

Program Operations Guidelines for STD Prevention



Surveillance and
Data Management

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Foreword

The development of the Comprehensive STD Prevention Systems (CSPS) program announcement marked a major milestone in the efforts of CDC to implement the recommendations of the Institute of Medicine report, *The Hidden Epidemic, Confronting Sexually Transmitted Diseases, 1997*. With the publication of these STD Program Operations Guidelines, CDC is providing STD programs with the guidance to further develop the essential functions of the CSPS. Each chapter of the guidelines corresponds to an essential function of the CSPS announcement. This chapter on surveillance and data management is one of nine.

With many STDs, such as syphilis, on a downward trend, now is the time to employ new strategies and new ways of looking at STD control. Included in these guidelines are chapters that cover areas new to many STD programs, such as community and individual behavior change, and new initiatives, such as syphilis elimination. Each STD program should use these Program Operations Guidelines when deciding where to place priorities and resources. It is our hope that these guidelines will be widely distributed and used by STD programs across the country in the future planning and management of their prevention efforts.

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Introduction

These guidelines for STD prevention program operations are based on the essential functions contained in the Comprehensive STD Prevention Systems (CSPS) program announcement. The guidelines are divided into chapters that follow the eight major CSPS sections: Leadership and Program Management, Evaluation, Training and Professional Development, Surveillance and Data Management, Partner Services, Medical and Laboratory Services, Community and Individual Behavior Change, Outbreak Response, and Areas of Special Emphasis. Areas of special emphasis include corrections, adolescents, managed care, STD/HIV interaction, syphilis elimination, and other high-risk populations.

The target audience for these guidelines is public health personnel and other persons involved in managing STD prevention programs. The purpose of these guidelines is to further STD prevention by providing a resource to assist in the design, implementation, and evaluation of STD prevention and control programs.

The guidelines were developed by a workgroup of 18 members from program operations, research, surveillance and data management, training, and evaluation. Members included CDC headquarters and field staff, as well as non-CDC employees in State STD Programs and university settings.

For each chapter, subgroups were formed and assigned the task of developing a chapter, using evidence-based information, when available. Each subgroup was comprised of members of the workgroup plus subject matter experts in a particular field. All subgroups used causal pathways to help determine key questions for literature searches. Literature searches were conducted on key questions for each chapter. Many of the searches found little evidence-based information on particular

topics. The chapter containing the most evidence-based guidance is on partner services. In future versions of this guidance, evidence-based information will be expanded. Recommendations are included in each chapter. Because programs are unique, diverse, and locally driven, recommendations are guidelines for operation rather than standards or options.

In developing these guidelines the workgroup followed the CDC publication “CDC Guidelines—Improving the Quality”, published in September, 1996. The intent in writing the guidelines was to address appropriate issues such as the relevance of the health problem, the magnitude of the problem, the nature of the intervention, the guideline development methods, the strength of the evidence, the cost effectiveness, implementation issues, evaluation issues, and recommendations.

STD prevention programs exist in highly diverse, complex, and dynamic social and health service settings. There are significant differences in availability of resources and range and extent of services among different project areas. These differences include the level of various STDs and health conditions in communities, the level of preventive health services available, and the amount of financial resources available to provide STD services. Therefore, these guidelines should be adapted to local area needs. We have given broad, general recommendations that can be used by all program areas. However, each must be used in conjunction with local area needs and expectations. All STD programs should establish priorities, examine options, calculate resources, evaluate the demographic distribution of the diseases to be prevented and controlled, and adopt appropriate strategies. The success of the program will depend directly upon how well

program personnel carry out specific day to day responsibilities in implementing these strategies to interrupt disease transmission and minimize long term adverse health effects of STDs.

In this document we use a variety of terms familiar to STD readers. For purposes of simplification, we will use the word patient when referring to either patients or clients. Because some STD programs are combined with HIV programs and others are separate, we will use the term STD prevention program when referring to either STD programs or combined STD/HIV programs.

These guidelines, based on the CSPS program announcement, cover many topics new to program operations. Please note, however, that these guidelines replace all or parts of the following documents:

- Guidelines for STD Control Program Operations, 1985.
- Quality Assurance Guidelines for Managing the Performance of DIS in STD Control, 1985.
- Guidelines for STD Education, 1985.
- STD Clinical Practice Guidelines, Part 1, 1991.

The following websites may be useful:

- CDC www.cdc.gov
- NCHSTP www.cdc.gov/nchstp/od/nchstp.html
- DSTD www.cdc.gov/nchstp/dstd/dstdp.html
- OSHA www.osha.gov
- Surveillance in a Suitcase www.cdc.gov/epo/surveillancein/
- Test Complexity Database www.phppo.cdc.gov/dls/cliia/testcat.asp
- Sample Purchasing Specifications www.gwu.edu/~chsrp/
- STD Memoranda of Understanding www.gwumc.edu/chpr/mcph/moustd.pdf
- National Plan to Eliminate Syphilis www.cdc.gov/Stopsyphilis/
- Network Mapping www.heinz.cmu.edu/project/INSNA/soft_inf.html
- Domestic Violence www.ojp.usdoj.gov/vawo/
- Prevention Training Centers www.stdhivpreventiontraining.org
- Regional Title X Training Centers www.famplan.org
- HEDIS www.cicatelli.org
- Put Prevention Into Practice www.jba-cht.com
- www.cdc.gov/nchstp/dstd/hedis.htm
- www.ahrq.gov/clinic/ppipix.htm

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Surveillance and Data Management

INTRODUCTION

Surveillance is the ongoing and systematic collection, analysis, interpretation, and dissemination of health data in the process of describing and monitoring disease trends. This information can assist programs to better plan, implement, and evaluate efforts to control STDs. For this reason, surveillance is a core public health function and must be considered one of the most essential and of the highest priority in any STD prevention program. This chapter examines the objectives of a STD surveillance system, describes the components and operation of such a system, and provides case definitions for selected STDs.

The national STD surveillance system uses a reported case registry method. Data sources include laboratory reports, morbidity reports, patient interviews, and information provided by or obtained from health care providers. The system is used to estimate the burden of disease, acquire and allocate resources, detect trends signaling changes in the occurrence of disease, detect epidemics, stimulate epidemiologic research, identify risk factors associated with disease occurrence, and assess the efficacy of control measures.

When using these guidelines, consideration should be given to the disease prevalence in the community, the characteristics of the existing networks of providers and laboratories, and the level of resources available to support STD prevention and control activities. Except for those areas where standardization is clearly indicated (e.g., essential data elements), these guidelines should not be construed as inflexible rules, but as a source of guidance to state and local health departments and laboratories and to their partners in STD prevention and control.

OBJECTIVES OF A PUBLIC HEALTH SURVEILLANCE SYSTEM

Surveillance supports public health efforts by providing a framework for:

- *Problem detection*—surveillance can identify the emergence of a disease as well as changes in the levels of existing endemic disease. Certain diseases, while not initially perceived as a problem in the population as a whole, may be a significant problem for specific sub-populations.
- *Problem description*—surveillance can present a picture of disease transmission; can describe both geographic and temporal trends in disease occurrence, populations affected, and changes in the etiologic agent (e.g., antibiotic resistance of microorganisms); and can identify factors mediating disease occurrence.
- *Problem solving*—surveillance can provide information needed to develop and implement strategies for disease control and prevention. It can help develop priorities for the proper allocation of resources necessary to deal with problems and provide a trigger mechanism to activate a public health response to a problem. Surveillance can also be used to generate or confirm a hypothesis.
- *Evaluation*—surveillance data can be used to determine how well a public health response addressed a specific health problem. It also provides a basis for predicting patterns of disease.

COMPONENTS AND OPERATION OF A SURVEILLANCE SYSTEM (GENERAL PRINCIPLES)

Legal Authority

Every state has communicable disease laws that give the department of health the authority to determine which diseases are reportable. However, not every disease is reportable in every state. For STDs, many states have statutes that define the reportable diseases. The legal authority for deciding which conditions (and which accompanying case data) are reportable in a given jurisdiction can vary by state, territory or local law or regulation, but is usually the state and/or local health department. Every state requires physicians to report diagnosed cases of, and/or laboratories to report tests indicative of, specific diseases. In most states, other health care or public health professionals (persons in charge of hospitals, clinics, prisons, detention centers) are also required to report cases of specified diseases to the health department. For more details, see the chapter on LEADERSHIP.

Some disease reports are legislatively mandated; others are declared notifiable by the state or local health officer, state epidemiologist, or board of health. The latter is particularly important in the face of a need to act quickly as new conditions arise. Mandated disease reporting requires demographic information, onset date or date of diagnosis, and responsible county. Other data collection requirements are normally left to the local health jurisdiction, but should be consistent with national surveillance case definitions. Reporting requirements should also be time-specific to provide the best opportunity for disease intervention. For example, the states of California, New York, and New Jersey require that acquired and congenital syphilis infections be reported within 24 hours of diagnosis.

Recommendation

- STD prevention programs should work with state/local health officers, epidemiologists, and departments/boards of health to determine which STDs and which accompanying case data should be mandated according to local needs and priorities.

Types of Surveillance Systems

Surveillance data are usually collected and used explicitly for a specific surveillance purpose.

- Case-based: Tracks the incidence of a disease with data reported through mandatory provider and laboratory reports of notifiable STDs.
- Prevalence monitoring: Utilizes testing at sentinel sites where specific populations are tested for STDs to determine prevalence. It can also be helpful for monitoring resistance (e.g., GISP—Gonococcal Isolate Surveillance Project).
- Population-based: Collects STD related information such as sexual and health care seeking behavior and provider clinical and prevention practices (risk assessment, screening, counseling, and behavioral interventions) through periodic surveys of at-risk populations, from case investigation/case interview reports, and from providers.

Case Reporting

Incidence is defined as the number of newly developed cases of disease in a specified time period. The incidence rate is the number of new cases of disease divided by the number of persons at risk during a specified time period. *Case-reporting* is the process of reporting cases of notifiable STDs by providers and/or laboratories to local and state health departments and from state health departments to CDC. Case reports remain the most common source of STD surveillance data for state and local health departments.

In addition, the reporting areas share data from case reports with the Centers for Disease Control and Prevention (CDC) via the National Electronic Telecommunications System for Surveillance (NETSS). NETSS collects information on a number of notifiable diseases and injuries that are nationally reportable in the United States for control of these conditions. The Council of State and Territorial Epidemiologists (CSTE) determines which conditions should be nationally reportable to the CDC. Reporting from states and other reporting areas to the CDC is voluntary (except for reports of quarantinable disease, which are required by international regulation). For more information, including record layouts and the NETSS implementation plan, contact CDC's Division of STD Prevention, Statistics and Data Management Branch.

