

## Syphilis Outbreak Detection Guidance



**STD Subcommittee** 

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# Introduction

In 2000, cases of primary and secondary syphilis were at the lowest rate ever reported (2.1/100,000) (1). Since that time, syphilis incidence has increased steeply with a rate of 8.7/100,000 reported in 2016 (1). The national epidemiology of early syphilis (primary, secondary, and early latent) is well-known, with cases occurring primarily among gay, bisexual, and other men who have sex with men (MSM). Reported cases of primary and secondary syphilis have a high rate of HIV coinfection, particularly among MSM (1). During 2000–2012, syphilis rates among women had been low; however these rates increased from 2013–2016 (1), and outbreaks are occurring in many areas. These outbreaks and increases among women are accompanied by increases in congenital syphilis, resulting in more syphilis deaths among infants and unborn babies than among adults. Outbreaks can be interrupted when they are identified early and appropriate interventions are implemented. State and local sexually transmitted disease (STD) programs are responsible for recognizing and understanding their local epidemiology to determine how best to target interventions to decrease the number of cases in their jurisdictions. While partner notification activities, usually accomplished through the work

of Disease Intervention Specialists (DIS), are often one of the primary methods used by STD programs to prevent the spread of syphilis and other STDs in their jurisdictions, sometimes these routine activities alone are not sufficient. It is important for STD programs to be able to identify those situations where additional resources might be necessary to curb transmission in a given community (for example, during an outbreak).

This document was developed to give STD programs a framework for understanding their epidemiology, determining if and when an outbreak might be occurring, and determining when additional resources and activities could be needed to prevent further transmission of disease. While many of the tools and strategies described here could be applied to any STD, given the scientific complexities of syphilis, its high impact on morbidity (e.g., congenital syphilis), and the special attention syphilis receives through partner notification efforts and funding from CDC, the focus of this document is syphilis. The tools and strategies described here are put forth as best practices in syphilis outbreak detection that can be adapted to any jurisdiction's incidence and burden of disease.

# **Routine Activities**

A routine review of case data for your jurisdiction and sub-areas within it will ensure that aberrations (or abnormal changes, whether increase or decrease, in the number of cases reported) can be easily identified as soon as case data are received by your disease surveillance system and investigated to determine if there is an outbreak. The frequency of review should be at least monthly, but will likely depend on staffing and data analysis capacity. Automation of data reports in SAS or other software such as Epi Info is helpful, and requires minimal resources to maintain once processes are established.

# Establish Normal Baseline Data and Determine Frequency of Reports

Good data review practices start with a weekly assessment of raw counts (by week) of reported/ diagnosed cases at the locality level. This type of review could include a year to date comparison with data from previous years in order to identify possible increases not attributable to seasonal variation. A monthly report displaying case counts for the previous 24 months could also be useful, and would show increases that might not be noticeable on a review of weekly case counts. Quarterly reports should include both case counts and population rates (for the previous years), as well as year to date case counts as of the end of the most recent quarter.

## Assess Data by Subpopulations of Interest

At least quarterly, data should also be assessed by a series of basic demographics and other available variables, in order to better characterize the population affected. Because congenital syphilis is the most important consequence of syphilis, and congenital syphilis outbreaks follow outbreaks among women, the most important subpopulation to assess is women. Other variables to stratify by include age, race, ethnicity, gender of sex partners, provider type, HIV coinfection, stage of disease, geography (county/locality of residence), as well as other meaningful data variables. Through this process, you will identify subpopulations of interest in your jurisdiction in order to be able to identify shifting patterns in disease trends over time. Subpopulations at risk can be defined not only based on demographics, but also on other factors such as: MSM, persons with multiple sexual partners within the interview period, persons coinfected with HIV, or geographic areas.

## Identify reporting providers/ laboratories and any reporting issues

Since data in any disease surveillance system depends entirely on case reporting from providers and laboratories, it is important to identify which facilities are usually submitting case reports in your jurisdiction. In the case of a data aberration it is a good idea to investigate whether there are new facilities reporting, whether any traditional facilities have stopped reporting, or whether any changes in testing practice (e.g. implementation of reverse sequence algorithm or expansions in screening) occurred. Changes in state reporting regulations as well as changes in your program reporting guidelines could affect the number of cases reported. In general, be aware of normal baseline data, both overall and for sub-areas and subpopulations, such that any changes in trends for your jurisdiction can be easily identified.

