Toward Improving Accessibility of Point-of-Care Diagnostic Services for Maternal and Child Health in Low- and Middle-Income Countries

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Abstract: Point-of-care (POC) testing can improve health care provision in settings with limited access to health care services. Access to POC diagnostic services has shown potential to alleviate some diagnostic challenges and delays associated with laboratory-based methods in low- and middle-income countries. Improving accessibility to POC testing (POCT) services during antenatal and perinatal care is among the global health priorities to improve maternal and child health. This review provides insights on the availability of POC testing designed for diagnosing HIV, syphilis, and malaria in pregnancy to improve maternal and child health. In addition, factors such as accessibility of POC testing, training of health work force, and the efficiency of POCT services delivery in low- and middle-income countries are discussed. A framework to help increase access to POC diagnostic services and improve maternal and child health outcomes in low- and middle-income countries is proposed.

Key Words: access, services, point-of-care testing, prevention of mother-to-child transmission, antenatal care, pregnant women, child, HIV, syphilis, malaria, LMICs

Infectious diseases such as HIV/AIDS, syphilis, and pneumonia are still indirect causes of maternal and child mortality, mostly in low- and middle-income countries (LMICs). Part of efforts to improve maternal and child health include the integrated delivery of services in antenatal care (ANC) and the prevention of mother-to-child transmission (PMTCT). Routine screening during the prenatal and postnatal period is an effective intervention in implementing prevention strategies to reduce not only risks associated with pregnancy and childbirth but also the risk of transmitting infections during pregnancy. However, most pregnant women, particularly in LMICs, are not tested in a timely manner for infections because of various reasons including lack of access to health care and diagnostic services. Diagnostic services are further challenged by poor laboratory infrastructure particularly in resource-limited settings. Limited skilled human resources, lack of equipment, inadequate quality control programs, and weak supply chains for reagents and consumables have also been reported in these settings.

Point-of-care (POC) diagnostics are the fastest growing medical diagnostic tools that have alleviated the challenges of delayed testing in settings with limited access to laboratory infrastructure and services worldwide. The goal of POCT is to provide a quick test result for immediate clinical decisions to improve patient’s health outcomes. Point-of-care testing can be used in outpatient clinics, emergency departments, operating theatres, mobile clinics, primary health care (PHC) clinics, or even small peripheral laboratories. In accordance with World Health Organization (WHO) ASSURED (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end-users) criteria, POC diagnostics are simple to use devices that can be used not only by laboratory staff but also by other health care professionals with basic training on POCT. Point-of-care technologies have become useful in the expansion and provision of PMTCT services for HIV, syphilis, and other diseases such as malaria and bacterial pneumonia rarely covered in PMTCT.

Several efforts have been made toward improving access to POC diagnostic services, which includes the development of a list of essential in vitro diagnostics by WHO. This list is required to diagnose common diseases and other global priority infections such as HIV, TB, syphilis, and malaria. Point-of-care technologies have progressively been rolled out and are currently being used in health care settings and global health programs in LMICs. Access to POC diagnostic services will require a strengthened health system for a functional delivery service. This review provides insights on the availability of POC diagnostic tests intended for the detection, diagnosis, and monitoring of HIV and diagnosis of other infections such as syphilis and malaria aimed for PMTCT in LMICs. Factors such as accessibility of POCT services, training of the health care work force, and efficiency of POCT service delivery are discussed. We proposed a framework for improving access and sustainability of POC diagnostic services in LMICs.
**AVAILABILITY OF POC TESTING FOR PMTCT IN LMICs**

**HIV POC Testing in LMICs**

Despite progress made in PMTCT, 160,000 new pediatric infections were reported in 2016.25 Running effective prevention programs will require improved access to testing technologies, such as HIV testing, CD4 testing, viral load (VL) testing, and early infant diagnostic testing (EID).14

