Report of the WHO Strategic and Technical Advisory Group for Neglected Tropical Diseases (STAG-NTD)

WHO headquarters, Geneva, Switzerland
30 June – 1 July 2010
Introduction

A meeting of the Strategic and Technical Advisory Group for Neglected Tropical Diseases (STAG-NTD) was held at the headquarters of the World Health Organization (WHO) in Geneva, Switzerland, from 30 June to 1 July 2010. The list of participating members, observers and secretariat is attached (Annex 1).

The Chairman, Professor Sir Roy Anderson, opened the meeting by welcoming the new members of the STAG. WHO’s Assistant Director-General, Dr Hiro Nakatani, addressed the meeting on behalf of the Director-General, Dr Margaret Chan, and expressed his pleasure at the increased support for NTDs and for the forthcoming launch of WHO’s first global report on NTDs. The Chairman expressed his desire to see increasing collaboration, rather than competition, within the area of NTDs.

1. Report from the Director of WHO’s Department of Control of Neglected Tropical Diseases

Dr Lorenzo Savioli, Director of the Department, summarized the progress, achievements and challenges made in controlling NTDs and highlighted accomplishments during the past year. Notable achievements include progress in preventive chemotherapy and data management and communication; and in Buruli ulcer, Chagas disease, human African trypanosomiasis, leishmaniasis and vector management.

He reported on WHO’s follow-up to the recommendations made at the STAG-NTD in 2009:

- Three working groups have been established; each will report to the STAG.
- A database is being developed for all NTDs. A preventive chemotherapy databank is already available, on the WHO/NTD web site, with country profiles.
- There has been enhanced collaboration with the Food and Agriculture Organization of the United Nations (FAO) for foodborne-trematode infections, human African trypanosomiasis, vector control and zoonoses.
- WHO continues to collaborate on promoting training and fellowships. Progress has been made at international, regional and national levels, with regular training programmes for Buruli ulcer, human African trypanosomiasis and leishmaniasis. Expansion of NTD expertise in all WHO regional offices is under way.

Dr Savioli also spoke of progress in building a collaborative and coordination platform. The discussion points for STAG’s consideration included:

- expanding access to preventive chemotherapy, case management and treatment;
- access to non-donated medicines and coordinating procurement;
- scaling up and monitoring and evaluation;
- capacity building for disease control.

The subsequent discussion highlighted the enthusiasm among STAG members for the progress that has been made in NTD control, WHO’s role in this and for the reports of the working groups. The pressing need for capacity building both at country level and at regional level was emphasized by several speakers. The need to seek better understanding of the impact of environmental issues (linked to population growth and urbanization) and climate change on NTDs, as well as to explore and exploit new technology in advocacy, communication strategies, monitoring and surveillance were also discussed.
2. **First WHO global report on NTDs**

Professor David Crompton presented a summary of the first WHO Global Report on NTDs, entitled “Working to overcome the global impact of neglected tropical diseases”. The report is embargoed until its scheduled launch in October 2010; STAG members were requested to keep the contents strictly confidential until such time.

The report has two parts. Part I chronicles NTDs as they feature in resolutions of the World Health Assembly and describes their evolution over 60 years of growing concern. It also outlines the five strategic approaches that are used to overcome NTDs. Part II analyses the human and economic burden of the 17 diseases categorized as NTDs, and provides global and regional plans for their control. The presentation focused on the seven gains and seven challenges presented at the beginning of the report. Comments were invited from the STAG members on each of these 14 statements so that their suggestions could be incorporated into the report. *The STAG endorsed the report and recommended that it be presented to the Director-General for publication.* The chair of the STAG also encouraged WHO to think about publication in book form to serve as a teaching text for health sciences students (or for public health, medical and veterinary students).


Professor Mamoun Homeida, Chairman of the working group, presented the report of its first meeting held on 28 June 2010. The working group has examined the following aspects in relation to benzimidazoles (albendazole, mebendazole and triclabendazole), praziquantel and ivermectin:
- standard operating procedures/guidelines for field monitoring of efficacy;
- laboratory network for monitoring drug efficacy;
- repository of samples;
- research and control issues;
- molecular tools for early detection of anthelminthic resistance.

For each of these five areas, progress, future steps, cross-cutting issues and recommendations for consideration by the STAG were presented.

Specific areas of major progress in the past year include the following:
- Completion of a multi-centric study on efficacy of albendazole for the treatment of soil-transmitted helminth infections. The study showed that albendazole continues to be effective against *Ascaris* and hookworms, regardless of drug pressure, while confirming poor efficacy against *Trichuris*.
- Genetic monitoring has shown that mass-drug administration using praziquantel narrows the genetic diversity, but no treatment failures have been observed.
- Information on ivermectin obtained from 12 sites in 5 countries in Africa confirmed earlier findings that the elimination of onchocerciasis is feasible. STAG concluded that “so far so good” but vigilance must be maintained.

Other areas reviewed by the working group include potential new anthelmintic drugs (tribendimidine, moxidectine, flubendazole, emodepside, derquantel and monepantel) and challenges for monitoring drug efficacy and resistance in human African trypanosomiasis, leishmaniasis and Chagas disease. The report from the Working Group is presented in Annex 2.

The working group recommended that its remit be expanded to include anti/protozoal agents in addition to anthelminthics.
The top priorities for future work were identified as:

1. development of new drugs and drug combinations for leishmaniasis;
2. operational research on prevention of and surveillance for resistance against drugs used for preventive chemotherapy;
3. create a network of reference centres to systematically monitor the efficacy of anthelminthic drugs in a routine setting.


Professor Nilanthi de Silva, Chairman of the working group, presented the report.

