MOLINA HEALTHCARE OF CALIFORNIA

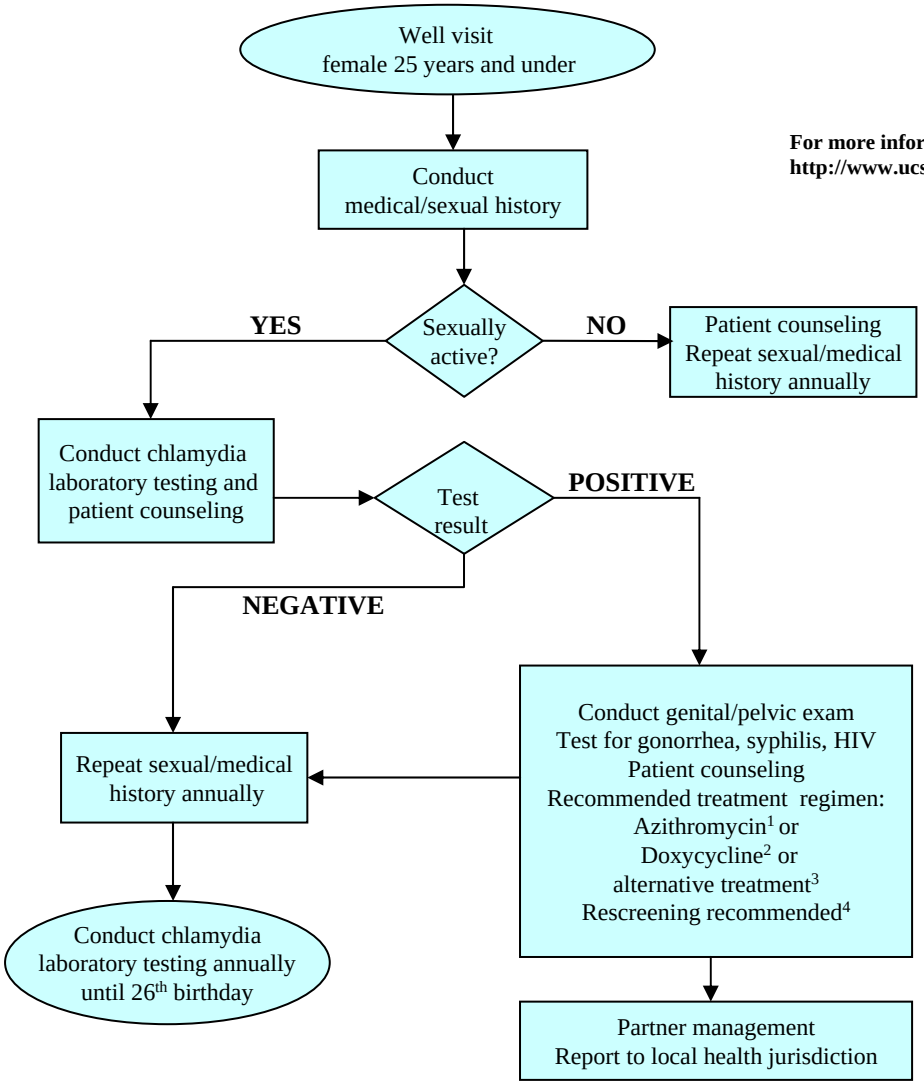
CHLAMYDIA GUIDELINE

The Chlamydia guideline was reviewed and adopted by the Molina Healthcare of California Clinical Quality Management Committee on December 12, 2001. CDC Re-screening Guideline adopted by Clinical Quality Management Committee on August 14, 2002. Chlamydia Screening and Treatment Practice Guidelines were adopted by Clinical Quality Management Committee on February 12, 2003, February 4, 2004, February 2, 2005, February 1, 2006, February 7, 2007, March 12, 2008, March 11, 2009, March 10, 2010 and March 16, 2011.

The Chlamydia Care Quality Improvement Toolbox, developed by the California Chlamydia Action Coalition, may be accessed from
http:// www.stdhivtraining.net/educ/training_module/tools.html

