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Effectiveness and Patient Acceptability of a Sexually Transmitted Infection Self-testing Program in an HIV Care Setting

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Abstract

Background—Rates of screening for bacterial sexually transmitted infections (STI) among men who have sex with men in HIV care settings remain low despite high prevalence of these infections. STI self-testing may help increase screening rates in clinical settings.

Methods—We implemented an STI self-testing program at a large, urban HIV care clinic, and evaluated its effectiveness and acceptability. We compared measures obtained during the first year of the STI Self-testing Program (Intervention Year, April 1, 2013 – March 31, 2014) to Baseline Year (January 1, 2012 – December 31, 2012) to determine: 1) overall clinic change in STI testing coverage and diagnostic yield and; 2) program-specific outcomes including appropriate anatomic site screening, and patient-reported acceptability.

Results—Overall, testing for gonorrhea and chlamydia increased significantly between Baseline and Intervention year, and 50% more gonococcal and 47% more chlamydial infections were detected. Syphilis testing coverage remained unchanged. Nearly 95% of 350 men who participated in the STI Self-testing program completed site-specific testing appropriately based on self-reported exposures, and 92% rated their self-testing experience as “good” or “very good”.

Conclusions—STI Self-testing in HIV care settings significantly increases testing coverage and detection of gonorrhea and chlamydia, and the program is acceptable to patients. Additional interventions to increase syphilis screening rates are needed.

Keywords

sexually transmitted diseases; HIV clinical care; screening programs; men who have sex with men

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The posters (Figure 1) can be made available for clinical use by request. Please email Amy Radford, Program Director, UW STD PTC at aradford@uw.edu.

Introduction

Bacterial sexually transmitted infections (STI) disproportionately affect HIV-infected men who have sex with men (MSM) compared with HIV-uninfected MSM. In 2012, HIV-infected MSM were diagnosed with primary or secondary syphilis nearly four times more often, and rectal gonorrhea and chlamydia almost twice as often as HIV-uninfected MSM.¹ At the same time, screening for bacterial STI in HIV care settings, particularly for gonorrhea and chlamydia at extragenital sites (i.e. the pharynx and the rectum), remains low.^{2,3} At 8 large urban HIV care clinics in the United States, between 2004 and 2006, only 2.3% - 8.5% of men were screened at the pharynx or rectum for gonorrhea and/or chlamydia.² The U.S. Centers for Disease Control and Prevention (CDC) recommends that all sexually active MSM undergo annual gonorrhea and chlamydia screening of all exposed anatomic sites, and have syphilis and HIV serologies. MSM at high-risk of acquiring STI should be screened as frequently as every three months.⁴ As routine HIV care visits are reduced from quarterly to semi-annually,⁵ high-risk HIV-infected MSM will need ways to screen for STI more frequently.

One option to increase STI screening in this population is patient-collected specimens. Several studies have evaluated the performance and acceptability of patient collected pharyngeal and rectal specimens for gonorrhea and chlamydia nucleic acid amplification tests (NAAT) among MSM. All have found a high (>96%) concordance between patient self-collected extragenital specimens and clinician-collected specimens,⁶⁻⁹ and most found that patients considered self-collection acceptable.^{8,10,11}

As part of a multi-step project aimed at increasing STI diagnosis and treatment among MSM in HIV care, we evaluated STI testing rates and both patient- and provider-related barriers to STI testing at the largest HIV care clinic in the Pacific Northwest.¹² In 2012, only 32% and 29% of HIV-infected MSM received pharyngeal and rectal gonorrhea and chlamydia testing, respectively, at least once in an eighteen month time period in this facility. Providers cited a lack of time, deficiencies in STI testing and treatment knowledge, and discomfort with sexual history taking and genital exams as barriers to more STI testing. Patients indicated that they preferred convenient and more frequent testing. In order to overcome some of these barriers and increase STI screening rates in this HIV care clinic, we developed an STI self-testing program. This paper evaluates the effectiveness and acceptability of this novel STI self-testing program in a large urban HIV care clinic.

