MEETING REPORT

MOLECULAR DIAGNOSTICS INTEGRATION GLOBAL MEETING REPORT

10–12 JULY 2019, GENEVA, SWITZERLAND

World Health Organization

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

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Molecular diagnostics integration global meeting report

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ACRONYMS

ASLM African Society for Laboratory Medicine
HBV hepatitis B virus
HCV hepatitis C virus
HPV human papillomavirus
TB tuberculosis

INTRODUCTION

Despite major progress in the global HIV and tuberculosis (TB) responses over the past 15 years, both diseases continue to be a public health burden in all regions, with inequitable coverage of diagnosis, prevention services and treatment. Additional diseases, such as hepatitis C, cervical cancer and sexually transmitted infections, have gained global prominence, with many low- and middle-income countries beginning to implement the necessary services to reduce morbidity and mortality. Effective interventions and services need to target the individuals and populations most in need while maintaining quality and efficiency in rapidly expanding programmes. Ending these epidemics is feasible given the tools currently available and in the pipeline. Evidence being generated from randomized clinical trials, implementation research and programmatic experience should be translated into global and national policies and programmes. This is essential for countries with a high burden of HIV infection as they look to implement and expand effective interventions.

Current diagnostic gaps in the response to several communicable diseases could be supported by optimally using existing technologies. Several technologies, both laboratory-based and point-of-care assays, can be used to diagnose and monitor multiple infections and diseases, including HIV and TB but also hepatitis C, human papillomavirus for cervical cancer screening, sexually transmitted infections and outbreak infections. Integrating testing using multiplex technologies (using the same technology for several assays and/or across diseases) at the appropriate level of care can lead to more efficient and cost-effective testing services. Further, diagnostic integration can help to simplify and streamline other systems, such as specimen referral, human resources and quality assurance. However, integration will require political commitment, coordination and strategic planning. In the current climate of stagnant or shrinking funding, innovative and efficient approaches and solutions that can maximize investments, while still increasing access, will be critical. WHO developed a key considerations document on integrated diagnostic testing *(1)*, while Unitaid, Médecins Sans Frontières and others developed a product pipeline *(2)* and a product guide to HIV and hepatitis testing *(3)*. To date, only a few countries have started introducing this novel innovation and integrating testing using multiplex technologies, primarily on a small scale. Sharing the experience of early adopters will therefore help countries to improve understanding of the operational challenges and best practices as they consider implementing and scaling up these new strategies.

WHO and the African Society for Laboratory Medicine (ASLM) therefore organized a meeting with countries and key stakeholders in diagnostics to discuss and find concrete ways to improve and increase access to integrated multiplex technologies and determine how they can be translated into public health policy and ultimately have global impact.

Photo © ??????????????

OBJECTIVES AND EXPECTED OUTCOMES

General objective

The overarching objective of this meeting was to convene key countries and diagnostic stakeholders to discuss current pilots and national scale-up experiences, best practices, policy frameworks and challenges in integrating diagnostic services to inform the development of best practice guidance to support public health policy change and accelerate uptake in countries.

Specific objectives

a. To review disease contexts, diagnostic capacity, coverage and needs and WHO guidelines across programmes

b. To present best practices, policy frameworks, funding frameworks, challenges, evidence and available tools of diagnostic integration from several country contexts

c. To better understand the financing and costing perspectives of diagnostic integration, available resources and cost-sharing techniques across programmes

d. To discuss the multiplex technology market and several mapping exercises to support the optimization of diagnostic networks and integration at both centralized laboratories and the point of care for optimal efficiency across programmes

e. To provide additional considerations for more efficient integration of systems across all aspects of implementation: clinical, laboratory network etc.

f. To develop and review country plans for implementing the integration of diagnostics within national laboratory networks and across health systems

Expected outcomes

It was anticipated that the meeting would generate discussion and provide insights on optimal approaches to strategically introduce and scale up diagnostic integration and address related key operational challenges, best practices, optimal co-financing strategies and lessons from the experiences of early adopters.

Expected output from the meeting included:

- a meeting report detailing the proceedings of the meeting and its participants as well as any key discussions and consensus decisions; and
- the components and structure of a diagnostic integration and multiplex toolkit developed to support uptake and scale-up.

PARTICIPANTS

Participants included HIV and TB programme managers and laboratory personnel from 17 countries from Africa, Asia, Europe and South America, global and regional diagnostics partners and donors. Countries participating included: Brazil, Cameroon, the Democratic Republic of the Congo, Eswatini, Georgia, India, Kenya, Malawi, Malaysia, Mozambique, Nigeria, Peru, Republic of Moldova, Ukraine, Zambia and Zimbabwe.

