The Strategic and Technical Advisory Group for Neglected Tropical Diseases (STAG-NTD) held its sixth meeting at the headquarters of the World Health Organization (WHO) in Geneva, Switzerland, on 29–30 April 2013. The list of participating members, observers and secretariat is attached as Annex 1.

**Day 1**

Dr Hiroki Nakatani, WHO’s Assistant Director-General for HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases (WHO/HTM-NTD), opened the meeting on behalf of the Director-General, Dr Margaret Chan, and welcomed the new Chairman of STAG, Professor Peter Holmes, the five new members and all other participants. Dr Nakatani emphasized that NTD is firmly positioned in WHO’s corporate strategy and future activities for the next six years; that NTD is a showcase for global health by setting an example of how to build public–private partnerships; and that NTD is a pathfinder for achieving the health-related Millennium Development Goals (MDGs) and setting the post-MDG agenda.

The Chairman, Professor Peter Holmes, welcomed the new members of STAG and emphasized the need to work together towards achieving the common goals of NTD control.

1. **Report from the NTD Director on status, progress and challenges with NTD control**

Dr Lorenzo Savioli (Director, WHO’s Department of Control of Neglected Tropical Diseases) presented highlights for the period 2012–2013, the key achievements in NTD control, the Department’s response to recommendations made by STAG in 2012, and key issues to be discussed at the meeting.

Highlights from the past year included the publication of the WHO Roadmap (January 2012) with clear identification of 5 interventions to overcome NTDs and the importance of capacity strengthening to implement interventions; publication of the second WHO Report on NTDs (January 2013); the resolution on all 17 NTDs recommended by the 132nd Executive Board for adoption by the 66th World Health Assembly (May 2013).

Key achievements during the past year included marked progress towards eradication of dracunculiasis and the strategy for yaws eradication; good progress towards the target for the elimination of human African trypanosomiasis and blinding trachoma; progress towards elimination of the visceral leishmaniasis in the Indian subcontinent; promising results for diagnosis and treatment of Buruli ulcer; development of a global control strategy for dengue; capacity strengthening for integrated vector management; and establishment of a Vector Control Advisory Group to advise STAG and the Malaria Policy Advisory Committee. Much progress has been made in communications and capacity strengthening through the CCB Unit that has been established under the Director’s office.
Dr Savioli summarized the current status of preventive chemotherapy for NTDs. He noted that the trajectory at the current rate of scaling up needs to increase if the global target is to be met. Coverage of mass drug administration for lymphatic filariasis in the African Region is only 25% and needs to be accelerated. Onchocerciasis elimination in the Region of the Americas is progressing well whilst the focus in the African Region is shifting from control to elimination. Although the availability of praziquantel will increase markedly over the coming years, expanded supply must be accompanied by strengthening the capacity to prevent and manage severe adverse events.

Good progress has been made in relation to all the recommendations made by STAG in 2012.

STAG congratulated the Department on its achievements during the past year.

2. Report from the Working Group on Capacity Strengthening for NTDs (WG-CS)

Professor David Molyneux, Chairman of the Working Group on Capacity Strengthening, presented the report of the Global Working Group (see Annex 2 for full report).

The objectives of the WG-CS are to:
- identify existing CS efforts
- recognize gaps in CS efforts and prioritize short- and long-term needs
- advise, standardize and support the implementation of training curricula to strengthen managerial and technical capacity for NTD control
- harmonize partners’ efforts and increase their contribution to fill identifiable gaps, qualify monitoring and assess CS products.

A conceptual framework of thematic areas for capacity strengthening in preventive chemotherapy was presented. Professor Molyneux noted the magnitude of the effort that will be needed to bridge the treatment deficit in order to meet the targets for preventive chemotherapy set out in the WHO Roadmap, and the need to focus on highly populous countries that contribute to this deficit.

Proposed activities in 2013 include reinforcing the South–South collaboration; building on existing platforms particularly in the African and South-East Asian regions; preparing an inventory of regional laboratory capacity; developing standardized accreditation criteria for NTD reference laboratories; adapting training workshops for national programme managers with regional focus in the Region of the Americas; organizing training workshops for activities focussed on control of soil-transmitted helminthiases in central Asia in the European Region; developing eLearning platforms for national preventive chemotherapy programme managers and monitoring and evaluation officers, and for the Joint Reporting Form and Joint Request for selected preventive chemotherapy medicines. Development of an “NTD app” will include definition and scope of the project; identification of software developers; mobilization of resources; and identification of partners. There is also a need to address legal, sustainability and intellectual property issues.

Currently available training activities that support NTD control were summarized.

The proposed workplan for WG-CS in 2013 includes identifying training material to be adapted to the eLearning concept; harnessing existing institutional capacity for laboratory strengthening; developing a regional network of training institutes; identifying cadres of trainers and organizing the first training of trainers for programme managers in the African Region; preparing ‘job descriptions’ for national NTD teams; and building requisite skills around these descriptions.

Recommendations to STAG
- Prioritize capacity strengthening in order to achieve the Roadmap’s goals.
- Harmonize partners’ activities towards capacity strengthening and the Roadmap’s goals.
• Focus capacity strengthening on ‘mega countries’ to reduce the implementation deficit at all levels, including district level.
• Utilize most appropriate available technologies (eLearning and NTD app) and existing structures within countries more effectively to achieve sustainable capacity.
• Maintain the momentum through ongoing technical focus, e.g. monitoring and evaluation, transmission assessment surveys, and managerial and advocacy skills.
• Examine needs for capacity strengthening in integrated vector management, intensified disease management and neglected zoonotic diseases during 2013–2014.

STAG endorsed the recommendations of WG-CS.

3. Economics of NTD control

Professor Deborah McFarland and Mr Chris Fitzpatrick made a joint presentation on the ‘Economics of NTD control: evidence to action’. There is no shortage of papers in PubMed on the economics of NTDs, but only a small percentage are dedicated economic studies with ‘economics’, ‘cost’ or ‘finance’ in the title – most studies refer to cost and cost-effectiveness only in the discussion. An even smaller percentage of these studies mention NTDs and most studies are disease-specific, but 21 dedicated economic studies have been published in the first quarter of 2013. There is a need for a common language for costing resource inputs for NTDs, along with an understanding of where NTD strategies are on the cost curves.

The NTD Department’s plans include identifying resource needs and tracking available resources at country level; disseminating new economic evidence; and supporting countries to finance scale-up. The Department proposes to achieve these goals by expanding its network within and outside the Department with WHO regional and country offices; partner organizations and institutions; new recruits; and STAG. A concept note regarding the WHO Task Force for Enhanced Monitoring of the impact and outcomes of Preventive Chemotherapy and control of NTDs (EMPaCT Task Force) was circulated.

Options for STAG in providing guidance and support to WHO’s work on NTD economics and translating available evidence into recommendations include:

• leaving the economics work as an informal network outside of STAG
• mainstreaming economics work within existing STAG structures (e.g. M&E), or
• creating a new working group to guide, support and translate evidence for public policy and finance.

4. Special Programme for Research and Training in Tropical Diseases (TDR)

Dr John Reeder, Director of TDR, made a presentation entitled ‘Making a difference: the Special programme for Research and Training in Tropical Diseases’. He summarized the mission and vision of TDR; its past achievements and challenges; the recent restructuring, renewed focus and the new TDR Strategy for 2012–2017; the criteria for setting priorities and implementation strategies, especially research capacity strengthening; and the intervention and implementation research planned for 2014–2015.

Professor Nilanthi de Silva, Chairman of the Working Group, presented a summary report of the activities undertaken by members and the Fifth meeting held on 26 April 2013. The detailed report is attached as Annex 3.

Presentations at the Fifth WGA meeting included global access to quality-assured praziquantel: update for 2012–2013; serious adverse events and pharmacovigilance in preventive chemotherapy; access to essential medicines for the Leishmaniases and quality concerns; survey on quality of albendazole and mebendazole in East Africa and South-east Asia; NGO quality assurance policy for drug procurement; and the joint request, review and reporting form for NTD medicines.

Joint planning and coordination of the global supply of praziquantel has estimated that 112 million tablets were delivered in 2012; and this is expected to increase to 172 million in 2013. The survey on the quality of albendazole and mebendazole in the three countries in the East African Community and the three countries in South-East Asia has highlighted the fact that nearly half of all samples tested in both regions did not conform to the required standards. All of the failures were due to non-conformity with dissolution standards. These medicines, however, were not provided through the donation programmes.

**Recommendations to STAG**

- Continue to use WGA as a facilitating platform for partners to monitor and manage response to evolving landscape of praziquantel availability and continue joint planning of national requirements.
- Mobilize resources to start prequalification of praziquantel, albendazole and Liposomal amphotericin B, and assist manufacturers to apply and achieve prequalification status.
- Prepare and implement quality surveys in collaboration with national regulatory authorities to assist detection of possible quality issues affecting selected NTD medicines (especially albendazole, mebendazole and anti-Leishmania agents).
- Facilitate sub-regional meetings of regulatory authorities to support their action against substandard NTD medicines not supplied through donation programmes.
- Further encourage and support countries to adopt and adapt existing tools and guidelines for safety monitoring in NTD treatment and control activities through effective collaboration between national pharmacovigilance systems and NTD programmes.
- Improve adverse event reporting and ensure its proper channeling through existing platforms for safety monitoring of medicines at national and international levels through enhanced collaboration between WHO’s NTD and EDM Departments.
- Further encourage and support countries to adopt tools developed for joint requests, review and reporting for preventive chemotherapy medicines, in close collaboration among the three WHO levels.
- Evaluate and report on the adoption of these tools at the next WGA meeting.

STAG endorsed the report of WGA.


Dr Antonio Montresor made the presentation on behalf of Professor Mamoun Homeida, Chairman WG-MDE. The detailed report is attached as Annex 4.

The working group is organized into four sub-groups: benzimidazoles (STH); praziquantel (schistosomiasis); ivermectin (LF and oncho); and IDM drugs (HAT, Leishmaniases, Chagas disease and yaws). Each sub-group works independently, has independent financial resources and reports during the annual meeting.
Achievements to date include documenting the reference levels of drug efficacy for albendazole and mebendazole; developing a manual to standardize the evaluation of drug efficacy; and preparing a mathematical model to predict the changes in STH prevalence and intensity of infection during ongoing control programmes. Molecular markers of drug resistance in *Onchocerca volvulus* and *Schistosoma* spp. have been identified. Oral azithromycin has been assessed as a valid alternative to penicillin injections for yaws, increasing the facility of administration and opening additional opportunities for integration.

In relation to STH and schistosomiasis, this includes distributing the manual on assessing drug efficacy, capacity strengthening in sub-regional reference laboratories, and including periodical evaluation of drug efficacy into routine monitoring and evaluation. The new STH predictive model needs to be validated and possible alternative drugs to be deployed if confirmed loss of drug efficacy need to be tested. The capacity of available models for schistosomiasis to predict changes in prevalence and intensity of infection in ongoing programmes needs to be tested, and novel drugs need to be developed and tested, based on new knowledge regarding drug resistance. Work to be done on LF and onchocerciasis includes conducting surveys in APOC countries to evaluate the impact of oncho interventions on LF (and vice-versa – of LF interventions on oncho in hypo-endemic areas); continuing the work on genetic markers for ivermectin resistance; developing guidelines on monitoring of drug efficacy during MDA for LF. New compounds and combinations of drugs for treatment of the Leishmaniases, HAT and Chagas disease need to be tested; and monitoring of treatment failures needs to continue.

Expected products for the next STAG include:

- Initiation of the evaluation of praziquantel in seven countries to establish reference levels of drug efficacy against different *Schistosoma* spp.
- Validation of the predictive capacity of STH and schistosomiasis models, using data from programmes which have been operational for several years.
- Survey in APOC countries to evaluate the efficacy of ivermectin alone on lymphatic filariasis and of ivermectin/albendazole on (hypo-endemic) onchocerciasis.

It was recommended that the WG continue to meet annually to maintain pressure on delivery of the expected products. After validation of the models, it should connect with the M&E working group to standardize approaches to alert of any suspected loss of drug efficacy and develop a response policy. The WG should also connect with the WG on Capacity Strengthening to identify networks of sub-regional laboratories and build capacity for implementation of standard operating procedures to confirm suspected loss of drug efficacy.

STAG endorsed the report of WG-MDE.


The report from the Working Group was presented by the Chairman of the Group, Dr Sam Zaramba (see Annex 5 for full report). The WG has three sub-groups, which work autonomously for most of the year, cross-interacting periodically as needed between M&E subgroups and other WGs; preparing background documentation for deliberation/policy formulation; and collaborating with partners and expert committees.

