

July 2019 | Issue 21



LAB CULTURE

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA



Special issue:
**Point-of-care and
near-point-of-care
technologies**



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ON THE COVER:

Entitled, "HIV in Uganda", this image was captured by CDC Audio-Visual Production Specialist, Susy Mercado, with NCHM. The photo depicts a newborn in Kampala, Uganda, receiving an antiviral drug to prevent the mother-to-child transmission of HIV.
Photo: CDC/ CDC Connects

Contribute to Lab Culture

ASLM is currently accepting article and photo submissions for upcoming issues of *Lab Culture*. We publish timely, informative, inspirational articles relevant to the unique challenges faced by laboratories in resource-limited settings. We are interested in articles on the critical aspects of laboratory medicine, best practices, success stories, leaders in the field, industry news, etc.

To submit articles, proposals, photos, etc., please contact the Editor at newsletter@aslm.org.

Lab Culture. Established along with ASLM in 2011 as a member newsletter, *Lab Culture* relaunched in 2017 as ASLM's magazine for laboratory medicine in Africa. Dedicated to bringing timely, informative articles relevant to the unique challenges faced by African laboratories, *Lab Culture* seeks to be Africa's premiere resource for laboratory professionals and other stakeholders working on with the continent. Published six times a year as a digital edition, *Lab Culture* includes features on critical aspects of laboratory medicine and best practices in resource-limited settings, success stories from the continent, industry news, and more.

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A special issue on a special topic: point-of-care technologies for early infant diagnosis of HIV

by Anafi Mataka, ASLM Senior Scientist, Special Issue Guest Editor

This special issue of *Lab Culture* is dedicated to point-of-care (POC) and near-POC technologies, which encompass all instrument and non-instrument-based technologies used to aid diagnosis, care and treatment while patients are at a health facility or in the community. It touches on the importance of investment in diagnostics and innovation, inclusive of POC, and the role of integrated diagnostics based on early lessons learned from GeneXpert testing programmes for HIV and tuberculosis. It further looks at the introduction of POC technologies in the context of optimised national diagnostic networks.

The introduction of molecular testing has been a game changer, particularly for major diseases such as tuberculosis and pediatric HIV. Tests for these diseases traditionally entailed transporting samples from local clinics to testing centres; patients and clinicians often waiting hours, and sometimes weeks or months, to receive results needed for care and treatment. POC technologies bring tests closer to patients in a convenient and timely manner. This reduces the risk of fragmentation of care due to unavailability of test results and reduces loss-to-follow-up rates, thus improving health outcomes. In low- and middle-income countries, POC technologies could complement existing conventional laboratory networks and bridge the technology-clinic gap to address

diseases and conditions of major public health importance. The advent of POC testing and its evolution in the laboratory space has provided options to improve access and coverage of diagnostic needs for meeting national targets for many diseases.

A key technological breakthrough in the last decade has been the development of molecular POC tests for the care and treatment of HIV, including early infant diagnosis (EID) and viral load (VL) testing outside of laboratories. Given that these technologies produce results that are used immediately for patient management, this special issue rounds out with a close look at the tenets of a quality-assured POC test result.

Together, these advances in POC and near-POC testing are lighting the way to a brighter future not only for pediatric HIV but for other diseases and conditions where fast, accurate return of results is critical for the best patient and public health outcomes.



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From months to minutes: On-the-spot diagnosis holds the key to ending pediatric HIV

by Lelio Marmora, Executive Director, Unitaid, Switzerland

Every year, thousands of mothers in Africa receive HIV test results for babies who have already died of AIDS.

The solution to stopping this inconceivable tragedy has come with the emergence of sturdy, portable machines that can perform molecular diagnostic tests even at tiny village clinics. The machines have cut down the median time it takes to get an HIV test result from about 122 days to two hours or less.

Since 2012, Unitaid has been investing heavily in innovations that can test infants for HIV and return the results on the same day. With a diagnosis in hand, a healthcare worker can immediately get an HIV-positive baby started on the right medicines – and on the path to a healthy life.

Laboratory-based centralized testing has not been up to the task. In large sub-Saharan

countries such as Mozambique or Cameroon, a blood sample taken from a baby in a village

treatment, statistics show, a third of HIV-exposed infants die within the first year.

Unitaid has been working in 15 sub-Saharan African countries with partners, including the African Society for Laboratory Medicine, Clinton Health Access Initiative (CHAI), Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)

and UNICEF, to increase access to the point-of-care technology and see how it fares in real-world conditions. After

performing hundreds of thousands of these tests across all corners of Africa, we've

proved that the technology works. More than 90% of babies diagnosed with HIV were able to begin treatment within sixty days, compared to 13-43% of babies under the

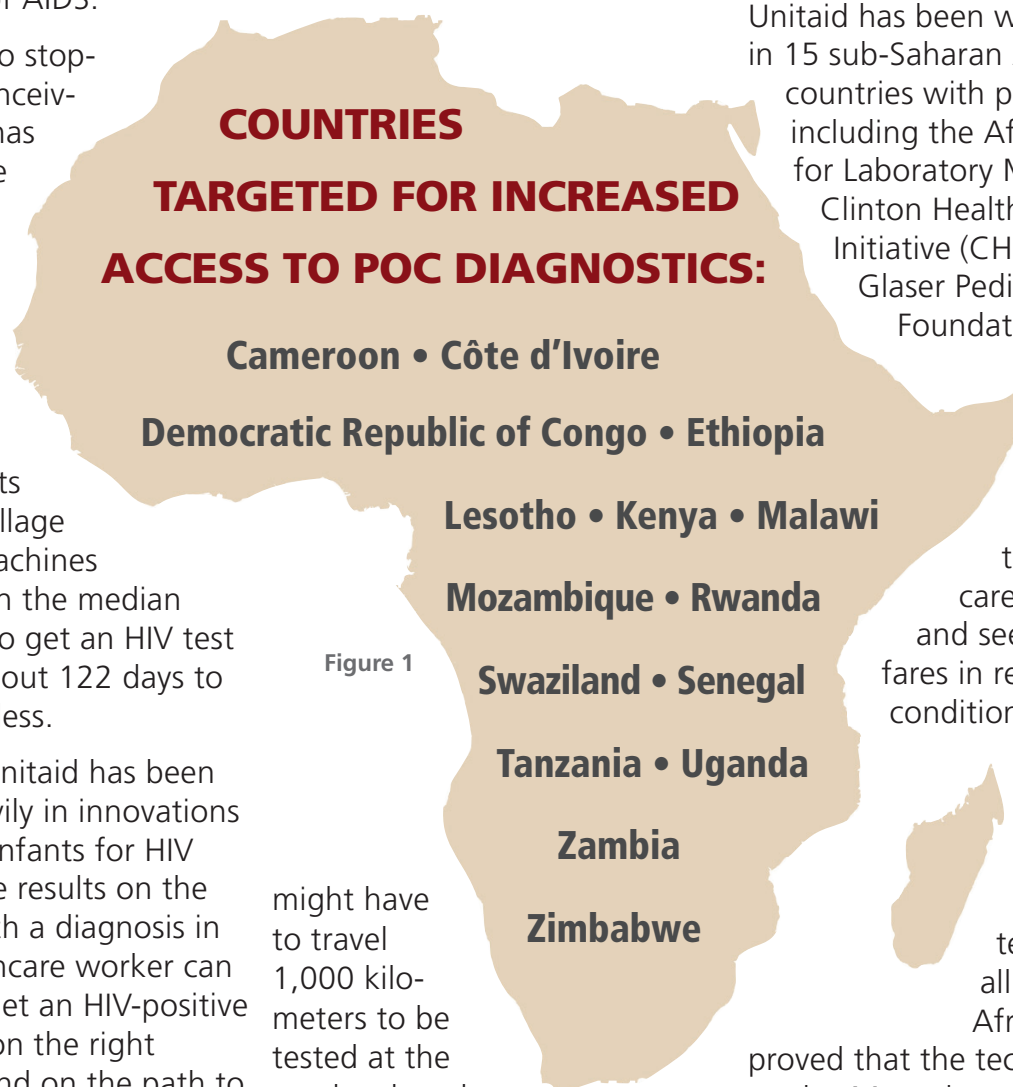


Figure 1

might have to travel 1,000 kilometers to be tested at the overburdened laboratory of a large hospital. The process of returning the results can easily take six months. Without



A healthcare worker operates Pima CD4, a point-of-care HIV diagnostic device.
(Photo courtesy of CHAI)

old system of centralized laboratory testing.