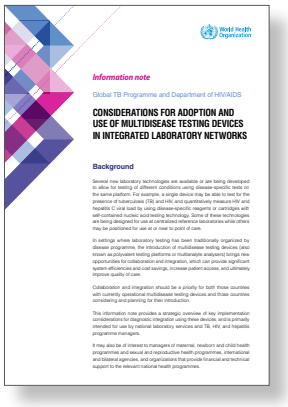
KEY OUTCOMES

The aim of universal health coverage and related services is to deliver high-quality people-centred integrated service delivery and care, including TB, HIV and hepatitis diagnosis and treatment as well as cervical cancer screening as key infectious disease indicators. Further, universal health coverage emphasizes a fundamental shift in service delivery such that services are integrated and focused on the needs of people and communities. This includes reorienting health services to ensure that care is provided in the most appropriate setting. One of these interventions, linked to universal health coverage and integrated service delivery and care, is diagnostic integration. Several technologies already exist that can test for many different diseases and analytes and/or be used for various monitoring approaches; therefore, **WHO strongly supports and encourages diagnostic integration across diseases and programmes**. Integrated testing at the appropriate levels of care can lead to more efficient and cost-effective testing services and can help to simplify and streamline other health systems, including specimen referral, human resources, service and maintenance, procurement and quality assurance. However, this will require political commitment, coordination and strategic planning. The current funding climate requires such innovative and efficient approaches, such as sharing technologies across diseases and tests, that can maximize investment while increasing access.

Essential to adopting and using diagnostic integration is a country-led and country-coordinated process to develop a strategic country plan, map sites, manage the diagnostic network and develop integrated systems, ideally across diseases.

The first step of diagnostic integration includes sharing technologies across programmes. These particularly include multiplex technologies: those that can test for multiple assays and, ideally, across diseases. Once or as such technologies are shared, diagnostic integration can take another step towards integrating additional laboratory services and structures, such as service and maintenance, supply chain, quality assurance etc. for a more efficient and comprehensive diagnostic system that considers multiple diseases within the network. Finally, diagnostic integration should support more integrated service delivery and care systems within the goal of universal health coverage.

In addition to sharing technologies across diseases and tests (diagnostic integration), efficiencies from integration can also be realized in most system areas, including but not limited to:


Information note

Global TB Programme and Department of HIV/AIDS

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

Background

- product and site selection (diagnostic network);
- funding;
- sample transport;
- inventory management, including forecasting, procurement and supply chain;
- delivery of results, laboratory information management systems and data management;
- service and maintenance; and
- quality assurance and quality management systems.

Diagnostic integration has impact across several levels: technology, health systems and patients (Fig. 1).

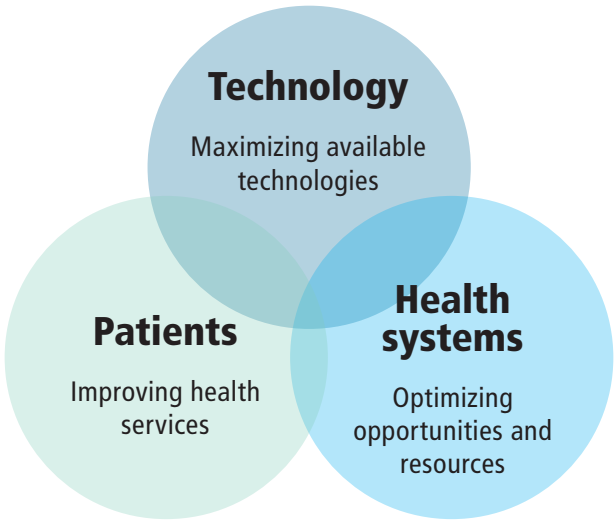
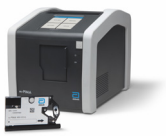
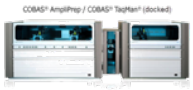
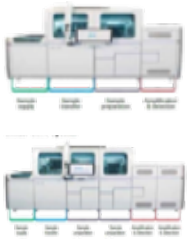


Fig. 1. Multi-level impact of diagnostic integration

		Abbott m2000sp	Abbott m-PIMA	Cepheid GeneXpert GX-4, 16, 48, 80	Hologic Panther	Roche CAP/CTM 96	Roche 4800/ 6800/8800
							
