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Running Title: The PPE to Screen for Chlamydia trachomatis

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Abstract

Purpose: This study assessed the prevalence of Chlamydia trachomatis in the college athlete and the benefit of using the Sports Preparticipation Examination (PPE) as a screening opportunity.

Methods: Chlamydia teaching and screening was part of the sports pre-participation exam. The 439 athletes (220 males, 219 females) answered a questionnaire and provided urine specimens. Using positive test results as an indication of prevalence, the Chlamydia prevalence rate was calculated by sex and race. Using the questionnaire responses, we determined the students' accessibility to health care and the percentage of sexually active students who were ever offered Chlamydial screening.

Results: 13 of 439 athletes tested positive. One test was a false positive. The test positivity was 2.7%: 3.2% males and 2.2% females. In sexually active athletes the test positivity rose to 3.8%: 4.0% males and 3.7% females. African American athletes had a higher prevalence of 9.1%: 8.9% in males and 9.5% in females, making them 6 times more likely to have Chlamydia than Caucasian athletes. (OR 6.43, 95% CI, 1.58, 30.55) The number of partners, contraceptive type, symptoms and prior history of Chlamydia were not statistically different between groups. Over 75% of students saw their private physicians, yet of the sexually active students only 31% of females and 6.8% of males were ever offered Chlamydial screening.

Conclusion: The CDC and USPSTF guidelines recommending annual Chlamydial screening for all sexually active women younger than 26 years of age are not being met in the community. Taking advantage of opportunities , including the mandated sports pre-participation exam, where sexually active men and women 25 years of age and younger interface with the health care system to screen for Chlamydia trachomatis is crucial to decreasing the continued rise of Chlamydial infection.

Keywords: sexually transmitted disease, prevalence, tested, African American

INTRODUCTION

Paragraph 1: Chlamydia trachomatis has been described as the "silent epidemic" whose incidence in the US has continued to climb despite the efforts of the CDC's decade long campaign to increase screening and curb disease. In 2007, 1.1 million diagnoses of Chlamydia were reported to the CDC, a 7.5% increase from the previous year. Since more than half of all cases go undiagnosed, it is estimated that there were approximately 2.8 million new cases in 2007. (35) It is the most commonly reported communicable infection in the United States. 90% of infected women and 60% of infected men are asymptomatic and 74% of all reported cases occur among 15 to 25 year olds. (9,28)

Paragraph 2: Untreated Chlamydia trachomatis is the major cause of pelvic inflammatory disease (PID), ectopic pregnancy, infertility among women and perinatal transmission of C. trachomatis to infants causing neonatal conjunctivitis, blindness and pneumonia. In addition, chlamydial infections enhance transmission of human immunodeficiency virus (HIV) infection. (4) Of women who test positive on C trachomatis screening, 96% will be cured with a single dose of Azithromycin 1 gm po. (21) 30% of women with untreated C. trachomatis infection will remain persistently infected (16), 40% will spontaneously cure (31) and 30% will develop acute PID within 6 months of the initial infection. (8) Women younger than 20 yrs of age have a reinfection risk of 12%. That is, women who have had C. trachomatis in the past, have a relative risk for reinfection approximately twice that of women with first-time acute infection. (17)

Paragraph 3: Because Chlamydia is more likely to be asymptomatic in women than in men, and because the burden of disease is greater in women than men, public health efforts have focused on screening women. The Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF) recommend at a minimum, annual screening for all sexually active women younger than 26 years of age. (7,26) The 2007 USPSTF guidelines conclude "that the current

evidence is insufficient to assess the balance of benefits and harms of screening for chlamydial infection for men." (7) The CDC outlined some considerations for screening men in high risk settings such as STD clinics, jails, and in prevalence regions greater than 2%-4%. But in the final consensus statement, due to lack of empiric evidence for a positive impact of screening for Chlamydia in men, screening men is considered a secondary focus to prevent infection and sequelae in women. (26)

Paragraph 4: Testing for Chlamydia trachomatis infection has become less invasive with the introduction of nucleic acid amplification tests (NAATs). This urine collection method eliminates the need for painful urethral swabs in men and uncomfortable pelvic examinations in women. This is a particularly pertinent point when discussing testing asymptomatic adolescents and young adults.

