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## PERSPECTIVES

## Using electronic readers to monitor progress toward elimination of mother-to-child transmission of HIV and syphilis: An opinion piece

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## ABSTRACT

Electronic readers and smartphones have the potential to standardize the interpretation of rapid diagnostic tests (RDTs) and provide timely surveillance program data. RDTs are widely used for HIV and are being increasingly used for syphilis screening in pregnant women. Following the WHO initiative for the validation of elimination of mother-to-child transmission of HIV and syphilis, there is a need for more extensive testing and data monitoring. However, access to timely and accurate data can be challenging once testing is decentralized as data quality at remote sites is often difficult to verify. Electronic RDT readers can help to ensure quality and allow automated data transmission, creating an opportunity for real-time surveillance to inform control strategies and assess intervention impact. Furthermore, by linking the data to existing supply chain management software, stockouts can be minimized. The present opinion piece looks at the opportunities and challenges of using these tools within national elimination programs.

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## 1. Background

Dual elimination of mother-to-child transmission (EMTCT) of HIV and syphilis is now a global health priority [1]. In 2007, WHO launched a strategy for the global elimination of congenital syphilis [2] and, in 2011, UNAIDS released a Global Plan toward the elimination of new HIV infections among children by 2015 [3]. Following on from these initiatives, in 2014, WHO launched the Criteria and Processes for Validation of Elimination of Mother-to-Child Transmission of HIV and Syphilis [1], which specifies impact and process targets to achieve EMTCT validation.

In recent years, rapid diagnostic tests (RDTs) have been introduced to increase HIV and syphilis screening in antenatal clinics, enabling same-day testing and treatment of infected mothers. This has reduced neonatal mortality and adverse outcomes of pregnancy [4]. However, when testing using RDTs is highly decentralized or data quality is difficult to verify, data gathering for the monitoring and evaluation of country progress toward EMTCT of HIV and syphilis can present challenges. Such challenges include: (1) ensuring quality assurance in the correct conduct of testing and interpretation of results; (2) obtaining valid and timely surveillance data; and (3) guaranteeing optimal supply chain management and availability of critical supplies.

New technological advances have resulted in a gradual move toward utilizing connectivity to support health systems programs. One such example is an electronic reader that uses digital imaging technology to interpret RDT results and transmit data. Readers may therefore offer a solution to the three challenges listed above through the standardization of RDT result interpretation and the potential for automated real-time surveillance and improved supply chain management. An opinion on current electronic readers and the opportunities and challenges of using these tools within national elimination programs is presented.

## 2. Electronic reader landscape

Electronic readers use digital imaging technology to produce an image of either the entire test device or just the test window—similar to the scenario that users are accustomed to seeing when interpreting RDTs with the naked eye. Readers are typically designed to be either universal or dedicated. Universal readers, which may take the form of a smartphone or a device containing smartphone technology, require a limited amount of software customization, permitting a number of tests from various manufacturers to be read on a single device [5]. One such example is a smartphone reader consisting of a small, lightweight stand on which a smartphone rests and under which the RDT is positioned for reading [6]. Dedicated readers contain software customized to a particular RDT. A number of electronic RDT readers are available in the market [7] and others are under development. Furthermore, a new technology able to test for HIV and syphilis directly using a dongle attached to a smartphone and cheap disposable cartridges has recently

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been developed [8], with the potential to transform the diagnostic landscape and provide simple, fast, low-cost, high quality tests using smartphone technology. Provisional results from a small field trial carried out in Rwanda are promising, but larger studies are needed [8].

Given the increasingly widespread adoption of smartphones and cellular phone networks in resource-limited settings [9], RDT readers have the potential to combine high resolution test images with the computing capability required to run image analysis software and transmit data. The readers range in price depending on the technical complexity of the instrument and their compatibility with the type of RDTs. Due to the multiplicity of RDTs for HIV and syphilis, it would be ideal to have diagnostic test readers that could accommodate a variety of test technologies (e.g. lateral flow, immunofiltration), formats (e.g. strips, cassettes of various sizes and shapes), and approaches to reading the test. However, readers customized for a single test format can also be useful. The criteria for selection depend on patient throughput and the available resources.

