ZIMBABWE

TB AND HIV FAST FACTS

1.3 MILLION PEOPLE LIVING WITH HIV

13.3% ADULT HIV PREVALENCE (AGES 15–49 YEARS)

37,000 PEOPLE FELL ILL WITH TUBERCULOSIS (TB)*

23,000 PEOPLE LIVING WITH HIV FELL ILL WITH TB*

63% OF TB PATIENTS ARE PEOPLE WITH KNOWN HIV-POSITIVE STATUS

63% OF HIV-EXPOSED INFANTS RECEIVED AN HIV TEST WITHIN THE FIRST TWO MONTHS OF LIFE

*Annually

Sources: UNAIDS estimates 2019; World Health Organization, 'Global Tuberculosis Report 2018'

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INTEGRATED TESTING FOR TB AND HIV USING GENEXPERT DEVICES EXPANDS ACCESS TO NEAR-POINT-OF-CARE TESTING

LESSONS LEARNED FROM ZIMBABWE

Introduction

With limited funding for global health, identifying practical, cost- and time-saving solutions while also ensuring quality of care is evermore important. Globally, there are fleets of molecular testing platforms within laboratories and at the point of care (POC), the majority of which were placed to offer disease-specific services such as the diagnosis of tuberculosis (TB) or HIV in infants. Since November 2015, Clinton Health Access Initiative, Inc. (CHAI), the United Nations Children's Fund (UNICEF) and the African Society of Laboratory Medicine (ASLM), with funding from Unitaid, have been working closely with ministries of health across 10 countries in sub-Saharan Africa to introduce innovative POC technologies into national health programmes.[1]

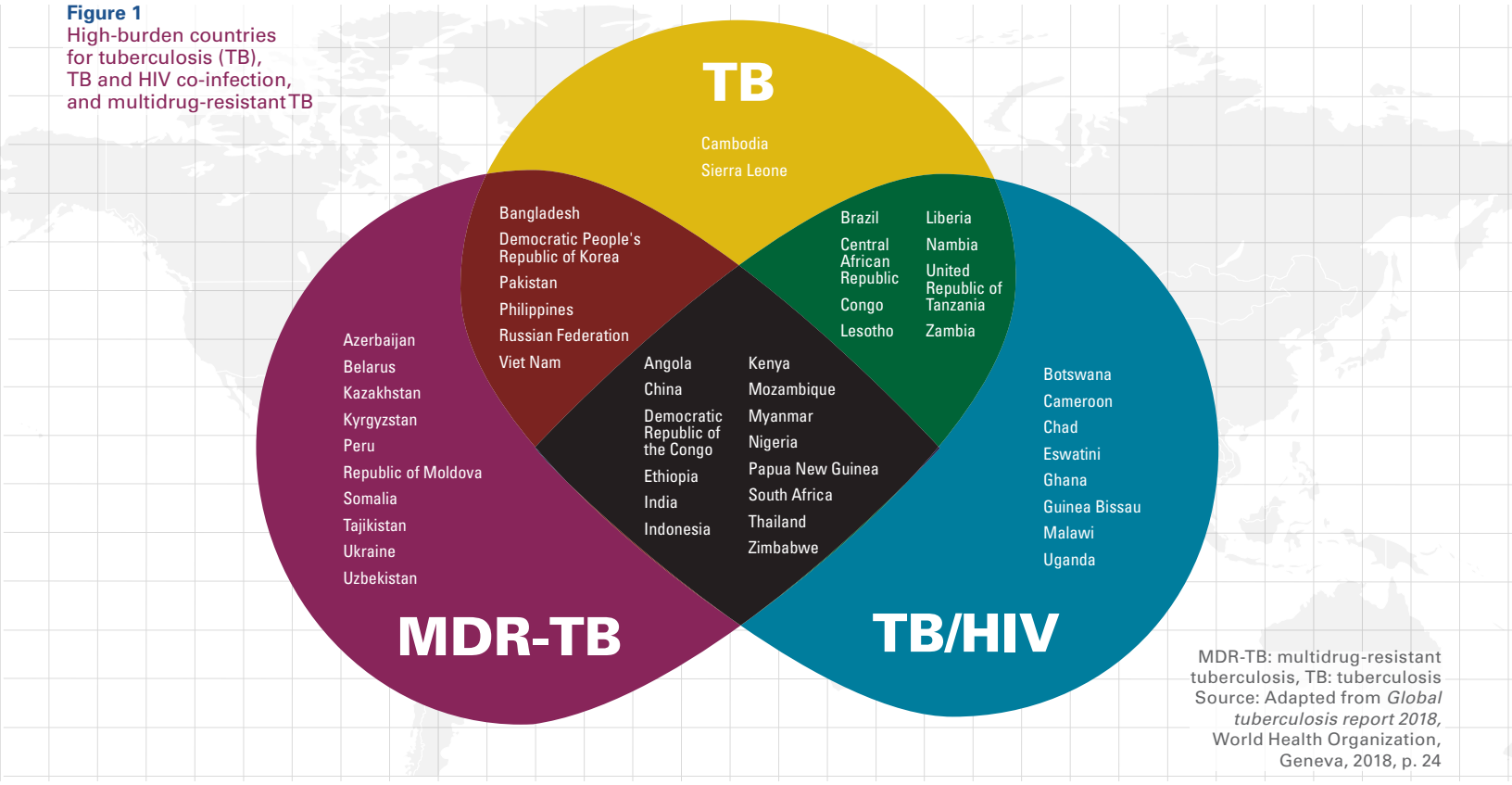
One approach to increasing access to POC testing is integrated testing (a term often used interchangeably with "multi-disease testing"), which is testing for different conditions or diseases using the same diagnostic platform.[2] Leveraging excess capacity on existing devices to enable testing across multiple diseases offers the potential to optimize limited human and financial resources at health facilities, while increasing access to

