Point-of-care testing to strengthen sexually transmitted infection case management in resource-constrained settings

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ABSTRACT

Syndromic management remains the standard approach for sexually transmitted infection (STI) care in many low-resource settings. Recent advances in point-of-care (POC) diagnostic testing offer the opportunity to improve STI case management by enabling targeted treatment, reducing unnecessary antibiotic use, and strengthening partner services. This educational article summarizes key insights from a symposium organised by the World Health Organization and Gates Foundation at the STI & HIV World Congress 2025. Evidence from modeling studies in Zimbabwe and South Africa demonstrates significant reductions in overtreatment and population-level STI burden with POC test integration. Acceptability among end-users and providers is high, contingent on rapid, confidential testing linked to same-day treatment. The article reviews the current landscape of STI POC tests, including WHO's REASSURED criteria and target product profiles, and discusses regulatory progress and technical specifications for prequalification. Implementation strategies emphasize integration into existing health services, capacity building, stakeholder engagement and importance of robust quality assurance processes. While cost-effectiveness data remain limited, strategic investment and policy development are essential to scale up STI POC testing. With growing technological feasibility and public health urgency, POC testing represents a paradigm shift in STI management, offering a pathway to more effective, equitable, and sustainable care in resource-constrained settings.

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The World Health Organization (WHO) estimated in 2020 that 374 million new cases of curable sexually transmitted infections (STIs) occur globally each year.[1] The highest incidence is observed in low-resource settings, where syndromic management is the standard of care. Introduced by WHO in 1984, syndromic management is a clinical approach that uses algorithms to guide empirical antimicrobial treatment based on signs and symptoms – such as vaginal discharge and urethral discharge – without diagnostic testing. Availability and implementation of rapid diagnostic tests for STIs will improve quality of care, reduce overtreatment and missed infections, and mitigate against antimicrobial resistance.[2]

This overview covers advances towards implementation of STI diagnostics in low-resource settings, as presented at a symposium co-organised by WHO and the Gates Foundation at the STI & HIV World Congress in Montreal, Canada (29 July 2025).

Benefits of STI point-of-care (POC) testing

Syndromic management is effective, easy to implement, and relatively inexpensive. However, it is associated with substantial overtreatment resulting in unnecessary antibiotic use and its effectiveness is often compromised by patient, provider, and healthcare system barriers such as limited knowledge and awareness, different levels of stigma, lack of equitable access and inadequate service delivery. To overcome some of these barriers, the 2021 WHO guidelines for the management of symptomatic STIs recommend that treatment for urethral and vaginal discharge be based on same-day results of a high-quality diagnostic test for *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* conducted during the initial clinical visit.[2]

Recent advances in point-of-care (POC) diagnostic tests for STIs offer an opportunity to strengthen the quality of STI management. POC STI testing improves outcomes through targeted treatment and reduced

antibiotic use in symptomatic individuals. A recent mathematical modelling evaluation showed that implementation of a POC test could reduce overtreatment for both *C. trachomatis* and *N. gonorrhoeae* by 85-95% among women with vaginal discharge syndrome in Zimbabwe, whilst reducing the population burden of *N. gonorrhoeae* and *C. trachomatis* by an estimated 24% and 15%, respectively, by 2040.[3] Similarly, based on a different model, excess use of antibiotics reduced by 78-88% (three different scenarios) in South Africa if *N. gonorrhoeae*, *C. trachomatis* and *Trichomonas vaginalis* near-POC testing was implemented within syndromic management of symptomatic men and women.[4] Other benefits of STI POC testing include strengthened partner services to prevent reinfection, an opportunity to link the right people to HIV prevention and treatment services, allocation of limited resources to those most in need, and enhanced stewardship of (novel) drugs for *N. gonorrhoeae*.[5]

Acceptability of STI POC testing

STI POC testing is widely regarded as acceptable among end-users, such as adolescent girls, young women and pregnant women, provided that the tests are rapid, confidential, and linked to same-day treatment.[6] Concerns include the potential for extended consultation times, and out-of-pocket expenses (i.e. direct costs paid by the patient for the test, treatment or related services), which may pose a barrier to uptake. Stigma may be reduced through education and counselling related to STI POC test results, and patient-provider relationship could be improved. Healthcare providers also view STI POC testing as acceptable, especially in its role of clinical decision making.[6,7] End-users and providers both acknowledge that STI POC testing can enhance patient-provider communication and education, foster trust in clinical care, and facilitate timely partner notification.[7,8] However, successful implementation requires careful consideration of test availability, service workflow integration, staff training, quality control and management systems and cost-effectiveness.[8]

Landscape of STI POC tests

The REASSURED criteria provide guidance on the ideal characteristics of POC tests for use in resource-limited settings: Real-time connectivity, Ease of specimen collection, Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free or simple, and Deliverable to end-users.[5] Aligned to these criteria, WHO has published target product profiles (TPP) for rapid diagnostic tests for *C. trachomatis, N. gonorrhoeae* and *T. vaginalis* that include specifications for test performance (sensitivity/specificity), price (<5 US$; optimally <1 US$), time to results (≤60 minutes; optimally <15 minutes) and device characteristics (single use, biodegradable with or without automated reader).[9]

