

WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTÉ WELTGESUNDHEITSORGANISATION ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ

> REGIONAL OFFICE FOR EUROPE BUREAU RÉGIONAL DE L'EUROPE REGIONALBÜRO FÜR EUROPA EBPOTIEЙCKOE РЕГИОНАЛЬНОЕ БЮРО

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Our reference: Notre référence: Unser Zeichen:

Your reference: Votre référence: Ihr Zeichen: Ha Bau Homeo:

Dear Dr Belkania,

Dr Sofiko Belkania
Head, Executive Department
National Counterpart

National Counterpart
Ministry of Internally Displaced Persons from the
Occupied Territories, Labour, Health and Social
Affairs

144, Ak. Tsereteli Ave. 0119 Tbilisi Georgia

Date: 13 February 2019

Experts Workshop on Policy Options for Innovations in Diagnostics and Service Delivery for impact in HIV, TB and Malaria Lima, Peru, 24–26 April 2019

I have the pleasure to inform you that the World Health Organization (WHO) Regional Office for the Americas in collaboration with WHO Headquarters and WHO Regional Office for Europe and the Global Fund to Fight AIDS, Tuberculosis and Malaria is jointly planning to convene the above-mentioned workshop for relevant member states of all six WHO regions.

The workshop will take place in Lima, Peru, from 24 to 26 April 2019.

The aim of the workshop is to provide a forum to exchange experiences across regions in the implementation of innovative approaches to diagnostics and delivery of diagnostic services for the TB, HIV and Malaria programs and other communicable diseases to explore ways to accelerate uptake of innovative diagnostics in all WHO regions. For additional information, please find attached the concept note.

I have the pleasure in inviting you to nominate three candidates to attend this event:

- Head of national TB and/or HIV programs;
- Heads of national references laboratories on TB and/or HIV;
- Representatives from Ministry of health responsible for public health.

The working language will be English. The workshop is planned to be very interactive and the country delegation is expected to present their country's good practices and lesson learned during the working group sessions.

Travel and accommodation for participants will be arranged and paid for by WHO in accordance with our travel regulations.

I look forward to receiving your nominations, giving the names, functional titles and e-mail

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addresses of the proposed participants at your earliest convenience no later than 8 March 2019. We shall then communicate with them directly and provide them with the necessary documentation and administrative information in good time.

For further queries, please contact Dr Sayohat Hasanova (hasanovas@who.int and eurotb@who.int).

Yours sincerely,

Dr Masoud Dara

Coordinator, Communicable Diseases
Division of Health Emergencies and Communicable Diseases

WHO Regional Office for Europe

**Encls:** 

Concept note

Copy for information to:

H.E. Mr Victor Dolidze, Permanent Representative, Permanent Mission of Georgia to the United Nations Office and other international organizations in Geneva, Rue Richard-Wagner 1, CH-1202 Genève, Switzerland Ms Louisa Vinton, United Nations Resident Coordinator, UNDP Resident Representative, United Nations High Commissioner for Refugees, UN House, 9 Eristavi St., 0179 Tbilisi, Georgia Dr Marijan Ivanusa, WHO Representative and Head of WHO Office, WHO Country Office, Georgia, 81

Barnov Street, Mailing address: UN House, 9 Eristavi street, 0179 Tbilisi, Georgia

# Concept Note Experts Workshop on Policy Options for Innovations in Diagnostics and Service Delivery for impact in HIV, TB and Malaria Lima, Peru, 24-26 April 2019

#### I. Background and Justification

In the context of the global efforts to end priority communicable diseases as public health problems, the development and implementation of cost-effective technological innovations and efficient service delivery strategies are essential for early detection, correct diagnosis and effective treatment success, as well as prevention, surveillance and control of communicable diseases such as tuberculosis (TB), HIV, sexually transmitted infections (STIs), including Human Papillomavirus (HPV) viral hepatitis, malaria and other neglected diseases. As countries are striving to reach universal access to health services and universal coverage with more equity, increasing effectiveness and optimizing efficiency of priority programs through the introduction of efficient and innovative technologies and service delivery strategies is critical in an environment of limited resources.

One important area with recent technological innovation is in diagnostic technology and diagnostics service delivery. As programs aim to improve access to testing services and provide people and community-centred services, the integration and optimization of laboratory services is of critical importance. This is relevant from sample collection, to testing analysis and up to improvement of test-result delivery through innovation such as connectivity among laboratories and clinical sites for more efficient return of results and timely clinical actions. Furthermore, new diagnostic technologies may be used to improve disease surveillance for decision making on prevention and control policies and practices.