rapid testing services. One such POC platform is GeneXpert (made by Cepheid), which is used for TB diagnosis, detecting resistance to the antibiotic rifampicin, early infant diagnosis of HIV, and HIV viral load testing in the treatment monitoring of patients on antiretroviral therapy (ART). Among further uses, it can also measure hepatitis C viral load and detect human papillomavirus DNA.[3]

Within this context, Zimbabwe has been at the forefront in generating important evidence on integrated TB, early infant HIV diagnosis and viral load testing using the near-POC GeneXpert platform. An initial study by Médecins Sans Frontières in the country, for example, found that the use of the GeneXpert platform for integrated TB and HIV testing in rural health-care settings was feasible and also increased access to early infant HIV diagnosis and viral load testing for priority populations.[4] Additionally, in 2017, Zimbabwe's TB and HIV programmes, through funding from Unitaid, piloted integrated testing to assess how spare capacity across existing GeneXpert devices could be used by both TB and HIV programmes to improve access to on-site early infant HIV diagnosis and viral load testing.

This brief summarizes the key findings and lessons learned from Zimbabwe's pilot implementation, while also highlighting the benefits of integrated testing for clients, health providers and the health system. It is intended to be a resource for countries interested in deploying and/or scaling up POC integrated testing in their own contexts. Although this brief specifically focuses on TB/HIV integration using the GeneXpert platform, the basic principles of integrated testing, and the lessons learned from Zimbabwe, may also be applicable to integrated testing for other diseases (e.g., human papillomavirus and HIV; hepatitis C virus and HIV), as well as to other POC and laboratory-based diagnostic platforms.

Figure 1
High-burden countries for tuberculosis (TB), TB and HIV co-infection, and multidrug-resistant TB



MDR-TB: multidrug-resistant tuberculosis, TB: tuberculosis
Source: Adapted from *Global tuberculosis report 2018*, World Health Organization, Geneva, 2018, p. 24

The TB and HIV epidemics in Zimbabwe

Tuberculosis

TB is one of the top 10 causes of death worldwide and a leading cause of mortality among people living with HIV.[5] In Zimbabwe, an estimated 23,000 people living with HIV fell ill with TB in 2017, and an estimated 63 per cent of TB patients in 2017 were people living with HIV who knew their HIV-positive status.[6] Zimbabwe is among the top 30 high-burden countries for TB and multidrug-resistant TB, as identified by the World Health Organization (WHO) (Figure 1).

