

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.

Dr Sathiyamoorthy then explained the eight steps within the process.

Step one consists of determining whether a WHO TPP is needed. The proposed TPP should focus on a public health issue or disease that is prioritized by WHO through the World Health Assembly or another documented WHO process for setting priorities that includes (i) a review of the available literature and (ii) external consultative processes.

An analysis of the available products and of the development pipeline should be conducted before the TPP is developed, to indicate that existing products in development do not meet critical public health needs in settings where that need is greatest. This may be because products do not exist, or licensed products are not suitable or accessible for relevant populations.

Step two is the drafting of a one-page scope and purpose document with regard to the specific TPP, for planning clearance within the relevant WHO technical unit. An entry would also be added to the Intranet information sharing portal for WHO's TPPs (once this is established). This portal will provide transparency across WHO about which TPPs are available or in development.

Step three consists of engaging in external consultations with relevant audiences, including the product development audience for the technical area, to determine whether a need exists for such a TPP outside WHO.

Step four involves constituting a scientific TPP development group including, where appropriate, leading scientists and experts, public health officials, regulators (in liaison with the regulatory unit at WHO/MVP cluster) and, as a minimum, some in-country end-user representatives. End-user representatives should include disease control programmes in health ministries and, where possible, patient representatives and/or civil society. For the TPP development group, the standard WHO declaration of interest procedures should be followed and experts with declared interests that cannot be managed adequately should be excluded. The group should not include current members of staff at for-profit industry entities.

Step five consists of developing a zero draft version of the TPP document and consulting on the draft with the TPP development group (via phone or face-to-face) to produce a 0.1 version.

Step six is to post version 0.1 with a proforma comment form for public consultation for a period of 28 days, to disseminate news of the public consultation widely and, specifically, to seek comments from industry, funders, scientists and end-users.

Step seven is to share the comments received with the TPP development group, along with a proposed next version of the TPP. Depending on agreement by the TPP development group, this version may then undergo further consultation with relevant audiences, or may be labelled as version 1.0, dated and posted on WHO's website as the first non-draft TPP for use in the technical area. WHO TPPs should be widely disseminated and in particular be made available to groups involved in the development of WHO policy recommendations for use later on in the development process, when data on products are being reviewed for their public health value.

Step eight is to consider all WHO TPPs as living documents that may require modification if the status of the associated science or the pipeline in the area changes. The status of active/archive should be changed in the Product Profile Directory.

It is also part of the TPP process that 5 years from the initial publication date, TPPs should be considered expired unless they have undergone a formal review and been updated appropriately with versioning and dating to indicate changes made.

Dr Sathiyamoorthy emphasized that throughout the process, each version of the TPP should be recorded and dated and kept current on the WHO intranet portal for transparency.

3.3 The road map for 2030

Dr Malecela presented the new road map for NTDs for 2021–2030, which had been prepared with her team at WHO over the previous 6 months through a global consultative process of the wider NTD community, national programme managers and various WHO departments. The road map will be a key guiding document for the global response to NTDs over the next decade and serve as a critical strategic document to assist in the delivery of programmes that span the 20 diseases and disease groups; it will also serve as a policy and advocacy document that draws attention to the key challenges in the NTD space and encourages continued commitment from the global community of partners. The WHO Department of Control of Neglected Tropical Diseases used a consultative approach to develop the road map, focused on cross-cutting themes and strategies that span multiple NTDs. Grateful thanks were expressed to those

who took part in developing the document, with the aim of ensuring that the road map itself reflects the views of all stakeholders who contribute to the fight against NTDs.

The road map was submitted to the Executive Board for approval in September 2019 and will be officially launched in 2020.

The road map has four chapters:

- Chapter 1, on the context and purpose, including the landscape of NTDs and the progress made to date globally;
- Chapter 2, on the overarching, cross-cutting and disease-specific targets and milestones;
- Chapter 3, on the strategies and actions required to achieve the 2030 targets, structured according to a strategic framework; and
- Chapter 4, on guidance for countries in developing their national NTD plans, including key components that should form part of this plan, and the process and steps required.

Dr Malecela then presented the “heatmap” component of the road map, which reflects the programmatic progress made for each disease, and the following headings: scientific understanding; diagnostics; effective intervention; operational and normative guidance; planning, governance and programme management; monitoring and evaluation; access and logistics; and health care infrastructure and workforce.

The heatmap identifies areas of common need. Diagnostics was clearly shown as an area of critical need for many NTDs to reach their 2030 goals. Better diagnostics can accelerate progress towards elimination, reduce morbidity, minimize programme costs and support monitoring and evaluation.

3.4 Diagnostic gaps for specific diseases

Each of the NTD focal points presented two slides describing the current status of diagnostics and the diagnostic needs identified by the technical focal point and team.

The presentation is summarized in the table below.

Disease	Current diagnostics	Diagnostic needs
Dracunculiasis	<ul style="list-style-type: none"> • Clinical with epidemiological link • Microscopy for individual clinical diagnosis • PCR test – confirmatory for individual clinical diagnosis 	<p>Serological tests to detect pre-patent Guinea worm:</p> <ul style="list-style-type: none"> • to anticipate interventions to stop transmission in endemic areas; would also ultimately help in the certification process. • for humans, dogs and other animals to detect pre-patent Guinea worm; • field pond-side test for detecting <i>D. medinensis</i> DNA in copepods • to identify water sources that are contaminated with <i>D. medinensis</i> to facilitate interventions
Yaws	<ul style="list-style-type: none"> • Clinical – unreliable, lesions similar to other causes • Dark field microscopy • POC test (SD Bioline) – individual diagnosis and screening; very high sensitivity and specificity • Treponemal serological test (DPP) – diagnosis and screening • PCR – confirmation, identify subspecies, can be used for AZT resistance monitoring; cannot distinguish/determine latent from seropositive cases 	<ul style="list-style-type: none"> • Detection of azithromycin resistance at the health facility/district • Automated high-throughput non-treponemal test for certification of elimination; large-scale serosurveillance of asymptomatic persons • Serological differentiation of yaws and syphilis – for individual diagnosis especially of adults
Human African trypanosomiasis (gambiense)	<ul style="list-style-type: none"> • CATT (Ab serology) – screening of <i>T. b. gambiense</i>, community; low prevalence during surveillance limits its use • RDT (SD Bioline HAT and Coris HAT Sero-K-SeT) – screening, community and peripheral health facility • Immune trypanolysis test (TL) – referral test for surveillance, feasible on dried-blood spots; cumbersome • ELISA serological test – test for surveillance (reference laboratories) • Microscopy of blood, lymph fluid or CSF – parasitological confirmation, low sensitivity • mAECT and HCT (Woo) • PCR; LAMP – to reinforce serological suspicion, lack of accuracy for confirmation (PCR-reference laboratories; LAMP – district hospitals) 	<ul style="list-style-type: none"> • Confirmatory tests for gHAT to be used in peripheral health systems – for screening of population at risk of gHAT and confirmation of cases • More sensitive and specific serological test, cheaper – for screening of population at risk of HAT • High throughput test on blood dried spots in filter paper – for surveillance in low prevalence or post-elimination settings; for validation/verification of elimination • Algorithm combining different tests – to improve specificity of current tests • Test of cure – to reduce long-term follow-up and replace the invasive lumbar puncture, depending on efficacy of treatment available • Availability of existing tests – to ensure that the production of currently available tests is continued and affordable ... • Serological rHAT – no screening test currently available