Subgroup 1 (National Programme Needs) has developed several programme management tools: the format for multi-year, national master plans; a Tool for Integrated Planning and Costing (TIPAC); joint information management tools; electronic platforms for sharing preventive chemotherapy information (using Basecamp, SharePoint); and has implemented related trainings, meetings and workshops. Tools for Programme Monitoring and Evaluation include Guidelines for Monitoring Drug
Coverage, development of databases, data triangulation and analyses, mobile health (mHealth), and regular publications and updates.

Subgroup 2 (Disease-Specific Issues) has developed or updated several guidelines. These include disease-specific strategic plans to guide programme implementation towards the 2020 WHO Roadmap goals; guidelines/tools to guide transition between programme phases; a provisional strategy for STAG approval to start interventions for LF in loiasis-endemic areas (preventive chemotherapy using albendazole alone combined with vector control); morbidity management and disability prevention for LF. Work has commenced on developing a common M&E framework for LF and ONCHO. The guidelines for Verification of elimination of human onchocerciasis: criteria and procedures have been revised and are ready for STAG approval. A research grant to address priority research gaps for preventive chemotherapy, including a common platform for monitoring multiple diseases targeted by the intervention, has been mobilized. In relation to diagnostics, Subgroup 2 has developed an integrated NTD monitoring and surveillance platform and a tool using blood spots which have been collected, either independently or as part of routine health surveys (e.g. DHS or malaria indicator survey). It has also evaluated new diagnostics for LF, schistosomiasis and trachoma.

Subgroup 3 has worked on the impact of preventive chemotherapy. It has carried out a comprehensive literature review of existing evidence (2010–2012); conducted a global online survey of NTD stakeholders (in 2012) to determine evidence needs for sustaining political commitment to NTD control/elimination; and organized two major meetings, which expressed a need for multi-sectoral and multi-disciplinary efforts, defined thematic areas for required evidence, and established a Task Force for Enhanced Measurement of Impact and Outcomes of PC (EMPaCT).

Work that can be shifted to other working groups was discussed.

Planned M&E priorities for 2013:

1. Monitoring scale-up of treatment coverage:
   - Monitor use and expansion of donated medicines in scaling-up deworming efforts
   - Significantly improve timeliness, completeness and triangulation of data
   - Improve data quality: in-process assessments, evaluation of reported coverage, data storage
   - Encourage use of mHealth to improve data transmission
   - Mobilize resources to support finalization and implementation of integrated national M&E plans
   - Strengthen data collection and M&E of morbidity management and disability prevention (MMDP) activities within national programmes

2. Intensify efforts for integrated monitoring:
   - Co-implement LF, STH and SCH transmission assessments
   - Harmonize LF and ONCHO frameworks for mapping, impact evaluations and programmatic decisions
   - Accelerate access to improved and affordable diagnostic tests for NTDs for use by national programmes
3. Strengthen end-stage strategies and surveillance methods:
   - Improve diagnostic tools and sampling methods
   - Define cost-effective surveillance strategies for scale-down phase
   - Progress work on xenomonitoring for vector-borne diseases
   - Finalize the handbook of practical entomology for lymphatic filariasis elimination

Specific recommendations to STAG
   - Accept revised wording of the provisional strategy of integrated vector management and albendazole monotherapy MDA (provided once or preferably twice per year to the entire population) for LF endemic areas where loiasis is co-endemic.
   “Where Loa loa infection is present based on RAPLOA and onchocerciasis is non-endemic or hypo-endemic (that is, less than 20% of nodule prevalence), mass drug administration could be implemented with albendazole alone (400 mg) once or twice per year, with twice a year being preferable. In addition to preventive chemotherapy, integrated vector management should be implemented to accelerate interruption of lymphatic filariasis transmission. Since all areas infected with Loa loa are also endemic for malaria, and given that lymphatic filariasis and malaria in these areas share the same vector species, human populations should receive universal coverage with malaria vector control interventions targeting the vectors of both lymphatic filariasis and malaria.”

   - Accept the new guidelines for Verification of elimination of human onchocerciasis: criteria and procedures that were revised based on the request to standardize approaches being used by the two regional onchocerciasis programs, APOC and OEPA.

STAG endorsed the report of WG M&E and affirmed the proposed recommendations.

8. Plenary discussion on merging Working Groups

Dr Dirk Engels made a brief presentation on a proposal to merge the working groups related to preventive chemotherapy (WG-M&E, WG-MDE). He recalled the purpose of creating the three Global Working Groups in 2009 as platforms that brought together partners and networks in these cross-cutting areas, and summarized their main roles and responsibilities. More recently, Working Groups have been created on Capacity Strengthening and on Neglected Zoonotic Diseases. It is proposed to establish a new WG on Economics and another on Dengue this year.

Much of the normative work of the WG-M&E on national programme needs has been accomplished and can be taken over by WG-CS. WG-M&E’s work on disease-specific needs is unfinished and should be continued. Evaluating the impact of NTDs and NTD control programmes needs to include not only health but also education, socioeconomic development, and the water and sanitation sector. This work can be included in the scope of the WG on Economics and Impact of NTDs. The WG-MDE has accomplished an enormous amount of work on preventive chemotherapy medicines as well as IDM medicines. The standard operating procedures for assessing drug efficacy can be implemented by the WG-CS by improving laboratory capacity. WGA will continue to address access to and quality of NTD medicines, as well as pharmacovigilance, and management and monitoring of adverse events and serious adverse events.

The WG-M&E and WG-MDE could be merged into one Working Group on Preventive Chemotherapy Interventions, which would address norms and standards for programmatic M&E, and norms and standards for drug efficacy monitoring. WG-CS would include technical and managerial capacity for preventive chemotherapy implementation, and strengthening laboratory capacity to support anthelmintic drug efficacy monitoring.

The WG on Economics and Impact of NTDs would cover the need and evidence for impact, public policy, economics and health financing. The EMPaCT Task Force would continue its work under this
WG. This WG would need to go beyond the preventive chemotherapy diseases, and to attract a much broader range of expertise.

**Day 2**

Professor Peter Holmes summarized the most important points from the presentations and discussions of Day 1.

9. **Update report on dengue**

Dr Ron Rosenberg presented an update on WHO’s “Global Strategy for Dengue Prevention and Control, 2012-2020”, published since the 2012 STAG. The goal is to reduce the burden of dengue, while the specific objectives are (i) to reduce dengue deaths by at least 50% by 2020; (ii) to reduce dengue morbidity by at least 25% by 2020; and (iii) to better ascertain the true burden of the disease by 2015. It has been newly estimated (Bhatt *et al*, *Nature*, 23 April 2013) that there are 390 million cases annually; 75% of these are ‘inapparent’ but possibly infectious. A large proportion of reported cases are from South and South-East Asia, and Latin America but there are ongoing epidemics in Africa, from which cases are underreported. Technical elements of the strategy include: diagnosis and case management; integrated surveillance and outbreak preparedness; sustainable vector control; future vaccine implementation; and basic operational and implementation research. Advocacy and resource mobilization are very important. The results of the most advanced vaccine trial (Phase IIb/III trial of the Sanofi tetravalent vaccine) have been disappointing but there are four other vaccines at some stage of clinical trials and several other candidates that might advance to clinical trials. It seems likely that within 10 years at least one vaccine will be commercially available.

He summarized the recommendations of an expert group that met at Geneva in December, 2012 to formulate a general action plan. Since the Director-General approved the consolidation of many dengue control activities in NTD, WHO’s role should be to take a leadership position in providing specific guidance to countries on diagnosis and management of cases; vector control; coordinated outbreak management; and vaccine implementation. It was stressed that with proper clinical management deaths from severe dengue should be very rare. Innovative web-based means of training clinicians should receive priority. WHO should also play a leading role coordinating data collection on seroprevalence and clinical incidence to be used in refining the burden of disease. In particular, there is an urgent need to model how vector control and surveillance should be coordinated with vaccine implementation in order to maximize effect.

STAG endorsed the NTD Department’s work on dengue control.

10. **Update report on rabies**

Dr François-Xavier Meslin, Dr Bernadette Abela-Ridder and Dr Simone Magnino made a joint presentation on the WHO Global Strategy for Rabies Elimination. The first draft of the Strategy has been developed by WHO, FAO and OIE together with GARC and PRP. It aims to eliminate all cases of human rabies by 2030, through adoption of a canine rabies vaccine. The document will contain essential information on human and animal health and economic burden, the rationale for control and elimination, programme components, and budget requirements. Estimates of numbers of human deaths due to rabies per region suggest that the highest numbers are from Africa and Asia. Some 3 billion people live in high-risk areas. Rabies is not a candidate for true eradication because of the significant involvement of wildlife, especially bats. However, canine rabies transmission can be stopped, as has been shown in the Americas and in the Philippines. Programme components for effective rabies prevention and control include laboratory-based surveillance combined with active health education and enhanced public awareness, application of post-exposure prophylaxis (PEP) and the strategic use of potent vaccines in animals. A roadmap for regional to global elimination of
rabies has been set out. Estimated costs of the South-East Asia regional strategy have been calculated, with preliminary estimates of the annual budget for PEP and dog vaccination in WHO regions.

**Recommendations to STAG**

- Support the further development and refinement of the Global Strategy for review and possible endorsement in April 2014.
- Work towards a WHA resolution on rabies elimination in May 2014, using the strategy document.
- Advise the WHO Secretariat to further build consensus on strategy to secure renewed country commitment to regional and global rabies elimination.
- Advocate rabies control whenever possible, recognizing that human rabies transmitted by dogs is targeted for regional elimination in the WHO Roadmap and that tools and strategy for control and elimination are readily available.


Professor Malika Kachani, Chairman of the Working Group, presented the report from WG-NZD (see Annex 6 for full report). The WHO Roadmap includes five high priority NZDs, with short-term objectives up to 2015. Guidance for control and treatment of cystic echinococcosis needs to be disseminated and implemented as do guidelines for treatment and control of taeniasis/cysticercosis, and foodborne trematodes.

Work is in progress to map the co-endemicity of cysticercosis, schistosomiasis and fish-borne trematode infections, and to investigate the zoonotic causes of non-malarial febrile illness, which include leptospirosis, brucellosis, rickettsioses and Q-fever.

Proposed NZD priorities include:

- Implement innovative control packages to achieve WHO Roadmap targets for rabies and cystic echinococcosis
- Seek funding to scale up operations
- Engage more strongly with the private sector and NGOs (explore donated vaccine and praziquantel)
- Foster more effective engagement and commitment among international organizations (FAO and OIE)
- Build capacity and strengthen institutions
- Strengthen medical–veterinary collaboration and establish cross-sectoral budget as a prerequisite

Advice was sought from STAG regarding the following questions:

- Are the priorities appropriate and consistent with the WHO Roadmap?
- How can NZDs be embedded in current national NTD control programmes?
- Can we learn from institutional strengthening and capacity building programmes already in place?
- How can we use existing OneHealth models to promote inter-sectoral collaboration?
- How do we better engage with the private sector and NGOs?
- How do we resource NZD control within the country NTD portfolio?
- How should febrile illnesses be addressed given the zoonotic origin of many febrile etiologies?
12. **Update report on yaws**

Dr Kingsley Asiedu presented an update on eradication of yaws (an endemic treponematosis). The idea of eradicating yaws was first promoted in the 1950s with the discovery of penicillin, on the basis of an assumption that there was only human-to-human transmission and single-dose treatment. Although prevalence was reduced by 95% in that period, eradication was not achieved. Yaws was included in the portfolio of NTDs in 2007 because of its re-emergence in several parts of the world. The WHO Roadmap has set a target of yaws eradication by 2020. A single dose of oral azithromycin has been found to be as effective as a single injection of penicillin. The new treatment strategies are based on azithromycin and they include total community treatment and total targeted treatment.

WHO held a second consultation on eradication of yaws in March 2013, at which the final results of a study comparing azithromycin and penicillin were presented which confirmed the previous findings. A new test for yaws diagnosis is being evaluated.

The NTD Department’s contributions has amounted to a total of US$ 500 000 to date, but much more will be required to achieve eradication of yaws. Some 36 countries are identified in the ITFDE 2012 report, and while status is known in 14 countries, it is still unknown in 22 countries.

There is an opportunity for collaboration with trachoma control because of the shared use of azithromycin, but there are crucial differences in the two control strategies. There is also an opportunity for collaboration with syphilis and control programmes for sexually-transmitted infections.

Today, better tools are available – an effective oral antibiotic and a simple rapid point-of-care diagnostic test. Eradication of yaws will require more funds for implementation, and establishment of appropriate governance structures, advisory and certification bodies. Certification criteria will need to be identified. High profile political support will be necessary. A strong partner that will support the eradication strategy is essential.