Zimbabwe has adopted the WHO End TB Strategy targets to reduce TB-related deaths by 95 per cent and new cases by 90 per cent, by 2035, with the goal of ending the TB epidemic.[7] Currently in Zimbabwe, all district hospitals offer TB testing and treatment. There are 180 TB diagnostic centres within the public health system, and TB diagnosis and treatment is provided through the public health sector. Prior to 2012, the primary method for diagnosing pulmonary TB in Zimbabwe was through sputum smear microscopy, which is inexpensive and simple. The TB detection rate, however, was low, especially among people with HIV and TB co-infection, who often have very low levels of TB bacteria in their sputum, making it difficult to detect with sputum smear microscopy, which has low sensitivity.

As a result, in 2012, the Ministry of Health and Child Care (MOHCC) introduced the Cepheid GeneXpert molecular diagnostic system and Xpert MTB/RIF assay as a more sensitive diagnostic tool for TB, including for identifying drug-resistant strains.[8] The Xpert MTB/RIF assay detects the presence of TB bacteria in sputum and other sample types, as well as resistance to rifampicin. The Xpert MTB/RIF assay is now used as the primary initial diagnostic test for all people living with HIV suspected to have TB as well as for all presumptive TB patients in Zimbabwe.

The MOHCC, in collaboration with partners, has procured 139 GeneXpert machines as of May 2019. All provincial hospitals as well as 70 per cent of district hospitals (37 out of 53) have a GeneXpert machine for TB diagnosis and rifampicin resistance testing. Through GeneXpert deployment, the ministry seeks to increase overall TB case notification rates, including among children, and improve early case detection for drug-resistant TB.

HIV

Zimbabwe has one of the highest HIV prevalence rates in the world (13.3 [10.8 - 14.5] per cent), with 1.3 million [1.1 - 1.5 million] people living with HIV in 2018. Importantly, there has been a significant decline in new HIV infections and AIDS-related mortality in Zimbabwe since 2010. This is due to a mix of factors, including strong commitment from government and development partners, the adoption of high-impact interventions, increased domestic funding for the HIV response, and the rapid scale up of service coverage.[9]

Simultaneously, Zimbabwe has made substantial strides in decentralizing and expanding access to HIV testing and treatment, including services for the prevention of mother-to-child transmission (PMTCT) and ART for all people living with HIV, including children and adolescents as well as pregnant and lactating mothers. In 2018, PMTCT coverage reached 94 [71 - >95] per cent and paediatric ART coverage (for children aged 0–14 years) was 76 [59 – 93] per cent.[10]

Moreover, in 2015, in addition to the test-and-treat approach of immediate treatment initiation for all people living with HIV regardless of their CD4 cell count, Zimbabwe adopted WHO recommendations to implement routine viral load monitoring for all people living with HIV on ART at 6 and 12 months after ART initiation, and annually thereafter. Adoption of these guidelines, coupled with the implementation of molecular testing for HIV viral load across 11 laboratories,[11] has led to both an increased demand for and a scale up of viral load testing services in Zimbabwe. In 2018, 33 per cent of people living with HIV on ART were tested for viral suppression.[12]

In terms of paediatric HIV, Zimbabwe was the first country in November 2016 to launch Start Free, Stay Free, AIDS Free, a super-fast-track framework for ending AIDS among children, adolescents and young women by 2020.[13] Early HIV diagnosis in infants is a critical first step towards ensuring the timely treatment of infants with confirmed infection. In 2017, however, only 63 [53-83] per cent of HIV-exposed infants received an early infant diagnosis within the WHO-recommended 2 months of age, highlighting the need to strengthen the early infant diagnosis programme.

A GeneXpert machine with MTB/RIF and HIV-1 viral load cartridges.

