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I. SIGNS AND COMPLICATIONS OF CHLAMYDIA INFECTION

More than 70% of genital chlamydia infections in women do not produce signs or symptoms. Because most chlamydia infections in women are asymptomatic, symptoms and abnormal findings are not a good predictor of infection. In addition, when symptoms are present (e.g. vaginal discharge caused by chlamydial cervicitis), they are usually mild and non-specific and may not prompt the patient to seek care.

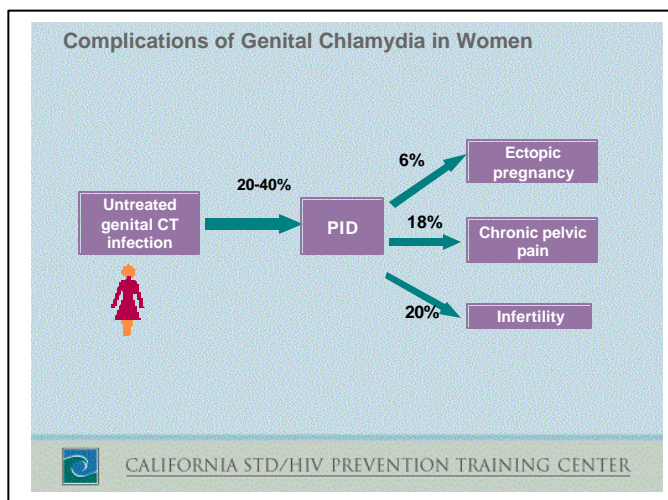
If symptoms occur, they may appear within 2-4 weeks after exposure. The physical findings most commonly associated with chlamydia infection include mucopurulent cervicitis (MPC) and/or cervical friability (i.e., cervical bleeding easily induced by a soft cotton swab). Acute infections also can manifest themselves as urethritis, proctitis, and conjunctivitis.

Complications in Women

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. Untreated chlamydia infection can lead to pelvic inflammatory disease (PID), ectopic pregnancy, infertility, chronic pelvic pain, and increased susceptibility to HIV. Chlamydia is also associated with neonatal complications and infections in non-genital sites.

As shown in the diagram, up to 40% of women with untreated chlamydia will develop PID, the leading cause of preventable infertility in the U.S. Approximately 20% of patients with PID will become

infertile, 6% will have ectopic pregnancies and 18% will suffer chronic pelvic pain. In addition, chlamydia may contribute substantially to the spread of heterosexually acquired HIV infection.

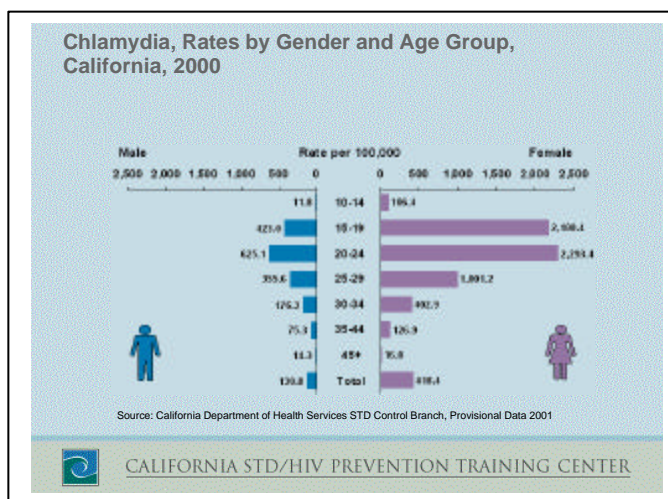


II. EPIDEMIOLOGY AND RISK FACTORS

Chlamydia is the most common bacterial STD and the most common reportable communicable disease in the U.S. and in California. It is estimated that over 3 million genital chlamydial infections occur each year in the U.S. with direct medical costs of about \$375 million.[1] In California, because most cases go undetected, it is estimated that there are an estimated 600,000 new infections each year.

