Point-of-care testing for sexually transmitted infections in low-and middle-income countries: a scoping review protocol

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http://sro.sussex.ac.uk
### Manuscript Number:
JBIISRIR-D-19-00381R2

### Keywords:
Developing countries; low- and middle-income countries; point-of-care testing; Sexually Transmitted Diseases; STIs

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### Manuscript Region of Origin:
UNITED KINGDOM
Dear Dr Aromataris,

We wish to submit an original article entitled “Point-of-care testing for sexually transmitted infections in low resource settings: A scoping review protocol” for consideration by the JBI Database of Systematic Reviews and Implementation Reports. We confirm that this work is original and has not been published elsewhere, nor is it currently under consideration for publication elsewhere.

All authors contributed to the development of the ideas, writing and/or final review of the submitted manuscript and all authors have read and approved this version of the manuscript and its submission to the journal. Furthermore, development of the submitted manuscript has adhered to ethical standards.

Sexually transmitted infections contribute to significant morbidity globally. In low resource settings, syndromic management of STIs is the strategy recommended by the World Health Organization. However, the limitations of syndromic management are becoming increasingly apparent, particularly with regards to the inability to detect asymptomatic infections. As a result, there have been increasing calls for the development and implementation of point-of-care tests for STIs in these settings.

However, there does not appear to be any reviews published or in progress collating how point-of-care tests have been trialled in low resource settings previously, the facilitators and barriers to doing so and the important research gaps that remain. This information will be vital in the near future to ensure any implementation on a wide scale is successful.

This scoping review protocol details how studies that explore the use of diagnostic STI testing for chlamydia, gonorrhea, trichomoniasis or syphilis and how they are implemented into models of care in low resource settings will be considered for inclusion. The scoping review will be conducted in accordance with the Joanna Briggs Institute methodology for scoping reviews.

Thank you for your consideration of this manuscript.

Sincerely,

Dr Kevin Martin
Point-of-care testing for sexually transmitted infections in low resource settings: A scoping review protocol

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**Point-of-care testing for sexually transmitted infections in low- and middle-income countries: A scoping review protocol**

**Abstract**

**Objective:** To explore how point-of-care tests for sexually transmitted infections (STIs) have been implemented into healthcare systems in low- and middle-income countries (LMIC) and the facilitators and barriers to implementation.

**Introduction:** Sexually transmitted infections contribute to significant morbidity globally. In LMIC, syndromic management of STIs is recommended. However, due to the limitations of syndromic management, there is increasing interest in the potential for point-of-care tests (POCTs) to be incorporated into models of care for STIs in low resource settings. It is therefore important to explore how POCTs for STIs have been used in these settings previously and the facilitators and barriers to implementation on a wider scale.

**Inclusion criteria:** This scoping review will consider studies that explore the use of point-of-care-testing for chlamydia, gonorrhrea, trichomoniasis or syphilis and how they are implemented into models of care in LMIC. Study participants may be those receiving STI testing or healthcare professionals providing testing. HIV testing will not be covered. Quantitative, qualitative and mixed methods study designs as well as review papers will be considered for inclusion.

**Methods:** The proposed scoping review will be conducted in accordance with the Joanna Briggs Institute methodology for scoping reviews. We will search databases including MEDLINE, EMBASE, EMCARE, CINAHL, SCOPUS, LILACS, African Index Medicus, and The Cochrane library from 1998 onwards. Results will be screened by two independent reviewers and data extracted using a data extraction tool developed by the reviewers. Data will be presented both narratively and in tabular form.

**Keywords:** Developing countries; low- and middle-income countries; point-of-care testing; Sexually Transmitted Diseases; STIs

**Abstract word count:** 244

**Total manuscript word count:** 2019
Introduction

Globally, there was estimated to be a total of 376.4 million new curable sexually transmitted infections (STIs) acquired among people aged 15 to 49 years in 2016, namely chlamydia, gonorrhea, trichomoniasis and syphilis. Low income countries, according to the World Bank classification, were found to have the highest prevalence of gonorrhea, trichomoniasis and syphilis. Both chlamydia and gonorrhea can cause pelvic inflammatory disease (PID) in women, leading to tubal factor infertility, risk of ectopic pregnancy or chronic pelvic pain. They can also be transmitted during delivery and can cause ophthalmia neonatorum, a potentially blinding neonatal conjunctivitis. Babies born to women with trichomoniasis are more likely to have a low birth weight or be delivered pre-term. Additionally, in 2012, an estimated 930,000 maternal syphilis infections globally caused around 350,000 adverse pregnancy outcomes. Furthermore, STIs increase both susceptibility to and infectiousness of HIV.

Therefore, in areas with a high prevalence of STIs, management of STIs may form an important component of HIV control.

