Program Operations
Guidelines for STD Prevention

Overview

CDC
Centers for Disease Control and Prevention

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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 Operation 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.

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 Operation 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.

Judith N. Wasserheit
Director
Division of STD Prevention

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 Categorization Database	www.phppo.cdc.gov/clia/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 www.cicatelli.org www.jba-cht.com
· HEDIS	www.cdc.gov/nchstp/dstd/hedis.htm
· Put Prevention Into Practice	www.ahrq.gov/clinic/ppipix.htm

At A Glance: Recommendations & Appendices

For ease of reference, we have compiled all Program Operations Guidelines (POG) recommendations and a listing of appendices, organized by chapter, in this At-A-Glance section. Page numbers for each section are identified in parentheses for easy cross-referencing to the larger document. It is important that recommendations be viewed within the context of supporting documentation. For this reason, the reader is encouraged to always consult the narrative text and references for each chapter to obtain background and rationale for various recommendations.

The target audience for the POG 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 comprehensive STD prevention and control programs. Recommendations stated in these guidelines are meant as a guide for STD program managers and staff. Many recommendations are stated in general terms, indicating particular activities that should be accomplished by all STD prevention programs. Intentionally not indicated in the POG is how a particular task should be accomplished. These decisions, of course, must be decided by state and local program management in accordance with local area needs and resources.

A camera-ready version of the entire POG document is also available on our website. Anyone wishing to duplicate individual chapters, or the entire document, may download a replica version of the hardcopy by going to http:/www.cdc.gov/nchstp/dstd/ProgGuidelines.htm

Leadership and Program Management Recommendations

STRATEGIC PLANNING (L-1)

- STD program management should develop and maintain statements of mission, vision, and values.
- STD program management should develop strategic plans.

PROGRAM MANAGEMENT: OPERATIONAL PLANNING AND EVALUATION (L-3)

- The STD program should establish and maintain a system for evaluating each component of the intervention program.

RESOURCE DEVELOPMENT AND MANAGEMENT (L-5)

- Management should establish appropriate policies and actions that recognize the importance and requirements for training, professional development, and career development programs.

ADVOCACY, MEDIA RELATIONS, & LEGISLATION (L-6)

- Each program should have a system to ensure that laws affecting STD prevention are routinely reviewed and revised, or developed, as necessary.
- Each state should have a complete set of legal authorities (statute or regulation with statutory authority) that contributes to the goals of STD prevention and reflects both sound scientific and technological developments. This set of legal authorities should include, but are not limited to, the following:
  - STD definitions
  - Morbidity reporting of defined diseases to include reporting of name, address, disease, sex, age, race, and source of report, date of report, and date of test
  - Laboratory reporting of positive tests to include date of report, date of test, name of physician, patient's name, age, race, sex, test performed, and test results
  - Confidentiality of STD records to the maximum extent legally possible including exemption from subpoena
  - Prenatal testing for STDs to include at least one serologic test for syphilis. In high morbidity areas and outbreak situations, serologic tests should be performed during the first and third trimester of pregnancy and at delivery
  - Ophthalmia neonatorum prophylaxis
  - Permission for minors to authorize their own STD examinations and treatment without parental consent and holding this and related information absolutely confidential

PARTNERSHIPS AND COLLABORATIONS (L-8)

- STD prevention programs should be partners with groups such as reproductive health, schools, corrections facilities, and religious organizations.
- STD programs should have a system to assure ongoing interaction with all agencies, including CBOs, that may affect STD prevention.
- STD programs should establish referral arrangements for STD prevention activities with appropriate service providers.

Program Evaluation Recommendations

INTRODUCTION (E-1)

- Programs should conduct appropriate, regular and ongoing evaluation for self assessment and quality improvement.

PLANNING AN EVALUATION (E-2)

- Programs should plan evaluations early in the development of interventions.
- Programs should have a plan of evaluation for all important program components, including how and when each will be evaluated.
- Program evaluations should be designed and conducted with a clear purpose.

STEPS IN DESIGNING AND CONDUCTING AN EVALUATION (E-3)

- Program managers should develop a written description of the program, including the involvement of stakeholders.
- Programs are encouraged to develop logic models for goals, objectives, activities, and the targeted groups.
- Evaluation results should be shared with stakeholders.
- Evaluation results should be used for program improvement and further program planning.

TYPES OF EVALUATION (E-6)

- A formative evaluation should be conducted when a new intervention or program is undertaken or when a different way of conducting an intervention is developed.
- An evaluability assessment should be conducted when planning an evaluation of any portion of an existing program.
- At a minimum, programs should calculate the cost per service unit for each of its major prevention programs.

