

E. Exhibit 1

Oregon DHS Public Health Family Planning Program – Sample Protocol

SUBJECT: Infections and STDs NUMBER: 402

TITLE: Chlamydia Testing and Treatment DATE: July, 2007

DATE REVIEWED/REVISED: _____

DEFINITION: Chlamydia is caused by infection with Chlamydia Trachomatis, and is the leading cause of preventable infertility and ectopic pregnancy. Infection may be suspected due to symptoms or because of known or suspected contact with an infectious partner. Asymptomatic infection is common in both men and women.

SUBJECTIVE

A. Men may complain of:

1. Dysuria or polyuria
2. Purulent urethral discharge
3. Epididymitis
4. Conjunctivitis
5. Arthritis

B. Women may complain of:

1. Abnormal vaginal discharge
2. Abnormal menses
3. Dysuria
4. Symptoms suggestive of PID, including fever, abdominal pain, painful intercourse, and nausea/vomiting.

C. Client may have no symptoms.

D. Either sex may complain of rectal symptoms: pain, ineffectual straining with BM, and discharge.

E. Client may present as a contact of a diagnosed or symptomatic partner

F. Female and male client may meet Region X Infertility Prevention Project Family Planning Clinic Screening Criteria:

1. Women age 24 and under should be tested at least annually whether or not they are undergoing a pelvic examination
2. All women age 25 and older who meet one of the following criteria should be tested:
 - a) Cervical findings consistent with cervicitis (friable cervix, mucopurulent discharge or ectopy with inflammation or edema)
 - b) Pelvic Inflammatory Disease (PID)
 - c) Exposed to Chlamydia (in last 60 days)
 - d) Symptomatic sex partner (in last 60 days)
 - e) Pregnant
 - f) IUD insertion
 - g) Prior Chlamydia infection within the past 12 months

3. Male partners of female clients who had a positive Chlamydia test in Family Planning Clinic can be tested under the Family Planning Lab Site number.
- G. Males and females may request STD testing in STD clinic services and be tested universally using the STD Clinic Lab Site number.

OBJECTIVE

A. Male client:

1. May include:
 - a) Epididymitis
 - b) Urethritis
 - c) Conjunctivitis
 - d) Arthritis
2. Collect Urine specimen using the following procedure:
 - a) Use only urine collection containers obtained from the Oregon State PH Lab
 - b) Client should not have urinated within 2 hours of specimen collection.
 - c) Client should collect 10 ml of first catch urine (about 1/3 tube)
 - d) Assure the urine container top is tight and label appropriately
 - e) Indicate "Urine" in the "Specimen Site" field of the lab slip

B. Female client:

1. Perform pelvic exam with attention to findings suggestive of PID: abdominal tenderness, cervical motion tenderness, adnexal/uterine enlargement or tenderness (refer to PID protocol).
2. Note presence or absence of cervical findings consistent with cervicitis.
3. Collect cervical specimen using the following procedure:
 - a) Collect other specimens first.
 - b) Clean excess discharge from endocervix.
 - c) Always use sterile device recommended by manufacturer.
 - d) For pregnant women, use a swab, **not a brush** for specimen collection.
 - e) Insert appropriate collection device into endocervix until most of tip is not visible.
 - f) Rotate device with firm pressure for at least 15 seconds (rotation time varies depending on type of specimen collection or test kit used).
 - g) Carefully remove collection device from vagina to avoid contamination.
 - h) Place device in transport tube or bottle provided.
 - i) Break off shaft of collection device (raise device well off the bottom of tube or bottle before snapping shaft).
 - j) Cap tube or bottle tightly.
 - k) Complete lab slip correctly.

ASSESSMENT

- A. Client is asymptomatic, tested due to meeting Region X IPP Screening Criteria.
- B. Client is a contact of a diagnosed case, needs treatment for Chlamydia
- C. Client with symptoms/exam suggestive of Chlamydia but test results are pending.
- D. Client has a positive (+) Chlamydia test result and needs treatment.

PLAN

- A. Client is asymptomatic, tested as meets screening criteria, awaiting results:
 1. Discuss how to contact the client in event of positive results.
 2. Review STD risk assessment, discuss ways to reduce risk.
 3. Offer and encourage condom use.
- B. Client is a contact of a diagnosed case:
 1. If possible confirm index case.
 2. Client should be evaluated, tested if possible, and treated if they had sexual contact with the index case during the preceding 60 days.
 3. If greater than 60 days from exposure, offer testing and await test results before TX.
 4. If treatment is indicated, follow "Treatment Plan" below.
- C. Client has symptoms or clinical findings suggestive of Chlamydia:
 1. Assure client contact information is accurate.
 2. Review STD risk assessment, discuss ways to reduce risk.
 3. Offer presumptive treatment, follow Treatment Plan below.
- D. Client has a positive (+) Chlamydia test result and needs treatment:
 1. Provide education about Chlamydia/method of spread, etc.
 2. Work with client to identify sexual partners in the last 60 days, if no partner in the last 60 days, client's most recent sexual partner.
 3. Discuss partner notification; offer to inform partners if client is unwilling or unable to notify partners.
 4. Provide treatment (see Treatment Plan below).
 5. Discuss and encourage rescreening for all female clients with a + Chlamydia test result at 3-4 months following original treatment.
 6. Advise clients that if symptoms persist or reinfection is suspected to RTC for retesting.
 7. Report positive Chlamydia test result to local health department/state STD Program.
- E. Treatment Plan:
 1. Assess for allergies and R/O pregnancy, if indicated.
 2. Treat with one of the following: Azithromycin 1 gram orally as a single dose OR Doxycycline 100 mg po BID x 7 days.
 - a) Azithromycin is preferred when compliance may be a problem, in pregnant or nursing women, and in persons allergic to Doxycycline.
 - 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
 - Stress the importance of partner treatment.
 - b) Doxycycline may be preferred in presumptive treatment.
 - Emphasize the importance of taking entire supply on twice-daily basis
 - Take with plenty of water
 - Can be taken with food
 - Emphasize sexual abstinence during treatment week
 - Avoid sunlight during treatment week or use sunscreen SFP 30 or greater
 - Stress the importance of partner treatment
 3. Alternative regimes for clients unable to take the above:

- a) Erythromycin base 500 mg po QID x 7 days.
 - b) Or follow another regimen in CDC 2006 Treatment Guidelines
4. Recommend condom use and dispense condoms

CLIENT EDUCATION

- A. Emphasize the importance of completing medical therapy, even if symptoms are gone.
- B. Avoid unprotected sex until client and partner(s) have been treated: after completion of 7 days regimen or 7 days after a single dose regimen. Return for evaluation if client has UPIC or if medication is not taken as directed.
- C. Advise female clients that they are at greater risk for PID/infertility if they become reinfected, stressing the importance of partner treatment and condom use to prevent reinfection. Inform client to RTC for retesting if reinfection is suspected.
- D. If the treated client is pregnant, advise to RTC in 4 weeks for test of cure (TOC).
- E. Return promptly for re-evaluation if symptoms persist/develop.
- F. Discuss risk reduction including small changes in behavior that will decrease risk (see *Know Your Risk for an STD* pamphlet section about risk reduction).
- G. Provide prescriptive drug information sheets to clients who received treatment medications.
- H. Offer and encourage condom use.

MEDICAL CONSULTATION

- A. Significantly ill clients with PID
- B. Clients with allergies that preclude treatment with the above recommended regimens.