Methods

The University of Washington Sexually Transmitted Disease Prevention Training Center (UW PTC) is one of eight regional PTC that aim to educate and train clinicians in STI prevention and management. In 2012, the CDC initiated an effort to increase STI screening in HIV care settings through enhanced technical assistance by the UW PTC. The UW PTC devised a stepwise plan to enhance STI screening. The first step, assessing baseline testing rates and barriers to STI testing, has been described previously.¹² Here we describe and evaluate the STI self-testing program developed for a large HIV care clinic aimed to overcome the barriers elucidated in the first step. Concurrent with the roll-out of this

program, we educated HIV care providers in this clinic about the importance of STI testing among HIV-infected MSM. Because this project was designed as a clinical quality improvement project, human subjects' approval was not required.

Setting for the Intervention: HIV Care Clinic

Harborview's Madison Clinic is the largest HIV care clinic in the Pacific Northwest region of the United States. In 2012, 2,570 HIV-infected patients attended at least one clinic visit. Of these 2,570 patients, 81% were men, 66% (n=1374) of the men were identified as MSM by their HIV care provider. Madison Clinic represents a community campus partnership. Although the clinic receives Ryan White Funding and is part of the Seattle – King County Harborview Medical Center, University of Washington physicians provide all medical care.

Overview of STI Self-testing Program

In order to overcome several of the barriers to STI testing elicited in the first steps of this program (described in detail elsewhere),¹² we designed a self-testing program that could be initiated either by providers at the end of a clinic visit or by patients at their convenience during clinic hours. We advertised the STI self-testing program in the waiting room with a large poster and pamphlets. Prior to self-testing, either the provider or a triage nurse would first ensure that the patient did not have symptoms of an active STI. Once a provider or nurse ensured that the patient was asymptomatic and thus eligible for STI screening, the provider or nurse gave him the Patient Assessment form and personalized labels, and directed the patient to the self-testing room. (Patients who reported symptoms or exposure to a sexual partner with an STI were seen by the attending physician and treated empirically.) The Patient Assessment form asked the patient a series of questions about their sexual exposures and based on those results advises him on which specimens to collect. The self-testing room is a restroom located centrally in the clinic near the nursing station. Large, visually appealing posters are posted on the wall to help walk the patient through the self-testing process both visually and verbally (Figure 1). The posters commence with washing one's hands and include instructions on labeling the tubes, anatomy and specimen collection. Additionally, a cabinet houses all necessary supplies including Aptima (Hologic (GenProbe), San Diego, CA) collection kits, urine collection cups, labels to indicate "Bottom" and "Throat" and biohazard bags. After completing the collection of pharyngeal, rectal and urine specimens, nursing staff directs patients to the central laboratory for syphilis serology. Laboratory testing of specimens collected through provider-initiated self-testing were ordered and the results managed by the physician recommending testing, and those specimens collected via self-initiated STI self-testing were ordered via standing orders. Based on the patient's Patient Assessment form, the nurse completed the standing order form which would be signed by the attending physician of the day. All tests ordered through the latter mechanism were followed by a single physician who ensured timely and appropriate treatment.

Evaluation: Effectiveness

In order to assess the effectiveness of the STI self-testing program, we evaluated data from the clinic overall, and from patients known to have participated in the STI self-testing program. We aimed to determine the change in testing coverage, number of gonococcal and

chlamydial infections detected, and test positivity in the clinic overall. Among the patients who performed self-testing, we aimed to determine the 1) proportion of patients who entered the program through physician referral or self-referral; 2) proportion of patient who obtained specimens from indicated anatomic sites based on their sexual exposures; 3) proportion of specimens incorrectly obtained or labeled; and 4) number of infections detected and test positivity.