Max daily throughput (incl. controls)		96 (8hrs) 288 (24hrs)	8 (8 hrs)	GX4: 16 (8hrs) GX16: 64 (8hrs)	320 (8hrs) 1,220 (24hrs)	168 (8hrs) 312 (24hrs)	384/960 (8hrs) 1,344/3,072 (24hrs)
Test menu	**HCV VL**	✔[a]	✘	✔[a]	✔	✔	✔[c]
	HBV VL	✔	✘	✔	✔	✔	✔
	HIV EID	✔[a]	✔[a]	✔[a]	✔	✔[a]	✔[c]
	HIV VL	✔[a]	✔[a]	✔[a]	✔[a]	✔[a]	✔[c]
	MTB	✔	✘	✔[b]	✘	✔	✔
	HPV	✔[a]	✘	✔[a]	✔	✔[c]	✔[c]

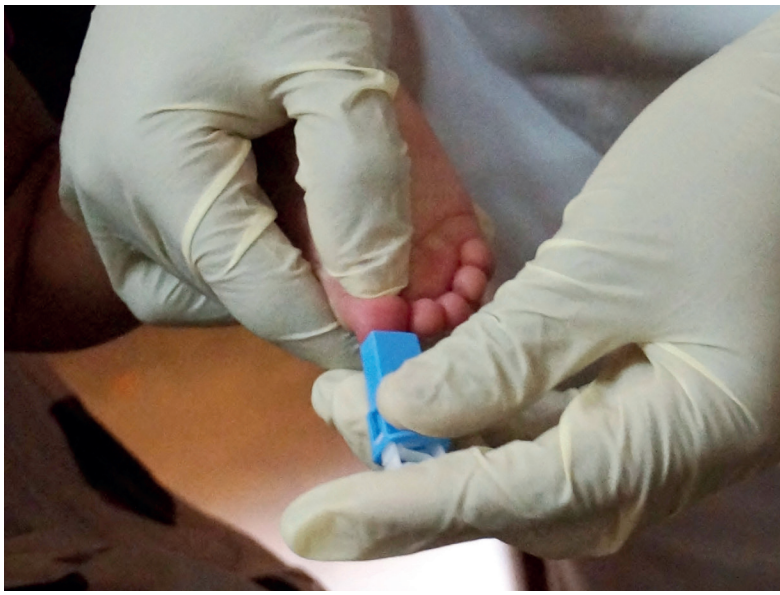
[a] Technologies with WHO prequalification listing
[b] Technologies endorsed by WHO (Global Tuberculosis Program)
[c] Technologies currently undergoing WHO prequalification review
Information included as of December 20, 2019. Pictures are not to comparable scale.

Source: Clinton Health Access Initiative.

Fig. 2. Multiplex technologies available for diagnostic integration as of 20 December 2019

Although this meeting focused on the diagnostic integration of infectious disease molecular testing, these same principles should apply to all multiplex technologies. Further, developing a holistic integrated system across diseases will benefit other programmes, including reproductive health, maternal and child health, noncommunicable diseases, emergent diseases and cancer programmes.

To support the meeting discussions, it was imperative to understand the current availability and pipeline of molecular assays capable of diagnostic integration. Fig. 2 provides the wide range of laboratory-based and near point-of-care technologies that can test across several diseases. Each technology has at least one test with WHO prequalification or endorsement as of 1 December 2019. Future technologies can also be considered as they enter the market and gain necessary international approvals.



Country pilots

Several presentations on country pilots of diagnostic integration were provided, including from Cameroon (HIV and TB), India, Malawi (HIV and TB), Nigeria (hepatitis C virus and TB) and Zimbabwe (HIV and TB). Brazil, the Caribbean, the Democratic Republic of the Congo and Malaysia provided additional best practices considering several different combinations of assays and integration in poster format. In addition, Médecins Sans Frontières provided its experiences with diagnostic integration across several countries, including the Central African Republic, the Democratic Republic of the Congo, India, Malawi, Mozambique and Zimbabwe. Several of the pilots focused on the shared or integrated use of the Cepheid GeneXpert given its significant existing footprint due to WHO endorsement and procurement by national TB programmes as well as the subsequent availability of several WHO prequalified assays.

Some common themes that emerged from the country pilots included:

- Existing Cepheid GeneXpert technologies typically have low overall utilization, although this was site-dependent in several countries.
  - TB programmes were concerned about potential cannibalization by HIV volumes (and human papillomavirus volumes in some circumstances), in particular. To ensure more rationale integrated testing, several countries continued testing all people with presumptive TB, with the addition of infant HIV diagnosis and targeted (rather than routine or all people in need) HIV viral load testing. These HIV volumes were generally small and ensured no overutilization or cannibalization.

