Preference Among Female Army Recruits for Use of Self-Administered Vaginal Swabs or Urine to Screen for Chlamydia trachomatis Genital Infections

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Background: Use of self-administered vaginal swabs (SAS) for the detection of Chlamydia trachomatis by nucleic acid amplification tests simplifies specimen collection and transport, especially for women in nonclinical settings.

We investigated the preference and comfort level of military women for the collection of SAS, compared with urine, for the diagnosis of genital chlamydial infections.

Study Design: During March through August 1999, female Army recruits in basic training at Fort Jackson, South Carolina, were invited to participate in the study. Participants were requested to complete a questionnaire after providing both first-void urine (FVU) and SAS specimens. Participant characteristics, preferences, and comfort levels were assessed using multivariate logistic regression.

Results: From 4496 eligible female recruits, 1403 (31%) completed questionnaires and 1382 provided both specimens; 11.8% (166 of 1403) of participants were infected with chlamydia. The relative sensitivity and specificity of the C. trachomatis Ligase Chain Reaction test on SAS in 1382 matched pairs was 81.1% and 98.6%, respectively, using the test result on urine specimens as the comparison standard. Most of the participants (90.8%) reported that they felt comfortable collecting the FVU specimen, and 69.6% indicated that they felt comfortable collecting SAS. Either specimen collection type received high acceptability at home and in the field, and more women reported that they would collect FVU than reported they would collect SAS in the future (in the field: FVU; 79.4%, SAS; 68.8%, P < 0.001; at home: FVU: 90.9%, SAS: 82.9%, P < 0.001). When questioned about ease of use, 60.4% of women reported that urine was the easier method. Preferences for SAS were associated with being white and having had sexual risk behaviors in the past 3 months.

Conclusion: A study of preferences for urine versus self-administered vaginal swabs for the detection of C. trachomatis in military women showed that women generally found SAS acceptable. SAS should be a feasible alternative to urine collection in situations in which specimen storage or transport is an issue.

GENITAL CHLAMYDIA TRACHOMATIS INFECTION, a leading notifiable infectious condition in the United States with an estimated 3 million new cases each year, causes urethritis, cervicitis, endometritis, salpingitis, and pelvic inflammatory disease. These infections have also been associated with adverse reproductive outcomes such as infertility, miscarriage, and ectopic pregnancy. The estimated annual cost of treating chlamydial infection is over $1.5 billion. Infection with C. trachomatis has also been shown to increase the risk of acquisition and transmission of human immunodeficiency virus (HIV) and could be a risk factor for the development of cervical cancer. During the past decade, the introduction of nucleic acid amplification tests (NAATs) for detection of chlamydial infections has resulted in enormous improvement in diagnostic sensitivity. These NAATs, including polymerase chain reaction (PCR), ligase chain reaction (LCR), transcription-mediated amplification, and strand displacement amplification, are highly sensitive compared with culture while maintaining high specificity. Nontraditional and noninvasive specimens such as vaginal swabs and urine specimens can be used with NAATs to detect chlamydia in place of cervical swabs in females and urethral swabs in men. The collection of noninvasive specimens does not require a clinician. Using NAATs on noninvasive specimens, screening programs in prenatal clinics, sexually transmitted disease (STD) clinics, middle and high schools, and military recruit training centers have demonstrated that C. trachomatis infections are highly prevalent among young, sexually active people. However, genital chlamydial screening programs are highly cost-effective in preventing severe, postinfectious sequelae.

In clinics, schools, and home settings, use of urine specimens for the diagnosis of chlamydial infections has received high marks for
acceptability. In some populations, such as female soldiers who are living and working in field settings or deployed to areas with meager facilities for shelter and hygiene, there might be acceptability, storage, or transport issues associated with collecting urine specimens. Self-administered (ie, self-obtained or self-collected) vaginal swabs (SAS) could be a feasible alternative to urine collection in some settings. SAS have been successfully used to detect STDs in women in rural, sub-Saharan Africa, in adolescents in the United States, and in military women attending an STD clinic. Generally speaking, participants in these studies were adept at self-collection, and similar chlamydia-positivity rates have been detected from SAS and physician-collected endocervical swabs, as well as clinician-collected vaginal swabs.

However, the sensitivity and specificity of SAS for detection of genital chlamydial infections, compared with urine samples, has not been well studied and little data exist to document women’s preferences for the different types of self-collected samples. We undertook this study to assess the acceptability of SAS as screening specimens for the detection of chlamydial infection in non-healthcare-seeking female soldiers who were invited to provide both SAS and urine specimens at a single visit. We also evaluated preference for SAS, compared with urine, and the sensitivity and specificity of SAS using urine as the standard.

