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ORIGINAL RESEARCH

How reliable is self-testing for gonorrhea and chlamydia among men who have sex with men?

Our study shows that patients who collected their own rectal and pharyngeal samples had test results that were of equal or better accuracy than those of clinical providers.

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ABSTRACT

Background► Recent studies have demonstrated a high prevalence of pharyngeal (P) and rectal (R) *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) infections among men who have sex with men (MSM). Guidelines by the Centers for Disease Control and Prevention recommend testing at least annually. But surveys of medical providers suggest that adherence to these guidelines is minimal as a result of limited time and staff. Because of these concerns, we evaluated the feasibility and accuracy of patient self-testing.

Methods► Three-hundred seventy-four patients at a Washington, DC clinic who identified themselves as MSM and requested testing for sexually transmitted infections (STIs) participated in the study. Patients performed self-screening using the Gen-Probe APTIMA Combo 2 (AC2) kit after viewing written and pictorial instructions. Trained providers also screened patients. We randomized the order in which patients or providers performed testing.

Results► Among those receiving specific tests, 8% of patients tested positive for R-GC, 9.3% for P-GC, 12.7% for R-CT, and 1.3% for P-CT. We performed McNemar tests, stratified by infection type and anatomic site to evaluate concordance. Self-administered testing was significantly better at identifying P-GC (discordant: 3%) and R-GC (discordant: 2.9%) ($P \leq .01$), and had results similar to provider-administered testing for P-CT (discordant: 0.5%) and R-CT (discordant: 1.1%) detection.

Conclusions► The equivalent or better detection rates for rectal and oral gonorrhea and chlamydia among patients suggest that patients are capable of performing their own screening for STIs, which may increase infection detection and treatment.

The prevalence of *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) infections among men who have sex with men (MSM) are common but unfortunately difficult to identify as a result of their anatomic location and lack of symptoms. In recent studies, 3.7% to 14.9% of MSM tested positive for GC, and 1.7% to 10.7% tested positive for CT on a first screening.[1-4] Even more striking, however, was that many of these infections were extragenital and asymptomatic, with rectal GC infections 5 times more common than urethral in one study,[3] and more than 80% of rectal GC and CT infections reportedly asymptomatic in another.[2]

Given the prevalence of undetected infection, the Centers for Disease Control and

Prevention (CDC) recommends screening all sexually active MSM at least yearly for rectal GC and CT and pharyngeal GC infections in addition to urethral infections.[5] However, research suggests that relatively few physicians follow these recommendations. In a survey of 3509 physicians, less than 14% reported screening their male patients for gonorrhea and chlamydia.[6] In another survey, approximately one-third of providers reported not having enough staff to talk with patients about sexually transmitted infections (STIs) and testing, not having enough time in patient visits, and having difficulty keeping up with guidelines for caring for high-risk patients, including MSM.[7]

These studies raise concern that GC and CT infections will go undiagnosed; failure to detect these infections in MSM is particularly dangerous, given the STIs' relationship to human immunodeficiency virus (HIV) transmission.[8] Urethral GC infections have been shown to increase shedding of HIV in semen,[9] and a recent study of MSM also demonstrated that having had multiple rectal GC or CT infections within a 2-year period made HIV seroconversion more likely.[10]

Due to the importance of identifying GC and CT infections and providers' concerns about lack of time to do so, studies have explored the possibility of patient-administered testing, which has numerous potential benefits. It decreases the time that a health care provider has to spend on STI testing, and it could lead to screening of larger numbers of patients. It may also enable providers to reach patient populations that are often not appropriately screened, including MSM, prison inmates, homeless patients, drug users, adolescents, and patients in rural or disadvantaged areas.[11-19]

Comparisons of patient- and clinician-collected samples have yielded encouraging results about the ability of MSM to perform self-administered testing. There was 98% concordance between patient and provider results for rectal GC/CT swabs in one study.[20] And another study found that self-collected rectal swabs had equivalent or better sensitivity and specificity for GC/CT detection than provider-collected swabs.[21]

Only one study has explored both pharyngeal and rectal self-testing of MSM patients, and it found that patient and provider results were concordant for 91.6% of rectal specimens and 93.6% of pharyngeal specimens. Most discordant cases involved patient-identified positives where the provider test was negative. The study authors considered these likely false positives; most occurred in patients who were positive for GC at another site, making cross-contamination probable.[22] It is important to investigate further, however, because it is also possible that patients were identifying cases that providers missed.

