB data. Although jurisdictions will deploy methods specific to their jurisdiction (e.g., matching software, methodology, manual review processes), all SSuN recipients are required to extract data on the earliest documented date of HIV infection, and to obtain laboratory data (all viral load and CD4+ tests with specimen collection dates from October 1st, 2018 forward) for all matching records from the HIV surveillance registry for inclusion in SSuN datasets. SSuN recipients should consider the burden of these matching activities and be prepared to provide resources appropriate to the planned frequency of matching. Moreover, data of interest to the HIV Surveillance or HIV Prevention Programs which help to improve the quality of HIV surveillance (risk information, current residence, etc.) or to identify patients who may have lapsed from care should be routinely provided back to the HIV Surveillance unit as part of SSuN matching activities.

Data matching or linking records between data sources can be an important means of strengthening STD and HIV surveillance data, including identification of co-infections, improve the completeness of existing databases, and guide public health program activities. Recipients will be able to assess their local burden of co-infection among reported STD cases and patients

presenting for STD care in key facilities. Matches will also enable CDC to investigate differences across multiple sites and to:

- Evaluate HIV testing among persons diagnosed with or at risk for syphilis, gonorrhea and other STDs and to stratify by behavioral risk, diagnosing provider characteristics, geography and demographics
- Understand the proportion of persons diagnosed with or at risk for syphilis, gonorrhea and other STDs who are eligible for and receiving HIV PrEP/PEP (at time of STD diagnosis) and to stratify these outcomes by multiple demographic, behavioral and healthcare factors
- Understand proportion of HIV-positive persons diagnosed with or at risk for syphilis, gonorrhea and other STDs who are in HIV-primary care, on ART and virally suppressed and to stratify these outcomes by multiple demographic, behavioral and healthcare factors
- Provide relevant patient-level and aggregate information at the recipient level to assist their jurisdiction's CDC-funded HIV surveillance and prevention programs to resolve cases with no risk reported (NRR), better monitor HIV care status of HIV-positive individuals, monitor local prevalence patterns, track current residence and to better understand gaps in and opportunities for promotion and uptake of high impact STD-related HIV prevention interventions.

Technical Assistance to STD Surveillance Units/Programs

All SSuN recipients are expected to develop and maintain robust collaborations within their jurisdictions with the STD prevention program (funded through STD-PSCHD, CDC-RFA-PS19-1901). The purpose of these collaborations is to provide ongoing, substantive technical assistance to improve the jurisdiction's STD case surveillance, provide analytic and interpretive data to enhance local programmatic action, collaborate in implementation of PCHD surveillance activities (including enhanced gonorrhea surveillance) and to assure that SSuN funds are leveraged to enhance STD prevention at the local level.

G Strategy C: STD Surveillance Focus Activities

Surveillance Focus Activities are intended to improve quality and use of surveillance data, explore new methods for monitoring the burden of reportable and/or non-reportable STDs, investigate incidence of sequelae and monitor adverse health outcomes of STDs across the full range of laboratory and provider settings. SSuN recipients are required to apply for at least one (1) but no more than five (5) surveillance focus activities in any given budget year. These activities will generally change annually, reflecting divisional priorities and emergent issues. Protocols and methods may be recipient based or collaboratively developed post award depending on the number of jurisdictions participating. The initial Surveillance Focus Activities include:

Lymphogranuloma venereum (LGV) surveillance among persons seeking care in STD clinics

Applicants will collect remnant *C. Trachomatis*-positive (by NAAT testing) rectal swabs/specimens from both symptomatic and asymptomatic male and female patients seeking care in clinics participating in Strategy A for shipment to the CDC-DSTDP laboratory for testing to determine the prevalence of LGV serovars (L1-L3).

- Recipients may collect specimens continuously for a specified period of time, or sequentially until 200 specimens are obtained per participating STD clinic.
- Recipients must be able to link specimens to SSuN clinic visit records through unique SSuN patient and event IDs.

