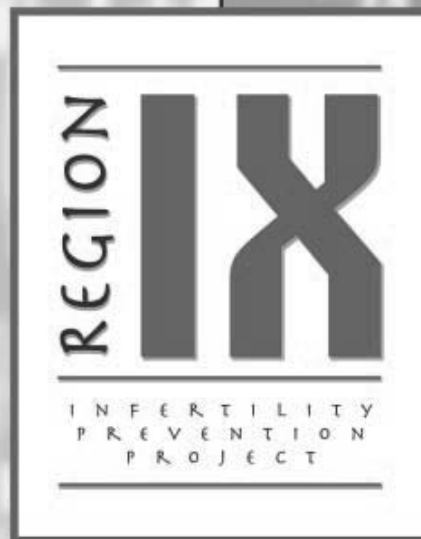


CHLAMYDIA CLINICAL GUIDELINES



Prepared by: The Region IX Infertility
Prevention Project Advisory Committee

February 2009

TABLE OF CONTENTS

TABLE OF CONTENTS	i
ACKNOWLEDGMENTS	v
I. INTRODUCTION	I-1
A. Overview of Project.....	I-1
B. Purpose of Protocols.....	I-2
C. Background Information.....	I-2
D. Overview of Clinical Guidelines.....	I-4
II. LABORATORY SERVICES	II-1
A. Testing Laboratories.....	II-1
B. Recommended Laboratory Test Methodologies for Screening for <i>C. trachomatis</i> Genitourinary Tract Infections.....	II-1
1. Screening Women.....	II-2
2. Screening Men.....	II-2
3. Predictive Value of a Test.....	II-3
4. Rapid Clinic-Based Tests.....	II-4
5. Additional Testing After a Positive Screening Test.....	II-4
6. Test of Cure.....	II-5
7. Re-Testing.....	II-5
C. Diagnostic Testing in Sexual Assault Cases in Adults and Adolescents.....	II-5
D. Specimen Collection and Preparation.....	II-6
E. Storage and Transport of Specimens.....	II-8
F. Test Procedures.....	II-9
G. Laboratory Request Forms.....	II-9
H. Public Health Reporting Regulations.....	II-9
I. Laboratory Reporting to Providers.....	II-10
J. Swab And Urine Specimen Results.....	II-10
K. Quality Assurance.....	II-11
L. Choosing a Quality Laboratory.....	II-11
M. Clinical Laboratory Improvement Amendment (CLIA).....	II-12
Table II. 2. Chlamydia Testing Technologies: Summary Tables ¹	II-13
III. HISTORY, RISK ASSESSMENT AND PHYSICAL EXAMINATION	III-1
A. Medical History and Risk Assessment.....	III-1
1. Medical History.....	III-1
2. Risk Assessment.....	III-2
B. Physical Examination.....	III-2
1. Female STD Examination.....	III-2
2. Male STD Examination.....	III-3
IV. CLINICAL PRESENTATION AND DIAGNOSIS	IV-1
A. Screening for Asymptomatic Chlamydial Infections.....	IV-1
1. Screening Criteria for Sexually Active Females.....	IV-1
2. Considerations for Sexually Active Males.....	IV-2
B. Testing for Symptomatic Chlamydial Infections.....	IV-2
C. Infections in Females.....	IV-2
1. Cervicitis.....	IV-2
2. Pelvic Inflammatory Disease (PID).....	IV-4
D. Infections in Males.....	IV-7
1. Urethritis.....	IV-7
2. Epididymitis.....	IV-9

V. TREATMENT OF CHLAMYDIAL INFECTIONS AND ASSOCIATED SYNDROMES

V-1

A. Treatment of Uncomplicated Chlamydial Infections	V-1
1. Non-pregnant Adolescents and Adults	V-1
2. Presumptive Treatment Criteria	V-2
3. Treatment Considerations During Pregnancy	V-2
4. Treatment Considerations for HIV-Infected Patients	V-3
5. Treatment of Gonorrhea and Chlamydia Co-infection, Non-Pregnant Patients/Clients	V-3
6. Treatment of Uncomplicated Genital and Rectal Gonorrhea in non-pregnant adults	V-4
7. Treatment of Pharyngeal Gonorrhea in non-pregnant adults	V-4
8. Gonorrhea Treatment – Pregnancy	V-4
B. Follow-up of patients/clients treated for uncomplicated chlamydia	V-5
C. Treatment of Cervicitis	V-5
1. Follow-up of Patients/Clients treated for Cervicitis	V-6
D. Treatment of Pelvic Inflammatory Disease (PID)	V-6
1. Oral Treatment	V-6
2. Alternative Oral Regimens	V-7
3. Parenteral Treatment: Hospitalization vs. Outpatient	V-8
4. Parenteral Treatment	V-8
5. Follow-up of Patients/Clients treated for PID	V-8
E. Treatment of Urethritis	V-9
1. Clinical and/or laboratory confirmation of urethritis	V-9
2. Follow-up of patients/clients treated for urethritis	V-9
3. Persistent Urethritis	V-10
F. Treatment of Epididymitis	V-10
1. Additional therapeutic recommendations:	V-10
2. Follow-up of patients/clients treated for epididymitis:	V-10

VI. FOLLOW-UP OF POSITIVE CHLAMYDIA TEST RESULTS VI-1

A. Positive Chlamydia Test Results	VI-1
1. Positive, Not Treated	VI-1
2. Positive, Treated Clients	VI-2
3. Medical Record Documentation	VI-2
4. Contacting Patient/Client by Telephone	VI-2
5. Contacting Patient/Client by Letter	VI-3

VII. CLINICIAN REPORTING PROCEDURES OF CHLAMYDIAL INFECTIONS... VII-1

A. Data to be reported	VII-1
B. State timelines for reporting	VII-1
C. Other Reporting Regulations:	VII-2

VIII. CLINIC STAFF EDUCATION AND TRAINING VIII-1

IX. PATIENT/CLIENT EDUCATION AND COUNSELING..... IX-1

A. General STD Information	IX-1
B. Chlamydia Positive or Presumptively Treated Patients/Clients	IX-1
C. Client-Centered Counseling and Risk Reduction Strategies	IX-2
D. Written Materials	IX-4

X. PARTNER IDENTIFICATION AND REFERRAL..... X-1

A. Critical Exposure Period (CEP)	X-1
B. Partner Identification	X-2
1. Importance of Partner Identification	X-2
2. Elicitation of Partner Names	X-3
C. Methods of Partner Referral	X-4

1. Patient or Client Self-Referral.....	X-4
2. Provider/Agency Referral	X-6
3. Health Department/STD Program Referral.....	X-7
D. Risk Reduction and Prevention Messages for Patients/Clients and Partners	X-7
XI. PARTNER ASSESSMENT AND TREATMENT	XI-1
A. Male Sex Partners	XI-1
B. Female Sex Partners of Males	XI-2
XII. OUTREACH ACTIVITIES	XII-1
A. Educational Outreach.....	XII-1
B. Street Outreach	XII-2
XIII. APPENDICES	XIII-5
Appendix A: Laboratory Test Selection	
Appendix B: Specimen Collection Instructions, by Test Method	
Appendix C: Descriptions of Chlamydia Testing Technologies	
Appendix D: Checklist for Laboratory Site Visit	
Appendix E: Patient-Administered Sexual History Questionnaire	
Appendix F: Sample Client Follow-Up Letter	
Appendix G: Sample Partner Referral Card	
Appendix H: Sample Partner Referral Letter	
Appendix I: <i>Guidance and Toolkit for the Use of Expedited Partner Therapy and Retesting at Three Months to Prevent and Detect Chlamydia and Gonorrhea Reinfections</i>	

ACKNOWLEDGMENTS

The *Region IX Infertility Prevention Project Chlamydia Clinical Guidelines, December 2003* were developed through a collaborative effort of Family Planning, STD and Laboratory representatives in Arizona, California, Hawaii, and Nevada. Funding for the development of this document was provided from the Centers for Disease Control, National Center for HIV, STD and TB Prevention in cooperation with the Office of Population Affairs, Office of Family Planning.

Revisions were made in October 2008 to reflect changes in treatment recommendations from the Centers for Disease Control in the *STD Treatment Guidelines, 2006* and the MMWR, April 13, 2007: *Update to the CDC's Sexually Transmitted Diseases Treatment Guidelines, 2006: Fluoroquinolones no longer recommended for treatment of gonococcal infections.*

Authors included: Heidi Bauer, M.D., M.S., M.P.H., Chief, Office of Medical & Scientific Affairs, California STD Control Branch; Gail Bolan, M.D., Chief, California STD Control Branch; Linda Creegan, F.N.P., Clinical Nurse Liaison, California STD Control Branch; Dennis Ferrero, M.P.H., Executive Director, California Association of Public Health Laboratories, Betty Foss, Retired Chief Technologist, Clark County Health District; Sally Liska, Dr.P.H., Director, San Francisco Public Health Laboratories.

Special thanks go to the Infertility Prevention Project Advisory Committee who provided input and reviewed the document during its development: Annette Amey, M.S., former Data Analyst, California Family Health Council; Melina Boudov, M.A., Project Coordinator, Los Angeles County STD Program; Monique Brammeier, Data Analyst, California STD Control Branch; Lei Chen, Ph.D., Epidemiologist, Washoe County Health District; Joan Chow, Dr.P.H., Epidemiologist, California STD Control Branch; Stacy Hardie, Washoe County Health District; Holly Howard, M.P.H., California IPP coordinator and Epidemiologist, California STD Control Branch; Kyle Bernstein, Surveillance/Research/Evaluation Coordinator, San Francisco STD Prevention & Control Section; Gail Kunimoto, Director, Hawaii State Public Health Laboratory; Stacie Hardie, M.S., R.N., Family Planning Director, Washoe County Health District; Jamie Miller, M.P.H., California STD Control Branch; Roy Ohye, Chief, Hawaii STD/HIV Prevention Program; Maryjane Puffer, Director, California Family Health Council; and Walter Penrada, Program Associate, Arizona Family Planning Council.

Support and production efforts provided by the Center for Health Training: Patricia A. Blackburn, President/CEO; Beatriz Reyes, Training Coordinator; David Herzstein Couch, Systems Administrator; and Shahasp Valentine, Graphic Design Artist.

I. INTRODUCTION

A. Overview of Project

In response to the serious health concern that *Chlamydia trachomatis* infections pose to the future of women's reproductive health, the Region IX Infertility Prevention Project (IPP) was established in 1994 in an effort to reduce the incidence of sexually transmitted disease (STD) and resulting medical complications that can cause infertility in women residing in the Region. Funded by the Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs, IPP activities occur in STD and family planning clinics and other sites throughout Arizona, California, Hawaii, Nevada, and the Pacific Territories.

At the project's initiation, a Regional Advisory Committee was formed by Family Planning, STD and Public Health Lab Directors, and Program Coordinators from throughout Region IX. The Regional Advisory Committee meets approximately twice a year to discuss and develop IPP policy and protocols. This committee governs the overall project and the project's management.

The Regional Advisory Committee and local IPP staff facilitate communication between federal, regional, state, county and local participants, and provide guidance in clinical standards for the detection and management of chlamydial infections. They assist with data collection and management necessary for program development and evaluation. In conjunction with the CA STD/HIV Prevention Training Center and the Region IX Family Planning Training Center (Center for Health Training), the Regional Advisory Committee also assists with provider training related to chlamydia prevention, screening, treatment, and partner follow-up.

The overall goal of the Region IX IPP is to assess and reduce the prevalence of chlamydial infection and associated complications in Region IX through increased education and training, targeted screening, timely and effective treatment, effective partner referral and treatment, and dissemination of chlamydia-related information to providers and policy makers.

Where appropriate to the goal of infertility prevention, gonorrhea-related activities are also pursued. Although project activities are principally targeted to women, activities relating to men are encouraged to prevent new and re-current infections in women.

For assistance with developing local partnerships with STD or family planning programs, optimizing chlamydia screening efforts, choosing partner management methods, developing outreach strategies and identifying and monitoring quality assurance and training issues please contact one of the following Infertility Prevention Project Coordinators:

- Arizona Family Planning Council: (602) 258-5777
- Arizona State Infertility Prevention Project Coordinator: (602) 364-4759

- California STD Control Program: (510) 620-3185 (IPP Coordinator), (510) 620-3718 (Epidemiology), (510) 620-3408 (Program development and evaluation)
- California Family Health Council: (213) 386-5614
- San Francisco STD Program: (415) 355-2010
- Los Angeles County STD Program: (213) 744-5956
- Hawaii Office of Family Planning: (808) 733-9030
- Hawaii STD/HIV Prevention Program: (808) 733-9287
- Nevada STD Program: (775) 684-5930
- Clark County Health District: (702) 383-1301
- Washoe County Health District: (775) 328-2444 (Family Planning), (775) 328-3759 (STD)
- Nevada Bureau of Community Health: (775) 684-5900
- Center for Health Training: (510) 835-3700, www.centerforhealthtraining.org
- CA STD/HIV Prevention Training Center: (510)625-6000, www.stdhivtraining.org

B. Purpose of Protocols

The Region IX IPP Chlamydia Clinical Guidelines and Protocols have been developed to guide health care providers in initiating, updating and maintaining chlamydia screening, treatment, and partner referral policies and procedures. The protocols have been designed to ensure that women at high risk for chlamydial infection and their sex partners are properly diagnosed and successfully treated.

C. Background Information

Chlamydia is the most prevalent bacterial sexually transmitted disease in the United States and the most common cause of preventable infertility. It is estimated that *Chlamydia trachomatis* is the causative agent of over five million cases of genital and neonatal infections annually. The increased availability of more affordable, cost-effective laboratory diagnostic tests for chlamydia has resulted in improved detection of this serious communicable disease. The primary risk factors for chlamydia are age (25 years of age and under) and unprotected sex. A history of multiple partners is another risk factor. Chlamydia has a variable incubation period of approximately 7-21 days or longer before the onset of symptoms. However, the vast majority of infections are asymptomatic and may persist for months. Infection may occur in the cervix, urethra, rectum, conjunctiva, or respiratory tract.

Chlamydial infections are among the common genital infections health care providers see in men. It has been estimated that *Chlamydia trachomatis* causes approximately 23-55% of reported cases of nongonococcal urethritis (NGU) among men. However, prevalence varies among age groups with lower prevalence found among older men, and the proportion of NGU caused by chlamydia has been declining gradually. NGU has an estimated incidence of at least 2.5 times that of gonococcal urethritis. Chlamydia is also responsible for approximately 50% of the estimated 500,000 cases of acute epididymitis seen each year in the United States.

Chlamydia trachomatis plays an important role in causing cervicitis, acute pelvic inflammatory disease (PID), and pre- and postpartum maternal and infant infections. Chlamydia accounts for one-quarter to one-half of the 1 million recognized cases of PID in the United States each year. These infections, in addition to sub-clinical *Chlamydia trachomatis* infections of the fallopian tube not clinically recognized as PID, contribute significantly to the increasing number of women who experience ectopic pregnancy or tubal factor infertility. Approximately 20% of women treated for PID will be infertile; another 18% will experience chronic pelvic pain resulting from the infection; and 6% will have an ectopic pregnancy.

Chlamydia also plays an important role in the acute urethral syndrome (dysuria-pyuria syndrome) and in perihepatitis (Fitz-Hugh-Curtis syndrome). Maternal chlamydial infection during pregnancy has been associated with preterm labor, premature rupture of membranes and postpartum endometritis.

Each year, more than 155,000 infants are born to chlamydia-infected mothers. Almost two-thirds of the infants born vaginally to chlamydia-infected mothers become infected during delivery. These newborns are at high risk for developing inclusion conjunctivitis and pneumonia. Chlamydia is the most common cause of neonatal eye infections and of afebrile interstitial pneumonia in infants less than six months of age.

Chlamydial infections are also associated with increased susceptibility to and infectiousness of HIV infections. Women and men infected with chlamydia or other STDs are three to five times more likely than non-infected individuals to acquire sexually transmitted HIV. Transmission of HIV is also facilitated by the presence of an STD such as chlamydia. An HIV-infected person who also is infected with an STD may be three to five times more likely to transmit HIV to another through unprotected sexual contact.

It is most important to recognize that the vast majority (70-90%) of chlamydial infections in women are asymptomatic as are a substantial proportion (at least 50%) in men. These infections remain undetected and untreated unless providers screen at-risk women and men. A recent study has shown that if the prevalence of chlamydia is at least 3% in a given population of women, (e.g., women <25 years), then annual screening of this group of women is cost-effective. Prevalence monitoring surveillance has indicated that women, less than 25 years of age, screened for chlamydia in family planning settings have a prevalence greater than 3%.

Enormous cost is associated with chlamydial infections. Chlamydial infections cost the U.S. health care system \$3 to \$4 billion annually. Much of this cost results from the management of women with PID and its complications and from the management of infants hospitalized with chlamydial pneumonia. This estimated cost does not reflect the human suffering experienced by those with chlamydial disease. The economic burden of chlamydial infections will continue to increase if these infections are not controlled. Screening programs can reduce the prevalence of chlamydial infection and complications in the individual and are cost-effective if the screening criteria are based on disease prevalence in the targeted population.

To reduce morbidity and subsequent complications associated with *Chlamydia trachomatis* infection in the United States, effective prevention and control strategies such as targeted screening and partner referral and treatment programs must be implemented.

D. Overview of Clinical Guidelines

The Region IX IPP Chlamydia Clinical Guidelines and Protocols are organized into twelve chapters and eight appendices. Following this introductory chapter, Chapter II. Laboratory Services describes the recommended laboratory test methodologies for chlamydia screening of women and men, including the predictive value of a test, additional testing after a positive test result, test of cure and re-screening. Testing in sexual assault cases is discussed. Next, specimen collection and preparation, including order of collection, are described, followed by specifications for the storage and transport of specimens. Appendix A describes seven factors to consider when choosing a specific chlamydia diagnostic test. Detailed specimen collection instructions are described in Appendix B and detailed descriptions of test procedures by method are included in Appendix C. A summary table of recommended test methodologies is included as Table II.2. The chapter continues with coverage of laboratory request forms and public health reporting regulations. Regional standards for laboratory reporting to providers are included. The chapter concludes with the components of quality assurance, factors to consider when choosing a quality laboratory, and the clinical laboratory improvement amendment (CLIA) requirements. A detailed laboratory site visit checklist is included in Appendix D.

Chapter III. History, Risk Assessment and Physical Examination provides an overview of how to take a medical history and perform a risk assessment and physical examination in the diagnosis of chlamydia and other related infections in both women and men. A sample patient-administered sexual history questionnaire is included in Appendix E.

Chapter IV. Clinical Presentation and Diagnosis provides information regarding the next step in diagnosing chlamydia and related infections. The chapter begins with general screening guidelines for females and males followed by the testing of symptomatic patients/clients. Specific infections common in females and males are characterized including their history, examination procedures, laboratory tests, and diagnostic criteria. Infections and syndromes covered include mucopurulent cervicitis (MPC) and pelvic inflammatory disease (PID) in females, and urethritis and epididymitis in males.

Chapter V. Treatment of Chlamydial Infections and Associated Syndromes provides detailed treatment regimens for both non-pregnant and pregnant adolescents and adults as well as information about presumptive treatment for chlamydia. Infections covered include chlamydia, MPC, PID, urethritis, and epididymitis, and gonorrhea. The treatment of gonorrhea and chlamydia co-infection is also discussed. The follow-up of treated patients/clients is discussed for each infection.

Chapter VI. Follow-up of Positive Chlamydia Test Results provides an overview of how to follow-up positive chlamydia test results with both treated and untreated patients/clients. Procedures for documenting medical records are included. The chapter concludes with information regarding contacting patients/clients by phone or letter. A

sample follow-up letter is included in Appendix F. Chapter VII. Clinician Reporting Procedures of Chlamydial Infections provides a brief overview of state reporting regulations in terms of what data should be reported and when. Information is included for the four states in Region IX.

Chapter VIII. Clinic Staff Education and Training lists what topics should be included in the training of staff as well as local resources for training throughout Region IX. Chapter IX. Patient/Client Education and Counseling provides a more detailed description of the specific general STD information that should be provided to all patients/clients offered a chlamydia test as well as what information should be provided to those with a positive test or presumptive diagnosis. Client-centered counseling and risk reduction strategies are described as are the necessity of providing written materials.

Chapter X. Partner Identification and Referral and Chapter XI. Partner Assessment and Treatment cover the treatment of sex partners of infected patients/clients. Chapter X begins with a description of the critical exposure period, provides the time frame for asking about sex partners for asymptomatic, symptomatic, and pregnant patients/clients. Partner identification is discussed including the importance of partner identification and how to elicit partner names. Three methods of partner referral are described including self-referral, provider/agency referral and health department/STD program referral. The importance of confidentiality is stressed. A sample partner referral card is included in Appendix G and a sample partner referral letter is included in Appendix H. The assessment and treatment of sex partners is outlined in Chapter XI.

