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Self-sampling for oropharyngeal and rectal specimens to screen for sexually transmitted infections: acceptability among men who have sex with men

S Wayal,¹ C Llewellyn,¹ H Smith,¹ M Hankins,¹ A Phillips,² D Richardson,² M Fisher on behalf of the Home Sampling Kit Project Steering Group

► An appendix is published online only at <http://sti.bmj.com/content/vol85/issue1>

¹ Division of Primary Care and Public Health, Brighton and Sussex Medical School, Falmer, Brighton, UK; ² Department of Genitourinary Medicine, Brighton and Sussex University Hospitals NHS Trust, Brighton, UK

Correspondence to: Ms Sonali Wayal, Room 323, Mayfield House, Division of Primary Care and Public Health, Brighton and Sussex Medical School, Falmer, Brighton BN1 9PH, UK; S.Wayal@bsms.ac.uk; sonaliwayal@yahoo.com

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ABSTRACT

Objectives: To explore the feasibility and acceptability of self-sampling for oropharyngeal and rectal specimens to screen for sexually transmitted infections (STIs) among men who have sex with men (MSM). Participant's willingness to self-sample at home was also explored.

Methods: Participants of a study to evaluate the sensitivity and specificity of self versus nurse taken oropharyngeal and rectal specimens were surveyed to assess the feasibility and acceptability of self-sampling using specimen collection methods (gargle, OraSure mouth pad to collect oropharyngeal specimens and APTIMA unisex swabs to collect rectal and pharyngeal specimens). Acceptability was measured using a five-point Likert-type response scale (for example, 1 = strongly disagree; 5 = strongly agree). Open-ended questions explored participants' experiences of self-sampling.

Results: Of 334 eligible MSM, 301 (90%) participated in the study. Altogether, 301 participants self-sampled using gargle and rectal and pharyngeal swabs and 288 using mouth pad. Complete questionnaire data from 274 participants showed that feasibility and acceptability of self-sampling using gargle and mouth pad was higher (92%) than pharyngeal swabs (76%). Rectal swabs were acceptable to 82% participants. Despite some discomfort and difficulty in using swabs, 76% were willing to use all four methods for self-sampling in the future. Home sampling was acceptable (84%) as it was perceived to be less intrusive and more convenient than a clinic visit and likely to reduce genitourinary medicine (GUM) waiting time.

Conclusions: Self-sampling for rectal and oropharyngeal specimens is feasible and acceptable to MSM. Self-sampling can be offered as an alternative to clinic-based testing and has the potential to improve choice, access and uptake of screening for STIs.

Prevention of onward transmission of sexually transmitted infections (STIs) is a vital public health strategy. Early diagnosis and treatment of STIs, particularly among at-risk groups (men who have sex with men (MSM), sex workers), and timely access to sexual health services are critical components of this strategy. Recent data from the UK report the increase in the rates of bacterial STIs like *Neisseria gonorrhoea*, *Chlamydia trachomatis* and syphilis among MSM.^{1,2} In a recent outbreak of *Lymphogranuloma venereum*, almost 99% of the diagnosed cases were among MSM.³ High rates of

STIs are also reported among MSM with HIV.⁴ This increase in the prevalence of STIs is a concern as STIs can enhance transmission of HIV.^{5,6} Recent epidemiological data show high prevalence of asymptomatic pharyngeal *N gonorrhoea* and rectal *C trachomatis* and *N gonorrhoea*,^{7,8} and high rates of partner acquisition and unprotected sex among MSM,^{7,9} emphasising the need to encourage and improve access to regular screening among MSM.

There is a high level of unmet need for sexual health services due to failure of genitourinary medicine (GUM) clinics to cope with the recent increase in demand for these services¹⁰ and GUM waiting times of up to 28 days have been reported.¹¹ Given the correlation between the average duration and transmission of STIs,¹² delay in diagnosis and treatment of STIs can enhance their onward transmission. Thus, novel strategies to improve access to sexual health services need to be devised.¹⁵

Compared to the older culture methods, nucleic acid amplification tests (NAATs) have greater sensitivity for detecting *C trachomatis* and *N gonorrhoea*.^{6,14} NAATs can be used to detect organisms in non-invasive specimens like urine and self-collected swabs¹⁵ and, thus, can create an opportunity to offer self-sampling for specimens to screen for STIs. Several studies conducted predominantly among heterosexual populations in the UK have shown the feasibility of screening for genital chlamydial infections using home-collected urine specimens from men and urine specimens or self-collected vulvo-vaginal swabs from women.¹⁶⁻¹⁸ Given the increase in pharyngeal and rectal infections among MSM, the feasibility and acceptability of self-sampling for specimens from these non-genital sites needs exploration. Recent studies conducted in the USA among MSM have reported the feasibility of using illustrated instructions to obtain self-collected rectal swabs.¹⁹ To date, no such studies of self-sampling with rectal swabs have been conducted in the UK and no studies anywhere have explored the feasibility of self-sampling for pharyngeal specimen using swabs.

