Rectal Specimen Self-Collection for Chlamydia and Gonorrhea Screening: A Cross-Sectional Pilot Feasibility Study at a Community Health Center

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Abstract

Purpose: Rectal self-collection increases detection of asymptomatic chlamydia and gonorrhea among at-risk men who have sex with men and transgender women. This feasibility study assessed patient and primary care provider (PCP) perceptions of implementing rectal self-collection at a large, general practice community health center.

Methods: PCPs offered rectal self-collection to at-risk patients due for routine or risk-based screening. Patients and PCPs completed brief cross-sectional assessments.

Results: Rectal screening was feasible in a large primary care setting despite clinical time and resource constraints and was universally accepted when offered (n=36; 91.6% of whom opted for self-collection). Both PCPs and patients preferred self-collection over clinician-collection.

Conclusions: Rectal self-collection can increase screening and improve extra-genital chlamydia and gonorrhea diagnoses. Adoption of rectal self-collection in primary care is a scalable, useful, and acceptable strategy to increase extra-genital screening among medically underserved sexual and gender minority patients and combat the current sexually-transmitted infection epidemic.

Introduction

Sexually transmitted infection (STI) rates continue to rise in the United States, with 1.8 million cases of *Chlamydia trachomatis* (chlamydia) and 583,000 cases of *Neisseria gonorrhoeae* (gonorrhea) reported in 2018. [1] Those at increased risk include racial and ethnic minorities and men who have sex with men (MSM); [1, 2] the burden of STIs is further increased for medically underserved and vulnerable patients. [3] A 2018 survey of 326 local health departments in the United States determined that over one-third of service areas had no clinics that offered STI screening, diagnosis, and treatment services for patients in the healthcare safety-net. [4] Safety-net treatment providers such as Federally Qualified Health Centers (FQHCs) allow access to screening, diagnosis, and treatment regardless of insurance status or ability to pay, and provide general primary care services to more than 30 million Americans at over 13,000 delivery sites, [5] presenting an opportunity to fill STI service coverage gaps.

The United States STI National Strategic Plan 2021–2025 identifies MSM as a priority population for STI risk reduction and care improvement. [2] Though chlamydia and gonorrhea testing in MSM has predominantly focused on urethral detection, MSM are also at increased risk for extra-genital (pharyngeal and rectal) STIs, based on exposure through oral and anal sex. Extra-genital chlamydia and gonorrhea may be present without concurrent urogenital infection [6] and are frequently asymptomatic among MSM, [7, 8] which increases risk of transmission to sexual partners [9, 10] and perpetuates reservoirs of infection. [9, 11] Given estimated mean prevalence rates among MSM of approximately 9% and 5% for rectal chlamydia and gonorrhea, respectively, [8, 12] routine rectal screening is indicated at least annually for asymptomatic MSM who engage in receptive anal sex, with more frequent screening indicated for those who engage in ongoing at-risk sexual behaviors and/or have multiple partners or partners who

have other sexual partners. [13] Screening recommendations for transgender women, who may engage in some of the same sexual practices as MSM, are currently based on individual sexual behavior. [13] Though studies of STI prevalence among transgender women have been limited in number and scope and have primarily focused on urogenital detection, a 2020 meta-analysis found estimated STI prevalence rates in transgender women ranging from 2.1%-19.1% for gonorrhea and 2.7%-24.7% for chlamydia.[14]

Barriers to chlamydia and gonorrhea rectal screening include increased visit complexity and time compared to urogenital testing; lack of provider awareness regarding need for extra-genital screening; stigma experienced or perceived by patients and/or providers related to sexual behavior; and discomfort with taking or providing a detailed sexual risk assessment and with the collection of rectal samples. [7] Self-collection of extra-genital samples for STI screening is one potential method of overcoming these barriers. Self-collection has been shown to identify asymptomatic infection, [8, 15] to be equally as or more effective than clinician-collection, [16] and to be preferred by patients.[17, 18] Self-collection of rectal samples may increase screening rates for at-risk MSM [19] by reducing stigma, improving patient comfort, [20] and reducing demand on healthcare provider time.[8]

Though self-collection in primary care has the potential to expand access to extra-genital screening, the feasibility of implementing routine self-collection for rectal chlamydia and gonorrhea during a primary care visit at a general medical practice FQHC has not been assessed. This pilot study was conducted among asymptomatic adult MSM and transgender female patients of three primary care providers (PCPs) at Community Health Center, Inc., a large, multi-site FQHC in Connecticut. We hypothesized that self-collection would be easy to adopt and would be accepted and preferred by the majority of patients and PCPs.