Dr Anne Moore, Center for Global Health, United States Centers for Disease Control and Prevention, updated STAG on HAT, focussing on elimination of *Trypanosoma brucei gambiense*, which accounts for 97% of HAT. Progress has been slow but steady in the steps that are required for elimination. There has been an improvement since the dire situation in 1997, to establishment of a HAT Network for drug availability and identify treatment failures, along with donated medicines for treatment. A new, more effective and less toxic first-line therapy with combination eflornithine-nifurtimox has become available. A HAT database and a HAT atlas have been drawn up, and distribution of the disease is now clearly mapped – 97% of cases occur in just five countries. Individual rapid diagnostic tests are now available. The human reservoir of HAT can be relatively easily identified with mobile active screening.

The target date for elimination is 2030, but the target date for ‘elimination as a public health problem’ is 2020. Milestones and indicators have been identified for the period leading up to 2020. Interventions include active case detection with mobile teams; passive case detection with sentinel surveillance; and vector control in selected sites. The combination of interventions to be used will depend on the intensity of transmission in a given area. Strategies for monitoring and evaluation, and for verification of elimination have been identified. However, there are numerous challenges. The capacity of the health systems to implement control and surveillance activities is one of the main challenges. The reservoir of infection is also an important issue – for example, the possible role of seropositive, aparasitaemc individuals or possible animal reservoirs in maintaining transmission.
Planned future activities include publication of the new Expert Committee Technical Report and identification of pilot countries to develop strategic plans for elimination. Maintenance of centralized management and oversight of the elimination programme, and increased human resource capacity will be essential.

The afternoon session of the second day was open to partners in NTD control and other invited stakeholders.

14. **Summary of STAG deliberations**

Professor Peter Holmes presented a summary report of the proceedings of the meeting. Particular mention was made of the importance of partners in NTD control, the forthcoming WHA resolution on NTDs, and WHO’s decision to have vector-borne diseases as the theme for World Health Day in 2014.

Short presentations were made regarding the activities of WG-CS, proposed work on economics of NTD control, activities of WGA, WG-MDE, WG-M&E, WG-D and WG-NZD.

15. **Statements from partners**

STAG received a joint statement from Ms Emily Wainwright (United States Agency for International Development) and Dr Chris Lewis (United Kingdom Department for International Development) regarding activities supported by their respective agencies in relation to NTDs (see Annex 7 for full statement). STAG was assured that they will support the forthcoming WHA resolution.

STAG also received statements from OIE (rabies control at the animal source), FAO (engagement in prevention and control of NZDs), ILEP (leprosy – cross-cutting issues with NTDs), Bill & Melinda Gates Foundation (NTD projects to be supported), NTD NGDO Network, Global Network for NTDs, Deworm the World and IFPMA.
Points for follow-up action

1. STAG members are urged to fully support the forthcoming WHA resolution on NTDs.

2. With regard to Working Groups, STAG recommends that:
   a. The Secretariat reviews its organization limiting the number of WGs to not more than six.
   b. Set clear Terms of Reference and deliverables for each WG.
   c. Identify a focal point within the NTD Department for each WG.
   d. Allocate financial resources to support the activities initiated by each WG.
   e. Set targets for each WG that are to be achieved within a set time period.
   f. Develop a standardized format for each WG to use when reporting to STAG.
   g. A proposal regarding reorganization of the Working Groups should be circulated to STAG by the June 2013.

3. STAG recommends that the Secretariat strongly supports capacity strengthening at all levels, harmonizing the work of partners towards achievement of the Roadmap goals, and drawing on existing resources within countries.

4. STAG endorsed the Revised Guidelines for Verification of elimination of human onchocerciasis: criteria and procedures, subject to a few amendments suggested by STAG members.

5. STAG endorsed the latest provisional strategy to start interventions for LF in loiasis-endemic areas: “Where Loa loa infection is present based on RAPLOA and onchocerciasis is non-endemic or hypo-endemic (that is, less than 20% of nodule prevalence), mass drug administration could be implemented with albendazole alone (400 mg) once or twice per year, with twice a year being preferable. In addition to preventive chemotherapy, integrated vector management should be implemented to accelerate interruption of lymphatic filariasis transmission. Since all areas infected with Loa loa are also endemic for malaria, and given that lymphatic filariasis and malaria in these areas share the same vector species, human populations should receive universal coverage with malaria vector control interventions targeting the vectors of both lymphatic filariasis and malaria”.

6. STAG recommended that the NTD Department should work towards capacity strengthening in relation to dengue diagnosis, management, prevention and control.

7. The NTD Department should maximize the opportunity for advocacy regarding dengue and HAT that will be provided by next year’s World Health Day theme on vector-borne diseases.

8. STAG recommended continued support for WHO to develop a Global Strategy for Rabies Elimination as part of a multi-agency programme with OIE and FAO.

9. High level advocacy with identification of a strong partner who will support the target of yaws eradication.

10. Continued support for the elimination of HAT.

The STAG 2013 meeting was closed by Dr Hiroki Nakatani, who thanked all the STAG members and partners in NTD control for their unswerving commitment. This meeting of the STAG was facilitated by the excellent administrative work of Ms Linda Aimé-McDonald and Ms Corinne Suchet, to whom warm thanks are extended.
List of Annexes:

Annex 1. List of participants
Annex 6. Report from Working Group on Neglected Zoonotic Diseases
Annex 7. Joint statement from USAID and DfID
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Report of the First Global Working Group meeting on Capacity Strengthening for Control of Neglected Tropical Diseases

World Health Organization, Geneva, Switzerland,
6–7 December 2012. Salle C102,

A meeting of the First meeting of the Working Group on Capacity Strengthening for Control of Neglected Tropical Diseases (WG-CS) was held at the headquarters of the World Health Organization (WHO) in Geneva, Switzerland, on 6 – 7 December 2012. The agenda (Annex 1) and list of participants (Annex 2) are included in this report.

Dr. Savioli opened the meeting and drew specific attention to the report of the Department of Control of Neglected Tropical Diseases (NTD) to the Executive Board of 18 – 29 January 2013 (EB132/19). In this report, capacity strengthening (CS) for NTD control is highlighted as a major priority and included in the draft resolution to be presented for consideration by the 66th World Health Assembly (of May 2013). Dr. Savioli stressed the importance of the WG CS to work closely with all of the teams in the NTD department at WHO HQ.

Overview of Working Group on Capacity Strengthening (WG CS)

Professor Molyneux provided background context for the establishment of the WG CS and reminded the group of the ambitious NTD Roadmap to 2020 goals. Although more than 700 million treatments are being delivered annually\(^1\), there is a need to increase this rate in order to reach the 2020 goals. While the London Declaration provides increased resources, the current capacity within national NTD programs will be insufficient to reach these goals. Consequently, the Strategic Technical and Advisory Group on NTDs (STAG-NTD) meeting of April 2012, recommended that a Working Group on Capacity Strengthening (WG CS) be established to give support for the operationalization interventions to empower national programmes with the capacity needed to implement various activities towards achieving NTD Roadmap goals.

The group was reminded of the goals of the WG CS which in summary are to;

- Identify existing CS efforts
- Recognize gaps in CS efforts and prioritize CS needs to be addressed in the short and long-term
- Advise, standardize and support the implementation of training curricula to strengthen managerial and technical capacity for NTD control
- Harmonize partner’s efforts and increase their contribution to fill identifiable gaps, qualify monitoring and assessment of CS products.

In the longer term, the WG CS it will also support capacity strengthening:

- for diseases that require intensified disease management, where specific clinical, treatment and surveillance skills are needed
- to train personnel to support a coordinated scale-up of effective vector control programmes in areas where human resources available in the field of medical entomology have declined
- to enhance an integrated human and animal health (One Health\textsuperscript{2}) approach.

Although a lower priority than capacity-building to support preventive chemotherapy (directed at program managers), county-adapted case management and surveillance training (directed at clinicians) to address the large burden of morbidity and some mortality from specific locally important NTDs should be pursued. This responds to expressed country needs. Integrated training would present NTDs within a unified approach to any acute disease presentation then provides support for differential diagnosis and case management. Clinical detection (through support for adequate assessment and differential diagnosis), reporting and response are particularly important to strengthen surveillance for NTDs targeted for elimination or eradication. The new WHO Integrated Manual for Adolescent and Adult Illnesses (IMAI) district clinician manual differential diagnosis tables include all of the important NTDs; more detailed disease-specific sections include more on case definition, diagnosis based on clinical and laboratory features, guidance for specific treatment(s) and supportive care, assessment of response to treatment, and instructions on when to report. The chapter on disease reporting lists all NTDs in the Integrated Disease Surveillance and Reporting (IDSR) system and cross-references to the sections of the IMAI DCM where each of these diseases can be found. Both case management and surveillance training can then be presented through in-service (short- and medium-term) and pre-service training (for a long-term and more cost-effective approach).

The main operational objective of the Working Group during the first 12 months is to enhance capacity needed to implement existing tools to achieve the further scale up of preventive chemotherapy interventions and, where appropriate, associated morbidity control. Subsequently, efforts will be extended to include CS for intensified disease management (IDM), vector ecology management (VEM) and neglected zoonotic diseases (NZD). Professor Molyneux emphasized that the members of the WG CS represented a group of individual experts with a variety of experiences and skillsets and not as representatives of their affiliated institutions.

\textsuperscript{2} One Health has been defined as “the collaborative effort of multiple disciplines — working locally, nationally, and globally — to attain optimal health for people, animals and the environment
Preliminary Inventory for NTD Capacity Strengthening

Dr. Rio provided a brief overview of the capacity strengthening resources currently available and plans for capacity strengthening in the upcoming year. It was pointed out that capacity strengthening goals should be in line with reaching the targets detailed in The NTD Roadmap to 2020 document.

The list of available resources presented includes:

- NTD Program Manager’s course
- Monitoring and Evaluation (M&E) training workshops
- Transmission Assessment Survey (TAS) training course
- Tool for Integrated Planning And Costing (TIPAC)
- Joint reporting form (JRF)
- Manual for drug distributors (for LF)
- Reprinted bench aids for laboratory technicians

During a meeting held on 4-5 December, 2012, WHO regional focal points presented broad conceptual ideas and subjects for CS for their respective regions. The plans for the upcoming year included a Program Manager’s training course for 10 countries, which should also include highly populous countries in which a large proportions of the population that require preventive chemotherapy have not been reached.

The key points which emerged from plenary discussions were the need to:

- accelerate the rate of scaling up programs by targeting CS efforts to include all of the highly populous countries in AFRO (Nigeria, Ethiopia, DR Congo, Tanzania) and SEARO (India, Bangladesh, Pakistan and Indonesia).
- coordinate training among all partners and to provide feedback to ensure quality control.
- identify appropriate trainers and potentially have those who have been trained as part of a CS evaluation team.
- provide adequate in-service training to NTD program managers in order to enhance their managerial, data management and advocacy skills.
- articulate the core skills required for program managers and NTD teams. This will be done by first writing a job description for NTD teams and then identifying the requisite skills needed at each level.
The role of WG CS in the NTD Roadmap

Dr. Engels presented the current status of the requirements to achieve preventive chemotherapy targets. There are currently 123 countries that require PC for at least one disease, and more than half (n=68) of those countries require PC for two or more diseases. Forty-two countries are implementing PC for all relevant diseases but may not be receiving the full package of interventions required. Although over 700 million treatments were delivered in 2010, the NTD Roadmap goals cannot be met if interventions continue at the current trajectory (Figure 1). There is a need to reach approximately 350 million more people than currently targeted for 2013. At present, the human capacity available within countries is not sufficient for reaching Roadmap goals in time. Dr. Engels called for a shift from disease-specific to intervention-specific approaches by building capacity of health personnel and national control programmes to deliver NTD interventions via different channels in an integrated manner.

**Figure 1** - Current and projected proportion of people (2008-2020) receiving PC for at least one disease among LF, SCH and STH out of the estimated number of people requiring PC (excluding India and Bangladesh)

Analysis of needs for treatment of populous African countries, namely Democratic Republic of Congo, Ethiopia, Nigeria and United Republic of Tanzania, indicates that about 300 million individuals require treatment for at least one of the diseases amendable to preventive chemotherapy. At present, only about 80 million people in these four countries are being treated. In order to cover the global implementation deficit of about 350 million more people in year 2013, intense efforts need to be made to enable implementation of interventions within each of these four populous African countries, and in Asia (notably India and Indonesia). Existing programme managers training courses will require further adaptation to country-specific contexts and dedicated resources made available to support effective CS for NTD control programmes in highly populous countries. A comprehensive CS strategy for these set of countries needs to be developed and country-specific CS plans
Annex 2

supported by a broad coalition of stakeholders at national level for implementation in each of these priority countries.

