Attachment 4

Protocol: Enhanced STD Surveillance Network (SSuN)

OMB# 0920-1072

Enhanced STD Surveillance Network (eSSuN)

Protocol and Project Implementation Guide

(Revised)

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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 specific

healthcare facilities (STD Clinics) serving populations at risk for STDs. These activities constitute 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)

Neuro/Ocular syphilis (Supplement)

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 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

<u>Domain 4: Partner services & HIV co-morbidity</u>

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

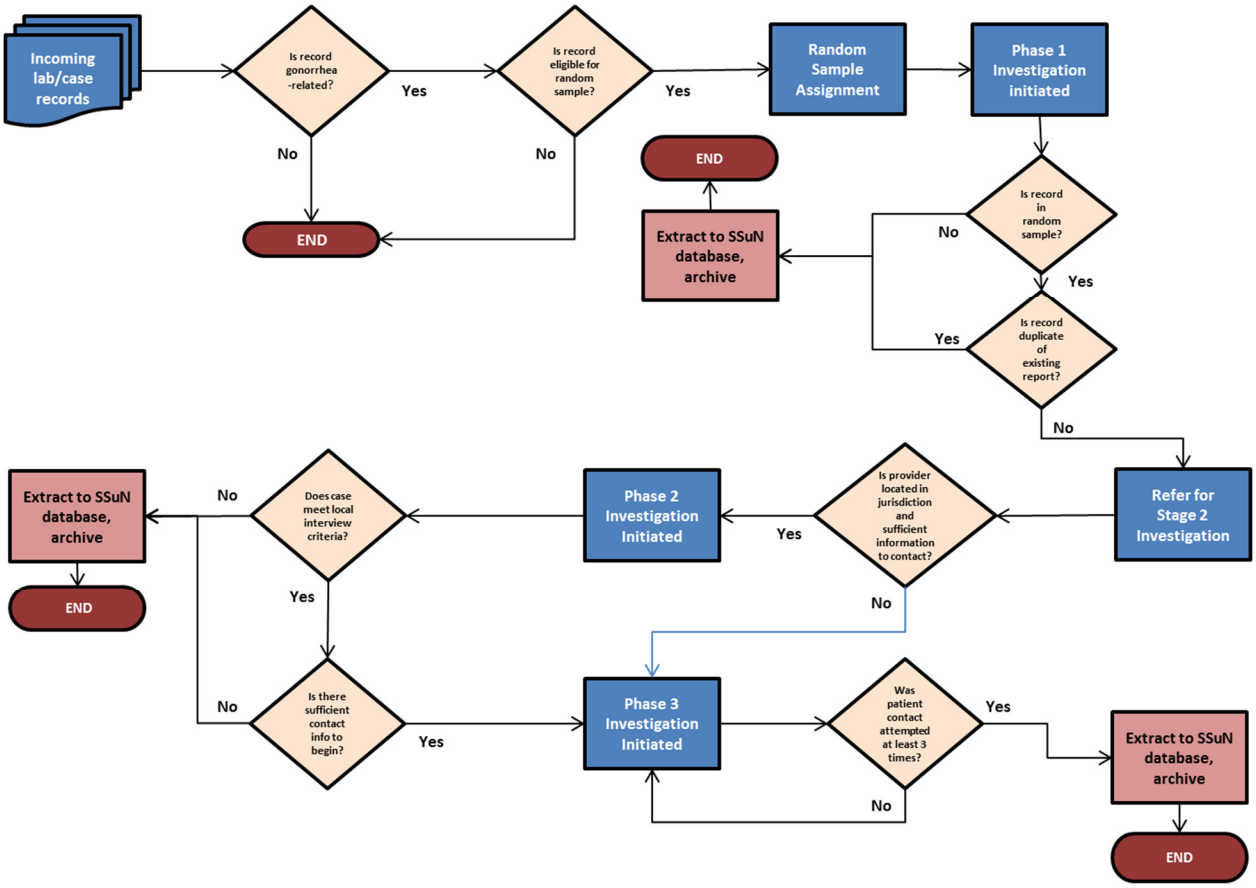
Data obtained for the population component will come from numerous sources within the health department and will need to be locally merged, recoded and appropriately structured to facilitate merging into the national SSuN datasets. Funded jurisdictions are expected to institute rigorous procedures to assure the quality and validity of data elements (Appendix2) 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 – Neuro/Ocular Syphilis Supplement