Disease	Current diagnostics	Diagnostic needs
Leprosy	<ul style="list-style-type: none"> No test available for diagnosis of infection Microscopy (demonstration of acid-fast bacilli in slit-skin smear) Individual clinical diagnosis (some forms only); disease classification (some forms of MB leprosy); follow up and diagnosis of relapse ELISA, lateral flow assays – individual clinical diagnosis for PB leprosy; low accuracy PCR – individual clinical diagnosis; higher sensitivity and specificity than ELISA and lateral flow assays; lack of standardization; not commercially available; requires technical and laboratory expertise 	<ul style="list-style-type: none"> Diagnosis of infection – to provide prophylaxis to those most at risk Screening for potential disease – to better identify suspected leprosy patients Diagnosis of disease – to confirm diagnosis of all forms of leprosy (especially indeterminate and PB leprosy) Prediction of future disease - to identify those at risk of disability Diagnosis of nerve function loss – to recognize early nerve function loss (before it becomes irreversible)
Onchocerciasis	<ul style="list-style-type: none"> Ov16 IgG4 – mapping and stopping; commonly used version: in low prevalence settings, low sensitivity and very high specificity; newer versions more sensitive but concerns about specificity Ov16 IgG4 RDT – maybe mapping, M&E; not specific enough for stopping, issues with reading in field, much lower sensitivity in low prevalence areas; good quality assurance O-150 PCR – entomology needed for stopping MDA and transitioning to post-treatment surveillance; being tweaked to enhance performance 	<ul style="list-style-type: none"> Serological test – for mapping low prevalence areas; have a bridge solution but may need new tools Serological test – for stopping MDA; higher sensitivity Serological test (ideally multiplex) – for post-transmission surveillance; need sensitive test of early recrudescence: possibly replace entomology long-term
Chagas disease	<ul style="list-style-type: none"> Microscopy – screening and diagnosis Blood concentration methods – screening and diagnosis Serology (including chemiluminescence and other related tests) – screening and diagnosis Molecular biology – Screening, diagnosis, discrete typing unit of <i>T. cruzi</i> 	<ul style="list-style-type: none"> Diagnostics – to detect current infection and assess treatment response RDT – for early detection of infection in neonates (congenital transmission) RDT – to identify the discrete typing unit of <i>T. cruzi</i>
Visceral leishmaniasis	<ul style="list-style-type: none"> Clinical plus epidemiological link – individual clinical diagnosis Microscopy – individual clinical diagnosis RDT rK39; RDT rk28 – individual clinical diagnosis; epidemiological surveys IFAT, ELISA – individual clinical diagnosis Loopamp™ <i>Leishmania</i> detection kit (LAMP) PCR – individual clinical diagnosis, species typing 	<ul style="list-style-type: none"> Rapid test – more sensitive and specific especially for eastern Africa and Latin America regions Test (serological or other preferably rapid test) – to monitor treatment response or test of cure Rapid test for PKDL – to distinguish PKDL from other skin conditions

Disease	Current diagnostics	Diagnostic needs
Lymphatic filariasis	<ul style="list-style-type: none"> • Microscopy (microfilaria in blood) – mapping and monitoring; low sensitivity, particularly after MDA • Filariasis Test Strip – for mapping, monitoring, stopping and transitioning to surveillance in areas endemic for <i>W. bancrofti</i>; recently identified as cross-reactive in patients with high <i>Loa loa</i> mf; operational issues; recent reliability issues on “failure to flow” • Brugia Rapid Test (BmR1 IgG4 RDT) – for stopping MDA and transitioning to post-MDA surveillance in areas endemic for <i>Brugia</i> spp.; point-of-care complexity – takes several steps, requires buffer, results after 30 min; some previous issues of reliability 	<ul style="list-style-type: none"> • Serology – for areas co-endemic with <i>Loa loa</i> and for mapping and stopping MDA • Serology – for stopping triple-therapy (IVM-DEC-ALB) MDA; need specific marker of worm viability to better assess impact of IDA on transmission potential • Post-MDA and post-validation surveillance – need biomarker specific of early exposure to confirm elimination of transmission and/or detect early recrudescence
Schistosomiasis	<ul style="list-style-type: none"> • Urine filtration – for <i>S. haematobium</i>; morbidity control/elimination as a PHP • Haematuria – for <i>S. haematobium</i>; morbidity control/elimination as a PHP, lacks specificity • Kato–Katz – for intestinal schistosomiasis; morbidity control/elimination as a PHP; lacks sensitivity in low prevalence settings • CCA – morbidity control/elimination as a PHP; recommended for <i>S. mansoni</i> only; used for mapping and surveillance • Serology tests – interruption of transmission (high sensitivity); moderate to low specificity • Molecular (PCR, LAMP) – interruption of transmission with high sensitivity and specificity • Hatching tests – interruption of transmission with high specificity; mainly for cercaria; time-consuming 	<ul style="list-style-type: none"> • RDT – for monitoring and evaluation of <i>S. haematobium</i>, <i>S. mekongi</i> and <i>S. japonicum</i> transmission; and of humans and animals in low transmission areas • RDT – for verification of interruption of transmission for verification surveys; human, animals, snails • RDT – to assess treatment/drug efficacy
Soil-transmitted helminthiasis including strongyloidiasis	<ul style="list-style-type: none"> • Kato–Katz/microscopy – Ascariasis, trichuriasis, hookworm infection; poor sensitivity for infection of low intensity; gold standard, widely used; samples should be examined in a few hours • Mini-FLOTAC/microscopy – Ascariasis, trichuriasis, hookworm infection; poor sensitivity for infection of low intensity • Baermann/microscopy – for strongyloidiasis, good sensitivity; gold standard but long and complex procedure • ELISA – for strongyloidiasis, good sensitivity and good performance when prevalence > 20% 	<ul style="list-style-type: none"> • RDT or artificial intelligence slide reader • The method should be capable of differentiating among the causative species and quantifying the intensity of infections