Chlamydia Care Path

ASYMPTOMATIC NON-PREGNANT FEMALES

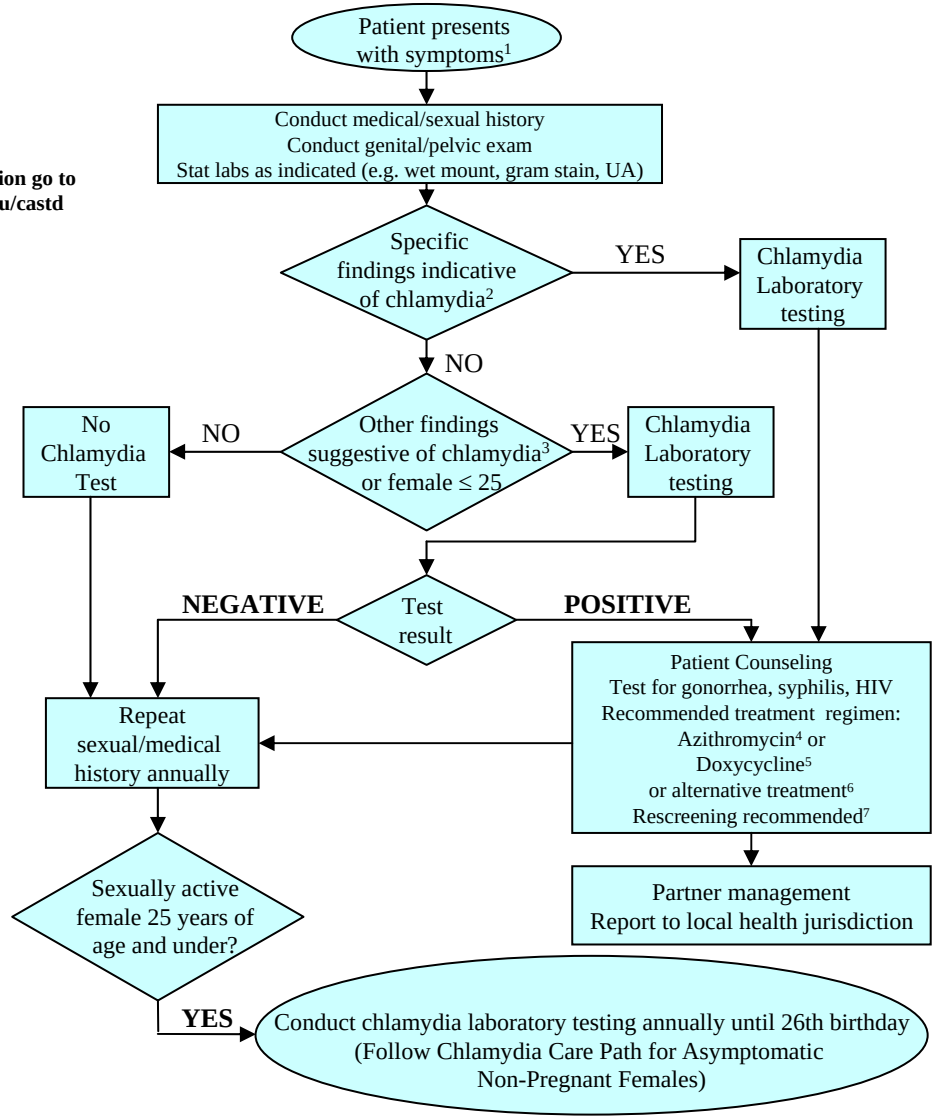


1 Azithromycin dose: 1 gram p.o., single dose.
2 Doxycycline dose: 100 mg p.o. BID for 7 days
3 Alternative treatment regimen: Erythromycin base 500 mg p.o. QID for 7 days or Erythromycin ethylsuccinate 800 mg p.o. QID f or 7 days or Ofloxacin 300 mg p.o. BID for 7 days or Levofloxacin 500 mg p.o. QD for 7 days.
4 Because chlamydia reinfection is common, it is recommended that rescreening of infected females be performed 3-4 months after treatment.

November 2002

For more information go to http://www.ucsf.edu/castd

Chlamydia Care Path
UNCOMPLICATED SYMPTOMATIC NON-PREGNANT FEMALES and MALES



1 Symptoms: Females - abnormal vaginal discharge, abnormal vaginal bleeding or dysuria; Males - urethral discharge or dysuria.
2 Females - mucopurulent cervicitis or cervical friability; Males – urethral discharge or evidence of urethritis by gram stain or UA.
3 Females: abnormal vaginal discharge of unknown etiology, abnormal vaginal bleeding of unknown etiology or dysuria without evidence of urinary tract infection
4 Azithromycin dose: 1 gram p.o., single dose.
5 Doxycycline dose: 100 mg p.o. BID for 7 days.
6 Alternative Treatment Regimen: Erythromycin base 500 mg p.o. QID for 7 days or Erythromycin ethylsuccinate 800 mg p.o. QID for 7 days or Ofloxacin 300 mg p.o. BID for 7 days or Levofloxacin 500 mg p.o. QD for 7 days.
7 Because chlamydia reinfection is common among females, it is recommended that rescreening of infected females be performed 3-4 months after treatment.