Patients' preferences and perspectives affect the outreach and uptake of novel healthcare strategies; thus, there is a need to explore the acceptability of self-sampling for rectal and oropharyngeal specimens and the willingness to self-sample in non-clinical settings. This study aims to assess the

feasibility, acceptability and experiences of MSM who self-sampled for oropharyngeal and rectal specimens in the clinic using various self-administered methods and illustrated information leaflets. Participant's willingness to self-sample at home was also explored.

METHODS

Study design

This study was part of a larger study to evaluate the sensitivity and specificity of self-collected rectal and oropharyngeal specimens tested using Gen-Probe APTIMA Combo 2 assay (Gen-Probe, San Diego, California, USA) to detect *C trachomatis* and *N gonorrhoea* compared with nurse-taken specimens tested using conventional clinic methods. Details of this study, including sample size calculations, are described elsewhere.²⁰

Study setting and population

MSM attending the Brighton GUM clinic for a routine STIs screen aged 18 years and above were eligible to participate in the study.

Study procedures

Written informed consent was obtained by a research nurse. First, the nurse collected urethral, pharyngeal and rectal specimens from all the study participants, as per the standard clinical guidelines, followed by additional rectal and pharyngeal specimens using the Gen-Probe APTIMA Unisex Swabs (Gen-Probe, San Diego, California, USA). Participants were then provided information leaflets containing photographs and instructions for self-sampling using these sampling materials. These information leaflets were developed during the formative phase of this project and were based on focus group discussions with MSM. Oropharyngeal specimens were collected using gargle, mouth pad and pharyngeal swab, and rectal specimen was collected using a rectal swab (table 1). Specimen collection using a mouth pad was subsequently discontinued halfway in the study as a planned interim analysis showed the poor sensitivity of this sampling method.

After self-sampling, participants completed a piloted questionnaire on socio-demographic factors (age, education, ethnicity, sexuality and employment) and frequency of STIs testing in the past year. Feasibility and acceptability of self-sampling using each specimen collection method was assessed using an eight-item scale: participants' experiences of self-sampling for rectal and oropharyngeal specimens with the help of information leaflets indicating the feasibility of self-sampling and attitude towards future use of these methods for self-sampling, and the willingness to use these methods at home indicating acceptability of self-sampling. An additional item (preference for

nurse-taken swabs) was included in the scales of the rectal and pharyngeal swabs. Half of these items were reverse-phrased to reduce response bias. Participants rated each item on a five-point Likert-type response scale: 1 = strongly disagree, 2 = disagree, 3 = not sure, 4 = agree and 5 = strongly agree. Finally, open-ended questions like "do you have suggestions for improvement (for each sampling method)" and "please provide additional comments" were included in the questionnaire.

Outcome measures and data analysis

The main study outcome was overall scale scores for feasibility and acceptability of self-sampling for specimens from the rectum and pharynx. Overall scale scores for each method were derived by adding the scores of all the individual items and dividing it by the total number of scale items. This score was then collapsed into categories with scores <2.5 indicating "unacceptability", 2.5 to <3.5 indicating "uncertainty" and ≥ 3.5 indicating "acceptability". Feasibility of self-sampling defined as the ability to self-sample with the help of instructions was measured through scores of individual item (1–6 and 9) and acceptability was defined as the willingness of participants to use these methods in the future and measured through individual items 7–8. Questionnaire data entry and cleaning was done using SPSS V.14 (SPSS, Illinois, USA). Reverse-phrased items in the acceptability scales were reverse-scored. Corrected item-total correlations and reliability (Cronbach's alpha) for each scale were computed. Medians and interquartile ranges were calculated for individual items on the scales. Bivariate analysis using χ^2 test explored the association of overall scale scores for each specimen collection method, indicating feasibility and acceptability of self-sampling with socio-demographic factors (age, education, sexuality and employment) and number of times tested for STIs in the last year. Continuous variables such as age and number of times screened for STIs in past year were collapsed into categorical variables. For this analysis, overall scale scores of <3.5 were categorised as "unacceptable" and scores ≥ 3.5 were categorised as "acceptable".