Although most jurisdictions accept a gonorrhea or chlamydia case report from either a clinician or a laboratory, some require that each case be reported from both sources, and reject case reports from a single source. While laboratory-based reporting is essential and more complete, reporting by clinicians should continue to be encouraged to obtain office-based, point-of-care tests for gonorrhea and chlamydia used by providers. Reporting by providers also affords local health departments an opportunity to establish ongoing relationships with community medical providers who serve at-risk populations. These relationships can result in better reporting, expanded demographic and treatment information, identification of problems with the current laboratory reporting systems, and identification of opportunities for additional STD prevention. These data can be used to better define and then target at-risk populations.

All cases of disease should be reported regardless of treatment status. If a program only reports cases of disease that have been treated, they will be under reporting the true number of cases and the incidence rate will be lower.

Recommendations

- Health departments should accept all reports of laboratory-confirmed gonococcal or chlamydial infection as case reports, in addition to reports from clinicians. A report from either should be considered sufficient for case-reporting purposes.
- Programs should consider untreated disease as morbidity and report as such (when the patient's symptom, serology, or sex partner history indicate new infection).
- National surveillance case definitions should be used when analyzing case reports so surveillance reports over time and between jurisdictions are interpretable.

Provider-based case reporting

All states require that certain STDs be reported by physicians and other health care providers when they suspect that a case has occurred or they have laboratory confirmation. Physicians can use confidential morbidity report systems that allow them to enter basic demographic information which is sent to the local or state health department by mail, dedicated FAX, or electronically. In some areas, use of FAX to report may pose a confidentiality issue. To provide adequate provider reporting and to improve reporting, routine contact with providers and feedback on disease trends in their area can help them to better understand the uses of data and to be more timely and complete in their case reporting.

The relationship between STD prevention program staff and health care providers should focus on communicating useful information on screening, treatment, and partner management for STDs. The provision of information on case-reporting requirements should be viewed as only one aspect of STD prevention program-provider relations. Routine contact with providers and the provision of feedback to providers on reporting may improve the timeliness, completeness, and validity of case reports and may also result in improvements in the quality of STD care. Programs should

work with providers to identify systems that may make reporting easier and less time consuming since provider based reporting is more difficult in common diseases like STDs.

Program staff should survey, regularly interact via phone, set up monitoring systems, and visit new providers to introduce themselves and the services available through the local health department in general, and the programs they represent in particular. In some areas it may be necessary to prioritize such provider visits based on morbidity levels and patient populations. Visits should also be used to inform providers of current disease trends within the community; program priorities; their responsibility to report promptly and completely; and to provide copies of treatment guidelines, report forms, pertinent laws and regulations, names of local contact persons; and to answer any questions. Particular attention should be given to the importance of and various methods or systems available for meeting their reporting responsibilities.

Programs should have systems in place to monitor which providers are reporting and at what frequency. If for some reason a provider stops reporting, the program would then be able to detect the deficiency. A computerized provider reporting list can be established that includes the provider, date of diagnosis, and date of report so that accounts can be kept and patterns monitored. This can be used to detect a change in the pattern of reporting and allow the program to rapidly contact the provider to discuss reasons why reporting patterns have changed.

Close working relationships should be established with individual and large medical care providers serving high-risk patients or reporting significant morbidity (delivery hospitals, juvenile detention centers, etc.). Protocols developed with delivery hospitals serving high-risk women might require that all mothers of newborns receive a stat serologic test for syphilis (STS) and that mothers and infants not be released before the results are known. Efforts should be made to obtain “blanket” permission from selected providers to follow up and to interview their patients identified as possibly having early syphilis or other program established priority infections. Programs should offer to provide “feedback” to those medical care providers treating these early syphilis infections and other priority STDs.

Recommendations

- State and local STD prevention programs should have a written protocol that outlines health department procedures for interacting with providers and provider responsibilities and procedures for case reporting. Depending on how health department activities are organized, this protocol may be part of a larger protocol that addresses syphilis, HIV, AIDS, tuberculosis, and other communicable diseases.
 - STD surveillance programs should be able to identify and monitor those providers reporting significant STD morbidity or serving high-risk populations.
 - STD prevention programs can facilitate provider-based reporting by making available multiple methods for receiving STD case reports including toll-free phone numbers, FAX machines, and direct electronic reporting (e.g., Internet-based systems).
 - Programs should approach medical and nursing schools, medical societies, and state licensing boards to provide information about reporting requirements and the diseases that are reportable to newly licensed physicians and upon renewal of license.
 - Programs should develop opportunities to interact with providers in their community. This interaction could include presentations at hospital in-services, presenting at local and state medical conferences, monthly news letters, etc.
 - State and local STD prevention programs should routinely provide feedback, (e.g., statistical reports or newsletters) to providers, emphasizing the importance of the data to public health prevention efforts.
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Laboratory-Based Case Reporting

Laboratory-based surveillance to support STD case reporting should be conducted by all state and local STD prevention programs. Provider-based reporting

should be performed in addition to laboratory-based reporting to capture the growing usage of point of care tests; that is, tests that are rapid, on-site tests for gonorrhea and chlamydia.

Surveillance information can be used to trigger laboratory visits to inform laboratories of their reporting responsibilities, to provide copies of appropriate laws and regulations, to discuss reporting procedures including appropriate mailing address, and to answer any questions the laboratories may wish to raise. Information to be included on laboratory reports slips and timeliness of reporting should be discussed. Laboratories must understand their statutory responsibilities to report all results for which reporting is mandated (e.g., reactive syphilis serologies, treponemal and non-treponemal).

Visits can also be used to identify a contact person, both in the laboratory and in the local health jurisdiction. Local public health laboratory staff should be aware of—and afforded—the opportunity to participate in such visits. Programs are further encouraged to provide information on alternative reporting mechanisms—telephone, dedicated FAX, or electronic—as available and deemed appropriate.

One method of gathering information is to survey laboratories. Laboratory survey formats should be consistent from year to year to allow programs to monitor levels of testing within the community. The information provided will help programs identify high-volume, high-priority laboratories and may help compare reports received throughout the year. Programs using surveys to obtain information from clinical laboratories should establish a mechanism for providing “feedback” to the laboratories. For example, a yearly report could be developed and included with each survey packet that presents and analyzes information obtained from previous surveys. The ability to provide information that spans multiple years would be dependant on the uniformity of the data being collected over time. Such a format does not preclude questions being added or dropped.

Laboratories that report large numbers of positives or serve providers who see high-risk patient populations or practice in high-morbidity communities should be closely monitored and targeted for close working relationships. Such relationships can be particularly

useful in identifying and then solving problems. Programs should have a computerized laboratory check list that allows the ongoing tabulation of reports from laboratories with the number of cases of disease reported, date of laboratory receipt, and date reported. This can be used to detect a change in the pattern of reporting and allow the program to rapidly contact the laboratory to discuss reasons why reporting patterns have changed.

STD prevention programs should work with laboratories to routinely collect gonorrhea and chlamydia testing data from both public and private laboratories. The number of gonorrhea and chlamydia tests performed, type of test, and the number positive by sex, age, race, ethnicity, zip code, and provider type, along with the number of laboratories providing data during the reporting period, should be recorded and maintained by STD prevention programs.

Recommendations

- Programs should establish a system to assure that local health jurisdictions are aware of laboratories newly licensed to perform STD testing services.
 - Laboratories performing STD testing should be surveyed at least once yearly to determine the type, level, and results (positive or negative) of testing performed.
 - Programs are encouraged to establish close working relationships with both public and private laboratories determined to be priority.
 - State and local STD prevention programs should routinely provide feedback, (e.g., statistical reports or newsletters) to laboratories, emphasizing the importance of the data to public health prevention efforts.
 - STD surveillance programs should have separate fields for provider and laboratory reporting information.
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Electronic reporting of laboratory data

In general, laboratories are more likely than providers to report STD positive test results. Many clinical laboratories maintain computerized data systems, and many of those include the minimum data elements needed for STD case reporting. Once STD prevention programs define variables and data formats for case reporting, they should make these data formats available to laboratories and begin to ensure complete and timely reporting. STD prevention programs and clinical laboratories should also be working collaboratively to develop or expand their abilities to transmit and to receive electronic line-listed data on all persons with positive tests for case reporting purposes. STD prevention programs need to collaborate with other disease control programs such as TB and HIV/AIDS to maximize the impact on disease control surveillance operations and avoid duplication.

Recommendations

- STD prevention programs should encourage laboratories to report data electronically. STD prevention programs should develop the expertise to import and use these data electronically.
- STD prevention programs should work with laboratories to electronically capture all of the essential data variables for case reporting. Revision of lab slips may help capture the necessary data from providers.

Reporting by out-of-state laboratories

Large commercial laboratories often receive specimens from many states. Many state STD prevention programs have reported that it is difficult to obtain data from out-of-jurisdiction laboratories. With increasing regionalization of commercial laboratories and the centralization of lab services within managed care organizations, out-of-jurisdiction testing may become more common. All of these laboratories should be notified of their legal responsibilities to report notifiable diseases to the appropriate state STD prevention program. State programs can assist this process by providing out-of-state laboratories with information regarding their reporting responsibilities, including

accurate mailing addresses and methods to transmit data. When problems continue, programs should request the assistance of the STD prevention program in the laboratory's home state to resolve the matter.

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

- a) the state where the patient resides;
- b) the state where the provider who ordered the test is located if information on a) is missing;
- c) the state where the laboratory that received the original specimen is located if information on a) and b) is missing; or
- d) the state where the laboratory that performed the test is located if information on a), b), and c) is missing.

In states where laws require reporting to counties, the state and county health departments need to work with laboratories to establish an algorithm.

Recommendations

- STD prevention programs should adopt and support the use of the CSTE algorithm described above to resolve disease source when there are multiple jurisdictions involved.
- If states have laws that require reporting to counties, the CSTE algorithm should be reviewed by state STD prevention programs, county health departments, and laboratories, and revised if necessary.

Coordination

Many laboratories are required to report data to multiple public health programs within the same health department. These public health programs may also request that data be reported in different formats and for different time periods. Collaboration and coordination between the health department programs that receive data from laboratories would improve efficiency of laboratory-based surveillance data and simplify the laboratories' reporting procedures.