The Clinical Guidelines conclude with a discussion of outreach activities in Chapter XII. Included are the specific topics that should be covered and settings in which outreach should occur. Peer-outreach services are discussed along with the role that family planning agencies and STD programs can play in outreach efforts.

II. LABORATORY SERVICES

Policy Statement: The Region IX Infertility Prevention Project Advisory Committee recommends that high quality CLIA approved laboratories be used to process sexually transmitted disease (STD) specimens to ensure that patients/clients receive accurate, cost-effective tests. Public health laboratories have the following qualities that make them a particularly good choice:

- Experience and expertise
- Strong communicable disease control mission
- Community-based focus
- Experience in public health data reporting
- Reliability and flexibility

A. Testing Laboratories

The Region IX Infertility Prevention Project is composed of STD and family planning programs in Arizona, California, Nevada, and Hawaii. Contact the Project Coordinator at the number listed below in each state for available testing laboratories.

- Arizona: (602) 364-4759
- California (other than Los Angeles): (510) 620-3185
- Los Angeles County: (213) 744-5956
- Nevada: (775) 684-5930
- Hawaii: (808) 733-9287
- San Francisco (415) 355-2010

B. Recommended Laboratory Test Methodologies for Screening for *C. trachomatis* Genitourinary Tract Infections

Because chlamydial infection often presents without symptoms, laboratory testing is vital to diagnosis and treatment. Furthermore, it is essential that health care providers choose a sensitive testing technology that maximizes accurate results (i.e., reduces the likelihood of false negative test results) for the target population to ensure the detection of asymptomatic infections. Using a test with high specificity ensures that the expense and potentially devastating psychosocial implications associated with false positive test results are reduced to a minimum.

In addition to sensitivity and specificity, there are several additional factors that are important to examine when determining the best test for a given population. (See Appendix A for a summary list of test selection considerations).

Citing MMWR, Volume 51, dated October 18, 2002, Screening Tests to Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections – 2002, the Region IX IPP Laboratory Sub-Committee recommends the following test methodologies, based on sensitivity and ease of specimen collection.

1. Screening Women

- a) Nucleic acid amplification tests are the most sensitive tests for detecting chlamydia in women. CT urogenital infection can be diagnosed by NAAT using urine or swab specimens collected from the endocervix or vagina. The sensitivity of NAATs by specimen source (urine, endocervix, and vagina) appears to be similar. The use of urine or self collected vaginal swabs allows expanded screening into non-traditional venues where pelvic examinations are not performed (e.g., schools, jails and detention centers, and street HIV or STD outreach programs).
- b) Although considerably less sensitive than NAATs non-amplified nucleic acid hybridization tests, EIAs, and DFA performed on an endocervical swab specimen are acceptable for screening. Use of these tests will depend on cost issues and number of false negative test results acceptable.

Performance of non-amplified nucleic acid hybridization tests, EIAs, and DFA depend on adequate specimen collection, including obtaining columnar cells. If non-NAATs are used, specimen adequacy quality assurance should be performed at least annually to minimize the number of false negative results.

Other than one EIA test cleared by FDA for *male* urine specimens, use of non-amplified nucleic acid hybridization tests, EIAs, and DFA with urine or vaginal swab specimens is not available.

- c) *C. trachomatis* culture performed on an endocervical swab specimen performs poorly when compared to NAATs for screening. Specificity of culture tests is high; however, sensitivity is less than for NAATs and variable because of technical complexity, lack of standardization, and the challenge of maintaining viable organisms.

2. Screening Men

- a) A NAAT for *C. trachomatis* performed on an intraurethral swab or urine specimen is the preferred test for men. NAATs performed on urine to detect *C. trachomatis* have distinct advantages over intraurethral swab specimens.
- b) A non-NAAT or culture for *C. trachomatis* performed on an intraurethral swab specimen, although less sensitive, is acceptable. Use of a non-NAAT will depend on cost issues and the number of false negative test results acceptable. The sensitivity of non-NAATs to detect *C. trachomatis* in urine from men is too low for them to be recommended for screening. Culture is the only method available for rectal or pharyngeal testing, however sensitivity is quite poor.
- c) Regarding MSM, NAATs for non-genital sites are not currently FDA approved. However, as the prevalence of rectal chlamydia and gonorrhea and pharyngeal gonorrhea is high amongst men reporting sex with other men, many laboratories are performing internal verifications to enable non-genital CT/GC screening. Reproducibility panels for such verifications are available.

If non-NAATs are used then specimen adequacy quality assurance should be performed at least annually to minimize the number of false negative results.

(For a summary of recommended laboratory test methodologies for chlamydia, see *Table II. 2. Chlamydia Testing Technologies: Summary Tables*, pages II-13-1)

3. Predictive Value of a Test

The predictive value of a test illustrates how probable it is that the result obtained in a certain prevalence population is the correct result. The predictive value of a positive test result (PPV) is the probability that a patient/client with a positive result actually has chlamydia. Conversely, the predictive value of a negative test result (NPV) is the probability that a patient/client with a negative test result is not infected. Test technologies with a specificity and sensitivity above 90% all give *negative* predictive values of approximately 99% or higher, in both low and high prevalence populations. The *positive* predictive value of a technology can vary dramatically, depending on the disease prevalence in a population (unless the specificity of the technology is 100%).

For example, it sounds impressive to say that technology “A” is 90% sensitive and 98% specific, but when these values are applied to different prevalence populations, the positive predictive values can vary from poor to good. Consider the following two examples of technology “A” applied to relatively low- and high- risk populations:

- In a fairly low-risk population (e.g., 2% disease prevalence), the predictive value of a positive result is 48% which means that only about 1 of every 2 positive results are correct (i.e., identify a patient/client who is truly infected).
- In a high-risk population (e.g., 10% disease prevalence), the predictive value of a positive result is 83%, which means that more than 4 out of 5 of the positive results are correct.

Table II. 1. Displays the proportion of positive chlamydia tests that are true positives (PPV) given varying levels of chlamydia prevalence and test specificity (based on a constant sensitivity of 90%.)

Table II. 1. Positive Predictive Value by Chlamydia Prevalence*

Specificity	Prevalence		
	2%	3%	10%
97.0%	38%	48%	77%
98.0%	48%	58%	83%
99.0%	65%	74%	91%
99.8%	90%	93%	98%

*based on 90% sensitivity

Numerous chlamydia test procedures are now available to the provider, but it is generally recognized that amplification tests provide better sensitivity and specificity, which translates to better predictive values, particularly in low-prevalence populations. The following table shows amplification technologies currently on the market. Other test technologies with lower specificity will result in more false positives in lower prevalence populations.

Technology	Test Name	Manufacturer
Polymerase Chain Reaction (PCR)	Amplicor Amplicor COBAS	Roche Diagnostics Systems
Transcription Mediated Amplification (TMA)	Amp-CT	Gen-Probe, Inc.
Target Capture with TMA	APTIMA Combo 2	Gen-Probe, Inc.
Strand Displacement Amplification (SDA)	BD ProbeTec ET	Becton Dickinson

4. Rapid Clinic-Based Tests

Rapid clinic-based tests for the detection of chlamydia (e.g., Clearview, ThermoBiostar OIA, Abbott TestPack), are ***not usually recommended*** in the clinical setting or for screening because their overall performance is inferior to currently available laboratory-based tests.

5. Additional Testing After a Positive Screening Test

As recommended in the MMWR, Volume 51, dated October 18, 2002, Screening Tests to Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections – 2002, all positive screening tests should be considered presumptive evidence of infection. It must be noted, however, that limited studies indicate repeat testing and possibly other strategies to improve results may not be warranted or cost-effective. Further work and analysis is currently being undertaken to clarify recommendations made in MMWR publication Screening Tests to Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections – 2002.

An additional test should be considered after a positive screening test if a false-positive screening test would result in substantial adverse medical, social, or psychological impact for a patient.

Approaches to additional testing, in order by theoretical consideration, after a positive screening test (as recommended in the 2002 MMWR publication cited above):

- Test a second specimen with a different test that uses a different target, antigen, or phenotype and a different format.
- Test the original specimen with a different test that uses a different target, antigen, or phenotype and a different format.
- Repeat the original test on the original specimen with a blocking antibody or competitive probe.
- Repeat the original test on the original specimen.

Appropriate test technologies for additional testing after a positive screening test (as recommended in the MMWR, Volume 51, dated October 18, 2002, Screening Tests

to Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections – 2002) are outlined below.

Positive Non-Nucleic Acid Amplification Tests (Hybridization probe, EIA, DFA (Non-NAAT):

- Culture with a *C. trachomatis*-specific anti-MOMP (major outer membrane protein) stain can be used after a positive non-NAAT because of the high specificity and the flexibility for additional testing, but culture poses increased difficulties in specimen transport and storage.
- Competitive probe and blocking antibody formats can be used after positive nucleic acid probe tests and enzyme immunoassays, respectively, but this approach is less likely, theoretically, to detect a false-positive result.
- A NAAT has high potential as an additional test after non-NAAT tests because of the increased sensitivity; however, this use of NAATs has received limited evaluation.

Positive NAAT:

- Only another NAAT has a sufficiently high sensitivity to serve as an additional test after a positive NAAT; however, such an approach to additional testing has received limited evaluation.

6. Test of Cure

- Non-pregnant patients do not need to be retested for chlamydia after completing treatment with a recommended or alternative regimen unless compliance is in question, symptoms persist or re-infection is suspected.
- Test of cure is recommended for pregnant women regardless of the treatment regimen because of efficacy concerns in pregnancy (see Chapter V).
- A test of cure should be performed 3-4 weeks after treatment. Caution should be used interpreting positive NAAT tests if collected less than 4 weeks after treatment due to continued presence of nucleic acid from dead organisms.

7. Re-Testing

Re-testing women and men 3 months following treatment is recommended as an effective strategy for detecting re-infection, which occurs in 10-25% of persons after an initial chlamydial infection.

C. Diagnostic Testing in Sexual Assault Cases in Adults and Adolescents

In the case of suspected sexual assault, cultures should be done for both *N. gonorrhoeae* and *C. trachomatis* from specimens collected from any sites of penetration or attempted penetration. Contact laboratory for guidance.

This is a complex issue. The MMWR, Volume 51, dated October 18, 2002 Screening Tests to Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Infections – 2002 offer the following general guidelines for testing specimens related to possible sexual assault or abuse.

- Endocervical specimens are appropriate for diagnosing *C. trachomatis* and *N. gonorrhoeae* infection of sexually active females. However, the immature vaginal epithelium of prepubescent females might be infected, and specimens can be taken from the vagina of these patients/clients.
- Culture is the recommended method for detecting *C. trachomatis* in urogenital, pharyngeal, and rectal specimens.
 - Only cell culture using standard methods that employ *C. trachomatis*-specific antibodies to detect intracytoplasmic inclusions should be used.
 - Nonculture/nonamplification tests for *C. trachomatis* are not sufficiently sensitive and specific for them to be used among either victims or alleged assailants implicated in a sexual assault.
 - Data, experience, and court cases are insufficient to assess the applicability of NAATs to detect *C. trachomatis* or *N. gonorrhoeae* in investigating sexual assault and abuse. However, certain researchers have indicated that NAATs for *C. trachomatis* could be used as an alternative to cell culture if cell culture is unavailable and if another NAAT that targets a different sequence can be performed as an additional test if the initial NAAT test is positive.

D. Specimen Collection and Preparation

(For detailed specimen collection instructions, by test method, see Appendix B.)

1. General Considerations:

- Columnar epithelial cells are the desired material for non-amplified test for *Chlamydia trachomatis* (CT) diagnosis, not polymorphonuclear (PMN) white blood cells, which are preferred for the diagnosis of gonorrhea.
- NAATs require DNA or RNA associated with the CT organism which is usually found in or near columnar epithelial cells. In the case of urine, the nucleic acid from the cervix or urethra washes out from vaginal secretions in females and from urethral secretions in males.
- Where non-amplified tests are used, monitoring of specimen adequacy for evidence of columnar epithelial cells should be a quality assurance tool.
- Quality assurance procedures need to be in place to avoid cross contamination with specimens in order to minimize false positive results.

2. Suggested Order of Collection for Endocervical/Urethral Specimens:

- a) Gram Stain (men only)
- b) GC Culture
- c) Pap Smear (female only)
- d) Chlamydia

Note: If a combination CT/GC test is to be used, collect the specimen after the Gram stain for men and after the Pap smear for women.

3. For males, a swab used for Gram stain may also be used for gonorrhea culture. For any other GC diagnostic tests, a second swab provided by the manufacturer of that GC test must be obtained and used.
4. For females, a swab or cytobrush used for Pap smears should not be used for chlamydia testing.

The assessment of cervical friability (e.g., for the diagnosis of cervicitis), should be determined with a swab before a cytobrush is inserted for a Pap smear.

5. Urine specimens:

- a) No urination one hour prior to collection.
- b) Collect urine according to manufacturer's instructions (consult the laboratory).
- c) Collect first 15-20 ml of urine.
- d) Large volume specimens contribute to dilute specimens, spillage and infectious waste disposal problems.
- e) In general, female urine specimens should be collected before pelvic examinations; male urine specimens should be collected after all other specimens (e.g., Gram stain and GC culture).

6. Endocervical swab specimens:

- a) Lubricate speculum with water only.
- b) Remove excess mucus from the cervical and surrounding mucosa using a cleaning swab provided in the cervical collection kit, and discard the swab.
- c) Use swab provided in kit only. Male swabs can be used on females with a small cervical os.
- d) Improperly collected specimens may cause false-negative results.

7. Vaginal swab specimens (both clinician-collected and patient-collected)

- a) Partially peel open the swab package. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new vaginal swab specimen collection kit.
- b) Remove the swab.
- c. Hold the swab, placing the thumb and forefinger in the middle of the swab shaft.

d) Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.

e) Withdraw the swab without touching the skin.

f) While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube spill, use a new vaginal swab specimen collection kit.

g) Immediately place the swab in the transport tube so that the tip of the swab is visible below the tube label.

h) Carefully break the swab shaft against the side of the tube. Do not spill the contents of the tube. If the contents of the tube spill, use a new vaginal swab specimen collection kit.

i) Tightly screw the cap onto the tube.

8. At a minimum, label each specimen tube, cup, or slide with the patient/client's name or identification number and the date the specimen was collected.
9. The test performance characteristics of some CT tests may be compromised by blood or other interfering substances (consult your lab director). If a patient/client is menstruating and follow-up can be assured ask the patient/client to return when her period is over. If the patient/client is at high risk or follow-up is in doubt, then CT testing is recommended even if the specimen is bloody, (even though it may be rejected by the laboratory). Test performance on bloody specimens varies by assay type and manufacturer. Consult the laboratory for guidance.

E. Storage and Transport of Specimens

(For specific storage and transport instructions, by test method, see Appendix C.)

Note: Always consult with your laboratory to verify storage and transport methods to use.

- Ideally, specimens should be sent to the laboratory the same day they are collected, either by courier or mail as specified by the laboratory.
- If specimens must be held overnight, they should be refrigerated at 2-8°C (or follow manufacturer's recommendations – see Appendix C) and transported promptly to the laboratory.
- Improper storage or transport may compromise test performance.
- If reasons for delay in prompt transportation to the laboratory exist such as weekends, holidays or other delays and the specimen cannot be sent within 24 hours of collection, refer to Appendix C or manufacturer's package insert and consult with your laboratory.

- During storage and transport to the laboratory, it is very important to maintain specimens at the temperature specified by the test manufacturer. Regardless of the method of transport, the system must be able to accommodate the temperature requirements specified by the manufacturer. This is especially important in areas with extremes in ambient temperatures.

Courier systems must be able to meet storage and transport standards and the standards should be included in any clinic contract or performance measure.

F. Test Procedures

See Appendix C for detailed test procedures, by method.

G. Laboratory Request Forms

In general, the following minimal data should be included on a laboratory request form:

- Patient/Client Full Name
- Age or Date of Birth
- Gender
- Specimen Collection Date
- Type and Source of Specimen
- Provider Location

Additional important information to be recorded on the form includes: patient/client address including zip code; race/ethnicity of patient/client; patient/client ID number; name, address, and telephone number of clinician; billing information; and other data as required by individual states. It is important to note that these data are for the laboratory request form and may differ from the data required by law when laboratories (or providers) report a suspected or confirmed case of CT (see following Sections H and I).

H. Public Health Reporting Regulations

All laboratories within Region IX must report positive chlamydia test results to their appropriate health department. Please note that state reporting requirements for positive test results vary and providers and laboratorians must be familiar with state laws and regulations.

- Arizona: written report within 7 days to the appropriate health authority.
- California: report to city or county health department where provider resides within 7 working days from the time the health care provider was notified.
- Nevada: report tests within 24 hours to the appropriate health authority.
- Hawaii: report within 3 working days to the state health department.

Healthcare providers are also required by law to report documented or suspected cases of chlamydia to their local health departments. (See Chapter VII. Clinician Reporting Procedures of Chlamydial Infections.)

I. Laboratory Reporting to Providers

Policy Statement: The laboratory results should be reported within three days of specimen receipt. This is the Regional standard for laboratory turn around time as defined as the time from receipt in the laboratory to transmission to the submitter.

J. Swab And Urine Specimen Results

The following result interpretations are recommended for reporting purposes; however, laboratories are required to consider the instructions contained in the FDA cleared manufacturer's package insert:

a. Initial results

CT Positive:	Positive for <i>C. trachomatis nucleic acid</i>
CT Negative:	Presumed negative for <i>C. trachomatis</i>
CT Equivocal:	Sample should be retested

GC Positive:	Positive for <i>N. gonorrhoeae nucleic acid</i>
GC Negative:	Presumed negative for <i>N. gonorrhoeae</i>
GC Equivocal:	Sample should be retested

b. Retest results

CT Positive:	Positive for <i>C. trachomatis nucleic acid</i>
CT Negative:	Presumed negative for <i>C. trachomatis</i>
CT Equivocal:	Indeterminate, a new specimen should be collected.
GC Positive:	Positive for <i>N. gonorrhoeae nucleic acid</i>
GC Negative:	Presumed negative for <i>N. gonorrhoeae</i>
CT Equivocal:	Indeterminate, a new specimen should be collected

Unsatisfactory: Specimens may be reported as unsatisfactory for any of the following reasons:

- Specimen submitted from an unacceptable anatomical site for the test methodology.
- Inappropriate/insufficient material collected.
- Inadequate specimen identification (e.g., specimen has no identifying information, or cannot be matched to a laboratory request form).
- Broken tube or specimen leaked.
- Wrong swab or cytology brush; wrong collection kit used.
- Gross contamination of specimen with blood.
- Expired or incorrect transport media.
- Specimens in transit longer than manufacturer's recommendations.
- Specimen transported at incorrect temperature.
- Enzyme Immunoassay (EIA) and Direct Fluorescent Antibody (DFA) tests are not acceptable for use in medicolegal cases.

K. Quality Assurance

Accurate chlamydia diagnosis is dependent on good laboratory practice for which quality assurance is integral. Recommended components of quality assurance include but are not limited to:

- Use of positive and negative control specimens in each testing batch per manufacturer's recommendation.
- Verification/blocking confirmatory testing on specimens found to be positive by EIA.
- For those laboratories using nucleic acid hybridization technology, the use of gray-zone testing with NAATs may increase test sensitivity.
- Adequate and updated training for technical staff.
- Participation in a recognized proficiency testing program for the particular test method used.
- A well-defined, written test protocol.
- Maintenance of testing equipment following manufacturer's recommendations or contract preventive maintenance.
- For those laboratories not using DFA or nucleic acid amplification testing, periodic monitoring of specimen quality is recommended.

L. Choosing a Quality Laboratory

Factors to consider:

- Chlamydia technology offered.
- Experience/expertise in STD testing with sufficient volume to maintain proficiency.
- Adequate number of licensed personnel performing the test.
- Caliber of testing personnel.
- Timely laboratory to clinic turnaround time.
- Consistently passes proficiency testing for chlamydia.
- Laboratory accreditation.
- Availability of technical consultation.
- Appropriate pick-up, handling and storage of specimens.
- Repeat testing of questionable results at no charge.
- Willingness to provide summary prevalence or other program reports.
- Electronic reporting capabilities.
- Test price is dependent on many factors, e.g., transportation, volume purchase, cost of reagents, personnel cost, packaging of tests, overhead, accessory services, etc. It is advisable to carefully determine what is included in the price and, to the extent possible, how it is determined. Price alone should not determine the choice of test.

Note: A visit to the laboratory is appropriate in order to review their quality assurance documents, see the physical facility and meet the managers, technical supervisor and staff. (See Appendix D for a checklist to use on Laboratory Site Visits.)

M. Clinical Laboratory Improvement Amendment (CLIA)

All laboratories providing services for clients in this project must have a current CLIA certificate.

