Decentralisation of HIV-Testing to Reduce Results Turnaround Time Through the Use of Point-of-Care HIV Diagnostic Devices

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Policy Brief

Introduction

Access to antiretroviral therapy (ART) for children under 12 months in resource limited countries is constrained by unavailability of HIV diagnostic devices that can perform DNA/Polymerase Chain Reaction (PCR) HIV tests at service delivery points (Deo, 2013). The Early Infant Diagnosis (EID) platforms currently used are too complex to be placed at district level and do not qualify as a point-of-care test method (Deo, 2013). The devices are located in central hospitals and special laboratories, which lead to long delays between sample collection, transportation to and from the referral molecular laboratory, and interpretation of the results by the care provider (Deo, 2013). Consequently, the children identified as living with HIV have delayed access to ART due to delayed results and caregivers may be frustrated to have to continuously ask for these results (Adeniyi, 2015).

In Malawi, there are nine DNA/PCR testing platforms; four are located in central hospitals, three are located in NGO-supported hospitals, while the remaining two are in the districts hospitals with improved laboratory infrastructure. These platforms are expected to process 60,000 samples from HIV-exposed infants nationwide. Currently, only 50% of the samples are processed due to sample transportation problems as well as delays in collection of results (Health, 2015). This is despite the availability of innovations such as use of 'short message service' (SMS) technology that could facilitate the sending and receiving of results in real time.

The demand and logistics involved in sample transportation has resulted in long turnaround time as it takes time to transport the samples to these nine laboratories and return results (Health, 2015). Some samples are delayed at the district hospital laboratory level since they have to be checked for validity. From July to September 2015, only 50% of children in need had accessed ART cumulatively compared to 68 percent of adults (Health, 2015). The average turnaround time from sample collection until the test result is received by the caregiver is 39 days, with Queen Elizabeth Central Hospital Laboratory leading by 91 days (Health 2015). UNICEF, in collaboration with the Ministry of Health (MoH), has embarked on a pilot study to explore the effectiveness of using drones (unmanned aero planes) to transport samples, to address long turnaround time. However, adopting a policy to decentralise DNA/PCR HIV testing using simple diagnostic devices to the district hospitals or high volume sites remains a priority in the HIV response. This would enhance acceleration of child treatment. This policy brief therefore, examines the evidence in support of this policy and its implications.

Key Messages

- Long sample turnaround time has been one of the principal root causes for low early infant diagnosis of HIV services in Malawi.
- Use of point-of-care HIV diagnostic devices technology for HIV diagnosis in children is one of the possible solutions for addressing the challenge of the long turnaround time in Malawi.
- This policy brief has critically examined evidence in support of the use of point-of-care machines and possible implications of the use of these devices in the country.

Methodology

This policy brief is based on a comprehensive review of existing literature. The literature reviewed included scientific papers, research reports and government policy documents.

Discussion of Policy Options

Reduced sample turnaround time

One of the benefits of decentralising DNA/PCR testing is that there would be reduction of sample turnaround time (Essajee, 2015). This was observed in Mzimba District in Northern Malawi after stopping use of Mzuzu Central Hospital laboratory due to presence of molecular laboratory in the district. The sample turnaround time reduced from 39 days to 8 days (Health, 2015). In Zimbabwe, when the DNA/PCR tests were decentralised,

sample turnaround time was reduced from 8 weeks to 4 days (Parirenyatwa, 2015). A reduction in turnaround time was also observed during DNA/PCR point-of-care pilot study in seven sites in Malawi using Alere Q testing devices; in this case, the turnaround time reduced from 39 days to 1 hour in the pilot sites (Mwenda, 2016).

Improved access of antiretroviral therapy uptake in children

In addition to increasing access to HIV test results, decentralising DNA/PCR tests to the district level or point-of-care level is likely to enhance HIV treatment uptake, which would in turn control the spread of HIV. A systematic review by Moore (2013) found that use of point-of-care helped in improving access to care and control of spread of diseases due to early treatment. However, the review emphasised the need for training to enhance sensitivity of the decentralised tests (Moore, 2013).

Reduced sample losses due to increased steps in transportation

Conventional laboratory networks face critical challenges such as loss of samples, need for more and specialised human resources (Adeniyi, 2015) compared to use of point-of-care machines where a sample is tested as soon as it is collected (Meggi, 2015). These challenges are also experienced in Malawi, where some samples have not been traced within the system despite evidence of being documented in the log book.

