Recommendations for Public Health Surveillance of Syphilis in the United States

Division of STD Prevention
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Executive Summary

Syphilis is a genital ulcerative disease that facilitates HIV transmission and if untreated during pregnancy may lead to fetal infection or perinatal death. In the United States syphilis surveillance is based on mandatory reporting from health care providers and laboratories to state and local health departments. Recommendations for national syphilis surveillance were developed by a group of invited experts who met in Atlanta on March 20-22, 2000. This consultation on "Recommendations for Public Health Surveillance of Syphilis in the United States" was cosponsored by CDC's Division of STD Prevention (DSTD), National Center for HIV, STD and TB Prevention (NCHSTP); the National Coalition of STD Directors (NCSD); and the Council of State and Territorial Epidemiologists (CSTE). The recommendations, which are summarized below, were developed for state and local public health programs. The intention of this report is to make the collection and reporting of syphilis surveillance data more uniform so that data from a variety sources are comparable.

Case Reporting

- State and local jurisdictions should adopt the CSTE and CDC surveillance case definitions for syphilis to ensure the quality and comparability of surveillance data.[1]
- Syphilis cases should be categorized and reported by stage at the time of initial examination (which is often the time of initial specimen collection), not at the time of treatment or interview.
- All cases of probable or confirmed syphilis should be reported as morbidity regardless of treatment or interview status. Stage determination should be based on available clinical and serological information.
- In the absence of symptom or serology history, sex partners for the last year should be evaluated to determine whether the case should be classified as early latent, late latent, or latent of unknown duration.
- The following should be reported to the local health department within one working day by public and private providers and laboratories:
  - All probable or confirmed cases of early (primary, secondary or early-latent infection) syphilis (regardless of treatment status).
  - All reactive, nontreponemal laboratory tests.
- All confirmatory treponemal test results should be reported when available, but their availability should not delay reporting a reactive nontreponemal test result.
- Health Department Follow-up:
  - Individuals with reactive serologies who are known or suspected of having lesions should be contacted for follow-up regardless of age, sex, or titer.
  - All women with reactive serologies who are known to be pregnant should be contacted for follow-up regardless of age or titer.
  - All women of child-bearing age (less than 45 years of age) with reactive serologies should be contacted for follow-up, regardless of titer.

  - All adolescents (< 20 years old) with reactive serologies should be contacted for follow-up regardless of titer.
  - Individuals with reactive serologies indicating a four-fold titer increase from a previous serology should be contacted for follow-up regardless of age or titer.
- The reactor grid is an administrative tool used to prioritize follow-up of reactive serologic tests for syphilis.
  - Reactor grids should be evaluated annually or more frequently if the local epidemiology of syphilis changes.
  - Prospective reactor grid evaluations should be completed at least every two to three years.
  - In areas with substantial syphilis morbidity, reactor grids should be evaluated twice annually to assess the effectiveness and sensitivity of the grid.

Prevalence Monitoring

- Syphilis prevalence data should be used to assess the yield of specific screening activities by identifying the number of new cases detected in relation to the number of screening tests performed. In addition to screening assessments, syphilis prevalence monitoring at local, state, and national levels should be used to:
  - monitor disease burden and trends
  - identify populations with high rates of infection
  - evaluate case-report surveillance data

Data Analyses and Dissemination

- In areas with substantial morbidity, surveillance data should be analyzed at least monthly to monitor changes in incidence or new patterns of disease.
- In low morbidity areas, cases should be reviewed as reports are received and a monthly overview should be routinely completed to monitor changes in incidence or patterns of disease.
- At a minimum, data should be analyzed by demographic and risk behavior characteristics, including gender of sex partners.
- A plan for regular dissemination of information derived from the analysis of syphilis case-reported data and prevalence data should be developed at local, state, and national levels.

Introduction

In 1999, the Division of Sexually Transmitted Disease Prevention (DSTD) at the Centers for Disease Control and Prevention (CDC) announced a national plan to eliminate syphilis from the United States.[2] The national plan established specific goals of reducing the number of primary and secondary syphilis cases to 1,000 or fewer and increasing the number of syphilis-free counties to 90% by 2005. The national plan outlines five strategies critical to achieve elimination: 1) enhanced surveillance, 2) strengthened community involvement and partnerships, 3) rapid outbreak response, 4) expanded clinical and laboratory services and 5) enhanced health promotion.

In response to the national plan, and particularly, the inclusion of "enhanced surveillance" as a cross-cutting strategy, a national meeting was sponsored in March of 2000 by the DSTD/CDC, the National Coalition of STD Directors (NCSD), and the Council of State and Territorial Epidemiologists (CSTE) to develop guidelines for syphilis surveillance. Meeting consultants included representatives from the 32 CDC funded syphilis elimination sites and representatives from NCSD and CSTE. Consultants were assigned to one of five workgroups formed to address the following issues: 1) case reporting, 2) prevalence monitoring, 3) congenital syphilis, 4) active surveillance and outbreak detection and 5) behavioral and social surveillance. Key questions were developed for each workgroup, and consultants were provided background materials (e.g.,published manuscripts, abstracts, and material presented at professional meetings) in advance of the meeting to help them address the key questions. Recommendations were developed based on the workgroups' responses to the key questions.

While surveillance must be tailored to the level of syphilis morbidity in a given jurisdiction, an important objective for national syphilis surveillance is to assure consistency of surveillance practices among states. In communities where syphilis has been absent for years, the focus of surveillance should be the identification of clinical symptomatic syphilis (primary syphilis presenting as genital ulcer disease or secondary syphilis presenting as rash). For such a focus, public health officials need to enlist the support of practicing clinicians who will be the first to see such cases. In such communities, serologic surveillance is not likely to be a particularly efficient approach. For those communities with continuing endemic syphilis, expanding serologic screening to high-risk populations and implementing or enhancing many of the traditional surveillance and control activities are essential.

This report provides updated syphilis surveillance guidelines for health department personnel to use in improving and developing syphilis surveillance techniques. Although reporting syphilis cases is mandated by state laws and regulations in the United States, and information about syphilis cases is reported to CDC from all states and territories, the usefulness of surveillance data has been limited by the lack of uniform public health surveillance practices. The intention of this report is to make the collection and reporting of syphilis surveillance data more uniform so that data from a variety sources are comparable.

General Principles

Components of Syphilis Surveillance

Surveillance for syphilis has two main components:

- Case reporting: the process of reporting cases (or reactive serologic laboratory results) of notifiable infectious diseases by providers or laboratories to local and state health departments and from state health departments to CDC.
- Prevalence monitoring: monitoring trends in prevalence in defined populations over time, where prevalence is the proportion of persons in a population that has the disease or condition at a specified point in time.

In contrast to case reporting, which is intended to be population-based, prevalence monitoring for syphilis is generally performed using data obtained from selected populations. Prevalence data are usually collected systematically from routine screening rather than from special studies performed for the primary purpose of assessing disease burden. The specific purposes of case reporting and prevalence monitoring are discussed in the following section, and the selection of priority populations for monitoring prevalence is discussed later in this report.

Purposes and Uses of Syphilis Surveillance

Public health surveillance is the ongoing and systematic collection, analysis, and interpretation of health data in the process of describing and monitoring a health event.[3] Surveillance data are useful for a variety of reasons, including the planning, implementation, and evaluation of public health programs and interventions. Syphilis surveillance data have traditionally relied on case reporting from providers and laboratories. Prevalence monitoring data for syphilis and other STDs have provided an additional perspective on disease occurrence in some populations. Behavioral and social surveillance data have been used to identify and monitor risk exposures of at-risk and infected populations.

Case Reporting

The purposes and uses of syphilis surveillance using case-reporting data at local, state, and national levels are:

- to monitor rates and trends of infection;
- to identify outbreaks rapidly;
- to identify persons at high risk for syphilis and the affected communities in which they live;
- to identify characteristics of infected persons and generate hypotheses regarding risk factors;
- to identify gaps in health care and missed opportunities for interventions;
- to demonstrate the need for funding of syphilis control programs;
- to design and target interventions.

At the local and state levels, case-reporting data should be used:

- to identify major providers or major laboratories that are or are not testing or reporting;
- to assure proper diagnosis, treatment, and partner management for all persons with early syphilis;
- to identify persons at risk for HIV infection;
- to assess the effectiveness of syphilis prevention and control programs;
- to assess patient management (ensure proper evaluation and treatment of persons with syphilis);
- to evaluate the effectiveness of prenatal syphilis screening in preventing congenital syphilis.

Monitor rates and trends of infection. Data obtained from case reports provide a minimum estimate of the burden of syphilis in the general population. The usefulness of these data for monitoring trends in disease burden is limited by three factors: a) the proportion of infected persons who seek medical attention because of symptoms; b) the extent to which the number and characteristics of asymptomatic persons screened remain stable over time; and c) the variability of reporting by providers and laboratories.

Identify outbreaks rapidly. An important use of case-reported data is determining whether increases in numbers of cases suggests an outbreak of disease that requires immediate investigation.

Identify persons at high risk for syphilis and the affected communities in which they live. Analyses of case-report data indicate that rates of syphilis vary by age, race or ethnicity, geographic place of residence, and type of health-care provider. These data should be used to identify persons at increased risk for syphilis infection and to develop interventions and screening criteria.

Identify characteristics of infected persons and generate hypotheses regarding risk factors. Information collected routinely through case reporting often provides valuable epidemiologic information with regard to the "person, place, and time" links that help identify characteristics of infected persons and aid in generating hypotheses.

Identify gaps in health care and missed opportunities for interventions. Information on prenatal care, testing, treatment, and follow up should be collected in case reports of early syphilis and congenital syphilis to allow local areas to identify gaps in care, to assess availability and use of these services for men and women at high risk of acquiring syphilis, and to develop informative programs for providers and outreach activities targeting high-risk populations.

Demonstrate the need for funding syphilis control programs. Surveillance data obtained through case reports may be used to demonstrate the need for continued or increased funding of syphilis prevention and control programs.

Identify major providers and laboratories that are or are not testing or reporting. Many state and local STD prevention programs maintain a registry of licensed laboratories and providers. Periodic analyses of syphilis case-reporting data by both providers and laboratories can identify variations in reporting that may require intervention by the health department. Providers and laboratories that do not report syphilis cases or that do not participate in efforts to

monitor syphilis prevalence can be identified by comparing the registries with information from case-reporting and prevalence-monitoring systems. Those providers and laboratories not testing or reporting should be contacted.

Assure proper diagnosis, treatment, and partner management for all cases of early syphilis. At local and state levels, STD prevention programs need to contact persons infected with syphilis or the reporting health care provider to ensure that patients with early syphilis are staged correctly, treated with appropriate therapy, offered partner-management services to prevent reinfection from and additional transmission by sex partners, and to ensure that exposed contacts are evaluated and treated appropriately.

Identify persons at increased risk for HIV infection. Persons infected with primary syphilis have an increased risk of acquiring HIV infection, and persons infected with HIV who are co-infected with primary syphilis are more likely to transmit HIV.[4] A diagnosis of syphilis is also an indication that the infected individual has had unprotected sexual contact with at least one other person. Consequently, case reporting can help identify individuals and population subgroups that may also be at high risk for HIV infection. This would assist health department personnel in their efforts to focus prevention and intervention activities.

