Attachment 3A

Enhanced STD Surveillance Network (eSSuN)

Protocol and Project Implementation Guide

December 2014

Table of Contents **Page Number**

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Introduction - Background

Disease surveillance is the systematic, ongoing collection of data, observation and monitoring of the spread and occurrence of diseases and infectious agents to answer fundamental questions of epidemiologic importance such as the characteristics of persons and groups affected, increase or decrease in cases and infections over time and geographic extent of affected populations. The primary purpose of these activities is to provide information necessary for preventing or limiting the harm to individuals and populations from diseases and illness. A foundational activity in modern disease surveillance is case reporting by clinicians, laboratories and healthcare facilities, which ideally provides basic information on all persons diagnosed with diseases and infections of public health interest. In the United States, this information is generally reported by providers directly to state and local public health agencies.

Case-level data are voluntarily reported to CDC by states, territories and independently funded county and/or city health departments through a framework called the National Notifiable Disease Surveillance System. These data are the primary source for reporting, analysis and interpretation of trends in the incidence, prevalence and societal impact of chlamydial infection, gonorrhea and syphilis in the United States and U.S. Territories. A limited core set of patient demographics is required for national case reporting including sex, age, race, Hispanic ethnicity, and county of residence. Behavioral information, such as the gender and number of sex partners, are important to understanding the changing epidemiology of STDs but these data are not routinely collected. CDC's ability to interpret trends in reported case incidence, assess inequalities in the burden of disease by population characteristics and to respond to issues such as co-morbidities and decreasing antibiotic susceptibility is therefore partly contingent on data supplied through supplemental sentinel and enhanced surveillance activities.

National case reporting data for STDs lack completeness with respect to critical patient demographics and are of narrow scope with respect to risk behavior, provider and clinical information, treatment and partner characteristics. Moreover, case data only provide information on the numerator of interest and are not optimal for estimating population prevalence of common STDs. Supplemental surveillance data are needed to refine estimates of the burden of STDs, including incidence and prevalence among at-risk and vulnerable populations, better monitor STD prevention program impact and STD-related care seeking behaviors.

The STD Surveillance Network (SSuN) was established in 2005 (Cycle 1) to create an ongoing network of collaborating health departments with the capacity to implement a wide variety of surveillance activities, the flexibility to modify activities over time as trends dictated, and the ability to use surveillance data to guide programmatic action.

SSuN Cycle 2 (2008 – 2013) expanded the network to include a greater number of collaborating health departments and further strengthened the human capacity and IT infrastructure. Activities in Cycle II 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.

The current cycle (Cycle III, SSuN 2013 - 2018) continues to address these issues through enhanced and sentinel STD surveillance activities in specific populations (population component) and in expanded

healthcare facilities (STD Clinics and Family Planning/Reproductive Health settings) serving populations at risk for STDs. These activities constitute Part A of SSuN and are the core activities of the network; this document outlines protocols and methods for implementing these enhanced and sentinel surveillance activities.

Additional information on SSuN may be obtained by contacting the Project Officers:

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SSuN Cycle III Funded Jurisdictions

The following 10 state, county and/or city health departments successfully competed for funding under CDC-RFA-PS13-1306, Enhanced STD Surveillance Network and were subsequently awarded funding under five-year cooperative agreements for Part A activities.

Part A – Sentinel and enhanced surveillance:

Baltimore City Health Department (Award#1H25PS004259-01)

California Department of Public Health (Award#1H25PS004244-01 Revised)

Florida Department of Health (Award#1H25PS004261-01)

Massachusetts Department of Public Health (Award#1H25PS004253-01 Revised)

Minnesota Department of Health (Award#1H25PS004255-01)

Multnomah County Health Department (Award#1H25PS004256-01)

New York City Department of Health & Mental Hygiene (Award#1H25PS004247-01 Revised)

Philadelphia Department of Public Health (Award#1H25PS004248-01 Revised)

San Francisco Department of Public Health (Award#1H25PS004258-01 Revised)

Washington State Department of Health (Award#1H25PS004271-01)

(An additional grantee, Utah Department of Health, was awarded funding for Part B activities not covered under this protocol)

Section 1

Part A Core Protocols:

Funded Site Responsibilities

CDC Responsibilities

Memorandum of Agreement

Enhanced Case-Based Population Surveillance (Gonorrhea)

Sentinel Facility Surveillance (Facility Component)

SSuN Part A – Funded Site Responsibilities

Jurisdictions receiving funding under PS13-1306 are required to participate in the planning, implementation, maintenance and evaluation of specific sentinel and enhanced activities as requirements of their cooperative agreement award.

- Awardees will assure sufficient human and technical resources dedicated to SSuN coordination, data collection, data management, data quality assurance, analysis, interpretation, and dissemination of data and findings from enhanced case-based and sentinel surveillance and monitoring activities.
- Awardees will assure timely and prompt data transmissions of all required datasets to CDC following collaboratively developed SSuN protocols.
- Awardees will participate in regularly scheduled conference calls, virtual meetings and annual face-to-face awardees meetings as required for developing or revising protocols, developing best practices, reporting progress toward meeting SSuN objectives, presenting preliminary data and describing status of ongoing activities.
- Awardees will assure that information systems necessary for the collection, management, integration, analysis, and transmission of SSuN datasets to CDC are available and will be modified as needed to appropriately collect, manage and transmit SSuN-related data.
- Awardees will assure that data management methods and information systems implemented in support of these activities are designed to provide efficient, sustainable, routine and automated processes to limit staff burden and minimize the effect of unanticipated staffing changes.
- Awardees will provide meaningful funding resources and/or technical assistance to facilities or agencies providing data as necessary to assure ongoing extraction, appropriate transformation, transmission, validation, quality assurance and data management of all required data. Meaningful resources may include direct assistance through staff time and/or financial support to the data-providing entity through sub-contract.
- Where significant information in the SSuN data supply chain depend on external resources (local health departments, other agency administrative units, commercial and/or non-profit healthcare entities, etc.), awardees will obtain letters of support (LOS) from these entities demonstrating specific commitment to providing SSuN data in compliance with collaboratively developed protocols.
- Awardees will work collaboratively with CDC and other funded project areas to standardize protocols and data elements for SSuN activities of national importance.
- Awardees will use findings from their SSuN activities to improve and enhance existing core STD (or STD/HIV, if integrated) surveillance in their jurisdictions. Wherever practical, awardees should incorporate efficiencies achieved in the course of SSuN implementation, with respect to data systems and electronic lab/case data, into routine surveillance practice.
- Awardees will collaborate with CDC subject matter experts on multi-site analyses of Enhanced SSuN data, development of presentations and manuscripts for publication. Such collaboration includes awardees proposing analyses and acting as lead author (where interest and expertise permit), co-authoring and/or approving use of data for multi-site analyses. Awardees and CDC collaborators will explicitly acknowledge SSuN funding for all multi and/or single site presentations and publications which include substantial analyses based on data collected in whole or in part with Enhanced SSuN project funding.
- In recognition of the expertise, STD surveillance capacity and specific experience of SSuN collaborators, awardees may occasionally be called upon to provide broader consultation to DSTDP and CDC on surveillance or other emergent issues.
- Awardees will provide required signatures on the SSuN Memorandum of Agreement (Appendix 1) within the first SSuN funding year.
- Awardees will ensure that all program activities adhere to the security and confidentiality guidelines as outlined in 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"* (http://www.cdc.gov/hiv/resources/guidelines/security_confidentiality_hiv.htm.)

Awardees will provide annual evidence of concurrence with SSuN activities by their jurisdiction's Overall Responsible Party (ORP).

Enhanced Case-Based Population Surveillance Activities

- Awardee's STD surveillance or supplemental data systems will support, or be modified to support random sampling of reported cases of gonorrhea in a timely manner following date of diagnosis and report to the health department (e.g. weekly or at time of initial data entry into surveillance system).
- Sampling methods will support the ability to modify sample fractions as needed to assure a representative probability sample of all cases reported in their jurisdictions and to maximize response/investigation completion rates. Awardees must complete a minimum of 250 enhanced case investigations, including provider and patient interview components, annually if gonorrhea morbidity (the initial target of the network's enhanced case-based component) is less than or equal to 10,000 cases annually, otherwise the number of completed investigations should equal or exceed 2.5% of all reported cases.
- Awardees will work collaboratively with CDC and other funded project areas to standardize sampling methods, protocols and data elements for enhanced surveillance activities.
- Enhanced surveillance case investigations, including health department records searches, clinical variables of interest obtained from providers and patient interviews and for a representative sample of STD cases will be implemented in compliance with collaboratively developed SSuN protocols. Awardees will assure maintenance and continuation of these activities as required by SSuN protocols.
- Documentation of HIV status is required at a minimum for sampled cases, including date of last HIV test (if known) for HIV-negative cases. Awardees will verify HIV-positive status using their jurisdiction's eHARS registry and document that this verification has been done.
- All gonorrhea cases will be geocoded to the US Census 2010 census tract level.
- Awardees will embed patient demographics, diagnosing facility type and geographic data on all reported gonorrhea cases in SSuN datasets, including those not sampled for enhanced investigations.
- Awardees will assure that unique patient and provider identifiers are available, providing for longitudinal monitoring of multiple disease episodes for persons and for calculating provider-level burden of disease.

Facility-Based and other Sentinel Surveillance Activities

- Awardees will make every effort to obtain required visit-level clinical, diagnosis, treatment and laboratory data for all patients attending at least one (1) categorical STD clinic in their jurisdiction, in compliance with these protocols.
- Awardees will obtain required visit-level clinical, diagnosis, treatment and laboratory data for all females over 14 and less than 45 years of age at the time of clinic visit from Family Planning/Reproductive health clinic(s) in compliance with these protocols.
- Awardees will assure that unique patient identifiers, at the facility level, are available to provide for longitudinal monitoring of multiple visits by unique patients within each facility. Unique identifiers across facilities are strongly encouraged wherever possible.

SSuN Part A – CDC Responsibilities

Collaborators in the Enhanced STD Surveillance Network are funded through a Cooperative Agreement rather than a grant mechanism in recognition of the substantial involvement of the funding agency 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 CDC collaborators includes:

- Coordination of development of methods and protocols for SSuN activities.
- Facilitation of routine SSuN communications.
- Coordination of routine conference calls and annual collaboration meetings to review and plan program activities.
- Provision of technical assistance facilitating secure electronic transmission of data.
- Provision of technical assistance with SAS licensure and SAS coding.
- Monitoring of grantee progress toward achieving SSuN objectives, including grantee implementation of data quality assurance processes.
- Management of SSuN data warehouse or other central data store to support data provisioning for collaborative analyses.
- Provision of guidance and technical assistance (where requested or identified by CDC) essential to implementation of activities in compliance with these protocol.
- Ensuring that analyses and dissemination of findings from SSuN surveillance activities are conducted collaboratively by both CDC and appropriate participating sites.
- Providing laboratory services for supplemental surveillance projects.
- Facilitating discussions with awardees to identify emerging trends/issues in STDs/HIV and sexual health, STD surveillance technologies and methods and other issues that merit further investigation by the Enhanced STD Surveillance Network.
- Coordinating the development, dissemination and approval of proposals for SSuN analytic projects
- Assisting co-authors and lead authors in the development of manuscripts.
- Facilitating CDC clearance for manuscripts and presentations based on SSuN findings.
- Working with awardees to assure that SSuN activities, at both the awardee and CDC level, adhere to NHHSTP data security and confidentiality guidelines.