Table II. 2. Chlamydia Testing Technologies: Summary Tables¹

Non-Amplified and Non-Nucleic Acid Amplified Test Technologies

	CELL CULTURE	DIRECT FLUORESCENT ANTIBODY (DFA)	ENZYME IMMUNOASSAY (EIA)	NUCLEIC ACID HYBRIDIZATION	HYBRID CAPTURE (HC)
Manufacturer	Wampole (Dist.), Trinity Biotech (Mfr.) (Syva), Diagnostic Products Corp., Bio-Rad, VWR Scientific Products (Bartels)	Kits available from Wampole (Dist.), Trinity Biotech (Mfr.) (Syva), Bio-Rad, VWR Scientific Products (Bartels)	Wampole (Dist.), Trinity Biotech (Mfr.) (Syva), and others	Gen-Probe, Inc. (PACE 2)	Digene Corporation (Hybrid Capture 2)
Collection Site	Endocervical, urethral, rectal, conjunctival, nasopharyngeal, pulmonary	Endocervical, male urethral, rectal, conjunctival, nasopharyngeal	Endocervical, male urethral, conjunctival	Endocervical, male urethral, conjunctival	Endocervical
Specimen Handling	Transport (mail, courier or by hand) and store at 4°C; test within 24 hours of collection.	Transport (mail, courier or by hand) and store at 20-30°C or store at 2-8°C; stain or fix within 7 days. Store at -20°C after fixation.	Transport (mail, courier or by hand), and store at 2-25°C; test within 7 days of collection.	Transport (mail, courier or by hand), and store at 2-25°C; test within 7 days of collection; can be frozen at -20°C until tested.	Transport and store at room temperature at 18-25°C and test within 14 days of collection, or refrigerate at 2-8°C and test within 21 days of collection.
Average Turn-Around Time (TAT) Varies with frequency of testing & volume	2-3 days	1-3 days	1-3 days	1-3 days	1-3 days
Test Comments	Technically difficult procedure; specimen transport, storage times & temperatures critical; most labor intensive method. Acceptable for medicolegal situations.	Only test method where specimen adequacy can be evaluated.	Automated Test	Semi-automated. Non-amplified nucleic acid test. One swab for both chlamydia and gonorrhea but 2 step process for definitive diagnosis.	Hybrid capture technology detects nucleic acid targets directly by hybridization and signal amplification. Non-amplified nucleic acid test. One swab for both chlamydia and gonorrhea but 2 step process for definitive diagnosis.
Proficiency Test Availability	Available	Available	Available	Available	Available

¹ For a detailed description of each test methodology, see Appendix C.

Table II. 2. Chlamydia Testing Technologies: Summary Tables¹
(continued)

Nucleic Acid Amplified Test Technologies

	POLYMERASE CHAIN REACTION (PCR)	TRANSCRIPTION MEDIATED AMPLIFICATION (TMA)	TARGET CAPTURE WITH TRANSCRIPTION MEDIATED AMPLIFICATION (TMA)	STRAND DISPLACEMENT AMPLIFICATION (SDA)
Manufacturer	Roche Diagnostic Systems (Amplicor & COBAS)	Gen-Probe, Inc. (AMP-CT) <i>NOT AVAILABLE IN THE US</i>	Gen-Probe, Inc. (APTIMA Combo 2, APTIMA CT, APTMA GC)	Becton-Dickinson (BD ProbeTec ET)
Collection Site	Endocervical, male urethral, urine (male & female). Not FDA approved for testing NG on female urine and on aSx male urethra.	Endocervical, male urethral, urine (male & female)	Endocervical, male urethral, urine (male & female), vaginal swab	Endocervical, male urethral, urine (male & female), “Dry” swab
Specimen Handling	Transport/store swabs at 18-25°C within 1 hr and urine at 18-25°C within 24 hrs of collection or at 2-8°C; test within 7 days of collection; can be frozen at -20°C until tested.	Transport/store swabs at 2-25°C within 7 days and urine at 15-30°C within 24 hrs or 2-8°C within 7 days; test within 7 days of collection; can be frozen at -20°C until tested.	Transport/store original urine specimen and urine in urine specimen collection kit at 2-30°C, transfer urine to urine specimen collection kit within 24 hours of collection; test within 30 days of collection. Transport/store swabs in swab collection kit at 2-30°C, test within 60 days; can be frozen at -20°C until tested.	Transport/store urine at 2-8°C, swabs at 2-27°C. Test urine & swabs within 4-6 days of collection. Urine processing pouch added in labs 2 hrs prior to processing to remove inhibitors & stabilize urine for transport at room temperature. Can’t freeze specimens until further processed (lysed) in the lab.
Average Turn-Around Time (TAT) <small>Varies with frequency of testing & volume</small>	1-3 days	1-3 days	1-3 days	1-3 days
Test Comments	Nucleic acid amplification method. Testing for CT/GC (with the exception of female urine and aSx male urethra) can be done from a single specimen in a one step process for definitive diagnosis.	Nucleic acid amplification method. Tests only for CT, not GC.	Combines the technologies of Target Capture, Transcription-Mediated Amplification (TMA) and Dual Kinetic Assay (DKA) to simultaneously detect and amplify target rRNA via DNA intermediates. Testing for CT/GC can be done from a single specimen in a one step process for definitive diagnosis.	Assay utilizes simultaneous amplification & detection of target DNA, using amplification primers & a fluorescent labeled detector probe. Testing for CT/GC can be done from a single specimen in a one step process for definitive diagnosis.
Proficiency Test Availability	Available	Available	Available	Available

¹ For a detailed description of each test methodology, see Appendix C.

III. HISTORY, RISK ASSESSMENT AND PHYSICAL EXAMINATION

A. Medical History and Risk Assessment

Policy Statement: A sexual and medical history must be obtained in order to assess a patient/client's risk for STDs including infections caused by *Chlamydia trachomatis*.

The basic STD medical history and risk assessment should be conducted by combining the techniques of open-ended and yes/no questions. Clinicians should provide patients/clients with an appropriate rationale for asking sensitive questions.

The basic medical history and risk assessment should include the following:

1. Medical History

- a) Reason(s) for the visit.
- b) Recent symptoms of STDs:
 - i) Abnormal vaginal discharge
 - ii) Penile or rectal discharge
 - iii) Abnormal vaginal bleeding, including post-coital bleeding
 - iv) Dyspareunia
 - v) Dysuria
 - vi) Pelvic pain
 - vii) Genital ulcer(s)
- c) If symptoms are present, description of symptoms, including:
 - i) Onset, duration, character and frequency.
 - ii) History of similar symptoms.
- d) Recent symptoms or STDs in a sex partner.
- e) History of STDs including dates and treatment.
- f) Medication history, including:
 - i) Use of antimicrobial agents within the last four weeks: date, type, purpose and duration (include both prescribed treatments and self-medication).
 - ii) Use of other medications: date, type, purpose and duration.
 - iii) Known drug allergies: drug, type of reaction and date.
- g) History of blood test for syphilis (dates, locations and results), HIV and Hepatitis B (dates and results).

- h) History of vaccination for Hepatitis B.
- i) Review of general health.

For women only:

- j) Date of last menstrual period and whether it was normal.
- k) Date of last Pap smear and results.
- l) History of abnormal Pap smears, diagnoses, dates, treatments, and follow-up.
- m) Obstetrical history (number and outcomes of intended and unintended pregnancies).
- n) Current pregnancy intentions and type of contraception.

2. Risk Assessment

- a) Review of recent sexual activity:
 - i) Number and gender of sex partner(s) in the past 2-3 and 12 months and whether there were any new partners.
 - ii) Presence of risk factors in partner (e.g., multiple partners, injection drug use, men who have sex with men (MSM)).
 - iii) Sites of sexual exposure (i.e., genital, oral, anal).
 - iv) Patterns of condom use with all partners for each site of sexual exposure.
- b) History of drug use and needle-injection practices (including needle-sharing and drug use in sex partners).
- c) Domestic Violence

Note: Please see Appendix E for Patient-Administered Sexual History Questionnaire (Chlamydia Care Quality Improvement Toolbox, California Chlamydia Action Coalition, December 2001).

B. Physical Examination

Policy Statement: An STD physical evaluation should be included for patients/clients who present with STD symptoms or STD risk factors identified in the risk assessment. For patients without symptoms, screening test can be performed without a physical exam if the exam is not otherwise indicated (e.g. pregnancy-test-only).

1. Female STD Examination

- a) General inspection of the skin (including trunk, back, extremities, palms and soles).

- b) Inspection of the oral cavity for lesions.
- c) Palpation of inguinal, cervical, supraclavicular, epitrochlear and axillary nodes.
- d) Abdominal examination noting any guarding or rebound tenderness.
- e) Inspection of pubic hair for lice and nits.
- f) Inspection of the external genitalia for discharge, masses, lesions and tenderness.
- g) Pelvic examination:
 - i) Palpation of the Bartholin's and Skene's glands.
 - ii) Inspection of the vaginal mucosa noting the presence, quantity and character of any discharge or lesions.
 - iii) Inspection of the cervix noting the presence, quantity and character of cervical discharge, presence and amount of ectopy, easily-induced cervical bleeding (friability), and any lesions or other abnormal findings.
 - iv) Bi-manual examination noting the presence or absence of cervical motion tenderness, the size, position and consistency of the uterus, the presence or absence of uterine or adnexal tenderness and the presence or absence of pelvic masses.
- h) Inspection of the anus and perianal region.

2. Male STD Examination

- a) General inspection of the skin (including trunk, back extremities, palms and soles).
- b) Inspection of the oral cavity for lesions.
- c) Palpation for inguinal, cervical, supraclavicular, epitrochlear and axillary nodes.
- d) Inspection of pubic hair for lice and nits.
- e) Inspection of the penis including retraction of the foreskin, examination of the meatus noting any discharge and milking of the penis to express discharge.
- f) Inspection of the scrotum and palpation of the scrotal contents noting testicular masses or other masses, and tenderness of the epididymis.
- g) Inspection of the anus and perianal region.

IV. CLINICAL PRESENTATION AND DIAGNOSIS

Policy Statement: Clinics should develop protocols that incorporate sexual and medical history, risk assessment, physical examination, and screening criteria to accurately diagnose patients/clients with chlamydia. The diagnosis of *Chlamydia trachomatis* (CT) infection can be made by using several laboratory techniques (see Chapter II.B, Recommended Laboratory Test Methodologies). Two points must be acknowledged when using clinical findings to support the diagnosis of CT infection:

- The vast majority of CT infections are asymptomatic in women and men. Thus, screening criteria must be established in a given population to identify these infections that would otherwise go undetected.
- The clinical signs of this disease closely parallel those caused by *Neisseria gonorrhoeae*. Both organisms act by infecting columnar and transitional epithelium and extending to contiguous structures from the initial site of infection.

A. Screening for Asymptomatic Chlamydial Infections

Policy Statement: Screening protocols should be guided by the prevalence of chlamydia in a given population. Contact your local or state STD Program to identify who is at risk in your population. The minimum screening criteria to be used for asymptomatic clients are outlined below.

1. Screening Criteria for Sexually Active Females

- a) Screen all sexually active females who are twenty-five years of age and younger *at the first visit and annually thereafter*.
- b) Re-test all females 3 months after treatment for chlamydia. If a patient does not return at this time, re-test whenever she next seeks medical care within the 12 months following treatment, regardless of whether or not she believes her sex partners were treated.
- c) A test of cure is not generally recommended. A test of cure is advised 3-4 weeks after completion of treatment for pregnant women only. (See Chapter II.B.6, Test of Cure.)

Routine screening of women over age 25 is not recommended, and should be targeted only to those with risk factors for chlamydia: more than 1 sex partner in the previous 12 months, new partner in the previous 3 months, and/or suspicion that a recent partner may have had concurrent partner(s) during the past 12 months.

In populations of female patients age 25-30 with CT prevalence of at least 3%, screening is likely to be cost-effective and should be considered. Examples of higher risk populations include women attending STD clinics, in correctional settings, and in some family planning settings.

Other reasons for testing in women

- a) Women who report contact (exposure) to an STD, specifically chlamydia, gonorrhea, nongonococcal urethritis, epididymitis, trichomoniasis, syphilis or HIV, should be tested for chlamydia.
- b) Women with a newly diagnosed STD, either confirmed or presumptively treated, should be tested for chlamydia.

2. Considerations for Sexually Active Males

Little data are available to guide chlamydia screening recommendations for men. Prevalence appears to be greatest in certain settings such as correctional settings and STD clinics. If funding permits, screening programs should be implemented for males who have sex with females, especially men in a sexual or social network of females with a high prevalence of CT. As a first step, screening sexually active males 25 years of age and younger at the initial exam could be considered.

B. Testing for Symptomatic Chlamydial Infections

Policy Statement: Patients/clients with syndromes associated with chlamydia, including cervicitis or pelvic inflammatory disease (PID) in females and urethritis or epididymitis in males, should be tested and presumptively treated for chlamydia. In females with symptoms that may be associated with chlamydia such as abnormal vaginal discharge of unknown etiology, abnormal vaginal bleeding with vaginal intercourse or unrelated to hormonal contraception, or dysuria without evidence of urinary tract infection, a chlamydia test should be obtained. All sex partners within the last two months of patients treated for chlamydia, either with a confirmed (test positive) or presumptive (chlamydia-associated syndrome) diagnosis, should also be evaluated, tested, and treated. Female partners should be evaluated for signs and symptoms of PID.

Although the test results will not influence the medical management of patients/clients who are treated presumptively before the test result is available, diagnostic testing is recommended to document chlamydia infections for the following public health reasons:

- To increase effectiveness of patient/client prevention education and risk counseling.
- To improve compliance with treatment regimens.
- To facilitate partner referral and additional case finding beyond the initial patient/client.
- To improve STD surveillance, prevention and control efforts.

Note: Every agency or program must have specific protocols and procedures for the identification of signs and symptoms indicating more serious conditions than uncomplicated chlamydial infection and the treatment of those conditions.

C. Infections in Females

1. Cervicitis

- Characterized by a mucopurulent exudate from the cervical os and/or easily induced endocervical bleeding.

- Patients may or may not have symptoms.
 - *C. trachomatis* and *N. gonorrhoeae* are among the causative pathogens of cervicitis, therefore testing to determine the specific diagnosis of chlamydia and gonorrhea is recommended. However, cervicitis is not a sensitive predictor of these infections, since most women with *C. trachomatis* or *N. gonorrhoeae* do not have cervicitis. In many cases no specific etiologic diagnosis is made. The value of testing for other organisms possibly associated with cervicitis and PID, such as mycoplasma, is unknown and is not recommended because the tests are expensive and not widely available, and because cervicitis and PID are generally treated with broad-spectrum antibiotics.
 - Herpes simplex virus and *T. vaginalis* can also produce cervicitis but these infections tend to affect the ectocervix, thereby not creating endocervical mucopus.
- a) History:
- i) Frequently asymptomatic.
 - ii) If symptomatic, patient/client may complain of vaginal discharge, post-coital bleeding, dyspareunia, dysuria, intermenstrual bleeding.
 - iii) Patient/client may have a partner who has had symptoms of urethritis or was diagnosed with urethritis.
- b) Examination:
- i) Assess for endocervical mucopus and easily induced cervical bleeding:
 - (a) Gently remove vaginal discharge covering the ectocervix and os.
 - (b) Visually examine the os for mucopus.
 - (c) Insert a clean, white swab into the cervical os, rotate and remove.
 - (d) Note if yellow or greenish mucopus is obtained on this swab.
 - (e) Observe for any easily induced (frank) bleeding from the cervix-not just blood on the swab. (Note that bleeding after placing a cytobrush in the endocervix may not be associated with cervical friability. Therefore, to determine if the cervix is friable, a cotton-tipped swab should be the first specimen collection device placed in the endocervix).
 - ii) Examine for lower abdominal, adnexal, uterine or cervical motion tenderness (CMT).
 - iii) Presence of fever ($>101^{\circ}\text{F}$) may support diagnosis of PID.
- c) Laboratory:
- i) More than 10 white blood cells per high power field on the wet mount of vaginal discharge may support a diagnosis of cervicitis or PID.
 - ii) Diagnostic tests for gonorrhea and chlamydia.

- iii) A nontreponemal syphilis test (RPR or VDRL) is recommended and an HIV antibody test should be offered.
 - iv) Pap smear, if none in past year.
- d) Diagnostic criteria:
- i) Presence of mucopurulent yellow endocervical exudate or the finding of yellow or greenish exudate on the first white cotton tipped swab inserted into the endocervical canal (positive swab test) after cleaning off the ectocervix;
or,
 - ii) Demonstration of cervical friability or easily induced bleeding when the first cotton-tipped swab is placed in the endocervix;
and,
 - iii) Absence of lower abdominal, adnexal, uterine or cervical motion tenderness.

If none of these criteria are present, then the patient/client has no evidence of cervicitis, and chlamydia and gonorrhea treatment should be deferred. The patient/client should be tested for *N. gonorrhoeae* and *C. trachomatis* and contacted to return for treatment in the event of a positive result.

2. Pelvic Inflammatory Disease (PID)

- Clinical syndrome resulting from the ascending spread of microorganisms from the vagina and the endocervix to the endometrium, the fallopian tubes or contiguous structures. May include endometritis, salpingitis, tubo ovarian abscess, and pelvic peritonitis.
 - Signs or symptoms include mild-to-moderate lower abdominal pain and tenderness, dyspareunia, abnormal vaginal discharge, or abnormal vaginal bleeding. No symptoms at all may be present; many women with late complications (e.g., infertility, ectopic pregnancy) report no history of symptoms.
 - *N. gonorrhoeae* and *C. trachomatis* may be implicated; however, organisms not necessarily associated with sexual transmission, such as anaerobes, Gram-negative rods, and streptococci, may also be etiologic agents.
 - Occasionally, acute infection becomes life-threatening because of extensive peritonitis, which is usually caused by rupture of a tubo-ovarian abscess.
 - Other complications and medical consequences include chronic pelvic pain, pelvic adhesions (requiring subsequent hysterectomy), tubal factor infertility, and ectopic pregnancy, which can also be life-threatening.
- a) History:
- i) Lower abdominal pain, fever, abnormal vaginal discharge, or dyspareunia.
 - ii) Menstrual abnormalities and abnormal vaginal bleeding are common.
 - iii) Nausea and vomiting may be present, but are nonspecific.

iv) Right upper quadrant pain is rare, but important to elicit as it indicates the presence of generalized peritonitis and perihepatitis (Fitz-Hugh-Curtis syndrome).

b) Examination:

i) Examine for lower abdominal tenderness, uterine or adnexal tenderness and cervical motion tenderness.

ii) Examine for cervical or vaginal mucopurulent discharge.

iii) Patients may be febrile ($\geq 101^{\circ}\text{F}$ or 38.3°C), may have peritoneal signs (i.e., rebound, guarding), or right upper quadrant tenderness (possible Fitz-Hugh-Curtis syndrome).

iv) Note evidence of any mass that may suggest tubo-ovarian abscess (TOA).

- c) Laboratory:
- i) Wet mount of vaginal discharge or secretions for abundant white blood cells. (Note: This diagnostic criterion is not standardized.)
 - ii) Diagnostic tests for gonorrhea and chlamydia.
 - iii) ESR or C-reactive protein, if available.
 - iv) A nontreponemal syphilis test (RPR or VDRL) is recommended and an HIV antibody test should be offered.
 - v) Pap smear, if none in past year.
 - vi) A pregnancy test is recommended if LMP is unclear or late, or if unprotected sex is reported at least two weeks after LMP.

d) Clinical diagnostic criteria:

Absolute diagnostic criteria remain uncertain and the clinical diagnosis of acute PID is difficult. The new “gold standard”, MRI, is too costly and impractical for most clinical settings. The gold standard had been laparoscopic evidence of tubal infection; however, laparoscopy will not detect endometritis and may miss subtle inflammation of the fallopian tubes. In addition, routine use of laparoscopy to diagnose PID is impractical and expensive. Therefore, less reliable clinical criteria must be used.

In the past, PID has been described as "mild" or "severe". These are very poor descriptors since PID reflects the site(s) of infection, not the degree of symptomatology, and severity of symptoms does not correlate with severity of disease or risk of complications. It is now believed that most women with PID have very mild, unrecognized or no symptoms, though many have extensive disease and resultant infertility. Therefore, clinicians should err on the side of over-diagnosing PID.

- i) In the absence of other causes of pelvic inflammation (e.g., ectopic pregnancy, appendicitis, etc.), all women with the following clinical criteria should be diagnosed and treated presumptively for PID:
 - (a) Cervical motion tenderness
 - or
 - (b) Uterine tenderness
 - or
 - (c) Adnexal tenderness (can be unilateral).
- ii) Additional diagnostic criteria: For women with severe clinical signs, more elaborate diagnostic evaluation may be warranted because incorrect diagnosis and management may cause unnecessary morbidity. These additional criteria

may be used to increase the specificity of the diagnosis. The following are additional criteria which support a diagnosis of PID:

- (a) Oral temperature $>38.3^{\circ}\text{C}$ (101°F).
- (b) Abnormal cervical or vaginal mucopurulent discharge.
- (c) Abundant white blood cells on wet mount.
- (d) Elevated erythrocyte sedimentation rate.
- (e) Elevated C-reactive protein.
- (f) Laboratory documentation of cervical infection with *N. gonorrhoeae* or *C. trachomatis*.
- (g) Male partner with urethritis symptoms or diagnosis – including GC or CT urethritis.

iii) Definitive criteria warranted in selected cases for diagnosing PID:

- (a) Histopathologic evidence of endometritis (plasma cells) on endometrial biopsy.
- (b) Radiologic abnormalities on MRI or transvaginal sonography (thickened fluid-filled tubes with or without free pelvic fluid or tubo-ovarian complex).
- (c) Laparoscopic abnormalities consistent with PID.