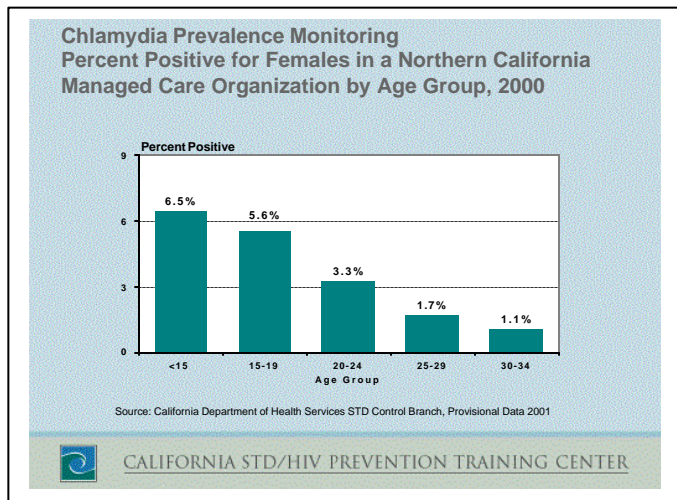
Young Women are at Highest Risk for Chlamydia

Chlamydia mainly affects adolescents and young adults. The graph shows provisional California chlamydia surveillance data from 2000.[2] Women ages 15-19 and 20-24 account for the highest

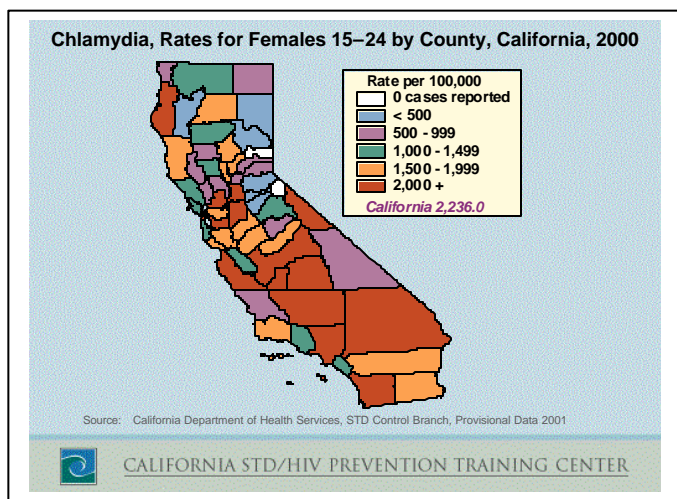


proportion of reported cases among females. In fact, young women ages 15-25 years account for over 70% of all reported infections among women.

In California family planning clinics, 5-10% of adolescent girls and 3-6% of women ages 20 to 24 years are infected with chlamydia.[2] As shown in the figure, nearly 6% of girls 15-19 years of age and 4% of women 20-24 tested in a large northern California managed care organization are infected.[2]



Chlamydia has a wide socioeconomic distribution. Although some studies find the highest rates in urban poor communities, high rates also occur in suburban and rural settings. This is a map of California counties showing the incidence of chlamydia among women ages 15-24 years.



Sexual Behavior Can Put Women at Risk

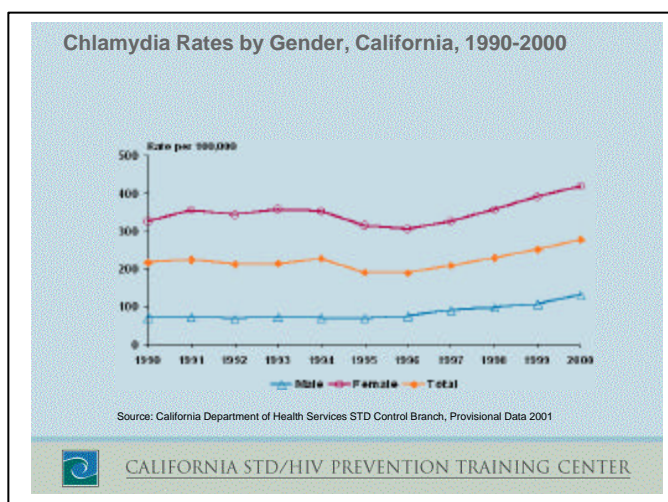
For some women, their behaviors put them at risk for chlamydia infection.[3] Behavioral risk factors include new or multiple sex partners, inconsistent use of condoms, oral contraceptive use and douching.[4, 5] When sexually active, adolescents tend to have higher risk sexual behavior.

Besides sexual behavior, cervical ectopy is more common in younger women and increases the accessibility of chlamydia's target cells (columnar epithelial cells) to infection.

Other women are at risk for infection because of their partner's behavior. The majority of women diagnosed with chlamydia report being in a monogamous relationship. These women may not be aware that their partner has other sexual partners.