These findings show us that never again should an infant have to die as the result of an undiagnosed HIV infection. Never again should a mother collect the test results alone.

It's time to look toward the horizon. Point-of-care diagnostic machines could be used for many other diseases—major killers such as tuberculosis, hepatitis and human papillomavirus. What

role could they play in integrating and strengthening countries' health systems, and in meeting international goals for universal health coverage?

We must work with the laboratory community and other strategically placed partners to best apply what we've learned. Point-of-care technology holds the promise to make profound, sustainable changes for the better in our global health landscape.

About Unitaid and its work

Since Unitaid was created in 2006, it has invested nearly US \$600 million to set the stage for the mass introduction of innovative HIV solutions for children. Working with a wide spectrum of partners, Unitaid secured price cuts of 80% for pediatric HIV medicines and deployed the first point-of-care CD4 diagnostic devices ever purchased in Africa to stop mother-to-child HIV transmission. From 2012 to the present, Unitaid has invested US \$172 million in piloting point-of-care HIV testing for infants.

Lelio Marmora,
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Integrated diagnostics: early lessons learned from integrated GeneXpert HIV-tuberculosis testing programmes

Globally in 2017, there were over 36 million people living with HIV and an estimated 10 million people living with tuberculosis — 900,000 of them were co-infected with both HIV and tuberculosis.¹ Tuberculosis remains the leading cause of AIDS-related mortality and killed 370,000 HIV-positive people in 2017 — 40 per cent of all HIV-related deaths.² Despite the high risk for co-morbidity between these diseases, HIV and tuberculosis health programmes are often managed and implemented separately, resulting in parallel systems and laboratory networks. Integration of laboratory systems and networks across test and disease types — including but not limited to HIV and tuberculosis — can optimise efficiency and expand patient access to the most timely and appropriate diagnostic assays.

Several molecular instruments exist that are capable of running tests for multiple infectious diseases. These include the centralised Abbott m2000sp and m2000rt, Roche COBAS Ampliprep/COBAS Taqman, Hologic Panther, and the near-point-of-care (POC) Cepheid GeneXpert platform, among others. While the introduction and initial scale-up of GeneXpert services in resource-limited settings was largely conducted to support tuberculosis testing, multiple countries in sub-Saharan Africa, including Cameroon, Ethiopia, South Africa, Tanzania, Malawi, Namibia, Nigeria, Sierra Leone, Uganda, and Zimbabwe, now conduct GeneXpert-based testing for other infectious diseases as well, including HIV, hepatitis C virus, Ebola, Chlamydia trachomatis, and *Neisseria gonorrhoeae*. The significant investment towards scaling up GeneXpert programmes has also successfully increased access to

tuberculosis drug resistance testing, which is particularly important for patients co-infected with both HIV and tuberculosis. However, it has also resulted in a large footprint of devices with excess capacity that is not currently being utilised. This underutilisation of devices is a source of wastage and inefficiency within the laboratory systems, as devices are purchased and maintained but not used to their full potential for the benefit of patients in need of testing.

The low utilisation of GeneXpert instruments, which varies from 1 per cent to 66 per cent³ across many high tuberculosis-burden countries, can be attributed to a variety of factors including weak health systems and poor linkages between referring clinics and testing laboratories, as well as poor clinical awareness and understanding of the Xpert MTB/RIF test and how to access testing, and weak infrastructure. Utilisation rates are now improving in a number of settings, with countries adopting improved tuberculosis case-finding approaches (as per guidance from the World Health Organization [WHO]) that are increasing tuberculosis testing demand. Many countries are also strengthening referral networks and training healthcare workers, which are expected to increase tuberculosis testing volumes. Examples of such actions include: clinical refresher trainings on accessing GeneXpert MTB/RIF testing and how to interpret test results, establishment of decentralised 'superuser' GeneXpert network monitors to support site assessments and technician trainings, and the introduction of solar panels as alternative power supply sources at testing sites to minimise downtime due to electricity outages. However,



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POC instruments are available in multiple configurations based on the number of cartridges that can be analysed simultaneously. Capacity can vary from 1 test per run to 80 tests per run, depending on the instrument. (Photo courtesy of Cepheid)

adoption of the new Xpert MTB/RIF ultra cartridge, which has a runtime of 80 minutes compared to 120 minutes using the standard MTB/RIF cartridge,^{4,5} is expected to result in increased throughput while maintaining current capacity across GeneXpert instrument networks, even as tuberculosis testing volumes increase. Based on previous experience and the known widespread gaps in tuberculosis case detection in high-burden settings, the current excess GeneXpert testing capacity should be viewed as a chance to continue to scale-up patient access to rapid tuberculosis and multi-drug-resistant-tuberculosis testing services. The spare capacity is also an opportunity to introduce diagnostic services for additional diseases across the GeneXpert instrument network.

In 2016, WHO recommended the use of POC devices for early infant diagnosis (EID) of HIV. The use of POC EID tests can have a significant

impact on patients through reduced turnaround times for results, higher result return rates, increased treatment initiation rates, and faster times to treatment initiation.^{6,7}

Cepheid's Xpert HIV-1 Qualitative viral load assay received WHO pre-qualification in July 2016, and has since been introduced in a number of countries as a near-POC test.⁸ (Near-POC is defined here as testing that occurs at an on-site laboratory, rather than in the clinic ward, or through short haul sample referral through a hub-and-spoke network.) In addition, Cepheid's Xpert HIV-1 Qualitative viral load assay also received WHO pre-qualification and is being used for treatment monitoring amongst people living with HIV, especially where access to viral load testing is limited. The Cepheid assay is also increasingly being used in targeted populations, such as pregnant and breastfeeding women, patients with previously elevated viral load, children, and

adolescents. Finally, Cepheid's Xpert HPV test for early identification of cervical cancer risk received WHO pre-qualification in December 2017.

Given the demonstrated available capacity of many GeneXpert instruments in countries with high tuberculosis and HIV burdens, the impact of POC EID testing for detection of HIV-positive infants, the potential benefits of viral load testing, especially for patients at greater risk of unsuppressed viral load, and the benefits of increasing access to additional diagnostics such as human papilloma virus (HPV) testing for cervical cancer, the implementation of GeneXpert-based integrated testing stands to provide significant benefit to patients and programmes across a number of disease areas. The same principles apply to other testing platforms — there are significant benefits to be gained by conducting multi-disease integrated testing on other platforms such as Roche, Abbott,

and Hologic instruments that are currently often utilised only for HIV viral load and EID.

Potential benefits of integrated testing

The integration of testing services is likely to result in increased utilisation of the system at no (or minimal) additional fixed cost, such as for devices, service and maintenance, and training. Integration reduces the need for separate networks of instruments to be run for different diseases and tests and enables the implementation of testing on more consolidated networks that are operationally easier to manage.