D. Infections in Males

1. Urethritis

- Characterized by mucoid, mucopurulent or purulent urethral discharge and/or dysuria.
- Two important sexually transmitted bacterial agents responsible for urethritis among men are *N. gonorrhoeae* and *C. trachomatis*. Ureaplasma, mycoplasma, trichomoniasis, HSV, other bacteria and non-infectious causes of inflammation are recognized as other possible etiologies.
- Testing to determine the specific diagnosis of gonorrhea and chlamydia is recommended. Additional testing for other possible pathogens is costly and not widely available. Since broad-spectrum antimicrobials are used to treat urethritis, additional testing is not recommended.

a) History:

- i) Dysuria with or without urethral discharge.
- ii) Discharge may be purulent, mucoid, scant, or only present in the morning.
- iii) Patients/clients may also present with minimal symptoms of itching/irritation at the urethral meatus and no discharge.

b) Examination:

- i) Note presence of discharge.
 - ii) If discharge is not present, the penis should be "milked" to see if an exudate can be expressed. This may be done by the clinician or by the patient/client.
- c) Laboratory:
- i) A chlamydia test should be done especially if the patient/client has female sex partners. Nucleic acid amplification tests (NAATs) allow this to be done on first-catch urine (the first 10-30 cc voided with initiation of the stream); these tests for chlamydia are more sensitive than traditional chlamydia tests, and offer a more patient/client-acceptable method of specimen collection.
 - ii) If Gram stain is available:
 - (1) A Gram stain of the discharge or secretions can be done to look for white blood cells and evidence of gonococcal infection (intracellular Gram negative diplococci). If a discharge is not present, a swab can be inserted into the urethra and held for 30 seconds to absorb any secretions. (Note: If a GC culture is used, the same swab can be used for both Gram stain and culture specimens. For any other GC diagnostic tests, a second swab specifically evaluated for that GC test must be obtained and used.)
 - (2) If the Gram stain is positive for intracellular Gram negative diplococci, then no further gonorrhea testing is necessary. Ideally, a gonorrhea test should be done if the Gram stain is negative.
 - iii) If Gram stain is not available:
 - (1) A urine dip-stick for leukocyte esterase (15 ml of first-catch urine) or a microscopic examination of spun urine sediment (15 ml of first-catch urine, spin at 500 RPM for 3-5 minutes and decant supernant) can be done to document evidence of inflammation. The examination of the urine sediment can also identify *T. vaginalis*.
 - (2) A GC test should be done if Gram stain is not available. Tests to consider include culture, DNA probe, and GC nucleic acid amplification tests (NAATs).
 - iv) A nontreponemal syphilis test (RPR or VDRL) is recommended and an HIV antibody test should be offered.

d) Diagnostic criteria:

Clinical and/or laboratory confirmation of urethritis should be performed routinely on male patients/clients with symptoms suggestive of urethritis using the following diagnostic criteria:

- i) Purulent discharge, or
- ii) Gram stain demonstrating ≥ 5 WBC per oil immersion field, or

- iii) Positive (small (1+) or greater) leukocyte esterase test on first-catch urine (the first 10-30 cc voided with initiation the stream), or
- iv) Microscopic exam of an aliquot of spun first-catch urine (the first 10-30 cc voided after initiating the stream) demonstrating ≥ 10 WBC per high power field.

If none of these criteria are present, then the patient/client has no evidence of urethritis and treatment should be deferred. The patient/client should be tested for *N. gonorrhoeae* and *C. trachomatis* and contacted to return for treatment in the event of a positive result.

Empiric treatment without documenting urethritis is recommended only when stat laboratory tests are not available; in the case of individuals at high risk for gonorrhea or chlamydial infection; or for whom follow-up is likely to be difficult. These patients/clients should be treated for gonorrhea and chlamydia and a partner management option should be implemented; see Section X, Partner Identification and Referral, below.

2. Epididymitis

- Characterized by scrotal pain, tenderness and swelling, usually unilateral.
- Often caused by *C. trachomatis* or *N. gonorrhoeae* in sexually active men less than 35 years of age.
- Sexually transmitted epididymitis is usually accompanied by urethritis, which is often asymptomatic.
- May be caused by sexually transmitted *Escherichia coli* or other enteric infections among men who are the insertive partners during anal intercourse.
- Non-sexually transmitted epididymitis associated with urinary tract infections caused by Gram-negative enteric organisms occurs more frequently among men more than 35 years of age, who have recently undergone urinary tract instrumentation or surgery, and who have anatomical abnormalities.
- Although most patients/clients can be treated as outpatients, hospitalization should be considered in those where severe pain suggests other diagnoses, such as torsion, testicular infections, abscess, or in patients/clients who are so ill as to be unable to tolerate oral medication or who may potentially be non-compliant with outpatient treatment for other reasons.

a) History:

- i) Patients/clients usually present with unilateral testicular pain and tenderness.

b) Examination:

- i) Palpable swelling of the epididymis is usually present.

Testicular torsion, a surgical emergency, should be considered in all cases but is more frequent in adolescents and is more common when there is no evidence of inflammation or infection. Emergency testing for torsion may be

indicated when the onset of pain is sudden or severe, or test results at initial visit do not permit a diagnosis of urethritis or urinary tract infection. Since testicular viability may be compromised, an expert should be consulted immediately if there is any doubt regarding diagnosis.

c) Laboratory:

The evaluation of men for epididymitis should be the same as for urethritis and include the following:

i) A chlamydia test should be done especially if the patient/client has female sex partners. Nucleic acid amplification tests (NAAT) allow this to be done on first-catch urine (the first 10-30 cc voided with initiation of the stream); these tests for chlamydia are more sensitive than traditional chlamydia tests, and offer a more patient/client-acceptable method of specimen collection.

ii) If Gram stain is available:

(a) A Gram stain of the discharge or secretions can be done to look for white blood cells and evidence of gonococcal infection (intracellular Gram negative diplococci). If a discharge is not present, a swab can be inserted into the urethra and held for 30 seconds to absorb any secretions. (Note: If a GC culture is used, the same swab can be used for both Gram stain and culture specimens. For any other GC diagnostic tests, a second swab specifically evaluated for that GC test must be obtained and used.)

(b) If the Gram stain is positive for intracellular Gram negative diplococci, then no further gonorrhea testing is necessary. Ideally, a gonorrhea test should be done if the Gram stain is negative.

iii) If Gram stain is not available:

(a) A urine dip-stick for leukocyte esterase (15 ml of first-catch urine) or a microscopic examination of spun urine sediment (15 ml of first-catch urine, spin at 500 RPM for 3-5 minutes and decant supernant) can be done to document evidence of inflammation. The examination of the urine sediment can also identify *T. vaginalis*.

(b) A GC test should be done if Gram stain is not available. Tests to consider include culture, DNA probe, and GC NAATs.

iv) A nontreponemal syphilis test (RPR or VDRL) is recommended and an HIV antibody test should be offered.

d) Diagnostic criteria:

Clinical symptoms and signs consistent with epididymitis with or without evidence of urethritis.

If none of these criteria are present, then the patient/client has no evidence of epididymitis and treatment should be deferred. The patient/client should be tested for *N. gonorrhoeae* and *C. trachomatis* and contacted to return for treatment in the event of a positive result.

V. TREATMENT OF CHLAMYDIAL INFECTIONS AND ASSOCIATED SYNDROMES

Policy Statement: Clinics should follow the latest CDC STD Treatment Guidelines' recommended regimens and have written treatment protocols. If all recommended regimens are contraindicated, an alternative regimen should be followed.

A. Treatment of Uncomplicated Chlamydial Infections

1. Non-pregnant Adolescents and Adults

- a) To maximize compliance with recommended therapies, medications for chlamydial infections should be dispensed on site.
- b) To minimize further transmission of infection, patients treated for chlamydia should be instructed to abstain from sexual intercourse for 7 days after single dose therapy or until completion of a 7-day regimen.
- c) To minimize the risk of re-infection, patients should also be instructed to abstain from sexual intercourse until 7 days after all their sex partners are treated.

Recommended Regimens:

Azithromycin 1 g orally in a single dose

OR

Doxycycline 100 mg orally twice a day for 7 days.

- d) Azithromycin is probably more cost-effective in populations with poor drug compliance, little follow-up, or erratic healthcare-seeking behavior, as it provides the opportunity for single-dose, directly observed therapy.
- e) Azithromycin is approved for use in persons of all ages including adolescents and may be particularly beneficial for use in treating adolescents (traditionally a non-compliant population).
- f) Doxycycline has the advantage of low cost and a longer history of extensive use.

Alternative Regimens:

Erythromycin base 500 mg orally four times a day for 7 days,

OR

Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days,

OR

Ofloxacin 300 mg orally twice a day for 7 days,

OR

Levofloxacin 500 mg orally once daily for 7 days.

- g) Ofloxacin and levofloxacin are similar in efficacy to doxycycline and azithromycin, but are more expensive and offer no advantage in dosing.

- h) With use of a recommended or alternative regimen, test of cure is not recommended for non-pregnant women, unless compliance is in question, symptoms persist, or reinfection is suspected.
- i) For pregnant women, test of cure is recommended at 3-4 weeks after treatment, preferable with a NAAT test, for all recommended and alternative regimens.
- j) Re-test women 3 months after treatment for chlamydia. (Re-testing 3 months following treatment for chlamydia is recommended as an effective strategy for detecting re-infection, which occurs in 10-25% of women after an initial chlamydial infection.)

2. Presumptive Treatment Criteria

Policy Statement: Among women, several serious sequelae may result from *C. trachomatis* infection, the most serious including PID, ectopic pregnancy, and infertility. Given the likelihood of infection and the fact that chlamydia test results are not available at the time of the visit and are not 100% sensitive, a presumptive diagnosis and empirical treatment given at the time of the visit should be considered if patients/clients present with syndromes or circumstances associated with chlamydial infection.

Criteria for Presumptive Chlamydia Diagnosis and Treatment

- Diagnosis of urethritis or epididymitis (males).
- Diagnosis of cervicitis or PID (females).
- Sex partner with history of cervicitis, PID, urethritis, epididymitis, chlamydia or gonorrhea infection.
- Rape victim.

- a) Chlamydia testing in patients/clients who are presumptively treated is desirable for public health and compliance reasons. (See Chapter IV.B for a list of public health justifications for testing after presumptive treatment.)

The goal of testing is chlamydia detection, treatment, and prevention of the associated sequelae for patients/clients, their sex partners and their children. While diagnostic testing is recommended when treating presumptively, depending on the resources of the agency involved, treatment may occur without chlamydia testing of the patient/client.

3. Treatment Considerations During Pregnancy

- a) Doxycycline, ofloxacin, and levofloxacin are contraindicated for pregnant women. Erythromycin estolate is contraindicated during pregnancy because of drug-related hepatotoxicity.
- b) Azithromycin is a recommended treatment for pregnant women, despite the limited data regarding efficacy and safety in pregnancy.

- c) Test of cure is recommended 3-4 weeks after treatment for all pregnant women because the efficacy of amoxicillin and erythromycin is poor, and data on the efficacy and safety of azithromycin are limited.

Recommended Regimens for Pregnant Women:

Azithromycin 1 g orally in a single dose,

OR

Amoxicillin 500 mg orally three times daily for 7 days,

Alternative Regimens for Pregnant Women:

Erythromycin base 500 mg orally four times a day for 7 days,

OR

Erythromycin base 250 mg orally four times a day for 14 days,

OR

Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days,

OR

Erythromycin ethylsuccinate 400 mg orally four times a day for 14 days.

4. Treatment Considerations for HIV-Infected Patients

Persons with co-occurring HIV and chlamydial infections should receive the same treatment as patients/clients without HIV infection.

5. Treatment of Gonorrhea and Chlamydia Co-infection, Non-Pregnant Patients/Clients

Policy Statements:

1. Rates of co-infection with *C. trachomatis* among patients/clients with gonorrhea remain high (25-50%). Therefore co-treatment for chlamydia is currently recommended for all patients/clients diagnosed with gonorrhea, unless there is a documented negative chlamydia test using a nucleic acid amplification test (NAAT).
2. Prevalence of fluoroquinolone-resistant gonorrhea has been increasing in the United States since about 2000. As of April 2007, fluoroquinolones are no longer recommended for treatment of gonococcal infections and associated conditions such as PID anywhere in the United States.

6. Treatment of Uncomplicated Genital and Rectal Gonorrhea in non-pregnant adults

Recommended Regimens:

Ceftriaxone 125 mg IM in a single dose

OR

Cefixime 400 mg orally in a single dose.

Alternative Regimens:

Cefpodoxime 400 mg orally in a single dose,

OR

Spectinomycin 2 g IM in a single dose,

OR

Azithromycin 2 g orally in a single dose,

PLUS (i.e., in addition to one of the regimens above), IF CHLAMYDIAL INFECTION IS NOT RULED OUT WITH A SENSITIVE TEST (NAATs)

Azithromycin 1 g orally in a single dose (if 2 g not used above)

OR

Doxycycline 100 mg orally twice a day for 7 days.

7. Treatment of Pharyngeal Gonorrhea in non-pregnant adults

Recommended Regimen:

Ceftriaxone 125 mg IM in a single dose

PLUS TREATMENT FOR CHLAMYDIA.

Alternative Regimen:

Azithromycin 2 g orally in a single dose

8. Gonorrhea Treatment – Pregnancy

Recommended Regimens:

Ceftriaxone 125 mg orally in a single dose

OR

Cefixime 400 mg orally in a single dose .

For patients with cephalosporin or penicillin anaphylaxis-type allergies:

Spectinomycin 2g IM in a single dose.

OR

Azithromycin 2 g orally in a single dose,

PLUS (i.e., in addition to one of the regimens above), TREATMENT FOR CHLAMYDIA IF CHLAMYDIAL INFECTION IS NOT RULED OUT WITH A SENSITIVE TEST (NAATs).

B. Follow-up of patients/clients treated for uncomplicated chlamydia

1. Patients/Clients should return for re-evaluation if symptoms persist or recur after treatment.
2. Re-testing 3 months following treatment for chlamydia is recommended as an effective strategy for detecting re-infection, which occurs in 10-25% of women after an initial chlamydia infection.
3. For non-pregnant patients, test of cure is not recommended after completing therapy with a recommended or alternative regimen unless compliance is in question, symptoms persist or re-infection is suspected.
4. For all pregnant women, test of cure, preferably using a NAAT test, is recommended 3-4 weeks after treatment because the efficacy of amoxicillin and erythromycin is poor, and data on the efficacy and safety of azithromycin are limited.
5. To minimize further transmission of infection and risk of re-infection, patients/clients treated for chlamydia should be instructed to abstain from sexual intercourse for 7 days after single dose therapy or until completion of a 7-day regimen and until 7 days after all of their sex partners are treated.
6. Refer partners in past 60 days for evaluation and treatment.
7. In some situations, patient/client delivery of medication for their partners is warranted. (See Chapter XI. Partner Assessment and Treatment, section A.4 Acceptable alternatives to examining partners.)

Note: Refer to Patient/Client Education and Counseling (Chapter IX), Partner Identification and Referral (Chapter X), and Partner Assessment and Treatment (Chapter XI) for more details.

C. Treatment of Cervicitis

All patients/clients with cervicitis should be treated presumptively for chlamydia at the time of the clinic visit, and partners should be referred for evaluation and treatment. If follow-up is likely to be difficult, the patient/client may be given treatment for gonorrhea as well. Pregnant patients/clients should follow the chlamydia recommended regimen outlined above (See Chapter V.A.3).

Recommended Regimens:

Azithromycin 1g orally in a single dose

OR

Doxycycline 100 mg orally twice a day for 7 days.

Alternative Regimens:

Erythromycin base 500 mg orally four times a day for 7 days,

OR

Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days,

OR

Ofloxacin 300 mg orally twice a day for 7 days,

OR

Levofloxacin 500 mg orally once daily for 7 days.

1. Follow-up of Patients/Clients treated for Cervicitis

- a) If signs or symptoms of cervicitis persist but gonorrhea and chlamydia tests are negative using sensitive tests (NAATs), partners have been adequately treated and the risk of re-infection is low, further antibiotic treatment is not recommended.
- b) To minimize further transmission of infection and risk of re-infection, patients/clients treated for cervicitis should be instructed to abstain from sexual intercourse for 7 days after single dose therapy or until completion of a 7-day regimen and until 7 days after all of their sex partners are treated.
- c) Refer partners in past 60 days for evaluation and treatment.
- d) Partners should be treated with the same regimen as the patient/client.

D. Treatment of Pelvic Inflammatory Disease (PID)

1. Oral Treatment

As with parenteral regimens (see below), clinical trials of oral outpatient regimens have provided information regarding short-term outcomes (relief of symptoms and microbiologic cure). The following regimens provide coverage against the common etiologic agents of PID, but evidence from clinical trials supporting their use in prevention of long-term sequelae is limited. Patients/Clients should be re-evaluated within 72 hours to assess for clinical improvement. Patients/Clients who do not respond to oral therapy within 72 hours should be re-evaluated to confirm the diagnosis, and be given parenteral therapy on an outpatient or inpatient basis.

Oral/IM Treatment - Regimen A*

Ceftriaxone 250 mg IM in a single dose,

OR

Cefoxitin 2 g IM in a single dose and **Probenecid**, 1 g orally administered concurrently in a single dose,

OR

Other parenteral third-generation cephalosporin,
(e.g., **ceftizoxime** or **cefotaxime**)

PLUS (i.e., in addition to one of the regimens above)

Doxycycline 100 mg orally twice a day for 14 days

AND

Metronidazole 500 mg orally twice a day for 14 days, if bacterial vaginosis is present or cannot be ruled out

* Preferred except in cases of contraindication because of allergy.

Oral Treatment - Regimen B**

Ofloxacin 400 mg orally twice a day for 14 days

OR

Levofloxacin 500 mg orally once daily for 14 days

****PLUS (i.e., in addition to one of the regimens above)*

Metronidazole 500 mg orally twice a day for 14 days.

** Test of cure (TOC) using a GC culture with susceptibility testing of any isolates.

***Poor anaerobic coverage by ofloxacin or levofloxacin necessitates the addition of metronidazole.

- a) While cefoxitin has better anaerobic coverage, ceftriaxone has better coverage against *N. gonorrhoeae*.
- b) Little data exist regarding the use of oral cephalosporins or azithromycin for the treatment of PID, therefore they are not recommended.

2. Alternative Oral Regimens

The following regimen has undergone at least one clinical trial and provides broad-spectrum coverage.

Alternative Oral Regimen

Amoxicillin/Clavulanic Acid 250/125 mg orally for 14 days

AND

Doxycycline 100 mg orally every 12 hours for 14 days.

- a) Gastrointestinal symptoms may limit the overall success of this regimen.

3. Parenteral Treatment: Hospitalization vs. Outpatient

- a) Parenteral Treatment: Hospitalization

Currently, no data are available to adequately assess the risks, benefits, and cost of inpatient versus outpatient treatment for PID. Now that parenteral treatment can be administered in an outpatient setting, hospitalization is recommended in the following situations:

- i) Surgical emergencies such as appendicitis or ectopic pregnancy cannot be ruled out.
- ii) Tubo-ovarian abscess.
- iii) Pregnancy.
- iv) Failure to follow or tolerate outpatient therapy.

- b) Parenteral Treatment: Outpatient

Parenteral regimens, administered in either an outpatient or inpatient setting, should be used in the following situations:

- i) The patient/client is unable to follow or tolerate an oral regimen.
- ii) Severe illness precludes oral management (e.g., high fever, dehydration, nausea and vomiting).
- iii) The patient/client has failed to respond clinically to oral therapy.

Note: Most clinicians favor at least 24 hours of direct inpatient observation for patients with tubo-ovarian abscesses, after which home parenteral therapy should be adequate.

4. Parenteral Treatment

Please refer to the 2006 CDC STD Treatment Guidelines for parenteral treatment regimens.

Parenteral and oral therapy appear to have similar clinical efficacy treating women with PID of mild to moderate severity. Evidence from clinical trials supporting the use of parenteral treatment in prevention of long-term sequelae is limited. The patient/client's clinical response should guide decisions regarding transition to oral therapy, which usually can be initiated within 24 hours of clinical improvement.

5. Follow-up of Patients/Clients treated for PID

- a) For oral or parenteral outpatient therapy, a follow-up examination should be performed within 72 hours to ensure clinical improvement.
- b) Substantial clinical improvement should occur within 3 days of initiation of therapy.

