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

Virtual meeting, 26–27 October 2021
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Dedication

Dr Mwelecele Ntuli Malecela
26 March 1963 – 10 February 2022

This report is dedicated to Dr Mwelecele Ntuli Malecela, Director of the WHO Department of Control of Neglected Tropical Diseases from 2018 until her untimely death on 10 February 2022.

Throughout her life, Dr Malecela had a profound and positive impact on all those who had the good fortune to meet and work with her.

The Diagnostic Technical Advisory Group for Neglected Tropical Diseases was formed under the leadership of Dr Malecela; her determination, focus and passion were and will continue to be a driving force for the group's endeavours.
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<tr>
<td>CDIM</td>
<td>clinical diagnosis, imaging and microscopy</td>
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<td>DTAG</td>
<td>Diagnostic Technical Advisory Group for Neglected Tropical Diseases</td>
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<td>FGS</td>
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<td>M&amp;E</td>
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<td>NTD</td>
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<td>PCR</td>
<td>polymerase chain reaction</td>
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<td>STAG</td>
<td>Strategic and Technical Advisory Group for Neglected Tropical Diseases</td>
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<td>TPP</td>
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1. Introduction

Due to the ongoing coronavirus disease (COVID-19) pandemic, the fourth meeting of the Diagnostic Technical Advisory Group for Neglected Tropical Diseases (DTAG), an advisory group to the World Health Organization’s Department of Control of Neglected Tropical Diseases (WHO/NTD), was held virtually. It comprised an open session on 26 October 2021 and a closed session (for DTAG members only) on 27 October 2021.

The meeting was opened by Dr Daniel Argaw Dagne, who offered thanks to the members of the DTAG and its subgroups for the significant progress made over the past 2 years. Between its inception in October 2019 and October 2021, the DTAG had created 10 disease-specific and cross-cutting subgroups, in addition to a resource mobilization subgroup to help attract and coordinate investments in diagnostics for NTDs.

Since the previous (third) DTAG meeting (3 June 2021), eight target product profiles (TPPs) had been published, with 11 more in the pipeline for publication. Two new subgroups had been formed, concentrating on visceral leishmaniasis and zoonotic NTDs. In addition, a small ad hoc task team of the zoonotic NTD subgroup had been formed to focus specifically on developing a TPP for dracunculiasis (Guinea-worm disease).

The fourth DTAG meeting was convened to provide DTAG members and the wider NTD community with an overview of progress made by the various subgroups, as well as to consider critical issues requiring recommendations for action from the DTAG.

The participants are listed in the Annex.

1.1 Declarations of interest

All the invited experts and observers were asked to declare any conflict of interest before the meeting. No conflicts of interest were declared.
2. Background

WHO/NTD manages a diverse portfolio of 20 diseases and disease groups, each with its own unique epidemiological and diagnostic challenges. Programmes to address each disease have different goals: disease control, elimination as a public health problem, elimination of transmission, or eradication. These programmatic goals may change over time as new tools are developed and global attention brings increased support.

In this context, the DTAG was set up to provide end-to-end support to WHO and the diagnostics community, based on the diagnostics agenda and actions needed to facilitate progress towards achieving the targets set out in WHO/NTD’s high-level document, *Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030* ("the road map").

The DTAG’s brief encompasses more than the tools themselves; it covers, in fact, everything from biomarker discovery and assay development to laboratory and field validation leading to WHO’s risk assessment for prequalification and recommendation, as well as issues relating to manufacturing, procurement, supply and deployment.

2.1 Meeting objectives

The fourth DTAG meeting’s objectives were described to the assembled participants. The recommendations from the previous DTAG were reviewed and participants heard that the present meeting would focus on progress made on each of these recommendations since then as well as any outstanding actions.

