

**-- FOR DISCUSSION ONLY --**  
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**Issue Paper: Chlamydia Testing & Treatment**

**Problem Description**

Chlamydia (*chlamydia trachomatis*) testing and treatment is a changing area of significant public health interest, with extensive effects on STD diagnosis and treatment rates in Milwaukee.

**[What's the "problem?" needs more flesh on it]**

**Issue Paper Summary**

As the most reported STD in the US, effective methods of testing and treatment of chlamydia are significant public health questions. Chlamydia can have severe health effects when untreated, including PID and infertility in women and pain and inflammation in men, despite a low rate of initial symptoms. New developments in testing techniques have both increased the sensitivity and specificity of tests as well as made point-of-care testing possible. Additionally, several city and state health departments have instituted various policies of empiric treatment criteria as well as partner treatment. These policies are still under study and discussion, but they may lead to cost-effective and comprehensive treatment of chlamydia in the communities they serve.

**Background**

*Data on scope of problem*

In the US, there are one million reported cases of chlamydia per year, and estimated 2.8 million Americans are infected with chlamydia each year.<sup>2</sup> Untreated chlamydia infection, and especially reinfection with chlamydia, is a major cause of pelvic inflammatory disease (PID) in women, which can cause infertility. PID can also cause scar tissue growth in the fallopian tube, ectopic pregnancy (a life-threatening medical emergency), and chronic pelvic pain. In men, inflammation from the infection can cause pain and inflammation in the testes (epididymitis) and blockages leading to sterility. In addition, an untreated chlamydia infection can increase one's chances of acquiring HIV infection.<sup>6</sup> Because the cervix of teenage girls and young women is not fully matured, they are at particularly high risk for infection if sexually active. In addition, pregnant women infected with chlamydia can pass the infection to their infants during delivery, potentially resulting in neonatal ophthalmia and pneumonia.<sup>7</sup>

Anyone who is sexually active can get chlamydia, but those at greater risk include:

- Sexually active adolescents
- Persons diagnosed with any STD
- Persons with a sex partner diagnosed with any STD
- Persons with more than one sex partner
- Persons with a new sex partner

Milwaukee, in particular, has a significant public health problem with chlamydia, among other STD's. Among the 63 largest American cities in 2004, Milwaukee was among the worst ranked for chlamydia and gonorrhea incidence (9th and 17th from the highest, respectively). In 2004, the infection rate of chlamydia in 15-19-year-olds in Milwaukee was 7,600 per 100,000 (3,660

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cases). Since many cases of chlamydia go undiagnosed, these rates are most likely underestimates.<sup>1</sup>

*Research on what works*  
Lab Methods of Testing<sup>11</sup>

The accuracy of chlamydia testing methodologies, as for all lab tests, are described using the concepts of “sensitivity” and “specificity.” While the details of these concepts are both important and beyond the scope of this paper, one can think of sensitivity as the likelihood that the test will find a chlamydia infection if it’s there, and specificity as the likelihood that a test will not find a chlamydia infection if it’s not there. In other words, lower sensitivity means the test will miss more cases of chlamydia, and lower specificity means that positive results will more often be falsely-positive. Generally speaking, an ideal screening test has high sensitivity (so as not to miss cases), an ideal diagnostic test has high specificity (so as not to be wrong when positive).

Historically, cell culture was the gold standard in chlamydia testing. While it does have almost 100% specificity, testing by culture involves a long turnaround time (2-7 days) and has a low sensitivity compared to newer techniques (50-80%). Culture is still used today, but is only recommended in special cases. The majority of testing methods are non-culture, non-amplified methods, including enzyme immunoassays (EIA), optical immunoassay (OIA), non-amplified nucleic acid probes, and direct fluorescent antibodies (DFA). These tests have very high specificity (95-99%) but are not very sensitive (50-80%) and cannot be done on urine samples, making them less practical than other methods. They can be done quickly, though, with time to results varying from 15 minutes to several hours.