- No negative impact was observed on TB testing, volumes or treatment, whereas clear benefits were observed across all test types, including:
  - patient improvements:
  - decreased test turnaround time;
    - decreased time to clinical action and increased proportion of patients with documented action (HIV viral load);
    - increased treatment initiation (infant diagnosis);
    - decreased time to treatment initiation (infant diagnosis);
    - increased access to testing (TB, HIV viral load and infant diagnosis);
  - system improvements:
    - decreased costs for both HIV and TB programmes;
    - increased technology utilization; and
    - staff acceptability and feasibility
- There were some consistent challenges across pilots and programmes, including:
  - Focus was required to adjust the laboratory and clinic workflow as well as the patient flow upon implementing additional assays on the integrated platform.
  - Systems considerations needed to be implemented to ensure that results were returned on the same day, particularly for more urgent tests and results, such as infant HIV diagnosis.
  - Adequate human resource capacity needed to be ensured to manage additional clinical patient demand as well as technology utilization and execution, both the quantity and quality of staff members.
  - Service and maintenance contracts and execution were often limited or challenging (this was specific to the technology implemented during pilots),
  - Significant support was necessary to ensure that adequate infrastructure was introduced, including a thermomixer (for infant HIV diagnosis using dried blood spot samples), a centrifuge (for HIV viral load), consistent electricity, temperature-controlled rooms, dust control, etc. (this was specific to the technology implemented during pilots).
- Site selection processes were well and clearly thought through across countries and pilots and focused on several key considerations (also see the section on **Diagnostic network optimization,** pp.9):
  - A primary concern was the current device capacity as well as projected volumes. There was keen interest not to overutilize the technology; therefore, pilots were given priority in settings with less current utilization but still significant patient volume need for the additional assays to ensure impact.

- Ensuring available adequate infrastructure and human resources was also necessary to maximize integration and testing.

- Due to potential high need and volumes for human papillomavirus testing, careful consideration is being made for whether human papillomavirus as well as other sexually transmitted infection testing should be expanded to the near point-of-care assays or focused primarily for laboratory-based assays.

- With the success of initial pilots, several countries and partners were also considering or expanding integration to additional assays, such as hepatitis C virus, human papillomavirus and Ebola virus.

- The goals of diagnostic integration can be multiple and should be discussed and decided upon by all key stakeholders. These could include:

  - patient impact: increased access, reduced turnaround time for testing and/or improved linkage to treatment, better monitoring and increased retention;

  - reduced overall programme costs; and

  - more efficient overall systems.

- In addition, several key lessons were further highlighted.

  - Engagement and collaboration across programmes and partners were critical to ensuring the success of the pilot and consideration for national scale-up.

  - Site selection and assessments (see the section on **Diagnostic network optimization**, pp.9) were needed to ensure patient impact, minimize disruptions in service, reduce the risk of overutilization and create maximum efficiency for all programmes.

Several overall benefits diagnostic integration provides for all health programmes were highlighted:

- more efficient and comprehensive patient care pathways;

- increased access for underserved or underfunded programmes;

- a more optimized and collaborative integrated diagnosis network with improved laboratory workflow;

- broader device footprints through shared technologies;

- overall more efficient laboratory services, including data management, sample transport, quality assurance, service and maintenance and supply chain;

- increased negotiating power with suppliers because of increased volumes as well as a stronger voice for lower, more inclusive, transparent and fair prices across programmes, countries and regions;

- reduced costs and more efficient use of limited resources by sharing operational costs;

- shared operational knowledge across programmes;

- streamlined diagnostic capabilities and approaches across stakeholders; and

- encouraging integrated cross-sectoral approaches to high-quality testing services and care.

Further, developing a holistic integrated system across diseases will benefit other programmes, including reproductive health, maternal and child health, noncommunicable diseases, emergent diseases and cancer programmes.

Finally, the successes of such pilots and eventual scaling up of diagnostic integration will become a model for successful integration across programmes, achieving one of the key aims of the universal health coverage agenda.

Additional publications and/or examples of diagnostic integration exist *(4–6)*.

The country pilots highlighted four key areas that required further discussion and in-depth consideration, including financing, diagnostic network optimization and mapping, systems integration and patient prioritisation.

Financing

Because of some key challenges across programmes and countries, including weak and expensive service and maintenance contracts, long wait times for repairs and spare parts and stock-outs of reagents and consumables, alternative pricing opportunities have been considered and introduced in some settings. Countries and partners have moved towards reagent rental and even price-per-

result mechanisms, within which a single price would include instrument placement, reagents and consumables, comprehensive service terms, errors and failures and controls and calibration. Ideally, through delivery duty paid, the responsibility for both costs and risk assumption from beginning to end shifts to the seller or manufacturer. The seller or manufacturer would then assume the risks and costs of transport (export fees, carriage, insurance, destination port charges and delivery to the final destination) and pay any import customs or duty. This shift in pricing mechanism will lead to more optimal instrument use, simplify budgeting and procurement, reduce hidden costs and ensure more consistent availability of testing for patients and clinicians.