- c) To minimize further transmission of infection and risk of re-infection, patients/clients treated for PID should be instructed to abstain from sexual intercourse until completion of at least 7 days of therapy and until 7 days after all of their sex partners are treated.
- d) Refer partners in past 60 days for evaluation and treatment.
- e) Partners should be treated with a regimen to cover both GC and CT.

E. Treatment of Urethritis

All patients/clients with documented urethritis should be treated presumptively for chlamydia at the time of the clinic visit, and partners should be referred for treatment. If follow-up is likely to be difficult, the patient/client may be given treatment for gonorrhea as well.

Recommended Regimens:

Azithromycin 1g orally in a single dose

OR

Doxycycline 100 mg orally twice a day for 7 days.

Alternative Regimens:

Erythromycin base 500 mg orally four times a day for 7 days,

OR

Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days,

OR

Ofloxacin 300 mg orally twice a day for 7 days,

OR

Levofloxacin 500 mg orally once daily for 7 days.

1. Clinical and/or laboratory confirmation of urethritis

Clinical and/or laboratory confirmation of urethritis (as described in Chapter IV) should be performed routinely on male patients/clients with symptoms suggestive of urethritis. Empiric treatment without documenting urethritis is recommended only when stat laboratory tests are not available and in the case of individuals at high risk for gonorrhea or chlamydial infection, or for whom follow-up is likely to be difficult. These patients/clients should be treated for gonorrhea and chlamydia and partners should be referred for evaluation and treatment.

2. Follow-up of patients/clients treated for urethritis

- a) To minimize further transmission of infection and risk of re-infection, patients/clients treated for urethritis should be instructed to abstain from sexual intercourse for 7 days after single dose therapy or until completion of a 7-day regimen and until 7 days after all of their sex partners are treated.
- b) Refer partners in past 60 days for evaluation and treatment.

3. Persistent Urethritis

- a) Instruct patients/clients to return for evaluation if symptoms persist or recur after treatment.
- b) Consider re-infection, non-adherence to treatment regimen, resistant organism (tetracycline-resistant ureaplasma) or other etiologies such as *Trichomonas vaginalis* as possible causes of persistent urethritis.
- c) Evaluate for possible trichomoniasis by examining the sediment of a first-catch urine (the first 10-30 cc voided after initiating the stream) or obtaining a culture for *T. vaginalis*.
- d) Do not re-treat unless signs or laboratory evidence of urethral inflammation are documented.

F. Treatment of Epididymitis

All patients/clients with suspected or documented epididymitis should be treated presumptively at the time of the clinic visit.

Recommended Regimens:

For epididymitis most likely caused by gonococcal or chlamydial infection:

Ceftriaxone 250 mg IM in a single dose

PLUS

Doxycycline 100 mg orally twice a day for 10 days.

For epididymitis most likely caused by enteric organisms, for patients/clients allergic to cephalosporins and/or tetracyclines, or for epididymitis in patients aged >35 years:

Ofloxacin 300 mg orally twice a day for 10 days

OR

Levofloxacin 500 mg orally once daily for 10 days.

1. Additional therapeutic recommendations:

Bed rest, scrotal elevation, and analgesics are recommended until fever and local inflammation have subsided.

2. Follow-up of patients/clients treated for epididymitis:

- a) A follow-up examination should be performed within 72 hours.
- b) After 3 days without improvement, re-evaluate diagnosis and therapy. Persistent swelling and tenderness should be evaluated comprehensively by referring to a specialist.
- c) Hospitalization should be considered when severe pain suggest other diagnoses such as torsion, testicular infarction or abscess, or when the patient/client is febrile or cannot comply with or tolerate outpatient treatment.

- d) To minimize further transmission of infection and risk of re-infection, patients/clients treated for epididymitis should be instructed to abstain from sexual intercourse until completion of at least 7 days of therapy and until 7 days after all of their sex partners are treated.
- e) Refer partners in past 60 days for evaluation and treatment.

VI. FOLLOW-UP OF POSITIVE CHLAMYDIA TEST RESULTS

Policy Statement: Clinics must have written protocols for confidential follow-up of patients/clients with positive chlamydia test results. Protocols must specify which staff are responsible for contacting patients/clients with positive chlamydia test results. Procedures must be established to document treatment, follow-up and partner referral efforts and to ensure patient/client confidentiality. (For detailed information about partner referral, see Chapter X. Partner Identification and Referral and Chapter XI. Partner Assessment and Treatment).

To facilitate follow-up procedures, clinic staff should communicate to all patients/clients the need for accurate contact information. Patients/Clients should be encouraged to provide their preferred method of contact, as well as other ways to confidentially contact them at work, home, or through employers, friends or relatives. Patients/Clients should be asked to provide telephone, cell phone, beeper numbers, and email address (including text messaging) as well as mailing address. Adolescents could provide the name of their school nurse or counselor in addition to a personal contact such as home of a relative or friend. Patients/Clients should be informed of the circumstances under which they may be contacted and that their cooperation is appreciated by clinic staff. Efforts must be made to protect the patient/client's confidentiality.

A. Positive Chlamydia Test Results

1. Positive, Not Treated

- a) As soon as a positive test result is received, the patient/client's medical record should be reviewed by a designated staff person to determine the appropriate course of action.
- b) Contacting untreated patients/clients should be an urgent priority.
- c) It is recommended that patients/clients return to a clinic within 24 hours for treatment and evaluation to rule out the possibility of PID, which may have developed during the interval from the time the test was obtained to the time the result was reported by the laboratory.
- d) It is not recommended to call in prescriptions for untreated cases in lieu of an office visit.
- e) A first attempt to contact patient/client should be made within 24 hours of receipt of their positive result; second and third attempts ideally should be made within 5 days.
- f) If an untreated patient/client cannot be contacted after phone and letter attempts described below, the agency should contact the local STD Control program for assistance.

Furthermore, in California and Nevada providers are required by law to report untreated patients/clients to the local health department (See Chapter VII.C.2).

2. Positive, Treated Clients

- a) All patients/clients should receive counseling to assist with partner referral efforts, ensure compliance with medication and prevention efforts, and schedule a re-testing appointment in 3 months.
- b) Confirmation of a positive test result may also increase compliance with medications, partner follow-up and behavioral change to reduce risk of future STDs.
- c) The first attempt to contact treated patients/clients should be made within 24 hours of receipt of their positive result; second and third attempts should be made within 5 days. These attempts are needed to avoid re-infection from untreated partners and to improve compliance. A re-testing appointment should be scheduled with the patient/client in 3 months.

3. Medical Record Documentation

- a) Medical records of all patients/clients with chlamydia should be flagged with the plan of action clearly documented.
- b) A minimum of three documented attempts must be made to contact the patient/client. Each attempt to contact a patient/client must be documented fully in the patient/client's medical record, along with the results of the attempt.

4. Contacting Patient/Client by Telephone

- a) The first attempt at contacting a patient/client should be by telephone, cell phone, or beeper when telephone contact is permitted by the patient/client.
- b) Telephone contact should be made by a physician, physician's assistant, nurse practitioner, nurse or an appropriately trained non-medical person with medical personnel available to respond directly to patient/client concerns.
- c) If the patient/client is not at home, ask that the patient/client return the call. Because of the sensitive nature of the infection, do not give confidential information to anyone other than the patient/client.
- d) When contacting a patient/client, first verify that the person you are speaking to is actually the patient/client. Sometimes code words are given at the time of the clinic visit since other information may be known by family members. This is especially important when contacting adolescents. Remind the patient/client that the information will be kept confidential.
- e) Alert patient/client to the serious nature of the disease and stress the need for immediate medical attention and the importance of partners getting treated as well. Explain that the disease is easily treated if medication is quickly obtained.

- f) Make an appointment for counseling and treatment as soon as possible and at least within three days of reaching a patient/client with a positive test result.

5. Contacting Patient/Client by Letter

(See APPENDIX F for Sample Patient/Client Follow-Up Letter.)

- a) If there is no way to contact the patient/client by telephone or other preferred method, or attempts at telephone contact have been unsuccessful, at least one letter should be sent to the patient/client.
- b) Do not include the words chlamydia, “STD” or “VD” in the letter. It should be written to maintain the confidential nature of its contents.
- c) Write the letter in the language and style most appropriate for the patient/client.
- d) Encourage the patient/client to call the clinic.
- e) Do not include identifying information (e.g., clinic name, address, phone number) on the envelope or letterhead.
- f) The final letter should communicate that this will be the last effort the clinic can make in contacting the patient/client. The letter should also inform the patient/client that their information will be referred to the local health department for further follow-up.
- g) If a clinical agency is unable to reach a patient/client with a positive chlamydia test and have them treated after efforts by phone and letter as described above, the agency should contact the state or local STD program and request assistance in locating and treating the patient/client. The agency should document in the medical record that they requested assistance from the state or local STD program in following-up with the patient/client.

VII. CLINICIAN REPORTING PROCEDURES OF CHLAMYDIAL INFECTIONS

Clinicians who know of or treat a suspected or documented case of chlamydia are responsible for completing and submitting a sexually transmitted disease confidential morbidity report (CMR) to their county STD Program. These reports require demographic and clinical information and are to be reported within the time interval specified by individual state laws. Failure to report to your local STD program is a misdemeanor. Forms may differ by state or county.

A. Data to be reported

In general, the minimal data that should be included on a morbidity report are:

Data	AZ	CA	HI	NV
Name of Disease	x	x	x	x
Date of Onset	x	x		x
Date of DX	x	x	x	x
Patient Name	x	x	x	x
Patient Address	x	x	x	x
Patient Phone	x	x	x	x
Race/ethnicity	x	x	x	x
Sex	x	x	x	x
Age/DOB	x	x	x	x
Name of person making report	x	x	x	x
Address of person making report	x	x	x	x
Phone of person making report	x	x	x	x

- Additional California variables to report: occupation, SSN, pregnancy status, site of infection, treatment (drug dosage, route, date), date of death, all suspected or documented cases of NGU and PID
- Additional Arizona variables to report: date of lab confirmation, name of laboratory, test results, marital status, treatment (date, site of infection, dosage, date of report)
- Additional Hawaii variables to report: date of treatment, treatment regimen, partner info
- No additional variables are required in Nevada.

B. State timelines for reporting

- Arizona - within 5 business days from date of diagnosis or treatment
- California - within 7 days from the time of identification
- Hawaii - within 3 days of confirmation
- Nevada - within 24 hours

C. Other Reporting Regulations:

1. Laboratories are also required by law to report positive chlamydia cases to their health departments. (See Chapter II.H, Laboratory State Reporting Requirements.)
2. In California and Nevada, providers are required by law to report untreated patients/clients to the local health department.

VIII. CLINIC STAFF EDUCATION AND TRAINING

Policy Statement: All clinic staff who are involved with client education and counseling, screening, diagnosis, treatment, partner referral or follow-up for chlamydia must be knowledgeable about chlamydial infections in women and men and ways of reducing morbidity and complications. Staff should provide care according to the standards outlined in this document and be provided with appropriate education and training.

Training for Clinic Staff Should Include:

Epidemiology

Prevalence and incidence

At-risk population(s)

Risk factors for infections including recurrent infection

Diagnostic Testing

Laboratory Test Selection

Specimen collection

Specimen handling and transport

Screening criteria

Screening program design

Clinical Assessment/Management

Sexual history & risk assessment

Clinical evaluation and diagnosis

Treatment regimens and follow-up

Partner identification and referral

Education and counseling

Patient-Delivered Therapy

Training for non-clinicians should also include a basic clinical component.

Contact the following local resources for training:

- a. Arizona Family Planning Council: (602) 258-5777
- b. Arizona State Infertility Prevention Project Coordinator: (602) 364-4759
- c. California STD/HIV Prevention Training Center: (510) 625-6000
- d. California Family Health Council: (213) 386-5614
- e. San Francisco STD Program: (415) 355-2010
- f. Los Angeles County STD Program: (213) 744-5956
- g. Hawaii Office of Family Planning: (808) 733-9030

- h. Hawaii STD/HIV Prevention Program: (808) 733-9287
- i. Nevada STD Program: (775) 684-5930
- j. Clark County Health District: (702) 383-1301
- k. Washoe County Health District: (775) 328-2444 (Family Planning), (775) 328-3759 (STD)
- l. Center for Health Training: (510) 835-3700, www.centerforhealthtraining.org
- m. CA STD/HIV Prevention Training Center: (510)625-6000, www.stdhivtraining.org

IX. PATIENT/CLIENT EDUCATION AND COUNSELING

Policy Statement: All patients/clients at risk for chlamydial infection should receive culturally and linguistically appropriate STD education and client-centered risk reduction counseling.

A. General STD Information

All patients/clients offered a chlamydia test should be provided with basic information about chlamydia and other STDs, including HIV, to help them assess their personal risk and understand the testing process. At the minimum, information about chlamydia should include:

1. What chlamydia is and how it is transmitted.
2. The asymptomatic nature of the disease (i.e., the patient/client or her/his partner(s) could be infected and not know it).
3. Possible female symptoms, including abnormal discharge or bleeding, pain with vaginal sex, burning on urination, and abdominal pain.
4. Possible male symptoms, including white or clear drip from the penis, irritation, burning or pain when urinating, and swollen, tender testicles.
5. Complications for women, including pelvic inflammatory disease (PID), infertility, ectopic pregnancy, chronic pelvic pain, and transmission to infant at birth.
6. Infection with chlamydia and other STDs can increase the risk of contracting HIV.
7. Test purpose, accuracy and limitations.
8. Treatability of chlamydial infections.
9. Risk reduction strategies - See Section C.
10. Requirement to report all clients/patients with a positive test result to the county health department.

B. Chlamydia Positive or Presumptively Treated Patients/Clients

All patients/clients with a positive chlamydia test or a presumptive diagnosis of chlamydia should be counseled with the following information:

1. The name of the drug(s) being administered.
2. For single-dose regimens, instructions on how single dose medication for chlamydia work. Acknowledge that many people confuse single-dose treatment with an instant cure. Explain that the drug is long-acting and must work in the body for a full seven days before the patient/client is cured and can no longer transmit the infection to partners.

3. For multi-dose regimens, instructions on proper use and frequency of dosage; need to complete the full course of treatment even if symptoms disappear; consequences of missed doses and incomplete treatment; and importance of not sharing medication with friends and partners.
4. Possible side effects and interactions.
5. Efficacy of treatment if the drug is taken properly, and instructions to call/return to clinic if symptoms persist after 7 to 10 days.
6. Need to treat all sex partners and their contacts to prevent re-infection and that the health department may contact them to ensure adequate treatment and to assist with partner treatment.
7. Instructions to abstain from sex until both client and partner(s) complete the full course of treatment. Remind patients/clients treated with a single dose of azithromycin to abstain for a full seven days after treatment. If abstinence is not feasible, encourage patient/client to use condoms consistently during this period to help prevent further transmission and re-infection.
8. Counseling should be provided to assist patients/clients in assessing and reducing their risk for HIV and other sexually transmitted infections. HIV testing or referrals to HIV test sites should be offered.
9. When to return for test of cure in situations where test of cure is warranted (i.e., when treated with erythromycin, or for all pregnant women).
10. All patients/clients should return in 3 months for re-testing to detect re-infections which occur in 10-25% of women after an initial chlamydial infection.

C. Client-Centered Counseling and Risk Reduction Strategies

All patients/clients should be counseled on strategies to reduce the risk of contracting chlamydia and other STDs. The effectiveness of risk reduction counseling may be improved by using “client-centered” counseling techniques, in which the interaction focuses on the individual’s situation and needs, rather than on the provision of information.

Client-centered counseling engages the patient/client at his or her own level of readiness to change, and takes into account the patient/client's particular life circumstances. It requires a conscious shift away from directing the interview toward dialog, support and negotiation with the client.

Begin a dialogue with patient/client to determine:

1. Risk history, which may include (Ask the patient/client specific questions about the following):
 - a) Number of sex partners during past 2 months, including new partners

- b) Gender of partners
- c) Sexual practices (anal, oral, vaginal intercourse) and patterns of condom use
- d) Unintended pregnancy(ies)
- e) Alcohol and/or drug use affecting sexual behaviors
- f) Prior STD's
- g) Past STD/HIV testing history
- h) Other information relevant to patient/client history such as partner history, domestic violence, etc.

Note: Also see Chapter III.A.1 and 2

2. Ask the patient/client what she/he has heard about chlamydia and other STDs (how transmission occurs, potential complications, etc.), then add information as needed.
3. Ask the patient/client if they think they are at risk of an STD given their history and sexual behaviors. (Note: If perception of risk is unrealistic, efforts should be made to assist patient/client in recognizing risk.)
4. Ask the patients/clients what they have done in the past to protect themselves from STDs. Positively reinforce any efforts. Examples include:
 - a) Use of barrier contraceptives with main and/or non-main partners
 - b) Intent to reduce number of sex partners
 - c) Enhancement of partner communication and sexual negotiation
 - d) Consideration of any of the above measures
5. Ask the patient/client what she/he might do to further reduce their risk. Ask what would make this hard and what would make it easier. Help the patient/client set small, achievable goals for risk reduction. Circumstances that may help or hinder risk reduction efforts include:
 - a) Accurate perception of risk for STD
 - b) Confidence in ability to negotiate condom use
 - c) Power and control differences in relationships
 - d) Cultural issues
 - e) Access to appropriate health care

- f) Encouragement by others to reduce risky behaviors
 - g) Other information relevant to client that may help or hinder risk reducing behaviors
6. Help the patient/client brainstorm solutions to risk reduction problems (e.g., let's think of some things you might say to your partner.) Possible solutions include:
- a) Monogamy
 - b) Partner testing
 - c) Reduction in number of sex partners
 - d) Increase in condom use with main and/or non-main partners
 - e) Abstinence
 - f) Sexual activities that do not involve exchange of blood, semen, or vaginal secretions
 - g) Discussion with partner(s) to negotiate risk reducing activities
 - h) Reduction in use of alcohol and/or drugs
 - i) Consideration of any of the above factors
 - j) Other patient/client-relevant behaviors

D. Written Materials

Patients/clients should be provided with written materials to reinforce and supplement verbal education and counseling. Materials should be selected that are culturally sensitive, written in the appropriate reading level, and available in appropriate languages.

Where possible, a local telephone number should be included so patients/clients can obtain additional information about STDs and HIV. Alternatively, a national 800 number (such as the National STD Hotline at 1-800-227-8922) could be included.

Lastly, referrals to primary care, drug treatment, mental health, domestic violence, or other appropriate services should be provided, as needed.

X. PARTNER IDENTIFICATION AND REFERRAL

Policy Statement: No person with *Chlamydia trachomatis* (CT) infection can be considered adequately treated until all of his or her sex partner(s) have also been treated. The treatment of sex partners is critical to disease control efforts for the following key reasons:

- Partners are often asymptomatic and therefore will not seek treatment without being contacted.
- Treatment of partners will prevent re-infection of the initial patient/client.
- A repeat infection is much more likely than an initial infection to result in the serious adverse consequences associated with chlamydia (e.g., chronic pelvic pain, PID, infertility and ectopic pregnancy).
- Minimizing re-infection is critical in ultimately reducing the level of infection in the community at large and in reducing the financial costs to the individual and the health care system.
- Treatment of partners is essential in preventing disease transmission to others.

Every health care agency should be able to offer a host of partner service options that can be individually tailored to CT-infected clients and their partners in order to assure the treatment of all sex partners who may have been exposed to the infection. Whenever possible, clinicians should request that client's bring their partner into the health setting with them for treatment. This option has been shown to be a very successful strategy in treating steady partners, in particular, and has the added advantage of allowing for clinical evaluation of the partner in addition to treatment.

Expedited partner therapy (EPT), which has been shown to be very successful among both steady and non-steady partners, is an alternative strategy for ensuring that sex partners get needed medication. Chapter XI, Partner Assessment and Treatment, includes more details about EPT options and Region IX IPP also has available a *Guidance and Toolkit for the Use of Expedited Partner Therapy and Retesting at Three Months to Prevent and Detect Chlamydia and Gonorrhea Reinfections* (see Appendix I).

If neither bringing in one's partner nor EPT options are appropriate or available for a client, and especially if client confidentiality is important, partner referral is another option for identifying and treating partners. Partner identification and referral may be accomplished in three ways: by patients/clients, by health care clinic staff, or by staff in the state or local health department. The primary focus in this chapter is on partner identification and referral. The next chapter (Chapter XI) will address issues of partner assessment and treatment, including EPT.

A. Critical Exposure Period (CEP)

The critical exposure period (CEP) is the retrospective time frame within which CT-infected patients/clients are asked about sex partners. Although it is possible that sex partners prior to the CEP are infected, the risk is lower than in those exposed within the CEP and therefore partners prior to the CEP are generally not pursued (two exceptions to this rule are noted in the box below).

The Critical Exposure Period (CEP) for clients with CT infection:

- Asymptomatic client: 60 days prior to date of diagnostic test and up to date of treatment
- Symptomatic client: 60 days prior to date of onset of symptoms and up to date of treatment
- Patient/client with no sex partner(s) in the CEP: refer the most recent sex partner
- Patient/client with pregnant sex partner(s): refer immediately, regardless of time interval since last sexual exposure with the infected client

B. Partner Identification

The process begins by counseling the patient/client diagnosed with *Chlamydia trachomatis* (CT) infection.

