

Technical Assistance Note # 1 | Case-based surveillance of STDs (CT, GC, syphilis)

From Strategy Area I: Conduct Surveillance

- 1. Conduct Chlamydia surveillance
- 2. Conduct Gonorrhea surveillance
- 3. Conduct syphilis surveillance
 - a. Collect, manage, analyze, interpret, and disseminate data on identified cases of chlamydia (1a), gonorrhea (2a), and syphilis (3a), ensuring timely capture of core epidemiologic variables available on laboratory reports

Why DSTDP included these strategies

Collecting, analyzing, and interpreting data are necessary to describe the local epidemiology of a disease and to be able to respond to suspected outbreaks; disseminating data helps to keep providers, the public, and other necessary stakeholders informed. These activities are at the heart of public health and surveillance. Chlamydia, gonorrhea, and syphilis are reportable in all jurisdictions and are nationally notifiable conditions. As many STDs are asymptomatic, case reports represent only a portion of new infections; however, case reports can describe the minimum burden of disease across population groups and provide information on the local epidemiology of STDs in a jurisdiction. Conducting regular data quality checks and implementing quality improvement activities can help ensure case reports accurately reflect diagnosed and reported cases in your jurisdiction.

Key Definitions

Core variables: Variables that are essential for counting and/or investigating reported cases accurately and for describing trends in reported cases in key populations at the local and state level. The majority of these variables should be reported to CDC for monitoring national trends; however, some core variables are not able to be transmitted via NETSS (National Electronic Telecommunications System for Surveillance) or the STD MMG (Message Mapping Guide). Variables considered core vary by disease.

Considerations for implementation

Activities for Conducting Case-based STD Surveillance

- Receive, process, and store laboratory and provider case reports in an STD surveillance information system
 - o Ensure data collected and stored are consistent with variables and value sets in the generic, STD, and congenital syphilis message mapping guides (MMGs)
 - o De-duplicate case reports which likely represent the same infection
 - o Ensure that the MMWR week variable is assigned to the date that most closely represents date of infection

- Ensure electronic laboratory reports (ELR) are processed electronically and are populating the correct fields in a case record in the STD surveillance system
- o Consider working with local laboratories to increase the proportion of cases that are reported electronically and with relevant information (e.g., anatomic site)
- Transmit STD case report data weekly to CDC
 - o Adopt generic, STD, and congenital syphilis MMGs and transmit data to CDC using these HL7 templates
 - Until MMGs are implemented, ensure mapping of the NETSS extract file is in adherence with the current NETSS Record layout
 - Notify DSTDP if a transition to a new surveillance information system is planned or if any issues are identified that will affect upcoming/future data transmissions
- Conduct routine (e.g., weekly) evaluation of trends in the STD case report data received year-to-date, month-to-date, and in the prior week for increases or decreases in reporting
 - Review data by meaningful geographic level (e.g., region, county), demographics, reporting provider and
 laboratory, and key dates (e.g., date of specimen collection and the date of report to the health department)
 - Identify any aberrations in reported cases (e.g., notable change in number of cases reported) that might indicate a data quality issue (e.g., a provider is no longer reporting) or a change in incidence (e.g., an outbreak)
 - o Investigate aberrations to determine likely cause. If needed, reach out to reporting providers to remedy data quality issues
 - o Consider creating a standardized weekly report that is automated



For the regular review of STD case report data, jurisdictions should consider forming a STD data quality workgroup that meets routinely to discuss increases or decreases in case reports, as well as the completeness and timeliness of STD case reporting, and identify and initiate action items for follow-up.

- Conduct routine (e.g., monthly) data quality checks of STD case report data, including, but not limited to:
 - Review data to ensure core epidemiological variables are complete for CT, GC, and syphilis case reports
 - o Identify any providers or laboratories with considerable reporting lags (e.g., providers who report cases with a specimen collection date >30 days prior)
 - o Identify any inconsistencies in case report data (e.g., conflicting dates, anatomic sites not appropriate for sex of patient or diagnostic test reported, etc.)
 - o Work with local reporting entities to investigate and remedy any identified data quality issues
- Perform a routine, automated electronic data match with the HIV Surveillance system (eHARS) to evaluate STD/HIV
 co-infection. These findings can be used to describe the epidemiology of STDs in your jurisdiction and to identify
 opportunities for STD and HIV prevention interventions
 - An integrated data advisory committee that supports PCSI (Program Collaboration and Service Integration)
 could also facilitate access to and use of related data sources from HIV, Hepatitis, TB, and other programs.
- On at least an annual basis, generate a summary report that provides the most current data on STDs in your jurisdiction, as well as important trends over time. Disseminate reports and other data summaries to key internal and external stakeholders
- Consider evaluating your STD surveillance system to ensure system is meeting public health objectives for STD surveillance. Creating a flow chart that documents flow of data into and out of your surveillance system may be useful

• To go above and beyond, implement electronic case reporting with high-volume providers

Specific Considerations for Chlamydia

- Core (e.g., specimen collection date) and non-core (e.g., race) variables should be reported to CDC if they are available at the local level and are in the NETSS record layout or the STD MMG
- Focus on conducting quality improvement activities to ensure complete data for core variables available on laboratory reports. Core variables for all chlamydia cases are: age, sex, county, diagnosing facility type, specimen collection date, and anatomic site of infection

Core variables	СТ	GC
Age	✓	✓
Sex	✓	✓
County	✓	✓
Diagnosing facility type	✓	✓
Specimen collection date	✓	✓
Anatomic site of infection	✓	✓

Specific Considerations for Gonorrhea

- Core (e.g., specimen collection date) and non-core (e.g., race) variables should be reported to CDC if they are available at the local level and are in the NETSS record layout or the STD MMG
- Focus on conducting quality improvement activities to ensure complete data for core variables available on laboratory reports for all cases of gonorrhea and conduct enhanced surveillance to collect enhanced variables on a representative sample of gonorrhea cases. Core variables for all gonorrhea cases are: age, sex, county, diagnosing facility type, specimen collection date, and anatomic site of infection. Core variables for enhanced surveillance of a representative sample of gonorrhea cases are: age, sex, county, diagnosing facility type, specimen collection date, anatomic site(s) of infection, race/ethnicity, gender identity/sexual orientation, sex of sex partner(s), clinical signs/symptoms, pregnancy status, HIV status, partner treatment (i.e., EPT provision), gonorrhea-related sequelae (i.e., presence of pelvic inflammatory disease (PID), disseminated gonococcal infection (DGI), etc.), substance use, date of diagnosis, treatment received (including names and doses of treatment), date of treatment, co-infection with other STDs, and history of GC infection
- Refer to **TA Notes #2 and #2b** for more information on conducting gonorrhea surveillance, including conducting enhanced surveillance

Specific Considerations for Syphilis

- Variables considered core vary by stage of syphilis. Regardless of the stage of syphilis, core <u>and</u> non-core variables should be reported to CDC if they are available at the local level and are in the NETSS record layout or the STD MMG
- For all stages of syphilis, focus on conducting quality improvement activities to ensure complete data for core variables available on laboratory reports. Core variables for all syphilis cases are: age, sex, county, diagnosing facility type, and specimen collection date.

- For primary and secondary syphilis, focus on conducting quality improvement activities to ensure completed
 data for core variables. Core variables specifically for primary and secondary syphilis cases are: age, sex, county,
 diagnosing facility type, specimen collection date, race/ethnicity, gender identity/sexual orientation, sex of sex
 partner(s), pregnancy status, clinical signs/symptoms, HIV status, substance use, treatment received, date of
 treatment, and history of syphilis.
- Refer to TA Note #3 for additional information on conducting syphilis surveillance, TA Note #4 for more about
 congenital syphilis surveillance and TA Note #5 for conducting surveillance on adverse sequelae of syphilis,
 including neurosyphilis and ocular syphilis.

Core variables	Syphilis (all stages)	All P&S syphilis
Age	✓	✓
Sex	✓	✓
County	✓	✓
Diagnosing facility type	✓	✓
Specimen collection date	✓	✓
Race/ethnicity		✓
Gender identity		✓
Sexual orientation		✓
Sex of sex partners		✓
Pregnancy status		✓
Clinical signs/symptoms		✓
HIV status		✓
Substance use		✓
Treatment received		✓
Date of treatment		✓
History of syphilis		✓



The STD MMG identifies "required," "preferred," and "optional" variables. Required variables are mandatory for sending the message and if not present, the message will error out. Preferred and optional variables are important to send to CDC but will not result in an error. The STD-specific variables designated as required in the NETSS Record Layout are equivalent to the preferred variables in the STD MMG. These designations are different from the definition of a core variable. Core <u>and</u> non-core variables should be reported to CDC if they are available at the local level and are in the NETSS record layout or the STD MMG;

however, quality improvement activities to increase completeness should only be conducted on core variables.



Some core variables are not included in the NETSS Record layout or the STD MMG. For example, date of treatment is a core variable for P&S syphilis cases but cannot be transmitted to CDC using the STD MMG. Regardless of inclusion in the STD MMG, jurisdictions should use core variables in local analyses to describe and respond to local epidemics.

Other Resources

- 2017 CDC STD Surveillance Report: https://www.cdc.gov/std/stats17/default.htm
- NNDSS Surveillance Case Definitions: https://wwwn.cdc.gov/nndss/case-definitions.html
- De-Duplication Guidance for Gonorrhea and Chlamydia Laboratory Reports: https://www.cdc.gov/std/laboratory/de-duplication-guidance-june2016.pdf
- Guidance on Classifying STD Case Reports into MMWR Week: https://www.cdc.gov/std/program/MMWR-week-guidance 2018January.pdf
- MMGs and Artifacts. Available at: https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html
- The National Electronic Telecommunications System for Surveillance (NETSS) CDC Implementation Plan for STD Surveillance Data: https://www.cdc.gov/std/program/STD-NETSSIMPLN-V5 2018Jan.pdf
- Groseclose SL, Buckeridge DL. Public Health Surveillance Systems: Recent Advances in Their Use and Evaluation.
 Annu Rev Public Health. 2017 Mar 20;38:57-79. doi: 10.1146/annurev-publhealth-031816-044348. Epub 2016
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- Centers for Disease Control and Prevention. Updated guidelines for evaluating public health surveillance systems: recommendations from the guidelines working group. MMWR 2001;50(No. RR-13). Available at: https://www.cdc.gov/mmwr/PDF/rr/rr5013.pdf

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Technical Assistance Note #2| Enhanced surveillance for GC cases

From Strategy Area I: Conduct Surveillance

- 2. Conduct Gonorrhea (GC) surveillance
 - a. Collect, manage, analyze, interpret and disseminate data on identified cases of gonorrhea, ensuring timely capture of core epidemiologic variables available on laboratory reports: age, sex, county, diagnosing facility type, specimen collection date, and anatomic site(s) of infection
 - b. To better understand GC epidemiology, conduct provider follow-up and, if needed, brief patient interviews of a random sample of GC cases from a well-defined high morbidity area or the project area as a whole. Ensure timely and quality capture of core epidemiologic variables including, but not limited to: age, sex, county, diagnosing facility type, specimen collection date, anatomic site(s) of infection, race/ethnicity, gender identity/sexual orientation, sex of sex partner(s), clinical signs/symptoms, pregnancy status, HIV status, partner treatment (i.e., EPT provision), gonorrhea-related sequelae (i.e., presence of pelvic inflammatory disease (PID), disseminated gonococcal infection (DGI), etc.) substance use, date of diagnosis, treatment received (including names and doses of treatment), date of treatment, co-infection with other STDs, and history of GC infection

Why DSTDP included these strategies

Case-level gonorrhea data are reported to CDC by states, territories and independently funded county and/or city health departments through 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 gonorrhea infection in the United States and U.S. Territories. Only a limited and core set of epidemiological variables are currently required for national case reporting, including sex, age, race/ethnicity, and county of residence. Behavioral information, such as the gender and number of sex partners, HIV and pregnancy status, are critically important to understand the changing epidemiology of STDs, however, these data are not routinely collected for most reported cases of gonorrhea. A jurisdiction's ability to interpret trends in reported cases of gonorrhea, assess inequalities in the burden of disease by population characteristics and to respond with an appropriately focused mix of targeted prevention, screening and treatment interventions is dependent on the local capacity to obtain sufficient information.

National case report data for gonorrhea may not be sufficiently complete to provide valid, useful information locally. However, a carefully crafted enhanced surveillance initiative obtaining relevant, programmatically useful information on a representative sample of <u>ALL</u> reported cases of GC in a well-defined geographic area or the project area as a whole can allow programs to infer case characteristics and monitor trends in important factors such as treatment, anatomic site of infection – along with relevant behavioral characteristics such as gender and number of sex partners. This strategy is being included to support programs to better focus their programmatic activities by refining estimates of the burden of gonorrhea in their jurisdictions, including estimating incidence among at-risk and vulnerable populations. Moreover, this strategy also supports efforts to better monitor STD prevention program impact, and to understand STD-related care seeking behaviors.

Key definitions

Surveillance: the systematic collection, management, analysis, interpretation and dissemination of data. **Enhanced surveillance:** Additional surveillance activities that expand upon routine surveillance efforts, including collection of data measures beyond core variables that have been reported by providers and/or laboratories to state and local health agencies.

Considerations for implementation

Case-Based gonorrhea surveillance for data collection, management, analysis, interpretation, & dissemination of core epidemiological variables

- Follow the best practices for general STD case surveillance covered in TA Notes #1
- Core (e.g., specimen collection date) <u>and</u> non-core (e.g., race) variables should be reported to CDC if they are available at the local level and are in the NETSS record layout or the STD MMG
- Focus on conducting quality improvement activities to ensure complete data for core variables available on laboratory reports (age, sex, county, diagnosing facility type, and specimen collection date) for all cases of gonorrhea

Enhanced gonorrhea surveillance

- Follow the best practices and methodology for performing enhanced gonorrhea case investigations covered in the companion TA Notes #2b
- Consider taking a phased approach to implementation of this activity. For jurisdictions that have never performed this type of enhanced surveillance, a critical first step is ensuring the ability and infrastructure (e.g., modifications to surveillance information systems) to select a representative random sample from **ALL** reported cases of GC in a well-defined geographic area from ALL providers for a pre-defined time period. Additional steps include developing protocols for how selected cases will be assigned to appropriate staff for investigation and how **ALL** core data will be captured in surveillance information systems, as well as piloting collection tools for provider and patient investigations. Developing a time-line for project implementation can help identify what resources will be required in different phases of implementation.

Other resources

The STD Surveillance Network (SSuN) is a collaboration of competitively funded state, city and county health
departments currently implementing similar enhanced surveillance following rigorous, standardized protocols.
More information about SSuN, including protocols and data collection tools are available:
https://www.cdc.gov/std/ssun/default.htm

For more information or feedback on this document, contact your DSTDP Prevention Specialist or email STD_PCHD@cdc.gov. CDC's Division of STD Prevention, Program Development and Quality Improvement Branch, developed this document for recipients of PS19-1901 STD PCHD to provide additional clarification of strategies outlined in that NOFO and to support program implementation. The content here does not represent additional NOFO requirements nor official CDC recommendations. Issue date: April 2019



Technical Assistance Note # 2b | Enhanced surveillance of GC cases: Methodology

From Strategy Area I: Conduct Surveillance

- 2. Conduct Gonorrhea (GC) surveillance
 - **b.** To better understand GC epidemiology, conduct provider follow-up and, if needed, brief patient interviews of a random sample of GC cases from a well-defined high morbidity area or the project area as a whole. Ensure timely and quality capture of core epidemiologic variables including, but not limited to: age, sex, county, diagnosing facility type, specimen collection date, anatomic site(s) of infection, race/ethnicity, gender identity/sexual orientation, sex of sex partner(s), clinical signs/symptoms, pregnancy status, HIV status, partner treatment (i.e., EPT provision), gonorrhea-related sequelae (i.e., presence of pelvic inflammatory disease (PID), disseminated gonococcal infection (DGI), etc.) substance use, date of diagnosis, treatment received (including names and doses of treatment), date of treatment, co-infection with other STDs, and history of GC infection

Why DSTDP included these strategies

To better understand the epidemiology of gonorrhea and to help interpret trends in reported cases of gonorrhea, STD PCHD PS19-1901 supports implementing enhanced case investigations among a representative random sample from <u>ALL</u> reported cases of gonorrhea in a well-defined high morbidity area or the project area as a whole as part of an overall gonorrhea surveillance strategy. This activity will increase the completion of key variables for reported cases of gonorrhea. The following document is meant to serve as a guide for use in the implementation of this strategy within jurisdictions.

Methodology

The following best practices should be used for implementing enhanced population-based surveillance of gonorrhea cases:

- Prospectively select a random, timely, and representative sample from ALL reported cases of gonorrhea:
 - in a well-defined geographic area (e.g., in lower morbidity areas, this might be the entire project area; in higher morbidity areas, this might be selected counties or a large metropolitan area)
 - from all provider types (e.g., private medical providers, urgent care facilities, emergency rooms, hospitals, STD clinics, etc.)
 - for a pre-defined time period (e.g., entire year, several months of the year, etc.).
- Conduct enhanced provider and patient investigations among the randomly selected cases

Enhanced investigations should include collection of key clinical, demographic and provider-level variables, a subset of which will be considered core. An expanded set of potential data elements are listed for consideration, if resources allow.



It is critical that the random sample is pulled from <u>ALL GC</u> cases in the selected area. For example, conducting enhanced investigations only with cases diagnosed in STD clinics or only among young women aged 15-24 years would not be considered representative of all cases in the area.

Variables for Data Collection

Core Variables

- 1) Age (e.g., date of birth)
- 2) Sex
- 3) County
- 4) Diagnosing facility type (e.g., STD clinic, correctional facility)
- 5) Specimen collection date
- 6) All anatomic site(s) of infection
- 7) Race/ethnicity
- 8) Gender identity of patient/sexual orientation
- 9) Sex of sex partner(s)
- 10) Clinical Symptoms and signs (i.e., healthcare seeking behaviors)
 - a. Including length of time symptoms were present
- 11) Pregnancy status
- 12) HIV status
- 13) Previous history of GC infection
- 14) Gonorrhea-related sequelae (i.e., PID, disseminated gonococcal infection)
- 15) Date of diagnosis
 - a. Note: if the person had a second infection after 30 days of an infection, they would be considered a new case
- 16) Treatment provided, including the name and dose of treatment/antibiotic
- 17) Date of treatment
- 18) Co-infection with other STDs
- 19) History of substance abuse (e.g., IVDU, etc.)
- 20) Partner treatment (e.g., EPT provision)

Additional variables to consider, if resources and staffing allow:

- 21) Insurance status/coverage
- 22) Antibiotic use in the last 2 weeks, including the name of the antibiotic (if possible)
- 23) Travel and related sexual history in past 30 days
 - a. Foreign vs. domestic travel
 - b. Country of birth of partner
- 24) Sexual partner characteristics
 - c. Number (as well as gender) of all sex partners in the past 30 days
 - d. Most recent sex partner history
 - i. Last sexual encounter with this partner (i.e., timeframe)
 - ii. Race/ethnicity of most recent partner
 - iii. Gender of most recent partner
 - iv. Age of most recent partner
 - v. HIV status of most recent partner

- vi. Sites of exposure
 - 1. Receptive and/or insertive
 - 2. Vaginal, anal and/or oral

Much of these data can be collected by conducting brief phone interviews with the patients; however, clinical information should be obtained directly from the provider through a provider investigation/or Electronic Case Reporting (ECR). Clinical data relating to specimen collection, anatomic site of infection and treatment information must be obtained from the provider, not from self-report from the patient.