Field studies on HIV and syphilis RDT readers are needed in antenatal care settings; however, one study evaluating the performance of a dual treponemal and non-treponemal rapid test in sexually transmitted infection clinics and high-risk groups showed the performance of the test read by an automatic reader was comparable to visual reading with the advantage of being able to specify cut-off values [10]. Similarly, studies on other diseases, such as malaria, have shown high concordance between visual and device interpretation (>98%), as well as the potential benefits of quality assurance, automated data transmission, and health system strengthening [11].

### 3. Quality assurance

One of the key challenges for large-scale screening programs is the need to ensure the quality of RDTs and implement comprehensive sustainable quality assurance [12]. Lateral flow RDTs are read with the naked eye and may be prone to human error and inter-user variability, especially in remote settings where healthcare providers receive limited initial or refresher training and where ongoing supervision and quality assurance (e.g. proficiency testing) are lacking. This has the potential to adversely impact both patient care and the accuracy of surveillance and program data [13]. When testing is decentralized, program managers may be unable to monitor testing coverage and quality; thus, local problems, such as incorrect use of the tests or misinterpretation of results by providers, incorrect reporting of the data in clinic records, and stockout of test kits or commodities, may not be identified in a

timely manner. Electronic readers could provide automated, standardized interpretation of results, thereby minimizing inter-user variability and possible transcription errors [11], and may enable quality assurance to be performed remotely. The readers may be used by healthcare workers with minimal training and guide patient care since protocols can be incorporated into the reader for users to follow, thereby empowering local health workers (Fig. 1).

To date, no studies have evaluated the use of readers in the EMTCT of HIV and syphilis. Nevertheless, one study assessing the interpretation of HIV RDT results in non-laboratory settings using photographs, indicated that supervisors could perform quality assurance remotely, thus potentially lowering costs and improving efficiency and accuracy [12]. Furthermore, another study evaluating the performance of a dual treponemal and non-treponemal rapid test concluded that using an automatic reader was superior to the naked eye as it gave the additional benefit of assessing the changes in the non-treponemal test titer used to monitor response to treatment or establish an active infection [10]. However, further field studies are needed to investigate whether the quality of data recorded by the reader compares with hand entry and whether readers are able to identify local quality control issues in the field.

### 4. Automating real-time surveillance

Another key challenge to achieving dual EMTCT of HIV and syphilis is the requirement of available systems to obtain valid and timely data to track country progress. This demands extensive data collection, monitoring, and evaluation, with the capacity for ongoing surveillance once elimination is achieved. Currently, in some settings, data from antenatal screening are not collected at all or must be manually accessed from individual clinics. Global, regional, and national partners need to work together to establish data quality and strengthen existing health information systems to ensure the capacity to monitor the generated data [13].

Through their ability to capture and automatically transmit data, electronic readers may serve a critical purpose in strengthening data collection and surveillance in the context of monitoring and evaluation of dual elimination as well as in other surveillance programs (Fig. 1) [11]. Automated data transmission could also reduce the potential for human error in data capture and surveillance. However, current evidence is limited and field studies are required to establish the effectiveness of electronic readers in supporting antenatal surveillance systems