Paragraph 5: Culture testing has been the reference standard for all other C. trachomatis testing. However, culturing C. trachomatis poses problems with maintaining viability during transport, standardization methods, technical issues and expense. Therefore, nonculture screening tests were developed and have been the standard of use, offering more convenient and more reliable methods than culture. The first generation of nonculture tests include enzyme immunoassays (EIAs) which detect specific chlamydial antigens(sensitivity 81%), direct fluorescent antibody (DFA) which use fluorescein-conjugated monoclonal antibodies. The next generation test were the nucleic acid hybridization tests which detect C . trachomatis-specific DNA and RNA sequences (sensitivity 90%). The problem with these tests is that they failed to detect a substantial proportion of infections. (6,27) The newest generation of tests, nucleic acid amplification tests, NAATs, are substantially more sensitive. (6) NAATs amplify nucleic acid sequences that are specific for the organism being detected. Their increased sensitivity is due to their ability to produce a positive signal from as little as a single copy of the target DNA or RNA. The ligase chain reaction (LCR) when performed on first voided urine specimens has a sensitivity that reaches 96.9% and a specificity of 94.1% -99.9%.

(1,22,2). Although NAATs are used in endocervical and urethral swabs, their use in urine had been a major advantage as testing can be done without a pelvic exam in women or an intraurethral swab in men.

Paragraph 6: In light of the young age range of Chlamydia prevalence and the ease of testing urine, new approaches to screening adolescents have been attempted. Cohen and Nsuami et al have offered repeated sexually transmitted disease (STD) screening to high school students in 3 Louisiana public schools. (9) Nsuami et al also explored the use of the high school sports physical examination as an avenue of screening. (29) They found that the prevalence of Chlamydia was 2.8% among males and 6.5% among female high school athletes. They also noted that 78% of the athletes used the sports physical examination as their annual health assessment. Other studies have shown that 50% of adolescents use the PPE as their only interaction with the medical system. (15,20)

Paragraph 7: In this study we used a mandatory university sports preparticipation exam (PPE) to examine the prevalence of Chlamydia trachomatis in college athletes taking into account sexual practices, demographics and symptoms and to treat those athletes with positive Chlamydia urine screening tests. We also determined the student athletes' access to health care and Chlamydia trachomatis screening. Metzl addressed the usefulness of the PPE in his article, "The adolescent preparticipation physical examination. Is It Helpful?"(35) In it, he quotes a study that found only 1.9% of examined high school athletes were disqualified from competition: a low incidence of disqualification and possibly an unfavorable cost-benefit analysis. (36) But Metzl argues that although there is a low disqualification rate, that same study found 11.9% of the athletes screened required further follow-up. Metzl makes the point that the PPE is not only meant to identify medical and orthopedic conditions that would make sports participation unsafe, it is also meant to screen for underlying illness and facilitate preventive measures.

METHODS

Setting

Paragraph 8: In Fresno County, CA, 1,500 cases of Chlamydia trachomatis were reported in 1997. In 2001, the time of this study, 3,500 cases were reported and in 2007 that number increased to 5,300. (13,5) In 1999 the California Department of Health Services STD Control Branch launched a campaign, "Get Tested," for Chlamydia screening in adolescents and young adults in diverse settings. The Fresno County Health Department agreed to collaborate with the study coordinators for education and laboratory testing using the urine LCR method. The Fresno Madera Medical Society, through its Community Health and Relations Committee, offered physician assistance. The California Endowment provided a grant for the study and test completion. The University athletic department allowed use of the sports physical examination as an opportunity to educate and screen student athletes for Chlamydia trachomatis.