The newest tests are the nucleic acid amplification tests, which use polymerase chain reaction (PCR) and similar techniques to detect very small amounts of chlamydia nucleic acid. These tests are much more sensitive than other methods (90-96%) and have very high specificity (98-99.9%). They can take several hours or overnight and can be used on both urethral swabs and urine, as well as in combination with gonorrhea testing. However, these techniques are relatively expensive and require specific equipment. Some patients who are treated with antibiotics and retested immediately may get a false positive from a nucleic acid amplification test, because it detects chlamydial DNA from dead organisms that have not yet been removed from the body.

Standard of Care for Treatment

The results of clinical trials indicate that azithromycin and doxycycline are equally efficacious<sup>3,4</sup> in treating chlamydia. These investigations were conducted primarily in populations in which follow-up was encouraged and adherence to a 7-day regimen was good.

In populations that have erratic health-care-seeking behavior, poor compliance with treatment, or unpredictable follow-up, azithromycin may be more cost-effective because it enables the provision of single-dose DOT. Therefore, azithromycin should always be available to health-care providers to treat patients for whom compliance is in question. Doxycycline costs less than azithromycin, and it has been used extensively for a longer period, but it requires twice daily dosing for a week. Erythromycin is less efficacious than either azithromycin or doxycycline, and gastrointestinal side effects frequently discourage patients from completing this regimen. Ofloxacin is similar in efficacy to doxycycline and azithromycin, but it is more expensive to use and offers no advantage with regard to the dosage regimen. Levofloxacin has not been evaluated for treatment of *C. trachomatis* infection in clinical trials, but because its pharmacology and *in vitro* microbiologic activity are similar to that of ofloxacin, levofloxacin may

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be effective as well. Other quinolones either are not reliably effective against chlamydial infection or have not been adequately evaluated.

To maximize compliance with recommended therapies, medications for chlamydial infections should be dispensed on site, and the first dose should be directly observed. 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 the risk for reinfection, patients also should be instructed to abstain from sexual intercourse until all of their sex partners are treated.

Because chlamydial infection is frequently asymptomatic, particularly in women, and because it is particularly common in women under age 25, sexually active adolescent women should be screened for chlamydial infection at least annually, even if symptoms are not present. Annual screening of all sexually active women aged 20-25 years is also recommended, as is screening of older women with risk factors (e.g., those who have a new sex partner and those with multiple sex partners). Additionally, it is now recommended that all women with chlamydial infections be rescreened three to four months after treatment is completed, because these women tend to have a high prevalence of chlamydia, presumably as the result of reinfection.<sup>5</sup> Some authorities also recommend screening of men with risk factors [**REF: Milw STD Screening Recs, available at [www.milwaukee-medical-society.org](http://www.milwaukee-medical-society.org) then click thru a few links**], and most recommend screening both men and women of any age whose partners have an STD.]

*What other cities are doing that is effective*

National/federal efforts:

Chlamydia screening and reporting are likely to expand further in response to the recently implemented [Health Plan Employer Data and Information Set](#) (HEDIS) measure for chlamydia screening of sexually active women 15 through 25 years of age who receive medical care through managed care organizations.<sup>8</sup>

Decisions on screening for chlamydia become complicated by issues of costs of screening tests and treatment, prevalence of infection in the population and testing and treatment protocols. The intent of SOCRATES (Screening Optimally for Chlamydia: Resource Allocation, Testing and Evaluation Software) is to provide a tool that allows users to determine the most cost effective screening strategy to prevent pelvic inflammatory disease in women who display no symptoms of chlamydial infection.<sup>9</sup>

Local efforts:

Denver - Sites offering HIV testing and counseling are a feasible alternative to clinical settings for *C. trachomatis* screening. Prevalence may be too low for screening to be cost effective unless higher-risk subpopulations can be identified.<sup>10</sup>

California- anonymous testing and treatment, including partner delivered therapy (according to Geof- can he provide some references?) [ask Matt for copy of draft CDC white paper on this; it has these refs and others; final version still in review at CDC]

