Point-of-care tests for sexually transmissible infections: what do ‘end users’ want?


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Abstract. Background: Clinicians and developers identify sensitivity as an important quality in a point-of-care test (POCT) for sexually transmissible infections (STIs). Little information exists regarding what patients want for STI POCTs. Methods: A qualitative study, encompassing five focus groups among attendees of STI and adolescent health centres in Baltimore, Maryland, and Cincinnati, Ohio, were conducted between March 2008 and April 2009. Discussion topics included advantages and disadvantages of having a POCT, perceived barriers to using POCTs in the clinic setting and at home, priorities for the development of new POCTs for STIs, and envisioned characteristics of an ideal POCT. All discussions were recorded and transcribed. A qualitative content analysis was performed to examine frequencies or patterns of recurring codes, which were regrouped and indexed to identify salient themes. Results: Patients attending STI and adolescent outpatient clinics are in favour of diagnostic tests that are rapid, easy to read and simple to use. Home testing options for POCTs were acceptable and provided better confidentiality, privacy and convenience, but clinic-based POCTs were also acceptable because they offer definitive results and ensure immediate treatment. Barriers to home POCTs centred on cost and the ability to read and perform the test correctly at home. Opinions did not differ by patient ethnicity, except that Hispanic participants questioned the reliability of home test results, wanted high sensitivity and desired bilingual instructions. Conclusions: Patients attending STI and adolescent medical centres are in favour of STI POCTs if they are affordable, rapid, easy to read and simple to use.

Additional keywords: acceptability, clinic-based test, diagnostics, home-based test.

Background

Point-of-care diagnostics refers to testing that is done at or near the site of the patient’s care, where the result leads to immediate diagnosis and treatment, and consequent improvement in patient care.1–3 It is not difficult to describe the ideal point-of-care test (POCT). It should be very cheap, very fast, easy to use, and very sensitive and specific. However, in the majority of situations, the ideal is not real or achievable. Defining acceptable is a better starting point.

Sexually transmissible infections (STIs) are prime candidates for POCT development. In the United States, recent estimates from the Centers for Disease Control and Prevention report that there are ~20 million new STIs every year.4 More than half of all sexually active individuals will contract an STI in their lifetime.5 Sequelae from STIs among women include tubal factor infertility, an increased risk of tubal pregnancy, and chronic pelvic pain.5 Unfortunately less than half of adults aged 18–44 years have ever been tested for an STI other than HIV.6 This represents a missed opportunity, as demonstrated by mathematical models that suggest increased screening coupled with increased treatment uptake could significantly decrease chlamydia (Chlamydia trachomatis) and gonorrhoea (Neisseria gonorrhoeae) community prevalence.7 Even if patients are tested, however, current diagnostic approaches rely on laboratory testing with turnaround times of 2–14 days, which can result in low rates of patient return for test results and consequent treatment.8,9 Although rapid POCTs for STIs have been available for over a decade, they have not been accurate, were difficult to interpret or were too costly.10

The World Health Organisation identified benchmarks for an ideal STI POCT in 2006, recognising the tremendous burden of bacterial STIs and the lack of access to laboratory diagnostic services in less industrialised parts of the world.10,11 Since then, newer, rapid and affordable POCTs for syphilis have become
available and are in use in several developing countries.\textsuperscript{12,13} The need to develop more POCTs for use in all settings, including the industrialised world, is an imperative. Though this need is recognised, perceptions of the qualities that describe the desired POCTs differ between frontline clinicians and the industry professionals who are charged with developing and marketing these tests.\textsuperscript{14} Whereas both clinicians and industry agree that a new STI POCT needs to be very sensitive, clinicians rank lower cost as their second priority and the industry ranks specificity as their second priority. Little data exist regarding what the patient wants. Therefore, we conducted focus groups among individuals attending several adolescent health and STI outpatient clinics in order to determine end users’ perceptions and needs regarding their ideal POCT for STIs. Since we also had access to a clinic that offered services primarily to Hispanic community members, we were able to determine if opinions and views on STI POCTs differed by Hispanic versus non-Hispanic ethnicity.

\textbf{Methods}

\textit{Ethics statement}

This study protocol was approved by Institutional Review Boards of The Johns Hopkins University School of Medicine and Cincinnati Children’s Hospital Medical Center, with a waiver of the requirement for written informed consent. Verbal informed consent was obtained from all participants involved in our study.

\textit{Focus group discussions}

Five focus group discussions were conducted between March 2008 and April 2009 in the following sites:

1) Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio. This is an urban clinic that delivers reproductive health services, including STI testing, to over 30,000 teens and young adults each year.