Assess the effectiveness of syphilis prevention and control programs. Trends in reported cases may provide one measure of the effectiveness of disease control programs.[3] Careful analyses of specific disease control initiatives using reported cases over time as an outcome measure may provide a sensitive assessment of the effectiveness of specific interventions. However, consideration of social, behavioral, and other secular trends is important when interpreting data for this purpose.

Prevalence Monitoring

Syphilis prevalence data have traditionally been used to assess the yield of specific screening initiatives by identifying the number of new cases detected in relation to the number of screening tests performed. In addition to screening assessments, the purposes and uses of syphilis prevalence monitoring at local, state, and national levels are:

- to monitor disease burden and trends;
- to identify populations with high rates of infection;
- to evaluate case-reporting surveillance data;
- to design and target interventions;
- to allocate public health resources.

Monitor disease burden and trends. A primary objective of surveillance is to monitor the occurrence of disease over time within specific populations. Prevalence-monitoring data can be used to estimate the prevalence of disease in specific populations that are routinely screened for syphilis. Disease trends in specific populations can often be measured with greater accuracy by using prevalence-monitoring data than by using data from case reports because the screened populations are better defined. Trends in prevalence in the population(s) screened may provide insight into trends in similar populations in the community.

Identify populations with high rates of infection. Prevalence data for syphilis suggest that demographic and behavioral characteristics are associated with a high prevalence of syphilis. Therefore, prevalence monitoring may be useful in developing syphilis control and

intervention programs. However, it may not be possible to generalize the results to populations for which no prevalence data exist.

Evaluate case-reporting data. Prevalence data provide an accurate measure of disease prevalence within the screened population. Prevalence data are less likely to be biased by the under-reporting inherent in case-reporting data. Under-reporting can result in biased estimates of disease occurrence when case-reporting data are used alone. Substantial variation between estimates based on case reporting and estimates based on prevalence data within defined populations may indicate inadequate reporting or screening, or both.

Design and target interventions. Prevalence data can provide information on populations at increased risk for STD acquisition and transmission. Information on risk factors for acquiring STDs may also be obtained from prevalence-monitoring data. Data about high-risk populations and associated risk factors may be used to develop prevention and intervention programs.

Allocate public health resources. Prevalence-monitoring data may be used by STD prevention programs in their efforts to obtain funding for syphilis control and intervention programs.

Case Definitions

State and local jurisdictions should adopt the following CSTE and CDC surveillance case definitions for syphilis to ensure the quality and comparability of surveillance data.

Syphilis infections should be categorized and reported by stage at the time of initial examination (which is often the time of initial specimen collection), not at the time of treatment or interview.

All cases of probable and confirmed syphilis meeting the case definitions should be reported as morbidity regardless of treatment or interview status. Stage determination should be based on available clinical and serological information, i.e., documented signs or symptoms of primary or secondary syphilis or evidence of an epidemiological link (named contact to primary or secondary case) or history of a negative serologic test for syphilis within the past year.

In the absence of symptom or serology history, sex partners for the last year should be evaluated to determine whether the case is classified as early latent, late latent, or latent of unknown duration.

Syphilis Case Definitions (All Definitions Revised 9/96)[1]

Syphilis is a complex sexually transmitted disease that has a highly variable clinical course. Classification by a clinician with expertise in syphilis may take precedence over the following case definitions developed for surveillance purposes.

Syphilis, primary

Clinical description

A stage of infection with *Treponema pallidum* characterized by one or more chancres (ulcers); chancres might differ considerably in clinical appearance.

Laboratory criteria for diagnosis

- Demonstration of *T. pallidum* in clinical specimens by darkfield microscopy, direct fluorescent antibody (DFA-TP), or equivalent methods

Case classification

Probable: a clinically compatible case with one or more ulcers (chancres) consistent with primary syphilis and a reactive serologic test (nontreponemal: Venereal Disease Research Laboratory [VDRL] or rapid plasma reagin [RPR]; treponemal: fluorescent treponemal antibody absorbed [FTA-ABS] or microhemagglutination assay for antibody to *T. pallidum* [MHA-TP])

Confirmed: a clinically compatible case that is laboratory confirmed

Syphilis, secondary

Clinical description

A stage of infection caused by *T. pallidum* and characterized by localized or diffuse mucocutaneous lesions, often with generalized lymphadenopathy. The primary chancre may still be present.

Laboratory criteria for diagnosis

- Demonstration of *T. pallidum* in clinical specimens by darkfield microscopy, DFATP, or equivalent methods

Case classification

Probable: a clinically compatible case with a nontreponemal (VDRL or RPR) titer >4

Confirmed: a clinically compatible case that is laboratory confirmed

Syphilis, latent

Clinical description

A stage of infection caused by *T. pallidum* in which organisms persist in the body of the infected person without causing symptoms or signs. Latent syphilis is subdivided into early, late, and unknown categories based on the duration of infection.

Case classification

Probable: no clinical signs or symptoms of syphilis and the presence of one of the following:

- No past diagnosis of syphilis, a reactive nontreponemal test (i.e., VDRL or RPR), and a reactive treponemal test (i.e., FTA-ABS or MHA-TP)
- A past history of syphilis therapy and a current nontreponemal test titer demonstrating fourfold or greater increase from the last nontreponemal test titer

Syphilis, early latent

Clinical description

A subcategory of latent syphilis. When initial infection has occurred within the previous 12 months, latent syphilis is classified as early latent.

Case classification

Probable: latent syphilis (see Syphilis, latent) in a person who has evidence of having acquired the infection within the previous 12 months based on one or more of the following criteria:

- Documented seroconversion or fourfold or greater increase in titer of a nontreponemal test during the previous 12 months
- A history of symptoms consistent with primary or secondary syphilis during the previous 12 months
- A history of sexual exposure to a partner who had confirmed or probable primary or secondary syphilis or probable early latent syphilis (documented independently as duration <1 year)
- Reactive nontreponemal and treponemal tests from a person whose only possible exposure occurred within the preceding 12 months

Syphilis, late latent

Clinical description

A subcategory of latent syphilis. When initial infection has occurred >1 year previously, latent syphilis is classified as late latent.

Case classification

Probable: latent syphilis (see Syphilis, latent) in a patient who has no evidence of having acquired the disease within the preceding 12 months (see Syphilis, early latent) and whose age and titer do not meet the criteria specified for latent syphilis of unknown duration.

Syphilis, latent, of unknown duration

Clinical description

A subcategory of latent syphilis. When the date of initial infection cannot be established as having occurred within the previous year and the patient's age and titer meet criteria described below, latent syphilis is classified as latent syphilis of unknown duration.

Case classification

Probable: latent syphilis (see Syphilis, latent) that does not meet the criteria for early latent syphilis, and the patient is aged 13–35 years and has a nontreponemal titer >32

Neurosyphilis

Clinical description

Evidence of central nervous system infection with *T. pallidum*

Laboratory criteria for diagnosis

- A reactive serologic test for syphilis and reactive VDRL in cerebrospinal fluid (CSF)

Case classification

Probable: syphilis of any stage, a negative VDRL in CSF, and both the following:

- Elevated CSF protein or leukocyte count in the absence of other known causes of these abnormalities
- Clinical symptoms or signs consistent with neurosyphilis without other known causes for these clinical abnormalities

Confirmed: syphilis of any stage that meets the laboratory criteria for neurosyphilis

Syphilis, late, with clinical manifestations other than neurosyphilis (late benign syphilis and cardiovascular syphilis)

Clinical description

Clinical manifestations of late syphilis other than neurosyphilis may include inflammatory lesions of the cardiovascular system, skin, and bone. Rarely, other structures (e.g., the upper and lower respiratory tracts, mouth, eye, abdominal organs, reproductive organs, lymph nodes, and skeletal muscle) may be involved. Late syphilis usually becomes clinically manifest only after a period of 15–30 years of untreated infection.

Laboratory criteria for diagnosis

Demonstration of *T. pallidum* in late lesions by fluorescent antibody or special stains (although organisms are rarely visualized in late lesions)

Case classification

Probable: characteristic abnormalities or lesions of the cardiovascular system, skin, bone, or other structures with a reactive treponemal test, in the absence of other known causes of these abnormalities, and without CSF abnormalities and clinical symptoms or signs consistent with neurosyphilis

Confirmed: a clinically compatible case that is laboratory confirmed

Comment

Analysis of CSF for evidence of neurosyphilis is necessary in the evaluation of late syphilis with clinical manifestations.

Syphilitic Stillbirth

Clinical description

A fetal death that occurs after a 20-week gestation or in which the fetus weighs >500 g and the mother had untreated or inadequately treated* syphilis at delivery

Comment

For reporting purposes, syphilitic stillbirths should be reported as cases of congenital syphilis.

Syphilis, Congenital

Clinical description

A condition caused by infection in utero with *Treponema pallidum*. A wide spectrum of severity exists, and only severe cases are clinically apparent at birth. An infant or child (aged <2 years) may have signs such as hepatosplenomegaly, rash, condyloma lata, snuffles, jaundice (nonviral hepatitis), pseudoparalysis, anemia, or edema (nephrotic syndrome and/or malnutrition). An older child may have stigmata (e.g., interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson teeth, saddle nose, rhagades, or Clutton joints).

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*Inadequate treatment consists of any nonpenicillin therapy or penicillin administered <30 days before delivery.

Laboratory criteria for diagnosis

Demonstration of *T. pallidum* by darkfield microscopy, fluorescent antibody, or other specific stains in specimens from lesions, placenta, umbilical cord, or autopsy material

Case classification

Probable: a condition affecting an infant whose mother had untreated or inadequately treated* syphilis at delivery, regardless of signs in the infant, or an infant or child who has a reactive treponemal test for syphilis and any one of the following:

- Any evidence of congenital syphilis on physical examination
- Any evidence of congenital syphilis on radiographs of long bones
- A reactive cerebrospinal fluid (CSF) venereal disease research laboratory (VDRL)
- An elevated CSF cell count or protein (without other cause)
- A reactive fluorescent treponemal antibody absorbed—19S-IgM antibody test or IgM enzyme-linked immunosorbent assay

Confirmed: a case that is laboratory confirmed

Comment

Congenital and acquired syphilis may be difficult to distinguish when a child is seropositive after infancy. Signs of congenital syphilis may not be obvious, and stigmata may not yet have developed. Abnormal values for CSF VDRL, cell count, and protein, as well as IgM antibodies, may be found in either congenital or acquired syphilis. Findings on radiographs of long bones may help because radiographic changes in the metaphysis and epiphysis are considered classic signs of congenitally acquired syphilis. The decision may ultimately be based on maternal history and clinical judgment. In a young child, the possibility of sexual abuse should be considered as a cause of acquired rather than congenital syphilis, depending on the clinical picture. For reporting purposes, congenital syphilis includes cases of congenitally acquired syphilis among infants and children as well as syphilitic stillbirths.

*Inadequate treatment consists of any nonpenicillin therapy or penicillin administered <30 days before delivery.