> *"The average turnaround time from sample collection until the test result is received by the caregiver is 39 days"*

Implications for Decentralisation of DNA-PCR Testing through Point -of-Care Machines

Despite the identified benefits, implications of decentralising DNA/PCR testing to the districts or high volume sites need to be considered. Some of the considerations are discussed here below.

Operational challenges

Though the machine is simple, some primary health care providers may have problems following the standard operation procedure. Therefore, this would require supportive mentorship and supervision to enhance quality of results (Alemnji, 2011). Supervision may be done by laboratory technologists in the reference laboratories supporting districts (Moore, 2013). Weather variations between districts may also affect test results unlike the conventional laboratories where temperature is controlled. This may be observed mainly in hot lake-shore and lower-shore districts. A pilot study in Malawi on Alere Q showed that the machine recorded some errors during hot weather (Mwenda, 2016).

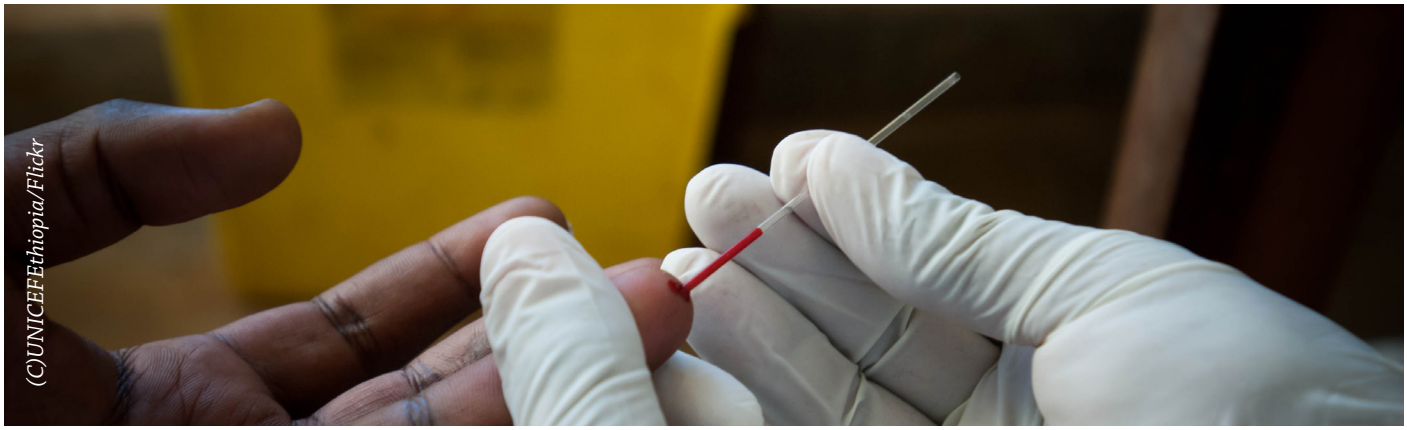
Interrupted availability of supplies such as reagents and cartridges, and lack of maintenance of the devices may also affect the performance of machines (Agarwal, 2013). This needs to be considered before scaling up as of the decentralisation of HIV testing. Two types of logistics need to be streamlined, namely: the system for supplying point-of-care machines and the one for the supply of molecular platforms. The other implication is that as time passes by, the benefits realised from use point of care machines may be diluted due to improved samples TAT for samples processed in the conventional laboratories due to reduced workload as most of the samples would be done at point-of-care (Deo, 2013).

Cost implications

The cost per test through use of point-of-care machines is higher compared to test done at conventional laboratory based PCR, therefore point-of-care machines may not completely replace but complement the existing conventional laboratory services (Essajee, 2015).

Programmatic challenges

Difficult decision-making may be encountered in the process of implementing this policy. For example, access versus accuracy of HIV test results from point-of-care testing devices. A study done by Deo (2013)



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looked at access versus accuracy of the test results and found that decentralising DNA/PCR HIV testing improved access. However, accuracy was compromised due to the reduced technical knowledge of technicians at the district level (Deo, 2013).

In Malawi, this limitation may be addressed by training and mentorship of the district laboratory technologist to improve accuracy of the results as well as access.

> *"A reduction in turnaround time was also observed during DNA/PCR point-of-care pilot study in seven sites in Malawi using Alere Q testing devices; in this case, the turnaround time reduced from 39 days to 1 hour in the pilot sites"*

Conducting quarterly proficiency testing may also assist to ensure that testers are competent to perform the test. This may also be mitigated by strengthening the confirmatory HIV test before ART initiation as recommended in the management of HIV in adults and children guidelines (Health, 2013). Accuracy concerns reported in Deo's study were addressed in the Jani et al's study, which found high sensitivity and specificity of point-of-care nucleic acid-based test (NAT) for early infant diagnosis testing performed by primary health care nurse (Jani, 2014).