We used two years of clinic data to conduct a pre- and post-intervention comparison of testing coverage, infections detected and test positivity. Data from the 2012 calendar year served as the baseline. The intervention period data spanned from April 1, 2013 until March 31, 2014. We did not include January through March 2013 in this analysis because during that time period we educated providers and began the self-testing program roll-out. Data were extracted in aggregate from the electronic medical record and include all STI testing that occurred at the HIV care clinic during the respective time periods among MSM. MSM were defined through provider documentation. Testing coverage was defined as the proportion of MSM engaged in care who had at least one test (for each particular anatomic site for both gonorrhea and chlamydia) divided by the total number of MSM engaged in care during that time period. Engagement in care was determined as attending at least 1 primary care or nurse visits during each of the 12 month study periods (i.e. Baseline, 2012 or Intervention April 2013 – March 2014). We calculated test positivity as the number of positive tests divided by the number of tests performed during the study periods. We compared these proportions using chi-square.

In order to analyze the effectiveness of the STI self-testing program, we collected Patient Assessment forms for participating men. We linked these forms with the patient's electronic medical record. Because the nursing staff collected these forms opportunistically, we cannot determine what proportion of self-testers they represent. We determined the proportion of self-testers who self-referred, the proportion who completed the appropriate testing based on self-reported sexual exposures, and the number of infections diagnosed through self-testing. We also identified the number of specimens that were incorrectly processed by self-testers.

Evaluation: Acceptability

We assessed patient acceptability of this program in two ways. We offered self-testers a short survey at the end of their self-testing experience in order to assess the usability of the process. Eleven months after the start of the STI self-testing program we offered a survey to all MSM patients in the waiting room in order to gauge the awareness and perceptions of the program. Both surveys were brief comprising of only 10–14 questions each and used a multiple choice format. Results were tallied and are reported as proportions. All statistical analyses were conducted in Stata 12.0 (StataCorp, College Station, TX); $p < 0.05$ was considered significant.

Results

Effectiveness

Similar numbers of MSM patients were engaged in care during the Baseline Year (N=1520) and the Intervention Year (N=1510). Following the institution of the STI self-testing program, all gonorrhea and chlamydia testing coverage significantly increased (Table 1), including a 32% increase in pharyngeal, from 444 to 586 tests performed, and a 33% increase in rectal gonorrhea and chlamydia testing, from 390 to 520 tests performed. Testing for gonorrhea and chlamydia at all three anatomic sites (pharynx, rectum and urine) concurrently increased by over 90% (from 16% to 31%, $p<0.001$). Despite significant gains in testing coverage, the absolute testing coverage remained low: only 39% tested at the pharynx, 34% at the rectum, and 46% at the urethra. Complete testing, that is testing at all three sites, was completed by only 31% of MSM engaged in care. There was no appreciable change in syphilis serologic screening coverage.

We detected 49 more gonococcal infections and 45 more chlamydial infections in the Intervention year than in the Baseline year, a 50% and 47% increased yield for gonorrhea and chlamydia case detection respectively (Table 2). This included 31 pharyngeal and 18 rectal gonorrhea infections, and 4 pharyngeal and 19 rectal chlamydia infections. The test positivity for pharyngeal gonorrhea increased by 22% from 6.4% to 7.8% ($p=0.292$) and for pharyngeal chlamydia by 21% from 1.4% to 1.7% ($p=0.639$). Test positivity for rectal infections declined by 4% ($p=0.836$) for gonorrhea and 16% ($p=0.239$) for chlamydia. Urethral chlamydia test positivity increased by 33% ($p=0.076$).

Nursing staff collected 390 Patient Assessment Forms, of which 350 (89.5%) were linkable to patient records. Of the 350 linkable records, one-quarter self-referred for STI self-testing, and the remainder were referred by their provider. Overall, 89 individuals (26%) were diagnosed with 131 infections. Of the 350 patients with complete data, 313 (89.4%) reported performing oral sex on their Patient Assessment form, and 297 (94.9%) of those men collected pharyngeal specimens for gonorrhea and chlamydia testing. An additional 23 individuals provided self-collected pharyngeal specimens but did not endorse giving oral sex. Two pharyngeal specimens (0.6%) were rejected by the laboratory for labeling and/or collection errors. Of the 318 tested specimens, 32 (10%) were positive for gonorrhea, including 3 positive results among men who self-tested but did not endorse performing fellatio, and 3 (0.9%) were positive for chlamydia.

