This article has been accepted for publication in SEXTRANS following peer review.
The definitive copyedited, typeset version is available online at
10.1136/sextrans-2025-056889

TITLE

Implementing STI Point-of-Care Testing Using a Whole-System Programme Model: the ProSPiRO Implementation Research Protocol

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ABSTRACT

Objectives

Sexually transmitted infections (STIs) continue to cause substantial global morbidity and mortality, compounded by reliance on syndromic management and limited access to laboratory diagnostics. Although point-of-care tests (POCTs) can enable timely diagnosis and treatment, their adoption within health systems remains inconsistent. Here we present an implementation research protocol that aims to generate evidence on the acceptability, feasibility and suitability of a collaborative whole-system programme model to support implementation of STI POCTs and improve access to STI testing and treatment across diverse populations and settings.

Methods

This implementation research protocol describes a whole-system programme model for STI POCTs that can be locally adapted across multiple countries and is delivered through structured, interest-holder-led workshops. Participating sites will vary across sexual and reproductive health services, antenatal care and general practice. Sites will implement POCTs for *Chlamydia trachomatis, Neisseria gonorrhoeae*, *Trichomonas vaginalis* and/or HIV/syphilis for one year. A mixed-methods evaluation will assess patient clinical outcomes, health system capacity, economic costs and acceptability among patients, healthcare professionals and policymakers. Quantitative data will be collected before and after implementation, alongside qualitative data from workshops, focus group discussions and interviews. A realist case-study comparison approach will examine mechanisms influencing implementation. Primary outcomes include changes in same-day diagnosis and appropriate treatment, patient and provider acceptability, service delivery capacity and incremental cost consequences compared with usual care. The evaluation will identify which components of the programme model are effective, for which services, and under what circumstances, and will generate policy-relevant evidence on barriers and facilitators to POCT adoption.

Conclusions

This study addresses a key evidence gap in how to integrate STI POCTs sustainably within health systems. By combining local co-design, structured knowledge exchange and rigorous evaluation, the programme model has the potential to support equitable scale-up of STI POCTs and inform national policy and service delivery.

KEYWORDS
Point-of-care testing; sexually transmitted infections; protocol; implementation research

KEY MESSAGES

What is already known on this topic

- Sexually transmitted infections (STIs) remain a major global public health challenge, due to syndromic management and limited laboratory capacity; although Point-of-care tests (POCTs) can improve timely diagnosis, treatment and antimicrobial stewardship, their uptake has been slow and uneven, particularly in low-resource and high-burden settings.

What this study adds

- This study protocol represents a generalisable, whole-system programme model to support contextually appropriate implementation of STI POCTs integrating structured interest-holder engagement, knowledge exchange and local co-design to align diagnostic adoption with clinical, operational, economic and policy priorities.
- A mixed-methods, realist evaluation will generate evidence on clinical impact, cost consequences, acceptability and health system readiness, identifying what works, for whom and under what circumstances.

How this study might affect research, practice or policy

- Findings from the study will inform evidence-based integration of STI POCTs into routine care and support equitable, sustainable scale-up through a practical implementation toolkit for healthcare providers, programme managers and policymakers.

MAIN BODY OF ARTICLE

Background

Curable STIs remain a global health priority. World Health Organization (WHO) estimates indicate that, among individuals aged 15-49 years, 374 million new infections with *Treponema pallidum* (syphilis), *Neisseria gonorrhoeae* (NG), *Chlamydia trachomatis* (CT) and *Trichomonas vaginalis* (TV) occurred annually [1]. Accurate diagnosis of these infections ideally relies on laboratory-based tests or specialised techniques such as microscopy and culture, which require both equipment and highly trained healthcare or laboratory professionals [2]. However, in many settings, STIs are still diagnosed and treated based on patients' clinical history and symptoms alone, so-called syndromic management. This approach risks missing infections, particularly in asymptomatic individuals, while also leading to unnecessary, inappropriate, or suboptimal treatment. Such practices contribute to adverse reproductive health outcomes and increased selection pressure for antimicrobial resistance (AMR) [3]. Point-of-care tests (POCTs) that are rapid, accurate, and deliver results within a single visit have the potential to transform STI control by improving case detection,

reducing sequelae and antimicrobial resistance, and enhancing access to screening, including antenatal care and key populations [4, 5].