The third DTAG meeting recommended that:

1. WHO should establish a DTAG subgroup to address critical issues related to the development and maintenance of laboratory capacity and networking to support NTD programmes;
2. DTAG should establish regular meetings (at least yearly) with the Working Group on Monitoring, Evaluation and Research of the NTD Strategic and Technical Advisory Group (STAG), or a mechanism to review evolving monitoring and evaluation (M&E) requirements for NTD programmes;
3. WHO should develop and implement a plan to attract new resources to support the diagnostics agenda – the present meeting is to hear an update on the resource mobilization subgroup’s work to generate a diagnostics landscape analysis;
4. WHO should work with the Foundation for Innovative New Diagnostics and WHO collaborating centres to investigate the establishment of biobanks (based in part on the experience of the human African trypanosomiasis (HAT) biobank) for NTDs;
5. The manufacturing and regulatory pathways (MARP) subgroup should examine the implications of the new European Union In Vitro Diagnostics Regulation, due to enter into application on 26 May 2022, on NTD diagnostics manufacturing and availability, and to propose ways to mitigate any negative impact;
6. DTAG should request the chairs of the disease-specific subgroups to address the challenges of test validation in the absence of a gold standard;
7. DTAG should encourage the disease-specific subgroups to work with WHO to convene meetings with test developers to promote information- and specimen-sharing;
8. DTAG should recommend the development of a TPP for dracunculiasis (Guinea-worm disease) under the newly-formed zoonotic cross-cutting subgroup.
3. Updates

3.1 Gap assessment tool
The gap assessment tool (GAT) is a product being developed by the STAG Working Group on Monitoring, Evaluation and Research. It represents the qualitative monitoring component of the road map’s M&E framework. The assessment provides a disease-specific and cross-cutting view of the gaps and hindrances to progress towards the 2030 road map targets and the actions required to address those gaps.

A subgroup of the STAG working group was tasked with refining the GAT by building upon the first iteration of the assessment conducted during the road map consultation process to improve standardization, transparency and engagement. This subgroup is working to define standardized criteria for the colour rankings identified for the four priority dimensions listed in the road map, namely diagnostics, M&E, access and logistics, and advocacy and funding.

The DTAG was specifically asked to review the draft criteria that have been developed for the diagnostics priority dimension.

3.2 Diagnostics investment landscape
The resource mobilization subgroup was formed to help increase alignment with and coordination among funders active in the NTD diagnostics field. A landscape analysis of diagnostics investments was requested, in order to more clearly understand where funding is available and where there are gaps that need filling either by new or existing donors. This analysis is ongoing, with the first phase to be completed by the end of the year. When combined with the outputs of the GAT, the results of the landscape analysis will provide a clear picture of the current state of affairs, what actions are required to move forward, where funding is in place, and where additional funding is needed to ensure progress.

Once all information about investments has been collected, it will be transformed into visualizations that clearly illustrate where funding is available and where the needs are. DTAG participants were presented with mock-up visualizations and invited to provide feedback.

The next step is to schedule a meeting to review the landscape findings and mock-ups. This is tentatively planned for December 2021 or January 2022.

Discussion
The discussion that followed centred on tracking the funding for newly developed TPPs, the type of mechanisms to be established so that all stakeholders can have access to available information, and how WHO can popularize or advocate for funding for new TPPs.

The meeting heard that the analysis includes a field in which donors can indicate whether the tool they are investing in meets a particular TPP. This is also related to the WHO risk-assessment process, under discussion within the MARP subgroup. Ideally, the meeting heard, there would be a way to summarize all tools that have gone through the formal assessment or review process. Regarding access, the issue of where and how these visualizations will be hosted is still under discussion and will be a topic at the next resource mobilization subgroup meeting. A discussion is under way in WHO about creating a new diagnostics portal to ensure the availability of all information relevant to NTD diagnostics work, including published TPPs and other DTAG work/products. Visualizations are being built to clearly highlight where funding is needed, in order to move tools forward towards the end user. The hope is that this will serve as an important advocacy tool, not only for WHO but also for all other donors and partners interested in diagnostics.
3.3 Laboratory capacity strengthening

Terms of reference have been drafted for the laboratory capacity subgroup and will be finalized and shared with participants as soon as possible after the present meeting. There was discussion of this subgroup’s role for laboratory networking and whether that networking role should be reflected in its name.