PRACTICAL CONSIDERATIONS (E-13)

- Programs should include funds for evaluations in their budgets.
- Programs should consider utility standards, feasibility standards, propriety standards, and accuracy standards when performing evaluations.

PROGRAM EVALUATION APPENDICES

Surveillance and Data Management Recommendations

COMPONENTS AND OPERATION OF A SURVEILLANCE SYSTEM (GENERAL PRINCIPLES) (S-2)

- 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.
- 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.
- 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.
- 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.

- 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.
- 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.
- 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.
- 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 (S-10)

- 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).

SURVEILLANCE SYSTEM ATTRIBUTES (S-12)

- 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 (S-12)

- 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 (S-13)

- 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 (S-17)

- 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.
- 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.
- 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 (S-21)

- STD prevention programs should evaluate STD surveillance systems at least annually.
- STD data quality should be routinely evaluated.
- STD prevention programs should routinely evaluate the effectiveness and sensitivity of their reactor grid.

PROGRAM EVALUATION APPENDICES

Training and Professional Development Recommendations

INTRODUCTION (T-1)

- Programs should have in place or should establish a system that incorporates the four basic steps of the training process identified under the definition for training.
- Programs should develop goals and objectives for appropriate training for both staff and external partners.
- Programs should utilize information collected from evaluation to update and improve the entire training process.
- Programs should establish a policy ensuring that training, professional development, and career development are part of their program.
- Program managers should designate individuals with management responsibility for training and staff development functions.

TRAINING PROCESS (T-3)

- STD prevention programs should have a systematic and regular method of assessing training needs and skills development of staff.
- STD prevention programs should consult with PTCs for conducting external partners training needs.
- Programs should perform a needs assessment within their STD prevention workforce (both staff and external partners).
- Programs should be aware of areas of training and orientation needed for all staff members.
- Programs should evaluate training activities and effects on performance.
- Programs should conduct post-training monitoring and reinforcement.

PROFESSIONAL/CAREER DEVELOPMENT PROCESS (T-10)

- Programs should consider the mentoring process as an effective method for career development.

TRAINING AND PROFESSIONAL DEVELOPMENT APPENDICES

Medical and Laboratory Services Recommendations

ACCESSIBILITY (ML-1)

- The clinic facility must be physically accessible in accordance with the Americans with Disabilities Act.
- Clinics should be located so that they are readily accessible through public and private transportation from residential areas.
- The general public should be able to easily determine how to obtain specialized STD services.
- Clinic hours and staffing should be sufficient to accommodate patients, with minimal patients turned away.
- A system to periodically assess clinic user (or patient) satisfaction with services should be in place.
- No patient should be denied care for lack of money. Medical services should be at no charge, minimal, or based on a sliding scale.
- Fees should not be assessed for examining persons referred by a disease intervention specialist.

RANGE OF SERVICES (ML-2)

- At a minimum, clinics should have the capability to accurately diagnose and treat bacterial STDs.
- Clinics should have the capacity to distribute medications for diseases diagnosed in the clinic. At a minimum, medications must be available for locally prevalent STDs, with prescriptions available for diagnosed diseases not prevalent in the community.
- Clinics should provide condoms and counseling on primary prevention to all patients.
- Clinics providing Pap smears should have specific protocols for follow-up of abnormal results that include guidelines for colposcopy referral.
- Clinics providing pregnancy tests should have specific protocols for follow-up and referral of positive tests.
- Clinics should collaborate with immunization programs and viral hepatitis programs to provide hepatitis B vaccinations to those at risk.
- Clinics should provide the basic range of HIV related services specified in state and federal statutes and, for patient convenience, should offer as many as possible on site (e.g., counseling and testing, partner services).
- Confidential counseling and testing for HIV should be offered at the time of the STD visit so that patients do not have to visit separate clinics or make return visits.
- Confidential counseling and testing for STDs, including HIV, should not be denied because a patient refuses other STD services.
- Anonymous HIV testing should be available on site for patients requesting the service or at community sites convenient to patients.
- Written policy and procedures should be in place for the referral of patients for HIV early intervention services (e.g., continuing medical evaluation, tuberculosis and immune system testing, treatment, and support group counseling).
- When not offered on site, the mechanisms for referral should be established for relevant health services (e.g., family planning, prenatal, adult immunizations, drug counseling).

CLINIC ENVIRONMENT (ML-3)

Facility

- The building in which a STD clinic is located should

have signs making it easy to locate. Signs at the building entrance should be easy to read and should clearly list STD among the services.

- Waiting areas should contain accessible patient education (i.e., handouts, posters, pamphlets, or audiovisuals) that emphasize risk reduction behaviors for the prevention of STDs, HIV, and viral hepatitis.
- Examination rooms should be clean and private and should have adequate equipment and supplies for physical examinations and specimen collection for both male and female patients.
- The number of examination rooms should be adequate to accommodate the number of clinicians (at least one room per clinician) and to serve patients promptly during the normal working day.