The mandate of the working group was to “promote and strengthen international collaboration to facilitate access to assured-quality essential medicines for NTDs”. There are four focus areas:

1. information: providing reliable and up-to-date information about availability of medicines, cost and suppliers;
2. forecasting: assisting countries to develop comprehensive national plans with accurate forecasts of all drug requirements at present and into the future as resources permit;
3. drug quality: creating the conditions for competitive tenders, including pre-qualification of potential drug manufacturers and monitoring of quality;
4. supply chain issues: advising countries about management of drug supply chains.

At its first meeting in July 2009, the Working Group identified eight projects or activities that would facilitate information-sharing, experience and expertise, and deliver results within 1–2 years, resulting in tangible progress towards improved access to quality-assured medicines. Progress in implementing these activities was reviewed at the working group’s second meeting, held on 28 June 2010, and presented to the STAG. Details of these activities are shown in the Report of Working Group (Annex 3).

*The Working Group presented a recommendation on quality assurance in procurement of praziquantel, which was endorsed by the STAG.* The recommendation is included in the report of the Working Group.

During discussion time, the possibility of shifting some activities to the Working Group on Monitoring & Evaluation was raised.

Priority areas for the working group were identified as:

1. ensuring the quality of medicines for NTD control, initially in the procurement of praziquantel, but subsequently for albendazole and DEC as well;
2. assuring the safety of medicines used in preventive chemotherapy programmes.

5. Report from the Working Group on Monitoring and Evaluation of Preventive Chemotherapy Interventions

The report was presented by the Chairman of the group, Dr Sam Zaramba.

The first meeting of the working group took place on 29 June 2010, but sub-groups have worked separately on three areas in the preceding year. The three sub-groups focus on:
1. country needs for monitoring and evaluation in NTD programmes, including integrated mapping
2. monitoring of disease-specific indicators;
3. measuring enhanced outcomes and impact.

The working group requested that the STAG consider endorsing the following recommendations:

- STAG should assist WHO in identifying and mobilizing sufficient resources to meet the requirements of the Global Monitoring & Evaluation Working Group in particular, and global working groups in general.
- The Working Group has developed a strategy and approach for integrated mapping; the African programme for Onchocerciasis Control (APOC) has developed another approach. A meeting has been planned on 2 July 2010 to harmonize the two approaches. STAG should charge the two groups to harmonize all efforts in the field of M&E of preventive chemotherapy interventions, with representations from both groups attending appropriate discussion groups, in order to avoid duplication of efforts.
- Treatment coverage for preventive chemotherapy interventions – as per WHA resolutions – should be included in country-level sector-wide indicators.
- WHO should convene a consultation to amend M&E guidelines to incorporate new methods for stopping LF MDA and transitioning to STH control.
- The Secretariat should include the participation of a member of the trachoma and APOC programmes in the Working Group on Monitoring & Evaluation.

The report from the Working Group is presented in Annex 4.

**The STAG recommended that coordination with APOC should be implemented as soon as possible.** It is necessary to monitor the effectiveness of integrated control programmes; that is, to measure treatment outcomes (especially anaemia and growth rates in children) or even develop new tools for monitoring effectiveness; and to set up a monitoring cascade for training personnel in measuring outcome indicators. However, monitoring should not require a large amount of money, so that significant funding is allocated to implementation. A few high-quality monitoring projects distributed in different regions should be supported as tools for advocacy of the impact of NTD control.

The possibility of shifting work on pharmacovigilance and safety of medicines used in preventive chemotherapy to this Working Group was also discussed.

The top priorities for monitoring and evaluation were identified as:

1. countries to report on NTD treatment coverage disaggregated by geographical region;
2. costing the NTD package: cost and cost–benefits of drug delivery;
3. setting WHO guidelines to adjust soil-transmitted helminthiasis and schistosomiasis control strategies in response to changes in disease epidemiology, and to enable a transition from lymphatic filariasis to soil-transmitted helminthiasis control strategies.

### 6. Report on Chagas Disease in non-endemic countries

The presentation was made by Dr Pedro Albajar-Viñas, WHO Department of Control of NTDs.
Dr Albajar-Viñas highlighted the problem of Chagas disease in non-endemic countries, as a result of migration from endemic countries. It is estimated that there are more than 300 000 infected patients in the United States; prevalence rates in European countries have also increased dramatically. There is some evidence for autochthonous transmission in several European countries. The main strategies for control of the disease in non-endemic areas focus on stopping transmission through blood or organ transplantation, as well as vertical transmission; and patient care in order to reduce the burden of Chagas disease. In May 2010 the World Health Assembly adopted resolution WHA63.20 on control and elimination of Chagas disease.

The ensuing discussion focused on data regarding DALY/QALY estimates, treatment costs and cost–benefit analyses. Accurate, up-to-date figures are not available, and need improvement. Currently available diagnostics include good ELISA-based techniques. In endemic countries, much more expensive medical management is required for patients with chronic disease.

7. Proposed Global Forum for NTDs

The presentation was made by Dr Isabelle Nuttall and Dr Lorenzo Savioli of WHO headquarters.

Although there are multiple initiatives, alliances or networks for NTDs, many focus on only one disease. However, at national level, there is only one national health plan and one NTD programme. There are opportunities to build on commonalities: mapping, procurement, delivery, case management, vector management, surveillance, research, and monitoring and evaluation. The momentum built after the Global Partners’ Meeting on Neglected Tropical Diseases, held at WHO headquarters in April 2007, has created the need to optimize space for dialogue, communication and consensus around the achievement of global goals against the NTDs.

The goal of the proposed forum would be to share information and experiences, avoid duplication of effort, facilitate dialogue and communication among all parties so that they can join their efforts against NTDs and achieve the goals of the WHO Global Plan to combat NTDs. The proposed specific objectives include reinforcing mobilization against NTDs and maintaining political commitment at local, national, regional and global levels to achieve the goals to combat NTDs along the strategic areas for action proposed by WHO.