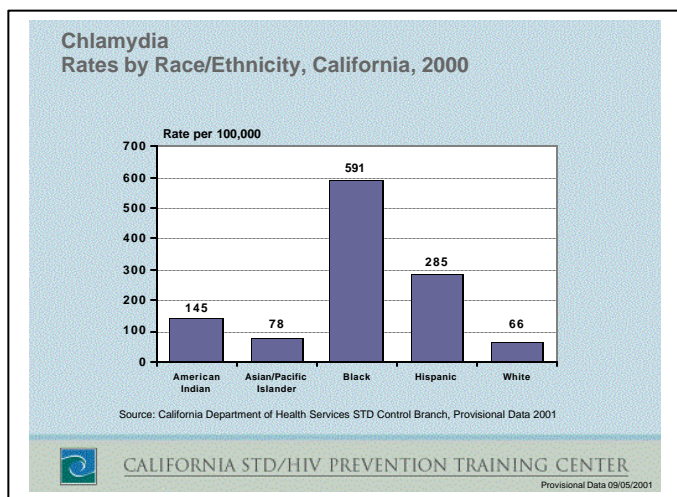
Chlamydia Cases are on the Rise

Reported cases among females in California have increased nearly 20% in the past 3 years. The graph shows the incidence of chlamydia infection in California for 1990 through 2000 stratified by gender (female in red at the top, male in blue at the bottom).[2] After some decrease in cases in the mid-90s, the rates have increased over the past 3 years for both women and men, in part because of increases in testing and use of more sensitive test technology. The relatively low rates among men partly reflect limited screening for asymptomatic infection.



Black and Hispanic Women are at Risk

The graph shows chlamydia incidence among different racial/ethnic groups in California.[2] In general, rates are highest among African-American and Hispanic groups. Although some of the variation is likely due to biases in reporting, the disparity also has been demonstrated in population-based and clinic-based surveys.



III. CHLAMYDIA SCREENING GUIDELINES AND RATIONALE

Sexually active females age 25 and younger should be screened annually for chlamydia. Because some patients do not know about their partners' risk or do not feel comfortable disclosing their risk to their provider, it is recommended that all females age 25 and younger are screened even if they are married or report being in a monogamous relationship.

Because scientific evidence most strongly supports screening among young women, where the prevalence and risks of complications are the greatest,[6] these guidelines are supported by the U.S. Preventive Services Task Force, the Centers for Disease Control and Prevention (CDC), the American College of Obstetrics and Gynecology, and a variety of professional medical organizations.

Other preventive services may include needed immunizations and counseling regarding injury prevention, diet and exercise, sexual behavior, and substance abuse.[7] Gonorrhea testing may be recommended for patients with high-risk sexual

behaviors (e.g., multiple sexual partners) or a recent STD.

NCQA HEDIS Chlamydia Measure

Recently, the National Committee on Quality Assurance added chlamydia screening in young women to the set of HEDIS quality measures that they monitor.[8] Consequently, your medical group's performance may be measured in part by the proportion of sexually active women ages 16-26 who received a chlamydia test within the past year.

California Chlamydia Screening and Treatment Practice Guidelines

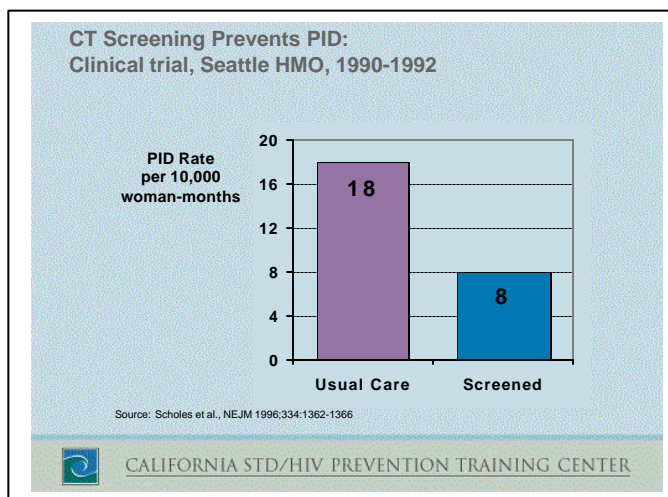
As part of the California Chlamydia Action Coalition efforts, a chlamydia clinical practice guideline was developed for health plans and providers with the recommendation to screen all sexually active females 25 years of age and under at the first visit and annually thereafter. These guidelines are available at www.ucsf.edu/castd.