SCREENING FOR CHLAMYDIA

Screen all sexually active females 25 years of age and under annually for chlamydia, consistent with Centers for Disease Control and Prevention and U.S. Preventive Services Task Force guidelines, as well as HEDIS performance measurement expectations. **Use nucleic acid amplification technology tests for screening. These tests can be performed using urine specimens,** allowing chlamydia screening even if a pelvic or genital exam is not being done.

TREATMENT OF CHLAMYDIA INFECTIONS IN NON-PREGNANT FEMALES AND MALES

Uncomplicated chlamydia infection (Asymptomatic and Symptomatic)

Recommended Regimens:

Azithromycin 1g p.o. in a single dose
or
Doxycycline 100 mg p.o. BID for 7 days

Alternative regimens: For patients allergic to Azithromycin or Doxycycline, alternatives are Erythromycin base* 500 mg p.o. QID for 7 days or Erythromycin ethylsuccinate* 800 mg p.o. QID for 7 days or Ofloxacin 300 mg p.o. BID for 7 days or Levofloxacin 500 mg p.o. QD for 7 days.

* Test of cure should be considered 3 weeks after completion of treatment with erythromycin because of lower efficacy.

California Chlamydia ACTION COALITION

November 2002

TREATMENT OF CHLAMYDIA INFECTIONS

General Principles

1. To maximize compliance with therapy, medications for chlamydia infections should be dispensed on site, if possible.

2. 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.

3. To minimize the risk of re-infection, patients should be instructed to abstain from sexual intercourse until 7 days after all of their sex partners are treated.

4. Azithromycin should be available to treat populations with poor drug compliance, little follow-up or erratic health care seeking behavior. Azithromycin may be more cost effective in these populations as it provides the opportunity for single-dose, directly observed therapy.

5. Azithromycin is approved for use in persons of all ages including adolescents and children and may be particularly beneficial for use in treating adolescents (traditionally a non-compliant population). Doxycycline has the advantage of low cost and a longer history of use.

6. All sex partners within the last two months should also be evaluated, tested and treated. Female partners, especially, should be seen and evaluated for signs and symptoms of PID. Under California law it is the duty of the attending physician to instruct patients with STDs "in precautionary measures for preventing the spread of the disease, the seriousness of the disease and the necessity of treatment and prolonged medical supervision." Additionally the attending physician is required to "endeavor to discover the source of infection, as well as any sexual or any other intimate contacts [when] the patient was in the communicable stage of the disease" and "to make an effort, through the cooperation of the patient, to bring those cases in for examination and, if necessary, treatment." The Patient-delivered Partner Therapy Law enacted January 1, 2001 states " Notwithstanding any other provision of law, a physician, nurse practitioner, certified-nurse midwife, and physician assistant who diagnoses a sexually transmitted chlamydia infection may prescribe to that patient's sexual partner or partners without examination of that patient's partner or partners".

7. All patients diagnosed with chlamydia are required to be reported by the provider or their designee to the local health department of the jurisdiction where the patient resides.

8. Patients testing positive for chlamydia should be tested for other sexually transmitted diseases including gonorrhea, syphilis and HIV. In patients where other sexually transmitted diseases are initially diagnosed, a chlamydia screen should be obtained.

9. Because chlamydia reinfection is common, it is recommended that infected females be rescreened 3-4 months after treatment.

Chlamydia Screening & Treatment Practice Guidelines

California Chlamydia Action Coalition

Developed by the California Chlamydia Action Coalition with the assistance of staff of the STD Control Branch of the California Department of Health Services, the University of California, San Francisco and PricewaterhouseCoopers, LLP.

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EXECUTIVE SUMMARY

Sexually transmitted *Chlamydia trachomatis* is the most common communicable disease reported in California with an estimated 600,000 new infections each year. The majority of infection is asymptomatic and goes undetected. Up to 40% of women with untreated chlamydia will develop pelvic inflammatory disease (PID), the leading cause of preventable infertility in the U.S. Early identification through annual screening and appropriate treatment can significantly reduce the short- and long-term complications in women and is cost-effective

Screening

Screen all sexually active females 25 years of age and under annually for chlamydia, consistent with U.S. Centers for Disease Control and Prevention and U.S. Preventive Services Task Force guidelines, as well as HEDIS performance measurement expectations. **Use nucleic acid amplification technology tests for screening. These tests can be performed using urine specimens,** allowing chlamydia screening even if a pelvic or genital exam is not being done.

