STD Surveillance Network (SSuN)

Project Protocol

&

Implementation Guide

SSuN Cycle 4

(2019 – 2024)

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TBD

Introduction - Background

The STD Surveillance Network (SSuN) was established in 2005 to create a robust network of collaborating health departments with the capacity to implement a wide variety of 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 focus on sentinel surveillance in STD clinics, expanded these sentinel surveillance activities to include patients being seen in reproductive health/family planning settings and revised case-based enhanced surveillance 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 analysis of sampled cases and routine dissemination of findings.

The current cycle (SSuN 2019 - 2024) continues the network's focus on issues in STD surveillance through continued sentinel surveillance activities in STD specialty clinics serving populations at

risk for HIV and STDs (Strategy A), and through enhanced, case-based surveillance among reported cases of STD (gonorrhea and adult syphilis, Strategy B). Additional shorter-term STD surveillance activities address emergent issues in STD incidence, prevalence of co-infections , complications of STDs and longer-term consequences of STDs (Strategy C, Focus Activities).

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 in Cycle 4 for reported cases and for patients being seen in STD specialty clinics 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 activities. 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).

LIST TBD

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A.   Overarching Responsibilities/Activities of Collaborators

SSuN funding 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 maintaining 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 to inform our understanding of the epidemiology of STDs in the U.S. and to guide efforts to prevent and control disease.

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

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.

All SSuN collaborators are required to complete the project Memorandum of Agreement (MOA, see section D below 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 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 record and case-level clinical, 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 <u>must not</u> 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 to specifically permit longitudinal monitoring of unique persons in Strategies A & B. To do this reliably, the identifiers associated with individual patients and related health event must be maintained over the full course of the cooperative agreement and should be static and immutable over the project period. Moreover, because identifiers assigned to uniquely identify

persons are transmitted to CDC, these IDs <u>must not</u> 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 was previously procured for SSuN Cycle 3 activities and a similar determination will be sought for SSuN Cycle 4 activities. Previously, SSuN have been exempted from CDC Institutional Review Board (IRB) review because project activities constitute public health surveillance, a disease control activity, and do not represent research activities. No incentives are to be provided directly to patients for participating in SSuN activities nor should any actual or perceived consequences devolve to patients for non-participation. 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 jurisdictions full participation in SSuN activities or 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 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. Data stored at CDC is maintained on secure servers with multi-layered access restrictions and available only to CDC staff 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 their SSuN colleagues from other sites and 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
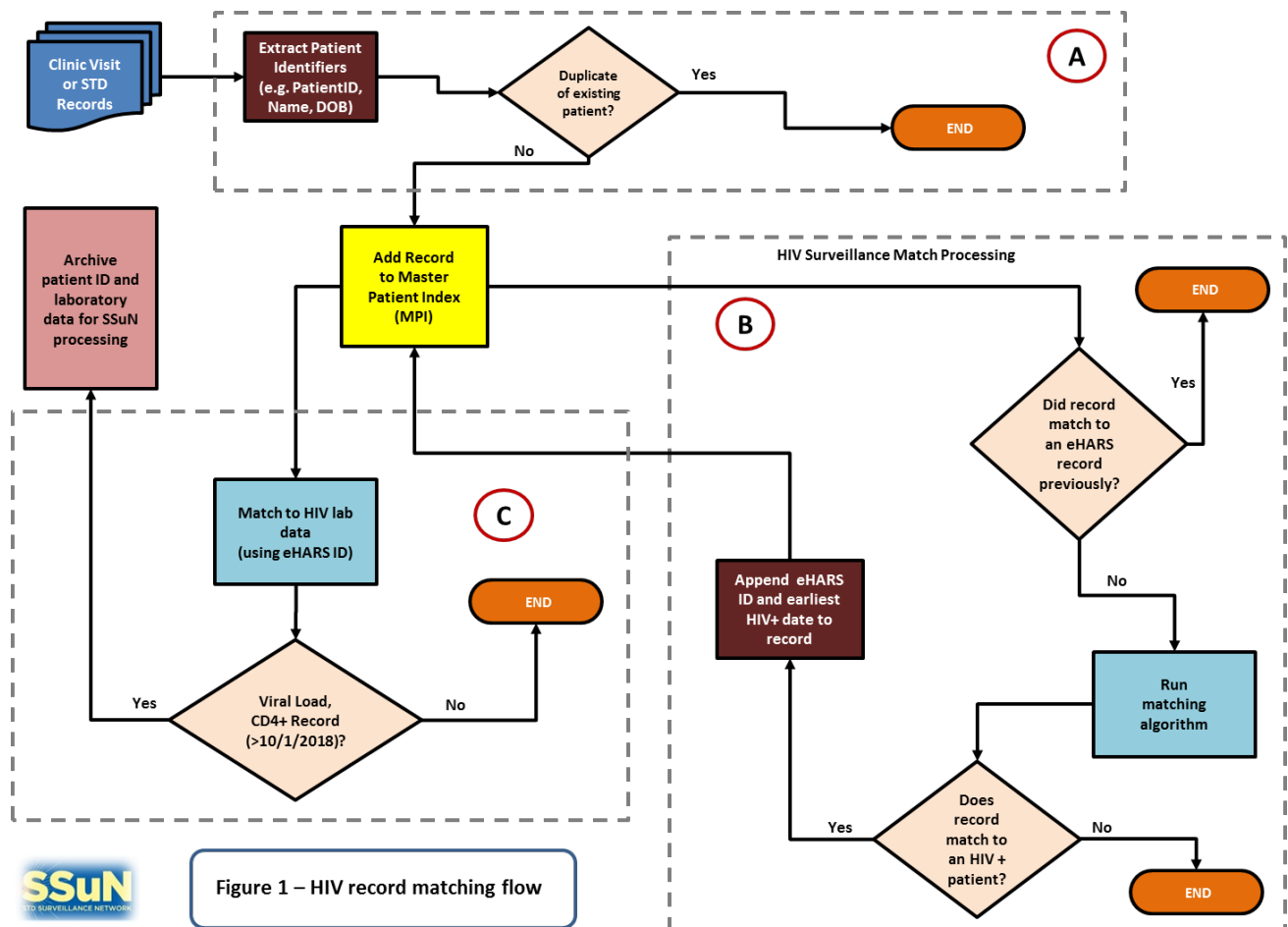
It is suggested that jurisdictions develop and maintain a separate patient index file for all patients for matched cases at the recipient's health department to obviate the need to rerun the patient through a matching algorithm. However, if a previously matched patient presents to a participating STD 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 and adult syphilis,

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 <u>ALL</u> cases of laboratory confirmed gonorrhea, chlamydia and adult syphilis cases diagnosed and reported from <u>ALL</u> 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 samples to fulfil stated project objectives:

   i. 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 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 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.

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

- o Record represents case of confirmed gonorrhea and is not a duplicate of a previously reported case
- o Patient determined to reside within jurisdiction at the time of diagnosis
- o 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
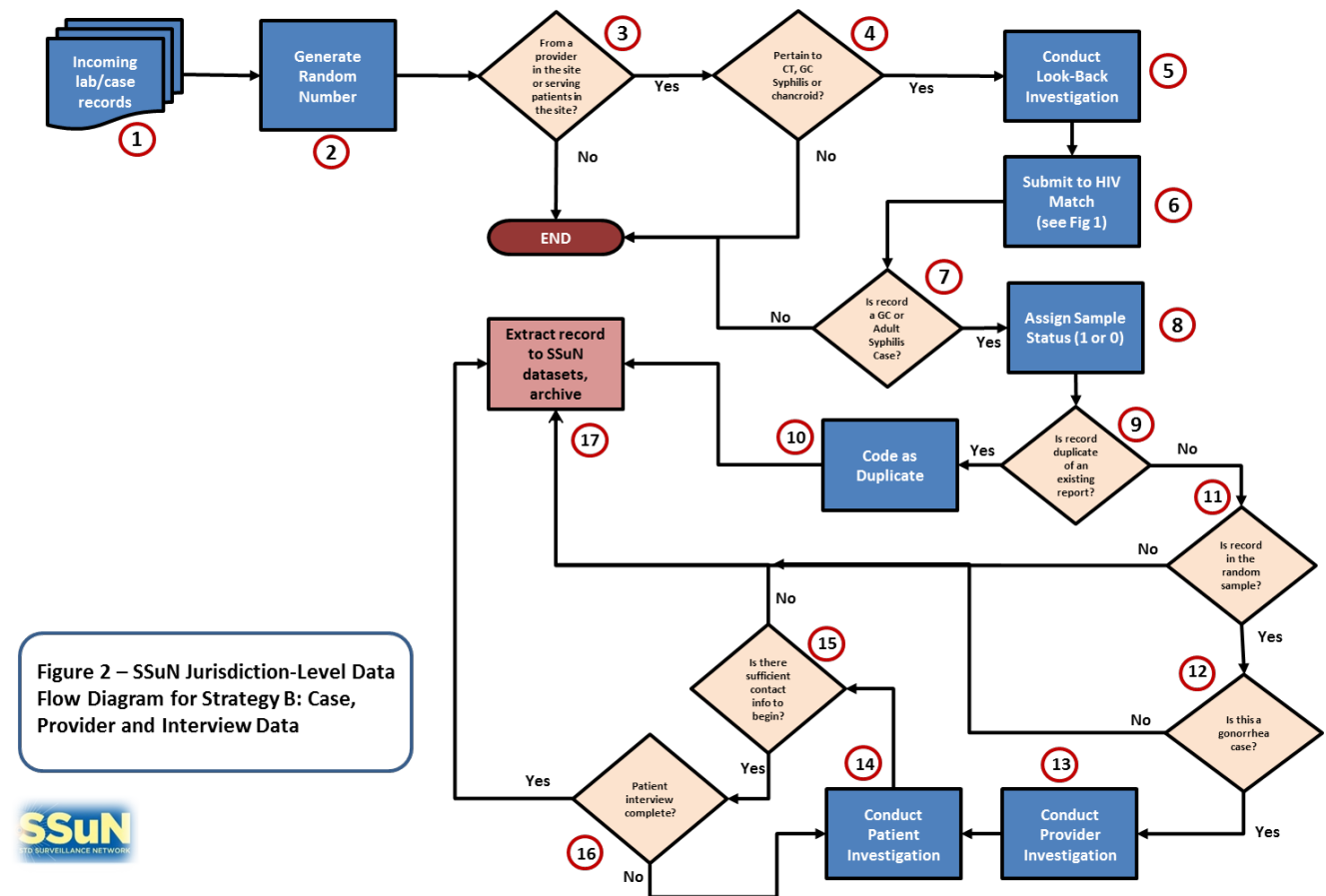
Figure 2 – SSuN Jurisdiction-Level Data Flow Diagram for Strategy B: Case, Provider and Interview Data

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 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 reported with all visits to 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,

Sites will send SSuN data through SAMS using specified encryption methods and biologic specimens (if required for Strategy C activities) through approved carriers per protocols. CDC agrees to accept and

securely store these data, accessible only to SSuN project staff. Data will not be integrated into other datasets maintained by CDC and will at all times be stored 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 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 and all such internal datasets will also be stored on secure servers with fully restricted access.

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 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:

_____   Date

Hillard Weinstock, MD, MPH
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

_____   Date

Mark Stenger, MA
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

_____   Date

Marvin Fleming
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 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).

_____   Date

Health Department SSuN Principal Collaborator

Name:_____

Title:_____

Health Department:_____

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

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

21. What is the ZIP code where you live? _____

END CLINIC PATIENT SURVEY

Appendix 3a: Sample Data Collection Templates (Strategy B)

Provider Investigation:

FAX

Confidential Patient Investigation Supplement

The _____Health Department is collaborating with the U.S. Centers for Disease Control and Prevention (CDC) to obtain additional information on a representative sample of gonorrhea cases reported to state and local health departments. This important information is urgently needed to help prevent emergence of antibiotic-resistant gonorrhea, to help prioritize public health resources for gonorrhea prevention and to better understand disease prevalence and incidence patterns in your community.

The patient named below was randomly chosen for this supplemental investigation from all cases routinely reported to the health department. This report is confidential; no identifying information on patients or clinicians will ever be released. Your cooperation in providing this information specific to the patient and diagnosis below is greatly appreciated. If you have questions or concerns about this supplemental investigation, please call (Local SSuN PI name/number) or the CDC SSuN Project Officer, Division of STD Prevention, U.S. Centers for Disease Control and Prevention (404-639-8356).