In May 2018, the World Health Organization (WHO) published the first edition of the Model List of Essential In Vitro Diagnostics (EDL), in recognition that in vitro diagnostics (IVDs) are an essential component to advance universal health coverage, address health emergencies, and promote healthier populations. The EDL outlines a group of IVDs that are recommended by WHO for use within a national health care system and provides guidance and serve as a reference to develop and/or update lists of national essential IVDs for defining universal health coverage interventions. These can be used along-side WHO guidelines to assist countries selecting and implementing such IVDs.

Several new technologies are currently available or will become available soon to allow for testing of different conditions using disease-specific tests on the same platform as well as multiplex assays to simultaneously measure multiple analytes in a single run/cycle of the assay. These diagnostic platforms may be used as a test for triage (i.e. for self-testing) at the point of care (e.g. multiplex rapid testing devices such as dual HIV/syphilis rapid test or point-of-care early infant diagnosis), or in the laboratory. Some platforms may also be used for integrated surveillance of neglected tropical diseases, such as the multiplex-bead assay (MBA). MBA is a platform for integrated population-based surveillance of several diseases based on serology to characterize immune profiles in target populations to inform decisions regarding subsequent public health prevention and control interventions.

Available at: http://www.who.int/medical\_devices/diagnostics/WHO\_EDL\_2018.pdf

These multi-disease testing devices (also known as polyvalent, multiplex testing platforms or multianalyte analysers) are being designed either for use in centralized reference laboratories, "at" or "near to" point of care, or in the context of public health surveillance. In addition, they bring new opportunities for collaboration and integration among priority programs and can provide significant system efficiencies and cost savings, increase equitable access to services in decentralized health facility or community-based settings. The implementation of multiplex testing platforms in most cases will require strengthening integration at the level of planning, development of protocols and standardized operating procedures, platforms for electronic data collection and analysis, operation/logistics and quality control, and service delivery.

Furthermore, connectivity among diagnostic devises and clinical services and unified laboratory information management systems (LIMS), linked to the national Health Management Information Systems (HMIS) and Electronic Medical Records (EMR), are another priority area for effective implementation of testing services. At the population level, test reporting with demographic information is critical to track the effectiveness of health sector response to specific communicable diseases. Automated test reporting is more efficient and reliable if using electronic means such as network-based data transmission. Ideally databases should be centralized at the National, or in some cases, the State level. Automated reporting may improve the timeliness of decision making through reduced delay between result acquisition and communication to the treating physician and patient for prompt clinical conduct leading eventually to improved health outcomes (e.g. HIV and TB treatment initiation, treatment for precancerous cervical lesions, monitoring of treatment process and assessment of treatment results, initiation of treatment and prophylaxis for opportunistic infection; etc.).

Finally, further supporting people-centred services, approaches and strategies, to date there are more than 25 conditions that can be assessed using self-testing devices from chronic to communicable diseases<sup>2</sup>, and many others are in the pipeline. In addition, an even greater range of direct-to-consumer (DTC) testing or self-collected sampling, where samples are sent/delivered to a centralized laboratory for sample processing, are also available. HIV self-testing, using either oral fluid or capillary whole blood, has been the most prominent new public health tool to increase access to HIV testing in adults. In addition, self-collection of rectum, oropharyngeal and urine samples for STI, as well as cervical samples for HPV testing are also available (i.e. HPV, *Chlamydia*, gonorrhoea, among others) and may have an important role to play to facilitate access to STI screening and treatment. Furthermore, there are guidance documents<sup>3</sup> on improving people-centeredness of care, introducing HPV testing into public health programs, addressing the linkages of service delivery, sustainable and efficient health financing and human resources mechanisms and approaches<sup>4</sup>.

Ensuring that diagnostic technology can be innovatively used to integrate diagnostic testing services requires investment in laboratory support systems, training of providers and laboratory personnel and proper planning to maximize the impact of the introduction of a new technology. It is very important that donors and implementing partners, together with governments continue to invest in laboratory service delivery systems, such as workforce development, supply chain, sample transportation, infrastructure improvement and maintenance including equipment maintenance, quality management systems (QMS). All this should have the goal to ensure that such technologies and their integrated use enhance the laboratory service delivery systems in a people-centred, more cost-effective and sustainable manner and are linked to treatment services to improve patient outcomes. Widespread application of these new technologies must be balanced against their overall cost and feasibility/acceptability to implement in low- and middle-income settings. Economic models are essential to determine when POC or near to POC tests as well as polyvalent testing platforms are affordable, cost-effective, and an appropriate component of a well-functioning lab and diagnostic services system in resource-limited settings.