Disease	Current diagnostics	Diagnostic needs
Trachoma	<ul style="list-style-type: none"> Clinical examination for TT and active trachoma (WHO-recommended) NAAT – detection of infection; for research use only 	<ul style="list-style-type: none"> Antibody detection test – for post-validation surveillance; potential application for excluding trachoma at baseline
Buruli ulcer	<ul style="list-style-type: none"> PCR (IS2404) – individual diagnosis; sensitivity and specificity > 90%; used in reference laboratories only; some quality issues F-TLC – individual diagnosis; sensitivity < 70%; under evaluation in four countries. Microscopy (standard Ziehl–Neelsen light microscopy) – sensitivity 60%; rarely done Culture – only method to identify viable AFB; identifies clinically suspected relapses after antimicrobial treatment; unsuitable for quick laboratory confirmation. 	<ul style="list-style-type: none"> Rapid point-of-care tests targeting mycolactone – for individual diagnosis at PHC/community level LAMP – design locked test could replace home-brewed PCR methods; RPA – for individual diagnosis; design locked test could replace home-brewed PCR methods
Dengue and chikungunya	<ul style="list-style-type: none"> RDT + ELISA–NS1 antigen – screening, individual clinical diagnosis; sensitivity range 49–90%; specificity range 91–100%; low performance RDT + ELISA–IgM antigen – screening, individual clinical diagnosis; sensitivity range 21–98%; specificity range 77–91%; low performance NAT-PCR screening, individual clinical diagnosis; sensitivity range 83–93%; specificity range 99–100%; irregular and low performance RDT + ELISA–IgG – for screening; high sensitivity, low specificity; cross-reactivity with flaviviruses and certain vaccines 	<ul style="list-style-type: none"> High performance dual IgM+NS1 – for screening and individual clinical diagnosis
Echinococcosis	<ul style="list-style-type: none"> Imaging: X-ray, ultrasound, computerized tomography, MRI – for individual diagnosis, classification and staging and for monitoring treatment response Serology: indirect haemagglutination test, ELISA, latex agglutination, immunoblotting – for individual diagnosis but must be used with imaging Histopathology – definitive individual diagnosis Molecular assays – conventional and real-time PCR; individual diagnosis and definitive after imaging 	<ul style="list-style-type: none"> Screening – antigen assay needed for communities endemic for echinococcosis; POC Ag detection Staging – biomarker antigen needed for suspected individuals, POC Ag detection Treatment follow up – Ab assay or NAT needed for suspected individuals; high throughput antibody assay or POC NAT

Disease	Current diagnostics	Diagnostic needs
Foodborne trematodiasis	<ul style="list-style-type: none"> • Imaging: X-ray, ultrasound, computerized tomography, MRI – for individual diagnosis, classification and staging and for monitoring treatment response • Serology: indirect haemagglutination test, ELISA, latex agglutination, immunoblotting – for individual diagnosis but must be used with imaging • Histopathology – definitive individual diagnosis • Molecular assays (conventional and real-time PCR) – individual diagnosis and definitive after imaging 	<ul style="list-style-type: none"> • Screening – antigen assay needed for communities endemic for echinococcosis; POC Ag detection • Staging – biomarker antigen needed for suspected individuals, POC Ag detection • Treatment follow up – Ab assay or NAT needed for suspected individuals; high throughput antibody assay or POC NAT
Taeniasis/(neuro) cysticercosis	<ul style="list-style-type: none"> • Microscopy (Kato–Katz) – taeniasis individual diagnosis, low sensitivity • Copro-Ag ELISA (taeniasis) – screening, clinical diagnosis, validation; sensitivity in field lower than published; not commercially available. • Copro-PCR (taeniasis) – confirmatory, test of cure; no test independently validated • EITB assay – for screening but verify positives with other methods • Serology: Ag-ELISA, Ab-ELISA (neurocysticercosis) – to support clinical diagnosis • Serology: Ag ELISA, Ab ELISA (porcine cysticercosis) – for selecting pigs for necropsy 	<ul style="list-style-type: none"> • Screening, track and treat (taeniasis) – biomarker not available; Copro Ag under evaluation; POC antigen detection or POC NAT (e.g. PCR or LAMP) • Test for selection of patients in need of brain scan (neurocysticercosis); treatment follow up – POC antigen detection or POC NAT (e.g. PCR or LAMP) • Porcine cysticercosis – screening, validation • Determination of cure and surveillance – biomarker not available; POC NAT (e.g. PCR or LAMP)
Cutaneous leishmaniasis	<ul style="list-style-type: none"> • Clinical and epidemiological link • Microscopy – smear, biopsy, gold standard but variable sensitivity • Immunological (ELISA, LST) and molecular (PCR, qPCR, LAMP) tests – occasionally used in reference laboratories, field surveys (LST) • Detect rapid test – not validated independently 	<ul style="list-style-type: none"> • Rapid test – for confirmation of suspected cases that at peripheral health facilities
Mycetoma	<ul style="list-style-type: none"> • Clinical diagnosis – triad of a subcutaneous mass, sinuses and granular discharge • Microscopy – smear, biopsy, gold standard but variable sensitivity • Culture • Histopathology, aspiration cytology • Serological tests • Molecular – PCR, LAMP • (1→3)-β-D glucan assay 	<ul style="list-style-type: none"> • Early (subclinical) case detection – to identify early (subclinical) cases in the general population • Treatment response – test to determine when to stop treatment • Culture – to determine optimum treatment; may require species identification • Susceptibility testing – to determine optimal therapy

Disease	Current diagnostics	Diagnostic needs
Chromoblastomycosis and sporotrichiosis	<p>Chromoblastomycosis:</p> <ul style="list-style-type: none"> • Clinical – itching nodulo- verrucous chronic skin lesion depicting a “black dot” surface usually after cutaneous trauma • Microscopy – direct exam skin scrapings, crusts, secretions, biopsied tissues • Histopathology • Culture • Immunodiagnosis – immunodiffusion and ELISA • Molecular <p>Sporotrichiosis:</p> <ul style="list-style-type: none"> • Commercially available lateral flow test in distinguishing cases from leishmaniasis, cutaneous NTM infection and chromoblastomycosis • Extracutaneous clinical form 	<ul style="list-style-type: none"> • Sensitive, specific molecular and POC tests
Snakebite envenoming	<ul style="list-style-type: none"> • Diagnostic algorithms and checklists • Clinical signs aided by a 20-min whole-blood clotting test (20WBCT) • Currently only one diagnostic test is commercially available to confirm the type of snake venom present in the body of an envenomed patient. 	<ul style="list-style-type: none"> • Diagnostic for envenoming • POC diagnostic – to confirm envenoming through detection of two or more of a group of ubiquitous venom components • Test to confirm envenoming by detection of two or more toxins present in almost all venoms • Bioclimatic analysis of venomous snake distributions • Risk mapping to improve prevention and control of snakebite envenoming