Early infant diagnosis testing services have been available in Zimbabwe for over a decade and are centralized in three regional laboratories. Samples, collected from infants at health facilities using the dried blood spot technique, are transported by motorcycle (twice a week) to a central point in a district or zone. A private courier company then collects the samples and delivers them to the three central laboratories; it is also responsible for returning the results to the district centres for onward distribution to the health facilities via motorcycle. Conventional testing for early infant diagnosis and viral load in Zimbabwe relies on the same sample transportation system and confronts many similar limitations, including long turnaround times (60–90 days) for results to be returned to caregivers and patients, high rates of loss to follow up, and low rates of clinical action, including treatment initiation, adherence counselling and regimen switching.[14]

One strategy that can address long delays in returning results is the implementation of POC or near-POC technologies, including the Cepheid GeneXpert platform, which enable the decentralization of testing to the facilities where patients receive care. POC platforms have been successfully employed for previously laboratory-based tests like CD4 testing, resulting in improved links to HIV care and timeliness of ART initiation,[15] and have been shown to substantially increase ART initiation rates among HIV-positive infants and young children.[16,17] Initial data are also emerging on the potential benefit of POC viral load monitoring; in a randomized control trial in a high-volume clinic in South Africa, a combination intervention that included POC viral load improved rates of viral suppression and retention in care by 13.9 per cent and decreased the median time before viral load results were communicated to patients from 28 days to the same day. [18]

Integrated testing for TB and HIV on GeneXpert platforms

POC and near-POC diagnostics are an innovative approach for strengthening case detection and improving clinical outcomes. The GeneXpert platform is one such technology, which additionally has the capacity to run a variety of molecular diagnostic assays.[19] Moreover, various programmatic analyses have documented spare capacity on GeneXpert devices globally,[20] including in Zimbabwe.[21]

Excess GeneXpert testing capacity can be used not only to meet TB testing demand, but also for early infant diagnosis and viral load testing, which may be mutually beneficial for TB and HIV programmes. Device sharing across programmes could enable more efficient device use in space- and resource-limited labs; may enable increased access to POC services for low-volume test types – like early infant diagnosis – which would not justify device placement as a stand-alone test; as well as increased negotiating power to reduce the price of test cartridges when pooling volumes across disease areas. There is also the potential for shared operational costs, including for human resources, service and maintenance agreements, and connectivity solutions (Box 1).

Box 1
Mutual benefits of integrated tuberculosis and HIV testing on GeneXpert

- Efficient device use in space- and resource-limited laboratories
- Increased negotiating power to reduce cartridge prices when pooling volumes across diseases
- Potential for shared operational costs, including human resources, device service and maintenance, connectivity and mentorship
- More efficient and integrated diagnostic networks

Overview of the TB/HIV integrated testing pilot

To generate evidence and inform decision-making on the potential for integrating TB and HIV testing services, Zimbabwe's MOHCC, in collaboration with CHAI, UNICEF and ASLM, and funded by Unitaid, designed and implemented an observational pilot to determine the feasibility and acceptability of integrated testing of TB, early infant diagnosis and viral load on GeneXpert platforms placed in selected public health facilities. The specific objectives of the pilot were to determine:

- The feasibility of integrated testing according to test volumes and turnaround times
- How integrated testing affects the provision of TB, early infant diagnosis and viral load services
- The acceptability of integrated testing on the existing GeneXpert devices by clinicians and lab staff

Integrated TB and HIV testing was implemented for five months in eight facilities[22] with existing GeneXpert platforms. Half of the facilities performed all three tests (TB, early infant diagnosis and targeted viral load), and half offered only viral load testing in addition to TB, as on-site early infant diagnosis testing was already available.

Data were extracted from facility registers and logbooks for the five months before integration (May to September 2017) and for the five months of the pilot (October 2017 to February 2018). Before integration, early infant diagnosis and viral load services were offered through referral to the conventional, centralized labs, and TB testing was conducted on site using the GeneXpert.