Treatment

1. Treat infected patients with either azithromycin 1 gm p.o. as a one-time dose or doxycycline 100 mg p.o. bid for 7 days. Dispense treatment on site if possible. Instruct patients to abstain from sexual intercourse for 7 days after single dose therapy or until completion of a 7-day regimen <u>and</u> until 7 days after all of their sexual partners are treated.

2. Evaluate, test and treat all sexual partners within the last 2 months if possible. A new California state law allows providers to prescribe treatment for partners without an examination.

3. Report infected patients to the local health department of the jurisdiction where the patient resides.

4. Test infected patients for other sexually transmitted diseases including syphilis, gonorrhea and HIV.

5. Because chlamydia reinfection is common, consider rescreening infected patients 10 weeks to 6 months after treatment.

BACKGROUND

Chlamydia trachomatis is the most common communicable disease reported in California with an estimated 600,000 new infections each year (1-3). The majority of infections are asymptomatic and go undetected. The medical consequences and costs of infection are greatest in women, who because of undetected and untreated disease, are at greatest risk of developing serious short-term and long-term complications. Up to 40% of women with untreated chlamydia will develop pelvic inflammatory disease (PID), the leading cause of preventable infertility in the U.S. (4-6). Approximately 20% of PID patients will become infertile, 6% will have ectopic pregnancies and 18% will suffer chronic pelvic pain. In men, chlamydia causes nongonococcal urethritis and acute epididymitis (6). Chlamydia may contribute substantially to the spread of heterosexually acquired HIV infection (7-9). Chlamydia is also a common cause of conjunctivitis and pneumonia in newborns born to an infected mother (10).

Risk Profile

The primary risk factors for chlamydia are age (25 years of age or under) and unprotected sex (2,6,11). Adolescent girls have the highest rates of infection, with approximately 5-10% of sexually active girls infected in California; 20 to 25-year-old women have the second highest rate ranging from 3% to 6% (12-13). Reported rates are much higher among women, largely because women are more likely to access care and be tested than men. Risk factors include new or multiple sex partners, inconsistent use of barrier contraceptives, oral contraceptive use and douching (2,6,11,14). Chlamydia has a wide socioeconomic distribution, with high rates occurring across urban, suburban and rural settings. Studies from a variety of practice settings in California, including HMOs, have consistently demonstrated high prevalence of chlamydia (5%-15%) in younger women (12,15). For example, in California in 1999, approximately 6% of girls 15-19 years of age and 4% of women 20-24 tested in a large northern California HMO were infected (12).

Screening Rationale

An estimated nine out of ten chlamydia infections in California are currently undetected and untreated because patients have no symptoms nor reasons to seek care and providers do not screen. It is estimated that 75-80% of women with chlamydia have no symptoms (3,6), and, as a result, the disease may not be diagnosed and treated until complications develop. Early identification through annual screening and subsequent treatment can significantly reduce the medical short- and long-term complications in women and has been shown to be cost-effective (16-19). A recent randomized controlled trial of chlamydia screening and treatment in an HMO demonstrated a 56% reduction in the incidence of PID in the 12 months following this intervention (19).

Screening younger women for chlamydia is recommended by the Centers for Disease Control and Prevention (CDC), the U.S. Preventive Services Task Force and a variety of professional organizations (see Resources, page 10). Recently NCQA included *Chlamydia Screening in Women*[*] as a HEDIS measure (20). Screening for chlamydia is simple and takes very little time. Highly sensitive and specific screening tests are available (21-23). **Tests can be performed using urine specimens, allowing chlamydia screening even if a pelvic or genital exam is not being done** (24-25).

Symptomatic Infection

Most chlamydia infections are asymptomatic, so symptoms and abnormal findings are not a good predictor of infections. In addition when symptoms such as abnormal vaginal discharge, abnormal vaginal bleeding or dyspareunia are present,

[*] HEDIS chlamydia screening measure definition: "The percentage of women age 16 through 26 years who were identified as sexually active, who were continuously enrolled during measurement year, and who had at least one test for chlamydia during the measurement year."

they are usually mild and non-specific, and may not prompt the patient to seek care. If symptoms occur, they may appear within 2 to 4 weeks after exposure. The physical findings most commonly associated with chlamydia infection include mucopurulent cervicitis (MPC) and/or cervical friability (i.e., easily induced cervical bleeding by a swab) (6).

SCREENING AND DIAGNOSTIC TESTING FOR CHLAMYDIA INFECTIONS *

1. **Screening Criteria for Asymptomatic Sexually Active Females** (see Chlamydia Care Path for Asymptomatic Non-Pregnant Females on page 6).