HIV testing is offered as part of basic routine care during ANC and is an entry into the PMTCT care cascade.26-29 Integration of PMTCT into ANC forms links with maternal and child health services, namely, HIV testing and provision of antiretroviral therapy (ART).30 However, uptake of ANC services remains suboptimal in LMICs.31 Studies have suggested that rapid HIV testing can increase HIV testing uptake, maternal HIV care, and uptake of ART.32,33 The effect of rapid HIV testing on maternal linkage to HIV care was found in a systematic review and meta-analysis by Mashamba-Thompson et al.32 The availability of rapid tests for HIV including self HIV testing technologies has increased in LMICs.33-39 Studies have demonstrated their acceptability and usefulness by increasing the proportion of pregnant women who are tested during ANC and provided same-day testing and treatment.33,34,39 Point-of-care HIV testing during time of labor and delivery offers the last opportunity for PMTCT in settings where women do not receive adequate ANC.40 Although the uptake of PMTCT services particularly in Sub-Saharan Africa improved from 3% to 73% in 2003 and 2014,31 integration of more PMTCT interventions including rapid HIV testing are still needed. Point-of-care testing is key intervention in the infant HIV continuum of care to alleviate problems in delivering prevention and treatment services to HIV-exposed infants. There are now several commercially available POC tests for EID suitable for use in LMIC.41-44 Studies have shown that they are accurate, can be performed by nonlaboratory personnel, can link infants to timely care, and link all HIV-infected children to ART.45-49 The revised treatment guidelines (option B+) for the PMTCT requires pregnant women and breastfeeding women to be tested and treated with lifelong ART regardless of their CD4 count or clinical stage. Countries such as Malawi, Zambia, and South Africa with a high HIV burden have introduced option B+,45 This approach has clinical benefits to the mother's own health through early initiation of ART and reduced vertical transmission.46,47 However, client refusal and drop out have been demonstrated to be among other obstacles that threaten the success of option B+.48-50 Although there is a policy shift toward treating all HIV-infected pregnant women irrespective of their CD4 count, CD4 count still remains a useful tool for monitoring patient’s response to treatment in settings where VL monitoring is limited.51-53 Point-of-care technologies for CD4 count are available,49-52 and studies have demonstrated that POC CD4 testing can overcome challenges associated with laboratory-based CD4 testing.49-55 Viral load monitoring is another important routine test for patients on ART and, hence, forms an essential part of HIV treatment programs in LMICs.56-58 There is now growing emphasis on scaling up access to VL testing for ART programs.56,59 Point-of-care VL assays that could facilitate access to VL monitoring are available,60,61 although studies in PMTCT settings are limited. However, POC technologies for HIV are available in LMIC, the population with least access to HIV testing is rural and poor women and their infants who are more vulnerable to infection and are not able to access essential services.62

**Antenatal Rapid Syphilis Testing in LMICs**

An estimated 1.5 million pregnant women are infected with active syphilis globally, with most infections occurring in LMICs.63,64 Undiagnosed and untreated maternal syphilis is associated with poor pregnancy outcomes such as still-birth, neonatal death, low birth weight, spontaneous miscarriages, and congenital syphilis.5,65 In addition, maternal syphilis in pregnancy is associated with an increased risk of HIV transmission.66 The WHO recommends syphilis and HIV screening and treatment of syphilis infected pregnant women with penicillin at the first antenatal visit as an effective strategy to treat and prevent congenital syphilis.67,68 as well as elimination of mother to child transmission of syphilis and HIV. To support this initiative, the WHO in 2007 launched the global initiative for the elimination of congenital syphilis. Many countries including Zambia are committed to elimination of mother to child transmission.68,69 Despite all these efforts, many pregnant women attending ANC are still not tested for syphilis.70 Antenatal rapid syphilis testing is cost-effective.70-73 and there are a wide range of low cost rapid syphilis tests (RSTs) relevant for antenatal screening, which can facilitate access to early diagnosis and treatment.74-79 Studies have shown that integration of RST in the context of ANC improves pregnant women uptake of syphilis testing.70-73 and treatment rates.74,75 Nonetheless, studies have observed nonsignificant increases in syphilis testing uptake49,76 and treatment71 due to test kit stock-outs. Dual HIV/syphilis rapid diagnostic tests (RDTs) that can detect both HIV and syphilis at the same time during a single clinic visit are also available.77 A cluster-randomized controlled study has shown the potential for dual HIV/syphilis RDT on timely treatment for women who tested positive for syphilis.78 The study also found that the costs for dual testing for HIV/syphilis and treatment for syphilis are high.79 Dual HIV/syphilis testing represents an important opportunity for PMTCT of HIV and syphilis.