Expected outputs:

- Dataset of IDs associated with all rectal swabs/specimens shipped to the CDC-DSTDP laboratory with event IDs linking specimens to Strategy A datasets - transmitted per protocol to CDC

Enhanced case investigations among a sample of reported chlamydia cases in a high morbidity area

- Following protocols specifying a limited set of pre-defined demographic, clinical and behavioral data elements, recipients will conduct enhanced provider and brief patient follow-up investigations on a random probability sample of reported chlamydia cases in a well-defined high morbidity county, neighborhood planning area or health planning region within the recipient's jurisdiction for two (2) discrete time periods per project year.
- Recipients will use the same methods to select a random sample of chlamydia cases that they employ for the selection of cases in Strategy B.
- Recipients will collaborate with CDC to propose and employ separate patient interview methodologies for each of the two (2) investigation periods (examples include traditional DIS follow-up, SMS text messaging, secure on-line survey with unique ID code, phone-based survey app, etc.). The purpose of this requirement is to evaluate the relative merits and costs of different methods of patient contact; process information on contact methods and outcomes will be evaluated locally, documented and reported with aggregate results to CDC. Additional guidance will be provided for this focus activity post-award.

Enhanced cases investigations among early syphilis cases reporting neuro, ocular and otic symptoms

Following SSuN protocols, recipients will conduct enhanced provider and patient follow-up on interviewed early syphilis cases to identify signs and symptoms of neuro, otic, or ocular syphilis as well as treatment provided and results of any clinical evaluations.

Expected outputs:

- Data elements for provider and patient follow-up of adult syphilis cases interviewed should be fully incorporated into Strategy B datasets and transmitted per protocol to CDC.

Syndromic surveillance for neuro, ocular and otic signs/symptoms to detect undiagnosed syphilis

Recipients will collaborate with CDC to propose and conduct active surveillance projects in a high volume emergency departments, ophthalmology, neurology or other appropriate clinical facility in their jurisdiction designed to apply a syndromic surveillance case definition to potentially identify patients with neuro, ocular or otic symptoms not otherwise explained by other underlying causes for follow-up testing and evaluation for syphilis. This activity will involve the active participation of an appropriate clinical partner. Recipients of funding for this focus activity will collaborate with CDC in the creation of the surveillance case definition, monitor project implementation in the clinical setting and to design and conduct evaluation of the project.

Expected outputs:

- Documentation of case definition and unique patient records queried - aggregate results summarized and transmitted per protocol to CDC

Implementation of HL7 case reporting through NNDSS

Recipients will collaborate with CDC to implement STD and congenital syphilis (CS) message mapping guides (MMGs) and complete the transition to HL7-based case reporting to CDC though the National Notifiable Diseases Surveillance System (NNDSS) Modernization Initiative (NMI). Additional information on NMI and the STD and CS MMG requirements can be found at https://www.cdc.gov/nmi/index.html.

Recipients funded for this focus activity will work with the Center for Surveillance, Epidemiology and Laboratory Science (CSELS) at CDC to begin the on-boarding process and agree to implement STD and CS message mapping guides for routine reporting of STD cases to CDC through NNDSS.

Expected outputs:

- Implementation package showing NNDSS data cross-walk and HL7 mappings - transmitted per protocol to CDC/CSELS
- HL7 test records transmitted per protocol to CDC/CSELS
- Limited production HL7 messages transmitted per protocol to CDC/CSELS
- Year-to-date matching datasets in both NETSS and HL7 formats transmitted per protocol to CDC/CSELS

- Cut-over to HL7 production for reporting of STDs to CDC through NNDSS

Technical assistance to STD-PCHD recipients implementing enhanced gonorrhea investigations

Recipients funded for this focus activity will work with CDC SSuN and Program Development and Quality Improvement Branch (PDQIB) staff to identify technical assistance needs in neighboring non-SSuN funded jurisdictions, design curricula and provide direct peer-to-peer assistance (facilitated through webinar, conference call, materials sharing and [infrequently] through site visit) to health departments implementing limited enhanced gonorrhea surveillance activities funded under STD-PCHD.

Expected outputs:

- Documentation of technical assistance needs, gaps identified, communications and technical assistance plans, summary results.

H Data Management

Transmission of Data to CDC

Required Strategy A, B and C (optional) datasets will be securely transmitted to CDC on a staggered schedule. On the 15th of each month, sites will transmit each of the datasets on an alternating basis. For example, on March 15th sites would send the Strategy A data and then on April 15th, sites would send Strategy B data, alternating throughout the year. Data for each transmission should be cumulative for that calendar year and complete through the last day of the month from 2 months prior. For example, for data due on May 15, the dataset should contain records from Jane 1st through March 30th. This allows approximately 6 weeks for case follow-up, for data to be cleaned, properly coded and all quality assurance processes to be completed prior to transmission. When the 15th falls on a holiday or weekend, datasets will be due the first business day following the holiday. A data transmission schedule will be distributed to SSuN collaborators post award.