The increasing focus on healthcare costs requires an efficiency approach to ensure the rational uptake and diffusion of innovative technologies by health systems, particularly resource limited health systems where priorities must be set for use of scarce resources and trade-offs will have to be made. In these contexts, ensuring sustainability once donor funding ceases is critical.

<sup>&</sup>lt;sup>2</sup> Add reference

<sup>3</sup> Add references

<sup>4</sup> Add references

#### **II. Objectives**

- 1. To review recent innovations in diagnostics and delivery of integrated diagnostic services that improve the response to priority communicable diseases including TB, HIV/STIs, viral hepatitis, malaria and other neglected diseases; as well as HPV testing for cervical cancer screening.
- 2. Review updates on WHO recommendations on TB, HIV and HCV diagnostics, testing and monitoring strategies. as well as HPV testing for cervical cancer screening.
- 3. Share experiences with using innovative diagnostic delivery, integrated services and improved connectivity among laboratories and clinical services
- 4. Identify best practices and lessons learnt that can guide the introduction and roll-out or scale up of innovative diagnostic technologies and integrated laboratory services at national level or subnational level.
- 5. Discuss next steps on the adoption and implementation of innovative diagnostic technologies, including multidisease integrated platforms and new self-testing devices to enhance effectiveness, efficiency and sustainability of the public health response to priority communicable diseases.

## III. Expected Results

### A. Outputs

- 1. Better understanding of recent innovations in diagnostics and integrated laboratory services and how to effectively deliver services to increase impact on priority communicable diseases, especially TB, HIV and Malaria.
- 2. Agreement on best practices, lessons learnt and challenges for the introduction and sustainable delivery of new diagnostic technologies for priority communicable diseases across regions (including prioritization of activities and requirements for implemenattion).
- 3. Meeting Report with policy recommendations for the effective implementation of two or three innovative technologies and integrated laboratory service delivery options which, brought to scale, can make a difference for HIV, TB and Malaria programmes.

#### **B.** Outcome

> Acceleration of cost-effective implementation of innovative approaches to diagnostics and integrated laboratory

#### IV. Method

# A. Selection of topics

Many recent innovations exist in the area of diagnostics and service delivery of diagnostics, and it is not possible to cover everything in one workshop. In order to provide practical advice to countries, the workshop will focus on sharing best-practice examples of implementation (roll-out and scale-up) of a limited selection of new innovations in diagnostic technologies and service delivery. To limit the scope of the workshop, a few examples will be selected for discussion. This will include:

- Multiplex rapid testing devices
- Connectivity
- Self-testing and Point-of-Care testing
- Innovative financing for diagnostics

# **B. Background documents**

The following background documents will be produced/used for the workshop

Review of recent innovations in diagnostic technologies and service delivery

#### IV. Participation

The workshop is organized by WHO in collaboration with the Global Fund and UNITAIDS. It will include a total of approximately 80-90 participants, including from countries, civil society, WHO, Global Fund, UNITAID and other partners.

#### WHO Regions:

Regional focal points for laboratories and/or diagnostics should be prioritized as the principle participants in the workshop. WHO GFATM regional focal points should engage with regional laboratories focal points to ensure their participation.

# Countries to be invited:

- The workshop will include countries from several WHO regions.
- Invited countries will include both countries that have best-practice experiences to share and countries that are good candidates for roll-out of innovative diagnostic technologies and service delivery approaches
- It is proposed to invite 2-4 participants each from approximately 12 to 15 countries.

#### Country selection criteria:

Countries will be selected for invitation in collaboration with regional focal points. Countries selected for participation should preferably:

- 1. be eligible to receive Global Fund grants
- have recent experience with implementing innovative new diagnostics technologies or service delivery; or be good candidates for rapid expansion and implementation of such innovations
- 3. be a priority country for at least one of HIV, TB or malaria.

#### **Target country participants:**

- Heads of national programs of HIV/STI(HPV)/VH/TB/malaria or communicable disease surveillance.
- Heads of national references laboratories.
- Representatives from academic institutions and experts in public health and/or health economics
- Representatives from stringent regulatory agencies

#### Partners:

- Africa CDC
- ASLM(Africa Society for Laboratory Medicine)
- CHAI
- CMLF/CARPHA
- FIND
- Fiocruz, Brazil
- Global Fund to Fight AIDS, TB and Malaria (GFATM)
- Instituto de Biologia Molecular do Paraná IBMP, Brazil
- London School of Hygiene and Tropical Medicine, UK
- PATH
- PEPFAR/CDC/USAID
- UNITAID
- UNAIDS
- WHO (Regional Offices and HQ)
- WHO Collaborating Centres (tbd)
- Other partners (national, global/regional) (self-financed; see below)