Benefits of Chlamydia Screening

The benefits of chlamydia screening include detection of asymptomatic infection, prevention of PID, and reduction of prevalent infection. Because chlamydial infections are typically asymptomatic, 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.

Screening Reduces the Risk of PID

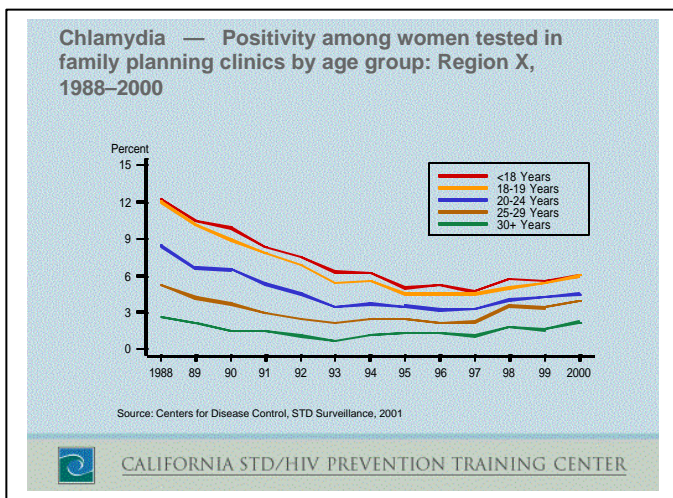
A randomized controlled trial of chlamydia screening and treatment in a managed care organization demonstrated a 56% reduction in the incidence of



PID in the 12 months following this intervention.[9] The graph shows the number of cases of PID per 1000 patients in each arm of the trial. The usual-care group had over twice the risk of developing PID (18 cases per 1000) compared to the group that was recruited for chlamydia screening (8 cases per 1000).

Screening Reduces the Prevalence of Chlamydia

Clinical settings that have routinely screened young women for chlamydia for several years have seen a decrease in chlamydia prevalence in their patient populations.[10-12] The graph shows data from U.S. Public Health Service Region X (Washington, Oregon, Idaho, and Alaska) where chlamydia screening started in 1988 when the prevalence of infection was over 10%. The first 5 years of screening produced the greatest decline, nearly 50% in most age groups.[13]



Chlamydia Screening Is Cost-Effective

Cost-effectiveness analyses have demonstrated that screening young women for chlamydia in populations with prevalence rates over 3% results in both cost savings and disease reduction.[14, 15] To simplify guidelines, age has been used as a proxy for prevalence with infection rates highest among sexually active women ages 25 years and younger.

IV. SEXUAL HISTORY TAKING

A sexual history is an essential component of a reproductive health assessment and is used to

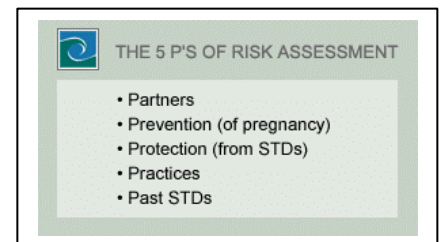
identify those at risk for STDs, including HIV and to guide risk-reduction counseling.

Patients Want to Discuss their Sexual Health

One barrier to sexual history taking is the provider's misconception that most patients do not want to discuss sexual health issues. Based on national surveys of adolescent and young women, the vast majority of female patients want and expect their providers to ask about their sexual history.[16, 17]

The 5 Ps

One simple framework for taking a sexual history focuses on the 5 P's: Partners, Prevention (of pregnancy), Protection (from STDs), Practices, and Past STDs.



Partners

For sexual risk, it is important to determine the number and gender of a patient's sexual partners. Keep in mind that it may be important to ask whether her partner has other sexual partners. Partner non-monogamy is an important risk factor for chlamydia infection.

Examples of questions include:

- "Do you have sex with men, women, or both?"
- "In the past 2 months, how many people have you had sex with?"
- "Does your partner have sex with other people?"

Prevention of pregnancy

Before discussing contraception, it is a good idea to assess pregnancy intention, particularly in a married woman.

Protection from STDs

Protection from STDs includes abstinence, condom use, monogamy, and a range of other harm reduction strategies. Examples of questions include:

- "What do you do to protect yourself from sexually transmitted diseases and HIV?"
- "Do you use condoms: never, sometimes, or always?"