Compared with operating individual, programme-specific vertical systems, integrating testing for multiple diseases into existing networks allows for cost-sharing between disease programmes that will result in cost savings for each programme. Since tuberculosis programmes are often operating GeneXpert testing systems alone, they are likely to realise the greatest savings compared to current levels of expenditure. Modelling suggests that cost savings are derived primarily from sharing costs, such as equipment expenses, service and maintenance, connectivity, human resources, and mentoring and supervision for laboratory technicians, across programmes. With higher testing volumes, programmes may also have increased negotiating power with suppliers to request improved services and reduced prices. In addition to cost savings on commodities and site-specific expenses, integrated testing may provide system-wide efficiencies for procurement and supply chain management, sample transportation, and connectivity-enabled data management, if multiple disease programmes can share these costs.

Last but not least, integrated testing has the potential to improve case finding across disease areas, particularly for populations with high comorbidity rates. For example, beyond providing access to both tuberculosis diagnosis and HIV treatment monitoring at one facility, HIV-positive women — who are at higher risk of cervical cancer — may benefit from introduction of HPV screening, a service which has previously been inaccessible in most countries.

Initial steps for introduction of integrated testing

Multi-disease testing can be feasible and successful with appropriate planning. For programmes with



ASLM stock photo.



ASLM stock photo.



Result transmission. Ensure immediate electronic transmission or printing of the result by the computer.

existing device fleets where integrated testing is being considered, preparations for integration should include:

Site mapping and site selection

It is important to conduct a data-driven site selection process that projects anticipated volumes across test types to ensure that device capacity will not be exceeded (and taking into account anticipated changes in testing algorithms). Site selection should be complemented by on-site assessment, if possible, to understand whether selected sites have the infrastructure and human resource capacity to offer additional testing on existing devices. For integrated testing on the GeneXpert platform, sites should have functioning air conditioning and may require accessory devices such as a centrifuge for processing viral load (VL) samples or a heating block for dried blood spots.

Stakeholder engagement

In order for integrated testing to be successful, a high degree of coordination is required from all stakeholders and their buy-in should be considered a pre-condition for scaling-up. Full support from each disease area to be involved is a crucial enabler of successful

integration. As such, planning and implementation should include Ministry of Health focal points and implementing partners across a number of programmes, such as HIV, prevention of mother-to-child transmission, tuberculosis, reproductive health, and laboratory services. Early engagement can enable time to ensure stakeholder buy-in and address concerns from each programme area before moving forward to develop guiding principles as a group. Establishing a platform for periodic review and discussion — such as through an existing technical working group or one established specifically for integration — is recommended,

and allows all stakeholders to meet periodically to discuss and review progress and challenges together. The group will need to address issues such as principles and criteria for site selection, product placement, fleet maintenance, investments to renovate or support sites, and data management solutions.



Confirm that the system shuts down correctly at the end of each day. Exit the software via the User menu when no cartridges are in the instrument modules. Turn off the instrument, shut down the computer, and finally cover the instrument with its plastic protector. (Photo courtesy of WHO AFRO, Clements Hunt)

Lessons from integration experiences

- Addition of EID and viral load increased device utilisation without exceeding device capacity
- Tuberculosis testing and treatment services were not compromised
- Laboratory staff found it feasible and acceptable to run multiple test and sample types
- Clinical staff from tuberculosis and HIV programmes believed that access to both services will allow improved patient management.
- Integration of HIV testing on tuberculosis instruments proved a cost-effective way to increase access to low volume HIV tests such as EID

Implementation planning

At the programme level the following activities are important:

- **Define testing criteria for eligible populations** based on programme priorities, available resources and available testing capacity to determine which patient populations will be tested on the newly integrated device.
- **Plan for enhanced mentorship and supervision during early implementation** to monitor integration progress and quickly address challenges at the site or programme level.
- **Assess data requirements** for monitoring integrated devices, and whether the existing monitoring and evaluation systems are sufficient to capture desired indicators or should be updated. For example, this may include overall site-level testing volumes, as well as volumes per disease area.
- **Update workflows within clinics and laboratories** with clear processes for sample collection, result return, and communication of results to patients and caregivers. This will facilitate timely clinical action and ensure that patients realise the benefits of near-POC testing.
- **Provide clear guidance on sample prioritisation within laboratories** taking into account disease area, patient category, sample type, and sample origin (on-site vs. referral). For example, EID samples may be given highest priority as this is an emergency test.
- **Address service and maintenance needs prior to introduction of new test types** to ensure all devices and modules are working properly in order to maximise utilisation.
- **Establish appropriate waste management practices for all test types** particularly for the introduction of EID and HIV viral load cartridges (in addition to HPV, chlamydia, gonorrhea, and Ebola), which may have special

At the site level the following activities are important:

requirements for disposal and may need to be transported to a site with a high temperature incinerator after use.

- **Ensure all relevant staff members receive training to facilitate integration**, including laboratory staff, clinicians from across disease programmes, quality assurance officers, data managers, and administrators.

Lessons from integration experiences

A number of countries have piloted and started to implement integration by adding HIV testing onto instruments previously used only for tuberculosis. The experiences from these programmes have resulted in a number of positive findings:

- The addition of EID and viral load to devices previously used just for tuberculosis increased device utilisation without exceeding device capacity.
- Tuberculosis testing and treatment services were not compromised — tuberculosis test results were returned within the same timeframe as before and patients were initiated on treatment at the same rate.
- Laboratory staff found it feasible and acceptable to run multiple test and sample types — including whole blood, dried blood spots, and sputum.
- Clinical staff from tuberculosis and HIV programmes believed that access to both services will allow improved patient management.
- Integration of HIV testing on tuberculosis instruments proved a cost-effective way to increase access to low volume HIV tests such as EID and showed that establishing a separate network of instruments purely for rapid EID testing would be too costly and impractical.

Conclusion

Experiences with integrated testing for HIV and tuberculosis using GeneXpert devices demonstrate that the use of a shared diagnostic infrastructure for multiple test types is operationally feasible. Initial pilots of integrated testing have successfully increased testing volumes without exceeding device capacity and compromising tuberculosis testing, while being acceptable to clinical and laboratory staff. Integrated testing on decentralised platforms expands access to the benefits of near-POC testing, including reduced result turnaround times and improved linkage to care. Through the addition of new test types on existing GeneXpert instruments, patients may also gain access to essential diagnostic services that were not previously available, and testing sites may be able to better manage patients with comorbidities, such as HIV, tuberculosis, cervical cancer risk, and hepatitis. Integrated testing provides an opportunity for Ministries of Health to realise savings through increased utilisation of existing diagnostic infrastructure, whilst promoting collaboration across disease areas and partners working to provide high quality diagnostic services to those in need.

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Information note

Global TB Programme and Department of HIV/AIDS

CONSIDERATIONS FOR ADOPTION AND USE OF MULTIDISEASE TESTING DEVICES IN INTEGRATED LABORATORY NETWORKS

Background

Several new laboratory technologies are available or are being developed to allow for testing of different conditions using disease-specific tests on the same platform. For example, a single device may be able to test for the presence of tuberculosis (TB) and HIV, and quantitatively measure HIV and hepatitis C viral load by using disease-specific reagents or cartridges with self-contained nucleic acid testing technology. Some of these technologies are being designed for use at centralized reference laboratories while others may be positioned for use at or near to point of care.

In settings where laboratory testing has been traditionally organized by disease programme, the introduction of multidisease testing devices (also known as polyvalent testing platforms or multianalyte analysers) brings new opportunities for collaboration and integration, which can provide significant system efficiencies and cost savings, increase patient access, and ultimately improve quality of care.

Collaboration and integration should be a priority for both those countries with currently operational multidisease testing devices and those countries considering and planning for their introduction.

This information note provides a strategic overview of key implementation considerations for diagnostic integration using these devices, and is primarily intended for use by national laboratory services and TB, HIV, and hepatitis programme managers.

It may also be of interest to managers of maternal, newborn and child health programmes and sexual and reproductive health programmes, international and bilateral agencies, and organizations that provide financial and technical support to the relevant national health programmes.