**Point-of-Care Tests for Malaria and Other Infections During Pregnancy in LMICs**

It is a global health priority to end preventable deaths due to HIV, syphilis, TB, malaria, and respiratory infections such as bacterial pneumonia among women and children by 2030.70 Consequently, WHO and its partners called for an integration of PMTCT and disease-specific programs beyond provision of PMTCT in maternal and child health services because of the mutual benefits PMTCT shares with other existing health care services.71 Malaria in pregnancy increases the risk of maternal death and remains a significant cause of neonatal and infant morbidity and mortality in malaria-endemic regions.72-77 It is associated with poor outcomes such as maternal anemia, low birth weight, foetal loss, preterm delivery, perinatal mortality, and congenital malaria.78-81 The WHO recommends a package of interventions for the control of malaria in pregnant women and case management in areas of moderate to high transmission. These interventions include distribution of insecticide-bed–treated nets and early diagnosis with prompt effective antimalarial treatment to prevent progress to severe malaria in malaria-endemic areas.2 In addition, sulphadoxine pyrimethamine (SP), has been recommended for intermittent preventive treatment during pregnancy in most malaria-endemic countries including Zambia.83 Recently, intermittent screening using rapid tests and treatment with Artemisinin-based combination therapy was proposed as an alternative approach due to SP resistance.84 The challenge in preventing congenital malaria in Sub-Saharan Africa has been due to a lack of tests, which are adequately sensitive to detect peripheral and placental malaria. Point-of-care tests including molecular techniques for diagnosis of malaria in pregnant women are now well established.73,85-87 Research has revealed that an easy-to-use molecular assay (loop-mediated isothermal amplification), with a turnaround time of 60 minutes has a superior sensitivity of 100% and specificity of 93.5% for
the diagnosis of peripheral malaria in pregnant women. Existing RDT for malaria, which can detect parasite antigen in blood such as HRP2/pLDH RDT for antenatal screening, has reported varying sensitivities of 45.6%, 75%, and 55.8%, for diagnosis of malaria in symptomatic pregnant women and 18.6% and 81% to detect malaria in asymptomatic pregnant women. Studies have also demonstrated the usefulness of HRP2 RDT in detecting cases of malaria infection in pregnant women ranging from 38% to 10.3% in malaria-endemic countries. Rapid diagnostic tests are easy to use, require minimum training, and do not need sophisticated infrastructure. Integrating HRP2 RDT in ANC was found to be cost-effective. Nonetheless, lessons learned from previous studies suggest that accessibility and the use of malaria RDTs remain poor in most rural endemic settings. A study in Ghana indicated that health care delivery constraints such as weak supply chain, limited quality assurance, and staffing limitations are some of the issues that may affect access to RDTs for malaria in PHC facilities. Another study reported in a systematic review found that nurses and nursing assistants were not proficient in execution of RDTs for malaria.

The available tests designed for use at the point of care are shown in summary form in Table 1. Most of them are lateral flow tests.

### Accessibility of POC Testing Services in LMICs

The availability aspect of access deals with whether the proper health services are available in the right place and at the right time to meet the needs of the population. It is important to note that distance plays a part on the availability dimension of access. Because of substantial differences in proximity to health facilities between people in rural areas who have to travel long distances to those in urban settings, the probability of using the service is lower for those that live in far-away places. Therefore, the availability of a test or onsite provision of POCT, diagnosis, and treatment during a single clinic visit is of importance to save patients from having to return for results, transportation costs, and loss to follow-up. It has been suggested to take into account the geographical position, ie, urban/rural during test selection and procurement of POC tests. Additional opportunities to ensure availability and accessibility to POCT services include implementation of POCT in existing laboratory network systems, which may, in some cases, serve as a temporary backup for laboratory-based testing sites in the event of equipment malfunction or shortage of reagents. Furthermore, implementing POC tests in various levels of tiered national health care systems can improve accessibility. For example, a study in Kenya demonstrated that availability of POC tests for HIV, syphilis, and malaria in peripheral dispensaries (tier-2) that offer maternal and child health services significantly improved accessibility to testing for pregnant women residing in remote areas. Integration of a dual HIV/syphilis rapid test in ANC has been suggested as a possibility for ensuring accessibility to both HIV/syphilis testing services during a single visit. Dual HIV/syphilis tests make it easier for integrated screening and creates another important opportunity to strengthen prevention programs.