Ab, antibody; Ag, antigen; AZT, azithromycin; CATT, card agglutination test for trypanosomiasis; CCA, circulating cathodic antigen; DPP, dual path platform; ELISA, enzyme-linked immunosorbent assay; EITB, enzyme-linked immunoelectrotransfer blot; HCT, micro-haematocrit centrifugation test; IFAT, immunofluorescence antibody test; IVM-DEC-ALB, albendazole–diethylcarbamazine (citrate)–albendazole; LAMP, loop-mediated isothermal amplification; LST, Leishmania skin test MB, multibacillary; M&E, monitoring and evaluation; MDA, mass drug administration; mAECT, mini-anion exchange centrifugation technique; mf, microfilaraemia; MRI, magnetic resonance imaging; NAAT, nucleic acid amplification test; NAT, nucleic acid test; NTM, nontuberculous mycobacteria; PB, paucibacillary; PCR, polymerase chain reaction; PHC, primary health care; PHP, public health problem; qPCR, quantitative PCR; PKDL, post kala-azar dermal leishmaniasis; POC, point of care; RDT, rapid diagnostic test; RPA, recombinase polymerase amplification; TT, trachomatous trichiasis

3.5 WHO Model List of Essential In Vitro Diagnostics and prequalification process

3.5.1 *Prequalification*

The Prequalification Programme, set up in 2001, is a service provided by WHO to facilitate access to medicines that meet unified standards of quality, safety and efficacy for treatment of HIV/AIDS, malaria and tuberculosis. From the outset, the Programme was supported by the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA) and the World Bank as a measurable contribution to the United Nations' priority goal of addressing widespread diseases in countries with limited access to quality-assured medicines. Its mission is to work in close cooperation with national regulatory agencies and partner organizations to make quality-assured priority medicines available for those who urgently need them by conducting assessment and inspection activities, building national capacity for manufacture, regulation and monitoring of medicines and working with regulators to register those medicines quickly.

WHO has been assessing the performance and operational characteristics of in-vitro diagnostics (IVDs) since 1988; however, the Prequalification Programme for IVDs was introduced in 2008. Although diagnostics for NTDs are currently not included in the process, discussions are under way with the WHO Department of Control of Neglected Tropical Diseases to include selected diseases based on needs. The aim of prequalification of diagnostics (PQDx) is to promote and facilitate access to safe, appropriate and affordable IVDs of good quality. Focus is placed on IVDs for priority diseases and their suitability for use in resource-limited settings.

The findings of PQDx generate independent technical information on safety, quality and performance of IVDs, principally used by other United Nations agencies, WHO Member States and other interested organizations to guide their procurement of IVDs.

The prequalification assessment process includes three components:

- review of a product dossier;
- inspection of manufacturing site(s); and
- performance evaluation (that is, independent verification of the performance of IVDs submitted for prequalification assessment).

3.5.2 *WHO Model List of Essential In Vitro Diagnostics (EDL)*

The EDL provides evidence-based guidance and sets a reference for developing or updating national lists of essential in vitro diagnostic tests. National lists of essential medicines have been successful in raising awareness and political will, guiding procurement and regulation policies and facilitating access to affordable medicines, particularly in low-resourced countries, by prioritizing the most important medicines all countries need to make available to their populations. It is expected that such national lists will provide similar benefits and improve access to essential in vitro diagnostic tests, as well as contribute towards health system strengthening and realizing universal health coverage, which is central to Goal 3 of the Sustainable Development Goals ("Ensure healthy lives and promote well-being for all at all ages").

The second EDL, published in 2019, includes a section on disease-specific IVDs (dengue, schistosomiasis and visceral leishmaniasis) for use in clinical laboratories.

The third meeting of the Strategic Advisory Group of Experts on In Vitro Diagnostics will take place at WHO headquarters in Geneva on 23–27 March 2020 and is currently accepting submissions for discussion.

4. Discussion

4.1 Managing complexity

The Chair, Dr Lammie, opened the discussion. Prior to the meeting the group had been sent a prioritization exercise the aim of which was to collect information systematically to help prioritize NTD diagnostic needs in order to reach the 2030 targets.

The WHO Department of Control of Neglected Tropical Diseases has developed a comprehensive methodology to ensure that the list of diseases prioritized for diagnostics best reflects targeted global health needs and focuses on the most pressing requirements of the 2030 road map targets. The approach relies on established best practice and is based on practical national and regional experiences in compiling similar lists. It also specifically attempts to address criticism of previous attempts by WHO and other parties to prioritize diseases by developing transparent tools and a stepped, wide-reaching consultative approach to addressing potential biases.

Prioritization of diseases is difficult and requires a defined set of criteria on which to base prioritization. These criteria can be qualitative, intangible or subjective, and can be variable for different stakeholders. The criteria can also be interdependent, complicating separate assessment. Given the complexity and the challenges of disease prioritization, ensuring that the process is transparent and reproducible is important.

To narrow the list of potential priority diseases, a three-step semi-quantitative Delphi technique was adapted from established prioritization methods. Each NTD was to be scored from 0 to 1000 (through scoring 10 criteria), whereby 1000 represented a disease with the highest need for a new or improved diagnostic and 0 the lowest. A mean would then be taken to allow comparison with those in which some criteria were not applicable.

The method entailed inviting a group of experts to reply anonymously to questionnaires. Subsequently, a smaller group would receive feedback, face to face, in the form of a statistical representation of the “group response”, after which the process would be repeated with only the members of the Working Group, the goal being to reduce the range of responses and arrive at expert consensus.

The group was presented with the results they had sent before the meeting, and it was fed back that they considered the process too complex for the time available during the sessions.

Dr Lammie presented a simplified algorithm to prioritize the needs (detailed in 4.1.1) and the group unanimously supported this approach.

4.1.1 Revised approach

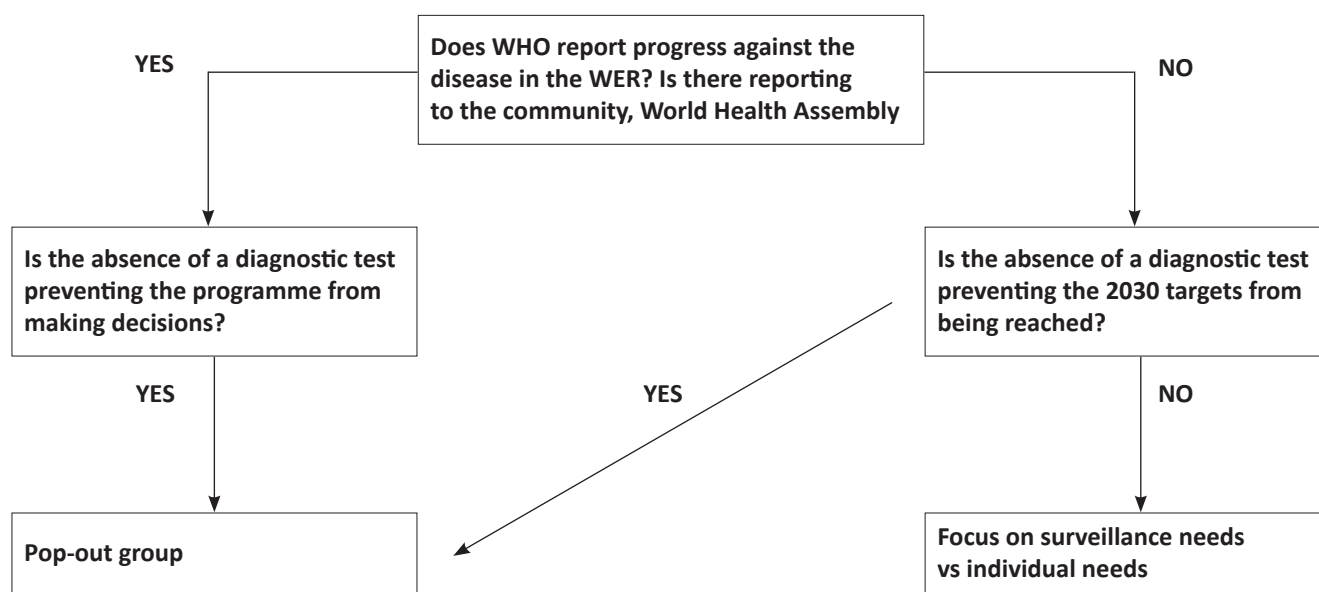
The revised approach distinguishes the indication addressed through preventive chemotherapy versus those requiring individual case management. The members and observers of the group were assigned to one or the other of these categories, with WHO focal points acting as resources for technical or specific questions. Three hours were allocated to each prioritization exercise, which only allowed a preliminary analysis. algorithm will be revisited at least once a year.