SSuN Part A – Memorandum of Agreement

Enhanced STD Surveillance Network sites will review and sign a Memorandum of Agreement (MOA) between the participating site and CDC (Appendix 1). The purpose of this agreement is to provide a framework governing the sharing and release of STD surveillance data collected, stored and transmitted to CDC as part of the Enhanced STD Surveillance Network activities.

Confidentiality

All SSuN participating sites are public health departments, not 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). Data sent to CDC will contain no personal identifiers such as name, social security number, date of birth, street address, or medical record number.

Human Subjects Protections

The Associate Director for Science (ADS) of the NCHHSTP, CDC, will review all final SSuN protocols. A Determination of Non-Research will be sought for SSuN Cycle III activities and, if approved, SSuN will be exempted from CDC Institutional Review Board (IRB) review because the project activities constitute surveillance, a disease control activity, and not research. No incentives are provided to participants or clinic personnel for SSuN activities. Collaborating health departments should assess their local needs for similar determinations.

Uses of SSuN Part A Data

Local collaborators retain 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. Any proposed use of multi-site data will be discussed with the SSuN Project Officers and Principal Collaborators of sites whose data are requested. CDC encourages sites to inform CDC and other SSuN collaborators of site-specific analyses of SSuN-related data in order to promote and stimulate use of data. Multi-site analyses are encouraged wherever collaboration is both feasible and the results of multi-site analyses can be of greater or different public health value than a site-specific analysis. Site-specific SSuN data maintained by CDC will be shared with non-CDC personnel for analysis only with documented permission from the site's Principal Collaborator. Guidelines for analysis of SSuN data are outlined below.

I. Analysis and Reporting of Multi-site Data:

The following guidelines apply to analyses using multi-site data generated as part of SSuN, including 1) proposed analyses, 2) public presentations, or 3) manuscripts to be submitted for publication.

1. **Authorship:**

    1. In general, the first author will be the individual who took the most responsibility for that specific analysis, based on genesis of the idea, conduct of analysis, and the actual writing of the manuscript. Ordering of authors (and number of authors per site) should be based on active and substantive participation in analysis and preparation of the manuscript.

    2. In developing manuscripts for submission to peer-reviewed journals/publications, primary author will offer collaborating sites contributing data the opportunity to identify co-authors. Where no restrictions limit the number of co-authors exist, all sites are encouraged to identify specific individuals to be listed as co-authors and to participate actively in manuscript development. In cases where there are limitations on the number of co-authors, sites electing only minimal involvement in analysis and manuscript development should identify an individual for formal inclusion as co-author under a "SSuN Working Group" designation. Enhanced STD Surveillance Network Working Group designations are ad hoc and may be comprised of different site representatives as need for each manuscript/abstract developed for publication.

    3. Sites may also choose to be omitted from the co-author list entirely, in which case the principal collaborator will be formally acknowledged (along with their agency) as contributing data. A formal request for sites to identify co-authors for analyses/manuscripts and abstracts, including preliminary tables or analyses, will be transmitted to sites with the proposal and should select from the following authorship categories:

        1. Lead (will be the lead on analysis, initial drafting of manuscripts)
        2. Primary (will take an active role in analysis/reviewing/editing)
        3. Contributing (can be listed in workgroup if there are restrictions on number of authors)
        4. Acknowledgement only (acknowledgement for use of data in body of the manuscript is sufficient)

        Collaborators are asked to respond promptly to such requests; non-response under normal circumstances of several weeks or more will be construed as actively declining co-authorship and granting tacit approval for inclusion of site's data, with the understanding that explicit acknowledgement for use of data will be included in any presentations or manuscripts.

    4. Authors are encouraged to include both individual contributing authors, and the SSuN Project as co-authors (e.g., author[1], author[2],.. author[15], SSuN Project Group). Published reports for which the SSuN Working Group is listed as an author (or in the title) will include mention of each Principal Collaborator and agency by name either in the author line, as a footnote, or as an acknowledgement.

5. Authors are encouraged to include Associate Collaborators in acknowledgements.

2. **Review:** Principal Collaborators will review all proposed multi-site projects, abstracts, and papers generated from multi-site data.

   A. For **proposed analysis projects**, each Principal Collaborator will be notified of proposed analyses using the recommended project proposal format (TBD), and all Principal Collaborators must be provided an opportunity to comment.

   B. At the discretion of SSuN Project Officers, exploratory analysis of multi-site data stored at CDC can be conducted, including sharing data internally with CDC-sponsored fellows or Epidemic Intelligence Service officers, in consultation with collaborators to assist in development of analytic proposals.

   C. Site collaborators should give feedback to the proposing author and the CDC Project Officer (or designee) about whether a proposed multi-site project is or is not an appropriate and acceptable use of their site's data within a reasonable amount of time.

   D. If a project is considered not appropriate or unacceptable by one or more collaborating site, the project will be discussed on a conference call and consensus regarding initiation of that analysis or project will be reached.

   E. Any Principal Collaborator of a site may elect to exclude their data from the proposed analysis.

   F. A site's data will not be shared externally and NOT be included in final analysis until the proposing author has received consent for the proposed activity from that site's Principal Collaborator(s).

   G. Request for submission of an abstract for oral or poster presentation at a relevant conference based on a new analysis proposal should be made in a timely manner, whenever possible, before the abstract deadline and should include a copy of the call for abstracts for the proposed conference. In some circumstances, timelines may need to be shortened due to circumstances beyond the control of Project Officers (CDC or local clearance requirements, etc.).

   H. **Abstracts/presentations** and **manuscripts** generated from the multi-site data should be submitted to all authors and Principal Collaborators for review prior to submission for CDC clearance.

      1. The first author should specify a deadline for the receipt of comments, and it will be the responsibility of secondary authors and Principal Collaborators (or their designees) to provide comments by that deadline.
      2. Non-response by the deadline will be assumed to signify approval of the draft.
      3. A reasonable time for review is at least 4 days for abstracts and 2 weeks for manuscripts.

3. **Clearance:** Abstracts/ presentations and manuscripts using data collected through SSuN or including a CDC co-author, must be submitted for CDC clearance prior to submission for review by conference organizers, journals, etc. CDC clearance involves review by the Division of STD Prevention (DSTDP) and other CDC authorities to ensure that all products are of the highest quality and are scientifically sound, technically accurate, and useful to the intended audience.

   Clearance also ensures compatibility of information with CDC recommendations, so that if findings have implications for changing recommendations or policies, the appropriate CDC personnel are made aware of these changes. Cross-clearance of a product may also be required if a topic is the responsibility of another Division or Center at CDC. Authors should be considerate of the need for local and CDC clearance requirements.

   A. Abstracts should be submitted to the Project Officer for CDC clearance a minimum of four weeks prior to the submission deadline, unless other arrangements are made in advance. For some large conferences (e.g., STD Prevention Conference, ISSTDR, International HIV/AIDS Conference), the Division or Center will specify an earlier clearance deadline, and this should be taken into consideration.

   B. Before CDC clearance can be initiated, CDC requires documentation of approval by all co-authors. Co-authors are asked to be sensitive to the time requirements for clearance and to respond to such requests promptly.

   C. Publication of a manuscript in a journal requires CDC clearance of that manuscript, even if an abstract was previously cleared.

   D. Authors should be aware that CDC clearance for journal articles may take a month or more.

   E. Authors should be aware that products that are not high quality, scientifically sound, technically accurate, and useful to the intended audience may not be cleared by CDC. Authors should also expect to receive requests for revisions or clarifications during the clearance process.

   F. The first author of an abstract or manuscript should provide all authors with a final edited copy of the abstract or manuscript as submitted for review by conference organizers, journals, etc., with the date and place of submission noted.

   G. After publication, the first author should provide all co-authors with a copy of the published version of the abstract or manuscript, as well as copies of slides and texts for presented papers.

4. **Additional guidelines:**

   A. Principal and Associate SSuN Collaborators will be given first opportunity to conduct analyses using collaborative data. However, individuals (e.g., EIS Officers, fellows, students) *may* be allowed to conduct analyses and write abstracts/papers using collaborative data if 1) sponsored by CDC Project Officer, a Principal or Associate Collaborator, and 2) the proposed

project is accepted by the Principal Collaborators prior to submission of an abstract.

B. In order to facilitate communication, the SSuN Project Officer (or designee) will maintain a list of SSuN proposed activities, presentations, and publications, and ensure that this list is available to all Principal Collaborators.

C. The SSuN Project Officer may present SSuN data within CDC without prior approval by SSuN Principal Collaborators. These data will not be disseminated externally without prior approval by SSuN Principal Collaborators. The SSuN Project Officer will request prior approval by SSuN Principal Collaborators for publications or formal presentations outside CDC. A copy of any internal or external presentation or publication by the SSuN Project Officer will be distributed to all SSuN Principal and Associate Collaborators.

D. Enhanced STD Surveillance Network Principal and Associate Collaborators may present informal analyses of SSuN data locally or internally within their agency without prior approval from the Principal Collaborators. These data should not be disseminated further without prior approval by SSuN Principal Collaborators. SSuN should be acknowledged on all slides presenting SSuN data, and a copy of the presentation should be shared with all SSuN Principal and Associate Collaborators. Prior approval must be obtained for any local presentation resulting in a published abstract, or any presentation involving significant or controversial findings.

E. All public presentations or publications using SSuN data should acknowledge the SSuN Project and CDC. For example: "This activity was funded by the Division of STD Prevention, CDC, through the Enhanced STD Surveillance Network (SSuN, CDC-RFA-PS13-1306)."

F. Concerns about use or misuse of data should be brought to the attention of the SSuN Project Officer and/or the Principal Collaborators immediately.

II. Analysis and Reporting of Site-Specific Data:

The following guidelines apply to analyses using site-specific (single site) data generated as part of SSuN, including 1) proposed analyses, 2) public presentations, or 3) manuscripts to be submitted for publication.

A. Site-specific analyses are appropriate when an individual site (or sites) has collected data that are unique to that site, or are addressing a question particularly pertinent to that site.

B. Use of SSuN local data by the respective local Principal Collaborators may be conducted at any time without review by SSuN as a whole.

C. In general, the first author should be the individual who took the most responsibility for that specific report, based on genesis of idea, conduct of analysis, and the actual writing of the paper.

D. If applicable, the SSuN Project (or other Principal Collaborators) should be recognized as co-authors if data used in the analysis were conducted on site-specific data collected

specifically for transmission to CDC for SSuN-funded activities.

E. The nature of the recognition should be based on the degree to which other sites, collaborators *or* SSuN *funding* contributed to collection of the data used in the analysis.

F. All authors should have the opportunity to review any reports on which they are listed prior to their presentation or publication.

G. Any report with CDC staff or the SSuN Project Group as a co-author should go through CDC clearance (see above).

H. Presentations (local or otherwise) based on data collected using SSuN funding should acknowledge CDC support for data collection activities and cite the SSuN Funding Announcement Number (CDC-RFA-PS13-1306).

SSuN Part A – Enhanced Case-based Population Surveillance (Gonorrhea)

Cycle 3 of SSuN builds on previous experience in enhanced population surveillance in Cycle 1 and 2, and focuses on persons being diagnosed and reported to funded health departments with infections due to *Neisseria gonorrhoeae* (GC). Data collection activities address the following surveillance objectives relative to patient, provider, laboratory and surveillance system characteristics. Funded jurisdictions will use SSuN resources to enhance completeness of information for all reported cases of gonorrhea, but at a minimum will obtain complete information for a probability sample of cases, allowing for accurate estimation of case characteristics in the domains described below.