### Training of Health Workforce

Health care workforce refers to individuals that include physicians, nurses, midwives etcetera tasked to deliver health care services. The concept of health care workforce encompasses and extends beyond health professionals and human resources for health. According to a WHO report, lack of health care professionals is a global health challenge, affecting access to health care services. Low- and middle-income countries are further troubled with lack of skilled health professionals, and because of new developments such as the introduction of POC diagnostics in medical care, the delivery of POCT is being challenged because of increased work load, time constraints, and overburdened health workers. Therefore, there is a dire need for context-specific education and training of health professionals to increase access to POCT services. Where possible providing competency-based training must be emphasized to equip health professional students with the skills needed for POCT. For instance, using a standardized training package can improve the skills set for POCT for health care workers including nurses and doctors responsible for managing patients. It has been noted that the reliability of a POC diagnostic services is affected by the competency of the user. In addition, to make sure that the knowledge and skills acquired are retained, an expert-driven process for professional oversight of trained health workers for POCT has been suggested. Studies have demonstrated that in addition to accuracy, training can improve accessibility to testing in health care systems.

### Efficiency of POC Testing Services

Some strategies that can increase the efficiency of POC diagnostic services include service integration and task shifting. Integrated service delivery is defined by WHO as the organization and management of health services so that people get the care they need, when they need it, in ways that are user-friendly, achieve the desired results, and provide value for the money. Integrating POCT services in maternal and child health services is a great opportunity for the delivery of POCT during ANC/PMTCT, labor/delivery, postpartum, and newborn services to reduce maternal and child mortality. Integration does not only increase access to care and treatment, but it also saves cost and time, improves efficiency, and leads to improved health outcomes. The integration of POCT in ANC settings was found to be cost-effective. Despite this, inadequate human resources remain a challenge to health care access and some approaches such as human resources training and task shifting have been proposed to address this problem in LMICs. For instance, task shifting involves moving some specific tasks from qualified health professionals to other health professionals or community health workers. Implementing a task shifting strategy in providing POCT services involves engagement with health professionals and the community for acceptance and training. Examples of empirical evidence drawn from HIV testing services suggested that task shifting strategies are highly acceptable by local people. This was observed in a feasibility study that reported that 93.5% of women accepted the HIV test.

### TABLE 1. Availability POC Tests Relevant for PMTCT in LMICs

| Type of POC Test | Disease Target | Type of Assay |
|------------------|----------------|--------------|
| HIV test         | HIV            | LFIA         |
| EID              | HIV            | LFIA         |
| CD4 count        | HIV            | NAT          |
| Dual HIV/syphilis RDT | HIV | LFIA         |
| RST              | Syphilis       | LFIA         |
| Malaria RDT      | Malaria        | LFIA         |
| LAMP             | Malaria        | NAAT         |

Abbreviations: EID, early infant diagnosis; LAMP, loop-mediated isothermal amplification; LFIA, lateral flow immunosassay; NAT, nucleic acid testing assay; NAAT, nucleic acid amplification based assay; RST, rapid syphilis test.