Critical needs for CS required to support acceleration of scaling-up preventive chemotherapy treatments were summarily presented as:

- Short term ‘in-service needs’ (immediate) CS on specific topics e.g. Program Manager’s Training, M&E, TAS, pharmacovigilance, drug efficacy monitoring, laboratory skills etc.
- ‘Upstream’ goals (mid-term) CS to incorporate NTD training into basic health personnel training
- ‘Long-term’ goals – Medical School undergraduate /post graduate training on NTDs. Laboratory strengthening to support of specific operational issues including those mentioned above.

There are some current opportunities to support acceleration of CS to scale-up preventive chemotherapy treatments. The broad introduction of the NTD Program Manager’s course could be accelerated by conducting inter-country trainings, inviting national (and several regional) programme managers from each priority country, then providing technical support for their own sponsorship of training within their countries. It was also recognized that there is potential within some countries that currently exists but is being underutilized. A number of PhDs with specific NTD expertise are currently not involved in NTD programs. A database of NTD experts should be established and maintained at regional and global levels for use in identifying individuals who could be actively in supporting various activities of national control programmes.

Additionally, most reference resources are not readily accessible for new NTD programme managers. These resources should be harnessed and consolidated into an “NTD Toolbox” that contains pertinent program information that can be used in field settings. Such a repository would contain individual components of the program that need to be addressed including program planning, costing, monitoring and evaluation, communication, morbidity management, research advocacy and resource mobilization. The group determined there is a need for an NTD toolbox that will be in accordance with the “Sunflower concept” Figure 2. The WG CS will work to develop the NTD toolbox and field test a prototype in 2013.
Figure 2 - Thematic areas for capacity strengthening for preventive chemotherapy

Note - The hexagonal “Sunflower” petals have been placed in accordance to the degree of inter-relatedness between activities. Each hexagon has an influence on the overall balance of the sunflower. For example the hexagon on research (and its outcomes) has an effect on what happens in programme operations.

Current Capacity Strengthening Initiatives and needs

Reports were given by Dr. Garba (WHO/AFRO), Dr. Castellanos (WHO/AMRO) and Dr. Padmadsiri (WHO/WPRO). The respective regional offices have identified priority capacity strengthening needs required to support their regional NTD workplans for 2013 and beyond. The main points of the presentations are summarized in Table 1 below.

The WHO regions for EURO (availed), EMRO and SEARO were requested to submit their CS plans to the WHO secretariat for inclusion in the final work plan and schedule of activities for the WG CS 2013.
<table>
<thead>
<tr>
<th>Current Initiatives</th>
<th>Needs</th>
<th>Solutions</th>
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| **AFRO** | - Mapping training (2)  
- M&E training (3 of 4)  
- Data management – Joint Reporting Form & establishment of national NTD databases  
- Media communication & training  
- Regional Laboratories for South–South activities  | - CS for delivery of interventions at community level  
- Program management skills  
- Morbidity management (Lymphatic filariasis in particular) and case management  
- How to scale down implementation and transition to post-MDA surveillance  
- Increased emphasis on social science and behavior change  
- Programme evaluation  
- PC coverage validation  
- Data quality assessments (DQAs)  
- impact assessment of PC implemented by national programmes and local research institutions  | - Regional advocacy for HR development for NTDs  
- Training of health workers, teachers, CDDs  
- TIPAC, MDA, mapping support  
- Surgery, lymphedema management  
- TAS, post-intervention surveillance, impact assessments in select countries  
- Development of reference labs  
- Country commitment  
- Implement standardized guidelines/protocols for evaluations |
| **AMRO** | - M&E Framework development  
- Integrated plans of action (e.g. STH/EPI)  
- Integrated tools and follow-up assistance for dossier development  
- Links to water and sanitation  | - Closer association with local partners  
- Standardized guides for verification and elimination (LF, TRA, SCH)  
- Integrated tools for both PC and IDM diseases  
- Implementing operational plans  
- Adopt global goals to regional situations  
- Social science and behavior change  | - Better coordination w/ NGO, FBO, MoE  
- Expanded TIPAC & JRF to include IDM  
- Promote access to drug donations  
- TAS training, surveillance  
- Verification of interruption of transmission (mainly for SCH and ONCHO) in select countries  
- Country commitment |

Note: EMRO and SEARO plans pending.
### Table 1 - Current Initiatives and Future Needs – Regional office priorities (EURO and WPRO)

| EURO | -Development of the Regional and National Strategies/Action plans  
-Establishment of the Regional and National NTD databases  
-Country situation assessments (Moldova, Romania, Georgia, Armenia, Kazakhstan) | -Strengthening human resources capacity  
-Strengthening capacity of the national programme managers (all countries)  
-Lab capacity strengthening, including QA  
-Establishment of the Regional Reference Laboratory (one of the options could be Martsinovskiy Insitute)  
-Assessment of country situation (Azerbaijan, Kyrgyzstan, Tajikistan, Turkmenistan)  
-Social science and behavior change | -Support national authorities to develop STH control programmes  
-Financial support for organizing trainings for health workers (Regional ToT and trainings at the national level)  
-Financial support for organizing training of programme managers  
-Development of the regional and national reference labs  
-Advocacy for strengthening country commitments |  
| WPRO | -Regional Action Plan  
-Joint advocacy for NTDs with GNNTD and ADB  
-Collaboration w/ USAID  
-Exploring expansion of JICA support | -Dedicated national NTD program managers  
-Expand Regional Peer Review Group mechanism to include other NTDs.  
-Drug regulation and QC  
-Lab capacity strengthening  
-Coverage validation surveys  
-Pharmacovigilance (esp. for SAEs)  
-Post MDA surveillance, especially in Pacific islands  
-STH programmes post LF interventions  
-Social science and behavior change | -Regional adaptation of global guidelines and tools for priority issues  
-Pre-qualify PC drug suppliers  
-QA initiative, train lab techs, equip for serodiagnosis  
-Support national authorities to develop STH control programmes as needed  
-Additional financial support for regional NTD programme managers meetings |  

Note: EMRO and SEARO plans pending.
CS for Public Health Initiatives – Lessons for NTD Control

1 - National Control Programs

Dr. Kabatereine presented a summary of lessons learned and capacity strengthening needs from the perspective of national programs relating to the Ministry of Health in Uganda. The areas where there is critical need for CS efforts for a national NTD control programme were outlined as follows:

- **GIS** – Capacity is currently inadequate to produce required digital maps even where data is available. There is a need to train personnel to acquire GIS skills. It may not be feasible to have GIS experts for individual national NTD programs, but more realistic to have regional hubs of expertise.

- **Laboratory capacity** – There is a critical need for reference laboratory with specialized skills to respond to changing requirements of NTD programs. Reliable verifiable data are needed to make decisions for when to modify strategies or to stop interventions, yet currently there is limited laboratory capacity to support all of the NTD programs. There is a need to train and re-train laboratory personnel.

- **Data management** – At a minimum, there is a need to train staff in the use relevant software for hosting and analyzing national programme data. Ideally, there needs to be an effort to train national data managers, recruit and train biostatisticians. This would enable standardization of data handling methods and improve the retrieval of NTD control implementation data from the field to center and to stakeholders.

- **Social science** – More local/national social scientists should be encouraged and supported to undertake in NTD-related research. Behavior change practices need to be implemented effectively and social science data acquired from within local contexts to better inform implementation strategies and to improve information, education and communication strategies.

- **Morbidity management** – The focus of NTD programs has been centered on preventive chemotherapy, but morbidity management is critical to advance these programs. Morbidity management for lymphatic filariasis and trachoma is typically included in most strategic plans, but funding and human resources to conduct these activities is lacking.

- **Integrated Vector Management** – Vector management will be critical for many elimination programs. There is a need for more training and resource mobilization focused on this topic.
Finally, it was noted that there is a need to improve coordination and management of integrated NTD control programs.

2 - Non-Governmental Organization perspectives and experiences

2.1 Sightsavers

Mr. Bush provided an overview of Sightsavers’ participation in CS initiatives. The Strategy Implementation and Monitoring (SIM) Card uses a balanced scorecard method to monitor what needs to be done within the organization and by partners. The following CS efforts were detailed:

- Developing Country Level Teams (DLCT) – As a result of an assessment conducted in 2009 by Sightsavers, the priority needs to increase CS within country level NTD teams was identified. DLCT addresses this need through several training topics including:
  - Leadership development
  - Program development
  - Financial management
  - Facilitation skills

DLCT concept has been well received, and improvements have been seen in countries. To assess the organizational capacity of partners, a Capacity Assessment Tool (CAT) has been developed. The CAT is broken down into seven key areas that can be monitored. Information gathered is then used to identify areas for improvement and the support that can be provided. Additionally, Sightsavers will also help to build capacity for trachoma mapping through the Trachoma mapping project. Through this project, 1,295 districts will be mapped for trachoma by the end of 2015.

The experience of Sightsavers indicates that there should be ongoing interaction between country and NGO staff in order to ensure complementarity perspectives. Countries should know what to expect from NGOs and vice versa.

Additionally, NTD programs should be encouraged to operate as a team with management responsibility shared. In order to develop effective leadership, pertinent information has to be imparted to motivated individuals. Although leadership can be taught, individual should also have motivation for leadership. There is a need to detail a leadership framework, generate a list of indicators and to determine how to operationalize it in a relatively simple way.
2.2 International Federation of Red Cross and Red Crescent Societies

Mr. Saaristo presented an overview of the International Federation’s (IFRC) involvement in health initiatives. The IFRC is involved in disaster management and recovery and resilience development and addresses cross cutting themes including software/hardware, tools development, quality assurance, training and human and financial resource management. The following programmes were described:

- **Global Water and Sanitation Initiative** – There are 161 water and sanitation projects in 54 countries serving approximately 1 million people per year at an average cost of 32 CHF per year.

- **Community based health and first aid** – A manual and toolkit have been developed with a standard set of indicators. This system utilizes 23,500 volunteers and 872 facilitators who reach more than 2.3 million beneficiaries globally. The IFRC approach is to empower communities and volunteers to take charge of their health. The core components of this system include comprehensive programme management, community systems strengthening, integration and partnerships and behavior change communication.

- **Pandemic Preparedness Programme** – This program equips communities with a fully prepared “off the shelf” response to an influenza pandemic.

The IFRC has a global network that reaches almost every country in the world with extensive volunteer networks in many communities.

There is significant potential for interaction between national IFRC societies and NTD programs at country level. Some overlap of responsibilities probably already exists within the IFRC networks and volunteer NTD community based drug distributors. Often, the same volunteers are responsible for numerous activities (e.g. polio, NTDs, disaster relief, etc.). As part of global advocacy efforts, consideration should be given to issuance of a WHO-IFRC joint statement encouraging engagement of the IFRC volunteer in NTD interventions at community level.

2.3 RTI International

Dr. Doherty presented the background and an overview of RTI’s involvement in NTD control programs. The focus on NTDs began in 2006 with a goal to support integrated NTD control programs organized and led by governments of selected countries. Several key lessons that have been learned from this experience include the need to:

- identify global NTD targets and utilize standardized guidelines to meet those targets
- define and promote integration
ensure complementarity of partner support to ensure value for money

link programmatic uncertainties with operational research opportunities to enable new approaches if required.

As NTD programs begin to scale up, good planning is critical. There should be a clear situational analysis before implementation of programs because every country context is different. Ongoing challenges for NTD programs were identified as:

- The need to ensure global and national commitment
- Meeting the needs for disease mapping
- The need to expand NTD program activities beyond MDA including:
  - Morbidity management
  - Modernizing data collection tools and to ensure the sharing of data across different platforms.
  - Expanding global guidelines for elimination and demonstrating impact
  - The need to enhance technical assistance and training support
  - The need to ensure appropriate resources are available, including human capacity.

RTI has also contributed to the development of training courses that can be used for CS and the development of the Tool for Integration, Planning and Costing of NTD programs (TIPAC). A training course is available to help programs utilize this tool effectively. RTI has also contributed towards the development of The Monitoring and Evaluation (M&E) training workshops which have been implemented in the AFRO region on collaboration with WHO, African Programme for Onchocerciasis Control (APOC), Centers for Disease Control (CDC), Center for Neglected Tropical Diseases (CNTD) and London School of Hygiene and Tropical Medicine (LSHTM). The training course for NTD Program Manager has been developed in partnership with WHO and RTI, its curricula has been finalized and the course piloted in Pemba in July 2012.

