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RESEARCH ARTICLE

At-Home Self-Collection of Urine or Vaginal Samples for Gonorrhea and Chlamydia Screening Among Young People Who Were Assigned Female at Birth

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Introduction: The U.S. has seen a rise in sexually transmitted infections; the need to increase access to screening is essential to reverse this trend, especially for vulnerable populations such as lesbian, gay, bisexual, and transgender/transsexual plus individuals, people of color, or those at a low SES. This study's primary objective is to assess preferences among people who were assigned female at birth for at-home self-collection for gonorrhea and chlamydia screening. This study aims to provide insight into the need for clinicians to adopt at-home self-collection of urine or vaginal samples to improve access to sexually transmitted infection screening.

Methods: A recruitment mailer was distributed in September−October 2021. Inclusion criteria included established patients (seen within the last 3 years for clinical services either in person or through telemedicine) at a local urban federally qualified health center in the state of Wisconsin, assigned female at birth, aged 18−24 years, and speaking English language. Participants completed an anonymous online survey regarding their preferences, experiences, and likelihood of self-collecting either urine or vaginal samples for gonorrhea and chlamydia screening at home.

Results: Among the total participants (N=88), 69% (n=61) overall preferred home collection for screening with no significance based on age; lesbian, gay, bisexual, and transgender/transsexual plus status; and race and/or ethnicity. However, patients were less likely to prefer at-home self-collection screening if they had lower educational attainment (OR=0.25; 95% CI=0.08, 0.77; p<0.05), lacked insurance (OR=0.19; 95% CI=0.06, 0.67; p<0.05), or were unemployed (OR=0.28; 95% CI=0.08, 0.95; p<0.05).

Conclusions: There is overall acceptability for at-home self-collection sexually transmitted infections screening (61 of 88=0.69; 95% CI=0.59, 0.79). Primary care clinics can expand needed screening by integrating such methods into workflows for established patients. Although this study showed that patients who are employed, attained a higher education level, and have their own insurance may prefer at-home self-collection, there is a need to focus on social determinants of health to decrease rising sexually transmitted infection rates in the U.S.

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INTRODUCTION

The U.S. has seen a recent rise in sexually transmitted infections (STIs), with infections caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae* among the most commonly reported STIs. Diagnosis rates of chlamydia

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and gonorrhea increased by 3% and 5%, respectively, from 2017 to 2018.[1] Untreated chlamydia and gonorrhea infections in women lead to significant morbidity, such as pelvic inflammatory disease, and associated complications, including ectopic pregnancy, infertility, and chronic pelvic pain.[1] The U.S. Preventive Services Task Force (USPSTF) recommends yearly screening for chlamydia and gonorrhea in all sexually active women aged ≤24 years and in women aged ≥25 years who are at increased risk for infection (Grade B recommendation).[2] Multiple factors drive low screening and high infection rates, including cuts to STI programs at the state and local level, decrease in condom use among vulnerable groups (such as young people and gay and bisexual men), drug use, poverty, stigma, and unstable housing, which can reduce access to STI prevention and care.[1]

Screening for STIs is traditionally done in person when presenting for annual wellness examinations or clinical concerns. Many people often decline clinical examination and screening because of reasons such as fear of invasive procedures; self-consciousness during genital examination; and the stigma associated with STIs, gender identity, or sexual practices.[3] In addition, the coronavirus disease 19 (COVID-19) pandemic caused limited face-to-face visits; even those patients who have been willing to undergo clinical examination and screening in the past have had decreased access to STI screening. The delay of STI screening for millions of patients is expected to result in increasing rates of infection, particularly among asymptomatic young adults.[4]