4. Feedback from disease-specific subgroups

4.1 Onchocerciasis

The following three use cases are being discussed as options for new TPPs.

- **Definition of transmission zones**: At this time, there is insufficient technical understanding of the transmission zones on which to base a TPP. This use case will be reconsidered as further evidence becomes available.

- **M&E**: The variety of epidemiological contexts in which programmes are implemented may make it difficult to develop a single TPP. This will be reconsidered as programmes progress.

- **Quality-assured reagents for molecular testing of black flies**: The meeting heard discussion of what it means to have quality-assured reagents for black fly polymerase chain reaction (PCR). Discussion is ongoing about whether this work is most appropriate for the onchocerciasis subgroup or the Manufacturing and Regulatory Pathways cross-cutting subgroup. This is likely to move forward.

4.2 Skin NTDs

- **Buruli ulcer**
  - **Diagnosis at the primary health care level**: Public consultation on the relevant TPP closed, with feedback now being incorporated.

- **Cutaneous leishmaniasis and post-kala-azar dermal leishmaniasis**:
  
  - A TPP on cutaneous leishmaniasis and post-kala-azar dermal leishmaniasis is awaiting public consultation.

- **Leprosy**
  
  - A TPP for a diagnostic test to guide post-exposure prophylaxis in contacts is currently awaiting public consultation.
  
  - A TPP for a diagnostic test to confirm the diagnosis of leprosy in individuals with clinical signs and symptoms is also awaiting public consultation.

- **Mycetoma**
  
  - A TPP for a diagnostic test to differentiate between eumycetoma and actinomycetoma is currently awaiting public consultation.
  
  - A TPP for a diagnostic test to determine when treatment can be stopped is also awaiting public consultation.

- **Scabies**
  
  - A TPP on starting mass drug administration is awaiting public consultation.
  
  - A TPP on stopping mass drug administration is also awaiting public consultation.

- **Yaws**
  
  - A TPP on detection of yaws cases is awaiting public consultation.
  
  - A TPP on detection of azithromycin resistance is also awaiting public consultation.
In addition to the disease-specific TPPs, the skin NTDs subgroup is interested in exploring platforms that can be used across several diseases where they may be co-endemic. Discussion is under way on how this work might fit in with the work of the clinical diagnosis, imaging and microscopy (CDIM) subgroup and should be discussed with the surveillance subgroup.

4.3 Schistosomiasis
The initial two TPPs have been published by WHO. The subgroup will now shift focus towards development of a TPP for female genital schistosomiasis (FGS).

4.4 Human African trypanosomiasis
The TPP for rhodesiense HAT has been published. The TPP for a gambiense HAT test to identify individuals to receive widened treatment is under review by the DTAG. Members were encouraged to provide comments if they have not already done so. The following use cases are under discussion for additional TPPs:
- diagnostic for individual-level HAT diagnosis in low prevalence settings; and
- high-throughput testing for verification of elimination.

4.5 Lymphatic filariasis
The initial TPPs were published earlier in 2021 and an accompanying manuscript on the importance of considering the performance characteristics of diagnostics tests in the context of M&E platforms has been submitted to PLOS Neglected Tropical Diseases.

The lymphatic filariasis subgroup produced a recommendation to evaluate the Brugia Rapid Test. However, independent laboratory evaluation was hindered by delays in the manufacturing of the test. The kits have recently become available, and the laboratory validation is now expected to be completed before the end of the year.

The subgroup met to discuss evaluation of new antigen detection tests. Data were reviewed by the subgroup and recommendations produced for the manufacturer, along with the output of the evaluation. These are potential tests which may act as an alternative to the current antigen test.

Additional use cases under discussion for future TPPs include:
- settings in which Loa loa is co-endemic; and
- xenomonitoring.

