

Self-Testing is a Feasible and Acceptable Option for Identifying Extra-genital Gonorrhea (GC) and Chlamydia (CT) infections in HIV Infected Persons

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Abstract

Background: Compliance with guidelines recommending extra-genital testing for GC/CT in HIV-infected men who have sex with men is variable. Proposed barriers to testing, such as patient reluctance and provider discomfort, could be eliminated by self-testing. In this study, we evaluate the feasibility and acceptability of extra-genital self-testing and assess the adequacy of an oral rinse for the diagnosis of GC/CT infections.

Methods: HIV-infected subjects receiving care at one of three military treatment facilities participated in this study. Subjects received standardized instructions on sample collection and participated in a questionnaire designed to evaluate acceptability of this method. In addition, all subjects underwent testing by their provider. Gen Probe Aptima Combo 2 assay was used for testing the swabs and the rinse.

Results: A total of 148 HIV-infected subjects (median age-43 years, 40% African-Americans and 35% Caucasians) enrolled in the study. Test results are tabulated below. Of the 126 oral rinses tested, 6 (4.7%) tested positive for GC and 1 for CT (0.8%). Of the 6 rinses testing positive for GC, 2 tested negative on concomitantly collected swabs, and 1 swab testing positive for GC was negative on the rinse. Of note, 2 swabs testing positive for GC on self-collection but negative on provider swabs tested positive on the rinse. Over 95% of the subjects indicated that they understood the instructions and had collected the swabs as instructed. Most subjects (≥90%) indicated that they were comfortable collecting the swabs and oral rinses at home. Approximately 15% of the subjects preferred that their providers collected the swabs.

Conclusion: In this study, self-collected samples yielded more positive results than provider collected samples, and the performance of oral rinses and pharyngeal swabs were similar. Our results suggest self-testing is a feasible and acceptable method for collecting extra-genital samples. Adoption of self-testing could improve compliance with the guidelines.

Background

- GC infections are common in the DoD HIV-infected population
- In a representative sample, 5% of those tested were positive for GC at rectal and pharyngeal sites and 7.5% were positive for CT at the rectum
- Extra-genital GC and CT infections are often asymptomatic (Morris CID 2006)-92% of pharyngeal GC & 84 - 86% of rectal GC
- Hence, the CDC recommends, irrespective of the presence or absence of symptoms
 - Testing for rectal infection with *N. gonorrhoeae* and *C. trachomatis* in men who have had receptive anal intercourse during the preceding year
 - Testing for pharyngeal infection with *N. gonorrhoeae* in men who have had receptive oral intercourse during the preceding year.

- Compliance with these guidelines is variable and are ascribed to provider/patient and system issues
- Purported factors that contribute to variable testing rates include
 - lack of an FDA-approved test
 - asymptomatic nature of the infection
 - time required to perform the test
 - provider knowledge and comfort with sexual history assessment
 - patients comfort with testing
- Self-testing could circumvent some of these barriers
- We performed a pilot study
 - To examine the degree of agreement between self- and provider-collected swabs for detecting GC/CT infection
 - To examine the feasibility and acceptability of performing self-administered rectal and pharyngeal swabs and oral rinses in HIV-infected persons

Methods

Study Population:

- HIV-infected DoD beneficiaries receiving care at one of three military treatment facilities (WRNMMC, SAMMC, and NMCS)

Study Design:

- Prospective cross sectional study
- After obtaining informed consent, willing subjects underwent both provider and self-testing at both anal and pharyngeal sites and undertook a mouth wash
- Prior to testing, all subjects were instructed orally on self-testing and all questions were answered. Further, all subjects were provided with a standardized pamphlet that provided a step-by-step basis instruction on self-testing
- In addition, all subjects had the option of watching an instructional video
- Testing material is presented below and can be obtained at the website iwantthekit.org
- 50% of the subjects underwent provider testing followed by self-testing, in the other half the order was reversed
- All participants participated in a self-administered feasibility and acceptability questionnaire
- The Hologic GEN-PROBE APTIMA assay, a Nucleic Acid Amplification Test (NAAT) was used for the study
- All the participating laboratory had undergone a quality control process and were certified to undergo testing at extra-genital sites

Statistical Methods:

- Concordance was assessed between patient and provider testing,
- Results of the feasibility and acceptability questionnaire are tabulated