Any case reporting issues in your jurisdiction will impact the number of cases in your disease surveillance data system. To identify a jurisdiction/ area that may not be reporting in a timely manner, look for decreased case counts compared to previous years, especially where surrounding areas continue to show high morbidity. Delays between diagnosis and report dates are also a good indicator of problems in reporting cases. Areas that are shortstaffed might experience investigation and reporting delays. Be aware of DIS and DIS supervisor position vacancies, whether any staff are on extended leave, or perhaps instances when an area is fully staffed, but dealing with an increased number of cases resulting in reporting backlogs. It is recommended that delays in reporting be routinely evaluated as part of a general surveillance evaluation and be considered when defining an outbreak. For example, programs can track average length of time from the laboratory specimen collection date to the date cases are entered into data systems, both to improve data interpretation and to develop targets for quality improvement.

### Meet Regularly with Field and Clinical Staff

## Another key tool for early outbreak identification is knowledge of ongoing field activities.

Regular weekly/monthly discussions about trends in observed cases should include DIS and DIS supervisors; they can often provide additional insight and possible explanations for observed trends in cases. It is important to assess any anecdotal information, including any unusual clusters/cases observed in populations not normally at risk. Many times this type of information is known by field staff ahead of the case reports' entry into the surveillance system. Field staff will also have information on the number of cases not yet reported that are still under investigation, as well as cases observed in areas where they do not normally occur. Furthermore, field staff can also tell you if they have noticed changes in methods of acquiring sex partners, such as usage of new websites/apps, or new hangout spots in their area. Information on local STD prevention efforts, such as large screening events, may result in an increased number of cases identified; other community events involving populations at risk, such as conventions or large parties, may also explain an observed increase in cases.

It may also be beneficial to **meet with clinic staff regularly**. Different clinics have different diagnosis capabilities; for example, they may or may not offer cultures or extragenital screening. Increases in clinic demand for services or changes in the number of clinic visits and/or populations requesting services are possible indicators of increased morbidity. However, changes in the number of cases detected may also be the result of modifications to clinic hours or schedules, such as the opening of an evening specialty clinic, or the implementation of extragenital screening.

# **Defining Outbreaks**

Outbreaks represent increases in disease above what is expected. The challenge in defining an STD outbreak is often determining "what is expected." Outbreaks of STDs differ from foodborne or other point source outbreaks. Since STDs are, by design, transmitted from person to person through sexual contact, outbreaks do not generally appear spontaneously with large numbers of cases, as is common in foodborne or waterborne outbreaks. Instead, outbreaks of STDs tend to grow gradually as the infection moves through sexual networks with increased velocity. A large increase in chlamydia cases in states where chlamydia is endemic may represent an outbreak situation. Additionally, a small number of new congenital syphilis cases in a county with no recent cases could also be considered an outbreak. Therefore, defining a true STD outbreak may be more complex than with other infectious pathogens. Here, we provide guidance on ways to apply locally available data to help establish and define an outbreak.

### **Potential Data Sources**

A number of data sources can be used to identify possible outbreaks among new risk populations. Routine case report data received by state or local health jurisdictions are the most readily available. Additionally, data collected through supplemental epidemiologic activities, such as studies or other research projects, and data collected through partner service investigations may be helpful. Health care or social service providers may also identify increases of STDs in their patient populations and alert the local and state health departments. Finally, sentinel surveillance data collected from activities in various settings (e.g., school-based screening or jail or prison screening programs) may also help in the identification of new populations with increased STD incidence.

## Approaches to Identifying an Outbreak

There are a number of approaches to identifying an outbreak, each with advantages and shortcomings. The most common approach to outbreak identification involves the review of case counts. Recent aggregate totals of case counts can be compared to historic trends to determine whether recent activity may represent an outbreak (2).

