

Published in final edited form as:

Curr Opin Infect Dis. 2013 February ; 26(1): 73–79. doi:10.1097/QCO.0b013e32835c21b0.

Point-of-care testing for sexually transmitted infections: recent advances and implications for disease control

Joseph D. Tucker^{a,b,*}, Cedric H. Bien^{a,*}, and Rosanna W. Peeling^b

^aUNC Project-China, Guangdong Provincial STD Control Center, Guangzhou, China

^bDepartment of Clinical Research, London School of Hygiene and Tropical Medicine, London, UK

Abstract

Purpose of review—Sexually transmitted infections (STIs) remain a major global public health issue, with more than 448 million incident bacterial infections each year. We review recent advances in STI point-of-care (POC) testing and implications for STI prevention and control.

Recent findings—Accurate immunochromatographic assays to detect HIV, hepatitis C virus (HCV) and syphilis antibodies have made home or supervised self-testing possible. Several studies have demonstrated feasibility and excellent test characteristics for HIV, HCV and syphilis POC tests. Rapid oral HIV tests are now available for purchase at retail sites across the United States. Combined HIV and syphilis tests using a single finger prick blood sample are under evaluation.

Summary—Oral POC STI tests with comparable performance to blood-based POC tests are available for self-testing. POC tests can expand screening, improve syndromic management and reduce loss to follow up. POC STI tests have the potential to facilitate prompt treatment and partner services. POC STI tests create opportunities for new social and financial models of community-based testing services. Increasing equity and access to testing will create challenges in linkage to care, quality assurance, partner services and surveillance. These important developments warrant research to understand appropriate contexts for implementation.

Keywords

HIV; point-of-care; sexually transmitted infection; syphilis; testing

INTRODUCTION

The WHO estimates that worldwide, 448 million new cases of curable sexually transmitted infections (STIs; specifically syphilis, gonorrhoea, chlamydia and trichomoniasis) are diagnosed each year [1]. Chlamydial and gonococcal infections can lead to chronic pelvic pain, ectopic pregnancy and infertility. Approximately 25% of untreated early syphilis infections during pregnancy result in stillbirth and 14% cause neonatal death [1]. These sequelae are entirely preventable if STI testing is utilized.

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Correspondence to: Rosanna Peeling, Department of Clinical Research and International Diagnostics Centre, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT, UK. Tel: +44 (0) 20 7927 2529; fax: +44 (0) 20 7637 4314; rosanna.peeling@lshtm.ac.uk.

*Both Joseph D. Tucker and Cedric H. Bien contributed equally to the writing of this article.

Conflicts of interest

There are no conflicts of interest.

STI tests with high sensitivity and specificity are commercially available, but they are often neither affordable nor accessible to many patients in the developing world where STI burden is greatest. Laboratory-based testing often requires patients to return for their test results, leading to loss to follow-up and delays in treatment and partner services. In recent years, advances in detection technology have made a range of point-of-care (POC) tests available [2,3,4[■],5,6]. It is now possible to screen and diagnose STIs at primary healthcare settings using blood from a finger prick or a noninvasive specimen such as oral exudate (Table 1). Molecular assays that can be performed with minimal user input, but provide fast and highly accurate results, are now available for the detection of chlamydia and gonorrhoea. Innovations in the delivery of these POC tests will ensure widespread access to diagnostics so that patients can benefit from evidence-based treatment at the same clinic visit [7]. POC reader technology can securely transmit remote testing results directly to proximate clinical services, decreasing loss to follow-up and improving linkage and retention to care (Fig. 1) [8].

The purpose of this review is to describe technological advancements in the diagnosis of STI at the POC in the past 18 months and the implications for linkage to care, partner services, surveillance and disease control. Although there is no universally accepted definition of POC testing, for the purpose of this review, we define POC test as any test that is simple and can provide a rapid result to guide clinical decisions and follow-up during the same encounter [9]. We searched Pubmed, Scopus and Web of Science using the terms 'rapid testing', 'point-of-care testing', 'self test' and 'home test' and the names of individual STIs. Our review included STIs for which POCs have been developed. We included hepatitis C virus (HCV) because of the importance of homosexual HCV transmission. We included novel multiplex tests that are currently under evaluation.