**Materials and Methods**

**Study Population**

Female Army recruits who entered basic training at Fort Jackson, South Carolina, during March through August 1999 were invited to participate in our study. The participants were given a study and educational briefing about genital chlamydial infection and its sequelae and were instructed about collection of both samples. The self-administered vaginal swabs instruction material included a diagram of the female genital anatomy, described steps of removing a Dacron swab from the swab packet, described how to self-collect a vaginal swab specimen, and indicated steps for putting the swab into the test tube. After signing a consent form, participants were asked to obtain a 20-mL first-void urine (FVU) specimen in a container provided by the study team, then to self-collect a vaginal sample using a Dacron swab (Baxter Scientific, McGaw Park, IL) and place it into the LCR transport tube containing transport buffer. Then participants were instructed to break off the shaft of the swab leaving the swab in the tube and replace the cap. After specimen collection, volunteers were asked to complete a questionnaire that addressed basic demographic information, sexual risk behaviors, history of sexually transmitted diseases, and questions on sample preference and comfort with use. The preference and comfort domains were assessed by questions relating to ease of collection, comfort in collection, pain during collection, handling of specimens, preference in collection method by setting (clinic, home, and field), and intention to use.

This study was approved by the institutional review boards of The Johns Hopkins University, the U.S. Army Medical Research and Material Command, Fort Detrick, Maryland, and Fort Jackson (supported by the Eisenhower Army Medical Center, Fort Gordon, Georgia). All diagnostic specimens, consent forms, and questionnaires were shipped to The Johns Hopkins University International Chlamydia Laboratory. FVU specimens and SAS samples were kept at 4°C until processing within 48 to 72 hours.

**Laboratory Procedures and Treatment**

FVU and SAS specimens were processed and tested for chlamydia by LCR (Abbott Laboratories, Abbott Park, IL) according to the manufacturer’s directions. FVU samples (1 mL) were centrifuged and the pellet tested in the assay. SASs were handled according to the manufacturer’s instructions for cervical specimens. Recruits whose specimens tested positive on any assay were promptly informed and requested to attend the installation Troop Medical Clinic, where they were treated with a single, 1-g oral dose of azithromycin and received an evaluation for other sexually transmitted diseases. They were also referred for counseling and encouraged to notify their sexual partners.

**Statistical Analysis**

Univariate analyses (chi-squared tests) were used to investigate associations of demographics, sexual risk factors, and LCR results with questionnaire data. For these analyses, age was categorized into >25 years and ≤25 years dichotomous variables because of previous findings regarding age-specific chlamydial infection prevalences in this population. Race was categorized into black, white, and other. Home states were recorded according to the Centers for Disease Control and Prevention (CDC), Atlanta, GA, reporting regions: West, Midwest, Northeast, South, or Territories. The geographic regions were further categorized as South or “other regions” for analyses. “Sexual risk behaviors” were defined as self-reports of more than one sexual partner in the 90 days before being studied, not always using condoms in the past 90 days, or a new sexual partner(s) in the past 90 days. Models corresponding to each acceptability/preference/comfortableness question were constructed by performing multivariate logistic regression analyses, including the variables age, race, region, and risk behaviors. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated and P values of <0.05 were considered significant. All analyses were performed using Statistical Analysis Software version 8.2 (SAS Institute Inc, Cary, NC) or Stata 6.0 (Stata Corp, College Station, TX).

Relative sensitivity and specificity of the LCR results on SAS were calculated using the LCR results on urine specimens as the standard, because this specimen has been cleared by the U.S. Food and Drug Administration for the LCR assay. Relative sensitivity and specificity on urine and SAS were also calculated using any positive LCR result as an analytical “true positive.”

**Results**

**Demographic Characteristics and Risk Factors for Sexually Transmitted Infections**

Thirty-one percent (1403 of 4496) of female Army recruits, who had volunteered to participate in a urine prevalence study, also volunteered to participate in the SAS study and completed questionnaires (Table 1). All but 21 provided both SAS and urine specimens (15 participants provided urine specimens only and 6 provided SAS only). Thus, there were 1382 matched urine and SAS samples. The mean age of participants was 20.3 ± 3.6 years (mean ± standard deviation; range, 17–36 y). White (48.3%) was the most common reported race, followed by black (35.7%) and other races (13.1%). Forty (2.9%) individuals did not report their race. Almost half of the study subjects identified their home of record as being in the South (656, 46.8%), followed by Northeast (268, 19.1%), Midwest (249, 17.7%), West (208, 14.8%), and the Territories (22, 1.6%). Most (1188, 84.7%) participants reported ever having had vaginal sex and 1166 (83.1%) women reported that they had practiced sexual risk behavior in the previous 90 days (more than one sexual partner, new sexual partner, or had had sex without using a condom). Only 2.1% (30 of 1403) of the women studied reported ever having been diagnosed with a sexually transmitted disease.
were FVU-positive/SAS-negative. Using the test result on the urine specimen as the comparison standard for the 1382 paired specimens, relative sensitivity for SAS specimens was 81.1% (95% CI, 73.8-87.0%) and relative specificity was 98.6% (95% CI, 97.8-99.2%). When any positive result on a FVU or SAS was considered a true analytical positive, the relative sensitivity for FVU and SAS were 89.7% (95% CI, 84.0-93.9%) and 87.6% (95% CI, 80.9-92.6%), respectively, and the relative specificity was 100.0% for both.

