

# Program Operations Guidelines for STD Prevention



## Outbreak Response Plan



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# Foreword

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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 outbreak response plan 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

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**T**hese 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

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

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# Outbreak Response Plan

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## INTRODUCTION

During the 1990s, the United States has experienced a significant decline in gonorrhea and syphilis. Historically, when STD rates decline, programs have reduced staffing and otherwise redirected program resources. In some areas, when morbidity continues to decline for extended periods, surveillance efforts sometimes fail to promptly detect an outbreak.

STD prevention programs must create, maintain, and utilize, plans to rapidly detect and respond to outbreaks. Outbreak plans should include careful and ongoing assessment of disease trends, establishment of disease thresholds, mobilization of resources, and efficient communication with the affected community. It is important to mount a rapid and thorough response so that small outbreaks do not become large ones. The diversion of resources and the restructuring of routine activities during an outbreak investigation and response require the program manager to carefully consider the potential consequences and benefits of a successful initiative. A deliberate decision to redirect resources, (e.g., to re-direct other prevention activities to implement the action), must include a consideration of potentially negative consequences as well.

An Outbreak Response Plan (ORP) should include the following:

- standards for surveillance and procedures for analysis of data;
- a schedule for review of disease trends;
- the threshold at which the plan is to be initiated;
- the meaningful involvement of the affected community in the effort;

- staffing considerations, including number, disciplinary mix, and specific responsibilities of response team members;
- the timely notification to CDC; and
- the evaluation of the effectiveness of the response.

The broad elements that constitute an ORP include outbreak detection, outbreak investigation, outbreak response, and evaluation of response. Another element which must be considered is the information flow between all of the agencies contributing to the outbreak investigation and response effort as well as communication with the health provider community, news media, and the public, particularly the affected community. Program management must decide when and how to involve these various entities.

## OUTBREAK DETECTION

Outbreak detection involves reviewing the standards for the surveillance system and developing procedures for the accurate and timely analysis of data gathered. For details on surveillance see the chapter “Surveillance and Data Management.” Once all surveillance systems and standards are in place, a program must determine the threshold level of various STDs that will trigger further investigation. In other words, a program must define what constitutes an outbreak.

In general, an outbreak can be defined as occurring whenever disease levels exceed what is expected in a given community. The community can be defined as small as a facility or establishment (e.g, a bar), census tract, neighborhood, city, county, or region. Threshold levels need to be locally defined and determined.

In setting thresholds, programs should consider the number of epi-linked cases, the number of cases with specified high risk behaviors, or the number of cases reported from a geographical area in a specific time period as compared to a previous time period (e.g., previous month, quarter, year). If these numbers exceed what is expected, the threshold may have been crossed. Programs may also want to review cases that have been interviewed, consider testing in high-risk settings, or cluster interview individuals related to a possible outbreak. Once a program has determined that an outbreak may be occurring, the next step is to investigate the increase in disease.

Regardless of whether an increase in cases is labeled an “outbreak”, some level of investigation should be initiated when the defined threshold for a particular STD is crossed. A program’s response should be tailored to the individual circumstances surrounding the increase. The intensity and scope of the investigation and response may differ depending on the number of cases, the magnitude of increase in a specified population, or some other factor. An outbreak may be very focal, with well-defined epidemiologic links or it may be dispersed over a large geographic area with few or no apparent links. The steps to be taken, number and types of staff involved, and who in the health care and general community is informed and involved will be necessarily different. The key is that management be able to rapidly detect an outbreak and, once identified, mount a timely, appropriate, effective investigation to determine the risk factors associated with the disease, and to respond appropriately.

## OUTBREAK INVESTIGATION

### Initiation

When an outbreak has been detected, the STD prevention program should arrange a meeting with public health officials, clinicians, and community leaders to discuss the outbreak. At that time, appropriate items to discuss would be:

- review available information,
- definition of an outbreak,
- purpose and scope of the investigation,

- resources available and needed,
- effect of the outbreak on the targeted area or community,
- roles of each group involved in the outbreak response,
- scheduling of regular updates with key persons,
- discussion of any political sensitivities pertaining to the outbreak and investigation,
- develop initial media and awareness strategy, and
- inform state and Federal STD staff of outbreak initiation and results of meeting immediately.

