

## Section II:

### Female Selective Screening Criteria

#### Screening, Specimen Collection and Treatment

It is neither economically feasible, nor cost effective, to screen all females. Furthermore, as the prevalence of disease decreases in a population, the likelihood of a false positive result increases. When screening low risk women in a lower prevalence population, the risk of false positive results may become unacceptably high. "If the prevalence of disease is low, even a highly valid test will yield a low predictive value (of a positive test)." [1] Therefore, selective screening criteria are used to identify the highest risk population in the project's family planning clinics and other (non-STD) clinics. These criteria were developed using published studies, data from clinics in the Region X Infertility Prevention Project (IPP), and from the CDC Screening Criteria published in 2002 Guidelines for Treatment of Sexually Transmitted Diseases, MMWR, May 2002; and Recommendations for the Prevention and Management of Chlamydia trachomatis Infections, MMWR, 1993.

In January, 2002, female selective screening criteria were simplified in all sites except some STD clinics. Because of the presumption of exposure and higher positivity for most clients seen in STD clinics, universal screening of women will continue there.

Due to restrictions on federal funding, the Project does not cover widespread screening and treatment services for males unless they are identified as a partner of an infected woman. Some project areas are able to utilize local or state funds to screen males in STD clinics or other community sites. Even when funds other than Infertility Prevention Project Funds are used for screening, the data collected may be used to enhance the state or regional IPP chlamydia data set.

**For Additional Specific Information,  
MMWR  
May 10, 2002, Vol. 51/RR-6**

[1] Mausner, JS and Kramer, S, eds. Epidemiology: An introductory text. WB Saunders Co: Philadelphia; 1985,pp.222-3.

## Female Selective Screening Criteria in Family Planning and Expansion Sites

1. Women **24 and under** should be tested at least annually when undergoing a pelvic examination.
2. All women 25 and older who meet one of the following criteria should be screened:
  - a) Cervical findings of MPC, friable cervix, ectopy with inflammation or edema)
  - b) Pelvic Inflammatory Disease (PID)
  - c) Exposed to CT (**in last 60 days**)
  - d) Symptomatic sex partner (in past 60 days)
  - e) Pregnant
  - f) Seeking an IUD insertion
  - g) Prior chlamydial infection within the past 12 months

## Symptoms Diagnostic of MPC – Testing required

### ➤ Mucopurulent cervicitis (MPC)

MPC is a clinical syndrome, not diagnostic of chlamydia or any other specific infection. Thus, MPC is an indication to test for infection.

With a physical examination consistent with MPC, empiric treatment for chlamydia may be started without waiting for chlamydia test results only if:

- There is no herpes, vaginitis, or foreign body (IUD, lost tampon) complicating the diagnosis,
- The prevalence of chlamydia is high in the patient populations, AND
- The client reports she is unlikely to be able to be located for treatment or expresses reluctance to return for additional clinic visits.

Criteria for **diagnosis** of MPC:

- Mucopurulent secretion from the cervical os (not vagina)-greenish or yellow discharge (positive Q-tip test) from the cervical os in absence of vaginal infection or foreign body such as an IUD.
- Cervical friability-easily induced bleeding on the ectocervix or from the canal characterized by bleeding due to increased vascularity of the area.
- Absence of lower abdominal adnexal, uterine or cervical motion tenderness.

## Symptoms diagnostic of PID – Treatment required

### ➤ Pelvic inflammatory disease (PID)

PID comprises a spectrum of inflammatory disorders of the upper genital tract among women and may include any combination of endometritis, salpingitis, tubo-ovarian abscess, and pelvic peritonitis.

Minimum criteria for **initiation of treatment** in young, sexually active women includes one or more of the following:

(Perform pregnancy test to **RULE OUT** pregnancy. **RULE OUT** other causes, e.g., appendicitis.

- Uterine/adnexal tenderness
- Cervical motion tenderness - moderate to severe pain elicited when cervix is manipulated or palpated

Additional criteria supportive of PID diagnosis:

- Client history of recent onset of pelvic pain or dyspareunia
- Presence of WBCs on wet mount
- Abnormal mucopurulent cervical or vaginal discharge.
- Intermenstrual bleeding or post-coital bleeding.
- Laboratory confirmation of cervical infection with gonorrhea or chlamydia
- Fever > 101°F, tachycardia
- Elevated erythrocyte sedimentation rate
- Elevated C-reactive protein

Refer to CDC MMWR May 10, 2002 for more specific criteria.