Patient Considerations

- Patient confidentiality must be maintained. Confidentiality should be promoted by using a system other than names when calling patients from waiting areas.
- Clinic personnel should be courteous and respectful of patients.
- Patients should be told what to expect during the clinic visit, including being told STDs for which they are being tested and the common ones for which they are not being tested.
- All clinic staff should develop and maintain cross-cultural awareness and display cultural sensitivity.
- An adequate portion of the clinic staff should have bilingual fluency that facilitates services to those patients who do not speak English.
- Clinics should assess the need for physical security during clinic sessions and have security protocols in place.

REGISTRATION PROCESS (ML-3)

Confidentiality

- Registration information should be obtained in a confidential manner.
- Acoustical barriers separating clerks from waiting areas in addition to methods of self registration should be considered when distance does not prevent persons from overhearing those who are registering.
- Information collected at the registration desk should be relevant: locating and demographic data, type of visit (referral, appointment, or walk-in); clerks should avoid discussing the medical reason for the visit including any symptoms or medical history.
- Patient address should be verified at every visit in the event that follow up is needed.

Procedure

- Telephone reports of test results must follow clinic procedures to ensure confidentiality.
- Clinics should have systems in place to assess and modify patient visits to assure minimal waiting.
- The "expected-in" file should be checked for every person at every visit as part of the registration process.
- Priority patients should be given preferential service.

CLINIC FLOW (ML-4)

Appointment and Walk-in Systems

- The responsibilities of the clinician will play a role in determining the number needed in a clinic.
- Walk-in patients with genital ulcers, discharges, and women with abdominal pain or who are pregnant should be examined that day.
- Patients referred by DIS should be seen on a priority basis on the same day.
- Walk-in patients who are not examined within the day should be given a list of STD medical resources and eligibility requirements (e.g., urgent care clinics, family planning clinics, private physicians) and encouraged to call for a next-session appointment.

Clinic Flow

- Clinic flow should be designed so that the next available clinician sees the next patient registered. An exception may be made where local medical practice standards or legislation stipulates gender requirements. Patients who request a clinician of a specific sex should be accommodated whenever possible.
- Patient stops should be kept to a minimum (ideally, not more than three—registration, clinical care, and an STD/HIV interviewing/counseling session, if needed).

- Patient flow analysis should be conducted periodically to provide a systematic understanding of where bottlenecks in clinic flow occur.

MEDICAL RECORDS (ML-5)

- Medical records should contain sufficient demographic information to contact the patient and sufficient clinical evaluation information to readily interpret the examining clinician's assessment and clinical findings.
- All procedures concerning content and filing of medical records should be in accordance with state and local laws and statutes.
- STD programs should follow written procedures for the management of medical records that includes forms management, organization of the medical record, records security, and adherence to statutes for record retention.
- An individual should be assigned the responsibility of managing the release of records due to subpoena, court order, etc. This person should track all matters relating to request to view medical records.

CLINIC MANAGEMENT STRUCTURE (ML-6)

- The clinic manager should have adequate specialized training in STD, clinic and personnel management, and public health.
- The medical director should have specialized training in STD, be available for consultation during clinic hours and ensure the overall quality of clinical services.

CLINIC MANUALS (ML-7)

Personnel Policies

- An STD clinic manual should contain the goals and the objectives of the clinic, including fully integrated STD/HIV services.
- Job descriptions and performance standards should be provided for all staff members. These descriptions and standards should include:
  1. qualifications and training requirements for each job;
  2. the role each job plays in the operation of the clinic;
  3. a description of the essential tasks required for each job;
  4. the mechanism for performance evaluation; and,
  5. attitudes expected to be conveyed to clinic patients.
- Policies regarding employee health (e.g., injury surveillance, HIV exposure, tuberculosis screening, and hepatitis B vaccination) should be consistent with state and local employee health regulations and should be clearly written and enforced.
- Procedures for formal quality assurance should be provided.
- Local policies and procedures included in the manual (frequency of staff meetings, fire drill instructions, sick leave, and vacation) should be current.

Medical Protocols

- Clinic protocols or standard medical instructions for specific patient management should include:
  1. patient evaluation;
  2. management of STDs (See CDC STD Treatment Guidelines);
  3. medical consultation and referral;
  4. follow-up after therapy;
  5. counseling/education;
  6. and management of sex partners.
- Protocols should include current recommended treatments for STDs.
- Emergency medical protocols should be current.
- Protocols for the safe handling of blood and body fluids (standard precautions) should be current and practical for most clinic situations.
- Current and signed standing orders for non-physician clinicians should be included if required or not prohibited by state laws and regulations (medical practice acts).