Methods

Our cross-sectional, observational study enrolled MSM and transgender female patients identified by the provider as requiring rectal chlamydia and gonorrhea screening during a primary care medical visit between 3/1/2018 and 3/1/2020. Those offered study participation had a visit during the study period, were 18+, English-speaking, reported history of receptive anal sex, and were due for routine or risk-based rectal STI testing.

Workflow. PCPs identified eligible patients during medical visits based on sexual orientation and gender identity (SOGI) data from the electronic health record, sexual risk assessments, and recent STI testing. Patients agreeing to rectal STI screening were offered participation in the rectal self-collection study or standard of care which would require the patient to undress, be draped, and have a chaperone present with the PCP for the intimate examination and specimen collection. Patients who opted to participate in the study were consented by the PCP or medical assistant (MA) at the end of the medical visit, verbally instructed on how to self-collect, and provided with a set of printed instructions. MAs provided the instruction and received the self-collected specimen, which allowed the PCP to wrap up the medical visit

as per their typical workflow, finish up the medical progress note, and move on to the next scheduled patient. Patients were given the opportunity to ask questions and then were left alone to self-collect their specimen in the exam room or bathroom. Almost all patients opted to stay in the exam room for collection. Patients and PCPs completed a short survey after self-collection or at the end of the study, respectively.

Descriptive statistics were analyzed using SPSS version 22 (Armonk, NY). The study was approved by the Institutional Review Board at Community Health Center, Inc.

Results

Approximately 6.5% (n = 87) of the 1,345 patients who presented for care during the study period identified as MSM (n = 67) or transgender female (n = 20). Twelve of the 87 had had a rectal STI screen within the past year while 39 had screening deferred (e.g. deemed not medically necessary or was a missed opportunity), leaving 36 patients who required and agreed to rectal screening and were offered participation in the self-collection study. Three patients (8.3%) declined self-collection due to current or prior history of rectal symptoms and proceeded with clinician-collection. All other patients (n = 33, 91.7%) opted for self-collection. (Fig. 1).

All of the 33 patients who completed self-collection were assigned male sex at birth (n = 33; 100%) with 26 identifying their gender as male (78.8%), five as transgender female (15.2%), and two (6.0%) chose not to disclose. Participants were 39.4% White, 18.2% Black, 39.4% Hispanic/Latinx, and 3.0% other race/ethnicity, with mean age 40.0 (range: 19–59, SD: 10.3). Most identified their sexual orientation as gay (n = 23, 69.7%). (Table 1).

Table 1
Patient Demographics (n = 33)

	Self-Collection (n = 33)
	n(%)
Age	
18−29	6(18.2)
30−39	10(30.3)
40−49	12(36.4)
50−59	5(15.2)
60+	0(0.0)
Race	
Non-Hispanic White	13(39.4)
Non-Hispanic Black or African American	6(18.2)
Hispanic/Latinx	13(39.4)
Other	1(3.0)
Sexual Orientation	
Straight or Heterosexual	2(6.1)
Gay or Homosexual	23(69.7)
Bisexual	2(6.1)
Choose Not to Disclose	3(9.1)
Other	3(9.1)
Gender Identity	
Male	26(78.8)
Female or Transgender Female	5(15.2)
Genderqueer	0(0.0)
Choose Not to Disclose	2(6.1)
Other	0(0.0)

The most common self-collection questions patients asked were: (1) how to seal the swab into the tube after collection; (2) how far into the rectum to insert the swab; and (3) how much to move the swab once inserted rectally. Nearly all self-collected specimens (32/33; 97.0%) were suitable for laboratory analysis.

