Report of the first meeting of the WHO Diagnostic Technical Advisory Group for Neglected Tropical Diseases

Geneva, 30–31 October 2019

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1. Introduction

The first meeting of the Diagnostic Technical Advisory Group (DTAG), an advisory group to the WHO Department of Control of Neglected Tropical Diseases, was held at the Inter-Parliamentary Union in Geneva, Switzerland, on 30–31 October 2019.

The meeting was opened by Dr Mwele Malecela, Director, WHO Department of Control of Neglected Tropical Diseases, who welcomed participants. She noted the importance of this inaugural meeting given that, during the process of developing the road map on neglected tropical diseases 2021–2030, it became apparent that failing to give adequate consideration to critical diagnostic needs would lead not only to the NTD community missing new targets that were being set but also to losing or compromising the gains made during the past decade.

Dr Malecela also noted that the Department currently manages a diverse portfolio of 20 diseases and disease groups, each with its own unique epidemiology and diagnostic challenges. The goals associated with individual disease programmes are disease-specific – whether for control, elimination as a public health problem, elimination of transmission or eradication – but each disease poses a unique diagnostic challenge that must be addressed in order to reach the 2030 road map targets.

Dr Patrick Lammie, Director, Neglected Tropical Diseases Support Center, a programme of the Task Force for Global Health, was appointed Chair of the Working Group and Dr Veerle Lejon, Director of Research at Institut de Recherche pour le Développement, as vice chair. Dr Rhea Coler, Senior Vice President of Preclinical and Translational Research, Infectious Disease Research Institute, was nominated rapporteur.

The meeting was attended by 10 invited experts, 17 observers and 15 staff from the WHO Secretariat (*Annex 1: List of participants*). The Working Group met in both plenary and breakout sessions.

1.1 Declarations of interest

All the members and observers were asked to declare any conflict of interest before the meeting. The declarations were returned to and reviewed by WHO in line with the procedures set for WHO experts and advisory group members, namely:

- a counter-signed copy of the invitation letter;
- a signed copy of the Memorandum of Agreement;
- the Confidentiality Undertaking; and
- the Declaration of Interest form together with a "Code of Conduct for WHO Experts".

2. Background

The WHO Department of Control of Neglected Tropical Diseases manages a diverse portfolio of 20 disease categories, each with its own unique epidemiological and diagnostic challenges. Programmes to address each of these diseases have different goals according to the targets set for a particular disease: control, elimination as a public health problem, elimination of transmission, or eradication. These programmatic goals may also change over time as programmes achieve success and disease prevalence declines, as new tools are developed or as global attention attracts increased support and commitment.

Accurate and reliable diagnostic tools are necessary for all of these programmes. While classical clinical and parasitological techniques are often adequate for mapping the distribution of disease and monitoring

the progress of interventions against neglected tropical diseases (NTDs), the need for improved diagnostics becomes critical as infection prevalence declines and elimination becomes a possibility.

For NTDs that require case management, diagnostics are essential to achieve the goals of control, elimination or eradication, as the intervention for this group of diseases relies on detecting individual cases and conducting surveillance. The addition of new diseases to the portfolio has highlighted the requirement for improved diagnostic tools. For diseases targeted by preventive chemotherapy, diagnostic tests are required to support programmatic decisions on changing the frequency of treatment or stopping mass treatment, or on conducting surveillance and validating or verifying elimination. Reports from the field indicate that NTD programmes are facing a number of problems that require urgent solutions. Recognition of the achievements accomplished on the road to 2020, and the enthusiasm generated by the Sustainable Development Goals for 2030, have renewed momentum for consolidating programme gains and accelerating progress towards programme end-points, as reflected in the new road map, which identifies critical gaps in diagnostics in order to meet the ambitious targets for 2030.

In view of the need to support programmes to deliver much-needed health interventions to vulnerable populations, and in order to demonstrate and maintain the health gains achieved so far, the Department has determined, in accordance with the recommendations of the Strategic and Technical Advisory Group for Neglected Tropical Diseases, that it is necessary to reassess needs and access-related issues around diagnostics for all the diseases in its portfolio.

