

BMJ Open Evidence of accessibility and utility of point-of-care diagnostics as an integral part of prevention of mother-to-child transmission services: systematic scoping review protocol

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ABSTRACT

Introduction Point-of-care (POC) testing has been shown to help improve healthcare access in resource-limited settings. However, there is paucity of evidence on accessibility of POC testing for prevention of mother-to-child transmission (PMTCT) in resource-limited settings. We propose to conduct a systematic scoping review to map the evidence on POC testing services for PMTCT. **Methods and analysis** A scoping review framework, proposed by Arksey and O'Malley, will guide the study. A comprehensive literature search will be performed in the following electronic databases: PubMed, Science Direct, Cochrane Central, Google Scholar and databases within EBSCOhost (Medline and CINAHL). The primary research articles published in peer-reviewed journals and grey articles addressing our question will be included. One reviewer will conduct title screening and the results will be exported to endnote library. Two independent reviewers will perform abstract, then full article screening in parallel. The same process shall be employed to extract data from eligible studies. Data analysis will involve a narrative summary of included studies and thematic content analysis aided by NVIVO software V.11. The mixed methods assessment tool will be used to assess the quality of studies that will be included.

Ethics and dissemination Ethical approval is not applicable to this study. The study findings will be disseminated through publication in a peer-reviewed journal and presentations at conferences related to syphilis, HIV, PMTCT, bacterial infections and POC diagnostics.

Trial registration number CRD42017056267.

INTRODUCTION

Paediatric HIV and syphilis infection among pregnant women remain a public health problem despite advances in biomedical research. By the end of 2015, The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated that 150 000 children became newly infected with HIV.¹ More than two-thirds of these newly infected children live in sub-Saharan Africa and they have

Strengths and limitations of this study

- The study findings will provide evidence which will be helpful in achieving the Sustainable Development Goals 3 and the 90-90-90 Joint United Nations Programme on HIV/AIDS target.
- The review has no language limitation.
- There will be a search date limitation for the literature that will be included in this study as a result, some relevant information could be missed.

been infected through mother-to-child HIV transmission.²

Over the last two decades, there has been growing health advances including the global plan to eliminate mother-to-child transmission (MTCT) of HIV by 90% and reduce HIV-related maternal deaths by 50%,³ as well as the global strategies for dual elimination of MTCT of HIV and syphilis.⁴ Countries such as Uganda, South Africa and Burundi have made substantial progress towards achieving the targets of reducing HIV vertical transmission by 90%.⁵ Syphilis in pregnancy is associated with an increased risk of HIV transmission.⁶ Therefore, the WHO has recommended strategies such as rapid syphilis and HIV screening for pregnant women in antenatal care (ANC) clinics.^{4,7} These strategies have been found to be effective in preventing MTCT of syphilis and HIV.⁸ Additionally, an intensive effort to scale up prevention of mother-to-child transmission (PMTCT) programme and integration of antiretroviral therapy (ART) within the programme has yielded significant results by reducing new HIV infections among children by 60% between 2009 and 2015.⁹ However, this is below the marked target of 90%³ and an indication that more work needs to be done. In addition to the above, malaria and Group B streptococci (GBS) infections

are also associated with morbidity and mortality for both mothers and infants.^{10–12} Vertical transmission of malaria is associated with increased infant susceptibility to malaria infection and other infections, whereas GBS infection increases the risk of bacterial pneumonia in infants.^{13 14}

Despite tremendous achievements made by PMTCT,^{15–18} these services in poor countries are still faced with challenges including inadequate laboratory infrastructure, inefficient health systems, poor access to laboratory facilities and patient loss to follow-up.^{19 20} To address the problem of access to diagnostic laboratory services, UNAIDS and its partners launched a diagnostic access initiative which focuses on the need to develop new affordable diagnostic tools that can increase access to prevention, treatment and care programme.²¹ In response to this initiative, there has been an increase in development of point-of-care (POC) diagnostics for use in settings with limited access to laboratory services to target infectious diseases.²² It has been reported that the use of POC diagnostics for bacterial pneumonia, syphilis, tuberculosis and malaria infections could prevent >1.2 million deaths from HIV/AIDS and coinfections per year in low-income and middle-income countries.²³

The expansion of PMTCT including the ‘test and treat’ strategies will require increased access to POC testing to ensure coverage and impact on public health. The PMTCT cascade which has evolved overtime is a series of steps that starts with HIV screening and diagnosis of pregnant women, and initiation of ART for HIV-positive pregnant women and their exposed infants. This is followed by HIV diagnosis in infants and ART initiation for those who are infected.^{9 24} Continued linkage to HIV care for HIV-positive women and infants is needed during post-partum period.