HIV POINT-OF-CARE TESTS

With more than 34.2 million people globally living with HIV, and 2.5 million new infections estimated to occur annually, there remains an urgent need to accelerate HIV prevention and control efforts [10]. Rapid and POC diagnostic tests are critical tools to help reduce the prevalence of undiagnosed infection, improve monitoring of clinical outcomes and identify incident infections to target prevention and control efforts. Rapid tests for HIV have been used for almost a decade now to increase access to screening in all levels of the healthcare system and for outreach programmes. These tests have been critical in allowing more individuals to know their HIV status and for monitoring disease trends. But it still requires at-risk individuals to attend a health facility, and as most-at-risk individuals are either marginalized from healthcare or stigmatized, innovations in the delivery of testing services are urgently needed.

HIV self-testing using POC tests introduces new opportunities for expanding screening, although a number of related issues must be addressed for effective implementation. In the first major self-testing project in a low-income setting, Choko *et al.* [11[■]] demonstrated the feasibility of HIV self-testing in Blantyre, Malawi, although linkage to care was not investigated. Home HIV POC testing among MSM with high-risk behaviours was acceptable in a small qualitative study in the United States [12]. A randomized controlled trial of HIV POC tests in drug users found that individuals who received POC posttest counselling had no difference in sexual behaviours compared with those who did not [13].

In July 2012, OraSure Technologies, Inc. (Bethlehem, PA) announced that the US Food and Drug Administration (FDA) had approved the OraQuick In-Home HIV test for sale directly to consumers, making it the first and only rapid over-the-counter HIV test approved in the United States. The OraQuick In-Home HIV Test can detect antibodies to both HIV-1 and

HIV-2 with an oral swab, providing a confidential in-home testing option with results in as little as 20 min. The OraQuick In-Home HIV Test is a consumer version of a rapid HIV test and is identical to that approved by the FDA for professional testing. In a phase III study, a population of 5662 individuals of unknown HIV status was self-tested under unobserved conditions and reported their results back to clinical sites. Overall specificity was 99.98% [95% confidence interval (CI) 99.90–100.0] and sensitivity was 93.0% (95% CI 86.6–96.9) compared with blood based specimens [14]. A systematic review showed that although OraQuick had a comparable positive predictive value to blood-based specimens in high-prevalence settings (oral 98.7%, 95% CI 85.7–99.9), its positive predictive value decreases to 88.6% (95% CI 77.3–95.9) for blood specimens in low-prevalence settings [15].

The OraQuick In-Home HIV Test is now available for purchase at more than 30 000 retail outlets throughout the United States and online. A consumer support centre provides consumers 24-h support and enables them to talk to highly trained professionals in English or Spanish. These professionals can provide information on HIV/AIDS, how to properly conduct the test and referrals to local organizations for follow-up testing and care. With a guide price of approximately 40 US dollars per kit, the OraQuick In-Home HIV Test will facilitate efforts to diagnose the more than 200 000 Americans who are unaware of their HIV infections. At the same time, concerns have been raised about whether those at greatest risk will be able to afford the test or do so more than once or twice a year to manage ongoing risks. In addition, community discussions have begun to consider whether the technology can assist at-risk individuals to screen potential sexual partners. As more experience with the OraQuick In-Home HIV Test is obtained, additional information on risk compensation, access and the context within which the tests are being used should be monitored and evaluated.

Acute HIV POC tests have been suboptimal to date [16,17,18[■]], but a POC test based on the nucleic acid amplification test is being developed [19] and an acute HIV POC test has shown promise in paediatric settings [20[■]]. Cell-phone based HIV POCs have also been developed [5], but more operational data are needed in order to understand how best they can be used.

Tests for HIV antiretroviral treatment initiation and monitoring are still severely lacking in resource-constrained settings. The WHO/UNAIDS Treatment 2.0 Initiative emphasizes the essential role that cheaper and simplified diagnostic tools, especially POC technologies, must play in efforts to further expand access to treatment. A number of simplified technologies for CD4 cell count and POC assays for viral load are already available, and for early infant diagnosis are in the pipeline [21]. POC CD4 cell count tests show comparable test sensitivity and specificity to laboratory-based methods and are acceptable to patients [22–24]. A study in Mozambique showed that the introduction of POC CD4 cell count monitoring reduced the proportion of patients lost to follow-up before antiretroviral therapy (ART) initiation from 64 to 33% and the median time to ART initiation from 48 to 20 days [25[■]].