Please FAX completed form to _____Department of Health, (XXX) XXX-XXXX: Attn SSuN Project Coordinator

Patient

Patient Last Name	Patient First Name	M.I.	Patient Date of Birth

Diagnosis Reported to Health Department

Gonorrhea		If patient is NOT KNOWN to this practice/facility, please check here and return by FAX to the health department. ☐
Diagnosis	Date of diagnosis/report to health department	

Provider Information (Please provide the following information)

Facility/Practice/Healthcare Organization Name	Name of clinician examining this patient:	☐ MD ☐ RN ☐ PA ☐ ARNP ☐ LPN ☐ Other	___/___/_____ Date of Patient Visit

Physical location/facility address		**City**	**State**	**ZIP**	**Phone**	**Fax**

Is this facility a Federally Qualified Health Center (FQHC)?		**Is this facility a Community Health Center (CHC)?**	
☐ Yes ☐ No		☐ Yes ☐ No	

Patient and Diagnostic Information

Does patient have health insurance?	**Were any of the following findings present on exam (check all that apply)?**					
☐ Yes ☐ No	☐ Urethritis ☐ Proctitis	☐ Epididymitis ☐ PID	☐ Discharge	☐ Other	☐ None

Anatomic sites tested for gonorrhea (mark all that apply):				**Anatomic sites testing positive for gonorrhea (mark all that apply):**			
☐ Urine	☐ Urethra	☐ Pharnyx	☐ Cervix/Vaginal Swab	☐ Urine	☐ Urethra	☐ Pharnyx	☐ Rectum
☐ Rectum		☐ Other_____		☐ Cervix/Vagina		☐ Other_____	

Was patient tested for HIV infection at this visit?		**Gender of patient's sex partners?**			
		☐	☐	☐	☐
☐ Yes ☐ No		Males only	Females only	Both	Unk

Treatment Information

Has patient been treated for gonorrhea?	☐ Yes, patient treated for gonorrhea	☐ No, patient not treated	Treatment Date: ___/___/_____

Please indicate treatment provided for gonorrhea (check ALL that apply, check dosage as indicated):

Ceftriaxone:___ ☐ 125mg ☐ 250mg ☐ 500mg   Azithromycin:___ ☐ 1g ☐ 2g

☐ Doxycycline   ☐ Cefixime   ☐ Other_____

Counseling / Referral

Were any medications/prescriptions provided to patient to give to their sex partners?	**Was patient counseled to prevent transmission/reinfection?**	**Was patient referred to health department for partner notification or other services?**
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Confidential

Version 11.0 (January 2019)

Appendix 3b: Sample Data Collection Templates (Strategy B, Patient Interview)

Suggested Introductory Script – Patient Verbal (Informal) Consent – GC/CT Interview

HELLO, My name is_____ and I am calling for the _____health department about your recent doctor's appointment with _____ (mention name & date of patient's visit to reporting provider/facility).

[Interviewer must assure that they are speaking to the appropriate person by confirming date of birth, date of doctor visit, etc. Local DIS protocols should be followed with respect to initial patient contact and confirmation of patient identity]

*We are gathering information about people recently diagnosed with (gonorrhea/chlamydia) in _____(**name of city/state**) to help make sure that the best available care is being provided to patients to treat their infection and to help prevent the spread of (**gonorrhea/chlamydia**) in the future. This project is being conducted by the _____(**health department**) in collaboration with the U.S. Centers for Disease Control and Prevention.*

Your name was randomly chosen from among all of the people recently diagnosed and reported to the health department. I would like to ask some questions about your experience at your recent doctor's visit and about your recent health behaviors related to your diagnosis. These questions should only take about 10 minutes and any information you give me will be kept strictly confidential.

You do not have to answer any question you do not want to, and you can end the interview at any time. Your name will not be shared with anyone and all of the information we gather will be combined with others so that no one individual can ever be identified. Is this a good time for you and would you be willing to help with this important project?

[If patient agrees, go to Module 1, Question 14]

[If patient refuses] *We're sorry you don't want to participate but thank you very much for your time anyway!*

[If patient agrees but states that it is not a good time:]

When would be a good time to call you back? _____

Is this the best telephone number to use for you? _____

[If patient states that they wish to call the interviewer back, provide your name HD affiliation and phone number; ask the patient to confirm approximately when they will call]

Thank you, I look forward to hearing from you on _____ (day) at _____(time).

***Interviewer Use Only*:**   **Was verbal consent obtained for interview?**   ☐Y   ☐N

Process Information

1 Interviewer:_____ID#_____

2 PatientID:_____

3 EventID:_____

Contact Attempts:

4 Date___/___/_____;   5 Outcome_____

Notes:_____

6 Date___/___/_____;   7 Outcome_____

Notes:_____

8 Date___/___/_____;   9 Outcome_____

Notes:_____

10 Date___/___/_____;   11 Outcome_____

Notes:_____

12 Interview/Disposition Date ___/___/_____

13 Phase 3 Investigation Disposition Code:

☐   00- Investigation complete: patient contacted, interview completed

☐   01- Investigation complete: patient contacted, partial interview completed

☐   10- Investigation not complete: Phase 3 investigation pending

☐   11- Investigation not complete: patient contacted, refused interview

☐   12- Investigation not complete: patient contacted, language barrier.

☐   22- Investigation not complete: patient did not respond to any/all interview contact attempts

☐   33- Investigation not complete: patient contact not initiated because patient resident in correctional, mental health or substance abuse facility.

☐   44- Investigation not complete: patient contact not initiated because patient is active military on foreign deployment.

☐ 55- Investigation not complete for other reason: Specify _____

Module 1 - Demographics

> **Interviewer Read:** *These first few questions are about you and where you live.*

14 What is your age?

____ ____ [code in years]

☐ 888- Refused

15 Do you consider yourself to be…?

Please read choices:[Check only one]

☐ 1- Male

☐ 2- Female

☐ 3- Transgender (M to F)

☐ 4- Transgender (F to M)

Do not read:

☐ 5- Transgender (refused to specify)

☐ 8- Refused

16 Do you consider yourself to be Hispanic or Latino/a?

☐ 1- Hispanic (Go to Question 16.1)

☐ 2- Non-Hispanic (Skip to Question 17)

☐ 3- Unknown (Skip to Question 17)

☐ 4- Refused (Skip to Question 17)

16.1 Do you consider yourself to be…?

☐ 1- Mexican, Mexican Am., Chicano/a, Latino/a

☐ 2- Puerto Rican

☐ 3- Cuban

☐ 4- Other Hispanic Origin (SPECIFY) **16.2** _____

☐   5- Unknown

☐   9- Refused

17 Which one or more of the following would you say best describes your race?

Please read all choices (except Other): [Check all that apply]

17	White	☐Y	☐N	☐U	☐R
18	Black or African American	☐Y	☐N	☐U	☐R
19	American Indian or Alaska Native	☐Y	☐N	☐U	☐R (If Yes, Go To 19.1)

      19.1 Tribal Affiliation (SPECIFY) _____

20	Asian	☐Y	☐N	☐U	☐R (If Yes, Go To 20.1)

    20.1 ☐ 1 - Asian Indian (India) ☐ 2 - Japanese ☐ 3 - Chinese

☐ 4 - Korean   ☐ 5 - Filipina/o ☐ 6 - Other Asian ☐9 - Refused

21	Native Hawaiian or Other Pacific Islander	☐Y	☐N	☐U	☐R (If Yes, Go To 21.1)

    21.1 ☐ 1 - Native Hawaiian ☐ 2 - Guamanian/Chamorro ☐ 3 - Samoan

☐ 4 - Other Pacific Island (SPECIFY) 21.2_____

      ☐ 9 - Refused

22   Other [**DO NOT READ**, probe and specify if no other response is appropriate]_____

_____

Do not read:

23	Refused all race information	☐Y	☐N

    23.1   Where were you born?

        ☐ In the U.S.   Specify State _____

    23.2   ☐ Outside of the U.S.   Specify Country _____

Module 2 – Healthcare Experience

> **Interviewer Read:** *These questions are about your recent doctor's visit (when you were tested for [gonorrhea/chlamydia]) and about your access to medical care in general.* **[Interviewer should mention specific provider, if known]**

24 Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare, Indian Health Services, the V.A. or Military?

    ☐   1- Yes **[GO TO 25]**

    ☐   2- No   [**SKIP TO 26**]

    ☐   3- Don't know / Not sure [**SKIP TO 26**]

    ☐   4- Refused [**SKIP TO 26**]

25 What kind of healthcare insurance do you have?

    ☐   1- Private healthcare insurance provided by my employer

    ☐   2- Private healthcare insurance I pay for myself

    ☐   3- Public healthcare insurance like Medicaid, Medicare, or [***insert state-specific Medicaid-like plan name***]

    ☐   4- Active/retired military or dependent plan like the V.A. or military

    ☐   5- Bureau of Indian Affairs/Indian Health Service/Urban Indian Health Board

    ☐   7- Other   Specify 25a _____

    ☐   8- Don't know / Not sure

    ☐   9- Refused

26 Do you have one person you think of as your personal doctor or health care provider?

If 'No', ask: 'Is there more than one, or is there no person who you think of as your personal doctor or health care provider?' *(Note: if respondent identifies a facility or provider setting rather than individual, then code response as 2)*

    ☐   1- Yes, only one

    ☐   2- More than one (or a facility)

    ☐   3- No

    ☐   4- Don't know / Not sure

☐   5- Refused

27 Was there a time in the past 12 months when you needed to see a doctor but could not because of cost?

☐   1- Yes

☐   2- No

☐   3- Don't know / Not sure

☐   4- Refused

28 When you went to see _____ **[interviewer: insert reporting provider, clinic or facility name from case report]** when you were diagnosed with (gonorrhea/chlamydia), did you need to pay anything out-of-pocket, like a co-pay, deductible or cash payment, at the time of your visit? *(Note: this question is meant to determine if respondent had to pay any amount of money to the provider at the time of visit; do not include billed amounts or deferred or waived charges.)*

☐   1- Yes

☐   2- No

☐   3- Don't know /Not sure / Don't remember

☐   4- Refused

29 Did you go to the doctor that time because you were having symptoms or pains you thought might be from an STD?

☐   1- Yes **[GO TO 30]**

☐   2- No **[SKIP TO 31]**

☐   3- Don't know / Not sure / Don't remember **[SKIP TO 31]**

☐   4- Refused **[SKIP TO 31]**

30 How long did you have these symptoms or pains before you were able to see the doctor? *(Note: probe as needed to elicit most specific response.)*

☐   1- 1 Day

☐   2- 2 to 6 days

☐   3- 1 to 2 weeks

☐   4- More than 2 weeks

☐   5- Don't know / Not sure / Don't remember

☐   6- Refused

31 Before you went to the doctor that time, did any of your sex partners tell you that you might have been exposed to an STD?

☐   1- Yes

☐   2- No

☐   3- Don't know / Not sure / Don't remember

☐   4- Refused

Are any of the following reasons why you went to _____ **[Interviewer: insert provider name]** for that medical visit *instead of going somewhere else*?

[Read all responses]

Did you go…

32. Because this is your usual/regular doctor.   ☐Y   ☐N

33. Because you could get seen for free.   ☐Y   ☐N

34. Because they take your insurance.   ☐Y   ☐N

35. Because you felt more comfortable about your privacy there.   ☐Y   ☐N

36. Because you could get seen right away.   ☐Y   ☐N

37. Because you wanted to see an expert specializing in STDs.   ☐Y   ☐N

38. Because this doctor is close to your house and easy to get to.   ☐Y   ☐N

39. Because you were embarrassed and didn't want to go to your regular doctor.   ☐Y   ☐N

40. Because I didn't want the insurance papers/info sent to my home/parents.   ☐Y   ☐N

41. Any other Reason? ☐Y   ☐N   (specify) 42. _____

43. ☐ Refused all reasons

44 During that visit, did the doctor, nurse or anyone else talk to you about the importance of getting your sex partners examined and tested for STDs?

☐   1- Yes

☐   2- No

☐   3- Don't remember / Not sure

☐   4- Refused

45 In the time since you found out that you had (gonorrhea/chlamydia), have you told any of your sex partners that they may need to be tested or treated for (gonorrhea/chlamydia)?

☐   1- Yes

☐   2- No

☐   3- Don't Know / Not sure

☐   4- Refused

> **Interviewer Read:** *"In some places, doctors, nurses or the health department may help you to get your sex partners treated for (gonorrhea/chlamydia) by providing extra medications or prescriptions for your partners."*

46 Did a doctor, nurse or someone at the health department offer to give you medications or a prescription for you to give to any of your sex partner(s)?

☐   1- Yes **[GO TO 47]**

☐   2- No **[SKIP TO QUESTION 52]**

☐   3- Don't know / Not sure **[SKIP TO QUESTION 52]**

☐   4- Refused **[SKIP TO QUESTION 52]**

47 Who was it that offered you medications or prescriptions for your partners? Was it someone from your doctor's office, someone from the health department or someone else?

☐   1- My doctor's office **[GO TO 48]**

☐   2- The health department **[GO TO 48]**

☐   3- Someone else **[GO TO 48]**

☐   4- Don't know / Not sure **[GO TO 48]**

☐   5- Refused **[SKIP TO QUESTION 52]**

48 Did you actually get the medications or prescriptions for your sex partners?

☐   1- Yes **[GO TO 49]**

☐   2- No **[SKIP TO QUESTION 52]**

☐   3- Don't know / Don't remember/ Not sure **[SKIP TO QUESTION 52]**

☐   4- Refused **[SKIP TO QUESTION 52]**

49 Did you get extra *medicine* to give to your partner? Or did you get *prescriptions* that your partners needed to have filled at a pharmacy?