CLINICIAN ROLES AND PERFORMANCE STANDARDS (ML-8)

- Nurses, nurse practitioners, and physician assistants should work in full compliance with established clinic protocols as clinicians responsible for the entire clinical care process, including history taking, physical examination, laboratory specimen collection, diagnosis, treatment, plan for follow-up, and counseling/education.
- Non-physician clinicians should have adequate physician backup and specific standing orders.
- All clinicians should have a specific STD training course and AIDS update course.

STANDARD PRECAUTIONS (ML-8)

- Standard Precautions should be applied to (1) blood; (2) all body fluids, secretions, and excretions, except sweat, regardless of whether or not they contain visible blood; (3) broken skin; and, (4) mucous membranes. Standard Precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in health care settings.
- Protective barriers should be appropriate and available for the type of exposure anticipated and may include latex or vinyl examination gloves, gowns, masks, and protective eye wear.
- Needles and syringes should not be recapped or removed from disposable syringes.
- Disposable syringes and other sharp items should be placed in puncture-resistant containers located in the immediate vicinity where venipuncture procedures take place.
- Gloves should be worn during venipuncture to reduce the incidence of blood contamination, recognizing that they cannot prevent needle-stick injuries.
- Clinicians and phlebotomists should change gloves between patients.
- Gloves should not be worn outside the examination room or the laboratory.
- Skin on hands or other parts of the body should be immediately and thoroughly washed if contaminated with blood or other body fluids. Hands should always be washed before and after the examination and before leaving the examination room.
- Infectious waste should be incinerated or autoclaved before disposal in a sanitary landfill.
- A surveillance system should be established for injuries such as needle-sticks, percutaneous injuries, and mucous membrane contamination; protocols should specify collection of confidential information about the worker and about the source individual (if applicable and possible), and about the cause and type of injury, medical treatment, counseling, and follow-up.

EMERGENCY PROCEDURES (ML-10)

- One copy of an emergency protocol should be kept in the clinic manual and one copy with the emergency supplies.
- Emergency equipment, supplies, and medications should be updated frequently according to an established schedule to ensure that they are not depleted or expired. Emergency supplies should be sealed when not in use.
- All clinical staff members should be trained in cardiopulmonary resuscitation and should be able to respond appropriately in an emergency.
- Staff members should be trained in specific safety procedures for managing potentially violent or abusive persons in the clinic.
- Mock emergency drills should be held at least twice yearly to ensure that all staff members recognize emergencies, know their roles and responsibilities, know the location and contents of emergency supplies, can use all equipment properly, and follow established protocols.
- STD prevention programs should develop and implement policies and procedures to manage occupational exposures of health care workers.

STAT LABORATORY MANAGEMENT STRUCTURE (ML-10)

Laboratory Direction

- The laboratory director should be trained in appropriate laboratory techniques and safety procedures associated with handling infectious agents.
- The director should have experience in public health and an understanding of the needs of clinicians and DIS staff.
- Optimal qualifications of the laboratory director include a doctoral degree in medicine or laboratory science (see Appendix ML-A).
- The director should ensure that the quality assurance committee's recommendations for laboratory testing are implemented.
- The laboratory director may be on site or at the state or local health department for laboratories that have the exemption for limited public health testing.
- Staff members should be familiar with work plans and should receive periodic performance evaluations.
- Only personnel who have been advised of potential hazards and who meet specific requirements should be allowed to enter the laboratory.
- The director should ensure adequate staffing to manage the volume of rapid testing during peak testing hours, lunch, and employee vacations.
- Accurate and updated test procedures and biosafety manuals should be available to all laboratory employees.
- Policies should be established to ensure the confidential storage of laboratory requisitions or log books containing patients' test results. Confidentiality statutes in each jurisdiction define the records that are protected from subpoena and may specify the time frame for retention and the method for destruction.