## **Specimen Collection**

The sensitivity of all types of Chlamydia trachomatis tests is dramatically influenced by the quantity of columnar epithelial cells. The greater the number of cells collected, the more likely a chlamydial infection will be detected. Careful and thorough specimen collection will increase the accuracy of patient test results. Additional information on specific laboratory tests is available under the laboratory tab in this manual. A video for clinicians, "Specimen Collection for CT: Cervix and Male Urethra" is available through each state's IPP coordinator.

### ➤ **Collection of cervical specimen from the female**

- Collect other specimens first
- Clean excess discharge from exocervix
- Always use sterile swab recommended by manufacturer
- Insert appropriate swab into endocervix until most of tip is not visible
- Rotate swab with firm pressure for at least 15 seconds (rotation time varies depending on type of specimen collection or test kit used)
- Carefully remove swab from vagina to avoid contamination
- Place swab in transport tube or bottle provided
- Break off shaft of swab (raise swab well off the bottom of tube or bottle before snapping shaft)
- Cap tube or bottle tightly

### ➤ **Collection of urethral specimen from the male**

- Collect other specimens first
- Insert a sterile swab recommended by manufacturer into the urethra
- Insert the swab a minimum of 2 ½ cm or 1 inch
- Rotate at least 2 complete revolutions for 5 seconds

### ➤ **Urine specimen collection (male and female)**

- Instructions to client:
  - ▶ Do not void for at least one, preferably four hours before giving specimen
  - ▶ **DO NOT** cleanse perineum/urethral meatus as for "clean catch" specimens.
  - ▶ Catch urine from beginning of the urine stream, not mid-stream.

- ▶ Collect only the first 20-30 ml voided. (Clients will need to be specifically told or shown how full the cup should be when 20-30 ml has been collected)
- ▶ Clinic staff will then transfer a smaller amount of urine to the appropriate collection tube for transport.

**NOTE:** Specific instructions may vary according to test manufacturer's instructions.

➤ **Specimen identification**

Each transport tube or bottle label must identify, at a minimum, the client's name and date specimen was collected.

➤ **Special circumstances**

*Women without a cervix*

- Use urine sample for amplified test (LCR, TMA , etc.)

**OR, if amplified test is not available**

- Use urethral swab sample for culture, or non-amplified test (EIA, DFA, etc.)

➤ **Suspect anal infection**

- Preferred method of examination and specimen collection is use of anoscope to swab for culture.
- DFA is the nonculture test approved for rectal specimens. There is a risk of false positive result due to cross reactivity with fecal flora.

➤ **Oral infection** - Ordinarily pharyngeal testing is not recommended.

## Treatment of Uncomplicated Chlamydial Infection

Treatment for PID is different than for uncomplicated chlamydial infection. Refer to the following section on PID treatment.

➤ **Definitive diagnosis of chlamydial infection is by a positive test for *C. trachomatis*.**

➤ **Presumptive diagnosis treatment criteria for females**

Clients presumed to have chlamydial infection may be treated prior to receiving test result using the following criteria:

- History of recent sexual partner with confirmed CT or GC
- Confirmed gonorrheal infection
- Symptomatic partner
- Physical exam consistent with MPC\*

With a physical examination consistent with MPC, empiric treatment for chlamydia may be started without waiting for chlamydia test results only if:

- There is no herpes, vaginitis, or foreign body (IUD, lost tampon) complicating the diagnosis,
- The prevalence of chlamydia is high in the patient population, AND
- The client reports she is unlikely to be able to be located for treatment or expresses reluctance to return to for additional clinic visits

➤ **Treatment for presumed or confirmed positive *C. trachomatis* in a non-pregnant female or any male is:**

Treatment of choice (Note: **both** are equally effective in reasonably compliant clients)

- Doxycycline 100 mg orally 2 times a day for 7 days

**-OR-**

- Azithromycin 1 gm orally in a single dose in compliance with project guidelines.\*\*

\*\* The cost of azithromycin can be as much as ten times the cost of doxycycline, thus prohibiting its use for all clients. A limited amount may be available for use with "hard to treat" clients. Please review criteria regarding use of project-purchased azithromycin. (p. 10)

### **Alternative regimens**

- Erythromycin base 500 mg orally 4 times a day for 7 days
- OR-**
- Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days
- OR-**
- Ofloxacin 300 mg orally 2 times a day for 7 days
- OR-**
- Levofloxacin 500 mg orally once a day for 7 days