In low- and middle-income countries (LMIC), syndromic management of STIs has traditionally been the recommended strategy due to the time and resource constraints in implementing etiological diagnosis. Syndromic management is the provision of treatment to cover the majority of organisms that could cause a set of signs and symptoms. By definition, it will therefore miss asymptomatic infections, which the majority of STIs are. Syndromic management of genital ulcer disease and male urethral discharge is cost-effective. However, the algorithms for vaginal discharge have low sensitivity and specificity for the detection of cervical infections, leading to both overtreatment and undertreatment. Undertreatment has the potential to lead to complications as a result of untreated STIs and also allows for ongoing transmission. Furthermore, overtreatment leads to unnecessary drug costs and may expose patients to the risk of adverse reactions and facilitate antimicrobial resistance. In particular, resistance is becoming increasingly widespread in Neisseria gonorrhoea and Mycoplasma genitalium. There are also consequences for relationships and social status associated with being diagnosed with an STI.

As a result of the shortcomings of syndromic management, there have been increasing calls for the implementation of point-of-care tests (POCTs) into management of STIs in LMIC. One example where this was trialled was in the women’s improvement of sexual and reproductive health (WISH) study, based in Kigali, Rwanda, where a risk-based algorithm was compared with both syndromic management and gold standard testing. They found that the WISH algorithm had higher sensitivity and specificity for detecting chlamydia, gonorrhea and trichomonas infections compared to World Health Organization (WHO) syndromic management.

In 2006, the WHO developed the ASSURED criteria, where POCTs for STIs should aim to be “affordable, sensitive, specific, user-friendly, rapid, robust, equipment-free and deliverable in low resource settings”. Historically, POCTs in STI management have included gram staining and wet...
mount microscopy. However, there are limitations to their sensitivity, especially in women.13 Furthermore, they require trained staff and specialist equipment.

The need for rapid results in low resource settings is due to the infrastructural, time and cost barriers that patients often face in reaching the clinic.14 If not treated during the visit, they may not have the means to return. Although ASSURED POCTs are currently available for trichomoniasis and syphilis, at present there are no POCTs for chlamydia or gonorrhea that meet all ASSURED criteria.15 However, the WHO Global Sector Strategy for STIs notes that innovations such as POCTs are on the horizon and that investing in POCTs now will generate future savings by reducing the burden of STIs through improved case management and detection of asymptomatic infections.16 Rapid HIV tests are an example where POCTs meeting ASSURED criteria have been widely and effectively introduced into low resource settings.

As the landscape changes regarding the availability of POCTs for STIs and their suitability for implementation into LMIC, it is important that we understand the feasibility and acceptability of their use in LMIC. Additionally, we need to identify the important facilitators and barriers to implementation to understand how best to implement them in real-world settings. Their success will ultimately be determined by how effectively they can be integrated into existing healthcare systems.17 It is therefore of utmost importance to examine the current literature to determine in what ways POCTs have been incorporated into different models of care in LMIC previously. This constitutes factors such as the populations involved, the healthcare settings, such as hospital or community-based, as well as to which individuals POCTs are offered. For example, in the WISH study algorithm all participants received point-of-care testing for trichomoniasis, however only those with positive risk factors received point-of-care testing for chlamydia, gonorrhea and syphilis.11

A preliminary search of PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews and the Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports was conducted. No current or underway scoping reviews or systematic reviews on the topic were identified that assessed strategies for testing using POCTs in LMIC for multiple curable STIs. A Cochrane review specifically assessed the use of POCTs for syphilis in pregnant women. They concluded that POCTs for syphilis showed promising results in antenatal care but that more trials were needed.18 In addition to including testing for other curable STIs, our review will also look at populations other than pregnant women.

The aim of this scoping review is to assess how point-of-care STI testing has been implemented into healthcare systems in LMIC and the facilitators and barriers to doing so.

**Review question(s)**

How have point-of-care STI tests been incorporated into different models of care in LMIC?
Which point-of-care STI tests have been trialled in LMIC?

What is the feasibility and acceptability of using point-of-care STI tests in LMIC?

What are the facilitators and barriers to using point-of-care STI tests in LMIC?

What gaps are present in the research knowledge base regarding the use point-of-care STI tests in LMIC?

**Inclusion criteria**

**Participants**

This scoping review will consider studies that include participants either receiving point-of-care STI testing or healthcare professionals providing point-of-care STI testing. Study participants can be of any age or risk group. Healthcare and systems assessments not directly involving patients will also be considered for inclusion.