☐   1- I got additional medications **[GO TO 50]**

☐   2- I got prescription(s) **[GO TO 50]**

☐   3- Don't know / Not sure **[SKIP TO QUESTION 52]**

50 Did you *give* the medications or prescriptions to at least one of your sex partners?

☐   1- Yes, I gave them to at least one of my partner(s)

☐   2- No, I did not give them to any of my partner(s)

☐   9- Refused

52 Did you get tested for HIV at the doctor's visit when you were tested for (gonorrhea/chlamydia)?

☐   1- Yes, I got an HIV test at that visit **[GO TO 53]**

☐   2- No, I did not get an HIV test **[SKIP TO 54]**

☐   3- Don't know / Not sure **[SKIP TO 54]**

☐   4- Refused **[SKIP TO 54]**

53 What was the result of your HIV test?

☐   1- My HIV test was Positive **[GO TO 57]**

☐   2- My HIV test was Negative **[SKIP TO 58.1]**

☐   3- Don't know / Not sure / Didn't get my results **[SKIP TO 58.1]**

☐   4- Refused **[SKIP TO 58.1]**

54 Have you ever been tested for HIV?

☐   1- Yes **[GO TO 55]**

☐   2- No **[SKIP TO 58.1]**

☐   3- Don't know / Not sure **[SKIP TO 58.1]**

☐   4- Refused **[SKIP TO 58.1]**

55 When was your last HIV test? Just month and year is ok?

Month _____ **[use probes and elicit best guess if patient is not sure]**

Year _____ **[use probes and elicit best guess if patient is not sure]**

[If patient refuses to guess, enter '..' for month and '….' for year.]

56 What was the result of that HIV test?

☐   1- My HIV test was Positive **[GO TO 57]**

☐   2- My HIV test was Negative **[SKIP TO 58.1]**

☐   3- Don't know /Not sure/Didn't get results **[SKIP TO 58.1]**

☐   4- Refused **[SKIP TO 58.1]**

57 When was your **most recent** visit to a doctor, nurse or other health care worker *specifically for HIV medical care*?   Just the month and year is ok.

Month _____ **[use probes and elicit <u>best guess</u> if patient is not sure]**

Year _____ **[use probes and elicit <u>best guess</u> if patient is not sure]**

*(Note: Enter '99' for month and '9999' for year if patient is still unable to remember; enter '88' and '8888' if patient explicitly refuses to provide date, enter '77' and '7777' if patient has not had first HIV primary care visit yet. **DIS should provide referral to HIV care if indicated.**)*

58 Are you taking antiretroviral medicines to treat your HIV infection?

☐   1- Yes **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐   2- No **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐   3- I don't know / I am not sure **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐   4- Refused **[FEMALES GO TO 59, MALES SKIP TO 60]**

58.1 Did your health care provider discuss medications to help you prevent getting HIV? This is often called PrEP, or pre-exposure prophylaxis.

☐   1- Yes **[GO TO 58.2]**

☐   2- No **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐ 3- Don't know / Not sure **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐ 4- Refused **[FEMALES GO TO 59, MALES SKIP TO 60]**

58.2 Did your health care provider offer to *prescribe* medications to help you prevent getting HIV?

☐ 1- Yes **[GO TO 58.3]**

☐ 2- No **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐ 3- Don't know / Not sure **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐ 4- Refused **[FEMALES GO TO 59, MALES SKIP TO 60]**

58.3 Did your health care provider give you medications or a prescription to help you prevent getting HIV?

☐ 1- Yes **[GO TO 58.3]**

☐ 2- No **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐ 3- Don't know / Not sure **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐ 4- Refused **[FEMALES GO TO 59, MALES SKIP TO 60]**

58.4 Are you currently taking medications to help you prevent getting HIV?

☐ 1- Yes **[GO TO 58.3]**

☐ 2- No **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐ 3- Don't know / Not sure **[FEMALES GO TO 59, MALES SKIP TO 60]**

☐ 4- Refused **[FEMALES GO TO 59, MALES SKIP TO 60]**

59 Were you pregnant at the time you were told that you had (gonorrhea/chlamydia)?

☐ 1- Yes, I was pregnant at that time

☐ 2- No , I was not pregnant at that time

☐ 3- Don't know / Not sure

☐ 4- Refused

Module 3 – Behaviors

> **Interviewer Read:** "*The following questions are about your sexual health and behaviors. Not all of these questions may apply to you but we have to ask them for everyone – please let me know if a specific question does not apply and we can move on to the next one. Remember, everything you tell me is strictly confidential and will not be shared except when combined anonymously with the information from all of the other people we talk with.*"

60 During the past 12 months, have you had sex with only males, only females, or with both males and females?

☐   1- Men only   ☐   2- Women only

☐   3- Both men and women   ☐   4- Unknown

☐   9- Refused

61 Do you consider yourself to be…?

[Read all choices]

☐   1- Heterosexual/Straight   ☐   2- Gay/Lesbian/Homosexual

☐   3- Bisexual   ☐   4- Other

[Do not read]   ☐   9- Refused

62 Thinking back to the **_3 months before_** you were diagnosed with (gonorrhea/chlamydia), how many MEN did you have sex with during that time? _____ **[Probe: "It's ok to guess if you don't know exactly."]**

☐   9999- Refused

63 Thinking back to the **_3 months before_** you were diagnosed with (gonorrhea/chlamydia), how many WOMEN did you have sex with during that time? _____ **[Probe: "It's ok to guess if you don't know exactly."]**

☐   9999- Refused

Based on responses to number of sex partners, EPT questions and to patient's knowledge of their partner's treatment status, DIS may facilitate EPT following local protocols at the conclusion of the interview. Please document EPT or other partner services provided to the patient in question 74 at the end of the interview.

Read: Regardless of your previous answers about getting extra medications or prescriptions…

   If patient reports <u>only a single sex partner</u>:

63.1 To the best of your knowledge, was your sex partner treated?

☐ 1- Yes, definitely   ☐ 2- Yes, probably   ☐ 3- Don't know / Not sure   ☐ 4- No, probably not

☐ 5- Refused

   If patient reports <u>multiple sex partners</u>:

63.2 To the best of your knowledge, would you say that all of your sex partners were definitely treated, at least one of your partners was definitely treated, or that none were treated?

☐ 1- All definitely treated   ☐ 2- At least one definitely treated   ☐ 3- At least one probably treated

☐ 4- Not sure   ☐ 5- Probably none treated   ☐ 6- Refused

64 In the past 12 months, have you <u>*given*</u> drugs or money in exchange for sex, or <u>*received*</u> drugs or money in exchange for sex? By sex we mean any vaginal, oral, or anal sex.

       ☐   1- Yes

       ☐   2- No

       ☐   3- Don't know / Not sure

       ☐   4- Refused

64.1 In the past year, how often have you used <u>*prescription*</u> pain medications other than as prescribed by a doctor?

       ☐   1- Never

       ☐   2- Once or Twice

       ☐   3- Monthly

       ☐   4- Weekly

☐   5- Daily or Almost Daily

64.2 In the past year, have you used any injection drugs such as heroin, cocaine or meth?

       ☐   1- Yes (Skip to 64.3)

       ☐   2- No (Skip to 65)

       ☐   3- Don't Know/Can't Remember

       ☐   4- Refused

64.3.   In the past year, did you inject…(read all, check all that apply)?

       ☐   1- Heroin

       ☐   2- Cocaine/Crack

       ☐   3- Crystal Meth/Methamphetamine

       ☐   4- Morphine

       ☐   5- Fentanyl/Carfentanil

       ☐   6- Other   Describe_____

Interviewer Read: "The next few questions are about the _most recent time_ you had sex and about _the person you had sex with_. By sex we mean any vaginal, oral or anal sex."

---

65 When was the last time you had sex with someone?

       ☐   1- In the last week

       ☐   2- More than 1 week ago but within the last month

       ☐   3- More than 1 month ago but within the last 2 months

       ☐   4- More than 2 months ago

       ☐   5- Don't know / Not sure

       ☐   9- Refused

66 Thinking back to that last time you had sex, was the person you had sex with…?

    Read all, select appropriate response:

- ☐ 1- Male

- ☐ 2- Female

- ☐ 3- M-F Transgender

- ☐ 4- F-M Transgender

Do not read: ☐   5- Unknown

☐   9- Refused

67 Thinking back to the last person you had sex with, how old do you think that person is? If you don't know for sure, it's OK to make your best guess. *[Note: probe with age groups, older, younger, etc. Attempt to elicit single number if at all possible.]*

_____ (years)

- ☐ 888- Unknown/Couldn't Guess

- ☐ 999- Refused

68 Would you say that person is Hispanic/Latino/a? If you don't know for sure, it's OK to make your best guess.

- ☐ 1- Yes, Hispanic

- ☐ 2- No, Not Hispanic

- ☐ 8- I don't know/Can't Guess

- ☐ 9- Refused

69 Thinking back to the last person you had sex with, what race would you say that person is? If you don't know for sure, it's OK to make your best guess.

Read all, select best response:

- ☐ 1- White

- ☐ 2- Black

- ☐ 3- AI/AN

- ☐ 4- ASIAN

- ☐ 5- NH/OPI

Do not read: ☐ 8- I don't know/I can't guess

☐ 9- Refused

70 Thinking back to the last person you had sex with, do you know if that person HIV positive?

☐ 1- I know this person is HIV+

☐ 2- I know this person in HIV-

☐ 3- I don't know this person's HIV status

☐ 4- Refused

71 Thinking back to the last person you had sex with; do you think you will have sex with this person again?

☐ 1 Yes

☐ 2 No

☐ 3 Don't know / Not sure

☐ 4 Refused

72 Thinking back to the last person you had sex with, about how far away do you think that person lives from you – how long do you think it would it take to get to where they live from your home? If you don't know for sure, it's OK to make your best guess. Which of these answers fits best?

[*Note: interviewer should clarify the question if the respondent expresses confusion, and elicit a response with probes if needed. If asked the reason why this is important, interviewer can explain that this information will help in promoting neighborhood and community prevention efforts]*

Read list:

☐ 0- They live with me

☐ 1- Less than 5 minutes away

☐ 2- 5 to 15 minutes away

☐ 3- 16 - 30 minutes away

☐ 4- 30 or more minutes but less than one hour away

☐ 5- > one hour away

☐ 6- They live in another state

☐ 7- They live in another country (outside of the United States)

Do not read: ☐   8- I Don't know/I'm not Sure

☐   9- Refused

SSuN Interview Conclusion Script

If no additional partner management activity:

That's all the questions we have – thank you for your time and for your help with this important project. Do you have any questions for me before we end? Remember, everything we talked about today is strictly confidential.

If referring to partner management or eliciting partners: proceed with local partner services protocol.

Optional Partner Services / Other Referrals Provided (*if applicable*)

73 Did interviewer/DIS provide EPT/PDPT to patient?

☐   1 Yes

☐   2 No

74 Number of partners EPT provided for _____

75 Did interviewer/DIS provide any other partner services to patient (DIS referral, partner notification, risk reduction counseling, HIV testing referral, etc.)?

☐   1 Yes

☐   2 No

Appendix 4: SSuN Strategy A & B Data Dictionaries and Coding Manuals

4a: Strategy A – STD Clinic Visit Dataset

	Data Element Name	Description/Response Coding
		Clinic Visit Dataset

1   **F1_FacilityID**

Unique facility identifier

This ID should be supplied by the site and is a unique facility identifier from underlying surveillance systems or may be generated specifically for SSuN. Regardless of source, this ID must be unique and allow for longitudinal tracking of the facility. This data element MUST NOT be 'null' or contain missing values.

2   **F1_SiteID**

Unique site code

BA=Baltimore (Cycle II & Cycle III)
CA=California (Cycle II & Cycle III)
FL=Florida (Cycle III)
MA=Massachusetts (Cycle III)
MN=Minnesota (Cycle III)
MC=Multnomah County (Cycle III)
NY=New York City (Cycle II & Cycle III)
PH=Philadelphia (Cycle II & Cycle III)
SF=San Francisco (Cycle II & Cycle III)
WA= Washington (Cycle II & Cycle III)
VA=Virginia (Cycle II)
AL=Alabama (Cycle II)
CO=Colorado (Cycle II)
CH=Chicago (Cycle II)
This data element MUST NOT be 'null' or contain missing values.

3   **F1_PatientID**

Unique patient identification number assigned by site

This ID should be supplied by the site and may be a unique patient identifier from underlying surveillance systems or may be generated specifically for SSuN. Regardless of source, this ID must be unique and allow for longitudinal tracking of patients within facilities. This data element MUST NOT be 'null' or contain missing values.

4   **F1_Visdate**

Date of clinic visit

This data element MUST NOT be 'null' or contain missing values.

5	**F1_EventID**	Unique visit identification

This record ID should be supplied by the site and may be an event or

6	**F1_GISP_yrmo**	What is the Year/Month isolate was collected?

This data element pertains only to facilities participating in GISP and refers to the year and the month the GISP specimen was collected. This data element should not be 'null' or contain missing values for GISP patients.

7	**F1_GISP_number**	What is the patient's GISP number?

This data element pertains only to facilities participating in GISP and refers to the GISP ID supplied by the site.   This data element should not be 'null' or contain missing values for GISP patients.

8	**F1_Gender**	What is the patient's gender?

1= Male
2= Female
3=Transgender M to F
4=Transgender F to M
5=Transgender unspecified
6= Other
9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected by the facility but is unknown for this record.

9	**F1_Age**	How old is the patient?(Age in years).

If age is unknown or missing, use null value.

10	**F1_Hisp**	Is the patient of Hispanic ethnicity?

1= Yes
2= No
9= Not captured

11	**F1_AIAN**	Is the patient American Indian or Alaskan Native?

1= Yes
2= No
9= Not captured

12	**F1_Asian**	Is the patient Asian?

1= Yes
2= No
9= Not captured

13   **F1_PIH**   Is the patient Native Hawaiian or Pacific Islander?

1= Yes
2= No
9= Not captured

14   **F1_Black**   Is the patient Black?

1= Yes
2= No
9= Not captured

15   **F1_White**   Is the patient White?

1= Yes
2= No
9= Not captured

16   **F1_Multirace**   Is the patient Multirace?