To enable better coordinated, uninterrupted provision of timely and high-quality HIV, TB, human papillomavirus and hepatitis test results in countries most in need, the Integrated Diagnostics Consortium *(7)* was developed. It has become a platform to support joint negotiations across assays and diseases with the goal of achieving lower, more transparent pricing. Future key activities include consideration of joint requests for proposals, collaborative diagnostic network optimization efforts and coordinated procurement.

Several potential mechanisms exist to reduce costs across assays and diseases, including:

- Increased volumes and utilization will enable more amortization of devices within cost and service and maintenance contracts, given the increase in the number of tests over which the fixed costs can be amortized. The cost per test decreases as utilization increases.
- Operational costs can be shared across numerous activities, including:
    - instruments
    - service and maintenance
    - logistics and commodity supply chain management
    - human resources
    - sample transport
    - training
    - waste management
    - data management
    - quality assurance
    - results delivery.

The Clinton Health Access Initiative has developed a tool to assess the financial benefit of integration across diseases *(8)*.

Diagnostic network optimization

As highlighted in the country pilots, product and site selection is a critical step to ensuring sustainable and optimal diagnostic integration. This is often completed or supported through country-driven, patient-focused, comprehensive and transparent diagnostic network optimization or mapping exercises. Diagnostic network optimization or mapping exercises help to define the optimal mix of devices, identify the most appropriate locations where the devices should be placed and design the referral network links, if necessary. Several tools, some of which are open access, currently exist to support diagnostic network optimization, including TB-Net Tool Assessment for Integration (for TB and HIV integration) and Llamasoft's LabEQIP *(9)* and Supply Chain Guru *(10)* as well as Excel-based tools.

Mozambique provided a country example of a comprehensive diagnostic network optimization or mapping tool. The government sought a tool that could be subnational, consider multiple potential technologies, be both laboratory-based and point of care, incorporate testing across several diseases (HIV, TB, hepatitis B and C and human papillomavirus), ensure both patient and operational considerations, consider both current and future demand and be easy to use *(11)*.

Several key concepts in developing diagnostic network optimization, regardless of platform or tool used, included (across test types and diseases):

- political will across the system from the health ministry, laboratory, regional, district and health facility personnel as well as across programmes and systems:

- data collection and analysis:
  - understanding the diagnostic algorithms;
  - patient volumes: focusing on current and potential future demand;
  - patient impact: likely outcomes of increased access (retention, test turnaround times, etc.) and optimized services;
  - distance from health-care facilities to the regional or central laboratory;
  - utilization: current availability of technologies;
  - device footprint: proportion and location of current technologies;
  - cost analyses;
- site visits for data collection, discussion and coordination;
- sample transport network; and
- patients' access to testing.

Although significant technology footprint already exists for both laboratory-based and near point-of-care technologies, it will be important to take into consideration both current test volumes as well as projected demand based on adopting current WHO recommendations. The Cepheid GeneXpert 2018 global utilization average was about 1.2 tests per module per day (the maximum expected throughput per module per day is four tests) *(12)*. Further, some variation and nuances may exist when reviewing utilization data, including testing days per week and hours of operation per facility.

Any diagnostic network optimization activity should inform facility prioritisation (based on nationally selected key metrics such as volumes, prevalence, potential impact, geography etc.), optimal technology and test placement, sample transport and referral needs, human resource needs, infrastructure requirements and quality assurance needs. Single-disease technologies should also be considered within optimization exercises as well as multiplex technologies, while upgrading of some technologies or re-placements may be necessary. The goals for diagnostic network optimization should be to create efficiencies across the diagnostic network and programmes, including for procurement; however, the primary goal is to expand and ensure patients' access to testing and to improve patient impact.

Systems integration

Beyond sharing technologies, several key aspects in the diagnostic and laboratory system can be further integrated.

Specimen referral networks are currently significantly fragmented across diseases and within programmes. Health-care facilities, collection points, hubs and laboratories should be clearly mapped and integrated to develop a clearly optimized specimen referral network. Volumes can be consolidated and co-travelled within the network. Data systems should be integrated, overall but especially within specimen referral networks. Support from the private sector could be considered. The specimen referral network should have multiple goals (Fig. 3).