WHO guidance on integrated testing

In June 2017, WHO released an information note on Considerations for Adoption and Use of Multidisease Testing Devices in Integrated Laboratory Networks. This document lays out 10 key considerations for the introduction of integrated testing. Translations are available in English, French, and Portuguese. https://www.who.int/tb/publications/2017/considerations_multidisease_testing_devices_2017/en/

Optimising national laboratory networks for effective disease control

Over the past 10-15 years, hundreds of conventional laboratory-based and point-of-care (POC) instruments have been procured across low- and middle-income countries to address diagnostic testing demands in an effort to move closer to improved testing coverage across a variety of disease areas. As countries move forward on the path to meeting the UNAIDS HIV 90-90-90 targets, additional targets are needed across the world and on the African continent such as ending the tuberculosis epidemic, eliminating hepatitis as a major public health threat by 2030, as well as increasing testing volumes and providing greater laboratory efficiencies.

Current trends of resource availability within the global health sector show that overall resources lag behind what is needed to achieve epidemic control across HIV/AIDs, tuberculosis, malaria, and hepatitis, among other diseases. For HIV/AIDS specifically, the resources available for in-country activities were estimated to be US \$19.1 billion in 2016. By 2020, the estimated need is US \$26.3 billion to be on track to end AIDS as a global public health threat by 2030.¹ Unfortunately, most donor resources will decline or remain constant over this period, with a portion of overall budgets slated for laboratory testing. Additionally, many low-income countries rely heavily on foreign aid, with 15 of 31 countries relying on external sources to fund over 30% of their total health expenditures.² With such a reliance on external funding, countries increasingly need to find ways to finance for sustainability beyond donor support.

In this global political and economic context, how should countries go about building financially sustainable and effective laboratory networks which can support growing testing volumes under

limited financial resources? Laboratory network optimisation is part of the answer.

Sustainable improvements to meet national testing targets, maximise patient health impact and minimise costs.

Laboratory network optimisation allows for the design of improved laboratory networks. It defines the most optimal instrument mix (type and number of instruments), identifies an appropriate location where each instrument should be placed based on their specific role and demand characteristics, and designs an efficient referral system to connect testing demand with POC, near-POC, or conventional laboratory-based testing sites.

As an example of potential cost and programmatic impact, it has been estimated that the fixed operational costs (not including the reagents and other consumables) associated with running an HIV early infant diagnostic (EID) test can range between US \$1.22 and US \$35.87 per test on a particular device, all of which depends on utilisation rate.³ Similarly, turn-around times have been reported to range between 1 to 150 days,⁴⁻⁷ based on the level of maturity of the sample referral network, leading to initiation on treatment rates of below 50% at some infant testing sites. Laboratory network optimisation can help address both of these cost efficiency and public health challenges. And, because it can be disease agnostic, it can generate efficiencies across disease areas, as testing instruments are strategically used for multiplexing and programmatic resources are shared among disease programme areas. A recent review of 2017 data from 120 countries revealed that over 90% of countries utilise less than 50% of their GeneXpert fleet capacity for tuberculosis testing.⁸



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Laboratory network optimisation could help remediate these low utilisation rates by informing referral testing strategies and multiplexing on instruments that are now only conducting tuberculosis tests.

Full-scale laboratory network optimisation in Nigeria and Zimbabwe. Nigeria's laboratory network experience is a testimony to the financial and public health impact such an initiative can have at the national level. The optimisation exercise led the country to a reduced conventional laboratory footprint, a recompete tender for new equipment placement, and better maintenance and service terms, overall. The implementation of the resulting optimised sample transport and referral networks have led to a significant increase of samples getting to testing facilities, as well as a significant decrease in sample rejection rates.^{9,10}

In Zimbabwe, laboratory network optimisation is helping inform the potential redeployment and new placement of conventional and POC instruments to increase testing coverage and generate cost efficiencies through higher device utilisation. In Eswatini, in light of the scale up of routine testing for all people living with HIV, efforts focused on improving long-term viral load capacity to inform placement of POC devices and to inform a rationalisation of the CD4 network. In Malawi, the Ministry of Health and population plans to use laboratory network optimisation to inform EID and viral load scale-up and to help optimise the existing national sample transportation network. In Rwanda, laboratory network optimisation led to the redeployment of existing CD4 testing equipment, which allowed the country to re-prioritise funds that were already

slated for the procurement of additional equipment (prior to the optimisation exercise).¹¹

Optimisation means greater visibility and ability to shape national laboratory networks.

The key to success in all countries where this exercise has been implemented include strong stakeholder engagement and political will throughout the entire process. Laboratory network optimisation has been and should continue to be a collaborative exercise, led by Ministries of Health, and supported by domestic and international partners. USAID, USAID's Global Health Supply Chain Program, the Global Fund, the US President's Emergency Plan for AIDS Relief, the US Centers for Disease Control and Prevention, Clinton Health Access Initiative, Elizabeth Glaser Pediatric AIDS Foundation, FIND, and Llamasoft have facilitated and provided technical assistance to countries in support of government laboratory network optimisation efforts. Current approaches have focused on the use of GIS mapping tools (e.g., Laboratory Efficiency and Quality Improvement Planning (LabEQIP) software and Supply Chain Guru™ from Llamasoft), to map laboratory networks, including instrument locations, utilisation, testing demands, existing sample transport lanes, specimen types, etc. LabEQIP is a software tool developed by USAID and Llamasoft and managed by Global Health Supply Chain Program. This GIS-based solution can improve laboratory network efficiency and advance quality service delivery through data-driven optimisation and modelling efforts. Virtual modelling, prior to instrument placement, or as part of formalising an overall shift in testing strategies is a critical component in informing laboratory network optimisation approaches.

For countries to build their laboratory infrastructure to effectively respond to disease management and epidemic control, under an ever-tightening budgetary environment, it is imperative to undertake a thorough assessment of existing laboratory networks that were established as part of the historic rapid response approach. Countries need to seek opportunities to achieve greater efficiencies through network redesign and to better align instrument location and capacity to current and projected disease burdens.

Disclaimer: The content and views expressed in this manuscript are those of the authors and do not necessarily reflect the view of the US President's Emergency Plan for AIDS Relief, the US Agency for International Development, or the US Government.

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A look back at the scale-up of POC CD4 testing: Successes, lessons, and what comes next

The scale-up of point-of-care (POC) CD4 testing was the first widespread introduction of a device-based diagnostic technology that could truly be provided at lower levels of care. Initially introduced when CD4 count thresholds were still used to determine patient eligibility for treatment initiation, POC CD4 testing was shown to reduce test turn-around time, decrease the time from HIV diagnosis to CD4 testing, and dramatically increase the proportion of patients that accessed antiretroviral therapy (ART).¹ At the same time, POC testing increased access to CD4 testing for treatment monitoring, allowing patients and providers to make same-day clinical decisions regarding the need for adherence counselling or the switch to second-line treatment. Since the 2016 introduction of 'Treat All' policies, along with the scale-up of viral load (VL) testing for treatment monitoring, the role of CD4 testing

— as well as how to utilise the remaining fleet of POC CD4 devices — has changed significantly and continues to evolve. This article will review the historical role of CD4 testing, explore the successes and challenges of its scale-up, and highlight lessons from POC CD4 testing that are applicable to new POC technologies — particularly for early infant diagnosis (EID) and VL monitoring. The future of POC CD4 testing is also discussed, highlighting the critical priority of ensuring widespread access to CD4 testing for patients with advanced HIV disease.

Pre-POC CD4 landscape

Since the start of the AIDS epidemic, CD4 cell count testing has been a critical tool used to assess patient immune status, determine when to initiate patients on ART, decide whether to screen for opportunistic infections or begin prophylaxis, and

monitor treatment response. In the early 2000s, at a time when ART was both prohibitively expensive and came with significant side effects, CD4 cell count thresholds were used to both ration limited resources for patients with the most advanced immunosuppression and prevent unnecessary treatment exposure to patients with higher CD4 counts who were at lower risk for AIDS-related illnesses.² However, as treatment availability improved, a lack of access to CD4 testing often delayed treatment initiation for those eligible and resulted in insufficient treatment monitoring for those already on ART.