Additional resources, such as information on how to develop data collection tools, will be provided in the future.



Increasing the percent completion of one or two variables (e.g., HIV status, pregnancy status, sex of sex partner(s), etc.) for all cases is NOT considered enhanced surveillance. For this objective, enhanced surveillance requires conducting provider follow-up and, if needed, brief patient interviews with a random sample of cases that would result in complete information for all variables of interest for sampled cases.

Sample Randomization Strategy/Implementation Plan

Sampling methods may vary across jurisdictions based on local surveillance infrastructure. Methods should be implemented in order to generate a timely random sample of ALL reported cases of gonorrhea in the selected area. Additionally, the data presented below are an example and should be modified based on the jurisdiction performing enhanced surveillance.

- All gonorrhea cases reported to the state health department during the selected investigation time period and
 resident in the selected geographic area at the time of their diagnosis should have the same probability of being
 sampled (i.e., a true random sample). This is best accomplished by modifying surveillance data management
 systems to select the random sample automatically as cases are entered into the system (or created from
 laboratory data) rather than as an external batch process.
- Some sampled cases may be determined to be ineligible for further investigation as a result of local or other
 policies specified prior to initiating sampling; jurisdictions should implement a method to track this information
 and record the reason for exclusion for subsequent analysis. Reasons for excluding a case from additional
 information might include:
 - Specimen collection date is more than 30 days prior to report of case,
 - o Patient's age ≤ 12 years, or
 - Patient's residence determined later to be outside of the targeted geographic area for enhanced surveillance
- The goal is to obtain completed GC case investigations that are sufficient to provide robust estimates of characteristics of interest:
 - o The target number for completed investigations should be based on examining the total number of ALL gonorrhea cases reported to the state health department in the identified geographic area for the specified time in the previous year, and based on a minimum number required to provide reliable estimates (i.e., 10% of all reported cases completing full investigations at a minimum).
 - o Based on the jurisdiction's target number of completed investigations, jurisdictions will need to determine the number of gonorrhea cases that are needed to be randomly selected for enhanced surveillance. For example, a jurisdictions goal was set at 500 cases and in the previous surveillance year, they had just over 5,000 case of gonorrhea reported. To reach a 10% sampling goal, and assuming a

minimum response rate of 40% the jurisdiction would need to sample 25 out of every 100 reported cases to meet their investigation target.

- Sampling methods should be implemented that allow for modifying the sample size as needed based on success in conducting investigations to assure that the target number of investigations are completed.
- Protocols should be created to assure that each case in the sample are afforded the same effort to complete all parts of the enhanced case investigation (e.g., one measure of assurance might include a protocol that states 3 attempts should be made to contact each patient).
- To assure that the sample is a true probability sample, cases selected for enhanced investigation should be compared to ALL reported cases of GC by sex, age and area (if multiple counties/regions are included); distribution of cases selected for enhanced surveillance by these characteristics should match ALL reported cases of GC in the identified geographic area. Additionally, non-response rates (e.g., interview refusals) should be monitored to ensure data are representative and that specific groups (by age group, sex, etc.) are not more or less likely to complete investigations. Variation in response rates do occur, but every effort should be made to address identified response biases.
 - After implementation of enhanced surveillance, periodic review of cases selected for enhanced investigation should be performed to ensure selected cases are similar to ALL reported cases of GC in the identified geographic area.
 - After implementation, periodic review of non-response rates should be performed to identify any biases.



It is critical that jurisdictions ensure they have the infrastructure in place to select a representative random sample from ALL reported cases of GC in the well-defined geographic area <u>prior</u> to implementing patient and provider investigations. Implementation of the selection of a valid, representative sample may take time, especially if the jurisdiction has not performed enhanced surveillance previously.

Data Weighting and Review of Enhanced Gonorrhea Surveillance Data

Jurisdictions sampling cases should evaluate the representativeness of their initial sample by comparing the distribution of cases in the sample with those in the overall population of reported cases of GC by age, gender, and other factors such as provider type and county of report if these data are complete and available for all cases. A true probability sample will closely correspond to the population of all reported cases on these key factors. A general rule of thumb is that differences of less than 2% difference between the samples on all other cases is acceptable.

As with all enhanced investigations, there is attrition with respect to completed investigations; some proportion of patients may not be successfully contacted for interview, and some providers may fail to respond to requests for complete clinical information. The sampled cases with completed investigations become the 'effective sample' for analytic purposes. Case weights should be developed to make these cases 'carry the weight' for the total population of reported cases. For example, if there are 100 reported cases, and complete investigations are obtained for 10 cases, each of these cases will have a case weight of 10 (e.g. 10 cases x weight of 10 = 100). As with the initial random sample, these cases should be compared to the population of all reported cases. Significant differences in the distribution by age, gender, and other factors such as provider type and county of report indicate bias in response and additional methods should be employed to adjust for this bias. However, diligent efforts to monitor progress and to obtain complete investigations for each and every sampled case to minimize the likelihood of response bias. Analysis of completed investigations, using case weights, will provide estimates of the proportion and number of cases in the overall population by characteristics of interest.

Collection of data for enhanced gonorrhea surveillance is the first step to better understand gonorrhea epidemiology. However, the data should be routinely analyzed, interpreted, and reviewed. As jurisdictions implement enhanced surveillance, the following quantitative and qualitative components are suggested to monitor and track for each jurisdiction on an on-going basis but will be used to also assist CDC surveillance colleagues an insight into this project. At a minimum, CDC suggests the following components be reviewed and summarized annually for each jurisdiction.

Quantitative components

- Total number of reported GC cases during [x] time frame
- Total number of interviews (completed), including completion rate
- Variable/data element completeness among interviewed patients
- Summary/distribution of cases by core/required variables

Qualitative components

- Methods used/implemented
- Feasibility of sustaining the activity
- Resources extended
- Challenges encountered (especially during implementation)

Transmission of data to CDC

Many of the variables collected during the enhanced investigation are included in the generic and STD message mapping guides (MMGs) and in the current NETSS Record Layout. If a case has been randomly selected for this enhanced surveillance activity, ensure that the data collected during the provider and patient investigations are entered into the case record and reported to CDC.

The STD MMG and current NETSS Record Layout include a variable to indicate if a case was randomly sampled for enhanced investigation within a jurisdiction. This should be marked as "Yes" if the case was selected for this activity even if the patient interview was not able to be completed. In addition, it is possible that some cases that are not in the random sample will be prioritized for partner services or other activity such as treatment assurance. In this situation, the information gathered during partner services or treatment assurance should be included in the case report and the variable indicating if the case was randomly sampled should be marked as "No."

Other Considerations

Jurisdictions should be aware that sampling is best accomplished by modifying surveillance data management systems to randomly flag cases as they are entered into the system. Most vendor-based systems have the capacity to be modified for this purpose, and locally built systems may also be amenable to modification. Prompt referral of cases in the random sample to staff for investigation will maximize the likelihood of successful follow-up. Additionally, jurisdictions should place equal priority on obtaining information from providers and should consider working with higher-volume providers to provide rationale, create buy-in, encourage prompt response and assure access to medical records for cases sampled for enhanced investigations.

When data obtained from investigations on a sample of cases is analyzed, proper consideration must be given to evaluating the representativeness of the cases with completed investigations to minimize the possibility of bias; this is especially true if the proportion of cases sampled is small (under 5%) or if the proportion of sampled cases with complete information is less than 50%. Jurisdictions should consider consulting with epidemiologists in their departments who have experience developing weights for analysis or working with complex survey data. Consider budgeting for training and workforce development for existing staff in using SAS or R for statistical analysis.

Additional Information

- The following persons in CDC's DSTDP can be contacted by jurisdictions to inquire about implementation of enhanced surveillance for GC: Emily Weston (csi7@cdc.gov) at 404-639-3603.
- The STD Surveillance Network (SSuN) is a collaboration of competitively funded state, city and county health
 departments currently implementing similar enhanced surveillance following rigorous protocols. Jurisdictions are
 encouraged to contact CDC Project Officers Mark Stenger (zpl4@cdc.gov, 404-639-6136) and Eloisa Llata
 (gge@cdc.gov, 404-639-6183) for referrals to project areas in SSuN that may be able to provide technical assistance
 in implementing these activities.

For more information or feedback on this document, contact your DSTDP Prevention Specialist or email STD_PCHD@cdc.gov. CDC's Division of STD Prevention, Program Development and Quality Improvement Branch, developed this document for recipients of PS19-1901 STD PCHD to provide additional clarification of strategies outlined in that NOFO and to support program implementation. The content here does not represent additional NOFO requirements nor official CDC recommendations. Issue date: April 2019



Technical Assistance Note #3| Conduct syphilis surveillance

From Strategy Area I: Conduct Surveillance

- 3. Conduct syphilis surveillance
 - a. Collect, manage, analyze, interpret and disseminate data on identified cases of syphilis, ensuring timely capture of core epidemiologic variables available on laboratory reports: age, sex, county, diagnosing facility type, and specimen collection date
 - b. To better understand primary and secondary (P&S) syphilis epidemiology, conduct provider follow-up and, if needed, brief patient interviews of **all cases of P&S syphilis**. Ensure timely and quality capture of core epidemiologic variables including, but not limited to: age, sex, county, diagnosing facility type, specimen collection date, race/ethnicity, gender identity/sexual orientation, sex of sex partner(s), pregnancy status, clinical signs/symptoms, HIV status, substance use, treatment received, date of treatment, and history of syphilis

Why DSTDP included these strategies

Syphilis is a genital ulcerative disease caused by the bacterium *Treponema pallidum* that can lead to severe clinical complications and can facilitate HIV transmission. Following a historically low rate of primary and secondary (P&S) syphilis among the US population in 2001, rates of P&S syphilis have increased almost every year. Syphilis surveillance is an important element of tracking these trends over time, and regular examination of data quality and case burden are central to timely identification of reporting issues and of potential changes in syphilis rates.

Rises in rates of P&S syphilis have coincided with increases in cases among men who have sex with men (MSM), who accounted for the majority of reported cases from 2012 to 2016. However, rates of P&S syphilis have also been increasing among men who have sex with women only (MSW) and women, sometimes by greater percentages than rates among MSM. Because of this, accurate data on sex and sex of sex partner(s) are essential for monitoring changes among these subpopulations. In addition, new data regarding gender identity and sexual orientation will enable epidemiologists to examine trends in P&S syphilis among gender and sexual minorities according to identity for the first time.

Key definitions

MSM: Men who have sex with men

MSW: Men who have sex with women only

Considerations for implementation

Data Collection, Management, Analysis, Interpretation, & Dissemination for All Stages of Syphilis

Follow the best practices for case-based STD surveillance covered in Technical Note #1.

- Verify that syphilis cases are categorized according to the most recent case definitions from CSTE and that providers are consistently supplying sufficient data to determine syphilis stage.
- Syphilis cases should reported by stage at the time of initial examination, which is often the time of initial specimen collection and not the time of treatment or interview.
- Update case information with new data obtained via follow-up with clinicians and patient interviews. If data sources are stored separately, develop a method for linking the data and update the combined data sources regularly.

Understanding Primary & Secondary Syphilis Epidemiology

- Conduct provider follow-up after laboratory reporting to determine treatment status and date for cases.
- Encourage providers to fill out case report forms. To go above and beyond, monitor provider case reporting and develop strategies for improving cooperation by providers.
- Collect and report data to CDC in a way that is consistent with the generic and STD message mapping guides (MMGs), including federally compliant race and ethnicity reporting as well as data on gender identity and sexual orientation. Adapt case report forms as necessary to reflect the variables and value sets.
- Capture complete data for variables that facilitate P&S syphilis epidemiology among subpopulations, such as individuals known to be living with diagnosed HIV, pregnant women, MSM, individuals with gender and sexual minority identities, and racial and ethnic minority individuals.
- For information regarding the sex of sex partners in the past year, complete all fields. For example, if a person
 has had only female partners, record "0" for number of male partners. This allows for more accurate
 categorization of behavioral risk.
- Minimize reporting missing or "unknown" responses for core and enhanced variables. To go above and beyond, implement quality improvement activities to reduce the proportion of cases with missing data.
- Conduct brief patient interviews of all cases of P&S syphilis, prioritizing pregnant women, male partners of women who are pregnant or who are of reproductive age, and men who have sex with men.
- Incorporate strategies to ascertain HIV status among P&S syphilis cases, including regular matching with eHARS. In the absence of eHARS data, refer to participant self-report. If eHARS data and patient self-report data are both available and are in conflict, select the most complete response. For example, if one source lists an indeterminate result and the other reports an HIV-negative result, record "HIV-negative." If one source indicates a case HIV-negative and the other indicates HIV-positive, record "HIV-positive."
- Record substance use data as completely as possible, selecting "yes" or "no" for each item. Avoid reporting only positive responses and leaving remaining items blank.
- To go above and beyond, consider using alternative data sources such as Medical Monitoring Project data, data from National HIV Behavioral Surveillance, and STD clinic data to examine P&S syphilis among key risk groups and according to HIV coinfection.



Strategies specific to congenital syphilis surveillance are provided in **TA Note #4**. Strategies specific to surveillance of adverse outcomes of STDs, such as neurosyphilis and otic/ ocular syphilis, are provided in **TA Note #5**.



Core variables for P&S syphilis include variables beyond those are considered core for chlamydia and gonorrhea, specifically race/ethnicity, gender identity/sexual orientation, sex of sex partner(s), pregnancy status, clinical signs/symptoms, HIV status, substance use, treatment received, date of treatment, and history of syphilis.

Other resources

- 2018 syphilis case definitions: https://wwwn.cdc.gov/nndss/conditions/syphilis/case-definition/2018/
- Recommendations for syphilis surveillance in the United States: https://www.cdc.gov/std/syphsurvreco.pdf
- Syphilis chapter in the 2017 STD Surveillance Report: https://www.cdc.gov/std/stats17/Syphilis.htm
- Webinar on syphilis staging: https://cste.webex.com/cste/lsr.php?RCID=a2c301a1f806ae978eb8b57e90d28413
- Message mapping guides: https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html
- NETSS Implementation Guide: https://www.cdc.gov/std/program/STD-NETSSIMPLN-V5 2018Jan.pdf
- Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity: https://obamawhitehouse.archives.gov/omb/fedreg 1997standards

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Technical Assistance Note # 4| Congenital syphilis surveillance and case review

From Strategy Area I: Conduct Surveillance

- 4. Conduct congenital syphilis (CS) surveillance
 - a. To better understand CS epidemiology, conduct provider and mother follow-up and review medical records of all reported CS cases. Based on information collected, manage, analyze, and disseminate data on reported cases of CS, ensuring timely and quality capture of epidemiologic core maternal, fetal, and neonatal variables including, but not limited to: mother's age, race/ethnicity, county, stage of syphilis diagnosed during pregnancy, date(s) of 1st prenatal visit, syphilis testing (and corresponding titers), treatment(s) and delivery; HIV status of mother, substance use, clinical settings of diagnosis and care; and fetal and neonatal information such as ultrasound findings, physical and laboratory findings, and HIV status of infant at birth
 - b. For applicants with **10** or more cases of congenital syphilis in the previous calendar year: Improve methods to match vital statistics birth and mortality data with syphilis surveillance data to review syphilis testing practices among women who delivered a stillborn baby, identify missed cases of syphilis-related stillbirth, and strengthen CS case report data
 - c. For applicants with 10 or more cases of congenital syphilis in the previous calendar year: Strengthen CS morbidity and mortality case review boards at the local and/or state level to help identify causes of CS and develop interventions to address causes

Why DSTDP included these strategies

There has been a sharp increase in the number of infants born with congenital syphilis (CS) in the United States. After a steady decline from 2008 to 2012, reported CS cases almost tripled during 2012–2017. This increase parallels a national increase in primary and secondary syphilis among women of reproductive age during the same years.

Timely identification (through screening) and treatment of pregnant women with syphilis can prevent CS. The resurgence of CS points to missed opportunities for prevention. CS surveillance monitors trends in cases over time and by geographic area, which is critical for identifying outbreaks and targeting resources. In addition, information collected as part of CS case reporting, such as data on maternal prenatal care, testing, treatment, and other potential risk factors, can assist in understanding barriers to CS prevention and suggest potential points of intervention.

For jurisdictions with a substantial burden of CS cases, enhanced activities such as matching syphilis surveillance and vital statistics data, and case review boards are useful to assess or improve completeness of case report data, gather additional information about CS cases, better describe missed opportunities for prevention, and develop appropriate interventions at the local level.

These strategies complement others in STD PCHD related to disease investigation and intervention of pregnant women, as well as the promotion of CDC-recommended STD clinical prevention services among health care providers that serve pregnant women. See **TA Notes # 7 and #12a** for more information on those strategies and ways to implement them.

Considerations for implementation

Collect maternal and clinical data on all reported CS cases to strengthen CS surveillance and better understand CS epidemiology

- Verify that CS cases are categorized and reported according to the most recent CSTE case definitions for confirmed CS, probable CS, and syphilitic stillbirth: https://wwwn.cdc.gov/nndss/conditions/congenital-syphilis/case-definition/2015/
- Collect and transmit CS case report data to CDC using the most recent (2013) version of the case report form: https://www.cdc.gov/std/program/congenital-syphilis-form-2013.pdf
- Assess and assure timeliness of case reporting to the local health department, state health department, and
 CDC; as a target, interval between report to the state health department and report to CDC should be ≤8 weeks
- Assess completeness of CS case report data and minimize incomplete or missing data fields on the CS case report form
- On a regular basis, review reported CS cases (as well as female syphilis surveillance data) to understand the populations affected and missed opportunities for prevention (e.g., lack of or late prenatal care; delay in testing or treatment; infection after initial screening test)
- Consider linking CS cases to the mother's syphilis case report record to further examine potential maternal demographic or risk behaviors associated with CS in your jurisdiction
- To go above and beyond, consider creating a system for tracking all pregnant females with syphilis that includes
 results from follow-up testing during pregnancy, interim and final outcomes of pregnancy, maternal and infant
 co-morbidities (e.g., HIV infection), and/or additional data on potential risk factors of interest. Having data on
 infants who do not meet CS case criteria may allow for additional quality assurance and other types of
 epidemiologic analyses.