The meeting heard that the subgroup had had a very helpful discussion about the evaluation of its current test and a conversation about the field evaluation of the new test. It is important to highlight that DTAG subgroups can play a role in helping to establish expectations around test performance. The MARP subgroup will discuss what is needed in terms of quality assurance in order to help NTD programmes.

4.6 Soil-transmitted helminthiases
The initial TPP on M&E has been published. There are two supporting manuscripts: the first of these has already been published in PLOS Neglected Tropical Diseases; it provides an explanation of the sensitivity and specificity requirements included in the TPP. The second paper is a follow-up paper that explores the link between spatial heterogeneity and the link to specificity, sensitivity, costs, and throughput. There is currently a TPP on the agenda for detection of Strongyloides.
4.7 Visceral leishmaniasis
The visceral leishmaniasis subgroup held its inaugural meeting on 11 October 2021. Draft TPPs are expected by early 2022 for the following use cases:

- diagnostic test for visceral leishmaniasis applicable in the context of elimination; and
- test of cure.

5. Cross-cutting subgroups

5.1 Surveillance
The surveillance subgroup is working with the DTAG chair to develop an agenda which will include reviewing assay platforms and conducting a landscape analysis of existing surveillance strategies.

5.2 Clinical diagnosis, imaging and microscopy
The CDIM subgroup was tasked with a very wide range of activities and has an equally wide range of expertise. Discussion is ongoing about how to work together effectively and what the schedule of activities should be. Some topics for early consideration include defining characteristics and imaging standards for image libraries, as well as standards for training in adapted digital technology and imaging.

5.3 Manufacturing and regulatory pathways
Since the formation of the DTAG, and perhaps even more acutely since the DTAG subgroups began producing TPPs which may lead to investments in new diagnostic tools, it has become apparent that there is a need for WHO to review systems required to approve new projects. Given the heterogeneity among NTDs and the lack of a large global market, the meeting heard that it is important to consider the risk profile for each disease and each tool, as well as the resources available.

The MARP subgroup was formed and tasked with working with WHO to advise on the best way forward in terms of a fit-for-purpose regulatory mechanism. Discussions have been ongoing between WHO’s NTD and prequalification and regulatory departments. An Expert Review Panel has been proposed as a potential transitional solution, but further discussion is needed, both between the relevant WHO departments and within the MARP subgroup.

MARP is also concerned with how the implementation of the new European Union In Vitro Diagnostics Regulation, which has implications beyond Europe, will affect NTD diagnostics. This demonstrates the need for a facilitated regulatory mechanism that can take into account the relatively small commercial market while also ensuring development and manufacture of high-quality products at affordable prices.

A meeting has been scheduled with the prequalification department in which a landscape review of NTD diagnostics grouped by risk category will be conducted.

Discussion
MARP representatives told the meeting that they were currently trying to establish a comprehensive list of options to take to the next full MARP meeting. Those options are still being discussed with the WHO prequalification unit, but the hope was that this would happen within a few weeks of the present meeting, in order to start working towards a date for the next meeting. Gathering options together was noted as a crucial first step.

The meeting then heard that the diagnostic tool prequalification process is employed for many diseases, including malaria, tuberculosis, HIV and viral hepatitis. It is currently unclear the extent to which the new in vitro diagnostics regulation will impact other disease areas.
The meeting heard a query about expert review panel coverage, once it has been fully established, and whether it would cover tools produced in countries outside of Europe and North America. In terms of WHO prequalification approval, the DTAG was told the WHO has a collaboration mechanism that ensures that if WHO approves a certain product, there is an agreement with collaborating national regulatory authorities in countries that allows them to look at the dossier and accept that WHO approval. The next step should therefore be to work with other units of the regulatory department within WHO that already has such a mechanism in place for medicines. This course of action, the meeting heard, would facilitate the registration process in countries.

Asked whether it was a goal to move diagnostics production closer to where the tools are needed, and the importance, as this mechanism is established, of it being shared with manufacturers and partners in endemic countries, the meeting noted that this was an issue that the MARP subgroup will have to take on board. It must be ensured that the regulatory processes are open to all producers. It is thus also important for WHO and DTAG to develop a systematic approach to assuring the high quality of tests that are produced.