The standard model for CD4 testing included flow cytometer instruments based in laboratories with samples shipped from a network of surrounding health facilities, some of which were hundreds of miles away. The initial years of CD4 deployment involved setting up many such referral-testing laboratories. However, there were challenges. By 2011–2013, a WHO review of laboratory capacity in 99 countries found that, whilst centrally-located laboratories had sufficient combined CD4 testing capacity to meet patient need, only 13.7% of instrument capacity was being utilised.³ Centralised CD4 laboratories faced challenges with long result turn-around times, lost results, and frequent device breakdowns, resulting in high patient loss to follow up at clinics. Despite investments in sample transport and result return systems, these challenges have been consistently documented for CD4 across many countries, as



Printed results are entered into the relevant clinic register where POC CD4 results are routinely captured. (Photo courtesy of CHAI)

well as for centralised EID and VL monitoring.⁴⁻⁷

Introduction of POC CD4

Over the last decade, technological advances have allowed the introduction of smaller, easier-to-use POC platforms. These low-throughput devices have limited infrastructure requirements and are robust enough for deployment in lower-level health facilities where they can be operated by non-laboratory healthcare workers. The first POC CD4 devices — Abbott Pima POC CD4 Analyzers — were introduced in Africa through a Unitaids-funded project and intended to facilitate same-day ART initiation for HIV-positive patients beginning in 2010. The importance of the test as a tool to rapidly initiate more patients on ART was quickly recognized. It was also used particularly in target populations, such as pregnant women, in order to reduce vertical transmission.

A systematic review of the patient impact of POC CD4 testing has shown significant reduction in result turn-around time compared to referral-based testing at conventional laboratories, a reduction in the time from HIV diagnosis to CD4 testing, and significant increases in retention along the diagnosis-to-treatment initiation cascade.¹ Observational data included in the same review suggested that POC CD4 testing increases projected life expectancy, is cost-effective, and is acceptable to both patients and healthcare workers.¹

POC CD4 scale-up

The early implementation of POC testing demonstrated the promise of POC diagnostics as tools to improve patient access to testing and treatment services at a time when HIV programmes were scaling up significantly. However, the POC



A Pima CD4 user ensures that the cartridge's sample capillary is completely filled, that no air bubbles are introduced, and the specimen is visible in the control window of the cartridge. (Photo courtesy of CHAI)

testing market was small and fragile and faced significant barriers to scale-up. A project supported by Unitaids was launched to accelerate the introduction and scale-up of POC technologies to enable earlier clinical action in high HIV-burden countries in Africa. The project started in 2012 in seven sub-Saharan countries: Ethiopia, Kenya, Malawi, Mozambique, Tanzania, Uganda, Zimbabwe; which represented over 25% of the global HIV burden. By 2016, the number of clinics with on-site POC CD4 testing had doubled from 990 to 2000, and 1.2 million POC CD4 tests were conducted annually, representing 20% of all CD4 testing in the seven countries and 8% of global CD4 testing volumes.

The impact of POC CD4

The decentralisation of CD4 testing on POC platforms has been marked by a number of successes in terms of patient impact and programme operations:

- **Significant patient impact along the cascade.** Data from routine testing across five

countries showed that on-site POC CD4 testing reduced the time between sample collection and results being received by the patient and decreased the time to ART initiation compared to referral-based testing. The median time from sample collection to result receipt decreased from 17 days for samples referred to a laboratory to 0 days using POC CD4 tests, with 74% of patients receiving their result on the same day as sample collection. In addition, the median time from sample collection to ART initiation decreased from 21 days to nine days, with 24% of patients initiated on the same day as sample collection.⁸

- **Transparent POC policy landscape.** As part of the POC CD4 scale-up, policies were adopted to guide national POC testing strategies regardless of the test type. These overarching POC policies facilitate the introduction and scale-up of new POC products and test types and reduce the need for additional policy development that can slow new product introduction.

The POC policies implemented during the POC CD4 scale-up have smoothed the introduction of new POC test types, including EID and VL.

- **Development of in-country training capacity.** The scale-up of POC CD4 testing was made possible through the use of a training-of-trainers model, which involves training for a group of in-country 'master trainers' who then conduct regional, end-user trainings in order to reach a high number of POC operators in a short period of time. The training-of-trainer model also develops in-country expertise for troubleshooting and ongoing mentorship at the national and regional levels in order to provide ongoing technical support and corrective action.
- **Introduction of wireless connectivity.** By 2016, 1750 POC CD4 sites had the necessary technology installed to facilitate data transmission and allow remote device monitoring, and over 1000 were transmitting data consistently. While infrastructure challenges limited consistent transmission from all sites, where connectivity was possible, remote monitoring was used to track testing volumes, monitor invalid rates, and assess the frequency of internal quality assurance procedures. In Mozambique, targeted corrective action based on remotely transmitted data successfully reduced the rate of invalid results from 11% to 5%.⁸
- **Quality assured testing.** Over 1500 POC CD4 sites implemented quality assurance measures appropriate for device-based POC testing. The quality assurance schemes utilised included a combination of external quality assurance for proficiency testing, remote device monitoring with connectivity, structured mentorship

and monitoring visits, and execution of daily internal quality control measures.

- **Improving the effectiveness of CD4 networks.** In 2015, BD's CD4 Access Solution was launched in Kenya and Swaziland to optimise device networks to meet changing demand for CD4 testing. The initiative established the first all-inclusive pricing for POC products and facilitated upgrading of aging diagnostic infrastructure. This program allowed Ministries of Health to swap out older, high-throughput instruments for new, POC CD4 devices that better aligned with testing needs. Through reagent rental agreements, new devices were placed without the need for upfront capital investment.

Lessons learned from POC CD4 scale-up

Ministries of Health and partners gained valuable lessons through the POC CD4 implementation process that will improve the efficiency and success of future deployment of POC testing for CD4 as well as other tests and diseases.

- **Streamlined evaluation procedures.** An initial challenge of POC CD4 testing implementation was that it was one of the first POC technologies to be scaled-up across many countries at a time when the technologies available were not yet WHO pre-qualified. As a result, many countries required local evaluations for registration or to approve use within national testing programmes. Nearly 50 evaluations were conducted. Many of these turned out to be redundant when ample evidence regarding technology performance in local settings existed. As more POC technologies have emerged for CD4, EID, VL, and other tests,

a more effective approach has emerged as well, whereby full evaluations are not required for product registration once a new technology is WHO pre-qualified. Instead, countries use WHO prequalification data from regional evaluations in their product registration process and, where necessary, large evaluations are replaced by smaller 'validations' on a limited number of samples. This streamlined regulatory approach has multiple benefits and has been used more recently by countries introducing new POC products. For example, the two WHO pre-qualified POC EID platforms have been adopted in at least four countries through streamlined national registration processes that did not require lengthy full-scale evaluations. The countries used WHO prequalification data based on a pooled, six-country evaluation. This saved time and enabled an essential new diagnostic test to be rigorously evaluated and to become available for use for patients.

- **Transparent and rational product and site selection process.** The introduction of POC platforms creates a significant challenge with deciding where and how to deploy, as many sites at once may be eligible for the technology. To be practical, a prioritisation approach is needed so that the sites with the most need and which are most suitable for POC technology are selected first, followed by other sites in order of priority. During the POC CD4 testing scale-up, a robust and transparent process for site selection was developed in many countries which has provided a blueprint for site selection that can be used for many other POC technologies. This process involves the use of selection tools based on important criteria

such as testing volumes and site readiness, POC instrument capacity and characteristics, and the overall testing network with an optimised distribution of testing capacity across other sites and laboratories. This was coupled with a coordinated data-driven decision-making process led by the Ministry of Health across stakeholders within technical working groups to arrive at prioritised lists of sites where POC should optimally be deployed. In the end, the site selection process led to POC deployment first at the sites that serve the largest proportion of patients. This process has also been successfully used by many countries to plan the scale-up of POC EID testing, whereby the strategic placement of devices at higher volume sites can provide access to testing for the majority of HIV-exposed infants.