For applicants with 10 or more CS cases in the previous calendar year, improve methods to match surveillance and vital statistics data

- If needed, establish a memorandum of understanding or data sharing agreement with the local or state Vital Statistics and MCH Programs to share pertinent data, and ensure a secure mechanism to view or transfer data
 - Confirm whether other health department groups (i.e., perinatal HIV) may have existing data sharing agreements and consider amending current agreements to include STD matching
- Search for mothers in MCH records, birth records, and/or infant or fetal death records that match females with reported syphilis in your STD program database
 - Matching is typically performed using a combination of key variables such as mother's name, date of birth, and geographic location
 - The method used for performing a match may vary depending on the volume of female syphilis cases or the volume of birth certificates included in the match; in general, computerized matching algorithms are preferred over manual record searches
- Review matched records to identify any previously unknown/unreported infants or stillbirths born to women
 with positive syphilis tests (i.e., potentially missed CS or syphilitic stillbirth cases), or any cases that warrant
 additional follow-up or investigation
- If MCH or vital records contain additional data of interest, including locating information or prenatal care history, consider using the match to enhance CS case data and better understand the local epidemiology of CS
- The frequency of matching will depend on health department resources and the timeliness with which vital statistics data are available; annual or semi-annual matching is likely appropriate for most programs



Matching with MCH or vital statistics data is a retrospective review that can identify potential gaps in CS surveillance and lead to improved case ascertainment and better epidemiologic data; it does not prevent CS cases, so ensure that time and resources spent on this activity are balanced appropriately with resources spent on CS prevention activities.

For applicants with 10 or more CS cases in the previous calendar year, strengthen CS morbidity and mortality case review boards

- Establish a multi-disciplinary review board that includes participants from within and outside of the STD Program
 - o Be sure to include at least one clinician with experience diagnosing and treating syphilis
 - Selection of external participants should be based on local epidemiology and may include Title V and Title X partners, Medicaid, corrections, high-volume provider groups or hospitals, and agencies or CBOs working in housing, transportation, and substance abuse
 - It is preferable to have a fixed set of Board members—both internal and external—that attend these meeting regularly
- Develop a structure to aid in the case review process. Suggested tools include a case abstraction form, a
 maternal interview form, and/or an after-action form that summarizes Board recommendations and suggested
 follow-up
- Determine meeting frequency based on CS morbidity; quarterly meetings are appropriate for most jurisdictions, but monthly meetings may be preferable in jurisdictions with very high CS morbidity
- Review all cases of CS, not only those cases that result in stillbirth or early infant death
- Consider integrating a CS morbidity and mortality review board with other review boards that may already be in
 existence. Some jurisdictions have high-functioning Fetal and Infant Mortality Review Boards that may be able
 to take on CS review—as a group or in sub-committee. Other jurisdictions already have review boards in place
 for infants exposed to HIV.



The aim of the CS Review Board should be to identify actions that the local health department can facilitate or take to address the underlying causes of CS—some of which may be attributable to individual actions and some of which may be attributable to entire systems in need of repair.

Other resources

- CSTE surveillance case definitions for CS and syphilitic stillbirths: https://wwwn.cdc.gov/nndss/conditions/congenital-syphilis/case-definition/2015/
- Most recent (2013) CS case report form: https://www.cdc.gov/std/program/congenital-syphilis-form-2013.pdf
- CDC STD Treatment Guidelines for management of CS: https://www.cdc.gov/std/tg2015/congenital.htm
- References for matching vital statistics to STD data:
 - Winscott, M, Taylor, MM, Kenney K. Identifying unreported and undiagnosed cases of congenital syphilis in Arizona using live birth and fetal death registries. Sex Transm Dis. 2010 Apr;37(4):244-7.
 - Biswas HH, Chew Ng RA, Murray EL, Chow JM, Stoltey JE, Watt JP, Bauer HM. Characteristics associated with delivery of an infant with congenital syphilis and missed opportunities for prevention California, 2012-2014. Sex Transm Dis. 2018 Jul;45(7):435-441.
 - Newman LM, Samuel MC, Stenger MR, Gerber TM, Macomber K, Stover JA, Wise W. Practical considerations for matching STD and HIV surveillance data with data from other sources. *Public Health Reports*. 2009 Nov;124(2 suppl):7-17.
 - O Drobnik A, Pinchoff J, Bushnell G, Ly S, Yuan J, Varma JK, Fuld J. Matching HIV, tuberculosis, viral hepatitis, and sexually transmitted diseases surveillance data, 2000-2010: Identification of infectious

disease syndemics in New York City. *Journal of Public Health Management and Practice*. 2014 Sep 1;20(5):506-12.

- Resources for conducting Case Review Boards using the FIMR methodology (adapted for HIV contexts but helpful for planning CS-related reviews):
 - o http://www.fimrhiv.org/
 - o Rahman, M, Hoover, A, Johnson, C, Peterman, T. Preventing congenital syphilis—Opportunities identified by syphilis case review boards. *Sex Transm Dis*. 2018. (epub ahead of print)

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Technical Assistance Note # 5 | Conduct surveillance of adverse outcomes of STDs

From Strategy Area I: Conduct Surveillance

- 5. Conduct surveillance of adverse outcomes of STDs
 - a. Conduct active surveillance of adverse outcomes of adult syphilis including neurosyphilis and otic and ocular syphilis through sentinel approaches, collecting variables including, but not limited to: neurologic manifestations, ocular manifestations, otic manifestations, and late clinical manifestations. These are in addition to the stage of syphilis and the core epidemiologic variables listed for P&S syphilis above

Why DSTDP included these strategies

Syphilitic infections in adults have continued to rise dramatically in the United States. In addition, multiple jurisdictions have observed increases in ocular syphilis, a clinical manifestation that is a severe consequence of untreated syphilitic infection and can occur at any stage of syphilis. However, previously, data on severe clinical manifestations such as ocular syphilis and neurosyphilis have not been sufficiently captured in national syphilis case report data.

Revisions to the syphilis surveillance case definition and case report variables related to clinical manifestations of syphilis were made and took effect January 1, 2018. These revisions were made to ensure consistent and accurate reporting of cases and the appropriate capture of clinical manifestations, especially neurologic and ocular manifestations and late clinical manifestations (see "Key Definitions" below). It is important that public health clinics and facilities are able to capture this information to improve active surveillance of adverse outcomes of adult syphilis such that we are able to accurately characterize the current epidemic and any future epidemiologic changes.

Because this information may not be routinely collected, it is important for health departments to actively work with providers to evaluate patients with syphilis appropriately for these clinical manifestations and include protocols in public health clinics to ensure this information is adequately captured.

Key Definitions

Neurologic Manifestations of Syphilis: Classification

- **Possible:** Reactive nontreponemal and treponemal serologic tests <u>AND</u> clinical signs/symptoms consistent with neurosyphilis without other known causes for these clinical abnormalities
- **Likely:** Reactive nontreponemal and treponemal serologic tests <u>AND</u> clinical signs/symptoms consistent with neurosyphilis without other known causes for these clinical abnormalities <u>AND</u> elevated cerebrospinal fluid (CSF) protein or CSF leukocyte count in the absence of other known causes for these abnormalities
- Verified: Reactive nontreponemal and treponemal serologic tests <u>AND</u> clinical signs/symptoms consistent with neurosyphilis without other known causes for these clinical abnormalities <u>AND</u> reactive VDRL in CSF in the absence of grossly bloody contamination of CSF

Ocular Manifestations of Syphilis: Classification

- **Possible**: Reactive nontreponemal and treponemal serologic tests <u>AND</u> clinical signs/symptoms consistent with ocular syphilis without other known causes for these clinical abnormalities
- **Likely:** Reactive nontreponemal and treponemal serologic tests AND clinical signs/symptoms consistent with ocular syphilis without other known causes for these clinical abnormalities AND findings on exam by an ophthalmologist that are consistent with ocular syphilis in the absence of other known causes for these abnormalities
- **Verified**: Reactive nontreponemal and treponemal serologic tests <u>AND</u> clinical signs/symptoms consistent with ocular syphilis without other known causes for these clinical abnormalities <u>AND</u> demonstration of *T. pallidum* in aqueous or vitreous fluid by darkfield microscopy, or by PCR or equivalent direct molecular methods

Otic Manifestations of Syphilis: Classification

- Possible: Reactive nontreponemal and treponemal serologic tests <u>AND</u> clinical signs/symptoms consistent with otosyphilis without other known causes for these clinical abnormalities
- Likely: Reactive nontreponemal and treponemal serologic tests <u>AND</u> clinical signs/symptoms consistent with
 otosyphilis without other known causes for these clinical abnormalities <u>AND</u> findings on exam by an
 otolaryngologist that are consistent with otosyphilis in the absence of other known causes for these
 abnormalities
- **Verified**: Reactive nontreponemal and treponemal serologic tests <u>AND</u> clinical signs/symptoms consistent with otosyphilis without other known causes for these clinical abnormalities <u>AND</u> demonstration of *T. pallidum* in inner ear fluid by darkfield microscopy, or by PCR or equivalent direct molecular methods

Late Clinical Manifestations of Syphilis: Classification

- **Likely**: Reactive nontreponemal and treponemal serologic tests <u>AND</u> characteristic abnormalities or lesions of the cardiovascular system, skin, bone, or other tissue in the absence of other known causes of these abnormalities <u>OR</u> clinical signs and symptoms consistent with <u>late</u> neurologic manifestations of syphilis (e.g., general paresis, including dementia, or tabes dorsalis) in a case that meets the criteria for <u>likely</u> neurologic manifestations
- **Verified (Non-neurologic)**: Reactive nontreponemal and treponemal serologic tests <u>AND</u> characteristic abnormalities or lesions of the cardiovascular system, skin, bone, or other tissue in the absence of other known causes of these abnormalities <u>AND</u> demonstration of *T. pallidum* in late lesions by special stains or equivalent methods, or by PCR or equivalent direct molecular methods or by demonstration of pathologic changes that are consistent with *T. pallidum* infection on histologic examination of late lesions
- Verified (Neurologic): Reactive nontreponemal and treponemal serologic tests <u>AND</u> clinical signs and symptoms
 consistent with <u>late</u> neurologic manifestations of syphilis (e.g., general paresis, including dementia, or tabes
 dorsalis) in a case that meets the criteria for <u>verified</u> neurologic manifestations

Considerations for implementation

- Health departments should plan for how surveillance of adverse outcomes of syphilis will be conducted, including, but not limited to, collecting information on neurologic, ocular, otic, and late clinical manifestations from persons reported with any stage of syphilis. Specifically, consider how these data will be:
 - o collected (e.g., patient interviews, provider follow-up)
 - consumed and stored in the surveillance information system (e.g., surveillance information system will be updated), and

- o transmitted to CDC as part of routine case reporting (e.g., weekly NETSS extract will be revised to include clinical manifestation variables or STD message mapping guide [MMG] will be implemented).
- Ensure STD case report form is updated with the 2018 revised syphilis case definitions as outlined in CSTE position statement (see "Other Resources" below)
- In order to collect variables required for this surveillance, local disease intervention specialists (DIS) and public health STD providers should routinely ask patients with syphilis about possible symptoms of neurologic, ocular, otic, or late clinical manifestations during patient interviews
 - o For those patients who are symptomatic, DIS and clinic providers should make appropriate and effective referrals to other providers and/or sub-specialists if there are clinical evaluations (e.g., ophthalmologic exam) and/or procedures (e.g., lumbar punctures) that public health clinics are unable to provide, and ensure that results are documented in patient's health department record
 - Public health departments should consider collaborating with local providers to ensure complete collection of clinical data
 - Cases with any of these manifestations should be reported according to their stage (Primary, Secondary, Early Non-Primary Non-Secondary, or Unknown Duration or Late Syphilis), and the clinical manifestations should be noted in the case report data using the appropriate variable
- Health departments should have treatment protocols for neurosyphilis/ocular syphilis in public health clinics to ensure that all cases are treated according to current CDC recommendations
- Consider following up on cases presenting with symptoms of neurosyphilis/ocular syphilis to evaluate for
 persistent or worsening symptoms and to ensure the evaluation and/or treatment is complete, if applicable
- To go above and beyond, consider monitoring screening and management practices of local providers, such as inquiring about presence of symptoms, ability to perform lumbar punctures/document CSF findings, perform ophthalmologic exams (when applicable), and other related procedures
 - This information can help with interpretation of data trends and can also be used to update provider referral sheets and identify opportunities for provider education
 - Health departments should consider facilitating provider education to improve the recognition of neurologic, ocular, otic, or late clinical manifestations of syphilis by providers and to familiarize them with current STD treatment guidelines

Other resources

- Clinical Advisory: Ocular Syphilis in the United States: https://www.cdc.gov/std/syphilis/clinicaladvisoryos2015.htm
- Ocular Syphilis Eight Jurisdictions, United States, 2014–2016: https://www.cdc.gov/mmwr/volumes/65/wr/mm6543a2.htm
- Syphilis 2018 Case Definition: https://wwwn.cdc.gov/nndss/conditions/syphilis/case-definition/2018/
- For transmittion of data to CDC:
 - o NETTS Implementation Guide: https://www.cdc.gov/std/program/STD-NETSSIMPLN-V5 2018Jan.pdf
 - STD Message Mapping Guide: https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html
- CDC treatment guidelines: https://www.cdc.gov/std/tg2015/default.htm

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Technical Assistance Note #6 | Outbreak response

From Strategy Area II: Conduct Disease Investigation and Intervention

- 6. Respond to STD-related outbreaks
 - a. Review STD surveillance data by the core epidemiologic variables at regular intervals to identify outbreaks and other significant changes in STD epidemiology
 - b. Develop and maintain an outbreak capacity plan to respond to significant changes in STD epidemiology. Ensure that staff are trained and ready to implement the outbreak capacity plan

Why DSTDP included these strategies

Outbreaks or unexpected sudden increases in disease burden over a short time period in a given area are indicators of possible breakdowns in the health and prevention systems and are often tied to various social determinants of health. They also may indicate an increase in risky behaviors, an influx of a new, at-risk population, changes in the sexual networking patterns in the jurisdiction. The causes of outbreaks are manifold, including structural, social, and individual level factors.

STD programs are the front line of defense against increased transmission of STDs, and as such, must routinely examine data to assess whether changes in burden in a given time period are of concern. Additionally, they must try to respond with appropriate staff, resources, and interventions to address the increase. Programs should share results and lessons learned with other programs, to build the knowledge and evidence base related to outbreak identification and response.

Key definitions

Outbreaks: An increase of disease among a specific population in a geographic area during a specific period of time

Routine review of data: Depending on the jurisdiction, this may be monthly, bi-monthly, or quarterly. The program staff should review case reports by county and by other geographic areas (e.g., cities, tribal reservations). Case report data should be reviewed, at a minimum, by sex, race/ethnicity, age, geography, and diagnosing provider.

After-action report: A report that describes the outbreak response from pre-outbreak to post-outbreak, including staff, financial, and other resources used in the response, indices of success in addressing the outbreak, fidelity to response plan, needed changes in the response plan, and lessons learned.

Considerations for implementation

Reviewing data to identify outbreaks and other changes in STD epidemology

- On at least a quarterly basis, generate descriptive reports that display monthly counts and rates of reported chlamydia, gonorrhea, and syphilis cases:
 - Stratify data by a meaningful geographic level (e.g., county), age (e.g., 5-year age categories),
 sex/gender, race/ethnicity, and diagnosing provider type

- o If available, stratify by additional variables such as HIV status, gender of sex partners, substance use history, or other known risk factors
- o For syphilis among adults, display data by stage of syphilis; primary and secondary (P&S) stages are often combined. Congenital syphilis should be reported separately.
- When possible, develop automated approaches to generating reports
- Review reports for findings that may warrant further data analysis, such as unexpected increases or decreases or changes in the demographic and other characteristics of reported cases
 - Investigate whether changes in reporting or data management are influencing the patterns observed in the data. For example, if a laboratory has suddenly stopped reporting, an apparent decline in disease could simply reflect under-reporting
 - Consider how to handle missing data and whether the amount of missing data affects data interpretation.
- Review other low morbidity STD case report data (e.g. LGV, congenital syphilis) by county and gender at least quarterly to identify potential clusters
- Convene meetings of STD program staff at least quarterly to review and discuss the data. Include individuals familiar with the program and the data, such as staff responsible for entering data and generating data reports, program managers, and partner services staff and supervisors
- Focus on changes in the number of cases of early syphilis (especially cases among women and pregnant women)
 and gonorrhea
- Identify changes in the case report data that warrant further investigation and/or public health action. These may include:
 - Organisms with clinically significant resistance (e.g., gonorrhea that is unsuccessfully treated with recommended therapy).
 - Organisms not previously or recently detected in the jurisdiction (e.g., LGV, chancroid).
 - New populations or subgroups affected (e.g., syphilis among females, among attendees of a school)
 - o New/rare clinical presentations of diseases (e.g., ocular syphilis).
 - New geographic areas (e.g., syphilis on a Native American reservation that has not seen syphilis in many vears).
 - Any other distinguishing characteristic related to cases in a cluster.



The threshold for declaring an increase in reported cases to be an "outbreak" depends on local epidemiology, thus jurisdictions use their own thresholds to assess increases and outbreaks.