- Trained staff must be available to successfully accomplish the partner identification and referral process.
- A patient's/client's initial reaction to a positive CT test may include anger, denial, blame or remorse.
- Patients/clients often incorrectly think they know who infected them and only want to contact those partners.
- The manner in which the patient's/client's counseling and education session is managed can enhance compliance with partner identification, evaluation and treatment (see Chapter IX, Client Education and Counseling).

1. Importance of Partner Identification

For partner identification to occur, its importance must be successfully conveyed to the patient/client, including explicit reasons why partner notification is crucial to the health of the patient/client, as well as to her/his partners. The following issues may be useful in emphasizing the importance of partner identification, referral, and treatment:

a) Partner consideration

Partners have the right to know that they have been exposed to CT infection and should be given a chance to receive treatment and medical evaluation, even if the patient/client does not intend to see his/her partner(s) again.. Denying a partner this important information about his/her health may result in serious health consequences for that person, as well as for that person's future sex partners.

b) Prevention of re-infection and serious complications in women

To prevent re-infection, it is imperative that patients/clients avoid sexual contact with partners until the patients/clients and their partners have completed prescribed treatment regimens. At a minimum, condoms should be used until treatment is complete, or for at least 7 days post-treatment if single-dose therapy

is used. Patients/clients need to know that a repeat infection is much more likely than an initial infection to result in the serious adverse consequences associated with chlamydia (e.g., chronic pelvic pain, PID, infertility and ectopic pregnancy).

c) Partner spread

Partners who are positive for CT infection may unknowingly spread chlamydia to others.

d) Pregnancy and serious complications in the newborn

Patients/clients or their partners may be pregnant. Chlamydial infection in pregnancy can cause serious adverse outcomes including premature or low birth weight newborns, as well as newborn and maternal infections.

e) Confidentiality

The identity of the infected patient/client will never be revealed to any sex partner.

2. Elicitation of Partner Names

Staff should assess the patient/client's attitude towards identifying and disclosing information about their partner(s). If the patient/client is reluctant, unwilling or unable to discuss their sex partner(s), staff can address and discuss barriers to sex partner disclosure.

It is important to give clients options for how to let their partner know they have been exposed to the infection. Explore with the client their level of comfort in speaking directly with their partners and let them know that they can also retain anonymity by having health department staff inform their partner of exposure. It is recommended that staff obtain as much partner information as is feasible from the client regardless of how the partner is to be informed. The patient/client may decide that they are unable to discuss their infection with their partner(s) after initial discussion with staff. Staff will then have the information to follow up with partners or contact the local health department for assistance. This process saves the staff and patient/client from a second meeting to discuss partner identification.

a) Staff may use the following transitional phrases to introduce the elicitation process:

(i) "Now that you have an idea of some things you can do to protect yourself from infection or re-infection with other STDs, we need to talk about your partners who are probably unaware of their exposure to chlamydia. Your partners need to be informed about their exposure and their need for treatment."

or

(ii) "Now that we have discussed the benefits of notifying your partners, it is important to identify who needs to be notified."

or

- (iii) “Now that we have talked about how important it is to notify partners and stop the spread of chlamydia, we need to talk about whom to notify.”
- b) Assist the patient/client in identifying sex partners and ask for all partner names and exposure dates. Ask the patient/client, “Who is the last person you had sex with and when did this occur?”
 - (i) Stress the importance to treat all partners in the Critical Exposure Period (see Section A). Any partners prior to the CEP should be initiated at the patient/client’s request. Review confidentiality procedures used by the clinic or health department and how it applies to the notification process; all information about the patient/client is kept confidential from her partner(s), and all information about partner(s) exposure is kept confidential from any third parties.
 - (ii) List the most recent partners first and work backwards over the CEP. It is often helpful to informally list or chart a time line or follow a calendar when identifying exposed partners, as it relates to significant dates (holidays, birthdays, vacation, etc.).
- c) Once the patient/client has identified all partners, staff can obtain descriptions of partners and locating information (e.g., home, work, and email addresses, living-with status, “hang outs”, age, race, sex, marital status, physical description, the best time to notify each partner, and any additional locating information and phone numbers). Agency staff should communicate to patients/clients the importance of collecting accurate contact information to facilitate notification.

C. Methods of Partner Referral

Patients/clients may choose a combination of the following methods for partner referral. For example, the patient/client may choose EPT for a current partner, self-referral for another recent partner, and health department referral for partners with whom they may not want to interact or may not see again.

1. Patient or Client Self-Referral

Patient or client self-referral can be a successful, expedient method of partner referral when the patient/client is willing.

- a) Patient/client notifies a partner of their exposure to chlamydia without any outside assistance. This can occur in a variety of means, including sending a confidential e-card to the partner via a website such as Inspot.org, an option which allows the client to maintain anonymity if desired. Staff should assess the patient/client’s attitude toward notifying their partner(s). If the patient/client is reluctant, unwilling or unable to notify partners, staff can address and discuss barriers to sex partner notification. Staff should determine whether barriers can be overcome or if another method of referral should be used.

The following transitional phrases can be used to lead into a specific discussion of partner(s):

- (i) “Now that we have talked about your partner(s), we need to talk about the best way to notify them about their exposure to chlamydia and their need for treatment.”
 - or
 - (ii) “Now that you have identified your partner(s) who need to know that they have been exposed to chlamydia, it is important to figure out a way to inform them.”
- b) Patient/client should be asked to discuss with staff strategies to inform their partners. When using this approach it is important to coach the patient/client on what to say to their partner and how to say it. The following questions can help with the coaching process:
 - (i) How much does your sex partner(s) know about his/her possible exposure?
 - (ii) What do you feel his/her response will be if you tell him/her you have a positive CT test result?
 - (iii) Do you have a private place where you can discuss your infection with your partner(s)?
 - (iv) How will you handle his/her reaction?
 - Is it possible that your partner might tell someone else that you do not want to know about your infection and if they did, is that ok with client? (Clients who are concerned about their confidentiality being compromised by a partner, might benefit from choosing the provider referral option.)
 - (v) Is it possible for you to accompany your partner(s) for evaluation and treatment?
- c) Discuss possible reactions and effects on the relationship. Assess and recognize the potential that abuse (i.e., psychological or physical battering) may result from patients/clients discussing these issues with partners. Consultation and assistance from health department staff for an alternative method of notification is advised in cases where abuse is considered a likely outcome of partner notification by patient/client referral. The following are important points to cover with the patient/client during the coaching process. The patient/client should:
 - (i) Inform sex partner(s) in a private setting.
 - (ii) Avoid accusations.
 - (iii) Anticipate that partner(s) may be upset or hostile.
 - (iv) Focus on the discussion of health issues that partner(s) must be treated, counseled and tested as soon as possible to avoid complications.
 - (v) Explain to partner(s) what to expect at the time of exam and treatment.
 - (vi) Provide appropriate referral cards. (See Appendices G and H for examples.)

- (vii) Make an appointment for the partner(s) immediately. If partner follow-up is not available at your facility provide written referral information for patient/clients' partner(s).
- (viii) Discuss alternative methods of notification if the patient/client does not follow through with partner notification and referral.
- d) It is helpful to have the patient/client practice or "role play" what she/he will say to her/his partner.
- e) When encouraging patients/clients to identify and notify their partners clinic staff should:
 - (i) Provide culturally and linguistically appropriate written information on CT infections, including the importance of notifying and treating partners.
 - (ii) Provide a partner referral card or letter (see Appendices G and H).
 - (iii) Emphasize discretion and confidentiality and the fact that the patient/client's identity is not revealed to partners when the partner is notified by health department staff (confidentiality is often a concern when patients/clients are reluctant to have health department follow-up). Assure patients/clients that all reports related to STDs are confidential under state law. (Please refer to your local, county or state laws and regulations.)

2. Provider/Agency Referral

Trained staff notifies partners of their exposure to chlamydia with or without the assistance of the patient/client 2. (Provider /agency Referral) and 3. (Health Dept/STD Program Referral) from below (Staff discusses strategies to inform her/his partner(s) with the patient/client.

Agencies that have the capacity to treat and possibly examine partners may offer to notify partner(s) of CT-infected patients/clients with the patient/client's cooperation and consent. The following steps should be followed by agency staff:

- a) A telephone call can be made while the patient/client is present in the room when the patient/client desires immediate assistance in notifying partners.
- b) Confirm that you are speaking to the partner.
- c) Identify yourself and alert the partner to the serious nature of the disease, stressing the demands for immediate medical attention. Explain that the disease is easily treated if medication is quickly received.
- d) Ask for a return phone call if the partner is not at home when confidentiality can be assured. To facilitate confidentiality it is helpful to leave a number that is not answered with an agency name but preferably anonymously with "Hello."
- e) Make an appointment for the partner(s) (at your facility) immediately.

3. Health Department/STD Program Referral

Trained health department staff confidentially notify partners of their exposure to chlamydia.

Clinic staff should contact the local or state STD Control Program to follow up with partners when: patient/client or staff are unable to locate partners or require assistance, partners are not willing to seek treatment, partners live out of the county or state, or when further assistance or advice is necessary.

CONFIDENTIALITY

Staff should **never** reveal the identity of the infected patient/client, the date of exposure or the gender of the positive patient/client when notifying a sex partner. In the event that the local health department staff assists in the notification process, under the law, the infected patient/client's identity is **never** revealed to a sex partner. However, the patient/client must be aware that if she/he is someone's only sex partner, the source of the referral may be obvious.

D. Risk Reduction and Prevention Messages for Patients/Clients and Partners

Please refer to Chapter IX, Patient/Client Education and Counseling, for a listing of risk reduction and prevention messages for patients/clients and partners.

XI. PARTNER ASSESSMENT AND TREATMENT

Policy Statement: Once a patient/client has been diagnosed with a *Chlamydia trachomatis* (CT) infection and appropriate therapy has been initiated, attention must be directed to the evaluation and care of her/his sex partner(s). Each provider site must have written policies and procedures for sex partner evaluation and treatment. These should include identification, examination, and treatment option guidelines, and/or referral procedures for examination or treatment.

Ideally, all medical programs should have the capacity to evaluate (history, physical examination and diagnostic testing) and treat both males and females for CT infection. Otherwise, programs must provide a referral with written documentation to appropriate clinical facility for examination, diagnosis or treatment.

Collaboration between medical programs and the local or state STD Program is strongly encouraged in developing policies and procedures concerning sex partner evaluation and treatment. A written memorandum of understanding will clearly define each agency's role in partner management.

A. Male Sex Partners

To protect the health of both male and female patients/clients and prevent re-infections, complications, and associated costs, it is crucial that all partners receive prompt and adequate treatment.

1. Generally there is a lack of available sources of medical care for asymptomatic or mildly symptomatic males.
2. Evaluation and treatment standards for male sex partners parallel the recommendations for females and include:
 - a) An on-site history and risk assessment, physical exam and testing.
 - b) STD testing including CT, gonorrhea (GC) and syphilis at a minimum; an HIV test should also be offered when indicated.
 - c) Assessment of allergies to treatment medications.
 - d) Immediate treatment on site upon completion of history and risk assessment and collection of diagnostic specimen. This may be limited by agency and partner resources. Partners should be treated before CT test results are available and regardless of CT test results. Testing is done primarily for the following compliance and public health reasons:
 - (i) To increase effectiveness of patient/client prevention education and risk counseling.
 - (ii) To improve compliance with treatment regimens.

- (iii) To facilitate partner referral and additional case finding beyond the initial patient/client.
 - (iv) To improve STD surveillance, prevention and control efforts.
3. Expedited partner treatment (EPT) for chlamydia is an alternative strategy for ensuring that sex partners get needed medication. EPT is the general term for the practice of treating sex partners of patients diagnosed with an STD without an intervening medical evaluation. Patient delivered partner therapy (PDPT), whereby the patient takes medication to his or her sex partners, is the most common method of EPT. EPT is not intended as the first and optimal choice of partner management, however programs are encouraged to include EPT options if possible.
- a) EPT can be considered in the following situations
 - (i) Partner is unable or unlikely to seek exam and treatment promptly.
 - (ii) Partner is unwilling to seek care.
 - b) EPT options
 - (i) Patient-deliver partner therapy (PDPT), whereby patients take medication or a prescription to their partner(s)
 - (ii) Pharmacy access programs, whereby partners are provided with medication at a pharmacy, or prescription for partners are given to the patient
 - (iii) Field-delivered therapy, whereby health department personnel deliver medication to the partner
 - c) The document Region IX IPP, *Use of Expedited Partner Therapy and Re-testing at Three Months to Prevent and Detect Chlamydia and Gonorrhea Re-infections provides guidance and resources for implementing EPT* (see Appendix I).
 - d) Consult with state or local STD Control Programs and/or State Medical Practice Laws prior to adopting EPT.

B. Female Sex Partners of Males

It is imperative to treat all female sex partners of infected males. In addition to the items outlined in Section A, “Male Sex Partners,” females should also receive a pregnancy test when she has had unprotected sex and her menstrual period is late.

XII. OUTREACH ACTIVITIES

Policy Statement: Educational and community outreach are necessary to educate and motivate high-risk adolescents and young adults to seek STD services as well as high-risk adults who do not access services in traditional settings. In some cases services need to be brought to patients/clients. In general, most sexually active adolescents will need information about family planning and STD prevention.

To maximize the benefits of chlamydia screening and treatment, family planning and STD control programs should appreciate the fact that many persons, especially adolescents, do not seek services in established medical care facilities. Some subgroups of at-risk individuals (e.g., groups with a high prevalence of chlamydia, frequent sex partner change or little or no contact with the health care system), may maintain chlamydial infections within their sexual networks.

A. Educational Outreach

1. Family planning agencies and STD programs should participate in efforts to educate adolescents and young adults about the following:
 - a) Reproductive health
 - b) Sexuality
 - c) Prevention of unintended pregnancy
 - d) Prevention of sexually transmitted diseases, including HIV
2. Information that is delivered to adolescents in schools or adolescents and adults in specific high-risk group settings should cover the following:
 - a) Information about chlamydia transmission.
 - b) Signs and symptoms (emphasizing that most infections are asymptomatic).
 - c) Complications of untreated chlamydia.
 - d) Importance of screening and treatment, including partner treatment.
 - e) Risk reduction strategies for STDs, HIV, and unintended pregnancy.
3. Family planning agencies and STD programs should ascertain who is providing reproductive and sexual health information (STDs, including HIV) and services in the following settings:
 - a) High schools
 - b) Universities

- c) Juvenile detention centers
 - d) Adult jails
 - e) Drug treatment centers
 - f) Halfway houses/shelters
 - g) Community based organizations serving adolescents and young adults including faith-based organizations
4. Family planning agencies and STD programs should assist by offering the following services:
- a) Review and/or distribute accurate, theory-based STD/CT and family planning health education materials.
 - b) Provide up-to-date information about reproductive health and STD service availability and referrals.
 - c) Collaboratively provide technical assistance, training, or screening and treatment as appropriate.

B. Street Outreach

High risk adolescents and young adults may benefit from field outreach-based health education services.

1. Peer-outreach services provide the following:
 - a) Efficient means to reach youth and other high-risk populations.
 - b) Targeted interventions for persons at high risk for chlamydia, with little knowledge of or access to family planning services.
2. Peer-outreach workers can specifically provide the following:
 - a) Urine-based chlamydia screening in the field for those who do not access medical care.
 - b) Information about chlamydia/STD prevention.
 - c) Information on how to access family planning and STD services.
 - d) Encouragement and assistance for clients to access services.
 - e) Condoms and information regarding risk reduction strategies for sexually active youth.

3. Family planning agencies and STD programs should collaborate by:
 - a) Reviewing outreach messages.
 - b) Providing up-to-date information about chlamydia and other STDs and family planning.
 - c) Conducting training for outreach workers.
 - d) Providing technical assistance about testing and treatment.
 - e) Assisting in the follow-up of untreated clients and partner services.
 - f) Cooperatively developing outreach programs from their respective agencies.

XIII. APPENDICES

Appendix A: Laboratory Test Selection

Appendix B: Specimen Collection Instructions, by Test Method

Appendix C: Descriptions of Chlamydia Testing Technologies

Appendix D: Checklist For Laboratory Site Visit

Appendix E: Patient-Administered Sexual History Questionnaire

Appendix F: Sample Client Follow-Up Letter

Appendix G: Sample Partner Referral Card

Appendix H: Sample Partner Referral Letter

Appendix I: *Guidance and Toolkit for the Use of Expedited Partner Therapy and Retesting at Three Months to Prevent and Detect Chlamydia and Gonorrhea Reinfections*

APPENDIX A: LABORATORY TEST SELECTION

Please refer to Section II Laboratory Services for more details on test selection.

The last several years have seen many new laboratory diagnostic products and procedures introduced for chlamydia detection. Therefore, selection of the "best test", or more appropriately the laboratory offering the "best test", has become more of a challenge. Some factors to consider in choosing a specific chlamydia diagnostic test are described below.

1. Accuracy

The accuracy of test results reflects the sensitivity and specificity of a given test. The recent introduction of nucleic acid amplification methodologies has added to the array of tests available as well as increased the level of sensitivity of chlamydia detection.

2. Cost

Always an important factor but with the advent of newer generation and often costlier tests one has to weigh the aspects of being able to test more clients with a less expensive, and perhaps less sensitive test, to utilizing the more expensive but more sensitive tests with a smaller number of clients.

3. Disease Prevalence (Morbidity) in the Given Population

The predictive value of the test is directly influenced by prevalence of disease in the population tested. The higher the prevalence the greater the Positive Predictive Value of the test.

4. Specimen and Test Collection Aspects

The advent of the nucleic acid amplification tests (NAATs) has expanded the types of specimens acceptable for testing. Urine is now an acceptable test specimen with many NAAT products and self-obtained genital swab specimens on females is being investigated. The greater ease in obtaining these "alternative" specimens may be an important factor to consider when testing certain populations, i.e. young women and clients in a non-clinic setting or clients not undergoing a pelvic examination in a clinic setting. Another consideration with respect to test type or type of specimen is specimen collection and handling requirements such as the need to collect columnar cells, especially for non-amplified test types, the need for immediate refrigeration or method of specimen transport.

5. Reported Performance

A source of information often overlooked in selection of an appropriate test is published reports in peer review journals. These provide detailed information on test performance and offer comparative information to the existing "gold standard". In addition to the written word, experienced colleagues are another useful source of information.

6. Purpose of Testing

Although to aid in diagnosis may be the most common reason to request chlamydia testing, how those results will be used (e.g. partner notification, medico-legal) may influence the type of testing needed. For instance, culture is still the recommended

choice when legal issues are involved.

7. Turn-around Time

Laboratory tests vary in the amount of "hands-on" time required per specimen. This influences the turn-around time for reporting and the number of specimens which can be processed in a given period.

APPENDIX B: SPECIMEN COLLECTION INSTRUCTIONS, BY TEST METHOD

1. DIRECT FLUORESCENT ANTIBODY (DFA)

FEMALE CYTOBRUSH: (preferred female collection device for DFA)

1. Remove excess mucus using cotton or dacron swab. Discard swab.
2. Insert cytobrush into endocervical canal past squamocolumnar junction. Leave in place 2-5 seconds.
3. Rotate brush one full turn 360°. Withdraw brush without touching vaginal surfaces.
4. Place portion of cytobrush containing the specimen across the center of the well.
5. Rotate and twist the brush, moving the brush back and forth across the well. Liquid clinging to the brush will disperse cells across the well.
6. Check coverage.
7. Label slide.
8. Air dry completely.
9. Fix with methanol.

FEMALE SWAB:

1. Remove excess mucus using cotton or dacron swab. Discard swab.
2. Insert second swab into endocervical canal until the tip is not visible.
3. Rotate swab 360° for 5-10 seconds inside endocervical canal. Withdraw swab without touching vaginal surfaces.
4. Prepare slide immediately by rolling one side of swab over top half of slide well and other side of swab over bottom half of slide well.
5. Label slide.
6. Air dry completely.
7. Fix with methanol.

MALE SWAB:

1. Preferably no urination one hour prior to collection.
2. Using manufacturer's male collection kit swab, insert into urethra a minimum of 2-4 cm.
3. Rotate at least one complete revolution for 2-5 seconds and withdraw swab.
4. Prepare slide immediately by rolling one side of swab over top half of slide well and other side of swab over bottom half of slide well.
5. Label slide.
6. Air dry completely.
7. Fix with methanol.

2. ENZYME IMMUNOASSAY (EIA)

FEMALE SWAB:

1. Remove excess mucus using large swab included in specimen collection kit. Discard swab.
2. Insert second swab into endocervical canal until the tip is not visible.
3. Rotate swab 360° for 5-10 seconds inside endocervical canal. Withdraw swab without touching vaginal surfaces.
4. Immediately place swab in the specimen collection kit transport tube.
6. Break swab shaft at score marking.
7. Replace cap tightly and label tube.