Enhanced Case-based Population Surveillance Objectives

Domain1: Case/Patient demographics and insurance characteristics

The following characteristics of cases/patients are often missing or not otherwise available in NETSS data streams.

1. **Objective:** Monitor the distribution of reported gonorrhea cases by demographic characteristics

   a. Race

   b. Hispanic ethnicity

   c. Sex (including transgender)

   d. Age

   Rationale: Race and Hispanic ethnicity are missing for ~20% of cases reported through NETSS. Complete ascertainment among a random sample of cases will allow for assessment of potential bias in reporting of race and ethnicity by other factors such as provider type or region, which may have implications for how inequalities in disease burden are determined and presented nationally. Misclassification of race may also be explored by comparing the patient self-reported race with that in the case/laboratory data reported by providers.

   Sources of Information: internal health department records, including laboratory data and patient report.

2. **Objective:** Monitor the distribution of reported gonorrhea cases by specific geography (census tract).

   Rationale: the lowest level of geography available in NETSS is Zip Code, which limits potential geospatial analysis. Census data are available on a broad range of social, economic and demographic factors at the census tract level that are not routinely available at the Zip Code level. Homeless and incarcerated populations are also of interest; information on the housing status and

incarceration are not available from any other source for persons diagnosed and reported with gonorrhea.

Sources of Information: Internal health department records, including laboratory data, and patient report. Geocoded street address information matched to 2010 US Census Tracts should be supplemented with information from provider (Phase 2) and patient (Phase 3) investigations where necessary to assure accuracy.

3. **Objective:** Monitor the proportion of reported gonorrhea cases are enrolled in/covered by/accessing health insurance:

   a. Individual insurance

   b. employer-provided insurance

   c. Medicaid / Medicare or other public-pool insurance

   Rationale: Health insurance coverage may be a significant factor affecting care seeking behavior and decisions. Changes in the proportion of patients covered by insurance may also be useful in assessing the impact of Affordable Care Act on STD prevention and care services. Meta data about state-level expansion of Medicaid and other public pool insurance will also be collected to assess differences between SSuN sites.

   Sources of Information: Patient and provider report (Phase 2 & 3) investigations.

4. **Objective:** Monitor the proportion of reported gonorrhea cases paying any immediate out-of-pocket expense at visit where initially diagnosed with GC.

   Rationale: The Affordable Care Act may change the way preventive services such as STD screenings are paid for. Information on the proportion of patients paying out-of-pocket expenses for routine preventive screening that should be covered without any co-pay or out of pocket expenses should be monitored over time to assess cost as a potential barrier to STD screening and integration of STD services into primary care. Some patients may choose to pay rather than use insurance for privacy or other reasons; this may be important to determine for planning safety-net services.

   Sources of Information: Patient report (Phase 3) investigations

Domain 2: Case/Patient behavioral characteristics

Analyses of behavioral characteristics is severely handicapped by a lack of enhanced (interview) NETSS data for gonorrhea cases, in 2010, 81.6% of all cases reported through NETSS were missing any enhanced behavioral data.

5. **Objective:** Monitor the proportion of male gonorrhea cases reporting male sex partners (MSM).

Rationale: The proportion of males reporting MSM behavior is important to the epidemiology of gonorrhea and allows for analyses addressing inequality in the burden of disease among MSM, a population of relevance to HIV infection as well.

Sources of Information: Patient investigation (Phase 3)

6. **Objective**: Monitor characteristics of period (3 months) and most recent sex partner(s) among reported gonorrhea cases.

   Rationale: The characteristics of recent sex partners are largely unknown for the majority of reported gonorrhea cases. This information is useful for enhancing understanding of sexual network dynamics and for modeling gonorrhea transmission.

   Sources of Information: Phase 3 investigations, possible overall # of partners question for provider investigation to determine if sexual history was taken.

7. **Objective:** Monitor the distribution of GC infection by anatomic site.

   Rationale: Knowledge of infected anatomic sites is important to assessing the burden of disease and to the epidemiology of GC. These data can also help assess the appropriateness of provider screening practices.

   Sources of Information: Phase 1 (laboratory data), and Phase 2 investigations

Domain 3: Facility type, clinical care and care-seeking characteristics

While provider type (INFOSRCE) is reasonably complete (13% missing) in NETSS, the provider type coding may not be as useful as desirable in light of changes in insurance coverage and the healthcare delivery system anticipated with the ACA. Moreover, the reasons why people seek care at specific facilities versus others is not well understood. Information about the clinical services provided to the patient (testing, screening, treatment, partner services, etc.) may be useful in assuring quality of care. These data will be ascertained both from providers and/or patients as appropriate.

8. **Objective:** Monitor the proportion of cases being diagnosed and reported by facility type:

   Rationale: Knowledge of provider status as FQHC or CHC and primary care versus other specialty care is currently unknown for gonorrhea cases being diagnosed in the community. Clinics designated as FQHC, and those providers classified as CHC are important as expanded primary care providers for newly insured populations under the ACA.

   Sources of Information: Phase 1 and Phase 2 investigations

9. **Objective:** Monitor the proportion of cases that are treated with appropriate/recommended antimicrobials.

   Rationale: Treatment data are currently unknown for the majority of gonorrhea cases being diagnosed and reported. These data are important for assessing provider compliance with CDC

recommendations and may be useful for interpreting susceptibility data from other sources (GISP). Partial funding for SSuN was received from the Office of Antimicrobial Resistance (OAR) and this activity is required of all Part A grantees.

Sources of Information: Phase 1 and Phase 2 investigations.

10. **Objective:** Monitor the proportion of gonorrhea cases presenting with signs/symptoms of GC infection as documented by self-report and duration of symptoms from onset to care seeking.

    Rationale: The proportion of reported cases that are symptomatic may change over time and could indicate whether screening is becoming more or less universal. Delay in care seeking after symptom onset may differ by insurance status, gender, age, etc. and indicate gap in safety net services.

    Sources of Information: Phase 2 and Phase 3 investigations

11. **Objective:** Monitor the primary reason(s) for care-seeking at visit where GC was diagnosed

    Rationale: Reason for healthcare visit is integral to understanding under what circumstances patients seek care and the extent to which STD care is integrated into primary care.

    Sources of Information: Phase 3 investigations

    Specific Data Elements: patient reported reason for visit (all that apply approach?), recent contact to STD (elicited).

12. **Objective:** Monitor the primary reason(s) for choosing the specific provider where GC was diagnosed

    a. is provider the patient's medical home/primary care provider for all other medical needs?

    Rationale: These data will help assess the degree of integration of STD services into primary health care settings and the future need for safety-net categorical STD care facilities.

    Sources of Information: Phase 3 investigation

13. **Objective:** Monitoring the pregnancy status of reported female gonorrhea cases:

    a. Pregnancy status at time of GC dx

    Rationale: These data will help assess the degree of integration of STD services into reproductive health care settings and the future need for categorical STD care facilities.

    Sources of Information: Phase 3 investigation

Domain 4: Partner services & HIV co-morbidity

14. **Objective:** Monitor the proportion of reported gonorrhea cases that are offered and accept partner services:

a. Patient referral

b. Provider referral

c. EPT (meds or Rx for partner)

Rationale: Partner services are a primary programmatic activity to reduce the likelihood of re-infection and interrupt the chain of transmission in the community. These data will also allow for the evaluation of specific interventions such as EPT.

Sources of Information: Phase 2 & Phase 3 investigations

15. **Objective:** Monitor the proportion of reported gonorrhea cases (not previously known to be HIV positive) that have been tested for HIV in previous year and at time of gonorrhea diagnosis?

    Rationale: HIV testing is critical to identifying new HIV cases; persons who know their status may be less likely to engage in ongoing risk.

    Sources of Information: Phase 1, Phase 2 and Phase 3

16. **Objective:** Monitor the proportion of reported gonorrhea cases that are HIV positive and proportion of HIV positive in HIV care/on ART:

    a. HIV status documented through HIV-surveillance match?

        i. Date of earliest HIV-positive test

    b. In HIV care by self-report?

    c. On ART?

    Rationale: HIV co-infection among persons diagnosed with gonorrhea is not well documented at the population level. GC diagnoses among HIV-positive persons indicate ongoing sexual exposure risk and a significant burden of disease among a vulnerable population. Engagement with HIV primary care and HIV treatment is important to assessing population risk

    Sources of Information: Phase 1, Phase 2 and Phase 3

Domain 5: Surveillance system evaluation

17. **Objective:** Monitor the proportion of reported gonorrhea case notifications to the health department that:

    a. originate with ELR

    b. originate as provider reports

    c. are duplicates of previously reported cases

i. time interval from most recent 'duplicate' report

d. are for patients previously reported with prior episodes of disease

i. GC

ii. Syphilis

iii. CT

iv. HIV

e. reported from out of jurisdiction

Rationale: These data are critical for monitoring/assuring the quality, completeness and representativeness of gonorrhea surveillance. These data support creation and maintenance of 'STD Surveillance Centers of Excellence' by providing system evaluation information.

Sources of Information: Phase 1 investigations

18. **Objective:** Monitor the median time elapsed between diagnosis (specimen collection date if available or earliest provider report of case) and receipt of notification by the health department/entry into surveillance system.

Rationale: These data are essential for monitoring/assuring the quality of STD surveillance.

Sources of Information: Phase 1 investigation

Specific Data Elements: date of report, date of specimen collection, date of provider diagnosis, date of laboratory report.

Domain 6: Population denominators and other useful metadata

19. **Objective:** Monitor the completeness of NETSS/STD MMG records for all cases in jurisdiction.

Rationale: These data are essential to calculating appropriate case weights for SSuN population data and developing estimates representative of the universe of reported cases.

Sources of Information: Internal, CSELS

20. **Objective:** Obtain census data for the jurisdiction (population, ACS, etc.).

Rationale: These data are useful for analyzing social determinants of GC incidence, calculating rates and other ecologic analyses.

Sources of Information: External

PART A Population Component – Methods

A. Generating Random Samples

A random sample of all reports of gonorrhea received by collaborating health departments will be obtained. Gonorrhea 'reports' will be locally defined to include provider case reports, laboratory reporting or any other original source documents as appropriate given the specific surveillance infrastructure in the funded jurisdictions. Although sampling methodologies will likely vary across jurisdictions, several criteria will be adhered to with respect to the quality of the random sample:

A. The sampling 'universe' will include ALL cases of laboratory confirmed gonorrhea diagnosed and reported from ALL public and private sources for patients residing within the geographic boundaries of the collaborating jurisdiction.
B. Records should be individually sampled at the time they are received into the system (or batched in a timely manner) such that all gonorrhea records meeting the criteria based on information contained in the report (patient resident in jurisdiction, laboratory/provider confirmed diagnosis of gonorrhea) have an equal probability of being sampled. Records sampled should be referred or assigned for enhanced investigation in the shortest practical timeframe. Sample may be stratified by county or other useful geography as needed to balance work-load within collaborating jurisdictions but no stratification based on patient sex, age, race, Hispanic ethnicity or provider characteristics should be applied.
C. If the sample is obtained through a batch process, the sampled records must be identified in a timely fashion so that at a maximum, with no more than 15 calendar days elapsing between receipt of the record at the health department, inclusion in a sample frame and subsequent referral for enhanced investigation.
D. The overall sample fraction must be adjustable (by the entire site or by specific geographic strata as locally appropriate) in order to assure that a sufficient volume of records are included in the random sample to result in enough completed case investigations to fulfil stated project objectives.
E. Funded jurisdictions will conduct routine and frequent quality assurance activities to assess the representativeness of their sample, with particular attention to equal probability of sampling by patient characteristics (race, Hispanic ethnicity, gender, age geographic region within jurisdictions and source of report).
F. Funded jurisdiction will assure that appropriate data are available on ALL reported cases to calculate valid stratification and non-response weights for their sampled cases.