Case Reporting

Sources of Case and Serology Reports

Health departments should accept case reports of syphilis infection and reactive syphilis laboratory tests from clinicians and laboratories. Although laboratory-based reporting is essential, clinicians should continue to be encouraged to report cases of syphilis. Health departments should maintain the authority to contact clinicians directly for demographic, medical, and risk information.

- Public and private providers should, within one working day of diagnosis, report probable or confirmed cases of early (primary, secondary or early-latent infection) syphilis to the health department.
- Public and private providers should report all other stages of syphilis in accordance with state notifiable disease statutes and regulations.
- Public and private providers should report reactive syphilis tests in pregnant women within one working day to the local health department so that the department can ensure appropriate treatment and follow-up of all pregnant women.
- Public and private laboratories should, within one working day of test result, report positive, nontreponemal tests. Associated treponemal test results should be reported when available, but their availability should not delay reporting a reactive nontreponemal test result.

Reporting Formats and Intervals

Uniform reporting formats and intervals should be adopted by STD prevention programs.

- Local health department syphilis surveillance data should be reported electronically, in line-listed format, to state health departments to improve local disease-control capacity and to promote integration of local surveillance data management and analysis activities. Electronic systems should be established that facilitate frequent analysis of local and statewide data.
- All state STD prevention programs should be capable of reporting electronic, line-listed syphilis case reports to the Epidemiology Program Office (EPO) at CDC weekly. At the request of STD prevention programs, CDC should provide technical assistance to facilitate the transition to electronic systems.
- States should submit congenital syphilis case reports to CDC using a CDC-compatible system at least monthly.
- State STD prevention personnel should coordinate the transmission of STD data to CDC with data for other diseases that need to be reported by the state.
- State and local STD-control programs should develop the information management capacity to support electronic STD surveillance case reporting to CDC and should become capable of receiving data electronically from providers and laboratories.

Reactor Grid Analysis

In contrast to many other infectious diseases, in which a positive diagnostic test generally indicates active infection, the likelihood that a reactive serological test for syphilis (STS) indicates active, untreated infection may be related to the titer and age of the patient. Because the resources necessary to conduct case investigations are frequently limited, especially in high morbidity areas, health departments often develop guidelines to ensure that disease intervention is worthwhile and effective. On the basis of such guidelines, some health departments choose not to evaluate or contact individuals whom they determine to be at low risk of having or transmitting active disease. As a result, older men and women, or persons with low titers may not be contacted, evaluated or reported. The administrative tool used to make this determination is generally referred to as a "reactor grid" and may include the age, sex, and nontreponemal serum assay titer. Regardless of local priorities and guidelines, positive STS should be evaluated for all persons in the following situations:

- Individuals with reactive serologies who are known or suspected of having lesions should be contacted for follow-up regardless of age, sex, or titer.
- All women known to be pregnant should be contacted for follow-up regardless of age or titer.
- All women of child-bearing age (less than 45 years of age) should be contacted for follow-up, regardless of titer.
- All adolescents (< 20 years old) should be contacted for follow-up regardless of titer.
- Individuals with reactive serologies indicating a four-fold titer increase (two tube dilution) from a previous serology should be initiated for follow-up regardless of age or titer.

Age, sex, and titer do not define the stage of infection or infectiousness of a person, and, depending on the local epidemiology of disease, relationships between these factors and infection may change over time. Therefore, reactor grids should be periodically evaluated at the local or state levels. In general, reactor grids should be adjusted to increase their sensitivity in identifying infectious persons.

Reactor grid evaluation should be based on local data. In general there are two approaches for evaluating reactor grids: prospective and retrospective analyses. Prospective evaluations are more accurate and they involve "opening up" all or part of the reactor grid for a specified time period and assessing all reported reactive tests to determine the yield of early syphilis for each sex, titer, and age category. Using this method, a "yield threshold" is determined based on program resources. Grid categories (sex, titer, and age combinations) where the yield of infectious or early syphilis falls below the designated threshold may be considered for "administrative closure" (i.e., cases that fall into these categories are not followed up).

Retrospective analyses may be conducted by a variety of methods. In general, this approach involves analyzing existing surveillance data (case-reporting or prevalence-monitoring) to determine which sex, titer, and age categories are least likely to yield infectious or early syphilis. Populations appropriate for retrospective analysis are those in which all individuals with reactive STS are followed. Care should be taken to ensure that retrospective analyses of reactor grids are not biased due to the exclusion of individuals with reactive serologies in a defined population and time period.

- Reactor grids should be evaluated annually or more frequently if the local epidemiology of syphilis changes.

- Prospective reactor grid evaluations should be completed at least every two to three years.
- In areas with substantial morbidity, reactor grids should be evaluated twice annually to assess the effectiveness and sensitivity of the grid.

Provider-Based Case Reporting

Although all states have mandated that health care providers report all cases of syphilis, in fact, most reported syphilis cases are identified through laboratory reporting. The prompt identification of persons likely to have acquired syphilis recently (e.g., symptomatic persons presenting for care with primary or secondary syphilis) is particularly important for interrupting disease transmission. The following recommendations are intended to increase the prompt identification and reporting of infectious cases of syphilis.

A national standard, outlined in the National Plan to Eliminate Syphilis from the United States, recommends that "public and private providers will within one working day of diagnosis, report presumptive or confirmed cases of early syphilis to the health department."[2] In addition, local and state STD prevention programs need to interact with providers to ensure that the diagnosis, treatment, and management of each case is appropriate. To accomplish these goals, it is essential that health departments do the following:

- Publicize reporting statutes or regulations that include early syphilis as a communicable disease priority (e.g., it must be reported within one working day of diagnosis).
- Distribute a written protocol to providers outlining responsibilities and procedures for reporting syphilis cases and procedures for communicating with health departments.
- Develop a plan to work with health care provider licensure and accreditation organizations to encourage providers to report notifiable conditions.
- Develop and implement a system to communicate and directly interact with large groups of health care providers and professional associations which can be notified of outbreaks and changes in the local epidemiology of syphilis and can help to increase compliance with reporting requirements. Such a system should enable health department personnel to:
  - identify and visit providers who report a large number of cases.
  - identify and visit providers who fail to report syphilis cases (by matching laboratory reports to health care provider reports).
  - identify and visit providers who care for persons living in communities with high rates of syphilis.
  - establish a listserv or e-mail communication to increase and improve communication with providers.
  - provide feedback to reporting providers about individual cases regardless of stage, informing them about the clinical manifestations and public health implications of the disease and emphasizing the important role they play in preventing its transmission.
  - identify a health department employee to serve as a liaison to the providers in the community.

- Develop the flexibility to receive syphilis case reports through a variety of mechanisms, including toll-free telephone numbers, facsimile machines, direct electronic reporting methods, and internet-based systems.

Laboratory-Based Case Reporting

While states have mandated that providers and laboratories report all reactive serologic tests for syphilis, some states do not enforce adherence to this requirement. When there is incomplete reporting by both providers and laboratories, marked under-reporting of diagnosed syphilis cases may take place.

The National Plan to Eliminate Syphilis indicates that "public and private laboratories will within one working day of test result, report positive tests that are quantified by titer." To achieve this standard, sufficient resources should be mobilized that enable laboratories to report promptly, and a laboratory communication plan should be developed that may include the following:

- State and local STD prevention programs should have a written protocol that outlines health departments' procedures for interacting with laboratories and the laboratories' responsibilities and procedures for syphilis case reporting.
- Where feasible, state and local STD prevention programs should work with laboratory licensure and accreditation organizations to encourage reporting of notifiable conditions as required by statute.
- The STD program should also maintain relations with laboratories to ensure compliance with reporting requirements. As part of these activities, a program should:
  - identify key laboratories [e.g., those that report a large number of serologic test for syphilis (STS), and large laboratories that rarely report].
  - maintain and update regularly a registry of laboratories within and outside of the local area or state that perform a significant number of STS for the local area or state.
  - visit laboratories, at least annually, that perform a large number of tests to assess the timeliness and completeness of reporting.
  - regularly provide reports back to laboratories to inform them of the number of STS that have been performed and the number of reactive STS that they reported.
  - establish a listserv or e-mail communication to increase and improve communication between laboratories and the STD program.
  - maintain correspondence with local and state professional associations that represent laboratories.
  - visit sites to review reporting rules with key, large-volume laboratories within and outside of their jurisdictions.
  - identify a public health department employee who may serve as a liaison to the area's laboratories.
  - provide multiple methods to receive serologic reports, including toll-free telephone numbers, facsimile machines, direct electronic reporting, and internet-based systems.
  - implement methods to monitor an individual laboratory's changes in reporting practices.

- promote the adoption of statutes or regulations to require laboratory reporting of the titer of reactive nontreponemal serology tests within one working day of the test result and without waiting for the completion of confirmatory testing.

Evaluating Laboratory-Based Reporting

Laboratory reporting of serologic test results is a critical component of syphilis surveillance. Laboratory reporting evaluation programs enable STD prevention programs to periodically evaluate the syphilis testing activities and reporting practices of laboratories to ensure prompt and complete laboratory-based reporting of possible cases.

Addressing the components of a program to evaluate reporting by laboratories can enhance STD surveillance (Box 1). Activities by STD program staff should also be assessed in all laboratory evaluation visits (Box 2).

Box 1. Components of a Laboratory Reporting Evaluation Program to Improve Syphilis Surveillance

1. Coordinate Laboratory Evaluations

- Identify a laboratory evaluation coordinator.
- Develop and maintain a registry of all laboratories that perform syphilis diagnostic testing for providers in the STD program's jurisdiction.
- Periodically prioritize laboratories for evaluation (e.g., laboratories that serve areas with substantial morbidity or laboratories that do report or should report substantial numbers of persons with reactive STS).
- Develop a schedule for evaluating laboratories (priority laboratories should be evaluated at least annually).

2. Develop Evaluation Criteria

- Evaluation criteria should be developed by setting action levels that define acceptable levels of reporting completeness and timeliness.
- Define corrective actions that will be taken when the laboratory's reporting performance falls below the defined action levels.

3. Determine a Time Period and Sampling Strategy for Evaluation

- The time period for evaluation will be retrospective (to account for reporting lag), and its duration will depend on the test volume of the laboratory (higher volume implies shorter sampling period). Reviewing a sample of STS results in which a minimum of 50 are positive should be adequate to calculate completeness and timeliness of reporting.

4. Laboratory Evaluation Visit

- The laboratory evaluation coordinator should train and monitor field staff to ensure that laboratory evaluations are conducted in a consistent, complete, timely, and professional manner (see Box 2).□

Data Collection

The laboratory evaluation coordinator must develop a uniform format for the collection of information during the laboratory visit. A sample format is included in Appendix 1. The minimum data required are:

- time period evaluated;
- total number of STS performed (by test type and sex); and
- number of reactive STS (by test type and sex).

Assessment of the Sensitivity of Laboratory Reporting

The proportion of reactive STS reported by the laboratory to the STD Program, or the sensitivity of reporting from that laboratory, is calculated by dividing the total number of reactive STS that the laboratory reports by the number of reactive STS processed by the laboratory during the designated time period. Out-of-jurisdiction reporting may be an issue for some project areas and should be considered when calculating the sensitivity of reporting.