One approach to STI testing supported by the WHO guideline on self-care interventions for health and well-being is the self-collection of samples for detection of *N. gonorrhoeae* and *C. trachomatis* (strong recommendation; moderate certainty evidence).[5] Self-collection occurs when an individual takes a sample themselves, either in a clinic or elsewhere, and sends it to a laboratory for testing.[6] Despite some heterogeneity in the results, a variety of studies and reviews have reported that self-collected vaginal samples are greater in accuracy than first void urine samples, comparable with provider-collected endocervical samples.[7−11] Self-collected vaginal samples are also easier to obtain than samples collected with other methods, and therefore, self-collection methods are the preferred methods of collection for STI screening.[7−11] Overall costs for at-home self-collection can be lower than those of clinic-based STI screening because of indirect costs such as child care, transportation, and time off from work. This cost-saving measure may benefit at-risk populations who may normally have less access to or utilization of clinic services.[12,13] Direct-to-consumer self-collection STI testing kits are available online, although they are not commonly covered by insurance and can range between $50 and $300 in out-of-pocket expenses.[14] At-home self-collection of samples increases choice and autonomy when they are accessible, acceptable, and affordable, with findings supporting the greater impact on uptake of STI screening than clinic-based sampling.[5,6,15] Transportation of samples to the laboratory is feasible and low cost by regular postal service, with stability at 2°C−30°C for vaginal or urine samples for up to 60 days or 30 days, respectively.[16] However, the need to evaluate the benefit of this method for patients already established with a primary care clinician is critical because positive screening tests require appropriate coordination of care, treatment, follow-up services, screening for other STIs, and counseling on preventative measures.

Assessing the acceptability of at-home self-collection for STI screening for patients with an established primary care clinic may provide insight into the need for clinicians to adopt this screening method for patients. The overall objective of this study is to evaluate participants' perception of at-home self-collection of urine or vaginal samples as a potential STI screening method. Recognizing that STIs affect all genders, this study focuses on participants referenced in the USPSTF recommendations, interpreting women as people who were assigned female at birth (AFAB). We acknowledge that not all people who were AFAB identify as women and not all women were AFAB. Other possible sources of asymptomatic infections include oropharyngeal and anorectal sites on the basis of sexual practices. In this study, we decided to focus on self-collection of urine and vaginal samples for detection of genital infections in people who were AFAB. Our primary aim in this study was to assess preferences for at-home self-collection methods for gonorrhea and chlamydia screening for young people who were AFAB. Our secondary aim was to determine whether certain variables such as lesbian, gay, bisexual, and transgender plus (LGBT+) identity, individual behaviors, or risk factors increased preference for at-home self-collection methods.

METHODS

Study Sample

For this cross-sectional study, participants were recruited through extraction from the patient database of a clinic located in an urban city in the state of Wisconsin. Inclusion criteria included those who were *established patients*, defined as having an assigned primary care provider at the study location's clinic and at least 1 face-to-face or telemedicine clinical visit within the last 3 years. Additional eligibility criteria included patients who were AFAB, English speaking, and aged between 18

and 24 years at the time of database extraction (August 2021). This age range was selected to coincide with the USPSTF screening recommendations.

From September 2021 to October 2021, letters were sent to the mailing addresses of eligible participants, inviting participants to fill out a questionnaire through the online survey tool Qualtrics (Qualtrics, LLC, Seattle, WA). Participants were provided a $1 cash preincentive to complete a survey and sent a reminder letter 2−3 weeks after the initial invite to complete the survey. Informed consent was obtained, and data were collected anonymously through the online survey. The survey closed in November 2021.

Measures

Basic demographic information was collected, including age, race/ethnicity, education, employment status, and insurance (survey instrument is provided in Appendix A, available online). Participants who had a birthday between the time of database extraction, recruitment, and completion of the survey were included in the study; therefore, participants included in the results had an upper age limit of 25 years. LGBT+ status was determined on the basis of individual self-identification of gender identity different from their sex at birth and/or identity with a sexual orientation other than heterosexual, such as lesbian, bisexual, or asexual, among others.[17]

Statistical Analysis

Statistical analyses were conducted using SAS software (SAS Institute, Inc., Cary, NC), Version 9.4. All reported p-values are 2 sided, and $p<0.05$ was used to define statistical significance. Descriptive statistics such as count and frequency were generated for categorical variables. Chi-square or Fisher's exact tests were used for comparison between home testing preferences. ORs and 95% CIs were calculated using logistic regression. The University of Wisconsin Madison Minimal Risk Research IRB conducted a review of this study (Identification Number 2021-0812), consisting of collection of nonidentifiable survey data, to meet the criteria for exempt human subjects because the probability and magnitude of harm or discomfort anticipated of the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological (under 45 CFR 46).