The DTAG agreed that getting TPPs out is critical, but that it was just as important to ensure that there is a system in place to monitor quality efficiently. It was suggested that donor interest and support might be lost if it not clear that there is an efficient approval process in place after tool validation that will not take 5–7 years. The need was stressed for an agile system that acknowledges the huge variation across NTDs.

In response to this, the meeting heard that the expert review panel mechanism was being proposed because it brings a high level of technical review along with an agile and flexible system that will not impose excessive time or money burdens on test developers. Once that approval is in place, it ought to be possible to take advantage of existing mechanisms to have that approval accepted by national regulatory authorities, so that manufacturers do not then have to go through national regulatory authorities individually in all countries where tests are needed.

The meeting then heard that the WHO-facilitated pathway to transfer regulatory information to different regulatory bodies works with different regional and subregional entities. Africa, for example, has a new platform for diagnostics, but it does not currently include NTDs in its portfolio. The need was stated for advocacy on behalf of an expansion in its portfolio to include NTDs.

With regard to regulatory pathways, the meeting was told, it is important to balance timeliness against rigour for the level of risk involved. A risk assessment, it was stated, is going to be an important first step in this process. Furthermore, all regulatory processes require the preparation of a dossier to demonstrate and produce the evidence that a product meets the required safety, quality and performance. Putting together that dossier requires access to samples so that performance characteristics can be measured. The meeting heard that a lack of available specimens is currently impeding manufacturers’ ability to put together these dossiers.

In response, the DTAG heard that the regulatory process is indeed being framed around risk. The ongoing landscape analysis includes the categorization of diagnostics by relative risk level. With regard to available specimens, the subgroup chairs are using the FIND information gathering tool to define specimen needs for development of the diagnostics outlined by the TPPs. Once this information has been collected, the meeting heard, the process of developing realistic estimates of the cost of this level of biobanking can begin.
6. DTAG second day session

The second day session heard by way of introduction that most subgroups had now completed the initial TPPs requested at the first DTAG meeting (Geneva, 30–31 October 2019) and are now considering additional use cases for which TPPs are needed. These proposals require review and approval by the parent DTAG before subgroups are able to start work. This, the meeting heard, would be the first subject for the second day session.

The cross-cutting subgroups, the session heard, all have a significant amount of work ahead of them and seem to be struggling to develop a detailed action plan by which to move forward. The DTAG and the WHO secretariat, it was stated, must work together to provide the support needed to build momentum in those groups.

Finally, it was noted that outstanding recommendations from the last meeting would be reviewed, and specific actions defined in order to move the agenda forward.

6.1 TPP proposal review

The DTAG TPP summary table was updated to include a sheet on proposed new TPPs.¹ It was stated that this sheet would be reviewed during the second day session and recommendations made on whether or not subgroups could move forward.

6.1.1 Human African trypanosomiasis

The HAT subgroup is proposing the following use cases for TPP development:

- A tool to assess gambiense HAT infection in low prevalence settings
  
  To support surveillance of *Trypanosoma brucei gambiense* transmission in low prevalence settings in which there would still be needed to identify cases. This test would be used at individual level (case detection) in suspects (e.g. serological, clinical, geographical proximity to confirmed cases) to determine if they are (ideally) or have been infected by *T. b. gambiense*. It requires high sensitivity and acceptable specificity. It can be a laboratory-based test.

- A high throughput gambiense HAT test for verification of elimination

  A high throughput test is desired for verification of elimination, to be used in settings with a prevalence of less than 1 in 10,000. In this situation, programmes must be able to test a large quantity of samples (i.e. dried blood spots) in a short period of time. Here the focus would be more on specificity than sensitivity.

There was some discussion on whether these two cases might be combined into a single TPP, but it was decided that the requirements for each were different enough to warrant individual TPPs.