RESULTS

Of the 334 eligible participants, 301 (90%) were recruited during the 20-month period from October 2005 to May 2007. Altogether, 10% declined to participate due to concerns of being unable to understand the information leaflets, feeling uncomfortable with self-sampling or concerns about DNA testing (performed to determine the accuracy of the specimens collected). All the 301 participants successfully self-sampled for oropharyngeal specimens using gargle and pharyngeal swab and rectal swab. Mouth pads were successfully collected by 228 participants prior to their discontinuation. Complete questionnaire data available from 274 participants were analysed. Median age of the study participants was 34 years (table 2). The majority were Caucasian, employed full-time, had higher education and 75% had previously tested for STIs.

Reliability of the acceptability scales

The corrected item-total correlations for each scale were all above 0.3 indicating a good range of correlations between each item and the total scale score. Item reduction did not take place as alpha values were reduced below the overall scale alpha indicating that all the items in the scale were positively contributing to the overall reliability of the scale. Cronbach alpha scores for each scale indicated that the scales devised to

Table 1 Materials used for self-sampling for rectal and oropharyngeal specimens

Sampling materials	Site of specimen collection
2 Gen-Probe APTIMA Unisex Swabs (Gen-Probe, San Diego, California, USA)	Pharyngeal specimen and rectal specimen
1 OraSure oral specimen collection device (OraSure Technologies, Philadelphia, USA)	Oral (mouth) specimen
1 container with saline water to gargle (Sterilin, Caerphilly, UK); 1 Gen-Probe APTIMA urine collection kit (pipette and a specimen transport tube)	Oropharyngeal specimen (using the saline water participants gargled for 45 s and spit back into the container. They then transferred this water using a pipette in the specimen transport tube).

Table 2 Profile of the study participants (n = 274)*

Factors	%
Median age, years (IQR)	34 (29–41)
Age distribution	
18–30 years	35.4
31–40 years	38.2
>40 years	26.4
Sexuality	
Homosexual	95.9
Bisexual	4.1
Ethnicity	
Caucasian	94.8
Education	
No formal education	5.2
A/O levels	32.5
Higher education (degree/higher degree)	62.3
Employment	
Unemployed	4.8
Full-time	63.8
Part-time/self-employed	15.5
Other	15.9
Times tested for STIs in the last year (n = 270)	
Range (tested for STIs)	0–12
0	25.3
1–2	53.2
≥3	21.5

*n = 274 unless otherwise specified. IQR, inter-quartile range; STI, sexually transmitted infections.

measure feasibility and acceptability of self-sampling were reliable (table 3).

Feasibility of using oropharyngeal specimen collection methods

Of the three oropharyngeal specimen collection methods, the overall scores were the highest for mouth pad (96%), followed by gargle (92%) and the pharyngeal swab (76%) (table 3). While 2.2% participants reported throat swabs to be unacceptable almost 22% reported being unsure of their acceptability. The

individual item scores (1–6) indicate that the majority of the participants found specimen collection using mouth pad and gargle to be feasible. However, the collection of a pharyngeal swab was reported to be difficult (24%) and uncomfortable (32.5%), and 37% participants expressed preference for nurse-taken pharyngeal swab, indicating that not all participants found self-sampling with throat swab to be feasible. Open-ended responses indicated the following difficulties experienced by participants while self-sampling with the pharyngeal swab: unclear illustration of the throat area to be swabbed, experiencing a gagging sensation and difficulty in avoiding the tongue while swabbing. Participants also reported that the time they were required to gargle (45 seconds) was too long and some expressed the need for a bigger pot to spit the gargle in.

Feasibility of using rectal specimen collection method

Overall scores indicate that 82% participants were able to self-sample using rectal swabs and were willing to use them in the future, whereas 14% were unsure and 4% found them unacceptable (table 3). As in the case of throat swabs, preference for nurse-taken rectal specimen was reported (26%) and individual item scores indicate that some participants found self-sampling for a rectal specimen to be difficult (19%) and uncomfortable (30.5%). Open-ended responses indicated that participants experienced the following difficulties in self-sampling with a rectal swab: difficulty inserting the swab in the anus, discomfort because of dryness, fear of causing bleeding while inserting the swab, not understanding the depth to which the swab needed to be inserted in the rectum. Participants suggested having a mark on the rectal swab to indicate the depth to which it needs to be inserted and providing thicker swabs.