- Moving towards all-inclusive pricing.** POC CD4 testing implementation demonstrated the importance of clear pricing structures for procurement of reagents, devices, service, maintenance, and the value of bundling the pricing of these products and services. The implementation of reagent rental agreements under the BD CD4 Access Solution and the service and maintenance surcharge provided for the Abbott Pima, simplified procurement and demonstrated the value of bundled procurement models, especially for POC testing, which requires reliable access to service. The ideal procurement model for POC testing is all-inclusive pricing. The all-inclusive pricing model will allow programmes to budget more accurately for the overall cost of running a POC diagnostic network.
- Decentralised POC fleet management.** The implementation of data solutions



Printed results and a clinic register of POC CD4 results. (Photo courtesy of CHAI)

on POC CD4 devices provided the first large-scale experience with POC testing connectivity. It helped define the necessary system requirements for successful wireless POC testing data transmission, management, and reporting for programmatic use on dashboards. Experience with connectivity has demonstrated that the visibility of POC fleet and operator performance combined with active management is important for reducing testing errors. Connectivity also provides the visibility across the fleet of machines to enable programme managers to prevent stock outs and ensure device repairs are done promptly. Ongoing upgrades to connectivity platforms (including both hardware and software) as well as telecommunications infrastructure will facilitate improved decentralised fleet management for future POC testing including networks of POC instruments for tuberculosis, EID, VL, and other tests.

A shift in recommendations on the use of CD4 testing

In 2015, the WHO introduced a recommendation for 'Treat All' policies that removed CD4 eligibility thresholds for ART initiation, as well as a preference for the use

of VL for treatment monitoring. Where VL monitoring is available, it is no longer recommended to conduct routine CD4 testing for patients who are stable on ART.⁹ However, access to CD4 testing is still critical for identifying patients with advanced HIV (defined as CD4 count less than 200) and guiding clinical decision-making around opportunistic infection screening and treatment, and therefore CD4 testing is still recommended at the time of HIV diagnosis and treatment initiation. Since up to 30% of ART-naïve patients still initiate treatment with advanced disease,¹⁰ and recent studies suggest an increasing rate of advanced HIV among ART-experienced patients, it is important to ensure that access to CD4 remains in place. POC testing is an advantageous way to provide CD4 results for these patients. For patients with advanced HIV presenting for hospital admission, rapid result return is particularly acute. In a study of hospitalised patients in Kenya and the DRC, 17% — 29% of patients died while hospitalised — approximately 25% of whom died within 48 hours of admission.¹¹ For this highly vulnerable population, access to POC CD4 testing — and same day results — may be lifesaving.

The role of CD4 going forward

The introduction of POC CD4 testing has represented a significant change in the diagnostic testing paradigm by bringing a service that was previously conducted in a centralized laboratory setting closer to the patient's bedside. At a time when CD4 eligibility thresholds posed a significant barrier to treatment initiation, the scale-up of POC CD4 testing increased access to ART for thousands of patients. The operational lessons from these experiences will not only inform the scale-up of future POC technologies for HIV and beyond but will guide the use of existing POC CD4 infrastructure for patients with advanced HIV disease who can directly benefit from greater access to CD4 testing.

CD4 testing continues to have clinical utility for assessing patients' immune status at baseline, evaluating patients who are unstable on ART, and monitoring patients' response to treatment in areas where VL monitoring is not yet available. Moreover, CD4 testing is critical for identifying patients with advanced HIV disease who are at increased risk of rapid deterioration and need test results as quickly as possible. In fact, lower throughput on-site POC platforms that can deliver test results rapidly for critically ill patients may be more appropriate to meet current CD4 testing needs than

laboratory-based CD4 testing that often takes days or weeks in many settings to return results. Past investments in POC CD4 scale-up have created a footprint of devices in many countries and can provide the rapid result return necessary for serving particularly vulnerable patients today.

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A health worker collects a blood sample for POC CD4. (Photo courtesy of CHAI)

Technical strategies for quality-assured results at POC and near POC testing settings

Introduction

Each year, thanks to technological advancements, the number of point-of-care (POC) or near-POC tests increases for many diagnostics that used to require a conventional laboratory. Testing in conventional laboratories at times meant long turnaround times for results to reach health workers or patients in order to counsel and begin treatment. POC testing brings diagnosis closer to the patient, thereby ensuring rapid action on the test results. This is key to reducing morbidity and mortality for a wide range of conditions. Therefore, it is crucial that diagnostic results from a POC test are of the highest possible quality.

The past few years have seen the introduction of POC molecular testing for HIV early infant diagnosis and viral load, which have traditionally required conventional, centralised testing methods. Early results from controlled pilot^{1,2} and routine use settings³ show encouraging patient outcomes that promise a bright future in the fight to end paediatric HIV/AIDS. These tests are operated not only by laboratory technicians but by non-laboratory health personnel as well. There is a need to guarantee the quality of this testing, if the gains from these innovations are to be fully realised. Following demand from many countries, the World Health Organisation is currently working on updating normative guidance for POC quality

assurance to incorporate present-day technologies and new types of users.

Several universal key aspects of ensuring quality assured POC test results are important to consider in such guidance. These cover both device-based POC testing, which often uses a small portable instrument, as well as instrument-free POC testing, such as rapid test kits for HIV, hepatitis, and malaria. A quality-assured result at or near the POC is a combined consequence of many initiatives that are concurrently being implemented, namely: built-in device internal quality controls; connectivity solutions; external quality assessments through proficiency testing; site monitoring visits and assessments; competency assessments and certifications; and overall continuous quality improvement initiatives (**Figure 1**).

Connectivity solutions. Most new-to-market devices do not require a complicated infrastructure and are well



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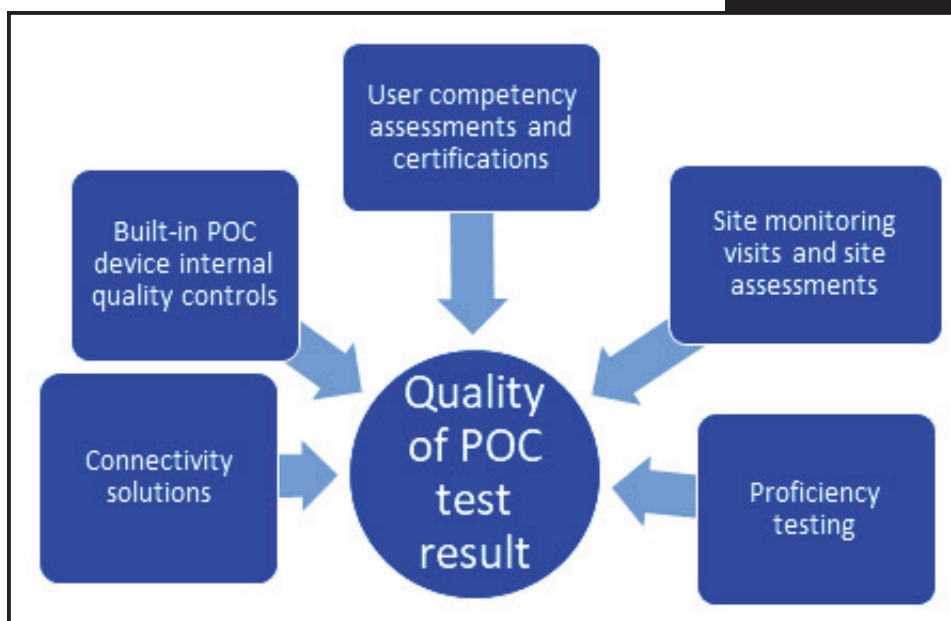


Figure 1: Technical factors contributing to a quality-assured POC test result

suited to decentralising diagnostic testing and reducing turnaround times. However, decentralising testing, especially with POC devices, can pose challenges for monitoring of performance and quality within a diagnostic testing network. Fortunately, connectivity solutions enable devices to be monitored in real time through transmission of performance data from a connectivity-enabled device to a central point. This dynamic is often managed by diagnostic personnel, who can proactively intervene in order to deliver accurate, timely test results to patients.