Recommendation

- State and local STD prevention programs should collaborate with public health programs that are conducting laboratory-based surveillance for other notifiable conditions to minimize the redundancy of efforts, to efficiently utilize the laboratory's reporting resources, and to ensure that core information required for case reporting is being consistently captured and reported.
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Laboratory Visitation

Laboratory reporting that is timely and complete is fundamental to effective STD control efforts. STD prevention programs should develop and maintain close, professional relationships with all laboratories providing STD testing services. Laboratory visits, ongoing dialogue, and surveys performed by STD prevention program staff can be an effective method for informing laboratories of and gaining their support for program objectives. Program size, established priorities, and available resources must all be carefully considered when determining how best to interact with private clinical and public health laboratories.

Public health and private clinical laboratories should be visited at least once yearly and more often if necessary to solve problems or as resources allow. The following suggestions should be carefully considered when undertaking a laboratory visitation program:

- The STD prevention program must develop a visitation protocol that is consistent with established objectives, policies, project area regulatory structure, and available resources. Building support for the visitation program with the appropriate state and local health officials is most important and can ensure the effective use of protocols.
- The STD prevention program should identify an individual who is responsible for ensuring that all forms of laboratory visitation are performed in accordance with program policy. That person should have experience and knowledge in program policy and laboratory procedures. He or she must be able to work effectively with program managers, laboratory managers, laboratory regulation workers, and DIS.
- The coordinator should work with the laboratory regulatory agency within the state to develop a list of laboratories licensed to perform STD testing and to determine how the programs can be mutually supportive.
- The coordinator should develop a visitation schedule that accounts for competing program priorities, available staff, training needs, priority laboratories, and those with a history of problems. Local public health laboratory staff should be approached and afforded the opportunity to participate in all or in selected visits as their schedules and interest allow.
- When preparing for visits, responsible staff should review the type and level of testing performed, timeliness of recent reporting, and completeness of information reported. The purpose of such a review is to examine enough records to achieve a representative sample of reporting practices. Timeliness of reporting can be determined by calculating the average length of time (number of days) from the date a laboratory receives a specimen until the date the health department is notified of the results. The reviewer should examine the system currently used by the laboratory to report positive findings to the local health jurisdiction. When evaluating the completeness of information provided, the reviewer should carefully examine the information reported and calculate the percent missing on laboratory slips received from the laboratory.
- Laboratory visits should be carefully planned and should be conducted in a professional manner, one that solicits the support of individual laboratories in efforts to control STD. Instead of simply requesting the information necessary to complete a visitation record and reminding laboratory staff of their reporting responsibilities, program staff should be prepared to discuss recent morbidity trends, program priorities and objectives, and the important role played by laboratories in achieving those objectives. Laboratory staff should also be given the opportunity to ask questions.
- Selection of staff to visit laboratories should be done in cooperation with appropriate supervisors. Those selected must be appropriately trained. Training should include information on arranging visits, how

to conduct a visit, how to address laboratory non-compliance issues, how to arrange follow-up visits, materials that should be left with the laboratory, and how to respond to questions where the health department representative does not immediately have the answer. Responsible staff should be well versed in the various methods available for the laboratory to report findings, and provide suggestions or alternatives (given resource availability) to comply with reporting timeliness, i.e., priority mail, FAX, or electronic reporting.

- STD representatives should be responsible for scheduling appointments to visit assigned laboratories. If this is the first time the health department representative has visited laboratories, he or she should be accompanied by an experienced employee on the first few visits. The coordinator or supervisor should monitor the health department representative to ensure that visits are conducted completely, promptly, and tactfully.
- The approach used during the visit should be at all times tactful. Data on the number or percentage of reactive serologies and other STDs identified for a recent reporting period by laboratory reporting in general or by the visited laboratory specifically and recent data for the specific laboratory on the timeliness and completeness of recent reports received should be presented. Tact should be a prominent aspect of the discussion at all times, both in discussing past reporting and in requesting information to be collected.
- The STD prevention program should determine the information to be collected and develop a visitation record to ensure that said information is uniformly collected. Data to be collected is at the discretion of the STD prevention program but should, at a minimum, include: the date of the visit, the different STD tests performed, the total number of tests performed, and the number of positives for a specific time period. Other information that might be collected includes information on the number of tests sent out of state, on those performed for out-of-state providers, on quality assurance measures, and on the names of high volume or high case reporting providers. Programs are encouraged to en-

ter information obtained from laboratory visits into computers so that information can be easily followed and updated over time. For this reason, the information collected from laboratories should remain uniform from year to year to simplify analysis.

- The coordinator should review all completed laboratory visitation records for completeness and accuracy before data entry. All questions, missing information, or identified training needs will be directed back to the appropriate supervisor.
- The coordinator should maintain a file of licensed laboratories that perform STD testing and copies of all visitation records. These records can be updated as necessary and used to identify appropriate laboratory staff when problems arise. The coordinator should work in concert with appropriate state laboratory licensing bodies and with local program officials to address reporting problems.

The results of laboratory evaluations should be routinely reviewed by the lab visitation coordinator and by the STD prevention program manager (See Appendix S-C for a sample Serology Laboratory Site Visit Report and Appendix S-D for a sample Clinical Laboratory Survey).

The intent of a laboratory survey is to identify those laboratories processing tests for STDs, to reinforce laboratory disease reporting requirements, to validate general testing volume including positive tests, and to determine specific high-volume laboratories. Designed in conjunction with staff from the public health laboratories, the survey may provide valuable quality assurance information about laboratory implementation of improved technology. The state laboratory licensing agency usually can provide a list of laboratories, often in electronic format. A survey of laboratories conducted by mail may be relatively inexpensive and may provide data for program evaluation. For example, it is important to determine if a downward trend for a specific disease reflects a true decrease in morbidity or whether it actually represents a decrease in testing.

Laboratory Compliance

The following steps should be implemented in an effort to ensure proper laboratory compliance with existing reporting requirements.

- Develop a response that is consistent with program policy, local health department protocol, and the existing regulatory structure. Involve program staff, the STD prevention program director, other appropriate local health officials, and the laboratory regulation office. Local health officials and the regulatory office can be very helpful, particularly with regard to information they require before they can take official action.
- Ensure that appropriate health officials are kept fully informed of and involved in all efforts to gain laboratory compliance.
- Once an appropriate protocol has been developed for laboratory visitations, assure appropriate personnel review and approve it prior to initiating laboratory visitations.
- The approved protocol should include a method of notifying the laboratory of any failures to meet mandatory requirements. The laboratory should be notified in writing, and a timeline for corrections and follow-up visits should be included. The timelines and specifics as to how the follow-up visits are conducted are local decisions.
- If the laboratory is unresponsive or continues not to meet mandated requirements, the laboratory regulation office should be informed. There should be a policy with the regulatory office and a defined set of procedures to follow after notification.
- Reports from the laboratory should be closely monitored during the next several months to ensure that they are now in compliance and to ensure that they do not regress.

Prevalence Monitoring

Prevalence of a disease or infection is defined as the proportion of persons in a population who have that disease or infection at a defined point in time. *Prevalence monitoring* is the observation of trends in prevalence in defined populations over time.

In contrast to case-reporting, which is intended to cover all health care providers and laboratories, prevalence-monitoring is most commonly performed using

data obtained on selected populations. These prevalence data are usually systematically collected from routine screening rather than case-based surveillance activities performed for the primary purpose of assessing overall disease burden.

This activity is performed by state and local health departments in collaboration with providers and laboratories; in many instances these data are also reported to CDC. Prevalence monitoring has been used in the Regional Infertility Prevention Program for the surveillance of gonococcal and chlamydial infections as well as in GISP for the surveillance of resistant gonorrhea.

Because prevalence-monitoring demands more resources than case-reporting, the participation of providers needs to be actively sought by the health department, often in collaboration with Regional Infertility Prevention Projects. For percentage of positive test results to be a valid estimate of prevalence, providers must routinely screen the target population. If diagnostic testing is included, the estimate will be biased and not reflect the true prevalence of disease in the target population.

Laboratories can be the primary source of prevalence monitoring data if the laboratory routinely receives data on sex, age, and provider type on persons testing positive and negative for chlamydia or gonorrhea. State and local STD prevention programs should work closely with their surveillance staff to collect these data. The purposes of prevalence monitoring, e.g., monitoring the effectiveness of chlamydia and gonorrhea prevention programs, must be communicated to laboratories. The state and local statutes that provide the authority for public health surveillance, including in some cases the authority for obtaining data on both positive and negative test results, should be provided and discussed with laboratories, and written procedures for data security and confidentiality should be provided and discussed. As the morbidity of a particular disease begins to decrease, negative test information will provide programs an additional indicator to determine if the decrease is real.

Unlike chlamydia and gonorrhea, positivity or prevalence of reactive serology for syphilis is not a measure of active disease in the community. Serologic tests for syphilis remain positive for long periods after infection is treated. Clinical information in combina-

tion with the patient's past serologic and treatment history need to be evaluated to determine if infection is present. In addition, it is sometimes necessary to determine the infection status of sex partners.

Recommendations

- The STD prevention program's written protocol for laboratory-based surveillance should include discussion of prevalence monitoring. Health department and laboratory responsibilities and procedures for prevalence monitoring should be clearly stated.
- Visits to laboratories should address prevalence-monitoring. For laboratories where these data have not yet been collected or examined, site visits can be a starting point for discussions, leading to the collection of these data.
- The laboratory registry should indicate those sites that are providing data on prevalence, type of tests performed, and provider types served.
- STD prevention programs should work with laboratories to determine whether line-listed data on persons testing negative should be submitted or whether aggregate data by sex, age group, race or ethnicity, provider-type, test-type, and testing period should be submitted electronically.
- STD prevention programs that support jail, juvenile detention, correctional STD screening programs, or other STD screening programs in teen clinics or managed care organizations should conduct prevalence monitoring among populations being screened.
- STD prevention programs should work with providers participating in prevalence monitoring to ensure they provide needed data to the laboratories.
- STD prevention programs should have screening protocols with providers who participate in prevalence monitoring.

METHODS OF SURVEILLANCE

Surveillance methods can be divided into four general categories: passive, active, sentinel, and special systems. In general, passive and active systems are based on conditions that are reportable to the health jurisdiction. Sentinel systems and special systems are usually designed to obtain information that is not generally available to health departments.

Passive Surveillance

Passive surveillance is the most common form of surveillance and relies on standardized reporting forms or cards provided by or available through the state or local health departments. These completed forms are returned to the health department when cases of disease are detected. The term *passive* is used to convey the idea that health authorities take no action while waiting for report forms to be submitted. It is also a potentially misleading term, since case reporting is not a passive activity for the reporter, who must complete the form. Additionally, case reports received by the public health authority may require further action to ensure completeness, proper case classification, and partner management.