Assessment of Timeliness of Laboratory Reporting

Timeliness is a measure of the delay between any two (or more) steps in the surveillance system.[5] Timeliness of reporting is usually measured in days or weeks. The allowable time frame for reporting is often outlined in state communicable disease reporting statutes and varies from state to state.

- A sample of reactive STS reports should be evaluated to determine the date when specimens were analyzed by the laboratory and the date when reports were received by the STD Program. Laboratory reports should be date stamped by health department personnel upon receipt.
- The lag time in days between analysis of the specimen by the laboratory and receipt of the report by the STD program needs to be calculated for a sample of serologic reports and compared to the state specific reporting requirements.
- Adding up the "days until report received" for all tests reviewed and dividing by the number of tests reviewed yields the mean lag time between analysis of specimen by a laboratory and receipt of reports from the laboratory by the STD program. Other options for measuring timeliness include calculating the range and median reporting delays or calculating the proportion of serologic reports received within a variety of day increments (e.g., 0 to 3 days, 4 to 7 days, 8 to 14 days, and greater than 14 days).

Laboratory Evaluation Feedback

- The laboratory evaluation coordinator should inform the laboratory director in writing of the results of each evaluation visit within one month of the visit. If the sensitivity or timeliness of reporting are below established action levels, a collaborative improvement plan should be devised.
- STD programs should distribute STD surveillance reports (including results of laboratory-based surveillance and summary findings from laboratory reporting evaluations) to all laboratories on an annual basis at a minimum.

- The laboratory evaluation coordinator should maintain records of laboratory evaluations, including data concerning the completeness and timeliness of reporting and document all feedback given to laboratories.
- A summary of the evaluation findings should be provided to the laboratory outlining strengths, deficiencies, and plans for improvement.

Box 2. Responsibilities of STD-Control Program Staff During Laboratory Reporting Evaluation Visits

1. Before the Laboratory Evaluation

Contact the laboratory director to arrange a date for the evaluation.

- Inform laboratory director of the reason for your visit.
- Inform the laboratory director that it will be necessary to meet with the person(s) responsible for reporting syphilis test results to the STD Program.
- Document the discussion with the laboratory director.
- Consult with the laboratory evaluation coordinator if request is denied.
- Review the laboratory's previous reporting patterns; note the number of reactive STS reported during the previous year; and note the mean and median number of days between analysis of specimens by the laboratory and receipt of the reports by the STD Program.

2. During the Laboratory Evaluation Visit

- Meet with the person(s) responsible for reporting syphilis test results to the STD Program.
- Assess and document the laboratory's reporting procedures.
- Review the laboratory's log for the designated time period and determine the total number of STS performed and the number of reactive tests listed during this period; for a sample of the reactive STS, note the date that the specimen was analyzed by the laboratory and the date the report was received by the STD Program.
- Determine the number of reactive STS tests reported during the time period of interest and review documentation of reporting, if available.

3. Following the Laboratory Evaluation

- Calculate the proportion of reactive STS reported to the STD Program.
- Calculate the timeliness of reporting.

Active Surveillance

Definition

Active surveillance involves routine communication with health care providers and laboratories to stimulate and maintain case reports. Potential reporters include but are not limited to public and private providers, laboratories, managed care organizations, substance abuse centers, and corrections facilities.

Purposes and Uses of Active Surveillance

Active surveillance at state and local levels can be used for a variety of purposes. In general, active surveillance may be used for evaluating the timeliness, completeness, and accuracy of the current surveillance system, improving the current system, and evaluating disease control initiatives. Specific purposes and uses of active surveillance at state and local levels include the following:

- Evaluate existing surveillance system
  - Permits comparison with existing passive system
  - Determine whether passive reports are representative of disease in the community
- Improve existing surveillance system
  - Improve timeliness of reporting
  - Improve the sensitivity of reporting (health department is receiving reports on all cases of disease)
  - Improve the completeness of reporting (disease reports are accurate and have complete information)
  - Strengthen case detection efforts (e.g., laboratory and provider visitation)
- Evaluate and improve disease control initiatives
  - Facilitate outbreak detection
  - Quickly and efficiently evaluate disease activity in the community by contacting providers and agencies likely to see persons with the disease
  - Prompt testing for disease detection
  - Evaluate the effect of disease intervention and prevention activities

Box 3. Key Steps in Developing an Active Surveillance System

1. Develop objectives for active surveillance, and design the system accordingly

- Outbreak detection and response
- Evaluate current surveillance system
- Improve completeness of reporting

2. Develop a list of providers, agencies, and laboratories

- Make a list of contact persons including telephone and facsimile numbers of providers and agencies and laboratories submitting a large proportion of disease reports received by the health department.
- Make a list of providers and agencies that would be expected to diagnose and treat patients with STDs and a list of laboratories that would be expected to perform clinical testing on patients with STDs.
- Make a list of agencies that serve persons at high risk for syphilis (e.g., corrections facilities, drug treatment centers, etc.).
- Develop a strategy to sample providers, agencies, and laboratories to determine the timeliness, completeness, and accuracy of reporting.

3. Include contact information on the list of providers and laboratories

- Include telephone numbers, facsimile numbers, e-mail addresses, procedures for visiting, etc.

4. Develop a data collection instrument

- Determine the information to be obtained when making contact.
- Create an instrument with the list of questions in order to obtain complete and consistent information from each facility contacted.
- Create a template with questions that pertain to patients with genital ulcer disease and syphilis.

5. Develop a plan for analyzing and interpreting the data

Programs implementing syphilis elimination activities should establish locally defined methods for active surveillance.

It is necessary to establish objectives, methods, and protocols for active surveillance so that the activity can be carried out systematically in a variety of sites. The components of and structure for active surveillance should be specified to provide state and local project areas with a framework for the activity so that specific protocols can be developed.

State and local health departments should develop active surveillance protocols based on the incidence of syphilis in their jurisdiction because the level of morbidity often helps define the uses of data derived from active surveillance. For example, in areas with low incidence of disease, the primary objective of active surveillance may be to evaluate the sensitivity of the surveillance system. In areas of high morbidity that may be experiencing one or more outbreaks, active surveillance may be employed continually to ascertain cases from providers on a real time basis, independent of the time lag for case verification and reporting.

State health departments should develop active surveillance protocol templates and should provide technical assistance to local jurisdictions in developing local protocols. CDC and the National Coalition of STD Directors should collaborate to develop model active surveillance protocols. State and local STD staff should consult with general communicable disease epidemiology staff when developing active surveillance protocols.

Health department personnel should increase interaction and communication with providers in low-morbidity areas. Close contact with providers in low-morbidity areas is essential to ensure that all identified early syphilis cases are reported rapidly and to prevent incipient outbreaks of syphilis.

Active Methods to Ascertain Cases

Disease control programs have generally relied on provider and laboratory reports for ascertaining cases. Intensive disease control activities, such as syphilis elimination, require additional methods of case ascertainment. Additional methods that have been utilized by state and local programs to ascertain cases include but are not limited to:

- Targeted screening (e.g., screening at designated sites using mobile units).
- Outreach efforts (street and otherwise) using community agencies to identify cases.
- Partner elicitation and notification to learn of potential cases from case-patients.
- Social network methods or "clustering" (e.g., contacting social contacts for testing and treatment services).

Genital Ulcer Surveillance

Genital Ulcer Surveillance in STD Clinics

- STD clinics should keep genital ulcer log books with listings of patients' names, clinical diagnoses given, and laboratory testing if available (an electronic format could be used in lieu of a log book).
- Darkfield microscopy log books should be kept in clinics performing darkfield microscopy.

- Routine review of these log books would help determine the proportion of STD clinic patients with genital ulcers, the proportion of persons with genital ulcers who were tested for syphilis and were subsequently found to have syphilis. Analyses also could include the proportion of cases with positive darkfield microscopy results and positive STS results [non-treponemal and treponemal].

The use of a log book allows the area to quantify the number of genital ulcers observed over time that are suspicious for syphilis and to quantify the proportion that are positive for *T. pallidum*, or associated with reactive tests for syphilis, and the proportion reported as cases.

Genital Ulcer Surveillance Sampling and Survey Strategies

- Health departments should periodically test genital ulcers for etiologic pathogens.
- Health departments should survey providers regularly to determine the numbers of persons diagnosed with genital ulcers in a specified time period and the results of diagnostic testing, if available.

Periodic sampling of genital ulcers in patients in both STD clinic settings and non-STD clinic settings enables disease control programs to determine the number of persons diagnosed with genital ulcers at facilities and the number of persons with genital ulcers that are positive for *T. pallidum,* HSV, *H. ducreyi* and other pathogens, and the number of persons with genital ulcers who have reactive serologic tests for syphilis for a specified period of time. Surveys to assess the number and etiologic nature of genital ulcer disease should be conducted with providers that serve populations at high risk for syphilis. In some circumstances, detailed surveys involving medical chart review and abstraction may be appropriate for monitoring the prevalence of genital ulcers and clinical management of genital ulcers diagnosed in persons at high risk for syphilis.

- DFA-TP should be utilized whenever available to provide diagnosis of syphilis in patients with genital ulcers.

DFA-TP testing allows specific diagnosis of syphilitic genital ulcers when darkfield is unavailable.

Outbreak Detection

Appropriate data sources that can be used to detect syphilis outbreaks include

- case reports (case registry data).
- laboratory reports.
- prevalence-monitoring sites.

Case reports and laboratory reports are good sources of surveillance data for the detection of outbreaks. Prevalence monitoring-data may be useful for detecting outbreaks in populations regularly screened for syphilis (e.g., arrestees, STD clinic patients, HIV infected patients). For conditions of unknown etiology (e.g., genital ulcers of undetermined etiology), clinician reports are often the initial indication that an outbreak is occurring.

When determining time frames to use for the detection of syphilis outbreaks, the following should be considered:

- Decisions regarding what time frame to use depend on the incidence of syphilis in, and the demographic characteristics of, a given area.
- In areas with substantial morbidity surveillance data should be analyzed at least monthly to monitor changes in the incidence of syphilis that may indicate the occurrence of an outbreak. Analyses should include demographic data, risk factors (e.g., sexual orientation, drug use, sex for drugs or money), geographic information (e.g., zip code, census tract) and other characteristics. In addition, analyses should be performed to identify increases in overall morbidity or increases in specific subgroups.
- In low morbidity areas, cases should be reviewed as reported and a monthly overview should be routinely completed to monitor changes.

Data must be systematically and routinely reviewed to identify the occurrence of outbreaks. Outbreak thresholds must be dependent on area-specific morbidity. For example, an area with endemic syphilis may set a threshold above the observed rate, whereas an area with no syphilis might set the threshold at a single case. The unit of observation may be defined in a variety of ways. One method is to make the unit of observation a defined geographic area and to look for an increase above the threshold of cases in that defined area. Another method is to make the unit of observation a defined demographic or risk group and to look for an increase above the threshold of cases in the defined group. Geographic units of observation are more conventional, but, they may not work well to detect outbreaks in such specific subgroups as men who have sex with men if they do not live in the same area. A combination of geographic, demographic, and risk factor units of observation may be best, especially in areas with substantial morbidity; when syphilis is rare and the threshold is low, either strategy may work well.