2) Two group sessions at the Healthy Teens and Young Adults Clinic, Western District, Baltimore, Maryland, and the Healthy Teens and Young Adults Clinic, Eastern District, Baltimore, Maryland. Both clinics serve inner city Baltimore teens and adults and offer reproductive health services including STI testing, diagnosis and treatment to over 20,000 individuals each year.

3) Ciudadania Citizenship Clinic, Baltimore, Maryland. This community-based clinic offers healthcare and other public services, such as assistance with citizenship applications, to over 500 people in the Baltimore Hispanic community.

\textbf{Participants}

For all sites, patients who were older than 18 years were informed regarding the focus group study sessions by clinicians or health educators. Flyers describing the study were also given to patients, and interested persons were referred to study personnel for more information regarding study participation and enrolment. Since not all clinic attendees were presenting for voluntary STI services, they could not be considered liberated minors and could not be admitted to the study without parental consent. We therefore excluded younger participants for this study. In total, 58 clinic patients aged \(\geq\) 18 years of age agreed to participate: 40 female patients and 18 male patients. Of these, 25 were Hispanic and 33 non-Hispanic.

\textit{Focus group discussion topics}

Trained structured group discussion facilitators introduced the purpose of the project and briefly outlined the definition of a POCT. The topics explored were: (1) the advantages and disadvantages of having a POCT, (2) perceived barriers to using POCTs in the clinic setting and at home, (3) priority setting for the development of new POCTs for STIs, and (4) the envisioned characteristics of an ideal POCT.

\textit{Data management and data analysis}

Each focus group discussion session, which included responses to the focus group facilitator and interaction between participants, was recorded and transcribed verbatim in Microsoft Word.\textsuperscript{15,16,17} Each verbatim transcription served as a primary text document. Within each primary document, specific quotations were selected and codes were assigned to a word or phrase. Interview transcripts were read repeatedly and were systematically coded multiple times by two investigators (YHH and MB) to increase precision, which was facilitated by using Atlas.ti ver. 6 software (Atlas.ti Scientific Software Development GmbH, Berlin, Germany). Consistency of the coding was checked and no discrepant codes were identified. A qualitative content analysis\textsuperscript{18} was performed to examine the frequencies or patterns of recurring codes for potential conceptual categories in each primary document and all verbatim transcripts. Codes were then regrouped and indexed in order to identify salient themes on STI POCTs by using Atlas.ti software. Recurring themes in relation to this topic were initially determined by a primary investigator (YHH) and checked independently by a second reviewer (MB), and were compared and tested by re-reading transcripts and fine-tuning interpretations.

\textbf{Results}

\textbf{Advantages and disadvantages of having access to a STI POCT in the clinic}

Patients reported that having access to an STI POCT in the clinic setting would save time, as they would not have to wait for test results and this would ensure quicker services. One patient stated that the biggest advantage was to know the results of the tests right away. Clinicians could ‘tell me now while I am right there.’

Most participants did not identify any disadvantages. The only disadvantage identified was with regards to privacy in that ‘other people might know what you there for.’

\textbf{Advantages and disadvantages of having access to an STI POCT at home}

Many advantages were noted for having access to an STI POCT at home. Convenience, confidentiality and privacy were most frequently mentioned. Patients also noted that home access could avoid the hassle associated with going to the clinic, making a clinic appointment and making the time to go to the appointment, and avoid the embarrassment associated
with going to the clinic. Most participants agreed that they would go to a clinic for treatment if the home test results were positive. Some patients thought that having a home POCT would increase health awareness and empower the patient to screen themselves.

As with the clinic STI POCTs, few disadvantages were reports for the home STI POCTs. However, some patients were concerned about reading instructions correctly and thus reading the results correctly. Some were concerned about not knowing which test they should perform and about negative consequences if they performed the test at home incorrectly. Some believed that the test at home could be less accurate than the test performed in the clinic.

Perceived barriers to having STI POCTs in the clinic
Many participants said there were no barriers, but others thought that having the POCT in the clinic may cause some people not to go because ‘people don’t want to hear the truth so they don’t go.’ Some thought that some patients wouldn’t have the time to wait for test results.

Perceived barriers to having STI POCTs at home
Although many participants did not think there were any barriers to having an STI POCT at home, others were worried about privacy issues: ‘Hope that your children don’t find it.’ Others identified cost as a barrier, and the theme of not knowing how to do the test or understanding the instructions regarding how to perform the tests (‘The instructions are only in English.’) were issues. The quality and accuracy of the test were also mentioned as concerns.