Acceptability of self-sampling and home-sampling

Although participants reported some discomfort in using the swabs, the majority of the participants expressed their willingness to use all the methods for self-sampling in the future

Table 3 Reliability of scales, overall feasibility and acceptability scores of each specimen collection method and median with inter-quartile range (IQR) of individual scale items

	Overall Cronbach alpha	Mouth pad (n = 201)	Gargle (n = 274)	Pharyngeal swab (n = 274)	Rectal swab (n = 268)
Overall feasibility and acceptability scores		0.77% (95% CI)	0.86% (95% CI)	0.85% (95% CI)	0.88% (95% CI)
Unacceptable		0 (0 to 1.9)	0.4 (0.6 to 2.0)	2.2 (1.0 to 4.7)	4.0 (2.3 to 7.2)
Not sure		4.0 (2.0 to 7.7)	7.7 (5.0 to 11.4)	21.7 (17.0 to 27.0)	14.2 (10.5 to 18.9)
Acceptable		96.0 (92.0 to 97.9)	92.0 (88.6 to 94.6)	76.0 (70.7 to 80.8)	81.7 (76.7 to 85.9)
Individual item scores (Likert scale of 1–5)		Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
1 Found collection of the specimen easy		5.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)	4.0 (3.0 to 5.0)	4.0 (3.0 to 5.0)
2 Instructions easy		4.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)
3 (Uncomfortable)* to self-collect the specimen		4.0 (4.0 to 5.0)	4.0 (4.0 to 5.0)	4.0 (2.0 to 4.0)	4.0 (2.0 to 4.0)
4 (Difficult)* to self-collect the specimen		5.0 (4.0 to 5.0)	4.5 (4.0 to 5.0)	4.0 (3.0–4.0)	4.0 (3.0–5.0)
5 Instructions (difficult)* to understand		5.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)
6 Confidence about specimen collected as instructed		4.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)	4.0 (4.0 to 5.0)	4.0 (4.0 to 5.0)
7 (Not)* use the method again		5.0 (4.0 to 5.0)	5.0 (4.0 to .0)	4.0 (4.0 to 5.0)	4.0 (4.0 to 5.0)
8 Happy to use the method at home		5.0 (4.0 to 5.0)	5.0 (4.0 to 5.0)	4.0 (4.0 to 5.0)	4.0 (4.0 to 5.0)
9 (Prefer)* collection of the specimen by nurse		NA	NA	3.0 (2.0 to 4.0)	4.0 (2.0 to 4.0)

*All the items included in the () were reverse coded so their scores reflect degree of disagreement with those statements, with higher scores indicating high levels of acceptability. NA, not applicable.

(table 3): “I found the swabs uncomfortable but then it is quite easy to do”; “simple to use, not very comfortable but is no different to visiting the clinic”. Altogether, 95% of participants agreed to use mouth pad and gargle at home and four of five participants expressed willingness to use swabs for rectal and pharyngeal specimen collection at home. The prospect of being able to use specimen collection methods at home and its likely impact on clinic waiting times appealed to the participants: “a lot of people would feel more at ease to use it at home”, “time saving due to the lack of need to wait for an appointment in the clinic”, “less worrying than a clinic visit”. Approximately 1% expressed concerns about losing the opportunity to interact with clinic staff, the possibility of error in collecting the sample or feeling unconfident about self-sampling: “don’t think I would have taken a deep (throat) swab”, “I trust clinicians lot more than I trust my unqualified self”.

Factors affecting acceptability of specimen collection methods for self-sampling

Sociodemographic variables (age, education, sexuality and employment status) and number of times tested for STIs in last year (categories as reported in table 2) were not significantly associated with the feasibility and acceptability of any of these specimen collection methods for self-sampling. Open-ended responses from some participants indicated that prior experience of STIs testing in the clinic enabled them to self-sample for rectal swab but this difference was not statistically significant ($p = 2.81$).

DISCUSSION

Self-sampling in non-clinical settings for specimens to screen for STIs can have a vital public health impact. It may help overcome barriers to clinic-based testing like embarrassment and stigma and potentially improve access to sexual health services. Prior to offering self-sampling as an alternative to clinic-based testing and/or for STIs screening at population level, feasibility and acceptability to self-sample for specimens to screen for STIs need to be understood. Our study findings indicate that self-sampling for oropharyngeal and rectal specimens is feasible and acceptable to MSM in the UK.

