Program Operations
Guidelines for STD Prevention

Medical and Laboratory Services

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 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 medical and laboratory services 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/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

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Medical and Laboratory Services

INTRODUCTION

High quality, accessible medical and laboratory services are essential elements in the prevention of sexually transmitted diseases within any community. While private providers, managed care agencies, and institutions such as emergency rooms and correctional facilities have become increasingly central to STD screening, diagnosis, and treatment services, categorical STD clinics remain an important source of accessible, affordable, and expert clinical care in most communities. With the integration of HIV testing, counseling, and treatment into routine STD care, the demand for services in STD clinics has increased. Therefore, it is important to examine all elements of clinic operation, from administration to the range and quality of services offered since they affect the ability of an STD clinic to play a crucial role in disease intervention. Though this chapter specifically addresses guidance for STD clinics in providing medical services, much of the information is relevant to any STD service provider or agency.

ACCESSIBILITY

The most common reasons given by clients for choosing an STD clinic for care are the availability of walk-in services or same-day appointments, lower cost of care, privacy or confidentiality concerns, convenience of the clinic's location, and expert care (Celum, 1997). Medical services at the public STD clinic should be low or no cost, confidential, and convenient to avoid the creation of barriers between the patient and the accessibility of services. It is important that the clinic be easily accessible by public transportation and the hours of operation should be varied and flexible to avoid long waiting times and turning patients away (Landry, 1996; Beilenson, 1995). This can be accomplished by evaluating waiting times and the number of patients turned away. To make services accessible, clinics should develop systems that provide walk-in services and same day appointments, remain open during lunchtime hours, provide services outside standard business hours (evening and Saturday services), and accommodate patients with immediate scheduling needs e.g., return visits and symptomatic patients, by operating at least three days a week. If a clinic is unable to provide services three days a week, a referral system should be in place so that persons needing immediate services can be accommodated. Expansion of clinical services, including the addition of evening hours, leads to an increase in overall clinic attendance and increased numbers of STD cases diagnosed (Lyttle, 1994; Hart, 1992). Despite convenient hours, outreach activities may be needed to access specific at-risk populations and should be strongly considered. For example, collaboration with a drug services program may be more likely to result in delivery of STD services to clients (Coutinho, 1987; Van den Hoek, 1997). The general public should be able to easily determine how to obtain specialized STD services. This can be done through listing the clinic in the telephone directory and among frequently called numbers or under a heading that is readily understandable to patients through advertising in locations and through media utilized by high-risk populations, listing in community medical resource directories, and providing automated telephone services to provide information about clinic hours to after hours callers.

Recommendations

- 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

STD clinics should provide basic STD prevention services emphasizing the particular needs of the at- risk populations within the community. At a minimum, clinics should be able to diagnose and treat syphilis (all stages), gonorrhea, chlamydia, bacterial vaginosis, trichomoniasis, and candida. Ideally, clinics should also be able to diagnose and treat genital warts and genital herpes, vaccinate for viral hepatitis, and perform Pap smears and pregnancy tests. Other services such as integrating HIV-related services and family planning services into routine STD services may lengthen the clinic visit, but may also address important patient needs. Condoms and primary prevention counseling should be provided at all STD clinics to help in the prevention and control of disease. A procedure should be established to accord priority care to any patient referred by a DIS, receiving HIV prevention counseling, or returning for follow-up examinations with an appointment. STD programs should also be prepared to handle the increased volume of patients that may occur with any outbreaks (see the Outbreak Response Plan chapter for details).

Recommendations

- 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.

Recommendations, continued

- 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

The quality of the physical facility as well as the professional attitudes of staff influence a patient's impression of services. Distinct public health benefits can come from maintaining an aesthetically pleasing and professional environment. The environment should reinforce confidentiality and support health education directed toward positive behavior change.

Recommendations

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.

Recommendations, continued

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

Registration is a critical component of an efficient and successful clinic. A well-trained clerical staff and a well-organized clerical system expedite patient flow at this critical point. Registration personnel see patients first; therefore, they set the tone for the visit and must be aware of their role in influencing patient attitudes.

Clinical, counseling, or other services must never be denied because a patient is unable or declines to provide identification. Patient address and locating information should be updated at every visit in the event that follow-up is needed. When a substantial proportion of patients needing follow-up testing, treatment, or disease intervention services cannot be located because of false identities or addresses, the clinic should strongly consider other methods to insure follow-up, including a policy of requesting identification at registration. It may be useful to have a supervisor speak with patients who cannot provide identification

to explain the importance of obtaining accurate information for the purpose of follow-up. Clinics that offer anonymous HIV antibody counseling and testing should advertise a waiver of positive identification for persons seeking that service only.

Clinics should have some system of "fast-track" registration, such as assigning letters instead of numbers, for persons who have priority referrals or who re-visit. The DIS referred or "expected-in" file should be checked each time a person registers for STD services to ensure that persons who have been referred by a DIS for examination, or those who need repeat serologic testing or HIV counseling are identified and receive these services. The "expected- in" file contains a brief summary of treatment or other information on persons needing follow-up for disease intervention services. The file may include the following: persons with positive STD/HIV test results in need of treatment, persons referred either by the STD clinic or other facilities, sex partners or cluster suspects/associates of diagnosed patients, and persons who need special repeat testing. With the registration staff attaching the expected-in form to a medical chart, a clinician will have additional epidemiologic information and medical information needed to provide immediate and appropriate treatment.

Recommendations

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.

Recommendations, continued

- 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

Clinic flow should facilitate the effective use of personnel and physical facilities while preserving confidentiality, dignity, and excellent medical care. Clinics should routinely evaluate space and financial resources critical to providing adequate services. The sequence of services should be logical so that confusion or unnecessary delays for patients are avoided; emphasis should be placed on staff moving when necessary so that patients make as few moves as possible. Special stops (such as venipuncture or treatment) often become a bottleneck. They tend to compromise efficient clinic operation with delays for patients because of the need for specialized staff, separate rooms, and separate waiting areas. Individual clinicians can safely perform venipuncture in the examination room if they observe universal precautions. In any case, the initial patient visit should take no more than 1.5 hours from registration to treatment. (This does not include STD/HIV interview sessions, partner services, or special circumstances which will vary in length depending on the STD diagnosis and individual patient needs.)

Recommendations

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

The format, composition, and maintenance of medical records are crucial. Review of the medical records can determine whether the records are properly maintained and documented, as well as whether clinicians are consistently following established protocols, thus ensuring high quality care for patients. Clinics that provide testing, treatment, and other early intervention services for HIV infection will need to collect additional information. Additional information on medical records should include HIV risk assessment, drug use, relevant sexual history, contraceptive use, condom use, recent travel outside the U.S., hepatitis B vaccination history, whether counseling was provided, and plans for follow-up or referral. In areas of high HIV prevalence, additional information may be included such as history of tuberculosis (including exposure and infection).

It is important that medical records contain sufficient demographic information to identify and locate patients promptly and contain accurate information on symptoms, medical history, physical examination findings, laboratory tests, diagnoses, and treatment. Brief narrative descriptions should accompany items needing additional explanation or to document other relevant information.

Medical records contain important and confidential information. They should be stored in locked files or locked rooms that are easily accessible to clinic personnel but inaccessible to unauthorized persons. It is important that medical records that are related to cases being managed by DIS be readily accessible to the DIS. Medical records should be removed from desk tops and filed in locked desk or file drawers at the end of each day. Computerized medical records also need to have rigorous access protection procedures to prevent unauthorized entry into the file, as well as back-up filing to prevent the loss of information.

Recommendations

- 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.

Recommendations, continued

- 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 the request to view medical records.

CLINIC MANAGEMENT STRUCTURE

Clinics should have one person (usually the clinic manager) who has the authority to develop and implement clinic goals, policies, and procedures, as well as to manage personnel, orchestrate all clinic functions, and ensure quality of care. Delegation of clinic manager functions depends on clinic resources, staffing, and space. Working as part of the clinic management team, the medical director supports and complements the efforts of the clinic manager by carrying out a number of special medical duties. The interrelationship between management staff members (clinic manager, medical director, laboratory director, DIS supervisor, and other supervisory staff members) is critical to accomplishing STD prevention program objectives.