   Recommended: Screen all sexually active females 25 years of age and under at the first visit and annually thereafter**. Urine testing may be utilized if the patient is not scheduled for a pelvic examination.** Amplified testing [e.g. ligase chain reaction (LCR), polymerase chain reaction (PCR), strand displacement amplification (SDA), and transcription mediated amplification (TMA)] is preferred for reasons of increased sensitivity, ease of specimen collection and patient acceptability (25, 26).

2. **Diagnostic Testing for Uncomplicated Symptomatic Infection** (see Chlamydia Care Path for Uncomplicated Symptomatic Non-Pregnant Females and Males on page 7).

   Recommended: Patients with symptoms or signs associated with chlamydia, including abnormal vaginal discharge, abnormal vaginal bleeding, dyspareunia, mucopurulent cervicitis (MPC) or cervical friability in females or dysuria, urethral discharge or urethritis in males, should be tested and presumptively treated for chlamydia (26).

*** Note: Screening, diagnostic testing, and treatment for pregnant females is not addressed in this clinical practice guideline.** There is a module addressing this issue in the California Chlamydia Action Coalition Quality Improvement Toolbox.

TREATMENT OF CHLAMYDIA INFECTIONS

General Principles

1. To maximize compliance with therapy, medications for chlamydia infections should be dispensed on site, if possible.

2. 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.

3. To minimize the risk of re-infection, patients should also be instructed to abstain from sexual intercourse until 7 days after all of their sexual partners are treated.

4. Azithromycin is probably more cost-effective in populations with poor drug compliance, little follow-up or erratic health care seeking behavior, as it provides the opportunity for single-dose, directly observed therapy.

5. Azithromycin is approved for use in persons of all ages including adolescents and children and may be particularly beneficial for use in treating adolescents (traditionally a non-compliant population). Doxycycline has the advantage of low cost and a longer history of use.

6. All sexual partners within the last two months should also be evaluated, tested and treated. Female partners, especially, should be seen and evaluated for signs and symptoms of PID. Under California law it is the duty of the attending

physician to instruct patients with STDs "in precautionary measures for preventing the spread of the disease, the seriousness of the disease and the necessity of treatment and prolonged medical supervision" (29). Additionally the attending physician is required to "endeavor to discover the source of infection, as well as any sexual or any other intimate contacts [when] the patient was in the communicable stage of the disease" and "to make an effort, through the cooperation of the patient, to bring those cases in for examination and, if necessary, treatment"(29). The Patient-delivered Partner Therapy Law enacted January 1, 2001 states " Notwithstanding any other provision of law, a physician, nurse practitioner, certified-nurse midwife, and physician assistant who diagnoses a sexually transmitted chlamydia infection may prescribe to that patient's sexual partner or partners without examination of that patient's partner or partners".

7. All patients diagnosed with chlamydia are required to be reported to the local health department of the jurisdiction where the patient resides (30).

8. Patients testing positive for chlamydia should be tested for other sexually transmitted diseases including syphilis, gonorrhea and HIV (31). In patients where other sexually transmitted diseases are initially diagnosed, a chlamydia screen should be obtained.

9. Because chlamydia reinfection is common, ranging from 10.5% (32) to 38% (33), several authors have recommended that patients be rescreened 10 weeks to 6 months after treatment (32, 34, 35).

TREATMENT OF CHLAMYDIA INFECTIONS IN NON-PREGNANT FEMALES AND MALES

Uncomplicated chlamydia infection (Asymptomatic and Symptomatic)

Recommended Regimens:

Azithromycin 1g p.o. in a single dose
or
Doxycycline 100 mg p.o. BID for 7 days

Alternative regimens: For patients allergic to Azithromycin or Doxycycline, alternatives are Ofloxacin 300 mg p.o. BID for 7 days or Erythromycin base* 500 mg p.o. QID for 7 days or Erythromycin ethylsuccinate* 800 mg p.o. QID for 7 days.

* Test of cure is recommended 3 weeks after treatment with erythromycin because of lower efficacy.