1= Yes
2= No
9= Not captured

17   **F1_Otherrace**   Is the patient another race not listed above?

1= Yes
2= No
9= Not captured
Indicate yes for all of the race/ethnic questions that apply. A response of 9 indicates the information is not captured/ collected by the facility or is not provided to SSuN. Response should be null if (1) race is collected by the facility but is unknown for this record, or (2) a response of "no" is not collected separately.

18   **F1_Insurance**   What is the primary health insurance status of the patient?

1= Insured, Public only

2= Insured, Private only

3= Insured, Multiple types

4=Unknown type

5=Uninsured

9= Insurance status not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected but is unknown for this record.

| 19 | **F1_Visit_type** | Type of clinic visit |

1 = Clinician

2= express/fast track

8= Other

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or not provided to SSuN. A response of null indicates that the information is collected but is unknown for this record.

| 20 | **F1_Reason_visit** | What was the primary purpose of the visit? |

2= Treatment only

3= Follow-up

4= Family planning

5= STD/HIV screening only

6= Prenatal care

7=PeEP Visit

8= Other

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected but is unknown for this record.

| 21 | **F1_Pregnant** | Is the patient pregnant today? |

1= Yes

2= No

3= Patient does not know/ not sure

9= Not captured

If information is collected but patient is not sure, then appropriate response is 3. A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values allowed for men or if information is collected by the facility but unknown for this record.

22	**F1_Contraception**	What is the patient's primary method of contraception at the end of her visit?

1= hormonal
2= IUD
3= Barrier
4= None
5= Natural
8= Other
9= Not captured
A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values allowed for men or if information is collected by the facility but unknown for this record.

23	**F1_Sympt**	Does the patient have STI symptoms?

1= Yes
2= No
9= Not captured
A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected by the facility but is unknown for this record.

24	**F1_Contact_STD**	Was the patient a contact or exposed to a STD?

1= Yes
2= No
9= Not captured
A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected by the facility but is unknown for this record.

25	**F1_Pelvic_exam**	Was a pelvic exam performed?

1= Yes
2= No
9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values allowed for men or if information is collected by the facility but unknown for this record.

26	F1_MENSEX	How many male sex partners has the patient had in the last 3 months?

If number of male sex partners is unknown, missing, or not captured, use null value.

27	F1_FEMSEX	How many female sex partners has the patient had in the last 3

If number of female sex partners is unknown, missing, or not captured, use null value.

28	F1_TranSEX	How many transgender sex partners has the patient had in the last 3

If number of female sex partners is unknown, missing, or not captured, use null value.

29	F1_MSM_12	Does the patient (male) have a history of having male sex partners in the previous 12 months?

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button), or 3(patient is a female).

1= Yes
2= No
9= Not captured

30	F1_SEXOR3	Has the patient had sex with men, women, or both over the past 3

1= Men
2= Women
3= Both
4= No sexual partners in the last 3 months
9= Not captured
A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected by the facility but is unknown for this record.

31	F1_NUMSEX3	How many sex partners has the patient had in the past 3 months?

If number of sex partners is unknown, missing, or not captured, use null value.

32   F1_SEXUALITY   Does the patient consider him/herself gay (homosexual), straight

1 = gay/homosexual
2= straight/heterosexual
3= bisexual
4= Other
9 = Not captured
A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the information is collected by the facility but is unknown for this record.

33   F1_NewSex   Did the patient have a new sex partner in last 3 months?
1= Yes
2= No
9= Not captured
A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the (1) information is collected by the facility but is unknown for this record or (2) that there was not an opportunity for a "no" response (radio button).

34   F1_Rectal_exposure   Does the patient report anal sex with a male in the last 3 months?
1= Yes
2= No
9= Not captured
A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the (1) information is collected by the facility but is unknown for this record or (2) that there was not an opportunity for a "no" response (radio button).

35   F1_Oral_Sex   Did the patient engage in receptive oral sex in last 3 months days?
1= Yes
2= No
9= Not captured
A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the (1) information is collected by the facility but is unknown for this record or (2) that there was not an opportunity for a "no" response (radio button).

36   F1_condom   Does the patient report receptive anal sex without a condom with a male in the last 3 months?

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the (1) information is collected by the facility but is unknown for this record or (2) that there was not an opportunity for a "no" response (radio button).

1= Yes
2= No
3= Unsure/ doesn't know
9= Not captured

| 37 | F1_HIV_partner | Does the patient report having sex with a known HIV positive partner in the last 12 months? |

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. A response of null indicates that the (1) information is collected by the facility but is unknown for this record or (2) that there was not an opportunity for a "no" response (radio button).

1= Yes
2= No
3= Unsure/ doesn't know
9= Not captured

| 38 | F1_IVDU | Does the patient report use of injected drugs in the past 3 months? |

1= Yes
2= No
3= Patient not sure/ unknown
4= Not captured

| 39 | F1_OPIOD | Does the patient report use of Rx opioids (but not under a physician's orders) in the past 3 months? |

1= Yes
2= No
3= Patient not sure/ unknown /refused
4= Not captured

| 40 | F1_HIVcare | Is the patient currently in HIV care? |

1= Yes
2= No
3= Patient is not HIV positive
4= Unknown

| 41 | F1_PrEP | Is the patient on PrEP at the time of their visit? |

1= Yes

2= No

9= Not captured

42	**F1_prep_referral**	Was the patient referred for PrEP at the STD clinic?

1= Yes

2= No

3= No, but a referral to outside clinic was given

43	**F1_EPT**	Is the patient eligible for expedited partner therapy?

1= Yes

2= No

3= Not indicated

9= Not captured

44	**F1_Partner_tx**	Was the patient prescribed or given medication for expedited partner therapy?

A response of 9 indicates that EPT is provided by the facility, but information is not captured or collected or is not provided to SSuN. A response of null indicates that the (1) information is collected by the facility but is unknown for this record, (2) facility does not provide EPT, or (3) information is collected by the facility but there is not an opportunity for a "no" response (radio button).

1= Yes

2= No

9= Not captured

45	**F1_SXRectal**	Did the patient report any rectal symptoms today?

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button).

1= Yes

2= No

9= Not captured

46	**F1_SXPharyngeal**	Does the patient report any oral symptoms (e.g., sore throat) today?

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button).

1= Yes
2= No
9= Not captured

47   F1_Partner_tx   Did the patient accept expedited partner therapy?

1= Yes
2= No
9= Not captured

A response of 9 indicates that EPT is provided by the facility, but information is not captured or collected or is not provided to SSuN. A response of null indicates that the (1) information is collected by the facility but is unknown for this record, (2) facility does not provide EPT, or (3) information is collected by the facility but there is not an opportunity for a "no" response (radio button).

48   F1_HIVTest   Has the patient ever been tested for HIV? (excluding HIV testing on today's visit)?

1= Yes
2= No
3= Patient does not know/ not sure
9= Not captured

If information is collected by the facility but patient is not sure, then appropriate response is 3. A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values allowed if information is collected by the facility but unknown for this record.

49   F1_HIVTestdate   When was the patient's last (most recent) test for HIV (month and year)? (excluding HIV testing on today's visit)?

Null values are allowed if (1) response to F1_HIVTest is either 2, 3, 9 or (2) patient does not know/ or not sure of the date of most recent HIV test.

50   F1_HIVResultlast   What was the result of the patient's most recent test for HIV (excluding HIV testing on today's visit)?

0 = Negative

1 = Positive/preliminary positive

2 = Indeterminant

3= Patient does not know/ not sure

9 = Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value are allowed if (1) response to F1_HIVTest is either 2, 3,9 or (2) patient does not know/ or not sure of the result of the most recent HIV test.

51	F1_HIVTest_refuse	Did the patient refuse an HIV test today?

1= Yes

2= No

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button).

52	F1_HregMatch	Was eHARS registry match done for this patient?

This data element may be initially coded as '2' if the grantee conducts a batch match with their HIV registry and the case is reported before that batch is processed. This information can be updated in the SSuN record in the next data transmission following the match. This data element should not be 'null' or contain missing values.

1=Yes

2=No

53	F1_HregMatchStat	Did this patient match a registry entry in eHARS?

This data element may be initially coded as '3' if the grantee conducts a batch match with their HIV registry and the case is reported before that batch is processed. This information can be updated in the SSuN record in the next data transmission following the match. This data element should not be 'null' or contain missing values.

1=Matching Record Found

2=No Matching Record

3=Match Not Performed

54	F1_HregID	Unique record number from HIV registry (such as stateno from eHARS).

This data element should not be 'null' or contain missing values if a matching record is present in eHARS

55	**F1_HDXMOYR**	What is this patient's earliest indication of HIV positive result?

This information can be obtained from the eHARS person table (HIVPMOYR). If eHARS match found. This should be coded as character data ("MM/YY") with missing information as "../.." or "../YY"

56	**F1_EXPMOD**	Exposure mode from HIV registry.

This data element should not be 'null' or contain missing values if a matching record is present in eHARS.

1=Male who had sex with another male (MSM)

2=Injected illicit or non-prescription drugs (IDU)

3=Had sex with someone with either 1 or 2 (above)

4=Had Sex with Someone of the Opposite Sex but May Not Have Known whether HIV Infection was
Diagnosed in that Person, or Any of the Risk factors of Sex Partners Described in Items 3 or 5

5=Had Sex with Someone of the Opposite Sex in whom HIV Infection was Diagnosed after Having

Any Risk Factor for HIV Infection in Items 6 (Receipt of Clotting Factor for Coagulation Disorder),

7 (Receipt of Blood Transfusion), or 8 (Receipt of Transplant or Artificial Insemination)

6=Received Clotting Factor Injection for Hemophilia or Another Coagulation Disorder

7=Received Transfusion of Blood or Blood Components (e.g., Platelets)

8=Received a Transplant of Tissue or Organ or Artificial Insemination
9=Worked in a Health-Care or Clinical Laboratory Setting with Possible Exposure to Human Blood
or Other Body Fluids

10=Had Other Exposure to Human Blood or Body Fluids
11=No Risk Reported

57	**F1_HPVVaxadmin**	Was the patient given HPV vaccination at this visit?

1= Yes

2= No, not indicated/refused

3= No, clinic does not administer/offer HPV vaccination

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button).

58	**F1_SXAbdomen**	Did the patient report abdominal pain?

1= Yes

2= No

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button).

59   F1_SXDysuria   Did the patient report dysuria?

1= Yes

2= No

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button).

60   F1_SXDischarge   Did the patient report a discharge?

1= Yes

2= No

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button).

61   F1_SXLesion   Did the patient report a genital lesion?

1= Yes

2= No

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button).

62   F1_MSM_12   Does the patient (male) have a history of having male sex partners in the previous 12 months?

1= Yes

2= No

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null values are allowed if the information is collected by the facility but (1) is unknown for this record or (2) there is not an opportunity for a "no" response (radio button), or 3(patient is a female).

4b: Strategy A – STD Clinic Diagnosis Dataset

	Data Element Name	Description/Response Coding
		Diagnosis Dataset
63	**F2_PatientID**	Unique patient identification number assigned by site
		Will be a secondary key for merging laboratory and case data; should correspond to F1_Visdate. This data element MUST NOT be 'null' or contain missing values.
64	**F2_Eventid**	Unique visit identification
		Will be a secondary key for merging laboratory and case data; should correspond to F1_Visdate. This data element MUST NOT be 'null' or contain missing values.
65	**F2_Visdate**	Date of clinic visit
		Will be a secondary key for merging laboratory and case data; should correspond to F1_Visdate. This data element MUST NOT be 'null' or contain missing values.
66	**F2_DXCODE**	Diagnosis Code
		SY01=Syphilis, primary
		SY02=Syphilis, secondary
		SY03=Syphilis, early latent
		SY04=Syphilis, late latent/Unknown
		SY05=Syphilis, neurosyphilis
		SY06=Syphilis, unspecified/other
		GC01=Gonorrhea
		CT01=Chlamydia
		GW01=Genital Warts
		HI01=HIV/AIDS
		BV01=Bacterial vaginosis (BV)
		TR01=Trichomoniasis
		GH01=Genital Herpes
		NU01=Nongonococcal Urethritis (NGU)
		MC01=Muco-purulent cervicitis (MPC)
		PI01=Pelvic Inflammatory Disease (PID)
		EP01=Epididymitis
		CC01=Chancroid
		LV01=Lymphogranuloma venereum (LGV)
		GI01=Granuloma Inguinale
		CD01=Candidiasis
		SC01=Scabies
		PD01=Pediculosis

CS01=Contact to STD

PG01=Pregnancy

NE01=Normal exam/diagnosis

OT01=Other

Null values allowed if information is collected by the facility but unknown for this record.

4c: Strategy A – STD Clinic Laboratory Dataset

	Data Element Name	Description/Response Coding
		Laboratory Dataset
67	**F3_PatientID**	Unique patient identification number assigned by site
		Will be a secondary key for merging laboratory and case data; should correspond to F1_Visdate. This data element MUST NOT be 'null' or contain missing values.
68	**F3_Eventid**	Unique visit identification
		Will be a secondary key for merging laboratory and case data; should correspond to F1_Visdate. This data element MUST NOT be 'null' or contain missing values.
69	**F3_Visdate**	Date of clinic visit
		Will be a secondary key for merging laboratory and case data; should correspond to F1_Visdate. This data element MUST NOT be 'null' or contain missing values.
70	**F3_SpecColdate**	Date of specimen collection for this laboratory observation
		This data element MUST NOT be 'null' or contain missing values.
71	**F3_Condtested**	What condition was the patient tested for?
		2 = Gonorrhea
		3 = Chlamydia
		6 = HIV/AIDS
		20 = Pregnancy
		Although a null value is allowed, sites should make every attempt to make sure the value is not a null value. A record for a lab condition not included in the list above, should not be submitted.
72	**F3_Anatsite**	What anatomic site was tested?
		1 = Urethral
		2 = Vaginal/cervical
		3 = Urine
		4 = Rectal
		5 = Pharynx
		6 = Blood
		8 = Other
		9= Not captured
		Although a null value is allowed, sites should make every attempt to make sure the value is not a null value.