Laboratory Services

- Each clinic that provides STD services should have an on-site stat laboratory or capacity to perform stat tests. The laboratory must have a current CLIA certificate and be in compliance with CLIA-88 (see Appendix ML-A).
- At a minimum, stat laboratories should perform the following tests, all of which are classified as of moderate complexity under CLIA, with the exception of urine pregnancy tests, which are classified as waived under CLIA:
  1. Gram stain to detect intracellular gram-negative diplococci and presence of white blood cells to detect cervicitis or urethritis
  2. nontreponemal antibody card tests for syphilis such as RPR, TRUST, RST
  3. darkfield examination for *Treponema pallidum*
  4. saline wet mount for *Trichomonas vaginalis* and detection of clue cells of bacterial vaginosis
  5. KOH wet mount for the identification of yeast and for amine odor (Whiff) test
  6. Urine pregnancy tests
- Point-of-care tests should only be used to provide immediate results and treatment to patients. If testing does not occur immediately, tests with greater sensitivity and specificity should be used.
- The stat laboratory should contain an appropriate number of brightfield and darkfield microscopes and adequate equipment, supplies, and reagents to process patient specimens rapidly.
- A sufficient number of staff should be trained in darkfield microscopy to provide coverage during all clinic hours where rapid syphilis diagnosis is desirable.
- The stat laboratory should send the following routine tests to the state health laboratory or other non-stat laboratory:
  1. presumptive and confirmatory identification and antimicrobial sensitivity tests for *N. gonorrhoeae; [presumptive-moderate complexity; confirmatory and sensitivity tests-high complexity-CLIA]*
  2. chlamydia diagnostic tests (most high complexity - CLIA) nontreponemal antibody tests for syphilis (VDRL - high complexity, RPR and other similar card tests - moderate complexity - CLIA **)**
  4. fluorescent treponemal antibody absorption (FTA-ABS) or other treponemal tests for syphilis [high complexity-CLIA]; and
  5. HIV antibody tests [moderate complexity-CLIA, many others, high complexity-CLIA]
- Additional stat testing may include;
  1. Tzanck stain for herpes [moderate-CLIA]
  2. spun urine for Gram stain and white cell count [moderate-CLIA]

- STD clinics should use routine and reference laboratory services which further facilitate the diagnosis of STDs.

LABORATORIAN ROLES AND PERFORMANCE STANDARDS (ML-12)

- Job qualifications for laboratorians include (at a minimum) high school graduation and training received at a medical or technical school; certification as a laboratory technician or technologist, professional registration as a microbiologist, or a degree in biological science; and, courses in basic stat laboratory methods for STD testing (brightfield and darkfield microscopy, gonorrhea culturing, rapid chlamydia tests, and syphilis serology) at one of the STD Prevention/Training Centers, or similar training.
- All laboratory workers should routinely participate in proficiency testing.
- A laboratory worker should possess a professional attitude and sensitivity about confidentiality; this includes not discussing laboratory results within patients' hearing.
- A laboratory worker should adhere strictly to universal precautions, safety procedures, and quality control procedures.

LABORATORY BIOSAFETY LEVEL CRITERIA (ML-13)

Microbiological Procedures

- Access to the laboratory should be limited to appropriate personnel and should be restricted when work with infectious agents is in progress.
- Work surfaces should be decontaminated daily, as well as immediately after a spill.
- All infectious waste should be decontaminated before disposal.
- Mouth pipetting is prohibited; mechanical pipetting devices are used.
- Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Contact lens wearers in laboratories should also wear goggles or a face shield. Food is stored in cabinets or refrigerators designated for that purpose only, outside the work area.
- Thorough hand washing should be performed after handling infectious materials and before leaving the laboratory.
- Procedures to minimize the creation of splashes or aerosols should be followed.
- An insect and rodent control program should be in effect.
- Universal biohazard symbols should be posted on the laboratory door.
- Laboratory personnel should receive appropriate immunizations or screening for the agent handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).Baseline serum samples for laboratory and other at-risk personnel should be collected and stored, when appropriate, considering the agent(s) handled. Additional serum specimens may be collected periodically.
- A biosafety manual should be prepared or adopted. Personnel should be advised of special hazards and should be required to read and follow instructions on practices and procedures.
- Contaminated sharp items, including needles and syringes, should be promptly placed in puncture-proof containers for decontamination.
- Laboratory personnel should receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel should receive periodic updates, or as necessary.
- Cultures, tissues, or specimens of body fluids should be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
- Laboratory equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis after work with infectious materials is finished, and especially after spills.
- Spills and accidents which result in overt exposures to infectious materials should be reported to the laboratory director immediately.

Safety Equipment (Primary Barriers)

- Biological safety cabinets, or other appropriate protective equipment should be used when procedures with a potential for creating infectious aerosols or splash are conducted, or high concentrations or large volumes of infectious agents are used.

- Face protection (goggles, mask, face shield or other splatter guards) should be used for anticipated splashes or sprays of infectious materials.
- Protective laboratory coats, gowns, smocks, or uniforms designated for lab use should be removed and left in the laboratory before leaving for non-laboratory areas.
- Examination gloves should be worn when handling infectious materials, contaminated surfaces or equipment. Gloves should be disposed of when contaminated, or when work with infectious materials is completed. Disposable gloves should not be washed or reused.

