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Field collection of rectal samples for sexually transmitted infection diagnostics among men who have sex with men

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Summary: Rectal sexually transmitted infections (STIs) are common in men at risk for urethral infections with these pathogens, particularly men who have sex with men (MSM). However, for those individuals not regularly seen by a clinician, screening for rectal STI is not currently a widespread option. Qualitative data and samples (i.e. self-obtained rectal specimens) were collected from 75 MSM in a variety of venues. Upon completion of the rectal self-sampling, each participant completed a brief interview regarding their overall experience with the process. Participants reported an overall high level of acceptability and comfort-level involved with self-sampling for rectal STI. Of the majority of men who agreed to provide a rectal self-sample, all reported that they would provide a sample again in the future. However, many men also appreciated the interaction with a health-care provider that a clinical setting offered. In conclusion, self-sampling is a feasible and acceptable option when offered to MSM in a range of community-based venues. Further research is needed to determine which combinations of STI testing and treatment methods (including self-sampling) are most appropriate for diverse groups of men.

Keywords: screening, chlamydia (*Chlamydia trachomatis*), gonorrhoea (*Neisseria gonorrhoeae*), men who have sex with men (MSM), North America

INTRODUCTION

Numerous studies have demonstrated that sexually transmitted infections (STI) increase the likelihood of human immunodeficiency virus (HIV) acquisition and transmission^{1–5} by increasing viral shedding in HIV-infected individuals⁶ and causing inflammation in genital tissues that enhances HIV entry portals in HIV-negative partners.⁷ For this reason and in order to decrease STI-related morbidity, the Centers for Disease Control and Prevention (CDC) recommends that men who have sex with men (MSM) be screened annually for HIV, syphilis, *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.⁸ Site-specific (e.g. urethral, pharyngeal or rectal) and more frequent testing (i.e. every 3–6 months) are recommended for this population depending on self-reported risk behaviours for anal and oral intercourse.⁸

Despite these recommendations and the longstanding existence of public health control programmes, incidence rates of STI continue to rise among MSM.^{9,10} These men experience higher reported rates of *C. trachomatis* when compared with the median rate among all men.¹¹ The Gonococcal Isolate Surveillance Project (GISP) has measured a steady rise of *N. gonorrhoeae* including fluoroquinolone-resistant strain rates of which have risen steadily from 1.6% (2001) to 29% (2005).¹²

The frequency of antibiotic-resistant gonorrhoea is disproportionately high among MSM. MSM seen at GISP clinics have also been reported to have increased median syphilis seroreactivity from 4% in 1999 to 10% in 2004.¹³ The collective increase of STI rates among MSM demands improved case finding and treatment in this population both to reduce the morbidity of these diseases and to prevent the potential rise in related HIV incidence.

Of critical importance to secondary prevention of HIV is improved adherence to the CDC STD Guidelines, which call for site-specific screening of the pharynx, urethra and rectum of MSM depending on their risk behaviours.¹⁰ Encouraging providers to follow these recommendations and promote viable alternative methods of screening for these infections at the rectal and pharyngeal sites is essential in treating existing infections and decreasing new infections. Men accessing services outside of STI clinics are not receiving the necessary screening battery because some clinicians only provide urethral/urine tests.¹⁴ A recent study in San Diego, CA estimated that 33% of *N. gonorrhoeae* cases among MSM would have been missed had rectal and/or pharyngeal testing not been performed.¹⁴ Similarly, a study in San Francisco, CA reported that 56% of *N. gonorrhoeae* cases would have been missed had clinicians solely relied on urethral/urine tests.⁵ These results underscore the need for both patient and provider education about rectal STI including site-specific testing as well improved recruitment strategies to expand alternative test venues as part of public health control efforts.