4.1.2 Preventive chemotherapy diseases

The following diseases were included in the list for discussion:

- lymphatic filariasis
- onchocerciasis
- scabies
- schistosomiasis
- soil-transmitted helminthiases
- taeniasis and (neuro)cysticercosis
- trachoma
- yaws

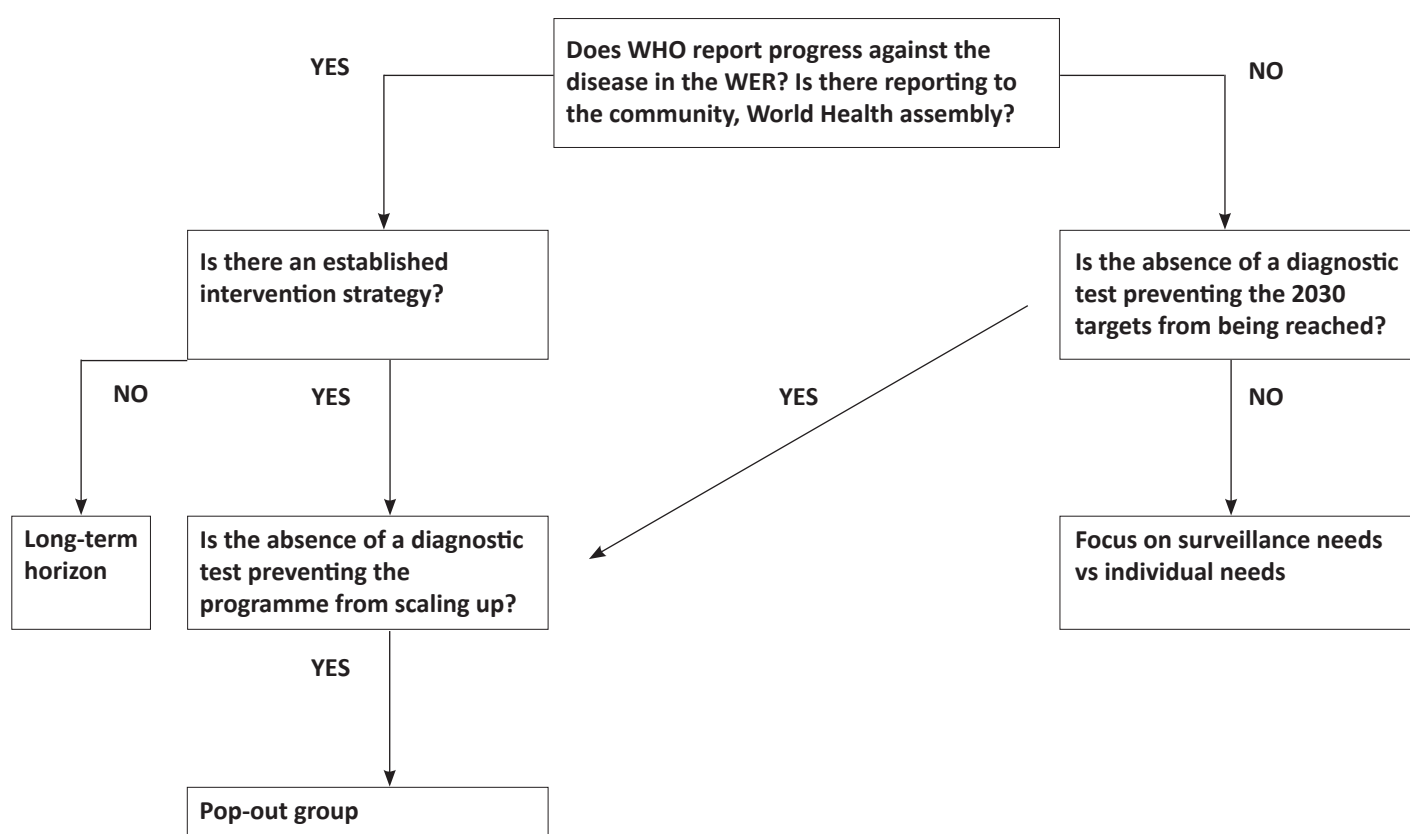
The algorithm starts by asking if epidemiological data are reported in the Weekly Epidemiological Record (WER). If so, this indicates an active WHO programme. The next question is if the absence of a diagnostic is currently hampering effective decision-making for existing programmes. If so, the need is high. If not, the question is if the absence of a diagnostic test jeopardizes the 2030 goals. If so, the need is high again. Other use cases were deemed of lesser priority.



4.1.3 Case management diseases

The diseases discussed in this sub-group were:

- Buruli ulcer
- Chagas disease
- cutaneous leishmaniasis
- dengue and chikungunya
- dracunculiasis
- echinococcosis
- human African trypanosomiasis
- leprosy
- mycetoma, chromoblastomycosis and other deep mycoses
- rabies
- snakebite envenoming
- visceral leishmaniasis



