Self-obtained Vaginal Swabs for Diagnosis of Treatable Sexually Transmitted Diseases in Adolescent Girls

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**Objective:** To ascertain the acceptability of testing and prevalence of 3 readily treatable sexually transmitted diseases (STDs) (infections with *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis*) with the use of patient-obtained vaginal swabs.

**Study Design:** Study participants at each initial session were asked to provide self-obtained vaginal swabs for ligase chain reaction testing to detect *N gonorrhoeae* and *C trachomatis*, and for culture of *T vaginalis*.

**Setting:** Behavioral intervention sessions with African American adolescent girls in a nonclinical program to reduce risk of STDs, human immunodeficiency virus infection, and pregnancy.

**Results:** All study participants were offered their choice of STD screening in the context of a traditional pelvic examination or using self-obtained vaginal swabs. All eligible participants chose self-administered vaginal swabs. Of the 512 participants examined at their initial study visit, 28.7% were found to be infected with 1 or more treatable STDs (5.3% with *N gonorrhoeae*, 17.8% with *C trachomatis*, and 12.9% with *T vaginalis*).

**Conclusions:** With the use of newer detection systems, STDs can be readily detected in nonclinical settings with the use of self-obtained vaginal swabs, providing new opportunities for efforts to control STDs.


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TREATABLE sexually transmitted diseases (STDs) caused by *Trichomonas vaginalis*, *Chlamydia trachomatis*, and *Neisseria gonorrhoeae* are relatively common among sexually active young women and may lead to serious complications and sequelae. Infections with *C trachomatis* and *N gonorrhoeae* are the 2 most common reportable bacterial STDs in the United States, and vaginal trichomoniasis is more common than chlamydial and gonococcal infection. Each of these infections is also an important contributor to the STD-related morbidity in women. Gonococcal and chlamydial infections cause pelvic inflammatory disease, ectopic pregnancy, infertility, and perinatal and congenital infections, and cost millions of dollars in health care costs. *Trichomonas vaginalis* infection is a common cause of symptomatic vaginal discharge and has been implicated in preterm birth. Moreover, recent studies have demonstrated increased efficiency of transmission of human immunodeficiency virus (HIV) in the presence of coinfection with bacterial STDs or trichomoniasis. However, each of these infections often remains undiagnosed because many infected women have mild, nonspecific symptoms or are asymptomatic. As a result, screening for bacterial STDs and trichomoniasis is a critical component of control efforts.

Until recently, diagnosis of these STDs required a pelvic examination. The development of diagnostic nucleic acid amplification technology has made chlamydial and gonococcal diagnoses in women possible in circumstances in which the usual endocervical specimen collection is difficult. Self-obtained vaginal specimens for diagnosis of genital infections have been used successfully in research settings; however, few data have been published on patient-obtained vaginal specimens for STD diagnosis in teenage girls.

This article reports the utility of patient-obtained vaginal swabs as tools for STD diagnosis in a nonclinical setting where they are collected without a pelvic examination according to instruction by nonclinicians. Questions we sought to address were 2-fold: (1) Are sexually active adolescent girls willing and able to obtain their own vaginal specimens? (2) Can the specimens obtained in a nonclinical setting be used for accurate diagnosis of genital infections?
SUBJECTS AND METHODS

SUBJECT POPULATION

From December 1996 through April 1999, project recruiters screened 1130 teenage girls in adolescent and school-based primary care clinics and in health education classes at local high schools to assess eligibility for STD/HIV prevention intervention. Recruiters presented a brief description of a young women’s health study, then assessed the eligibility of those expressing an interest in participating by means of a short questionnaire. Adolescents were eligible to participate in the study if they were African American girls, were between the ages of 14 and 18 years at the time of enrollment, had been sexually active (vaginal or anal sex) in the previous 6 months, and provided written informed consent. In this study, African American female teenagers were selected as the target population because of reports of high escalating risk for HIV and STD.12-14 The recruitment sites were in neighborhoods characterized by high rates of unemployment, substance abuse, violence, and STDs.