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Community-based screening for HIV has effectively been used to target and recruit high-risk individuals who otherwise may not have sought testing services.¹⁵ The findings from a street-based intervention for homeless youth in San Francisco, CA demonstrate that outreach programmes delivered by trained, non-medical staff are effective, feasible and acceptable. Of the 218 participants, 216 (99%) consented to testing, 16 (6.9%) and two (0.9%) tested positive for chlamydia or gonorrhoea, respectively; nearly all ($n = 16$; 94%) were treated, eight (50%) within seven days.¹⁶ A mobile outreach programme in Louisiana was established to provide confidential testing and treatment in neighbourhoods with high STI incidence. Over three years, 256 community screening events were held and 2807 blood samples were drawn for HIV testing, 3110 blood samples were drawn for syphilis testing and 2229 urine samples were collected for chlamydia and gonorrhoea testing. Overall positivity was high; 70 individuals screened positive for HIV, 37 new cases of syphilis, 185 new cases of chlamydia and 108 new cases of gonorrhoea were diagnosed.¹⁷ These studies demonstrate that community-based screening is an effective mechanism for recruiting, testing and treating hard-to-reach populations.

Given the significance of untreated rectal sexually transmitted diseases in the MSM community, it is critical to explore novel approaches to STI screening that expand the public health system's capacity to serve populations with elevated risk. Little is known about the feasibility and acceptability of self-obtained rectal samples collected by MSM in community-based settings. Offering these types of services may assist MSM who are unlikely to seek care in overcoming the barriers associated with traditional STI screening approaches. The objectives of this study were to: (1) explore the awareness of rectal STI risk among MSM living in an under-studied and under-served Midwestern city; (2) assess this population's experience with and attitude towards rectal STI screening in general; and (3) determine the feasibility of field-collected self-obtained rectal samples. We report high acceptability and feasibility of this venue-based effort.

MATERIALS AND METHODS

Participants

Participants were 75 sexually active MSM (i.e. men who had engaged in at least one sexual act with another man during the previous six months) who were recruited from a variety of settings within the greater Indianapolis community. This city was chosen for several reasons. No previous studies on rectal STI among men have focused on Midwestern samples. However, Indianapolis has historically had some of the highest rates of STI in the United States and infection rates are particularly high among MSM. Additionally, the state of Indiana is dramatically under-served in terms of public health funding; indeed, it was recently ranked second-to-last (49/50) in states receiving federal funding for health programmes by the CDC.¹⁸ The under-studied and under-served nature of the study site warranted conducting this exploratory research project in this setting.

The study sample was limited to biological men. All participants were at least 18 years of age. To ensure relevance in terms of risk, all individuals reported engaging in sexual activity with at least one male partner during the previous six months. We recruited an ethnically diverse sample in order to ensure that

issues associated with rectal self-sampling were sufficiently explored among diverse ethnic subpopulations, given disparate rates of infections within these groups.

Men who reported taking antibiotics within the previous three weeks were not included in the study. Lastly, men who reported rare but chronic anorectal conditions such as ulcerative colitis, active anal herpes or other anal lesions, current rectal bleeding, or recent anorectal surgery were also not eligible to participate.

Recruitment

In order to obtain a wide variety of respondents, researchers identified seven culturally and ethnically diverse locations thought to be representative of MSM throughout the city including four pilot interviews conducted at Bell Flower STD Clinic to ensure comprehensibility of the interview protocol. The remaining 71 interviews were conducted at a combination of Black- and Latino-oriented community-based organizations (CBOs): a large HIV/AIDS service organization; an all-male bathhouse and two primarily 'gay-oriented' bars.

Instrument

Members of the study team collectively constructed a closed- and open-ended interview guide to explore themes related to the participants' experience of rectal self-sampling. The guide that incorporated constructs from the Health Belief Model (HBM),¹⁹ included items related to acceptability, comfort and facilitators of, or barriers to, using a rectal self-sampling device in the future. Perceived susceptibility has been shown to be the strongest predictor of preventive health-care utilization of the HBM constructs.²⁰ Example of items measuring perceived susceptibility in this study included: did you know that the rectum can become infected with STI; and did you know that if you have an infection in your rectum, a urine sample would not detect it? Items to detect barriers specific to self-obtained rectal swabs included: how would you describe your experience of collecting this sample to others; how would you describe the steps you followed to collect the sample; and were the visual instructions helpful? Prior to use, the instrument was reviewed by a panel of experts with a long history of performing acceptability studies regarding protective sexual behaviours.