Hispanic participants had less trust in POCTs performed at home: ‘If you test on yourself, you not, like, trained on the subject and you might do something wrong.’

Priority for the development of new POCTs for STIs
Gonorrhoea was ranked as the top priority for development of a new POCT for STIs in two out of five focus groups, closely followed by chlamydia, which was also nominated in all five sessions. Other STIs were infrequently indicated as priority by the participants. HPV, genital warts, HIV and trichomonas were nominated in two different focus groups. Herpes was brought up by two participants in one group session. Syphilis, pubic lice and a POCT test for all STIs were proposed in only one group.

Characteristics of an ideal POCT for STIs
The groups unanimously cited the over-the-counter home-use pregnancy test as the prototype model for an ideal POCT for STIs. Most focus group members stated they wanted a POCT ‘just like a pregnancy test’, both characteristically and physically.

Participants mentioned that ease of use was one of the most important characteristics that an ideal POCT should possess. This test should be ‘simple to use’ and ‘user-friendly’. For example, it ‘should automatically change colours to tell you what disease you have,’ should have ‘colours such as green means go, you are ok, and red means get to the doctor,’ and ‘should have a window that spells actually what it is.’ The accuracy of the POCT was also important for the participants with a preferred accuracy of at least 90%.

The ideal STI POCT should have a rapid turnaround time. Most participants preferred to have a much shorter turnaround time; as one participant stated: ‘It’s taking too long, it don’t work.’ The majority’s consensus indicated that 20 min was acceptable as the limit of required time but that 5 min or less was preferred. However, one participant stated ‘I would say like 90 minutes, cause… the longer it takes, the better the positive might come… It’s better cause if time goes fast, like, you might get the wrong result and a positive is really a negative.’

Participants also preferred the ideal POCT to be small in size and have an appealing appearance. Swabs were the main preferred sample collection method, and the ideal test would detect multiple organisms. Some specific quotations from participants are presented in Tables 1 and 2.

Hispanic focus group sessions versus non-Hispanic focus group sessions
Most opinions on the issues that were discussed in the focus group sessions were similar between Hispanic and non-Hispanic group sessions except the following three issues. First, participants in two Hispanic group sessions showed less trust in POCTs performed at home. Two supporting quotes from them are: ‘If you test on yourself, you not, like, trained on the subject and you might do something wrong,’ and ‘There is (bad) consequences you do it by yourself.’ This type of statement was not observed in the non-Hispanic sessions. Second, regarding characteristics of the ideal STI POCT, compared with non-Hispanic group sessions, more Hispanic participants in their group sessions were happy that the ideal STI POCT has an accuracy of 80–90%. Meanwhile, more non-Hispanic participants preferred the accuracy to be over 90%. Finally, Hispanic participants expressed a strong desire that the ideal STI POCT should have bilingual instructions: ‘Make sure the instructions are not only in English.’

Discussion
In this qualitative study, we determined that patients attending STI and adolescent medicine outpatient clinics are in favour of diagnostic tests that are rapid, easy to read and simple to use. Not
surprisingly, the over-the-counter home-use pregnancy test was reported as the prototype model for an ideal POCT for STIs. Home testing options for POCTs were acceptable and provided better confidentiality, privacy and convenience, but clinic-based POCTs were also acceptable because they offered definitive results and ensure immediate treatment specific to the results. More barriers were discussed with home POCTs than with clinic-based POCTs, and these centred on the cost and the users’ ability to read and perform the test correctly at home. Few perceived differences were detected in the opinions of Hispanic versus non-Hispanic participants. Of those, Hispanic participants questioned the reliability of home test results, wanted high sensitivity and desired bilingual instructions.

The results of these focus group sessions, although not surprising, are informative. Patients are not novices to the concept of POCTs given the introduction, use and reported acceptability of rapid POCTs for HIV in various settings, including emergency departments, general practices and walk-in clinics.\textsuperscript{19-21} However, patients may not be as accepting of POCTs for other STIs if the test costs too much, as reported in a study evaluating the acceptability of herpes simplex virus type 2 POCTs among at-risk women in Indiana.\textsuperscript{22} Although provider satisfaction with POCTs is, most likely, the first step towards the successful introduction of such protocols into clinical practice,\textsuperscript{1,14} patient satisfaction with point-of-care testing forms an important part of the assessment of introducing this technology into general practice and may improve the patients’ satisfaction with their overall healthcare and personal disease control. For example, as part of a large multicentre randomised controlled trial assessing the use of POCTs in Australian general practice, satisfaction was measured for patients having pathology testing performed by POCT devices or pathology laboratories. Compared with control patients having tests done at pathology laboratories, patients having POCTs were not only satisfied with the POCTs but also viewed the process as strengthening their relationship with