All 33 study participants endorsed comfort with self-collection and the majority agreed self-collection was easy (n = 31; 93.9%). Two-thirds of participants preferred self-collection over clinician-collection (n = 23; 69.7%), and the remaining third expressed no preference (n = 10; 30.3%). All PCPs (n = 3) agreed that self-collection was time-efficient and not disruptive to the clinical workflow. Two agreed and one somewhat agreed that self-collection increased their likelihood to obtain a rectal specimen from a patient. (Table 2)

Table 2
Patient and PCP Self-Collection Survey Results

	Agree 5.0	Somewhat Agree 4.0	Neutral 3.0	Somewhat Disagree 2.0	Disagree 1.0	Average Score
Patient Survey (n = 33)	n(%)	n(%)	n(%)	n(%)	n(%)	
The instructions were easy to follow	31(93.9)	2(6.1)	0(0.0)	0(0.0)	0(0.0)	4.94
It was easy to swab my own bottom	27(81.8)	4(12.1)	2(6.1)	0(0.0)	0(0.0)	4.76
I felt comfortable swabbing my own bottom	31(93.9)	2(6.1)	0(0.0)	0(0.0)	0(0.0)	4.94
I did not feel pain when swabbing my own bottom	22(66.7)	1(3.0)	4(12.1)	5(15.2)	1(3.0)	4.15
I felt I was able to ask questions about swabbing my own bottom	32(97.0)	1(3.0)	0(0.0)	0(0.0)	0(0.0)	4.97
I prefer to swab my own bottom (vs. no preference or clinician-collection)*	23(69.7)	N/A	10(30.3)	N/A	0(0.0)	4.39
PCP Survey (n = 3)	n(%)	n(%)	n(%)	n(%)	n(%)	
Explaining the rectal swab self-collection procedure to the patient was easy	3(100.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	5.00
Patient rectal swab collection was more time-efficient than provider collection	3(100.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	5.00
Patient rectal swab collection was less disruptive to the clinical visit compared to provider collection	3(100.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	5.00
Patient self-collection increases the likelihood that I would collect a rectal swab during a clinical visit	2(66.6)	1(33.3)	0(0.0)	0(0.0)	0(0.0)	4.67

	Agree 5.0	Somewhat Agree 4.0	Neutral 3.0	Somewhat Disagree 2.0	Disagree 1.0	Average Score
Given a choice, I prefer that patients collect their own rectal swabs (vs. no preference or clinician-collection)*	2(66.6)	N/A	1(33.3)	N/A	0(0.0)	4.33

Discussion

This implementation study assessed provider and patient acceptability of rectal self-collection and feasibility of offering self-collection during a medical visit. We found that incorporating self-collection for rectal chlamydia and gonorrhea screening among MSM and transgender women was effective, efficient, highly acceptable, and preferred by patients and clinicians. Our findings are in line with other studies indicating that patients prefer self-collection [17,18] and provide additional insight into how to integrate self-collection into routine primary care at a large FQHC serving the general population. Self-collection in FQHCs, which care for patients in the healthcare safety-net, many of whom are racial and ethnic minorities who are disproportionately affected by STIs relative to non-Hispanic white patients, [1] is a potential strategy to overcome access barriers.

Neglecting extra-genital testing in MSM and transgender women leads to missed diagnoses and can contribute to persistent disparities in STIs among sexual and gender minorities. Rectal mucosa is vulnerable to STIs and symptomatic or asymptomatic extra-genital chlamydia and gonorrhea infections are associated with increased risk of HIV transmission among MSM. [7,13,21] Identifying rectal infections, especially those without symptoms, provides an opportunity to discuss HIV risk and offer prevention strategies, such as HIV pre-exposure prophylaxis (PrEP). Since MSM and transgender women, especially those of color, may not have access to LGBT-focused health centers and are the most vulnerable to acquiring HIV, offering rectal self-collection in FQHCs may be the first critical step to STI and HIV prevention. [1,13]