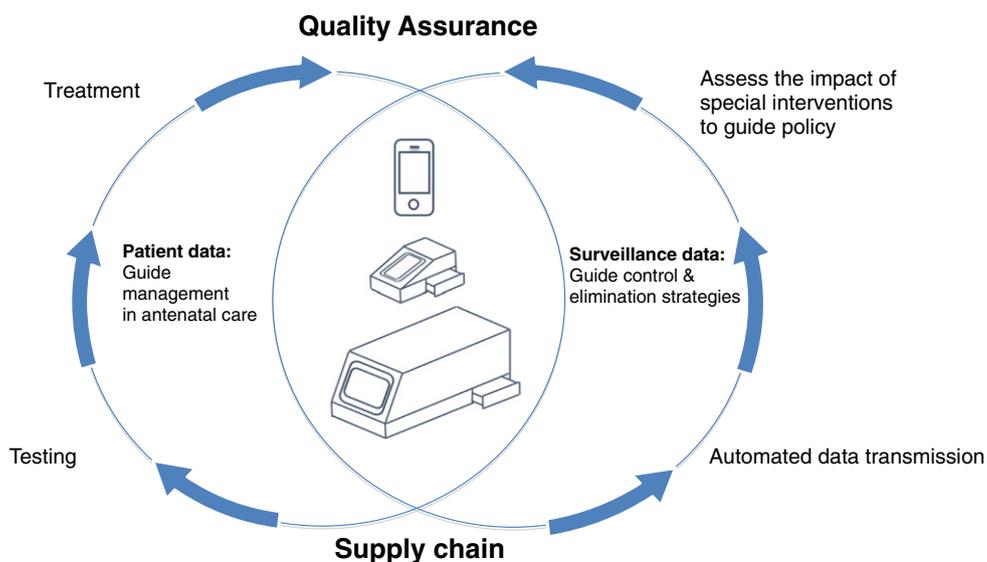


Fig. 1. Electronic readers provide an innovative connectivity solution to capture patient and surveillance data.

in low- and middle-income countries and the timeliness of data availability to upper level management.

### 5. Improving supply chain management

Supply chain management is another key aspect of surveillance programs that may present challenges in decentralized settings. In many countries, multiple public and private partners work with or report data to the government, and it is often difficult for health ministries to coordinate the management of supplies. Real-time data monitoring via electronic readers could help overcome these coordination and supply chain management difficulties by providing valuable information on stock status and device maintenance. Operational data on stocks and device condition and usage can be uploaded via the internet or cellular networks and transmitted to central databases. By linking the data to supply chain management software, stockouts could potentially be avoided and health system efficiency improved (Fig. 1).

### 6. Additional considerations for electronic readers

As noted, limited data exist, to date, on the use of electronic readers. Field studies would therefore be useful to assess how well different types of readers can be adapted to the antenatal care setting. In particular, their ease of use and acceptance by healthcare providers, whether healthcare providers may be trained to use them appropriately, their effect on clinic flow, their sturdiness to withstand daily use in busy clinics by multiple providers, and whether they actually improve the quality of data and are able to report data directly to central databases, are all aspects that need to be addressed. Furthermore, certain settings may require a central database to be created to collect surveillance data from electronic readers in primary healthcare facilities. This may involve obtaining consensus on where to host the data and the type of data to be collected, and finding affordable software or, alternatively, implementing an open-source middleware solution.

Confidentiality is another key concern. Specialized technology may be needed to ensure data are collected, transmitted, and stored according to ethical and legal standards [14]. These governance issues may potentially be resolved by ensuring separate levels of access to operational data versus patient data. In addition, data storage locations should be in line with country-specific regulations, although further discussion may be warranted regarding data ownership [9]. Requirements for instrument calibration, ongoing maintenance, frequency of failure, power usage, and environmental sustainability should also be considered, as well as the capital costs of connectivity (electricity) and recurrent costs (internet). Pilot projects are required to assess several of these issues, as well as the cost-benefit of including readers in surveillance and elimination programs.

### 7. Conclusions

Electronic readers may provide fast, accurate, standardized interpretation of RDT results and real-time data reporting, and therefore have the potential to improve quality assurance, supply chain management, and disease surveillance. With the increasing decentralization of testing using RDTs, innovative technologies such as electronic readers may be used to strengthen health systems and enhance surveillance capacity.

A good example is in supporting countries in meeting WHO targets for dual EMTCT of HIV and syphilis; however, they have the potential to be used in other settings as well.

To date, limited published data are available on the uptake and benefits of using readers in real-world settings and pilot studies are needed to help inform programs. Cost is a key issue for countries to consider adopting them into antenatal clinics. Pilot risk–benefit studies of RDT readers are required to determine whether the quality and rapidity of the surveillance data provided by RDT readers outweigh the costs and difficulty of including these within national programs.

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### Conflict of interest

The authors declare that they have no conflicts of interest.

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