Despite their potential, diagnostic innovations face multiple barriers to adoption within health systems [6]. Poor understanding of social and political factors and lack of evidence for real-world clinical utility have been identified as significant barriers to adoption of new diagnostics into clinical practice [7]. Implementation research aims to bridge the gap between research-based evidence and clinical practice. Use of 'whole health systems' approaches in implementation research allow for integration of innovations based on evidence of their fitness for purpose in specific contexts [8, 9]. A health system has been broadly defined as 'all the activities whose primary purpose is to promote, restore or maintain health' within a given country [10].

Sustainable national implementation of STI POCTs requires involvement of the whole health system, beyond individual clinical services (11). Considerations for implementation include clinical utility across different populations and upfront and ongoing costs [11–13]. Implementing new diagnostics may also require a level of service restructuring, which are central concerns for healthcare professionals and managers [9, 14]. Perspectives from communities and service users are equally relevant, as these changes impact their care delivery [15]. Policy can also play a critical role in integration success or failure [15, 16].

Knowledge exchange, a bidirectional process of sharing and applying knowledge between interest-holders, facilitates problem-solving for barriers to complex system changes [9, 17]. An evaluation of a complex intervention to 'modernise' three services, including sexual health, across two London boroughs, found that knowledge exchange between interest-holders was crucial for integration of once-fractured service provision[18]. Generation of locally specific clinical utility, alongside published clinical trial data, led interest-holders to trust in the initiative [19]. The SEED-SCALE theorical model utilises a whole system approach and is guided by simple, replicable steps to establish and foster knowledge transfer and has been applied in urban and rural localities across multiple low-mid and high-income countries [17].

We have developed a *collaborative whole-system* programme model for STI POCT implementation integrating SEED-SCALE principles for knowledge exchange alongside generation of locally specific clinical utility data. Our programme model uses standardised core components to embed knowledge exchange between key interest-holders, promoting their ownership of the decision-making process for choice and implementation pathways for new diagnostics. The core components also promote self-efficacy for generation of locally specific evidence of the diagnostics' success (or failure) to produce value within their services. By keeping the core components simple, the model also allows for critical local adaptation. The model foresees a series of workshops across a wide and diverse range of interest-holders nationally, and, for those local services that agree to move forward, the identification, negotiation and development of localised plans for POCT implementation (Figure 1).

The programme model workshops were recently piloted to facilitate implementation of Binx CT/NG io™ POCTs within National Health Service sexual health clinics in England [20]. In our

pilot, qualitative findings highlighted the benefits of locally led implementation strategies. Interest-holder workshops identified key social and political facilitators for adoption and leveraged these to design and implement new clinical pathways for CT/NG POCT [14, 21].

Project description:
The proposed study protocol is for implementation and evaluation of the *collaborative whole-system* programme model for STI POCTs. We provide a completed Standards for Reporting Implementation Studies (StaRI) checklist [22] in supplemental material 1. We will evaluate both diagnostic test clinical utility and the programme model. This allows us to understand if the model facilitated choice of specific POCTs and their associated clinical pathways at sites, and how it maps to clinical, facility and economic (costing) outcomes, and patient and healthcare professional acceptability. Success will be measured by our ability to determine which aspects of the model worked for which types of sites under which circumstances, and create specific tools to promote evidence-based, equitable implementation of STI POCTs.

Aims:
1. To improve access to STI testing and treatment among various populations across different settings including specialised clinics, primary health care, community outreach (intervention)
2. To generate evidence of the acceptability, feasibility and suitability of a programme model designed to facilitate the implementation of STI POCTs across different health systems and populations (implementation)

Study sites/countries
This is a generalised evaluation protocol. While the evaluation can be implemented across multiple countries and diverse health services, with local adaptation. We provide a single-country example in (supplemental material 2).

Each country is expected to include one or more sexual health services as local sites for implementation. A sexual health service is defined as the organisational structure within which specialist or non-specialist clinics operate to provide sexual healthcare for either the general population or targeted groups.

Recruitment
All countries are eligible to express interest in this programme with eligibility assessed based meeting these criteria: a local lead able to engage key interest-holders for diagnostic implementation; commitment in principle to adopt one or more CT/NG, TV, and/or HIV/syphilis POCT; availability of service(s) with sufficient capacity to support their implementation. Participation will be determined through an online survey completed by self-identified country leaders to assess eligibility, with countries meeting the described criteria invited to take part.