B. Internal Case Investigation (Phase 1)

At a minimum, sampled records 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 HIV infection and to document any recent history of STDs. Previous GC, CT, Syphilis, viral hepatitis and TB diagnoses occurring within 365 days of the specimen collection date/diagnosis date of current GC diagnosis should be documented and included in the SSuN record. It should also be

determined at this time whether the record represents a 'duplicate record' (defined as a GC diagnosis within 21 days of the specimen collection date/diagnosis date of a previously reported record for the same anatomic site); this should also be documented and similarly included in the SSuN record. For duplicate cases/records, previous report date and specimen collection date (used to determine duplicate status) should be documented.

All laboratory data associated with the patient and specific episode of disease/infection should be obtained and documented for SSuN with provisions for multiple tests across multiple anatomic sites. Wherever available, negative laboratory results should also be included in the SSuN dataset to demonstrate screening practices. Laboratory data obtained in Phase 1 investigations will be managed as a relational table, with a one-to-many relationship between primary case records and laboratory results. Results and status of all Phase 1 investigation should be documented with an appropriate disposition code.

All SSuN population records should be assigned a phase 1 investigation disposition regardless of sampled status and appropriate Phase 1 disposition codes used to indicate cases not actively followed-up on. Jurisdictions are encouraged to complete phase 1 investigations on all incoming records including those not in the random sample.

Criteria for referral to phase 2 investigations will include:

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

C. Provider Investigation (Phase 2)

For phase 2 investigations, the diagnosing provider is contacted to provide additional information about the case's clinical characteristics, the specific care setting and demographics of the patient not present in the original case or laboratory report. These investigations can be 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. Phase 2 also represents an opportunity for funded jurisdictions to obtain contact information necessary for completing Phase 3 investigations if this information is missing from initial laboratory or case reports. Funded jurisdiction must institute quality assurance and follow-up procedures to assure the highest possible completion rate for Phase 2 investigations, including tracking investigation status and periodic re-contact to assure provider completion.

Criteria for referral to phase 3 investigations (patient interview) will include:

- Record represents case of confirmed gonorrhea and is not a duplicate of a previously reported case
- Patient determined to reside within jurisdiction at the time of diagnosis

- Initial case report or notification was received by health department within 60 days of the diagnosis (or specimen collection) date

D. Patient/Case Investigation (Phase 3)

Patient-level investigations/interviews may be conducted either by phone or in-person with *at least* 3 documented attempts to contact each patient referred for Phase 3 investigations. Sites are required to develop local protocol documents and data collection instruments (paper and/or electronic) for investigators, required to provide adequate training to investigators conducting patient contact and to address local human subject's requirements.

All reasonable attempts must be made to obtain contact information for cases eligible for Phase 3 investigations. Methods for obtaining contact information for patients may include vital record searches, registry searches, provider contact, social media (following local conventions), driver's license and/or vehicle registration registries if available.

Funded jurisdictions may also find it productive to integrate SSuN data collection into local partner management and treatment assurance protocols; this is appropriate as long as SSuN-related data elements are collected in a manner consistent with SSuN questions and coding conventions.

E. Data Management

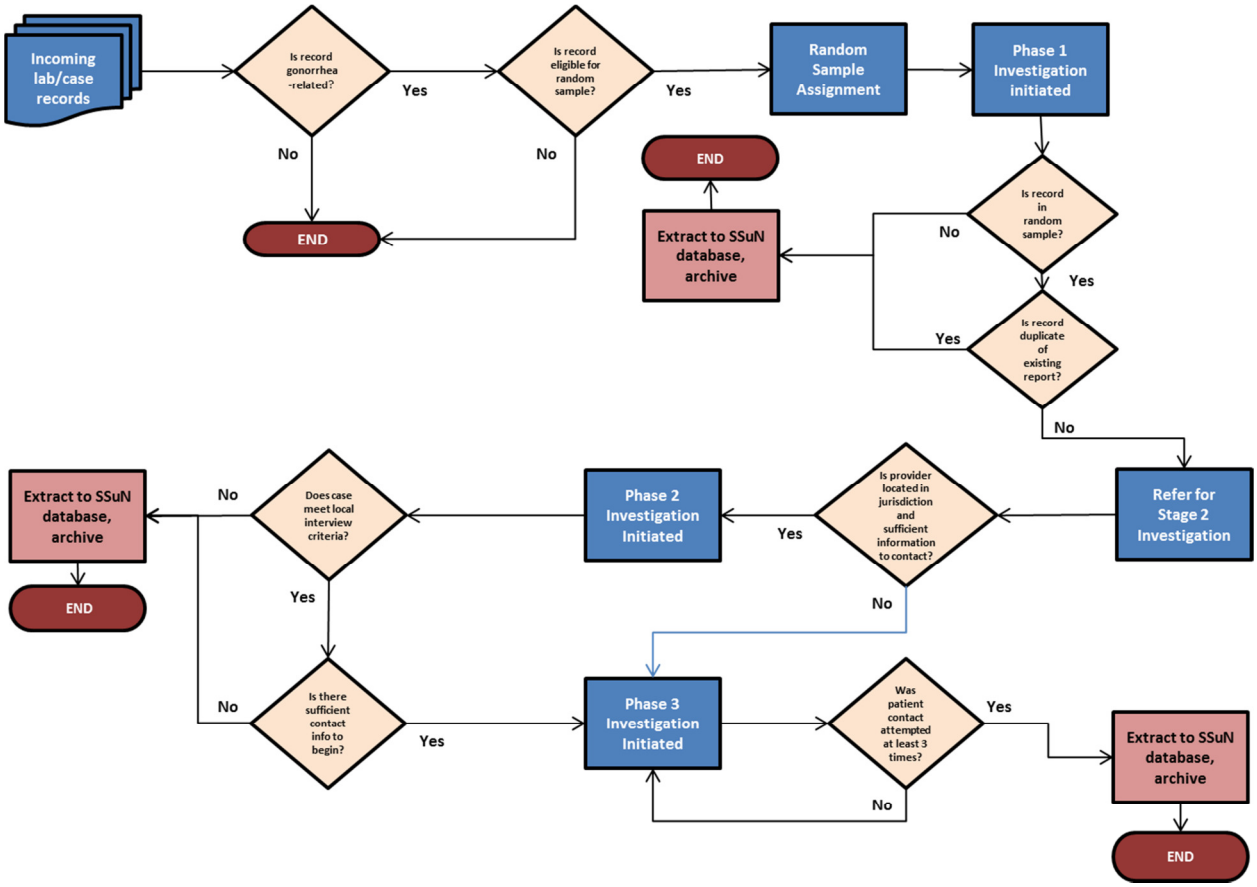
Data obtained for the population component will come from numerous sources within the health department and will need to be locally merged, recoded and appropriately structured to facilitate merging into the national SSuN datasets. Funded jurisdictions are expected to institute rigorous procedures to assure the quality and validity of data elements (Appendix 2) 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 (e.g. 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 appropriate quality assurance. Jurisdictions will apply these validation checks and fix the offending 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 before transmission to fix historical errors that recur because of the cumulative data process.

Jurisdictions will provide clean, validated datasets to CDC on a monthly basis, alternating facility and population component datasets such that each component is updated with new data every two months with cumulative data back to the beginning of each calendar year. A final, validated annual dataset will be transmitted each year 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 1: Suggested Site-Level Record Process Flow for Population Component of Enhanced SSuN Part A



F. Transmission of Data to CDC

Required datasets will be securely transmitted to CDC each month, on the 15th of the month, with complete data though the last day of the preceding month. When the 15th falls on a holiday or weekend, datasets will be due the first business day following the holiday.

Record-level data will only be transmitted to CDC following the Secure Access Management Service (SAMS) protocols. Sites may also be required to encrypt data using at least 128-bit RSA-compliant strong key-pair encryption (such as PGP).

CDC will formally acknowledge all data transmissions and data 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 whenever possible.

G. Data Management at CDC

CDC will formally acknowledge data transmission with a return e-mail. 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 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, the on-time status of all transmissions and summary process measures such as the number/proportion of cases with matching laboratory records, the random sample fraction, the completed phase 1 – 3 investigations and other information as determined by consensus.

SSuN PART A – Facility Component

Cycle 3 of SSuN will build on previous experience in enhanced facility-based surveillance in Cycle 1 and 2, and will focus on capturing information on STD-related clinical and prevention services across a broad range of practice settings, including STD and family planning and reproductive healthcare clinics. Data collection activities will address the following surveillance objectives relative to trends in infections and sequelae as well as compliance with screening guidelines, treatment recommendations and use of appropriate diagnostic technologies not available at the national level from any source. Monitoring and surveillance activities in selected clinical settings in diverse geographic areas can provide key insights into shifting patterns of STD care delivery, patient access and the social determinants of STDs.

Facility-based Surveillance Objectives

Domain1: Trends in infections and sequelae

1. **Objective:** Monitor positivity trends in lab-confirmed chlamydia and gonorrhea infection by patient demographics, behavioral and clinical characteristics, and/or facility characteristics.

   ***Rationale*:** Chlamydia and gonorrhea are usually asymptomatic and trends in case report data are influenced by screening coverage and changes in population tested. Additionally, behavioral and clinical characteristics of cases are not routinely collected.

   Target population:

   Family planning clinics**:** females of reproductive age (15-44 years);
   STD clinics**:** all clinic attendees

   Data elements required: patient id, event id, facility id, date of visit, gender, age, race/ethnicity, gender of sex partner(s), facility characteristics (available from facility reference file), tested (chlamydia, gonorrhea); lab result; anatomic site of test; diagnostic test type; reason for visit

   Additional data elements of interest (in addition to required variables): risk behaviors; pregnancy status; contraceptive use; co-morbid STD diagnoses; self-reported STD history; symptoms

2. **Objective:** Monitor positivity trends in HIV by patient demographics, behavioral and clinical characteristics, and facility characteristics.

   Rationale: Understanding the proportion of HIV cases that are identified in safety net clinics (e.g., STD and/or family planning clinics) can provide an opportunity to target public health interventions and provide important information on high risk population sub groups. In addition, persons who know their status may be less likely to engage in ongoing risk and prevent further transmission.

   Target population:

   Family planning clinics: females of reproductive age (15-44 years);
   STD clinics: all clinic attendees

   Data elements required: patient id, event id, facility id, date of visit, gender, age, race/ethnicity, gender of sex partner(s), facility characteristics (available from facility reference file), tested for HIV; laboratory result; HIV status

Additional data elements of interest: **(in addition to required variables):** reason for visit; risk behaviors; pregnancy status; co-morbid STD diagnoses; self-reported STD history

3. **Objective:** Evaluate NAAT test of cure (TOC) at 7 days following treatment for potential treatment failures as outlined by current STD treatment guidelines

   Rationale: Gonorrhea differs from most other bacterial sexually transmitted diseases (STDs) because of its formidable ability to develop antibiotic resistance, which limits the options for effective treatment and control of the disease. Current CDC guidelines recommend dual therapy for uncomplicated gonorrhea (ceftriaxone plus azithromycin or doxycycline as first-line therapy) at all anatomic sites. If a therapy other than ceftriaxone is used, a TOC is recommended at 7 days post-treatment. TOC may allow clinicians to rapidly detect patients for whom treatments were ineffective and may provide active public health surveillance for resistant gonococcal infections.