Developing and practicing a plan for outbreak response

- Consider using existing examples (from within or outside your jurisdiction). Check with your Emergency
 Preparedness office for recent outbreak response plans developed for other situations. Tailor them to the STD
 program in your area.
- Explore possible barriers and challenges in responding to an increased STD burden in your jurisdiction, as well as how your jurisdiction could overcome these challenges. For example, consider resources needed to respond to a 50% increase in syphilis in the locality, specifically addressing anticipated needs for data entry, case and partner interviewing, and epidemiology capacity, as well as potential treatment needs (such as Benzathine penicillin G)
- Consider methods of mobilizing additional resources (personnel, financial, treatment, and others) to respond to an increase in STD burden

- Consider the state's ability to pull health department staff from other departments to provide additional help
- Consider capacity and feasibility to cross-train health department staff (such as those from other departments) in partner services techniques
- Consider the ability to move staff in a timely manner within the state to respond to increases
- o Pro-actively develop memoranda of understanding (MOUs) to allow the transfer of staff or supplies (e.g. Benzathine penicillin G) between counties or surrounding states in emergency situations
- o Develop relationships with local health department emergency preparedness and response staff
- Include plans to collaborate with tribal entities or neighboring states that may be affected by an increase

Outline for an Outbreak Response Plan

1. Outbreak Preparedness

- a. Activation of the outbreak plan
- b. Roles and responsibilities
- c. Additional staffing capacity
- d. Data security
- e. Communication plan
- f. Identify existing partnerships, both internal and external to the health department

2. Managing a response

- a. Management structure and staffing mix
- b. Informing, coordinating, and engaging with partners
- c. Prioritization of disease

3. Outbreak Investigation and response

- a. Determine the existence of an outbreak
- b. Verify the diagnoses
- c. Establish a case definition and find cases
- d. Describe the data in terms of person, place, and time
- e. Determine who is at risk of becoming ill
- f. Develop a hypothesis that explains the etiology of the outbreak
- g. Compare the hypothesis with established facts
- h. Plan a more systematic study
- i. Implement prevention and control measures
- j. Summarize findings and evaluate response
- Practice implementing the outbreak response plan. Conduct STD-related "Tabletop Exercises" or other STD emergency-situation practice drills, to ensure staff readiness
- During an outbreak
 - o Monitor staff resources devoted to outbreak response
 - Monitor indices of success in outbreak response, such as partner services indices
 - Note the date that an outbreak was declared, the date it ended, and important "milestone" dates throughout the response
 - o Note any deviations from the protocol outlined in the outbreak response plan
- Share response activities, results and lessons learned to other jurisdictions via a webinar, poster, presentation, or other document. Update any protocols or policies that need revision based on lessons learned from most recent outbreak

Other resources

- Program Operations Guidelines for outbreak response
- <u>CSTE Syphilis Outbreak Detection Guideline</u>
- STD Outbreak response plan guide: https://www.cdc.gov/std/funding/docs/outbreak-response-plan.pdf

For more information or feedback on this document, contact your DSTDP Prevention Specialist or email STD_PCHD@cdc.gov. CDC's Division of STD Prevention, Program Development and Quality Improvement Branch, developed this document for recipients of PS19-1901 STD PCHD to provide additional clarification of strategies outlined in that NOFO and to support program implementation. The content here does not represent additional NOFO requirements nor official CDC recommendations. Issue date: April 2019



Technical Assistance Note # 7 | Disease investigation and intervention for pregnant women and other women of reproductive age with syphilis

From Strategy Area II: Conduct Disease Investigation and Intervention

- 7. Conduct health department disease investigation for pregnant women with syphilis and other reproductive-age women with syphilis
 - a. Prioritize for investigation all reported females of reproductive age with reactive serology, including provider follow-up to confirm stage, treatment, and pregnancy status
 - b. Regardless of pregnancy status, conduct follow-up on new syphilis cases among women of reproductive age, to obtain more information, if needed, on treatment and other information needed to ensure linkage to related STD, MCH, HIV prevention and other services. For those who are pregnant, investigation should also include follow-up with the pregnant female, prenatal care providers, birthing centers, and neonatal care providers as needed to ensure adequate maternal follow up and stillbirth and neonatal evaluations per clinical guidelines
 - c. Provide timely partner services to all pregnant women who are diagnosed with syphilis and all other women of reproductive age who are diagnosed with early syphilis

Why DSTDP included these strategies

Disease investigation and intervention are fundamental to the public health response to many infectious diseases, including STDs. The goal of these activities is to interrupt disease transmission networks by diagnosing and treating individuals in those networks and preventing various potential adverse outcomes of syphilis in women, particularly pregnant women. Taken to scale, disease intervention, including partner services, can slow and even stop transmission at a population-level. Additionally, disease intervention can also help link persons to much needed services if appropriate, including HIV re-engagement in care and PrEP. Health department STD programs have unique authority and responsibility to conduct disease investigation and intervention.

After more than a decade of extremely low case rates, primary and secondary syphilis among women, and congenital syphilis among pregnant women, have steadily increased since 2012. The prevention and control of congenital syphilis is the strategic priority for DSTDP and should also be considered a priority for all DSTDP funded programs.

Why prioritize women of reproductive age

- Women of reproductive age (WRA) are generally defined as women between 15-44 years old, but STD programs may opt to define this as women under age 50
- Disease investigation for all pregnant women who test positive for syphilis, regardless of stage, is important because treatment of a pregnant woman with syphilis may prevent congenital syphilis. Partner services for pregnant women with syphilis (or those who have been recently treated for syphilis) can reduce the chance that the individual is re-infected with syphilis during pregnancy

Intervention and partner services for other women of reproductive age with <u>early syphilis</u> is highlighted because
case and laboratory reports for syphilis often do not include information on pregnancy status, and therefore the
woman may be pregnant or could become pregnant



STD programs should ensure that their follow up for these groups is as strong as possible, before designating other groups of STD cases eligible for health department investigation.

Considerations for implementation

Prioritizing reactive lab and provider reports

- Record search all lab and provider reports on WRA within 48 hours of receipt to determine history of testing or treatment. Prioritize all lab and provider reports for additional follow-up if there is no documented history that confirms that the case is a former or "old" case not in need of any follow-up. If there is any doubt, err on the side of caution and proceed with follow-up
- Prioritize reactive lab and provider reports among women for physician outreach to determine pregnancy status, reason for testing, symptom history, treatment information, and patient locating information.
 Determining pregnancy status is paramount at this stage of investigation and should not wait for a patient interview
- Prioritize reactive lab and provider reports from prenatal care providers for immediate follow-up to ensure timely treatment. Consider other facilities that aren't traditional medical providers that might be a priority for review: for example prisons/jails and drug treatment facilities that serve women
- Create program standards for the timely follow-up of reactive lab reports on pregnant women and other females of reproductive age. Monitor timeliness and completeness of laboratory and provider reporting
- Don't wait for confirmatory test results before initiating provider follow-up for a pregnant woman with a reactive syphilis serology. If communication between the provider and the health department is stalled, initiate health department follow-up with the patient immediately. However, do wait for a confirmatory test before recommending treatment, in most cases
- Beyond cost barriers, explore whether there are other barriers that may prevent a WRA from receiving care or engaging with the health department, including transportation, child care, inability to take leave from work, etc.
- Regularly inventory the available resources needed by staff that routinely manage of WRA with syphilis, such as sites providing no/low cost prenatal and reproductive health services, high-risk maternity services, penicillin desensitization, case management resources, etc.
- Consider identifying a liaison to carry out active surveillance with delivery hospitals, OB/GYNs, and other key
 providers in high-morbidity areas and/or that serve large populations of women at-risk for syphilis. Perinatal
 hepatitis B or perinatal HIV coordinators may be particularly helpful in making connections and navigating
 systems
- Consider the environmental context. For example, during times of an opioid outbreak, you may consider
 provider outreach to facilities who may see at risk women to discuss symptoms and the need for testing among
 certain populations, like those who exchange sex for money or drugs.

Following up on cases

- First priority should be given to pregnant women, then to pregnant contacts to active syphilis cases, then to
 women of reproductive age with positive syphilis tests, and then to women of reproductive age who are
 contacts to active cases
- Consider whether there may be cost barriers to treatment (among uninsured and under insured women) and consider health department support/coverage for the treatment of those for whom treatment or treatment cost is a barrier.
- Consider a daily debriefing on these female cases once assigned to ensure prioritization by DIS, front line supervisors, and field operations managers. Frequently monitor the status of cases and provide a forum for DIS to discuss case management (e.g. chalk talks, case conferences) in a timely way, so that the discussions can benefit active follow-up/ investigation efforts. All congenital syphilis cases will merit special review (see STD PCHD Strategy and TA Note #4)
- Don't hesitate to have health department staff visit the hospital to talk to a patient or provider related to a congenital syphilis case. Infection Control Nurses at hospitals are often an excellent resource
- Pursue public-private partnerships and/or collaborations with maternal and child health organizations to enhance provider awareness of congenital syphilis and to conduct social marketing efforts to promote prenatal care and ensure timely referral of pregnant women to case management

Conducting partner services

- Ensure that high morbidity providers regularly inform their patients that the health department may be
 contacting them for interview and partner elicitation. Because provider buy-in is essential to successful partner
 services, consider creating a brief script that providers can use to talk about health department follow-up for
 partner services
- Partner services is essential for all women reported as index cases. In addition, pregnant female contacts and associates, and other women of reproductive age named as partners or associates to male syphilis cases, should also be prioritized for follow-up
- Offer partner services as quickly as possible after a case is diagnosed. This is particularly important in pregnant
 females to reduce the chance of reinfection by an untreated partner. Ensure DIS have appropriate access to
 records and resources that could assist them in locating and referring partners (e.g. eHARS, Accurint, Facebook,
 etc.)
- During every interview of a diagnosed case of syphilis, ask the person if they have partners who are or who may be pregnant, as well as any other women they know who may be pregnant. Assist with linking any women who are not yet in prenatal care into care, and assist with linking women who are not pregnant and want to use contraception to family planning services. HIV prevention services, including education about and linkage to PrEP, should also be a part of this assessment and assistance to both cases and partners, as appropriate.



Recommended follow-up on congenital syphilis cases is described in a separate strategy of STD PCHD and in a separate **TA Note #4**. Please reference those alongside this document.

Other resources

- IPS tool kit: https://www.cdc.gov/std/program/ips/default.htm
- PS evaluation field guide: https://effectiveinterventions.cdc.gov/docs/default-source/partner-services-materials/Partner-services-evaluation-field-guide-041610.pdf?sfvrsn=0
- DIS training centers: http://distc.org/
- Recent review paper on partner services:
 - http://journals.lww.com/stdjournal/Fulltext/2016/02001/Partner Services in Sexually Transmitted Disease.8.aspx
- CDC Call to Action: Let's Work Together to Stem the Tide of Rising Syphilis in the United States: https://www.cdc.gov/std/syphilis/syphiliscalltoactioapril2017.pdf
- 2018 revised syphilis case definitions: https://wwwn.cdc.gov/nndss/conditions/syphilis/case-definition/2018/

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Technical Assistance Note # 8 | Promoting Expedited Partner Therapy (EPT)

From Strategy Area II: Conduct Disease Investigation and Intervention

- 8. Promote Expedited Partner Therapy (EPT) (where permissible) to partners of chlamydia and/or gonorrhea cases
 - a. Assess EPT practices to identify and prioritize providers, organizations, and areas to target for promotion and improvement. Provide technical assistance and education to promote EPT to providers and organizations who frequently report cases of chlamydia and/or gonorrhea, including cases of repeat infections

Why DSTDP included these strategies

Expedited Partner Therapy (EPT) is the clinical practice of treating the sex partners of patients diagnosed with chlamydia (CT) or gonorrhea (GC) by providing prescriptions or medications to the patient to take to their partner without the health care provider first examining the partner. The most common form of EPT is to give patients diagnosed with infection medications to give to their partners: patient-delivered partner therapy (PDPT).

EPT represents an important component of partner management, and can reduce the risk of reinfection in a treated patient and curtail further transmission. CDC has concluded that EPT is a useful option to facilitate partner management, particularly for treatment of male partners of women with chlamydial or gonorrheal infection.

Key definitions

Medication-EPT: The practice of giving medications to patients to give to their sex partners, without an intervening clinical assessment

Prescription-EPT: The practice of giving prescriptions to patients to give to their sex partners, without an intervening clinical assessment

Considerations for implementation

While progress has been made in reducing legal barriers to EPT, there is still much to be done to support broader implementation and scale-up of EPT usage among clinical providers. Recipients are encouraged to work with the health care sector and policy makers to advance the use of EPT. Activities can include, but are not limited to those listed in the section below.

Where EPT Is Permissible:

At the provider level

 Work directly with providers and health centers that see large numbers of chlamydia and gonorrhea cases to assess their EPT policies, procedures, barriers, and facilitators

- Target pediatricians, adolescent medicine, OB/GYN and school-based (e.g., high school or college) providers
- Assess knowledge, attitudes, and beliefs of providers to identify EPT uptake barriers
- Use findings from assessments to develop tailored EPT education materials for providers
- Provide technical assistance to facilitate partner treatment through EPT
- o Review ways to better utilize EHRs or e-prescribing to facilitate EPT uptake
- o Identify community clinician-champions to help advance provider knowledge, implementation of EPT
- Educate pharmacists about EPT by delivering presentations at schools of pharmacy, and at local professional organizations of pharmacists
 - Where "nameless" EPT prescriptions are allowed, examine the frequency with which these prescriptions are received in pharmacies, and the proportion that pharmacists refuse to fill
 - Compile a list of frequently asked questions (FAQs) about EPT for pharmacists that can be distributed at presentations and faxed to pharmacies that refuse to fill EPT prescriptions
- Conduct EPT policy and practice overviews at relevant meetings of medical providers or administrators

At the patient level

- Develop patient and partner EPT informational materials (in English and Spanish) and make electronic copies available to providers (see Resources below for links to some examples)
- Incorporate EPT education & messaging as part of routine partner management where EPT is indicated

At the health department level

- Explore the feasibility of purchasing EPT medication(s) in bulk and distributing them to provider groups who see a large number of patients eligible for EPT
- Identify state or local chapters of national professional medical organizations (e.g. American Academy of Pediatrics, American College of Obstetricians and Gynecologists), and work with them to disseminate information to their members via e-newsletters, webinars, annual meetings, etc. Identify health department partner agencies (e.g., Adolescent Health, Primary Care, or Medicaid Offices) that work with providers who diagnose chlamydia and gonorrhea; set up meetings to help coordinate and promote EPT messaging
- Consider opportunities to facilitate EPT medication delivery through health department partner agencies that work closely with high-diagnosing providers and eligible patient populations
- Host a health department-EPT website that includes relevant local EPT laws/regulations/professional board decisions
- Track provision of EPT at the population level
 - Add question(s) to local provider case report forms to document whether and how partner services are performed for the index patient in question, including whether the patient was given EPT, and if so, by what mode (medication-in-hand or prescription) and for how many partners
 - Identify data sources to monitor aspects of EPT uptake, such as the extent to which EPT is offered, provided, filled (if by prescription)

At the health systems level

Reach out to health plan administrators (including urgent care networks) to assess the extent to which EPT is
included in their system protocols and procedures, including facilitating treatment through partnerships with
area pharmacies or other walk-in care centers

- Consider developing pre-printed prescriptions for EPT that: 1) reference STD program website where relevant EPT law or professional body decision can be viewed, 2) has set regimens for treating gonorrheal or chlamydial infections, 3) can be tracked (record numbers on supply of prescription pads given to provider groups, track prescriptions at local pharmacies)
- Ask schools of pharmacy to add EPT to their legal curriculum
- Work with local pharmacies and chains to identify facilitators and barriers to EPT access
- Assist in clarifying local laws and regulations pertinent to EPT
 - Pursue policy allowing prescriptions for index patient and partner(s) to be written on the same prescription
 - o Promote medication-EPT over prescription-EPT where medication-EPT is available
 - o Pursue mechanisms to cover payment for prescription-EPT through Medicaid or insurance programs

Where EPT Is Not Permissible:

- Educate relevant policy makers and stakeholders about EPT, describing the sequelae of repeat STI, and
 presenting data on the local burden of infections for which EPT could be used
- Work with NCSD or other partners to gather additional evidence and examples of EPT in other settings
- Conduct or encourage local pilot evaluations (e.g., through Targeted Evaluation Projects), including measures to address specific local concerns
- Identify an EPT champion (adolescent medicine provider, etc.) with whom to partner/collaborate
- Build coalitions of stakeholders to advance EPT on the agenda of legislators, professional societies, etc.

Other resources

- CDC EPT Homepage (includes links to position papers, articles, and infographics): https://www.cdc.gov/std/ept/default.htm
- Expedited Partner Therapy Legal/Policy Toolkit: https://www.cdc.gov/std/ept/legal/legaltoolkit.htm
- EPT White Paper (2006) https://www.cdc.gov/std/treatment/eptfinalreport2006.pdf
- New York City's Universal Reporting Form; https://www1.nyc.gov/assets/doh/downloads/pdf/hcp/urf-0803.pdf
- New York State health department's EPT resource page: https://www.health.ny.gov/diseases/communicable/std/ept/
- Maryland health department's EPT resource page: https://phpa.health.maryland.gov/OIDPCS/CSTIP/Pages/Expedited%20Partner%20Therapy.aspx

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Technical Assistance Note # 9 | Disease investigation and intervention with men with syphilis

From Strategy Area II: Conduct Disease Investigation and Intervention

- 9. Conduct health department syphilis disease investigation and intervention for men with primary and secondary syphilis
 - a. Conduct follow-up on primary and secondary syphilis cases among men, to obtain more information, if needed, on treatment, sex of sex partners, HIV serostatus, HIV care status, PrEP use, and other information to ensure linkage to appropriate STD and HIV related prevention services
 - b. Provide timely and comprehensive partner services to men with primary and secondary syphilis who report pregnant or other female partners of reproductive age
 - c. Use program and epidemiologic data to identify subgroups of MSM with primary and secondary syphilis and factors associated with transmission to target for partner services to yield high numbers of all partners treated in a timely fashion and for whom consequence of transmission is the greatest. As resources permit, provide timely and comprehensive partner services including comprehensive STD and HIV testing and linkage to care and needed prevention services to those subgroups of MSM with primary and secondary syphilis

Why DSTDP included these strategies

Disease investigation and intervention are fundamental to the public health response to many infectious diseases, including STDs. The goal of these activities is to interrupt disease transmission networks, by diagnosing and treating individuals in those networks. Taken to scale, disease intervention, including partner services, can slow and even stop transmission at a population-level. Additionally, disease intervention can also help link persons to much needed services, including HIV re-engagement in care and PrEP.

Why the investigation of men with female partners is high priority

After more than a decade of extremely low case rates, primary and secondary syphilis among women, and congenital syphilis among pregnant women, have steadily increased since 2012. The prevention and control of congenital syphilis is the top priority for STD programs. Investigation of females with reactive serology should remain the programmatic priority, followed by investigation of men with female partners. This includes men who have sex with women (MSW) and men who have sex with men and women (MSMW).

Why the investigation of men who have sex with men (MSM) with P&S syphilis is high priority

As a group, MSM are at high risk of STDs. To stem the spread of syphilis in the US, MSM with P&S syphilis, must be a high priority group for investigation and intervention. Moreover, given the overlapping epidemiology of HIV and syphilis among MSM in the US, follow-up of this group is as important for STD prevention as for HIV prevention -- whether helping link cases and partners to testing, PrEP, HIV care, counseling, or other prevention services. In addition, many men who have sex with men are also having sex with women. Therefore in order to address syphilis is women, it is important to also address syphilis in men.

Considerations for implementation

Following-up on cases

- Health departments should make every effort to ensure that all cases of syphilis are treated according to current CDC recommendations, which may require additional efforts to educate and engage providers.
- Interviews of prioritized syphilis serologic reactors (SSRs) are important to describe the epidemiology of syphilis among men, including characteristics such as HIV status, drug use, mental health, and recent sexual behaviors.
- All P&S cases should be assessed for comprehensive STD and HIV prevention service needs and should be followed-up accordingly (e.g., offered a new HIV test)
- Health departments often do not know the sex of a client's sex partner from laboratory or provider reports, and a reasonable amount of effort should go into verifying the sex of sex partners (SSPs) with the provider before initiating an investigation.