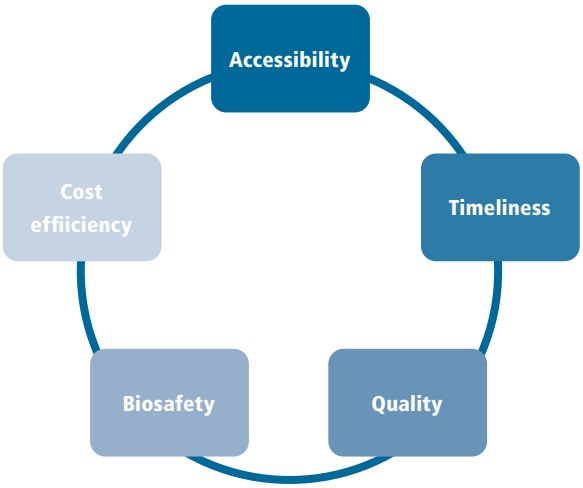


Fig. 3. Goals for the specimen referral network

Several critical aspects of **supply chain and procurement** can be integrated across diseases, including forecasting (both for procurement and supplier negotiation), product selection, quantification, procurement, storage, transport and distribution. These components are necessary for all diagnostics and, considering integration across assays and diseases, will create efficiencies and reduce redundancies and costs. Further, a robust, integrated laboratory management information system (LIMS) is essential for a more streamlined supply chain and procurement system and will further support integration efforts. Key procurement goals include transparency, key performance indicators and a shift towards all-in costs that include service and maintenance, device rental, installation, training, removing devices and connectivity.

Several countries have impressive **data management systems** for diagnostics, with some considering the best avenues for integrating these systems. Especially for point-of-care and near point-of-care but also for laboratory-based technologies, connectivity solutions must be compatible with national dashboards and databases and/or laboratory information management systems (LIMS) to create an integrated national system. Although private partners can be considered and support data management systems, country ownership and leadership in developing an integrated, robust data management system is critical. Several tools were discussed to create a maximized integrated data management system, including data quality assessment, laboratory handbook and integrated laboratory request forms. Further, an integrated central data management system would benefit from cost

considerations, the need for and placement of servers and necessary equipment, easier navigation of dashboards across diseases and functions and more centralized management for all programmes and groups: for example, programme staff, health-care facility clinicians and staff, quality assurance managers, supply chain experts, monitoring and evaluation personnel and suppliers. Finally, although an integrated data management system would be ideal, utilization of the system and data across programmes and needs will support improved systems and better patient care.

Many different tools and checklists support **quality assurance** across diseases and test types; however, many components are similar and could be integrated. These include policies and policy development, site and user certification, proficiency testing panels, post-market surveillance, standardized registers and logbooks, new kit lot verification and training.

Patient considerations

Although ensuring adequate and efficient systems, resources and capacity is critical to executing testing across diseases, whether integrated or siloed, ensuring appropriate generation of patients' demand for and clinical utilization of all test results remains critical. This requires:

- adequate human resource capacity, both in the clinic and laboratory;
- community-based demand generation, including education sessions, posters and pamphlets and radio spots;
- considerations and adjustments as necessary based on patient flow;

- incorporating infection control practices;
- developing and/or updating diagnostic algorithms;
- necessary clinical training and in-service mentorship;
- patient education and advocacy;
- treatment availability; and
- robust and completed documentation and data systems.

Finally, countries and programme managers emphasized improving understanding of how to prioritise patients for more rapid, same-day or near point-of-care testing. Laboratory-based multiplex technologies generally have significant capacity to conduct testing across assays and diseases, with some having the ability for remote access and testing multiple assays within the same run. However, point-of-care and near point-of-care technologies typically have lower daily throughput potentials, and thus patient prioritisation may be necessary to ensure optimal utilization and to improve patient care.

Calculating disability-adjusted life-years (DALYs) is a way of quantifying the burden of disease from morbidity and mortality. This is calculated by considering the sum of years of life that may be lost from premature mortality caused by a disease and the sum of years lost due to disability for people living with the disease. Several diseases have very high DALYs, including pneumonia, HIV, malaria, TB, syphilis, measles and hepatitis B.

Taking the known DALYs and general morbidity and mortality expectations of several diseases, it was generally considered that people's need for testing can follow a suggested prioritisation:

- people living with advanced HIV disease who need cryptococcal, toxoplasmosis and pneumonia testing (these are generally non-molecular technologies);
- people with a fever suspected of having Ebola;
- HIV-exposed infants who need diagnosis;
- people with signs and symptoms of TB;
- people living with HIV for whom treatment failure may be suspected and/or people living with advanced HIV disease who need CD4 testing, viral load and an infectious disease panel;
- people living with HIV with an elevated first viral load and who need follow-up monitoring;
- although still critical to minimize onward transmission and reduce morbidity, the impact of immediate testing may not be as great as the populations above for:
    - viral load testing for pregnant and breastfeeding women living with HIV;
    - hepatitis B virus;