Two-hundred and eighty-two (80.6%) men reported receptive anal intercourse on their Patient Assessment form, and 272 (96.5%) of them provided rectal specimens for STI testing. Another 31 patients also provided rectal specimens but did not endorse receptive anal intercourse on their Patient Assessment Form. The laboratory rejected two (0.7%) specimens for collection issues. Of the 301 specimens tested, 33 (11.0%) were positive for gonorrhea, including 4 positive tests among men who did not report receptive anal intercourse, and 28 (9.3%) specimens were positive for chlamydia.

Men who participated in the STI self-testing program submitted 308 urine specimens, one of which was rejected for incorrect labeling. Urethral gonorrhea and chlamydial infection was

diagnosed in 8 (2.6%) and 13 (4.2%) of tested men, respectively. Half of the urethritis cases occurred in men referred by providers. Eighty men were diagnosed with either gonorrhea or chlamydia or both in this analysis, and 61 (76%) of them were infected only at an extragenital site. This included 43 of 51 (84%) gonococcal infections and 29 of 42 (69%) of chlamydial infections.

Of the 350 MSM included in this analysis and eligible for syphilis testing, 268 (76.6%) underwent syphilis testing. The proportion undergoing syphilis testing did not differ between those who were referred by provider (77.8%) and those who self-referred (76.4%). Fourteen (5.2%) of the men tested for syphilis were diagnosed with a new syphilis infection.

Clinic staff documented treatment in the electronic medical record for 84/89 (94%) of the men with at least one STD. Treatment occurred at a median of 4 days (range 0 to 90 days) after testing. The five infections without documented treatment included one individual with both rectal and urethral chlamydia, two individuals with pharyngeal gonorrhea, one isolated rectal chlamydia infections and one isolated urethral chlamydia infection.

Patient Acceptability

Of the 390 men who participated in the STI self-testing program, 79 (20%) completed the end of visit survey and 92% rated their overall experience as “very good” or “good.” Most (85%) found the Patient Assessment Form to be “extremely helpful”, and the majority reported that the instructional posters (Figure 1) were “extremely helpful” (99% throat poster, 87% rectal poster). Patients also indicated that the supplies were “very easy” (98%) to locate.

Ninety-eight MSM completed the survey offered in the waiting room 11 months following the inception of the STI self-testing program, and the majority (n=75, 77%) reported seeking STI testing at the Madison Clinic . About half (n=43) of the respondents had heard about the STI self-testing program, and just 26 (28%) had self-tested. Of the 26 who self-tested, 68% had been referred by their provider and 32% self-referred. Half of the respondents who had self-tested thought that the availability of the STI self-testing program increased their frequency of STI testing, and all indicated that the STI self-testing experienced was either better (54%) or no different (46%) than STI testing by their provider. The majority (76%) felt that self-testing did not affect their relationship with their provider. Overall, respondents who had completed STI self-testing rated their overall experience as good (46%) or excellent (54%), and almost all (96%) would recommend the STI self-testing program to a friend.

Discussion

Our STI self-testing program for HIV-infected MSM in a large urban HIV care setting was effective in increasing both gonorrhea and chlamydia testing coverage and the detection of asymptomatic gonococcal and chlamydial infections. Importantly, after the implementation of this intervention, rates of testing at all three anatomic sites increased significantly. As the majority of gonococcal and chlamydial infections in MSM are detected at extra-genital sites and are asymptomatic, these infections would be missed by urine testing alone, highlighting the importance of testing at all exposed anatomic sites. However, despite improvements in

STI testing coverage after the implementation of a STI self-testing program, testing coverage remained at a suboptimal level.