STUDY DESIGN

Subjects recruited from a variety of settings were informed, via telephone and mailed brochure, about the methods of the study, including surveys, interviews, specimen collection, incentives, workshops, and follow-up. These adolescents were then invited to ask questions about the study and to sign a consent form to participate. For the study, 4 intervention workshops and data collection sessions were held in a local clinic facility on Saturdays. For baseline data collection and each workshop, participants received a $20 cash incentive. The study protocol was reviewed by the university’s Institutional Review Board Committee on Human Research before implementation of the study.

SPECIMEN COLLECTION METHODS

During the baseline data information collection session and before randomization to a behavioral STD/HIV risk-reduction intervention, each adolescent was instructed by a nonclinician research assistant to obtain 2 vaginal swabs for STD testing by means of a written protocol. Research assistants instructed adolescents in appropriate procedures for collecting vaginal specimens. During a preliminary 2-hour training session, research assistants were instructed on the methods used in obtaining self-obtained vaginal swabs, the efficacy of this procedure for STD analysis relative to pelvic examination, and how to address questions posed by participants.

The research assistant explained the purpose of collecting the vaginal specimens, presenting a discussion biased toward self-obtained vaginal specimen collection rather than specimen collection by a clinician on a pelvic examination table. The discussion included the relative advantages of self-obtained vaginal specimens, such as being under their control, less painful, not as invasive, and more convenient. For participants preferring not to collect vaginal swabs, free pelvic examination appointments for specimen collection were available for girls the following week at a local adolescent clinic. Choosing the pelvic examination option would still allow for study entry and receipt of the $20 incentive. After research assistants described the insertion procedure to the adolescents and answered any questions regarding it, participants were asked about their willingness to collect self-obtained vaginal swabs. Adolescents completed specimen collection within 3 to 4 minutes in a private clinical examination room. Vaginal swabs were not collected from adolescents in their third trimester of pregnancy or 6 weeks postpartum; these adolescents provided a first-void urine specimen for ligase chain reaction testing.

For specimen collection, each participant was asked to obtain 2 vaginal specimens by sequentially inserting 2 sterile Dacron-tipped swabs about 2.5 in or as far as comfortable into the vagina, rotating them for 15 to 30 seconds, and removing them. After specimen collection, the first swab was placed in a specimen transport tube for subsequent ligase chain reaction testing (LCx Probe System for N gonorrhoeae and C trachomatis assays; Abbott Laboratories, Diagnostics Division, Abbott Park, Ill), and the second swab was used to inoculate culture medium for T vaginalis (TV Test; BioMed Diagnostics Inc, Santa Clara, Calif).

Ligase chain reaction specimens were stored at 4°C until delivered to the laboratory. Pouches for T vaginalis culture were immediately incubated at 37°C. All specimens were transported to the laboratory in insulated containers within 48 hours.

LABORATORY METHODS

Study participants were examined for 3 prevalent sexually transmitted organisms: N gonorrhoeae, C trachomatis, and T vaginalis.6-10 On receipt in the laboratory, cultures for T vaginalis were incubated at 37°C and read daily until the fifth day after inoculation. Cultures were considered positive on the basis of identification of motile trichomonads within the pouch.3 Swab specimens for ligase chain reaction were processed immediately on receipt in the laboratory. Ligase chain reaction assays for C trachomatis and N gonorrhoeae were performed according to the manufacturer’s instructions.5,10