73	**F3_Test_Type**	What type of test was used?

1= Culture
2= Nucleic acid amplification test (NAAT)
3= Non-amplified nucleic acid test/DNA probe
4= Gram stain
10= HIV Nucleic acid test (NAT)
11= rapid HIV-1 or HIV-1/2 antibody (Ab) test
12= HIV-1 Immunoassay (IA)
13= HIV-1/2 IA
14= HIV-1/2 Ag/Ab IA
15= HIV-1 WB
16= HIV-1 IFA
17= HIV-1/HIV-2 differentiation IA
18= pooled RNA
19=HIV Viral Load (ultra quantitative)
20=HIV Viral Load (quantitative)
21=CD4+ assay
40= Pregnancy
88= Other
99=Not captured
Although a null value is allowed, sites should make every attempt to make sure the value is not a null value.

74	**F3_Qualres**	What was the qualitative test result?

0 = Negative
1 = Positive
2 = Nonreactive
3 = Reactive
4 = Indeterminate
5= Weakly Reactive
6 = QNS/Contaminated/Unsaturated
8 = Other/pending
9=Not captured
Although a null value is allowed, sites should make every attempt to make sure the value is not a null value.

75	**F3_Quantres**	Numeric - or Ratio (for RPR/VDRL, e.g. 1:2, 1:4, etc.)

76	**F3_QuantUnits**	Units for quantitative results:

1=Copies/mL
2=Log Copies/mL
3=Cells/Cubic mm

4=CD4%

5=Titer Ratio

6=Cycles/Time (rtPCR)

4d: Strategy A – STD Clinic Treatment Dataset

	Data Element Name	Description/Response Coding
		Treatment Dataset

77 | **F4_PatientID** | Unique patient identification number assigned by site

Will be a secondary key for merging treatment and case data; should correspond to F1_PatientID. This data element MUST NOT be 'null' or contain missing values.

78 | **F4_Eventid** | Unique visit identification

Will be a secondary key for merging treatment and case data; should correspond to F1_EventID. This data element MUST NOT be 'null' or contain missing values

79 | **F4_Visdate** | Date of clinic visit

Will be a secondary key for merging treatment and case data; should not be 'null' or contain missing values

80 | **F4_TxDate** | Treatment Date

Date treatment dispensed or prescribed; should not be 'null' or contain missing values

81 | **F4_Medication** | What medication was prescribed to the patient (brand name)?

10= Amoxicillin (Amoxil, Polymox, Trimox, Wymox)
11= Ampicillin (Omnipen, Polycillin, Polycillin-N, Principen, Totacillin)
20= Azithromycin (Zithromax)
21= Erythromycin base
22= Clindamycin (Cleocin)
23= Gentamicin (Garamycin, G-Mycin, Jenamicin)
30= Cefixime (Suprax)
31= Ceftizoxime (Cefizox)
32= Cefotaxime (Claforan)
33= Cefoxitin (Mefoxin)
34= Cefpodoxime (Vantin)
35= Ceftibuten (Cedax)
36= Cefdinir (omnicef)
37= Ceftriaxone (Rocephin)
38= Cefuroxime (Ceftin, Kefurox, Zinacef, Zinnat)
40= Ciprofloxacin (Cipro, Cipro XR, Ciprobay, Ciproxin)
41= Levofloxacin (Cravit, Levaquin)
42= Moxifloxacin (Avelox, Vigamox)
43= Ofloxacin (Floxin, Oxaldin, Tarivid)

44= Gemifloxacin (Factive)

50= Doxycycline (Doryx, Vibramycin)

60= Metronidazole (Flagyl, Helidac, Metizol, Metric 21, Neo-Metric, Noritate, Novonidazol)

61= Tinidazole (Tindamax)

70= Truvada (Tenofovir/emtricitabine)

88= Other

Although a null value is allowed, sites should make every attempt to make sure the value is not a null value.

| 82 | **F4_Medication** | If the patient received a medication other than what is listed above as *indicated by response option #88, please provide name of other medication (Free text description of other medication)* |

| 83 | **F4_Dosage** | What was the dosage of the medication prescribed? |

1= 100mg

2= 125mg

3= 150mg

4= 200mg

5= 240mg

6= 250mg

7= 300mg

8= 320mg

9= 400mg

10= 500mg

11= 600mg

12= 750mg

13= 800mg

14= 1g

15= 2g

88= Other

99= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value allowed if dosage is unknown or missing.

| 84 | **F4_Number_doses** | Total number of doses prescribed? |

Null value allowed if (1) number of total doses is unknown or missing or (2) the information is not captured or collected by the facility or is not provided to SSuN.

| 85 | **F4_Dose_Freq** | What is the frequency of doses? |

1=one single dose

2= twice day

3= three times a day

4= four times a day

8= other

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value allowed if frequency of doses is unknown or missing.

| 86 | F4_Duration | What duration was the medication prescribed for? |

1= 1 day

2= 3 days

3= 5 days

4= 7 days

5= 10 days

6= 14 days

8= Other

9= Not captured

A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN. Null value allowed if duration of medication is unknown or missing.

4e: Strategy A – STD Clinic Facility Reference Dataset

Data Element Name	Description/Response Coding
Facility Reference Dataset	

87	**F5_Facility_ID**	Unique facility identifier
		This ID should be supplied by the site and is a unique facility identifier from underlying surveillance systems or may be generated specifically for SSuN. Regardless of source, this ID must be unique and allow for longitudinal tracking of the facility. This data element MUST NOT be 'null' or contain missing values.
88	**F5_SiteID**	Unique site code
		BA=Baltimore
		CA=California
		FL=Florida
		MA=Massachusetts
		MN=Minnesota
		MC=Multnomah county
		NY=New York City
		PH=Philadelphia
		SF=San Francisco
		WA= Washington
		VA=Virginia (Cycle II)
		AL=Alabama (Cycle II)
		CO=Colorado (Cycle II)
		CH=Chicago (Cycle II)
		This data element MUST NOT be 'null' or contain missing values.
89	**F5_Facility_name**	What is the name of the facility?
90	**F5_Facility_type**	What is the facility type?
		1= STD clinic
		2=FP/RH
		88= Other
91	**F5_FQHC**	Is this facility a FQHC?
		1= Yes
		2= No
92	**F5_Title_X**	Is this facility a Title X clinic?
		1= Yes

2= No

93	**F5_CHC**	Is this facility a Community Healthcare Center?
		1= Yes
		2= No

94	**F5_School_based**	Is this facility a school-based facility?
		1=Yes
		2=No

95	**F5_Facility_Address**	What is the physical street address of the facility?

96	**F5_Facility_City**	In what city is the facility located?
		FIPS code, example: 3290 (City of SF)

97	**F5_Facility_State**	In what state is the facility located?
		FIPS code

98	**F5_Facility_Zip**	Zip code for the facility (9-digit ZIP code of facility)

99	**F5_Point_contact**	Point of contact at facility

100	**F5_EPT**	Does the facility have written policies governing EPT?
		1= Yes
		2= No
		3= facility does not employ EPT

101	**F5_HPV_vaccine**	Does the facility have written policies governing HPV vaccination?
		2= No
		3= facility does not provide HPV vaccination

102	**F5_HIV_algorithm**	Does the facility have written policies governing HIV testing?
		1= Yes
		2= No
		3= facility does not provide HIV testing

103	**F5_Screening_CT**	Does the facility have written policies governing chlamydia screening?
		1= Yes
		2= No
		3= facility does not provide CT testing

104	**F5_Screening_GC**	Does the facility have written policies governing gonorrhea screening?
		1= Yes

2= No
3= facility does not provide GC testing

105	**F5_Billing**	Does the facility bill for STD services?

1= Yes
2 = No
3= Other

106	**F5_Medical_record**	Type of medical record system?

1= paper-based
2= electronic
3=combination
9= not sure

107	**F5_Insurance**	Is the facility in an insurance network?

1=Yes
2=No

108	**F_Unassigned1**	Unassigned variable (TBD)
109	**F_Unassigned2**	Unassigned variable (TBD)
110	**F_Unassigned3**	Unassigned variable (TBD)
111	**F_Unassigned4**	Unassigned variable (TBD)

4f: Strategy B – STD Case Dataset

Data Element Name	Description/Response Coding
Case Dataset	
112 P1_SiteID	SSuN Site ID
	This 2 character code primarily identifies sites funded under SSuN Cycle 2 & 3 and will include additional sites as required for Cycle 4. This data element MUST NOT be 'null' or contain missing values.
	BA=Baltimore (Cycle II & Cycle III)
	CA=California (Cycle II & Cycle III)
	FL=Florida (Cycle III)
	MA=Massachusetts (Cycle III)
	MN=Minnesota (Cycle III)
	MC=Multnomah County (Cycle III)
	NY=New York City (Cycle II & Cycle III)
	PH=Philadelphia (Cycle II & Cycle III)
	SF=San Francisco (Cycle II & Cycle III)
	WA= Washington (Cycle II & Cycle III)
	VA=Virginia (Cycle II)
	AL=Alabama (Cycle II)
	CO=Colorado (Cycle II)
	CH=Chicago (Cycle II)
113 P1_EventID	Site generated unique event identifier
	This record ID should be supplied by the site and may be an event or report identifier from underlying surveillance system. Regardless of source, this ID must be unique for each confirmed case report. This data element MUST NOT be 'null' or contain missing values.
114 P1_PatientID	Site generated ID allows for longitudinal tracking of unique persons
	This ID should be supplied by the site and may be a unique patient identifier from underlying surveillance systems or may be generated specifically for SSuN from identifying information provided through case reporting. Regardless of source, this ID must be unique and allow for longitudinal tracking of persons reported with multiple episodes of disease. This data element MUST NOT be 'null' or contain missing values.
115 P1_RecRepDte	Earliest date this specific disease event/report received at health department?

This date should reflect the earliest information available to the health department regarding the case. This date should include laboratory records received if lab results were reported prior to receipt of a provider case report. This data element MUST NOT be 'null' or contain missing values. This should be coded as a 'SAS' numeric date.

| 116 | P1_RandSamp | Is this record/case selected in the random sample? |

This data element MUST NOT be 'null' or contain missing values.

0=Not in random sample
1=In random sample

| 117 | P1_SampDte | Date record/case sampled by jurisdiction |

For jurisdiction deploying a batch process for record sampling, this should be the actual date that the batch was sampled. For jurisdictions deploying real-time sampling of cases through their surveillance system, this date should match the report date (or date case status was confirmed if appropriate). This data element should not be 'null' or contain missing values. This should be coded as a 'SAS' numeric date.

| 118 | P1_RecSx | Was lab or provider report how case was initially reported to the health department? |

This data element is intended to capture the source of the initial case notification to the health department. If the grantee is not able to reliably capture this information for a specific case, this must be documented by entering a value of '3' for that case record. This data element should not be 'null' or contain missing values.

0=Laboratory report, electronic
1=Laboratory report, paper
2=Provider report, electronic or paper
3=Report source not captured by surveillance system

| 119 | P1_PrevPtx | Is patient previously known to HD from infectious disease reporting records (TB, HIV, STDs, Hep)? |

This data element is designed to capture whether this patient is known to the HD from a previous case report. This data element should not be 'null' or contain missing values. If a match with previous patients is not done, please code as a new patient. If a subsequent match is performed and patient found to be previously reported, the value should be changed accordingly.

0=New Patient, not previously reported
1=Patient previously reported

120	P1_InitSx	If patient previously reported, what is the registry/source of earliest report for this PATIENT?

0=STD Registry
1=HIV Registry
2=Viral Hepatitis Registry
3=Other Disease Registry
4=Unknown

121	P1_HregMatch	Was eHARS registry match done for this patient?

This data element may be initially coded as '2' if the grantee conducts a periodic batch match with their HIV registry and the case is reported before that batch is processed. This information can be updated in the SSuN record in the next data transmission following the match. This data element should not be 'null' or contain missing values.

1=Yes
2=No

122	P1_HregMatchStat	Did this patient match a registry entry in eHARS?

This data element may be initially coded as '3' if the grantee conducts a periodic batch match with their HIV registry and the case is reported before that batch is processed. This information can be updated in the SSuN record in the next data transmission following the match. This data element should not be 'null' or contain missing values.

1=Matching Record Found
2=No Matching Record
3=Match Not Performed

123	P1_HregID	Unique record number from HIV registry (such as stateno from eHARS).

This data element should not be 'null' or contain missing values if a matching record is present in eHARS.

124	P1_HDXMOYR	What is this patient's earliest indication of HIV positive result?

This information can be obtained from the eHARS person table (HIVPMOYR). If eHARS match found. This should be coded as character data ("MM/YY") with missing information as "../.." or "../YY"

125	P1_EXPMOD	Exposure mode from HIV registry.

This data element should not be 'null' or contain missing values if a matching record is present in eHARS.