Clinic Manager

At a minimum, job qualifications for clinic manager should include: 1) adequate medical knowledge to make valid comparisons between observed clinician performance and clinic protocols, 2) specialized STD training (see Clinician Performance Standards), 3) clinic management training, 4) public health experience or an orientation toward STD intervention concepts and activities to understand the needs of DIS supervisors and staff, and 5) understanding of standard laboratory procedures and methods to coordinate clinical and laboratory functions effectively.

The clinic manager needs to have the necessary training and authority to carry out various personnel management responsibilities. These include: 1) development of accurate job descriptions and reasonable performance standards for clinicians, 2) providing staff orientation, familiarity with work plans, and knowledge of performance expectations, 3) arranging for adequate staffing to care for the patient population (even when vacations are scheduled), and assuring staff training and updates in STD patient management and universal precautions.

The clinic manager also ensures that 1) clinic policies and procedures for all aspects of clinic operations are developed, implemented, and updated, 2) the clinic manual is current and accessible to all employees, visiting clinicians, and clinicians-in-training, 3) information is communicated to all staff through regular staff meetings and that staff members are encouraged to make suggestions about policies, 4) standard blood and body fluid precautions are observed by all personnel, 5) patient flow is optimal including developing policies for triage, quality assurance procedures for the clinical aspects are implemented and maintained, 7) the clinic facility, including equipment and supplies, is adequate for the patient population, 8) that appropriate medical oversight is available as needed, 9) quality assurance functions related to clinic operations are performed at regular intervals and the results are used to modify operations manuals .

Medical Director

The responsibilities of the medical director include: 1) ensuring the best use of non-physician providers within the limits of state and local regulation, 2) signing standing orders for non-physician clinicians and acting as the final authority on medical care in the clinic, 3) being available, or arranging for other physician coverage in the director's absence, for consultation with non-physician clinicians during all clinic hours, 4) identifying and assisting with the training of clinicians to improve clinical practice and learn new techniques, 5) assisting the clinic manager in clinician performance evaluations by observation and chart reviews, 6) assuring that clinic manuals are up-to-date and appropriately used by the clinic manager to guide clinic activities, 7) routine auditing of medical records to ensure quality clinical care and that clinic protocols are followed, 8) ensuring that the quality assurance committee's recommendations concerning medical care are implemented, 9) seeing patients in the STD clinic on a routine basis.

Recommendations

- 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

Clinic manuals should include all policies and procedures that relate to the operation of the clinic. This should include personnel policies and medical protocols that are followed in the local area, as well as any emergency or injury protocols. 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). Standing orders are the signed instructions of a licensed physician which outline the medical assessment, appropriate testing, and treatment that a clinician may perform or deliver on behalf of the physician. In some states, non-physicians are authorized to perform assessments and prescribe medications independently. Standing orders also serve to standardize the clinical care practiced by all clinicians.

Recommendations

Personnel Policies

- A 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;

Recommendations, continued

  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

The use of non-physician clinicians is critical to STD medical management. Non-physician clinicians can manage most STDs and can provide HIV prevention counseling. Nursing and physician assistant roles should not be limited to history taking, assisting physicians, and dispensing medication. Having a single clinician manage each patient lessens the patient's sense of fragmentation and impersonal interaction; it also improves patient flow and patient satisfaction. Patients' perceptions and experiences during the examination can influence their willingness to comply with staff instructions at any step in the process. The extent to which various categories of non-physicians can function as clinicians is defined in medical practice statutes and legal precedent in each state or locality. Clinicians who perform HIV prevention counseling or partner services should receive specific skill training and should be evaluated regularly in those skills.

At a minimum a clinician must have the appropriate licensure or credentials required by the state or locality. New clinicians should have a preceptorship before caring for patients independently. Specific training for clinicians inexperienced in STD examinations should include completion of the Comprehensive or Intensive STD Clinician Course at a STD/HIV Prevention/Training Center or a similar course; completion of an AIDS Update Course, or equivalent, that includes clinical and epidemiologic information about HIV infection; a course in HIV client centered counseling, if this service is a clinical care responsibility; and certification or special training in Mantoux skin testing for tuberculosis (when testing is provided in the clinic).

The manner in which clinicians relate to patients, especially in a STD clinic, is critical to patient acceptance and follow through on treatment, behavioral intervention, and prevention of transmission to others. Clinicians should present an image of sensitivity and competence to the patient. The importance of good interviewing, counseling, and education skills on the part of the clinician cannot be overstated. All relevant medical history, risk assessment, examination, diagnosis, and treatment should be accurate and noted in the medical record. Counseling messages should be specific, clear, and allow the patient time to ask questions. Clinicians should strictly adhere to standard (formerly known as universal blood and body fluid standards) precautions. Clinicians should facilitate a seamless transfer of the case to other team members such as DIS when appropriate.

Recommendations

- 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

Standard Precautions are a set of protocols designed to reduce the risk of (or prevent) transmission of pathogens. Standard precautions synthesize the major features of Universal (Blood and Body Fluid) Precautions (designed to reduce the risk of transmission of bloodborne pathogens) and Body Substance Isolation (designed to reduce the risk of transmission of pathogens from moist body substances). Under standard precautions blood, all body fluids, and all body substances of patients are considered potentially infectious (CDC, 1997).

Standard precautions should be observed by all clinical personnel for all patients as part of routine infection control. Clinicians, laboratory technicians, phlebotomists, and other health care professionals routinely come into contact with blood and body fluids during the course of examination and testing. Blood is the single most important source of infection with HIV

and viral hepatitis in the workplace. The potential for hepatitis transmission in the clinic is greater than for HIV. Health care workers should be particularly alert to the need for preventing tuberculosis transmission in settings in which persons with HIV infection receive care.

Federal regulations on preventing the spread of bloodborne pathogens are contained in the final rule (Department of Labor, Occupational Safety and Health Administration, Occupational exposure to bloodborne pathogens; final rule (29 CER 1910.1030) Federal Register, pp. 64004-64182, Dec. 6, 1991.) These regulations, which took effect on March 6, 1992, outline in detail what employees must be taught about the hazards of working with potentially infectious materials and what precautions must be taken to prevent or minimize exposure to such materials. The regulations are summarized below.

- Every employer is required to have a written exposure control plan designed to eliminate or minimize worker exposure. The document must include all job classifications and job tasks in that place of employment that could lead to occupational exposure and the names of workers at risk for exposure to infectious materials. The written exposure control plan must have a record keeping element that includes a training records section and a medical records section.
- Training records must include the date, content outline, trainer's name and qualifications, and names and job titles of all persons attending the training sessions.
- A medical record must be established for each employee with occupational exposure. This record is confidential and separate from other personnel records. The medical record contains the employee's name, social security number, hepatitis B vaccination status, including the dates of vaccination and the written opinion of the health care professional regarding the Hepatitis B vaccination. If an occupational exposure occurs, reports are added to the medical record to document the incident and the results of testing following the incident.
- Any employee whose job requires contact with blood or other body fluids must receive free biosafety training during working hours, followed by annual refresher courses.
- All workers to whom standard precautions apply should be offered and should strongly consider receiving hepatitis B vaccine.
- Each clinic in which persons with HIV infection receive care should have a policy for Mantoux tuberculin skin testing of all health care facility workers (not just those interacting with patients). A baseline skin test administered within 2 weeks of employment and a follow-up based on the prevalence of tuberculosis in the patient population and community is suggested.

Recommendations

- 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.

Recommendations, continued

- 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

STD clinics should be prepared for medical emergencies, particularly life-threatening drug reactions of patients and occupational exposures that may place health care workers at risk for acquiring any bloodborne infections, including HIV. Each clinic should have established procedures, adequate and properly maintained equipment, and appropriately trained staff. Each clinic should have a written protocol for prompt reporting, evaluation, counseling, treatment, and follow up of occupational exposures (CDC, 1998).

Recommendations

- 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.

Recommendations, continued

- 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

An on-site laboratory prepared to perform immediate (stat), high quality testing to assist with the diagnosis of various STDs is an indispensable component of any STD clinic. Results of stat tests should be given to the patient during the clinic visit. Links should be established or maintained with reference laboratories for nonroutine or special testing to provide comprehensive coverage for clinical services. For information on commonly used stat tests, see Appendices ML-B through ML-E. All laboratories must comply with state and federal regulations governing diagnostic testing. 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 (see Appendix ML-A).