*What's going on in Milwaukee*

The City of Milwaukee Health Department's STD Clinic is the biggest single site of testing for chlamydia, with Planned Parenthood's multiple sites cumulatively performing even more tests. Planned Parenthood, however, sends their tests to the State Lab of Hygiene in Madison. The MHD has a policy of empiric treatment criteria that increases the number of infected person

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receiving same-day treatment. Laboratory tests are still done on almost all patients at the STD clinic. Additionally, the MHD uses field-testing to identify infected partners who decline to come to the clinic for testing. For these partners, therapy can be delivered in the field.<sup>12</sup>

### **Barriers and Gaps**

There are several barriers to effective testing and treatment for Chlamydia. The biggest gap in testing is the selection bias in populations being tested. STD clinics only test the people who come in for testing, and because Chlamydia is largely asymptomatic, this might represent a small percentage of infections. Partner notification is a further barrier to both testing and treatment. Adherence to drug regimen is potential barrier to proper treatment, although with direct observed therapy and single-dose therapy, this can be minimized.

### **Community Strength and Opportunities**

Historically, Chlamydia testing was done using urethral swabs, which are more time-consuming for the clinician as well as more uncomfortable for the patient than collecting a urine sample. While there are some technical aspects of proper collection that require attention from health care providers, the increasing ability to use urine samples instead of swabs can increase the willingness of people to be tested for Chlamydia.

Additionally, decreasing cost of NAAT techniques will make NAAT more available, resulting in more sensitive testing with faster results. Rapid testing allows the clinician to know the patient's Ct status before they leave the clinic, which allows for better treatment for both the patient and possibly, any partners who may also be infected.

### **Recommendations**

Using point-of-care testing and empiric treatment criteria can increase the rate of treatment for infected patients and their partners. Empiric treatment criteria have been shown to be a cost-effective way to treat Chlamydia infections, but carry a risk of over-treating the Ct-negative population. By utilizing testing methods that allow the clinician to review the results while the patient is still in the clinic, more effective treatment plans can be utilized, as well as discussing partner notification and treatment with the patient. Furthermore, field delivery of drugs for partners (possibly with anonymous testing) is an idea that should be researched and tested in the Milwaukee area. (See Matt Maxwell for more information on such programs.)

### **Resources**

1. <http://www.ci.mil.wi.us/DISPLAY/displayFile.asp?docid=16576&filename=/Groups/healthAuthors/DCP/PDFs/finalteenpregnancyfactsheetrev406.pdf>
2. CDC's chlamydia site- <http://www.cdc.gov/std/chlamydia/STDFact-chlamydia.htm>
3. Thorpe EM, Stamm WE, Hook EW, et al. Chlamydial cervicitis and urethritis: single dose treatment compared with doxycycline for seven days in community-based practices. *Genitourin Med* 1996;72:93--7.
4. Stamm WE, Hicks CB, Martin DH, et al. Azithromycin for empirical treatment of the nongonococcal urethritis syndrome in men: a randomized double-blind study. *JAMA* 1995;274:545--9.
5. <http://www.cdc.gov/OD/OC/MEDIA/pressrel/fs020509.htm>

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6. <http://dhfs.wisconsin.gov/communicable/Communicable/factsheets/chlamydia.htm>
7. <http://www.cdc.gov/std/stats/chlamydia.htm>
8. National Committee for Quality Assurance (NCQA). *HEDIS 2000: Technical Specifications*, Washington, DC, 1999, pp. 68-70, 285-286.
9. <http://www.cdc.gov/nchstp/dstd/Software/Socrates.htm>
10. Hamel MJ, Judson FN, Rietmeijer CA. *Sex Transm Dis.* 2001 Mar; 28(3):153-7.
11. Region V Infertility Prevention Project Self Study Manual, Infertility Prevention Training Committee, June 2002.
12. G. Swain, personal communication, June 28, 2006.