### ➤ **General medication/treatment instructions**

- Azithromycin
  - ▶ Single dose treatment should be directly observed
  - ▶ Tablets and sachet can be taken with food
  - ▶ Capsules must be taken on an empty stomach
  - ▶ Emphasize sexual abstinence for 7 days after treatment as it takes several days to kill all the organisms
  - ▶ Stress the importance of partner treatment
- Doxycycline
  - ▶ Emphasize importance of taking entire supply on twice-daily schedule
  - ▶ Take with plenty of water
  - ▶ Can be taken with food
  - ▶ Emphasize sexual abstinence during treatment week
  - ▶ Stress the importance of partner treatment

### ➤ **Test of cure (TOC)**

- Doxycycline or azithromycin-resistant chlamydia has not yet developed, so patients do not need to be retested after completing treatment with doxycycline or azithromycin.

- Indications for test of cure are:
  - ▶ Persistent symptoms
  - ▶ Patient is pregnant,
  - ▶ Reinfection is suspected
  - ▶ Patient was noncompliant with doxycycline treatment.
- Post-treatment test of cures are not routinely covered through the project. TOC should not be done in any case less than 4 weeks after initiation of treatment because:
  - ▶ Culture may be false negative due to low number of organisms.
  - ▶ Amplified DNA tests may be false positive due to continued excretion of dead organisms.

➤ **Treatment options for pregnant women**

**Recommended regimen**

- Azithromycin 1 gm orally in a single dose

**Alternative regimens**

- Amoxicillin 500 mg orally 3 times a day for 7 days

**-OR-**

- Erythromycin base 500 mg orally 4 times a days for 7 days

**-OR-**

- Erythromycin base 250 mg orally 4 times a day for 14 days

**-OR-**

- Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days

**-OR-**

- Erythromycin ethylsuccinate 400 mg orally 4 times a day for 14 days

**Test of cure (TOC) or rescreening pregnant women**

The project will cover a test of treatment efficacy for pregnant women. This should be done no sooner than 4 weeks after initiation of treatment.

A retest is recommended in the last 6 weeks of pregnancy.

**NOTE:** At this time, azithromycin, erythromycin base, erythromycin ethylsuccinate, and amoxicillin are all classified as Category B drugs for use during pregnancy. (See Class B definition, p. 10).

➤ **Treatment options for women who are breastfeeding**

**Recommended regimen:**

- Azithromycin 1 gm orally in a single dose

**Alternative regimen:**

- Erythromycin base 500 mg orally 4 times a day for 7 days

**-OR-**

- Erythromycin base 250 mg orally 4 times a day for 14 days

**-OR-**

- Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days

**-OR-**

- Erythromycin ethylsuccinate 400 mg orally 4 times a day for 14 days

**-OR-**

- Amoxicillin 500 mg orally 3 times a day for 7 days

**FDA Assigned use-in-pregnancy rating system**

Definition Category B:

“Adequate, well-controlled studies in pregnant women have not shown increased risk of fetal risk despite adverse findings in animals, or, in the absence of adequate human studies animal studies show no fetal risk. The chance of fetal harm is remote, but remains a possibility.”

Source: PDR Nurse’s Handbook, (1999) Appendix III, p. 1333.

➤ **Recommended criteria for selection of azithromycin as treatment medication**

- Azithromycin is an effective antibiotic against chlamydial infection. Clinical trials have shown azithromycin and doxycycline to be equally efficacious (about 95%) when properly used by a reasonably compliant patient. While azithromycin has the compliance advantage of single dosing, it is considerably more expensive (up to \$20.00) than a comparable treatment regimen of doxycycline (\$2.00). Each state in the Region X Infertility Prevention Project makes its own decision regarding the medications to be provided based on budgetary constraints. It may not be possible to provide azithromycin for general

use. Where a shortage exists, priority for treatment with azithromycin should be given to the following clients who have had positive test results:

- ▶ those who probably won't take the meds consistently for seven days, e.g. homeless
- ▶ pregnant women
- ▶ clients with repeat infections (2 or more in 6 months)
- ▶ clients who are doxycycline intolerant
- ▶ developmentally disabled clients
- ▶ teenagers
- *DO NOT use project azithromycin*
  - ▶ as general "take home" treatment for partners (its packaging does not meet regulatory standards for self-delivered therapy).
  - ▶ to treat PID
  - ▶ to treat MPC without a positive chlamydia test

➤ **PID Treatment options**

PID comprises a spectrum of inflammatory disorders of the upper genital tract among women and may include any combination of endometritis, salpingitis, tubo-ovarian abscess, and pelvic peritonitis. No single therapeutic regimen has been established for persons with PID. PID therapy must provide empiric, broad-spectrum coverage of likely pathogens. Antimicrobial coverage should include *N. gonorrhoeae*, *C. trachomatis*, gram-negative facultative bacteria, anaerobes, and streptococci. Treatment options described here are for outpatient treatment only.