The simplest approach is to examine the absolute number of excess cases over the established baseline or background count. This has the advantage of being computationally simple and easy to explain to a range of stakeholders. However, this method does not account for the magnitude of the background. For example, an increase from 5 to 25 cases and an increase from 2,400 to 2,420 would both represent an increase in 20 absolute cases, but these increases likely represent two very different epidemiologic phenomena. Using a percent increase method can help better contextualize the relative increase in cases. Using the example above, while both scenarios show an increase of 20 cases, the first represents a 400% increase compared to a 0.8% increase in the second. A more statistically

robust approach uses standard deviations to define outbreaks (3). This method is more objective, but may be more computationally complicated and may not be easily understandable to the lay population or community stakeholders. Finally, qualitative approaches and epidemiologic judgment may be appropriate in assessing STD increases in areas where no or few cases were previously reported. For example, 5 congenital syphilis cases reported in an area without a reported case in the prior 10 years represents a potential outbreak. Given the long history of no reported cases, such a potential outbreak would require further investigation.

While application of statistical testing may help alleviate spurious inferences regarding increases, caution is warranted. Statistical significance is driven in part by sample sizes. Therefore, statistically significant differences that are not important from a public health perspective may be seen with large sample sizes. Conversely, important increases may be missed when the background rate and sample size are small. The determination to investigate a potential outbreak should not be solely based on statistical significance testing. It may be prudent to develop an escalating scale related to potential outbreaks locally. One approach is to use visual cues, such as green/yellow/red, to delineate no increases, potential increases, and likely outbreaks, respectively. This may help flag situations for further investigation without having to label the situation as an outbreak.

Important caveats (or *surveillance artifacts*) to bear in mind when reviewing cases counts include delays in reporting of cases, under-reporting of cases, and asymptomatic and undiagnosed infections. Each of these factors can contribute to falsely low estimates of disease burden. Additionally, it is important to keep in mind that geographic boundaries are generally arbitrary; individuals often cross state, county, and city boundaries for work and recreation.Therefore, **caution is needed in defining a geographic boundary too narrowly; this could obscure or minimize possible outbreaks affecting at-risk populations**. Alternatively, markers of possible new infections may also be useful to monitor. For example, analysis of trends in reactive or high-titer syphilis serologic reports to the local or state health jurisdiction may help identify possible increases in local infection (4). Increases in syphilis in women may predict increases in cases of congenital syphilis.

# What Parameters/Criteria Should be Included in Defining an Outbreak?

### Define Outbreak and Establish Thresholds *A Priori*

Quantitative approaches to defining the beginning and end to an outbreak should be developed and documented a priori and applied systematically to locally derived data. Consider how sensitive you want your outbreak threshold to be: lower (more sensitive) thresholds will likely result in a higher number of outbreak investigations to be conducted. Prior to evaluating increases in recent STD morbidity, the baseline rate of disease needs to be established. A number of options are available for defining the baseline time period. Recent data can be compared to the prior quarter or, if there is concern about seasonal variability, the same quarter in the prior year. For a more robust approach, a moving average of quarters can be established, and the period of interest

can be compared to that average. This approach reduces some of the variability of choosing one quarter as the baseline. Additionally, data can be compared to the same time period from the prior year, which would also reduce the variance in these data. Regardless of approach, it is important to consider lags in reporting. Case report data are often delayed in reaching the local and state health departments, and, even if reported, the disposition of the case may change upon further investigation. Exploration of the most recently reported data may be useful to get a more real-time picture of a possible increase in morbidity, but these data may also present a distorted picture of true increases and decreases. Past outbreaks should be excluded when establishing baselines. Appendix A includes examples of how various jurisdictions have defined a cluster or outbreak of syphilis.

# Approaches to Thinking about Outbreaks

### **Geography and Population**

Thinking broadly about the context of outbreaks within the context of STD prevention and control is useful. The typical approach to exploring outbreaks involves identifying increases in disease in a specified geographic area over a defined period of time. The wider availability of geographic information systems (GIS) allows for the creation of maps at various levels (states, counties, cities, neighborhoods, or block groups). Furthermore, statistical software packages, such as SatScan, are available to conduct statistical analysis of geographic disease clusters and can be useful in describing geographic areas of increased STD morbidity. It is critical to consider how social networks interact with geographic space. STD morbidity data is often assigned to the residential address of the case. However, the location of the residence may not represent the same area where the sexual exposure has taken place. For example, in peri-urban areas, people may travel to larger cities to meet partners (5). Robust public transportation or car access may also facilitate sexual partnering across neighborhoods within a city.