**Concept**

This review will consider studies that explore the use of point-of-care STI tests in terms of how they are implemented into models of care and the feasibility, acceptability, facilitators and barriers to doing so. Facilitators are factors whereby their presence promotes implementation or adoption of POCTs, whereas barriers are factors that impede implementation or adoption of POCTs in these settings. For example, a potential facilitator could be improved job satisfaction through providing a diagnosis, whereas a likely barrier will be material costs. How feasibility and acceptability are defined will vary between studies. However, feasibility will generally refer to the ease and success with which POCTs are implemented logistically, whereas acceptability will be based on levels of uptake of POCTs by individuals. Studies featuring testing for chlamydia, gonorrhea, trichomoniasis or syphilis infection will be considered. This review will not cover HIV testing and so studies where only HIV testing is used will be excluded. There is already a substantial literature base regarding point-of-care testing for HIV and WHO guidelines are available regarding implementation of HIV POCTs.

**Context**

Only studies that are based in LMIC will be considered for inclusion. We will therefore include countries defined as low, lower-middle and upper-middle income economies, according to the World Bank.

**Types of sources**

This scoping review will consider quantitative, qualitative and mixed methods study designs for inclusion. Quantitative study designs to be considered for inclusion include randomized controlled trials, non-randomized controlled trials, before and after studies, interrupted time-series studies, retrospective and prospective cohort, case-control, analytical and descriptive cross-sectional studies,
case series and individual case reports. Qualitative studies with methodologies including but not
limited to grounded theory, phenomenology and ethnography will be considered. In addition,
systematic reviews will be considered for inclusion in the proposed scoping review. Articles published
in English from 1998 onwards will be included as the earliest treponemal rapid diagnostic tests for
syphilis were developed at this time.21,22

Methods

The proposed scoping review will be conducted in accordance with the Joanna Briggs Institute
methodology for scoping reviews.23

Search strategy

The search strategy will aim to locate both published and unpublished primary studies and reviews. An
experienced clinical librarian was heavily involved in development of the search strategy. An initial
limited search of MEDLINE and EMBASE was undertaken to identify articles on the topic. The text
words contained in the titles and abstracts of relevant articles, and the index terms used to describe the
articles were used to develop a full search strategy for MEDLINE (see Appendix I). The filter for LMIC
is a Cochrane filter based on the 2009 classification of countries by The World Bank.24 This is to prevent
exclusion of studies from countries that were low or middle income at the time of publication but have
since become high income countries. The search strategy, including all identified keywords and index
terms will be adapted for each included information source. The reference lists of articles included in
the review will be screened for additional papers.

Information sources

The databases to be searched include MEDLINE, EMBASE and EMCARE on the Ovid SP platform,
CINAHL on the EBSCO platform, SCOPUS, LILACS and African Index Medicus through their own
websites, and the Cochrane Library, including the Cochrane Central Register of Controlled Trials, on
Wiley. These databases have been chosen to allow for a broad range of studies including those focused
on biomedicine, nursing and social sciences. Study authors may also be contacted for further
information if necessary.

Sources of unpublished studies and gray literature to be searched include Google Scholar, ProQuest
Dissertations & Theses, and the WHO website.

Study selection

Following the search, all identified records will be collated and uploaded into EndNote X9 (Clarivate
Analytics, PA, USA) and duplicates removed. Titles and abstracts will then be screened by two
independent reviewers for assessment against the inclusion criteria for the review. Potentially relevant
papers will be retrieved in full and their citation details imported into the Joanna Briggs Institute’s
System for the Unified Management, Assessment and Review of Information (JBI SUMARI) (The Joanna Briggs Institute, Adelaide, Australia). The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers. Reasons for exclusion of full text papers that do not meet the inclusion criteria will be recorded and reported in the scoping review. Any disagreements that arise between the reviewers at each stage of the selection process will be resolved through discussion, or with a third reviewer. The results of the search will be reported in full in the final scoping review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.

Data extraction

Data will be extracted from papers included in the scoping review by two independent reviewers using a data extraction tool developed by the reviewers. As shown in the draft data extraction tool in appendix II, the data extracted will include specific details about the study country, setting, population, methods, the POCTs used, feasibility, acceptability, facilitators and barriers to POCT use. The draft data extraction tool will be modified and revised as necessary during the process of extracting data from each included paper. Modifications will be detailed in the full scoping review. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer. Authors of papers will be contacted to request missing or additional data, where required.

Data presentation

Characteristics of research studies, including population, setting, point-of-care test used and how they were incorporated into a model of care will be presented in tabular form. A narrative summary will accompany the tabulated results and will describe the feasibility, acceptability, facilitators and barriers noted during implementation of the point-of-care tests. Apparent gaps in the literature will also be identified. Given the differences in antenatal care compared to the general population, results for pregnant women will be presented separately.

Funding

No funding was provided for this review protocol. As such, there was no role for any funders in the review process.

Conflicts of interest

The other authors declare no conflict of interest.

References


### Appendix I: Search strategy

MEDLINE (Ovid) search conducted in April 2020.

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98382

#13
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624
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## Appendix II: Data extraction instrument

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<td>How test integrated into model of care</td>
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<tr>
<td>Feasibility</td>
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