Pilot facilities were purposefully selected against a set of clear criteria, which were designed to ensure the existing devices could manage the additional HIV testing volumes and that there was appropriate commitment, as detailed in Box 2. Preparatory activities included initial training and certification of device operators for early infant diagnosis and viral load testing; refresher training for TB testing on GeneXpert; the development of standard operating procedures on sample preparation and test performance as well as waste management specific to the new test types (i.e. HIV early infant diagnosis and viral load); and clinical workflow mapping.

Testing was offered at the pilot sites in accordance with national guidelines. Routine viral load testing is recommended in Zimbabwe at 6 and 12 months after ART initiation, and annually thereafter. In addition, clinicians have the discretion to order targeted viral load tests for patients with immunological or clinical suspicion of treatment failure, as well as 3 months after adherence counselling for patients who have one documented elevated viral load measurement (more than 1,000 copies/ml). POC viral load testing during the pilot was available at each facility, with clinicians using their discretion to prioritize which patients should be tested using POC versus referral-based tests, with the rationale for prioritization documented. During the pilot, POC early infant diagnosis testing was offered to HIV-exposed infants under 18 months of age who presented with their mothers through the PMTCT programme.

As set out by the programme's implementation standards, routine supervision and monitoring visits were conducted, which included the monitoring of test consumption to ensure an adequate supply of test reagents. Surveys of health-care workers were also used to assess their opinions on integrated testing services.

Box 2
Pilot site selection

Primary site selection criteria

- Sites already performing tuberculosis (TB) testing on GeneXpert with excess test capacity
- Low to moderate volume of suspected TB cases (fewer than 50 presumptive TB patients per month), as sites with high TB volumes may not have had excess capacity to accommodate additional HIV testing
- Moderate to high volume of clients on antiretroviral therapy (ART; more than 1,500 patients on ART) and HIV-exposed infants
- Result turnaround time of four weeks or more for early infant diagnosis and viral load

Other considerations

- Willingness of facility to support implementation pilot and take ownership beyond pilot
- Site assessment to confirm pilot site eligibility, i.e. testing volumes, infrastructure requirements, etc.

Key findings from the pilot

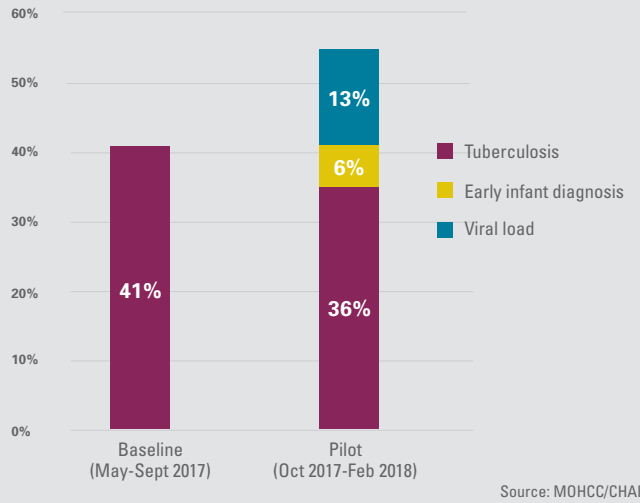
TB testing and treatment service quality was maintained following integration

One major question that motivated the pilot was whether the added HIV-related testing volumes would harm the provision of TB testing and treatment. Fifty-nine per cent of TB results were documented to have been received at the clinic before the pilot, and 67 per cent were documented to have been received during the pilot. The median time to clinic receipt of results was 1 day, both prior to and during the pilot. In addition, 47 per cent of patients who tested positive for TB were documented to have initiated treatment both before and after integration, and the median time to treatment initiation remained 1 day. Finally, the addition of early infant diagnosis and viral load testing did not increase the TB testing error rate or cause any significant disruptions to TB testing services.

Looking specifically at the facilities that offered all three test types, the overall utilization rate increased from an average of 41 per cent to 55 per cent, without exceeding device capacity (Figure 2a), and the majority of tests continued to be for TB diagnosis (Figure 2b). Differences in TB volumes reflect a TB campaign that was conducted during the baseline period, which artificially increased testing volumes.

