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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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.

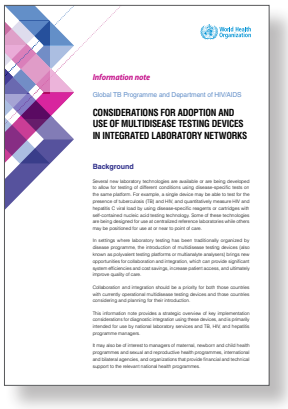
KEY OUTCOMES

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).