The use of point-of-care tests can have significant treatment and economic benefit in populations in which follow-up treatment rates are relatively low. How much benefit they have relative to the use of other tests depends upon their performance characteristics

and cost, and the notification and treatment rates that would occur if other tests were used.

Some laboratories take advantage of the relative performance simplicity of the point-of-care tests and "batch" tests from individual patients together, performing them after the patient has left. The performance characteristics of point-of-care tests are often not as good as other tests, lessening their comparative advantage. In such instances as these, use of the tests is justified only when positive results are available to permit diagnosis of patients at the time of their visit.

Clinic laboratorians should have access to a brightfield microscope. In addition, laboratorians in those clinics where rapid syphilis diagnosis is important, should have available at least one darkfield microscope, or the ability to convert a brightfield microscope for use as a darkfield microscope. There is a need for additional darkfield microscopes in areas with greater prevalence of genital ulcer disease.

Recommendations

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.

Recommendations, continued

- 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

Recommendations, continued

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)
  3. 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]

Recommendations, continued

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

LABORATORIAN ROLES AND PERFORMANCE STANDARDS

Quality stat laboratory testing by trained personnel contributes to rapid diagnosis and efficient clinic flow. Laboratory testing is inherently amenable to objective, continuing methods of quality assurance. Federal regulations stipulate the professional training needed to conduct laboratory tests. The employment of personnel failing to meet the professional training requirements mandated by federal regulations governing diagnostic testing may place persons and facilities in jeopardy of legal prosecution.

Recommendations

- 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

Biosafety levels consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed, the hazard posed by the infectious agents, and for the laboratory functions or activities. STD stat laboratories fall under Biosafety Level 2. This means that the laboratory is suitable for work involving agents of moderate potential hazard to personnel and the environment, laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists, access to the laboratory is limited when work is being conducted, extreme precautions are taken with contaminated sharp items, and procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

Recommendations

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.

Recommendations, continued

- 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.

Recommendations, continued

- 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.

Recommendations, continued

- 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

Basic stat laboratories should adhere to the recommended practices and techniques for a Biosafety Level 2 facility. The laboratory should be close to the examination rooms for easy access by clinicians who are transporting specimens; however, it should be separated from public areas and general offices where non-laboratory staff members require frequent access. Each facility should develop or adopt a biosafety manual. All staff responsible for performing laboratory testing should adhere to the recommended microbiological practices and follow approved procedures.

Protocols for transport and storage of specimens should be established and followed. For example, blood specimens should be delivered to the laboratory for processing at the earliest practical time, avoiding extended periods in a car or similar sitting where temperatures may become excessive. If blood specimens cannot be delivered to the laboratory on the day of collection they should be stored upright in the refrigerator. Do not freeze, as hemolysis may occur, ruining the specimen. For chlamydia testing, urine samples should be transported in an insulated transport container rack to restrict movement and spillage. Ice packs to maintain a cold atmosphere must be used in the transport container. If urine samples cannot be delivered to the laboratory on the day of collection, samples must be frozen and delivered, without being allowed to thaw, on the next day. Urine specimens stored at room temperature cannot be used for testing.

Recommendations

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.

Recommendations, continued

- 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

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) are federal minimum quality standards for all laboratory testing. On February 28, 1992, regulations implementing CLIA were published in the Federal Register, Vol. 57, No. 40, February 28, 1992, Rules and Regulations, pp. 7137-7288.

Tables summarizing the personnel requirements for moderate (including Provider Performed Microscopy) and high complexity laboratories are contained in Appendix ML-A, as well as instructions for obtaining a complete list of categorized test systems, a list of waived test systems from the Internet, and a brief history of CLIA. Appendix ML-A also discusses the opportunity for an exemption to the certification requirements for limited public health testing.

Recommendations

- 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

Venipuncture skills are desired and very often required of STD staff, including Disease Intervention Specialists (DIS). Venipuncture is often performed to obtain a blood specimen for STD/HIV testing. This is a safe procedure when performed correctly by individuals who have received proper training. Training and certification (if necessary) for proficiency in venipuncture is usually obtained by working with a licensed physician or other persons skilled in venipuncture. In many areas the STD staff may perform venipuncture only under a physician's standing order and must adhere to all the stipulations outlined in the standing order. Observation and practice is required to become skilled and self-confident in the art of venipuncture. Several of the STD/HIV Prevention Training Centers (PTCs) offer training in venipuncture techniques. Other opportunities for training include on-the-job, one-on-one training in a clinical practicum with a health care worker properly qualified to train and certify (if necessary), or local private providers who can be contractors (e.g., Red Cross, blood banks, community colleges). The training provider may be a city or county clinic or health department, state health department, local hospital, school of medical technology in a college or university, or a Red Cross training program. A sample training program is included in Appendix ML-F.

When performing venipuncture, the STD staff should always be aware that this procedure is being done under the legal authority of the local health officer. The staff must become familiar with the relevant legal authorities and adhere to the procedural requirements of the health department Laboratory Director. It is imperative that the staff exercise the utmost care and professional judgment in the application of venipuncture procedures. If a needle-stick injury occurs, the injured employee should immediately contact their supervisor and follow local health care worker occupational exposure policies (see section on emergency procedures). In addition, for Federal employees, immediate notification of the exposure should be provided to the CDC Office of Health and Safety.

Venipuncture in the field (field bloods) is most commonly performed by DIS on members of identified groups at high risk of syphilis and HIV infection; partners of known syphilis or HIV positive patients; associates of known syphilis patients (including cluster suspects); and previously examined persons for whom a physician desires another serologic test only. Each program area should determine their priorities for field bloods.

Professional judgement may compel the DIS to draw a blood specimen from an individual who clearly is in need of clinical evaluation or treatment. It would be prudent for the DIS to extract a specimen when the opportunity presents itself, if it appears the individual is deemed unreliable or expresses reluctance to accept medical services. Such applications of field venipuncture must be considered judiciously and in context with local policies. When these situations arise, the DIS must report such activities to the supervisor at the earliest opportunity.

Recommendations

- 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.

Recommendations, continued

- 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

The work performed by disease intervention specialists (DIS) is essential to the successful operation of a STD clinic. DIS reinforce the education and counseling messages provided by the STD clinician during the examination. More importantly, they interview and counsel patients and perform investigations to locate people who may be at risk for STD and refer them for examination, treatment, and counseling (see the chapter on partner services for more detail on DIS activities outside the clinic). It is appropriate for the DIS to offer a full range of intervention services in a single session rather than ask a patient to repeat the same information to several people. Because STD-related information is sensitive, the patient's transition between clinical care and the STD interview or HIV prevention counseling session must be smooth and appear to be natural extensions of each other.

Recommendations

- 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

Quality assurance activities and programs within clinics are important functions that ensure a minimal standard of acceptable clinical care, clinic management, and clinic operations. A well designed quality assurance program provides opportunity for clinic personnel from diverse areas to interact in the process of objectively reviewing clinical, management, and operations outcomes. The results of quality assurance activities should be used to modify clinic policy and procedures in an effort to improve clinical care, clinic management, and/or clinic operations.

Recommendations

- 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

Morbidity

Epidemiologic surveillance is the continuing and systematic collection, analysis, and interpretation of health data in the process of describing and monitoring a health event. Surveillance reporting permits a program to fulfill its mandated function of informing the public about a health problem, and facilitates basic program planning, implementation, and evaluation to determine public health action. State law specifies which diseases to report and which practitioner or facility is responsible for reporting diseases and situations (e.g., child abuse) to the official state agency. Reportable STDs mandated by state laws and included in federal and other voluntary surveillance systems usually include cases of gonorrhea, chlamydia, syphilis, chancroid, lymphogranuloma venereum, and granuloma inguinale. Some states also require reporting of HIV, PID, or genital herpes. Uniform STD surveillance case definitions are vital to the management of disease prevention programs. Case definitions may differ from diagnostic criteria meant to assist the clinician in arriving at a certainty of diagnosis for a given patient and disease. (See Surveillance and Data Management for further information.)