## STD outbreaks may also occur in new populations, and it is important to look for shifts in affected

**populations.** This information is important even if the overall case number does not increase. If your area experiences an increase in cases among women and heterosexual men while the baseline data indicates that a majority of cases have historically occurred among MSM, this indicates a shift in disease transmission into the heterosexual population, including the possibility of congenital syphilis cases. For example, early syphilis declined dramatically through the 1980s and 1990s, and the disease was focused in urban sex workers and drug using populations. After this decline, syphilis began to increase significantly among MSM (6, 7). STD outbreaks have also been reported among Native American populations (8), gang members (9), sex workers (10) and suburban adolescents (11).

## New Venues or Partner Recruitment Locations

**STD outbreaks may also occur in new venues or sexual partner recruitment locations.** For example, an outbreak of syphilis was recently investigated in a state correctional facility (12). Modern approaches to dating and meeting sexual partners may also influence STD outbreaks. Online chat rooms (13), dating and hook-up sites found on the internet (14, 15), and cell-phone-based sexual partner recruitment apps (16, 17) have been associated with increased STD risks. These virtual sites for sexual partner recruitment also function alongside more traditional physical locations, such as sex clubs, bathhouses, and cruising areas (18).

## **Changes in Clinical Presentation**

STD outbreaks may also be defined by changes in the clinical presentation of disease identifiable through surveillance systems. For example, increased case reports of ocular syphilis in Washington and California (19) called into question whether there have been changes in the tissue tropism of a particular strain of *Treponema pallidum* subspecies *pallidum*. While this has not previously been shown to be of concern for *Treponema pallidum* subspecies *pallidum*, the availability of new molecular sequencing techniques may someday reveal subtleties in sequence changes that are linked to changes in rates of neuro, ocular, or otic syphilis.

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# **APPENDIX A** Examples of Syphilis Outbreak Definitions

The following examples of syphilis outbreak definitions illustrate how some states and localities define an outbreak.

### Kansas

- » Cluster is defined as an increase in any geographically defined area ranging between 10–19% for a given time frame OR identification of 5 cases (or 3 linked cases) of early syphilis in a county within a 30-day period OR identification of any single case of novel treatment resistance.
- » Short-term incidence outbreak is defined as an increase in morbidity >19% in any geographically defined area for a given time frame when compared to the same geographic area and corresponding previous time frame.
- » Sustained incidence increase is defined as an increase in morbidity >19% in any geographic area for a given time frame where the increase persists for a period of longer than 6 months.

## Tacoma, WA

» An outbreak is defined as 10 or more cases of primary, secondary, or early latent syphilis for 3 consecutive months OR 15 cases in one month.

## New York City, NY

» Examine reported syphilis cases by sex; then examine county, age, and race/ethnicity quarterly for males. Compare case numbers for a given quarter to those in the previous 3 quarters to get a "moving average." Outbreak detection mode occurs when a higher than expected number of cases is sustained over a 3-quarter period.

## Illinois

- » For counties reporting ≤ 5 cases of early syphilis during the previous year, an outbreak is defined as ≥ 2 early syphilis cases reported in a 3-month period.
- » For counties reporting 6–10 cases of early syphilis during the previous year, ≥ 2 early syphilis cases reported for 2 consecutive months OR the total number of early syphilis cases reported year-todate being 50% greater than the previous year for the same time period with at least a 2-case increase constitutes an outbreak.
- » For counties reporting > 10 early syphilis cases in the previous year, it is considered an outbreak if the number of cases reported during 1 month is 100% greater than the monthly average for the previous 3 months.

## Florida

- An outbreak is defined as the mean exceeding the expected norm of annual trends over the previous 5 years by 25% during the time period reviewed, OR the occurrence of a significant sentinel event (that is increase in congenital syphilis, lesion disease, or local needs).
- » Routinely monitor year-to-date comparisons for all 67 counties and alert local officials of acute overall increases and sub-population- and geographyspecific increases (e.g., zip code, census track, venue-specific).

## APPENDIX B Resources

### **Analytical Software**

#### Epi Info

Free-to-use analytical software from CDC. Epi Info contains various statistical tools that can assist in outbreak detection. This software contains tools for regression analysis, survival analysis, means, frequencies, and graphical construction. Epi Info also contains form creation software, data entry capabilities, and a GIS mapping function. Epi Info also allows for editing of data and data management. A menu-driven user interface allows for users to select menu options as opposed to writing code to perform analysis.