4.2 Overview of discussion

Preventive chemotherapy diseases	Reported in WER?	Is absence of test hampering decision-making?	Is absence of test threatening 2030 targets	Additional comments	Overall priority at this time
Onchocerciasis	YES	YES Preventing: (i) when-to-start decision in low-endemic areas, (ii) mapping in <i>Loa loa</i> co-endemic areas and (ii) when-to-stop-decision based on serology	YES PVS (long-term need)	Entomological assay (O-150 PCR) is cumbersome so seeking a qPCR; serology for stopping is the main need; TPP developed with support from BMGF	HIGH
Lymphatic filariasis	YES	YES Mapping is affecting (i) <i>Loa Loa</i> endemic areas due to cross-reaction with FTS and (ii) there is no good tool for stopping decisions in IDA settings	YES PTS surveillance is a major need	Test for viable adult worms is needed; is what looks like recrudescence due to migration or to recent transmission? Long-term manufacturing partners are lacking, therefore posing a risk	HIGH
Trachoma	YES	NO But PVS would be enhanced with diagnostic tool that did not rely on clinical sign	NO	Fewer cases of trachoma, so more difficult to provide training for graders	LOW
Soil-transmitted helminthiasis Ascaris Hookworm (including strongyloidiasis)	YES	YES	YES	Kato–Katz works reasonably well for most infections except strongyloidiasis and is standardized; an improved test is desired, but it is not preventing some progress; faecal samples are suboptimal (easily obtained from children but not adults)	HIGH
Schistosomiasis	YES	YES	YES	Kato–Katz/urine filtration available for tracing progress towards morbidity targets; need to avoid future morbidity; as a public intervention; more sensitive test than Kato–Katz needed; M&E affected	HIGH
Yaws	YES	NO	NO	Detection of resistance would be helpful; certification of elimination; serological differentiation of syphilis; false positives are a problem M&E red in assessment of critical gaps; when should surveys be done; donation programme from EMS for eradication (153 million tablets) but no funding for implementation; access to the tests which are available is the issue	LOW

Preventive chemotherapy diseases	Reported in WER?	Is absence of test hampering decision-making?	Is absence of test threatening 2030 targets	Additional comments	Overall priority at this time
Scabies	NO	NO	NO	Diagnosis is clinical (skin examination) so longer-term need; M&E strategy still under development	LOW
<i>Taenia solium</i> / (neuro) cysticercosis	NO	YES No established strategy	YES	Neurocysticercosis (NCC) should be considered a case management disease, and taeniasis a preventive chemotherapy disease. Praziquantel is distributed for treatment of schistosomiasis, although the diseases are not co-endemic in many areas, and the target groups are different. No position of WHO on intervention strategy. There are limitations in establishing a programme due to lack of taeniasis diagnostics. Existing porcine cysticercosis test not adequately specific. Porcine tests complementary to taeniasis diagnostics. TPPs are published already for taeniasis, NCC and porcine cysticercosis.	LOW
Foodborne trematodiasis	NO	NO	YES	There is an established intervention strategy in Asia (e.g. specific Ab test would be easier than Ag test for mapping) Mapping test is most needed at this stage Are there <i>Fasciola</i> tests that could be repurposed for human use?	LOW
Human African trypanosomiasis: <i>T. b. rhodesiense</i> <i>T. b. gambiense</i>	YES	YES Tests are available to guide treatment decisions for gHAT but not for rHAT, which is an acute disease	YES rHAT	gHAT is close to elimination DBS testing for surveillance	rHAT: HIGH
Cutaneous/mucocutaneous leishmaniasis	YES	YES Better tests would facilitate diagnosis and treatment	YES	First priority: RDT for cutaneous leishmaniasis (now mainly macroscopy/clinical)	HIGH
Dengue/chikungunya/Zika virus disease	YES	YES Dengue diagnostic test for early infection would facilitate clinical management	YES	First priority: Combo RDT test Highly sensitive RDT to facilitate initial diagnosis and reduce mortality (including QC) = 2030 goal Action point: prequalification even more than EDL listing	HIGH It was felt being addressed elsewhere
Mycetoma	YES	YES Better tests would facilitate diagnosis and treatment	YES	RDT for early case detection	HIGH

Preventive chemotherapy diseases	Reported in WER?	Is absence of test hampering decision-making?	Is absence of test threatening 2030 targets	Additional comments	Overall priority at this time
Dracunculiasis	NO	YES	NO	Non-issue for humans; in state of eradication; concentrate on detecting infection in dogs for containment and surveillance	LOW
Buruli ulcer	YES	YES Better tests would facilitate diagnosis and treatment: Test for confirmation of diagnosis TLC and RDT	YES	RDT to confirm diagnosis Digital microscopy (cross-cutting)/ cell phone	HIGH
Snakebite envenoming	NO	YES Test to detect envenomation would facilitate clinical management	NO	No objectives defined for 2030; clinical signs + epidemiology + clotting test: very useful RDT and clinical treatment decisions; minimum of two toxins vs usefulness to know the snake	LOW
Chagas disease	NO	YES RDT to detect infection and for treatment response	Second priority • RDT congenital Chagas • RDT for discrete typing units • Automatic diagnosis (blood bank screening improvement)	Digital microscopy: improving recognition of the parasite in slides, image library, reference material, tele diagnosis could be important; cross-cutting issue	HIGH
Echinococcosis	NO	YES Better tests would facilitate diagnosis and treatment	NO Clear outcome/impact targets not yet established	Based on imaging complemented by serology. Potential for expertise in China, Italy and other countries. Validation of serological tests for canine echinococcosis from China is required	LOW
Visceral leishmaniasis	NO	YES Better tests would facilitate diagnosis and treatment	YES	First priority: RDT in East Africa RDT for PKDL Leishmania skin test for mapping, disease transmission and to assess vaccine effectiveness Second priority: RDT test cure (crucial for immunodepressed)	HIGH
Sporotrichosis	NO	YES Better tests would facilitate diagnosis and treatment	NO Clear targets not yet established	First priority: telemicroscopy	LOW

Preventive chemotherapy diseases	Reported in WER?	Is absence of test hampering decision-making?	Is absence of test threatening 2030 targets	Additional comments	Overall priority at this time
Rabies	NO	No diagnostic need since immunization based on exposure Surveillance need in stray dogs (seroconversion rate)	NO		LOW
Chromoblastomycosis	NO	YES Better tests would facilitate diagnosis and treatment	NO Clear targets not yet established	First priority: telemicroscopy	LOW
Leprosy	YES	YES	YES	Better POC tests would facilitate implementation of PEP and disease surveillance	HIGH

Ab, antibody; Ag, antigen; BMGF, Bill & Melinda Gates Foundation; DBS, dried blood spot; EDL, WHO Second Model List of Essential In Vitro Diagnostics; FTS, filariasis test strip; IDA, ivermectin, diethylcarbamazine (citrate), albendazole; M&E, monitoring and evaluation; NCC, neurocysticercosis; PCR, polymerase chain reaction; PEP, post-exposure prophylaxis; POC, point of care; PTS, post-transmission surveillance; PVS, post-validation surveillance; qPCR, quantitative PCR; RDT, rapid diagnostic test; TLC, thin-layer chromatography; TPP, target product profile.

A detailed landscape analysis would facilitate future discussions, especially in identifying promising work on biomarkers and new test platforms. The discussion also touched on the need for back up supplies and other manufacturing concerns and capabilities; multiple tests will be needed to make certain that back-ups and confirmatory tests are available. The group called for an exercise to identify which companies are willing and able to manufacture on the scale needed for these diagnostics. The group also wanted to consider how best to engage with manufacturers (both big but especially small).