Connectivity solutions often require a connectable device that can send data through a mechanism such as a modem to a software platform and a server which stores raw and analysed data. For most devices, transmission of data is automatic, which implies capability of real-time remote performance monitoring and quality assurance; sending results automatically to clinicians, laboratory information management systems or electronic registers; and real-time inventory management and disease surveillance. Therefore, connectivity can provide cost-effective ways to ensure proper functioning of networked diagnostic devices and improve linkages to care and patient management. In general, a connectivity solution is an integral part of POC testing implementation and a valuable complement to existing diagnostic and disease surveillance systems.^{4,5}

POC device with built-in internal quality controls. Built-in internal quality controls are used to validate the result obtained from a POC test. They range from procedural control lines in instrument-free tests, such as lateral-flow rapid tests for HIV, malaria, pregnancy tests, etc., to advanced control samples

embedded into an automated, instrument-based, POC testing process. For rapid lateral-flow assays, it is important to note that procedural tests validate that the test sample has moved through the strip from the point of application through the reading pane or reaction area of the test strip and do not always necessarily imply that the test is working. Therefore, external quality controls may be required at determined intervals in order to demonstrate that the testing system has not been altered by extraneous factors such as temperature, humidity, and other environmental conditions that could adversely affect test device performance. Some device-based POC/near-POC tests, such as the m-Pima and Cepheid GeneXpert instruments, have automatic 'lock-out features' that require various internal quality controls be passed first, before a result is released by the instrument.⁶ These assay strategy controls include probe checks, sample adequacy, sample volume, endogenous sample processing, and amplification control systems. It is therefore important for users and programmers to monitor the rates of failed internal quality controls and other errors as part of the routine operations and post-market surveillance.

Site monitoring visits, user competency assessments, and certifications. Regular site monitoring visits provide information and opportunities to address various site-level elements related to human resources, patient flow, platform function, end user performance, specimen transport, data quality, and capacity building. Site monitoring and assessments often require standardised tools in order to be able to monitor and track progress from one visit to another. Typical tools, including the generic Stepwise Process for Improving the Quality

of POC Testing Checklist, can help sites improve quality, as well as work towards certification by grading the performance of POC facilities on subsequent visits.⁷ Tools may also be test or disease specific and focus on processes and patient management; examples include POC early infant diagnosis, HIV viral load, and rapid HIV testing.^{8,9}

Regularly assessing the competency of POC testing personnel ensures the quality of the testing procedure at the individual level and can also serve as a key component of a POC testing quality assurance scheme. Ascertaining competency is particularly important in the early stages of POC test introduction, as such assessments can limit the number of errors resulting from end-user operations. Proper documentation of each competency assessment, combined with a regular assessment scheme, will enable better tracking and maintenance of a register of all 'certified' end-users within a country.

Proficiency testing. Alongside site visits and retesting of samples as major forms of external quality assessments, proficiency testing schemes offer a means of comparison of a laboratory's testing to a source outside the laboratory. Comparison with peer or reference laboratories provides some measure of confidence to both clinicians and testing facilities that the results are accurate and reliable. In general, while similar to conventional laboratory testing, external quality assessments for POC may require special considerations given POC's decentralised nature and the often high numbers of testing instruments and facilities. This poses challenges for full coverage due to insufficient budget and logistics, including turnaround times from analysis of proficiency testing results to

corrective action. Another key challenge will always be sample stability, given the location of many POC sites, particularly for new molecular tests such as early infant diagnosis and viral load. The use of dried tube specimens for HIV rapid testing and Xpert MTB/RIF assays is one typical successful solution to the challenge of sample stability and may be applicable to the new-to-market POC tests for early infant diagnosis and viral load.⁷

Conclusion

The increasing number of sites offering POC and near-POC testing pose operational challenges related to overseeing decentralised testing programmes at the national level. Therefore, implementation and adherence to quality assurance mechanisms at both the site and

national levels are vital components of effective POC programme management in any national diagnostic system. Connectivity solutions, internal quality controls, site visits and monitoring, user and site competency assessments, certifications, and proficiency testing schemes are all key technical strategies to make certain that quality-assured results are readily available for better patient outcomes and public health.

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Frequently asked questions on POC testing

With the increasing availability and interest in point-of-care (POC) molecular technologies for early infant diagnosis (EID) and viral load (VL) testing, many countries in Africa have introduced and are scaling up routine POC EID as well as considering the targeted use of POC VL testing and other molecular technologies such as hepatitis and human papilloma virus testing within their national health programs. With this huge interest, a number of questions have been raised by many of our community members. We answer four of the most frequently asked questions, here:

1. Conventional, centralised laboratories are the backbone of diagnostic testing. What is the role of POC testing in a national laboratory diagnostic testing network?

Patient samples are transported from the point of collection. Patient results are then sent to the health facility or clinic after testing. Conventional laboratory testing offers the ability to perform high numbers of diagnostic tests, often cost effectively, due to economies of scale. POC testing comes in to complement the role of conventional testing where issues of access and turnaround times need to be addressed. There are some disease conditions or situations, such as HIV EID, that may benefit from an instant result to avoid potential loss-to-follow-up or morbidity and mortality. A benefit of POC testing is the convenience of being able to obtain a rapid result at the patient's bedside, allowing immediate action, saving time, and improving the potential outcome for the patient.

2. What international standards are available for POC testing?

The ISO 22870:2016 used in conjunction with the ISO 15189:2012 contains the requirements for quality and competence with respect to POC testing in a hospital, clinic, and by a healthcare organisation providing ambulatory care. The standards address: oversight and governance, document control, process improvement, equipment, purchasing and inventory, quality assurance, personnel policies and training, pre-analytical processes, and analytical processes.

3. Why have multiplexed POC testing and multi-disease platforms become more and more important for in vitro diagnostics?

Multiplexed testing is defined as simultaneous detection of different substances in a single specimen using one test procedure or test run. Multidisease platforms can test for multiple analytes either simultaneously or sequentially. Integrating testing



using multiplexed technologies at the appropriate level of care can lead to more efficient and cost-effective testing services and can help to simplify and streamline other systems, such as specimen referral, human resources, and quality assurance.

4. Is there any guidance for countries planning, piloting, and integrating these new POC diagnostic technologies into their national health programmes?

To support countries with planning, piloting, and integrating these new POC diagnostic technologies into their national health programmes, global health partners launched two important resources in April 2018 for countries implementing HIV molecular testing: Key Considerations for Introducing New HIV Point-of-Care Diagnostic Technologies in National Health Systems,¹ and the HIV Point-of-Care Diagnostics Toolkit.² Both resources are based on robust implementation experience from more than 10 countries and on the technical expertise of a variety of stakeholders.

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Meet Mr Nqobile Ndlovu

Chief Executive Officer African Society for Laboratory Medicine

Mr Ndlovu holds a Master's degree in Public Health and a degree in Medical Laboratory Sciences from the University of Zimbabwe. After years of working on the bench as a laboratory medicine scientist, Ndlovu became the Laboratory Surveillance Officer in Zimbabwe. He then worked as a Lecturer for the Zimbabwe Field Epidemiology Training Program (FETP). In 2009, he joined African Field Epidemiology Network (AFENET) as a Laboratory Coordinator for their regional laboratory programmes. In 2013, after four wonderful years in Uganda with AFENET, he moved to ASLM as a Program Manager. He was promoted through the ranks at ASLM over a period of five years until his appointment as the Chief Executive Officer. He received a SLIPTA "Outstanding Champion" award for spearheading and implementing two flagship programs, SLMTA and SLIPTA, for the African and Caribbean regions.