The key components presented for discussion included flexible arrangements that facilitate current processes without adding bureaucracy or rigidity; a forum that is built around the working groups with a global meeting perhaps every two years; and a common web site. STAG guidance was requested on endorsing the concept with or without changes, so that WHO could further work on a detailed proposal including resources and set a tentative date and location for the next global forum meeting.

Members of the STAG welcomed the concept and endorsed the idea of establishing a forum that builds on existing bodies (STAG and working groups) rather than creating an entirely new body. The importance of determining the best constituencies within the forum was noted. The idea of having a global meeting with satellite meetings for the individual diseases was suggested. Concern was expressed regarding the cost of establishing such a forum against the benefit and value addition that the forum could bring to Member countries, as well
as the danger of losing the ability to deal with details of specific diseases in the move towards integration.

**STAG recommended the establishment of a small working group** that would work out a more detailed proposal based on the views expressed by its members, and most importantly, to clearly define the aims of the forum, its governance, how best to consult the interested parties and organizations. The forum should not have a rigid bureaucratic structure. Dr Sam Zaramba was nominated to chair the working group.

8. **Economic analysis of NTD programmes**

The presentation was made by Dr Donald Shepard of the Schneider Institutes for Health Policy.

Studies on the economic impact of disease are of two types: cost of illness studies and cost-effectiveness or cost–benefit studies. Dr Shepard summarized some recent studies on cost of illness, especially in relation to dengue. Cost-effectiveness studies based on comparative analyses can be used to inform strategy. Such studies can be based on projected programmes or on actual programmes that form a natural or an artificial experiment. Some recent studies on cost-effectiveness of control strategies in relation to dengue and lymphatic filariasis were also presented in summary. Analysis of both financial and economic costs is useful.

Performing economic cost–benefit studies can help to evaluate rigorously the importance of NTDs in country morbidity and mortality. Such studies can aggregate across NTDs, and are feasible for any geographical unit (e.g. province, county, continent, global). Conducting cost-effective studies can answer strategy questions: whether and how to deliver MDA as well as whether and how to add or enhance vector control.

9. **Progress with dengue prevention and control**

The presentation was made by Dr Raman Velayudhan, WHO Department of Control of NTDs.

Dengue is probably the fastest growing infectious disease burden in the world today, and about 2.5 billion people now live under the threat of infection. The number of cases and deaths are very different between the three WHO regions that have endemic and epidemic dengue. The pattern of dengue in Africa has changed and expanded in the recent past: Cape Verde had a major epidemic in 2009, while Sudan has an on-going epidemic this year. The distribution of *Aedes albopictus* has spread dramatically over the last three decades. WHO has adopted several resolutions with regarding to dengue prevention and control. WHO published guidelines for diagnosis, management, prevention and control of dengue in 2009. Capacity building in medical entomology and vector control has been supported by WHO through several postgraduate courses run in endemic countries. WHO’s expertise and work on the many aspects of dengue are now better coordinated through the Wider Dengue Group.

The key challenges in dengue control include resistance of the vector to temephos; inadequate tools for vector surveillance; lack of rapid diagnostic tests for early detection of cases and immediate response with vector control; and a more accurate estimate of the burden of dengue using serodiagnostic tools as well as case reports. Several new tools are available for vector control but they need to be used in an appropriate manner. The need for better advocacy and communication strategies and for capacity building was highlighted.
**STAG recommended enhanced advocacy for dengue** as a vector-borne disease amongst the larger group of NTDs at global and regional levels, and to advocate for mobilization of more resources through NTD partnership. The need to increase awareness among policy-makers and health administrators (especially in AFRO and EMRO regions) as well as the pharmaceutical and health diagnostics industries were highlighted. They also suggested WHO consider how best to orchestrate expanded activity on dengue within the organization.

Research priorities include the need to develop assured-quality rapid diagnostic tests; to develop antiviral agents that can be used for treatment and prevention of mortality; to develop an effective vaccine against dengue.

**Final recommendations**

**General issues**

1. The gains and challenges presented in the first global report on NTDs have been amended as proposed by STAG members and submitted for inclusion in the report. The report was endorsed and recommended for presentation to WHO’s Director-General for publication by the WHO.
2. The work done by the Department of Control of NTDs was strongly endorsed and indeed praised. The first global report on NTDs should be used for advocacy and as a means of broadening the resource base that supports NTD control, in both developed and emerging economies.
3. WHO should continue to support the working groups since their establishment has facilitated better focus on specific areas of concern in NTD control.
4. WHO should formulate a more detailed proposal for establishing a Global Forum for NTDs and circulate it to STAG members by November 2010.
5. WHO should further explore the idea of developing a business plan to identify global demand for NTD medicines, in order to make a better case for attracting funding for developing new and improved pharmaceutical products against NTDs, and expanded manufacturing facilities in both developed and emerging economies.
6. WHO should strengthen capacity in regional offices and within-country NTD capability to correspond with growth in the Department of Control of NTDs at headquarters, in order to assure expansion of access to interventions at regional and national levels.
7. At national level, NTD control and treatment should be better integrated into the health system in all countries, with linkages, where necessary, to educational systems.
8. Capacity building and training of health professionals in the area of NTDs should be supported at all levels by WHO and by Member States as an urgent priority.