Figure 2a

Utilization rate across four sites offering all three tests (tuberculosis, early infant diagnosis and viral load)



Source: MOHCC/CHAI unpublished pilot study data, 2018

Integrated POC testing reduced turnaround times for early infant diagnosis and viral load testing and enabled faster rates of clinical action for HIV-positive infants and people living with HIV on ART experiencing viraemia

For early infant diagnosis, the median time from sample collection to clinic receipt of results, and from sample collection to ART initiation for HIV-positive infants, decreased from 14 days to 1 day and from 41 days to 2 days, respectively, for patients managed using POC testing. Although only a few infants were diagnosed with HIV during the pilot, all infants found to have HIV were linked to treatment.

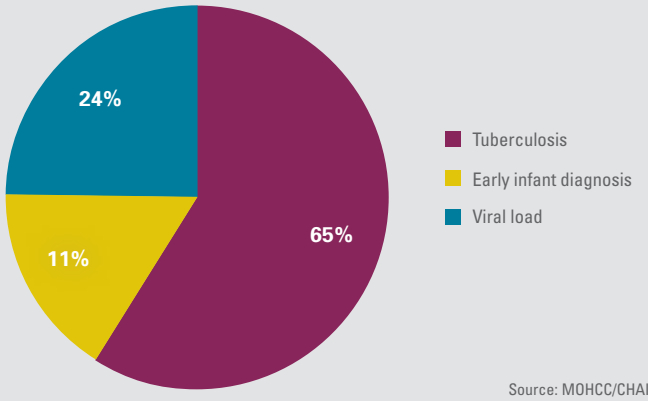
For viral load, 42 per cent of samples (477 out of 1,126) run on the GeneXpert during the pilot were for targeted viral load testing of pregnant and breastfeeding women, children, patients with suspected treatment failure, or for repeat testing of those with a previously elevated viral load result (more than 1,000 copies/ml) – all populations who may experience additional benefit from access to on-site viral load testing and the rapid return of results. The remaining viral load samples were documented as either routine (52 per cent) or the indication was missing/other (6 per cent). For patients with a documented elevated viral load, the median time between sample collection and initiation of enhanced adherence counselling decreased from 35 days to 2 days, and the median time between sample collection to regimen switch decreased from 113 days to 19 days.

Integration enables cost savings for the TB programme

Using the operational testing costs experienced during the pilot that can be shared – including device service and maintenance, laboratory staff salaries and mentorship/supervision – the potential cost reduction for the TB

Figure 2b

Test use at four sites offering all three tests (tuberculosis, early infant diagnosis and viral load) during pilot



Source: MOHCC/CHAI unpublished pilot study data, 2018

testing programme was projected, assuming some or all of these services are absorbed by the HIV programme for 90 GeneXpert devices (which had excess capacity at the time of the analysis, and thus could be eligible for integrated testing).

The total cost of TB testing on the 90 GeneXpert platforms was estimated to be US$3M in 2018[23] , of which US$1M (32%) accounts for the above mentioned operational costs that could be split between the HIV and TB programmes. The proportion of the $1M that would be saved by the TB programme is dependent on the terms of the agreement for cost-sharing between the two programmes; in the specific case of Zimbabwe, the HIV and TB programmes have agreed to evenly split the shared operational costs, therefore about US$0.5M savings is expected to be realized by the TB programme annually as a result of integrated testing, representing 16% of the total cost of the TB testing programme (Figure 3). The

specific cost categories that contribute to this cost sharing are shown in Figure 4. It should be noted that with increased integration of programmatic services (e.g., combined sample transport, device connectivity, data management, etc.) the overall savings to the TB and HIV programmes are expected to increase significantly, as system-wide efficiencies are realized.

Integration benefits clients, health-care workers and the health system

In addition to quantitative findings from the pilot study, the benefits of integrated services were emphasized in interviews with clients and health workers as well as MOHCC leadership. As Dr Owen Mugurungi, Director of HIV and TB at the MOHCC in Zimbabwe, explains, "There have been different technologies for testing TB and HIV, but one of the best technologies that have come to us is the GeneXpert. It was used initially to detect TB and is much better than microscopic testing. With the GeneXpert, all one needs is to buy the proper cartridges. We have this technology everywhere in this country, in every district. This has helped with cost, in that we do not need any other technology because we can utilize what we already have [for both TB and HIV]."

