

MEETING REPORT

MOLECULAR DIAGNOSTICS INTEGRATION GLOBAL MEETING REPORT

10–12 JULY 2019, GENEVA, SWITZERLAND



MEETING REPORT

**MOLECULAR
DIAGNOSTICS
INTEGRATION
GLOBAL MEETING
REPORT**

10–12 JULY 2019, GENEVA, SWITZERLAND



**World Health
Organization**



Molecular diagnostics integration global meeting report

ISBN 978-92-4-000213-5 (electronic version)

ISBN 978-92-4-000214-2 (print version)

© World Health Organization 2020

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Molecular diagnostics integration global meeting report. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

This publication contains the report of the Global diagnostics integration global meeting and does not necessarily represent the decisions or policies of WHO.

Printed in Switzerland

CONTENTS

Introduction	4
Objectives and expected outcomes	5
General objective	5
Specific objectives	5
Expected outcomes	5
Participants	5
Key outcomes	6
Country pilots	8
Financing	9
Diagnostic network optimization	10
Systems integration	11
Patient considerations	12
Next steps	13
References	14
Annex 1. Agenda	15
Annex 2. List of participants	17

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.



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.

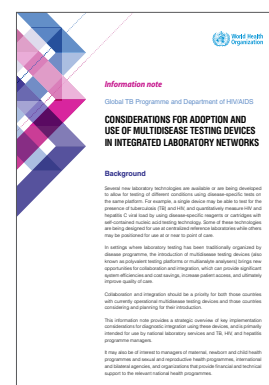
The first step of diagnostic integration includes sharing technologies across programmes. These particularly include

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:

- 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).



预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_24721