The Centers for Disease Control and Prevention's Recommendations for Providing Quality Sexually Transmitted Disease Clinical Services (2020) note that STIs are increasingly treated in primary care [22] and recommend that basic STI services should be made available in these settings. However, primary care community health centers, including FQHCs, have only recently (January 2018) been required to collect SOGI data [23], and often do not conduct risk-based sexual health screening. [24] Though our pilot study demonstrates the feasibility of offering rectal STI screening during a primary care visit, further studies are needed to determine how primary care clinics can increase their capacity to offer comprehensive STI clinical services including sexual risk assessment, risk reduction counseling, and partner-services, which are commonly available in specialty STI clinics. [25]

Nevertheless, continued emphasis on SOGI data collection in primary care health centers is critical. SOGI information must be recorded in the electronic health record in a systematic manner that allows for effective patient-level use by clinical teams and organization-level use for population health. The majority of our sample (n=1191, 88.6%) had SOGI data on file. We found that 7.3% (n=87) of these patients self-identified as MSM or transgender female, which exceeds the estimated percentage of U.S. adults who self-report any sexual and gender minority identity (4.5%). [26] This illustrates the crucial role that FQHCs can play in tackling the STI burden that many members of sexual and gender minority populations carry, and which fuels the STI epidemic.

Clinical dashboards using SOGI data can thus identify patients with potential risks for STIs and consequently trigger any member of the clinical team to offer rectal self-collection, standardize and normalize STI screening, and provide opportunities to offer PrEP and maximize HIV prevention efforts. As this study demonstrated, MAs were able to facilitate patient rectal self-collection. Since nurses and MAs are already able to collect pharyngeal and urine specimens, rectal self-collection can shift the burden of STI testing from PCPs to clinical support staff by extending capability for MAs to assist with screening and for nurses to conduct comprehensive assessment and screening under standing orders from a PCP.

Limitations of our findings include a small sample size concentrated in a primary care FQHC which may affect generalizability and lack of a clinician-collection comparison group. Future studies should draw conclusions about the amount of time saved through specimen self-collection and whether it presents significant additional workload for non-PCP members of the primary care team. The FQHC where this study was conducted began routinely collecting SOGI in 2016, which helped provide PCPs with the information necessary to identify potential at-risk individuals and to offer appropriate extra-genital STI screening. We did not capture specific data on the number of individuals with a missed opportunity for screening. Future studies should assess extra-genital screening rates before and after introduction of SOGI collection and determine whether systematic use of SOGI data from the electronic health record could improve rates. Our pilot study was conducted in a U.S. state and at a medical practice that provided above-average acceptance, support, and affirmation of sexual and gender minority people, which may limit generalizability of these findings to other settings where patients may feel less accepted and potentially uncomfortable disclosing sexual behaviors with their primary care team.

Conclusion

STI rates continue to rise in the U.S., disproportionately affecting certain populations like MSM and transgender women, particularly those of racial and ethnic minorities. As access to STI clinics becomes more limited, primary care centers, especially those catering to the medically underserved, need to ensure they offer comprehensive STI services. Rectal self-collection can and should be considered as part of any strategy to increase STI screening rates given that rectal specimen collection is the most invasive, discomforting, and time-consuming of all STI testing required for MSM and transgender women. Our study demonstrated that rectal self-collection was highly accepted and preferred by both PCPs and patients and was easily implemented in a busy safety-net primary care setting.

Declarations

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Figures

Adult patients in PCPs' panels with visit 3/1/18-3/1/20 (N =1345)

Provided sexual orientation and gender identity data (n = 1191; 88.6%)

Did not provide sexual orientation and gender identity data (n = 154; 11.4%)

MSM or transgender female (n=87; 6.5%)

Not MSM or transgender female (n= 1258; 93.5%)

Had not received rectal screen for chlamydia and gonorrhea in past 12 months (n=75; 5.6%)

Received rectal screen for chlamydia and gonorrhea in past 12 months (n= 12; 0.9%)

Offered self-collection (n=36; 2.7%)

Screening not medically necessary or missed opportunity (n= 39, 2.9%)