Project Description

Overview

The objectives of this pilot project are to:

1. Enhance understanding of the frequency and type of neurologic and/or ocular symptoms and signs in early syphilis

2. Enhance understanding of the current practices for screening and/or testing for neurologic and/or ocular syphilis

3. Determine the rate of neurologic and/or ocular symptom resolution within 3 months following appropriate treatment among early syphilis cases reporting neurologic or ocular manifestations of syphilis

This surveillance activity is observational and descriptive and is conceived as part of a comprehensive response to increasing cases of ocular syphilis observed nationally.

Justification and Background

Symptomatic neurosyphilis is considered to be a rare complication of syphilis, however estimates of the prevalence of neurosyphilis have been largely based on retrospective studies of health department syphilis records. Although syphilis is a nationally notifiable condition, information on neurologic manifestations such as ocular involvement are not standard data elements that can be transmitted to CDC through the National Electronic Telecommunications System for Surveillance (NETSS). Additionally, information about neurologic manifestations may not be systematically collected and reviewed at the local level as syphilis case-report forms and investigations records may not be completely capture this information. To date, no population-based studies have been conducted to prospectively identify symptoms of neurologic, otologic, or ocular complications in patients reported with syphilis.

Reported rates of syphilis have been increasing in the United States since 2001 with an estimated 19.0% increase in the rate of primary and secondary syphilis in 2015 compared with 2014. Concomitantly the proportion of early syphilis cases reporting neurologic and/or ocular manifestations has also been increasing with clusters of ocular syphilis cases being reported in certain jurisdictions. CDC has received more than 200 cases reported over the past 2 years from 20 states. At present, there are significant gaps in the surveillance of early syphilis cases with neurologic and/or ocular manifestations and there is a need to engage in systematic surveillance to estimate the proportion of cases with neurologic and/ocular manifestations and to monitor whether there has in fact been a rise in the proportion of syphilis cases with neurologic and/or ocular symptoms over time.

Most jurisdictions conduct partner investigations for patients with early (primary, secondary, and early latent) syphilis through Disease Intervention Specialists (DIS). These partner investigations ascertain demographic, behavioral, and clinical information relevant to the syphilis diagnosis. No work has been done to determine the feasibility and utility of including standardized screening questions for neurologic and/or ocular symptoms of syphilis during this partner investigation. It is also not known whether systematically screening early syphilis cases typically prioritized for partner services will increase the proportion of cases presenting with neurologic and/or ocular symptoms identified through current passive surveillance.

Intended Potential uses of surveillance findings

This project is designed to enhance surveillance of early syphilis cases with neurologic and/or ocular syphilis manifestations. Some studies have indicated that the proportion of early syphilis cases with neurologic and/or ocular manifestations has increased over time and that the profile of these cases presenting with neurologic and/or ocular manifestations has changed over time. This project will investigate this issue in selected jurisdictions. Currently uveitis is reported to be the most common presentation. However syphilis can affect nearly all of the eye's structures and cause neuro-ophthalmic disorders. Enhanced surveillance of early syphilis cases with regards to neurologic and/or ocular symptoms may help to record additional symptoms or symptoms associated with earlier disease.

Participating Sites

This activity will be a component of the STD Surveillance Network (SSuN), a multi-site sentinel surveillance network that collects data on demographic, clinical, behavioral, and laboratory data on persons attending STD clinics and diagnosed with STDs in STD clinics or other settings. SSuN sites participating in this project were required to document the number of early syphilis cases reported annually.

The following five sites were funded for participation in CDC_ RFA #-PS13-130604CONT16 STD Surveillance Network (SSuN). In alphabetical order:

1. Florida Department of Health
2. Multnomah County Health Department
3. New York City Department of Health and Mental Hygiene

4. Philadelphia Department of Public Health
5. Washington State Department of Public Health

Number of subjects

Assuming that the five SSuN sites participating in this pilot project experience a similar burden of early syphilis as reported for 2015, and by implementing similar protocols regarding the proportion of primary, secondary, and early latent syphilis cases that are prioritized for partner services, we anticipate a total of 5,064 cases of early syphilis will be identified for enhanced interviewing following a syphilis diagnosis across all participating jurisdictions over a one-year period.