Sexual Abuse and Assault

The management of STDs in children and the suspected sexual abuse of children requires close cooperation between clinic personnel and child protection authorities. Some diseases, such as gonorrhea and syphilis are virtually 100% indicative of sexual contact if diagnosed in children after the neonatal period. The association of other STDs in children and the occurrence of child sexual abuse is not definitive. Most STD clinic personnel lack experience in the management of suspected child sexual abuse evaluations. Suspected victims of child sexual assault or abuse should be examined by a provider trained and/or certified to do such evaluations. Alternatively, suspected victims can be referred to an Emergency Department where trained clinicians are on call 24 hours/day. Clinic protocols should address referral policy and clinic staff should facilitate a referral, if necessary, in a manner that minimizes the victim's discomfort and anxiety.

Domestic Violence

The US Department of Justice estimates that 55% of women are raped and/or physically assaulted during their lifetime.(U.S. Department of Justice, 1998) Overall, estimates of numbers of women who experience abuse annually in the United States range from 8 to 12 percent. (Wilt, 1996) Many believe that these estimates are low. Victims and their abusers, more often than not, know each other and frequently live in the same household. The term domestic violence generally refers to violence and abuse within the home but also includes violence and/or abuse between people who know each other regardless of where the abusive event(s) takes place. Physical violence and abuse is only one method that an abuser may utilize to maintain control over the victim. Other abuse tactics include emotional and verbal abuse, isolation, and threats and intimidation. (U. S. Department of Justice, Website) Risk factors for domestic violence and abuse, such as young age, and drug and alcohol abuse are frequently the same as those for having a STD. This suggests, at least, that screening for domestic violence and abuse in venues where there is screening and treatment for STDs would lead to the identification of intervention opportunities for what is a universal health care problem.

The federal Violence Against Women Act, passed as part of the Violent Crime Control Law Enforcement Act of 1994, established the National Domestic Violence Hotline. This nationwide, toll free hotline serves victims of domestic violence by providing local referral information. The hotline can be reached by dialing 1-800-799-SAFE or 1- 800-787-3224 (TDD).

A Community Checklist: Important Steps to End Violence Against Women, (Department of Justice, 1995) identified several strategies that health care professionals can employ to intervene effectively into the problem of domestic violence in their communities and amongst their clients. These include:

- Incorporate Training into Curricula
- Make Resources Available to Patients
- Support Incorporation of Protocols into Accreditation Process
- Encourage Continuing Education on Violence Against Women Issues
- Involve Medical Organizations and Societies in Increasing Awareness
- Feature Violence Against Women on Meeting Agendas
- Highlight Commitment to Violence Against Women Issues
- Develop a Standard Intake Form
- Ensure Employee Assistance Programs are Responsive to Victims of Domestic Violence
- Volunteer in Community Organizations That Serve Victims of Domestic and Sexual Violence

Recommendations

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.

Recommendations, continued

- 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.

SCREENING

Because many sexually-transmitted diseases are asymptomatic, seeking care when symptoms occur is unlikely to lead to detection of most infections. Therefore, screening is critical for early detection and treatment. Although persons with STDs may not specifically seek infection-related treatment services, they do visit several health care settings for other purposes. These visits are an opportunity to diagnose and treat STDs. Examples of healthcare settings in which this screening can take place are family planning clinics, prenatal clinics, emergency rooms and walk-in clinics, community and migrant-worker health centers, clinics for adolescents, school-based clinics, clinics in correctional facilities, and primary-care provider offices.

Screening criteria have been defined in national guidelines. But, in the absence of well-defined screening criteria, prevalence of infections should be assessed in clinical settings that serve people who are potentially at risk. In populations where the prevalence is high (i.e., >2%), routine screening should be implemented. Previously described examples of populations at risk are people who abuse illicit drugs, who have more than one sex partner per year, who are entering correctional facilities, and who live in communities with high rates of STDs. Determination of risk should also take into account the prevalence of HIV infection in the population being considered.

Early detection and treatment of STDs among HIV-infected persons can be effective and cost-beneficial in reducing HIV transmission for three reasons: most STDs promote increased shedding of HIV (Cohen, 1997); the number of HIV-infected persons is smaller than the number of persons at risk for becoming infected; and HIV-infected persons often receive regular medical care. All HIV-infected persons who are having unprotected sex should be screened for other sexually-transmitted infections, including gonorrhea, chlamydial infection, syphilis, and trichomoniasis. Persons with HIV/AIDS should be assessed for genital herpes, informed about the symptoms of herpes, and counseled particularly to avoid sex during periods with symptoms of reactivation of genital herpes, which are associated with higher rates of HIV viral shedding (Schacker, 1998). Sexually active, HIV-infected persons should be screened annually. If the person's risk behavior, risk behavior of the person's partner(s), and the incidence of STDs in the local population place the HIV-infected person at greater risk for another sexually-transmitted infection, screening should occur more frequently.

Guidelines for screening for the major sexually-transmitted pathogens and for screening specific population groups (e.g., adolescents) have been recently published (U.S. Preventive Task Force, 1996; American Medical Association, 1992). The Advisory Committee for HIV and STD Prevention endorses these existing screening guidelines and extends them to include the following recommendations:

- All sexually active females less than 25 years old who visit a health care provider for any reason should be screened for chlamydia and gonorrhea at least once per year, unless screening in that setting has been documented to yield a low prevalence of infection (i.e., <2% using sensitive tests).
- All young, sexually active men should be screened

routinely for chlamydial and gonococcal infections in an acceptable fashion which may include using urine as a specimen for screening.

- Older males and females at risk because of their behavior should be screened for chlamydial infection and gonorrhea at least once per year when visiting health care providers for any reason.
- Serologic screening for syphilis should be conducted in all persons at risk (e.g., persons who exchange sex for money or drugs, persons with multiple sex partners or partners who have exchanged sex for money or drugs, persons admitted to jails, and users of illicit drugs).
- Sexually active, HIV-infected persons should be screened at least annually for STDs.

Appendix ML–A

CLIA

CLIA Background

CLIA has categorized more than 150,000 test systems based on the complexity of their method. The three test categories are: 1) waived complexity; 2) moderate complexity, with a subcategory of provider performed microscopy; and 3) high complexity. Criteria for classification into these levels include (1) degree of knowledge needed to perform the test; (2) training and experience required; (3) complexity of reagent and materials preparation; (4) characteristics of operational steps; (5) characteristics and availability of calibration, quality control, and proficiency testing materials; (6) troubleshooting and maintenance required; and (7) degree of interpretation and judgement required in the testing process.

The subcategory of Moderate Complexity, Provider Performed Microscopy (PPM), was created in 1993 and includes the following microscopic tests:

- all direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements;
- all potassium hydroxide (KOH) preparations;
- pinworm examinations, fern tests, post-coital direct, qualitative examinations of vaginal or cervical mucous;
- urine sediment examinations;
- nasal smears for granulocytes;
- fecal leukocyte examinations; and
- qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

These are procedures limited to bright field or phase-contrast microscopy with unique characteristics that are not adequately addressed within the moderate complexity category. For example, specimens are labile and need to be examined immediately so the accuracy of the test results is not compromised. In addition, there are no recognized quality control procedures available for these tests. Initially, providers included only doctors of medicine, osteopathy, or podiatric medicine. The category was modified later to include dentists, nurse practitioners, nurse midwives, and physician assistants.

Some test systems have been waived or exempted from CLIA requirements. These tests are waived because they (1) have been approved by the Food and Drug Administration (FDA) for home use, (2) use methods that are so simple and accurate that the likelihood of erroneous results by the user is negligible, or (3) DHHS has determined they pose no unreasonable risk of harm to the patient, if performed incorrectly. Waived tests that may be used in STD include dipstick/tablet urinalysis, and urine pregnancy tests. In September, 1995, the Centers for Disease Control and Prevention proposed criteria to be used to determine whether test systems could be waived from CLIA requirements. Currently, requests for waiver are reviewed using these proposed waiver criteria.

Certification

Implementation and enforcement of the Clinical Laboratory Improvement Amendments (CLIA) are the responsibility of the Health Care Financing Administration (HCFA). Laboratories must first register, after which HCFA surveys the laboratory, issues a certificate of compliance, and collects the appropriate fees. As waived and PPM laboratories are not subject to routine inspections, they apply to HCFA directly for the certificate. Laboratories may be issued a certificate of accreditation by a HCFA-approved organization or HCFA-approved state program in lieu of HCFA certification. Under CLIA, HCFA is also responsible for establishing proficiency testing programs, approving accreditation programs, and exempting state applications when indicated.