Passive reporting systems are generally less costly than other reporting systems, data collection is not burdensome to health officials, and the data may be used to identify trends or outbreaks if providers and laboratories report. Limitations include non-reporting or under-reporting, which can affect representativeness of the data and thus lead to undetected trends and undetected outbreaks. A positive test may not be reported to prevent the stigmatization associated with STD, because of a lack of awareness of reporting requirements by health care providers, or the perception on the part of the health care provider that nothing will be done. Incomplete reporting may reflect lack of interest, surveillance case definitions that are unclear or have recently changed, or changes in reporting requirements. Incomplete reporting also may be a result of the patient not being willing to provide the information or hardware/software systems that cannot capture the information in databases.

Active Surveillance

Active surveillance involves outreach by the public authority, such as regular telephone calls or visits to laboratories, hospitals, and providers to stimulate reporting of specific diseases. Because it places intensive demands on resources, implementation of active surveillance should be limited to brief or sequential periods of time and for specific purposes. It is a reasonable method of surveillance for:

- conditions of particular importance - to document a suspected outbreak, or to augment timely disease intervention or epidemiologic investigation (e.g., for congenital syphilis in certain jurisdictions);
- episodic validation of representativeness of passive reports and as a departure point for enhancing completeness and timeliness of reporting (e.g., lab visitation programs to ensure all reactors reported);
- diseases targeted for elimination or eradication (e.g., smallpox, syphilis).

Operationally, active surveillance includes visits or telephone calls to such key reporting sources as clinicians or laboratories by public health authorities on a regular or episodic basis to elicit (or verify) case reports and/or reviewing medical records and other alternative sources to identify diagnoses that may not have been reported. It is generally employed when it is expected that more disease is in the community than is shown in the passive surveillance systems.

Recommendation

- STD prevention programs should develop active surveillance protocols to be initiated when there is a suspected outbreak of disease, when an evaluation of the surveillance system is occurring, or in other instances when active surveillance is appropriate (e.g., elimination and eradication campaigns).

Sentinel Surveillance

Sentinel surveillance involves the collection of case data from only part of the total population (from a sample of providers) to learn something about the larger population, such as trends in disease. The advantages of sentinel surveillance data are that they can be less expensive to obtain than those gained through active surveillance of the total population, and the data can be of higher quality than those collected through passive systems. This is because it is logistically easier to obtain higher quality information from a smaller population. A vulnerability of sentinel systems is not being able to ensure the representativeness of the sample selected. Sentinel surveillance systems may be useful in identifying the burden of disease for conditions that are not reportable, or behavioral characteristics that are of sufficient public health importance to merit monitoring. Candidates for sentinel systems might include: human papilloma virus, herpes simplex primary infection, congenital infection, or other adverse outcomes of STDs. One sentinel surveillance system already in place is the Gonococcal Isolate Surveillance System (GISP), which monitors the antibiotic resistance patterns of gonococcal isolates in selected sites by clinic-type, patient characteristics, and changes over time. Sentinel systems for antimicrobial resistance patterns for chlamydia, herpes, and trichomoniasis may be useful, as would sentinel surveillance of relevant risk behaviors.

Special Systems

Special systems are occasionally designed and implemented to generate surveillance information that is not possible to acquire by any of the other systems already mentioned. Special systems include those designed for chlamydia prevalence monitoring, which consist of collection of information regarding all tests performed—positive or negative—to determine the number of infections in the population at risk over a particular time interval (period prevalence). Because chlamydia is only diagnosed by testing, the population at risk for a chlamydia diagnosis is defined as those tested for chlamydia.

SURVEILLANCE SYSTEM ATTRIBUTES

The MMWR Supplement, dated May 6, 1988, titled: *Guidelines for Evaluating Surveillance Systems* describes surveillance system attributes in detail. Each surveillance system has elements that are designed to meet specific objectives. The combination of these attributes determines the strengths and weaknesses of the system. The attributes must be balanced against one another (e.g., high sensitivity may be possible only with a complex reporting system from a wide array of providers). Appendix S-E describes these attributes.

Recommendation

- STD prevention programs should apply the information presented in the Appendix to determine the individual strengths of current surveillance activities and to identify those areas where changes may be needed to better monitor disease levels within the program area.

PERSONNEL, TRAINING, AND RESOURCES

Historically, STD prevention programs have put most of their surveillance resources into data collection and data management functions rather than into data analysis, interpretation, and dissemination. Although data collection and data management are the foundation of surveillance, data alone are not meaningful without appropriate analysis, interpretation, dissemination, and application of surveillance data. These surveillance functions are critical to making informed decisions on quality of case report or prevalence data, applying science-based information to local program's prevention and intervention strategies, and increasing data completeness and quality within and across STD prevention programs.

Many state and local STD prevention programs, however, have no one assigned to data analysis and interpretation functions. Every program must have or must develop the capacity to properly collect, assess, analyze, interpret, and disseminate surveillance data.

This requires individuals with specific training or expertise. Toward this end, programs should cooperate with local, state, and federal agencies to implement the approaches necessary to have or develop these skills in STD prevention programs.

Designation of a surveillance coordinator in each project area provides a focal point for developing analytical capacity. The surveillance coordinator should be made responsible for building analytical and data interpretation capacity. Recommendations on building capacity and on training recognize the limited resources that can be allocated to these necessary activities. These recommendations thus indicate the use of innovative approaches to staff training that will require cooperation between STD prevention programs and all levels of the public health system. Improvements in a STD prevention program's capacity to analyze and interpret surveillance data will likely save money over time because of improved data quality and availability—allowing for data-based prevention program planning.

A variety of options can be explored to help programs meet identified training and resource needs associated with the development of a surveillance coordinator position. These may include:

- providing training and supervision by other program staff who have appropriate expertise;
- cross-training persons within the health department to take advantage of expertise in other programs (e.g., STD, HIV, or communicable diseases) and public health disciplines (e.g., epidemiology, biostatistics, or program management) and to improve surveillance capacity without requiring additional hiring;
- promoting and providing technical assistance to other less-developed programs by using experienced staff from those programs that have enhanced surveillance capacity or from other public health-affiliated organizations such as CSTE;
- using training opportunities sponsored by local health department(s), distance learning, train-the-trainer programs, teleconferences, Internet based modules, EpiInfo or other workshops, attendance at academic-sponsored workshops and seminars, co-

operative agreements between the STD prevention programs and Schools of Public Health or other academic departments;

- sponsoring academic training for staff as deemed necessary and appropriate; and
- checking with Surveillance and Data Management Branch, Division of STD Prevention, CDC, for additional sources of training.

The role and related responsibilities of the Surveillance Coordinator should be determined by program needs and individual employee skills and experiences, but that role could be expected to include:

- designing, reviewing, and revising of STD surveillance system procedures and written protocols on provider-based reporting, laboratory-based reporting, and quality assurance, including provider and laboratory visitation efforts;
- coordinating data collection, management, and reporting for case-reporting data, prevalence-monitoring data, and sentinel systems such as the Gonococcal Isolate Surveillance Project (GISP);
- coordinating quality assurance activities for completeness, validity, and timeliness;
- designing information systems that have adequate capacity, and integrity;
- analyzing and interpreting data;
- disseminating data;
- evaluating the STD surveillance system annually;
- conducting active surveillance, as indicated.

Although provider and laboratory visits may be shared by program staff, the surveillance coordinator should be responsible for supervising these activities. Therefore, the surveillance coordinator should be versed in these skills or afforded training that includes observing visits performed by experienced staff and then being observed.

Long-term collaboration addressing staff training and career development to support common surveillance goals and tasks is difficult without formal relationships. Formal collaboration refers to joint activities based on a) written agreements, contracts, or

memoranda of understanding; b) shared grant goals and objectives (e.g., Infertility Prevention Projects and STD/HIV Prevention Training Center); or c) participation in program decision-making (e.g., state epidemiologist on an Infertility Prevention Project Executive Advisory Committee).

Some state health departments have elected to reorganize program activities to include interdisciplinary teams proficient in program evaluation and data analysis. These professional staff may not work solely in STD prevention programs but rather may provide technical services to improve assessment and quality assurance for several health department programs. STD prevention program efforts should be increased to use this expertise, where available.

Recommendations

- Each program should designate a coordinator who is responsible for surveillance activities. Depending upon program size, additional staff may also be necessary.
- State and local STD prevention programs should consider establishing formal staff training and career development activities in the area of surveillance information systems.
- To develop and maintain a well-trained surveillance staff, STD prevention programs should build on public health system initiatives that support the core public health functions of assessment and assurance and work closely with other public health surveillance programs such as HIV and TB.

DATA ANALYSIS, INTERPRETATION, AND DISSEMINATION

Data analysis and interpretation are necessary to accomplish the purposes of case-reporting and prevalence monitoring. This section focuses on those types of analyses that should routinely be performed by STD prevention programs and by the Regional Infertility Prevention Projects. The analyses recommended here are intended to assist program efforts to properly ad-

dress STD surveillance activities. Data analysis required for evaluating and assuring data quality is discussed later in this chapter.

Planning an Analysis

The collection, analysis, and dissemination of local STD data are acknowledged as important components of the efforts to prevent sexually transmitted disease. STD project areas continue to collect large amounts of data. Unfortunately, all too often, the only apparent reason for collecting these data is “to satisfy CDC reporting requirements” that enable the assessment of national STD morbidity levels and characterization of persons infected with STDs. Although important, this reason is usually not relevant when considering state and local-area informational needs.

The reality is that the sheer number and variety of demands placed on program managers very often leaves little time and energy for analysis. This can result in a “catch 22” for managers—little time for the analysis that can help to answer the questions that are vitally important to the effective operation of STD prevention programs at the state and local levels. Who are the infected persons? Who is the at-risk population? Where is transmission occurring? Which interventions work best with different groups of infected persons and when and how should they be implemented? How effective was the targeted intervention in reducing risk or infections? Are we doing a good job of controlling STD in the community, and how do we know it? What are the data needs of the community to assist in planning and policy efforts? These questions should be driving data collection and analysis efforts. Issues to consider in planning an analysis include:

- **Proceed from the simple to the complex**

Do not begin your analysis by trying to examine trends over time for four different STDs by various characteristics. Start by asking a question or stating a hypothesis that you want to answer. How many cases of a given STD were reported each year? Then look at characteristics of the case. Again, start with the simple ideas. How many cases of a particular STD were reported in each age group each year?