# V. Organization and Logistics

#### A. Organization

The workshop will be organized by PAHO together with HQ, EURO and EMRO, and in collaboration with the Global Fund, UNITAID, and other WHO regions. The organizing group will include the following:

# Lead organizers:

1. Dr Freddy Perez, Regional Advisor on Communicable Diseases Research, Communicable Diseases and Environmental Determinants of Health Department, PAHO

2. Dr Mubashar Sheikh, Director Strategic Partnerships and Cross Cutting Collaboration, Communicable Diseases Cluster, WHO

#### PAHO core group:

Giovanni Ravasi, Ernesto Montero (HT unit)

Marta Saboya (VT unit)

# WHO Regional Focal Points:

EURO:

Sayohat Hasanova, Martin van den Boom (plus laboratory focal point)

EMRO:

Hoda Youssef Atta (plus laboratory focal point)

AFRO:

Harilala Nirina Razakasoa (plus laboratory focal point) Partha Pratim Mandal (plus laboratory focal point)

SEARO: WPRO:

Rodel Nodora (plus laboratory focal point)

#### WHO Headquarters:

CDS Cluster:

Clarisse Mason

HQ focal point: HIV Department: Kerry Kutch (HIV Department)

Cheryl Johnson

Lara Vojnov

Global TB Programme:

Christian Gunneberg

Christopher Gilpin

Global Malaria Programme:

Leonard Ortega Andrea Bosman

EMP department:

Clive Ondari (Coordinator, Safety and Vigilance)

Anita Sands (Safety and Vigilance)

Sarah Garner (Coordinator, Innovation, Access and Use)

Francis Moussa (Innovation, Access and Use)

**Global Fund:** 

Eileen Burke, Laboratory Specialist Olga Bornemisza, Senior Advisor, RSSH

Igor Oliynyk, Lead Analyst, RSSH

UNITAID:

Robert Matiru Smijlka De Lussigny

#### B. Venue:

The proposed venue for the workshop is Lima, Perú

#### C. Time frame:

The workshop is proposed to take place 24-26 April, 2019 (three days).

#### D. Translation

Simultaneous translation will be available in English, Spanish and French. Other languages to be considered as needed, pending finalization of list of participants

# VI. Budget and Finance

The workshop will be funded through the WHO/Global Fund strategic initiative, with possible contributions from other donors.

# docmanager

From:

info

Sent:

Wednesday, February 13, 2019 4:19 PM

To:

docmanager

**Subject:** 

FW: Experts Workshop on Policy Options for Innovations in Diagnostics and Service

Delivery for impact in HIV, TB and Malaria, 24-26Apr19

**Attachments:** 

GEO\_Nomination\_InterRegWorkshop 24-26April2019.pdf; Innovation Concept Note

V13 (Feb 11-2019).pdf

From: Sopo Belkania

Sent: Wednesday, February 13, 2019 4:16 PM

To: info

Subject: FW: Experts Workshop on Policy Options for Innovations in Diagnostics and Service Delivery for impact in

HIV, TB and Malaria, 24-26Apr19

გთხოვთ დაარეგისტრიროთ.

საუკეთესო სურვილებით,

სოფო ზელქანია

ანალიტიკის, ადამიანური რესურსების მართვისა და საერთაშორისო ურთიერთობების დეპარტამენტის უფროსი საქართველოს ოკუპირებული ტერიტორიებიდან დევნილთა, შრომის, ჯანმრთელობისა და სოციალური დაცვის სამინისტრო

აკ. წერეთლის გამზირი 144, თბილისი, საქართველო, 0159

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From: EURO TBM [mailto:eurotb@who.int]
Sent: Wednesday, February 13, 2019 3:49 PM
To: Sopo Belkania <sbelkania@moh.gov.ge>

Cc: geomission.geneva@mfa.gov.ge; louisa.vinton@undp.org; registry.ge@undp.org; IVANUSA, Marijan

<ivanusam@who.int>; MAMULASHVILI, Nino <mamulashvilin@who.int>; HASANOVA, Sayohat

<hasanovas@who.int>; PRADHAN, Bhim pradhanb@who.int>

**Subject:** Experts Workshop on Policy Options for Innovations in Diagnostics and Service Delivery for impact in HIV, TB and Malaria, 24-26Apr19

Dear Dr Belkania,

Please see the attached nomination letter for the Experts Workshop on Policy Options for Innovations in Diagnostics and Service Delivery for impact in HIV, TB and Malaria, to be held in Lima, Peru, 24–26 April 2019.

We look forward to hearing from you at your early convenience.

Thank you for your kind attention.

Yours sincerely,

Elena Chulkova Programme Assistant

Tel: +4545337106 | Email: chulkovae@who.int