Completed self-collection (n=33; 2.5%)
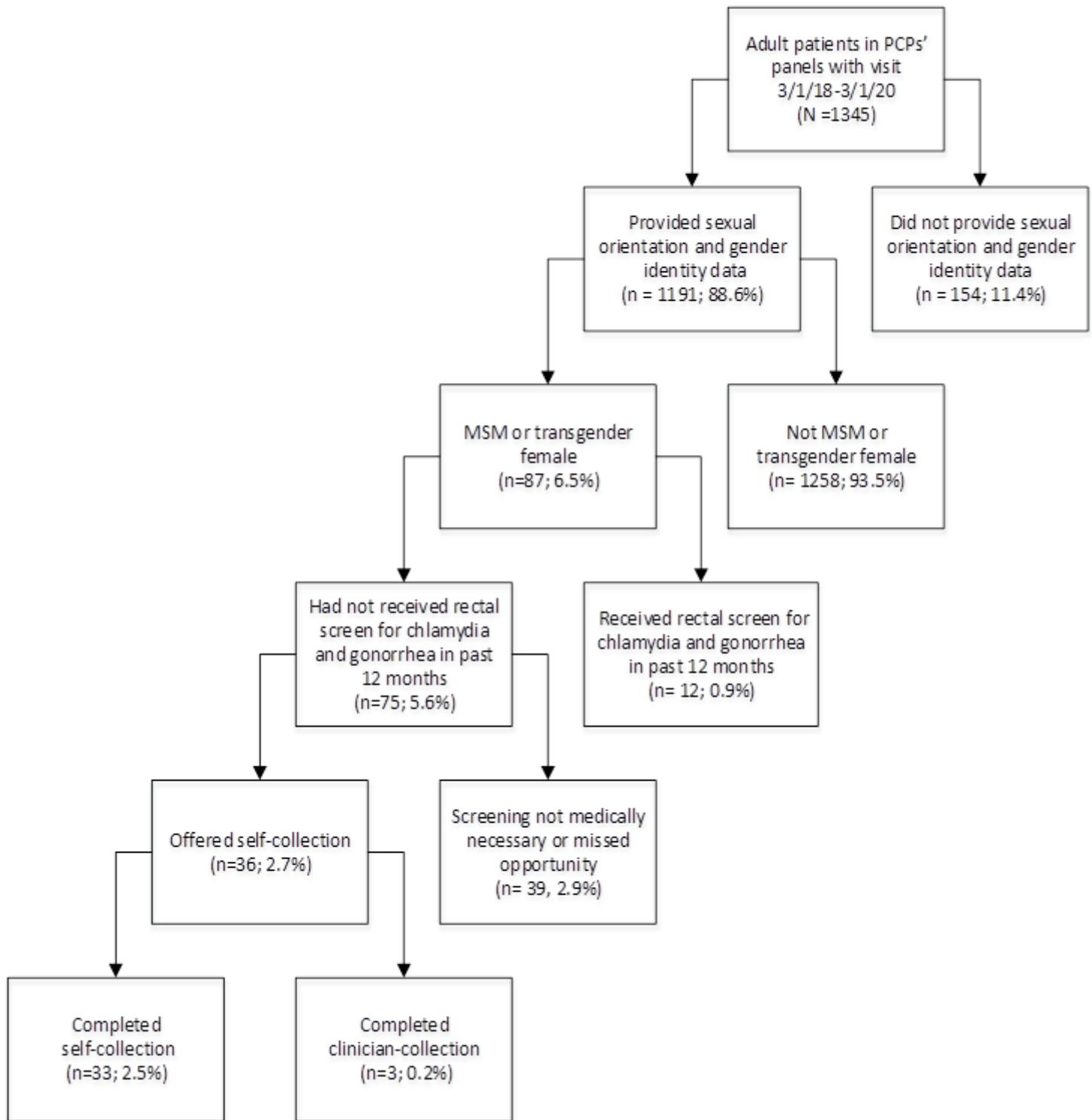
Completed clinician-collection (n=3; 0.2%)

Figure 1

Eligibility Screening. Of the 1345 unique patients seen by the 3 participating primary care providers (PCPs), 75 were men who have sex with men (MSM) or transgender females who were eligible for routine rectal screening, and 33 completed study participation. Percentages are reported out of a total of 1345 patients in the 3 PCPs' panels.