\begin{table}[h]
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\begin{tabular}{|l|l|}
\hline
\textbf{Topic} & \textbf{Quotes} \\
\hline
Having access to an STI POCT in the clinic & \\
\hline
Advantages & ‘Tell me now while I am right there.’ \\
& ‘Don’t have to wait.’ \\
\hline
Disadvantages & ‘Other people might know what you there for.’ \\
\hline
Barriers & ‘Having the doctor touch your private area.’ \\
& ‘Don’t have time to wait for test results.’ \\
& ‘People don’t want to hear the truth so they don’t go.’ \\
\hline
Having access to an STI POCT at home & \\
\hline
Advantages & ‘I think it will be a good advantage to be able to do the test at home for convenience.’ \\
& ‘So just to be able to do it at home, I think, will be wonderful better. I’ll feel like a doctor.’ \\
& ‘At home, [there’s] no need to make appointment.’ \\
\hline
Disadvantages & ‘I really don’t see any disadvantages. I think it’s great! Well!’ \\
& ‘You may not know what you’re doing exactly, may read the directions incorrectly and you may mess the test up and have to do it all over.’ \\
& ‘There is [bad] consequences [if] you do it by yourself.’ \\
& ‘If you test on yourself, you not, like, trained on the subject and you might do something wrong.’ \\
\hline
Barriers & ‘Like, if I did it at home, it would be like I cheated on her and I got caught up.’ \\
& ‘Hope that your children don’t find it…’ \\
& ‘The instructions are only in English.’ \\
\hline
Characteristics of an ideal POCT for STIs & ‘Like a pregnancy test.’ \\
& ‘It should have a window that spells actually what it is. It will say chlamydia, no chlamydia.’ \\
& (Regarding prioritising STIs for new STI POCTs) ‘I would buy all of them.’ \\
& ‘Automatically change colours to tell you what disease you have.’ \\
& ‘Colours, such as green means go, you are ok, and red means get to the doctor.’ \\
& ‘I’m not going to stand there no longer than 60 seconds. I’ll think it’s taking too long.’ \\
& ‘It’s taking too long, it don’t work.’ \\
& ‘I would say, like, 90 minutes, cause, you know, like, the longer it takes, the better the positive might come, like; maybe, like, it’s better cause if time goes fast, like, you might get the wrong result and a positive is really a negative.’ \\
& ‘Make it look fun, girly.’ \\
\hline
\end{tabular}
\caption{Some quotes on point-of-care tests (POCTs) for STIs from the participants of structured discussion sessions}
\end{table}
their general practitioner (\(P = 0.01\)) and motivational in terms of better managing their conditions (\(P < 0.001\)), which included diabetes, hypertension and hyperlipidemia.\(^{23}\) Similarly, we previously showed that patient trust in results with a POCT increased when they were able to perform the POCT in a clinical setting and compare their results to the clinician’s result.\(^{24,25}\)

In this study, patients seemed eager and ready to accept POCTs for STIs in clinic venues or for home testing. Patients want to know their infection status and receive directed therapy using POCTs for STIs in clinic venues or for home testing. Patients want for quick STI tests.

Sexual Health

Clinical decision-making in rural healthcare settings and compare their results to the clinician’s result.\(^{24,25}\)

What patients want for quick STI tests

Sexual Health

increased when they were able to perform the POCT in a clinical setting and compare their results to the clinician’s result.\(^{24,25}\)

interrupting transmission and providing a definite diagnosis to treat other potentially infected partners. These results are important not only for the industry in the development of STI POCTs that will be acceptable to end users, but also for clinicians who may be offering such tests in the future. This study is qualitative and there are limitations to conducting qualitative research. The number of participants is small; the facilitator may have an impact on participant responses, and the participant interactions may influence the responses. In addition to those standard considerations, this study focussed on patients attending STI clinics and patients attending adolescent clinics in Cincinnati, Ohio and Baltimore, Maryland; individuals attending other types of clinics, such as primary care offices or gynaecology clinics, and those from other metropolitan or rural areas may have different opinions.

We hope that this high patient acceptability of POCTs for STIs will inform and encourage the industry to develop and market these POCTs in the immediate future. This will allow further studies to evaluate if having immediate and accurate diagnoses, treatment and counselling for various STIs will decrease disease transmission and positively impact sexual health.

Conflicts of interest

None declared.

References