Patient groups included within each service will be defined according to international and local guidance, and local epidemiology, with the final decision made by the local healthcare implementation group, and/or established national decision-making processes. Our focus will be:

- Screening for asymptomatic STIs and HIV/syphilis in antenatal clinics;
- Screening for asymptomatic STIs in key populations, young adults at risk, and in primary health care settings;
- STI case management in settings traditionally reliant on syndromic management.

POCT tests used

POCTs at each participating centre are expected to be implemented in one or more of the following configurations: CT/NG + TV screening; HIV/syphilis screening; CT/NG + TV case management; HIV/syphilis case management.

Specific types of tests will be decided by international and national policy, regulations, guidance, and availability.

Procedures

The implementation research will be coordinated by the WHO in collaboration with academic researchers (SSF, STS, IT), who will oversee data collection, management and analyses. This international research team will work together with national clinical and/or academic investigators, who will facilitate local activities.

Objective 1: Using the collaborative whole-systems programme model, co-design and implement localised plans to adopt diagnostics for STIs within multiple countries' sexual health services.

National interest-holders will be asked to self-organise a face-to-face workshop with the international research team (Workshop 1). This workshop will be central to co-creating the local implementation plan, including decision on additional clinical utility data, selection of specific diagnostic test(s), and identification of leads for key tasks, (e.g., training and materials transfer). It will also provide an opportunity to identify and include any missing interest-holders, with site leaders responsible for engaging them.

Some site attrition is anticipated at this stage, as plans become more concrete. Sites that remain engaged will be considered enrolled, while those that withdraw prior to enrolment will be replaced until the purposive sampling framework is complete.

Following enrolment, site leaders will be asked to establish national and local interest-holder advisory boards to meet as needed throughout the project. Clinical leads will also be asked to identify key clinic-based interest-holders to form a local healthcare implementation group responsible for organising Workshop 2. This workshop will focus on developing detailed implementation plans, including defining target patient groups, timing and care pathways. Smaller task-oriented sub-groups (e.g., data collection, quality assurance, supply management) will support delivery, including peer-led training to mitigate knowledge loss due to staff turnover.

Implementation at each site will begin shortly after Workshop 2. Diagnostics will be selected by the local healthcare implementation group, and/or national decision-making process. Each site will implement the diagnostic(s) for one year to accommodate the anticipated iterative changes in service delivery.

Objective 2: Evaluate changes resulting from POCT at all participating sites, specifically: patient clinical outcomes, patient and healthcare professional acceptability, health system changes and economic cost. These data will provide an essential evidence-base for implementation sustainability and scale-up decisions.

A. Patient clinical outcomes

Aggregate patient data for all patients will be collected from patient records and analysed per clinic at baseline (pre-implementation) and post-implementation (final three months of implementation). Outcome measures will include, at minimum, the number of patients receiving same-day results and those appropriately treated. Where available, we will also assess numbers of partners appropriately treated. Additionally, patient attendance for those targeted for POCT use after implementation will be captured and compared with data from site selection questionnaires to assess changes, including the number of follow-up visits averted.

B. Health system capacity

We will adapt the WHO Service Availability and Readiness Assessment (SARA) questionnaire to quantitatively capture changes in staffing and resources before and after STI POCT implementation. Descriptive statistics (percentages, median) will be used to describe any change in service delivery at each site before and after diagnostic implementation.

C. Acceptability of diagnostics

We will conduct a before-and-after cross-sectional survey of patients at participating services, to assess patient acceptability of care pathways. A consecutive cohort of patients receiving at least one new STI diagnostic as part of their routine care in the final three months of the programme implementation will be invited to complete a self-administered survey on their care experiences.

Focus group discussions (FGDs) with healthcare professionals will be held before and after the one-year implementation period to measure acceptability of diagnostic implementation as well as the reach, fidelity and effectiveness of implementation methods.

D. Incremental cost-consequence analysis

We will undertake an incremental cost–consequence analysis comparing POCT implementation with usual care, presenting costs alongside key outcomes in a disaggregated manner. Outcomes will align with those defined above, including clinical endpoints (e.g. same-day diagnosis and appropriate treatment, sequelae at follow-up), health system measures (e.g. service capacity and number of visits), and acceptability among patients and healthcare professionals.

The primary base case analysis will adopt a healthcare perspective. Prospectively collected resource use and cost data will include all initial and ongoing costs, with unit costs sourced from published or locally confirmed information. Longer-term outcomes will be informed by 10-month follow-up data from a subset of patients at each site. Results will be presented as incremental costs alongside differences in each outcome.