What were the sex-specific rates? Only after looking separately at each characteristic should you begin looking at relationships between these characteristics. For example, how many cases in teen-age males were reported? What was the rate for teen-age males? Proceed from the simple to the complex. For example, using EpiInfo or STD*MIS, run frequencies by data element in a given patient population.

- **Know your data**

Some of us may want to know immediately about the trends over time for several different STDs by various characteristics of the cases. However, what happens if our rates for the STDs by the characteristics of the cases are not consistent with our day-to-day observations about the STD problem in our community and in other communities similar to ours? Is it because our day-to-day observations are incorrect, or is it because there are problems with one or two cases aged 75 years? How did these two cases affect the computation of the average age of our cases? Only by knowing your data can you understand and appropriately interpret the results of more complicated analyses. There is no substitute for knowing your data. Individuals from the community, medical providers, outreach workers, etc., should be included in preparing to conduct analysis of the data. These individuals may ask questions of the data not typically asked in a STD prevention program. Asking the proper questions of the data can often drive the type and direction of the analysis needed.

- **Ensure valid data**

The final guiding principle of data analysis is a familiar one: “*garbage in; garbage out.*” How much care is given to collecting and managing the data in standard ways so as to minimize error and maximize validity? Just because data are stored in a computer and because computer programs can generate official-looking reports from those data does not necessarily mean the data are valid. STD prevention programs must expend the additional time and effort necessary to ensure that STD data on which analysis can be performed are valid. This can be accomplished by reviewing source documents such

as patient charts, laboratory reports, and case reports and comparing them to the final outcome data.

Performing the Analysis

Statisticians and epidemiologists receive training in a variety of analytical methods that require knowledge of the underlying statistical and mathematical foundations used to develop those techniques, and their proper application. Providing an exhaustive and detailed description of the different methods available to explore, summarize, analyze, or display surveillance data goes well beyond the scope of guidance that can be provided within this document. However, one reference that STD prevention program areas will likely find helpful in preparing for the analysis and interpretation of surveillance data is *Principles and Practice of Public Health Surveillance* (Teutsch, 1994). It presents an excellent overview of the types of analytical presentations and methods that are commonly employed, and it discusses many of the associated data issues that need to be considered in analyzing and interpreting data. In addition, examples of standard tabular and graphical data displays can also be found in any of the annual STD Surveillance Reports produced by CDC's Division of STD Prevention.

One very important general recommendation for programs is to have access to a statistician or epidemiologist. The STD prevention program staff and management should work with the epidemiologist to clarify what data need to be collected to answer the question. Without the availability of staff adequately trained and skilled in collecting valid data to answer proposed questions and in analyzing and interpreting analytical methods, the likelihood of misinterpretation and under-utilization of data increases, and therefore programs have a weakened ability to quantitatively monitor and describe the effects of STDs in their area.

Ideally, any analysis, summarization, graphical display, or interpretation of data should be based on data that are deemed reliable (i.e., reproducible), valid (i.e., accurate), complete, and timely. Statistical summaries based on data that do not satisfy these characteristics require a discussion of these shortcomings or limitations and the possible effect on the analysis and interpretation of the data being analyzed.

Case counts and crude rates (i.e., unadjusted rates) are common measures of disease burden that often are presented with respect to time, by geographic area (e.g., county, zip code, or census tract), personal characteristics (i.e., sex, age, race or ethnicity), and various combinations (e.g., age-by-race-by-sex). Crude rates are a measure of the actual public health burden from STDs in a community, and are appropriate to use for public health planning, policy making, and resource allocation.

Interpretation of Data

State and local STD prevention programs should perform the following analyses of STD surveillance data to facilitate monitoring of disease burden and trends.

Quarterly analysis

- Compare number of case reports, rates, and prevalence (if available) with same quarter during the previous year.
- Examine trend in the number of reported cases, rates, and prevalence for the past 1-5 years, overall, and by specific variables. For example, 1) geographic area, 2) sex, 3) age-grouping, 4) race or ethnicity, 5) provider-type, 6) provider-site, 7) laboratory, 8) test-type information, and 9) anatomic site might provide helpful insights. Those programs providing behavioral interventions, community health education, provider training, and partner services around selected STDs may consider additional categories such as reason for examination and individual risk factors.

Annual analysis

- Stratify case reports annually, by the nine variables listed above.
- Identify annual trend in overall population-based rates of reported cases, using the most recent census data, or the most recent intercensal estimates, and stratify by the basic demographic categories (geographic area, sex, age group, and race or ethnicity).

- Compare annual or point prevalence with prevalence for several previous years, overall, and stratified by the nine variables listed above.
- Examine rates of gonococcal or chlamydial co-infection.
- For clinic populations tested for HIV and other STDs, including chlamydia and gonorrhea, examine rates of HIV/STD co-infection.

The following points should be considered when analyzing and interpreting STD data.

- Acute changes in reported morbidity or prevalence may be real or may be the result of changes in screening or reporting practices or test type.
- Case-reporting data can most reliably be used to monitor trends in disease burden when the amount of screening is stable, when no changes are occurring in access to and use of clinical services, and when diagnostic and reporting practices are consistent over time. A decline in the number of reported cases can result from a reduction in screening or from a decline in reporting by providers or laboratories.
- For comparing the disease burden of different groups, it is necessary to identify and use appropriate denominators. Census data stratified by geographic location, sex, age group, and race or ethnicity must be used for calculation of population-based rates of case reports for each of these variables.
- In all large jurisdictions, and especially in areas of high or increasing rates of disease, it is especially important to stratify simultaneously by sex, age, and race or ethnicity within each geographic area to determine which subgroups have the highest reported rates of disease.
- High prevalence of disease in an area where case reports are few suggests that screening coverage is inadequate or that cases are not being reported.
- Examination of number of case reports can be used to identify new sites that have recently begun more testing and reporting sites screening higher risk clients or those sites where there has been an acute decline in reported cases.

- Analysis between STD data sets and other data sets such as HIV, TB, Drug and Alcohol, etc., need to be conducted to determine co-infection rates, commonality of risk factors, and opportunities for collaboration.
- Behavioral and social surveillance should be a component of a comprehensive STD surveillance system.
- When stratifying data, confidentiality of individuals must be protected.

Development and Evaluation of Screening Criteria

Periodically, state and local STD prevention programs should work with participating clinics to evaluate their chlamydia and gonorrhea screening criteria, as these have implications for both case-reporting and prevalence-monitoring activities. To evaluate the sensitivity and positive predictive value of the provider's selective screening criteria, the STD prevention program can compare universal screening data with selective screening data initially, and periodically thereafter. Screening coverage according to screening criteria used should be evaluated periodically and at a minimum annually.

Dissemination and Communication

Feedback on data collection and analysis can take place at multiple levels. Careful monitoring of data for completeness and validity must be a regular part of data collection and interpretation. Inconsistencies in data collection, missing data, and other issues require immediate attention to ensure that reports provide information that accurately reflects program efforts.

Each state, local, and regional program should develop a plan to effectively communicate the analysis and interpretation of STD case-reporting and prevalence monitoring data to the general public, priority health care providers (especially those providing data), laboratories, community clinicians, support agencies, community-based organizations, HIV program directors, HIV community planning groups, corrections facilities, drug treatment centers, policy makers, public

relations office, and other local, state, and national health care and public health agencies and partners. With the assistance of communications specialists and input from partners receiving the reports, state and local STD prevention programs should carefully tailor the communication of STD surveillance data to the specific needs of the target audience.

- Reports presenting case-reporting or prevalence monitoring data should include a concise interpretation of the data presented.
- When communicating the findings from their case reporting or prevalence monitoring activity, STD prevention programs should consider preparing the following types of reports:
 - annual report of case rates and prevalence by demographic variables and by trends;
 - reports to providers of data that identify their specific contributions to STD prevention efforts, prevalence data to guide their screening practices, and feedback on screening coverage;
 - newsletters or bulletins that provide clear, concise data interpretation and advice to clinicians, and laboratory directors, and community groups;
 - letters or limited reports to targeted providers that present information that would serve to stimulate additional reporting, e.g., reports of outbreak investigations or unexpected changes in epidemiological patterns;
 - limited reports (fact sheets for ready distribution for ad hoc requests); and
 - web page and two-way feedback to providers and laboratories.

When analyzed and organized for dissemination, selected STD case-reporting and prevalence monitoring data have been successfully used by many organizations to demonstrate the need for STD prevention services and to direct resources to specific populations. Studies have shown that contact between providers and health departments increased reporting; therefore, dissemination of useful STD surveillance to providers likely serves to increase or maintain reporting. State and local STD prevention programs garner good will

from students, faculty, and other organizations that need data for grant and report writing by providing timely STD surveillance data. In some program areas, acknowledging the reporters of STD surveillance data in public reports has gained their good will and stimulated others to report.

Recommendations

- State STD prevention programs should send line-listed, electronic prevalence data, not just summary data reports, to those local control programs with participating providers in their jurisdictions.
- State and local STD prevention programs should consider media other than hard copy for dissemination of case-reporting and prevalence monitoring information, e.g., Internet distribution via a state or local web site.
- STD prevention programs should obtain input from partners about types of reports needed and disseminate data in a timely fashion.
- Dissemination protocols should be in place, should include the providers or laboratories who provided the data, and should be periodically evaluated in terms of utility and timeliness.

DATA MANAGEMENT

Central Registry

The central registry is the administrative heart of a surveillance system. The efficiency of its operation determines whether a surveillance activity is an asset or a liability to the efficiency and effectiveness of disease intervention, prevention, and outreach activities. How well the central registry operates is determined by the performance of the staff, machinery used, and the procedures selected to guide the operation. Their selection, training, and supervision, along with periodic quality assurance review of performance and op-

erations are major management responsibilities. Regardless of whether the central registry is manual, mechanical, or computerized, all systems will depend on human judgement for final decisions regarding program operations.

Recommendation

- STD prevention programs should have an efficient, up-to-date central registry that includes the following: 1) patient name, 2) address, including zip code or census tract, at time of diagnosis, 3) date of birth and age, 4) race/ethnic origin, 5) sex, 6) diagnosis, 7) date and results of all positive anatomic sites, 8) treatment dates and regimens, 9) provider of services, and 10) laboratory, date of report by provider and laboratory. Additional data that are important and should be considered are pregnancy and HIV status. Other local variables should be added, as needed.

