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Comparison of self-obtained penile-meatal swabs to urine for the detection of *C. trachomatis*, *N. gonorrhoeae* and *T. vaginalis*

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Abstract

Background—Self-obtained penile-meatal swabs and urine specimens have been used for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and *Trichomonas vaginalis* (TV) for outreach screening in men.

Objective—To compare the sensitivity of self-collected male penile-meatal swabs and urine for the detection of CT, NG and TV.

Methods—Matching penile-meatal swabs and urines were collected at home after recruitment to the study; via the internet programme, <http://www.iwantthekit.org>. The instructions directed the participant to place the tip of a Copan flocked swab at the meatal opening of the urethra to collect the penile-meatal sample. Two ml of urine was collected after the swab onto a Copan sponge-on-a-shaft collection device. Both swab and urine were placed into individual Aptima transport media tubes and mailed to the laboratory for testing. All specimens were tested for CT and NG using the GenProbe Aptima Combo2 Assay and for TV using GenProbe Aptima Analyte Specific Reagents with TV oligonucleotides.

Results—Of 634 men, 86 (13.6%) were positive for CT, 9 (1.4%) were positive for NG and 56 (9.3%) positive for TV. For CT, swab sensitivity was 81/86 (94.2%), and urine sensitivity was 66/86 (76.7%). For NG, swab sensitivity was 9/9 (100%) and urine sensitivity was 8/9 (88.9%). For TV, swab sensitivity was 45/56 (80.4%) and urine sensitivity was 22/56 (39.3%).

Conclusions—Self-obtained penile-meatal swabs provided for the detection of more CT, NG and TV, than urine specimens.

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Contributors LD wrote the manuscript and contributed to performance of tests and provided statistics. PA was involved in testing of samples and data maintenance and wrote the manuscript. NQ was involved in testing of samples and data maintenance. MRB was the project coordinator, prepared kits and wrote the manuscript. CAG designed the study and wrote the manuscript. Y-HH provided statistical analysis of the data presented in this manuscript.

Competing interests CAG has received research funding from Gen-probe and speaker honoraria.

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Data sharing statement There are no unpublished data from this study, but we will make available to others primary data output from the test platform such as Relative Light Units for samples tested.

INTRODUCTION

In the USA, 19 million new cases of sexually transmitted infections (STIs), primarily affecting adolescents and young adults occur annually, costing \$10–17 billion.¹ *Chlamydia trachomatis* is the most prevalent cause of bacterial STI reported to the Centers for Disease Control and Prevention (CDC).² The CDC recommends yearly screening for chlamydia in sexually active women <25 years of age, but not men.³ Screening men for STIs is important because infected asymptomatic men can increase STI sequelae in their female partners. Nucleic acid amplifications tests (NAATs) are recommended by CDC as the test of choice, with urine being the specimen of choice for men.⁴ Since urine samples are difficult to transport, the penile-meatal swab offers a potential alternative. Our internet programme, <http://www.iwantthekit.org>, has shown feasibility for testing home-collected specimens for STIs in men and women.⁵⁶ Our objective was to compare the sensitivity of self collected penile-meatal swabs and urines for the detection of *C. trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) in men.

METHODS

From September 2006–November 2009, 634 men requested and submitted home collection kits for CT, NG and TV testing via <http://www.iwantthekit.org>. Participants were instructed to collect specimens as previously described.⁶ Specimens were tested for CT and NG using Gen-Probe APTIMA Combo2 transcription-mediated amplification, according to manufacturer's instructions, and for TV using GenProbe APTIMA Analyte Specific Reagents with TV oligonucleotides. The cutoff for positive specimens for TV was >60 000 relative light units.⁷ Discordant urine and swab results were tested for CT and NG using GenProbe APTIMA standalone assays, APTIMA *Chlamydia trachomatis* (ACT) or APTIMA *Neisseria gonorrhoeae* (AGC). Discordant testing was not performed for TV.

'Infected patient status' for CT and NG were those who had two positive results by GenProbe Combo2 (urine and swab) or were ACT/AGC positive when specimens were discordant. In the case of TV, any positive specimen result was considered a true positive. This assay had been defined previously as highly sensitive and specific.⁷ The study was approved by the Johns Hopkins University Institutional Review Board and written consent was obtained from participants.

RESULTS

Of the 634 matching swabs and urines, 81 swabs and 66 urines were positive for CT; nine positives for NG by swab and eight by urine (table 1). Of these, 86 were considered to be CT infected (13.6%) and 9 (1.4%) were considered NG infected, after discordant sample analysis. The sensitivities of urines and swabs for CT were 76.7% (95% CI 67% to 84.8%) and 94.2% (95% CI 87.6% to 97.8%); for urines and swabs for NG were 88.9% (95% CI 56.1% to 99.4%) and 100% (95% CI 71.7% to 100.0%), respectively. Forty five swabs and 22 urines were positive for TV. By our definition, 56 (8.8%) were considered to be infected with TV. Of the 56 TV infected men, the sensitivities of urines and swabs were 39.3% (95% CI 27.2% to 52.5%) and 80.4% (95% CI 68.4% to 89.2%).

From 634 matching specimens collected, there were 20 CT, 1 NG from urines and 34 TV urine results considered to be false-negatives, while for penile-meatal swabs there were 5 CT and 11 TV false-negative results (table 1).