Despite the diversity of the programme goals, common areas exist across programmes that lend themselves well to consideration by a single working group for diagnostics. Individual programmes, depending on their goals, may need diagnostics for case detection, diagnosis, prognosis, mapping of endemicity, monitoring and evaluation, test of cure and whether to stop mass treatment, determination of infectivity and/or post-treatment surveillance. A single WHO working group will ensure a unified approach to identifying and prioritizing diagnostic needs and to informing WHO strategies and guidance on the subject.

In accordance, the objectives of the first meeting of the DTAG were:

- to review the terms of reference, structure and working modalities of the group;
- to introduce the WHO process for developing target product profiles (TPPs) development and including TPPs in the WHO Model List of Essential In Vitro Diagnostics; and
- to discuss critical gaps in and prioritization of NTD diagnostics and the use cases for these tools.

3. Sessions

3.1 Terms of reference, structure and objectives of the Working Group

Dr Daniel Argaw Dagne, Coordinator, Innovative and Intensified Disease Management, WHO Department of Control of Neglected Tropical Diseases, summarized the terms of reference, structure and working procedures of the DTAG. He reiterated that planning for the 2030 road map required a reassessment of diagnostic needs and links with partners to redefine priorities for new and in-development diagnostics and other platforms.

Dr Dagne reviewed the responsibilities of the DTAG members. He noted that all of the NTDs in the road map require diagnostics and that limited resources will require the group to prioritize urgent needs, recognizing that all such needs will have to be addressed over time in a phased manner. He noted also the need to define test characteristics – use case, target population, ideal performance and ease of use – in order to support WHO in ensuring a harmonized TPP and establishing standards that the wider community can agree upon and endorse.

Reflecting on the membership of the DTAG (12 members and one alternate member, to serve in a personal capacity and represent a range of disciplines), Dr Dagne commented that maximum effort must be exerted to ensure representation by geographical WHO regions and various areas of NTDs and of the importance in securing a balanced perspective. He reminded the group that experts were present in the fields of epidemiology, public health, infectious diseases health systems and management, as well as regulatory authorities. He reiterated that all members would serve for a 4-year term and may subsequently be invited for a further 3 years.

Dr Dagne reminded the group that experts should not bring their institutional positions or interests to the discussions and that members should attend all meetings, if possible. Members who were not able to attend two consecutive meetings would be asked to step down. The DTAG would meet once a year, with additional meetings and teleconferences to be scheduled as agreed upon by the Chair and the Department. Furthermore, only DTAG members could participate in voting or decisions by consensus, and in the formulation of final recommendations.

The report on the meeting will be written by the rapporteur and the WHO secretariat, approved by members of the DTAG and posted on the WHO website.

The role of the DTAG is to define priority gaps, coordinate the creation of a TPP for each priority use case, including synopses of position/policy statements, and to advise on strategy and access to NTD diagnostics. The DTAG will also advise the Department on the establishment of ad-hoc use-cases or disease specific sub-groups in order to deliver on specific tasks and target product characteristics.

Discussion turned then to the scale of the task facing the DTAG and the need for its processes to be nimble. Dr Malecela reflected on the need for tests that could be used in the most remote areas, not just in primary care centres; she agreed with the group that feasibility and production are real issues that should be addressed via a rapid but rigorous TPP process. There was general agreement from the group that the practical end-use should be considered from the outset, especially as there are few resources for diagnostics.

3.2 Introduction to WHO target product profiles

Dr Vaseeharan Sathiyamoorthy, Team Lead, Data Sharing and Target Product Profile workstreams of the R&D Blueprint, and Coordinator, Research, Ethics, Knowledge Uptake at the WHO Department of Information, Evidence and Research – summarized the new WHO process for TPPs.

He explained that the existence of a WHO TPP in a given area should be taken as a strong indication that products meeting the criteria are highly desirable for public health, and that critical gaps exist in the current landscape of available products. WHO TPPs should be considered as guidance from an end-to-end perspective, linking product development, access and affordability, as well as regulatory, policy and financing considerations, in order to enable line-of-sight so that product development can proceed with public health goals in mind.