Laboratory Facilities (Secondary Barriers)

- Each laboratory should contain a sink for washing hands.
- The laboratory should be designed for easy cleaning.
- Bench tops should be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- Furniture in the laboratory should be sturdy, with spaces between benches, cabinets, and equipment accessible for cleaning.
- If the laboratory has windows that open, they should be fitted with fly screens.
- A method for decontamination of infectious or regulated laboratory wastes should be available (e.g., autoclave, chemical disinfection, incinerator, or other approved decontamination system).
- An eyewash facility should be readily available.

LABORATORY PRACTICE AND TECHNIQUES (ML-14)

Microbiological Practices

- All procedures should be consistent with recognized standard and specialized microbiologic practices.
- Biological safety cabinets, previously termed "hood," (Class I or II) or other physical containment devices should be used during procedures in which infectious aerosols may be created.
- Any activity with the potential for creating aerosols (e.g., centrifugation of blood) should be performed in low-traffic areas in the laboratory.
- All testing should be performed under quality assurance guidelines specific for each test (e.g., control specimens, temperature, time).
- Safety equipment should include items for personal protection such as gloves, coats, face shields, and safety glasses.
- Cultures, tissues, or specimens of body fluids should be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping. Laboratory specimens should be placed in durable trays or containers for safe transport, even for short distances.

Procedures Manual

- The manual should include step-by-step descriptions of all methods; modifications of procedures should be initialed by the laboratory director.
- The manual should include criteria for laboratory specimen acceptability.
- Daily quality control records pertaining to test controls and to equipment, temperature, and speed of rotation should be noted in the manual.
- Procedures for quality control checks on new lots of reagents, whether purchased or prepared, should be noted in a special section.
- Instructions for routine tests and special studies should be documented in the manual.

Biosafety Manual

- All new employees should read and understand the biosafety manual before working in the laboratory. (See section, Standard Precautions, for OSHA mandated training required for all employees who may have contact with blood or other body fluids.)
- The manual should include information on standard and special microbiologic practices appropriate to laboratory Biosafety Level 2.
- The biosafety manual should be regularly updated.
- Laboratory procedures should be reviewed for compliance with established safety practices by a safety proctor appointed by the laboratory director.

PROVIDING STAT LABORATORY SERVICES IN COMPLIANCE WITH CLIA (ML-15)

- The exemption to the certification requirement for each location available for limited public health testing (LPHT) should be pursued, if feasible. The state public health laboratories may be the only facilities with the mandate, expertise, and infrastructure to facilitate laboratory partnerships between large numbers of locally administered clinic laboratories.

VENIPUNCTURE (ML-16)

- A continuing Quality Assurance program should be in place to monitor the venipuncture performance of STD staff.
- The DIS supervisor should closely monitor DIS until assured that their venipuncture performance is satisfactory.
- Periodic monitoring should continue after the initial observation period. See Appendix ML-F for an example of a venipuncture evaluation tool.
- When labeling and transporting specimens, the DIS should:
- Print the patient's name and date of birth (if known) or place a pre-printed label on the specimen tube after the blood has been collected. Include the date the specimen was drawn. To prevent the incorrect labeling of blood specimens do not pre-label blood collection tubes.
- Maintain blood specimens in an upright position with the stopper at the top, either by placing in a specimen rack or in a cardboard container. Pack the containers tightly so the specimens will be secure in transit.
- Blood specimens should be delivered to the laboratory for processing at the earliest practical time. Avoid leaving for extended periods in a car or similar place where temperatures may become excessively high or low. Also, make sure specimens remain in your care and that they are not handled by unauthorized persons.
- When blood specimens cannot be delivered to the laboratory on the day of collection, make sure they are stored upright in a refrigerator. Do not freeze, as hemolysis may occur, ruining the specimen.

DISEASE INTERVENTION SPECIALIST SERVICES IN MEDICAL FACILITIES (ML-17)

- Consistent prevention messages to patients should be facilitated through regular communication between clinic providers and DIS.
- Clinic procedures should promote a smooth and confidential exchange of relevant disease intervention information between clinical staff and DIS.
- DIS should be on site or on call to provide disease intervention services during clinic hours. Where resources are lacking for specialized disease intervention staff, or work is reassigned based on disease priorities, clinicians and counselors can perform intervention services.
- DIS should have a thorough understanding of STD clinical care and STD diagnostic test results.
- Clinic protocols should specify which patients are to receive STD and HIV intervention services from DIS.
- DIS should be provided with an adequate number of private rooms to ensure that confidential STD interviews and HIV prevention counseling sessions can be conducted without interruption.
- All personnel should be evaluated for STD intervention and HIV test counseling skills to assure consistency of messages.