Evidently, there are a number of technical resources available from WHO and various partner agencies supporting NTD control programmes. The WG CS should work to provide recommendations for maximizing these resources. There is a need to determine the most cost effective ways to deliver training packages. It will be essential to utilize e-training with the understanding that poor internet connections may not be conducive for implementing certain web-based trainings hence it may be appropriate to disseminate information via DVD/CD. Additionally, some of the available resources, such as the TIPAC, can be further improved upon to accommodate IDM diseases.
2.4 Liverpool School of Tropical Medicine

Prof. Imelda Bates emphasized that CS requires a systematic approach. CS is important because there is a need to assess whether goals have been achieved. With sustainability as the ultimate goal, the concept for designing and evaluation CS projects has three levels (individuals, organization and environment) and four phases. (Figure 3)

Figure 3 - Concept for designing and evaluating capacity strengthening projects: 3 levels, 4 phases

The 5-stage pathway involves steps 1) to define the goal of the CS project 2) to describe the ideal capacity needed to achieve the goal 3) to determine existing capacity and identify gaps 4) to devise and implement an action plan to plug the gaps, define indicators and aim for sustainability 5) to learn through doing. Tensions and challenges for CS include difficulty in harmonizing the goals of individual funders, evaluators and recipients. Additionally, there can be difficulty in balancing learning versus Accountability, and external versus participatory evaluation.

There is a need to articulate a common goal(s)/purpose(s) for CS for NTDs. Ultimately this is to ensure there is adequate capacity to achieve the NTD Roadmap goals and accountability for the resources made available to WG CS. All recommendations should be in line with the goals stated in the CS WG Terms of Reference.

2.5 E-Learning

Ms. Won presented on the availability and potential for e-learning. There has been significant increase worldwide in internet and social media usage. The NTD community should identify opportunities to best use the electronic environment including identifying resource repositories and online learning platforms. e-learning resources should widely be used as they can easily disseminate current information, and complement classical training courses. It was suggested that the NTD community needs to:
- Share information more effectively and widely
- Identify appropriate resource repository for capacity strengthening materials (including for Information, Education and Communication (IEC), social mobilization and training materials
- Consolidate and properly manage online resources for both classical training and e-learning
- Find an appropriate balance between e-learning and traditional didactic classroom instruction
- Create awareness of the capacity strengthening deficits for NTD elimination/control
- Be innovative in harnessing existing technologies to support dissemination of CS resources.

Moving forward, there is a need to use learning environments that are comfortable for the work commitments of a national programme managers and his/her environment. Increasingly this environment is moving toward electronic platforms. The WG CS suggested the creation of an electronic NTD application (NTD app) that could link to essential resources. Presently, there is potentially too much information currently available and there is a need to carefully select information to be included.

### 2.6 CS for Monitoring and Evaluation Activities

Dr. Baker reminded the group that the breadth of M&E required for national NTD programs is extensive. In order to properly conduct M&E there is a need for trained personnel at all levels (field, district, national and international). The M&E training course that has been conducted in AFRO has identified the need for M&E specialists within programs, but these positions often do not exist in Ministry of Health structures. Additionally, Dr. Baker pointed out that there are other courses that address M&E (Program Manager’s course and Transmission Assessment Survey course). It is important to be aware of any potential overlap and to identify gaps. All trainings should be targeted toward the appropriate audience. Although several M&E courses currently exist, there are still unmet training needs including laboratory training, database management and management of M&E systems. Finally the group was reminded that training individuals is only one component of CS. There is also a need to develop the capacity of local and regional institutions.

It was noted that M&E plans are drawn out of multi-year comprehensive plans. Often, only a small proportion of the overall budget is allocated for M&E. This proportion is often a gross underestimate of the resources needed. Additional mobilization of resources from local and external resources will be required to support implementation of national M&E plans.
2.7 CS for Large-Scale Implementation

Dr. Mbabazi highlighted the fact that though policy documents, strategic plans and technical guidelines have been developed by the various disease control programmes, operational guidelines are largely missing. Capacity strengthening of programs must be undertaken in a sustainable way that utilizes existing WHO, Ministry of Health structures and CS models for low-resource settings. The key strategies that have been employed for CS for public health initiatives with community-orientated implementation were summarized as follows:

- **In-service training**: using informal models that make educational resources which professionals independently access as they choose, and/or formal models that rely on academic institutions to providing structured courses and continuing education targeting working professionals.
- **Context-specific course development**: which incorporate competency based standards and skills into courses that are designed to respond to a technical need requested by health professionals that are already working or intend to work on a specific topic.
- **Professional development opportunities & Continuing Medical Education (CME)**: through systematic dissemination of information about the NTD control to students and professionals (through conferences, seminars, workshops, bulletins, etc), and providing facilitation for interested individuals to undertake further training.
- **Technical supervision mechanisms & professional support**: using peer support systems, buddy systems, twinning of programme personnel with external experts or networks which provide access to specialist advice.
- **Performance management systems & appraisals**: using standardized evaluation protocols to appraise, promote and create motivation for continued learning by working professionals thereby sustaining technical competency and integrity to appropriately support different phases of the national control programme.

The above actions would need to be supported with a well-planned and integrated CS framework in which priority activities and associated timeliness for implementation are well defined. Prior to determining such a CS framework, comprehensive inventories of available and missing resources (technical, logistical, organizational and human capacity) should be compiled through a consultative process with a broad group of stakeholders. The development of a CS for a diverse group of funders who support a variety of initiatives for NTD control in a number of different countries and work with a range of partners though challenging is necessary. This will enable the establishment of mechanisms to evaluate and monitor efforts of the WG CS.
2.8 Laboratory Networks

A presentation made on behalf of Dr. Vercruysse highlighted the importance of accurate evaluation of the efficacy of the preventive chemotherapy drugs used as well as their impact on the health of the populations treated. A draft protocol for monitoring drug efficacy has been developed and is ready for field-testing and adaptation for use in national control programmes. Dedicated efforts are required to establish a network of reference laboratories to undertake drug efficacy monitoring for preventive chemotherapy.

Specific activities that need to be implemented in support of this include:

- Establishing and maintaining an inventory of laboratories with NTD expertise
- Organizing and developing a laboratory network for NTDs
- Promoting the use of mobile technology (mHealth) for data collection, transmission, reporting and management in field sites.

It was proposed that the WG CS for NTD laboratory networks should be collaborated with that of CNTD’s laboratory inventory initiative that has already begun. A detailed proposal of how to operationalize the deployment of drug efficacy monitoring guidelines should be available to the WG CS following proposals of the forthcoming meeting of the Working Group on Monitoring Drug Efficacy (WG DE) of February 2013.

2.9 South-South Collaboration

Professor Gyapong presented examples of CS activities conducted by The Noguchi Memorial Institute for Medical Research (Accra, Ghana). Training courses have aimed to improve laboratory skills of national Lymphatic Filariasis (LF) elimination programmes and to enhance the professional efficiency of national programme managers in the African region. Activities have included strengthening laboratory skills (e.g. good lab practices, blood smears, ICT, PCR and ELISA). A program management skills course conducted in 2006 focused on general principles of management, basic accounting and communication in administration. Additionally, the course had a more specific focus on how to run programs within the health sector.

As an outcome of these training workshops, participants received additional knowledge on LF that can be used to improve local patient management practices. The workshops also provide a forum for exchange among active (and potentially active) field projects thereby creating a network of resource persons which emerges from such gatherings, who can be called upon to lend technical support to existing or future field project for LF disability prevention.

Although Noguchi has the ability to continue these CS efforts with additional financial support, there is a need to identify other institutions within all WHO regions with similar capacity as Noguchi to implement the same courses. The Institutions identified should have the infrastructure to host and run international training courses in support of national NTD control programmes.
Recommendations and WG CS Workplan 2013

The presentations and related discussions clearly indicate that CS for accelerating the implementation of preventive chemotherapy will require a collaborative process to positively influence both human resource capabilities and organizational systems in a sustainable manner. The CS process will be comprised of a discrete set of activities in the short-term, intermediate and long-term phases of the global NTD control and elimination initiatives. CS efforts undertaken should maintain and upgrade the appropriate expertise for NTD control in national programmes.

WG CS 2012 identified and proposed a series of activities to be implemented as part of a work plan for 2013, as presented in Table 2 (below). WHO secretariat will be involved in supporting all the proposed activities.

Table 2 – Proposed Work plan for WG CS 2013

<table>
<thead>
<tr>
<th>Actions</th>
<th>Main players</th>
<th>Timeline</th>
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</thead>
<tbody>
<tr>
<td>1. Write ‘job description’ for NTD teams and build requisite skills around this description</td>
<td>Focal point – Dr. Kabatereine</td>
<td>April 2013</td>
</tr>
<tr>
<td>a. Identify components/levels of NTD team and what skills should be acquired</td>
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<tr>
<td>b. Relate to ‘Sunflower’ (Thematic Areas for Capacity Strengthening for Preventive Chemotherapy – Figure 2)</td>
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<tr>
<td>c. Construct an organogram of NTD team members; In-country coordination mechanism</td>
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<tr>
<td>2. Develop NTD toolbox and determine appropriate content</td>
<td>Focal point – AMRO, Dr Albonico</td>
<td>April 2013</td>
</tr>
<tr>
<td>a. Identify missing links</td>
<td></td>
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<tr>
<td>b. Outline a clear plan to disseminate packages within the NTD toolbox (high, mid and low level information)</td>
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<tr>
<td>c. WHO to manage content of toolbox with regional partners</td>
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<td></td>
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<tr>
<td>d. Management of Severe Adverse Events (SEAs)</td>
<td></td>
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<tr>
<td>3. Identify partners to collaborate with WHO to develop an NTD app in order to provide easy access to available resources, and present an outline of a prototype to NTD STAG 2013</td>
<td>WHO</td>
<td>March 2013</td>
</tr>
<tr>
<td>4. Add EMRO, EURO and SEARO needs perspectives</td>
<td>EMRO, EURO, SEARO</td>
<td>February 2013</td>
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</tbody>
</table>
Table 2 – Proposed Work plan for WG CS 2013 (continued)

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Responsible Parties</th>
<th>Date</th>
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<tbody>
<tr>
<td>5</td>
<td>Draft advocacy statement encouraging the engagement of volunteer networks at national level to participate in national NTD control activities.</td>
<td>WHO + Red Cross</td>
<td>April 2013</td>
</tr>
<tr>
<td>6</td>
<td>Need to adapt training material to current landscape (i.e. electronic environment) (by end of 2013)</td>
<td>Focal points - Ms. Won Dr Baker Mr Bush</td>
<td>End 2013</td>
</tr>
<tr>
<td></td>
<td>a. Compile comprehensive inventories of ‘classical’ training and e-learning</td>
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<td></td>
<td>b. Identify weaknesses of existing information repositories (e.g. websites) and make changes</td>
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<td></td>
<td>d. Identify ways to use technology (mHealth) to collect data.</td>
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<td></td>
<td>e. Draft a document of needs in order to engage mobile phone companies</td>
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<tr>
<td>7</td>
<td>Harness Institutional capacity that exists for laboratory strengthening and beyond; build capacity of local national/regional Institutions and develop regional network of training Institutes to deliver training packages, improve diagnostic tools for mapping and monitoring etc.</td>
<td>Focal points – Prof. Vercruysse Dr. Doherty Prof. Bates</td>
<td>April 2013 (Include proposals from WG on drug efficacy Feb. 2013)</td>
</tr>
<tr>
<td></td>
<td>a. Create an inventory of institutions with similar capacity of Noguchi (Ghana) that can support CS efforts (e.g. KEMRI, VRIE)</td>
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<td></td>
<td>b. Use drug efficacy meeting (Feb. 18-19, 2013) to convene meeting of lab experts</td>
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<td>8</td>
<td>Identify cadres of trainers and run the first Training for Trainers (ToT) for Program Managers’ training in AFRO region (tentatively in Noguchi)</td>
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<td>July 2013</td>
</tr>
<tr>
<td></td>
<td>a. Establish and maintain a database of expertise for deployment to support national NTD control and elimination activities.</td>
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<td></td>
<td>b. Adapt courses to contexts and undertake country-specific training for the highly populous countries to develop a standing in-country multidisciplinary team to cascade training to sub-national levels.</td>
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<tr>
<td>9</td>
<td>Develop a well-planned and integrated CS framework</td>
<td>Focal point - Prof. Bates</td>
<td>April 2013</td>
</tr>
<tr>
<td></td>
<td>a. Determine who does what, where and when</td>
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<tr>
<td></td>
<td>b. Define timelines</td>
<td></td>
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<tr>
<td></td>
<td>c. Enact mechanisms to evaluate and monitor CS efforts</td>
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Summary

Following the unprecedented response from industry in support of WHO’s call to combat neglected tropical diseases (NTDs), there is an urgent need to address important capacity constraints in recipient countries. National capacity to implement recommended interventions for effective control and elimination of targeted neglected tropical diseases is insufficient in many countries and will have to be strengthened if the targets set by the World Health Assembly in many resolutions over the years are to be met. Such large-scale programmes may pose challenges in regard to ownership, accountability and respect for due process, and therefore require organizational capacity for effective collaboration among national and international stakeholders. National neglected tropical control disease programmes must be empowered with appropriate tools and clearly defined responsibilities in order to coordinate and implement essential functions at all levels of the national system.