Because prompt provider reporting of early syphilis cases is critical to outbreak detection, state reporting laws should ensure that reporting syphilis cases is a high priority activity and should require that suspected cases of early syphilis are reported immediately to the health departments (see case reporting section).

Electronic Reporting of Laboratory Data

Case Reporting

Some of the data elements necessary for reporting syphilis cases and for monitoring prevalence are already available in computerized systems maintained by many clinical laboratories. Laboratories should be encouraged to report laboratory data electronically to STD prevention programs, and STD prevention programs should develop the ability to receive and transmit these data.

When STD prevention programs define variables and develop data formats for case reporting and prevalence monitoring, they should provide the data formats to laboratories and collaborate with them to ensure reporting. Laboratories should be encouraged to submit electronic line-listed data on all persons with reactive STS for case reporting. For prevalence monitoring, STD prevention programs should work with laboratories to determine whether line-listed data for persons with nonreactive STS can also be submitted.

Reporting by Out-of-State Laboratories

Large commercial laboratories often receive specimens from many states. With increasing regionalization of commercial laboratories and the centralization of laboratory services within managed-care organizations, out-of-jurisdiction testing has become more common. Laboratories that perform STS should report reactive STS to the appropriate STD control program for the local area or state in which the tested person resides.

Out-of-State Reporting Algorithm

The Council of State and Territorial Epidemiologists recommends that the following algorithm be used by laboratories when reporting reactive STS to public health authorities in multiple jurisdictions (in order of preference):

a) state where the patient resides;

b) state where the ordering provider is located ("a" is missing);

c) state where the original receiving laboratory is located ("a" and "b" are missing); or

d) state where the laboratory that performed STS is located ("a," "b," and "c" missing).

STD prevention programs should ensure that laboratories within their state are familiar with the algorithm.

Coordination of laboratory-based reporting of reactive STS with reporting of other notifiable diseases

State and local STD-control programs should collaborate with other public health programs that are conducting laboratory-based surveillance for other notifiable conditions to minimize the duplication of efforts and to efficiently use the laboratory's reporting resources.

Many laboratories are required to report data to multiple public health programs within the same health department. These public health programs also may request that the data be reported in different formats and for different time periods. Collaboration and co-ordination within the health department programs that receive data from laboratories will improve the efficiency of reporting laboratory-based surveillance data and will simplify reporting procedures by laboratories. Because of the large number of laboratories reporting reactive STS, a standardized laboratory reporting format should be developed that will accommodate public health laboratories at all levels, clinical laboratories, major reference laboratories, and other facilities that perform syphilis testing.

Prevalence Monitoring

Priority Populations

Populations that may be appropriate for routine syphilis screening, and among whom prevalence data may be sought, include:

- arrestees (jails, prisons, juvenile detention centers, at admissions
- pregnant women (screen during 1st trimester, at approximately 28 weeks gestation, and at delivery)
- STD clinic patients
- patients with STDs in non-STD settings (private medical providers, urgent care facilities, and emergency rooms)
- clients attending drug treatment facilities (at admission)
- HIV counseling and testing clients
- HIV specialty clinic patients (initial and annual visits; more frequently depending on local epidemiology)
- homeless populations
- family-planning clinic clients
- community-based site clients (e.g., mobile clinics, bars, bath houses)
- emergency room patients
- community health center clients

Arrestees. Local STD-control programs should establish syphilis screening programs in city and county jails. Jail screening programs have demonstrated that there is a high prevalence of untreated syphilis in arrestees in numerous jails throughout the United States.[7]

Pregnant women. The most efficient prevention method for congenital syphilis is screening of pregnant women. Such screening should be conducted at the beginning of prenatal care and upon delivery for all women. Testing should be done at or near 28 weeks' gestation for women living in areas with substantial morbidity and for women at high-risk for syphilis.

Clients attending drug treatment facilities. Areas with substantial morbidity should develop screening and prevalence-monitoring projects in facilities specializing in drug treatment.

HIV counseling and testing clients. Screening for syphilis should be offered regularly to clients of HIV counseling and testing sites based on local epidemiology.

Community-based site clients. Screening for syphilis should be considered in areas with high rates of syphilis. Community-based screening may be conducted with the use of mobile clinics, at designated sites, or with a "door-to-door" approach. Local epidemiology and information from geographic information systems should help guide these activities.

Calculation and Definition of Seropositivity and Prevalence

There are several ways to define prevalence for monitoring disease burden within specific, screened populations. What method to use should be based on the analysis being considered and on the available data. Prevalence monitoring requires the collection of both negative and positive STS results. STD prevention programs should have information systems in place for data collection and management, and these systems should facilitate the transmission and analysis of data.

Seropositivity is calculated by dividing the number of reactive STS tests by the number of valid STS tests performed during a specified time period. Prevalence is estimated using a single test per person during a specified time period. Seropositivity rates may include multiple tests per person during a specified time period but may be used to estimate prevalence. Four ways to calculate prevalence and seropositivity are listed below, beginning with the most basic and proceeding to the most specific approach. Which approach to use should be made on the basis of the program's ability to record and manage these data over time. The use of laboratory requisition forms that can be scanned may facilitate prevalence-monitoring activities for large screening programs such as those in jails.

Option 1. Seropositivity (reactive non-treponemal tests)

Seropositivity should be calculated as the proportion of reactive non-treponemal tests among those persons with valid tests in a specified time period. Knowing the seropositivity of non-treponemal STS may be used to 1) give crude estimates of the disease burden within the screened population; and 2) evaluate the productivity of a given screening site (this may be most beneficial in areas with a high incidence of syphilis).

Option 2. Seropositivity (reactive non-treponemal tests with treponemal test confirmation)

Seropositivity should be calculated as the proportion of reactive non-treponemal tests with reactive treponemal tests (confirmatory) of those persons with valid non-treponemal tests in a specified time period. The seropositivity rate of non-treponemal STS with reactive confirmatory STS may give a more accurate estimate of the disease burden within the screened population than the seropositivity rate of non-treponemal STS alone does and it is useful for determining the productivity of screening sites.

Option 3. Quantitative non-treponemal tests with titers >1:8

Prevalence should be calculated as the proportion of reactive non-treponemal tests with a titer of 1:8 or greater in persons with valid tests in a specified time period. A titer of 1:8 or greater has been shown to correlate with infectious syphilis (primary and secondary stages).[8] If available, treponemal tests should be used to confirm syphilis infection in persons with positive non-treponemal tests.

Option 4. Prevalence of Early Syphilis

Prevalence should be calculated as the proportion of early syphilis diagnoses (primary, secondary and early latent stages) in persons tested the first time in a specified time period. A unique patient identifier is required for monitoring early syphilis prevalence. Individuals re-infected during the specified time period should be counted twice both in the numerator and denominator.

Provider-Based Prevalence Monitoring

Because prevalence monitoring may require more resources than case reporting, participation by providers should be actively sought by health departments. Participation of all providers or all programs is not necessary. State and local STD-control programs should develop written criteria for assessing the value of prevalence monitoring and for selecting providers. Programs also should seek to obtain access to existing data collected on populations that are routinely screened for syphilis. Providers that have one or more of the following characteristics should be given the highest priority:

- those who serve populations at high risk for syphilis (e.g., men who have sex with men, incarcerated persons, person enrolled in drug treatment centers) or who serve populations who may be particularly susceptible to the effects of syphilis (e.g., pregnant women)
- those who provide care in areas where there is substantial morbidity
- those who have sufficient patient volume and consistency
- those who have electronic information systems that can capture data efficiently
- those who are capable of screening a representative sample of their clientele

STD prevention programs should collaborate with providers to develop and maintain prevalence-monitoring activities. In developing a collaborative relationship with providers, STD prevention programs should:

- clearly communicate the purposes of prevalence-monitoring activities;
- consider reimbursement of testing and treatment costs;
- provide training (with continuing medical education [CME]) and offer technical assistance in specific areas of interest (e.g., case management, follow-up procedures, diagnostic procedures, treatment, data management, and epidemiology);
- give providers regular reports of the results of prevalence monitoring, including a discussion of their implications for the prevention of syphilis.

Laboratory-Based Prevalence Monitoring

Laboratories can be the primary source of prevalence-monitoring data if they routinely receive data regarding the sex and age of, and the provider type for persons tested for syphilis. State and local STD-control programs should work closely with public health laboratory staff members to encourage private laboratories to report these data. The purposes of prevalence monitoring must be communicated to the laboratories. In addition, laboratory personnel should be informed of state statutes that give health departments the authority to conduct public health surveillance (which includes provisions for obtaining both positive and negative test results). The relevant statutes and procedures should be provided with written procedures that will assist them in ensuring data security and patient confidentiality. To establish and maintain laboratory-based prevalence monitoring, health departments should consider the following:

- Developing a written protocol for laboratory-based surveillance that includes discussion of prevalence monitoring. Health department and laboratory responsibilities and procedures for prevalence monitoring should be clearly stated.

- Maintaining and regularly updating a registry of laboratories that perform STD testing (such a registry may be available through CLIA, state, or laboratory proficiency providers).
- Developing protocols that outline procedures for conducting laboratory visits by the health department personnel.
- Providing laboratories with a standardized list of data elements, reporting formats, and intervals for reporting syphilis and prevalence-monitoring data.
- Identifying a health department employee to serve as a liaison to laboratories or to serve as the laboratory evaluation coordinator. This person would be the contact person for all laboratory surveillance activities.
- Determining provider types served by each laboratory and the volume and positivity rate of syphilis testing completed by each laboratory.
- Providing regular feedback to laboratories, emphasizing the importance of their data to public health prevention efforts.
- Supporting the development of procedures for reporting prevalence-monitoring data electronically to STD-control programs.

Reporting Formats and Intervals

Formats. Whenever possible, prevalence-monitoring data should be collected and reported in line-listed format. Line-listed data are preferable to aggregate prevalence data because they provide the greatest flexibility for data analysis, data management, and data transfer.

- Programs that monitor prevalence should adopt standardized, essential data elements for line-listed data and ensure that their data systems can export the data in a standard format.
- If aggregate data are collected, they should be reported by sex, site, time period, type test, test result, and confirmatory test result.

Time frames for reporting. Prevalence-monitoring data should be reported quarterly to CDC either in line-listed or in aggregate format.

- STD prevention programs and other prevalence-monitoring programs should provide data within 90 days after the end of each quarter. Programs are also encouraged to send updated, end-of-year data to allow the data set to be closed out each year.
- If line-listed data are provided, a mechanism should be established to enable amendment, correction, and updating of records previously submitted within the year of report.
- Local and state public health programs that monitor syphilis prevalence should have the flexibility to establish daily, weekly, monthly, or quarterly reporting time frames according to the needs of individual programs.

Data Elements for Prevalence Monitoring

Many of the data elements that should be collected for purposes of syphilis prevalence monitoring are identical to those being collected for the purposes of case reporting.

The compatibility between case-reporting and prevalence-monitoring data systems at state and local levels should facilitate collection, transmission, and analysis of data.