Record-level data will only be transmitted to CDC following SAMS protocols. CDC will formally acknowledge all data transmissions and communicate all validation results. Datasets failing to comply with pre-determined data structures will be rejected, with notification to sites. Sites must re-format, recode or resolve issues and retransmit corrected datasets within 5 working days to remain in compliance with SSuN requirements.

Data Management at CDC

Datasets received at CDC will be validated and merged to the national SSuN database within two weeks of receipt; the national dataset will be maintained current as of the end of the previous reporting month for purposes of reporting process measures back to funded jurisdictions. Funded sites will receive an individual summary report documenting the status of all datasets received to date and identifying any datasets that were due and have not been received, and the on-time status of all transmissions as part of grants management and quality assurance processes.

Appendix 1

Memorandum of Agreement for
Collection and USE of STD Surveillance Network (SSuN) Surveillance Data between
The Division of STD Prevention (DSTDP),
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP)
and
<Insert State Department of Health>

PURPOSE

The purpose of this agreement is to provide a mutually agreed framework between CDC and funded entities for the collection, sharing and release of surveillance data collected as part of STD Surveillance Network (SSuN) activities.

BACKGROUND & OBJECTIVES

The STD Surveillance Network is comprised of state/local and/or city health departments funded by cooperative agreement (CDC-RFA-PS19-1907) to implement common protocols for enhanced and sentinel STD surveillance. The purpose of SSuN is to improve the capacity of national, state, and local STD programs to detect, monitor, and respond rapidly to trends in STDs through enhanced data collection, reporting, analysis, visualization and interpretation of disease information. Data are collected locally by funded jurisdictions following prescribed protocols, cleaned, formatted and transported to CDC for merging into national datasets that will be used by SSuN collaborators and CDC subject matter experts for a broad range of reporting and analysis as provided for in SSuN protocol documents. This Memorandum of Agreement is intended to explicitly document concurrence of funded sites with SSuN data collection protocols, procedures and guidelines for the protection and use of SSuN data.

STORAGE OF SSuN DATA

The health department identified above agrees to send to CDC appropriately de-identified datasets with data elements (Appendix 4) as specified in SSuN protocols on all persons visiting collaborating STD clinics, and for all persons diagnosed and reported with gonorrhoea and/or all stages of adult syphilis. Separate SAS datasets will be required for clinic patient visits, diagnoses associated with patient clinic visits, laboratory observations associated with patient clinic visits, treatments associated with patient clinic visits, reported cases of gonorrhoea and adult syphilis, laboratory data associated with reported cases of gonorrhoea and adult syphilis, treatment data associated with reported cases of gonorrhoea and adult syphilis, and information on providers reporting cases of gonorrhoea and adult syphilis.

Sites will send SSuN data through SAMS using specified encryption methods and biologic specimens (if required for Strategy C activities) through approved carriers per CDC-supplied protocols. CDC agrees to accept and securely store these data and specimens, accessible only to SSuN project or CDC laboratory staff. 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. Biologic specimens (if required for supplemental projects) will be received directly by DSTDP's Laboratory Reference and Research Branch.

To protect the confidentiality of persons reported with STDs, state and local surveillance program staff and/or contractors agree to abide by the Data Security and Confidentiality Guidelines for NCHHSTP. (http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf) and will be required to document compliance as part of annual project reporting. Full names, street addresses, social security numbers, telephone numbers, or any other specific identifying information will not be sent to CDC. Databases will contain geographic information at the census tract level as well as other demographic, clinical, and behavioral data elements specified in SSuN protocols collaborative developed by SSuN collaborators. Census tract data collected in the population component will be linked with US census data (American Community Survey and decennial Census data) and all such internal datasets will also be stored on secure servers with fully restricted access. A CDC Assurance of Confidentiality is being sought for SSuN data; SSuN and CDC staff agree to adhere to these data protection standards at all times.

The Surveillance and Data Management Branch in the Division of STD Prevention is charged with the responsibility of maintaining the security and confidentiality and the scientific integrity of all SSuN databases, dataset and subsequent analyses. Appropriate CDC staff will be designated custodians of the SSuN data and accept full responsibility for observance of all conditions of use and for establishment and maintenance of CDC-standard security precautions to prevent unauthorized use. Other CDC staff in the Division of STD Prevention may be granted access to dataset derived from SSuN data as needed for legitimate data management or analytic purposes.