   Target population:

   STD clinic attendees with laboratory-confirmed GC

   Data elements required: patientid, eventid, facility_id, visdate, gender, age, race/ethnicity, gender of sex partner(s), facility characteristics (available from facility reference file), lab result for gonorrhea; anatomic site of test; diagnostic test type; risk behaviors; treatment; assessment of risk exposure and symptoms at initial and return visit.

4. **Objective:** Monitor trends in pelvic inflammatory disease (PID) by patient demographics, behavioral and clinical characteristics, and facility characteristics.

   Rationale: PID is not a nationally notifiable disease and sentinel surveillance is necessary to monitor trends and to increase understanding of the epidemiology of PID.

   Target population:

   Family planning clinics: females of reproductive age (15-44 years)
   STD clinics: all female clinic attendees

   Data elements required: patientid, eventid, facility_id, visdate, gender, age, race/ethnicity, gender of sex partner(s), facility characteristics (available from facility reference file), PID diagnosis; physical exam signs (adnexal tenderness; cervical motion tenderness, etc.)

   Additional data elements of interest: reason for visit; risk behaviors; pelvic exam; prior PID history; contraceptive use; pregnancy status; co-morbid STD diagnoses results; self-reported STD history; symptoms

5. **Objective:** Monitor trends in HIV-STD co-infection by patient demographics, behavioral and clinical characteristics, and facility characteristics.

   Rationale: HIV/STD co-infection cannot be assessed at the national level through exact match methods. The heavy burden of co-infection with HIV disease and then a STD is indicative of continued high risk behavior. Understanding both the incidence of STDs among persons known to be infected with HIV and the incidence of co-diagnosis can help inform and evaluate prevention interventions.

   Target population:

Family planning clinics: females of reproductive age (15-44 years);
STD clinics: all clinic attendees

Data elements required: patientid, eventid, facility_id, visdate, gender, age, race/ethnicity, gender of sex partner(s), facility characteristics (available from facility reference file), laboratory result for HIV, gonorrhea, chlamydia; other STD diagnoses; prior testing history and current HIV status

Additional data elements of interest: reason for visit; risk behaviors and exposure; pregnancy status; self-reported STD history.

6. **Objective:** Monitor etiologic trends in STD-related conditions such as non-gonococcal urethritis (NGU), PID or other non-pathogen specific diagnoses in categorical STD clinics through supplemental laboratory analysis.

   Rationale: Numerous pathogens have been isolated from men and women with STD-related conditions such as NGU, PID and cervicitis. Little is known about the prevalence of non-reportable genital-tract bacterial infections in patients presenting for care in categorical STD clinics. Moreover, the extent of co-infection with multiple pathogens is unknown for persons diagnosed with chlamydia, gonorrhea and other reportable STDs. The susceptibility of these co-occurring pathogens to commonly used antibiotics is unknown.

   Data elements required: No additional patient-level data elements are needed.

   Additional data elements of interest: Specimen ID (if biologic samples are analyzed at CDC).

Domain2: Trends in preventive healthcare services

1. **Objective:** Monitor adherence to STD/HIV screening and re-screening recommendations (screening and rescreening recommendations listed in Appendix 3).

   ***Rationale*:** Monitoring adherence to screening and re-screening recommendations can help inform and evaluate interventions. Currently the CDC recommends:

   - annual chlamydia screening for young women and older women at increased risk
   - gonorrhea screening for all persons at increased risk
   - annual HIV tests
   - annual syphilis and chlamydia/gonorrhea screening at exposed sited (MSM).
   - Re-screening at 3 months for persons diagnosed with chlamydia or gonorrhea

   Target population:

   Family planning clinics**:** females of reproductive age (15-44 years);
   STD clinics**:** all clinic attendees

   Data elements required: patientid, eventid, facility_id, visdate, gender, age, race/ethnicity, gender of sex partner(s), facility characteristics (available from facility reference file), tested chlamydia, gonorrhea, HIV; lab result; HIV status; anatomic site of exposure for MSM; risk behaviors

   Additional data elements of interest (in addition to required variables): reason for visit; pregnancy status; self-reported STD history

2. **Objective:** Monitor trends in appropriate treatment of diagnosed STDs

   Rationale: Treatment information is not routinely reported for most STDs and little is known about the prevalence of presumptive treatment. Understanding appropriate treatment of identified infections and sequelae can evaluate implementation of the treatment guidelines and identify areas for intervention.

   Target population:

   Family planning clinics: females of reproductive age (15-44 years);
   STD clinics: all clinic attendees

   Data elements required: patientid, eventid, facility_id, visdate, gender, age, race/ethnicity, gender of sex partner(s), facility characteristics (available from facility reference file), laboratory result for chlamydia, gonorrhea, and PID other STD diagnoses, medications prescribed on visit

   Additional data elements of interest: pregnancy status

3. **Objective:** Monitor changes in patient clinic population, including demographic in light of ACA and integration of STDs in primary care

   Rationale: In the face of a changing funding and policy landscape, it remains to be seen whether publicly funded providers will continue to be used as providers of choice for many clients with health-care coverage and remain a "safety net" for uninsured persons in need of family planning and STD services. Tracking such trends to monitor the demand for FP and STD services in SSuN clinics may help inform budget planning and resource allocation.

   Target population:

   Family planning clinics: females of reproductive age (15-44 years) ;
   STD clinics: all clinic attendees

   Data elements required: patientid, eventid, facility_id, visdate, gender, age, race/ethnicity, gender of sex partner(s), facility characteristics (available from facility reference file), and insurance status

4. **Objective:** Monitor trends in partner treatment for STDs

   Rationale: To ensure patients are not re-infected, partner management services is necessary (including traditional partner management, EPT, provider referral) . Monitoring whether patients received partner treatment can inform implementation of the preventive services and identify areas for intervention.

   Target population:

   Family planning clinics: females of reproductive age (15-44 years) ;
   STD clinics: all clinic attendees

   Data elements required patientid, eventid, facility_id, visdate, gender, age, race/ethnicity, gender of sex partner(s), facility characteristics (available from facility reference file), lab result (chlamydia, gonorrhea); medications prescribed on visit; provision of partner treatment

PART A Facility Component – Methods

A. Clinic selection

STD clinic: Each SSuN site has identified at least one (1) categorical STD clinic in their jurisdiction in which to conduct enhanced STD surveillance. Where multiple categorical STD clinics exist, awardees considered the following priorities for inclusion: (1) those with highest patient volume, greatest representation from at-risk populations, and reporting a meaningful proportion of gonorrhea and syphilis diagnosed in their jurisdiction, (2) clinics serving most representative population of MSM and young people relative to other clinic options, (3) clinics serving racial and ethnic minorities, and, (4) clinics with stable funding streams (billing infrastructure, university/medical school support, etc.) to maximize likelihood that selected facilities remain operational throughout the project period. Inclusion of multiple STD clinics where cost efficient, quality surveillance data can be obtained is highly desirable. Selected STD clinics are expected to maintain line-listed data on all patients and all visits in an electronic format that allows for extraction of de-identified data for inclusion in the warehouse and analysis.

Family planning and reproductive health clinic: Each SSuN site has identified one or more FP/RH clinics providing family planning and/or reproductive health (FP/RH) services to 15 – 44 year old females. Inclusion of multiple clinics where cost efficient, quality surveillance data can be obtained is highly desirable. FP/RH clinics proposed for inclusion must be representative of the highest risk population(s), serve at least 2,000 females 15 – 24 years old annually and have current chlamydial infection/gonorrhea screening coverage of 70% or greater among that population. Selected FP/RH clinics are expected to maintain line-listed data on all female patients age 15-44 and all visits in an electronic format that allows for extraction of de-identified data for inclusion in the warehouse and analysis.

B. Facility data collection

Visit-level clinical, diagnosis, treatment and laboratory data should be from all clinic attendees either at the time of registration or during the clinic encounter and documented in the clinic electronic medical record. Such data is necessary for STD program monitoring and implementation, much of which is currently routinely collected by the participating clinics. Unique patient identifiers (at the facility level) must be available in all facility-based data collection and management systems to provide for longitudinal monitoring of multiple visits by unique patients within each facility providing data for SSuN activities. This unique patient identifier must be submitted as part of each visit record. Unique identifiers applicable across facilities are also strongly encouraged wherever possible. Sites will develop and maintain information management systems sufficiently robust to provide for archival, query-based data retrieval and comprehensive quality assurance on clinical visit and laboratory data extracted from, or submitted by, all participating facilities. Required data elements (Appendix 2) will be collaboratively defined by SSuN Collaborators and transmitted to CDC on all facility clinic patient visits on a TBD basis. These data elements may be modified by SSuN Collaborators over time in response to changing objectives. The actual data collection instruments will be designed locally to conform to local clinic data collection needs. Sites are encouraged to update data collection instruments on a regular basis.

Information on each participating clinic will be provided to CDC annually in a facility reference file. Each facility will be given a unique facility ID. These facility IDs will be included in the visit-level dataset so that patient-level data can be linked to facility data. Required facility-level characteristics reported will be collaboratively defined by SSuN Collaborators. These data elements may be modified by SSuN Collaborators over time in response to changing objectives.

C. Data Management

Data obtained for the facility-based components will come from numerous sources and will need to be locally merged, recoded and appropriately structured prior to submission to CDC. Funded jurisdictions are also expected to institute rigorous procedures to assure the quality and validity of data before submitting 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 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 (e.g. 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 appropriate quality assurance. Jurisdictions will apply these validation checks and fix the offending records prior to transmission. In cases where errors are repeatedly introduced from underlying, primary data sources, an exception file should be maintained locally and applied before transmission to fix historical errors that recur because of the cumulative data process.

Jurisdictions will provide clean, validated datasets to CDC (transmission frequency to TBD), with cumulative data back to the beginning of each calendar year. The final, validated annual dataset will be archived and become the primary repository of that site's annual reporting and should be preserved at the local level as 'frozen' data for local analytic purposes.

Datasets required for the facility component include four files:

1. Clinic table (Clinic_SITE_MMDDYY.SAS)
2. Related laboratory table (ClinicLAB_SITE_MMDDYY.SAS)
3. Related diagnosis table(ClinicDX_SITE_MMDDYY.SAS)
4. Related treatment table (ClinicTX_SITE_MMDDYY.SAS)
5. Annual facility reference file (ClinicREF_SITE_MMDDYY.SAS)

D. Transmission of Data to CDC

Required clinic and population 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 population data and then on April 15th, sites would send the clinic data, on May 15th the population data, etc. Data should be complete through the last day of the preceding 2

months. When the 15th falls on a holiday or weekend, datasets will be due the first business day following the holiday.

Record-level data will only be transmitted to CDC following SAMS protocols. Sites may also be required to encrypt data using at least 128-bit RSA-compliant strong key-pair encryption (such as PGP).

CDC will formally acknowledge all data transmissions and the 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 whenever possible.

E. Data Management at CDC

CDC will formally acknowledge data transmission with a return e-mail. Datasets failing to comply with pre-determined data structures will be rejected, with e-mail notification. Sites must re-format, recode or resolve issues and retransmit corrected datasets within 5 working days.

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. Summary process measures will also be provided and may include:

Facility component:

- the proportion of laboratory records without a corresponding clinic record
- What proportion of unique eventIDs are duplicative
- The proportion of observations which have missing data of key variables (e.g., missing sex of sex partner for male patients)

Appendix 1: Memorandum of Agreement

Memorandum of Agreement for

Analysis of Enhanced STD Surveillance Network (SSuN) Surveillance Data between

The Division of STD Prevention,

National Center for STD, Viral Hepatitis, STD and TB Prevention

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 sharing and release of STD surveillance data collected as part of the Enhanced STD Surveillance Network activities.