According to the CDC all sexually active MSM should undergo annual STI testing at all exposed sites. Even with a 91% increase in “complete” testing, that is testing at all three anatomic sites, less than one-third of the clinics’ MSM engaged in care were tested. Although our data do not permit us to associate sexual behavior with testing data, based on previously described sexual behavior data from MSM in this clinic,¹² more than 30% of men should receive complete testing at least once per year. Although we cannot define the optimal testing coverage goal for a given setting, presumably that number should be in excess of 60%. Improving patients’ self-assessment of STI risk might be one way to increase self-referral to STI testing. Asking men to complete a computer assisted self-interview (CASI) that focuses on sexual behavior prior to clinic visits and makes recommendations based on their answers, similar to other CASIs used to assess depression and medication adherence,¹³ might lead more men to request STI self-testing. Alternatively, this same CASI could alert physicians to their patient’s risk and recommend STI testing.

Concomitant with the increase in testing, we also documented an increase in the number of infections detected – 49 more gonococcal and 45 more chlamydial infections. For gonorrhea, these were primarily extra-genital infections, as would be expected because the program was designed to detect asymptomatic infections, and gonococcal urethritis is usually symptomatic. However, for chlamydia, these additional infections were a mix of rectal and urethral infections. Although urethritis is often thought of as symptomatic, this finding serves as a reminder that 40% of urethral chlamydial infections are asymptomatic.¹⁴

Unfortunately, our STI self-testing program did not expand syphilis serologic testing coverage. Although it is unclear why syphilis testing remained at 65% - 75% in both analyses, we hypothesize that the additional component of visiting the laboratory in a separate location from the clinic was a barrier. The additional time required for this step might have deterred compliance with this step. Alternatively, men may not have known that complete STI testing includes serologic examination for syphilis. With the current syphilis epidemic among HIV-infected MSM in the United States,¹⁵ and in particular in Seattle,¹⁶ methods to improve syphilis testing in this population are needed. Two studies from Melbourne, Australia suggest that computer prompts in the electronic medical record¹⁷ and routinizing syphilis serologies with every routine HIV laboratory monitoring¹⁸ increase both testing and diagnosis. Either one of these interventions could be implemented in this clinical setting.

Providers referred patients for STI self-testing in 75% of the testing episodes, a finding consistent in both the evaluation of patient testing episodes as well as in the waiting room survey. The frequency of provider referral suggests provider acceptability of the program, presumably due to time-saving or other factors. Attempts to increase bacterial STI screening in HIV care settings that have bypassed the clinician have been met with success. In London, an intervention for a nurse-led STI testing clinic increased STI testing at the time of HIV diagnosis from 39% to 52%.¹⁹ At the same time, patients also find the STI self-testing

program highly acceptable, a finding consistent with previously published self-testing programs.^{8,10,11}

There are several limitations to this evaluation. Due to the clinical nature of this intervention, we were limited in the data available to evaluate it. In our pre- and post-intervention comparison, we were unable to assess risk status and anatomic sites of exposure to determine adequacy of screening. The CDC recommends screening at all exposed sites at least annually and as frequently as every 3 to 6 months for MSM at higher risk.⁴ We were unable to assess for those standards given the limitations of our data. Additionally, in our analysis of MSM who participated in the STI self-testing program, we could only evaluate testing episodes in which a member of the nursing staff retained their patient assessment form. Although we believe that there was a high degree of completion on this task, certainly some patient assessment forms were missed. Thus, we do not have an accurate count of how many MSM participated in the program in its first year. However, we know that there were 1096 urine tests submitted during the year, and if our waiting room survey is an accurate reflection of the proportion of men who tested through the STI self-testing program (~30%), our analysis represents the majority of the participants. Second, although the STI self-testing program was designed as a screening program, we cannot be assured that participants were entirely asymptomatic, and thus we report testing coverage in lieu of screening coverage data.