Procedure

Each interview was conducted by one male research assistant trained in qualitative research methods. Interviews lasted approximately 20 minutes in length and were conducted in a private area at each recruitment location. Interviews were digitally recorded and, upon completion, transcribed for analysis. In order to ensure the anonymity of participants, individual identifiers were not collected. Participants received US\$25 for their involvement in the first phase of the interview and an additional US\$25 if they were willing to provide a self-collected rectal swab and complete the second phase of the interview. All participants provided informed written consent and the study was approved by the Institutional Review Board at the Indiana University School of Medicine (Indianapolis).

For each individual who consented to take part in the study, the semi-structured interview guide included two phases.

Phase 1 included nine 'Yes/No' questions that asked about rectal STI knowledge, risk of infection and willingness to provide a self-collected sample. Participants who did not provide a swab ($n = 7$) were asked their reasons for declining to do so at that time. Those who agreed to provide a rectal sample on themselves ($n = 68$) were given instructions on how to properly collect the sample and were directed to a private restroom in order to do so. In phase 2, participants were asked, using a series of open-ended questions, about their experiences in collecting the sample.

Data analysis

A thematic analysis was applied to the transcribed interviews and field notes. Transcripts from each of the interviews were independently analysed and coded by three researchers to confirm the major themes that were represented in the transcripts. The researchers then identified recurrent themes within the categories and specific quotes within each theme. Researchers compared the categories and themes across all groups and noted specific themes unique to a particular group. Once the themes were organized into broad categories, refinements were made to both the coding scheme and labelling of themes. In the final stage of analysis, the coding framework was applied to all of the data by annotating each transcript with the codes that indexed the categories.

RESULTS

Sample

All 75 participants who consented to take part in the study answered questions in the first section of the interview. The mean age of the sample was 32 years old ($SD = 10$), with a range from 18 to 57 years of age. In terms of race/ethnicity, we recruited a diverse sample of self-identified White ($n = 35$), Black ($n = 27$) and Latino ($n = 13$) participants. A pilot sample of four participants were recruited from the local STI clinic. Subsequently, 16 participants were recruited from a

CBO serving predominantly Black men, 10 from a CBO serving a large Latino population, 11 from a large HIV/AIDS service organization, 19 from predominantly gay bars and 15 from an all-male bathhouse. Table 1 displays the breakdown of recruitment venue by age, sexual identity, race/ethnicity, acceptance of the rectal self-swab test and infection with a rectal STI.

Phase 1

Knowledge about rectal STI and perceived risk was evenly divided. Almost half ($n = 34$) of the participants believed they may have been exposed to an STI that could infect their rectum. The same number of participants ($n = 34$) said they did not know that the rectum could become infected with an STI. Further, of the total sample, 40% ($n = 30$) were unaware that if an infection was present in the rectum, a urine sample would not detect it.

Most men had experienced having something in their rectum during sexual activity, including 87% of men having been the receptive partner in anal intercourse. While 67 participants had previously been tested for STI, only 39% of them had ever specifically had their rectum tested. In the words of one participant:

I would have never done it. I never have thought about it. I never questioned my rectum at all, you know, I never, I never, if I went to get tested, I would get tested for HIV, gonorrhoea, but I would never ask for a rectal test because nothing looks like it is wrong, nothing feels like it's wrong, but if there was something wrong, I would never know. It's not something that you ... it's kind of taboo.

However, participants overwhelmingly ($n = 72$; 96%) said that they would be willing to have their rectum tested in the future.

After completing the questions in phase 1, participants were asked whether they would be willing to provide a rectal self-swab at the time of the interview. Nearly all ($n = 68$) agreed to provide a sample and subsequently provided feedback in

Table 1 Demographic and rectal STI characteristics of participants recruitment venue ($n = 75$)

Venue of recruitment	All-male bathhouse		Predominantly gay bars		Health-related venue (CBO, Clinic)	
	%	n	%	n	%	n
Age (years)						
18–25	2.7	2	8.0	6	33.3	17
26–35	6.7	5	13.3	10	12.0	2
36–45	5.3	4	1.3	1	2.7	2
46 and over	5.3	4	1.3	1	2	2.7
Race/ethnicity						
Black	1.3	1	12.0	9	22.7	17
Latino	0.0	0	1.3	1	16.0	12
White	18.7	14	12.0	9	16.0	12
Sexual identity						
Gay	20.0	15	22.7	17	38.7	29
Bisexual	0.0	0	2.7	2	16.0	12
Accepted self-swabbing for rectal STI						
Yes	20.0	15	18.7	14	52.0	39
No	0.0	0	6.7	5	2.6	2
Infected with rectal STI (of 62 samples tested)						
Yes	0.0	0	5.0	3	5.0	3
No	18.7	14	13.3	10	68.0	32