SYPHILIS POINT-OF-CARE TESTING

Globally, WHO estimates that 12 million new cases of syphilis occur each year. Of the 1.4 million pregnant women who are infected each year, almost a million women will transmit the infection to their foetus resulting in stillbirth, low birth weight, prematurity and congenital infection [7]. However, prenatal screening for syphilis has been hampered by the lack of access to laboratories that can offer testing. POC tests provide opportunities for increased access to testing of both pregnant women and at-risk populations, thereby reducing disease burden among sexually active adults and accelerating efforts to eliminate

congenital syphilis [3]. Integrating POC syphilis screening into Prevention of Mother to Child Transmission (PMTCT) programmes for HIV in Uganda and Zambia showed increased uptake of testing for syphilis [26[■]]. Integration of HIV and syphilis POC testing in South China increased uptake of both tests compared with lone HIV testing [27[■]]. A study showed that treponemal POC tests for syphilis can be introduced in the following contexts: rural antenatal clinics in Tanzania, Uganda and China; both rural and urban clinics in Peru and Zambia; and remote indigenous communities in Brazil. By working with the existing healthcare system to integrate testing, the introduction of POC tests resulted in large numbers of women being tested and treated for syphilis, averting many stillbirths and reducing neonatal mortality [28[■]]. The study also showed that the introduction of POC testing can strengthen health systems by increasing prenatal screening coverage, improving health outcomes, increasing client and health worker acceptability, and changing policy guidelines to ensure the sustainability of the service offered. In the long term, the development and implementation of an essential POC prenatal package to include essential noncommunicable disease (e.g. anaemia and preeclampsia) testing could be useful.

The persistence of treponemal antibodies mandates the use of a nontreponemal test to identify those who have an active infection and to avoid overtreatment. The availability of treponemal POC tests has fuelled a debate about the merit of screening with a treponemal test followed by confirmation of syphilis with a nontreponemal test. Linkage to clinical care remains a priority in these populations, especially in light of the trend that a substantial portion of syphilis-infected individuals are lost to follow-up prior to confirmatory testing [29[■]]. The availability of POC treponemal/nontreponemal combination tests will hopefully clarify questions about the optimal order of tests and concerns about overtreatment [6]. POC tests that offer multiple tests with a single finger prick specimen for HIV and syphilis are under evaluation [4[■]]. These will be important tools for the joint elimination of mother to child transmission of HIV and syphilis.

HEPATITIS C VIRUS POINT-OF-CARE TESTING

HCV infection is now recognized to be among the most prevalent chronic bloodborne infections, with more than 150 million people chronically infected and at risk of developing liver cirrhosis and/or liver cancer worldwide, and 3–4 million people infected annually [30]. Although HCV is not efficiently transmitted sexually, except possibly among HIV-positive MSM, persons at risk for infection through injection drug use might seek care in STD treatment facilities, HIV counselling and testing facilities, correctional facilities, drug treatment facilities, and other public health settings where STD and HIV prevention and control services are available. HCV antibody POC tests were recently approved in Europe for bodily and oral fluid [31]. The FDA also approved HCV POC tests for finger stick and venipuncture specimens [32]. OraQuick tests using oral samples or blood have been shown to be comparable to laboratory-based enzyme immunoassays with better specificity and sensitivity compared with four other POC tests [31,33]. US premarket studies in the field and laboratory demonstrated high sensitivities and specificities for the OraQuick fingerstick assay [34,35[■]], although two other POC tests were less sensitive and produced false negatives in patients who were coinfecting with HIV [34,35[■],36[■]]. An OraQuick oral swab POC test implemented in community-based organizations (CBOs) showed similar test characteristics to laboratory-based tests [37[■],35[■]].