The aim of our study, therefore, was to explore the ability of MSM patients to perform both pharyngeal and rectal testing for gonorrhea and chlamydia by evaluating the concordance of patient- and provider-administered testing results. We designed the study so that both patients and trained providers performed testing using Gen-Probe's APTIMA Combo 2 (AC2) kits at pharyngeal, rectal, or both sites, depending on the patient's recent sexual practices. As discussed, prior studies suggested that concordance would be good for rectal swab specimens. But only one study had examined pharyngeal swab concordance in addition to rectal, and it led to concerns about patient-generated false positives. We wanted our study to evaluate whether patient-administered testing produced accurate results for both pharyngeal and rectal specimens, and whether patient testing behaviors led to cross-contamination and subsequent false-positives when performing both tests.

Self-testing may enable providers to reach patient populations that are often not properly screened, including men who have sex with men.

METHODS

Patient recruitment and eligibility

We recruited patients from STI testing clinics and from primary and HIV care clinics at the Whitman-Walker Clinic in Washington, DC from September 15, 2009 to April 19, 2011. Eligible participants were men who'd had sex with men in the last 6 months and who wanted testing for gonorrhea and chlamydia. The presence of symptoms, reports of condom use during sex, and HIV status did not affect eligibility.

Interested patients signed a consent form and completed a behavioral questionnaire, which included questions about de-

Widespread implementation of this self-administered testing would likely require clearer instructions.

mographics and sexual behavior. A patient's responses to this questionnaire determined whether he was eligible to participate and the type of testing needed. For example, if a patient had had only oral or anal sex but not both, we limited testing to either pharyngeal or rectal swabbing.

Testing procedures

We randomized patients to either perform self-testing first or to have provider-administered testing first. When patients were ready to self-administer the swabs, we gave them placards that explained how to properly collect samples[23] and Gen-Probe AC2 testing kits (Hologic Gen-Probe, San Diego, Calif) for each test they needed to perform. The provider remained in the room while the patient performed the testing to ensure that the patient made an attempt at screening and to identify any common problems with the instructions. If the provider observed problems with how the patient performed the screening, he or she recorded that on a spreadsheet after the patient left.

The 4 providers who performed testing (a nursing student, a medical student, and 2 clinical research assistants) had all been previously trained in STI testing techniques by clinic MDs. When these providers performed testing, they swabbed the patient twice at each site. One of these swabs was stored for research testing, and the other went immediately to the clinic laboratory for testing so that the patient could receive the standard of care antibiotic treatment if the test was positive. The designated research samples were tested in a Gen-Probe laboratory in California.

Statistical methods

Based on a previous study by Lampinen et al that examined concordance between patient- and provider-obtained rectal swabs, we planned on a total sample of 360 patients to achieve 80% power in detecting a difference in positive tests of 5% between patients and clinicians at a one-sided 5% significance level.[24] This plan assumed that the percentage of discordant pairs would be 15%, where one pair consists of one test result each from a clinician and a patient at the same site. We performed sample-size calculations in nQuery Advisor version 6.0 (Statistical Solutions, Saugus, Mass). Ultimately, we enrolled 374 men in the study. We tested 5 patients twice, but only their first screening was included in the primary analyses.

We entered demographic and behavioral data from the patient questionnaires into an online database. We also generated descriptive statistics for demographics and baseline characteristics from the questionnaires.

We performed an exact McNemar's test for each anatomic site and STI to evaluate whether there were significant differences between patient- and provider-performed swabs. We also calculated Kappa coefficients for each site and STI as a measure of concordance. We regarded as positive any test results that were equivocal, because in clinical practice a provider would likely provide treatment. However, we also performed McNemar testing and Kappa calculations with these results excluded and classified as negative to ensure that no significant differences resulted. We evaluated statistical significance at the 0.05 level (2-sided), and performed all analyses in SAS software version 9.2 (SAS Institute, Cary, NC).

RESULTS

The patients who enrolled in the study represented a wide range of ages and ethnic backgrounds, with a median age of 33 years and with Caucasian patients accounting for 54.8%. Patients who had had sex with only men in the past year accounted for 89.8% of the sample, while 8.6% had both male and female partners (the final 1.6% had either no sex partners or missing data). The average number of male partners in the last 2 months was 2. As for sexual practice, 86.9% had insertive oral intercourse in the past year, 70.8% had insertive anal intercourse, 87.2% had receptive oral intercourse, and 67.9% had receptive anal intercourse (**TABLE 1**).