The development of a standard list of core data elements (an abbreviated list of required data elements) that can be transmitted in a uniform format is necessary for comparing data collected by different screening sites, project areas, and regions throughout the United States. Standard data elements would facilitate the collection and transmission of data. Additional variables could be collected and used by health departments to evaluate screening programs, to manage resources, to generate research questions, and to plan intervention activities (Appendix 2).

Behavioral and Social Surveillance

Behavioral and social data can complement case-reporting and prevalence-monitoring data by tracking and anticipating changes in the epidemiology of disease and by identifying risk factors associated with infection.[9] Prompt and accurate behavioral and social data are necessary to maintain effective prevention and intervention programs.[10] Questionnaire-based behavioral data to inform prevention can be collected in a number of ways including general population surveys, behavioral surveillance of populations at risk for, or infected with, syphilis, and as part of specific intervention studies.

Purposes and Uses of Behavioral and Social Surveillance

- To monitor and track the risk behaviors and social factors that contribute to disease acquisition and transmission
- To identify populations that are at risk for acquiring STDs
- To help identify behaviors and social factors that can lead to the prevention of STDs

The development of effective behavioral interventions aimed at syphilis control and elimination must be guided by behavioral, social, and contextual data from infected populations, at-risk populations, and from communities with high rates of syphilis.

Existing and Potential Data Sources

Behavioral and social surveillance data are generally collected at three levels: the general population, an infected population, and a population at high risk for infection. General population surveys have been used to monitor change in risk exposures in the general population over time. Such surveys are limited in their ability to monitor changes in uncommon behaviors (e.g., risky sexual behaviors), and in their ability to monitor risk exposure in infected, at-risk populations or affected communities. Behavioral surveillance of infected populations and of populations at risk is critical for monitoring and controlling the spread of disease.

Existing Behavioral Surveillance Data Sources

1. General Population Surveys
    - National Health Interview Survey (NHIS)
    - Behavioral Risk Factor Surveillance System (BRFSS)

- Youth Risk Behavior Survey (YRBS)
- National Household Survey on Drug Abuse (NHSDA)
- National Survey of Family Growth (NSFG)
- National Health and Nutrition Examination Survey (NHANES)
- General Social Survey (GSS)

2. Infected Populations

- HIV/AIDS Reporting System (HARS)
- Sexually Transmitted Disease Management Information System (STD-MIS)
- Supplement to HIV/AIDS Surveillance (SHAS)
- Locally developed information management systems
- Gonococcal Isolate Surveillance Project (GISP)

3. Surveys of Populations at High Risk for Infection

- Arrestee Drug Abuse Monitoring HIV addendum (ADAM)
- HIV Testing Survey (HITS)
- Drug Abuse Warning Network (DAWN)

Potential Data Sources

Successful control of the transmission of syphilis depends on the ability to identify populations at risk for infection and to identify behaviors associated with syphilis. Behavioral surveillance is required for both of these activities. Behavioral surveys of infected persons and of groups at risk for infection have been conducted primarily to help design and evaluate specific interventions rather than to monitor trends over time. Surveys of persons at risk for syphilis and of persons infected with syphilis are necessary to describe risk exposures and to develop appropriate intervention strategies. Methods that state and local programs could use to obtain this information include the following:

- Routinely administered supplemental items to the syphilis interview record collecting behavioral information
- Routinely or periodically administered surveys of at risk persons (e.g., sexually transmitted disease clinic patients, incarcerated populations, sex workers, men who have sex with men)
- Cross sectional interviewer-assisted street-intercept surveys conducted in areas of high morbidity, repeated periodically

Data Elements

Selection of behavioral and social data elements can be guided by the three determinants of transmission:[11]

- Exposure to infection
  - Number of sex partners
  - Prevalence in sex partners
  - Location of sex partner recruitment
  - Sexual mixing patterns

  - Exchange of sex for money or drugs
  - Drug use by individual or sex partner
  - History of STDs or incarceration
  - Recent partners
  - Gender of partners
  - Concurrent partners
  - Frequency of intercourse
- Efficiency of transmission
  - Sexual practices
  - Condom use
    Duration of infection
    Access to treatment
    Interval between onset of symptoms and treatment
  - Perceptions about service providers
  - Self treatment
  - Symptom awareness

Data Collection Methods

Collection of behavioral information is based on self-report most of the time. Potential biases inherent in self-reported information include recall bias and information bias. In some instances recall bias can be minimized by careful wording of survey questions. The "critical event" approach asks respondents to recall behavior only for the last time the event occurred (e.g., the last time you had sex, did you or your partner use a condom?).[12] This method has been used to minimize recall bias. Bias caused by a respondent's desire to give "correct"or socially acceptable responses may be minimized by:

- Considering population characteristics when selecting data collection methods
  - Language spoken or facility with English
  - Literacy
  - Comfort level
  - Facility (public vs. private)
  - Cultural characteristics
- Establishing quality control for information-collection efforts
  - Instrument development
  - Interviewer training and supervision
- Considering alternative methods of information collection to enhance validity and reliability of data and to gain access to populations that are generally difficult to reach
  - Computer-assisted methods
  - Web-based surveys

Analysis and Interpretation of Behavioral and Social Data

- Develop a common set of standard data elements for all data collection systems to enhance comparability of data
- In areas of high morbidity, behavioral data should be monitored regularly to assess changes in risk behavior over time

Community Involvement with Data Collection, Analysis and Interpretation

- Health departments should develop structured communications with:
  - Community representatives
  - HIV community planning groups
  - Advisory boards
  - Academia
  - Other health department agencies

Data Quality

Data Quality for Case Reporting

Incomplete reporting of data elements and reporting delays can adversely affect data quality. All programs should have written quality assurance plans that specify quality control procedures for data collection. Data quality-assurance activities should be documented, and the results of these activities should be monitored. Specific surveillance indicators should be established and monitored regularly at defined intervals. Reports on data quality should be distributed to providers and laboratories on a quarterly basis in an effort to provide feedback on reporting performance.

Examples of indicators include the following items:

- proportion of specific variables for which data is complete;
- time between the date of the index diagnostic test and other significant events in the investigation;
- laboratory and provider reporting time frames (time from diagnosis or laboratory analysis to when the health department received the report);
- data comparisons between surveillance systems, and;
- validity of data (e.g., no pregnant males, valid dates).

Transmitted data should be reviewed to identify duplications, errors, and omissions on a quarterly basis at local, state, and national levels. Data transmitted to CDC should be reviewed for accuracy, completeness, sensitivity, promptness, validity, and quality on an annual basis.

Quality-control procedures should be used to provide routine, continuing assessments of the accuracy of demographic data (e.g., the patient's age, race and ethnicity, and geographic location). The following quality-control measures should be considered by local and state programs:

- Design data-entry systems with built-in error checks.

- Use logic checks and restricted data-entry protocols because of the large volume of collected and transmitted syphilis cases reports. For example, such procedures could ensure that logical dates are recorded (e.g., the date of specimen collection must be before the date of report to the health department).
- Generate frequency distributions of selected data elements to evaluate data validity. The selected data elements should allow direct comparison with other appropriate data distributions and should not be open to variable interpretation. For example, a clinic's review of its population's age or race distributions may identify inconsistencies when compared to the expected distribution. In addition, test type should match the actual test type being used.
- Trends in positivity rates by risk factor should be evaluated regularly to assess data validity. Once disease trends are established, any unexpected changes should be investigated.

State and local STD prevention programs should submit updated or corrected case-report data to CDC as soon as possible.

Data Quality for Prevalence Monitoring

Prevalence monitoring programs should have written protocols that specify quality control procedures for data collection. Data quality assurance activities should be documented, and the results of these activities should be monitored. Specific surveillance indicators (e.g., the proportion of data fields that are completed and reporting lag time) should be established and monitored at regular, defined intervals. Periodically, data-quality reports should be distributed to providers and laboratories to provide feedback on data quality. STD prevention programs should monitor the completeness, validity and timeliness of prevalence data.

Completeness refers to the proportion of data fields with complete information. The following recommendations should be considered with respect to completeness of prevalence data and methods for assessing completeness of these data.

Routine Analyses for Assessing Completeness of Prevalence Data

- Examine proportion of fields completed
- Examine proportion of test results that were unsatisfactory
- Examine and monitor the proportion of eligible individuals actually screened. This analysis provides one indication of the representativeness of the population being monitored (i.e., the higher the proportion the more representative of the population).
- Examine screening protocols to eliminate or identify sources of systematic bias (e.g., not screening on weekends)

Criteria for Assessing Completeness of Prevalence Data

- Sex should be 100% complete
- Age, race, ethnicity, and geographic location (e.g., county and zip code) should be > 90% complete
- Type of clinic to which the patient presented (e.g., family planning or STD) should be 100% complete

- Programs should compare the volume of reported data to actual screening activity using laboratory or clinic sources (e.g., records and logs)

Validity refers to the accuracy of the information contained in each data element. The validity of STD surveillance has two components. The first is the extent to which the data in the prevalence monitoring record correctly reflects what exists in the primary data source (e.g., medical record or laboratory report). The second is the extent to which the primary data source is accurate. The following recommendations regarding validity should be considered for prevalence monitoring data.

- Data entry systems should have built-in error checks
- Frequency distributions should be examined to identify gross irregularities of data
- Quality-control procedures should be used to provide routine, on-going assessments of the accuracy of basic demographic data

Timeliness refers to the time intervals between steps in surveillance, expressed as a mean or median number of days or as a proportion that is greater or less than a defined interval. The following recommendations regarding timeliness should be considered by programs conducting prevalence monitoring activities.

- Prevalence monitoring sites should submit corrected data (line-listed and aggregate) at least quarterly to the state or local programs involved with these activities and within 90 days of the end of the quarter
- Prevalence monitoring sites submitting data to state or local programs or sites submitting data to CDC should submit corrected end-of-year data within 90 days of each calendar-year

Data Analysis and Interpretation

Case-Reporting Data

Analysis and interpretation of data and dissemination of the resulting information are necessary to complete the process of case reporting. The analyses recommended here are intended to address the overall purposes of syphilis surveillance discussed previously.

Every local, state, and national program should perform a comprehensive analysis of its case-reporting data annually. In addition, abbreviated analyses should be performed more frequently. Abbreviated analyses should be performed monthly in areas with substantial morbidity and in low morbidity areas, cases should be reviewed as reported.

Types of Analyses

Analyses that are performed more frequently than annually should include an examination of quarterly or monthly trends in the number of reported early syphilis cases for the preceding two

years. These analyses should be presented for all reported cases and may be stratified by the following categories depending on local epidemiology:

- geographic area (e.g., census tract, zip code, county, state)
- sex
- age group
- race/ethnicity
- provider type
- provider site
- reporting laboratory
- test type
- disease stage
- anatomic site of primary lesions
- sexual behavior (e.g., gender of sex partners, exchange of sex for money)

On an annual basis, every local area and state should analyze all early syphilis cases reported during the year and all cases stratified by the categories listed above. In addition, as part of the analysis, local areas, states, and CDC should determine the annual rates in syphilis using the most recent census data available or intercensal estimate. Calculated rates represent the minimum incidence of early syphilis. These rates should be compared with the rates for previous years for all cases and stratified by the categories listed above.