RESULTS

A total of 640 recruitment mailers were sent out, 101 responses were received, 9 were incomplete, and 4 were completed by participants aged <18 years, so they were not included in the final analysis. A total of 88 responses were included in the data analysis (14% response rate). The mean response time was approximately 6 minutes. A breakdown of other demographic information is included in Table 1.

Overall, there was a higher preference for at-home self-collection screening methods (61 of 88, 69%; 95% CI=59%, 79%) than for in-clinic screening methods among respondents. Variables such as LGBT+ identity, age, recent clinical encounter, relationship status, living situation, or race/ethnicity were not significantly associated with preference for at-home self-collection (Table 1). Respondents were less likely to prefer at-home self-collection if reporting an education level equivalent to high school or lower (OR=0.25; 95% CI=0.08, 0.77; $p<0.05$), if they lacked insurance (OR=0.19; 95% CI=0.06, 0.67; $p<0.05$), or if they were unemployed (OR=0.28; 95% CI=0.08, 0.95; $p<0.05$).

Of the total, 86% of participants (n=76) were considered sexually active if they ever engaged in any type of sexual activity and had ≥1 partner in the last 12 months. Of these participants, 54% (n=41) had not had screening within 12 months of the survey collection. These participants did not have a higher preference for at-home self-collection than those sexually active but had had screening within 12 months of the study (OR=1.03; 95% CI=0.38, 2.80; p=0.95).

Of participants who reported that they were likely to do at-home testing if offered, 55% (n=41) preferred urine self-collection, and 45% (n=33) preferred vaginal-self collection. Participants were asked how they would like to receive their results as a nonranking multiple select option (Table 2). There was a higher desire to receive results from an electronic notification (such as e-mail or text directing to electronic health record patient portal) (n=71), followed by phone call from a nurse (n=43).

To determine whether certain characteristics, behaviors, or risk factors increased the desire for at-home self-collection, information was collected on self-perceived risk or worry about STIs, clinical risk factors (such as ≥2 sexual partners, history of STI, engaging in transactional intercourse, and infrequent use of barrier protection), and comfort with healthcare provider (Table 3). Results did not show significance in preference for at-home self-collection related to these factors. A total of 52% of participants (n=45) were aware of the USPSTF recommendations for gonorrhea and chlamydia screening.

DISCUSSION

The primary objective of this cross-sectional survey was to determine whether patients established with the study location's family medicine clinic would prefer at-home