Considering only provider-identified positives, 5.1% of the patients tested positive for rectal gonorrhea, 11.6% for rectal chlamydia, 6.3% for pharyngeal gonorrhea, and 0.8% for pharyngeal chlamydia (**TABLE 2**). Considering both provider- and patient-

TABLE 1

Characteristics of men participating in the study

Demographic	N=374
Age, y	
Median	33
Range	18-70
	n (%)
Race/ethnicity	
White/non-Hispanic	205 (54.8)
Black/non-Hispanic	85 (22.7)
Latino/Hispanic	40 (10.7)
Asian	13 (3.5)
Mixed	8 (2.1)
Other	19 (5.1)
Missing data	4 (1.1)
Modes of GC/CT testing	
Rectal and pharyngeal	272 (72.7)
Rectal only	5 (1.3)
Pharyngeal only	97 (25.9)
Sexual partner(s) in the last 12 months	
Men	336 (89.8)
Men and women	32 (8.6)
None	1 (0.3)
Missing data	5 (1.3)
Number of male sexual partners in the past 30 days	
0-1	178 (47.6)
2-3	130 (34.8)
4 or more	64 (17.1)
Missing data	2 (0.5)
Number of male sexual partners in the past 60 days	
0-1	104 (27.8)
2-3	135 (36.1)
4 or more	133 (35.6)
Missing data	2 (0.5)
Practiced insertive oral intercourse in past 12 months	
Yes	325 (86.9)
No	20 (5.4)
Missing data	29 (7.7)
Practiced insertive anal intercourse in past 12 months	
Yes	265 (70.8)
No	78 (20.9)
Missing data	31 (8.3)
Practiced receptive oral intercourse in past 12 months	
Yes	326 (87.2)
No	20 (5.3)
Missing data	28 (7.5)
Practiced receptive anal intercourse in past 12 months	
Yes	254 (67.9)
No	90 (24.1)
Missing data	30 (8.0)

CT, *Chlamydia trachomatis;* GC, *Neisseria gonorrhoeae*.

TABLE 2

Comparison of provider and patient testing results for GC/CT by anatomic site reveals ≥75% concordance on all tests

Patient test result	Total tests, N	Provider positive test result, n (%)	Provider negative test result, n (%)	*P* value	Kappa coefficient
Rectal GC	276				
Patient *positive* test result		14 (5.1)	8 (2.9)*	<.01	0.76
Patient *negative* test result		0	254 (92)		
Pharyngeal GC	367				
Patient *positive* test result		23 (6.3)	10 (2.7)*	.01	0.79
Patient *negative* test result		1 (0.3)*	333 (90.7)		
Rectal CT	276				
Patient *positive* test result		32 (11.6)	3 (1.1)*	.25	0.95
Patient *negative* test result		0	241 (87.3)		
Pharyngeal CT	367				
Patient *positive* test result		3 (0.8)	2 (0.5)*	.50	0.75
Patient *negative* test result		0	362 (98.7)		

CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*.

*Discordant patient-provider test results.

It might be possible for patients to simply perform testing after a physical exam or to come in when it is convenient and leave a sample in the lab.

identified positives, 8.0% of patients tested positive for rectal gonorrhea, 9.3% for pharyngeal gonorrhea, 12.7% for rectal chlamydia, and 1.3% for pharyngeal chlamydia. Five equivocal results were identified—2 for a patient rectal gonorrhea test, one for a patient pharyngeal gonorrhea test, one for a provider pharyngeal gonorrhea test, and one for a provider rectal chlamydia test.

In only one case did a provider identify a positive result when the patient's result was negative. In 23 cases, however, the patient identified a positive result when the provider's result was negative. Patients identified significantly more positives for rectal and pharyngeal gonorrhea than providers, but there were no significant differences in patient and provider results for the chlamydia tests.

Even with these 24 discordant results, there was ≥75% concordance between patient and provider results on all tests, with very strong concordance (95%) for rectal chlamydia results (**TABLE 2**). When we reran the McNemar tests and the Kappa coefficients with equivocal results considered missing and negative, there were no statistically significant differences when compared with the calculations done with equivocal results considered positive.

Some difficulties observed with self-testing. Observing providers noted anecdotally that there were minor difficulties with the self-administered testing instructions. Three patients spilled the preservative liquid in which swabs are placed, 5 patients used the incorrect swab to perform testing, and 2 other patients had samples that were noted as compromised by the provider. None of these documented problems involved the 24 discordant cases.

DISCUSSION

The prevalence of gonorrhea and chlamydia in this study population was similar to what has been observed in previous studies of MSM,[1-4] which confirms the need for improved detection of infections. Self-administered testing is one possible means of increasing the number of patients who are screened and treated, as the results of this study suggest it is equally or more accurate than provider-administered testing at detecting cases of gonorrhea and chlamydia.

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Implementation of self-administered testing should be considered for female patients, as well.

Patient and provider results were equivalent for chlamydia detection, and patients appeared to identify more cases of gonorrhea, although interpretation of the significance of this finding is difficult given the relatively small number of cases. However, it is likely that the 23 cases in which patients identified positives that providers did not were true positives, given the sensitivity (84%-100%) and specificity (≥99.4%) of the AC2 test for detecting GC and CT.[25]

Assuming that our population has a similar prevalence of these STIs as prior studies, we would expect positive predictive values of approximately 100% for rectal GC, 95% for pharyngeal GC, 86.4% for rectal CT, and 71.4% for pharyngeal CT.[26]

Possible explanations for patients achieving better results than providers in some cases. The most likely explanation for better patient performance on some of the tests is that patients swabbed more meticulously and contacted more surface area.