GONORRHOEA AND CHLAMYDIA POINT-OF-CARE TESTING

Gonorrhoea and chlamydia POC tests have been hampered by low sensitivity and specificity compared with nucleic acid amplification assays in low-prevalence populations and cross-reactivity with nongonococcal *Neisseria* [38–40]. Given decreasing susceptibility to first-

line antibiotic treatment [41], there is also a growing need for POC resistance testing. At the same time, POC tests for the simultaneous detection of chlamydia and gonorrhoea based on isothermal amplification technologies are in final stages of development. They will be more rapid and less expensive than the GeneXpert platform, which is already being sold as a POC test platform [42,43].

OTHER SEXUALLY TRANSMITTED INFECTION POINT-OF-CARE TESTS

Self-testing for trichomoniasis with POC tests has been shown to be acceptable and feasible with training [44]. Bacterial vaginosis POC tests have been available for several years, but no recent studies have examined linkage to care or treatment. Bacterial vaginosis POC tests detect sialidase activity in vaginal fluid, and a recent study confirmed excellent sensitivity and specificity when compared with Gram stain [45].

NEW ORGANIZATIONAL AND FINANCIAL MODELS FOR POINT-OF-CARE TESTING

POC tests offer unprecedented opportunities for a variety of organizational and financial models for improving health, similar to at-home pregnancy tests and blood sugar tests. STI POC tests accelerate decentralization of testing to remote locations, CBOs, pharmacies and in the home. CBO-based testing provides an opportunity to provide more community-responsive services to most-at-risk populations who are in greatest need of frequent testing. Building on the CBO POC testing model, the Barcelona Checkpoint HIV POC service uncovered a substantial share of new HIV diagnoses in the city [46]. A pilot programme launched by the US Centers for Disease Control in 2012 made HIV POC testing available at 40 pharmacies free of charge [47]. Those who received tests were required to provide identifying information at check-out in order to ensure follow-up. Home testing is another organizational model made possible by simple technology that does not require trained personnel. These new organizational models raise important questions about optimal venues, times, linkage to care follow-up, partner services and quality control. STI POC tests also provide opportunities to create new financial models, giving options outside of the traditional public health service model for most at-risk populations. Revenue generation through the sales of STI POC tests or testing services could be reinvested in CBOs and run as a social enterprise [48]. These models may be especially feasible in middle-income countries among subsets of MSM who are able to pay for POC test services. Pure business models for diagnostic services have also emerged [9,49].

LINKAGE TO CLINICAL CARE

The decentralization of testing services has increased, not decreased, the importance of clinics. Clinical services are critical for diagnostic confirmation, treatment, counselling and follow-up services. This necessity reflects both the limits of decentralized testing and the increasing importance of collaboration between clinic and nonclinical partners (CBOs, pharmacies, businesses) in providing testing and partner services. Local multisectoral networks that incorporate knowledge and expertise from a number of sectors are more likely to be community responsive, sustainable and effective in expanding testing to most at-risk populations [48].

QUALITY ASSURANCE

Although STI POCs are generally simple and easy to perform, ensuring proper implementation that leads to adequate sensitivity and specificity onsite is important. Visually read and manually prepared tests can lead to decreased accuracy of POC tests.

Methods for measuring STI prevalence outside of clinics (e.g., dried blood spots) and formalized systems for quality assurance are both needed. Quality assurance on POC testing and case management can help ensure test quality in decentralized settings and identify where remedial training is required [8]. Devices that interpret POC tests can remove the subjectivity of reading and reduce transcription error by automated transmission of testing results to a central database for disease surveillance.

CONCLUSION

Oral POC STI tests with comparable performance to blood-based POC tests are now available for supervised self-testing or home use. POC STI tests can be used to expand screening, improve syndromic management and reduce loss to follow up. Their use can result in accelerated treatment initiation and delays in partner services. They also create opportunities for new social and financial models of community-based testing services. Increasing equity and access to testing creates challenges in linkage to care, quality assurance, partner services and monitoring of disease trends to inform control strategies. These important developments warrant further research to understand appropriate contexts for implementation.