QUALITY ASSURANCE PROCEDURES (ML-18)

- A quality assurance committee should meet regularly and follow an approved protocol to conduct audits, analyze findings, and deliver recommendations.
- Medical records should be audited regularly (checked against clinic protocols) to determine the appropriateness of diagnoses and treatment and the completeness of documentation.
- The quality of stat laboratory procedures should be monitored regularly.
- Staff interactions with patients should be observed regularly.
- Semiannual safety audits should be performed to determine the appropriate use of electrical equipment, storage of chemicals, emergency procedures,

and first-aid stations.
- A mechanism should be established for receiving, reviewing, and responding to complaints of patients.
- Representatives of the finance office and data processing unit should also be included on the quality assurance committee so that they can gain and maintain an understanding of clinic operational needs.

REPORTING (ML-18)

Disease Morbidity

- Clinics should promptly submit morbidity reports following the diagnosis of a case in the format determined by the state or local prevention program.
- Morbidity reports should be complete, legible, and checked for accuracy before submission.
- The quality assurance of morbidity reports should involve periodic comparison with medical records.
- Computerized medical record systems should be linked to electronic morbidity reporting to expedite rapid data collection.
- Clinic reporting systems should have the necessary safeguards to ensure the proper and nonduplicative reporting of laboratory results and diagnostic determinations.

Sexual Assault and Abuse

- All clinic staff should be familiar with provisions of the state child abuse and neglect statute and their obligations under it.
- Clinic staff members should be familiar with applicable STD and HIV confidentiality statutes and should be sensitive to any limitations on the reporting of supplementary information about suspected abuse cases.
- The clinic manual should specify the management of patients of alleged abuse, listing the required examination and proper handling of laboratory specimens for evidence, and reporting procedures.
- Testing of abused or assaulted patients should be performed using the most specific tests available.
- Clinics should set up a mechanism for referrals to perform additional confirmatory testing necessary to make a definite diagnosis.
- Clinics should have a patient advocate who maintains links with victim's assistance programs.

Domestic Violence

- All clinic staff members should be familiar with domestic violence statutes.
- STD programs should incorporate domestic violence issues into their staff training.

MEDICAL AND LABORATORY SERVICES APPENDICES

Partner Services Recommendations

INTRODUCTION (PS-1)

- Programs should establish the mix of partner services that is appropriate to local epidemiology.
- Programs should prioritize patients for partner services in terms of specific diseases, local area data, the potential for productive intervention, case load, and available resources.
- Programs must ensure that DIS and managers possess the tools, training, and resources necessary to conduct program business successfully.
- Programs must have some form of case management process in place. Case management "tools" should reflect established information needs, should be easy to complete, and should provide information that can be used to define at-risk populations and to target them for intervention.
- Programs should provide interview space that is quiet and confidential, and contains at least a desk or table, three chairs, a telephone, and educational materials needed by the DIS.
- Programs must have written safety guidelines and procedures in place and follow these policies.
- Programs must ensure that DIS are aware of and comply with safety guidelines.

PARTNER SERVICES (PS-5)

- Interviews with patients about partner services should be planned, client-centered, culturally appropriate, and voluntary.
- Anyone reasonably believed to have been exposed to a STD should be treated prophylatically at the time of exam based on CDC treatment guidelines.
- Documentation of partner services must be systematic, confidential, and regularly reviewed by the next level of supervision.
- Partner services should be delivered in one of three ways: provider referral, patient referral, or contract referral.
- Partner services should be one of a number of public health strategies, including accessible clinics, outreach, and targeted screening of at risk populations.
- Programs should have the capacity to deliver services such as counseling, testing, and treatment, as well as referral for other services (e.g., family planning, drug treatment, social support, and housing).

SPECIAL CONSIDERATIONS (PS-20)

- Programs should implement a protocol for collaboration with non-health department care providers within their own area and with STD programs in other jurisdictions.
- Programs should implement a protocol for identifying and developing a case management plan for patients with repeat infections.

EVALUATION AND QUALITY ASSURANCE (PS-20)

- Supervisors should regularly observe and document individual DIS in the performance of their day-to-day activities and should be willing and able to demonstrate appropriate skills and behaviors.
- Supervisors should conduct sessions that facilitate DIS discussion of case management efforts and provide opportunity for input from others.

- Programs should routinely monitor partner services to improve efficiency, effectiveness, and quality of services.
- Trends in disease found through evaluating partners should be used to monitor disease transmission and to increase program awareness regarding potential outbreaks.
- At a minimum, programs should analyze partners who are positive by residence (zip code, address). If resources permit, programs should also analyze location, demographics, and risk behaviors of partners and should compare positive (including previously treated partners) with negative partners to see what, if any, factors predict positive partners.
- Programs must have a means of regularly evaluating the effectiveness of partner services by time period and disease.
- Programs should develop the capacity to evaluate the effectiveness of the partner services by other locally set criteria to improve services and target them better.