Who is Nqobile Ndlovu? What key experiences led you to a career in laboratory medicine?

I have always been passionate about the laboratory and truly enjoyed bench work. Early on, I saw a role for laboratory medicine to improve public health. It was this passion and vision that eventually took me from the bench to become a public health leader — realising the need for strong laboratory skills and leadership that transforms and raises the profile of laboratory services in Africa. Knowing that we also need to make an impact on policy and decision making, I am now ready to lead ASLM and continue our footprint of quality laboratory medicine on the continent.

You were appointed as the Chief Executive Officer of ASLM in 2018. What is your vision for the organization over the next five to 10 years?

ASLM is a community and has become both a network and voice for laboratory medicine in Africa. Africa continues to provide us with young, eager scientists. I see ASLM taking us further as we address

gaps in workforce development and build expertise around every aspect of healthcare, bring innovations to the forefront, and contribute to research programmes on the continent. We will still maintain our efforts to ensure access to quality diagnostics, so as to contribute to health security and universal health coverage.

What will be the most important emerging challenges for public health in Africa over the next five years? What are ASLM's plans to meet those challenges?

Outbreaks of infectious diseases and antimicrobial resistance are growing concerns globally — particularly for Africa. ASLM will



Mr Ndlovu attending a plenary session at ASLM2018 in Abuja, Nigeria, December 2018. (ASLM photo)

continue to work with partners, such as the Africa Centres for Disease Control and Prevention and the World Health Organization, to assess lessons learned from previous outbreaks. We will also look to how we can continue our valuable collaborations with PEPFAR to maintain quality HIV and tuberculosis laboratory programmes. ASLM will also work with key stakeholders to ensure that needed diagnostics are made available and accessible and that quality testing and quality data are the cornerstone for public health across Africa.

What is your best advice for the next generation of African laboratory scientists? How can they best equip themselves and their communities for the challenges to come?

Africa will need a well-trained and highly motivated workforce to face emerging threats, but also a critical cadre of laboratory medicine professionals involved in research designed to address emergency preparedness and infection prevention and control. We want to work with the next generation of laboratory scientists and help them see their role beyond the laboratory—being active participants in the efforts to ensure long-lasting health security and universal health coverage.



Mr Ndlovu speaking at the 22nd International AIDS Conference in Amsterdam, the Netherlands, July 2018. (ASLM photo)



Mr Ndlovu speaks with ASLM board members and other delegates to the ASLM2018 conference in Abuja, Nigeria, December 2018. (ASLM photo)

The Mapping Antimicrobial Resistance and Antimicrobial Use Partnership (MAAP)

The Mapping Antimicrobial Resistance and Antimicrobial Use Partnership (MAAP) is a multi-organization and multi-national collaboration led by ASLM that seeks to establish a system for the collection, storage, and analysis of antimicrobial resistance (AMR) and antimicrobial use (AMU) data across 14 initial African countries, including Burkina Faso, Cameroon, Eswatini, Gabon, Ghana, Kenya, Malawi, Nigeria, Senegal, Sierra Leone, Tanzania, Uganda, Zambia, and Zimbabwe.

OBJECTIVES

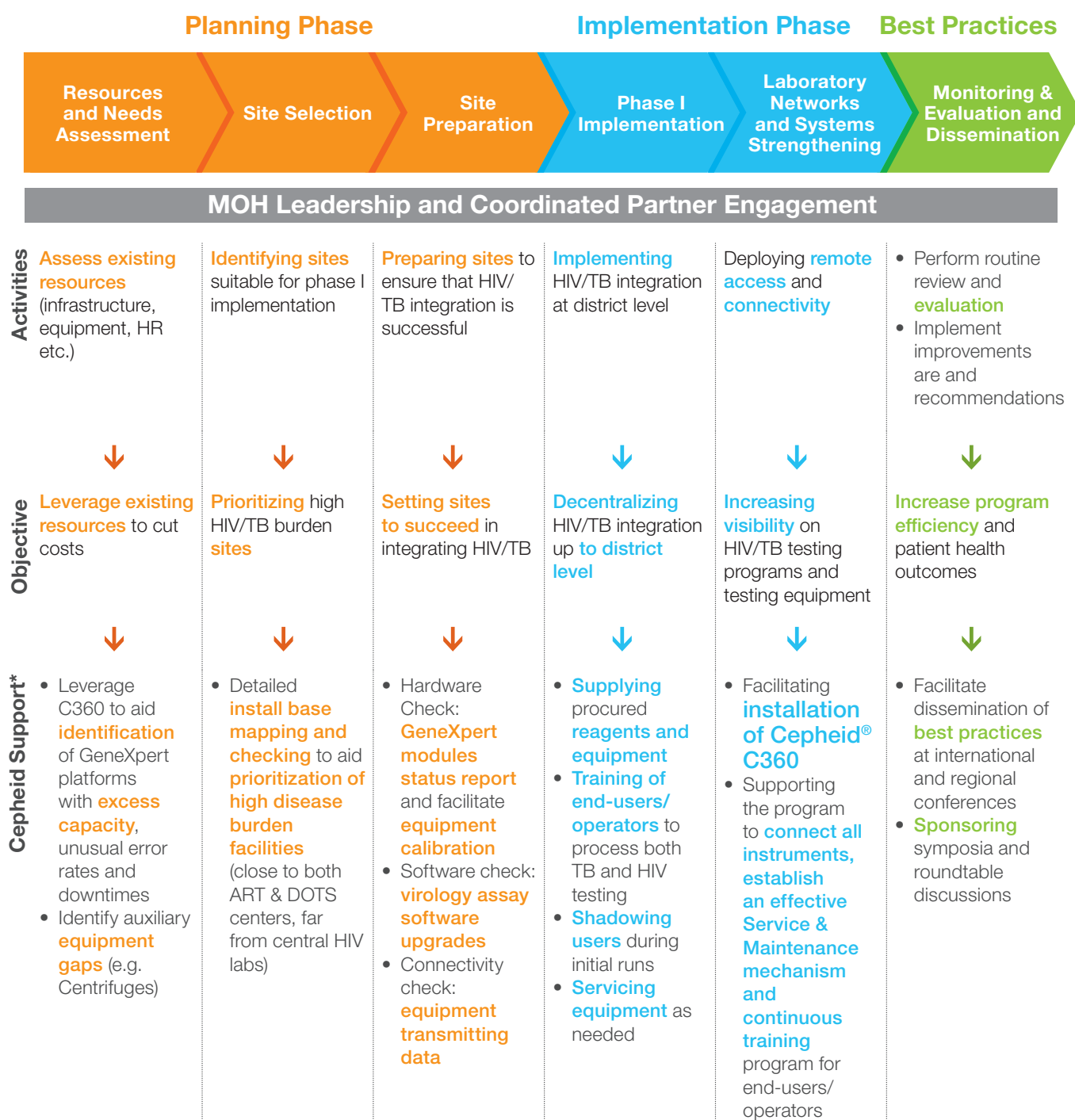
Collect and analyze AMR and AMU data to better understand the AMR burden

Inform public health and policy interventions with the end goal of reducing the global AMR burden, improving access to antibiotics, and strengthening national health and laboratory systems



For more information about MAAP visit <http://www.aslm.org/what-we-do/MAAP>

Framework for GeneXpert® Systems HIV & TB Integration



* Direct or through an approved local partner

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CE **IVD** In Vitro Diagnostic Medical Device Not available in all countries. Not available in the United States

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