**Specific issues**

9. Mechanisms should be established for procuring quality-assured supplies of praziquantel for schistosomiasis control and albendazole for control of soil-transmitted helminthiasis (as lymphatic filariasis control programmes are phased out).
10. Zoonotic NTDs are of growing importance. The Department of Control of NTDs should increase collaboration with other sectors involved in the prevention and control of these diseases, and establish another working group.
11. Monitoring and mapping is important and high-quality studies should be carried out in order to provide evidence of the effectiveness of control programmes.
12. Drug efficacy is not a major problem as yet, but constant vigilance against the emergence of drug resistance is required.
STRATEGIC AND TECHNICAL ADVISORY GROUP
FOR NEGLECTED TROPICAL DISEASES 2010

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Meeting on the WG on Monitoring of Anthelminthic Drug Efficacy
Department of Control of Neglected Tropical Diseases (NTD)
28 June 2010
WHO, Geneva, Switzerland

Chair: Professor Mamoun Homeida
Rapporteurs: Dr Marco Albonico, Dr Kwablah Awadzi
Tables by Drug: BENZIMIDAZOLES Albendazole/mebendazole (parasite targeted STH).
- future parasites that may be addressed because of collateral impact in special studies:
  Taeniasis, Giardiasis, Strongyloidiasis.

Major progress was the implementation of a multicentric albendazole efficacy trial that shows with SOP that efficacy of albendazole is sustained for Ascaris and hookworms whilst confirm poor efficacy for Trichuris regardless of drug pressure.

<table>
<thead>
<tr>
<th>PROGRESS</th>
<th>FUTURE STEPS</th>
<th>CROSS-CUTTING ISSUES</th>
<th>RECOMMENDATIONS FOR STAG</th>
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</thead>
<tbody>
<tr>
<td><strong>SOP for field monitoring /GUIDELINES</strong></td>
<td>Multicentric study in 7 countries to monitor albendazole efficacy with SOP (sampling, diagnostic method, post treatment assessment, statistical analysis), performed.</td>
<td>Develop guidelines for SOP for BZ efficacy. Implement a multicentric study to monitor mebendazole efficacy. Implement an efficacy study on triclabendazole for fascioliasis for developing SOP.</td>
<td>Monitoring drug quality. Integrated parasitology monitoring with Schistosomiasis. Link with disease- specific impact monitoring. Cure Rate alone is not a good indicator for BZ efficacy (unless stratified by class of intensities). FECR is the best indicator for BZ efficacy. Suggestion to change the existing WHO thresholds for BZ efficacy for STH.</td>
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<tr>
<td><strong>LABORATORY NETWORK</strong></td>
<td>Potential laboratories exists but lack of network</td>
<td>Establish a network through identification of available centre of excellence in each region to build capacity for BZ drug efficacy monitoring. Training of staff on SOP for BZ efficacy monitoring at regional level</td>
<td>Collaboration between any existing networks for other NTDs. Link with future initiatives for capacity building in PCT Ref laboratories to be assigned in each Region to build capacity for comprehensive drug efficacy monitoring</td>
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<tr>
<td>REPOSITORY OF SAMPLES</td>
<td>None yet</td>
<td>Establish SOP for repositories of samples for STH, particularly for Ancylostoma, Necator, and Trichuris. Need to collect potentially resistant strains</td>
<td>SOP for repositories of samples to be coordinated for other parasites</td>
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<tr>
<td>RESEARCH/CONTROL ISSUES</td>
<td>None</td>
<td>More sensitive diagnostic methods to be explored (FLOTAC, dipstick with copro-antigens, serum antibodies).</td>
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<tr>
<td>MOLECULAR TOOLS FOR EARLY DETECTION OF AR</td>
<td>Non available yet</td>
<td>Comparing sensitive and resistant strains in order to understand the molecular basis of BZ resistance</td>
<td></td>
</tr>
</tbody>
</table>
Tables by Drug. PRAZIQUANTEL (parasite targeted *S. mansoni, S. haematobium, S. japonicum, S. bovis hybrids*)

- future parasites to be considered: Food-borne Trematodes apart from Fasciola.

Summary: major progress in genetic monitoring that shows that MDA with PZQ narrows the genetic diversity but no treatment failures have been observed.

<table>
<thead>
<tr>
<th>PROGRESS</th>
<th>FUTURE STEPS</th>
<th>CROSS-CUTTING ISSUES</th>
<th>RECOMMENDATIONS FOR STAG</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SOP for field monitoring /GUIDELINES</strong></td>
<td>Limited. Studies for monitoring PZQ efficacy available but lack of standardization</td>
<td>Sub-group to meet up Analysis of SCORE/CONTRAST results. Fill gaps to achieve SOP Use of CCA/CAA as efficacy markers</td>
<td>Monitoring drug quality. Integrated parasitology monitoring with STH. Link with disease-specific impact monitoring</td>
</tr>
<tr>
<td><strong>LABORATORY NETWORK</strong></td>
<td>Existing networks (SCI/SCORE/CONTRAST)</td>
<td>Identify available centre of excellence in each region to build capacity for PZQ drug efficacy monitoring</td>
<td>Collaboration between any existing networks for other NTDs</td>
</tr>
<tr>
<td><strong>REPOSITORY OF SAMPLES</strong></td>
<td>Ongoing at SCI. Proposal to Wellcome Trust to establish one at NHM</td>
<td>Establish SOP for repositories of samples for schistosomes</td>
<td>SOP for repositories of samples to be coordinated for other parasites</td>
</tr>
<tr>
<td><strong>RESEARCH/CONTROL ISSUES</strong></td>
<td>Major advances in genetic monitoring according to SOP. Phenotype test for miracidia being developed</td>
<td>How to apply genetic monitoring in operational field settings</td>
<td>How genetic monitoring can be applied to other parasites</td>
</tr>
<tr>
<td><strong>MOLECULAR TOOLS FOR EARLY DETECTION OF AR</strong></td>
<td>Non available YET. Validation of candidate genes for OXA resistance ongoing</td>
<td>Possible application of OXA resistant genes for PZQ resistance</td>
<td>Reinforce North to South collaboration on molecular tools</td>
</tr>
</tbody>
</table>
There has been reports of sub-optimal response of adult female worms to multiple doses of ivermectin manifested by a rapid repopulation of skin by microfilaria. A suggested alternative explanation is poor geographical and treatment coverage with high probability of reinfection. Recent information obtained from 12 sites in five countries in Africa confirmed earlier findings that the elimination of *O. volvulus* infection is feasible.