**Discussion**

In the discussion that followed it was noted that the decision to opt for separate TPPs makes sense given the differences between the use cases and the associated impact on required performance characteristics. Ideally a single test or a single biomarker could be used for both, but this is not a necessity.

**Decision:** DTAG recommends separate TPPs for both use cases.

¹ See DTAG TPP summary table (https://www.who.int/groups/diagnostics-technical-advisory-group-for-neglected-tropical-diseases)
6.1.2 **Lymphatic filariasis**

The lymphatic filariasis subgroup is not yet ready to present new use cases for development of TPPs for DTAG recommendation. TPPs are being considered for the Loa loa use case and for xenomonitoring. For the Loa loa use case, it is not clear whether this represents a need for a new TPP or if the characteristics defined in the IDA (ivermectin, diethylcarbamazine citrate, albendazole) use case TPP will be sufficient. Further discussion is required in order to arrive at a recommendation on this question. Similarly, more discussion is needed on xenomonitoring, particularly about whether there is sufficient epidemiological information on which to build a TPP.

**Decision:** The lymphatic filariasis subgroup will have more internal discussion on both use cases before either are put forward for DTAG recommendation.

6.1.3 **Onchocerciasis**

The onchocerciasis subgroup has been active in discussing needs around new TPPs. It considered three options, but the only one ready to move forward as a proposal, the session heard, is one related to the need for quality-assured reagents for black fly PCR. The proposal consists of defining the minimum standards for PCR reagents. The subgroup is seeking DTAG and WHO secretariat guidance on the following questions:

- Should this use case be addressed under the onchocerciasis subgroup remit or is it more appropriate for the parent DTAG or MARP subgroup to address it?
- Is a TPP needed, or is there another format that would be more appropriate for this case?

**Discussion**

In attempting to answer the above questions, and the question of the responsible group in particular, the meeting heard that this would require a significant amount of technical expertise and a deep understanding of the assay. Therefore, it is recommended that this work be completed by the onchocerciasis subgroup. The final product, as well as the methodology for creating it, should be shared more broadly to benefit other diseases. A preferred product characteristic (PPC) is the recommended format in this respect.

**Decision:** DTAG recommends that the onchocerciasis subgroup move ahead with a PPC. This recommendation should be shared with the WHO Onchocerciasis Technical Advisory Subgroup for additional input or information.

6.1.4 **Skin NTDs**

The meeting heard that the next priority for skin NTDs is a single platform that can test for multiple pathogens. Conceptually, it was stated, this makes sense, but further discussion is needed on how to set about achieving this. This skin NTD subgroup work is closely related to the work of the CDIM subgroup; therefore these groups will need to collaborate. WHO is also conducting ongoing work related to the diagnosis of skin NTDs and this information will also need to be shared with the skin NTD subgroup.

The question of whether a TPP would be the correct format, or whether another format would be more appropriate, was also raised.

**Decision:** The skin NTD subgroup, the CDIM subgroup, and the WHO skin NTD team should meet to discuss the best ways forward.

6.1.5 **Schistosomiasis**

FGS has become a high priority in recent years and it is acknowledged that the absence of a clear diagnostic strategy is an impediment to providing appropriate care for FGS. In order to move forward, it was
stated that the subgroup requires an official recommendation from DTAG and support from WHO to recruit new members or experts in FGS. A list of proposed members has been shared with WHO.

**Decision:** The DTAG recommends the development of a TPP for the FGS use case. There will be a call for new members with a specific interest in FGS.

### 6.1.6 Soil-transmitted helminthiases

The soil-transmitted helminthiases subgroup has requested approval for a *Strongyloides* diagnostic test TPP. Additional expertise will be needed, as well as support for the TPP development process.

**Decision:** The DTAG recommended moving ahead with a *Strongyloides* diagnostic test TPP. There will be a call for new members with specific interest in *Strongyloides*.

**Discussion**

In the general discussion that followed, the meeting heard that other NTDs not prioritized at the initial DTAG meeting, such as echinococcosis, cysticercosis and dracunculiasis (Guinea-worm disease), will be covered under the new zoonotic subgroup. For the other diseases, the meeting was told that their needs would be revisited at the next DTAG meeting.