There is a large pipeline of STI POC tests, but many of these are in pre-clinical stage of development, have unknown regulatory status or are restricted to research use. To date, several tests have received US FDA clearance: binx io CT/NG (Binx health Limited), Xpert® CT/NG (Cepheid), and cobas® liat CT/NG and CT/NG/MG (Roche); the Sexual Health Test (Visby Medical) received FDA clearance for at-home use.[10] These molecular tests have excellent performance but are unlikely to be affordable for use at large scale in low-resource settings. Rapid antigen tests utilizing lateral flow detection may provide a lower cost option, but quality assurance is critical to ensure that they meet the required performance characteristics.[11] However, ultra-sensitivity of such tests may not be required for health impact, especially in settings without access to other types of diagnostic testing. The WHO guidelines for the management of symptomatic STIs recommend a high-quality molecular test for men and women with genital discharge to optimize syndromic management.[2] However, if such a molecular test is unavailable, WHO suggests treatment of vaginal discharge syndrome based on a quality-assured rapid test for *C. trachomatis* and/or *N. gonorrhoeae* with minimum sensitivity of 80% and specificity of 90% as another option to strengthen STI case management.[2]

An important catalyst in this diagnostics development field is the recent publication by WHO of the Technical Specification Series (TSS) that set out performance evaluation criteria for meeting

prequalification (PQ) requirements for three types of STI diagnostic test: 1) in vitro medical device used for qualitative detection of *C. trachomatis*, *N. gonorrhoeae* and/or *T. vaginalis* nucleic acid (TSS-24), 2) rapid diagnostic test to detect *N. gonorrhoeae* antigen (TSS-25), and 3) rapid diagnostic test to detect *C. trachomatis* antigen (TSS-26) (available from: extranet.who.int/prequal/vitro-diagnostics/technical-specifications-series-ivds). PQ status promotes industrial investment in technical development, supports regulatory processes and market access, and facilitates procurement of prequalified tests by countries. These take important considerations for LMICs into account including heat stability, ease of use, storage and field performance. PQ plays a significant role in access to POC STI tests but implementation ultimately depends on local regulatory pathways, affordability and operational feasibility.

Implementation of STI POC testing in low-resourced settings

STI POC test results should inform treatment decisions. Implementation models should consider important elements such as who will perform the test, how and where the test will be performed, while ensuring that waiting times are limited and the clinic flow is maintained, and how costs will be covered comprehensively and in a sustainable way (e.g. workforce, quality assurance programmes).[11] Important opportunities include self-collection of specimens (and future possibility of self-testing), and testing by lay workers if adequately trained. Service integration is another essential element; acute care, HIV prevention and treatment, sexual and reproductive health, and antenatal care services provide important entry points for STI POC testing.[12] The reverse is also true: STI testing can be the portal of entry for additional services, such as HIV prevention, antenatal care, and other reproductive health services.

Capacity building of healthcare workers and facility support including quality management are essential for successful implementation. This will establish user and provider trust in STI POC testing (reducing stigma), stimulate testing uptake, and ensure appropriate patient counselling and management decisions.

Importantly, the larger healthcare eco-system and stakeholders should be included in the process to ensure a supportive environment and avoid implementation barriers.

Cost-effectiveness of implementation of STI POC tests

Studies on the cost-effectiveness of STI POC testing are lacking, especially in low resource settings. The cost of syndromic treatment is lower than the initial cost of implementing currently available STI POC tests.[5] Opportunities to reduce the cost of STI POC test implementation include multiplex testing for the appropriate pathogens, pooling of samples (without affecting diagnostic accuracy), and context-specific targeted screening approaches, for example based on risk factors.

Important effectiveness measures of STI POC testing include appropriate patient management, infection cure rate and related health outcomes (e.g., pelvic inflammatory disease), partner notification and management, antibiotic stewardship and impact on antimicrobial resistance, health facility utilization, and decreased population infection burden. However, for various reasons including study variability,[8] estimation of these effectiveness measures remains challenging.

Future perspectives

Syndromic treatment has been at the core of STI management for over four decades. However, a paradigm shift is emerging.[13] Strengthening STI case management through POC testing, as recommended by WHO, represents an important strategy to improve STI treatment outcomes and mitigate health impact. This approach is both acceptable and technologically feasible, and it can be integrated into existing service delivery models. Furthermore, STI POC tests could be leveraged for targeted screening of asymptomatic infections within integrated service settings, helping to prevent onward transmission and improve health outcomes.

Despite its promise, an important gap remains due to the lack of investment cases, missed effectiveness data and limited cost-effectiveness data, acknowledging that the initial costs of implementation may lead to long-term saving. For countries to successfully adopt STI POC testing, comprehensive policy development and adaptation are required. This includes investment in the procurement, distribution and quality assurance of diagnostic tests, alongside capacity building for healthcare workers.[11] Furthermore, the establishment of clear testing guidelines, treatment algorithms and standard operating procedures is essential. Active engagement of community stakeholders and the private sector will be key to advocacy and driving uptake, including local production of low-cost assays. To ensure effective implementation, robust monitoring and evaluation systems must be put in place.

In conclusion, with recent advances across multiple sectors, the implementation of POC testing to strengthen the quality of STI management in resource-constrained settings is increasingly within reach. To achieve this paradigm shift, strong advocacy and strategic investment are essential to ensure that public health programs prioritize and integrate STI POC testing into routine care.

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