Collection Method Preference and Comfort Issues

Overall, 90.8% of respondents (1255 of 1382) indicated that they felt comfortable collecting a FVU specimen, whereas 69.6% (962 of 1382) felt comfortable collecting SAS (P<0.001). When queried about ease of use, 60.4% (834 of 1382) reported that urine was the easier method, 33.2% chose SAS, and 6.4% did not have a preference (P<0.001). Either specimen collection type received high acceptability at home and in the field (FVU at home: 90.9%, vs. in the field: 79.4%; SAS at home: 82.9%, in the field: 68.8%). When given a choice of collection method (FVU or SAS), collecting a FVU specimen was the preferred method in the clinic (56.4% vs. 32.9%; P<0.001), the home (52.0% vs. 39.1%; P<0.001), and the field (50.4% vs. 36.5%; P<0.001).

The reasons given for preferring the collection of urine over SAS were varied (Table 2). Some women reported feeling uncomfortable collecting a FVU specimen, whereas 69.6% (962 of 1382) felt comfortable collecting SAS (P<0.001). When asked about ease of use, 60.4% (834 of 1382) reported that urine was the easier method, 33.2% chose SAS, and 6.4% did not have a preference (P<0.001). Either specimen collection type received high acceptability at home and in the field (FVU at home: 90.9%, vs. in the field: 79.4%; SAS at home: 82.9%, in the field: 68.8%). When given a choice of collection method (FVU or SAS), collecting a FVU specimen was the preferred method in the clinic (56.4% vs. 32.9%; P<0.001), the home (52.0% vs. 39.1%; P<0.001), and the field (50.4% vs. 36.5%; P<0.001).

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Multivariate logistic regression analyses, adjusting for age, *P < 0.05.

than one sexual partner, new sexual partners, or sex without a condom) in the past 90 days had more favorable ratings for the use of SAS (Table 3). Having reported any sexual risk behaviors in the past 90 days was associated with the choice of SAS as the collection method in the clinic and at home (Table 3).

In another model controlling for age, region, and risk behaviors, “other races” indicated that they felt pain in collecting SAS as compared with black participants (felt pain: OR, 3.68; 95% CI, 1.94–6.98). When findings were adjusted for region, race, and risk behaviors, women who were aged 25 years were less likely to report that they would collect FVU in the field compared with those who were >25 years (OR, 0.54; 95% CI, 0.29–1.00). There were no significant differences by age with regard to other preferences, acceptability, and comfortableness questions (data not shown).

### Discussion

This study compared the preference, comfort level, sensitivity, and specificity of 2 specimen collection methods in young female military recruits. When queried in conjunction with the use of FVU and SAS sampling, these women preferred the collection of FVU specimens but viewed SAS as an acceptable alternative. We found that the use of SAS did not diminish the sensitivity and specificity of the LCR assay for detection of chlamydia when compared with FVU, and we demonstrated that only SASFVU and SASFVU were significant for detection of female genital tract infections.

Females with sexual risk behaviors reported being comfortable in collecting the SAS and that they would be likely to use SAS in different settings. This is an important finding because sexually active women reporting high-risk sexual behaviors are at significant risk for chlamydial infections. Women of races other than white reported less preference for the SAS and felt more uncomfortable using the SAS. After obtaining a better understanding of different cultural backgrounds and biases, more detailed and specific “how-to-collect SAS” instructional materials might be helpful in some subgroups of women.

Studies on young military women have demonstrated that they are at high risk for chlamydial infections.8,35 Periodic screening using NAAT assays recommended by the CDC can reduce the
burden of genital chlamydial infections and the subsequent complications. Providing an acceptable alternative specimen collection method in a *C. trachomatis* screening program has the potential to benefit military women, especially when they are in the field. The self-administered vaginal swab might be an alternative specimen collection method for implementing sexually transmitted infection screening programs in unique populations in nontraditional settings or remote areas where urine specimens might not be feasible. Our young female recruit population preferred collecting FVU to SAS, but SAS was generally an acceptable option. Our results support SAS as an acceptable and feasible alternative to FVU collection in situations in which collection, storage, or transport of urine specimens could be problematic.

**References**