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Improving accessibility to testing by bringing testing services closer to the point at which care is delivered has major implications in the provision of POC services in LMIC. The WHO has recognized the need for country-specific programs to pay attention to a variety of factors that may influence access to POC services as part of a national health care system.\textsuperscript{122} Improving access to these technologies means strengthening the health system by addressing overarching challenges such as lack of adequate human resources, training of available personnel, laboratory infrastructure, supply chain management, regulatory/quality assurance systems, financial resources and information technology capabilities, and managing them in a way that is sustainable across health services.\textsuperscript{91,97} As seen in this review, POC services are part of this dynamic and complex health system; therefore, all issues and challenges that exist in health care systems need to be resolved for a successful POC program. The WHO has developed a framework that is instrumental in strengthening the overall health system including medical products and technologies.\textsuperscript{122} Other frameworks in relation to POC diagnostic services such as supply chain management,\textsuperscript{21} POC proficiency and staff retention,\textsuperscript{102} and quality management systems\textsuperscript{123} have been proposed to sustain POC services in LMICs. Drawing some principles from these existing frameworks and taking into account the clinical need to test pregnant women and children, we therefore incorporated some ideas from all the previously mentioned frameworks and propose a holistic framework to improve accessibility and sustain POC delivery services for improved health outcomes (Fig. 1). The most intriguing feature of this framework is a “check list box”\textsuperscript{124} embedded in a health system. The box is the main building block that includes various components such as instrument availability, quality management systems, training of personnel, supply chain, and efficiency of health delivery platforms. Although interventions/inputs to support or maintain each component have been provided, some interventions are common to some components. Availability is mainly supported by supply chain management process, which captures aspects such as production and prequalification, selection, quantification, procurement and storage, quality assurance, distribution and redistribution, and inventory management\textsuperscript{124} that can contribute to continual improvement of POC diagnostic services. The quality system management takes into consideration the regulatory and policy aspects, quality monitoring, and availability of guidelines in relation to quality-ASSURED criteria for sustaining POC diagnostic services in LMICs;\textsuperscript{125} Bloom's taxonomy-guided framework has extensively explained the strategies and approaches on staff training that captures competency, testing proficiency, and staff retention to ensure the quality, reliability, and sustainability of POC diagnostic services.\textsuperscript{102} Maintaining an efficient health delivery platform involves addressing issues of manpower, task shifting, workload, equipment, an appropriate care platform such as maternal and child health services, and infrastructural adjustments. For POC diagnostic service to function optimally, integration of all components listed previously within the existing health system is paramount. Taking into account the disease burden, need for disease elimination, economic status, testing infrastructure, personnel requirements, impact, and cost benefit, a framework to increase accessibility for POC diagnostic services to improve maternal and child health and to ensure sustainability in real-world settings in LMICs has been proposed (Fig. 1).

The major threats that may impede accessibility of POC in health care systems are availability and poor implementation challenges.\textsuperscript{49,71,74,88} Some of the major issues that may affect availability of the tests required in antenatal care are the costs and supply chain management.\textsuperscript{21,23,91} The cost of the test itself needs to be considered together with the cost of transport, storage, 

a saliva-based HIV rapid test performed by traditional birth attendants in homes and that traditional birth attendant administered nevirapine to women in labor and infants after birth to prevent MTCT.\textsuperscript{109} Capacity building for POC seems to be critical for a successful task shifting strategy.\textsuperscript{53,77,86} Studies have demonstrated that it could be cost-effective in resource-constrained settings and that POC can accurately be performed by trained nonlaboratory personnel such as nurses and lay counsellors.\textsuperscript{42,108} For example, a study on HIV proficiency testing reported that there was no significant difference between laboratory and nonlaboratory personnel on the accuracy of rapid HIV testing (97%\textsuperscript{95%} confidence interval = 96.1–97.8).\textsuperscript{109} The lessons and experiences in task shifting drawn from HIV testing services and the role lay health workers play in increasing access to health care services particularly for HIV/AIDS care can be extended to other platforms of POC.\textsuperscript{110–112} Other approaches that might improve efficiency of POC service delivery include investing in connectivity infrastructure such as information and technology techniques and healthy management information systems.\textsuperscript{113,114} These technologies may be used in monitoring reagent consumption and transmitting test results, improve timely communication, create real-time information exchange, and may help improve access to rural and remote areas.\textsuperscript{115,116}