Stratification by sex, age group, and race and ethnicity is important in the analyses because it allows specific detection of disease activity in groups of people that may be particularly susceptible to or at increased risk for infection. Stratified analyses are recommended when populations are large and when disease rates are high or increasing.

Other important analyses that should be performed annually:

- Examination of the syphilis and HIV co-infection rates
- Comparison of the rates and trends of syphilis obtained from case reports and from prevalence monitoring

The following factors should be considered when analyzing and interpreting data from syphilis case reports and prevalence monitoring:

- Changes in case reports or prevalence may be real or the result of changes in screening, reporting practices, or test type. Any marked change in reported cases or prevalence should be investigated to determine the probable cause.
- Case-reporting data can be used reliably to monitor trends in disease burden when the screening activities are not changing, when access to and use of clinical services are stable, and when diagnostic and reporting practices are consistent over time. During periods when program activities increase, increases in reported cases may reflect elevated rates of screening. A decline in the number of reported cases may be the result of reduced screening activities or a decline in reporting by providers or laboratories.
- The identification and use of correct population totals are crucial for comparing disease burden among groups. Census data stratified by geographic location, sex, age group, and race/ethnicity must be used for calculation of population-based rates of case reports for each of these categories.

- Low case-reporting rates in areas with a high prevalence of disease may indicate that rates of screening are low or that cases are being under-reported.
- Analyses of rates of syphilis and HIV co-infection at local, state, and national levels can help elucidate relationships between these diseases in different areas and nationally.
- Determining the number of case reports submitted by major providers and large laboratories can help to identify sites that have recent increases or decreases in levels of testing and reporting. Providers and laboratories with recent increases or decreases in reported cases should be contacted to determine whether an outbreak is occurring or whether there has been an interruption in screening for syphilis or reporting cases.
- Determining the number of imported cases reported, the demographic characteristics, and risk factors of imported cases that cross jurisdictional borders is important.

Prevalence-Monitoring Data

Analysis and interpretation of data are necessary to complete the process of prevalence monitoring. State and local STD-control programs should perform the following analyses, quarterly and annually, of syphilis prevalence data to monitor disease burden and trends.

Examine syphilis prevalence (seropositivity, confirmed seropositivity, high-titer seropositivity, and actual prevalence of untreated disease) by the following:

- prevalence monitoring site
- site type
- sex
- age group
- race and ethnicity
- year
- zip code or census tract
- behavioral risk factors
- disease status or stage

Analyses of changes in the prevalence of syphilis in screened population are important for identifying and describing trends.

- Laboratory prevalence monitoring sites should analyze syphilis prevalence by provider type (e.g., family planning physician, jail).
- Prevalence of syphilis during the current year should be compared with prevalence during previous years and stratified by the categories listed above.
- Rates of co-infection of syphilis with other STDs (e.g., HIV, gonorrhea, chlamydia) should be determined regularly.

Assessment of Screening Coverage

State and local STD-control programs should collaborate with participating clinics to evaluate syphilis screening procedures and rates. Local and state STD prevention programs

should periodically assess syphilis screening coverage in their jurisdictions, particularly in settings that serve populations at increased risk for syphilis (e.g., clinics that provide care for HIV-infected persons, men who have sex with men, drug treatment facilities, correctional facilities, and emergency rooms).

Dissemination and Communication of Findings

Case-Reporting Data

A plan for regular dissemination of information derived from the analysis of syphilis cases should be developed at local, state, and national levels. Special consideration should be given to providing data to local STD-prevention programs, reporting laboratories, or other agencies that significantly contribute to the collection of the data. Findings based on information obtained from syphilis case reports should be summarized in newsletters, presentations, e-mail correspondence, website presentations, or formal reports on a quarterly basis. Formal reports should be prepared annually. In areas where syphilis occurs rarely, information may be disseminated less frequently than in areas with high rates of disease, but reports should be prepared at a minimum on an annual basis.

Prevalence-Monitoring Data

STD control programs should tailor the dissemination and communication of STD prevalence monitoring data to specific audiences. Public relations personnel or Public Health Information Officers should be consulted when practical. These reports should include a concise interpretation of the data. Quarterly reports of prevalence monitoring activities should be prepared for the following:

- sites involved with monitoring activities (e.g., jails, drug treatment centers);
- health departments;
- laboratories;
- syphilis advisory groups;
- professional medical groups.

Annual reports of prevalence monitoring activities should be prepared for:

- community-based organizations;
- organizations representing populations at risk for syphilis;
- general public through mass media;
- HIV programs and community planning groups;
- legislators and policy makers;
- faith communities;
- public and private health care providers;
- local and state public health agencies.

Information Systems

Information System Design

Effective information systems allow public health agencies to 1) monitor disease trends; 2) collect data to improve decision making; 3) collect and use data for solving health problems and for planning interventions; and 4) ensure the effectiveness, accessibility, and quality of personal and population-based health services. The CDC is collaborating with state and local health departments in implementing the National Electronic Disease Surveillance System (NEDSS) to better manage and enhance the large number of current surveillance systems and allow the public health community to respond more quickly to public health threats.[13] When completed, NEDSS will electronically integrate and link together several types of surveillance systems with the use of standard data formats; a communications infrastructure built on principles of public health informatics; and agreements on data access, sharing, and confidentiality. Specific recommendations for designing information systems include the following:

- Information systems must have the flexibility to accommodate new data elements and new technologies.
- Information systems should facilitate the analysis of electronic data at local and state levels.
- Systems should include a unique patient identifier to link multiple serologic tests for syphilis, syphilis case reports, and for other notifiable STD and communicable disease reports (i.e., systems should be patient-based not event-based).
- Systems should allow the transmission of provisional data that can be updated at a later time to improve the timeliness of syphilis surveillance.
- Local and state programs should be fully capable of collecting, storing, and transmitting required data elements.
- Systems should allow additional data not included in required data elements to be collected at local and state levels.
- New information systems must be capable of accommodating all variables from the old information systems.
- Adequate technical support is necessary to operate and maintain systems.
- Information systems must be capable of transmitting syphilis case data in a line-listed fashion using an extended record format.
- Once information used by STD-control programs is entered electronically, efforts should be made to maintain the data electronically, eliminating duplicate data entry efforts at various points within the system.
- CDC and local and state programs should describe risk behaviors of people with syphilis.
- Information systems should allow case-reporting data to be linked to the data collected and used for case management and partner follow-up.
- Information systems should facilitate the production of standardized reports summarizing data from case reports, and these reports should be accessible to

health-care providers and laboratories, STD program managers, health department policymakers, and others in the medical and general community.

- STD information systems should be capable of linking with other data systems including ones developed to collect, store and transmit data about immunizations, tuberculosis and HIV/AIDS. Public health departments should establish a working group, comprised of information systems experts, program managers, epidemiologists, and other stakeholders, to plan a unified information system structure across public health disciplines.
- Information systems at state and local STD prevention programs should be capable of receiving syphilis data electronically from laboratories. Information systems should enable the collection, storage, and transmission of data from persons with reactive STS and nonreactive STS, so that syphilis seroprevalence can be monitored in clinics and other defined populations.

Although laboratory protocols for electronic reporting are being developed, certain data elements essential for surveillance are not routinely available from laboratory information systems. Until other sources of data can be electronically linked to laboratory information systems (e.g., provider information systems, pharmacy information systems, hospital information systems, insurance and health plan information systems, and vital records), linking provider case reports with health department follow-up information will be necessary to obtain complete information on syphilis cases.

Privacy and Data Security

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandates that the United States adopt national uniform standards for electronic transactions related to health insurance enrollment and eligibility, health-care encounters, and health insurance claims; for identifiers for systems used in these transactions; and for security of these transactions.[14] The exchange of health data must include provisions for the protection of patient privacy. STD control programs must develop and maintain comprehensive data-security policies to ensure the following:

- the confidentiality of disease-control data and the privacy of individuals (prevention of unauthorized disclosure of information);
- the integrity of disease-control data (prevention of unauthorized modification of information);
- the availability of disease-control data for authorized persons (prevention of unauthorized or unintended withholding of information or resources); and
- appropriate use of surveillance data solely for public health purposes.

Maintaining the privacy of the collected information is necessary because significant personal, psychological, and economic damage may occur if information about the personal health and behavior of individuals is disclosed. Most states have statutes and laws protecting the confidentiality of public health data maintained by governmental agencies. Policies concerning data security must be developed in compliance with state and local statutes protecting the privacy of individuals and the confidentiality of public health information.

Some state and local statutes limit reporting requirements to persons who test positive for notifiable diseases. The legality of reporting data for persons with negative tests should be addressed. Guidelines should be developed which clarify procedures for the transmission of line-listed data with or without personal identifiers to help protect the confidentiality of reported data.

Training and Personnel

Innovative approaches for training and career development of STD surveillance personnel should be developed and supported at the national level and local levels. Some approaches may include:

- providing training for health department personnel in a variety of program areas (e.g., STD, HIV, or communicable diseases) and public health disciplines (e.g., epidemiology, biostatistics, and program management), to improve the capacity of existing personnel to conduct effective surveillance;
- using a variety of training approaches (e.g., rotation of staff through "model programs," distance learning, train-the-trainer programs, teleconferencing, data analysis workshops); and
- encouraging NCSD and CSTE to work with CDC to help provide technical assistance to STD prevention programs that have a limited capacity to conduct syphilis surveillance.

Analysis, interpretation, and dissemination of surveillance data are essential for effective surveillance systems and they allow health departments to make informed decisions and to apply evidence-based information in their efforts to design and implement prevention and intervention strategies.

Case-reporting and prevalence-monitoring activities require a variety of skills. Local, state, and federal public health agencies should cooperate to develop approaches for training and career development of STD surveillance personnel. Skills and areas that training should address include:

- epidemiology;
- data management;
- information systems;
- data entry;
- basic disease knowledge;
- STD surveillance;
- outbreak detection and response.

In addition to case reporting and prevalence monitoring, there are specific personnel and training needs for active surveillance and outbreak detection:

- each project area should collaborate with an epidemiologist;
- state and local health departments should obtain funding to support an epidemiologist position for STDs even if not full time;
- each project area should have an STD information management specialist;
- each project area should have an STD surveillance coordinator;
- each project area should communicate with their state epidemiologist to assure that the state epidemiologist is familiar with state STD epidemiologic data.

Epidemiologic expertise is necessary to help ensure that syphilis surveillance data are collected systematically, data are analyzed and interpreted appropriately, and that surveillance findings are disseminated effectively to promote the elimination of syphilis transmission.

Data management and coordination are necessary for the systematic collection of surveillance data, appropriate analysis, and interpretation of data, and effective dissemination of surveillance findings to promote the elimination of syphilis transmission.