### 6.2 Review of outstanding recommendations

There then followed a review of the outstanding recommendations from the previous DTAG meeting (see 2.1 above).

The outstanding recommendations and suggested outcomes were as follows:

1. **WHO should prioritize the establishment of a DTAG subgroup to address critical issues related to the development and maintenance of laboratory capacity to support NTD programmes.**
   
   a. **Next step:** WHO to finalize the scope of work and issue a call for members.

2. **WHO should prioritize the development and implementation of an advocacy plan to attract new resources to support the NTD diagnostics agenda with support from a working group.**

   a. The investment tool presented on day one of the fourth DTAG meeting will be a critical element of the advocacy plan and should be shared with the DTAG upon completion. Beyond that, there is a need to be strategic to push for the translation of TPPs into the development of products.

   b. This is also related to recommendation 4, namely that the DTAG is to encourage disease-specific subgroups to work with WHO to convene meetings of test developers to promote information- and specimen-sharing. It has already been noted that manufacturers must be kept aware of developments in the regulatory approval pathway as they occur.

   c. **Next steps:** Form a small group of existing members to support development of an advocacy strategy. This should be shared, in the form of a presentation to the resource mobilization subgroup.

3. **DTAG requests that the chairs of the disease-specific subgroups address the challenge of test validation in the absence of a gold standard through the establishment of a working group.**

   a. **Next steps:** Next steps: WHO will discuss a way forward.

**General discussion**

In the general discussion that followed, the idea of a trachoma-specific subgroup was endorsed. The meeting heard that guidelines for the use of serology in post-validation surveillance were intended for development next year, and that it would therefore be helpful to have the TPP built in parallel.

**Decision:** DTAG recommends the formation of a trachoma subgroup.
7. Recommendations

7.1 General recommendations

Action: WHO to develop a TPP status summary and repository for the WHO/NTD website.

Action: External quality assurance issue to be sent to the MARP cross-cutting subgroup for consideration and discussion.

Action: Ideas for possible new TPPs to be consolidated by subgroups and sent to the DTAG for review and approval.

Action: If subgroups require additional expertise to address new TPPs, suggestions should be compiled and sent to the WHO secretariat.

Action: WHO to draft a guidance note on how to facilitate engagement with test developers on a collegial rather than competitive basis and circulate it to the DTAG.

7.2 Recommendations to the WHO secretariat

Action: WHO secretariat to schedule a follow-up session on biobanks.

Action: WHO secretariat to work with the DTAG chair and members to organize an advocacy event, either as a webinar or participation in a global advocacy event.

7.3 Recommendations to the WHO secretariat

Recommendation 1: WHO should establish a DTAG subgroup to address critical issues related to the development and maintenance of laboratory and networking capacity to support NTD programmes.

Recommendation 2: WHO should develop and implement a plan to attract new resources to support the NTD diagnostics agenda.

Action: WHO to host a summary table of TPP work on the WHO/NTD webpage.

Recommendation 3: WHO to work with FIND and WHO collaborating centres to investigate the establishment of biobanks for priority NTDs.

Recommendation 4: DTAG to request that the MARP subgroup examine the implication of the new in vitro diagnostics regulation that will enter into application on 26 May 2022 for NTD diagnostics manufacturing, availability etc., and to propose ways to mitigate any negative impacts.

Recommendation 5: DTAG to request that the chairs of the disease-specific subgroups address the challenge of test validation in the absence of a gold standard.

Recommendation 6: DTAG to encourage disease-specific subgroups to convene meetings of test developers to promote information- and specimen-sharing.

Recommendation 7: DTAG to recommend development of a TPP for dracunculiasis (Guinea-worm disease) under the remit of the newly formed zoonotic group.

Action: WHO secretariat to make a recommendation on where One Health fits into this, whether in the surveillance subgroup or the zoonotic cross-cutting subgroup.
Annex. List of participants

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