STD Surveillance Network Principal Collaborators will be promptly notified of any CDC personnel changes that affect access to data collected and managed for this project. All CDC staff with access to SSuN data will 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 SSuN data as long as the data are protected as described herein and local use of these data to direct STD surveillance and prevention activities is ongoing. 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 analysis will be conducted.

DATA RE-RELEASE & USE

Local collaborators retain full control of and rights to analysis, research, and publication of their locally collected data, regardless of whether these data are also provided to CDC as part of SSuN activities. However, collaborators agree to acknowledge CDC funding in publications resulting from analyses of data collected through SSuN funding. Principal Collaborators may request and receive multi-site SSuN dataset for specific analytic purposes provided the SSuN Project Officer and the Principal Collaborator (or designated representative) of sites contributing data have reviewed and approved the analysis proposal. Proposals for such analyses must include all of the information required in SSuN protocols prior to consideration for approval.

AUTHORSHIP & ACKNOWLEDGEMENT

All collaborators are encouraged to participate in generating and proposing analytic ideas, conducting analysis, drafting abstracts and manuscripts as first or with colleagues as co-authors. At least one co-author from each site is strongly recommended for all analyses using site-specific or site-stratified data.

This agreement may be amended at any time in writing by mutual agreement of CDC and SSuN Principal Collaborators. Such amendments will not be binding unless and until they are signed by personnel authorized to bind each of the parties.

Signatures:

_____

Hillard Weinstock, MD, MPH — Date
Chief, Surveillance and Data Management Branch,
Division of STD Prevention,
National Center for STD, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

_____

Mark Stenger, MA — Date
Lead Science Officer – STD Surveillance Network (SSuN)
Surveillance and Data Management Branch,
Division of STD Prevention,
National Center for STD, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

_____

Marvin Fleming — Date
Project Officer – STD Surveillance Network (SSuN)
Surveillance and Data Management Branch,
Division of STD Prevention,
National Center for STD, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Collaborators:

I/We have read and agree to stipulations in the Memorandum of Agreement for collection, stewardship, uses and transmission of data to CDC for CDC-RFA-PS19-1907, STD Surveillance Network (SSuN).

_____

Health Department SSuN Principal (or Co-) Collaborator(s) — Date

Name:_____ Name:_____

Title:_____ Title:_____

Agency:_____ Agency:_____

Appendix 2: Data Use/Analytic Proposal Template

SSuN Analysis Proposal Form

1) Date proposal initiated: _____/_____/_____

2) Proposal Submitted by:

☐ SSuN Site Collaborator ☐ DSTDP Staff ☐ Other CDC Staff/Fellow

☐ External/Academic Partner

3) Title of proposed Analysis:_____

4) First Author Full Name:_____

5) Affiliation (SSuN Site, Division/Branch/Team, Academic Institution, etc.):

_____

(If applicable, include SSuN Principal Collaborator/CDC Project Officer sponsor here)

_____

6) Additional Collaborators/Investigators:

_____

_____

_____

(Not binding. Final product may or may not include these, or may include additional co-authors.)

7) Intended audience for analysis: (e.g., abstract or manuscript, name of conference or meeting)

_____

8) SSuN Data to be used: (e.g., single site data (specify site); multi-site data (specify sites).

_____

_____

_____

_____

_____

_____

9) Specific analysis planned (describe intended methods):

_____

_____

_____

10) How will this analysis be translated into program action?:

_____

_____

_____

11) Proposed timeline:

_____

_____

_____

12) Additional description or notes: (optional)

_____

_____

_____

_____

_____

_____

_____

_____

_____

Appendix 3: Sample Data Collection Templates (Strategy A)

Clinic Patient Survey – Sample Template (implementation deferred at present)

1. Is this your first time to this clinic?
   [ ] Yes [ ] No

2. Do you feel that this clinic provides a welcoming and respectful environment?
   [ ] Yes [ ] No [ ] Not sure

3. What are the reasons for your visit to this clinic today (choose all that apply)?
   [ ] Health problem or symptoms
   [ ] No health problems or symptoms, but came to get STD screening/check-up
   [ ] Told to get checked by partner
   [ ] Referred by health department/disease intervention specialist (DIS)
   [ ] Follow-up visit
   [ ] Came to get STD test results
   [ ] Came to get HIV test
   [ ] Came to get medication that I can take every day to prevent getting HIV infection before I am exposed to the virus (PrEP)
   [ ] Came to get medication that I can take right away because I think I was exposed to HIV in the past few days (PEP)
   [ ] Came to get contraception
   [ ] Some other reason
   Please specify _____