POC testing is essential for routine screening of pregnant women for HIV and syphilis in ANC clinics.⁷ Throughout the PMTCT cascade, POC testing is important, as a prerequisite for entry into care as well as in monitoring of HIV-infected mothers who are on treatment to reduce onward transmission.^{7 25} POC testing fits into the infant HIV continuum of care by facilitating early diagnosis, enrolment into care and reducing loss to follow-up to ensure chances of child survival.²⁶ POC testing is also useful in detecting asymptomatic malaria and GBS infections, which can be transmitted vertically during the gestational period.^{13 27 28}

The potential impact of POC testing have been shown on some global programme including HIV and syphilis.²⁹ However, little is known regarding the level of accessibility and utility of POC testing for PMTCT in resource-limited settings. ‘Accessibility’ and ‘usage’ are some of the factors affecting effective implementation of POC testing.^{26 30} We define ‘accessibility’ as the availability or the presence of a POC test in each health facility as opposed to how closer the test is in terms of distance to be accessed to achieve the greatest impact. ‘Usage’ is defined as the level or a measure of uptake of a given POC test given that its access has improved to achieve the desired outcome. Universal

access to quality essential healthcare services has been emphasised as one of the essential components to fulfil the Sustainable Development Goal number 3 (SDG3), whose target is to ensure health and promote the well-being for all people at all ages.³¹ The aim of this review is to map the evidence on accessibility of POC testing for PMTCT. It is anticipated that the results of this study will help identify research gaps and guide future research.

METHODS AND ANALYSIS

The study design for this study is a scoping review. The study will be guided by Arksey and O’Malley scoping review framework and will include a quality assessment.³² The study title was registered under PROSPERO international prospective register for systematic reviews with a registration number: CRD42017056267 and can be accessed via the following link: https://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42017056267

Scoping review framework

The scoping review methodological framework proposed by Arksey and O’Malley has been used to guide the development of our protocol.³³ The framework outlines the following five stages: (1) identify the research question; (2) identify relevant studies; (3) study selection; (4) chart the data; (5) collate, summarise and report the results.

Identify the research question

The main research question that will be addressed in this review is: what is the evidence of accessibility of POC testing on PMTCT?

Specific research questions are as follows:

- ▶ What is the evidence of POC testing for preventing HIV vertical transmission?
- ▶ What is the evidence of POC testing on preventing syphilis vertical transmission?
- ▶ What is the evidence of POC testing on preventing malaria and bacterial vertical transmission?
- ▶ What is the evidence of POC testing on child survival and infant mortality?
- ▶ What is the evidence of POC testing and linking mothers and infants to care?
- ▶ What is the evidence of POC testing on facilitating access treatment?
- ▶ What is the evidence of POC testing on facilitating access ART?

The eligibility of the question was framed based on the PICO: population of interest; intervention: showing POC tests of interest; comparison: studies that do not have POC testing and outcomes: the included studies that will have PMTCT-related outcomes as described in [table 1](#).

Identifying relevant studies

The search will include both published and unpublished (grey literature) primary studies as well as systematic reviews. There will be no language restriction. We will search for primary research articles published between

Table 1 A PICO framework to determine eligibility of the review question

Population (P)	Pregnant and breast feeding women Infants
Intervention (I)	POC test for: <ul style="list-style-type: none"> ▶ HIV ▶ CD4 ▶ Viral Load ▶ EID tests ▶ Syphilis ▶ Malaria ▶ Group B streptococci
Comparison (C)	Absence of POC diagnostics
Outcomes (O)	Primary outcome: PMTCT Secondary outcomes: HIV infection; syphilis infection; malaria, bacterial pneumonia; access to ART; access to HIV and syphilis treatment; linkage to care as defined by WHO; infant mortality; patient loss to follow-up, timely results

ART, antiretroviral therapy; EID, early infant diagnostic; PICO, population, intervention, comparison and outcome; PMTCT, prevention of mother-to-child transmission; POC, point-of-care.

2013 and 2017. The electronic search will involve the following databases: PubMed, Science Direct, Cochrane Central, Google Scholar and databases within EBSCOhost (Medline and CINAHL). Reference lists of key articles will be hand searched for additional studies. Other sources of literature will include presentations from conferences and publications on organisational websites such as WHO and UNAIDS. The search key terms will include a combination of pregnant and breast-feeding women, infant, POC testing and PMTCT or timely results or access to HIV and syphilis treatment or linkage to care as defined by WHO (a confirmation of HIV-positive diagnosis and the first HIV clinic visit)³⁴ or access to ART or infant mortality or reduced patient loss to follow-up. Our search will use Boolean terms (AND, OR) to separate the keywords and medical subject headings terms will also be used during the search. Researchers

will keep record of the number of publications retrieved and the search date after each session. The draft literature search for PubMed and Google Scholar is provided in [table 2](#).