Information System Design

Persons responsible for designing STD surveillance systems should be familiar with current information technologies and aware of issues in health information system development, including ongoing efforts to develop standards, (e.g., data standardization issues related to the Health Insurance Portability and Accountability Act of 1996 and the Health Plan Employer Data Information Set (HEDIS) performance measures). Key steps in designing surveillance information systems are as follows:

- **Analysis of existing systems**
 - What tasks should the system support
 - Current system inputs and outputs
 - Strengths and weaknesses of current information system
 - Hardware and software support
 - Cost of current system
- **Interfacing with other management information systems**

- **Analysis of system requirements**
 - Define program goals and functions in relation to information systems support
 - Define user needs
 - Define resource constraints
- **Redesign of information system**
 - Analyze existing user operations and unmet needs for matching and extending systems development
 - Consider simplification (e.g., deletion, consolidation, redistribution), integration with other information systems, automation, procedure changes, and database changes
- **System selection**
 - Develop selection criteria for hardware, software, and connectivity
- **Implementation**
 - Develop implementation plan, including procurement, training, and conversion
 - Develop evaluation plan to measure system performance and other user criteria before and after implementation
- **System testing, evaluation, and documentation**
 - Test system performance
 - Conduct ongoing assessment of quality control
 - Formally document redesign process, including operational characteristics, information flow, implementation plan, resources, and operating instructions.

The following items should also be considered in information system design.

- STD prevention programs (in collaboration with other health department components) should involve public health practitioners, health care providers, epidemiologists, and laboratorians in information system development. Information system technical experts cannot design adequate systems without their input.
- The system that is developed should allow the interchange of data between case interviews, partner services, STD clinic diagnosis and treatment, laboratory data, pharmacy data, and medical billing/administrative data systems. Any person in the STD

care team, from clinician to DIS to laboratorian to support staff should be able to access the data in the clinical setting. For reported STD surveillance data, only health department staff should have access to the data.

- Automation should be the norm for most information management systems. However, in a low morbidity setting at the level of a small local health department, a paper record system may be an efficient data-management scheme. Once data used by STD prevention programs are entered into an electronic medium, every effort should be made to maintain those data electronically rather than duplicating data entry efforts at various points within the system.
- Familiarity with industry standards for data transmission and linkage is necessary for developing interfaces between clinical, laboratory, pharmacy, administrative, and health department systems, and for developing methods of transferring data between different systems.

Information System Capacity

In the past, handwritten or computer-generated paper reports were used for transferring information from the laboratory to the health care provider and to the public health system. With computerization of laboratories, it has become possible for laboratories to send reportable data to health departments electronically. Over the past few years, substantial work in the public and private sector has led to greater understanding of laboratory information systems and their potential contribution to public health surveillance.

Information systems that were initially designed for reporting positive test results may have insufficient capacity to manage the large volume of data on persons testing negative. New electronic data systems that are designed to report data on positives should also be able to report the same data elements on negatives (such as in the non-name section of STD*MIS).

While substantial development of electronic laboratory reporting protocols has taken place, it is recognized that some data elements essential for disease control and surveillance will not be available from

laboratory information systems. Therefore, STD prevention programs should transfer the lessons learned regarding data standards, data transmission protocols, and data linkage from laboratory reporting activities to other potential sources of electronic data, including provider information systems, pharmacy information systems, hospital information systems, insurance and health plan information systems, and vital records.

To encourage electronic reporting from providers, STD prevention programs might initially focus on the improvement of reporting within the health system itself—are public health clinics electronically reporting surveillance and disease control information? If not, what will it take? Are the data already available in other computerized databases? As part of an overall strategy, STD prevention programs should identify the types of data that may be available from other information systems instead of creating parallel systems or duplicating systems.

Assessment, policy development, and assurance are core public health functions. Each of these functions is enhanced and facilitated by effective information systems that allow public health agencies to collect data to improve decision-making, to retrieve and use data for identifying and solving health problems and for planning and evaluating interventions, and to assure the effectiveness, accessibility, and quality of personal and population-based health services. STD prevention program staff need to have the appropriate skills to use information technologies to perform the core public health functions and should have access to an electronic network that provides access to federal, state, and local information systems.

Public health agencies must ensure that appropriate staff training and career development opportunities are available to support their information needs, which are likely to increase in the future. STD prevention program staff may benefit from activities and training intended to increase their ability to use data effectively, such as informatics training, CDC-sponsored epidemiology courses, applied EpiInfo, and other computer or database training courses.

The business community's paradigm for information management has been established over a number of years and can be considered to be based on business's need to monitor costs relative to benefits in order to

maximize “value.” The health care industry has used information technologies to support financial processing and to improve their care delivery processes by efficiently managing diagnostic, therapeutic, and patient management data. The public health community must identify the similarities and differences between its information needs and those of other participants in the health care system. Proactive information management is important for effective STD prevention program efforts, and to develop and implement an information technology plan to meet STD prevention program goals more efficiently.

Public health’s need to monitor the health of populations and preventive health services in the community must be accommodated by private sector information systems that may have an individual focus and that may emphasize medical treatment of an existing condition rather than preventive health services. The public health community must articulate the benefits of information systems that facilitate both clinical care improvement and population-based health assessment. Informatics fellowships or informatics graduate program externships with public health agencies may provide opportunities for development of information systems which support essential public health functions.

Recommendations

- All STD prevention programs should have a plan for increasing their capacity to develop, maintain, and evaluate information systems.
 - State and local STD prevention programs should develop the information system capacity for electronic laboratory reporting of all reportable STDs.
 - STD information systems should allow for the collection, management, and analysis of line-listed data on persons infected with all reportable STDs.
 - Information systems used for electronic reporting of persons testing positive for syphilis, chlamydia, or gonorrhea should be modified to include data on persons testing negative.
 - Once electronic laboratory reporting procedures and protocols have been developed and implementation has begun, STD prevention programs should evaluate other sources of electronically reported information to determine their potential contribution to STD surveillance activities. This evaluation should identify the standards, relationships, and protocols that will need to be developed.
 - E-mail and Internet access should be readily available to STD surveillance coordinators and other STD prevention program staff.
 - All health departments should familiarize the general informatics and health informatics community to public health concepts and increase their familiarity with public health information systems.
-

Privacy and Data Security

STD prevention programs must establish comprehensive data security policies for the following purposes:

- to ensure the confidentiality of disease control data and the privacy of individuals (prevention of unauthorized disclosure of information);
- to ensure the integrity of disease control data (prevention of unauthorized modification of information); and
- to ensure the availability of disease control data to authorized persons (prevention of unauthorized or unintended withholding of information or resources).

Privacy of the information collected during public health program activities is necessary because of significant economic, psychological, and social harm that can come to individuals when personal health and behavioral information is disclosed. Forty-nine states have some statutory protection for governmentally maintained health data for public health information in general. Forty-three states have protections for data related to STDs. Data security policies must be developed in compliance with state and local statutes regarding privacy protection of public health information. For more detailed information on the Model STD Information System (MSIS), contact the Division of STD Prevention, Statistics and Data Management Branch, CDC.

Recommendations

- STD prevention programs should have policies in place and implement them to ensure confidentiality of data and data security.
- STD prevention programs should work with other programs such as TB and HIV/AIDS to standardize confidentiality protocols.

EVALUATION AND QUALITY ASSURANCE

The overall purpose of evaluating STD surveillance is to promote the most effective use of health resources. The most important steps in evaluating a surveillance system are a) describing the health events under surveillance; b) stating explicitly the objectives of the system; and c) describing how the system has actually been used to help prevent and control STDs. These three steps begin to evaluate a program's surveillance system properly and help to determine areas where improvement may be needed. The following sections provide more specific information for the proper evaluation of STD surveillance activities. For more detailed information on evaluating surveillance systems, see *Guidelines for Evaluating Surveillance, MMWR, May 6, 1988*. The surveillance attributes described in the MMWR should be used as the basis for evaluation. Where systems fall short, corrective action is needed until high quality STD surveillance systems are in place.

Recommendation

- STD prevention programs should evaluate STD surveillance systems at least annually.

Data Quality

All prevalence monitoring programs should have written protocols that specify data quality control procedures. Many Regional Infertility Prevention Programs, for example, already have data quality assurance programs in place to evaluate validity, completeness, and timeliness. Data quality assurance procedures should be documented and the results of data quality assurance activities carefully monitored. Specific surveillance performance indicators, (e.g., 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 reporting performance.

Recommendation

- STD data quality should be routinely evaluated.
-

Evaluation of the Reactor Grid

The reactor grid is a tool employed by STD prevention programs to prioritize incoming reactive serologic tests for syphilis (STS). Reactive serologic titers are categorized by age group, sex, and test type or titer levels and are separated for follow-up based on likelihood of yielding a case of untreated, infectious syphi-

lis. They are program specific and may differ from one program to another because they are dependent on current and past epidemiologic trends of syphilis in the local program. Grids should be periodically evaluated to confirm that they remain sufficiently sensitive to ensure that early syphilis cases are not being missed. (See Appendix S-B for example.)

Recommendation

- STD prevention programs should routinely evaluate the effectiveness and sensitivity of their reactor grid.
-

Appendix S-A

SURVEILLANCE CASE DEFINITIONS

To ensure the quality of STD surveillance data and their comparability within and between state and local jurisdictions, all program areas should adopt CDC case definitions.

(1) Chlamydia trachomatis, Genital Infections

Clinical description

Infection with *Chlamydia trachomatis* may result in urethritis, epididymitis, cervicitis, acute salpingitis, or other syndromes when sexually transmitted; often, however, the infection is asymptomatic. Perinatal infections may result in inclusion conjunctivitis and pneumonia in newborns. Other syndromes caused by *C. trachomatis* include lymphogranuloma venereum (see Lymphogranuloma Venereum) and trachoma.

Laboratory criteria for diagnosis

Isolation of *C. trachomatis* by culture or demonstration of *C. trachomatis* in a clinical specimen by detection of antigen or nucleic acid

Case classification

Confirmed: a case that is laboratory confirmed

Comment

For all surveillance case reports, laboratory confirmation of chlamydial infection is required. In some jurisdictions, syndromes such as MPC and NGU have been accepted as reports of chlamydial infection without any laboratory test; however, a high proportion of NGU is caused by other pathogens, and for MPC, often no bacterial etiology can be found.

(2) Gonorrhea

Clinical description

A sexually transmitted infection commonly manifested by urethritis, cervicitis, or salpingitis. Infection may be asymptomatic.

Laboratory criteria for diagnosis

Isolation of typical gram-negative, oxidase-positive

diplococci (presumptive *Neisseria gonorrhoeae*) from a clinical specimen, or demonstration of *N. gonorrhoeae* in a clinical specimen by detection of antigen or nucleic acid, or observation of gram-negative intracellular diplococci in a urethral smear obtained from a male.