Practices

If a patient reports more than one male partner in the past year, or the patient's partner has risks, you may want to explore further her sexual practices and condom use. You need to ask about sexual practices that affect her risk for STDs and HIV. Examples of questions include:



- “Have you had vaginal sex? Anal sex? Oral sex?”

Past history of STDs

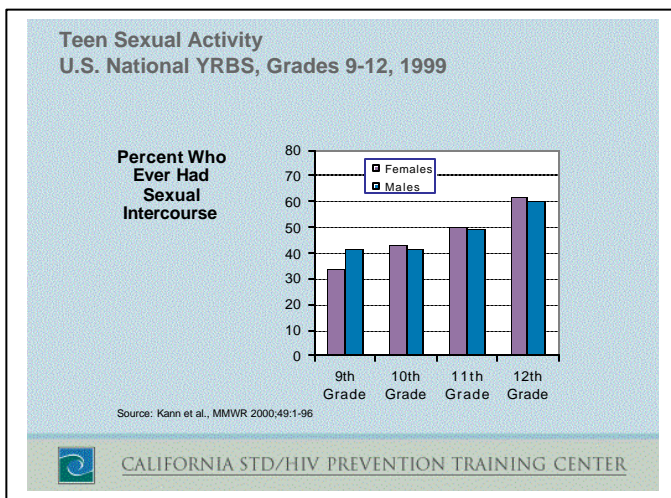
Patients with a recent chlamydia or gonorrhea infection or PID, especially in the past year, are at increased risk of repeat infection. Recent STDs may indicate recent high risk behaviors; a history of genital warts or herpes may inform your exam.

Beyond the 5 Ps

Additional questions may involve immunization history for hepatitis A and B, risk behaviors for HIV and hepatitis (e.g. intravenous drug use), HIV testing history, and douching practices. Douching is an established risk factor for chlamydia and PID.[5] Vaginal douching should be discouraged to prevent other complications like bacterial vaginosis.

Sexual History Taking for Teens

About 50% of young women age 16 are sexually active. According to the Youth Risk Behavioral Survey, 33% of 9th grade girls, 43% of 10th grade girls, 54% of 11th grade girls and 66% of 12th grade girls are sexually active.[18]



Because it is important to interview the teen alone and reinforce confidentiality, you may want to introduce the topic with a statement like,

- ◆ “Now I am going to take a few minutes to ask you some questions about sexual health that I ask all of my patients. Anything we discuss will be completely confidential. I won’t discuss this with anyone, not even your parents, without your permission.”

The best beginnings are those that communicate open mindedness, link the conversation to the patient’s health, and create opportunities for further exploration of the patient’s risk behaviors.

Examples of good opening questions include:

- “Some of my patients your age have started having sex. How about you?”
- “What do you do to protect yourself from HIV and other sexually transmitted diseases?”

Once you’ve confirmed sexual activity, you will want to ask follow up questions that assess partners, practices, and protection strategies. If an adolescent says that he/she is not sexually active, probe for more information before ending the sexual history. Since many teens do not consider oral and anal sex to be “sex”, or may misunderstand the term “sexually active”, adolescents may have STD risk even if they say that they are not sexually active.[19, 20]

Minor Rights to STD Care in California

In California, patients age 12 and older are able to consent for reproductive health and STD services and clinicians are required to ensure confidentiality if these services are provided. These provisions allow special exceptions for reproductive health and infectious disease care, however other types of medical care may require parental consent.

Parental involvement should be encouraged, however STD services should never be withheld because of concerns over parental objection. Clinics must take care to develop systems so that billing statements and lab results are not mailed to the home of an adolescent. Also, care must be taken to protect confidentiality when calling a patient or leaving a voice message.

Risk-Reduction Counseling

When the sexual history reveals risk taking behavior, it is important to work with patients to reduce their risk. The most effective methods involve allowing patients to identify the behaviors that they would like to change and develop a plan of action. One strategy, adapted from the Project RESPECT Brief Counseling Intervention Manual,[21] has the acronym **R-E-S-P-E-C-T**.

Review patient’s protective behaviors and support patient-initiated behavior change.

Enhance patient self perception of risk.

Situations, including facilitators and barriers, affecting risk behaviors should be addressed. One important situation to consider is dating violence.