COMMUNITY-BASED OUTREACH (PS-23)

- Programs should establish strategies for finding at-risk persons not identified by an infected index case or partner**.**
- Programs should evaluate or assess the social networks that influence disease transmission in their area.
- Programs should target screening based upon program morbidity data, including information on core transmission groups.
- Programs should use information from social network analysis, if available, to assist in targeting both field and clinic screening efforts.
- Programs should build partnerships with people affected by sexually transmitted diseases to increase trust and to facilitate partner services and other interventions.
- Programs should assess which diseases are being transmitted within their jurisdiction and how, including partner selection patterns and other risk factors for infection.

PARTNER SERVICES APPENDICES

Community and Individual Behavior Change Interventions Recommendations

INTRODUCTION (BC-1)

- STD prevention programs should develop and maintain the capacity to implement community and individual behavior change interventions.
- STD prevention programs should develop and utilize a behavioral data system to help determine the choice of intervention to be implemented and to evaluate intervention effectiveness after implementation.
- STD prevention programs should partner with local behavioral intervention experts or STD prevention training centers.

IDENTIFICATION OF BEHAVIORS & CONTEXTS THAT PLACE INDIVIDUALS AND COMMUNITIES AT RISK (BC-2)

- STD prevention programs should consider using RECAP in the STD program to help determine prevention strategies.

PREVENTION INTERVENTION PLANNING (BC-5)

- Program managers should develop an appropriate plan for health communications interventions.
- STD prevention programs should develop behavioral and social surveillance systems appropriate for their communities.
- STD prevention programs should develop an appropriate plan for designing, implementing, and evaluating behavioral interventions based on local surveillance, demographic, and behavioral data within the community.
- Program managers must evaluate the outcome of behavioral interventions.
- Outcome measures should be linked with behavioral surveillance activities.

TYPES OF INTERVENTIONS (BC-10)

- Program managers should develop interventions based on a sound theoretical knowledge and should utilize interventions shown to be effective.
- Programs should collaborate with existing intervention programs such as TB and HIV, and with behavioral scientists as needed.
- Programs should have trained, quality staff and quality assurance procedures in place when implementing interventions.
- Programs should have an evaluation plan and results should be compared to established findings. Interventions developed at the local level should have a strong evaluation plan.

COMMUNITY AND INDIVIDUAL BEHAVIOR CHANGE INTERVENTIONS APPENDICES

Outbreak Response Plan Recommendations (OR-5)

- 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.

Areas of Special Emphasis Recommendations

CORRECTIONS (SE-1)

- Programs should assess the need for STD services in adult and juvenile correctional facilities.
- At a minimum, all programs should implement the following low intensity correctional activities (also listed in Appendix SE-2).
- Visit the facility to assess the need for STD services
- Meet regularly with corrections representatives
- Distribute STD Treatment Guidelines and other relevant guidelines to adult and juvenile facilities
- Provide referrals to the STD clinic for inmates being released
- Refine the surveillance system to capture jail-based morbidity

- Programs should consider developing special projects coordinator positions or specialized corrections positions.

ADOLESCENTS (SE-3)

- Programs should consider identifying a person to serve as "youth liaison" to prevention partners and to help develop and improve youth services.
- Programs should facilitate effective partnerships with agencies and organizations involved with youth.
- Programs should focus adolescent screening efforts on those at highest risk, e.g., youth in detention.
- Programs should train staff to counsel and educate adolescents.
- Programs should assess barriers for adolescents in seeking and accessing care.

MANAGED CARE (SE-3)

- STD prevention programs need to collaborate with state and national-level MCO groups to promote STD prevention and control (e.g., best practices guidelines in MCOs; develop local and other surveillance data on STDs; feasibility projects examining innovative strategies for capturing and reporting performance data, including the HEDIS chlamydia screening measure; outreach methods to attract populations at high-risk for STD screening; provide the range of partner services through partner elicitation through partner notification and management).

STD/HIV INTERACTION (SE-5)

- Programs should link STD diagnostic and treatment services with HIV counseling, testing, and treatment services.

SYPHILIS ELIMINATION (SE-6)

- STD prevention programs should identify a person to coordinate syphilis elimination activities.
- STD prevention programs should implement the national syphilis elimination plan.

OTHER HIGH-RISK POPULATIONS (SE-7)

- STD prevention programs should identify populations that include persons engaging in high-risk behaviors or persons with barriers to care and develop appropriate interventions.

AREAS OF SPECIAL EMPHASIS APPENDICES