The Working Group on Capacity Strengthening has been constituted as grouping of individuals from developing and developed countries with multi-disciplinary expertise aimed at sharing expertise, identifying problems, seeking solutions, coordinating activities and working towards the common goal of facilitating capacity strengthening for control of NTDs. The First meeting of the Working Group on Capacity Strengthening devised a list of priority activities to be undertaken as part of an iterative process of empowering individuals and control national programmes to perform their functions more effectively.
ANNEX 1 - Agenda

FIRST NTD STAG GLOBAL WORKING GROUP MEETING ON CAPACITY STRENGTHENING FOR CONTROL OF NEGLECTED TROPICAL DISEASES (WG-CS)

PROVISIONAL AGENDA

<table>
<thead>
<tr>
<th>Day I</th>
<th>Item</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00-09:10</td>
<td>Welcoming Remarks</td>
<td>L. Savioli and H. Nakatani</td>
</tr>
<tr>
<td>09:10 – 09:30</td>
<td>Introductions: WG CS Members (and brief portfolios)</td>
<td>All</td>
</tr>
<tr>
<td>09:30 – 10:00</td>
<td>Working Group Capacity Strengthening (WG-CS) Vision, Responsibilities and Expected outputs</td>
<td>D. Molyneux, Chair, WG CS</td>
</tr>
<tr>
<td>10:00 – 10:30</td>
<td>Preliminary Inventory for NTD capacity strengthening</td>
<td>F. Rio</td>
</tr>
<tr>
<td>10:30 - 11.00</td>
<td>Coffee break</td>
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<tr>
<td>11:00 – 11:20</td>
<td>Capacity strengthening Current initiatives and future needs for preventive chemotherapy</td>
<td>D. Engels</td>
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<tr>
<td>11:20 – 11:30</td>
<td>AFRO</td>
<td>WHO NTD Regional focal points</td>
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<tr>
<td>11:30 – 11:40</td>
<td>AMRO</td>
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<tr>
<td>11:40 – 11:50</td>
<td>EURO</td>
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<td>11:50 – 12:00</td>
<td>SEARO</td>
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<tr>
<td>12:10 – 12:20</td>
<td>WPRO</td>
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<tr>
<td>12:20 – 13:00</td>
<td>General discussion of priorities for successful implementation fo NTD roadmap to 2020</td>
<td>All</td>
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<tr>
<td>13:00 – 14:00</td>
<td>Lunch break</td>
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<tr>
<td>14:00 – 14:10</td>
<td>CS for Public Health initiatives – Lessons for NTD control National Control Programmes NGO participation in CS initiatives</td>
<td>N. Kabatereine</td>
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<tr>
<td>14:10 – 14:20</td>
<td>Sight savers</td>
<td>S. Bush</td>
</tr>
<tr>
<td>14:20 – 14:30</td>
<td>Int. Federation of Red Cross and Red Crescent Societies</td>
<td>P. Saaristo</td>
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<tr>
<td>14:30 – 14:40</td>
<td>NTD ENVISION - RTI International</td>
<td>A. Doherty</td>
</tr>
<tr>
<td>14:40 – 14:50</td>
<td>Establishing and maintaining laboratory networks for programmes Contribution of institutions to CS for NTD control</td>
<td>J. Vercruysse</td>
</tr>
<tr>
<td>14:50 – 15:00</td>
<td>Experience of Liverpool School of Tropical Medicine</td>
<td>I. Bates</td>
</tr>
<tr>
<td>15:00 – 15:10</td>
<td>Availability and potential of e-learning</td>
<td>K. Won</td>
</tr>
<tr>
<td>15:10 – 15:20</td>
<td>CS for Monitoring and Evaluation activities</td>
<td>M. Baker</td>
</tr>
<tr>
<td>15:20 – 15:30</td>
<td>CS for large-scale implementation</td>
<td>P. Mbabazi</td>
</tr>
<tr>
<td>15:30 – 16:00</td>
<td>Coffee break</td>
<td></td>
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<tr>
<td>16:00 – 16:15</td>
<td>South-South collaboration in CS for NTD control Formulation of Strategy for Capacity Strengthening for NTD control: proposed strategic areas - intervention delivery mechanisms &amp; logistics, clinical management &amp; morbidity guidelines, laboratory networks (national &amp; regional capacity), M&amp;E (mapping, surveillance, databases etc.), advocacy &amp; resource mobilization, mass communication, community mobilization &amp; media relations, etc.</td>
<td>J. Gyapong</td>
</tr>
<tr>
<td>16:15 – 17:50</td>
<td></td>
<td>All</td>
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<tr>
<td>17:50 – 18:00</td>
<td>Conclusion of Day 1</td>
<td>D. Molyneux, Chair, WG CS</td>
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</table>
## PROVISIONAL AGENDA

### Day II:

<table>
<thead>
<tr>
<th>Time</th>
<th>Item</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00 – 09:10</td>
<td>Re-cap of Day 1</td>
<td>Rapporteurs</td>
</tr>
<tr>
<td>09:10 – 09:20</td>
<td><strong>Capacity Strengthening</strong></td>
<td>J. Jannin, F. Meslin, M. Zaim, R. Velayudhan</td>
</tr>
<tr>
<td>09:20 – 09:30</td>
<td>For Innovative and Intensified Disease Management (IDM)</td>
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<tr>
<td>09:30 – 09:40</td>
<td>For Neglected Zoonotic Diseases (NZD)</td>
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<tr>
<td>09:40 – 10:30</td>
<td>For Vector Ecology Management</td>
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<tr>
<td>09:40 – 10:30</td>
<td><strong>Capacity Strengthening Work plan: 2013- 2014 and beyond</strong></td>
<td>All</td>
</tr>
<tr>
<td>10:30 - 11.00</td>
<td>Coffee break</td>
<td></td>
</tr>
<tr>
<td>11:00 – 12:00</td>
<td><strong>Capacity Strengthening Work plan: 2013- 2014 and beyond</strong></td>
<td>D. Molyneux, Chair, WG CS</td>
</tr>
<tr>
<td>12:00 – 12:45</td>
<td>Recommendations to STAG 2014</td>
<td>All (Rapporteurs)</td>
</tr>
<tr>
<td>12:45 – 13:00</td>
<td>Wrap up and conclusion</td>
<td>L. Savioli</td>
</tr>
<tr>
<td>13:00hrs</td>
<td><strong>Closure of Day II</strong></td>
<td></td>
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</tbody>
</table>
ANNEX 2 – List of Participants

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Dr Adiele Onyeze  
Dr Amadou Garba  
Dr Louis-Albert Tchuem Tchuenté

AMOR/PAHO  
Dr Luis Gerardo Castellanos  
Dr Martha Saboya

EMRO  
Dr Jaouad Mahjour  
Dr Riadh Ben-Ismail  
EURO - Dr Elkhan Gasimov  
SEARO - Dr Aditya Prasad Dash - unable to attend  
WPRO - Dr Padmasiri Eswara Aratchige

WHO/HQ, Geneva

Dr Lorenzo Savioli, Director NTD  
Dr Dirk Engels, Coordinator, NTD/PCT  
Dr Jean Jannin, Coordinator, NTD/IDM  
Dr Morteza Zaim, Coordinator, NTD/VEM  
Dr Raman Velayudhan, NTD/VEM  
Dr François Meslin, Team Leader, NTD/NZD  
Dr Denis Daumerie, NTD  
Dr Pamela Mbabazi, NTD/PCT  
Dr Francesco Rio, Team Leader NTD/CCB  
Ms Véronique Salamin, Support Staff, NTD/CCB
Fifth Meeting of the Working Group on Access to Assured-Quality Essential Medicines for Neglected Tropical Diseases (WGA)
WHO, Geneva, Switzerland – 26 April 2013

Report

List of Participants and Agenda are provided in Annex 1 and 2.

The meeting commenced at 9.00 a.m. under the chairmanship of Prof. Nilanthi de Silva. Dr. Lorenzo Savioli welcomed the participants and highlighted the main issues that the WGA needs to address. Prof. Nilanthi de Silva recalled the mandate given to WGA by the STAG in 2009 and presented the objectives for this meeting.

Agenda Item 1: Global access to quality-assured praziquantel: an update – presentation by D Daumerie
The available information on PZQ availability and supply is summarized as follows:

PZQ global supply in 2012
- Total 180 million tablets planned
- Delivered 112 million tablets as of December 2012
- PZQ joint planning and global supply in 2013
  - Total 172 million tablets planned as follows:
    - WHO/Merck: total 50 million tab in 15 countries
    - WHO/WB: total 4 million tab in 1 country
    - USAID/RTI/FHI: total 84 million tab in 11 countries
    - DFID/CA/SCI: total 34 million tab in 4 countries

Recommendations
Continue to use WGA as facilitating platform for partners to:
- Monitor and manage response to evolving praziquantel availability landscape
- Continue joint forecast and coordinated supply
- Expand use of WHO quality assurance policy for the procurement and provision of praziquantel tablets
- Further encourage NGOs to join the platform

Agenda item 2: Serious adverse events and pharmacovigilance in preventive chemotherapy – presentation by V Kumaraswami
The Secretariat has developed a manual for PC interventions and more efforts should be invested in supporting endemic countries to adopt and adapt it to meet their national situations. Proposed actions include the following:
- Develop guidelines for comprehensively managing AE-fMDAs
- Develop simple and robust mechanisms for reporting and investigating SAEs.
- Data management using harmonized tools
- Develop links with pharmacovigilance programmes and utilize opportunities to integrate with existing systems
- Build capacity for SAE recognition and management and identify resources required
- “A platform for open dialogue and intellectual discussion with a common goal of a comprehensive, high-quality [PCT] pharmacovigilance system”
Recommendations

- Further encourage and support countries to adopt and adapt existing tools and guidelines for safety monitoring in NTD treatment & control activities through effective collaboration between national pharmacovigilance systems and NTD programmes
- Improve AE reporting and ensure its proper channeling through the existing platforms for safety monitoring of medicines at the national and international level through enhanced collaboration between WHO’s NTD and EDM Departments.

Agenda item 3: Access to essential medicines for leishmaniasis: quality concerns – presentation by M Den Boer and D. Dagne

Quality concerns have been identified and should be addressed by:

- **Continuous independent evaluation** (monitoring quality evaluation surveys) needed for WHO validated generic sources
  - Generic SSG (Albert David India)
  - Paromomycin (Gland Pharma India)
- **Development of tools for evaluation of newly emerging generics**: pharmacopoeial monographs do not exist for paromomycin and miltefosine, and are outdated for antimonials. Clear guidance on evaluation of liposomal products is lacking.
- **Encourage and support existing manufacturers** to sustain production despite small marketing potential
  - Paladin - miltefosine
  - Gland Pharma - paromomycin
  - GSK – SSG

**Recommendations** (to be read in conjunction with recommendations for Agenda items 4 and 5)

- Prepare and implement quality surveys in collaboration with national regulatory authorities to assist detection of possible quality issues affecting anti-Leishmania agents

Agenda item 4: Survey on the quality of albendazole and mebendazole in East Africa and South-east Asia – presentations by H. Sillo and Doan Cao Son

Surveys were conducted on samples collected from the highest levels of the distribution chain. Brands sampled were those used in largest quantities and included locally manufactured, imported and donated medicines. Testing was conducted in WHO-prequalified laboratories according to USP35. Survey results are summarized in the following table. The fact that such a large proportion of samples failed quality testing is cause of concern and calls for effective action.
### Recommendations (to be read in conjunction with recommendations for Agenda items 3 and 5)

- Prepare and implement quality surveys in collaboration with national regulatory authorities to assist detection of possible quality issues affecting albendazole and mebendazole
- Facilitate sub-regional meetings of regulatory authorities to support their action against substandard NTD medicines

### Agenda item 5: NGO Quality Assurance Policy for drug procurement: a proposal for discussion – presentation by V. Reggi

Information has been collected through quality surveys and investigation of serious adverse event reports. This shows that donations sometimes include medicines that are sourced from manufacturing sites without stringent regulatory oversight. There is a need to further promote internationally accepted guidelines for medicines donations and for procurement agencies. At the same time, there is need to expand the number of reliable sources of quality-assured NTD medicines.