Given an estimated prevalence of 2% of early syphilis cases reporting neurologic or ocular complications of syphilis we expect an estimated 102 cases of early syphilis will report neurologic and/or ocular manifestations of syphilis requiring enhanced follow-up investigations.

Sites that have the capacity to interview latent syphilis cases should include and submit all relevant data for these cases on the condition that it does not detract from the expected number of early syphilis cases to be interviewed.

Methods and Materials

Operational Plan

Per current health department protocols in the five participating jurisdictions, persons diagnosed with primary, secondary, or early latent syphilis will continue to be prioritized for partner services, and reporting providers will be contacted for additional information on early syphilis cases. In addition participating SSuN sites that do not interview all of their early syphilis cases will select a 10% random sample from early syphilis cases that would not be prioritized based on current health department protocols.

For this pilot activity, standardized information on neurologic and/or ocular manifestations will be gathered from early syphilis cases:

- Using a standardized protocol, all interviewed cases will be screened to determine the presence and nature of self-reported neurologic and/or ocular manifestations of syphilis (vision changes, hearing changes, and tinnitus)
- Using a standardized protocol, a follow-up evaluation with the medical provider will be conducted for all cases:
    - reporting neurologic and/or ocular symptoms
    - who have neurologic and/or ocular symptoms reported on the sexually transmitted disease case-report form by the reporting provider
    - treated with a regimen recommended by the CDC for otologic, ocular, or neurosyphilis
    - for whom there is a record of cerebrospinal fluid (CSF) testing

In addition to ascertaining additional information on clinical symptoms, diagnostic information, testing performed, laboratory tests results, including CSF results, and prescribed type and duration of treatment, the provider will be asked whether the patient received a lumbar puncture as well as the reasons precipitating the lumbar puncture.

- Using a standardized protocol, syphilis cases reporting neurologic and/or ocular symptoms will be re-contacted at approximately three months following prescribed treatment to ascertain whether initial symptoms have resolved.

Data Handling and Analysis

Surveillance Data Collection

Routine data elements are collected from all prioritized early syphilis cases during the partner services interviews and documented in the health department surveillance records. These data include demographic, behavioral, clinical, and laboratory data ascertained acquired during a routine management of early syphilis cases and these data are used locally for STD program monitoring.

For this pilot activity, additional data elements will be added to routine data collection including screening questions on the presence of neurologic and/or ocular symptoms, the nature and timing of neurologic and/or ocular symptoms, diagnosis information, prescribed treatment, clinical and laboratory information on the screening and diagnosis of neurologic and/or ocular manifestations of syphilis, and resolution of symptoms after prescribed treatment. A full list of data elements to be collected from the early syphilis case (Table 1 and Table 2) and the reporting provider (Table 3) are listed below.

These data elements will be collected according to established local data collection methods (electronic medical records or paper records) and transmitted securely to the CDC for analysis following previously established SSuN protocols.

Intended Source of Data

Generally sites should rely on their normal investigative procedures where applicable keeping in mind that the most reliable source of information would be preferable. For example if sites usually rely on a HIV registry database to get information on CD4 count and HI viral load as opposed to relying on patient self-report then sites should continue to do so. In jurisdictions where STD and HIV programs are not integrated, patient self-report of viral load, CD4 count, and antiretroviral therapy would be the next option.

One particular exception would be patient self-report of neurologic and/or ocular symptoms. Specifically, the variables listed below (corresponding to #28– 47 listed in Table 1) should be recording patient self-reported symptoms and not rely on patient medical records as we would like this information in addition to information reported by the provider.

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 in STD 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:

   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 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:

   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:

   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:

   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:
   - 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:
   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:
   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 STD services. Tracking such trends to monitor the demand for STD services in SSuN clinics may help inform budget planning and resource allocation.
   Target population:
   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:
   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.

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 for

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

The Division of STD Prevention,

National Center for HIV/AIDS, 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, and all visits to collaborating STD 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

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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

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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

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