Conducting partner services among men with female partners

- Health departments should always seek to provide high quality partner services, such as offering the services as soon as possible, ensuring the services are client-centered and culturally-sensitive, and providing comprehensive services beyond just those related to possible syphilis infection
- Refer to the **TA Note #9** for disease investigation among women of reproductive age for other ideas that could apply to partner services for men, such as ensuring that high volume providers inform patients that they may be contacted by the health department for interview

Conducting partner services among MSM with syphilis

- For partner services for MSM populations, HIV prevention and care is particularly important, given the epidemiology of HIV in the US. Protocols for partner services for MSM should explicitly promote HIV testing, linkage to care, linkage to PrEP, and reengagement with HIV prevention services, as appropriate to each partner.
- Coordination with protocols for partner services for HIV cases is important. Where partner services programs are not integrated, ensure that HIV program staff understand the MSM syphilis partner services protocols, and vice versa and make every effort to prevent individual clients from being contacted by separate STD and HIV program staff.
- Appropriate use of modern technology to facilitate partner services among MSM populations may be
 particularly important to maximize reach and impact, given the nature of some MSM sexual networks and client
 preferences. These technologies may include use of text messaging, email, websites for patient-led partner
 notification, video conferencing, smartphone apps, among others.
- Regularly train partner services staff so they remain culturally competent and current on advances, trends and strategic priorities that impact their work and are able to provide expert guidance to clients and providers.
- Health departments may consider coaching higher-risk men to regularly test for STDs, refer their own partners, including use of widely available online notification tools, and only elicit and notify partners if the client would like the health department's expert assistance to link partners to medical evaluation and linkages to other relevant services such as PrEP.
- Health departments may also be able to engage high-volume providers to assist their clients to ensure partners
 are tested and treated, including potentially caring for the partners in their own practices.

Why the investigation of MSM with syphilis should be focused

Ideally, all MSM with P&S syphilis would be fully investigated by the health department and offered partner services. However, with resource limitations, it may be not feasible for health departments to follow up every case of P&S syphilis in MSM to the same extent. Partner services, in particular, may merit additional targeting. For example, cases with numerous anonymous or unnamed partners may generate substantial work for the health department, but little disease intervention, if partners cannot be identified or only a small fraction of the disease transmission network can be impacted through partner services. Local and state health departments must analyze their data to identify which MSM are the highest priority for investigation, using outcomes such as named sexual partners in the critical period, named partners either prophylactically treated or brought to treatment, index cases and named partners referred back into HIV care, and index cases and named partners referred to HIV PrEP.

Identifying MSM reactors to prioritize for partner services

- First, identify available resources for MSM partner services, by examining total investigative capacity (e.g. number of DIS staff, case load, timeliness measures, extent of work to be done to investigate syphilis among women of reproductive age)
- Based on the resources available for disease intervention for MSM, health departments should explore which
 case investigations would be most productive. Using available data, MSM reactive serologic investigations
 should be analyzed to see if any factors could help predict the most impact. Some outcomes to consider in
 these analyses:
 - Investigations that resulted, for example, in new syphilis cases, in prophylactic treatments, in at least 1
 named partner who was ultimately interviewed, in 0 named partners, and in linkage to HIV care, for
 those newly diagnosed with HIV
 - o Investigations that resulted in individuals being linked to PrEP or re-engaged in HIV care, where appropriate.
- Possible aspects of the reactors which may be helpful for prioritizing investigations include:
 - Date of report, age, high titers, primary or secondary cases, HIV status (if able to be determined through record matching with HIV surveillance), viral suppression (among HIV infected persons), engagement in care (among HIV infected persons), previous syphilis diagnoses, timeliness of report to health department after diagnosis, and diagnosing provider (i.e., STD clinics, larger medical system, LGBT health center)
- Individual factors from the index case that are most associated with favorable outcomes determined at the local level can then be used to prioritize investigations

Other resources

- IPS tool kit: https://www.cdc.gov/std/program/ips/default.htm
- PS evaluation field guide: https://effectiveinterventions.cdc.gov/docs/default-source/partner-services-materials/Partner Services Evaluation Field Guide 041610.pdf?sfvrsn=0
- DIS training centers: http://distc.org/
- Recent review paper on partner services:
 http://journals.lww.com/stdjournal/Fulltext/2016/02001/Partner_Services_in_Sexually_Transmitted_Disease.8.
 aspx
- CDC Call to Action: Let's Work Together to Stem the Tide of Rising Syphilis in the United States: https://www.cdc.gov/std/syphilis/syphiliscalltoactioapril2017.pdf
- 2018 revised syphilis case definitions: https://wwwn.cdc.gov/nndss/conditions/syphilis/case-definition/2018/



Technical Assistance Note #10 | Promoting quality STD specialty care

From Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

- 10. Promote quality STD specialty care services
 - a. Identify all STD specialty care clinics in the project area
 - b. Promote quality STD care in those settings based on clinical guidelines and recommendations and promote strategies for expanding access to care in those settings

Why DSTDP included this strategy

STD clinics and other health care settings that provide specialized STD care are essential partners for state and local health departments to reduce and prevent STDs in every project area. While health department STD programs may not directly support these settings with federal funding or staffing, programs need to maintain close relationships with them. These settings play a critical role in STD control and prevention. They are unique sources of more local expertise in specialized STD care, which STD programs should leverage in their efforts to promote quality STD services in primary care and other health care settings. Moreover, assuring high quality of care and ready access to these settings promotes public health interest by serving populations in need of STD care. This strategy recognizes the important roles specialized STD care clinics play to an STD program and promotes mutual support.

Considerations for implementation

Identify STD specialty care clinics in the project areas

- Maintain a brief directory of clinics that regularly provide STD specialty care, including information on key
 personnel, contact information, location, and basic information about their services (e.g., hours of operation,
 any special populations served)
- Regularly confirm or update the information on file (e.g. every 6-12 months)
- Be prepared to provide basic information on these to DSTDP, the NNPTCs supporting the jurisdiction, or other stakeholders who may want to reach out to these specialty care clinics
- Help provide basic location and service information to the public, by including links or other appropriate information on STD program websites and other communication materials
- To go above and beyond, considering mapping the location of those clinics against STD epidemiology, to inform
 discussions of service gaps and potential collaborations to strengthen screening and treatment

Promote quality STD care in those settings and strategies to expand access

- Make sure that the staff at STD specialty care clinics receive new information or updates on STD-related clinical
 and laboratory practices from CDC and other trusted sources. Consider making a special email and mail
 distribution list just for them, to quickly send relevant updates and reminders
- Conduct a high-level visit to the highest volume STD specialty care clinics in the project area to understand their client base, strengths, and weaknesses, so the STD program can be better positioned to assist the clinics and can strengthen relationships for future collaboration

- Schedule more routine in-person visits to such clinics to promote aspects of quality care, through public health detailing or other targeted health education approaches
 - o DIS or other health department staff who work onsite in such clinics could also facilitate discussions of, and education on, aspects of quality care
- Talk with clinic staff about how they assess and think about their quality of care
 - o To what extent do they use electronic health records? Do they track measures of quality over time?
 - O What do they know about their provision of care already? Do they have aspects of their care they are already hoping to work on?
- Discuss with clinic staff the merits of systematically assessing or evaluating the care and services offered at these clinics. These assessments could be related to various aspects of care and services, such as:
 - Taking sexual histories
 - Adhering to STD clinical guidelines and HIV prevention and care guidelines, as appropriate
 - Offering welcoming and accessible clinical environments for populations served, such as LGBTQ persons, adolescents, people with disabilities, or people with limited English proficiency
 - o Implementing express services/clinics, screening-only visits, or other service models that might serve more patients or serve them more quickly or efficiently
 - Managing and using patient data, including the exchange of relevant information with health department staff
 - o Using clinical decision supports or other reminder systems through electronic health records
- Be prepared to help implement quality of care assessments and participate in discussions with clinic staff on ways to act on the findings and fill any gaps identified
- Consider tapping the NNPTCs or other resources to support training needs and the implementation of clinical quality improvement projects, to address any services gaps



Under STD PCHD, recipients can facilitate access to Benzathine pencillin G for patients at risk of not receiving recommended syphilis treatment. Note that recipients cannot pay for HIV PrEP medications with these funds.

Other resources

- STD Treatment Guidelines website: https://www.cdc.gov/std/tg2015/default.htm, and links to apps and other education tools
- NNPTC website: https://nnptc.org/
- Clinical Consultation Network (CCN): https://www.stdccn.org/
- National STD Curriculumum website: https://www.std.uw.edu/
- Service Gap Assessment Tools: https://www.cdc.gov/std/program/gap/default.htm



Technical Assistance Note # 11a | Gonorrhea treatment assurance

From Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

- 11. Promote CDC-recommended treatment for gonorrhea and syphilis
 - Assess GC treatment practices to identify and prioritize providers, organizations, and areas to target for promotion and improvement. Provide education and technical assistance to providers and organizations who prescribe non-recommended treatment for gonorrhea

Why DSTDP included these strategies

Gonorrhea is the second-most commonly reported communicable disease in the United States, and rates of reported cases have been increasing. Increasing burden of disease affects communities in multiple ways and is often a reflection of overall sexual health. Because of the continued emergence of *Neisseria gonorrhea* antibiotic resistance to the drugs used for gonorrhea treatment and a dwindling antibiotic development pipeline, only a single treatment regimen (dual therapy with injectable ceftriaxone and oral azithromycin) is currently recommended. The risk of emerging resistance to these drugs threatens to undermine public health prevention and control efforts.

Compliance with treatment guidance is important to ensure effective therapy and may slow the emergence or spread of antimicrobial-resistant gonorrhea. State and local health departments are uniquely positioned to monitor the use of recommended treatment and to help ensure that all providers have the information and support they need to treat their patients in accordance with CDC guidelines. Such efforts helps ensure that all patients are adequately treated in a timely manner, reducing both the spread of disease and the long-term individual and community-level health consequences of untreated or repeated infections.

Key definitions

"CDC-recommended treatment": CDC's Treatment Guidelines are specific with respect to classes of antibiotics and specific dosages recommended for specific infections. CDC's 2015 STD Treatment Guidelines recommend dual treatment with ceftriaxone (250 mg IM) and azithromycin (1 g orally) for treating uncomplicated gonococcal infections. These recommendations are periodically revised and updated based on the best available evidence of clinical efficacy, patterns of reduced susceptibility, basic science, diagnostics, and clinical care. Treatment recommendations are intended to guide clinical practice and provide an additional tool to inform provider decisions regarding the best treatments for their patients.

Considerations for implementation

Assess GC treatment practices to identify and target promotion efforts

- Assess the quality, completeness, and timeliness of data on GC treatment available to health departments through case-based surveillance and/or other complementary/supplemental sources:
 - What proportion of reported cases have complete information on the treatment provided or administered, including treatment name, dosage, and date of treatment?

- Are there significant differences by patient characteristics, provider type or region between cases with known versus unknown treatment?
- To what extent do those differences affect the program's ability to understand overall GC treatment practices or to identify areas, patient groups or providers to target with quality improvement initiatives?
- How quickly are the data on GC treatment made available for analysis, monitoring and feedback to providers/facilities potentially using treatment regimens that are not recommended?
- Based on local information and needs, how frequently should information be collected, analyzed and incorporated into program planning?
- Consider assessing GC treatment practices using a random sample of GC cases, if obtaining data on all reported GC cases is not feasible
 - o If most cases are not reported with treatment information, random sampling may be a viable alternative for reliably estimating treatment patterns
 - o Programs must think carefully through this process to ensure their sample is large enough, and with acceptable follow-up completion rates to be useful to prioritizing and targeting follow up efforts
 - o Programs should refer to **TA Notes #2b** to better understand the steps for selecting a random sample of GC cases
 - Programs should continue to work to improve routine reporting of GC treatment, to the extent feasible in their jurisdiction. Can reporting forms be improved, or reporting procedures made easier? Do reporting forms need to be changed to better capture use of dual therapy specifically for GC? Can cases reported only through laboratory reporting be supplemented by basic provider reporting to capture treatment?
- Monitor the use of unexpected GC treatments such as higher-thanrecommended ceftriaxone dosages or frequent use of gentamicin/azithromycin, as potential indicator of resistant infection

Preparing for antibiotic resistant gonorrhea (AR GC)

- GC TX assurance work will take on additional urgency if/when AR GC emerges in the U.S.
- Develop outbreak response plans for AR GC
- Ensure that GC TX-related data and systems are adequate for responding to that

Provide education and TA to providers who prescribe non-recommended treatment for GC

- Using best practices in health communication, create standard GC treatment response document(s), to be used with individual providers or organizations that demonstrate patterns of non-recommended treatment
- Consider automated, routine methods to follow up with individual providers reporting non-recommended treatment, for example through FAX-back mechanisms or other electronic messaging
- Assess the amount of time staff spend on GC treatment follow up, and the amount of provider contact that results from that effort, to help inform the value of this activity and identify ways to increase efficiency
- Contact the National Network of STD Clinical Prevention Training Centers or other clinical training resources to
 assist with providing education and TA to providers and organizations with relatively high use of nonrecommended treatment. More intensive TA may be warranted in some cases and could be offered by clinical
 training centers



These strategies are different from those related to health promotion to the broader provider community (see TA Notes #13/14). Here, the idea is to conduct more targeted follow-up on use of non-recommended treatment. General, broad-based education about recommended GC treatment therapy, or about any new guidelines or notices, would be activities described under the work plan for Health Promotion, not for this strategy.

Other resources

- CDC's webpage on GC treatment: https://www.cdc.gov/std/gonorrhea/treatment.htm
- STD Treatment Guidelines: https://www.cdc.gov/std/tg2015/default.htm
- National Network of Prevention Training Centers (NNPTC): http://www.nnptc.org
- STD Clinical Consultation Network: https://www.stdccn.org/
- National STD Curriculum: https://www.std.uw.edu/



Technical Assistance Note # 11b| Syphilis treatment assurance

From Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

- 11. Promote CDC-recommended treatment for gonorrhea and syphilis
 - Assess syphilis treatment practices to identify and prioritize providers, organizations, and areas to target for promotion and improvement. Provide education and technical assistance to providers and organizations who prescribe non-recommended treatment for syphilis

Why DSTDP included these strategies

Rates of reported syphilis cases have been increasing. Increased disease burden affects communities in multiple ways and is often a reflection of overall sexual health. Recent shortages in some forms of penicillin have heightened the need to monitor syphilis treatment practices more closely. State and local health departments are uniquely positioned to monitor the use of recommended treatments and to help ensure that providers have the information and support needed to appropriately treat their patients. In turn, these efforts help ensure that all patients are adequately treated in a timely manner, reducing both the spread of disease and the long-term individual and community-level health consequences of untreated or repeated infections.

Key definitions

"CDC-recommended treatment": CDC's Treatment Guidelines are specific with respect to classes of antibiotics and specific dosages recommended for specific infections. CDC's 2015 STD Treatment Guidelines recommend Penicillin G, administered parenterally, as the preferred drug for treating persons in all stages of syphilis. The preparation used (i.e., benzathine, aqueous procaine, or aqueous crystalline), dosage, and length of treatment depend on the stage and clinical manifestations of the disease. These recommendations are periodically revised and updated based on the best available evidence of clinical efficacy, patterns of reduced susceptibility, basic science, diagnostics, and clinical care. Treatment recommendations are intended to guide clinical practice and provide an additional tool to inform provider decisions regarding the best treatments for their patients.

Considerations for implementation

Assess syphilis treatment practices to identify and target promotion efforts

- Assess the quality of syphilis treatment data available through syphilis surveillance and disease investigation
 - o Determine what proportion of reported cases have complete information on the treatment administered, including medication, dosage, mode of administration, and date(s) of treatment
 - o Of those treatment characteristics, focus first on data quality related to how quickly patients are treated and whether the recommended medication is used
- Assess, at least annually, the extent to which syphilis treatment is a problem in the jurisdiction
 - o Is non-use of recommended treatment an isolated and rare issue, specific to a few individual providers? Or is the problem more widespread and tied to any structural gaps, such as Benzathine penicillin G

- shortages or other issues? Are there issues of "over treatment", especially for persons with uncomplicated primary or secondary syphilis or living with diagnosed HIV infection?
- The answers should directly inform the program's response

Provide education and TA to providers who prescribe non-recommended treatment for syphilis

- Using best practices in health communication, create standard syphilis treatment response document(s), to be used with individual providers or organizations that demonstrate patterns of non-recommended treatment
- Given most reported syphilis cases involve some disease investigation and case follow-up, speak with individual
 providers to understand why they chose the non-recommended treatment regimen and to identify barriers to
 providing recommended treatment
- Contact the National Network of STD Clinical Prevention Training Centers or other clinical training resources to
 assist with providing education and TA to providers and organizations with relatively high use of nonrecommended treatment. More intensive TA may be warranted in some cases and could be offered by clinical
 training centers
- Take advantage of the release of new or updated CDC STD Treatment Guidelines to convene virtual or in-person STD clinical practice updates to promote collaboration and increase compliance with recommended STD treatment among area health care providers

Other resources

- CDC STD Treatment Guidelines for syphilis: https://www.cdc.gov/std/tg2015/syphilis.htm
- Benzathine penicillin G shortage: https://www.cdc.gov/std/treatment/drugnotices/Benzathine penicillin
 Gshortage.htm
- STD Treatment Guidelines: https://www.cdc.gov/std/tg2015/default.htm
- National Network of Prevention Training Centers (NNPTC): http://www.nnptc.org
- STD Clinical Consultation Network: https://www.stdccn.org/
- National STD Curriculum: https://www.std.uw.edu/



Technical Assistance Note # 11c | Benzathine penicillin G (Bicillin L-A®) tracking and forecasting

From Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

- 11. Promote CDC-recommended treatment for gonorrhea and syphilis
 - c. Implement a Benzathine penicillin G forecasting inventory management system to monitor supply, and have a plan to address shortages in the applicant's project area. Assist providers and organizations who are unable to provide timely, recommended treatment for syphilis in getting access to medication or dispensing the treatment to the patient, as needed

Why DSTDP included these strategies

In recent years, the demand for Benzathine penicillin G in the US has outstripped its supply. As a result, some providers have faced drug shortages needing emergency supplies and/or not prescribed the best treatment of syphilis or administered it in a timely manner, as recommended by CDC. Health departments have a responsibility to play an active role in monitoring these issues, mitigating shortages, and facilitating recommended treatment of syphilis. Providing prompt treatment to reduce the spread of syphilis in the community is a core public health function required in many states by statute or regulation.

This TA Note addresses the first part of the strategy outlined above.