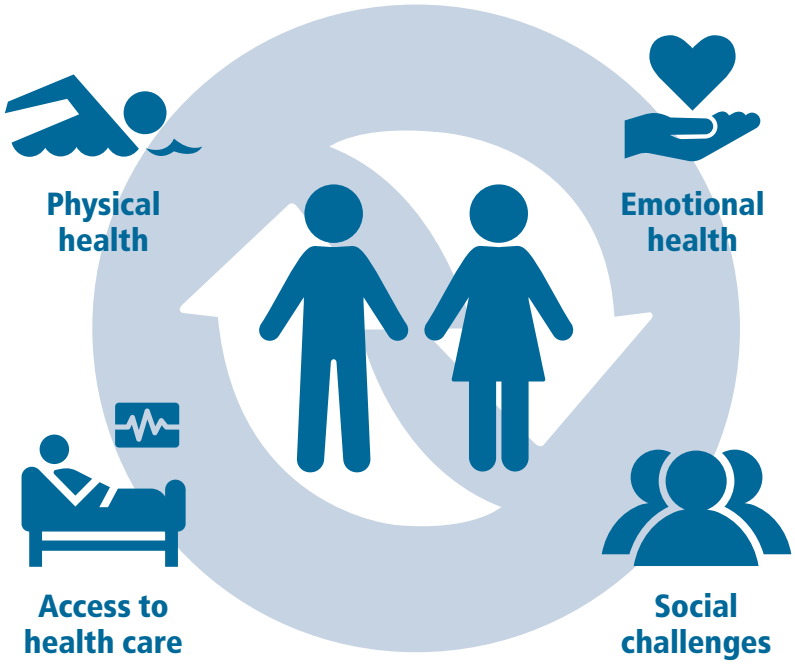
- hepatitis C virus;
- human papillomavirus; and
- other sexually transmitted infections, such as chlamydia and gonorrhoea.

In addition, screening for comorbidities is critical for many people entering health-care systems in low- and middle-income countries; however, it rarely occurs. Some currently available assays need technological improvements, although just as importantly, a more integrated and holistic approach to patient management and care is needed. A move towards patient-centred care, in which each individual is treated and supported as a whole and receives the appropriate diagnosis (for example, cryptococcal testing, human papillomavirus screening and cardiovascular workups as necessary and appropriate) in an integrated fashion, is critical.

Sharing technologies through diagnostic integration is the start to integrating diagnostic systems more holistically. These can lead to more integrated and comprehensive people-centred service delivery and care services that are central to achieving universal health coverage. Together and collaboratively across diseases, personnel and services, a paradigm shift can begin.

Additional useful resources from WHO and others:

- Considerations for adoption and use of multidisease testing devices in integrated laboratory networks *(1)*;
- ASLM Resource Center *(13)*; and
- Global Laboratory Initiative's guidance and tools *(14)*.



NEXT STEPS

The meeting participants identified several next steps that built and expanded on the expected outputs. These include:

- publishing a meeting report detailing the proceedings of the meeting and its participants as well as any key discussions and consensus decisions;
- identifying the components and structure of a diagnostic integration and multiplex toolkit developed to support uptake and scale-up;
- continuing advocacy and efforts towards developing integrated networks across disease areas by developing a diagnostics integration call to action; and
- identifying evidence and information gaps for future guideline questions.

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ANNEX 1. **AGENDA**

Day 1—10 July 2019

Time	Agenda	Presenter
09:00–9:30	**Welcome and introductions**	Ren Minghui (WHO) and Ndlovu Nqobile (African Society for Laboratory Medicine (ASLM))
9:30–10:00	**Workshop outline and outcomes:** towards scaling up access to diagnostic technologies	Meg Doherty (WHO)
10:00–10:30	**Keynote: the need for and role of integration**	Ndlovu Nqobile (ASLM)
10:30–11:00	Break	
	Disease introduction and guidelines	Moderator: Anna Laura Ross (Unitaid)
11:00–11:10	HIV: current state and guidance	Lara Vojnov (WHO)
11:10–11:20	Tuberculosis: current state and guidance	Chris Gilpin (WHO)
11:20–11:30	Hepatitis C virus (HCV): current state and guidance	Philippa Easterbrook (WHO)
11:30–11:40	Human papillomavirus (HPV): current state and guidance	Nathalie Broutet (WHO)
11:40–11:50	Essential Diagnostics List	Mercedes Perez (WHO)
11:50–12:15	**Discussion**	Chair
12:15–13:30	Lunch	
	Country integration pilots and scale-up	Moderator: Anafi Mataka (ASLM)
13:30–13:50	Zimbabwe: HIV and TB integration	Raiva Simbi (Ministry of Health)
13:50–14:10	Malawi: HIV and TB integration	James Kandulu (Ministry of Health)
14:10–14:30	Cameroon: HIV, TB and HCV integration	Joëlle Bouba Haman (Ministry of Health)
14:30–14:50	India: HIV and HCV integration	Nishant Kumar, Sandhya Kabra and Naresh Goel (Ministry of Health)
14:50–15:30	Médecins Sans Frontières: HIV and TB integration across settings	Teri Roberts (Médecins Sans Frontières)
15:30–16:30	**Discussion**	
16:00–16:30	Break	
16:30–18:00	**Country planning**	