DISCUSSION

Efforts to expand the accessibility of POC have significantly improved the continuum of care for patients to commence treatment. Although interventions such as POC improve maternal and child health exist,\textsuperscript{8} HIV, syphilis, and malaria are still infections of public health concern.\textsuperscript{17,17} The review has shown the impact of POC in the PMTCT cascade services on linkage to care, timely results, and reduced MTCT\textsuperscript{32–34,43,44} The impact of antenatal RST in increasing uptake and treatment rates has also been highlighted in some studies.\textsuperscript{70–73} Although the review has shown the inclusion of molecular techniques, which are more sensitive, for example, for early diagnosis of HIV infection in infants\textsuperscript{41,42} and for screening for malaria in pregnant women,\textsuperscript{109} there is still a need for high-quality assays in remote and rural primary care settings. The review also found various performance of HRP2 RDT, particularly for asymptomatic malaria, which can still be used although it would miss some malaria cases. HRP2 has already been considered on the WHO list of essential in vitro diagnostics for primary care.\textsuperscript{22} Generally, POC tests for malaria diagnosis in pregnant women can detect significant cases of malaria\textsuperscript{77,85–87} that would prompt clinical decisions. This review has also shown strategies that may improve accessibility of POC services during prenatal, ANC, and postnatal care services.\textsuperscript{33,35,43,51–53,71,72,77,87,105} However, others have argued that the mere availability of a rapid test does not always translate into a desired outcome.\textsuperscript{117} Engel et al.\textsuperscript{118} for instance, found that despite the availability of rapid tests for HIV in South African clinics, actual HIV treatment was delayed, of which the implications would be loss to follow-up or advanced disease progression. To ensure a greater impact on health outcomes, the availability and provision of POC testing services at PHC level require addressing important health system’s barriers and issues regarding linkage to care such as referral systems, availability of care and treatment at facility-based sites, and structural links between testing and treatment centers.\textsuperscript{92,119} Selection of simple tests that can easily be performed by nonlaboratory personnel should be based on the WHO quality-ASSURED criteria.\textsuperscript{120} In addition, proficiency testing needs to be emphasized on these simple to use tests and recognized by nonlaboratorians.\textsuperscript{109} Proficiency testing programs should be an integral part of all forms of POC technologies to monitor the performance of the test used and the quality of testing.\textsuperscript{91,121}
remodeling laboratory structures, training, and supply chain management.\textsuperscript{21} However, most of the existing guidelines on procurement do not consider costs, which is particularly important for more complex tests.\textsuperscript{21,125} It has been suggested that choosing better ways of evaluating the cost-effectiveness of interventions that take into account budgetary constraints would provide some guidance to policy makers on selection of in vitro diagnostics and allocation of resources, which can contribute to improvements in accessibility to POC diagnostic services in LMICs.\textsuperscript{126}

Many barriers in supply chain management exist including, irregular supply, inconsistencies and delays in purchasing, insufficient accountability between the community, and the health care system, and this usually results in test kits and treatment stock outs.\textsuperscript{91,93,97,127,128} Studies have identified and suggested potential solutions for sustaining supply chain management such as agile, responsive and flexible POC supply chain, political will, and cooperation with communities and resource mobilization through existing multilateral and funding organizations such as PEPFAR and UNITAID to ensure availability and accessibility to health services including diagnostic tests.\textsuperscript{91,93,129}

Availability of adequately trained human resources is further required for successful POC diagnostic services.\textsuperscript{97,130} Because physicians and nurses in many LMICs are not traditionally trained to perform tasks meant for laboratory staff, it is important to train a new cadre of nonlaboratory health professionals so that they possess the skills and use them to carry out POCT especially at lower levels of health care.\textsuperscript{101} Competent health professionals may improve access to health care including POC services in LMICs.\textsuperscript{23,97} To address the problem of human resources, it has also been suggested that standard tools for personnel training should be used and that POCT should be incorporated in the medical curriculums.\textsuperscript{101,102}

In addition to supply chain and human resource issues, lack of infrastructure such as constant power supply, refrigerators, storage space, waste disposal mechanisms, phlebotomy supplies, and temperature control may make it difficult to implement some types of POC tests in PHC clinics in rural areas, which can affect availability of POCT services.\textsuperscript{91,98} The availability of POCT and its promise to produce efficient results are essential to avoid consequences of delayed results, and this promise has changed the delivery of health care to improve patient's outcomes and impact on public health in LMICs.\textsuperscript{96,118}

CONCLUSIONS

The importance of POCT in health care cannot be overemphasized particularly in resource-constrained settings. In this regard, there is an urgent need to put measures in place that can improve accessibility of POCT services for maternal and child health. To meet these needs, reliable evidence-based research and practical requirement frameworks as recommended by the WHO are required. We recommend country-specific evaluation studies of POC diagnostic services to inform health policy and relevant stakeholders as well as a strengthened health system for POC diagnostic services to improve access and patient’s health outcomes in LMICs.

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