STD PCHD

Strengthening STD Prevention and Control for Health Departments

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 **ALL** 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 ALL GC 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,
    - 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:
    - 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).
    - 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 prior 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