### Investigation

When beginning an investigation, the program should review the attributes of the data management system, review surveillance data, evaluate the quality of the surveillance system, and seek other sources of surveillance data. In addition, the program should confirm the diagnosis of cases; evaluate disease investigation, clinical, and laboratory services; and develop hypotheses about contributors to the increase in cases.

#### *Review attributes of data management system*

- **Review case report data.** How are case report data formatted and stored (hard copy or electronic case reports, morbidity reports, aggregate numbers of cases per geographic area)? What information is available for analysis of case reports?
- **Review reporting sources.** What agencies are reporting cases—clinicians, laboratories, health department staff, corrections institutions, substance abuse treatment centers, hospitals, or STD clinics?
- **Review data collection.** How is data collected from the source of the report and entered (if computerized) into the system? How complete and accurate are case reports?

#### *Review surveillance data*

- Review the most recent disease trends based on available surveillance data. When does the program think the increase in cases started and stopped (if it has stopped)? Define this period of the noted increase in cases.

- Compare the number of cases during the period of the increase with the number of cases for a specified time period before the increase began. Compare these data for all stages of disease.
- Consider reviewing disease trends for several different time periods: plot several years of data before the increase in cases began; plot the cases over days, weeks, months or quarters if appropriate.
- Consider any prior periods in the last 5-10 years when another increase in disease cases was noted. Discuss hypotheses for past increases.
- Create a geographic, census tract, or zip code spot map of cases. Are the cases during the period when the increase was noted geographically similar to those before this period?
- Describe demographic and risk characteristics of cases. Are the cases during the period of the increase in cases demographically similar to cases before that time?

***Evaluate the quality of the surveillance system (See Guidelines for Evaluating Surveillance Systems. MMWR. 1988; 37:S-5)***

- **Sensitivity.** What is the case definition? Has it changed? Have there been any changes in surveillance practices or case ascertainment? Survey health care providers and laboratories—is the program getting all the reports it should be getting? Are they complete?
- **Quantitative attributes.** Evaluate the other quantitative attributes of the system: predictive value positive, representativeness, timeliness.
- **Qualitative attributes.** Evaluate the qualitative attributes of the system: simplicity, flexibility, and acceptability.

***Seek other sources of surveillance data***

- Analyze screening data and trends. Which populations are routinely screened (prevalence monitoring)—prenatal patients, STD clinic patients, arrestees? What are the trends in prevalence monitoring data? Compare the case report trends with the prevalence monitoring trends.

- Determine if additional trend data is needed. Based on hypotheses for the increase in cases, would additional corrections, emergency department, or drug treatment facility screening data be helpful?
- Review the records at the STD clinic (if applicable). Are different clinicians examining patients? Has there been a change in laboratory tests or technician?
- Review records at laboratories with large numbers of positive tests. Has there been a change in procedures or technician?
- Consult with adjacent jurisdictions to inform them about what you know and to ask if similar trends are being seen elsewhere.

***Confirm the diagnosis and review clinical and risk indicator data on the cases***

- **Review clinical and laboratory data on cases.** Do the cases fit the case definition? At what stage of disease are the cases being detected? How is the stage of disease detected different for the period of the increase than from other periods? What is unusual about the clinical presentations?
- **Review symptom history of cases.** What proportion of cases is symptomatic at detection or report a history of symptoms? What proportion of cases present for clinical care with symptoms (volunteers) as distinguished from those referred by a contact or provider? Is this different from the usual distribution of “method of case detection”?
- **Determine co-infection rates.**
- **Determine risk factors.** What risk indicators are common to the cases? Are these different from those seen before the increase?

***Evaluate Disease Investigation, Clinical and Laboratory Services***

- **Evaluate disease investigation issues.** How many disease intervention specialists (DIS) are available to carry-out program activity? Has the number of DIS changed? What are the program’s contact and partner notification indices?