Consider physician consultation or referral, hospitalization, or IV antibiotics for patients who:

- are pregnant
- are not responsive to out patient regimens within 72 hours
- have a pelvic mass on examination
- have high fever (>38°C or 101°F)
- have acute nausea and vomiting

➤ **Options for outpatient treatment of PID**

**CAUTION:** Azithromycin in a single oral dose is not indicated for treatment of PID.

The following regimen provides coverage against the common etiologic agents of PID. Patients who do not respond to outpatient therapy within 72 hours should have the PID diagnosis confirmed and be considered for parenteral therapy.

- Treatment of choice
    - ▶ Ceftriaxone 250 mg IM
- PLUS-**  
Doxycycline 100 mg orally 2 times a day for 14 days

**-OR-**

- ▶ Cefoxitin 2 g IM, concurrently with probenecid 1 g orally in a single dose

**-PLUS-**

Doxycycline 100 mg orally 2 times a day for 14 days

NOTE: Many experts recommend adding metronidazole 500 mg orally 2 times a day for 14 days to either of the above regimens for better coverage of anaerobes or when Bacterial vaginosis (BV) is present

**Alternative Regimen in extenuating circumstances only:**

- Ofloxacin 400 mg orally 2 times a day for 14 days

**-OR-**

- Levofloxacin 500mg orally once a day for 14 days

**-PLUS-**

Metronidazole 500 mg orally 2 times a day for 14 days

NOTE: The ofloxacin regimen is considerably more expensive than the ceftriaxone regimen. The project cannot bear the expense of this treatment except for extreme cases. Contact your state project director if this is indicated.

➤ **Instructions to patients given outpatient treatment**

- NSAIDs PRN for pain. Some evidence suggests a reduction in inflammation and scarring with NSAID use.
- No intercourse throughout treatment
- Emergency or urgent care instructions
- Monitor temperature twice a day for two days
- Increased rest
- Push fluids by mouth
- All patients treated for PID must receive re-examination 48-72 hours after treatment is initiated or telephone call follow up.

➤ **Follow up of treated clients**

- Clients must receive complete education (see Chlamydia Counseling/ Education Protocol).

➤ **Contact/partner notification and treatment**

- Clients must be educated about the importance of partner notification and treatment (See Chlamydia Counseling/Education Protocol.)
- Sex partners exposed within 60 days of diagnosis for chlamydial infections should be promptly examined for STD, if possible, and treated with one of the regimens described above.

**Case Reporting of Positive Laboratory Results**

Clinical providers in each state are required by law to report chlamydia cases to public health authorities. Reporting procedures and case reporting forms are available from the states' Sexually Transmitted Disease program. These procedures vary from state to state. It is important to follow your state's procedures. Report laboratory confirmed cases only, i.e. not presumptively treated cases.

## **Partner Notification, Examination, and Treatment**

One of the goals of the Region X Infertility Prevention Project is to promote closer working relationships between the family planning and STD clinics. Partner notification is an area where collaboration should occur. STD services field staff could assist family planning staff in providing contact tracing for clients with a positive *C. trachomatis* test since most family planning clinics do not have any field staff. While resources may be limited in some areas, there should be an effort to reach high priority patients. Family Planning providers are strongly encouraged to seek out assistance as needed.

The purpose of partner notification is to ensure that sexual partners exposed to a client with a diagnosis of chlamydia (by a positive *C. trachomatis* test or a CT-related syndrome, i.e., MPC, PID, NGU, epididymitis) are examined and tested for *C. trachomatis*. They should also be tested for other STDs and offered HIV counseling and testing services if indicated by risk assessment. In addition, sexual partners should be presumptively treated at the time of their initial visit with one of the regimens for uncomplicated chlamydial infection.

The Centers for Disease Control and Prevention has set standards for the management of sex partners of individuals with diagnosed chlamydia. These are summarized in the 2002 Sexually Transmitted Disease Treatment guidelines. The standards include:

### **➤ Refer All Sex Partners Within past 60 Days or Most Recent Sex Partner if Over 60 Days**

- Two methods of partner notification are provider referral and patient self-referral. Only where there is staff available for conducting the referral process can provider referral be accomplished. All CT positive clients should be told to have their partners evaluated and treated. Clinics are strongly encouraged to establish systems whereby follow-up for partner treatment is tracked.
- Not only should sex partners of known CT positive clients be referred, but any woman diagnosed with PID should be told to refer her partner(s) for evaluation and treatment. A woman whose sex partner(s) is not treated, is at continued high risk for persistent or recurrent infection.