The issue around quality assurance/quality control and regulatory pathways was discussed. This group needs to engage with the European Medicines Agency and the United States Food and Drug Administration in order to adapt regulation on medical devices and serve as advisors to the committee.

The need for technology to support the clinical diagnostic process was also discussed.

5. Recommendations

After the discussion sessions, the members reviewed the outcomes in a closed session, with input from the WHO focal points around programmatic and diagnostic needs. The members discussed priorities for the year ahead as well as how to manage the complexity of supporting the diagnostics agenda across the entirety of WHO's portfolio of NTDs.

The following recommendations were made, based on the understanding that they would be reviewed at the next meeting, as it had been made clear that all NTDs had diagnostic needs which would have to be addressed in due course.

5.1 Tasks

Among the important priorities to be addressed as early as possible in the work of the DTAG were the following:

5.1.1 *Conduct a formal landscape analysis, including biomarker discovery*

Members recognized the limitations of their own knowledge of the “state of play” across the diagnostic landscape and the importance of this analysis to priority-setting. WHO will conduct or commission a detailed landscape analysis for review by the DTAG.

5.1.2 *Expand the technical expertise that DTAG can all upon*

In recognition of the need for expanded technical expertise, WHO will draft terms of reference and guidance for the sub-groups or pop-out groups for review by the DTAG.

5.1.3 *Formulate a process to bring existing TPPs under development into the DTAG structure*

The DTAG recognized the important investments of time and energy in the development of TPPs. WHO will establish a process to review existing TPPs for review by the DTAG. The DTAG pop-out groups will then review these TPPs against the WHO criteria to determine those that can be shared through WHO.

5.1.4 *Develop a repository of TPPs*

WHO will establish a repository of approved TPPs and make them publicly available. The development of sub-groups or pop-out groups represents an important strategy to maximize the reach and impact of the DTAG. Extensive discussions in the closed session led to the prioritization of the sub-groups listed below. This list is not intended to be exclusive – new groups will be identified over time – or permanent. Sub-groups are intended to be time-limited in order to help channel or advocate for specific tasks and critical work.

5.2 Sub-groups

The following sub-groups will be formed (within the next 12 months).

Disease-specific topics (within 3 months)

5.2.1 *Case management diseases*

The following skin-NTDs will require new diagnostic tests to facilitate treatment:

- Buruli ulcer
- mycetoma
- leishmaniasis (cutaneous and post kala-azar dermal leishmaniasis) and
- leprosy.

For human African trypanosomiasis, diagnosis is needed to initiate treatment for the rhodesiense form of the disease.

5.2.2 *Preventive chemotherapy diseases*

Diagnostic tests are required for the following diseases:

- Onchocerciasis – tests for mapping and stopping mass treatment;
- Lymphatic filariasis – tests for stopping IDA and starting MDA for lymphatic filariasis in areas endemic for *Loa loa*;
- Soil-transmitted helminthiases – new tests for supporting changes in programme implementation;
- Schistosomiasis – new tests for supporting changes in programme implementation.

Cross-cutting topics (to be established within 6 months)

- 1) Surveillance and surveillance platforms, including:
 - a. One Health
 - b. Verification of elimination
 - c. Post-elimination surveillance
- 2) Improving the quality of microscopy and clinical diagnosis
 - a. Microscopy and image analysis
 - b. Clinical examination
- 3) Manufacturing and regulatory pathways
 - a. Access
 - b. Quality assurance
 - c. Regulatory pathways

Annex 1. List of participants

WORKING GROUP MEMBERS

Dr Pascal Millet

Université de Bordeaux
Laboratoire de Parasitologie
Pôle Biologie, Hôpital Pellegrin
33000 Bordeaux, France
Tel: +33 6 95070778
Email: pascal.millet@u-bordeaux.fr

Dr Veerle Lejon

Directeur de Recherche
Institut de Recherche pour le Développement
Unité Mixte de Recherche UMR177
Campus International de Baillarguet TA A17/G
34398 Montpellier, France
Tel: +33 6 45 55 22 98
Email: veerle.lejon@ird.fr

Professor Bruno Levecke

Faculty of Veterinary Medicine
Ghent University
Salisburylaan 133, 9820 Merelbeke, Belgium
Tel: +32 92647404
Email: bruno.levecke@ugent.be

Professor Patrick Lammie

NTD Support Center
Task Force for Global Health
325 Swanton Way, Decatur, GA 30030, USA
Tel: +1 404 687 5613
Email: plammie@taskforce.org

Dr Fabricio K. Marchini

Public Health Researcher
Carlos Chagas Institute – Fiocruz Parana
R. Prof. Algacyr Munhoz Madeir
3375-CIC Curitiba, Brazil
Tel: +55 41996995444
Email: fabricio.marchini@fiocruz.br

Dr René Paulussen

Managing Director, Mondial Diagnostics
357 Woodcroft, Hudson, Quebec JOP 1H0
Canada
Tel: +1 4504580449
Email: rene.paulussen@mondialdx.com

Professor Rahmah Noordin

Director
Institute for Research in Molecular Medicine
Universiti Sains Malaysia
11800 Penang, Malaysia
Tel: + 604 653 4800
Email: rahmah8485@gmail.com

Dr Marco A. Biamonte

Chief Executive Officer
Drugs and Diagnostics for Tropical Diseases
4898 Ronson Ct. Suite C
San Diego, CA 92111, USA
Tel: +1 858 405 1277
Email: marco-biamonte@ddtd.org

Dr Rhea N. Coler

SVP, Preclinical and Translational Research
Infectious Disease Research Institute
1616 Eastlake Ave. E., Ste 400
Seattle WA 98102, USA
Tel: +1 206 612 2565
Email: Rhea.Coler@idri.org

Professor Sammy M. Njenga

Chief Research Scientist
Kenya Medical Research Scientist (KMRI)
P.O. Box 54840, 00200 Nairobi, Kenya
Tel: +254 722945243
Email: sammynjenga@gmail.com

Dr Esvawaran Sreekumar

Chief Scientific Officer
Rajiv Gandhi for Biotechnology Thycaud, P.O.
Thiruvananthapuram
695 014 Kerala, India
Tel: +919 447 698943
Email: esreekumar@rgcb.res.in

Dr Isra Cruz*

Head International Health Department
National School of Public Health
Instituto de Salud Carlos III
8 Sinesio Delgado, 28029 Madrid, Spain
Tel: +34 918 222 312
Email: cruzi@isciii.es

Dr Michael Marks*

Associate Professor
NIHR Clinical Lecturer in Infectious Diseases
School of Hygiene and Tropical Medicine
Keppel Street, London WC1E 7HT,
United Kingdom
Tel: +44 (0)7984 643424
Email: Michael.Marks@lshtm.ac.uk London

OBSERVERS AND WHO COLLABORATING CENTRES

Dr Francisco Javier Moreno Nuncio

Instituto de Salud Carlos III
Centro Nacional de Microbiología
Ctra. Majadahonda-Pozuelo KM. 2,2
28220 Majadahonda, Spain
Tel: +34 918223771
Email: javier.moreno@isciii.es