Considerations for implementation

Forecast and monitor Benzathine penicillin G (Bicillin L-A®) inventory

- Monitor local supply of Benzathine penicillin G and determine local pattern of use. At regular intervals,
 proactively take inventory of any supplies maintained by the public health sector. Do so more frequently if
 product is found to be low in order to inform ordering of product
- Determine rate of increase of syphilis cases and contacts in the previous year and contact distributors to procure Benzathine penicillin G based on a projection of future cases and contacts expected rather than based on prior orders. For example, the simplest approximation of potential cases for 2019 would be to apply the percentage increase in syphilis cases from 2017 to 2018 to the number of cases of syphilis treated in 2018

Plan for shortages

- Implement a usage strategy, if inventory is less than 2 months of product, based on projections
- Identify inventories with sufficient product based on the usage pattern, and facilitate movement of product, if feasible, in your project area
- Communicate with healthcare providers and pharmacists regarding any limited supply issues. Remind health care providers and pharmacists of the limited availability of Benzathine penicillin G so they are aware, can plan, and forecast demand based on the epidemiology of syphilis in the project area. Ask providers to report to you

- any shortages when inventory is less than 2 months of product based on projected use and inform DSTDP of limited supply issues
- Discourage the use of Benzathine penicillin G for treatment of other infectious diseases (e.g. streptococcal pharyngitis) where other effective antimicrobials are available
- Encourage the adherence to the recommended dosing regimen of 2.4 million units of Benzathine penicillin G IM for the treatment of primary, secondary, and early latent syphilis (early syphilis) as outlined in the most current STD Treatment Guidelines. Additional doses to treat early syphilis do not enhance efficacy, including among patients living with HIV infection
- Encourage clinicians with questions about syphilis clinical management to contact the on-line National Network
 of STD Clinical Prevention Training Centers (NNPTC) STD Clinical Consultation Network (https://www.stdccn.org)
 or a local ID specialist

Other resources

- CDC's website on the Benzathine penicillin G (Bicillin L-A®) shortage: https://www.cdc.gov/std/treatment/drugnotices/bicillinshortage.htm
- FDA Drug Shortage website (search here for Benzathine penicillin G): https://www.accessdata.fda.gov/scripts/drugshortages
- National Coalition of STD Directors website: http://www.ncsddc.org/resource/bicillin-forecasting-and-inventory/
 - This includes a link to an Excel-based forecasting tool



Technical Assistance Note # 11c | Syphilis treatment public health program

From Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

- 11. Promote CDC-recommended treatment for gonorrhea and syphilis
 - c. Implement a Benzathine penicillin G forecasting inventory management system to monitor supply, and have a plan to address shortages in the applicant's project area. Assist providers and organizations who are unable to provide timely, recommended treatment for syphilis in getting access to medication or dispensing the treatment to the patient, as needed

Why DSTDP included these strategies

In recent years, the demand for Benzathine penicillin G in the US has outstripped its supply. As a result, some providers have faced drug shortages needing emergency supplies and/or not prescribed the best treatment of syphilis or administered it in a timely manner, as recommended by CDC. Health departments have a responsibility to play an active role in monitoring these issues, mitigating shortages, and facilitating recommended treatment of syphilis. Providing prompt treatment to reduce the spread of syphilis in the community is a core public health function required in many states by statute or regulation.

This TA Note addresses the second part of the strategy outlined above. See **TA Note 11.c.1** for additional guidance about monitoring and forecasting syphilis treatment.

CDC/DSTDP allows the use of grant funding to create a public health program to facilitate access to Benzathine penicillin G for the treatment of syphilitic infections among uninsured and underinsured patients and their sex partners whose clinical service providers are not able to administer timely treatment with Benzathine penicillin G.



In these critical public health situations, Benzathine penicillin G should be provided under medical orders of the medical director of the STD program or the health department. The health department physician prescribing the Benzathine penicillin G must keep a medical record of all patients treated under his or her orders. DSTDP will provide a template MOU that health departments can take to their general or legal counsel to modify according to state/local policies, to then use with referring providers.

Considerations for implementation

Setting up a public health program for Benzathine penicillin G assistance

- This program is for patients or partners who might otherwise go untreated for syphilis because they are uninsured or underinsured. Fundamentally, it is about setting up a system in which individuals needing timely treatment are formally referred to the public health program for treatment
 - However, treatment does not have to be given at a public health clinic. Most patients needing treatment should not be sent to a public health clinic, as that usually creates additional barriers to timely treatment for patients

- Under this program, treatment can be delivered to the referring health care setting for a particular patient to be dispensed by the referring provider, so long as appropriate protocols and standing orders are in place
- An MOU must be signed between the referring provider and the public health program for every patient treated through this program. The MOU should clearly state that the provider has referred a patient to the health department for treatment because of unique circumstances, and that the health department has agreed to take responsibility for the patient's treatment
- Programs may want to start on a smaller scale, beginning with syphilis hotspots and high volume providers in those areas with a history of providing non-recommended treatment or delayed treatment
 - Health departments should <u>not</u> become the favored source of syphilis treatment for any providers, but rather they should be a back-up option for exceptions when under/uninsured patients are at risk of not being treated according to clinical guidelines because of unique circumstances
- Documentation of the program is critical. Keep a brief record of all patients treated under the medical orders of the STD program or health department. This information may be stored in a separate tracking database or integrated into existing syphilis case follow up systems
- Recipients must be prepared to report to DSTDP on a regular basis, at a minimum:
 - o # of MOUs signed (as measure of the # of individuals referred under the program)
 - o # of individuals provided at least one shot Benzathine penicillin G through the public health program

Important questions for the STD program to consider, before starting a program

For areas new to this work, the first step is to think carefully through the protocol and logistics for such a public health program:

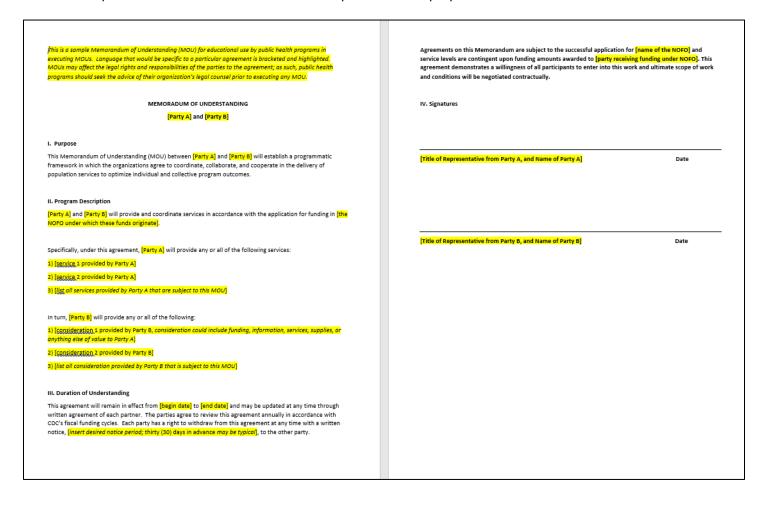
- Which providers are likely to need and use this program to treat their patients?
- Are there changes at the health care provider or clinic level, such as implementing or expanding health insurance billing, which could mitigate the need?
- Are appropriate protocols, MOUs, and standing orders in place at the clinical sites and the health department to cover dispensing by the referring provider and treatment by treatment a public health clinician?
- How will providers request assistance?
- What entity in the health department will purchase recommended syphilis treatment, and through what vendor or program?
- Who from the health department will deliver the treatment to providers requesting this assistance?
- How will the health department track use of this program?
- Where and how will the doses designated for public health use be stored and monitored (i.e., for expiration dates, storage environment, lot numbers, etc.)?
- How much Benzathine penicillin G should the health department stock and make available through this program?
- How will the health department inform providers about the program and handle questions from the provider community?

Important questions for the STD program to discuss with its general counsel

Because an MOU is a legally binding document, prior to executing any MOU, a public health program should discuss the MOU's language with its legal counsel in order to ensure that it is valid and effective based on the program's state law. Issues to discuss with legal counsel might include:

- The purpose of the MOU in the context of the Benzathine penicillin G program: to acknowledge and document the public health program's role in providing syphilis treatment to the patient
- How to ensure that the diagnosing provider provides the public health program with the supporting documentation required to be reported to DSTDP (as discussed above in this document)
- Should one MOU be executed per patient, or one MOU per provider
 - o In the case of providers who see a high volume of STD cases and have a more integrated and longstanding relationship with the public health program, particularly those providers who receive funding from the public health program, it would be a good business practice to formalize the full extent of this arrangement via an MOU even beyond the scope of Benzathine penicillin G delivery
- The duration of the MOU, and how the parties to the MOU can withdraw from it prior to its expiration
- The liability implications of this MOU for the public health program

Here is a sample outline of an MOU that could be adapted for these purposes:





Technical Assistance Note # 12a | STD clinical preventive services for pregnant women

From Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

- 12. Promote CDC-recommended screening, diagnosis, and treatment of STDs among high priority populations:
 - a. **For pregnant women**: Assess screening and treatment practices to identify and prioritize providers, organizations, and areas to target for promotion and improvement. Provide education and technical assistance, for prenatal-care providers and organizations who do not regularly screen for syphilis as recommended

Why DSTDP included these strategies

CDC recommends screening all pregnant women for syphilis at their first prenatal visit. Re-screening at 28-32 weeks gestation and again at delivery is also highly recommended for women: (1) at high risk for syphilis; (2) who live in areas with high numbers of syphilis cases, or (3) who either were not screened in the first trimester, or had a positive test in the first trimester. Screening for chlamydia and gonorrhea is recommended at the first prenatal visit for pregnant women younger than 25 years of age, and older pregnant women at increased risk (defined as having a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has a sexually transmitted infection). Rescreening for chlamydia and gonorrhea in the third trimester is recommended if the patient is at continued high risk, or if she is younger than 25 years of age.

Untreated STDs in pregnant women can result in problems during pregnancy, including pre-term labor, premature rupturing of membranes, and low birth weight. Pregnant women with syphilis can pass the infection to their developing fetus, resulting in congenital syphilis, a condition linked to premature births, stillbirths, and in some cases, death shortly after birth. Untreated infants that survive tend to develop developmental disabilities and problems in multiple organs, including the brain, eyes, ears, heart, skin, teeth, and bones.

In order to prevent these complications and sequelae, screening for STDs in pregnancy is critical. STD PCHD recipients should work with providers of pre-natal care, birthing centers, maternal and child health programs and other organizations serving pregnant women at high risk for STDs, to promote the routine screening of pregnant women according to CDC recommendations. While it is not always possible to obtain data on screening rates from every provider, programs should identify high-priority providers in at-risk communities who can provide such data. In areas where congenital syphilis cases have occurred, provider education and technical assistance should be intensified. Where possible, STD PCHD recipients should use quality improvement (QI) methods to measure and increase screening in provider groups, health departments, health plan members, and other providers of care to pregnant women at high risk for STDs.

Considerations for implementation

Know the providers of prenatal care and providers offering service to pregnant women

- Examine vital statistics data, state medical licensing offices, or local chapters of professional organizations like ACOG to identify high priority providers of prenatal care
- Examine insurance (including Medicaid), laboratory and provider data to identify providers offering services to pregnant women; include Maternal and Child Health (MCH) programs and newborn visiting programs
- Obtain data from insurance plans (including Medicaid), hospitals, clinics, and other service providers to assess screening rates
- Assess screening practices of providers that have provided services to women that have congenital syphilis investigations
- Review congenital syphilis cases to identify providers not following screening and treatment recommendations
- Consider partnering with larger hospital systems or providers that have electronic medical records, as they may be able to more easily provide accurate data about screening,
- Focus on high prevalence areas; avoid spending much time in areas where there is no syphilis among women.
- Consider who can provide data about screening in pregnancy, and how to find out which providers are not screening
- Monitor screening rates in jurisdictions where syphilis among women is high, or where congenital syphilis cases have occurred or increased in recent years

Actively promote screening among prenatal care providers and other providers of care for pregnant women

- Provide Health Alerts or other provider communications, including provider visitation, to raise providers' awareness of the need to screen
- Offer continuing education credits to attract clinical providers to a presentation or meeting
- Conduct trainings, presentations at professional meetings, technical assistance, and other education efforts to increase providers' awareness of the need to screen
 - Conduct trainings directed at prenatal care provider physicians and nurses. In the training, show data on the missed opportunities.
 - Consider distributing a provider packet with screening recommendations, fact sheets showing STDs in pregnant women including congenital syphilis
 - o Adopt a structured provider detailing program to target highest priority areas or providers
- Consider using program funds to support screening of uninsured pregnant women in state owned clinics
- Offer provider incentives to prenatal care providers and Ob/Gyns for STD screening in pregnant women
- To go above and beyond, conduct quality improvement in one or more providers who do not screen routinely
- Develop regular assessments of screening rates, conduct training and technical assistance, and collaborate on ways to continuously improve rates

Other resources

- CDC STD fact sheet on pregnancy and STDs: https://www.cdc.gov/std/pregnancy/stdfact-pregnancy-detailed.htm
- CDC STD Treatment Guidelines: https://www.cdc.gov/std/tg2015/specialpops.htm
- Syphilis Call to Action: https://www.cdc.gov/std/syphilis/syphiliscalltoactionapril2017.pdf
- March of Dimes Infographic: https://www.marchofdimes.org/complications/protect-yourself-and-your-baby-from-syphilis-infographic.aspx
- Provider Guide to Syphilis: https://www.cdc.gov/std/syphilis/Syphilis-Pocket-Guide-FINAL-508.pdf



Technical Assistance Note # 12b | STD clinical preventive services for adolescents & young adults

From Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

- 12. Promote CDC-recommended screening, diagnosis, and treatment of STDs among high priority populations:
 - b. **For young adults and adolescents**, particularly those seen in family planning clinics, adolescent health clinics, and primary care settings: Assess screening and treatment practices to identify and prioritize providers, organizations, and areas to target for promotion and improvement. Provide education and technical assistance to targeted providers and organizations to promote recommended screening and treatment

Why DSTDP included these strategies

CDC recommends screening for chlamydia (CT) in women younger than 25 years of age, and women older than 25 years of age if they are at risk (defined as having a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STD.) Men should be considered for screening if they are seen in a high-prevalence clinical setting or if they are members of a population with a high burden of infection, such as men who have sex with men.

Many persons with CT are asymptomatic and therefore are not aware that they are infected or may have negative health outcomes. Screening tests are defined as testing asymptomatic people for diseases or conditions for which they are at risk. Screening for CT and gonorrhea (GC) is necessary because of the asymptomatic nature of these infections, and the risk for sequelae (conditions that are consequences of a disease or injury) if infections are not treated. These sequelae include pelvic pain, pelvic inflammatory disease, tubal factor infertility, and potentially fatal ectopic pregnancy.

In order to prevent these complications and sequelae, screening for STDs is critical. STD programs should work with health care providers who serve adolescents and young adults, including primary care, family planning, and adolescent health providers, to ensure awareness of the need to screen for CT and GC. This screening is important enough that it is counted among the 94 performance measures in the Health Effectiveness Data and Information Set (HEDIS) that is used to measure quality control in healthcare by over 90% of health insurance plans in the United States. Despite the fact that programs should be measuring screening rates for their HEDIS measure collected for Medicaid and other insurance plans, it is not always possible to obtain screening data from every provider. STD programs may choose to focus on high-priority providers in at-risk communities who can provide such data. In areas where CT and GC rates are high, provider awareness-raising, education and technical assistance should be intensified. Where possible, STD programs should use quality improvement methods to measure and increase screening in provider groups, health departments, health plan members, and other providers of care adolescents and young adults.

Considerations for implementation

Know the providers of care and services for adolescents & young adults

- Examine insurance, laboratory, and provider data from your jurisdiction to identify providers that see adolescents: school clinics, adolescent clinics, sports screening programs, juvenile detention programs, drug treatment programs, homeless youth programs, etc.
- Obtain any readily available HEDIS measures, Medicare or similar data from insurance plans, clinics, municipalities and other organizations to assess screening rates
- Consider partnering with larger hospital systems or systems that have electronic medical records, as these may
 be able to more easily provide accurate data about screening,
- Look at local population data to determine where large numbers of adolescents may reside, and compare this with reported screening data. This may help identify which providers are not screening
- Prioritize resources to higher prevalence areas; focus on areas that need it most
 - Identify providers who see adolescents in areas where there are high disease rates and consider focusing on providers who are not reporting much CT/GC
- Interact with schools, social services, correctional organizations, drug treatment facilities and CBOs serving adolescents to create a professional network of people who can support screening efforts
 - o It may be more useful to interact with schools at a school district level than with individual schools
 - It is often useful to establish a relationship by having one point person who consistently interacts with organizations
 - Consider bundling CT/GC screening services with other services your health department may already be providing to these organizations

Actively promote screening among providers of care for adolescents & young adults

- Encourage providers to make structural changes to their systems and practices that ensure young women are automatically screened at their first care visit each year, as these have been shown to be most effective at raising screening rates
- Provide Health Alert, Grand Rounds, and other provider communications to raise providers' awareness of the need to screen
- Ensure that providers are emphasizing rescreening 3 months after treatment for all patients who test positive for CT and GC, and for women who test positive for trichomonas
- Offering continuing education credits is a good way to attract clinical providers to a presentation or meeting
- Consider using program funds to support screening of uninsured women in family planning and other clinics Continuously monitor data to ensure claims for reimbursement are for patients who meet the screening criteria
- Provide data to providers in high morbidity areas about their patient population, and show them their screening data in context with other areas of the jurisdiction. Providers who see how they measure up with others in their area may help champion screening efforts
- Provide presentations at professional meetings (such as local and regional branches of medical specialty groups like American Academy of Pediatrics), technical assistance, and other education efforts to increase providers' awareness of the need to screen
 - o Trainings directed at school nurses who interact exclusively with adolescents may be useful

- Consider distributing a handbook of screening recommendations and local health resources for confidential screening of adolescents to school nurses
- Train providers to consider special issues pertaining to adolescents, such as the need for confidential and teenfriendly services
- To go above and beyond, implement a quality improvement initiative with one or more providers who do not screen routinely. Develop regular assessments of screening rates, conduct training and technical assistance, and collaborate on approaches to improve screening
- Consider implementing programs to improve condom availability in tandem with increased screening. Condoms can be offered at sites that routinely interact with adolescents, such as schools, adolescent clinics, after school programs, and sports programs

Example strategies include:

- Supporting high school screening programs, where health department personnel schedule routine mass screening and treatments at the schools
- In high morbidity zip codes, working with EDs to screen anyone who meets specific criteria despite the reason for their ED visit
- Screening at juvenile court and routinely at intake to juvenile detention facilities, jail screening of older adults may also be productive
- Providing expedited partner therapy to adolescents treated for chlamydia or gonorrhea
- For condom availability programs, ensuring that condoms are accessible to adolescents in a way that minimizes
 the need for them to have to ask for condoms out loud, such as free dispensers in school bathrooms or nurses'
 offices, or online condom ordering and distribution
- Supporting implementation of automatic STD screening at routine adolescent visits
- Instituting text message screening reminders
- Routinely placing chlamydia screening test swabs next to PAP test supplies in providers' exam rooms
- Establishing routine provider protocols for taking sexual histories
- Providing medication to providers that is meant for adolescents who are reluctant to use insurance or for the uninsured

Other resources

- CDC STD fact sheet on screening recommendations: https://www.cdc.gov/std/tg2015/screening-recommendations.htm
- CDC STD fact sheet on chlamydia: https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm
- CDC STD fact sheet on gonorrhea: https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea-detailed.htm
- CDC STD page on adolescents: https://www.cdc.gov/std/life-stages-populations/adolescents-youngadults.htm
- National Coalition for Sexual Health: https://nationalcoalitionforsexualhealth.org/



Technical Assistance Note # 12c | STD clinical preventive services for MSM

From Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

- 12. Promote CDC-recommended screening, diagnosis, and treatment of STDs among high priority populations:
 - c. **For MSM**, particularly those seen in lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ) health centers, HRSA-funded HIV care settings, primary care settings, and clinics providing HIV PrEP: Assess screening and treatment practices to identify and prioritize providers, organizations, and areas to target for promotion and improvement. Provide education and technical assistance to targeted providers and organizations to promote recommended screening and treatment

Why DSTDP included these strategies

The incidence of many STDs in gay, bisexual, and other men who have sex with men (MSM) is greater than that reported in women and men who have sex with women only. In addition to the negative effects of untreated STDs, elevated STD burden is of concern because it may indicate high risk for subsequent HIV infection. Data on sexual behaviors and gender of sex partners are limited at the national level, so understanding these trends on a local level is critical.