#### Recommendations
- Further promote interagency guidelines for medicines donations and procurement agencies
- Mobilize resources to start prequalification of PZQ, ALB and L-AMB and assist manufacturers to apply and achieve prequalification status

### Agenda item 6: NTD Medicines – joint request, review and reporting - presentation by A. Gabrielli and A Mikhailov

A mechanism for a joint process of requesting, reviewing and reporting on medicines for PC has been developed by the Secretariat together with its partners in NTD control. It has gone into effective implementation in a number of countries and its use is expanding. There is a need to further engage all partners in the process of developing this process.

#### Recommendations
- Further encourage and support countries to adopt developed tools in close collaboration between the three WHO levels.
- Evaluate and report at next WGA meeting.
Summary of recommendations to be submitted to STAG

Global Access to quality-assured selected NTD medicines

- Continue to use WGA as facilitating platform for partners to monitor and manage response to evolving landscape of praziquantel availability and continue joint planning of national requirements
- Mobilize resources to start prequalification of PZQ, ALB and L-AMB and assist manufacturers to apply and achieve prequalification status

Quality surveys of selected NTD medicines

- Prepare and implement quality surveys in collaboration with national regulatory authorities to assist detection of possible quality issues affecting selected NTD medicines (especially albendazole, mebendazole and anti-Leishmania agents)
- Facilitate subregional meetings of regulatory authorities to support their action against substandard NTD medicines

NTD medicines Safety Monitoring

- Further encourage and support countries to adopt and adapt existing tools and guidelines for safety monitoring in NTD treatment & control activities through effective collaboration between national pharmacovigilance systems and NTD programmes
- Improve AE reporting and ensure its proper channeling through the existing platforms for safety monitoring of medicines at the national and international level through enhanced collaboration between WHO’s NTD and EDM Departments.

Joint Request/Review/Reporting Tools

- Further encourage and support countries to adopt developed tools in close collaboration between the three WHO levels.
- Evaluate and report at next WGA meeting.
ANNEX 1 – LIST OF PARTICIPANTS

Fifth Meeting of Working Group on Access to Assured-Quality Essential Medicines for Neglected Tropical Diseases (WGA)

Geneva, 26 April 2013
WHO, Room M.505

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Annex 3

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### Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
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| 9:00 - 9:30| Opening & Introduction to the Meeting<br>
|            | *L. Savioli & N. De Silva*                                                                     |
| 9:30 - 10:00| Global access to quality-assured praziquantel: an update<br>
|            | *D. Daumerie*                                                                                 |
| 10:00 - 10:30| Serious adverse events and pharmacovigilance in preventive chemotherapy<br>
|            | *A. Montresor & V. Kumaraswami*                                                                |
| 10:30 - 10:45| Coffee/Tea break                                                                             |
| 10:45 - 11:15| Access to essential medicines for leishmaniasis: quality concerns<br>
|            | *M. Den Boer & D. Dagne*                                                                      |
| 11:15 - 12:30| Survey on the quality of albendazole and mebendazole in East Africa and South-east Asia<br>
|            | *H. Sillo & Doan Cao Son*                                                                     |
|     | Discussion and recommendations                                                                |
| 12:30 - 14:00| Lunch                                                                                        |
| 14:00 - 14:30| NGO Quality Assurance Policy for drug procurement: a proposal for discussion<br>
|            | *V. Reggi*                                                                                    |
| 14:30 - 15:30| NTD Medicines. Joint request, review and reporting<br>
|            | *A. Gabrielli & A. Mikhailov*                                                                 |
| 15:30 - 16:00| Coffee/Tea break                                                                             |
| 16:00 - 16:30| WGA: review of work done, achievements and proposals for future action<br>
|            | *N. De Silva, V. Reggi & D. Daumerie*                                                         |
|            | Discussion and recommendations                                                                |
| 16:30 - 17:30| Additional issues raised by participants<br>
|            | Key points to report to the STAG<br>
|            | Closure of the meeting                                                                        |
Fourth Meeting of the Working Group
on Monitoring of Neglected Tropical Diseases Drug Efficacy

Department of Control of Neglected Tropical Diseases
Geneva, 18-19 February 2013

Chair: Prof Mamoun Homeida
Rapporteurs: Dr Marco Albonico, Dr Bruno Levecke

FINAL DRAFT FOR COMMENTS BY PARTICIPANTS
Annex 4

1 Background ................................................................................................................................................. 3
2 Progress of ongoing work, future plans and recommendations from the different subWGs .............................................................................................................................................................................................................................................................................. 3

2.1 SubWG on benzimidazoles (BZ; soil-transmitted helminthiasis) ....................................................... 3
   2.1.1 Progress of on-going work .................................................................................................................. 3
   2.1.2 Summary and recommendations for STAG in 2013 ......................................................................... 4
   2.1.3 Achievements since establishment of the WG ................................................................................... 4
   2.1.4 Future plan of activities to fill the remaining gap ............................................................................ 4

2.2 SubWG on ivermectin (IVM, onchocerciasis and lymphatic filariasis) ............................................. 4
   2.2.1 Progress of ongoing work .................................................................................................................. 4
   2.2.2 Summary and recommendations for STAG in 2013 ......................................................................... 5
   2.2.3 Achievements since establishment of WG ......................................................................................... 5
   2.2.4 Future plan of activities to fill the remaining gap ............................................................................ 6

2.3 SubWG on praziquantel (PZQ, schistosomiasis) ..................................................................................... 6
   2.3.1 Progress of ongoing work .................................................................................................................. 6
   2.3.2 Summary and recommendations for STAG in 2013 ......................................................................... 8
   2.3.3 Achievements since establishment of WG ......................................................................................... 8
       Future plan to fill the remaining gap ...................................................................................................... 8
   2.3.4 ............................................................................................................................................................. 8

2.4 SubWG on human African trypanosomiasis, leishmaniasis, Chagas disease and Yaws ............................................. 8
   2.4.1 Progress of ongoing work .................................................................................................................. 8
   2.4.2 Summary and recommendations for STAG in 2013 ......................................................................... 12
   2.4.3 Achievements since establishment of WG ......................................................................................... 12
   2.4.4 Future plan to fill the remaining gap ............................................................................................... 12

2.5 SubWG on DNDi and research on NTD drugs .................................................................................... 12
   2.5.1 Progress of ongoing work .................................................................................................................. 12

3 Strengthening laboratory capacity for NTD control: on-going and future initiatives
   (cross cutting issues with the WG on Capacity Strengthening) ...................................................................... 14
4 Conclusions and way forward .................................................................................................................... 15
1 Background
The goal of the Working Group (WG) on Monitoring Drug Efficacy is to put a system in place to monitor and respond to the need of neglected tropical diseases (NTD) control programmes and promote capacity building on monitoring preventive chemotherapy (PC) management, with special focus on drug efficacy. Due to the fact that the work of this WG has been particularly effective, future perspectives should be based on its cost-effectiveness, and options were: (i) continue as it is as more work needs to be accomplished, (ii) continue and meet biannually, (ii) incorporate it into other WG (Monitoring & Evaluation or Capacity Building/Laboratory Network). This report is structured to facilitate the response to this question and to suggest the way forward: for each subgroup the tasks achieved so far and future plan of activities to fill gaps in order to fulfil the primary goal are highlighted.

2 Progress of ongoing work, future plans and recommendations from the different subWGs

2.1 SubWG on benzimidazoles (BZ; soil-transmitted helminthiasis)

2.1.1 Progress of ongoing work
(i) Assessment of drug efficacy. The drug efficacy of a single dose mebendazole (500 mg, J&J) against soil-transmitted helminths (STH) was evaluated in 6 countries (Brazil, Cameroon, Cambodia, Ethiopia, Tanzania and Vietnam). The results revealed a high efficacy (measured by egg reduction rate) against *Ascaris lumbricoides* (96.1%), a moderate efficacy against hookworms (79.8%) and a poor efficacy against *Trichuris trichiura* (58.5%). Drug efficacy across hookworm species (*Necator americanus* and *Ancylostoma duodenale*) was comparable. From these results thresholds for drug efficacy were proposed; *A. lumbricoides* ≥ 95%, hookworms ≥ 90%, and *T. trichiura* ≥ 50%.

(ii) Development of guidelines on how to assess drug efficacy. Guidelines on assessing efficacy of anthelminthic drugs against schistosomiasis and STH have been finalized and will be distribute to WHO offices in endemic countries in hard and electronic copy in May 2013.

(iii) Simplifying procedures to assess infections. Application of pooling stool samples to assess infection intensity of STH has been validated in 14 schools in Jimma Town (Ethiopia). The results indicated this strategy has potential as a cost-effective strategy to assess infection intensity. In addition a mathematical framework has been developed to determine prevalence and to guide researchers/health decision makers to calculate sample size for egg reduction rate and lot quality assurance sampling. A web based model for data entry calculating the prevalence, intensity and proportion of heavy intensity infections is under development.

(iv) Capacity building: Examples on how to standardize data collection (Open Data Kit and Magpi) and laboratory methods (videoclips) were demonstrated.

(v) Defining the alarm bell: A statistical model to predict the prevalence of STH after different rounds of PC has been developed. This model will be useful for determining if the expected impact of STH interventions has been achieved. If not, further investigation of possible explanations for this are indicated.
2.1.2 Summary and recommendations for STAG in 2013

2.1.3 Achievements since establishment of the WG

(i) Evaluation of both albendazole and mebendazole efficacy across various endemic countries based on a standardized protocol.

(ii) Guideline on assessing efficacy of anthelminthic drugs against schistosomiasis and STH is finalized.

(iii) Development of a statistical model to predict the prevalence of STH after different rounds of PC.

(iv) Evaluation of diagnostic methods for the detection and qualification of STH infections in various endemic countries.

(v) Review of the importance of anthelmintic resistance in STH and identification of potential confounding factors of anthelminthic drug efficacy.

2.1.4 Future plan of activities to fill the remaining gap

(i) Assessment of single nucleotide polymorphisms (SNP) of the beta-tubulin gene associated with benzimidazole resistance

(ii) Assessment of the role of animals (dogs and pigs) as a reservoir for STH

(iii) Need for soliciting drug manufacturers of pyrantel/oxantel, to assess its efficacy and as a back-up scenario should anthelmintic resistance to benzimidazoles occur.

(iv) Assessment of drug efficacy of praziquantel against Schistosoma based on a standardized methodology used for albendazole and mebendazole.

(v) Validation of mathematical modelling using additional STH data

(vi) Development of methodology to systematically sample for emerging reduced efficacy

2.2 SubWG on ivermectin (IVM, onchocerciasis and lymphatic filariasis)

2.2.1 Progress of ongoing work

Onchocerciasis

(i) Identification of markers of putative low response of O. volvulus to the embryostatic effect of ivermectin. Six laboratories in Australia (Drs Grant and Doyle), Burkina Faso (WHO/MDSC, Dr. Adjami), Cameroon (Dr. Wanji and. Kamgno), Canada (Drs Prichard and Bourguinat), Ghana (Drs Boakye, Osei-Atweneboana, Wilson) and France (Dr. Boussinesq) are collaborating to investigate whether the higher than expected increase in skin microfilaria levels after ivermectin treatment observed in some people/communities in Ghana and Cameroon is due to selection of parasites with a low response to the embryostatic effect of ivermectin under ivermectin pressure. The project started in 2011. The number of single nucleotide polymorphisms (SNPs) between O. volvulus from ‘good’ and ‘suboptimal’ responders has been narrowed down to 140. The next step is to examine a still larger number of parasites for the presence and correlation of these SNPs with the response phenotype to arrive at around 10 SNPs to be validated as response markers in an even larger number of samples. Should this last validation step result in the conclusion that there is a genetic correlate of the phenotypic responses, a tool will be developed for control programmes to monitor for the emergence of low response strains. The work of the laboratories has been financed to date exclusively by APOC. Unfortunately there is an
important budget shortfall, which, until APOC and TDR can raise external funding, will slow down and possibly even stop any further work. APOC and TDR are seeking additional funding.

(ii) Epidemiological Evaluation Results. Epidemiological assessment has been considered as a proxy indicator of efficacy of ivermectin on onchocerciasis in the absence of molecular marker. Epidemiological data has been collected in 30 foci in 11 different countries. An overview of the epidemiology data collected between 2008-2012 indicated that

a. the number of foci assessed increased from 2 foci in 2008 to 9, 10, 12 and 30 foci in 2009, 2010, 2011 and 2012 respectively.

b. of the 45 foci surveyed 20 probably already achieved elimination, 8 are close to elimination, 12 are on track, but that 5 did not progress as predicted by ONCHOSIM.