DISCUSSION

From September 2006 through 2009 the internet-based STI screening programme began enrolling men to determine if self-collected penile-meatal swabs would be a suitable method for testing men for CT, NG and TV. We demonstrated that in this study of home-collected samples, penile-meatal swabs performed better than urine specimens, when tested by the Gen-Probe assay. Sensitivities of swab and urine specimens for CT detection were 94.2% and 76.74% respectively, and for NG the sensitivity of penile-meatal swabs was 100% while the urine sensitivity was 88.89%, indicating excellent performance for swabs. Unlike other reports, for which glans swabs were used, we found that penile-meatal swabs out-performed urine specimens, perhaps because the swab only collected cells at the meatal orifice of the urethra, rather than the glans area.⁹¹⁰

Significant differences between swab specimens and urines were found when testing for TV: 45 swab specimens were positive, while 22 urine samples were positive. Sensitivities were 39.9% for urines and 80.4% for swab specimens, when any TV positive was considered to be a true positive. Swabs detected 34 more positives than urines, while urine detected 11 positive TV infections not detected by swabs. No explanation for these differences exists, except perhaps there is more lysis of TV in urine or there were differences during home self-collection. The APTIMA TV assay is now US Food and Drug Administration cleared for women; it may be possible in the future to better confirm true positives for trichomonas in urine and swab samples, when further studies involving men are performed.⁸ Determining the most sensitive collection method in men is highly desirable due to the fact that STI infections in men are often asymptomatic, resulting in the spread of infection to partners. Men are often hesitant to be screened for STIs due to the pain associated with the collection of intra-urethral swabs, so more comfortable penile-meatal swabs may overcome that barrier. It appeared that self-collected penile-meatal swabs were acceptable in our earlier study by questionnaires⁶ and for those who participated in this study, since all men but eight submitted both sample types, while the directions listed the swab specimen as not required for study participation.

There are limitations to our study. We were unable to ascertain whether samples were adequately self-collected by the men in our home sampling study. We instructed men to collect the penile-meatal swab first; however, we cannot confirm this was done. Our return rate of home-collection kits requested by men has been lower than 50% and may indicate the collection of penile swabs was not as acceptable as we measured through number of matched sample types returned.

Internet testing programmes have eliminated some barriers that men in low- and high-risk populations face when screening is desired, including transportation, cost, stigma, and confidentiality. The results of this study show self-obtained penile-meatal swab specimens detected more positives than self-obtained urines. Further comparison testing of urine and penile-meatal swab specimens will be needed in order to conclude the best possible sample type when testing men for STIs.

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REFERENCES

1. Chesson HW, Blandford JM, Gift TL, et al. The estimated direct medical cost of sexually transmitted diseases among American Youth, 2000. *Perspect Sex Reprod Health*. 2004; 36:11–19. [PubMed: 14982672]

2. Centers for Disease Control and Prevention. Sexually transmitted disease surveillance, 2010. US Department of Health and Human Services; Atlanta, GA: 2011. p. 1-155.2010. CDC
3. Centers for Disease Control and Prevention. Sexually transmitted disease treatment guidelines 2010. MMWR Dec 17 2010. 2010; 59:1–110. <http://www.cdc.gov/std/treatment/2010>. CDC.
4. Gaydos CA, Ferrero DV, Papp J. Laboratory aspects of screening men for *Chlamydia trachomatis* in the new millennium. Sex Transm Dis. 2008; 35(supple):S45–50.
5. Gaydos CA, Barnes M, Aumakham B, et al. Can E-technology through the Internet be used as a new tool to address the *Chlamydia trachomatis* epidemic by home sampling and vaginal swabs? Sex Transm Dis. 2009; 36:577–80.
6. Chai SJ, Aumakham B, Barnes M, et al. Internet-based screening for sexually transmitted infections to reach nonclinic populations in the community: risk factors for infection in men. Sex Transm Dis. 2010; 37:756–63.
7. Hardick A, Hardick J, Wood BJ, et al. Comparison between the Gen-Probe transcription-mediated amplification *Trichomonas vaginalis* research assay and real-time PCR for *Trichomonas vaginalis* detection using a Roche LightCycler instrument with female self-obtained vaginal swab samples and male urine samples. J Clin Microbiol. 2006; 44:4197–9. [PubMed: 16943353]
8. Schwebke JR, Hobbs M, Taylor S, et al. Molecular testing for *Trichomonas vaginalis* in women: results of a pivotal US clinical trial. J Clin Microbiol. 2011; 49:4106–11. [PubMed: 21940475]
9. Moncada J, Schachter J, Liska S, et al. Evaluation of self-collected glans and rectal swabs from men who have sex with men for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by use of nucleic acid amplification tests. J Clin Microbiol. 2009; 47:1657–62. [PubMed: 19369445]
10. Raheison S, Peuchant O, Clerc M, et al. Glans swabs are not appropriate specimens for diagnosis of *Chlamydia trachomatis* infection in asymptomatic men. J Clin Microbiol. 2009; 47:2686. [PubMed: 19553578]

Key messages

- ▶ Self-collected penile swabs collected at home performed better and identified more positive specimens than did urine samples for the detection of chlamydia, gonorrhoea and trichomonas by nucleic acid amplification tests.
- ▶ Internet recruited participation in home-collected urogenital samples may remove barriers, such as confidentiality and stigma, for men getting screened for sexually transmitted infections.

Comparison of penile swabs to urine specimen for detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* using nucleic acid amplification tests^{*}

Table 1

	Positive by swab	Positive by urine	True positives	Swab sensitivity	95% CI swabs	Urine sensitivity	95% CI urines
<i>Chlamydia trachomatis</i> (CT)	81	66	86	94.2%	67.0 to 84.8	76.7%	87.6 to 97.8
<i>Neisseria gonorrhoeae</i> (NG)	9	8	9	100%	56.1 to 99.4	88.8%	71.7 to 100.0
<i>Trichomonas vaginalis</i> (TV)	45	22	56	80.4%	27.2 to 52.5	39.3%	68.4 to 89.2

^{*} (n=634).