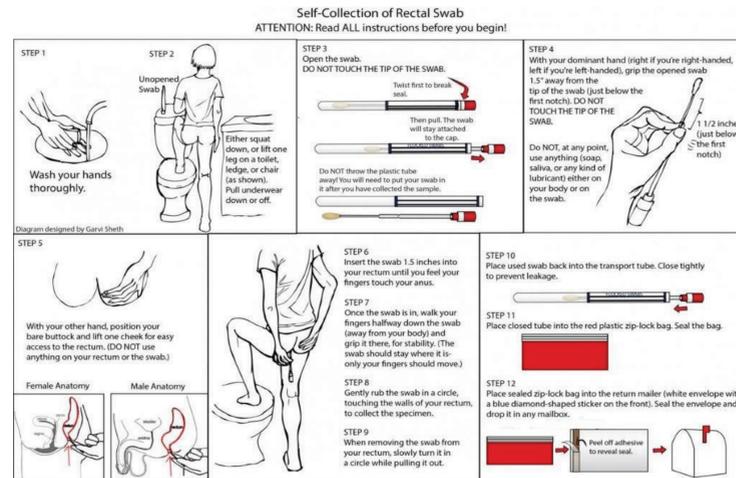


Figure 1- Instructions for Self- Collection of Rectal Samples

Results

Table 1 Performance Characteristics of Self versus Provider Administered Swabs for Identifying GC Infections

	Self Test Positive	Self Test Negative
Gold Standard Positive (Provider Positive)	7	0
Gold Standard Negative (Provider Negative)	3	137

Overall self-testing performed better than provider testing at identifying extragenital GC infections; 2 additional pharyngeal and 1 additional rectal GC infections were identified by self-testing

Table 2 Performance Characteristics of Self versus Provider Administered Swabs for Identifying CT infections

	Self Test Positive	Self Test Negative
Gold Standard (Provider Test positive)	5	1
Gold Standard Negative (Provider Test Negative)	0	141

Overall provider testing performed better than self testing at identifying extra-genital CT infections; 1 additional rectal CT infection identified by provider testing

Table 3 Results of Feasibility and Acceptability Questionnaire

	Strongly Agree/Agree	Neither Disagree nor Agree	Disagree/Slightly Disagree	N/A or missing
Understood the instructions	83 (100%)	0%	0%	0%
Comfort with collecting swabs	76 (91%)	3 (4%)	4 (5%)	0%
Comfortable Collecting swabs at home	74 (89%)	4 (5%)	3 (4%)	2 (2%)
Confident that they collected the swab as instructed	80 (96%)	2 (2%)	1 (1%)	0%
Preferred if the Provider had collected the swabs	15 (18%)	40 (48%)	22 (26%)	6 (7%)

Most subjects undertaking rectal testing understood the instructions and were comfortable and confident about collecting swabs

Most subjects undertaking pharyngeal testing understood the instructions and were comfortable and confident about collecting swabs

	Strongly Agree/Agree	Neither Disagree nor Agree	Disagree/Slightly Disagree	N/A or missing
Understood the instructions	81 (98%)	0%	0%	2 (2%)
Comfort with collecting swabs	81 (98%)	2 (2%)	0%	0%
Comfortable Collecting swabs at home	78 (94%)	1 (1%)	2 (2%)	2 (2%)
Confident that they collected the swab as instructed	82 (99)	0%	1 (1.2%)	0%
Preferred if the Provider had collected the swabs	12 (15%)	42 (51%)	23 (28%)	6 (7%)

Results (cont.)

Table 4 Performance Characteristics of an Oral Mouth wash for identifying GC/CT infections

Oral mouth wash for GC	Provider testing for GC	Self-testing for GC
Positive	Positive	Positive
Positive	Negative	Positive
Positive	Negative	Positive
Positive	Negative	Negative
Positive	Positive	Positive
Positive	Negative	Negative
Positive	Negative	Negative
Negative	Positive	Positive

Overall the mouth wash identified three additional GC cases that were not identified by either provider or self testing, while 1 infection picked up on a pharyngeal swab was negative on the mouth wash. Of note, the two discordant results on the comparison of self vs. provider testing were positive with the mouth wash

Conclusions

- Self-testing identified 2 additional pharyngeal and 1 additional rectal GC infection
- Provider testing identified 1 additional rectal CT infection
- An oral mouth wash (using sterile water) identified 3 additional GC infections
- A majority of the patients undertaking self-testing felt that they understood the instructions, were comfortable collecting swabs and confident that they had collected the tests appropriately. About 15-20% of the patients preferred provider collection over self-testing.
- In summary self-testing is a feasible and acceptable option for collecting extra-genital samples and could improve testing rates

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