### Tables by Drug. IVERMECTIN (parasite targeted Onchocerca and LF)

<table>
<thead>
<tr>
<th>PROGRESS</th>
<th>FUTURE STEPS</th>
<th>CROSS-CUTTING ISSUES</th>
<th>RECOMMENDATIONS FOR STAG</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SOP for field monitoring /GUIDELINES</strong></td>
<td>The epidemiological evaluation guideline has been revised to incorporate sample collection, preservation and transportation to a reference laboratory</td>
<td>Review the overall approach and revise the guideline including the sampling of efficacy monitoring sites taking into consideration the new development in the landscape of oncho elimination Criteria for interpreting data to be determined To develop similar SOP for LF</td>
<td>Linking with other institution involved with collection and storage of samples</td>
</tr>
<tr>
<td><strong>LABORATORY NETWORK</strong></td>
<td>Potential laboratories has been identified and submitted a proposal which have been reviewed</td>
<td>Review previous work done with the view to transfer technology to African laboratories</td>
<td>Linking with other institution involved with collection and storage of samples</td>
</tr>
<tr>
<td><strong>REPOSITORY OF SAMPLES</strong></td>
<td>APOC started to collect samples from epidemiological evaluations</td>
<td>• PDT will define information required to be provided with each sample to facilitate interpretation of genetic data. • Establish SOP for repositories of samples for LF</td>
<td>Linking with other institution involved with collection and storage of samples</td>
</tr>
</tbody>
</table>
### RESEARCH/CONTROL ISSUES

Product Development team (PDT) has been reactivated to continue the research where they left off some years ago.

Assay the material that has been collected to study the molecular markings.

Collaboration with scientist working in similar research work.

### MOLECULAR TOOLS FOR EARLY DETECTION OF AR

Not available yet.

Genetic markers previously identified by TDR PDT will kick-start the process.

Resumption of work on the genetic markers will be with the view of technology transfer to African partners.

Reinforce North to South collaboration on molecular tools.

### POTENTIAL NEW ANTHELMINTHIC DRUGS

**TRIBENDIMIDINE:** converted to amidantel (nicotinic agonist like pyrantel/levamisole). Partnership between STI - Chinese manufacturer - One World Health is ongoing to develop this product.

**MOXIDECTINE:** drug in phase 3 clinical trials for onchocerciasis. Challenge: how much better is than ivermectin and likely shares same mechanism for resistance.

**FLUBENDAZOLE:** approved for human use for GI nematodes. Gold standard macrofilaricide in animal models but it is not orally bioavailable: need of different formulation.

**EMODEPSIDE:** not good against filarial but very potent against onchocerca in cultures.

**DERQAUNTEL and MONEPANTEL:** New anthelmintics that target nicotinic receptors but different from those of levamisole/pyrantel. Drugs targeted for ruminants but probably not good for ascaris and filaria:

TDR anthelminthic research project: Monepantel, Nitazoxanide, Emodepside, Oxibendazole
CHALLENGES FOR MONITORING DRUG EFFICACY/RESISTANCE FOR HAT, LEISHMANIASIS, CHAGAS

HAT. Drugs available: melarsoprol, pentamidine, eflornithine, nifurtimox plus eflornithin.

LEISHMANIASIS. Drugs available: Pentostam, Amphotericin B, Paromomycin, Miltefosine. Drugs are given: oral drug given for 28 days, theratogenic, not yet resistance in the field but selected in the lab: mutation of drug transporters. Used also resistance is likely to occur. Possible fluorescent test for miltefosine resistance

CHAGAS. Drugs available: Nifurtimox, Benznidazole

Challenges:
1) Parasite remains quiescent for many years: diagnosis and markers of cure difficult.
2) New drugs are slow to emerge
3) No standardized reporting system for treatment failures
4) No definitive tests for resistance
5) Difficulties of measuring drug effects, parasite burden
6) Trypanosomes are difficult to isolate and investigate at molecular level.
7) Drugs are either toxic or difficult to use because of route of administration (IM or EV) and length of treatments.
8) Potential of cross resistance between dogs and man (leishmania) and between cattle and man (HAT) because use of the same drugs.

RECOMMENDATION TO STAG

This group of NTDs would benefit from a dedicated working group on drug efficacy monitoring. Separate sub-groups should be established (based on diseases and not on drugs) but linkages with WG on anthelminthic resistance monitoring should be maintained for cross-cutting issues.
2nd Meeting of The Working Group on Access to Assured-Quality Essential Medicines for Neglected Tropical Diseases (WGA)
WHO HQ, Geneva, Switzerland - 28 June 2010

Minutes

List of Participants – (see Attachment 1)

The meeting, under the chairmanship of Prof. Nilanthi de Silva, commenced at 9.00 a.m. Prof. Samuel Asaolu kindly accepted to act as Rapporteur.