Exemption to Certification

It is generally accepted that CLIA regulations affect the staffing needed for STD clinic laboratories and who is allowed to perform certain tests, such as the Rapid Plasma Reagin Card Test for syphilis (RPR). In addition, fees collected by HCFA for certification have to be factored into the budgets of STD clinic laborato-

ries, as well as costs for enrollment in proficiency testing programs. Laboratories that obtain a certificate for moderate or high complexity testing must enroll in a proficiency testing program and pass proficiency testing for each certified speciality and subspeciality, e.g., syphilis serology. Each laboratory must establish and follow written quality control and quality assurance procedures to ensure accurate and reliable results and to monitor their testing process.

An exemption to this certification requirement is available for limited public health testing (LPHT). This exemption allows not-for-profit or federal, state, or local government laboratories at multiple sites to file a single application. This certificate provides administrative and financial relief because: (l) only one registration fee is required (rather than separate fees for each site); (2) the inspection fee is determined on the total test volume and specialities among all sites; (3) only one site must enroll in proficiency testing (although other sites must compare performance).

Thus, the LPHT reduces the costs of registration fees, training, proficiency testing, and personnel requirements. A number of states currently have programs in effect to help maintain STD laboratory testing by enrolling local public health laboratories in multiple site certificates operated by the state public health laboratory. In these states, the state laboratory director often serves as the laboratory director for all of the smaller public health laboratories. Necessary training is conducted in the state laboratory or at a regional location. All programs report that they perform at least one on-site visit per year for each LPHT laboratory. Because there has been up to 150 sites per certificate, concern has been raised about effective supervision of these laboratories.

CLIA '88 Test Categorization

As stated earlier, Test Categorization criteria are defined as (1) degree of knowledge needed to perform the test; (2) training and experience required; (3) complexity of reagent and materials preparation; (4) characteristics of operational steps; (5) characteristics and availability of calibration, quality control, and proficiency testing materials; (6) troubleshooting and maintenance required; and (7) degree of interpretation and judgement required in the testing process.

Test categorization is a continuing process. New products are categorized, and names of test system manufacturers change. The Test Categorization Database is updated monthly.

A current list of all categorized test systems is found on the Internet at:

www.phppo.cdc/dls/clia/

If you have questions regarding test systems on the test list or how to gain access to the list, please call (770) 488-8155.

CLIA '88 Personnel Requirements

The Clinical Laboratory Improvement Amendments (CLIA '88) have established standards for personnel, quality control, quality assurance, patient test management, and proficiency testing based on the complexity of the testing performed. The following table summarizes the personnel requirement for Moderate Complexity, including Provider Performed Microscopy (PPM), and High Complexity laboratories. Laboratories performing only waived testing do not have any personnel requirements.

Test Complexity Level and Personnel*	Education, Experience, and Training Requirements
Waived	**None**
Provider Performed Microscopy (PPM)	
Laboratory Director	• M.D., D.O., D.P.M., D.D.S., Nurse Midwife, Nurse Practitioner, Physician Assistant.
Testing Personnel	• M.D., D.O., D.P.M., D.D.S., Nurse Midwife, Nurse Practitioner, Physician Assistant.
Moderate Complexity	
Laboratory Director	• M.D. or D.O. certified in anatomic or clinical pathology or both or • M.D., D.O., D.P.M. and training consisting of 1 year directing or supervising non-waived lab testing or at least 20 CMEs in laboratory practice or lab training in medical residency equivalent to 20 CMEs or • Ph.D. and certification by board approved by HHS or 1 year directing or supervising non-waived lab testing or • Master's in Science plus 1 year laboratory training or experience or both and 1 year supervisory experience in non-waived testing or • Bachelor's in a Science plus 2 years laboratory training or experience or both and 2 years supervisory experience in non-waived testing or • Grandfather provisions.
Technical Consultant	• M.D. or D.O. certified in anatomic or clinical pathology or both or • M.D., D.O., D.P.M. and 1 year laboratory training or experience or both in non-waived testing or both in the designated specialty or subspeciality or • Ph.D. and 1 year of laboratory training or experience or both, in non-waived testing in the designated specialty or subspeciality or • Bachelor's in Science and 2 years laboratory training or experience or both in non-waived testing in the designated specialty or subspeciality.
Clinical Consultant	• Qualify as a Laboratory Director as stated above or • M.D., D.O., D.P.M.
Testing Personnel	• M.D., D.O., Ph.D., Master's or Bachelor's in Science or • Associate degree in Science or • High school graduate or GED and military trained or • High school graduate or GED and documentation of training appropriate for testing performed

CLIA, continued

Test Complexity Level and Personnel*	Education, Experience, and Training Requirements
High Complexity	
Laboratory Director	• M.D. or D.O. certified in anatomic or clinical pathology or both or • M.D., D.O., D.P.M. and 1 year of laboratory training during medical residency or 2 years experience directing or supervising high complexity testing or • Ph.D. and certification by board approved by HHS • Grandfather provisions.
Technical Supervisor	• M.D. or D.O. certified in anatomic or clinical pathology or both or • M.D., D.O., D.P.M. and at least 1 year of laboratory training or experience or both in high complexity testing of the specialty or subspeciality and for microbiology, a minimum 6 months experience in high complexity testing within the specialty is required or • Ph.D. and at least 1 year of laboratory training or experience or both in high complexity testing of the specialty or subspeciality and for microbiology, a minimum 6 months experience in high complexity testing within the subspeciality is required or • Master's in Science and at least 2 years of laboratory training or experience or both in high complexity testing of the specialty or subspeciality and for microbiology, a minimum 6 months experience in high complexity testing within the subspeciality is required or • Bachelor's in Science and at least 4 years of laboratory training or experience or both in high complexity testing of the specialty or subspeciality and for microbiology, a minimum 6 months experience in high complexity testing within the subspeciality is required.
Clinical Consultant	• Qualify as a Laboratory Director as stated above or • M.D., D.O., D.P.M.
General Supervisor	• Qualify as Laboratory Director or Technical Supervisor as stated above or • M.D., D.O., D.P.M., Ph.D., M.S., B.S., and at least 1 year of laboratory training or experience, or both, in high complexity testing or associate degree in laboratory science, or equivalent or • Grandfather provisions.
Testing Personnel	• M.D., D.O., D.P.M., Ph.D., M.S., B.S. or • A.S. or appropriate education and training (specified in 493.1489(b)(2)(ii)) or • High School graduate with accredited laboratory training or military training or • Grandfather provisions.
*Personnel also must possess a current license issued by the state if such licensing exists.	

Moderate Complexity level testing covers most of the stat STD tests requested routinely. Under professional training requirements for a laboratory holding a certificate for moderate complexity testing only, the director of the laboratory would need to meet the requirements listed above. The director also may serve as the technical consultant or as the clinical consultant and may perform testing. Other testing personnel would need to meet the training requirements listed above for moderate complexity testing. Appropriate training might be acquired on-the-job, through attendance at formal courses at one of the STD Prevention Training Centers, or through the National Laboratory Training Network, institutions of higher learning, state or regional laboratories (formal or informal), satellite video training sessions (distance learning), or use of computerized self-study training products.

Appendix ML–B

Commonly Used Stat Tests—Useful Tips
SALINE AND 10% KOH WET MOUNTS , VAGINAL PH

Test Principles

Vaginal secretions or exudates may be directly examined for the presence of yeast, *Trichomonas vaginalis*, or clue cells by using saline wet mounts (Stamm, 1988). KOH mounts are used to dissolve surrounding mucus or tissue for easier examination of specimens for yeast or fungal elements. In addition, a characteristic amine odor may be observed in patients with bacterial vaginosis and *T. vaginalis* when vaginal secretions are combined with 10% KOH. Vaginal pH greater than 4.5 also indicates presence of bacterial vaginosis or trichomoniasis.

Specimen Collection

Vaginal secretions and other appropriate specimens should be collected on a swab, which may be used for immediate examination. If the swab is placed in approximately 1 mL of sterile saline in a small test tube, this saline solution may be used for the wet prep and KOH prep. For determination of vaginal pH, touch pH paper to vaginal wall or to discharge in speculum. Avoid contact with cervical mucus because it has a high pH. Match pH paper to color scale to determine the pH value.