BACKGROUND & OBJECTIVES

The Enhanced STD Surveillance Network (hereafter, SSuN) is comprised of state/local and/or city health departments funded by cooperative agreement (CDC-PS13-1306) 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 collection, reporting, analysis, visualization (e.g., mapping) and interpretation of disease information. Data are sent by funded jurisdictions following prescribed protocols to CDC and merged into a national dataset that can be used by Principal Collaborators and CDC subject matter experts for analysis as provided for in SSuN protocols. This memorandum of agreement is intended to explicitly demonstrate concurrence between funded sites and CDC with SSuN procedures and guidelines allowing the use of data collected and contributed by Enhanced SSuN collaborating sites.

STORAGE OF SSuN DATA

The health department identified above agrees to send to CDC de-identified datasets with data elements (Appendix 2) specified in SSuN protocols on all persons reported with gonorrhoea, all visits to collaborating STD clinics, other collaborating speciality clinics, and females 15 – 44 years of age seen in collaborating family planning/reproductive health clinics.

Sites will send SSuN data through SAMS using specified encryption methods and biologic specimens (if required for supplemental projects) 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 the 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.

Enhanced 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 Enhanced SSuN data as long as the data are protected as described herein. CDC will annually review the need for the data with Enhanced 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 of analyses of data collected specifically 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.

All analyses and dissemination of SSuN multi-site data collected during the project period in the form of peer and non-peer reviewed manuscripts, technical reports, manuals, and presentations require the written approval of CDC and every SSuN site that has contributed data for that analysis. All publications with a CDC author must be cleared through DSTDP/NCHHSTP/CDC clearance.

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:

I have read and agree to follow the stipulations in the Memorandum of Agreement for collection, transmission to CDC and analysis of Enhanced STD Surveillance Network (SSuN) Surveillance data.

_____

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

_____

Eloisa Llata, MD MPH Date
Project Officer – Enhanced 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

_____

Mark Stenger, MA Date
Project Officer – Enhanced 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

_____

Health Department Enhanced SSuN Principal Collaborator Date
Title:
Health Department:

Appendix 2: Enhanced SSuN Data Dictionary

This appendix provides guidance on coding selected data elements and defines response coding to assure uniformity of interpretation and provide standard definitions for code sets.

Population Component – Phase 1 – Case Report and Internal Health Department Investigation

1 P1_SiteID — SSuN Site ID

This 2 character code primarily identifies sites funded under SSuN Cycle 3 and may include additional sites as required throughout the grant period.

BA=Baltimore
CA=California
FL=Florida
MA=Massachusetts
MN=Minnesota
MC=Multnomah County
NY=New York City
PH=Philadelphia
SF=San Francisco
WA=Washington

Supplemental codes – for historical data only:
VA=Virginia (Cycle II)
AL=Alabama (Cycle II)
CO=Colorado (Cycle II)
CH=Chicago (Cycle II)
This data element cannot be 'null' or contain missing values.

2 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 cannot be 'null' or contain missing values.

3 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 cannot be 'null' or contain missing values.

4	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.***
5	P1_RandSamp	Is this record/case selected in the random sample? ***This data element cannot be 'null' or contain missing values.*** 0=Not in random sample 1=In random sample
6	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 cannot be 'null' or contain missing values.***
7	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 cannot 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
8	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 cannot 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

9	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
10	P1_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 cannot be 'null' or contain missing values.*** 1=Yes 2=No
11	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 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 cannot be 'null' or contain missing values.*** 1=Matching Record Found 2=No Matching Record 3=Match Not Performed
12	P1_HDXMOYR	What is this patient's earliest indication of HIV positive result? ***This information can be obtained from the eHARS person table (HIVPMOYR).***
13	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.***

14 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

15 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 by #13 & 14 above, what was the initial diagnosis indicated by that record? Should be 'Null' if no previous diagnosis is confirmed.

10311=Syphilis, primary
10312=Syphilis, secondary
10313=Syphilis, early latent
10315=Syphilis, unknown latent
10314=Syphilis, late latent
10318=Syphilis, late with symptoms
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

16 P1_PrevDxDte

Date of most recent previous diagnosis documented above.

Must not be null if P1_PrevDx is not null.

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

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

16.2 P1_PrevGCDxDte — Date of most recent previous diagnosis of GC documented above.
Must not be null if P1_PrevGCDx = 1

17 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 cannot be 'null' or contain missing values.

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

18 P1_FacilityID — Site generated facility ID. Each reporting provider/facility must have a unique facility ID and link to a record in the provider table.
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 providers, this field should be populated with that facility's new number and be included in the next update of the provider reference file.

19 P1_Dispo — What is the status of the internal health department (Phase 1) investigation for this record?
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 cannot be 'null' or contain missing values. Jurisdictions may choose to initiate phase 1 investigations on all reported cases, regardless of whether they fall into the random

sample, or may elect to initiate phase 1 investigations on only those records in the random sample.

0=Investigation complete: record referred to phase 2
1=Investigation complete: no further action, record determined to be a duplicate of previously reported case
2=Investigation complete: no further action, case determined to reside outside of jurisdiction based on existing department of health information
3=Investigation complete: no further action, case not in SSuN random sample
4=Investigation complete: no further action, case not eligible for SSuN sample
10=Investigation not complete: P1 investigation pending
11=Investigation not complete: no further action, insufficient information in originating record to initiate and complete internal investigation
22=Investigation not complete: record not in random sample

20 P1_Referral1 Is this record/case referred for provider (Phase 2) investigation?
This indicates whether the record has been referred to provider investigation (methods of which will differ across SSuN sites). If provider is not contacted, surveyed or otherwise followed up with to supply any additional case-specific information, code as '1'.

0=Referred to P2 Investigation
1=Not Referred to P2 Investigation
2=Referral Pending

21 P1_PtxSex Sex of the patient as indicated on initial health department report?
This data element cannot 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

22 P1_PtxRace_White White Race
Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in #110 – 116.

If additional information from any source (other than patient report) is received, #22 through 27 may be updated as required by underlying surveillance system.

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

23 P1_PtxRace_Black Black Race

Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in #110 – 116. If additional information from any source (other than patient report) is received, #22 through 27 may be updated as required by underlying surveillance system.

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

23 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 #110 – 116. If additional information from any source (other than patient report) is received, #22 through 27 may be updated as required by underlying surveillance system.

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

25 P1_PtxRace_Asian Asian Race

Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in #110 – 116. If additional information from any source (other than patient report) is received, #22 through 27 may be updated as required by underlying surveillance system.

1=Yes
2=No

3=Unknown
4=Refused

26 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 #110 – 116. If additional information from any source (other than patient report) is received, #22 through 27 may be updated as required by underlying surveillance system. .

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

27 P1_PtxRace_Other Other Race
Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in #110 – 116. If additional information from any source (other than patient report) is received, #22 through 27 may be updated as required by underlying surveillance system.

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

28 P1_PtxRace_UNK Is all information on race and Hispanic ethnicity missing from initial reporting record/documents?
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 in #29 below.

1=Yes
2=No

29 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

30 P1_PtxHisp

Patient Hispanic ethnicity
Information from case/lab reports to the health department only. Patient self-report from interviews should be captured in #109. If additional information from any source (other than patient report) is received, #30 may be updated as required by underlying surveillance system.

1=Hispanic
2=Non-Hispanic
3=Unknown
4=Refused

31 P1_PtxHISPSource

What is the source of the final Hispanic ethnicity information ascertained for this patient?
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

32 P1_PtxAGE

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

33 P1_PtxAgeUnit

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

1=Years
2=Months

34	P1_PtxCountyres	County of patient residence ***If information is missing/unknown, code to null value ('.')***
35	P1_PtxCTract	Census Tract of patient residence ***If information is missing/unknown, code to null value ('.')***
36	P1_PtxAddrStat	Was patient street address present and complete in initial reporting documents? ***This data element cannot be 'null' or contain missing values.*** 1=Street Address Known 2=Street Address Missing 3=Street Address Incomplete
37	P1_GCAccuracy	What is the basis of census tract assignment (XY coordinates, street segment, place/zip centroid, not geocodable)? ***This data element cannot be 'null' or contain missing values.*** 1=Close (based on direct street segment, parcel, or l ongitude/latitude match) 2=Approximate (modification of address required to match 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 Site policy 9=Missing (no address available)
38	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 cannot be 'null' or contain missing values.***
39	P1_DxCode	Diagnosis (for gonorrhea cases, this value = 10280) ***This data element cannot be 'null' or contain missing values.*** 10280=Gonorrhea

40 P1_SiteUrine

Urine 'site' of infection, usually a proxy for urethral infection in men but not as specific for women.
If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

41 P1_SiteVagCerv

Vaginal or cervical site of infection in women - combined because there are no clear analytic reasons to separate.
If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

42 P1_SiteUreth

Urethral site of infection - only if this is specifically indicated, if the only specimen source available is a urine-based NAAT, default to 'Urine'
If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

43 P1_SiteRect

Rectal site of infection
If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

44 P1_SitePhar

Pharyngeal site of infection
If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

45 P1_SiteEye

Ocular site of infection
If information is missing/unknown, code as '3'

1=Yes

2=No
3=Unknown

46 P1_SiteSera Blood or sera infection
If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

47 P1_SiteJoint Joint or synovial fluid infection

1=Yes
2=No
3=Unknown

48 P1_SiteOTH Site of infection, not specified above
If information is missing/unknown, code as '3'

1=Yes
2=No
3=Unknown

49 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

Population Component – Phase 1 – Laboratory Records

50 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 cannot be 'null' or contain missing values.

51 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 cannot be 'null' or contain missing values.

52 P1_L1_Accession — Unique identifier (accession number) for laboratory record
Leave blank (null) if not available/ascertained

53 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 cannot be 'null' or contain missing values.

54 P1_L1_CondTested — specific condition/pathogen tested
This data element cannot 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

55 P1_L1_SpecColDte — Specimen collection date - this is often used as a proxy for diagnosis date and is important to obtain
This data element cannot be 'null' or contain missing values.