RESULTS

Of the 609 eligible adolescents referred to intervention workshops, 522 (85.7%) attended and agreed to participate in the study. Of the 522 adolescents, 512 were asked to collect vaginal swabs. Ten (2.0%) were excluded because they were known to be in their third trimester of pregnancy and were not asked to provide vaginal swabs. Of the 87 recruited teens (14.3%) who did not participate, 31% (27 subjects) could not be reached because of incorrect contact information given at screening, 29% (25) stated that they were not interested in taking part in the health promotion program, 22% (19) had employment or child care conflicts, 9% (8) expressed interest but never showed up to enroll, 3% (3) declined because of chronic illness, 3% (3) were incarcerated after the initial refer-
In this study, sexually active teens were willing to obtain their own vaginal swab specimens for STD diagnosis. No participant declined to obtain the vaginal swabs or reported difficulty in doing so. Some aspects of the study methods may have influenced participants in favor of the self-obtained specimen collection over the traditional pelvic examination collection. The convenience of immediate swab collection as opposed to having to make another trip to a clinic for specimen collection on a pelvic examination table, as well as presenting the self-obtained method first with all of the relative advantages, may have influenced some participants to prefer the self-obtained method. Perhaps, given a choice of an immediate pelvic examination or immediate self-obtained swabs, some girls may have chosen the pelvic examination. However, with no participants opting for the pelvic examination or refusing specimen collection, collection of vaginal swab specimens for STD screening appears to be readily acceptable to this group of high-risk adolescents.

Nearly all participants were asymptomatic at the time of enrollment, yet unsuspected gonorrhea, Chlamydia, and Trichomonas infections were common. Since we did not compare the prevalence of infection detected by means of patient-obtained specimens with the results of testing with specimens collected by clinicians in the context of a speculum-guided genital examination, it is possible that some infections were missed by allowing participants to collect their own specimens. On the basis of our own earlier work comparing performance of patient-obtained vaginal swabs with that of clinician-obtained specimens, as well as the work of others, we suspect that the diminution of sensitivity was slight, if any.

These data add to growing literature that suggests that, for women, patient-obtained vaginal swabs are adequate and appropriate specimens for STD screening at sites or in situations where pelvic examinations are not otherwise required.

In some situations, urine may be a favored analyte for gonococcal and chlamydial screening; however, the sensitivity of urine culture for T vaginalis is poor. In addition, transport and laboratory processing of swab specimens for STD diagnosis is simpler (no aliquoting or centrifugation is required) than for urine. Thus, patient-obtained vaginal swab specimens, analyzed by newly developed nucleic acid amplification assays, enhance the likelihood that individuals will provide a specimen and increase the potential for detecting asymptomatic infection. This method should be evaluated further as a potential tool for STD screening and control efforts.

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Table 1. Population Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Finding (N = 512)</th>
</tr>
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<tbody>
<tr>
<td>Age, y</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>16</td>
</tr>
<tr>
<td>Range</td>
<td>14-18</td>
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<tr>
<td>History of sexually transmitted disease</td>
<td></td>
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<tr>
<td>self-report, No. (%)</td>
<td></td>
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<tr>
<td>Gonorrhea</td>
<td>38 (7.4)</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>71 (13.9)</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>52 (10.2)</td>
</tr>
<tr>
<td>Ever pregnant, No. (%)</td>
<td>199* (39.3)</td>
</tr>
<tr>
<td>Multiple partners in past 6 mo, No. (%)</td>
<td>48 (9.4)</td>
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</tbody>
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* n = 507; 5 participants did not respond to this question on survey.

Table 2. Laboratory Test Results of Subjects at Enrollment (Baseline) Visit*

<table>
<thead>
<tr>
<th>STD</th>
<th>No. (%) Positive (N = 512)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia†</td>
<td>91 (17.8)</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>27 (5.3)</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>66 (12.9)</td>
</tr>
<tr>
<td>Any STD‡</td>
<td>147 (28.7)</td>
</tr>
</tbody>
</table>

*D indicates sexually transmitted disease.
†One specimen had insufficient quantity for Chlamydia ligase chain reaction test.
‡Eight patients (1.6%) had all 3 STDs; 20 patients (3.9%) had 2 different STDs.

Prevalence of sexually transmitted diseases by participant age (N=512).

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REFERENCES