For health workers and clients alike, reduced turnaround times for test results have been a dramatic improvement both in terms of quality of care and faster clinical decision-making.

Farirayi Bvepfepfe, Laboratory Microscopist at Mabvuku Polyclinic, explains: "This is a departure from the long processes of sending samples to the central laboratory and waiting for up to a month to get the results." With POC testing, "it takes us two hours to get the TB results, and only one and a half hours for viral load testing, allowing us to give same-day results to pregnant women." Waiting for test results can create hardship and anxiety for clients, while same-day results can help improve clients' confidence in the health system. A 27-year-old woman living with HIV explains the anxiety: "I still remember the first time I took my viral load tests two years ago. The first test results never came, and I had to come back to the clinic to take a second test, which took six months to get the result. It was very time-consuming to repeatedly visit the clinic as I had to travel a long distance to get here, not to mention the anxiety that comes with waiting for a long time to find out whether the medicines are working or not." In contrast, she continued: "I couldn't believe it when I came in this time around and was given my results on the same day. What is most satisfying is that I can now talk to my partner to encourage him to visit a facility like this because it helps to know what treatment roll-out one needs on the same day of testing – something that was not possible before."

Timely results not only help to accelerate clinical decision-making and improve the quality of care – timely diagnosis and rapid treatment initiation for HIV-positive infants can make a life-saving difference. Anna Pingani, Laboratory Microscopist at Kuwadzana Polyclinic in Harare, explains: "Early infant diagnosis [EID] of HIV is crucial for timely initiation of antiretroviral therapy in infected children who are at high risk of mortality. The primary aim of EID is to identify HIV-infected children early so that treatment can be started promptly before symptoms of HIV develop. This technology is therefore a very crucial intervention for this to be possible."

Figure 3

TB testing programme savings according to proportion of shareable costs absorbed by HIV program (0%, 50%, and 100%)

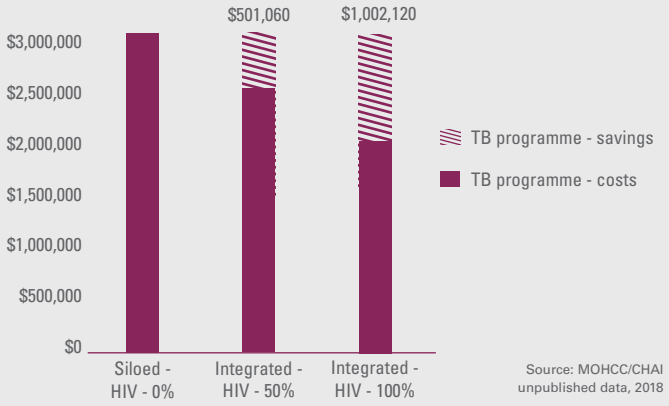
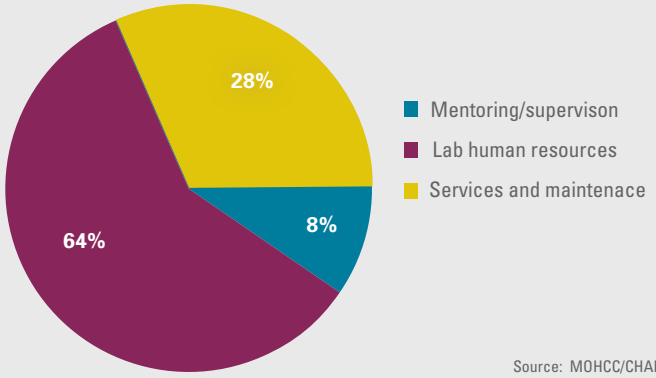


Figure 4

TB programme savings proportions, by cost category



Lessons learned and recommendations for countries considering integrated testing

There were numerous lessons learned during the implementation of the integration pilot that may be useful more broadly as country programmes consider introducing integrated TB and HIV testing using the GeneXpert platform. While this brief has focused on the findings of the pilot, the following recommendations primarily highlight the importance of fostering an enabling environment and simultaneously investing in health systems strengthening to realize the benefits of integrated testing.