MALE SWAB:

1. Preferably no urination one hour prior to collection.
2. Using manufacturer's male collection kit swab, insert into urethra a minimum of 2-4 cm.
3. Rotate at least one complete revolution for 2-5 seconds and withdraw swab.
4. Immediately place swab in specimen collection kit transport tube.
5. Break swab shaft at scoreline.
6. Replace cap tightly and label tube.

3. NUCLEIC ACID PROBE (PROBE)

FEMALE SWAB:

1. Remove excess mucus using one of the swabs included in specimen collection kit. Discard swab.
2. Insert second swab into endocervical canal until the tip is not visible.
3. Rotate swab 360° for 10-30 seconds inside endocervical canal. Withdraw swab without touching vaginal surfaces.
4. Immediately place swab in the specimen collection kit transport tube.
6. Break swab shaft at score marking.
7. Replace cap tightly and label tube.

MALE SWAB:

1. Preferably no urination one hour prior to collection.
2. Using manufacturer's male collection kit swab, insert into urethra a minimum of 2-4 cm.
3. Rotate at least one complete revolution for 2-3 seconds and withdraw swab.
4. Immediately place swab in specimen collection kit transport tube.
5. Break swab shaft at scoreline.
6. Replace cap tightly and label tube.

4. POLYMERASE CHAIN REACTION (PCR)**FEMALE SWAB:**

1. Remove excess mucus using a cotton swab or sponge. Discard swab or sponge.
2. Insert either a Dacron, rayon or calcium alginate swab on a plastic or non-aluminum wire shaft into endocervical canal until the tip is not visible.
3. Rotate swab 360° for 5-10 seconds inside endocervical canal. Withdraw swab without touching vaginal surfaces.
4. Place swab in the Specimen Transport Medium and leave in tube.
5. Replace cap tightly and label tube.

MALE SWAB:

1. Using either a Dacron, rayon or calcium alginate swab on a plastic or non-aluminum wire shaft, insert into urethra a minimum of 2-4 cm.
2. Rotate at least one complete revolution for 2-5 seconds and withdraw swab.
3. Place the swab in the Specimen Transport Medium and leave in tube.
4. Replace cap tightly and label tube.

MALE and FEMALE URINE:

1. Preferably no urination two hours prior to collection.
2. Collect first 10-50 ml of urine in a sterile polypropylene container without preservatives.
3. Replace lid tightly and label cup.

5. TARGET CAPTURE TMA (COMBO 2)

FEMALE SWAB:

1. Remove excess mucus using the cleaning swab included in specimen collection kit. Discard swab.
2. Insert second swab into endocervical canal until the tip is not visible.
3. Rotate swab 360° for 10-30 seconds inside endocervical canal. Withdraw swab without touching vaginal surfaces.
4. Immediately place swab in the specimen collection kit transport tube.
5. Replace cap tightly and label tube.

MALE SWAB:

1. Preferably no urination one hour prior to collection.
2. Using manufacturer's male collection kit swab, insert into urethra a minimum of 2-4 cm.
2. Rotate at least one complete revolution for 2-3 seconds and withdraw swab.
3. Immediately place swab in the specimen collection kit transport tube.
4. Replace cap tightly and label tube.

FEMALE SWAB:

1. Partially peel open the swab package. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use use a new vaginal swab specimen collection kit.
2. Remove the swab.
3. Hold the swab, placing the thumb and forefinger in the middle of the swab shaft.
4. Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
5. Withdraw the swab without touching the skin.
6. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube spill, use a new vaginal swab specimen collection kit.
7. Immediately place the swab in the transport tube so that the tip of the swab is visible below the tube label.
8. Carefully break the swab shaft against the side of the tube. Do not spill the contents of the tube. If the contents of the tube spill, use a new vaginal swab specimen collection kit.

9. Tightly screw the cap onto the tube.

MALE and FEMALE URINE:

1. Preferably no urination one hour prior to collection.
2. Collect first 20-30 ml of urine in a standard sterile urine collection cup without preservatives.
3. Replace lid tightly and label cup.

6. STRAND DISPLACEMENT AMPLIFICATION (SDA)

FEMALE SWAB:

1. Remove excess mucus using one of the large tipped cleaning swabs included in specimen collection kit. Discard swab.
2. Insert second swab into endocervical canal until the tip is not visible.
3. Rotate swab 360° for 5-10 seconds inside endocervical canal. Withdraw swab without touching vaginal surfaces.
4. Immediately place swab in either the dry transport or wet transport (contains medium) tube.
5. Replace cap tightly and label tube.

MALE SWAB:

1. Using manufacturer's male collection kit swab, insert into urethra a minimum of 2-4 cm.
2. Rotate at least one complete revolution for 2-5 seconds and withdraw swab.
3. Immediately place swab in either the dry transport or wet transport (contains medium) tube.
4. Replace cap tightly and label tube.

MALE and FEMALE URINE:

1. Preferably no urination one hour prior to collection.
2. Collect first 15-20 ml of urine in a sterile plastic, preservative-free urine collection cup.
3. Replace lid tightly and label cup.

APPENDIX C: DESCRIPTIONS OF CHLAMYDIA TESTING TECHNOLOGIES

1. CELL CULTURE TEST FOR *CHLAMYDIA TRACHOMATIS*

Manufacturers: Syva, Diagnostic Products Corp., Kallestad, and Baxter (some components).

Collection Sites: Vaginal (<12yrs old), endocervical, urethral, conjunctival, respiratory, rectal and biopsies

Specimen Handling: Transport/store at 4°C; test within 24 hours of collection. Otherwise, specimen can be stored at -70°C. **NOTE:** Check with laboratory first since periodic revisions to transport protocols often occur.

Principle: Specimens are inoculated and centrifuged into cycloheximide-treated McCoy (human strain) cells. Specimens are incubated for 48-72 hours. Cells are fixed and stained either with iodine or with monoclonal fluorescent antibody (FA). Iodine stained cells exhibit a dark inclusion if infected with chlamydia. FA stained cells exhibit a fluorescent inclusion if infected with the organism. Non-infected cells appear normal.

Turn Around Time (TAT): 2-3 days.

Test Comments: Culture is still considered the preferred test for medicolegal cases and has been the "gold standard" for comparison of other methods. Also, it is the only method recommended for specimen sites for which nonculture methods have not been developed or evaluated.

Limitations: Technically difficult procedure requiring expertise in tissue culture techniques; specimen transport and storage times and temperatures are critical; probably the most labor intensive method; longer turn around time.

Verification Testing Availability: Not Necessary.

Proficiency Test Availability: Available.

2. DIRECT FLUORESCENT ANTIBODY (DFA) TEST FOR *CHLAMYDIA TRACHOMATIS*

Manufacturers: Syva, Kallestad, Bartels.

Collection Sites: Endocervical, urethral, rectal, conjunctival, nasopharyngeal

Specimen Handling: Transport/store at room temperature (20°-30°C) or refrigerate at 2°-8°C, and stain within 7 days. If not stained within 7 days, fix with methanol and store in freezer indefinitely at -20°C. **NOTE:** Check with laboratory first since periodic revisions to transport protocols often occur.

Principle: Fluorescein isothiocyanate labeled monoclonal antibodies against the chlamydia major outer membrane protein (MOMP) are used to stain specimens applied directly to slide. Positive smears contain apple-green elementary bodies.

Turn Around Time (TAT): 1-3 days.

Test Comments: Only test in which the adequacy of specimen collection can be evaluated while performing the test.

Limitations: Cannot be used for medicolegal cases; critical specimen collection technique: must remove excess mucous before preparing adequate slide.

Verification Testing Available: No.

Proficiency Test Availability: Available.

3. ENZYME IMMUNOASSAY (EIA) TEST FOR *CHLAMYDIA TRACHOMATIS*

Manufacturers: Syva, Kallestad, Abbott and others

Collection Sites: Endocervical, urethral, conjunctival

Specimen Handling: Transport/store at 2°-25°C; test within 7 days of collection. **NOTE:** Check with laboratory first since periodic revisions to transport protocols often occur.

Principle: EIA tests detect soluble chlamydia lipopolysaccharide (LPS) antigen which is genus specific. The monoclonal or polyclonal antibody against the LPS is labeled with an enzyme. The enzyme converts a colorless substrate into a colored product. The intensity of the color is measured with a spectrophotometer, which provides a numerical readout.

Turn Around Time (TAT): 1-3 days.

Test Comments: Test format promotes laboratory efficiency.

Limitations: Not approved for nasopharyngeal or rectal specimens; not acceptable for medicolegal cases; proper specimen collection is critical. Adequacy of specimen cannot be determined. Positive results should be confirmed by secondary testing. EIA results, as with some other nonculture methods, should be considered presumptive. Additional testing may be warranted.

Verification Testing Available: Yes.

Proficiency Test Availability: Available.

4. NUCLEIC ACID PROBE TEST FOR *CHLAMYDIA TRACHOMATIS*

Manufacturer: Gen-Probe, Inc. (PACE 2)

Collection Sites: Endocervical, male urethral, conjunctival

Specimen Handling: Temperatures for transport and storage are 2°-25°C. Specimens must be tested within 7 days of collection or can be frozen at -20° to -70°C and tested within 60 days. **NOTE:** Check with laboratory first since periodic revisions to transport protocols often occur.

Principle: A direct specimen test where copies of a chemiluminescent labeled, single-stranded DNA probe combine with target organism's ribosomal RNA to form stable DNA:RNA hybrids. The labeled hybrids are separated from nonhybridized probe and are measured in a luminometer. The test results are calculated as the difference between the response of the specimen and the mean response of the negative reference.

Turn Around Time (TAT): 1 day for negative results, 2-3 days for positive results.

Test Comments: Test format promotes laboratory efficiency. Testing for CT/GC can be performed from a single swab.

Limitations: Not approved for nasopharyngeal or rectal specimens; not acceptable for medicolegal cases. Adequacy of specimen cannot be determined. Grossly bloody specimens may interfere with test performance. Because false-positives may occur: positives can be confirmed using the Probe Competition Assay (PCA). Because of sensitivity concerns, gray-zone analysis (i.e., low level, borderline positives) could be done to improve test performance. Combination test for CT/GC does not differentiate between chlamydia and gonorrhea; therefore, secondary testing must be done for definitive diagnosis.

Verification Testing Available: Yes.

Proficiency Test Availability: Available.

5. POLYMERASE CHAIN REACTION (PCR) TEST FOR *CHLAMYDIA TRACHOMATIS*

Manufacturer: Roche Diagnostic Systems (Amplicor and COBAS).

Collection Sites: Endocervical, male urethral, male and female urine

Specimen Handling: Swab specimens may be transported/stored at room temp (18°-25°C) within 1 hour of collection and urine may be transported/stored at room temp (18°-25°C) within 24 hours of collection. Otherwise, swabs and urines must be transported/stored at 2°-8°C; and processed within 7 days. Specimens may be held at -20°C and tested within 30 days for swabs and within 60 days for urine. **NOTE:** Check with laboratory first since periodic revisions to transport protocols often occur.

Principle: Detection of chlamydia by specific polymerase chain amplification of chlamydial plasmid DNA present in specimen, hybridization of the amplified product to a specific nucleic acid probe, and detection of the amplified product probe hybrid by an enzyme immunoassay.

Turn Around Time (TAT): 1-3 days.

Test Comments: Assay very sensitive. Internal controls may be used to detect specimen inhibition. Use of amperase aids in the prevention of amplicon contamination. Testing for CT/GC can be performed from a single specimen in a one-run procedure, except not FDA approved for NG testing on female urine and asymptomatic male urethra.

Limitations: Not approved for nasopharyngeal or rectal specimens. Has not yet replaced culture for legal purposes but is an acceptable substitute when verification is performed using a test based on a different diagnostic principle. Tests are usually negative 3-4 weeks after treatment.

Alternate Target Amplification Available: Not necessary.

Proficiency Test Availability: Available.

6. TARGET CAPTURE/TMA TEST FOR CHLAMYDIA TRACHOMATIS

Manufacturer: Gen-Probe (APTIMA Combo 2)

Collection sites: Endocervical, male urethral, male and female urine

Specimen Handling: Transport/store both original urine specimen and urine in Urine Specimen collection kit at 2°-30°C. Original urine must be transferred to the Urine Specimen collection kit within 24 hours; test within 30 days. Transport/store swab specimens in Swab collection kit at 2°-30°C, test within 60 days.

Specimens can be frozen at -20° to -70°C and tested within 90 days. **NOTE:** Check with laboratory first since periodic revisions to transport protocols often occur.

Principle: The Gen-Probe APTIMA Combo 2 Assay combines the technologies of target capture, Transcription-Mediated Amplification (TMA) and Dual Kinetic Assay (DKA) to simultaneously detect and amplify target rRNA via DNA intermediates. End detection is by a chemiluminescent reaction and the relative light units are read.

Turn Around Time: 1-3 days.

Test Comments: Assay very sensitive. Because of the target capture technology; specimen inhibition is not a problem. Do not need to centrifuge urine. Testing for CT/GC can be performed from a single specimen in a one-run procedure.

Limitations: Not approved for nasopharyngeal or rectal specimens. Has not yet replaced culture for legal purposes but is an acceptable substitute when verification is performed using a test based on a different diagnostic principle. Tests are usually negative 3-4 weeks after treatment.

Alternate Target Amplification Available: Yes.

Proficiency Test Availability: Available.

7. STRAND DISPLACEMENT AMPLIFICATION (SDA)

Manufacturer: Becton-Dickinson (BD Probe Tec ET)

Collection sites: Endocervical, male urethral, male and female urine

Specimen Handling: Transport/store urine at 2°-8°C, swabs at 2°-27°C. Test urine and swabs within 4-6 days of collection. Urine processing pouch must be added in the lab to the specimen 2 hours prior to processing. **NOTE:** Check with laboratory first since periodic revisions to transport protocols often occur.

Principle: The assay uses Strand Displacement Amplification which utilizes simultaneous amplification and detection of target DNA using amplification primers and a fluorescent labeled detector probe.

Turn Around Time: 1-3 days

Test Comments: Assay sensitive. Internal controls may be used to detect specimen inhibition. Urine specimens cannot be frozen. However, processed specimens (lysed) may be frozen at $\leq -20^{\circ}\text{C}$. Testing for CT/GC can be performed from a single specimen in a one-run procedure.

Limitations: Not approved for nasopharyngeal or rectal specimens. Has not yet replaced culture for legal purposes but is an acceptable substitute when verification is performed using a test based on a different diagnostic principle. Tests are usually negative 3-4 weeks after treatment.

Alternate Target Amplification Available: No.

Proficiency Test Availability: Available.

8. HYBRID CAPTURE (HC)

Manufacturer: Digene Corporation (Hybrid Capture 2 CT and GC test)

Collection sites: Endocervical

Specimen Handling: Swabs may be transported/stored at room temperature and tested within 14 days of collection, or refrigerated at 2°-8°C and tested within 21 days of collection. **NOTE:** Check with laboratory first since periodic revisions to transport protocols often occur.

Principle: The Digene CT-ID Hybrid Capture[®] 2 Test is a nucleic acid probe-based chemiluminescent assay to detect DNA of *C. trachomatis* and *N. gonorrhoeae* in cervical specimens. It uses a signal amplification method that couples hybridization to an antibody capture microplate system. The target DNA hybridizes with CT RNA probes. End detection is read on a luminometer as relative light units.

Turn Around Time: 1-3 days

Test Comments: Test is signal amplification and not target (nucleic acid) amplification. Approved for endocervical swabs only. Testing for CT/GC can be performed from a single swab.

Limitations: Not approved for urethral, nasopharyngeal, rectal or urine specimens. Not acceptable for medicolegal cases. Combination test for CT/GC does not differentiate between chlamydia and gonorrhea; therefore, secondary testing must be done for definitive diagnosis.

Alternate Target Amplification Available: Not available.

Proficiency Test Availability: Available.

APPENDIX D: CHECKLIST FOR LABORATORY SITE VISIT

Facility

1. Does the general laboratory have adequate space?
2. Does the laboratory appear to be at a comfortable temperature (assays can be affected by temperature)? Ask to see room temperature logs.
3. Does the laboratory appear well organized with no trash or other debris on floors or in passageways?
4. Do the bench tops seem clean and uncluttered?
5. Does the laboratory have refrigerators and freezers convenient to the work areas?
6. Is the lighting adequate?
7. Are there sinks in the work areas?
8. Does the area where chlamydia testing is done look adequate and efficient?

Personnel

1. Are all laboratory personnel wearing lab coats and gloves?
2. Ask to be introduced to the technical supervisor and the individuals directly responsible for the chlamydia testing. Ask them specific questions such as:
 - the technology used for chlamydia detection?
 - sensitivity of technology?
 - number of repeats necessary?
 - length of experience with technology?
 - confirmation testing available and if they use it?
 - written criteria for doing confirmation testing?
(ask to see it)
 - volume of testing?
 - why they chose the particular technology they did?
 - problems they have experienced with the technology?
3. How many testing personnel meet the CLIA requirements for moderate and high complexity testing? What is the ratio of these qualified personnel to the entire laboratory staff? If the number seems small compared to the overall personnel total, consult your state laboratory regulatory agency and discuss the staffing ratio relative to the average in other laboratories.
4. Does the laboratory staff participate in continuing education programs?

Reporting

1. Ask to see an example of the chlamydia test-request and report form(s). Evaluate the ease of use of the forms from the clinicians viewpoint. Check the test-request form for required STD data collection.
2. Ask how results are transmitted to the submitter.
3. Inquire as to the mechanism and frequency of reporting state mandated STD results.
4. Inquire about their Laboratory Information Systems (LIS) capability.
5. Ask what type of reports can be generated either for Q/A purposes or other reasons. Find out how frequently the reports are generated.

Quality Assurance

1. Ask to see chlamydia proficiency results for the last three years. If there were any "unacceptable" results, ask what corrective action was taken.
2. Ask to see records that document adherence to their published turn-around-times.
3. Ask to see the deficiency report from their last CLIA, CAP or State regulatory agency inspection.
4. Ask to see their chlamydia testing "Quality Control" records.
5. Ask what kind of internal quality assurance system they have in place.
6. Ask about their courier system. Examples:
 - Do you have your own courier system or do you contract with a courier service? If the answer is the latter, ask if it's a medical courier service specifically.
 - Who trains the couriers on correct specimen transport and what type of quality monitoring is in place?
 - How frequently and at what times of day would we get courier service?
7. Are there written procedures for the proper collection and handling of culture or other CT test specimens?
8. Ask to see their written specimen rejection policy. Ask if clinicians are called before specimens are rejected.

APPENDIX E: PATIENT-ADMINISTERED SEXUAL HISTORY QUESTIONNAIRE

Please take a few minutes to fill out these questions about your sexual health. Your information is strictly confidential. This form will be shared with no one but your health care provider. Your honest answers will help your provider to provide the best care possible and work with you to help you be healthy. Leave all questions blank that do not apply to you.

1. Have you had more than one partner in the last year?
 Yes No, I've had one partner No, I've never had sex

If you were sexually active in the past year, with one or more partners, please proceed to the next question. If you have never had sex, skip to question 9.

2. Do you have sex with...
 Males only Females only Both
3. What method(s) do you currently use to prevent a pregnancy, if applicable? (*check all that apply*)
 Condoms (for men or for women) Foam, spermicides, film, or suppositories
 Oral contraceptives (birth control pills) Depo provera shot or Norplant
 I/my partner and I are trying to get pregnant Rhythm method or withdrawal
 I am not concerned about getting pregnant Nothing
 Other (*please specify*)

4. How often do you use condoms with vaginal sex?
 Always Most of the time Sometimes
 Never I do not have vaginal sex

5. How often do you use condoms with anal sex (penis in anus or rectum)?
 Always Most of the time Sometimes
 Never I do not have anal sex

6. Have you ever been told by a doctor or nurse that you had a sexually transmitted disease?
 No
 Yes (*circle all that apply*)
Chlamydia Genital Herpes Genital warts
Gonorrhea PID HIV
Trichomonas Syphilis
Other _____

If yes, when was the last time you had one of these diseases? _____ month/_____ year

7. Have any of your sexual partners...
a. had a sexually transmitted disease in the past year?
 No I do not know Yes (*please specify*): _____
b. had other partners while still in a relationship with you?
 No I do not know Yes
c. had sex with prostitutes?
 No I do not know Yes
d. injected drugs?
 No I do not know Yes

8. Have you ever gotten hepatitis B vaccine (3 injections)?
 No I do not know Yes (all 3 doses) Yes (less than 3 doses)

9. Have you ever been tested for HIV, the virus that causes AIDS?
 No Yes

10. Have you ever injected drugs?
 No Yes

11. How many drinks of beer, wine, or hard liquor did you have in the past week?
 drink(s)

12. Have you had sex while under the influence of alcohol or drugs in the past year?
 No Yes

13. Have you ever had sex when you didn't want to?
 No Yes

Source: California Chlamydia Action Coalition, December 2001. This form can be downloaded at <http://www.ucsf.edu/castd>.