Acknowledgments

J. Tucker is the recipient of an NIH Fogarty Career Development Award (US NIH 1K01TW008200-01A1), the BWH/ASTMH Postdoctoral Fellowship, and C. H. Bien is the recipient of a Doris Duke Medical Foundation International Medical Student Fellowship. Special thanks to Kevin Fenton for his contributions and providing comments on a previous version of this article.

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- of special interest
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KEY POINTS

- Accurate STI POC tests to detect HIV, HCV and syphilis antibodies now make home or supervised self-testing possible.
- Several studies have demonstrated the feasibility of STI POC self-testing, but linkage to care, quality assurance and surveillance remains a concern.
- Oral POC HIV tests are available for purchase at retail sites in the United States.
- STI POC tests can expand STI screening, improve syndromic management and reduce loss to follow up.

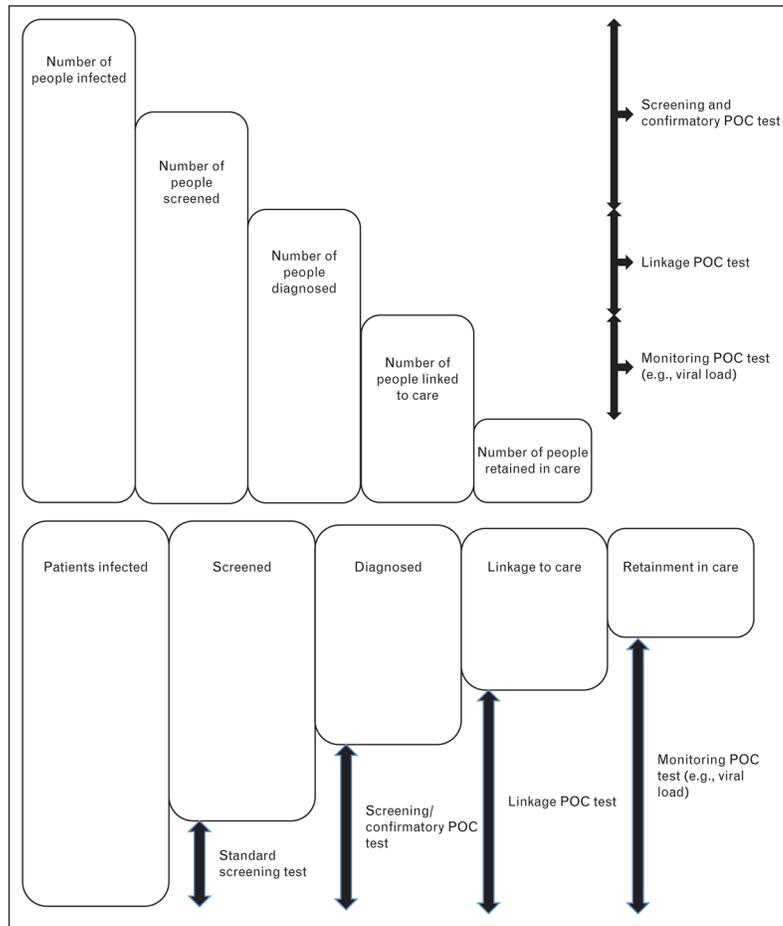


FIGURE 1. Overview of the cascade of sexually transmitted infection services and point-of-care testing functions. POC, point-of-care.

Table 1
 Overview of point-of-care technologies for selected sexually transmitted infections

Pathogen	Specimen	POC technologies			Antibody	Multiplex
		NAAT	Antigen	Antigen		
HIV	Blood (fingerprick), oral swab	In development	Yes	Yes	Duplex antibody tests with syphilis	
Syphilis	Blood (fingerprick)	NA	NA	Yes		
HCV	Blood (fingerprick), oral swab	No	No	Yes	With HIV tests in development	
Gonorrhoea	Urethral/vaginal swab	In development	Yes	NA	NAAAT with chlamydia	
Chlamydia	Urethral/vaginal swab	In development	Yes	NA	NAAAT with gonorrhoea	
Trichomonas	Vaginal swab	No	Yes	NA	No	
Bacterial vaginosis	Vaginal swab	No	Enzyme detection	NA	No	

HCV, hepatitis C virus; NA, not applicable; NAAT, nucleic acid amplification tests; POC, point-of-care.