STI = sexually transmitted infection

section two about the experience of doing so. For those participants who did not agree to provide a rectal swab, a final open-ended question was asked eliciting reasons for not wanting to provide the sample. Responses to this question included issues of sanitation, inappropriate venue location and lack of trained personnel to assist with the collection. For example, one participant stated:

I am not sure that it would turn out correctly if I did it myself and I am not, it's not that I am uncomfortable, I just think that I would rather have it done by someone who knows what they are doing.

Phase 2

All 68 participants who provided a rectal sample stated that they would be willing to be tested for rectal STI at some point in the future. The next time they were tested, 72% of participants said that they would want to collect their own sample and only 13 participants would prefer to do it in a clinical setting. The majority of participants ($n = 61$) indicated that they would be likely to tell their friends that self-swabbing was available and most ($n = 51$) said they would be comfortable asking their physician to allow them to collect their own sample. As explained by one participant, 'Well I would tell [friends], you know everyone needs to be tested back there as well as pee samples, because they won't pick up the same type of thing'.

When discussing specifically the experience of collecting the sample in a non-clinical setting, the advantages most often described included: convenience ($n = 22$), comfort ($n = 19$) and privacy ($n = 12$) and disadvantages were lack of privacy ($n = 18$), lack of accuracy ($n = 12$) and sterility ($n = 3$). Participants' responses included:

Well, because if I am going to mess around with any parts of my body I would rather it would be me doing it.

and

It's pretty easy to do, fairly non-invasive, not painful, and I think I can find my hole a little bit better than someone else is going to be able to.

A total of 62 participants indicated that they wanted their swab to be sent for laboratory-based STI testing. Overall STI prevalence in this sample was 11% ($n = 9$), with a total of five chlamydia cases and four gonorrhoea cases. Participants were instructed that in order to receive test results they would be required to call in and provide an anonymous ID number. Only 16% ($n = 10$) of participants called for test results. When asked what would be the preferred method to receive STI test results, over half ($n = 37$) indicated the telephone as being most appropriate. Other responses included in person ($n = 18$), email ($n = 7$) and paper mail ($n = 6$).

DISCUSSION

In this study, men found rectal self-sampling to be a feasible and acceptable option when offered to them during their attendance at a range of venues typically found in communities of MSM, including CBOs, bars and bathhouses. Acceptability was high across all types of venues. When resistance to self-

sampling was encountered, it more commonly occurred in bars and was primarily associated with the patron's concerns related to cleanliness and privacy (given that most bathroom stalls had no doors). These findings indicate that future efforts to make venue-based sampling available in community-based venues should include formative work to ensure that the structural properties of each space are considered in the design of project protocols and alternative options are made available when issues related to privacy or hygiene might be challenged. Considering these findings, there appears to be great potential for expanding community-based STI focused outreach and prevention programmes to include venue-based screening components to expand surveillance efforts and reach populations who may be more resistant to clinic-based screening.

When men were asked about traditional forms of screening for rectal STI in clinical settings, some described both clinicians and clinics as presenting what they perceived to be barriers; most often these were related to clinic access and issues related to stigma and difficulty with disclosing behaviours with providers. On the contrary, while many men preferred the opportunity to self-sample, others remained more comfortable with having sampling conducted by a clinician. While it was the case that data were collected at one STI clinic site, this was predominantly for pilot testing of the interview guide and only four participants were recruited from this site. It was not the purpose of this study to compare acceptability of self-sampling between clinics and community-based settings, yet these study findings support the notion that such comparative studies would be valuable.

Findings also indicated that many men were unaware of their level of susceptibility to rectal infections, and most men who were aware of this reported assumptions that urine testing would identify such infections. This indicates the need for continued focus on STI education in MSM communities. Additionally, the lack of men's awareness regarding the potential for rectal infections may indicate that providers (including both clinicians and community-based public health professionals) may also benefit from focused efforts to facilitate their ability to introduce this topic to men during other health-related interactions that remain commonplace in organizations and clinics that serve this community.

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