Case classification

Probable: a) demonstration of gram-negative intracellular diplococci in an endocervical smear obtained from a female or b) a written morbidity report of gonorrhea submitted by a physician

Confirmed: a case that is laboratory confirmed

Comment

This case definition for gonorrhea includes only those cases confirmed by laboratory testing. Previous surveillance case definitions for gonorrhea have defined a probable case as “demonstration of gram-negative intracellular diplococci in an endocervical smear obtained from a woman or a written (morbidity) report of gonorrhea submitted by a physician.” The endocervical gram stain should not be considered a definitive test for gonorrhea because of limitations in both sensitivity and specificity. A clinical diagnosis of gonorrhea without laboratory confirmation (e.g., based on the presence of urethral discharge alone) should not be reported as a gonorrhea case.

(3) Syphilis

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. It must be emphasized that syphilis infections should be categorized as to their status at the time of specimen collection, not at the time of treatment or interview. Diagnosed cases of syphilis should be reported regardless of whether they have been treated or interviewed. A case of syphilis does not have to be treated or interviewed to be reported.

(A) 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. There may also be localized lymphadenopathy.

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), *Treponema Pallidum* Particle Agglutination (TPPA), IgG-EIA. Although not yet endorsed as part of the case definition by CSTE, treponemal tests such as the TPPA and IgG-EIA (that are generally considered to be equivalent confirmatory tests) may be used.

Confirmed: a clinically compatible case that is laboratory confirmed

(B) 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, DFA-TP, 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

(C) 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 TPPA), or a history of syphilis therapy and a current nontreponemal test titer demonstrating fourfold or greater increase from the last nontreponemal test titer

(D) 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 negative test in the last 12 months or fourfold or greater increase in titer of a nontreponemal test during the previous 12 months, or a history of symptoms consistent with primary or secondary syphilis during the previous 12 months, or a history of sexual exposure to a partner who had confirmed or probable primary or secondary syphilis or probable early latent syphilis, or reactive nontreponemal and treponemal tests from a person whose only possible exposure occurred within the preceding 12 months.

(E) 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. In the absence of symptom or serology history, sex partners for the last year must be evaluated to determine if the case is classified as early or 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.

(F) 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. In the absence of symptom or serology history, sex partners for the last year must be evaluated to determine if the case is classified as early or late latent.

Case classification

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

(G) 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 fluids (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, and clinical symptoms or signs consistent with neurosyphilis in the absence of other unknown causes for these clinical abnormalities

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

(H) 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, or bone. Rarely, other structures (e.g., the upper and lower respiratory tract, 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 seen in late lesions)

Case classifications

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.

(I) SYPHILIS, 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.

(J) SYPHILIS, CONGENITAL

Clinical description

A condition caused by infection in utero with *Treponema pallidum*. A wide spectrum of severity exists, and only severe infections 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 or malnutrition). An older child may have stigmata (e.g., interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinsonian teeth, saddle nose, rhagades, or Clutton joints).

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, *or* any evidence of congenital syphilis on radiographs of long bones, *or* a reactive cerebrospinal fluids (CSF) venereal disease research laboratory (VDRL), *or* an elevated CSF cell count or protein (without other cause), *or* 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 judgement. 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 in infants and children as well as syphilitic stillbirths.

Appendix S-B

EXAMPLE REACTOR SURVEILLANCE FOLLOW-UP GRID

Patient Type	Qual. Or MHA/FTA Only	1:1	1:2	1:4	1:8	1:16	1:32	≥1:64	+DF
Prenatal	P	P	P	P	P P	P		P	P
0-19	P	P	P	P	P P	P		P	P
20-29	F-P M-Q	F-P M-Q	F-P M-Q	P	P	P	P	P	P
30-39	F-P M-AC	F-P M-AC	F-P M-Q	F-P M-Q	P	P	P	P	P
40-49	AC	AC	AC	Q	Q	P	P	P	P
50-59	AC	AC	AC	AC	Q	P	P	P	P
60+	AC	AC	AC	AC	AC	AC	Q	Q	P
Age Unk	F-P M-Q	Q	Q	Q	P	P	P	P	P

Codes:

“F” FEMALE

“M” MALE

“P” PRIORITY: If no record is found, initiate Field Record (2936), and assign to the field.

“Q” QUERY LETTER: If no record is found, initiate query letter to provider. Initiate 2936 to the field if no response to letter after 14 days.

“AC” ADMINISTRATIVE CLOSURE: May be closed on basis of age, titer or negative treponemal test. No action required.

“DF” DARKFIELD

The above is an example reactor grid. Each program area should individualize this grid based on local disease profiles and priorities.

General Instructions:

1. All incoming reactors should be date-stamped and prioritized. This will assure that priority (1) reactors get handled first.
2. Update Laboratory Log/Cards as to number of reactors received. Such a system enables the program to track laboratory activity and reporting habits.

3. Record search all reactors against “open” and “closed” investigative files. The medical records of those patients reported from the STD clinic should also be pulled and reviewed.

- If a prior reactor(s) is found, serologies must be carefully reviewed to determine whether additional follow-up is indicated—i.e., does the current serology represent a two fold or greater increase in titer?
- Update any records to reflect the current results. At a minimum, this should include the date and result(s).
- When a record search identifies an “open” 2936, it should be pulled, updated to reflect the new information, and immediately brought to the attention of the assigned worker.

4. Initiate and assign 2936 for each priority (1) reactor that is not closed by record search.

5. Initiate query letters. It is recommended that a 2936 also be initiated at this time and filed by date. It can be used to document any information received from the health care provider or initiated to the field after 14 days.

6. Document and close any “administrative closures.”

EXAMPLE REACTOR SURVEILLANCE FOLLOW-UP GRID, continued

Example Format for the Evaluation of the Reactor Grid

MALES

Age	No. reactive serologies	No. (%) completed investigations	No. (%) untreated syphilis	No. (%) previously treated syphilis	No. (%) not found to be syphilis
30 - 39 yrs.					
Titer					
1:1					
1:2					
1:4					
1:8					
1:16					
1:32					
1:64					
≥1:128					

 Not routinely investigated

 Routinely investigated

Evaluation of the Reactor Grid

To evaluate a reactor grid, a program must first explicitly decide what outcome it hopes to achieve through using a reactor grid to evaluate reports of positive serologic tests for syphilis (STS). Two different goals have, from time to time, been proposed as appropriate outcomes for the follow-up of positive STS.

Goal A: The purpose of the reactor grid is to identify untreated syphilis infections of any stage. The STD prevention program may assist medical providers in determining who needs to be treated, regardless of diagnosis or stage but should assist if it is an untreated infectious case or a pregnant female.

Goal B: The purpose of the reactor grid is to identify early syphilis infections so that the STD prevention program can intervene in disease transmission through treatment of the infected person and persons exposed to disease or testing those associated with the chain of infection. Medical providers are responsible for their patients, and the health department's interest is in new infections.

The purpose of evaluating a reactor grid is to maximize the number of syphilis infections identified with the most efficient use of available resources. Evaluation of the grid is accomplished by evaluating each sex category, age group, and titer category routinely initiated and by calculating what proportion of investigations result in identifying persons with early syphilis. The program must decide whether the current reactor grid is sensitive in identifying persons with syphilis and how it might be manipulated to identify persons with syphilis in a more sensitive manner. This is accomplished by "opening up" the grid to evaluate the lower titer categories not routinely initiated and by determining what proportion of investigations result in identifying persons with infectious syphilis in these titer categories. This requires that the program investigate reactors that would normally not be initiated. The program must then decide whether the returns (additional cases identified) justify the expenditure of resources.

EXAMPLE REACTOR SURVEILLANCE FOLLOW-UP GRID, continued

- **Evaluation of the current reactor grid**

Select each sex, age, and titer category of the reactor grid that results in the routine initiation of an investigation. For each category, calculate what proportion of investigations result in identifying persons with syphilis.

- **Evaluation of additional grid parameters**

Expand the current grid to include the next lowest titer category for each sex and age grouping. Field records (FRs) are initiated on the resulting laboratory slips that cannot be closed by record search. For example, if the current cut-off is males aged 30-39, with titers of 1:16 and higher, then males aged 30-39 with titers of 1:8 would be investigated to identify those with syphilis. Depending on the

productivity of this group, the program may want to evaluate what proportion of investigations of males aged 30-39, with titers of 1:4, 1:2, and 1:1 result in identifying persons with syphilis.

- **Efficient Use of Available Resources**

To support the final design of the grid, the program should review each category of the reactor grid to determine the number of syphilis infections identified and the availability of resources for investigation. Special attention should be given to women of childbearing age. Programs are encouraged to investigate women with lower titer categories and a low yield of cases rather than run the risk that pregnant women with syphilis may go untreated.

Appendix S-C

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 Agency Private

Type of Testing
Nontreponemal RPR VDRL ART Other _____
Treponemal TPPA FTA-ABS 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 of test 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 does lab state were reported to the Health Department? _____

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

Mean reporting time for the laboratory _____ 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 reactivities reported that is acceptable. 100% of reactivities 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 receives the specimen to the time that the health department receives notification of a positive serology.

- A. Pull representative samples of reactive serology received by the STD program from the laboratory and for the time period under evaluation.
- B. For each serology reviewed write down:
date serology received by lab. ___/___/___
date report received by health dept ___/___/___
days btwn serology & report rec. _____
- C. Add the column "days between serology and report received."
- D. Divide the sum of "days between serology and report received" by the number of serologies evaluated.
- E. The result will equal the mean reporting time for the laboratory.

Periodicity of Laboratory Evaluation

The STD prevention program should evaluate laboratory reporting of reactive serologies regularly. The program manager should look at resources that are available locally when determining how often to visit laboratories. Laboratories with a large volume should be visited more frequently than laboratories with few reactivities. Laboratories slow in reporting should be visited more frequently. At a minimum, all laboratories within the program's jurisdiction should be visited at least once per year. The number of visits to a laboratory is a local program decision, based on laboratory reporting, program manpower, and program resources.

Appendix S-D

EXAMPLE: ANNUAL CLINICAL LABORATORY SURVEY CALENDAR YEAR ---

(Use space below to record name or address changes)

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.)