1 Convene joint planning and policy discussions between TB and HIV programmes at the onset. Strong coordination and communication, shared accountability, and an enabling policy environment are needed to realize programmatic synergies, device sharing and cost savings for mutual benefit.

2 Invest in laboratory infrastructure, including air conditioners for temperature control, extra fridges to store samples, and backup generator/solar panels to provide power during times of power cuts. Infrastructure and room conditions that do not meet the necessary specifications for operating the GeneXpert platform (e.g., lack of air conditioners) can compromise the proper functioning of the platform as well as testing quality.

3 Use data-driven site-selection criteria to ensure that multi-disease testing is proposed only on devices that can accommodate the projected testing demand and where the appropriate infrastructure is in place to ensure appropriate sample preparation and test operation.

4 Involve clinicians and facility staff in the determination of optimal patient flow processes, the identification of roles and responsibilities, the prioritization of different sample types and the development of simplified job aids to support integrated testing. Engaging facility staff promotes ownership and accountability.

5 Conduct regular monitoring visits and refresher training to proactively address any challenges and concerns operators may have with using the GeneXpert platform and providing integrated testing services.

6 Develop and implement waste management solutions and standard operating procedures for the safe handling of medical waste associated with integrated testing. This includes standard operating procedures for moving waste to incinerators capable of achieving the high temperatures (1,000°C) needed to safely dispose of used test cartridges, when not available at the testing site. Waste management requirements should be part of the overall site selection process.

7 Ensure a consistent supply of cartridges and commodities as well as timely and consistent service and maintenance mechanisms to prevent service disruptions and machine/module downtime.

8 Ensure connectivity for each device. Connectivity enables the transmission of data from testing sites to a centralized server, where they can be stored, analysed, displayed and acted on in real time. Once transmitted, data can be used by programme managers and decision makers to oversee a decentralized testing network, including the real-time monitoring of inventory, device use and operator performance – all of which can inform the identification of corrective actions to ensure the consistent delivery of accurate and timely test results to patients.

9 Clearly define the workflow and communication to patients and caregivers to ensure rapid return of results and clinical action. Clear documentation and processes will help health workers to make appropriate clinical decisions on test results and ensure timely and appropriate referral and links to treatment and care.

10 Provide mentorship and supportive supervision to monitor, support and strengthen documentation and recording in laboratories and health facilities. It is also essential that health facility staff have the necessary supplies (e.g., logbooks and registers) to enable timely and accurate documentation, and that these data are used for data-driven programme management and process improvement.

Conclusions

Offering TB, early infant diagnosis and viral load testing through integrated testing increases device use without exceeding capacity or compromising the provision of TB testing and treatment services.

Integrated TB and HIV testing on existing POC platforms enables timely infant diagnosis and viral load testing, as well as accelerates the rates of clinical action for HIV-positive infants and for people living with HIV on ART who experience viremia.

Leveraging existing device fleets is a feasible and acceptable approach to increase access to POC testing in a cost-efficient manner. Cost savings and system efficiencies can be achieved across testing operations through integrated diagnostic testing.

An enabling environment and simultaneous investments in health system strengthening are needed to realize the benefits of integrated POC testing.

The benefits of integrated testing can be realized through different diagnostic platforms – both POC and laboratory-based – and for a variety of diseases, as countries strive for universal health-care coverage.

"Early infant diagnosis [EID] of HIV is crucial for timely initiation of antiretroviral therapy in infected children who are at high risk of mortality. The primary aim of EID is to identify HIV-infected children early so that treatment can be started promptly before symptoms of HIV develop. This technology is therefore a very crucial intervention for this to be possible."

Anna Pingani
Laboratory Microscopist

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