Plan an acceptable and achievable risk-reduction strategy. If necessary suggest possible risk reduction options (e.g. reduce number of partners, use condoms more).

Examine the specifics of the plan. Get the client to say exactly when, where, and how he/she will take the risk-reduction step.

Challenge the plan. Ask about facilitators and barriers to change, and make sure that the change is achievable.

Tell. Ask the patient to tell you about her risk-reduction plan. If necessary, refer the patient to other counseling resources or schedule a follow-up visit.

V. DIAGNOSTIC TESTS

The best diagnostic and screening tests are the nucleic acid amplification tests (NAATs). Amplified testing is preferred because of increased sensitivity, ease of specimen collection and patient acceptability. NAATs provide excellent sensitivity (90-95%) and specificity (98-100%).[22] These tests are based on a variety of technologies: polymerase chain reaction (PCR), ligase chain reaction (LCR), transcription mediated amplification (TMA), and strand displacement amplification (SDA). The development of NAATs has markedly improved our ability to diagnose chlamydial infections by identifying up to 40% more chlamydial infections compared to other test technologies.[23]

Urine Testing is Appropriate when a Pelvic Exam is not Indicated

The increased sensitivity of NAATs has enabled the use of noninvasive specimen collection, such as first voided urine, which significantly increases patient acceptability and satisfaction. For the purposes of chlamydia screening, urine testing may be utilized whether or not the patient is scheduled for a pelvic examination or has no clinical indications for a pelvic exam (i.e. no genitourinary symptoms).[24]

Many Diagnostic Technologies are Currently Available

The diagnostic methods to detect chlamydia have changed significantly in the past few years.[25] This table summarizes the different technologies and tests currently available for chlamydia testing.



DIAGNOSTIC TESTS FOR CHLAMYDIA

Tissue Culture

Direct Fluorescent Antibody (DFA)

Enzyme ImmunoAssay (EIA)

Direct DNA Probe Hybridization -- GenProbe PACE 2

Nucleic Acid Amplification Test

Polymerase chain reaction (PCR) – Roche Amplicor

Ligase chain reaction (LCR) – Abbott LCx

Transcription mediated amplification (TMA) – GenProbe AmpCT, APTIMA

Strand displacement amplification (SDA) – BD ProbeTec

Hybrid Capture – Digene HC2

These technologies vary significantly in their sensitivity, or ability to detect infection. Based on a variety of comparative studies, NAATs have the highest sensitivity.



CHLAMYDIA DIAGNOSTIC TESTS


	Sensitivity	Specificity
EIA	50-75%	95-99%
DNA probe	65-75%	95-99%
DFA	70-75%	95-99%
Culture	75-85%	100%
NAATs	90-95%	98-100%

VI. MANAGEMENT OF CHLAMYDIA-INFECTED PATIENTS

TREATMENT REGIMENS

The current CDC recommendations for the treatment of uncomplicated chlamydial infection include azithromycin 1 gram orally in a single dose or doxycycline 100 mg orally 2 times a day for 7 days. [26] The results of clinical trials indicate that azithromycin and doxycycline are probably equally effective (94.9% and 95.9%) in eradicating infection.





TREATMENT OF CHLAMYDIA INFECTION
(non-pregnant adolescents and adults)

Azithromycin	1 gm orally once
Doxycycline	100 mg orally bid for 7 days

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). Azithromycin is probably more cost-effective in populations with poor treatment compliance or uncertain follow-up because it provides the opportunity for single-dose, directly observed therapy. Azithromycin should be available to health care providers for treatment of at least those patients for whom compliance is in question. Doxycycline has the advantage of low cost and a longer history of extensive use but has the disadvantages of a longer course and resultant problems with adherence.

Treatment Must Be Verified

To maximize compliance with therapy, medications for chlamydia infections should be dispensed on site. Public health law indicates that treatment must be verified. Calling the patient about the test results and phoning a prescription to the pharmacy is not enough. If medication cannot be dispensed on site, patients need to be contacted to ensure that the medication was received.


Treatment Precautions

To minimize further transmission of infection, patients treated for chlamydia should be instructed to abstain from sexual intercourse for 7 days after the single dose therapy or until completion of the 7-day regimen. Furthermore, patients should be instructed to abstain from sexual intercourse until 7 days after all of their sex partners have been treated to minimize risk for re-infection.