APPENDIX F: SAMPLE CLIENT FOLLOW-UP LETTER

(Use hospital or general facility name on letter only; do not use on outside envelope)

Date

Dear _____

It is important that you contact this office immediately by calling (XXX) XXX-XXXX. We need to discuss with you the results of one of your recent laboratory tests.

Sincerely,

Agency name

APPENDIX G: SAMPLE PARTNER REFERRAL CARD

NOTE: This is designed to be given to the client's partner by the client

YOU HAVE BEEN EXPOSED TO AN INFECTION CALLED CHLAMYDIA. This infection is passed from person to person during sex and may cause serious health problems if left untreated. Your partner was seen and treated for chlamydia on the above date.

You need a medical exam or treatment.

Call your: STD Clinic
 Private Physician or
 Family Planning Clinic

For an appointment right away.

Note: The back of this card could contain names, addresses and phone number of STD and Family Planning Clinics.

APPENDIX H: SAMPLE PARTNER REFERRAL LETTER

Note: This is designed to be given to the client's partner by the client

Date

Dear _____:

A partner of yours is being treated for a disease called chlamydia. You get this disease during sex. If you and your partner don't get treated, this disease may cause serious health complications. For women they may not be able to have children. You need a medical exam and treatment. Call us at XXX-XXXX or your health care provider or the Department of Health to find the clinic nearest you where you can get tested or treated. Don't have any sexual or genital contact until you and all your partners are treated. If that isn't possible, use a condom each time you have sex.

Thank you,

Clinic

**APPENDIX I: Guidance and Toolkit for the Use of Expedited Partner Therapy
and Retesting at 3 months to Prevent and Detect Chlamydia and Gonorrhea
Reinfections**

Infertility Prevention Project (IPP), Region IX
Guidance and Toolkit for the Use of Expedited Partner Therapy and
Retesting at Three Months to Prevent and Detect Chlamydia and Gonorrhea
Reinfections

Summary Recommendations

1. Partner management using Expedited Partner Therapy (EPT)

Where it is a legal to do so, providers in IPP Region IX project areas are strongly encouraged to offer EPT options for partner management to their patients diagnosed with chlamydia or gonorrhea.

While patients should be encouraged to bring their partners in to the clinic for evaluation, testing and treatment whenever possible, it is understood that this strategy for partner management is not always an option or successful. EPT, which allows for empirical partner treatment without provider evaluation, has been shown to be an effective alternative, especially when a partner is unable or unlikely to otherwise receive treatment. Patient-delivered partner therapy (PDPT), a partner management strategy where patients are given medication or a prescription to deliver to their partner(s), is the most widely-used EPT approach; however specific EPT methods and procedures may vary from site to site.

2. Retesting of patients treated for chlamydia or gonorrhea

Retesting patients optimally at 3 months after initial treatment for chlamydia or gonorrhea, or whenever they next seek care within the 3-12 months following treatment, is standard policy for all IPP project areas in Region IX. (Note: For purposes of program evaluation, Region IX IPP analyzes retest estimate data obtained from tests performed 2 through 11 months after the date of the first positive test.) In addition to counseling patients about the importance of retesting, IPP delegate agencies are strongly encouraged to choose and institute an active protocol designed to maximize their retesting rates.

IPP programs operate in a wide variety of clinical settings, and no single approach to increasing retesting rates will likely work for all programs. Choosing and instituting a retesting protocol appropriate and effective for a particular program and patient population is recommended.

Clinics should develop a comprehensive retesting protocol with active strategies that focus on three equally vital objectives:

- 1) To ensure patient's understanding about their high risk for reinfection and related complications, including infertility in women, and the importance of getting retested;
- 2) To assist patients to remember and prioritize their retesting clinic visit approximately 3 months after their initial treatment; and
- 3) To prevent missed opportunities for retesting by developing systems to remind providers to retest if patients return to the clinic for any reason anytime two months or later following the initial treatment.

Introduction

Chlamydia and gonorrhea can result in medical complications in women that lead to infertility, ectopic pregnancy and chronic pelvic pain. Reinfection following an initial chlamydia or gonorrhea infection is common, with reinfection rates often twice as high as the initial prevalence rate in the base population. Repeat infections confer an elevated risk for PID and other complications when compared with the initial infection.

The Infertility Prevention Project (IPP) was established by the Centers for Disease Control and Prevention (CDC) in 1994 with the goal of reducing the incidence of sexually transmitted diseases that can lead to infertility. As stated in the IPP Region IX Chlamydia Clinical Guidelines, interventions to achieve this goal include targeted screening and effective partner treatment. To prevent repeat infection and to reduce further transmission of infection in the community, all sexual partners in the prior 60 days must be provided timely and appropriate antibiotic treatment. In addition, routine retesting of positive patients approximately 3 months after treatment is strongly recommended, regardless of whether the patient believes that his/her sex partners were treated.

This document is intended to provide guidance for implementing policies for both expedited partner therapy (EPT) and retesting at 3 months after initial treatment for chlamydia or gonorrhea in Region IX IPP settings. The guidelines follow the CDC Dear Colleague letter of May 11, 2005¹, the CDC report *Expedited Partner Therapy in the Management of Sexually Transmitted Diseases* 2006², and the CDC 2006 STD Treatment Guidelines³. Please consult these documents for more information.

Background

Persons infected and treated for chlamydia or gonorrhea are known to be at high risk for reinfection. Numerous studies in various clinical settings, including family planning sites, have documented chlamydia reinfection rates that range from 10 to 15% at 3-6 months post-treatment⁴⁻⁶. In Region IX, estimates of reinfection vary by project area and clinic type. Reinfection rates within 1-6 months during 2006 among female patients at family planning sentinel sites ranged from 10-11% in California to 18% in Washoe County NV. In STD clinic sentinel sites, reinfection rates ranged from 16% in Los Angeles, CA for Jan-Jun 2007 to 37% in Washoe County, NV in 2006 (preliminary data, CDPH, unpublished).

Partner Management and EPT

Many reinfections occur because of re-exposure to untreated sex partners⁷. Effective clinical management of persons with laboratory-confirmed or presumptive chlamydia or gonorrhea infections (including urethritis, cervicitis and pelvic inflammatory disease) includes notification and treatment of the patient's current and recent sex partner(s).

Timely and appropriate antibiotic treatment needs to be provided to all partners who had sexual contact with the patient during the 60 days prior to onset of symptoms or diagnosis of chlamydia or gonorrhea. If the last sexual contact was over 60 days prior to the diagnosis, the most recent sexual partner should be treated. Traditionally, partner management has been accomplished by notification and referral of sex partners for medical evaluation. Partner notification and referral

to services can be carried out by the patients themselves, by the provider, or by staff of the local health jurisdiction.

EPT approaches are new options for partner management that facilitate treatment of partners by not requiring an intervening clinical assessment. Research investigating various innovative EPT methods has provided important information about the effectiveness of EPT. One EPT option is patient-delivered partner therapy (PDPT), where patients are given medication or a prescription to deliver to their partner(s) for empirical treatment. In a study of men with urethritis, PDPT reduced reinfection rates by half, from 43% to 23%, compared with patient referral⁸. In women with chlamydia, PDPT reduced reinfection rates from 15% to 12% ($p=.10$)⁷. A recent randomized trial funded by the CDC demonstrated that partner management strategies that included EPT as an option reduced reinfection with gonorrhea among heterosexual men and women by nearly 70% compared with conventional strategies⁹. Repeat gonorrhea infection was 11% in the control group and only 3% in the PDPT group ($p<.05$). Despite potential medical concerns (e.g. STD co-morbidity in partners, antimicrobial resistance, adverse drug effects) and implementation issues (e.g. legal status of EPT¹⁰, funding and privacy concerns, medication packaging), the CDC supports the use of EPT options because of increases in preventing reinfection.

A recent evaluation of family planning clinics in California compared the success of various partner management strategies in their ability to ultimately treat the male partners of chlamydia-positive female patients. Partner treatment was most likely when patients were asked to bring their partners into clinic with them for treatment. Requesting that a patient bring her partner into clinic with her so that both patient and partner could be treated at the same visit was shown to be a highly effective, and was the obvious first choice for providers who offered male services. However, this strategy for partner management was not always an option for patients and was not always successful. PDPT was more likely to result in successful partner management when a patient had a non-steady partner, and this was especially the case when the clinic could directly provide the patient with an extra dose of medication to take back to her partner (as opposed to a prescription that the partner would need to fill). Partner notification and referral, currently the most commonly-used partner management strategy in many family planning sites across the region, was shown to be the least successful in treating partners.

As many local health jurisdictions do not have the resources needed to contact the partners of all persons diagnosed with chlamydia and gonorrhea, partner notification and referral by the health department is often not an option. (CDPH, unpublished)

Retesting after Treatment

The 2006 CDC STD Treatment Guidelines recommend retesting of all women treated for chlamydia or gonorrhea at approximately 3 months following treatment so as to identify reinfections in a timely manner³. However, return rates for retesting continue to be low, despite clinicians' best efforts to educate their patients regarding the importance of getting retested. Estimates of retesting rates in Region IX vary widely by project area and clinic type. Retesting rates within 1-6 months after initial positive test for 2005-2006 in family planning sentinel sites ranged from 6.5% in AZ, 29%-45% in California, Los Angeles, and San Francisco project areas

to 46% in Washoe County, NV. Retesting rates in 2006 for STD clinic sentinel sites ranged from 9% in Washoe County, NV to 37% in San Francisco (preliminary data, CDPH, unpublished).

Certain limitations regarding retesting for chlamydia using highly sensitive tests such as nucleic acid amplification tests (NAATs) should be noted. Because these tests identify nuclear material from chlamydia organisms and not live organisms themselves, positive tests may occur up to 4 weeks following adequate treatment because of residual nuclear material present in host cells still being shed from genital tract tissues. For this reason, retesting should not be performed prior to 4 weeks post-treatment.

Various approaches have been studied or tried to ensure that patients return for retesting. Two studies found that reminder phone calls were effective in increasing clients' retesting rates^{11,12}. Use of mail-in specimens of either urine or self-collected vaginal swabs was also found to be moderately useful¹³.

Guidance for Program Planning, IPP Project Areas, Region IX

Recommendation

Partner management using Expedited Partner Therapy

Where it is a legal to do so, providers in IPP Region IX project areas are strongly encouraged to offer EPT options for partner management to their patients diagnosed with chlamydia or gonorrhea.

Implementation

Infertility prevention programs operate in a wide variety of clinical settings, and no single approach to EPT will likely work for all programs. Instead, choosing and instituting a protocol appropriate and effective for the particular program and patient population is recommended. Specific methods and procedures will vary from site to site because of factors such as differences in program operations and patient populations, the cost of the medication to the program or to the patient, and the number of positive patients the clinical site must manage. EPT procedures should be instituted with written policies and provider training. Procedures should be monitored and evaluated, allowing periodic reassessment and revision as needed.

Providers should use their best judgment when discussing partner treatment with their patients, considering factors such as the patient's report that a partner lacks insurance or a primary care provider, faces significant barriers to accessing care, or will be unwilling to seek care. Whenever feasible, patients should be encouraged to bring partners to the clinic for treatment. EPT has been shown to be particularly successful when used to treat non-steady partners. It is probably most effective to offer several partner management options to each patient, discussing them and individualizing the partner management plan on a case by case basis.

EPT options include

- Patient-delivered partner therapy (PDPT), whereby patients take medication or a prescription to their partner(s). Ideally, medication would be provided by the clinic at no cost.

- Pharmacy access programs, whereby partners can obtain medication at a participating pharmacy.
- Field-delivered therapy, whereby health department personnel deliver medication to partners.

The preferred medication to use would be administered in a single oral dose.

For chlamydia, azithromycin 1 gm is the recommended single-dose oral treatment. There is no alternate single oral dose.

For gonorrhea, cefixime 400mg is the recommended single oral dose in the 2006 CDC STD Treatment Guidelines³. Cefpodoxime 400 mg in a single dose is an alternate treatment that may be less expensive than cefixime. As of April 2007, fluoroquinolones (ciprofloxacin, ofloxacin and levofloxacin) are no longer recommended for treatment of gonococcal infection because of widespread and increasing prevalence of antimicrobial resistance to this class of medications¹⁴.

The following key information and counseling messages must be provided in written format and delivered with the medication or prescription to partner(s):

- Type of medication, contraindications because of allergy, and possible side effects
- Partners who have symptoms should seek care as soon as possible
- Partners should seek a complete STD evaluation in addition to EPT, even without symptoms
- Partners who have allergies to antibiotics or serious health problems should not take EPT, but should see a health care provider as soon as possible
- Partners should abstain from sex for at least 7 days after treatment and until 7 days after all partners have been treated, to decrease the risk of reinfection

Recommendation

Retesting of patients treated for chlamydia or gonorrhea

The retesting of patients optimally at 3 months after initial treatment for chlamydia or gonorrhea, or whenever they next seek care within the 3-12 months following treatment, is standard policy for all IPP project areas in Region IX. (Note: For purposes of program evaluation, Region IX IPP analyzes retest estimate data obtained from tests performed 2 through 11 months after the date of the first positive test.) In addition to counseling patients about the importance of retesting, IPP delegate agencies are strongly encouraged to choose and institute an active protocol designed to maximize their retesting rates.

Implementation

Infertility prevention programs operate in a wide variety of clinical settings, and no single approach to increasing retesting rates will likely work for all programs. Choosing and instituting a retesting protocol appropriate and effective for a particular program and patient population is recommended. Retesting procedures should be instituted with written policies and provider training. Procedures should be monitored and evaluated, allowing periodic reassessment and revision as needed.

Clinics should develop a comprehensive retesting protocol with active strategies that focus on three equally vital objectives:

- 1) To ensure patient’s understanding about their high risk for reinfection and related complications, including infertility in women, and the importance of getting retested;
- 2) To assist patients to remember and prioritize their retesting clinic visit approximately 3 months after their initial treatment; and
- 3) To flag CT- and GC-positive patient charts so that providers do not miss retesting opportunities if patients return to the clinic for any reason anytime two months or later following the initial treatment.

Programs are responsible for counseling any patient with chlamydia or gonorrhea at the time of initial treatment regarding the importance of retesting in 3 months. Clinic staff are also responsible for flagging these patient charts to ensure that opportunities for retesting are not missed if patients return to clinic for any reason anytime two months or later after their initial treatment. In addition, clinics are encouraged to institute a feasible follow-up system in order to assist patients in remembering to get retested at the appropriate time. For this purpose, one or more of the following methods could be employed:

- Advance appointment at the time of initial treatment, and giving patient an appointment card
- Reminder telephone calls
- Reminders by mail (self-addressed letters or postcards)
- Reminder cell-phone text messages
- Reminder e-mail notifications
- Mailed-in specimens
- Field visits for specimen collection
- Internet access to downloadable lab slips for testing at local lab sites
- An internal “tickler system”, with follow-up for patients who do not return

See the Resources Toolkit that accompanies this document for examples of materials to use in implementing a retesting protocol.

References

IPP Guidance, Region IX

Use of Expedited Partner Therapy and Retesting at Three Months to Prevent and Detect Chlamydia and Gonorrhea Reinfections

1. CDC Dear Colleague letter of May 11, 2005 <http://www.cdc.gov/STD/DearColleagueEPT5-10-05.pdf>
2. CDC report *Expedited Partner Therapy in the Management of Sexually Transmitted Diseases* 2006 <http://www.cdc.gov/STD/treatment/EPTFinalReport2006.pdf>
3. CDC 2006 STD Treatment Guidelines <http://www.cdc.gov/std/treatment/2006/rr5511.pdf>
4. Mehta SD, Erbeding EJ, Zenilman JM and Rompalo AM. Gonorrhoea reinfection in heterosexual STD clinic attendees: longitudinal analysis of risks for first reinfection. *Sex Transm Infect* 2003;79:124-8
5. Peterman TA, Tian LH, Metcalf CA, et al. High incidence of new sexually transmitted infections in the year following a sexually transmitted infection: a case for rescreening. *Ann Intern Med* 2006;145:564-72
6. Whittington WL, Kent C, Kissinger P, et al. Determinants of persistent and recurrent Chlamydia trachomatis infection in young women: results of a multicenter cohort study. *Sex Transm Dis* 2001;28:117-123
7. Schillinger JL et al. Patient-delivered partner treatment with azithromycin to prevent repeated *Chlamydia trachomatis* infection among women; a randomized, controlled trial. *Sex Trans Dis* 2003;30:49-56
8. Kissinger P, Mohammed H, Richardson-Alston G, et al. Patient-delivered partner treatment for male urethritis: a randomized, controlled trial. *Clin Inf Dis*. 2005; 41:623-29
9. Golden MR, Whittington WL, Handsfield HH, et al. Effect of expedited treatment of sex partners on recurrent or persistent gonorrhea or chlamydial infection. *N Engl J Med*. 2005; 352: 676-85.
10. Hodge JG Jr., Pulver A, Hogben M, et al. Expedited partner therapy for sexually transmitted diseases: assessing the legal environment. *Am J Public Health*. 2008 Feb;98(2):238-43
11. Malotte CK, Ledsky R, Hogben M, et al. Comparison of methods to increase repeat testing in persons treated for gonorrhea and/or chlamydia at public sexually transmitted disease clinics. *Sex Transm Dis*. 2004; 31:637-42
12. Gift TL, et al. A cost-effectiveness analysis of interventions to increase repeat testing in patients treated for gonorrhea or chlamydia at public sexually transmitted disease clinics. *Sex Trans Dis* 2004;32:542-549
13. Sparks R, Helmers JR, Handsfield HH, et al. Rescreening for gonorrhea and chlamydia infection through the mail: a randomized trial. *Sex Transm Dis* 2004; 31:113-6
14. MMWR April 13, 2007. Update to CDC's *Sexually Transmitted Diseases Treatment Guidelines, 2006*: fluoroquinolones no longer recommended for treatment of gonococcal infections. Vol 56: No.14: 332-336 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5614a3.htm?s_cid=mm5614a3_e

Resources Toolkit
IPP Guidance, Region IX
Use of Expedited Partner Therapy and Retesting at Three Months to Prevent and Detect Chlamydia and Gonorrhea Reinfections

1. Guidance documents, EPT

Centers for Disease Control

General information re: EPT, website

<http://www.cdc.gov/STD/ept/default.htm>

EPT Review and Guidance

<http://www.cdc.gov/STD/treatment/EPTFinalReport2006.pdf>

CDC 2006 STD Treatment Guidelines

<http://www.cdc.gov/std/treatment/2006/rr5511.pdf>

California STD Control Branch, Department of Public Health

PDPT for Chlamydia and Gonorrhea: Guidance for medical Providers in California, March 2007

<http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/PDPT%20Guidelines%20and%20Ptnr%20Info%20Engl-Span%2008-06-07.pdf>

Guidelines for the Treatment of Chlamydia and Gonorrhea Cases and Exposed Sexual Partners by Health Department Staff in Non-Clinical Settings, March 2007

<http://www.cdph.ca.gov/HealthInfo/discond/Documents/Chlamydia-Gonorrhea-LHD-staff-field-delivered-treatment-Guidelines.pdf>

Region IX IPP Chlamydia Clinical Guidelines, revised October 2008

http://www.centerforhealthtraining.org/projects/pr_ipp_IX.html

2. Dear Colleague letter, Centers for Disease Control, EPT

<http://www.cdc.gov/STD/DearColleagueEPT5-10-05.pdf>

3. Legal issues, EPT

CDC legal resources website, with state-by-state map

<http://www.cdc.gov/std/ept/legal/default.htm>

CDC, Dear Colleague letter, John Douglas

<http://www.cdc.gov/STD/ept/DearColleagueEPTLegal12-19-2006.pdf>

4. Examples of STD information/fact sheets for patients

Centers for Disease Control

CT: <http://www.cdc.gov/std/Chlamydia/chlamydia.pdf>

GC: <http://www.cdc.gov/std/Gonorrhea/gonorrhea.pdf>

California STD/HIV Prevention Training Center

CT: http://www.stdhivtraining.org/resource.php?id=86&ret=clinical_resources

GC: http://www.stdhivtraining.org/resource.php?id=87&ret=clinical_resources

San Francisco Department of Public Health

CT: <http://www.dph.sf.ca.us/sfcityclinic/providers/Chlamydia.pdf>

GC: <http://www.dph.sf.ca.us/sfcityclinic/providers/Gonorrhea.pdf>

5. Examples of instruction sheets, Patient Delivered Partner Therapy

San Francisco Department of Public Health

CT, azithromycin, English:

<http://www.dph.sf.ca.us/sfcityclinic/providers/PDTCTAENG.pdf>

CT, azithromycin, Spanish

<http://www.dph.sf.ca.us/sfcityclinic/providers/PDTCTASPAN.pdf>

6. Example of clinic posters

San Francisco Department of Public Health

http://www.dph.sf.ca.us/sfcityclinic/providers/87_RestedPoster0606.pdf

7. Training on issues related to EPT and retesting

California STD/HIV Prevention Training Center

<https://www.stdhivtraining.org/>