56 P1_L1_LabRepDte — This is the date that the performing lab reported the results to the health department

57 P1_L1_SecType — Type of specimen
This data element cannot 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

58 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 cannot 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

59 P1_L1_TestType — As test technology advances, it is important to obtain the type of test performed
This data element cannot 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

60 P1_L1_QualRes — Qualitative result: For most pathogens/tests, positive, negative, equivocal and unknown
This data element cannot 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

61 P1_L1_Quantres — Not relevant to GC/CT but may become relevant in the future or for other pathogens of interest (default to 'null' value)

Population Component – Phase 2 – Provider Investigation

62 P2_ProvID — Unique facility/provider ID
This data element cannot be 'null' or contain missing values.

63 P2_ProvCO — County FIPS code for provider/facility physical location

64 P2_ProvZIP — Facility/provider physical location 5-digit ZIP

65 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

66 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

67 P2_ProvPTXvisitDte Date of patient initial visit for this issue, can be supplied/filled in from case or laboratory report information

68 P2_ProvClinType What was the category of provider examining/treating this patient (e.g. MD, RN, ARNP, etc.?)

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

69 P2_ProvPTX_GenderSP Provider documented gender of sex partners

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

70 P2_ProvPTX_Insure Insurance status of patient from provider's records

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

71 P2_Urethritis Was urethritis found on exam
Missing/unknown information code as null ('.').

1=Yes
2=No

72 P2_Proctitis Was proctitis found on exam

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

1=Yes
2=No

73 P2_Epididymitis Was epididymitis found on exam
Missing/unknown information code as null ('.').

1=Yes
2=No

74 P2_PID Was PID diagnosed.
Missing/unknown information code as null ('.').

1=Yes
2=No

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

1=Yes
2=No

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

1=Yes
2=No

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

1=Yes
2=No

78 P2_ProvScrnUreth Was patient screened/tested for infection at urethral site

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

79 P2_ProvScrnVagCerv Was patient screened/tested for infection at vaginal/cervical site

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

80 P2_ProvScrnAnal Was patient screened/tested for infection at anorectal site

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

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

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

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

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

83 P2_ProvPTX_TxDte Treatment date

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

1=Yes
2=No

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

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

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

1=Yes
2=No

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

1=1 gram
2=2 grams

88 P2_ProvPTX_Doxy Was patient treated with doxycycline?
Missing/unknown information code as null ('.').

1=Yes
2=No

89 P2_ProvPTX_Cefx Was patient treated with cefixime?
Missing/unknown information code as null ('.').

1=Yes
2=No

90 P2_ProvPTX_Oth Were other medications prescribed/provided for treating GC
Missing/unknown information code as null ('.').

1=Yes
2=No

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

92 P2_ProvPTX_PDPT Were any medications/prescriptions provided for patient's partner(s)?
Missing/unknown information code as null ('.').

1=Yes
2=No

93 P2_ProvPTX_HIBC Was patient counseled to prevent transmission/reinfection?
Missing/unknown information code as null ('.').

1=Yes
2=No

94 P2_ProvPTX_Refer Was patient referred to HD (or other) for partner services?
Missing/unknown information code as null ('.').

1=Yes
2=No

Population Component – Phase 3 – Patient Interview

95 1P3_IDX_ID Interviewer/Investigator ID
This is a locally assigned ID to uniquely identify the person conducting patient interview. This data element cannot be 'null' or contain missing values for interviewed cases.

96 P3_PatientID Unique identifier for person (allowing longitudinal tracking of persons)
Will be a secondary key for merging data; should correspond to P1_PatientID. This data element cannot be 'null' or contain missing values for interviewed cases.

97 P3_EventID Unique identifier for record
Will be a primary key for merging data; should correspond to P1_EventID. This data element cannot be 'null' or contain missing values for interviewed cases.

98 P3_IDX_CADate1 Contact attempt date 1
This data element cannot be 'null' or contain missing values for interviewed cases.

99 P3_IDX_CAout1 Contact attempt outcome 1
This data element cannot 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

100 P3_IDX_CADate2 Contact attempt date 2

101 P3_IDX_CAout2 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

102 P3_IDX_CADate3 Contact attempt date 3

103 P3_IDX_CAout3 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

104 P3_IDX_CADate4 Contact attempt date 4

105 P3_IDX_CAout4 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

106 P3_IDX_Ixdate Interview/Disposition Date

107 P3_IDX_Dispo Phase 3 investigation/Interview Disposition
Cannot be 'null' for cases included in random sample.

0=Investigation complete: patient contacted, interview completed
1=Investigation complete: patient contacted, partial interview completed
10=Investigation not complete: P3 investigation pending (Default)
11=Investigation not complete: patient contacted, refused interview
12=Investigation not complete: patient contacted, unable to complete interview because of language barrier
22=Investigation not complete: patient did not respond to at least 3 interview contact attempts
33=Investigation not complete: patient contact not initiated because patient determined to be resident in correctional, mental health or substance abuse facility.
44=Investigation not complete: patient contact not initiated because patient determined to be active military on foreign deployment.
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 reason

108 P3_PTX_age What is your age?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

888=Refused

108.1 P3_PTX_sex 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

109 P3_PTX_HispEthnic Do you consider yourself to be Hispanic or Latino/a?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

110 P3_PTX_White patient reported White race
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

111 P3_PTX_Black patient reported Black race
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

112 P3_PTX_AIAN patient reported AIAN race
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes

2=No
3=Unknown
4=Refused

113 P3_PTX_Asian patient reported Asian race

This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

114 P3_PTX_NHOPI patient reported NHOPI race

This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

115 P3_PTX_OTHrace patient reported other race

This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview. Code as 1 if anything specified in by patient that is not otherwise captured above.

1=Yes
2=No

116 P3_PTX_RefRace patient refuses provision of all race information

This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

117 P3_PTX_Insure

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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

118 P3_PTX_InsType

What kind of healthcare insurance do you have?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (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 plan from my state
4=Active or retired military or dependent plan like the V.A. or military
5=Bureau of Indian Affairs/IHS/Urban Indian Health
7=Other
8=Don't know / Not sure
9=Refused

119 P3_PTX_OthInsSpecify

Other type of insurance (text)

120 P3_PTX_PriCareDoc

Do you have one person you think of as your personal doctor or health care provider?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (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

121 P3_PTX_Hccost

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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

122 P3_PTX_OOPE

When you went to see _____ (mention reporting 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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

123 P3_PTX_SYMP

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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

124 P3_PTX_Delay

How long did you have these symptoms or pains before you were able to see the doctor?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (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

125 P3_PTX_ExpSTD 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 cannot be ‘null’ or contain missing values for interviewed cases. May be ‘Null’ if #107 (P3_IDX_Dispo) = ‘1’, partial interview.

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

126 P3_PTX_reasA Reason for going to specific doctor: regular doctor: Because this is your usual/regular doctor.
This data element cannot be ‘null’ or contain missing values for interviewed cases. May be ‘Null’ if #107 (P3_IDX_Dispo) = ‘1’, partial interview.

1=Yes
2=No

127 P3_PTX_reasB Reason for going to specific doctor: Because you could get seen for free.
This data element cannot be ‘null’ or contain missing values for interviewed cases. May be ‘Null’ if #107 (P3_IDX_Dispo) = ‘1’, partial interview.

1=Yes
2=No

128 P3_PTX_reasC Reason for going to specific doctor: Because they take your insurance.
This data element cannot be ‘null’ or contain missing values for interviewed cases. May be ‘Null’ if #107 (P3_IDX_Dispo) = ‘1’, partial interview.

1=Yes
2=No

129 P3_PTX_reasD

Reason for going to specific doctor: Because you felt more comfortable about your privacy there.
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

130 P3_PTX_reasE

Reason for going to specific doctor: Because you could get seen right away.
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

131 P3_PTX_reasF

Reason for going to specific doctor: Because you wanted to see an expert specializing in STDs.
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

132 P3_PTX_reasI

Reason for going to specific doctor: Because this doctor is close to your house and easy to get to.
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

133 P3_PTX_reasG

Reason for going to specific doctor: Because you were embarrassed and didn't want to go to your regular doctor.
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

134 P3_PTX_reasH Reason for going to specific doctor: Because I didn't want the insurance papers/info sent to my home/parents.
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

135 P3_PTX_reasJ Reason for going to specific doctor: Any other reason?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

136 P3_PTX_othReasonText Other reason text.

137 P3_PTX_refusreason Refused all reasons
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

138 P3_PTX_PartnerTest 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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

139 P3_PTX_TellParts

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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

140 P3_PTX_EPToffer

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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

141 P3_PTX_EPTWHO

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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (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

142 P3_PTX_EPTGET

Did you actually get the additional medications or prescriptions for your sex partners?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

143 P3_PTX_EPTMEDORRX 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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

144 P3_PTX_EPTGAVE Did you give the additional medications or prescriptions to at least one of your sex partners?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
9=Refused

145 P3_PTX_HIVtested Did you get tested for HIV at that visit?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

146 P3_PTX_HIVresult What was the result of your HIV test at that visit?
This data element cannot be 'null' or contain missing values if #146=1.

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

147 P3_PTX_everHIVtst Have you ever been tested for HIV?
May be 'Null' if #143=1. This data element cannot be 'null' or contain missing values for cases responding with 2, 3 or 4 to #146.

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

148 P3_PTX_whenHIVtest When was your last HIV test? Just month and year is ok? (IF PATIENT UNABLE TO RECALL, PROBE UNTIL APPROXIMATE RESPONSE ELICITED)
May be 'Null' if #148=2, 3 or 4.

149 P3_PTX_HIVeverResult What was the result of that HIV test?
This data element cannot be 'null' or contain missing values for cases responding to #148=1.

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

150 P3_PTX_inHIVcare When was your most recent visit to a doctor, nurse or other health care worker for HIV medical care? (IF PATIENT UNABLE TO RECALL, PROBE UNTIL APPROXIMATE RESPONSE ELICITED)
This data element cannot be 'null' or contain missing values for cases identifying as HIV positive (150=1 or 147=1).

151 P3_PTX_ART Are you taking antiretroviral medicines to treat your HIV infection?
This data element cannot be 'null' or contain missing values for cases identifying as HIV positive (150=1 or 147=1).

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

152 P3_PTX_PrEP Has your health care provider prescribed medications to help you prevent getting HIV?
This data element should be 'null' for patients reporting being HIV positive. This data element cannot be 'null' or contain missing values

for patients identifying as HIV negative or unknown HIV status (150=2, 3 or 4; 147=2, 3 or 4).

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

153 P3_PTX_Pregnant Were you pregnant at the time you were told that you had gonorrhea?
This data element cannot 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

154 P3_PTX_GenderSP During the past 12 months, have you had sex with only males, only females, or with both males and females?
This data element cannot be ‘null’ or contain missing values for interviewed cases. May be ‘Null’ if #107 (P3_IDX_Dispo) = ‘1’, partial interview.

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

155 P3_PTX_Sxorient Do you consider yourself to be…
This data element cannot be ‘null’ or contain missing values for interviewed cases. May be ‘Null’ if #107 (P3_IDX_Dispo) = ‘1’, partial interview.

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

156 P3_PTX_MaleSPL3MO Thinking back to the 3 months before you were diagnosed with gonorrhea, how many MEN did you have sex with during that time?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview. Probe for approximate response or 'best' guess. Enter 0 to indicate 'None'.

157 P3_PTX_FemaleSPL3MO Thinking back to the 3 months before you were diagnosed with gonorrhea, how many WOMEN did you have sex with during that time?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview. Probe for approximate response or 'best' guess. Enter 0 to indicate 'None'.

157.1 P3_PTX_SPtreatOne 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

157.2 P3_PTX_SPtreatMult 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

158 P3_PTX_SexExch 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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

159 P3_PTX_LastSex When was the last time you had sex?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (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

160 P3_PTX_GenderMRSP Thinking back to the last time you had sex, was the person you had sex with…(male/female)?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (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

161 P3_PTX_AgeMRSP 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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview. If patient refuses, please enter 888.

162 P3_PTX_HISPMRSP 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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

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

163 P3_PTX_RaceMRSP 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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (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

164 P3_PTX_MRSPHIV Thinking back to the last person you had sex with, do you know if that person HIV positive?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (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

165 P3_PTX_SexAgainMRSP Thinking back to the last person you had sex with; do you think you will have sex with this person again?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No
3=Don't Know /Maybe/ Not Sure

4=Refused

166 P3_PTX_GEOMRSP 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 cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (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

167 P3_PTX_DIS_EPT Did the interviewer/DIS provide EPT/PDPT to patient?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

168 P3_PTX_DIS_EPTnum Number of partners EPT provided for
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

169 P3_PTX_DIS_OtherPS Did interviewer/DIS provide other partner services to patient (DIS referral)?
This data element cannot be 'null' or contain missing values for interviewed cases. May be 'Null' if #107 (P3_IDX_Dispo) = '1', partial interview.