Recommendations

i. Decentralise HIV diagnostic devices for children to enable faster HIV testing - Upon examining literature, program data and the frustrations that both the mothers and health providers go through as the result of delayed samples, it is fair to conclude that decentralisation would enhance timely initiation of ART in children (Mwenda, 2016). However, there is need to strengthen use of confirmatory sample to be drawn before ART initiation which is in line with the existing clinical guidelines for HIV management in Malawi.

ii. Train health care workers at lower levels of the health care system - There is need to train health care workers at lower level of the health scare system to enhance accuracy of HIV test results and proper handling of the point-of-care machines and ensure that standard operating procedures are adhered to.

iii. Put in a place a system to ensure sustainable quality control - A strong system needs to be developed to ensure sustainable internal and external quality control mechanisms as well as a reliable logistical system that would ensure uninterrupted supply of reagents and consumables.

iv. Conduct implementation science studies - There is a need to conduct implementation science studies on routine program evaluation especially to determine how many machines are required per a given population size to bring about desired impact.

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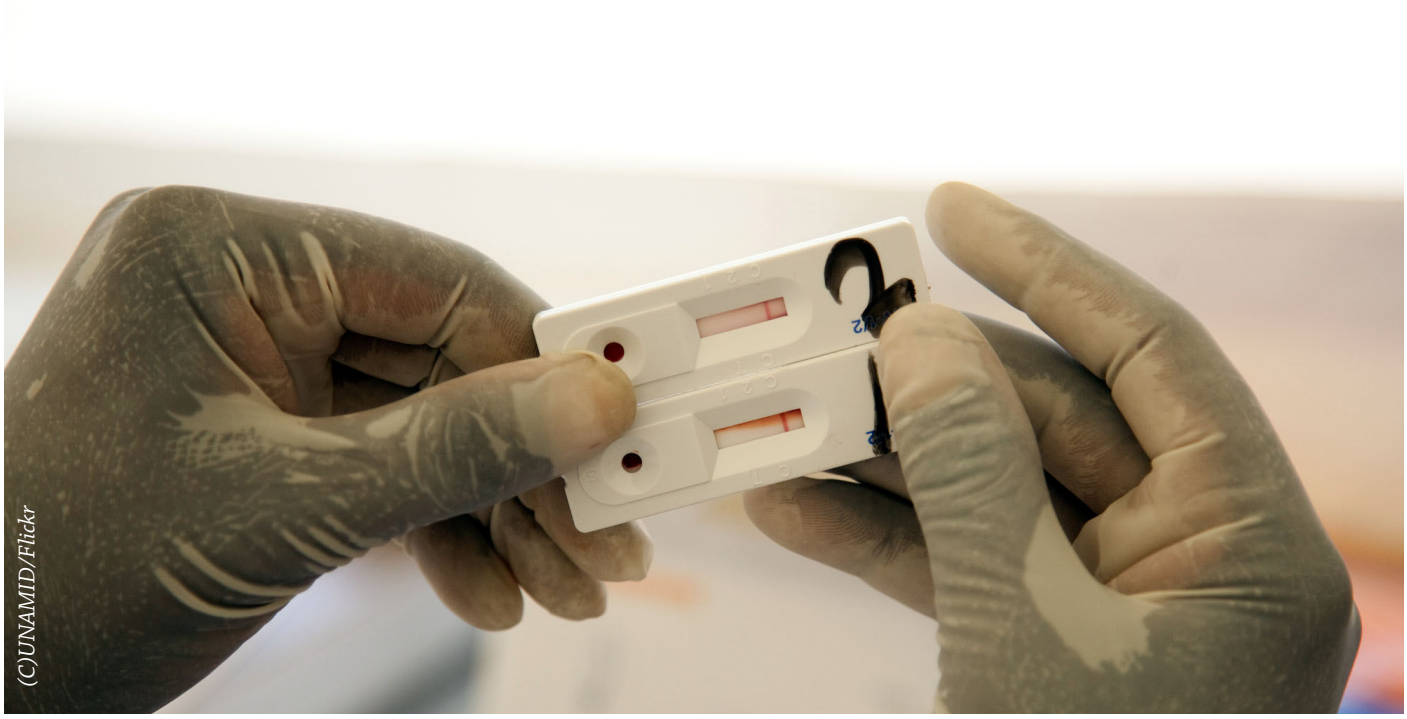

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