Table 1. Preference for Home Testing and Participants Demographics

Demographics	Total N=88	Preference for home testing		Preference against home testing					
		n=61	%[a]	*n*=27	%[a]	χ^2 (*p*-value)	ORs	95% CI	OR (*p*-value)
Age, years									
18–20	23	13	21%	10	37%	2.49 (0.29)	1		
21–23	40	29	48%	11	41%		2.03	0.69, 5.96	0.20
24–25	25	19	31%	6	22%		2.43	0.71, 8.37	0.16
Identify as LGBT+									
No	45	28	46%	17	63%	2.18 (0.14)	1		
Yes	43	33	54%	10	37%		2.00	0.79, 5.07	0.14
Obtained health care in the last 12 months									
Yes	67	45	74%	22	81%	0.61 (0.44)	1		
No	21	16	26%	5	19%		0.64	0.21, 1.97	0.44
Relationship status									
Partner/not living together	20	15	25%	5	19%	2.23 (0.33)	1		
Married/living with a partner	23	18	30%	5	19%		2.19	0.69, 6.97	0.19
Single, divorced, or widowed	45	28	46%	17	63%		1.82	0.56–5.92	0.32
Living situation									
Lives alone	16	12	20%	4	15%	0.96 (0.62)	1		
Lives with other people	50	33	54%	17	63%		0.65	0.18, 2.31	0.50
Lives with spouse or partner	21	16	26%	5	19%		1.07	0.24, 4.84	0.93
Race/ethnicity									
Caucasian/White	42	32	52%	10	37%	2.87 (0.24)	1		
Hispanic/Latinx	20	11	18%	9	33%		0.38	0.12, 1.18	0.10
African/Black, Asian, multi, other	26	18	30%	8	30%		0.70	0.24, 2.10	0.53
Education									
College degree or higher	43	35	57%	8	30%	**6.46 (0.04)**	1		
Some college	22	14	23%	8	30%		0.40	0.13, 1.28	0.12
High school or less	23	12	20%	11	41%		**0.25**	**0.08, 0.77**	**0.02**
Medical insurance coverage									
Private insurance (on own plan)	17	15	25%	2	7%	**11.40 (0.009)**	1		
Private insurance (not on own)	37	29	48%	8	30%		2.07	0.39, 10.99	0.40
Public insurance	17	10	16%	7	26%		0.39	0.11, 1.37	0.14
Uninsured or not sure	17	7	11%	10	37%		**0.19**	**0.06, 0.67**	**0.01**
Employment status									
Student	23	14	23%	9	33%	5.22 (0.07)	1		
Employed	51	40	66%	11	41%		0.43	0.15, 1.25	0.12
Unemployed	14	7	11%	7	26%		**0.28**	**0.08, 0.95**	**0.04**

Note: Boldface indicates statistical significance ($p<0.05$).
[a]Percentage of total respondents.
LGBT+, lesbian, gay, bisexual, and transgender plus.

Table 2. Preference for How to Receive Results After Home Collection

Follow-up method	*n*	%
Prescheduled telemedicine appointment with a nurse	14	15.91
Prescheduled telemedicine appointment with a physician	15	17.05
Phone call from a nurse when results return	43	48.86
Phone call from a physician when results return	36	40.91
Electronic notification (i.e., EMR)	71	80.68
Letter through the mail	23	26.14
Other	2	2.27

EMR, electronic health record.

self-collection methods for STI screening as opposed to in-clinic collection. The results of this study did not show a statistically significant preference for at-home self-collection among those identifying as LGBT+, those with higher worry about or risk for STIs, those with lower educational attainment, those lacking health insurance, or those unemployed. The results of this survey were limited by sample size and low participation rate. This study used a convenience sample and lacked representation from diverse communities such as Black, Hispanic, indigenous, and other people of color as well as non-English speakers, contributing to selection bias in the study. Owing to the study's purpose of targeting participants who are established within this urban-located family medicine clinic, results do not reflect the potential impact at-home self-collection can have on people with limited healthcare access. Future studies should expand recruitment for a more diverse sample, by making the survey available in multiple languages and expanding it to rural locations, community centers, or other sites to reach participants lacking insurance or an established primary care clinician.

This study found potential acceptability for at-home self-collection methods, although it found a higher preference for a self-collected urine sample than for a vaginal sample. Although self-collected urine samples are slightly less sensitive as a screening tool, this may be more acceptable for some participants, particularly transgender patients or those not comfortable with vaginal self-collection. The USPSTF also recommends screening of the oropharynx and rectum, depending on sexual practices.[2] Studies have shown that self-collection

Table 3. Associations of STI Risk in Participants Who Prefer Home Testing

Risk factors for STIs	*n*	OR	95% CI	*p*-value
Self-perceived risk of STIs				
Low or no risk	73	1		
At risk	8	1.47	0.28, 7.83	0.65
High or moderate risk	7	2.94	0.34, 25.80	0.33
Worry about STIs during sexual encounters				
Rarely or never	52	1		
Sometimes	18	1.56	0.44, 5.47	0.49
Every time or most of the time	17	0.64	0.21, 1.97	0.43
Number of partners in the last 12 months				
≤1 partner	66	1		
≥2 partners	21	3.21	0.86, 12.05	0.08
History of STI				
No	71	1		
Yes	17	1.08	0.34, 3.43	0.90
Transactional intercourse in the last 12 months				
No	83	1		
Yes	5	0.65	0.10, 4.11	0.64
Use of barrier protection				
Every time	12	1		
Sometimes	33	3.21	0.76, 13.69	0.11
Never	38	1.1	0.29, 4.10	0.89
Level of comfort in talking about sexual health				
Not comfortable	11	1		
Comfortable	77	1.21	0.29, 4.96	0.79

STI, sexually transmitted infection.

of these extragenital sites is as sensitive as clinician-collected samples.[18] Future studies could examine the acceptability of at-home self-collection of oropharyngeal and rectal samples for STI screening.