1=Male who had sex with another male (MSM)
2=Injected illicit or non-prescription drugs (IDU)
3=Had sex with someone with either 1 or 2 (above)
4=Had Sex with Someone of the Opposite Sex but May Not Have Known whether HIV Infection was
Diagnosed in that Person, or Any of the Risk factors of Sex Partners Described in Items 3 or 5

5=Had Sex with Someone of the Opposite Sex in whom HIV Infection was Diagnosed after Having

Any Risk Factor for HIV Infection in Items 6 (Receipt of Clotting Factor for Coagulation Disorder),

7 (Receipt of Blood Transfusion), or 8 (Receipt of Transplant or Artificial Insemination)

6=Received Clotting Factor Injection for Hemophilia or Another Coagulation Disorder

7=Received Transfusion of Blood or Blood Components (e.g., Platelets)
8=Received a Transplant of Tissue or Organ or Artificial Insemination
9=Worked in a Health-Care or Clinical Laboratory Setting with Possible Exposure to Human Blood
or Other Body Fluids

10=Had Other Exposure to Human Blood or Body Fluids
11=No Risk Reported

126   P1_Othno   Additional registry number
If this patient also has a record in other/ancillary disease registries. This is primarily for local use in matching patient records to update missing information.

127   P1_Othsx   Additional registry source
If this patient also has a record in other/ancillary disease registries and P1_Othno is not blank, this element should be populated with the source.

0=STD Registry
1=HIV Registry
2=Viral Hepatitis Registry
3=Other Disease Registry
4=Unknown

128   P1_PrevDx   Most recent previous diagnosis (if applicable; could include hep, TB or HIV)

If this patient also has a record in other/ancillary disease registries as indicated above, indicate the diagnosis documented by that record. Should be 'Null' if no previous diagnosis is confirmed.

10311=Syphilis, primary
10312=Syphilis, secondary
10313=Syphilis, early non-primary non-secondary
10320=Syphilis, unknown duration or late
10280=Gonorrhea
10274=Chlamydia
10100=Hepatitis B, acute
10105=Hepatitis B, chronic
20001=Hepatitis C
10562=HIV infection (non-AIDS)
10560=AIDS
10307=Nongonococcal Urethritis (NGU)
10308=Muco-purulent cervicitis (MPC)
10309=Pelvic Inflammatory Disease (PID)
10273=Chancroid
10306=Lymphogranuloma venereum (LGV)
10276=Granuloma Inguinale
20002=TB
20003=Other

129   P1_PrevDxDte   Date of most recent previous diagnosis documented above.
Should not be null if P1_PrevDx is not null.

130   P1_PrevGCDx   Has the patient been previously diagnosed and reported with GC?

1=Yes
2=No
3=Registry records not searched

131   P1_PrevGCDxDte   Date of most recent previous diagnosis of GC documented above.
Should not be null if P1_PrevGCDx = 1. This should be coded as a 'SAS' numeric date.

132   P1_CaseDup   Is this record/case a duplicate report, new report or was duplicate status not determined?

The grantee should document if an initial case report was subsequently found to be a duplicate of an existing case – the record should be retained in the SSuN dataset and coded as a duplicate ('1')? If the jurisdiction receives a report that they know to be a duplicate at the time of report, the record can be omitted from the SSuN datasets and not sampled for enhanced investigation. This data element should not be 'null' or contain missing values.

0=New Case
1=Duplicate Case (previously reported <15 days)
9=Unknown, site surveillance system does not capture

133   P1_FacilityID

Site generated facility ID. Each reporting provider/facility must have a unique ID.

This is a primary key for linking the provider type and other provider information to the case record. Historically, the majority of cases in any grantee's jurisdictions will be reported from known providers, but for cases reported from entirely new or unknown providers, this field should be populated with that facility's new number and be included in the next update of the provider reference file. This data element should not be 'null' or contain missing values.

134   P1_Dispo

What is the status of the internal health department (look-back) investigation

The investigation referred to for this data element includes the search of existing health department records, matching and merging with electronic or other laboratory data, eHARS match and other disease registries. At initial report, cases may be coded as '10'. This should be updated as appropriate. Cases listed as "pending" should be updated within 60 days and this information updated in the next SSuN data transmission. This data element should not be 'null' or contain missing values. Jurisdictions may choose to initiate provider investigations on all reported cases, regardless of whether they fall into the random sample, or may elect to initiate investigations on only those records in the random sample.

0=Investigation complete: record referred to provider investigation
1=Investigation complete: no further action, record determined to be a duplicate
2=Investigation complete: no further action, case determined to reside OOJ
3=Investigation complete: no further action, case not in Sample
4=Investigation complete: no further action, case not eligible for SSuN
10=Investigation not complete: investigation pending

11=Investigation not complete: no further action, insufficient contact/provider information

22=Investigation not complete: other reason

135   P1_Referral1

Is this record/case referred for provider investigation?

This indicates whether the record has been referred to provider investigation. If provider is not contacted, surveyed or otherwise followed up with to supply any additional case-specific information, code as '1'.   This data element should not be 'null' or contain missing values.

0=Referred to P2 Investigation

1=Not Referred to P2 Investigation

2=Referral Pending

136   P1_PtxSex

Sex of the patient as indicated on initial health department report?

This data element should not be 'null' or contain missing values.

1=Male

2=Female

3=Male-to-Female TG

4=Female-to-Male TG

5=TG Unknown or Unspecified

9=Unknown

137   P1_PtxRace_White

White Race

Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in interview variables. If additional information from any source (other than patient report) is received, these data may be updated as required by underlying surveillance system.

1=Yes

2=No

3=Unknown

4=Refused

138   P1_PtxRace_Black

Black Race

Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in interview variables. If additional information from any source (other than patient report) is received, these data may be updated as required by underlying surveillance system.

1=Yes
2=No
3=Unknown
4=Refused

139 **P1_PtxRace_AIAN** American Indian/Alaska Native Race

Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in interview variables. If additional information from any source (other than patient report) is received, these data may be updated as required by underlying surveillance system.

1=Yes
2=No
3=Unknown
4=Refused

140 **P1_PtxRace_Asian** Asian Race

Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in interview variables. If additional information from any source (other than patient report) is received, these data may be updated as required by underlying surveillance system.

1=Yes
2=No
3=Unknown
4=Refused

141 **P1_PtxRace_NHOPI** Native Hawaiian/Other Pacific Islander Race

Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in interview variables. If additional information from any source (other than patient report) is received, these data may be updated as required by underlying surveillance system.

1=Yes
2=No
3=Unknown
4=Refused

142 **P1_PtxRace_Other** Other Race

Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in interview variables. If additional information from any source (other than patient report) is received, these data may be updated as required by underlying surveillance system.

1=Yes
2=No
3=Unknown
4=Refused

143 P1_PtxRace_UNK Is all information on race and Hispanic ethnicity missing from initial
If additional/supplemental information is received on race and ethnicity of patient but this information was missing from the initial report to the health department, please leave this data element coded as '1' and capture the source of supplemental information below.

1=Yes
2=No

144 P1_PtxRaceSource What is the source of the final race information of record as ascertained for this patient?
For grantees able to distinguish the source of information for race, please indicate as appropriate. For grantees NOT able to distinguish the source of race data at all, code as '6'. If race information is missing/unknown from all sources, code as '5'.

1=Patient Self-Report
2=Provider Case Report
3=Laboratory Report
4=Previous Registry Record
5=No Information Available from Any Source
6=Source not Identifiable

145 P1_PtxHisp Patient Hispanic ethnicity
Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in interview variables. If additional information from any source (other than patient report) is received, these data may be updated as required by underlying surveillance system.

1=Hispanic
2=Non-Hispanic

3=Unknown
4=Refused

146   P1_PtxHISPSource   What is the source of the final Hispanic ethnicity information
For grantees able to distinguish the source of information for Hispanic ethnicity, please indicate as appropriate. For grantees NOT able to distinguish the source of Hispanic ethnicity data at all, code as '6'. If information is missing/unknown from all sources, code as '5'.

1=Patient Self-Report
2=Provider Case Report
3=Laboratory Report
4=Previous Registry Record
5=No Information Available from Any Source
6=Source not Identifiable

147   P1_PtxAGE   Age of patient from initial reporting record/document .
If age information is missing/unknown from all sources, use null value.

148   P1_PtxAgeUnit   Age unit
If #32 is null, use null value for this data element ('.')

1=Years
2=Months

149   P1_PtxCountyres   County of patient residence
If information is missing/unknown, code to null value ('.')

150   P1_PtxCTract   Census Tract of patient residence
If information is missing/unknown, code to null value ('.')

151   P1_PtxAddrStat   Was patient street address present and complete in initial reporting documents?
This data element should not be 'null' or contain missing values.

1=Street Address Known
2=Street Address Missing
3=Street Address Incomplete

152   P1_GCAccuracy   What is the basis of census tract assignment (XY coordinates, street
This data element should not be 'null' or contain missing values.

1=Close (based on direct street segment, parcel, or lon/lat match.

2=Approximate (modification of address required to match to to street segment)

3=Very approximate (based only on zip or city centroid)

4=Not-geocodable (insufficient data to geocode, PO Box, General Delivery)

5=Data suppressed by policy

9=Missing (no address available)

153   P1_DxDte   What is the diagnosis date for the current episode of disease (may be date of provider visit, specimen collection date, laboratory report date or other suitable proxy)

This data element should not be 'null' or contain missing values. This should be coded as a 'SAS' numeric date.

154   P1_DxCode   Diagnosis (for gonorrhea cases, this value = 10280)
This data element should not be 'null' or contain missing values.

10273=Chancroid
10274=Chlamydia
10280=Gonorrhea
10311=Syphilis, primary
10312=Syphilis, secondary
10313=Syphilis, early non-primary non-secondary
10320=Syphilis, unknown duration or late

155   P1_SiteUrine   Urine 'site' of infection, usually a proxy for urethral infection in men but
If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

156   P1_SiteVagCerv   Vaginal or cervical site of infection in women - combined because there
If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

157   P1_SiteUreth   Urethral site of infection - only if this is specifically indicated, if the only
If information is missing/unknown, code as '3'

1=Yes
2=No

3=Unknown

158	**P1_SiteRect**	Rectal site of infection

If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

159	**P1_SitePhar**	Pharyngeal site of infection

If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

160	**P1_SiteEye**	Ocular site of infection

If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

161	**P1_SiteSera**	Blood or sera infection

If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

162	**P1_SiteJoint**	Joint or synovial fluid infection

If information is missing/unknown, code as '3'
1=Yes
2=No
3=Unknown

163	**P1_SiteOTH**	Site of infection, not specified above

If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

164	**P1_SiteUNK**	All site of infection information missing for this case - use only if no other information is available.

If the answer to any one of 40-48 above is '1' or '2' then this data element should be coded '2'. If all data elements 40-48 are coded as '3' then code this data element as '1'.

1=Yes
2=No

165	**P2_ProvID**	Unique facility/provider ID

This data element MUST NOT be 'null' or contain missing values for cases in the random sample. SHOULD NOT be null for all other cases (collaborators requested to include this information for all gonorrhea case records – this can be accomplished with a default coding of P2_ProvID= P1_FacilityID.

166	**P2_ProvCO**	County FIPS code for provider/facility physical location

This should be coded as the 3-digit FIPS code for the county.

167	**P2_ProvZIP**	Facility/provider physical location 5-digit ZIP

168	**P2_ProvCHC**	Is facility/provider a Community Health Center (CHC)?

Community Health Centers are not-for-profit primary care organizations governed by a community board and whose primary mission is to provide medical services to traditionally under-served populations. The primary way of determining CHC status is by self-identification (though some put it in their name). The National Association of Community Health Centers (NACHC) does maintain member lists as well. Non-profit and community board governance are the key features.

1=Yes
2=No
3=Unknown/Missing

169	**P2_ProvFQHC**	Is facility/provider a Federally Qualified Health Center (FQHC)?

Federally qualified health centers (FQHCs) include all organizations receiving grants under Section 330 of the Public Health Service Act   (PHS). These are a matter of public record and lists are available from HRSA

1=Yes
2=No
3=Unknown/Missing

| 170 | **P2_ProvPTXvisitDte** | Date of patient initial visit for this issue, can be supplied/filled in from |

This should be formatted as a 'SAS' numeric date.

| 171 | **P2_ProvClinType** | What was the category of provider examining/treating this patient (e.g. |

1=MD
2=RN
3=PA
4=ARNP
5=LPN
6=Other
7=Unknown/Not Ascertained

| 172 | **P2_ProvPTX_GenderSP** | Provider documented gender of sex partners |

1=Males only
2=Females only
3=Both Males and Females
4=Not Documented

| 173 | **P2_ProvPTX_Insure** | Insurance status of patient from provider's records |

1=Yes, Insured
2=No, Not Insured
3=Unknown/Missing

| 174 | **P2_Urethritis** | Was urethritis found on exam |

Missing/unknown information code as null ('.').

1=Yes
2=No

| 175 | **P2_Proctitis** | Was proctitis found on exam |

Missing/unknown information code as null ('.').

1=Yes
2=No

| 176 | **P2_Epididymitis** | Was epididymitis found on exam |

Missing/unknown information code as null ('.').