CDC Recommended Alternative Therapies

Alternative regimens include erythromycin base, erythromycin ethylsuccinate, ofloxacin and levofloxacin. Erythromycin is less efficacious (80-85%) compared to azithromycin or doxycycline, and gastrointestinal side effects and frequent dosing

discourage patients from complying with this regimen. A test of cure should be considered 3 weeks after completion of treatment with erythromycin.



ALTERNATIVE TREATMENTS FOR CHLAMYDIA
(non-pregnant adolescents and adults)

Erythromycin base	500 mg orally four times daily for 7 days
Erythromycin ethylsuccinate	800 mg orally four times daily for 7 days
Ofloxacin	300 mg orally twice daily for 7 days
Levofloxacin	500 mg orally for 7 days

No Presumptive Treatment for Gonorrhea

Generally, patients diagnosed with chlamydia are not presumptively treated for gonorrhea. Surveillance data in California indicate that only about 10% of women infected with chlamydia are co-infected with gonorrhea, so presumptive treatment would over-treat about 90% of people infected with chlamydia. In contrast, it is recommended that patients with gonorrhea be treated presumptively for chlamydia.

STD TESTING

The CDC recommends that patients who test positive for chlamydia also be tested for gonorrhea. These patients should also be offered testing for syphilis and HIV infection. Although syphilis is relatively rare among adolescent females in the U.S., it is treatable with antibiotics. Experts disagree on screening recommendations for HIV among adolescents, however adolescents diagnosed with a STD are in a higher risk group compared to other sexually active adolescents. Currently, there are no specific screening guidelines for trichomonas, herpes, and HPV infections.

COUNSELING AND RISK REDUCTION

The Basics of Chlamydia Information

Providers should explain the diagnosis: a sexually transmitted bacterial infection of the lower genital tract. Although infection has been documented to persist for many months, for the vast majority of patients, this infection was recently contracted from a sex partner.

Patients should understand the potential for ascending infection and the warning signs of PID. When patients return for treatment, they should be asked whether they are experiencing pelvic or





KEY COMPONENTS OF PATIENT COUNSELING MESSAGES

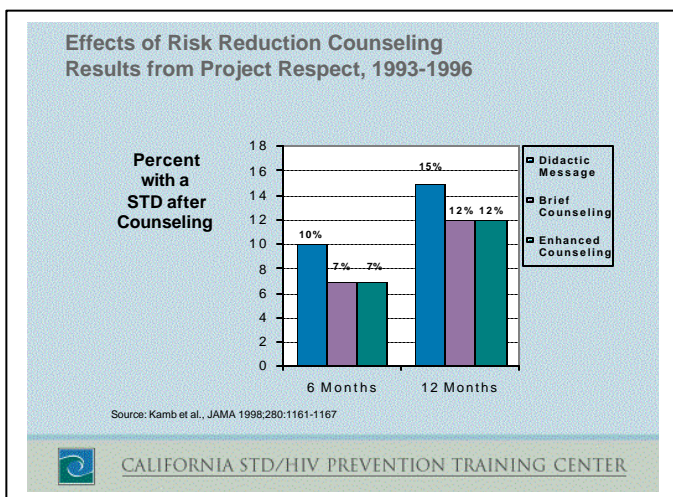
- The nature of the infection
- Medication use and potential side effects
- The need for abstinence for 7 days and until all partners complete treatment
- The importance of partner treatment
- Risk-reduction counseling

abdominal pain or fever and may need an exam to rule out PID. The potential long-term complications (ectopic pregnancy and infertility) of an advanced infection should be explained as possible but not inevitable. Pregnant patients should be informed about complications in pregnancy and the risk of neonatal transmission.

Abstinence is Critical for Preventing Re-infection

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. To minimize their risk of re-infection, patients should also be instructed to abstain from sexual intercourse until 7 days after all of their partners have completed treatment.

Patients need to understand the importance of discussing the diagnosis with their partners so that partners will know to seek medical evaluation and treatment.



Risk-Reduction Counseling to Prevent STD

A STD diagnosis is an important opportunity to conduct risk-reduction counseling. In a randomized controlled trial of STD/HIV counseling techniques, patients receiving brief risk counseling had 20% fewer STDs at the follow-up visit compared to patients receiving traditional didactic messages.[27] The graph demonstrates that brief counseling was as effective as extensive counseling. This counseling was conducted successfully by existing clinic staff and should be offered to all patients with a STD according to CDC guidelines.