- | | |
|--|---|
| <input type="checkbox"/> Private Hospital | <input type="checkbox"/> Free-Standing Private |
| <input type="checkbox"/> Public Health | <input type="checkbox"/> Non-Profit Hospital |
| <input type="checkbox"/> Blood Bank | <input type="checkbox"/> Custody Facility |
| <input type="checkbox"/> VA/Military Hospital | <input type="checkbox"/> Community Clinic |
| <input type="checkbox"/> Student Health Services | <input type="checkbox"/> Physicians Office/Group Practice |
| <input type="checkbox"/> HMO | <input type="checkbox"/> 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%

EXAMPLE: ANNUAL CLINICAL LABORATORY SURVEY CALENDAR YEAR ---, continued

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? (Circle)	# Performed	# Positive	Number of Days Test is Performed*
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	_____	_____	_____
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? (Circle)	# Performed	# Positive	Manufacturer of Test (If appropriate)
Urethral Gram Stain*	No Yes	_____	_____	_____
GC Culture	No Yes	_____	_____	_____
DNA Probe (Single)	No Yes	_____	_____	_____
DNA Probe (Combo)	No Yes	_____	_____	_____
LCR	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? (Circle)	# Performed	# Positive	Manufacturer of Test (If appropriate)
Culture	No Yes	_____	_____	_____
DFA	No Yes	_____	_____	_____
EIA	No Yes	_____	_____	_____
DNA Probe (Single)	No Yes	_____	_____	_____
DNA Probe (Combo)	No Yes	_____	_____	_____
LCR	No Yes	_____	_____	_____
PCR	No Yes	_____	_____	_____
TMA	No Yes	_____	_____	_____
Other: _____	No Yes	_____	_____	_____

If applicable:

EXAMPLE: ANNUAL CLINICAL LABORATORY SURVEY CALENDAR YEAR ---, continued

Is verification assay performed on positive EIA findings? Yes No

Is verification assay performed on positive DNA probe findings? Yes No

Are DNA probe findings in the "gray zone" repeated? Yes No

If yes, define the gray zone used: _____

Does laboratory perform C. trachomatis serologic testing? Yes No

8. HEPATITIS B:

Hep. B Surface Antigen No Yes # performed _____ # positive _____
 Test Manufacturer _____

9. HUMAN IMMUNODEFICIENCY VIRUS (HIV):

EIA	No Yes	_____	_____	_____
Western Blot	No Yes	_____	_____	_____
IFA	No Yes	_____	_____	_____
PCR	No Yes	_____	_____	_____
Other: _____	No Yes	_____	_____	_____

10. HERPES SIMPLEX VIRUS (HSV):

Culture	No Yes	_____	_____	_____
DFA	No Yes	_____	_____	_____
Other _____	No Yes	_____	_____	_____

11. HUMAN PAPILLOMA VIRUS INFECTION (HPV):

Test Type _____	No Yes	_____	_____	_____
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12. CHANCROID
(Haemophilus ducreyi):

	Performed? (Circle)	# Performed	# Positive
Gram Stain	No Yes	_____	_____
Culture	No Yes	_____	_____

13. TUBERCULOSIS (TB):

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 ___

Sample

Appendix S–E

SURVEILLANCE SYSTEM ATTRIBUTES

Qualitative Attributes

In describing a surveillance system, three desirable qualitative attributes should be addressed: simplicity, flexibility, and acceptability.

- Simplicity of a surveillance system refers both to its structure and to its ease of operation. STD surveillance systems should be as simple as possible, while still meeting their objectives. This task is more difficult with STDs because of the complexity of case definitions (e.g., latent and congenital syphilis) and the multiple levels of reporting. It may be useful to think of the simplicity of a surveillance system from two perspectives: the design of the system and the size of the system. The following measures might be considered in evaluating the simplicity of a system:
 - Amount and type of information necessary to establish a STD diagnosis
 - Number and type of STD reporting sources
 - Methods of transmitting STD case information and data
 - Number of staff needed to efficiently handle workload
 - Type and extent of data analysis
 - Amount of computerization
 - Methods of distributing reports
 - Amount of time spent operating the system

The cost estimates for a system are also an indirect indicator of simplicity. Simple systems usually cost less than those that are more complex.

- Flexibility of a STD surveillance system refers to its ability to adapt to changing information needs (such as the addition of new conditions or data-collection elements) or operating conditions with little additional cost in time, staff, or allocated funds. STD prevention programs have often been challenged to quickly adapt to such emerging priorities as resistant gonorrhea and AIDS. Generally, simpler systems will be more flexible—fewer components will need to be modified when adapting the

system for use with another disease; therefore, the system should be able to track and analyze trends of other STDs and new pathogens. All systems should have the ability to easily share data sets with other systems (STD-MIS, HARS, TIMS) to determine co-infection rates, similar populations at risk, commonalities between affected populations, etc. This should be done while maintaining patient confidentiality.

- Acceptability reflects the willingness of individuals and organizations on whom the system depends to participate in the STD surveillance system. This attribute refers to the acceptability of the system to health department staff and to those individuals outside the sponsoring agency (e.g., doctors or laboratory staff) who are asked to report STDs. To assess acceptability, programs should carefully review the points of interaction between the system and its participants. Measurable indicators of acceptability include:
 - Subject or agency participation rates
 - Time required to generate acceptable participation of key providers or agencies
 - Interview completion rates and question refusal rates, if the system involves case interviews
 - Completeness of report forms
 - Physician, laboratory, or hospital or facility reporting rates
 - Timeliness of reporting
- Time and degree of complexity required of local health departments to capture positive case reports in the system

Quantitative Attributes

The four quantitative attributes of a surveillance system include sensitivity, predictive value positive, representativeness, and timeliness. Often difficult to measure precisely, even indirect estimates can be useful in improving the efficiency of a system and in comparing it to other systems.

SURVEILLANCE SYSTEM ATTRIBUTES, continued

- Sensitivity of a STD surveillance system can be considered on two levels. First, at the level of STD case reporting, sensitivity refers to the ability of the system to identify the completeness of reporting from the community. That is, how many cases were reported in relation to the number of actual cases in the community. Another aspect of completeness of reporting concerns the completeness of each individual report. That is, how complete is the information gathered for each report. Second, the system can be evaluated for its ability to detect epidemics. The sensitivity of a STD surveillance system is affected by the likelihood that:
 - Persons with certain STDs seek medical care.
 - The STD is correctly diagnosed, which reflects the skill of care providers and the accuracy of the diagnostic tests.
 - The case will be reported to the system once it has been diagnosed.

The measurement of sensitivity in a STD surveillance system requires a) validation of information collected by the system and b) collection of information external to the system to determine the frequency of STD in the community. Practically speaking, the primary emphasis in assessing sensitivity is to estimate the proportion of the total number of cases of STD in the community being detected by the system. A surveillance system that does not have a high degree of sensitivity can still be useful in monitoring trends, as long as the level of sensitivity remains reasonably constant. Questions concerning sensitivity most commonly arise when changes in the disease occurrence are noted. These changes can be precipitated by such events as increased awareness of a disease, introduction of new diagnostic tests, increasing morbidity, or changes in the method of conducting surveillance.

Quality of reported data is an important element in any STD surveillance system. This may be influenced by the clarity of surveillance reports, the quality of training and supervision of persons who com-

plete surveillance forms, the care exercised in data entry and data management, and the regularity with which the system is reviewed.

- Predictive Value Positive (PVP) is the proportion of persons identified as being infected with STD who actually do have the disease under surveillance. With STDs, the PVP for a positive syphilis screening test (e.g., RPR) is considerably lower than that for a positive chlamydia or gonorrhea test. Therefore, the effect on available public health resources to confirm syphilis is different from that for chlamydia or gonorrhea. A record of the number of case investigations and the proportion of persons who actually have the condition under surveillance allows the calculation of the PVP at the level of case detection. When assessing PVP, primary emphasis is placed on the confirmation of cases reported through the surveillance system. Its effect on the use of public health resources can be considered on two levels: the ability to detect a single infection; and potential epidemics. At the individual case level, PVP affects those resources required for investigation of cases. A STD surveillance system with low PVP, and therefore with frequent false-positive case reports, will require a heavy expenditure of program resources to identify very few new cases. False positives or negatives result in disruption of patients' lives and create negative impressions of the system. With regard to potential "outbreak" situations, a high rate of erroneous case reports over the short term might trigger an inappropriate and costly response. A low PVP means that (a) non-cases are being investigated, and (b) there may be mistaken reports of epidemics. False-positive reports to surveillance systems lead to unnecessary interventions, and falsely detected "epidemics" lead to costly investigations. A surveillance system with high PVP will minimize unnecessary and inappropriate expenditure of resources. Understanding and properly applying PVP can help programs to make the most appropriate and cost-effective use of available resources.

SURVEILLANCE SYSTEM ATTRIBUTES, continued

- Representativeness of a STD surveillance system refers to its ability to accurately describe: a) the occurrence of STD over time, and b) its distribution in the population by place and person. This may be examined through special studies or surveys that seek to identify a probability sample of all cases. Although this information is not generally available in specific detail, some judgment of the representativeness of surveillance data is possible on the basis of knowledge of the following:
 - characteristics of the population (e.g., age, geographic location, etc.)
 - natural history of the STD (e.g., latency period, outcome, etc.)
 - prevailing medical practices (e.g., site performing diagnostic tests, and physician-referral patterns, etc.)
 - multiple sources of data (e.g., laboratory reports for comparison with physician reports, etc.)

An important benefit to determining the representativeness of a STD surveillance system is the opportunity to identify population subgroups (e.g., migrant workers or prison inmates) that may be systematically excluded from the reporting system.

Errors and bias can make their way into a STD surveillance system at any stage. Because STD surveillance data are used to identify high-risk groups, to target interventions, and to evaluate interventions, it is important to be aware of the strengths and limitations of the information in the system.

- Timeliness of a surveillance system reflects its ability to identify the need to take appropriate action based on the urgency of the problem and the nature of the public health response. Timeliness is usually measured in days or weeks; for diseases that do not necessitate an immediate response, it might be measured in months or even years. Several dates are critical to properly evaluating timeliness of reporting. They are (a) date of symptom onset (date the patient first noticed symptoms); (b) date of examination or specimen collection; (c) date of laboratory tests; (d) date of diagnosis; and (e) date reported to the responsible public health agency. Other dates that can be used to determine program effectiveness include date treated, date assigned, and date interviewed. It is also affected by the time that 1) the clinician takes before sending orders to the laboratory and 2) the laboratory takes to report results to the health department and clinician.

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- Website: <http://www.cdc.gov/epo/surveillancein/toc.htm>
- This website is called "Surveillance in a Suitcase" and has lessons around many of the sections covered in this chapter. You can obtain lessons, an instructors guide, overheads, objectives, etc. This site is basically an introduction to public health surveillance.