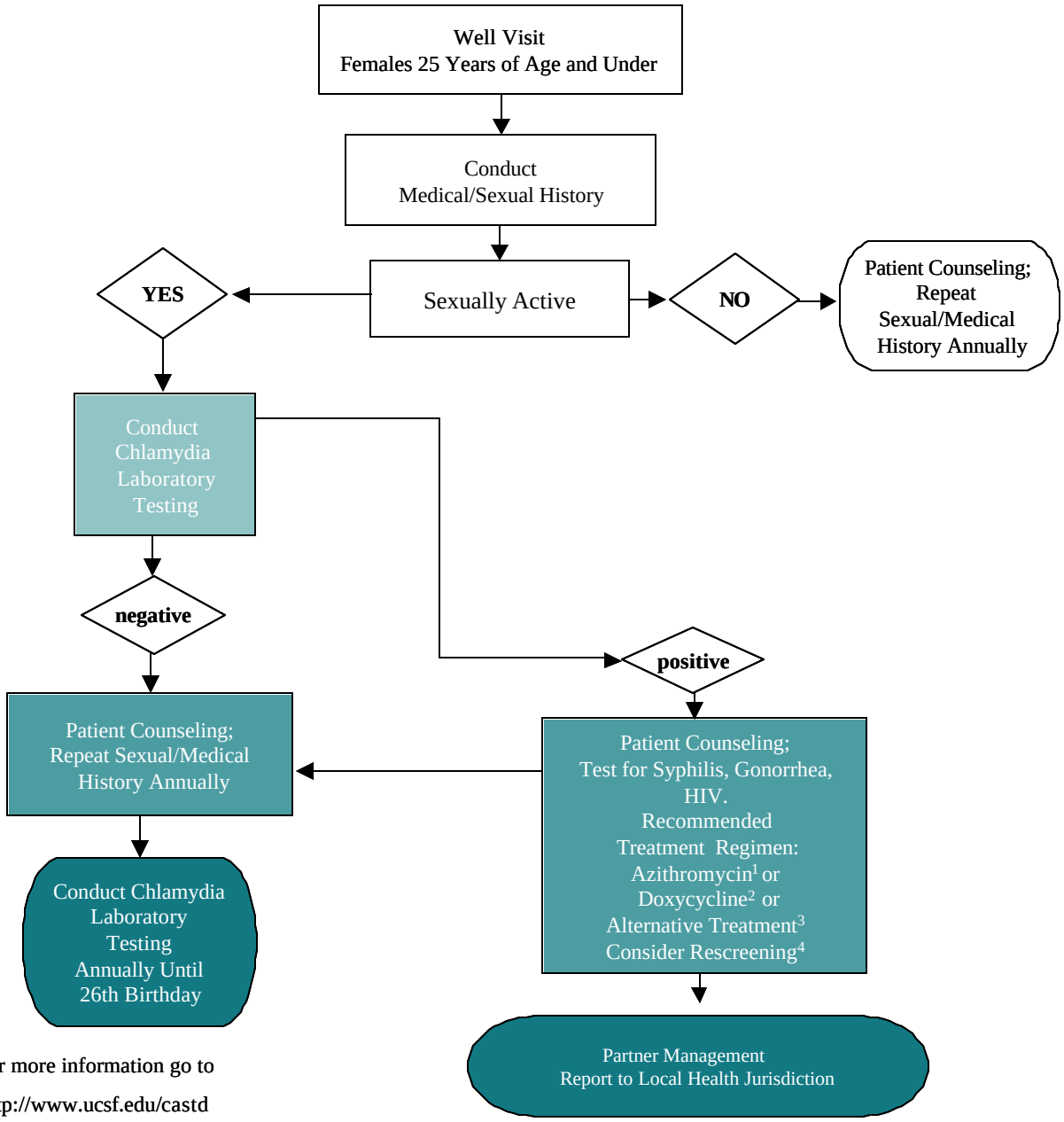
Comparison of Chlamydia Testing Technologies (21,22,25)

	NUCLEIC ACID AMPLIFICATION TECHNOLOGY*	CELL CULTURE	DIRECT FLUORESCENT ANTIBODY (DFA)	ENZYME IMMUNOASSAY (EIA)	NUCLEIC ACID PROBE
Test Type and Brand Name	• *Ligase Chain Reaction (LCR) – LCx CT Test (Abbott)* • *Polymerase Chain Reaction (PCR) – Amplicor CT Test (Roche)* • *Transcription Mediated Amplification (TMA) – Amplified CT Assay, APTIMA (Gen-Probe)* • *Strand Displacement Amplification (SDA) - BD Probe Tec (Becton Dickinson)*				*PACE II (Gen-Probe)*
Preferred Test	Yes	No	No	No	No
Collection Site	Male and female **urine**, endocervical and urethral swabs	Endocervical, urethral, rectal, conjunctival, pulmonary	Endocervical, urethral, rectal, conjunctival, nasopharyngeal	Endocervical, urethral, conjunctival	Endocervical, urethral, conjunctival
Sensitivity	90-95%	75-85%	70-75%	50-75%	65-75%
Specificity	98-100%	100%	95-99%	95-99%	95-99%
Test Advantages	**More sensitive.** Non-invasive urine specimens in addition to genital swabs. For some of these tests: • Refrigeration during transport not required. • Single specimen for chlamydia and gonorrhea.	Recommended test for medicolegal purposes, if available.	Internally controlled for specimen adequacy. Refrigeration during transport not required.	Automated test. Refrigeration during transport not required.	Semi-automated. One swab for both chlamydia and gonorrhea. Refrigeration during transport not required.
Test Disadvantages	Contamination possible if specimen not handled properly in the clinic or lab. More costly.	Less sensitive. Longer turn around time. Technically difficult. Specimen transport, storage times and temperatures critical. Labor intensive. QA for specimen adequacy required.	Less sensitive. Technically difficult. Labor intensive.	Poor sensitivity. QA for specimen adequacy required. Confirmatory testing recommended.	Less sensitive. QA for specimen adequacy required. Confirmatory testing recommended. Negative gray zone testing recommended.