Procedure

1. Emulsify the specimen by immersing the end of the swab into the tube containing saline to make a heavy suspension.
2. Place specimen on a slide and cover with a coverslip carefully to avoid trapping air bubbles under the coverslip.
3. Examine the slide immediately for the presence of yeast, trichomonads, or clue cells. Scan first on low power with reduced light; Trichomonads can often be identified on low power. Switch to high power to check for the presence of yeast cells, pseudo hyphae, clue cells, or less vigorously motile trichomonads. A KOH prep may be needed to better examine for yeast in purulent specimens.
4. The KOH prep is made by placing the specimen on a slide, adding 10% KOH, and mixing with a wooden applicator or swab. Cover with a coverslip and avoid trapping air bubbles. Sniff for a "fishy" odor.
5. Use low power to scan for yeast and confirm on high power.

Examination of Slide and Interpretation of Results

1. Trichomonads are only seen in the saline prep; they are lysed (broken down) by KOH. They have ameboid properties, are generally ovoid, slightly larger than polymorphous nuclear leukocytes (PMNs), and in fresh preparations are recognized by their jerky, swaying movement. The presence of even one organism is diagnostic. Actively motile trichomonads are easily seen on low power. High power is necessary to detect less vigorously moving organisms when only the flagella or undulating membrane may be in motion. Numerous PMNs are often present.
2. Numerous "clue" cells and few or no PMNs are indicative of bacterial vaginosis. "Clue cells" are irregularly bordered squamous epithelial cells whose cell outlines are obliterated by sheets of small bacteria. "Clue" cells are seen in saline, not KOH preps.
3. Yeast may be obscured by epithelial cells in the saline wet mount, but pseudo hyphae and budding yeast cells are sometimes visible. PMNs may or may not be visible. In the KOH preparation, budding yeasts and pseudo hyphae are more easily seen because epithelial cells and PMNs have been lysed. Use low power to scan for yeasts and confirm on high power. Care should be taken in interpreting

apparent results; artifacts are common in KOH preps as a result of cell degeneration, air bubbles, crystallization, and glycerol.

Sources of Error

The following errors in technique will decrease the sensitivity of the wet mount for detection of *T. vaginalis:*

1. Collection of the specimen from the endocervix
2. The use of cool saline (saline should be at room temperature).
3. Delay in reading the smear
4. Contamination of the saline prep with KOH
5. Too much saline on the slide, causing the material to move rapidly across the field
6. Making a preparation too thick
7. Failure to read the slide with condenser lowered (too much light)
8. Examination of only a small area of the slide.

Appendix ML–C

Commonly Used Stat Tests—Useful Tips
GRAM STAIN FOR MICROORGANISMS

Test Principles

The Gram stain is the most commonly used stain in bacteriology. It is classified as a differential stain and serves to distinguish the gram-positive from the gram-negative bacteria. The original Gram stain technique has been modified a number of times, and the usual recommended procedure is the Hucker modification.

Although the Gram stain is among the least complicated and least time-consuming of all microbiological tests, the information that may be obtained from a properly stained smear of a specimen from a client is one of the most valuable aids to the clinician and the laboratorian. A properly performed stain can provide important diagnostic information concerning the type of organisms present, and the therapy to initiate while waiting for other test results. In the stat STD laboratory setting, the Gram stain is used to aid in the diagnosis of gonorrhea, candidal vulvovaginitis, and bacterial vaginosis, and in the assessment of urethritis, cervicitis, proctitis, and other infections characterized by infected discharges. Both the numbers of polymorphonuclear leukocytes (PMNs) and microbial flora present can be assessed (Stamm, 1988).

Specimen Collection

Male urethral smear
Patient should not urinate prior to specimen collection. Insert a small swab into the urethra.

Cervical smear
Wipe the cervix before collecting the specimen to reduce the amount of vaginal bacteria and cells in the smear.

Rectal smear
Use an anoscope to collect the specimen and sample areas containing pus.

Smear Preparation
To prepare a *direct smear* from a patient, roll swab with patient's specimen on a clean glass slide, making a thin spread; do not smear (leukocytes may be disrupted) or prepare a thin smear from a culture in a drop of water on the slide. Air dry the smear and fix to the glass by rapidly passing the slide through a Bunsen burner flame two or three times. The slide should be slightly warm to the skin on the back of the hand. Do not use swab from a DNA probe or Pap smear for a Gram stain.

Staining Schedule

1. Stain smears with crystal violet ammonium oxalate.
2. Wash in tap water.
3. Apply Gram's iodine solution.
4. Wash in tap water.
5. Decolorize with 95% ethyl alcohol until washes are no longer blue
6. Wash and shake off excess water.
7. Apply counterstain of safranin.
8. Wash in tap water and blot dry.

Examination of Slide and Interpretation of Results

1. Scan the stained smear with the 10X objective to locate the best area for viewing.
2. Examine the smear microscopically with the oil immersion objective.
3. Gram-positive organisms appear purple and gram-negative organisms appear red. Search for organisms and count PMNs. Cells and mucus should stain pink. Yeast stain purple. Bacteria are characterized as gram-positive (purple) or gram-negative (pink) and as cocci (round), bacilli (rod shaped), or coccobacilli (in between rods and cocci).

4. Control slides of representative gram-positive and gram-negative organisms should be examined each time Gram stains are performed.

Note: If using commercial kits or reagents, follow manufacturer's instructions in the product insert.

Sources of Error

1. Scrubbing, not rolling, the swab across the slide may destroy cellular morphology.
2. Failure to heat-fix the slide may cause material to wash off during staining.
3. Overheating the slide may cause artifacts to be stained and cells to be distorted.
4. Use of Gram's Iodine solution beyond expiration date (shelf life of reagent at room temperature is approximately 90 days).
5. Over-decolorizing the slide may cause gram-positive organisms to appear gram-negative.
6. Under-decolorizing the slide may cause gram-negative organisms to appear gram-positive.
7. Reagents contaminated with microorganisms may give erroneous results.

Appendix ML–D

Commonly Used Stat Tests—Useful Tips
EXAMINATION OF SPECIMENS BY DARKFIELD MICROSCOPY

Test Principles

A diagnosis of syphilis is confirmed by using darkfield microscopy to demonstrate *Treponema pallidum* in material from suspected lesions or regional lymph nodes (Creighton, 1990). A positive darkfield result is an almost certain diagnosis of primary, secondary, or early congenital syphilis. In primary syphilis, the darkfield examination may provide a means by which to identify the etiologic agent of syphilis and diagnose the disease before antibodies to *T. pallidum* can be detected.

Proper equipment and adequately trained personnel are required to demonstrate the presence of *T. pallidum* in lesion material by darkfield microscopy. The examination of several slides may be required.

Principles of Darkfield Microscopy

The standard brightfield microscope can be equipped for darkfield examination by replacing the brightfield condenser with a darkfield condenser. Illumination for darkfield microscopy is obtained when light rays strike the object in the field at such an oblique angle that no direct rays enter the microscope objective, only the rays reflected from the object. Therefore, the object appears self-luminous against a dark background, hence the term darkfield. When a fluid containing particles, including bacteria or treponemes, is placed on a slide, the oblique rays are reflected from the surfaces upward into the barrel of the microscope; these particles appear brightly illuminated against a black background.

Specimen Collection

Lesions in general

a. Remove any scab or crust covering the lesion.

b. Secondary infection exudate, if any, should be removed with a gauze sponge.

c. If necessary, compress the base of the lesion or apply a suction cup to the lesion to promote the accumulation of tissue fluid on the ulcer surface.

d. Apply a glass slide to the oozing lesion, or use a sterile bacteriological loop to transfer the fluid from the lesion to the glass slide. Three specimens should be collected from each lesion.

e. Place a cover glass on the specimen and flatten or depress it evenly on the slide, using the blunt end of an applicator stick to remove air bubbles.

f. Examine the slide immediately.

g. To prevent drying, place additional slides with specimens in a moist chamber, such as a large plastic petri dish containing a moistened paper towel.

The slide preparations should not contain a large volume of fluid (large volumes cause a rapid liquid flow across the field), nor should the preparation be so thin that it begins to dry before and adequate examination can be made.

Microscope adjustment should always be completed and the microscope should be in satisfactory working condition BEFORE collecting the patient's specimen for examination.

Procedure for adjustment of the microscope

1. Place a blank slide on the stage and raise the substage containing the darkfield condenser to its maximum height. The top of the darkfield condenser should be slightly below the level of the stage but as close to the glass slide as possible without pushing it up. Remove blank slide.