Dr. Lorenzo Savioli welcomed the participants and highlighted the main topics of the meeting. The Chairperson, Prof. Nilanthi de Silva, reiterated the mandate given to the WGA by the STAG and the points to be addressed in the discussions

Agenda Item 1 - Template for National Plans for NTD Control and Single Application Form for Medicines - presentations by P. Mbabazi and M. Rosenberg

Dr Pamela Mbabazi, NTD/PCT, presented a template for national plans that has been developed through intensive collaboration with countries. She described a comprehensive, multi year Country Plan of Action (PoA) addressing 4 main components: (i) scaling-up plan; (ii) standard budgeting tool; (iii) in-country mobilization of resources; (iv) "gap" funding. Its main content is as follows:

2. Endemic situation of NTDs: epidemiological situation of each NTD, current situation of control activities, co-endemicity of NTDs.
3. National plan for integrated NTDs control, including: one national steering committee to coordinate and integrate implementation of activities; integrated activities such as mapping, trainings, MDA schedules, social mobilization, monitoring and evaluation, morbidity control, improving water and sanitation, vector control, etc.
4. Budget summary: Total budget - Total funded = Funding gap

Dr Mbabazi also outlined a standardized Joint Reporting Form (JRF) adopted in Bamako, Mali, 2010. Its aim is to minimize the burden of reporting, improve timeliness and completeness of national reporting of implementation and morbidity data. Meetings of national NTD programme managers reiterated the need to develop joint drug request forms for ivermectin, praziquantel, albendazole / mebendazole, diethylcarbamazine, and azithromycin. It is on this basis that the WGA meeting of July 2009 had decided to support the development of the template of a single drug application form.

Dr Mark Rosenberg reported that the preparatory work for development of a single drug application form revealed the need for more research and analysis in order to better describe the overall picture of the procurement, supply and distribution cycle. After some discussion, the Working Group came to the following conclusions:

a) analysis of the procurement, supply and distribution cycle should continue;
b) existing drug application forms should be collected and a meeting of selected persons convened to discuss the content of such forms with a view to identifying areas of possible further harmonization. This meeting should take place as soon as possible and involve key staff at the Taskforce, WHO, and a small number of national NTD programme managers.

Action point: Dr M. Rosenberg.
**Agenda Item 2 - Mapping deworming activities by NGOs for STH infections. Presentation by K. Koporc**

Ms Kim Koporc presented the progress made by Children Without Worms in developing a data collection tool aimed at gathering information on deworming activities carried out by NGOs in NTD endemic countries. After some discussion the meeting came to the following conclusions:

a) the project must serve to strengthen collaboration between WHO, Ministries (both Health and Education), and NGOs;

b) the information collected should be posted on the WGA web site that is password protected. Access to information will be limited until data is validated and considered reliable; it may be then posted on WHO/NTD web site with a clear indication that such data is from NGO sources (but see point d below);

c) CWW will continue to be the focal point for this activity;

d) After the current data collection exercise is completed, the WGA will study the information collected and decide on how to use, disseminate, and maintain it.

Action point: Kim Koporc

**Agenda Items 3 and 4 - Prequalification of APIs for NTD medicines and The market for praziquantel from 2010-2015: procurement and quality assurance aspects. Presentations by V. Reggi and D. Daumerie**

Dr Valerio Reggi and Dr Denis Daumerie presented proposals for a Quality Assurance Policy and a Coordination Mechanism for the procurement of praziquantel for large scale preventive chemotherapy interventions. After some discussion the meeting came to the following conclusions:

a) coordination among major schistosomiasis control initiatives is essential;

b) the following recommendation should be submitted to the STAG for consideration and possible endorsement:

> To achieve maximum benefit from the increased resources made available for preventive chemotherapy aimed at schistosomiasis control, a coordination mechanism should be established as soon as possible, in particular to consolidate demand forecasts, to agree on common quality standards for procurement and to consider other ways to ensure supplies to meet the demand for quality-assured drugs. It shall function as a collaboration within the scope of the WGA and invite participation from all major schistosomiasis control initiatives such as WHO, DFID, USAID, UNICEF, BMGF, and representation from recipient countries and implementing organizations. Such mechanism shall ensure that procurement of praziquantel is based on the following principles:
>
> - driven by country needs;
> - shared information among all participating entities;
> - coordination of procurement timing and specifications;
> - establishment of common quality assurance guidelines;
> - transparency of procedures and absence of conflicts of interest;
> - autonomous purchase decisions by each participating entity.

The common quality assurance guidelines shall be formulated by the participating entities taking into account the Global Fund's Quality Assurance Policy and making use of appropriate independent assessment procedures.

Action points: Denis Daumerie and Valerio Reggi
**Agenda Item 5** - Survey on quality of NTD medicines - Presentation by V. Reggi and Doan Cao Son

The meeting was informed on the progress made. Seventy-two samples of albendazole (27 samples), diethylcarbamazine (3), ivermectin (1), mebendazole (34) and praziquantel (7) have been collected in Laos PDR, Thailand and Vietnam. These samples are being tested at the WHO prequalified laboratory of Hanoi, Vietnam. Samples are now being collected in Mali, Niger and Senegal and will be tested at the WHO prequalified laboratory of Rabat, Morocco. Results of both arms of the survey will be complete by October 2010.

**Action point:** Valerio Reggi

**Agenda Item 6** - Supply issues that may reduce risks of operational errors - Presentation by K. Gustavsen

Concurrent or proximate use of many drugs for integrated or coordinated MDA creates potential for confusion between various drugs during pre-distribution handling and at time of distribution. After some discussion the meeting came to the following conclusions:

a) to fully appreciate the incidence of confusion and to better understand the need for methods to address any confusion, WGA will actively solicit input on actual issues of confusion from various stakeholders while field-testing the safety manual (see Activity 8).

b) to evaluate the potential for confusion between the other drugs, and to ensure a complete list of the drugs used in NTD MDA programs, WGA will gather input from field programs and NTD stakeholders while carrying out the survey of supply chain issues (see Activity 7).

**Action point:** Ken Gustavsen

**Agenda Item 7** - Survey on supply chain issues - Presentation by D. Daumerie

Availability of NTD medicines is hindered or delayed by hurdles/problems in transportation, customs clearance, storage, and other supply chain steps. However, there has been no systematic collection of facts concerning these problems. Neither has there been a satisfactory analysis of the problems and identification of strategies to overcome them.