Extragenital screening for chlamydia and gonorrhea is also critical; urethra-only screening for these infections in MSM misses most infections. Though nucleic acid amplification tests (NAATs) have not been cleared by the Food and Drug Administration (FDA) for the diagnosis of extragenital chlamydia or gonorrhea, laboratories may validate their FDA-cleared NAATs for use on extragenital specimens. Partnerships with laboratories are essential for facilitating these approvals.

STD programs should work with health care providers who serve MSM, especially LGBTQ health centers, HRSA-funded HIV care settings, primary care settings, and clinics providing HIV pre-exposure prophylaxis (PrEP), to ensure awareness of the need to screen for STDs. It is not always possible to obtain data on STD screening rates from every provider, but if these data are available, the program should monitor and evaluate the data to determine where screening rates need improvement. STD programs may choose to focus on high-priority providers in at-risk communities who can provide such data. In areas where STD incidence and prevalence are high in MSM, provider awareness-raising, education and technical assistance should be intensified. Where possible, STD programs should use quality improvement (QI) methods to measure and increase screening in health care settings where MSM receive care.

Key definitions

Extragenital: Situated or originating outside the genital region or organs. For STD screening, usually refers to the pharynx (throat) and rectum (butt)

LGBTQ: Lesbian, gay, bisexual, transgender, and/or queer **MSM**: Gay, bisexual, and other men who have sex with men

PrEP: Pre-exposure prophylaxis for HIV prevention

Considerations for implementation

Know the providers of care and services to MSM

- Identify and establish relationships with local LGBTQ providers:
 - Examine laboratory and provider data, and insurance data if available, from the program's jurisdiction to identify providers of care to MSM
 - o Ensure these providers are following CDC's STD screening guidance for MSM
 - Interact with LGBTQ organizations, CBOs serving MSM, and HIV/AIDS support groups to create a professional network of people who can support screening and linkage to care efforts
- Obtain any readily available screening data from insurance plans, clinics, municipalities and other organizations to assess screening rates and find areas for improvement:
 - Encourage these organizations to collect and report gender of sex partners and anatomical location of chlamydia and gonorrhea infections
 - o Consider modifying data systems and analyses to include these variables

Actively promote screening, diagnosis, treatment and linkage to care for MSM

- Add gender of sex partners and anatomical site of chlamydia and gonorrhea infections to case report forms and surveillance summaries to ensure data are available to drive resource allocation
- Raise awareness of the need for STD screening:
 - Conduct trainings, presentations at professional meetings, technical assistance, and other education efforts
 - o Provide regular Health Alerts or other provider communications
- Prioritize and monitor STD screening of MSM in Ryan White care, especially of extragenital sites
 - o Inclusion of non-syphilis STD measures in Ryan White care audits can be an effective monitoring tool for quality STD screening in those settings
- Encourage health plans and provider groups to adopt quality improvement measures that include syphilis and extragenital STD screening rates of MSM
- Work with all clinical settings and medical providers to:
 - Promote MSM standards of care and routinely elicit risk-based sexual histories
 - Screen for rectal chlamydia and gonorrhea infection in men who had receptive anal intercourse in the past year
 - Screen for pharyngeal gonorrhea infection in men who had receptive oral intercourse in the past year.
 CDC does not recommend testing for pharyngeal chlamydia infection, but most providers use combination tests for both chlamydia and gonorrhea
- Discuss and offer or refer for initiation of Pre-Exposure Prophylaxis (PrEP) for HIV-negative men with any STD, but especially syphilis or rectal chlamydia or gonorrhea
- Implement effective strategies for improving screening rates in clinic settings, including standing orders for STD testing
- Consider self-collection of rectal and pharyngeal specimens when a full exam is not feasible
- Work with laboratories to:
 - Internally validate NAAT for diagnosis of extragenital chlamydia and gonorrhea infections. If this is not feasible, work with the Association of Public Health Laboratories (APHL) to identify and link clinical providers to laboratories that have already validated rectal and pharyngeal specimens for chlamydia and gonorrhea testing

- Work with MSM-focused community-based organizations (CBOs) to:
 - Facilitate STD testing of MSM who may not be accessing testing elsewhere. Many CBOs offer HIV-only testing, which is a missed opportunity for identifying new STD infections
 - o Educate and promote extragenital testing as an essential sexual health practice
 - o Educate and promote PrEP, especially for those HIV-negative MSM with a history of STDs
- Encourage MSM constituents to request regular risk-based STD screenings from their healthcare providers
- Navigate high-risk, HIV-negative MSM constituents to PrEP services
- To go above and beyond:
 - Monitor screening rates in jurisdictions where STD prevalence is high, or where prevalence has significantly increased in recent years
 - Conduct quality improvement in one or more providers who do not screen routinely. Develop regular
 assessments of screening rates, conduct training and technical assistance, and collaborate on ways to
 continuously improve rates
 - o Consider calculating, monitoring, evaluating, and reporting STD rates for MSM
 - Consider evaluating the sexual history documentation and practices of providers, to make sure they are eliciting the behavioral information needed to determine which anatomical sites have been exposed and how frequently their clients should be tested

Other resources

- CDC STD fact sheet on screening recommendations: https://www.cdc.gov/std/tg2015/screening-recommendations.htm
- CDC STD web page on MSM: https://www.cdc.gov/std/life-stages-populations/msm.htm
- NCSD's MSM Sexual Health Standards of Care: http://www.ncsddc.org/resource/msm-sexual-health-standards-of-care/



Technical Assistance Note #13 & #14 | Promoting STD prevention to the public and providers

From Strategy Area IV: Promote STD Prevention and Policy

- 13. Promote STD prevention to the public
 - a. Provide audience-appropriate, 508-compliant, STD prevention information online, including answers to common STD questions (e.g., symptoms, testing methods, treatment) and places where testing and treatment are available
- 14. Promote STD prevention and reporting to provider community
 - a. Notify local providers and organizations about important or timely STD-related issues, such as outbreaks, emerging diseases, recommended treatment changes, biomedical advances, and reporting requirements

Why DSTDP included these strategies

Health department STD programs must be a trusted source for basic information on STDs for the public as well as the broad spectrum of providers who may need information on STD epidemiology and clinical care. While STD programs do not have to be experts in all aspects of STD prevention and control, they should be able to provide strong referrals to resources that have that expertise. They should be able to both respond to inquiries and actively disseminate information to broad audiences as needed.

Considerations for implementation

Providing online health promotion information to the public and providers

- Define the audiences the program seeks to reach through the website
- Define the messages and information that the STD programs want to relay about STDs and the program
- Define clear and specific communication goals for each of those audiences
- Identify the webmaster in charge of the STD program's content and understand protocols for requesting and making updates to it
- Identify any health communication resources or staff available to the STD program for creating the content
- Incorporate sections tailored to specific audiences and those goals. For example, the site may have:
 - o Detailed clinical information for providers needing latest treatment information
 - STD Q&A site including information for people seeking answers to common STD-related questions
 - Surveillance data presented various ways, with technical surveillance reports for public health counterparts and more streamlined, high-level versions for the public
- Include updated links and syndicated content from trusted partner sites
- Incorporate service finders for people wanting to know where they could get tested or treated
- When possible, incorporate a feedback loop where visitors can provide suggestions for additional content or improvements
- Ensure websites are:
 - Cleared by appropriate authorities

- o 508 compliant
- o "Digital first" or built to be viewed on various devices (e.g., phones, tablets, desktops)
- Labeled and described clearly to make all content easier to use and navigate
- Reviewed and updated regularly particularly the most popular webpages accessed
- Social media channels such as Twitter, Facebook, and Instagram are also effective ways of reaching target audiences online. Similar to the process for a website, you should:
 - o Define your audiences and messages
 - o Set clear and specific communication goals for each of those audiences

Conducting outreach to the broader provider community

- Maintain an updated Health Alert Network (HAN) system for sending out alerts and updates to a broad range of providers in the jurisdiction, or high morbidity areas within a jurisdiction
- Advertise the use of any available STD clinical warm line/hot line (e.g., NNPTC's <u>Clinical Consultation Network</u>)
- Distribute notices about changes in STD reporting policies, procedures, and forms through automated email or FAX systems
- Participate in relevant local provider conferences to share information and identify opportunities for new collaborations/partnerships/educational opportunities
- Tap staff from regional and national STD prevention training centers to present at relevant local conferences and meetings



Strategy #14 is different from those related to promoting CDC-recommended screening, diagnosis, and treatment practices for high priority populations (see TA Notes #12a-12c). Those describe efforts that are more intensive and tailored to particular providers and populations, compared to this strategy. Strategy #14 is about providing a public service to the broader provider community in a jurisdiction.

Other resources

- Plain language: https://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html
- Writing for the web: https://www.usability.gov/how-to-and-tools/methods/writing-for-the-web.html
- Syndicated content from CDC's Division of STD Prevention: https://www.cdc.gov/std/products/syndicated.htm
- CDC's Get Tested website: https://gettested.cdc.gov/
- Customizable "State of STDs" infographic: https://www.cdc.gov/std/stats17/infographic.htm
- Social Media tools and guidance: https://www.cdc.gov/socialmedia/



Technical Assistance Note #15 | Monitoring STD-related policies and policy development

From Strategy Area IV: Promote STD Prevention and Policy

- 15. Monitor STD-related policies and policy development
 - a. Work with the CDC, the NNECS recipient, and other partners to identify STD-related policies of interest. Monitor proposed and actual changes in policies that may affect STD prevention programs
 - b. Work with local policy liaisons and with partner organizations on the development of policies that enhance the work of the STD prevention program

Why DSTDP included these strategies

Policy is a core domain for public health—policies can have a large impact on a number of people, from changing fundamental services that can affect health, such as employment or housing, to impacting patients of an STD clinic. The goal of these activities is to understand how policies may be affecting STD prevention and control in a jurisdiction, and use that information to educate the community, providers and other stakeholders about relevant policies, for example, to increase uptake of Expedited Partner Therapy (EPT). A health department STD program also may want to make changes in policies, such as those that govern information sharing between agencies, determine access to HIV and STD systems, or determine billing and reimbursement at an STD clinic.

Key definitions

Policy can operate at the state and national level, in the form of legislation, regulations, statutes, and other laws. Policies also exist at the health department level, in the form of protocols, procedures, and guidelines. All are included in this NOFO's definition of "policy" and are a part of this strategy.



Monitoring, educating about, and helping to develop policies are distinct from lobbying and advocating for particular policies. When planning policy work, recipients must make sure their work is within the legal bounds of policy work. Even when operating within what are thought to be legal limits, attention must be paid to appropriateness of policy positions, Congressional intent regarding the use of appropriations, and the appropriateness of grantee activities. When in question, please reach out to DSTDP or NCSD for guidance.

Considerations for Implementation

Working with others to identify and monitor policies of interest

- Identify a champion in the STD program who will take the lead on this activity. Ensure they have appropriate background and training to work effectively in this arena.
- Identify which policies may be affecting STD outcomes, including the prevention, screening, and treatment of STDs in the highest priority populations. Talk to colleagues in other programs, clinical and public health partners, NCSD, CDC, and other partners for ideas and input.

- Examples of policy issues that operate outside the health department include:
 - Medicaid regulations/guidelines such as those affecting reimbursement and what appears on EOBs (Explanation of Benefits);
 - STD clinic policies, such as billing and reimbursement, extra-genital testing, walk-in vs. express/same-day models, confidentiality practices, EPT, and access to treatment
 - o EPT laws, medical and pharmacy group support, implementation, access to medication, and uptake
 - o Policies that affect syphilis testing in pregnant women, such as third trimester testing laws, barriers to prenatal care access, case follow-up, and provider education
- Examples of policy issues that operate within the health department include:
 - Job classification and its impact on hiring/staffing
 - o Timing, execution, competition requirements, and data sharing restrictions for contracts or MOUs
 - Rules or policies that may create challenges for DIS to access certain websites or apps, restrict how and when they can communicate during contact tracing and partner services
 - o Rules that may restrict data sharing between public health or other governmental programs
 - o Policies that may inhibit sharing STD information and data on the HD website
 - o Practices that restrict sharing important STD-related information with the public via the news media
 - Policies governing publication or presentation of STD data and findings
- Stay aware of the activities of state and local governing bodies for relevant legislative activities, by monitoring legislative websites, signing up for legislative and news alerts, working with partner organizations
 - Programs could go over and above by doing a policy analysis for particularly complex policies, or ones with unknown impacts

Working with others on the development of policies that enhance the work of STD programs

- Have a staff person in the STD program participate in a policy training for health department staff (e.g. NCSD's Policy Academy), and also consider bringing a partner (e.g. HIV program, safety-net provider, county STD program) to the table to work as a team
- Analyze the policies being monitored and whether there are any barriers or gaps in policies. For example, an
 STD program could:
 - Conduct a business assessment to determine if billing Medicaid and private insurance should be considered in an STD clinic
 - Work with the state Medicaid agency or other third-party payers to revise any policies that may be barriers to effective care, such as reimbursement for screening multiple times per year when warranted and extra-genital testing or EOB policies
 - Work with clinical partners to change any policies, billing practices, or other barriers to extra-genital testing
 - Engage with pharmacy, nursing and medical state boards and professional organizations to remove any barriers to, and promote, EPT
 - Remove any barriers to treatment, such as access to Benzathine penicillin G, to increase timely and recommended treatment
 - o Talk to DIS to identify barriers that may slow disease investigation and follow-up, and remedy them
 - Identify ways to enhance data sharing with governmental, clinical, and other partners

- Be sure NOT to engage in lobbying/advocacy or conduct activities that are prohibited in a jurisdiction
- Please do let DSTDP and others know when policy barriers have been successfully overcome
- An STD program could go above and beyond by establishing some pre/post implementation metrics or more formal evaluation to better assess the effects of this work with people in its jurisdiction, NCSD, CDC, and others

Other resources

- Anti-lobbying restrictions: http://intranet.cdc.gov/ofr/documents/grants/Anti-Lobbying-Restrictions.pdf.
- CDC EPT site with legal permissibility map: https://www.cdc.gov/std/ept/default.htm
- NCSD policy academy: http://www.ncsddc.org/project/ncsd-policy-academy/
- NASHP website: https://nashp.org/
 CSG website: http://www.csg.org/
 NCSL website: http://www.ncsl.org/



Technical Assistance Note #16 | Epidemiologic analysis

From Strategy Area V: Analyze and Use Data for Program Improvement

- 16. Conduct epidemiologic analysis, translation, and dissemination
 - a. Conduct regular analyses of trends in, geographic distribution of, and factors associated with reported cases using core epidemiologic variables
 - b. Disseminate, interpret, and discuss data and findings with internal and external stakeholders
 - Assist local jurisdictions with analyzing their data on a regular basis, including analyses of trends,
 epidemiologic factors, and geographic distribution of cases, and help local areas identify outbreaks, gaps in services, or inequalities in the burden of disease that should drive resource allocation

Why DSTDP included this strategy

In STD PCHD, the analysis of STD surveillance data was elevated as its own strategy because of both the importance of this aspect of public health surveillance and need for STD PCHD recipients to ensure that staff have the skills and time required to analyze, interpret, and disseminate surveillance data effectively. Resources dedicated to collection and management of surveillance data may be wasted if the data are not analyzed and translated to public health action.

Public health surveillance – the systematic ongoing collection, management, analysis, interpretation, and dissemination of data to stimulate public health action — is a cornerstone of public health practice. While resources are often invested into collection and management of STD surveillance data, sufficient investment into analysis, interpretation, and dissemination is less common. Yet without these crucial steps, STD PCHD recipients may make programmatic decisions in the absence of information that could help target resources. Additionally, routine, timely, and frequent data analyses are critical for identifying possible outbreaks and emerging disease trends that may require rapid redirection of resources. Effective, timely, and targeted dissemination of data, such as sharing data with both internal and external stakeholders, can raise awareness of changing epidemiology, inform resource allocation decisions, and galvanize providers, affected population, and other stakeholders to take action.

In some jurisdictions, substantial public health authority and decision-making resides at the local level. State health departments have opportunities to assist local jurisdictions with improved data analysis, interpretation, and use for public health decision-making.

Key definitions

Stratification: The data analysis approach of splitting data into groups to uncover patterns and control for confounding. A simple example is to display male gonorrhea rates and female gonorrhea rates separately, thus stratifying gonorrhea rates by gender. Stratifying data by multiple variables (such as county and gender) can be useful for exploring patterns in the data.

Measure of association: A measure of association quantifies the relationship between two groups, such as comparing disease occurrence among one group with disease occurrence in another group. For example, a rate ratio is the ratio of rates of two groups.

Example: If the rate of reported gonorrhea among men is 120 per 100,000 males and the rate among women is 80 per 100,000 females, the rate ratio is 1.5 (120/80). This means that the rate of reported gonorrhea among men is 1.5 times the rate reported among women.

There are multiple measures of association, such as rate ratios, odds ratios, and prevalence ratios. The measure of association that should be calculated depends on the analytic study design. An association is not the same as causation and associations may be confounded.

Confounding: The distortion of a measure of association between an exposure and an outcome by a third variable related to both the exposure and the outcome.

Example: The association between county (exposure) and reported chlamydia rates (outcome) may be distorted by age (confounder) as chlamydia is most common among young women and age distribution may differ by county. For example, overall rates of reported chlamydia in County A are 2.5 times the rates of chlamydia in county B (rate ratio = 2.5). However, County A has a much younger population than County B. When stratified by age and gender, rates of chlamydia among women aged 15-24 years were similar in County A and County B (rate ratio = 1.1 in each county). In this scenario, age confounded the association between county and reported chlamydia rates. As shown here, stratifying can help determine if confounding is occurring.