2. Turn on the variable transformer to produce maximum light intensity.

3. Lower the substage slightly and place immersion oil on the top of the condenser.

4. Place the slide with specimen (gingival scraping) on the stage and use the mechanical slide carrier to center the specimen over the condenser.

5. Slowly raise the substage until there is a complete oil contact between the top of the condenser and the bottom of the slide.

6. Rotate the nosepiece to center the low power objective over the specimen.
7. Bring the specimen into focus by using the coarse adjustment knob.
8. At this point, center the light in the field by rotating the two centering screws located at the base of the darkfield condenser.
9. Focus the darkfield condenser by slightly raising or lowering the substage until you observe the smallest diameter of the circular area of intense light.
10. Rotate the nosepiece until the high-dry objective is in place over the specimen.
11. Bring the specimen into focus by using the fine adjustment knob only.
12. If a satisfactory image is obtained, place a SMALL drop of immersion oil on the cover glass.
13. Rotate the nosepiece until the oil-immersion objective is in place over the specimen and is in contact with the oil on the cover glass. If the oil-immersion objective is equipped with an iris diaphragm, close the diaphragm to reduce the numerical aperture below that of the darkfield condenser. A funnel stop will serve the same purpose in an oil-immersion objective without an iris diaphragm.
14. Bring the specimen into focus by using the fine adjustment knob only. The light intensity from the illuminator may be decreased or increased slightly to give the best contrast.

Examination of the client's specimen for *T. pallidum*

1. Place the slide to be examined (client's specimen) on an adjusted darkfield microscope. Since minor adjustments may be required, it may be necessary to repeat steps already described.
2. Search the entire specimen methodically with the high-dry objective for spiral organisms that have the characteristic morphology and motility of *T. pallidum*. (*T. pallidum* is a thin, delicate, spiral organism, with 6- 20 (average 10) rigid, tightly wound coils, capable of extreme bending which occurs in the middle and is stiffly executed, snapping back to its original form, like the bending of a coil spring. The average organism is slightly longer than the diameter of a red blood cell. Coil appearance is maintained despite active motility of the organism. It may spin rapidly about the longitudinal axis (like a corkscrew) without any forward or backward movement, move slowly forward and backward without obvious change in direction of rotation or pitch of coils, or the organism may move slowly, threading its way corkscrew-fashion in viscous material. A spring-like rigidity is constant, and *T. pallidum* does not move rapidly from place to place with a serpentine motion. Any coarsely wound spiral organism exhibiting great flexion and rapid movement from place to place is NOT *T. pallidum*. Search carefully, systematically, and exhaustively before making a negative report. A typical systematic scheme for searching the specimen adequately is to start in the upper left corner of the cover glass area, traverse to the right edge of the cover glass, drop down slightly and traverse to the left; continue to search in this pattern, until the entire cover glass area has been searched.
3. At least 10 minutes should be spent on each of the three specimens collected before a negative report is rendered. The additional slides may be placed in a moist chamber (moistened paper towels placed in a Petri plate, for example) until examined.
4. Safety precautions should be followed, including gloves for the microscopist and proper biohazard discard containers for the disposal of slides.

Reporting and Interpretation of Results

Report	*Results*
Darkfield positive	Organisms that have the characteristic morphology and motility of *T. pallidum*
Darkfield negative (inconclusive)	No treponemal organisms or spiral organisms; no organisms with characteristic morphology and motility of *T. pallidum*
Darkfield unsatisfactory	No *T. pallidum* found, but specimen has too many refractile elements (blood cells, air bubbles, tissue fragments), or specimen is drying.

Every genital lesion should be considered syphilitic until proven otherwise. Extragenital lesions characterized by indolence (causing little or no pain), induration (firm or hard), and regional lymphadenopathy should be regarded as probably syphilitic. Failure to find the organism does not exclude a diagnosis of syphilis.

Negative results may mean that

1. The number of organisms was insufficient for detection.
2. The patient has received antitreponemal drugs locally or systemically.
3. The lesion is "fading" or approaching natural resolution or disappearance.
4. The lesion is one of late syphilis.
5. The lesion is not syphilitic.

Sources of Error

Preparation Errors

a. If the specimen contains too many blood cells, air bubbles, or tissue fragments, these refractile elements can obscure the presence of *T. pallidum*.

b. If the microscope slides are not of the proper thickness, or if slides and cover glasses are dirty or scratched, it will be difficult to obtain a good darkfield.

c. If there is excessive fluid in the specimen or too little fluid, the examination will be difficult.

Microscopy Errors

a. If immersion oil is not placed between the condenser and slide, no light will reach the specimen.

b. If the darkfield condenser is not properly centered or focused the illumination will not be optimum.

c. If immersion oil is on the lens of the low-power or high-power objectives, the resulting view will be hazy.

Interpretation Errors

a. If one is unfamiliar with the morphology and motility characteristics of *T. pallidum*, a false-positive or false- negative report could be issued.

b. If one mistakes nonspecific spiral organisms or objects, tissue debris, fibrin strands, and other extraneous objects for treponemes, a false-positive report could be issued.

c. If one sees occasional erratic movement of *T. pallidum* or no movement at all, too much time may have elapsed between making the slide and examining it.

Appendix ML–E

Commonly Used Stat Tests—Useful Tips
RPR CARD TEST

Test Principles

The rapid plasma reagin (RPR) 18-mm circle card test is a macroscopic, nontreponemal flocculation card test used to screen for syphilis (Creighton, 1990). The antigen is prepared from a modified Venereal Disease Research Laboratory (VDRL) antigen suspension containing choline chloride to eliminate the need for heat inactivation of serum, ethylenediaminetetraacetic acid (EDTA) to enhance the stability of the suspension, and finely divided charcoal particles as a visualizing agent. For the test, the RPR antigen is mixed with unheated or heated serum or with unheated plasma on a plastic-coated card. The RPR test measures antibodies to lipoidal material released from damaged host cells as well as to lipoprotein-like material, and possibly cardiolipin released from the treponemes. If antibodies are present, they combine with the lipid particles of the antigen, causing them to agglutinate or clump. The charcoal particles coagglutinate with the antibodies and show up as black clumps against the white card. If antibodies are not present, the test mixture is uniformly gray. Without some other evidence for the diagnosis of syphilis, a reactive nontreponemal test does not confirm *T. pallidum* infection.

Specimen Collection

Serum—Collect whole blood into a clean, dry tube without an anticoagulant.

Plasma—Collect blood in a tube containing EDTA as an anticoagulant. Completely fill the tube or collect blood until the vacuum in the collection tube has been exhausted.

Label each specimen with patient identifier, and date.

Procedure

Qualitative Test

1. To prepare antigen for testing, attach the hub of the dispensing needle to the fitting on the plastic dispensing bottle. Shake the antigen ampule to resuspend the particles. Open the ampule. Squeeze the dispensing bottle to collapse it. Insert the needle into the ampule and withdraw all the antigen suspension into the dispensing bottle.
2. Place serum or plasma onto a 18-mm circle of the RPR test card, using a disposable Dispenstir or a safety pipetting device.
3. Using the inverted Dispenstir (closed end) or flat toothpicks, spread the serum or plasma to fill the entire circle. Do not spread the specimen beyond the confines of the circle.
4. Gently shake the antigen dispensing bottle to resuspend the particles.
5. Holding the dispensing bottle and needle in a vertical position, dispense several drops to clear the needle of air. Then add antigen suspension to each circle containing serum or plasma. Do not mix.
6. Place the card on the mechanical rotator under a humidifying cover. Rotate the card.
7. Immediately remove the card from the rotator; briefly rotate and tilt the card by hand to aid in differentiating nonreactive from minimally reactive results.
8. Perform the quantitative test on serum specimens showing any degree of reactivity (clumping) or "roughness."

Reading and Reporting of Qualitative Results

1. Read the test reactions in the "wet" state under a high-intensity incandescent lamp. Read the test without magnification.
2. Report the results as follows:

Reading	*Report*
Characteristic clumping ranging from marked and intense (reactive) to slight but definite (minimally to moderately) reactive	Reactive (R)
Slight roughness or no clumping	Nonreactive (N)

Note: Only two reports with the RPR card test are possible: Reactive, no matter how much clumping, or Nonreactive.