1=Yes
2=No

| 177 | **P2_PID** | Was PID diagnosed. |
| | | *Missing/unknown information code as null ('.').* |

1=Yes
2=No

| 178 | **P2_Discharge** | Was discharge found on exam |
| | | *Missing/unknown information code as null ('.').* |

1=Yes
2=No

| 179 | **P2_OtherFinding** | Were there other STD-related findings on exam |
| | | *Missing/unknown information code as null ('.').* |

1=Yes
2=No

| 180 | **P2_NoFinding** | Were there no findings on exam |
| | | *Missing/unknown information code as null ('.').* |

1=Yes
2=No

| 181 | **P2_ProvScrnUreth** | Was patient screened/tested for infection at urethral site |

1=Yes
2=No
3=Unknown
4=Refused

| 182 | **P2_ProvScrnVagCerv** | Was patient screened/tested for infection at vaginal/cervical site |

1=Yes
2=No
3=Unknown
4=Refused

| 183 | **P2_ProvScrnAnal** | Was patient screened/tested for infection at anorectal site |

1=Yes
2=No

3=Unknown
4=Refused

184   P2_ProvScrnPhar   Was patient screened/tested for infection at pharyngeal site

1=Yes
2=No
3=Unknown
4=Refused

185   P2_ProvScrnHIV   Was patient screened/tested for HIV infection at time of visit

1=Yes
2=No
3=Unknown
4=Refused

186   P2_ProvPTX_TxDte   Treatment date
This should be coded as a 'SAS' numeric date. Missing/unknown information code as null ('.').

187   P2_ProvPTX_CFTRI   Was patient treated with ceftriaxone?
Missing/unknown information code as null ('.').

1=Yes
2=No

188   P2_ProvPTX_CFTRI_DS   Ceftriaxone dosage
Missing/unknown information code as null ('.').

1=125mg
2=250mg
3=500mg

189   P2_ProvPTX_Azit   Was patient treated with azithromycin
Missing/unknown information code as null ('.').

1=Yes
2=No

190   P2_ProvPTX_Azit_DS   Azithromycin dosage
Missing/unknown information code as null ('.').

1=1 gram
2=2 grams

191	**P2_ProvPTX_Doxy**	Was patient treated with doxycycline?

Missing/unknown information code as null ('.').

1=Yes
2=No

192	**P2_ProvPTX_Cefx**	Was patient treated with cefixime?

Missing/unknown information code as null ('.').

1=Yes
2=No

193	**P2_ProvPTX_Oth**	Were other medications prescribed/provided for treating GC

Missing/unknown information code as null ('.').

1=Yes
2=No

194	**P2_ProvPTX_OtherTXT**	Specific other medications prescribed/provided for treating GC (text)

195	**P2_ProvPTX_PDPT**	Were any medications/prescriptions provided for patient's partner(s)?

Missing/unknown information code as null ('.').

1=Yes
2=No

196	**P2_ProvPTX_HIBC**	Was patient counseled to prevent transmission/reinfection?

Missing/unknown information code as null ('.').

1=Yes
2=No

197	**P2_ProvPTX_Refer**	Was patient referred to HD (or other) for partner services?

Missing/unknown information code as null ('.').

1=Yes
2=No

198	**P3_IDX_ID**	(1) Interviewer/Investigator ID

This is a locally assigned ID to uniquely identify the person conducting patient interview. This data element should not be 'null' or contain missing values for interviewed cases.

199	**P3_PatientID**	(2)Unique identifier for person/patient

Will be a secondary key for merging data; should correspond to P1_PatientID. This data element should not be 'null' or contain missing values for interviewed cases.

200	**P3_EventID**	(3) Unique identifier for record

Will be a primary key for merging data; should correspond to P1_EventID. This data element should not be 'null' or contain missing values for interviewed cases.

201	**P3_IDX_CADate1**	(4) Contact attempt date 1

This data element should not be 'null' or contain missing values for interviewed cases.

203	**P3_IDX_CAout1**	(5) Contact attempt outcome 1

This data element should not be 'null' or contain missing values for interviewed cases.

0=Answer/Partial or Complete Interview Obtained
1=No Answer/No Message
2=No Answer/Message Left
3=Answer/Hang up
4=Answer/Refusal
5=Answer/Reschedule DIS call-back
6=Answer/Reschedule Patient Callback
7=Number out of service
8=Other

204	**P3_IDX_CADate2**	(6) Contact attempt date 2

This should be coded as a 'SAS' numeric date.

205	**P3_IDX_CAout2**	(7) Contact attempt outcome 2

0=Answer/Partial or Complete Interview Obtained
1=No Answer/No Message
2=No Answer/Message Left
3=Answer/Hang up
4=Answer/Refusal
5=Answer/Reschedule DIS call-back

6=Answer/Reschedule Patient Callback
7=Number out of service
8=Other

| 206 | **P3_IDX_CADate3** | (8) Contact attempt date 3 |

This should be coded as a 'SAS' numeric date.

| 207 | **P3_IDX_CAout3** | (9) Contact attempt outcome 3 |

0=Answer/Partial or Complete Interview Obtained
1=No Answer/No Message
2=No Answer/Message Left
3=Answer/Hang up
4=Answer/Refusal
5=Answer/Reschedule DIS call-back
6=Answer/Reschedule Patient Callback
7=Number out of service
8=Other

| 208 | **P3_IDX_CADate4** | (10) Contact attempt date 4 |

This should be coded as a 'SAS' numeric date.

| 209 | **P3_IDX_CAout4** | (11) Contact attempt outcome 4 |

0=Answer/Partial or Complete Interview Obtained
1=No Answer/No Message
2=No Answer/Message Left
3=Answer/Hang up
4=Answer/Refusal
5=Answer/Reschedule DIS call-back
6=Answer/Reschedule Patient Callback
7=Number out of service
8=Other

| 210 | **P3_IDX_Ixdate** | (12) Interview/Disposition Date |

This should be coded as a 'SAS' numeric date.

| 211 | **P3_IDX_Dispo** | (13) Patient Investigation/Interview Disposition |

Should not be 'null' for cases included in random sample.

0=Investigation complete: patient contacted, interview
1=Investigation complete: patient contacted, partial interview
10=Investigation not complete: P3 investigation pending

11=Investigation not complete: patient contacted, refused
12=Investigation not complete: patient contacted, unable to
22=Investigation not complete: patient did not respond to at
33=Investigation not complete: patient contact not initiated
44=Investigation not complete: patient contact not initiated
55=Investigation not complete: >60 days from diagnosis
66=Investigation not complete: case determined to be OOJ
77=Investigation not complete: insufficient contact information
88=Investigation not complete: provider refused patient contact
99=Investigation not complete: administrative closure/other

212   P3_PTX_age   (14) What is your age?
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

888=Refused

213   P3_PTX_sex   (15) What gender or sex do you consider yourself to be?

1=Male
2=Female
3=Male-to-Female TG
4=Female-to-Male TG
5=TG Unknown or Unspecified
8=Refused

214   P3_PTX_HispEthnic   (16) Do you consider yourself to be Hispanic or Latino/a?
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Unknown
4=Refused

215   P3_PTX_White   (17) patient reported White race
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Unknown
4=Refused

216   P3_PTX_Black   (18) patient reported Black race

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Unknown
4=Refused

217   P3_PTX_AIAN   (19) patient reported AIAN race

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Unknown
4=Refused

218   P3_PTX_Asian   (20) patient reported Asian race

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Unknown
4=Refused

219   P3_PTX_NHOPI   (21) patient reported NHOPI race

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Unknown
4=Refused

220   P3_PTX_OTHrace   (22) patient reported other race

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

3=Unknown
4=Refused

221   P3_PTX_RefRace   (23) patient refuses provision of all race information
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

222   P3_PTX_Insure   (24) Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare, Indian Health Services, the V.A. or Military?
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

223   P3_PTX_InsType   (25) What kind of healthcare insurance do you have?
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Private healthcare insurance provided by my employer
2=Private healthcare insurance I pay for myself
3=Public healthcare insurance like Medicaid, Medicare, or a
4=Active or retired military or dependent plan like the V.A. or
5=Bureau of Indian Affairs/IHS/Urban Indian Health
7=Other
8=Don't know / Not sure
9=Refused

224   P3_PTX_OthInsSpecify   (25a) Other type of insurance (text)

225   P3_PTX_PriCareDoc   (26) Do you have one person you think of as your personal doctor or   health care provider?
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes, only one
2=More than one or facility

3=No
4=Don't Know /Not Sure
5=Refused

226   P3_PTX_Hccost   (27) Was there a time in the past 12 months when you needed to see a doctor but could not because of cost?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

227   P3_PTX_OOPE   (28) When you went to see _____ (mention provider,   clinic or facility name) when you were diagnosed with gonorrhea, did you need to pay anything out-of-pocket at the time of your visit?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

228   P3_PTX_SYMP   (28.1) Before you went to see _____ (mention provider, clinic or facility name) when you were diagnosed with gonorrhea, did you have any unusual discharge or oozing from your (penis/vagina)?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

229   P3_PTX_SYMP   (28.2) Before you went to see _____ (mention provider, clinic or facility name) did you notice any unexplained sores or bumps on your (penis/vagina)?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes

2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused
4=Refused

230   P3_PTX_SYMP   (28.3) Before you went to see _____ (mention provider, clinic or facility name) when you were diagnosed with gonorrhea, did you have any pain or burning when you urinated?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused
4=Refused

231   P3_PTX_SYMP   (289) Did you go to the doctor that time because you were having symptoms or pains you thought might be from an STD

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused
4=Refused

232   P3_PTX_Delay   (30) How long did you have these symptoms or pains before you were able to see the doctor?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=1 Day
2=2 - 6 Days
3=1 - 2 weeks
4=More than 2 weeks
5=Don't know / Not sure / Don't remember
6=Refused

233   P3_PTX_ExpSTD   (31) Before you went to the doctor that time, did any of your sex   partners tell you that you might have been exposed to an STD?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

234   P3_PTX_reasA   (32) Reason for going to specific doctor: regular doctor: Because this is your usual/regular doctor.

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

235   P3_PTX_reasB   (33) Reason for going to doctor: Because you could get seen for free?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

236   P3_PTX_reasC   (34) Reason for going to doctor: Because they take your insurance?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

237   P3_PTX_reasD   (35) Reason for going to specific doctor: Because you felt more comfortable about your privacy there?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

238   P3_PTX_reasE   (36) Reason for going to specific doctor: Because you could get seen right away?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

| 239 | **P3_PTX_reasF** | (37) Reason for going to specific doctor: Because you wanted to see an expert specializing in STDs. |

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

| 240 | **P3_PTX_reasI** | (38) Reason for going to specific doctor: Because this doctor is close to your house and easy to get to. |

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

| 241 | **P3_PTX_reasG** | (39) Reason for going to specific doctor: Because you were embarrassed and didn't want to go to your regular doctor. |

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

| 242 | **P3_PTX_reasH** | (40) Reason for going to specific doctor: Because I didn't want the insurance papers/info sent to my home/parents. |

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

| 243 | **P3_PTX_reasJ** | (41) Reason for going to specific doctor: Any other reason? |

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

| 244 | **P3_PTX_othReasonText** | (42) Other reason text. |

245   P3_PTX_refusreason   (43) Refused all reasons

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

246   P3_PTX_PartnerTest   (44) Did the doctor, nurse or anyone else during that visit talk to you about the importance of getting your sex partners examined and tested for STDs?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

247   P3_PTX_TellParts   (45) In the time since your visit, did you tell any of your sex partners they may need to tested or treated for STDs?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

248   P3_PTX_EPToffer   (46) Did a doctor, nurse or someone at the health department offer to give you medications or a prescription for you to give to any of your sex partner(s)?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

249   P3_PTX_EPTWHO   (47) Who was it that offered you the additional medications or prescriptions? Was it someone from your doctor's office or someone from the health department?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=My doctor's office
2=The health department
3=Someone else
4=Don't know / Not sure
5=Refused

250   P3_PTX_EPTGET   (48) Did you actually get the additional medications or prescriptions for your sex partners?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

251   P3_PTX_EPTMEDORRX   (49) Did you get medicine to give to your partner? Or did you get prescriptions that your partners needed to have filled at a pharmacy?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=I got additional medications
2=I got prescription(s)
3=Don't know / Not sure

252   P3_PTX_EPTGAVE   (50) Did you give the additional medications or prescriptions to at least one of your sex partners?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
9=Refused

253   P3_PTX_HIVtested   (52) Did you get tested for HIV at that visit?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

3=Don't Know /Don't Remember/ Not Sure
4=Refused

254   **P3_PTX_HIVresult**   (53) What was the result of your HIV test at that visit?
This data element should not be 'null' or contain missing values if P3_PTX_HIVtested=1.

1=Positive
2=Negative
3=Don't Know / Not Sure / did not get results
4=Refused

255   **P3_PTX_everHIVtst**   (54) Have you ever been tested for HIV?
May be 'Null' if P3_PTX_HIVtested=1. This data element should not be 'null' or contain missing values for cases responding with 2, 3 or 4 to P3_PTX_HIVtested.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

256   **P3_PTX_whenHIVtest**   (55) When was your last HIV test? Just month and year is ok? (IF PATIENT UNABLE TO RECALL, PROBE UNTIL APPROXIMATE RESPONSE ELICITED)
This should be character data "MM/YYYY", missing/REFUSED information as"../YYYY" or   "../…."

257   **P3_PTX_HIVeverResult** (56) What was the result of that HIV test?
This data element should not be 'null' or contain missing values for cases responding to P3_PTX_everHIVtst=1.