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APPENDIX 1

Sample Serology Laboratory Site Visit Report

Region _____ Worker _____ Date of Visit ____/____/____

Laboratory Name and Address: Contact Person: Phone Number:

Type of Laboratory [ ] Hosp [ ] PMD [ ] Clinic [ ] Public [ ] Private

Type of Testing
Nontreponemal [ ] RPR [ ] VDRL [ ] Other _____
Treponemal [ ] TPPA [ ]FTA-ABS [ ] EIA [ ] Other _____

Person or Unit Responsible for Reporting _____

How is STS information maintained at the facility?
_____
_____

Format of Report (Attach sample) [ ] Lab slip [ ] Report form [ ] Electronic

How often are reports submitted to the Health Department? _____

Please describe reporting process.
_____
_____
__

Components of the Report (match to state requirements)

[ ] Type of specimen	[ ] Name of patient	[ ] Patient DOB
[ ] Specific test	[ ] Age of patient	[ ] Address of patient
[ ] Date test performed	[ ] Physician/Agency name	[ ] Medical record number
[ ] Result	[ ] Physician/Agency address	

Time Period for the Evaluation
Begin date: ____/____/____ End date ____/____/____

How many serologies were done in this laboratory during the time period? _____

How many reactive serologies were there during the time period? _____

How many reactive serologies were reported to the Health Department? _____

Proportion of reactive serologies reported to the health department _____% (See Worksheet if needed.)

Mean and median reporting time for the laboratory reporting (days). (See Worksheet if needed.)

Sample Serology Laboratory Site Visit Report

Worksheet

Completeness of Reporting

All laboratories are required to submit reports of reactive serology to state or local health departments. The program should decide in advance the minimum percentage of reported reactive serologies that is acceptable. 100% of reactive tests should be reported to the health department, but the actual percentage required is a local area decision.

A. How many reactive serologies were documented at this laboratory during the time period?_____

B. How many reactive serologies were reported to the health department from this laboratory during the time period?_____

C. Divide B by A = _____= Proportion of reactive serologies reported by the laboratory to the STD program or Completeness of reporting.

Completeness of Information

Completeness of information assesses the degree to which laboratories are providing complete information in their reports. For example, a laboratory may report 100% of its tests but provide patient names for only 60%, clinician names for only 70%, and serology titers for only 90%. The following steps will provide an indicator of completeness of information.

A. How many data fields are required to be reported for each lab report (e.g., patient name, address, age, date of birth, race, sex, test type, test date, test result, submitting clinic/clinician name and telephone number, etc.)?

B. In separate categories, record the number of laboratory reports with complete information, and the number missing one, two, three, four, or more data fields.

C. Divide each of the numbers in B by the number of laboratory reports reviewed to obtain the percentage of reports with complete information, or with one, two, three, four, or more items missing.

Timeliness

State statutes regulate the time period within which reports of reactive serologies must be submitted to the health department. This time period is the time from when the laboratory analyzes the specimen to the time that the health department receives notification of a positive serology.

A. Pull a sample of reactive serologies received by the STD program from the laboratory and for the time period under evaluation.

B. For each serology reviewed record:

date serology analyzed by lab.	date report received by health dept.	days btwn serology & report received
__/__/__	__/__/__	_____

C. Calculating the mean reporting time for the laboratories is one measure of the timeliness of reporting. However, a more useful measure is the median reporting time which is less vulnerable to outliers.

Example: Annual Clinical Laboratory Survey Calendar Year

(Use space below to record laboratory name and address)

_____

_____

CLIA Number: _____

Laboratory Director: _____ Phone: _____

Professional Degree(s): _____

Contact Person: _____ Title: _____

Phone: _____ FAX: _____

1. Which of the following categories best describes your laboratory? (Check one.)

___	Private Hospital	___	Free-Standing Private
___	Public Health	___	Non-Profit Hospital
___	Blood Bank	___	Custody Facility
___	VA/Military Hospital	___	Community Clinic
___	Student Health Services	___	Physicians Office/Group Practice
___	HMO	___	Other (specify) _____

2. If **no** STD (syphilis, chlamydia, gonorrhea, chancroid, herpes, HIV, etc.) or TB tests were performed on site, please check the appropriate line below and return the survey in the envelope provided.

___ No STD or TB tests were **processed through or performed by** this facility this year.

___ This facility is a Draw Station for: _____

3. Are any STD specimens sent to laboratories outside the state or county for testing?____ Yes ____ No

If **"Yes,"** please indicate the approximate percentage _____ and laboratories used:

Lab Name _____ CLIA # _____ State _____

Lab Name _____ CLIA # _____ State _____

4. Are any STD specimens for testing received from clinical providers located outside the state or county?

___ Yes ___ No If "**Yes**," indicate the approximate percentage (*check one).*

___0% ___5% ___10% ___25% ___50% ___75% ___90% ___100%

Indicate by circling **"No"** or **"Yes"** those tests currently performed by your laboratory. Record the number of tests and the number positive for CALENDAR YEAR ----. **Please be as precise as possible.**

5.	**SYPHILIS:**	**Performed?**	**# Performed**	**# Positive**	**Number of Days***
	RPR (Qualitative)	No Yes	_____	_____	_____
	RPR (Quantitative)	No Yes	_____	_____	_____
	VDRL (Qualitative)	No Yes	_____	_____	_____
	VDRL (Quantitative	No Yes	_____	_____	_____
	FTA-ABS	No Yes	_____	_____	_____
	TPPA	No Yes	_____	_____	_____
	VDRL on CSF	No Yes	_____	_____	_____
	Darkfield	No Yes	_____	_____	_____
	DFA-TP	No Yes	_____	_____	_____
	EIA	No Yes	_____	_____	_____
	Other:_____	No Yes	_____	_____	_____
	_____	No Yes	_____	_____	_____

***** Please indicate the number of days per week test is performed.

Are "rough" non-treponemal tests diluted to rule out prozone reactions? ____ Yes ____ No

What is policy for performing confirmatory (treponemal) tests:

____ Routinely, on all reactive non-treponemal findings

____ By Request Only

6.	**GONORRHEA:**	**Performed?**	**# Performed**	**# Positive**	**Manufacturer**
	Urethral Gram Stain*	No Yes	_____	_____	_____
	GC Culture	No Yes	_____	_____	_____
	Gen-Probe PACE 2	No Yes	_____	_____	_____
	Digene Hybrid Capture 2	No Yes	_____	_____	_____
	LCR	No Yes	_____	_____	_____
	PCR	No Yes	_____	_____	_____
	TMA	No Yes	_____	_____	_____
	SDA	No Yes	_____	_____	_____
	Other: _____	No Yes	_____	_____	_____

* Please do not include gram stains done to identify culture isolates

Does the laboratory perform MICs on positive gonorrhea cultures? ____ Yes ____ No

Does laboratory perform beta-lactamase testing on GC isolates? ____ Yes ____ No

7. **CHLAMYDIA:**

	Performed?	# Performed	# Positive	Manufacturer
Culture	No Yes	_____	_____	_____
DFA	No Yes	_____	_____	_____
EIA	No Yes	_____	_____	_____
Gen-Probe PACE 2	No Yes	_____	_____	_____
Digene Hybrid Capture 2	No Yes	_____	_____	_____
LCR	No Yes	_____	_____	_____
PCR	No Yes	_____	_____	_____
TMA	No Yes	_____	_____	_____
SDA	No Yes	_____	_____	_____
Other: _____	No Yes	_____	_____	_____

If applicable:

Is a confirmatory assay routinely performed on positive EIA findings? ____ Yes ____ No

Is a confirmatory assay routinely performed on positive DNA probe findings? ____ Yes ____ No

Are specimens giving positive DNA probe findings in a "gray zone" retested? ____ Yes ____ No

If yes, please describe your negative gray zone cut-off, type of test, and dates.

_____

Does laboratory perform *C. trachomatis* serologic testing? ____ Yes ____ No

8. **HEPATITIS B:**

Hep. B Surface Antigen ____No ____Yes # performed _____ # positive ____

Test Manufacturer _____

9. **HIV:**

	Performed?	# Performed	# Positive	Manufacturer
EIA	No Yes	_____	_____	_____
Western Blot	No Yes	_____	_____	_____
IFA	No Yes	_____	_____	_____
PCR	No Yes	_____	_____	_____
Other: _____	Yes	_____	_____	_____

10. **HERPES SIMPLEX VIRUS (HSV):**

	Performed?	# Performed	# Positive	Manufacturer
Culture	No Yes	_____	_____	_____
DFA	No Yes	_____	_____	_____
Other: _____	Yes	_____	_____	_____

11. **HUMAN PAPILLOMA VIRUS INFECTION (HPV):**

	Performed?	# Performed	# Positive	Manufacturer
Test Type _____	No Yes	_____	_____	_____

12. **CHANCROID (*Haemophilus ducreyi*):**

	Performed?	**# Performed**	**# Positive**
Gram Stain	No Yes	_____	_____
Culture	No Yes	_____	_____

13. **TUBERCULOSIS (TB):**

	Performed?	**# Performed**	**# Positive**
Culture	No Yes	_____	_____
Smear	No Yes	_____	_____

14. Does this laboratory use a reference lab to confirm any positive STD tests? _____ Yes _____ No

If **"Yes,"** please indicate for which tests and the laboratories used.

Test	Laboratory	City
_____	_____	_____
_____	_____	_____
_____	_____	_____

15. Does your laboratory have a computerized data system? ____ Yes ____ No

If **"Yes,"** please answer the following questions:

Is it a commercially available software program? ____ Yes ____ No

If **"Yes,"** specify _____

Information Collected: _____ Billing _____ Provider _____ Patient _____ Test Results

Is lab able to generate periodic reports of negative and positive results for individual providers?
____ Yes ____ No

16. How does your laboratory report test results?

By mail _____ By FAX ____ Electronically ____ Other _____

17. How often does your laboratory report?

Daily ____ Weekly ____ Monthly ____

APPENDIX 2

Table 1. Minimum data elements for syphilis prevalence monitoring

Variable	*Standardization*
Date of birth (or age)	MM/DD/YYYY (or age at date of specimen collection)
Sex	Male, Female
Race	American Indian/Alaskan Native, Asian, Black or African-American, Native Hawaiian or other Pacific Islander, White, Other, Unknown
Ethnicity	Hispanic or Latino, Not Hispanic or Latino, 7=Other, 8=Unknown
County of patient residence (or other appropriate geographic locator including city, zip code or census tract)	3-Digit FIPS code
Date of specimen collection	MM/DD/YYYY
Site Identifier	Jail, Family planning, Prenatal, STD clinic
Laboratory test type	Type of laboratory test (e.g., RPR, VDRL, FTA)
Qualitative laboratory test result	Qualitative result of laboratory test (i.e., non-reactive, reactive, unsatisfactory, missing)
Quantitative laboratory test result	Serology titer (e.g., 1=1:1, 2=1:2, 3=1:4, 4=1:8, 5=1:16, etc.)

Table 2. Enhanced data elements for syphilis prevalence monitoring

Variable	*Standardization*
Unique patient identifier	Social security number (SSN) + date of birth (DOB), last 4 digits SSN + DOB, and SOUNDEX coding of last name
ZIP code or census tract	5 or 9 digit number
Behavioral risk history	Two or more sex partners during previous 90 days, New sex partner during previous 90 days, Condom use during last intercourse, sex for money or drugs, Anonymous sex, IDU, crack use
Pregnancy status	Yes or No