#### <u>R</u>

Free-to-use program for statistical computing and graphics. As with Epi Info, R offers a wide variety of statistical and analytical tools and offers the ability to download other statistical packages from other users. R does use its own command language, so although there is a certain barrier to entry, there are multiple online resources, including manuals, on R's webpage. R can also create plots and other graphics.

#### **Statistician**

An Excel-based add-in statistical tool that has 2 versions, one free (lite) and one paid. Statistician allows users to create and store an actual data set as opposed to having to reselect data each time they use the spreadsheet. Video tutorials are available on YouTube. Statistician includes data management tools along with statistical tools, such as ANOVA, regression, and binary modeling. The free version includes descriptive statistics, covariance/correlation, means test, ANOVA, and multiple regression analysis.

### **Purchasable Statistical Software**

| <u>SPSS</u>    |
|----------------|
| <u>MiniTab</u> |
| <u>SAS</u>     |
| <u>Stata</u>   |

## Geographic Information System (GIS) Software

#### <u>SaTScan</u>

SaTScan is a GIS program that can be used to analyze spatial, temporal, and space-time data. It is commonly used to detect disease clusters using geographic boundaries via Poisson- or Bernoulli-based models. The program is also commonly used to perform geographical surveillance of disease, detect statistical significance of disease clusters, and perform repeated time period surveillance for early detection of outbreaks. This software is free.

#### Epi Info

Epi Info has a GIS component which is built around the Environmental Systems Research Institute (ESRI), the same company that produces both ArcGIS and MapObjects software. Epi Info is able to use shape files to construct geospatial boundaries. It also has case cluster tools, chloropleth mapping (thematic map in which areas are shaded or patterned in proportion to the statistical variable being displayed on the map), and dot density features. This software from CDC is free.

#### <u>ArcGIS</u>

ArcGIS is a GIS program with an interactive map component used to show disease distributions across geospatial boundaries. It is commonly used as the foundation for GIS analysis due to its ability to create maps in conjunction with other programs, like SaTScan, to map the disease clusters. ArcGIS has a wide range of tools and options, including geospatial analysis, cluster detection, geocoding capabilities, and advanced imageries. Pricing is available online, and a free trial is available.

#### **Networking Software**

#### <u>NetDraw</u>

NetDraw is a free-to-use program that is used for visualizing social networks. This network visualization tool allows for the graphical representation of networks and includes some limited analytical capabilities that overlap with UCINET. Features include multiple relations to a single node, node attributes, analytical ability to identify isolates, the ability to save network maps as images, and print options. Guides and FAQs are available on NetDraw's website.

#### **UCINET**

UCINET is network analytical software that is available for purchase. This software allows for the analysis of social network aspects as well as hypothesis testing. UCINET includes NetDraw network visualization software.

#### **Communication Tools**

<u>CDC Single Overriding Communication Objective (SOCO) Worksheet</u> <u>CDC Crisis & Emergency Risk Communication (CERC)</u>

### **CDC Syphilis Resources**

<u>Syphilis</u> <u>National STD Database</u> <u>Syphilis Profiles (2016)</u> <u>Syphilis Stats</u>

## **APPENDIX C** Outbreak Response

#### **Summary Action Steps**

- » Convene Outbreak Response Team and identify coordinator
- » Ensure confidentiality throughout response
- » Establish a case definition
- » Generate hypothesis about causal factors
- » Intervene
- » Leverage partnerships with community stakeholders
- » Utilize communication channels to notify public and stakeholders
- » Conduct ongoing epidemiologic analysis
- » Evaluate and report on outbreak response findings

#### » Convene members of Outbreak Response Team (ORT) and identify coordinator

The ORT represents an investigation team of individuals within each county and regional office who could provide expertise and leadership during an outbreak. Following detection of an outbreak, an initial meeting of the ORT is convened to designate an Outbreak Response Coordinator who will serve as the main point of contact for team members and lead the response. During the initial team meeting, the Outbreak Response Coordinator reviews the roles and responsibilities of team members and ensures that personnel are designated to serve in established roles. A schedule for communication and routine team meetings is also established. As part of the initial response process, the ORT conducts an assessment of resources and supplies required to implement a response.