This was also seen in a study that compared the ability of patients and physicians to identify human papillomavirus infection in swabs taken from areas where skin scraping had been performed. Patients were found to collect an appropriate sample significantly more often, which was thought to be due to physician hesitation to thoroughly scrape the patient's skin.[27] In our study, patients were anecdotally observed to be less likely to gag on a self-administered throat swab and to have less visible tensing of the rectal sphincter on self-administered rectal swab, which could have contributed to improved results.

Potential changes to the patient instructions before clinical implementation. These results suggest that self-administered testing could be substituted for clinician-administered testing, potentially improving detection. But widespread implementation would require a few modifications to the testing instructions based on the trained providers' observations. Although the evidence is anecdotal, providers noted that several patients had difficulty with the instructions. For example, the placard said to use only the swab with the "blue shaft," but 5 patients got confused and used the white swab either in addition to or instead of the blue swab. (The additional white swab was intended for use in making wet preps, when women are tested.) Many more patients ultimately used the correct swab, but appeared confused by the presence of the additional swab in the kit.

The confusion in these situations might have been avoided if the instructions had told men to throw one swab away and to use only the "blue swab" or the swab with the "blue handle" to avoid potential confusion over the word "shaft." Another helpful modification to the instructions would be to alert men to the presence of the preservative liquid in the tubes. Several patients laid the tube horizontally with the cap off and spilled much of the liquid. It was still possible to test these samples, and there were no discrepancies between patient and provider results involving them. But ensuring standardization of the test tube contents should still be a priority in editing the instructions.

Incorporating self-testing into clinical practice. While the results of this study suggest that self-testing could be used with a few modifications to the instructions, how best to incorporate self-testing into the clinical setting still needs to be addressed. It might be possible for patients to simply perform testing after a physical exam; for patients to come in when it is convenient for them and leave a sample in the lab; or even for patients to perform testing at home and bring the swabs back to their clinic at a later time.

We obtained the results in this study when patients performed testing in a clinic with a trained provider in the room. One concern in implementing widespread self-testing would be that a provider's presence in our study might have made patients more likely to spend the time needed to read instructions thoroughly and to put effort into performing the test correctly. However, it is also possible that knowing a provider will be duplicating the testing could lead to decreased patient effort. It may be that having responsibility for one's own test results is what ensures adequate performance.

Further studies could explore the impact of a provider in the room, but studies have already examined testing done in private and yielded similar results for concordance, which suggests that any impact of the pro-

vider's presence was relatively minimal. A 2009-2010 study at a London clinic, for example, allowed patients to perform testing privately following instructions from a nurse and identified a 9.8% prevalence of rectal CT infection and a 4.2% prevalence of rectal GC infection. These results are similar to those seen in our study and therefore suggest that patients were appropriately identifying infections without observation.[28]

Another study published in 2012 demonstrated that GC/CT testing swabs sent through the mail without any accompanying transport medium yielded results equivalent to those for swabs shipped in the liquid medium. This approach would make testing at home significantly easier, as patients would not have to be concerned about appropriate storage of their samples before returning them to a clinic.[29]

Applicability to female patients. Implementation of self-administered testing should be considered for female patients. In fact, most prior studies on the feasibility of self-testing have focused on women, as detection of their chlamydia and gonorrhea infections is equally critical. CDC guidelines stress the importance of yearly chlamydia screening for all women <25 years and for women >25 years who are at high risk (ie, multiple partners); and yearly gonorrhea screening for women at high risk, given the risk of medical complications including pelvic inflammatory disease and infertility if infections are missed.[5]

Researchers have found that after women participate in self-testing, they report that they would get STI testing more regularly if they could perform it themselves.[19,30] Additionally, in studies similar to ours, women performing testing for gonorrhea and chlamydia using self-collected vaginal swabs have achieved similar sensitivity and specificity results to provider-performed testing.[12,15,31]

Study limitations. This was a self-selected MSM sample seeking STI testing from an urban community health center. Thus, one might assume that the detection of pharyngeal and rectal gonorrhea and chlamydia infections was higher in this sample compared with the general MSM population. That seems unlikely, however, given the similarity (noted earlier) between our findings and data reported in previous studies.[1-4] Additionally, the presence of a provider in the room may have influenced patient performance, as we discussed earlier.

It therefore appears that self-administered testing could have universal applicability. Once optimal ways to incorporate self-testing for both men and women are identified, providers should be able to comply with the CDC testing guidelines without an increase in time or staff needed, thereby leading to increased detection and treatment of STIs and benefits for both patients and providers. JFP

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