Inclusion criteria

Studies will be included based on the following criteria:

- ▶ Studies that show evidence on pregnant and breast-feeding women
- ▶ Studies that include mother–infant pair or infant as a population
- ▶ Studies that include POC testing related to HIV, syphilis, malaria and GBS
- ▶ Studies that show PMTCT as the main outcome
- ▶ Studies that report on HIV, syphilis, malaria and bacterial pneumonia infections
- ▶ Studies that show access to HIV and syphilis treatment
- ▶ Studies that show access to ART
- ▶ Studies that report on linkage to care
- ▶ Studies that report on infant mortality
- ▶ Studies that report on loss to follow-up
- ▶ Studies published between 2013 and 2017
- ▶ Primary studies using qualitative and quantitative (randomised, non-randomised and observational) and mixed method study designs.
- ▶ Studies that were conducted in low-income and middle-income countries

Exclusion criteria

The following will be used as the exclusion criteria:

- ▶ Studies that do not include pregnant and breast-feeding women or infants as a population
- ▶ Studies that do not include POC testing related to HIV, syphilis, malaria and GBS infections
- ▶ Studies that do not show PMTCT as the main outcome
- ▶ Studies that do not report on HIV, syphilis, malaria and bacterial pneumonia infections
- ▶ Studies that do not report on linkage to care or treatment
- ▶ Studies that do not report on infant mortality
- ▶ Studies that do not report on loss to follow-up
- ▶ All narrative reviews

Table 2 Search record

Search date	Keywords	Search engine	Number of publications retrieved	Search terms
12 August 2017	Pregnant and breast-feeding women, infants, POC diagnostics, PMTCT, access to treatment, access to ART	PubMed	974	(((Pregnant and breast feeding women) AND infants) AND point of care diagnostics) AND prevention of mother to child transmission) AND access to treatment) OR access to ART
15 August 2017	Pregnant and breast-feeding women and infants, POC testing, PMTCT	Google Scholar	470	Pregnant and breast feeding women and infants prevention OR of OR mother OR of OR child OR transmission 'point of care testing'

ART, antiretroviral therapy; PMTCT, prevention of mother to child transmission; POC, point-of-care.

Study selection

This will be conducted in stages: title, abstract, followed by full article screening. One reviewer will perform title screening using the inclusion criteria. The search results will be exported to endnote software V.X7, where an endnote library will be created. The use of endnote will be useful to manage all citations. Studies that do not meet the inclusion criteria and duplicates will be excluded. The endnote library will be shared with another independent reviewer for abstract screening. Two independent reviewers will conduct abstract screening, concurrently. All discrepancies from the results of abstract screening will be discussed and resolved by the third reviewer. Two independent reviewers will then carry out full article screening and all disagreements with the results will also be tackled through discussions and consultation with a third reviewer for consensus. The study selection results of various databases will be presented in a modified Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart.³⁵

Charting

A data-charting form to record key information found from the included studies will be developed. The extracted data will include the following sections:

- ▶ Author(s)
- ▶ Date of publication
- ▶ Study design
- ▶ Aims/purpose
- ▶ Study population (from 12 weeks gestation period up to 6 months breast feeding)
- ▶ Methodology
- ▶ Intervention type
- ▶ Outcomes
- ▶ Key findings and conclusions that relate to this systematic scoping review research question

Collating, summarising and reporting the results

Collating and summarising means analysis of the data. This process involves providing a narrative summary of all the included studies. Content thematic analysis will be performed which involves identifying of themes in relation to the objectives of the study. Emerging themes will also be included. Thematic content analysis will be aided by NVIVO V.11.

QUALITY ASSESSMENT

The mixed methods appraisal tool (MMAT) V.11 will be used to assess the methodological quality of the studies that will be included in our search.³⁶ The advantage of using the MMAT for our review is that it allows reviewers to assess the methodological quality of all the qualitative, quantitative and mixed methods research studies that will be included in this scoping review. The overall score of the included studies will be calculated as a percentage, by dividing the number of the criteria that each study will meet by the total number of criteria according to the study design.

DISCUSSION

This scoping review is part of the larger study on evaluation of accessibility of POC testing for PMTCT services in resource-constrained settings. The review will map evidence on existing literature on POC diagnostics for PMTCT. There has been an increase in the development of POC diagnostics in the past 5 years³⁷ and therefore, we will search for literature published between 2013 and 2017 because we hope to obtain the most recent information. The findings of the scoping review will generate important information that will be useful to WHO and its partners that advocate for universal access to healthcare and in resolving healthcare challenges in settings with poor access to diagnostics services. The proposed study will thus contribute to healthcare systems strengthening in developing countries. It will also help review the gap in knowledge on this topic and influence direction for future research. The study intends to build and contribute to a body of literature on diagnostics research, which can improve maternal health.

We anticipate finding relevant literature on studies that have been conducted on POC testing for PMTCT. Our study findings will help inform POC diagnostics programme implementers and policy-makers on ensuring efficient implementation of POC testing services and future scale up of POC technologies. This will therefore aid countries in achieving the SDG3 which highlights the need to prevent MTCT³¹ and to reach the UNAIDS 90% target of people knowing their HIV status and prevent chances of viral transmission.³⁸

CONCLUSION

The findings of our systematic scoping review will provide evidence that will be useful to POC diagnostic implementers to design POC testing programme that can effectively improve PMTCT services globally.

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Contributors The study was conceptualised by JK under the supervision of TM-T. TPM-T: contributed to developing of methods relating to the review and analysis and data extraction process. JK: prepared the manuscript. TPM-T and LH: reviewed the manuscript. All authors: contributed towards developing the background and planned output of the research as well as the design of the study; contributed to the reviewed draft version of the manuscript and approved the final version.

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Competing interests None declared.

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