Day 2—11 July 2019

Time	Agenda	Presenter
9:00–9:20	**Recap of day 1**	
	Financing and resources	Moderator: Heather Alexander (United States Centers for Disease Control and Prevention)
9:20–9:35	Costs and pricing	Smiljka de Lussigny (Integrated Diagnostics Consortium)
9:35–9:55	Donor perspectives: Global Fund to Fight AIDS, Tuberculo-sis and Malaria	Eileen Burke and Shufang Zhang (Global Fund to Fight AIDS, Tuberculosis and Malaria)
9:55–10:10	Donor perspectives: PEPFAR	George Alemnji (PEPFAR)

10:10–10:25	Cost-sharing considerations	Paolo Maggiore (Clinton Health Access Initiative)
10:25-11:00	**Discussion**	
11:00–11:30	Break	
	Patient and technology optimization mapping	Moderator: Solange Baptiste (International Treatment Preparedness Coalition)
11:30–12:10	Overview of product pipeline and placed diagnostics mapping	Elena Ivanova and Kekeletso Kao (Foundation for Innovative New Diagnostics) Kaiser Shen and Dianna Edgil (United States Agency for International Development)
12:10–12:30	Cepheid GeneXpert device footprint: improving utilization and access	Wayne van Gemert (Global Drug Facility)
12:30–12:50	Patient and technology mapping example	Adebola Lawanson (Ministry of Health, Nigeria)
12:50–13:10	Comprehensive patient and technology mapping approach	Tim Bollinger (Clinton Health Access Initiative)
13:10–13:30	**Discussion**	
13:30–14:30	Lunch	
14:30–17:30	**Country planning**	

Day 3—12 July 2019

Time	Agenda	Presenter
9:00–9:15	Recap of day 2	
	Systems integration	Moderator: Wayne van Gemert (Stop TB Partnership)
9:15–9:45	Sample transport integration	Kameko Nichols (Global Health)
9:45–10:15	Supply chain and procurement integration	Dianna Edgil (United States Agency for International Development)
10:15–10:45	Data connectivity integration	Nancy Bowen (Ministry of Health, Ken-ya)
10:45–11:15	Quality assurance systems integration	Heather Alexander (United States Centers for Disease Control and Prevention)
11:15–11:30	**Discussion**	
11:30–12:00	Break	
	Patient considerations	Moderator: George Alemnji (PEPFAR)
12:00–12:30	Demand generation and clinical utilization integration	Jen Cohn (Elizabeth Glaser Pediatric AIDS Foundation)
12:30–13:00	Patient prioritisation	Meg Doherty (WHO)
13:00–13:30	Patient perspective of diagnostic needs	Solange Baptiste (International Treatment Preparedness Coalition)
13:30–14:00	**Discussion**	
14:00–15:00	Lunch	
15:00–16:00	**Country planning**	
16:00–17:00	Country perspectives (5 minutes)	
17:00–17:30	**Discussion**	
17:30–18:00	**Meeting wrap-up**	WHO and ASLM

ANNEX 2. **LIST OF PARTICIPANTS**

Ministry of Health, Brazil
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Ministry of Health, Cameroon
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Ministry of Health, Eswatini
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Ekaterine Adamia
Ia Kamarauli

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Benedita Jose
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Uba Sabo Ado

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Henry Hermes Hernandez Caballero

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Valerie Wilson

Clinton Health Access Initiative
Namita Bansil
Timothy Bollinger
Paolo Maggiore
Jilian Sacks

Elizabeth Glaser Pediatric AIDS Foundation
Martina Casenghi
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Foundation for Innovative New Diagnostics
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Kekeletso Kao
Sonjelle Shilton

Global Drug Facility, Stop TB Partnership
Wayne van Gemert

Global Health
Kameko Nichols

Global Laboratory Initiative
Kathleen England
Alaine Nyaruhirira (also Management Sciences for Health)

Global Fund to Fight AIDS, Tuberculosis and Malaria
Eileen Burke
Shufang Zhang

International Treatment Preparedness Coalition
Solange Baptiste

KNCV Tuberculosis Foundation
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Médecins Sans Frontières
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United States Agency for International Development
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United States President's Emergency Plan for AIDS Relief
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