1=Positive
2=Negative
3=Don't Know / Not Sure / did not get results
4=Refused

258   **P3_PTX_inHIVcare**   (57) When was your most recent visit to a doctor, nurse or other health
This data element should not be 'null' or contain missing values for   cases identifying as HIV positive (P3_PTX_HIVResult=1 or P3_PTX_HIVeverResult=1). This should be   entered as character data "MM/YYYY", missing/REFUSED information   as"../YYYY" or "../…."

259   **P3_PTX_ART**   (58) Are you taking antiretroviral medicines to treat your HIV infection?

This data element should not be 'null' or contain missing values for   cases identifying as HIV positive (P3_PTX_HIVResult=1 or P3_PTX_HIVeverResult=1). This should be   entered as character data "MM/YYYY", missing/REFUSED information   as"../YYYY" or "../...."

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

260   P3_PTX_PrEP

(58.1) When you were diagnosed with gonorrhea, did your health care provider or anyone else discuss medications to help you prevent getting HIV? This is often called PrEP, or pre-exposure prophylaxis.

This data element should be 'null' for patients reporting being HIV positive. This data element should not be 'null' or contain missing values for patients identifying as HIV negative or unknown HIV status.

1=Yes
2=No
3= Don't know / Not sure
4=Refused

261   P3_PTX_PREP1

(58.2) Did your health care provider offer to prescribe or give you medications to help you prevent getting HIV?
This data element should not be 'null' or contain missing values if patient reports PrEP.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

262   P3_PTX_PREP2

(58.3) Did you fill a prescription or get medications to help you prevent getting HIV?

This data element should not be 'null' or contain missing values for those answering "Yes" to P3_PTX_PrEP.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

263   **P3_PTX_PREP3**   (58.4) Are you currently taking daily medications to help you prevent getting HIV (on PrEP)?
This data element should not be 'null' or contain missing values.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

264   **P3_PTX_Pregnant**   (59) Were you pregnant at the time you were told that you had gonorrhea?

This data element should not be 'null' or contain missing value for female cases interviewed. May be null for partial interviews, must be   null for male cases.

1=Yes
2=No
3=Don't Know /Don't Remember/ Not Sure
4=Refused

265   **P3_PTX_GenderSP**   (60) During the past 12 months, have you had sex with only males, only
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo) = '1', partial interview.

1=Males only
2=Females only
3=Both Males and Females
4=Unknown
9=refused

266   **P3_PTX_Sxorient**   (61) Do you consider yourself to be…
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo) = '1', partial interview.

1=Heterosexual/Straight
2=Gay/Lesbian/Homosexual
3=Bisexual
4=Other
9=Refused

267   **P3_PTX_MaleSPL3MO**   (62) Thinking back to the 3 months before you were diagnosed with

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview. Probe for approximate response or 'best' guess. Enter 0 to indicate 'None', 9999 to indicate "Refused".

268   P3_PTX_FemaleSPL3MO   (63) Thinking back to the 3 months before you were diagnosed with

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview. May be 'Null' if P3_IDX_Dispo = '1', partial interview. Probe for approximate response or 'best' guess. Enter 0 to indicate 'None', 9999 to indicate "Refused".

269   P3_PTX_SPtreatOne   (63.1) To the best of your knowledge, was your sex partner treated?

This data element is for patient reporting only a single sex partner.

1=Yes, definitely
2=Yes, probably
3=Don't Know / Not Sure
4=No, probably not
5=Refused
6=No need/no partners infected

270   P3_PTX_SPtreatMult   (63.2) To the best of your knowledge, would you say that all of your sex partners were definitely treated, at least one of your partners was definitely treated, or that none were treated?

This data element is for patients reporting multiple sex partners.

1=All definitely treated
2=At least one definitely treated
3=At least one probably treated
4=Not sure
5=Probably none treated
6=Refused
7=No need/no partners infected

271   P3_PTX_SexExch   (64) During the past 12 months, have you given drugs or money in exchange for sex or received drugs or money in exchange for sex? By sex we mean vaginal, oral, or anal sex.

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=Yes
2=No

3=Don't Know /Don't Remember/ Not Sure
4=Refused

| 272 | P3_PTX_LastSex | (64.1) In the past year, how often have you used prescription pain medications? |

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=Never
2=Once or Twice
3=Monthly
4=Weekly
5=Daily or Almost Daily
9=Refused

| 273 | P3_PTX_LastSex | (65) When was the last time you had sex? |

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=In last week
2=> 1 week but within last month
3=> 1 month, but within 2 months
4=> 2 months ago
5=Don't Know / Not sure
9=Refused

| 274 | P3_PTX_GenderMRSP | (66) Thinking back to the last time you had sex, was the person you had sex with…(male/female)? |

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=Male
2=Female
3=Male-to-Female TG
4=Female-to-Male TG
5=TG Unknown or Unspecified
9=Unknown

| 275 | P3_PTX_AgeMRSP | (67) Thinking back to the last person you had sex with, how old do you think that person is? If you don't know for sure, it's OK to make your   best guess. |

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

276   P3_PTX_HISPMRSP   (68) Would you say that person is Hispanic/Latino/a? If you don't know for sure, it's OK to make your best guess.

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=Yes, Hispanic
2=No, Not Hispanic
8=Unknown/Can't guess
9=Refused

277   P3_PTX_RaceMRSP   (69) Thinking back to the last person you had sex with, what race(s) would you say that person is? If you don't know for sure, it's OK to make your best guess.

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=White
2=Black
3=AI/AN
4=ASIAN
5=NH/OPI
7=Other race
8=Unknown/Can't guess
9=Refused

278   P3_PTX_MRSPHIV   (70) Thinking back to the last person you had sex with, do you know if that person HIV positive?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=Yes, I know that person is HIV positive
2=No, I know that person is HIV negative
3=Don't Know /Don't Remember/ Not Sure
4=Refused

279   P3_PTX_SexAgainMRSP   (71) Thinking back to the last person you had sex with; do you think you will have sex with this person again?

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=Yes
2=No

3=Don't Know /Maybe/ Not Sure
4=Refused

280 **P3_PTX_GEOMRSP** (72) Thinking back to the last person you had sex with, about how far away does that person live from you. If you don't know for sure, it's OK   to make your best guess.

This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

0=Partner lives with me
1=less than 5 minutes
2=5 to 15 minutes
3=15 to 30 minutes
4=30 minutes to 1 hour
5=> 1 hour
6=They live in another state
7=They live in another country
8=Don't know / Not sure
9=Refused

281 **P3_PTX_DIS_EPT** (73) Did the interviewer/DIS provide EPT/PDPT to patient?
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=Yes
2=No

282 **P3_PTX_DIS_EPTnum** (74) Number of partners EPT provided for
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

283 **P3_PTX_DIS_OtherPS** (75) Did interviewer/DIS provide other partner services to patient (DIS referral?)
This data element should not be 'null' or contain missing values for interviewed cases. May be 'Null' if P3_IDX_Dispo = '1', partial interview.

1=Yes
2=No

4g: Strategy B – STD Laboratory Observation Dataset

Data Element Name	Description/Response Coding
Laboratory Observation Dataset	

284 **P1_L1_EventID** Unique identifier for associated surveillance record

Will be a primary key for merging lab and case data; should correspond to P1_EventID. This data element MUST NOT be 'null' or contain missing values.

285 **P1_L1_LabID** Unique identifier for laboratory performing testing

Site assigned; may be ID from other system or specifically created for SSuN. If performing lab is not known, site should still create a lab record with a locally defined ID corresponding to unknown lab that they will use throughout the SSuN data collection period. This data element should not be 'null' or contain missing values.

286 **P1_L1_Accession** Unique identifier (accession number) for laboratory record

Leave blank (null) if not available/ascertained

287 **P1_L1_PatientID** Unique identifier for person (allowing longitudinal tracking of persons)

Will be a secondary key for merging lab and case data; should correspond to P1_PatientID. This data element MUST NOT be 'null' or contain missing values.

288 **P1_L1_CondTested** specific condition/pathogen tested

This data element MUST NOT be 'null' or contain missing values.

1=Syphilis
2=Gonorrhea
3=Chlamydia
4=Genital Herpes
5=Trichomoniasis
6=HIV
7=Hep A
8=Hep B
9=Hep C
10=BV
11=Other

289 **P1_L1_SpecColDte** Specimen collection date - this is often used as a proxy for diagnosis

This data element should not be 'null' or contain missing values. This should be coded as a 'SAS' numeric date.

290   P1_L1_LabRepDte   This is the date that the performing lab reported the results to the

This should be coded as a 'SAS' numeric date.

291   P1_L1_SecType   Type of specimen

This data element should not be 'null' or contain missing values.

1=Exudate
2=Blood/sera
3=Synovial fluid
4=Urine
5=CSF
6=Tissue
7=Saliva
8=Other
9=Unknown

292   P1_L1_AnatSite   This is the anatomic site from which the specimen was obtained and is important in determining the anatomic site of infection.

This data element should not be 'null' or contain missing values.

1=Urethra
2=Vagina/cervix
3=Urine
4=Rectum
5=Pharynx
6=Eye
7=Sera/Blood
8=Joint
9=Other Anatomic Site
10=Unknown Anatomic Site

293   P1_L1_TestType   As test technology advances, it is important to obtain the type of test performed

This data element should not be 'null' or contain missing values.

1=Culture,
2=NAAT
3=Non-amplified nucleic acid test/DNA probe
4=Gram Stain
5=DFA
6=Rapid HIV
7=ELISA

8=Western blot
9=Pooled RNA
10=RPR
11=VDRL
12=FTA
13=TP-PA
14=MHA
15=Wet Mount/Clue Cell
16=PH
17=Other
18=Unknown
19=HIV Viral Load (ultra quantitative)
20=HIV Viral Load (quantitative)
21=CD4+ assay

294   **P1_L1_QualRes**   Qualitative result: For most pathogens/tests, positive, negative,
This data element should not be 'null' or contain missing values.

1=Positive
2=Negative
3=Reactive
4=Weakly Reactive
5=Non-Reactive
6=Equivocal/Indeterminate
7=Specimen Inadequate/Contaminated
8=Other
9=Unknown

295   **P1_L1_Quantres**   Numeric - or Ratio (for RPR/VDRL, e.g. 1:2, 1:4, etc.)

296   **P1_L1_QuantUnits**   Units for quantitative results:
1=Copies/mL
2=Log Copies/mL
3=Cells/Cubic mm
4=CD4%
5=Titer Ratio
6=Cycles/Time (rtPCR)

4h: Strategy B – Provider Reference Dataset

Data Element Name	Description/Response Coding
Provider Reference Dataset	

2987 P4_ProvID Unique identifier for provider/facility
This data element MUST NOT be 'null' or contain missing values.

298 P4_ProvName Name of provider or facility

299 P4_ProvCO FIPS code for provider/facility physical location

300 P4_ProvZIP Facility/provider physical location 5-digit ZIP
This data element should not be 'null' or contain missing values.

301 P4_UpdateDate Date provider information last updated/verified
This data element should not be 'null' or contain missing values. This

302 P4_LocationLon Provider physical location longitude

303 P4_LocationLat Provider physical location latitude

304 P4_CensusTract Census tract of provider physical location

305 P4_Prov_Fac_Type Facility or provider type code (PHINVAD compatible)
This data element MUST NOT be 'null' or contain missing values.

1=Blood Bank
Includes for-profit sera collection centers
2=Correctional Facilities
Includes jails, prisons, juvenile detention, etc.
3=Day care center (environment)
4=Dentist
5=Drug Treatment Facility
6=Emergency Room/Emergency Department
Include HMO/other urgent care in this category
7=Family Planning Facility
Includes reproductive health clinics
8=Other Federal Agencies
Do not include bureau of prisons in this category (should be 2,
9=HIV Care Facility
Includes and care facility whose primary service is HIV care
10=HIV Counseling and Testing Site

Include HIV outreach & street testing in this category
11=Hospital - Not ED/ER
This should include in-patient facilities where the patient was
12=Labor and Delivery
13=Laboratory
14=Managed Care/HMOs
15=Mental Health Provider
16=Military
17=National Job Training Program
18=Other, not otherwise specified
19=Other Health Department Clinic
Do not include health department clinics whose primary
20=Other State and Local Agencies
21=Other Treatment Center
22=Pharmacy
23=Prenatal/Obstetrics Facility
24=Private physicians' group office
25=Public Health Clinic
Include ONLY public clinics not otherwise categorized
26=Data/Disease Registries
27=Rural Health Clinic
Includes clinics specifically designated as RHCs on the Centers
28=Categorical STD Clinic
29=School-Based Clinic
30=TB Clinic
31=Tribal Government Clinic
Do not include IHS hospitals (those are coded as 32)
32=Indian Health Service
33=Veterinary Sources
34=Vital Statistics
99=unknown

306   P4_ProvCHC   Is facility/provider a Community Health Center (CHC)?
This data element should not be 'null' or contain missing values.

1=Yes
2=No
3=Unknown/Missing

307   P4_ProvFQHC   Is facility/provider a Federally Qualified Health Center (FQHC)?
This data element should not be 'null' or contain missing values.

1=Yes

2=No
3=Unknown/Missing

308	**P_Unassigned1**	Unassigned variable (TBD)
309	**P_Unassigned2**	Unassigned variable (TBD)
310	**P_Unassigned3**	Unassigned variable (TBD)
311	**P_Unassigned4**	Unassigned variable (TBD)
312	**P_Unassigned5**	Unassigned variable (TBD)
313	**P_Unassigned6**	Unassigned variable (TBD)