Purpose of the survey: a) to obtain information on flow of NTD medicines throughout supply chain, b) to identify problems, hurdles, and useful elements for improving effectiveness of NTD medicines supply chain, and c) to develop data collection tools which will contribute to standardizing the assessment of supply chain issues. Survey will commence later in 2010.

**Action points:** Denis Daumerie and Patricia Atkinson

**Agenda Item 8** - Draft manual on medicines safety in preventive chemotherapy interventions - Presentation by V. Reggi and Hitit Sillo

A draft manual 'Assuring Safety Of Preventive Chemotherapy Interventions For The Control Of Neglected Tropical Diseases - Practical Advice For National Programme Managers On The Prevention, Detection And Management Of Serious Adverse Events' has been prepared and widely circulated for comments. Input from WGA members as well as from WHO's Advisory Committee on the Safety of Medicinal Products has been incorporated in the final draft. Aim of the manual is to assist national programme managers to establish safety surveillance systems to better manage serious adverse events occurring in conjunction with large scale preventive chemotherapy interventions. The manual will be field-tested, later this year, in Tanzania and possibly in at least one additional endemic country.

**Action point:** Valerio Reggi

**Agenda Item 9** - Next steps

A new manual is in preparation: 'Marketing Authorization Of Selected Medicines For Neglected Tropical Diseases'. It includes practical suggestions such as checklists, flow charts, and model
evaluation reports that will be of assistance to regulatory authorities that have to assess
documentation with a view to authorizing the marketing of medicines used in the treatment of
NTDs, especially those used in preventive chemotherapy interventions. The specific focus of this
manual is on medicines used in soil-transmitted helminthiasis, lymphatic filariasis,
schistosomiasis, and onchocerciasis. The manual is based on and complements the existing
WHO manual on the assessment of applications for marketing authorization of generics. The
first draft is expected to be circulated for comments by September 2010.

Action point: Valerio Reggi
Second Meeting of Working Group on Access to Assured-Quality Essential Medicines for Neglected Tropical Diseases (WGA)

Geneva, 28 June 2010
WHO, Room D-46031

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The M and E Working Group consisted of three sub groups which each reported separately, plus a group who considered the mapping approach.

(1) Integrated mapping approach

During the past year the group has undertaken consultative meetings and developed draft guidelines that are in the process of being reviewed. The WG had developed the following conclusions and recommendations:

- The goal of disease mapping is to produce geographic drug-package delivery plans that result in action (intervention).

- The purpose of developing integrated mapping guidelines is to identify areas of opportunity for NTD programs to maximize their resources, not to standardize individual disease programs against one another.

- The WG recommended that there is no need to change WHO’s established disease specific indicators or thresholds in order to develop integrated mapping guidelines. However, disease specific objectives must be maintained in NTD programs.

- The WG noted that NTD programs can’t afford to wait for all or “perfect” data before beginning interventions. There is an urgency to take advantage of current momentum, support, and resources for NTDs – which is unprecedented and won’t exist indefinitely.

Challenges noted by the subgroup as priorities to be addressed in coming year:

- Countries often wish to prioritize non-PCT NTDs, these need to be included in the National Plans of Action
- Countries want to gather “new data” rather than relying on old data; thorough review and assessment of existing data needs to be done in situation analysis/POA
- There is a need to streamline and improve flow of data from mapping to M&E to impact assessments. The country roll-out strategy should address this—the POA should generate standard elements (the country disease map, establish M&E indicators and elimination targets) that can then be used for monitoring and impact.
- For impact assessment, integrated sentinel sites may be the best way to monitor disease-specific impact. It is important to identify the sites at program outset.
(2) Working sub-group on Programmatic needs for monitoring and evaluation in neglected tropical diseases programmes

During the last year the group undertook a meeting in Addis Ababa attended by 23 country representatives from the Africa region.

Conclusions from the working group are summarized below:

1. Most NTD control programmes have defined a minimum set of quantitative indicators. Drug coverage is common indicator for all PC diseases that can be reported in an integrated manner. A WHO guideline - *Monitoring drug coverage for preventive chemotherapy* - has been developed to facilitate reporting drug coverage.

2. Conversely, IDM programme indicators are quite diverse and no integrated indicator has been defined.

3. A vast set of indicators are required for the effective monitoring and evaluation of NTD control programmes, separately and collectively. Preliminary efforts undertaken at the meeting identified sets of core and complementary indicators, along with the related data requirements for PCT and IDM programmes.

4. Categorization of all indicators identified into a comprehensive framework has been proposed. Some indicators in NTD programmes should be part of routine national health information management systems for reporting and tracking morbidity (particularly for the IDM strategy), and included in the IDSR reporting system wherever appropriate.

5. Programme-specific M&E guidelines and related tools have been developed for a number of NTD control programmes. However, many of these guidelines need to be updated or revised, and subsequently adapted for use in an integrated manner at Regional and National levels.

6. Disease-specific programme manager’s guidelines are available for a few NTD control programmes (mainly for PCT). Some programme-specific tools have been developed to facilitate the monitoring and management of a particular component of the programme, such as Buruli ulcer data collection forms (BU01, BU02), drug supply and utilization (e.g. ivermectin requisition). However, these exist in isolation of comprehensive guidelines that should encompass all aspects of programme management.
Specific recommendations

Work within the integrated national NTD program context and according to the national NTD control plans which also govern the monitoring and evaluation of activities at national level

Gather existing tools to develop standard integrated tools to facilitate programme management, particularly for cross-cutting issues that are common to all NTD control programmes, including:

- Standardized macro and micro planning approaches and formats
- Joint reporting forms for MDA and other program activities
- Joint drug request forms
- Integrated NTD database, decentralized at country level
- Standardized checklist for program evaluation
- Advocacy and resource mobilization kits
- Capacity building for program management, especially for district level
- Promote and facilitate the adoption and adaptation of new mobile communication technologies to complement current information management infrastructure

Priority activities for Next Year

Finalize comprehensive M&E framework (WHO PCT guidelines in press) AFRO regional guidelines for planning and implementation of NTD control activities should be finalized by the end of Dec 2010. Focus on AFRO with expectation that it can be adapted to other regions.