Study Sample

Paragraph 9: Because student athletes are required to attend annual preparticipation sports physical exams, we used a University setting in Fresno, CA to capture student athletes, age 18-23 to educate and screen for Chlamydia trachomatis as part of this exam. A total of 439 student athletes participated, 220 males, 219 females.

Design

Paragraph 10: Approval from the University IRB as well as Saint Agnes Medical Center, Fresno, CA IRB was obtained. Education and screening for Chlamydia trachomatis was provided to all athletes. A questionnaire regarding demographic, behavioral and symptom data was completed by each athlete. Those students with positive tests for Chlamydia were treated with single dose

Azithromycin and encouraged to bring their partners in for screening and treatment. No positively screened students had a history of macrolide allergy.

Procedure

Paragraph 11: Students congregated on the assigned days as defined by their sports team. All team sports exams were completed within a 1 month period. Prior to the sports exam, the students were given information regarding the Chlamydia screening and a consent form. The students received a brief didactic Chlamydia education session orchestrated by the primary investigator and the County Health Department followed by a question/answer period. The students then dispersed to their assigned rotation of exam stations. An additional station was added to the usual sports exam rotation where the student completed a numbered confidential questionnaire. The student was then given a matching numbered specimen container for a first void urine. A physician was available at the station for any questions. The urine specimens were sent to the County Public Health laboratory for Chlamydia testing.

Data Collection

Paragraph 12: Demographic and behavioral data were collected via a questionnaire. Questions included: ethnicity, age, sexual activity, STD contact, STD-related symptoms, abdominal pain, contraceptive use and prior STD history. Students reported their prior access to the health care system by frequency and location type as well as their use of the sports physical exam as their general medical care. Students also reported if they had ever been offered or ever received a Chlamydia screening test.

Laboratory Methods:

Paragraph 13: A station was established at the PPE where the students were instructed on supplying 15-20ml of a first-catch voided urine specimen. The urine was collected at the PPE site

then transported the same day on ice to the Fresno County Lab. Urine specimens were tested via the Abbott LCX Probe System.

Data Analysis

Paragraph 14: Descriptive statistics and Chlamydia prevalence based on positive LCX results from the participating student athletes and by demographics and behavioral variables were conducted for all student athletes. Odds ratios (OR) and 95%confidence intervals (95% CI) to test for differences in demographic and sexual behavior variables were calculated. Descriptive statistics involving student access and use of the health care system were measured against the availability of Chlamydia screening to the students.

RESULTS

Paragraph 15: Of the 439 student athletes tested, 13 urine LCR tests were positive for Chlamydia trachomatis. One positive test in a student who questioned the result due to the fact that she had not been sexually active was repeated and was negative. Chlamydia trachomatis test positivity in the student athlete population was 2.7% overall, 3.2% in males and 2.2% in females. See table 1. When only the sexually active athletes were assessed, test positivity rose to 3.8% overall, 4.0% in males and 3.7% in females. See table 2.

African American student athletes had a higher prevalence of 9.1% overall, 8.9% in males and 9.5% in females. African Americans were 6 times more likely to have Chlamydia trachomatis than Caucasians. (OR 6.43, 95% CI, 1.58, 30.55) See table 3. In the Latino and Asian student athlete population there were no positive test results. See table 4.

The number of partners in the past 12 months, contraceptive type, symptoms and prior history of Chlamydia infection did not show a statistical significance between those with disease and those without.

Paragraph 16: 76.8% of all student athletes (65.5%males, 88%female) and 75% of positively tested athletes (71%males, 80% females) accessed health care within the past 12 months.

Of the sexually active students, only 17% were ever offered Chlamydia testing: 6.8% males, 31% females. Of the 12 athletes who tested positive for Chlamydia, only 1 female was ever tested. A total of 4 athletes, three males and one female had been offered the test. See table 5.