PARTNER MANAGEMENT AND PATIENT-DELIVERED PARTNER TREATMENT

All sexual partners within the last 2 months should also be evaluated, tested and treated. No person with genital chlamydial infection can be considered adequately treated until all of his or her sex partners have also been treated. Since chlamydia is efficiently transmitted and diagnostic tests are not 100% sensitive, it is recommended that all partners within the past 2 months receive treatment regardless of their test result. Resumption of sex with an untreated partner is considered the most common cause of repeat infection, which conveys a higher risk of complications.

Partners are often asymptomatic and therefore may not seek treatment without being notified. Approaches for enhancing partner treatment should include involving the index patient in the referral of their partners for evaluation and treatment. Referrals to care may be conducted by patients, clinic staff, or public health workers. Regardless of the method, California public health law indicates that medical providers are responsible for ensuring the treatment of contacts to STD.

Testing of partners, although not essential for the medical management of the partner, is still recommended for public health purposes since a positive result allows for additional partner treatment of the partner's partners and improves patient compliance with treatment.

Patient-Delivered Partner Treatment: New California Legislation

As of January 1, 2001, California medical providers have a new option for ensuring partner treatment for patients with chlamydia.[28] By allowing clinicians to



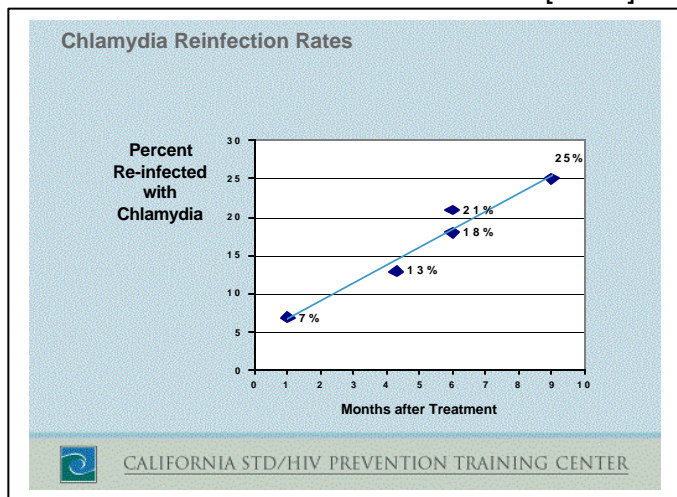
treat the partners of chlamydia-infected patients without an exam, this law provides another method for ensuring the treatment of potentially exposed or infected partners. This method may be particularly useful when the partner is unlikely to seek care or cannot easily get an evaluation or diagnosis in the community due to economic status or lack of access to medical care. Further, providing medication to male partners of infected women patients has been demonstrated as a cost effective strategy to reduce rates of re-infection by 20% among women patients.[29] Guidelines for PDPT are available at www.ucsf.edu/castd.

PATIENT FOLLOW-UP AND SCREENING FOR RE-INFECTION

Re-Screening in 3-4 Months to Detect Re-infection

Female patients should be scheduled for an appointment in 3-4 months for a repeat chlamydia screening test for re-infection. In general, a test-of-cure for chlamydia is not recommended after completing treatment with doxycycline or azithromycin. Although they would need to return if they developed symptoms (e.g. lower abdominal pain), symptomatic follow-up alone is insufficient.

Because re-infection is common, ranging from 10.5% to 38%, the California Chlamydia Action Coalition recommends that patients be re-screened within 3-4 months after treatment. Although a few of these cases represent non-compliance and treatment failures, the majority are due to subsequent exposure to an untreated partner. The graph shows the results of several studies of women who were re-screened several months after treatment.[30-32] In



general, up to 20% of women may become re-infected by 6 months.

REPORTING TO THE HEALTH DEPARTMENT

In California, both laboratories and medical providers are required to report patients diagnosed with chlamydia infection to the local health department where the patient resides.[33] A standardized form, the Confidential Morbidity Report, is available for filing these reports. Once reported, cases become part of local, state and national surveillance systems and allow public health agencies to track the epidemic and develop control programs.

CHECK LIST FOR THE MANAGEMENT OF CHLAMYDIA CASES

- Ensure timely and appropriate treatment
- Additional tests for gonorrhea, syphilis, and HIV
- Patient counseling
- Ensure that sex partners are treated
- Schedule follow-up for repeat test in 3-4 months
- Report case to the local health department

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