### **➤ Evaluate and Treat All Sex Partners**

- No person with chlamydia can be considered adequately treated until their sex partner(s) is also treated. Prevention of re-infection is critical to reducing the serious long term consequences of chlamydia, e.g., chronic pelvic pain, PID, infertility, and ectopic pregnancy.
- Clinics participating in the Region X project must provide for partner evaluation and treatment of CT positive clients. If such evaluation and

treatment is not provided on site, the clinic must provide the client and any partners a referral and information to locations where evaluation and treatment will be provided.

- Examination and testing of a male partner of a CT positive female is strongly encouraged. Treatment of male partners without examination is preferable to no treatment. Dispensing of medication to partners without an interview for symptoms, medication allergies, and other contacts is not allowed in the project.

➤ **Instruct Clients to Abstain from Sex Until They and Their Partners are Cured**

- All parties should be instructed to abstain from sex until all concerned have completed the full course of medication and any symptoms have subsided. Patients and their partners should also be counseled to complete the full course of medication, regardless of whether they have symptoms. Inadequate treatment may result in continuation of the infection. When treating with azithromycin advise to abstain or at least use condoms for 7 days after partners have been treated because the medication is actually working to kill bacteria for 5 to 7 days after the single dose.
- If a client cannot negotiate abstinence, explore the problem and help the client consider alternative behaviors with his/her partner:
  - ▶ Mutual masturbation
  - ▶ Penis in vagina sex with condom
  - ▶ Oral sex with protection

➤ **Contact/Partner Notification and Treatment**

- Clients must be educated about the importance of partner notification and treatment (See Chlamydia Counseling/Education Protocol.)
- Sex partners exposed within 60 days of diagnosis for chlamydial infections should be promptly examined for STD and treated with one of the regimens described above.

➤ **Reporting**

- Fill out and submit a Sexually Transmitted Disease Confidential Case Report and other forms as required by your state program.

## Rescreening women with positive chlamydia tests

**Note:** The following policy and procedures on rescreening are relevant to only certain project areas within the Region X IPP. The decision to implement a rescreening policy is resource-based. Clinicians are urged to adhere to their state or project area policy to conserve project resources. A rescreening program should not divert resources from an aggressive partner management effort. If there is any question regarding a state's policy on rescreening, clinicians should call their state IPP representative or the Regional Project Coordinator.

Centers for Disease Control and Prevention (CDC) guidelines released May, 2002 discuss rescreening women treated for Chlamydial infection as a means to identify women with recurrent infection, thus preventing further adverse sequelae and interrupting disease transmission. Data show individuals with confirmed infection in the recent past are at especially high risk of reinfection. Region X IPP screening criteria already include screening individuals with infection in the past 12 months.

### **CDC statement on rescreening**

“A high prevalence of *C. trachomatis* infection is found in women who have had chlamydial infection in the preceding several months. Most post-treatment infections result from reinfection, often occurring because patient's sex partners were not treated or because the patient resumed sex among a network of persons with a high prevalence of infection. Repeat infection confers an elevated risk of PID and other complications when compared with initial infection. Therefore, recently infected women are a high priority for repeat testing for *C. trachomatis*. For these reasons, clinicians and health care agencies should consider advising all women with chlamydial infection to be rescreened 3-4 months after treatment.”

The rescreening effort is only directed at females. The effort is not yet shown to be cost-effective for males.

Rescreening women (as opposed to test-of-cure) is recommended at 3-4 months after original treatment of confirmed chlamydial infection, regardless of age, partner Rx, resumption of sex, or other risk factors.

### ➤ **Approaches to recalling patients**

- At treatment visit, advise to return 3-4 months later for rescreening.
- Make a specific return appointment if clinic “books” that far ahead.
- Add rescreening message to client education materials and handouts.
- Send reminder letter if client has not returned by end of 4 months (if contact by mail will not violate client confidentiality).

- Phone call reminder if client has not returned by end of 4 months (if confidentiality is not breached).
- Flag chart and/or problem list and opportunistically test whenever the patient returns to clinic for any reason (refill contraceptive Rx, immunization, etc).