Given the ongoing epidemic of bacterial STI among HIV-infected MSM and the lack of biomedical preventions for bacterial STI at the current time, screening and treatment is the mainstay of public health control methods. However, multiple studies have shown that relying on medical providers to conduct complete STI testing in HIV care settings at the recommended frequencies is likely not enough.^{2,3} Innovative approaches to systematically incorporate STI testing in HIV care are needed. The STI self-testing program described here is one such option.

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TEST YOURSELF

The Visual Guide for a Self-collected Rectal Swab

1 Wash your hands with soap and water.

2 Remove the transport tube and collection swab from packaging.

3 Label the transport tube with your **Patient label**.

4 Label the transport tube with the **Rectal label**.

5 Open the package containing the collection swab.

6 Firmly hold the collection swab above the dashed line (closer to the swab tip).

7 Get into a comfortable position that allows you access to your anus. Putting your foot on the step stool may help.

8 Gently insert the swab 1 inch into the rectum and twirl the swab in a circle at least 5 times.

9 Unscrew the cap from the transport tube.

10 Place the collection swab into the transport tube, snapping it at dashed line.

11 Put the cap back on the transport tube and twist it closed to prevent leaks.

12 Put the transport tube into the biohazard bag.

13 Wash your hands with soap and water.

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TEST YOURSELF

The Visual Guide for a
Self-collected Throat Swab

1 Wash your hands with soap and water.

2 Remove the transport tube and collection swab from packaging.

3 Label the transport tube with your Patient label.

4 Label the transport tube with the Throat label.

5 Open the package containing the collection swab.

6 Hold the collection swab far enough from the tip.

7 Say AHH... and reach the collection swab into your mouth to gently touch your throat.

8 Gently rub the swab tip on your throat side to side, up and down at least 5 times.

9 Unscrew the cap from the transport tube.

10 Place the collection swab into the transport tube, snapping it at dashed line.

11 Put the cap back on the transport tube and twist it closed to prevent leaks.

12 Put the transport tube into the biohazard bag.

13 Wash your hands with soap and water.

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Figure 1.
Extragenital STI Self-testing Posters to Help Patients through the Process of Self-collection

Table 1

Comparison of Testing Coverage among MSM attending at least 1 HIV primary care or nurse visit: Baseline Year (2012) vs. Intervention Year (April 1, 2013–March 31, 2014)

	Baseline N= 1520	Intervention N= 1510	Percent change	p-value *
Any site GC/CT	670 (44.1%)	770 (51.0%)	+15.0%	<0.001
Pharyngeal GC/CT	444 (29.2%)	586 (38.8%)	+32.0%	<0.001
Rectal GC/CT	390 (25.7%)	520 (34.4%)	+33.3%	<0.001
Urethral GC/CT	510 (33.6%)	697 (46.2%)	+36.7%	<0.001
All three sites	243 (16.0%)	466 (30.9%)	+91.8%	<0.001
Syphilis	962 (63.3%)	976 (64.6%)	+1.5%	0.440

*
chi-square

Table 2

Infections Detected, Test Positivity and Change in Detected Infections among all Gonorrhea and Chlamydia Testing done in MSM at Madison Clinic: Baseline (2012) vs. Intervention Year (April 1, 2013–March 31, 2014)

	Baseline	Intervention	Change in Detected Infections	Percent change in Detected Infections
GONORRHEA				
Overall	98 / 1794 (5.5%)	147 / 2706 (5.4%)	+49	+50%
Pharyngeal	41 / 642 (6.4%)	72 / 926 (7.8%)	+ 31	+76%
Rectal	43 / 557 (7.7%)	61 / 828 (7.4%)	+18	+42%
Urethral	18 / 679 (2.7%)	16 / 1096 (1.5%)	−2	−11%
CHLAMYDIA				
Overall	96 / 1794 (5.4%)	141 / 2706 (5.2%)	+45	+47%
Pharyngeal	9 / 642 (1.4%)	13 / 926 (1.7%)	+4	+44%
Rectal	74 / 557 (13.3%)	93 / 828 (11.2%)	+19	+26%
Urethral	13 / 679 (2.4%)	35 / 1096 (3.2%)	+22	+169%