When asked where usual medical care was received, many students gave more than one answer. The vast majority of students see their private physicians, 75% of all athletes (62% males, 89% females). Of the athletes who tested positive, 83% see their private physician, 71% males and 100% females.

Discussion/Conclusion:

Paragraph 17: Chlamydia infection in young adults is prevalent and increasing. The CDC and USPSTF guidelines recommending annual Chlamydia screening for all sexually active women younger than 26 years of age are not being met in the community. Responses to the questionnaire demonstrate that all our students had multiple prior interactions with health care, yet only 31% of sexually active women and 7% of sexually active men were ever offered chlamydial screening. Our findings of inadequate screening are supported by the preventive health service study of seven Health Maintenance Organizations (HMOs) in Massachusetts. Of the 15-19 year old females only 18% received a Pap smear and only 11% received an STD test during the course of a year. 53% of those women were sexually active. Health care providers who evaluate this age population for any health related visit should take every opportunity to offer these patients Chlamydial screening. With the prevalence rate 8 times higher in African Americans than Caucasians nationally (26) and six times higher in our study, it is especially important to take advantage of opportunities to screen this population. The benefits of screening for Chlamydia have resulted in a significant decline in disease

sequelae. Scholes et al presented data to suggest that Chlamydia screening and treatment can reduce the incidence of PID by over 50%. (34)

Paragraph 18: Although it is difficult to prove that Chlamydial infection in men bares a direct relationship to morbidity in women, we know that male infection is directly related to chlamydial transmission to sex partners. Studies have shown that many young women diagnosed with Chlamydia become re-infected by male partners who were not treated. (39,33) The CDC's 2006 STD Treatment Guidelines recommend that when an index case of Chlamydia is discovered, the partners also be treated, even if it is necessary for the physician to give the antibiotic to their patient to give to their partner, i.e. expedited partner therapy. (6) We found that in our population the incidence of Chlamydial infection in men was equal to that of women, which suggests that treatment of both sexes is needed to decrease disease prevalence.

Paragraph 19: In 2002, the CDC recommended that NAATs be used to screen for chlamydial infection in men and women. (18) In 2005, after performing a systematic review, Cook et al concluded that urine-based NAATs screening had comparable sensitivity and specificity to cervical and urethral specimens. (11) Although the NAATs is the most effective screening approach, it is relatively expensive and Ginocchio et al concluded that at a prevalence of chlamydial infection of 5% among asymptomatic men, prescreening urine with the leukocyte esterase test (LET), followed by confirmatory testing with the urine based LCR was the most cost-effective strategy. However, after review of all the data the CDC's 2006 conclusions do not recommend LET screening, but recommend urine based NAATs as the screening test of choice for men and women.

Paragraph 20: Dicker et al found that in STD and family planning clinics in 16 states where Chlamydia prevalence ranged from 3.4-5.5%, the percentage of positive repeat tests was the same as or higher than the prevalence of Chlamydia trachomatis disease, concluding that test positivity can be

used as an indicator of Chlamydia prevalence in screened women at family planning and STD clinics. (14) The authors did not delineate the testing methods used.

Paragraph 21: At the time of this testing, California averaged 293.4 cases of Chlamydia per 100,000 people. In Fresno County, where this study took place, the rate was 512.9 cases per 1000,000. (12) Using test positivity as a marker for disease prevalence, we found that the Chlamydia prevalence rate of 4% in sexually active student athletes mirrored the incidence in the overall community in this age population, supporting the idea that testing student athletes during the preparticipation sports physical is a useful tool.