4. What is the main reason you chose this clinic for care (choose only one)?
   [ ] Could walk in or get same day appointment
   [ ] Cost
   [ ] Privacy concern
   [ ] Expert care
   [ ] Embarrassed to go to usual doctor
   [ ] Some other reason
   Please specify _____

5. Where would you have gone today if this STD clinic did not exist (choose only one)?
   [ ] I would have waited to see how I felt and then decided what to do
   [ ] Community health center
   [ ] Public clinic/ health department clinic
   [ ] Family planning clinic
   [ ] Private doctor's office

[ ] Urgent care clinic/walk in clinic
[ ] Hospital emergency room (ER)
[ ] Hospital outpatient department
[ ] School-based clinic
[ ] Some other place
Please specify _____

6. Is there a place that you USUALLY go to when you are sick or need advice about your health?
[ ] Yes [ ] No → GO TO QUESTION #8

7. If YES, what kind of place do you go to most often (choose only one)?
[ ] Community health center
[ ] Public clinic/health department clinic
[ ] Family planning clinic
[ ] Private doctor's office
[ ] Urgent care clinic/walk in clinic
[ ] Hospital emergency room (ER)
[ ] Hospital outpatient department
[ ] School-based clinic
[ ] Some other place
Please specify _____

8. Is there a place you USUALLY go to when you need routine care or preventive care such as a physical exam or check-up?
[ ] Yes [ ] No → GO TO QUESTION # 10

9. If YES, what kind of place do you go to most often (choose only one)?
[ ] Community health center
[ ] Public clinic/ health department clinic
[ ] Family planning clinic
[ ] Private doctor's office or HMO
[ ] Urgent care clinic/walk in clinic
[ ] Hospital emergency room (ER)
[ ] Hospital outpatient department
[ ] School-based clinic
[ ] Some other place
Please specify _____

10. Do you have health insurance (choose only one)?
[ ] Yes, parents' insurance plan
[ ] Yes, government (Medicaid, Medicare, etc.)

[ ] Yes, private insurance (through employer)
[ ] Yes, private insurance (purchased by yourself/healthcare.gov exchange)
[ ] No coverage of any type → GO TO QUESTION # 13
[ ] Don't know → GO TO QUESTION # 13

11. If YES, would you be willing to use your health insurance for today's visit?
    [ ] Yes → GO TO QUESTION # 13
    [ ] No

12. If No, why not (choose all that apply)?
    [ ] I do not want my insurance company to know
    [ ] Insurance company might send records home
    [ ] I do not want my parents/spouse/significant other to know
    [ ] Usual doctor might send records home
    [ ] I cannot afford to pay the co-pay or deductible
    [ ] My insurance will not cover this visit
    [ ] Some other reason
    Please specify _____

13. What sex were you assigned at birth on your original birth certificate?
    [ ] Male
    [ ] Female
    [ ] Refused
    [ ] Don't know

14. Do you currently describe yourself as male, female, or transgender?
    [ ] Male
    [ ] Female
    [ ] Transgender
    [ ] None of these

15. How old are you? Age in years_____

16. What is your ethnicity?
    [ ] Hispanic or Latino
    [ ] Not Hispanic or Latino

17. What is your race (choose all that apply)?

    [ ] American Indian or Alaska Native

[ ] Asian
[ ] Black or African American
[ ] Native Hawaiian or Other Pacific Islander
[ ] White

18. Which of the following best represents how you think of yourself?
[ ] Lesbian or gay
[ ] Straight, that is not lesbian or gay
[ ] Bisexual
[ ] Something else
[ ] I don't know the answer

19. What is your current employment status (choose all that apply)?
[ ] Full-time employment
[ ] Part-time employment
[ ] Unemployed
[ ] Disabled
[ ] Student
[ ] Other

20. What is your highest level of school you have completed or the highest degree you have received ?
[ ] Middle school
[ ] Some high school
[ ] High school diploma
[ ] GED or equivalent
[ ] Some college
[ ] College degree or higher

END CLINIC PATIENT SURVEY