Technical meeting to standardize software and tools. Pilot-test for the use of mobile technologies in PCT in countries where NTD integration are currently implemented.

(3) Disease-Specific Indicators Sub-group

During the past year the sub-group developed summary tables of key features for mapping and monitoring NTD control programs, including highlighting areas where additional efforts are needed, either through operational research or development and dissemination of guidelines.
### Priority disease-specific M&E Activities

<table>
<thead>
<tr>
<th>NTD</th>
<th>Objective</th>
<th>Activities</th>
<th>Potential Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onchocerciasis</td>
<td>Adapt criteria to verify the elimination of onchocerciasis to the African context</td>
<td>Draft LOI Consultation to develop work plan</td>
<td>WHO, APOC, BMGF, CDC, Carter Center</td>
</tr>
<tr>
<td></td>
<td></td>
<td>M&amp;E WG to summarize results of Gates-supported phase 2 studies undertaken by Task Force and partners WHO consultation to review data and draft guidelines Operationalize guidelines</td>
<td>WHO, Task Force, CDC, CNTD, WHO , USAID</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Screen new antigen candidates Document assay sensitivity and specificity Validate assay utility for field use</td>
<td>WHO, NIH, CDC, USAID</td>
</tr>
<tr>
<td>Lymphatic Filariasis</td>
<td>Introduce new guidelines for stopping MDA and conducting post-MDA surveillance</td>
<td>Develop new diagnostic tools for post-MDA surveillance which are <em>W. bancrofti</em>-specific</td>
<td>WHO, Task Force, CDC, CNTD, WHO , USAID</td>
</tr>
<tr>
<td>Schistosomiasis</td>
<td>Develop guidelines for altering MDA frequency</td>
<td>Review existing data WHO consultation to draft recommendations Evaluate urine antigen test and other appropriate tools in the field Further validate tools to verify elimination (human antibody testing; PCR-DNA on snails) Review data</td>
<td>WHO, SCORE, Carter Center, SCI, USAID, CDC SCORE, SCI, CDC, academic institutions</td>
</tr>
<tr>
<td>Soil transmitted helminths</td>
<td>Develop recommendations to scale down treatment frequencies or for implementing STH programs following cessation of MDA for LF</td>
<td>M&amp;E WG to draft initial recommendations WHO consultation to review recommendations</td>
<td>Children without Worms, WHO, involvement of WHO WG on Drug Efficacy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evaluate tools needs via WHO-consultation Draft LOI</td>
<td>WHO, ITI, CDC, academic institutions</td>
</tr>
<tr>
<td>Trachoma</td>
<td>Develop tools for stopping MDA and post-MDA surveillance</td>
<td>Evaluate tools needs via WHO-consultation Draft LOI</td>
<td>WHO, ITI, CDC, academic institutions</td>
</tr>
</tbody>
</table>
Priorities for next year

- Convene meeting of sampling methodology experts to move towards a harmonized guideline for verification of testing of various survey methodologies for post-elimination diseases, especially trachoma
- Tailor existing guidelines for epidemiologic and diagnostic tools (July diagnostics workshop)
- Develop a harmonized approach for sentinel sites for integrated NTD control programs
- Harmonize among disease programs to develop impact assessment approaches
- Establish links with drug efficacy monitoring group to see if survey methodologies can be developed to monitor emerging resistance.

(4) Enhanced outcomes and impact working group

The purpose of the WG is to identify enhanced outcomes and impacts which could be measured, especially:

- Increased numbers of people protected against groups of diseases
- Efficiencies and economies of scale in implementation
- Increased cost-effectiveness of integrated interventions

During the past year the WG has focused on implementing a literature review which resulted in conclusions and recommendations as follows:

- Need to develop an agenda for the evaluation of the impact of PCT on the health and socio-economic status of beneficiary populations potentially involving design of studies carried out in various endemic situations.
- Need to examine existing evidence on enhanced outcomes and impacts indicators of preventive chemotherapy that can be used to develop and/or enhance advocacy messages for a wide range of partners.
- Need to broaden the participation of the WG to include expertise in health systems, social and socio-economic disciplines, health education, and health promotion.
**Priorities for next year**
During the year the WG will examine the enhanced outcomes identified, to identify research gaps and prioritize research activities to fill the gaps
For example priority impact indicators that will target new donors may include:

1. Gender Equity & Maternal Health
2. Nutrition in Children and Children
3. Morbidity/Disability
4. Education
5. Health System Strengthening
6. Economic Status

**Summary – Requested endorsements by STAG 2010**

1. The WG asks STAG to assist WHO in identifying and mobilizing sufficient resources to meet the requirements of the Global M&E WG, and the Global WGs in general.

2. The WG has developed a strategy and approach for integrated mapping, while APOC is developing another approach. These efforts need to be harmonized. STAG should charge the two groups to harmonize the two approaches to avoid duplication.

3. The WG recommends that STAG in turn recommends to the DG that treatment coverage for PCT NTDs – as per WHA resolutions - should be included in country level sector-wide indicators.

4. The WG recommends that WHO should convene a consultation to alter M&E guidelines to incorporate new methods for stopping LF MDA.

5. The WG observed that the Secretariat should include the participation of a member of the trachoma and APOC programs in the M&E WG.