Paragraph 22: Looking at the Chlamydia results in relation to the cardiac exam in preparticipation sports physicals, it is estimated that 200,000 adolescents (even higher in college athletes who have been screened multiple times in high school) would need to be screened to detect 1,000 athletes at risk for a significant cardiac event, and one athlete who would actually die. (24) Our study estimates that 27,000 sexually active women athletes would need to be screened to detect 1,000 athletes with Chlamydial trachomatis infection. At a 30% probability of developing PID, (33) that would be 300 women who would eventually contract PID. 25,000 sexually active men athletes would need to be screened to detect 1000 cases of Chlamydia. Our study revealed an average of 3.5 partners per positively tested male. At a 60% transmission rate, (30) that would be 2,100 additional women with Chlamydia and 630 additional cases of PID that could be prevented.

Paragraph 23: Chlamydial screening with a simple, noninvasive urine test has the potential to reduce years of significant morbidity such as PID, infertility, ectopic pregnancies and chronic pelvic pain in at least 4% of the captured female population screened by the preparticipation sports physical. In addition, it has the potential to prevent transmission of Chlamydia from 4% of the male athletes to women beyond the sports physical. Chlamydial screening has one of the highest benefit to effort ratio

of any of the medical problems screened for during the sports exam. With the US national incidence of Chlamydia climbing nearly 7% each year, and approximately 2.8 million new cases each year and 74% of all reported cases occurring in the 15-25 year old age group, how can we ignore screening for Chlamydia in the PPE?(22,7,18)

Paragraph 24: Regarding cost-effectiveness, we refer to Hu et al.'s computer-based mathematical model. (17) Their model simulates screening, diagnosis and treatment of chlamydial trachomatis infection in a representative cohort of sexually active US women. They selected model variables and their plausible ranges to estimate direct medical costs and time costs of testing for and treating C. trachomatis.

They estimated Screening Costs to include: Urine NAATs $13 (range $4-$40) and

1 g azithromycin $10. We did not include a clinic visit since the screening is part of the Preparticipation Physical Exam (PPE) and the follow-up is with salaried trainers.

Table 6 itemizes the expense incurred by symptomatic Chlamydia trachomatis infection. This does not include the additional costs associated with transmitting C. trachomatis to neonates.

Paragraph 25: With this information, we calculate from our study that testing 310 sexually active student athletes at $13 a test plus retesting 13 positives and treating 12 individuals and their current partners with $10 of Azithromycin costs: $4,439.

Contrast this with the future cost of untreated Chlamydia trachomatis infection.

We found 5 Chlamydia trachomatis positive women athletes. According to the probabilities that 30% of untreated women develop PID (33), at least one of these women will suffer from PID. The 7 men had a total of 25 partners in the past year. With a 60% transmission rate from men to their partners (30), 15 more women were infected with C. trachomatis, resulting in 4.5 more cases of PID. A conservative estimate would be if we

could prevent just 2 cases of inpatient PID 2($4715 + $1084), 3 cases of outpatient PID 3($490 + $513), 1 case of chronic pelvic pain ($1146 + 684), 1 case of ectopic pregnancy ($4355 + $1445), and 1 case of tubal infertility ($5000 + $321) we would save: $27,558, nearly 7 times the cost of the initial screening.

Paragraph 26: Of our 13 positively tested students, one woman contested her result. On repeat testing, with a second urine specimen, her LCR was negative. Zenilman et al address LCR testing in screenings of low prevalence populations. (40) Because test specificity is not 100%, they believe that confirmatory algorithms are necessary to deal with the decreased positive predictive value (PPV). They calculate that with a prevalence rate of 3.0%, and the specificity of a single LCR test of 99.0-99.6%, the expected PPV for a single LCR Chlamydia test would be 73%-87%. They recommend confirmation testing of positive results with a different, highly specific and sensitive test. For example, if testing with LCR, one could confirm with a PCR (polymerase chain reaction) repeat assay. Kohl et al. also raise the issue of the possible need for confirmation testing when using NAATs if the prevalence of disease is less than 2%. They calculate that if the NAAT sensitivity is 85%, specificity 99% and disease prevalence 2%, the PPV would be 63%.(19)

Paragraph 27: Rather than blanket screening, as we did, more directed screening of the sexually active individuals, followed by confirmatory testing would improve the positive predictive value (PPV) of the test. We did not find that further directed screening based on sexual habits or symptoms would add any further benefit.