* Examples of current nucleic acid amplification tests are provided. Others are being developed.
Note: Sensitivity somewhat lower for urine compared to cervical swab specimens in nucleic acid amplification technology
Sensitivity = the proportion of patients who truly have chlamydia for whom the test is positive.
Specificity = the proportion of patients who truly do not have chlamydia for whom the test is negative.
Adapted from: USPHS Region IX Infertility Prevention Project. Clinical Guidelines. San Francisco, CA: Region IX Infertility Prevention Project Advisory Committee, 1998.

Chlamydia Care Path

ASYMPTOMATIC NON-PREGNANT FEMALES



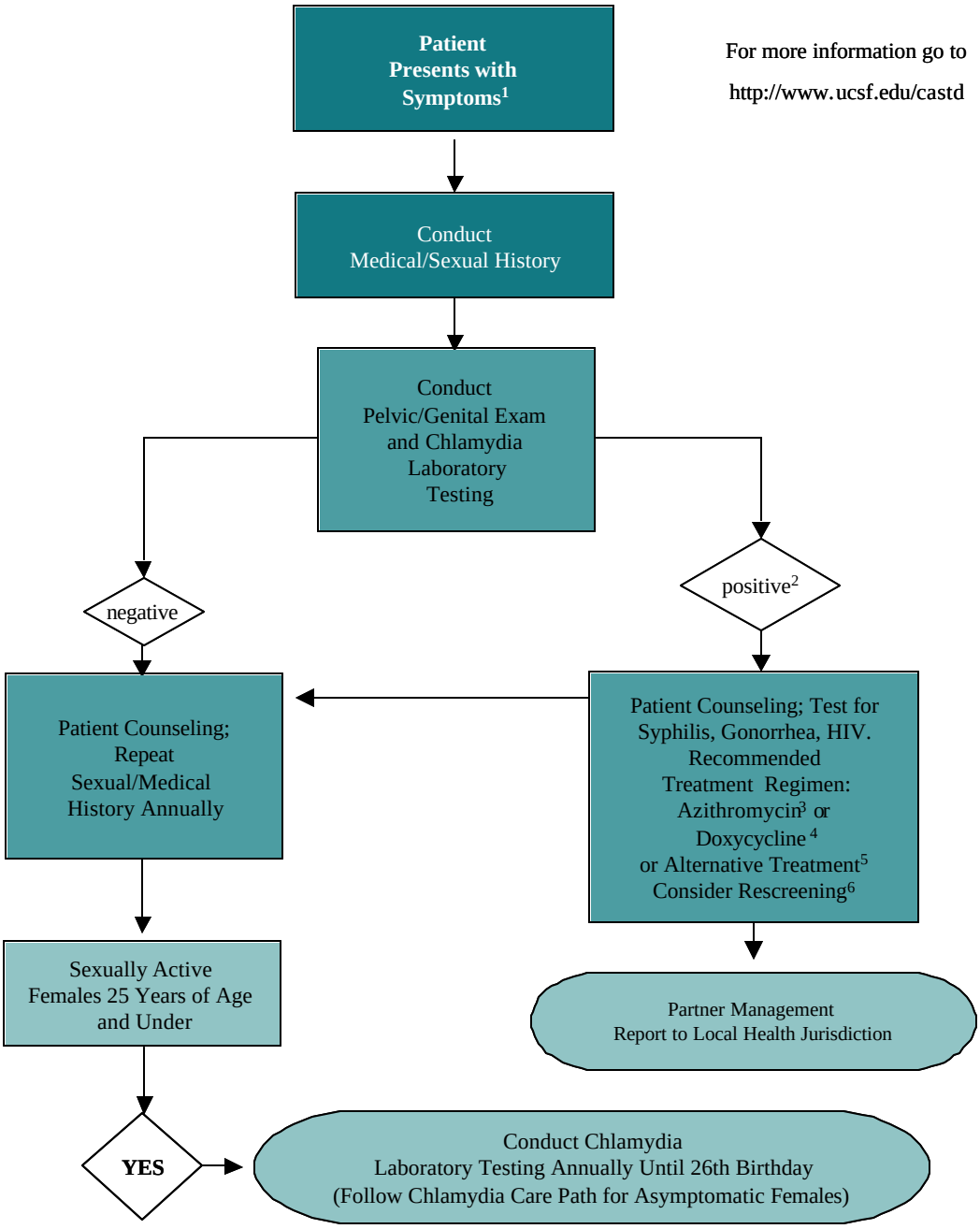
For more information go to

http://www.ucsf.edu/castd

1 Azithromycin dose: 1 gram p.o., single dose.
2 Doxycycline dose: 100 mg p.o. BID for 7 days
3 Alternative Treatment Regimen: Ofloxacin 300 mg p.o. BID for 7 days or Erythromycin base 500 mg p.o QID for 7 days or Erythromycin ethylsuccinate 800 mg p.o. QID f or 7 days.
4 Because Chlamydia reinfection is common, ranging from 10.5% (32) to 38% (33), several authors have recommended that patients be rescreened 10 weeks to 6 months after treatment (32, 34, 35)

Chlamydia Care Path

UNCOMPLICATED SYMPTOMATIC NON-PREGNANT FEMALES and MALES



For more information go to

http://www.ucsf.edu/castd

1 Symptoms: Females - Abnormal Vaginal Discharge, Abnormal Vaginal Bleeding, or Dyspareunia; Males - Urethral Discharge, or Dysuria.
2 Positives include: Positive Chlamydia Test and/or Positive Physical Exam in Females - Mucopurulent Cervicitis or Cervical Friability; Positive Chlamydia Test and/or Positive Physical Exam in Males - Urethritis.
3 Azithromycin dose: 1 gram p.o., single dose.
4 Doxycycline dose: 100 mg p.o. BID for 7 days
5 Alternative Treatment Regimen: Ofloxacin 300 mg p.o..BID for 7 days or Erythromycin base 500 mg p.o. QID for 7 days or Erythromycin ethylsuccinate 800 mg p.o. QID for 7 days
6 Because Chlamydia reinfection is common, ranging from 10.5% (32) to 38% (33), several authors have recommended that patients be rescreened 10 weeks to 6 months after treatment (32, 34, 35)

ENDNOTES

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RESOURCES