#### » Ensure confidentiality throughout response

The ORT is responsible for identifying staff with both a need and permission to access data, including laboratory, surveillance, and case management information. Data collection is limited to information essential to the investigation and is maintained and transmitted in a secure environment. Data collection, analysis, and reporting adhere to confidentiality and security statutes and protocols.

#### » Establish a case definition

In general, case definitions for notifiable diseases apply in outbreak investigations of syphilis, although the case definition may be modified for local use contingent upon increased knowledge of the outbreak. Case definitions are used to confirm the diagnosis. A systematic review of clinical findings, symptom history, and laboratory results for the cases should be conducted. In addition, coinfection and risk factors should also be assessed. This information is used to establish a case line list for review by ORT members. The line list is a single, comprehensive summary that is unduplicated, accurate, and timely. An ORT member with surveillance or epidemiologic experience should be responsible for generating and updating the line list.

#### » Generate hypotheses about factors contributing to case increase

The initial hypotheses are generated by a review of the epidemiology, case interviews, and medical records, as well as interviews with local and regional health departments and key stakeholders. The hypotheses should address the at-risk population, transmission source, and mode of transmission, as well as the exposure(s) and risk factors that caused the outbreak. The hypothesis will be evaluated and refined based on ongoing systematic review of epidemiologic and surveillance information collected during the course of the outbreak.

#### » Intervene

Design interventions based on the hypotheses generated from review of epidemiologic and surveillance information. Unlike the response to many other outbreaks, a syphilis outbreak response is complicated and often prolonged, and the details of specific interventions are beyond the scope of this document. Interventions for syphilis outbreaks include enhanced surveillance (e.g., targeted screening of high-risk populations), expanded clinical and laboratory services (including partner services for preventative treatment and partner notification), and enhanced health promotion through health care provider alerts and media and community outreach (20). The ORT should be aware that active case finding is anticipated to (at least transiently) increase the number of reported cases. It is important to evaluate the effectiveness of interventions after implementation.

## » Leverage partnerships with community stakeholders

Informing community stakeholders of the outbreak expands opportunities for intervention and outreach to affected populations. The Public Information Officer (PIO) plays a central role in these communication efforts and should ensure the messages are culturally appropriate.

#### » Utilize communication channels to notify public and stakeholders

Use existing channels of communication to notify partners and external stakeholders of the outbreak situation. Methods of communication include issuing a health care provider alert (or HAN), notifying CDC and states/jurisdictions that border the outbreak area, and informing public health officials and health care and laboratory providers. Community-based organizations (CBOs) that serve affected populations can promote disease intervention and prevention efforts. Notification of the media is conducted by the state PIO who will apply a single overriding communication objective (SOCO) to ensure uniform messaging about the outbreak. If multiple jurisdictions are involved, PIOs should ensure that similar information is shared to media and community partners to avoid confusion.

#### » Conduct ongoing epidemiologic analysis according to established procedures and timeframe

Description of the epidemiology of the outbreak should begin early and should be updated regularly as additional data is collected. Analyze surveillance and case management data to characterize the outbreak by person, time, and place, which may include the development of an epi-curve, geographic and social network maps, and descriptive summaries of demographic and risk characteristics. A review of case management data should include a cluster analysis to identify connections between cases with such analysis performed by network analysis software (e.g., NetDraw). Contingent upon resources, additional advanced techniques, such as molecular susceptibility testing and molecular epidemiology, may be useful for identifying casepartner relationships.

#### » Evaluate and report on outbreak response

The evaluation of the outbreak response will occur both during the response and after activities are completed, and it will primarily focus on the following aspects: 1) effectiveness of the outbreak response; 2) efficient use of resources, including public and private agencies; 3) productivity of epidemiologic interventions; 4) relationships with providers and CBOs; and 5) organization and leadership of the response effort. A summary of the findings includes an oral briefing for state and local health authorities and a written report that serves as an official summary of the outbreak investigation. It serves as a record of performance, a document for potential legal issues, and a reference for the health department for any future outbreaks. The findings may also be presented at conferences and/or published in peer-reviewed journals to contribute to the scientific knowledge base of epidemiology and public health.

The ORT should convene following the end of the outbreak to review the evaluation findings and discuss strengths and weaknesses of the outbreak response plan. This report should then be presented to executive staff.

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