Dr Pascale Ondoa

Director of Science and New Initiatives
African Society for Laboratory Medicine
Joseph Tito Street, Nega City Mall, Suite 800
P.O. Box 5487, Addis Ababa, Ethiopia
Email: pondoa@aslm.org

Dr Supaporn Wacharapluesadee

Deputy Director
WHO Collaborating Center for Research and
Training on Viral Zoonoses
Rama IV Road, 10330 Bangkok, Thailand
Tel: +66 22564000
Email: spwa@hotmail.com

Dr Men-Bao Qian

Vice Chief of the Department of Soil and
Food-Borne Parasitic Diseases
National Institute of Parasitic Diseases
Chinese Center for Disease Control and
Prevention
No. 207, Ruijin Er Road, Shanghai 200025, China
Email: qianmb@nipd.chinacdc.cn

Dr Emily Wainwright

Senior NTD Advisor
United States Agency for International
Development
Neglected Tropical Diseases Program
1300 Pennsylvania Ave, NW
Washington, DC 20523, USA
Tel: +1 571 551 7373
Email: ewainwright@usaid.gov

Dr Michele Helinski

Project Officer NTD diagnostic projects
The European & Developing Countries
Clinical Trials Partnership (EDCTP)
P.O. Box 93015, 2509 AA The Hague,
The Netherlands
Email: helinski@edctp.org

Dr William E. Secor

Team Lead, Elimination and Control
Laboratory Parasitic Diseases Branch
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30329–4018, USA
Tel: +1 404 718 4141
Email: was4@cdc.gov

Dr Stephanie R. Bialek

Chief
Parasitic Diseases Branch, Division of Parasitic
Diseases and Malaria
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta GA 30329–4027, USA
Tel: 1 404 639 7785
Email: zqg7@cdc.gov

Dr Roger Peck

Senior Program Officer PATH
2201 Westlake Avenue, Suite 200
Seattle, WA 981121, USA
Tel: +1 206 218 2237
Email: rpeck@path.org

Dr Allison Golden

Scientific Program Officer
Diagnostics Program
PATH
2201 Westlake Avenue, Suite 200
Seattle, WA 981121, USA
Tel: +1 206 302 4735
Email: algolden@path.org

Dr Tom Cummins

Senior Program Officer, Diagnostics
Innovative Technology Solution
Bill and Melinda Gates Foundation
P.O. Box 23350
Seattle WA 98102, USA
Tel: +1 585 704 3114
Email: tom.cummins@gatesfoundation.org

Dr Jordan Tappero

Senior Program Officer
NTDs, Global Health Program
P.O. Box 23350
Seattle WA 98102, USA
Tel: +1 206 770 1930
Email: jordan.tappero@gatesfoundation.org

Dr Sarah Nogaro

Scientific Officer – Schistosomiasis
FIND, Campus Biotech Chemin des Mines 9
1202 Geneva, Switzerland
Tel: +41 22 710 05 94
Email: sarah.nogaro@finddx.org

Professor Joseph Ndung'u

Head, Neglected Tropical Diseases Programme
FIND
Campus Biotech
Chemin des Mines 9
1202 Geneva, Switzerland
Tel: +41 79 540 4114
Email: joseph.ndungu@finddx.org

Dr Olaf Valverde Mordt

Clinical Team Leader
Drugs for Neglected Diseases initiative
Chemin Louis-Dunant 15
1202 Genève, Switzerland
Tel: +41 79 543 1713
Email: ovalverde@dndi.org

Dr Fabiana Alves

Head of Visceral Leishmaniasis Clinical Program
Drugs for Neglected Diseases initiative
Chemin Louis-Dunant 15
1202 Genève, Switzerland
Tel: +41 79 775 2344
Email: falves@dndi.org

Dr Catherine K. Ohura

CEO and Executive Director
Global Health Innovative Technology Fund
Ark Hills Sengokuyama Mori Tower 25F
1-9-10 Roppongi, Minato-ku
Tokyo 106-0032, Japan
Tel: +81 3 6441 2032
Email: catherine.ohura@ghitfund.org

Dr Hayato Urabe

Senior Director of Investment Strategy
and Management
Global Health Innovative Technology Fund
Ark Hills Sengokuyama Mori Tower 25F
1-9-10 Roppongi, Minato-ku, Japan
Tel: + 813 644 12032
Email: Hayato.urabe@ghitfund.org

WHO SECRETARIAT

Dr Mwelecele Ntuli Malecela, Director NTD

Tel: +41 22 791 4611
Email: malecelam@who.int

Dr Daniel Argaw Dagne, Coordinator IDM

Tel: +41 22 791 4532
Email: daniel@who.int

Dr Pedro Albajar Vinãs, NTD/IDM

Tel: +41 22 791 1261
Email: albarvinasp@who.int

Dr Kingsley Asiedu, NTD/IDM

Tel: +41 22 791 2803

Email: asieduk@who.int

Dr Jose Ramon Franco Minguell, NTD/IDM

Tel: + 41 22 791 3313

Email: francoj@who.int

Dr Gerardo Priotto, NTD/IDM

Tel: +41 22 791 1375

Email: priottog@who.int

Dr Jose Ruiz Postigo, NTD/IDM

Tel: +41 22 791 3870

Email: postigoj@who.int

Dr Saurabh Jain, NTD/IDM

Tel: +41 22 791 3849

Email: jains@who.int

Dr Amadou Garba Djirmay, NTD/PCT*

Tel: +41 22 791 3322

Email: garbadjirmaya@who.int

Dr Jonathan King, NTD/PCT

Tel: +41 22 791 1423

Email: kingj@who.int

Dr Pamela Sabina Mbabazi, NTD/PCT

Tel: +41 22 791 4855

Email: mbabazip@who.int

Dr Antonio Montresor, NTD/PCT

Tel: +41 22 7913367

Email: montresora@who.int

Dr Dieudonné Sankara, NTD/PCT

Tel: +41 22 791 2164

Email: sankarad@who.int

Dr Anthony Solomon, NTD/PCT

Tel: +41 22 791 2823

Email: solomona@who.int

Dr Afework Tekle, NTD/PCT*

Tel: +41 22 791 4640

Email: teklea@who.int

Dr Raman Velayudhan, NTD/VEM

Tel: +41 22 791 1868

Email: velayudhanr@who.int

Dr Bernadette Abela-Ridder, NTD/NZD*

Tel: +41 22 791 12072

Email: abelab@who.int

Dr Camilla Ducker, NTD consultant diagnostics

Email: camilla@troda.org

Dr Lea Knopf, NTD consultant NZD*

Email: knopfl@who.int

Dr Lauren Carrington, NTD consultant VEM

Email: carringtonl@who.int

Dr Annette Kuesel, TDR

Email: kuesela@who.int

Ms Sophie Lambert, NTD/IDM

support staff

Email: lamberts@who.int

* Unable to attend