Objective 3

A. Theory of barriers and facilitators to creating policies for local adoption of STI diagnostics

Following site enrolment, policymakers and policy experts will be invited to informal discussions to explore interest-holder roles in national health policy making, perceptions of diagnostics for sexual health, the clinical utility evidence required for local STI POCT policy adoption, and alignment with existing policies with POCT implementation. A grounded theory approach will be used to analyse these data and develop theories on the drivers and barriers influencing local policy adoption of STI diagnostics.

B. Toolkit for STI POCT adoption and implementation

Data from objectives 1-3 will inform the development of a toolkit to guide interest-holders in adopting and implementing STI POCTs. The toolkit will include a step-by-step implementation booklet for clinical implementers along with targeted information briefs summarising evaluation findings for programme managers, policymakers, and other relevant interest-holders.

Objective 4:

We will evaluate reach, fidelity and acceptability of the implementation programme at each participating health centre using a realist, case-study comparison approach to understand "what works for whom and in what circumstances" (44). For comparability, sites with similar implementation plans (e.g., CT/NG + TV case management) will be grouped for analysis where possible. This evaluation will require qualitative re-analysis of both quantitative and qualitative data collected for objectives 1-3.

A. Quantitative evaluation of implementation feasibility (site attrition; enrolment)
   - Site selection data will be analysed to compare the characteristics of services that applied with those that did not fully enrol, providing insights into feasibility limitations and theoretical generalisability of our approach.
   - Analyses of cost-consequence results and health systems capacity assessments will evaluate the impact of POCT implementation on patient outcomes and service delivery at each site, including any unintended consequences.

B. Qualitative evaluation of context, implementation (process, fidelity, reach) and mechanism(s) of impact (acceptability, unexpected pathways)
   - Workshops data will provide insights into process, fidelity and reach of the programme model. Thematic analysis will examine the process of implementation including adherence to the model in implementation (fidelity) and the effectiveness of workshops in disseminating knowledge on POCT implementation at each service (reach). Patient questionnaire data will further inform understanding of acceptability and fidelity of care pathways.
   - Analysis of informal interviews with policymakers together with workshop data on intended pathways and focus group discussions on implemented pathways, will provide insights into the acceptability of the programme as a knowledge-exchange mechanism for POCT implementation.
   - Analysis of informal interviews with policymakers combined with workshop data, cost consequence and clinical outcomes and health systems capacity

assessments will evaluate the usefulness of implementation data on informing policy decisions, including intentions for sustainability and scale-up.

Community participation

Patients and community involvement is central to this project, particularly to improve testing uptake and engagement with participating sexual health services. Patient groups will be identified by site contacts and invited by the research team to join a community advisory board (CAB) providing input on implementation from the patient perspective. In sites without an existing CAB, this project will initiate patient participation in the service. Local healthcare professionals will collaborate with the research team to ensure the sustainability of these groups beyond the project period.

Research capacity strengthening

The *collaborative whole-systems programme model* promotes knowledge exchange though workshops, which are led and organized by local site teams supervised by the central WHO research team. This approach facilitates hands-on learning among partners, enhancing understanding of research through collaborative decision-making on site-specific outcomes, such as co-developing facility surveys and planning cost-consequence and clinical data collection, thereby creating lasting value for participants beyond the study period.

Conclusion

While rapid technical advances in STI POCT development are occurring, insufficient attention has been given to health system capacity and the conditions necessary for the swift integration. Without recognizing and mapping the complexity of health systems, including context, institutions, health equity and problem perception, simplistic approaches to policy design and programme implementation are likely to result in unequal uptake, low levels of implementation sustainability, and other unintended outcomes. This study will test and potentially provide a generalisable model based on a whole-system approach to support integration and scale up of STI POCTs within the national STI prevention programme. Once implemented, such a model, could reduce the time required for sustainable adoption of new medical technologies, and contribute to global efforts to ensure universal access to evidence-based sexual health services.

Ethical review

This study has received preliminary approval by the WHO Research Ethics Review Committee (ERC), pending local country approvals. Protocol ID: ERC.0004275 Full approvals will be provided prior to study commencement.

Author Contributions

SSF and IT conceived the study. SSF conceived the programme model methodology, led the drafting of the manuscript and protocol implementation and evaluation strategy. All authors contributed to developing the protocol and drafting the manuscript. SSF is the guarantor.

Competing Interests

Author VP is a guest editor of this special issue. All authors declare they have no competing interests.

Funding statement
We have currently received no funding for this project.

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