1=Yes
2=No

Population Component – Provider/Facility Metadata File (Annual)

170	P4_ProvID	Unique identifier for provider/facility ***This data element cannot be 'null' or contain missing values.***
171	P4_ProvName	Name of provider or facility
172	P4_ProvCO	FIPS code for provider/facility physical location
173	P4_ProvZIP	Facility/provider physical location 5-digit ZIP ***This data element cannot be 'null' or contain missing values.***
174	P4_UpdateDate	Date provider information last updated/verified ***This data element cannot be 'null' or contain missing values.***
175	P4_LocationLon	Provider physical location longitude
176	P4_LocationLat	Provider physical location latitude
177	P4_CensusTract	Census tract of provider physical location
178	P4_Prov_Fac_Type	Facility or provider type code (PHINVAD compatible) ***This data element cannot 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, above)
9=HIV Care Facility
Includes and care facility whose primary service is HIV care regardless of funding source, categorical HIV clinics associated

with hospitals or provider networks should be included in this category.
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 admitted for care. Ambulatory Care Clinics associated with HMO or HMC plans should be coded as 14
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 function is STD services or reproductive health (code as 28 and 7, respectively)
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 for Medicare & Medicaid Services (CMS) website
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

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

1=Yes
2=No
3=Unknown/Missing

180 P4_ProvFQHC Is facility/provider a Federally Qualified Health Center (FQHC)?
This data element cannot be 'null' or contain missing values.
1=Yes
2=No
3=Unknown/Missing

Facility Component – Patient Visit Records

181 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 cannot be 'null' or contain missing values.

182 F1_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

This 2 character code primarily identifies sites funded under SSuN Cycle 3 and may include additional sites as required throughout the grant period. Supplemental codes – for SSuN cycle II historical data only:
VA=Virginia (Cycle II)
AL=Alabama (Cycle II)
CO=Colorado (Cycle II)
CH=Chicago (Cycle II)
This data element cannot be 'null' or contain missing values.

183 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 cannot be 'null' or contain missing values.

184 F1_Visdate — Date of clinic visit

This data element cannot be 'null' or contain missing values.

185 F1_EventID — Unique visit identification

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 clinic visit. This data element cannot be 'null' or contain missing values.

186 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 cannot be 'null' or contain missing values for GISP patients.

187 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 cannot be 'null' or contain missing values for GISP patients.

188 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.

189 F1_Age

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

If age is unknown or missing, use null value.

190 F1_Hisp

Is the patient of Hispanic ethnicity?

1= Yes
2= No
9= Not captured

191 F1_AI/AN

Is the patient of American Indian or Alaska Native?

1= Yes
2= No
9= Not captured

192 F1_Asian Is the patient of Asian?
1= Yes
2= No
9= Not captured

193 F1_PIH Is the patient of Pacific Islander or Hawaiian?
1= Yes
2= No
9= Not captured

194 F1_Black Is the patient Black?
1= Yes
2= No
9= Not captured

195 F1_White Is the patient White?
1= Yes
2= No
9= Not captured

196 F1_Multirace Is the patient Multirace?
1= Yes
2= No
9= Not captured

197 F1_Otherrace Is the patient another race not listed above?
1= Yes
2= No
9= Not captured

For #190-197 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.

198 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= Insured, 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.

199 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.

200 F1_Reason_visit

What was the primary purpose of the visit?

1= Symptomatic/new problem
2= Treatment only
3= Follow-up
4= Family planning
5= STD/HIV screening only
6= Prenatal care
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.

201 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.

202 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.

203 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.

204 F1_Contact_STD

Was the patient a contact or exposed to 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.

205 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.

206 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.

207 F1_FEMSEX

How many female sex partners has the patient had in the last 3 months?

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

208 F1_SEXOR3

Has the patient had sex with men, women, or both over the past 3 months?

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.

209 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.

210 F1_SEXUALITY

Does the patient consider him/herself gay (homosexual), straight (heterosexual), or bisexual?

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.

211 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).

212 F1_Rectal_exposure Did the patient engage in receptive anal sex 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).

213 F1_Pharynx_exposure 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).

214 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).

215 F1_GISP_Travel Has the patient traveled outside of the United States (50 US states) during the previous 60 days?

1= Yes
2= No
9= Not captured

Null values are allowed for (1) non-GISP patients or (2) GISP patients when the information is collected but unavailable for patient record. A

response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN.

216 F1_GISP_Sex_work

Does the patient have a history of giving or receiving drugs/money for sex in the previous 12 months?

1= Yes
2= No
9= Not captured

Null values are allowed for (1) non-GISP patients or (2) GISP patients when the information is collected by the facility but unavailable for patient record. A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN.

217 F1_GISP_Antibiotic

Has the patient had any antibiotic use during the previous 60 days?

1= Yes
2= No
9= Not captured

Null values are allowed for (1) non-GISP patients or (2) GISP patients when the information is collected by the facility but unavailable for patient record. A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN.

218 F1_GISP_IDU

Does the patient have a history of injection drug use in the previous 12 months?

1= Yes
2= No
9= Not captured

Null values are allowed for (1) non-GISP patients or (2) GISP patients when the information is collected but unavailable for patient record. A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN.

219 F1_GISP_Non_IDU

Does the patient have a history on non-injection drug use in the previous 12 months?

1= Yes
2= No
9= Not captured

Null values are allowed for (1) non-GISP patients or (2) GISP patients when the information is collected but unavailable for patient record. A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN.

220 F1_GISP_GC_12 How many previous episodes of gonorrhea are documented in the patient's medical record within the past 12 months?
Null values allowed (1) for non-GISP patients, (2) for GISP patients when the information is collected but unavailable for patient record, or (3) if information is not captured by underlying electronic medical record or is not provided to SSuN .

221 F1_Gisp_GC_Ever Has the patient ever (lifetime) been diagnosed with GC?
1= Yes
2= No
9= Not captured
Null values are allowed for (1) non-GISP patients or (2) GISP patients when the information is collected but unavailable for patient record. A response of 9 indicates the information is not captured or collected by the facility or is not provided to SSuN.

222 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.

223 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 #222 is either 2, 3, 9 or (2) patient does not know/ or not sure of the date of most recent HIV test.

224 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 #222 is either 2, 3,9 or (2) patient does not know/ or not sure of the result of the most recent HIV test.

225 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).

226 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).

227 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).

228 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).

229 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).

230 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).

231 F1_Pedischarge Was there vaginal discharge on exam?

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).

232 F1_Peabdomen Was there lower abdominal pain on exam?

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).

233 F1_CMT — Was there cervical motion tenderness on exam?

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).

234 F1_Adnexal — Was there adnexal tenderness on exam?

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).

Facility Component – Diagnosis Records

235 F2_PatientID — Unique patient identification number assigned by site

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

236 F2_Eventid — Unique visit identification

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

237 F2_Visdate — Date of clinic visit

Will be a secondary key for merging diagnosis and case data; should correspond to F1_Visdate. This data element cannot be 'null' or contain missing values.

238 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.

Facility Component – Laboratory Records

239	F3_PatientID	Unique patient identification number assigned by site ***Will be a secondary key for merging laboratory and case data; should correspond to F1_PatientID. This data element cannot be 'null' or contain missing values.***
240	F3_Eventid	Unique visit identification ***Will be a secondary key for merging laboratory and case data; should correspond to F1_EventID. This data element cannot be 'null' or contain missing values.***
241	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 cannot be 'null' or contain missing values.***

242 F3_Condtested

What condition was the patient tested for?

2 = Gonorrhea
3 = Chlamydia
6 = HIV/AIDS
20 = Pregnancy

Null values allowed if patient was not tested for any of these conditions during the clinic visit or if information is collected by the facility but unknown for this record.

243 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
40= Pregnancy
88= Other

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

244 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

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

245 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

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

Facility Component – Treatment Records

246 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 cannot be 'null' or contain missing values.

247 F4_Eventid — Unique visit identification
Will be a secondary key for merging treatment and case data; should correspond to F1_EventID. This data element cannot be 'null' or contain missing values.

248 F4_Visdate — Date of clinic visit
Will be a secondary key for merging treatment and case data; should correspond to F1_Visdate. This data element cannot be 'null' or contain missing values.

249 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
99= No medication prescribed

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

249.1 F4_Medication — Description for other medication
Free text description of other medications

250 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.

251 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.

252 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.

253 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.

Facility Component – Provider Metadata File (Annual)

254 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 cannot be 'null' or contain missing values.

255	F5_Site	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 ***This 2 character code primarily identifies sites funded under SSuN Cycle 3 and may include additional sites as required throughout the grant period. Supplemental codes – for SSuN cycle II historical data only:*** ***VA=Virginia (Cycle II)*** ***AL=Alabama (Cycle II)*** ***CO=Colorado (Cycle II)*** ***CH=Chicago (Cycle II)*** ***This data element cannot be 'null' or contain missing values.***
256	F5_Facility_name	What is the name of the facility?
257	F5_Facility_type	What is the facility type? 1= STD clinic 2=FP/RH 88= Other
258	F5_FQHC	Is this facility a FQHC? 1= Yes 2= No
259	F5_Title_X	Is this facility a Title X clinic? 1= Yes 2= No
260	F5_CHC	Is this facility a Community Healthcare Center? 1= Yes 2= No
261	F5_School_based	Is this facility a school-based facility? 1=Yes 2=No

262	F5_Facility_Address	What is the physical street address of the facility?
263	F5_Facility_City	In what city is the facility located? FIPS code, example: 3290 (City of SF)
264	F5_Facility_State	In what state is the facility located? FIPS code
265	F5_Facility_Zip	Zip code for the facility 9-digit ZIP code of facility
266	F5_Point_contact	Point of contact at facility
267	F5_EPT	Does the facility have written policies governing EPT? 1= Yes 2= No 3= facility does not employ EPT
268	F5_HPV_vaccine	Does the facility have written policies governing HPV vaccination? 1= Yes 2= No 3= facility does not provide HPV vaccination
269	F5_HIV_algorithm	Does the facility have written policies governing HIV testing? 1= Yes 2= No 3= facility does not provide HIV testing
270	F5_Screening_CT	Does the facility have written policies governing chlamydia screening? 1= Yes 2= No 3= facility does not provide CT testing
271	F5_Screening_GC	Does the facility have written policies governing gonorrhea screening? 1= Yes 2= No 3= facility does not provide GC testing
272	F5_Billing	Does the facility bill for STD services? 1= Yes 2 = No 3= Other

273 F5_Medical_record Type of medical record system?

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

274 F5_Insurance Is the facility in an insurance network?

1=Yes
2=No

Appendix 3: STD/HIV screening recommendations

Women
-Annual HIV test
-HIV test at time of STD diagnosis
-Test for other STDs at time of STD diagnosis
-Chlamydia/gonorrhea test if at risk (young women or older at increased risk)
-Rescreening for chlamydia/gonorrhea if positive

MSM
-Annual syphilis, HIV, chlamydia/gonorrhea (at exposed sites) or more frequently if indicated
-Test for other STDs at time of STD diagnosis
-rescreening for chlamydia/gonorrhea if positive

Heterosexual men
-Annual HIV test
-HIV test at time of STD diagnosis
-Test for other STDs at time of STD diagnosis
-Gonorrhea test if at risk
-Rescreening for chlamydia/gonorrhea if positive

Other preventive services
-Pregnancy test