- **Evaluate clinical issues.** Where are cases seen initially? What are the hours of the local STD clinic? Have the hours changed? What is the volume of patients at the STD clinic? Has the patient volume changed? Compare the volume during the period of the increase in cases with the past volume. What is the policy regarding patient scheduling—appointments, walk-ins, a combination? How quickly are patients seen? Is there a co-pay? Has the policy changed? How well do STD clinical services meet the needs of the community? Where are sources of STD care in the community?
- **Evaluate clinical staff.** How many clerks are available for registration, phone calls, and medical records? How many clinicians are available to serve patients in the STD clinic? Has the number of clinicians changed? Are there enough clinicians to address the volume of patients at the clinic? What is the background and training of the STD clinicians? If the clinic has a multi-cultural clientele, how many multilingual staff are assigned to the clinic? Assess the quality of clinician services through chart reviews, observations, and clinic surveys.
- **Evaluate laboratory issues.** What are the available STD laboratory services (Darkfield, stat RPR, serology, Genprobe, LCR DNA Probe, NAATS)? Are these services adequate to meet the needs of the clinic and the community? Assess the quality of the laboratory services through site reviews, proficiency testing, and quality assurance protocols. If there is any doubt about laboratory results, send the specimen to a reference laboratory for confirmation of results.
- **Evaluate access to care.** Determine where cases are accessing care and barriers for those who have not accessed care.

## OUTBREAK RESPONSE

### *Develop hypotheses about contributors to the increase in cases*

- Generate hypotheses using the following steps.
  - 1) Conduct a focus group with disease intervention specialists and clinicians. Explore reasons for the increase in cases and attempt to define some commonalities of cases that they have interviewed.
  - 2) Construct hypothesis using information from interviews with several related cases.
  - 3) Review medical records of selected cases for risk indicators and other demographic data.
  - 4) Compare cases with disease during the period of increase with STD clinic and other clinic attendees without disease.
  - 5) Interview members of the affected community.
  - 6) Review the evaluation of the surveillance system and clinical, laboratory, and programmatic operational policies to identify systems issues that would lead to the increase or a perceived increase in cases.
- Discuss feasibility of hypotheses with key persons from the public health, clinical, and affected communities in the local area.
- Inform public health officials, health care providers, clinical and laboratory managers, affected communities, and the media of the findings of the outbreak investigation and outline the response plan. Keep state and Federal partners updated as well.

### *Execute control measures based on hypotheses, if appropriate*

- Determine if the rate of disease increase exceeds the threshold at which an outbreak is suspected and at which an enhanced control and prevention plan needs to be executed.
- Provide training to health care providers and CBOs, as appropriate.
- Develop transmission-specific control and prevention strategies.

- Consider the following activities when developing control and prevention strategies:
  - Convene an interdisciplinary team to discuss the outbreak methods of prevention and control. Membership of the interdisciplinary team could include public health officials, clinicians, members of the affected community, and community leaders. Consider inviting members of the state or local HIV community planning board to participate. Meet on a regular basis until the outbreak is resolved.
  - Meet with members of the affected community to discuss the increase in disease, possible reasons for the increase, and acceptable control measures. Discuss with members of the affected community ways they could assist with disease control and prevention.
  - Meet with representatives from community-based organizations (CBOs) to discuss the increase in disease and possible reasons for the increase. Discuss with CBOs ways they could assist with disease control and prevention.

### Closure

- Schedule a debriefing meeting. Make sure to invite all partners in the investigation.
- Prepare a written report that summarizes the investigation to date.
- Present debriefing.
- Plan and execute a more systematic study to test hypotheses, if indicated.

## OUTBREAK EVALUATION

Evaluation occurs both during the outbreak response and after all activities are completed. Evaluation of activities during the outbreak are addressed above. Items that should be considered for evaluation after closure of the outbreak response are the effectiveness of the response, cost of response, relationships with

private providers and CBOs, effectiveness of the interventions, and organization and leadership of the response effort. If the outbreak persists, then reassessment of outbreak, hypothesis, and interventions implemented is needed.

### Recommendations

- STD prevention programs must develop an outbreak response plan for specific STDs.
- Outbreak response plans should include:
  - standards for surveillance and data management
  - procedures for analysis of data, especially in subgroups to identify outbreaks in special populations and small geographic areas
  - a timetable and schedule for review of disease and epidemiologic trends
  - the threshold at which the plan is to be executed
  - involvement of the affected community
  - staffing and resource considerations
  - notification to state and CDC
  - evaluation of the response
- STD prevention programs should implement their outbreak response plans upon reaching the threshold that has been set.
- STD prevention programs should evaluate the effectiveness of the outbreak response plan immediately after the outbreak has been controlled.
- STD prevention programs should periodically review the outbreak response plan to ensure that necessary staff and other resources are ready to respond to an outbreak.
- STD prevention programs should annually review and evaluate the attributes of their surveillance systems to maximize the ability to detect an outbreak.