This is the first study to report the feasibility and acceptability of self-sampling for pharyngeal specimens using swabs. Participants expressed greater preference for gargle and mouth pad compared with the pharyngeal swabs. High acceptability of gargle is similar to that of the oral-throat rinses reported in other studies.²¹ However, pharyngeal swabs have better sensitivity compared with oral rinses for detection of *C trachomatis* and *N gonorrhoea*.²¹ Similar to the findings from other studies,¹⁹ participants in our study found self-sampling for the rectal specimen to be feasible and acceptable. No significant difference was observed in the sensitivity or specificity between the clinician-taken and the patient-taken swabs screened using Gen-Probe APTIMA Combo 2 assay for rectal *N gonorrhoea* and *C trachomatis* and pharyngeal GC,²⁰ indicating that these methods can be offered to screen for STIs to MSM willing to self-sample.

Ease and convenience of using these methods at home and the lack of need to wait for a clinic appointment appeared to assume significance over the discomfort experienced in self-sampling. Although 76% participants reported self-sampling with all four methods to be feasible and acceptable the remaining 24% were unsure or did not prefer self-sampling. Some expressed concerns about lack of interaction with

clinicians. Thus patients should be offered a choice between home self-sampling and regular clinic testing for STIs.

Participants in our study expressed the need for more illustrations to be included in the information leaflets. Another study has reported success with self-sampling for rectal specimens with the help of illustrated instructions,¹⁹ emphasising that illustrations are necessary to make the information leaflets user-friendly. Participants also provided many suggestions to improve the written instructions, indicating the significance of integrating users’ perspectives in developing such materials.

Studies conducted among women have reported the association between ethnicity and acceptability of self-sampling.^{22–23} We did not explore the association of ethnicity and acceptability because our study population was a relatively homogenous group—that is, mainly Caucasian—indicating that the acceptability of these methods in other ethnic groups needs further exploration.

Our study was clinic-based and therefore has limited generalisability to MSM in community settings. Some MSM did not participate in our study because of concerns about self-sampling, although the proportion that declined was small (10%). If analysis was conducted assuming worst case scenario—that is, non-participants to have reported all the self-sampling methods to be unacceptable (see supplementary table A)—65% feasibility and acceptability of self-sampling would still have been achieved.

Studies have reported the acceptability of the internet to order self-sampling kits to screen for STIs,²⁴ and home self-sampling for bacterial infections increased screening for STIs^{25–26} and improved screening in asymptomatic high-risk women.^{24–25} Home self-sampling can also be used for contact tracing²⁷—that is, partners of MSM diagnosed positive and reluctant to access GUM services can be offered home sampling and encouraged to screen and access care. Further studies to evaluate the cost-effectiveness of home self-sampling as an alternative model to screen for bacterial STIs among MSM are essential to understand the policy and public health implications of such interventions and are being undertaken as the next stage of this research study. Studies should also explore the effect of home self-sampling kits on screening and treatment of partners.

Key messages

- ▶ High prevalence of asymptomatic sexually transmitted infections (STIs), unprotected sex among men who have sex with men (MSM) and delays in access to sexual health services in the UK can contribute to onward transmission of STIs.
- ▶ Novel strategies are needed to improve access and promote early diagnosis and treatment of STIs.
- ▶ Nucleic acid amplification techniques have high sensitivity and enable self-sampling using non-invasive sampling methods like urine and swabs to screen for STIs in non-clinical settings.
- ▶ Self-sampling for oropharyngeal and rectal specimens using swabs, mouth pad and gargle is feasible and acceptable to MSM attending genitourinary medicine services. The majority of the participants were willing to use these methods at home.
- ▶ Home self-sampling for specimens can provide an alternative to clinic-based testing for STIs and has the potential to improve access and frequency of STIs screening.

In conclusion, our study findings indicate that self-sampling for oropharyngeal and rectal specimens using illustrated information leaflets is feasible and acceptable to MSM. Self-sampling can provide an alternative to clinic-based testing for STIs, especially among asymptomatic and at-risk groups willing to self-sample, and has the potential to improve access and reduce intervals between STIs screenings.

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Competing interests: APTIMA unisex swabs were provided free of costs by Gen-Probe (San Diego, California, USA). The findings reported in this study do not reflect the opinion of Gen-Probe.

Ethics approval: Ethics approval was obtained from the Brighton and Mid Sussex Research Ethics Committee.

Contributors: SW: study management, data analysis and interpretation, wrote first and subsequent drafts of the manuscripts and final approval of the published version; CL: study design, study management, critical appraisal and final approval; HS: conception and study design, interpretation of the data and critical appraisal and final approval; MH: conception and study design, interpretation of data and critical appraisal and final approval; AP: data collection and final approval; DR: data collection and final approval; MF: conception and study design, critical appraisal and final approval.

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