Paragraph 28: We recommend taking every opportunity, where the population of sexually active males and females below the age of 26 encounters the health care system, including sport screening exams, to offer Chlamydial screening. Since there have been no trials examining the effects of more than one screening round and no trials examining the harms of Chlamydia screening (23) we

foresee the use of the college preparticipation sports screening as a mechanism to educate this population, to detect and treat significant, prevalent disease, and lastly to provide the opportunity to rescreen individuals over four years allowing for the evaluation of education, treatment, benefits and harm.

Paragraph 29: We believe that screening athletes for C. trachomatis during the PPE is in alignment with the goals of the American Academy of Family Physicians, American Academy of Pediatrics, American college of Sports Medicine, American Medical Society for Sports Medicine, American Orthopaedic Society for Sports Medicine, American Osteopathic Academy of Sports Medicine. In their consensus PPE monograph, they state the "The overall goal in performing a preparticipation examination (PPE) is to promote the health and safety of the athlete in training and competition. The PPE is a tool to screen athletes for injuries, illness, or factors that might put them or others at risk." They state that two of the primary objectives of the PPE are to screen for conditions that may be life-threatening or disabling and to screen for conditions that may predispose to injury or illness. They also state that for a screening tool to be effective, it must identify diseases that will affect the athlete, be sensitive and accurate and be practical. We believe that Chlamydia trachomatis screening meets all these requirements.

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Table 1: Positive Chlamydia trachomatis test results in all screened student athletes

	STUDENTS ATHLETES SCREENED		
	positive test	total	prevalence rate
male	7	220	3.20%
female	5	219	2.20%
total	12	439	2.70%

Table 2: Positive Chlamydia trachomatis test result in sexually active student athletes

		SEXUALLY ACTIVE ATHLETES		
	positive	total	prevalence rate	
male	7	175	4%	
female	5	135	3.70%	
total	12	310	3.80%	

Table 3: Positive Test Results by Race

			POSITIVE TEST RESULTS BY RACE					
	Caucasian			African American			American Indian	
	Positive	total	prevalence	positive	total	prevalence	positive	total
male	1	112	0.90%	5	56	8.90%	1	2
female	3	171	1.70%	2	21	9.50%		
total	4	283	1.40%	7	77	9.10%	1	

Table 4: Demographics of the Student Athletes Screened

		Demographics of the Athletes Tested							
	Caucasian	African American		Latino	American Indian		Asian/Pacific Islander		
Male	112	56		36	2		14		
Female	171	21		15	4		6		
Total	283	77		51	6		20		

Table 5: Percentage of all sexually active student athletes who were ever offered Chlamydia trachomatis screening and the percentage of the positively tested athletes who were ever offered Chlamydai screening

	SEXUALLY ACTIVE ATHLETES		
	test	total	
	offered		
male	12(7%)	175	
female	42(31%)	135	
total	54(17%)	310	
+ male	3(43%))	7	
+female	1(20%)	5	
+total	4(33%)	12	

Adopted from: Hu D, Hook EW III, Goldie SJ. Screening for Chlamydia trachomatis

Ref 29

in Women 15 to 29 Years of Age: A Cost-Effectiveness Analysis

	Treatment Cost of	Time cost	Work days lost	Diminished life quality duration
Outpatient PID:	$490	$513	7.1	11d
Inpatient PID:	$4,715	$1,084	15	11d

PID Sequelae:

Chronic pelvic pain:
$1,146

$684

9.5

5 yrs

Ectopic pregnancy:
$4,355

$1,445

20

4 wks

Tubal infertility:
$5,000

$321

4.5

until age 50 yrs

Acute urogenital infection: $36

0.5

4 wks

*Quality duration was based on the Health Utility Index and obtained from a study commissioned by

the Institute of Medicine (37)