Increased disparities in the rates of reported STIs have been evident over the recent years among adolescents and young adults aged 15−24 years, racial minority or Hispanic groups, and men who have sex with men. The Centers for Disease Control and Prevention states that these disparities are unlikely to be explained by differences in sexual behavior but are rather in the quality and systemic inequity of sexual health care, particularly for LGBT+ communities because of heteronormative healthcare practices.[19,20] Further evidence is needed to update recommendations for LGBT+ individuals because these and other barriers such as patient concerns about confidentiality (e.g., concern about parents obtaining information), social stigma, cost, and lack of knowledge of STIs contribute to low rates of screening.[21] In this study, only 52% of respondents reported being aware of STI screening recommendations, reflecting the need for more education and outreach by clinicians.

In addition, in this study, it was presumed that the vaginal/urine samples would be collected at the participant's home and sent by email from the participant's home; this does not consider potentially vulnerable communities such as those without stable housing. The use of mail-in methods has potential applications outside of the home, including community centers serving those who lack permanent housing.

There was no difference in preference between participants who were considered sexually active and up to date in STI screening and those who were due for screening. Overall, there was a higher preference for at-home self-collection STI screening for certain demographics, such as those with a college degree or higher, those with private insurance, and those who were employed. Therefore, clinicians can consider the use of at-home self-collection screening for these patients, especially those already aware of existing recommendations and the need for screening. Special attention should be paid to vulnerable populations who may benefit from at-home self-collection despite these survey results. These findings may be in part due to the unfamiliar method, lack of clarity on costs associated with this process, or low perceived benefit. Clinics can address these concerns and improve acceptability by ensuring that this method is either covered by insurance plans to minimize out-of-pocket costs to patients or by providing testing at minimal or no cost to the patient. Overall presumed time saved, convenience, and maximum comfort for the patient when using mail-in methods are additional benefits; this needs to be made clear to the participants. Because of the ongoing COVID-19 pandemic and increased use of telehealth, at-home self-collection methods for STI screening can be a vital tool for primary care clinics. A future study could assess the acceptability by medical providers of at-home self-collection methods.

More evidence is needed to support innovative strategies to increase STI screening for patients who may have cost-prohibitive factors such as being uninsured or unemployed. Although integration of at-home self-collection methods for STI screening into a clinical workflow may show promise in increasing screening rates, implementation barriers such as local laboratory validation protocols for mail-in self-collection samples may hinder programs. Advantages to using a local laboratory versus outsourcing to a central laboratory may include speeding up of results, ease of viewing results for provider and sharing results with the patient due to integration with shared electronic health record, and decreased time to initiation of treatment if necessary.

CONCLUSIONS

Rising rates of STIs among young adults and delays in routine STI services secondary to the ongoing COVID-19 pandemic and budget cuts emphasize the importance of new approaches to STI screening.[22] Primary care clinics can increase access to STI screening by integrating home-collection methods in their clinical workflow and clinical care. Results from this survey demonstrate the desire for at-home self-collection screening methods among individuals from all demographics, influenced by social determinants of health such as education level, employment status, and insurance status. These findings indicate a need for innovative outreach efforts to curb rising rates of STIs in the U.S. with additional consideration for research specific to LGBT+ healthcare needs, updated USPSTF recommendations for screening, and inclusive public health messaging.

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CREDIT AUTHOR STATEMENT

Tana Chongsuwat: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Writing — original draft, Writing — review & editing. Paula J. Cody: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Writing — original draft, Writing — review & editing.

SUPPLEMENTARY MATERIALS

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