Interpretation of Results

1. The RPR card test is an aid in the diagnosis of syphilis. Clinicians combine the RPR card test with results of other serologic tests, darkfield examinations, clinical signs and symptoms, and risk factors in arriving at a syphilis diagnosis. Without some other support for the diagnosis of syphilis, a reactive RPR card test is commonly unrelated to Treponema pallidum infection. The predictive value of a reactive RPR card test in a serologic diagnosis of syphilis is increased when combined with a reactive treponemal test, such as the fluorescent treponemal antibody absorption (FTA-ABS) test.
2. A reactive RPR card test may suggest past or present infection with a pathogenic treponeme; however, it may also be a false-positive reaction. False-positive reactions can result from laboratory error as well as serum antibodies unrelated to syphilis infection. Technical errors are detected by a nonreactive RPR card test with a second serum specimen. False-positive RPR card tests from infections with nontreponemal diseases or other disease conditions are identified by an accompanying nonreactive treponemal test.
3. A nonreactive RPR card test without clinical evidence of syphilis may suggest no current infection or an effectively treated infection. A nonreactive RPR card test with clinical evidence of syphilis can be seen in early primary syphilis; in secondary syphilis, as a result of the prozone reaction (see test limitations); and in some cases of late syphilis. A nonreactive RPR card test result does not rule out an incubating syphilis infection.
4. When the quantitative RPR card test is performed on patients with syphilis, a fourfold rise in titer on a repeat specimen may suggest an infection, a reinfection, or a treatment failure; a fourfold decrease in titer in early syphilis usually indicates adequate syphilis therapy.
5. All reactive qualitative RPR card tests should be diluted to an endpoint and the endpoint titer reported.

Sources of Error

1. If the temperatures of the sera, reagents, or testing area are less than 23%C (73%F), test reactivity decreases; if temperatures are greater than 29%C (85%F), test reactivity increases.
2. If the speed of the mechanical rotator is too fast or too slow, improper antigen-antibody interaction will cause unpredictable test results.
3. If the time of rotation is too long test reactivity may be increased, or if too short test reactivity may be decreased.
4. If the card is excessively rotated and tilted (to-and-fro motions) by hand after removal from the rotator, a false- reactive result may occur.
5. If lighting produces a glare on the card, the reactions may be obscured.

6. If the antigen is outdated or not adequately tested for standard reactivity, the results may be unpredictable.
7. If the serum is unevenly spread in the circle, the antigen and antibody may not mix properly.
8. If hemolyzed, contaminated, or improperly collected serum or plasma samples are tested, the reaction may be masked.
9. If the moistened humidifying cover is not used to cover tests as they are being rotated, proper humidity will not be maintained, and test components may dry on card, and false reactive results may occur.

Test Limitations

1. The RPR card test cannot be used to test spinal fluids.
2. A prozone reaction may be encountered occasionally. In a prozone reaction, complete or partial inhibition of reactivity occurs with undiluted serum (maximum reactivity is obtained only with diluted serum). The prozone phenomenon may be so pronounced that only a rough reading is produced in the qualitative test by a serum that will be strongly reactive when diluted. All test specimens producing any degree of roughness or reactivity with the RPR card test antigen in the qualitative test should be retested by using the quantitative procedure.
3. The RPR card test may be reactive in persons from countries where yaws, pinta or nonvenereal syphilis is endemic. Generally, residual titers from these infections will be no higher than 1:4.
4. Biological false-positive (BFP) reactions occur occasionally with cardiolipin antigens, mainly in specimens from persons who abuse drugs; who have diseases such as lupus erythematosus, mononucleosis, malaria, leprosy, or viral pneumonia; or who have recently been vaccinated.
5. Nontreponemal test titers of persons who have been treated in latent or late stages of syphilis or who have become reinfected do not decrease as rapidly as do those of the persons in the early stages of their first infection. In fact, these individuals may remain “serofast,” retaining a low-level reactive titer for life.

Appendix ML–F

VENIPUNCTURE

This appendix contains additional information on venipuncture that might be useful to a Program Manager in conducting venipuncture training. One element is a model training program which could be adapted to local areas. A second element is a list of equipment and supplies needed for training in venipuncture, which can also serve as a checklist for equipping a venipuncture kit for field activity. The third element is a Performance Evaluation Checklist with a step by step procedure guide to evaluate the performance of a trainee in venipuncture.

Suggested Components of a Venipuncture Training Program

Lecture

- Overview of Standard Precautions
- Basic anatomy and physiology of the blood supply
- Equipment and supplies
- Venipuncture technique
- Potential patient reactions to venipuncture and complications
- Interventions in caring for patient reactions and complications
- Preparation for practicum
- Evaluation

Practicum

- Venipuncture technique demonstration using training arm or student partner.
- Venipuncture technique experiences in clinic and field setting with preceptor.

Documentation

- Skills checklist (venipuncture performance evaluation)

Venipuncture Equipment List for Field Activity

Disease Intervention Specialists (DIS) should be able to draw blood in field settings as part of disease investigation or outreach activities. Appropriate equipment and supplies on hand to make up a fully-equipped venipuncture kit should include the following:

- disposable examination gloves
- eye protection
- container of alcohol sponges or cotton balls
- container of dry cotton balls
- bandages or Band-Aids
- vacutainer holder, vacutainer tubes, sterile needle, 20-22 gauge
- tourniquet (one-inch width preferred)
- laboratory specimen slips; container for blood specimens
- puncture-resistant container for used needles
- re-sealable plastic bag for other waste materials
- spirits of ammonia (inhalant)
- arm board (optional)
- small rubber bands
- small bottle of disinfectant or towelettes with disinfectant
- venipuncture identification card, if needed or available (need varies from state to state)

Technique for Procedure of Venipuncture

The complete technique of venipuncture is contained in manuals or guides published by state departments of health in a number of states, e.g., Texas, Washington, and California. An outline of the technique of venipuncture procedure is contained in the following Venipuncture Evaluation Checklist.

Venipuncture Performance Evaluation

Name _____ Date _____

Instructions:

1. Practice performing a venipuncture.
2. Demonstrate the procedure for performing a venipuncture satisfactorily for the instructor. All steps must be completed as listed on the instructor's Performance Check Sheet.

S=Satisfactory; U=Unsatisfactory

PROCEDURE	S	U	COMMENT
1. Wash hands with hand disin-fectant or soap and water, if available.			
2. Assemble equipment and materials. Place within easy reach.			
3. Identify patient properly.			
4. Explain venipuncture procedure to patient and position patient properly.			
5. Attach a sterile capped needle to vacutainer holder. Remove cap and position needle so that bevel faces upward. Inspect needle to see that point is smooth and sharp.			
6. Partially push vacutainer tube into needle in holder.			
7. Place the tourniquet around the patient's arm above the elbow. CAUTION: Do not allow the tourniquet to remain in place for more than one minute. Instruct the patient to open and close the hand three times, making a fist when closing the hand the third time.			
8. Inspect the bend of the elbow to locate a suitable vein. Palpate the vein with the finger tip(s) to determine the direction of the vein, to estimate its size and depth, and any tendency to roll.			
9. Cleanse the skin of the puncture site using a alcohol prep or cotton ball soaked with alcohol. Allow alcohol to dry.			
10. Hold the needle at a 30 degree angle to the arm and insert the needle into the vein. Push the collecting tube onto the needle in the vacutainer holder to fill the tube with blood. Watch for blood flow into the vacutainer tube.			
11. Instruct the patient to open the fist as soon as the vein has been entered.			
12. Release the tourniquet when the desired amount of blood is obtained.			

Venipuncture Performance Evaluation, continued

PROCEDURE	S	U	COMMENT
13. Place a dry cotton ball over the puncture site and withdraw the needle from the vein (do not press down on the needle). Instruct the patient to press the cotton ball over the wound for three to five minutes with arm extended upward.			
14. Adhere to Standard Precautions when disposing of all contaminated items including gloves, needles, vacutainer holder, cotton balls and other contaminated equipment. **Note:** Universal Precautions should be adhered to throughout procedure.			
15. Check patient to be sure that bleeding has stopped; apply band-aid if necessary.			
16. Clean work area with surface disinfectant.			
17. Wash hands with hand disinfectant or soap and water if available.			

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Website: http://www.ojp.usdoj.gov/vawo/manual/what.htm U.S. Department of Justice: Domestic violence...What is it?