Considerations for implementation

Conduct regular analysis of epidemiologic and surveillance data

- Identify data that could be used for epidemiological analyses of STDs in your jurisdiction, including, but not limited to, data from case reports, data collected during partner services or enhanced investigations, STD clinic data, data from other surveillance systems (such as eHARS or the National HIV Behavioral Survey [NHBS]), and Medicaid or other administrative claims data on healthcare services (such as chlamydia screening)
- Establish data sharing agreements with related programs, as needed, to ensure timely access to HIV, viral hepatitis, or other surveillance systems that contain important variables for analysis
- Conduct descriptive analyses to describe trends in STDs in your jurisdiction
 - Stratify rates by key variables (such as gender, race/ethnicity, age categories, and geography [county])
 and investigate how rates differ by these variables and how rates may have changed over time
- Conduct analyses to understand which factors are associated with STDs in your jurisdiction.
 - Consider quantifying the measure of association between STDs and behaviors (such as use of geolocating apps), clinical history (such as previous STDsor HIV co-infection), and other factors. These analyses can focus on identifying factors or populations that can be targeted for public health action
 - When interpreting measures of association, do consider possible confounders
- Consider creating and presenting maps of disease by geographic area (such as at the county or census tract level) to identify patterns. Overlaying additional data on the maps of disease, such as healthcare provider locations and socioeconomic indicators, may provide additional insight into the STD epidemic in your jurisdiction
- To go above and beyond, link available STD data with additional data sources, such as data on social determinants of health
- To go above and beyond, consider partnering with faculty and/or students at a local college/university to
 conduct more advanced epidemiologic analyses. Data sharing agreements can help ensure shared data adhere
 to your health department's and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention's
 confidentiality and data security policies

Disseminate findings to internal and external stakeholders

- Identify key internal and external stakeholders for your jurisdiction
 - o Internal stakeholders may include staff in the STD program (such as DIS), other health department sections (such as reproductive health or school health), and health department leadership
 - External stakeholders may include medical providers, laboratories (public and private), policy makers, and school officials
- Hold routine (perhaps quarterly) meetings between data management, epidemiologic, and programmatic staff
 to review data, identify additional analyses that would inform decision-making, and discuss contextual factors
 that may be contributing to findings
- On at least an annual basis, generate a summary report that provides the most current data on STDs in your
 jurisdiction, as well as important trends over time. Disseminate the report and other data summaries to key
 internal and external stakeholders
 - o Do keep tables and figures simple and uncluttered
 - o Don't share multiple tables or figures without any summarization or interpretation
 - o Do consider creating and disseminating power point slides to accompany summary reports
- Consider creating additional materials that are tailored to the needs of specific audiences (such as healthcare providers)
 - Consider asking stakeholders what kinds of data and in what format are most useful
 - Novel presentations of data, such as infographics, may be an effective way to communicate information.
- Consider presenting the findings from your epidemiological analyses at local and national scientific conferences, as well as publishing your findings in peer-reviewed journals and Morbidity and Mortality Weekly Reports (MMWRs)
- To go above and beyond, develop an online query system for stakeholders to access data



Do not spend time creating complicated data reports that are run frequently and never reviewed! To ensure data are translated into public action, ensure that findings are discussed and meet the needs of stakeholders.

Assist local jurisdictions to analyze and use data

- Identify a point of contact in your health department who will provide technical assistance to local jurisdictions on ways to analyze and use their local data
- Don't assume that local jurisdictions have the capacity to analyze and interpret their local data
- Consider periodically providing a brief summary report to local jurisdictions that highlights key trends in the STD epidemic in their area. This could be an automated report that is run and disseminated quarterly
- Consider creating and sharing a template for a report that a local jurisdiction could complete independently using their own data
- To go above and beyond, have local jurisdictions present their analyses of their local data at a jurisdiction-wide conference or webinar



This strategy is closely related to routine surveillance (see TA Notes #1 - #5). Those efforts describe the methodology for collecting and managing surveillance data, including reviewing data quality.



Additionally this strategy is related to outbreak response (see TA Note #6) which provides more detailed information on how to detect and respond to an increase in disease in your jurisdiction.

Other resources

- 2017 STD Surveillance Report: https://www.cdc.gov/std/stats17/default.htm
- NCHHSTP Atlas Plus: https://www.cdc.gov/nchhstp/atlas/index.htm
- Principles of Epidemiology in Public Health Practice, Third Edition. An Introduction to Applied Epidemiology and Biostatistics. Available at: https://www.cdc.gov/ophss/csels/dsepd/ss1978/
- Sources for data on social determinants of health: https://www.cdc.gov/socialdeterminants/data/index.htm
- Data visualization resources for presenting data effectively:
 - o http://stephanieevergreen.com/wp-content/uploads/2016/10/DataVizChecklist May2016.pdf
 - o https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/STD-Data-Infographic-Resources-for-STD-Prevention.aspx
 - o https://www.cdc.gov/std/products/infographics.htm



Technical Assistance Note #17a | Data-driven reviews

From Strategy Area V: Analyze and Use Data for Program Improvement

17a. Conduct data-driven planning, analysis, monitoring, and evaluation for program improvement

- a. Routinely analyze, synthesize, and interpret surveillance, epidemiologic, program, and other data to strengthen the program's understanding of local STD epidemiology and program context. Evaluate progress, using scientific methods, program data, performance data, and cost data, and adjust program plans accordingly
- b. Use findings from those analyses to identify the program's STD prevention and control priorities, populations, and geographic areas, to develop program plans and to allocate staffing and other resources accordingly

Why DSTDP included these strategies

Public health programs must be data-driven to the extent possible. In the area of STDs, like many others, the resources are too scarce, and the needs too great, to make decisions about program allocation based on old, low quality, or scant information. STD programs operate under greatly varying epidemiologic and programmatic contexts, so program-specific information is essential to decision-making. Program and epidemiologic contexts also can change rapidly. Therefore, STD managers must revisit their decisions about program allocation and priorities on a regular basis. STD program staff have a responsibility to institute regular, comprehensive reviews of pressing issues, using available data. The purpose is to identify whether, where, and how to change their program to be more effective and efficient. This strategy supports a culture of improvement, to which all STD programs and DSTDP should aspire.

Key definitions

A **data-driven review** is a meeting where leaders review program and performance data to understand the drivers of performance on high priority topics, share challenges and successes, and identify where action is needed. Leaders make evidence-based decisions using the program data and information reviewed at these meetings. These meetings are at the heart of data-driven planning and monitoring for program improvement.

To engage in data-driven reviews, the following needs to be in place: 1) programs have identified their strategic priorities, 2) there is authentic leadership support to engage in the process; and 3) programs have the capacity to gather and synthesize data related to those priorities. The U.S. Government Accountability Office (GAO) outlines several factors that make Data-driven Reviews successful:

Key leader attendance to facilitate problem solving and hold managers accountable

Capacity to collect accurate, useful, and timely data Rigorous preparation and sustained follow-up on identified issues Questions asked at a data-driven review meeting and throughout a data-driven planning process may include:

- **Performance Measure Status**: Where are we on this issue? Are we currently on track to meet our targets? If off track, is this currently of concern? Why or why not?
- **Data Needs and Gaps**: Do we currently have all of the information we need to truly understand progress? What additional information do we need to know to understand a measure's or program's status?
- **Driving Factors of the Measures**: Are data trends reflecting actual performance issues or measurement issues? What are the biggest factors/contributors to whether or not we will meet our goals? What are the risks?
- **Program Performance**: What are we doing to influence this measure? Do program data reflect the progress we see in this performance measure?
- **Solution Development**: What strategies have we employed to strengthen this measure's progress so far? Based on what the measures are telling us, what new actions/strategies can we use to help improve this measure's progress?

Data-driven reviews are opportunities to reflect on the forest, above the trees. Ideally, the review process should be repeated over time, on a regular schedule, with the key stakeholders returning to those high priority issues and asking those questions again, to both monitor and propel progress.

Topics for data-driven reviews can range widely but should be important and somewhat focused. They could be population-based (e.g., STDs in adolescents), geography-based (e.g., STDs in X County), STD-specific (e.g., congenital syphilis), or process-oriented (e.g., quality of STD surveillance data), among other options.

See below under Other Resources for ideas for running a Data-driven Review meeting, including whom to involve, how to prepare, how to facilitate the meeting, and how to follow up.

Considerations for implementation

Here is one way to think about the steps to data-driven reviews and planning:



Clarify program priorities and select one for a data-driven review

- Start with the program's priorities. If those are unclear, then the program may need to embark on a strategic planning process to identify those.
- Decide which priority issue to focus on for a data-driven review. Some criteria for selection may include: Which of those priorities is most pressing? Where does the program staff have the most concerns? What is changing rapidly?

Ensure key staff are on board

- Leadership and staff support is essential. Ensure they understand the expectations for participation and followup, how this is different from general program reviews or strategic planning.
- Ongoing education and support for a culture of improvement should help create work place conditions that make data driven reviews easier to "sell" to staff
- It is key that STD program leadership and relevant staff leads/subject matter experts allocate sustained time for this kind of review. It can be easy to postpone such reviews due to the demands of day-to-day work

Pull trends in relevant epidemiologic and performance data

- Which of the program's current performance measures speak to the selected priority issue? CDC program
 outcome or performance measures may be useful for internal program monitoring, but programs should not
 rely exclusively on those for deciding what to track
- Hone in on the most relevant and strongest indicators to use to do the review. Strong indicators are those that can be interpreted easily, generated regularly, and relate to core aspects of the program or issue
- Limit the number of key indicators for the review process, so the work is more manageable. Having too much data or too many indicators can hinder progress and lead to data-driven review processes focusing only on wading through data, as opposed to analysis and decision-making

Identify other data and information relevant to that issue

- What other information is important to have on hand, for context or additional perspectives? Consider data and information that resides *outside* the STD program, such as those from HIV programs, health care providers, insurers, relevant programs like Title X, and behavioral surveillance surveys like Youth Risk Behavior Survey
- It is good to be proactive about this. A staff person could be assigned to routinely scan potential sources of complementary information or reports to ensure the STD program has access to new reports as soon as they become available
- To the extent possible, STD programs should also start to better integrate costs into their program reviews and evaluation work. Budgets and expenditure data should be considered relevant datasets to use in data-driven reviews.

Carefully facilitate a data-driven review

- Analyzing and synthesizing indicators and other data on the priority issue is demanding, requiring hard decisions about what is most important to present and discuss at the meeting
- Use good facilitation and meeting planning skills to help run productive, structured meetings to discuss data and their implications for the program. Selecting the right facilitator is critical to success.
- Consider using prioritization criteria and decision tools at relevant meetings, to help identify priorities or action items in a systematic and transparent way; general group discussion alone is unlikely to yield clear decisions

Follow up with accountability and repeat

- Ensure follow-up steps identified at such reviews are realistic, concrete, and given high priority. Most, if not all, follow-up steps should be actions that can be taken and reported back within weeks of a review meeting, so that progress is evident and momentum is sustained
- One-off reviews of important issues can help galvanize work around those issues, but ideally, these reviews would be repeated on the same issues, to assess progress



Evaluation and Epidemiologic Analysis are also essential tools for data-driven planning and implementation. Those respective strategies and TA Notes (#16 and the Targeted Evaluation Plan or TEP guidance) should be reviewed alongside this one, and all fall under the same Strategy Area. The findings from epidemiologic analysis and evaluation projects could be used in data-driven reviews, just as new analyses and projects could be initiated as a *result* of data-driven reviews.

Other resources

- Data-driven decision in federal government (concepts apply at various levels of decision making):
 - o Government Accountability Office: https://www.gao.gov/key_issues/data-driven decision making/issue summary
 - o Urban Institute: https://www.urban.org/research/publication/guide-data-driven-performance-reviews
- Meeting facilitation tools:
 - o Community Tool Box: https://ctb.ku.edu/en/table-of-contents/leadership/group-facilitation/main
 - o Seeds for Change https://www.seedsforchange.org.uk/facilitationmeeting
- STD Program Evaluation Trainings and Tools: http://www.ncsddc.org/std-pett



Technical Assistance Note #18 | Up to 10% funding for safety net assistance

From Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

Assistance for STD clinical prevention services

In addition, applicants may provide assistance, no more than 10 percent of the overall award amount without prior approval from CDC, to not-for-profit or governmental clinics that can document their ability to provide safety-net STD clinical preventive services as per CDC guidance. At a minimum, clinics receiving assistance should have the capacity to rapidly diagnose and treat bacterial STDs. This assistance could be used to screen, diagnose, or treat uninsured and underinsured people. Applicants must have memoranda of understandings (MOU), contracts, or other forms of written agreements describing the terms of this assistance with the organizations that receive it. CDC may request copies of these agreements throughout the period of performance.

These activities should be conducted in compliance with CDC's STD Treatment Guidelines, and as permitted under relevant federal, state, and local laws and regulations. CDC reserves the right to reduce the allowable amount that may be used to support these services in subsequent years.

Why DSTDP included these strategies

State and local STD programs have an important role in promoting and supporting STD clinical preventive services for uninsured and underinsured individuals who lack access to clinical services. Support for these services can help strengthen STD programs' ability to influence health care practices and to collaborate with other key partners in the STD prevention landscape in their project areas. However, the primary purpose of federal funds for health department STD programs should not be routine clinical care, but surveillance and other core strategies outlined in STD PCHD, such as disease investigation. Federal funding from STD PCHD should be used to strategically leverage funding from other sources to increase access to STD clinical preventive services for under/uninsured individuals. Those sources may include state and local governments; federally funded HRSA programs such as Health Centers; MCH; FQHCs; school-based, public housing, homeless, and migrant health centers; and Ryan White HIV/AIDS programs; Title X-funded programs, third party payers, including state Medicaid programs; and others.



The funding target of 10% or less for this safety net assistance is flexible, so programs can implement comprehensive STD prevention and control programs of highest impact tailored to local epidemiology and context. This clinical safety net assistance is also optional under STD PCHD. Funded STD programs can choose <u>not</u> to use any STD PCHD funds for clinical safety net services.

Key Definitions

Safety net: In this case, the safety net refers to clinical service providers who offer subsidized, free, or sliding scale services for individuals who have limited access to health care service by virtue of being uninsured or underinsured.

Clinical preventive services: These services include screening, testing, diagnosis, and treatment that support STD prevention and control and are recommended by CDC. The support can include screening for CT, GC, or syphilis for individuals at risk, as well as treatment for those under/uninsured individuals infected and their partners (includes expedited partner therapy (EPT), where permitted by law).

Capacity to rapidly diagnose and treat: Such clinics should have on-site testing and treatment for bacterial STDs and should not rely on referral for treatment. However, they do not have to provide the level of care available at STD specialty care clinics. For example, testing may be done by external laboratories, but providers still need to ensure timely follow-up and treatment of infected patients.

Underinsured: Being "underinsured" takes many forms, may be location-specific, and is not easy to define in simple terms. Underinsured individuals may have health insurance coverage for a highly limited set of services or conditions (e.g., for prenatal care and delivery only) or face high deductibles or co-pays that strongly influence their health care seeking behavior and restricts their access to preventive health care services. This may include patients who seek STD care in the private sector and cannot afford the cost of treatment or co-pays.

Considerations for implementation

Deciding which providers and preventive services to support

- Identifying safety net clinics or providers in a project area should start with epidemiologic analyses of morbidity by geographic area, priority populations and type of clinical setting where cases are identified. Updated surveillance data to identify new areas of high burden and/or notable STD increases should be used in the decision-making process.
- This process should also include profiles of safety net providers. These profiles may include a summary of the patient population served by each provider, including number and percent of patients stratified by age, gender, sexual orientation, race/ethnicity and insurance status.
- Given resource limitations, project areas likely need to prioritize among those safety net providers or clinics, based on volume, need, population, and likely public health impact of the assistance provided.
- Data should drive decisions about whom to support under STD PCHD. This safety net assistance should be directed at the following priority populations: pregnant women at risk for STDs, adolescent and young adults (particularly women), and MSM, in accordance with CDC and USPSTF screening recommendations.

What kind of assistance can be provided

- All assistance under this program must be directed at serving under/uninsured individuals and at addressing aspects of CT, GC, and/or syphilis clinical preventive services
- The assistance does not have to be committed to a single program of assistance; providers who participate in the program do not have to receive the same type of assistance. For example, 3% of total funding could go to one set of safety net providers for syphilis treatment, while another 5% of total funding could support three high volume providers that serve priority under/uninsured females for limited use of the public health laboratory for cervical/vaginal screening for CT/GC in young females.
- This safety net assistance for under/uninsured individuals can take various forms, and it could be indirect and/or direct or in-kind, including:
 - Funding public health laboratories for routine CT/GC/syphilis screening or testing services
 - Purchasing test kits for CT/GC for clinics that meet the program criteria
 - o Purchasing syphilis testing reagents for clinics that meet the program criteria
 - Purchasing Benzathine penicillin G for infected patients and partners at risk of not receiving timely recommended treatment for syphilis

- Purchasing medication for CT or GC for infected patients and partners at risk of not receiving timely recommended treatment, including expedited partner therapy (EPT)
- Contracts or health department staff time needed to implement the MOUs and collect the data requirements of the above programs or services
- This assistance should not be used to cover:
 - o Testing or treatment related to infections other than CT, GC, and syphilis
 - o CT/GC/syphilis clinical preventive services for individuals who are not under/uninsured
 - Salary, stipends, or benefits for health professionals providing direct care
 - Condom purchases and condom distribution programs
 - Expedited Partner Therapy when part of a EPT program that targets populations other than just the under/uninsured (see TA Notes #8)
 - Social marketing campaigns to reach target population and promote awareness and use of services for the under/uninsured

Establishing MOUs, contracts, or other written agreements with the providers

- Written agreements should govern assistance for safety net services to ensure that the funding is used as intended, and to allow the STD programs to adequately monitor the use and value of any assistance provided
- It is essential that any MOU, contract, or other written agreement clearly stipulates the intent of the program -- i.e. to serve under/uninsured individuals -- and that the agreements place responsibility for documenting that is the case on the recipient providers
- Each STD program should consult their respective contracting/procurement/legal offices to identify the most efficient way to establish written agreements. Memoranda of Understanding may be sufficient in some cases, while formal contracts may be merited in others
- Written agreements should be used to outline the assistance provided by the STD program, what the providers
 will do, and what information or data the STD programs needs in return. The type of program monitoring and
 evaluation required under an assistance program will differ depending on what kind of assistance is being
 offered. Generally, STD programs should be able to assess, when possible, what they "bought" (e.g., tests
 purchased or paid for) & what they "got" as a result, or outcomes associated (e.g., screening, diagnosis,
 treatment)
- DSTDP may request copies of these written agreements
- DSTDP will request information and data about how these funds are used, populations served and associated screening, diagnosis, and treatment outcomes. Details on this information are forthcoming

Justification to devote more than 10% to this asssistance

- Justification for using more than 10% of STD PCHD funding for this purpose must be strong and based on the STD epidemiology, local context, and available resources. Such proposals will be reviewed by DSTDP and considered in the context of the entire prevention and control program supported under STD PCHD.
- Discussion of proposals to exceed 10% will cover the following:
 - Evidence that other parts of STD PCHD implementation are not being under-supported as a result of spending more in this particular area
 - o A description of the priority population(s) that will benefit from this assistance
 - o The geographic area(s) or clinical partner(s) that will be receiving assistance
 - o Documentation of need (e.g., insurance status of target population)
 - Any other concrete benefits to the STD program that the additional funding provides (e.g., by virtue of partnerships strengthened through the funding)
 - Anticipated impact of limiting assistance to 10%

- A data collection plan to assess populations served and public health outcomes obtained through the assistance
- Historical funding for such safety net assistance and what efforts were made to identify other funding sources, programs or strategies
- Reasons that other funding sources or programs at the state/local level cannot be used or leverage to meet the expressed need
- Intention and plans to decrease the project area's allocation over the course of the period of performance towards 10% of budget through other funding sources, programs or strategies