General STD Resources

- California STD/HIV Prevention Training Center:
  http://itsa.ucsf.edu/~bolan/
  (510-883-6600)

  The California STD/HIV Prevention Training Center specializes in training health care providers in the prevention, diagnosis, treatment and management of sexually transmitted diseases. Contact the center for information on course schedules and registration.

- CDC National Center for HIV/STD/TB Prevention:
  http://www.cdc.gov/nchstp/od/nchstp.html

  Home page of the National Center for Sexually Transmitted Diseases (STD), Human Immunodeficiency Virus (HIV) and Tuberculosis (TB) Prevention of the Centers for Disease Control. (CDC Voice Information System 888-CDC-FACT)

- CDC National Prevention Information Network:
  http://www.cdcnpin.org/std/start.htm

  STD Resource page of NPIN, a service of the National Center for HIV, STD and TB Prevention of the Centers for Disease Control. Links to databases, publications and other resources. (NPIN: 800-458-5231)

- The American Social Health Association:
  http://www.ashastd.org/

  Home page of ASHA, a nonprofit organization based in North Carolina dedicated to stopping STDs. Includes links to HPV/Cervical Cancer Prevention Resource Center, Herpes Resource Center and more.

- CDC STD Hotline: 800-227-8922 or 800-342-2437

Clinical Screening and Treatment Guidelines

- CDC Treatment Guidelines:
  http://www.cdc.gov/nchstp/dstd/1998_STD_Guidlines/1998_guidelines_for_the_treatment.htm

  The Centers for Disease Control and Prevention 1998 Guidelines for the Treatment of Sexually Transmitted Diseases.

- US Preventive Services Task Force. Screening: Chlamydial Infection. Update, 2001 Release.
  http://www.ahrq.gov/clinic/uspstf/uspschlm.htm

Chlamydia Resources

- California Chlamydia Action Coalition:
  http://www.ucsf.edu/castd/chlamydia_coalition.html

  This web site includes a downloadable cost-effectiveness program to determine costs and benefits of chlamydia screening in managed care organizations. The program can be modified by chlamydia prevalence in the target population, cost of laboratory tests and cost of drugs.

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