Lymphatic filariasis

(i) Development of guidelines on how to assess drug efficacy. The LF community has developed a robust monitoring and evaluation framework (diagnostic method, sampling strategy and field validation) that now has resulting in new WHO guidelines ‘Monitoring and epidemiological assessment of mass drug administration in the global programme to eliminate lymphatic filariasis: a manual for national elimination programmes’. Recently a manual on Transmission Assessment Survey (TAS) has been developed with potential of integration with STH monitoring.

(ii) Development of predictive model. Progress has been made in re-evaluating the global burden of LF, modelling the reduction in Mf prevalence and the trend in function of the number of treatments.

2.2.2 Summary and recommendations for STAG in 2013

2.2.3 Achievements since establishment of WG

(i) Collection and expanding of epidemiological surveys in APOC countries as a proxy indicator of the status of ivermectin efficacy until a genetic marker for identification of resistance is readily available.

(ii) Identifying potential genetic markers of O. volvulus susceptibility to ivermectin is in progress despite financial constraints

(iii) Expansion of Multi Diseases Surveillance Centers’ repositories with samples from epidemiological evaluations in APOC and ex-OCP countries.


(v) First step towards a predictive model for LF.
2.2.4 Future plan of activities to fill the remaining gap

Onchocerciasis

(i) Continue conducting epidemiological evaluation (phase 1a and 1b) in 53 APOC projects and entomological survey (phase 1b) in 25 countries
(ii) Expansion of Multi Diseases Surveillance Centers’ repositories with samples from epidemiological evaluations (use for IVM response marker project)
(iii) Seek funding to continue the work on IVM resistance markers
(iv) Look more in depth in the 5 foci for which epidemiological evaluation showed unsatisfactory results
(v) Implementation of research for molecular markers of response of *O. volvulus* to IVM and personnel capacity building on laboratory network if funding mobilized and available

Lymphatic filariasis

(i) Improve the existing model for prediction of LF burden after several rounds of MDA
(ii) Test the impact of treatment against the pre-TAS data in sentinel and spot check sites.
(iii) Potential integration of TAS to monitor efficacy against STH in LF-STH co-endemic areas and to provide evidence for using ALB/MEB for STH control after MDA for LF is stopped.

2.3 SubWG on praziquantel (PZQ, schistosomiasis)

2.3.1 Progress of ongoing work

(i) Monitoring of drug efficacy. Despite the increased drug pressure on schistosomes and the change in vision to elimination there is a lack of studies monitoring/assessing efficacy of PQZ. Recent studies have been conducted across Asia (*S. japonicum*), South America (*S. mansoni*) and sub-Saharan Africa (*S. mansoni* and *S. haematobium*)
   a. epidemiological surveys indicate that
      i. animals play an important role in maintaining *Schistosoma* infections in humans
      ii. *S. haematobium* - *S. mansoni* co-infection status may impact clearance and/or subsequent reinfection patterns relative to single species infections.
   b. molecular analysis indicates that
      i. Re-infection (and/or immature worms) may explain apparent lack of clearance in some cases, however
      ii. Periodic administration of PZQ reduces the genetic diversity in schistosomes
      iii. Hybrids of *S. haematobium* with *S. bovis* and/or *S. currassoni* may be prevalent in certain areas of West Africa although the impact of these hybrids on the control of schistosomiasis has yet to be fully elucidated.
(ii) Development of guidelines on how to assess drug efficacy. A draft of the guidelines on assessing efficacy of anthelminthic drugs against schistosomiasis and STH has been finalized and will be distributed in May 2013.
(iii) Meta-analysis. A Cochrane systematic review of treatments of *S. mansoni* has just been completed. An extended meta-analysis of PZQ efficacy and safety in under-way coordinated by TDR.
(iv) Development of resistance markers. Oxamnique (OXA) is a drug that is effective against S. mansoni but not S. haematobium nor S. japonicum. S. mansoni has developed resistance to OXA in the field and in the laboratory. Genetic experiments followed by gene sequence analysis revealed and confirmed by independently by RNAi that

a. An S. mansoni sulfotransferase (SmSULT) is responsible for OXA mode of action: The sulfotransferase activates OXA by transferring a sulfur from a donor (3′-phosphoadenosine 5′-phosphosulfate, PAPS) to OXA, allowing it to bind to macromolecules like DNA and kill the adult parasite.

b. Mutations in the gene are responsible for drug resistance.

c. Biomarkers can be developed to assess the frequency of alleles that contribute to drug resistance to OXA and used as a surrogate for PZQ

The approach to identify the gene responsible for oxamnique mode of action will be employed to identify the genes involved in praziquantel mode of action/resistance.

(v) Development of drugs:

a. The crystal structure of the sulfotransferase with OXA was solved at a resolution that will allow modification of drug to improve its efficacy against S. mansoni and potential against S. haematobium. The goal is to improve the efficacy of OXA to make it function against drug resistant S. mansoni and also be an effective drug against S. haematobium. The approach to identify the gene responsible for oxamnique mode of action is being employed to identify the gene(s) involved in praziquantel mode of action. Praziquantel resistance can be experimentally induced in the laboratory so the proposed approach is feasible. This will allow the development of biomarkers and the question of whether PZQ resistance occurs in nature can be addressed.

b. Due to the concern about praziquantel treatment as a monotherapy and the prospect of drug resistance, efforts by a number of laboratories are underway to modify praziquantel or develop new drugs to complement praziquantel. For example studies have shown that two genes, SMDR2 (P-glycoprotein) and SmMRP1 (multidrug resistance-associated proteins) are up-regulated in response to PZQ treatment and seem to be associated with drug tolerance.

c. An exciting development is the synthesis of PZQ as a single enantiomer that is responsible for PZQ efficacy. This is significant because the other enantiomer is responsible for the side effects. The developed synthesis has a low cost. However what is exciting is that the synthesis was worked out as an open source notebook in which the academic and private scientific community participated. There were two syntheses developed, one by open source and the other by contract. These are currently being tested for scale up. The outcome will be a more potent drug that may be more efficacious and have even less side effects, in part due to the need for a lower dose and for the lack of the enantiomer responsible for the side effects.
2.3.2 Summary and recommendations for STAG in 2013

2.3.3 Achievements since establishment of WG

(i) Providing novel insights into
   a. the epidemiology of schistosomes (role of animals as important reservoir and occurrence of hybrids)
   b. Population genetics (microsatellite biomarkers) in response to drug pressure
   c. Monitoring drug efficacy in countries with periodic treatment with PZQ (e.g. potential difference in drug efficacy in co-infected individuals).

(ii) Unravelling the mode of action of OXA, and allow to further improve the potency of OXA against S. mansoni and S. haematobium.

(iii) Development of an approach to get more insights into the mode of action of PZQ

2.3.4 Future plan to fill the remaining gap

(i) To develop mathematical predictive curve following the STH model

(ii) To collect samples for repositories

(iii) In countries like Brazil and China there are Institutions which are monitoring drug treatments and these groups should be contacted to gather data and information

(iv) Look at modified OXA to improve its efficacy

(v) Have some clearer information about PZQ: select drug resistance in the lab and develop molecular markers in the lab to be applicable for the field, use the OXA model for PZQ.

2.4 SubWG on human African trypanosomiasis, leishmaniasis, Chagas disease and Yaws.

2.4.1 Progress of ongoing work

Human African Trypanosomiasis (HAT)

International efforts through the first decade of the 21st Century appear to have driven the decline of reported cases HAT to fewer than 10,000 and the goal elimination by 2020. A distribution of disease and risk map has been recently designed by WHO. New estimates of people at risk are available. Notwithstanding, a number of issues remain with regard to HAT, relating to drug efficacy.

The problems related to manufacture have been solved: all available drugs have ensured manufacture. The drugs in the pipeline have industrials partners and also distribution is working quite well since the agreement WHO / MSF in 2001.

(i) remaining problems are related to:

   a. Stage 1 vs. stage 2 & diagnostics. For Stage 1 in addition to the CATT Tests, the serological rapid-test SD Bioline HAT is recently made available and there has been improvement in LED fluorescence microscopy. The late stage of the disease is however only diagnosed through lumbar puncture and molecular tools are not yet available.
b. Efficacy & resistance:
   i. Pentamidine (Sanofi) donated to WHO until 2020. Resistance: few reports in the field, difficult to select in the laboratory; loss of uptake through loss of transporters. Possible tests: molecular status of TbAT1 and TbAQP2 genes; fluorescence tests.
   ii. Suramin (Bayer) donated to WHO until 2017 (10,000 vials/yr). Resistance: few reports in the field, selected in the laboratory, mechanism = loss of uptake (easily selected using RNAi; endocytosis loss)
   iii. Melarsoprol (Sanofi) donated to WHO until 2020. 1/20 people die from toxicity, but it is the only back-up drug available after the Eflornitine/Nifurtimox combination. Resistance: increasing treatment failure in the field (up to 60% in some foci in DRC), mechanism = transporter mediated. Possible tests: molecular status of TbAT1 and TbAQP2 genes; fluorescence tests.
   iv. Eflornithine (Sanofi) donated to WHO until 2020. Resistance: increasing treatment failure in the field (South Sudan 10% relapse, Uganda 21% treatment failure), not given any more in monotherapy. Mechanism = loss of uptake. Possible tests: molecular status of eflornithine transporter gene.

(ii) Challenges:
   a. Mechanisms still poorly understood and no definitive tests for resistance
   b. No standardised reporting systems for treatment failure, nor follow up to determine resistance
   c. Little national or international coordination for responding to resistance
   d. Few drugs to replace failing compounds and new products (oral melarsoprol, fexinidazole, novel diamidines) slow to develop (although a pipeline is emerging – see DNDi presentation below).

Leishmaniasis
Leishmaniasis are distinct diseases caused by 17 species with different response to treatment.

(i) Efficacy and resistance and production.
   a. Antimonials: Resistance to SbV is widespread in N. Eastern India (Bihar); different sensitivity by species (L. donovani and L. braziliensis more sensitive to SbV than L. major, L. mexicana or L. tropica). For CL, especially forms caused by L. tropica, efficacy is very low. GSK halted the production of Pentostam, while generic sodium stibogluconate (SbV) production continues especially in India; Sanofi Aventis continue with Glucantime (meglumine antimoniate)).
b. Amphotericin B. Liposomal Amphotericin B (e.g. AmBisome®) is significantly less toxic than Amphotericin B deoxicholate (Fungizone) and requires shorter treatments (in general 3-5 dose regimens, and a single-dose of 10mg/kg used in the Indian subcontinent). Clinical trial (Bihar) have reported some treatment failures. WHO NTD and TDR, in collaboration with ICDDR-Bangladesh are undertaking a study using AmBisome® single-dose regimen at the primary health centres level to determine its feasibility to be used as first line treatment in Bangladesh. Gilead committed to donate 445,000 vials of AmBisome® until 2017. Amphotericin B-resistant parasites can be selected experimentally in the laboratory. – changes in sterol metabolism restricting ergosterol production (mutation in the metabolism of cholesterol enzyme in resistant parasites) that limits the binding of the drug. There is a fear that by using Ambisome as single drug regimen resistant strains might be selected, and the resistance of Ambisome is stable and spreadable. At present the WHO recommended SSG-Paromomycin combination for East Africa has been accepted by the countries and is being incorporated in the national treatment guidelines. Single shot Ambisome should be used only during the attack phase of the VL elimination programme in the ISC as recommended by the Leishmaniasis WHO expert committee.

c. Paromomycin. Resistance: not yet known in field, possible surface changes limiting uptake in lab-induced resistance.

d. Miltefosine. Resistance: now reported treatment failures are emerging in India and Nepal, laboratory studies show changes to transporter, or its destination mediated-accessory factor LdRos. Possible tests: molecular basis of the LdMT carrier or Ros; Fluorescent tests. There is a significant increase in the failure rate of oral Miltefosine for treatment of Visceral Leishmaniasis in India and Nepal. A recent publication from Nepal reported up to 20% treatment failure rate at one year follow up after treatment.

(ii) Challenges:

a. As there is the risk of selected drug resistant by the use of single drug therapy, drug combination is the best option for improving efficacy, slow the speed of inducing resistance, reduce toxicity and lessen costs. Several drug combination regimens are under trials as below, but Ambisome is recommended to be always part of the drug combination.

- AmBisome + Miltefosine 8 days, India
- AmBisome + Paromomycin 11 days, India
- Miltefosine + Paromomycin 10 days, India
- AmBisome + SSG, East Africa
- AmBisome + Miltefosine 8 days, East Africa

b. New candidates

- Fexinidazole, a oral nitroimidazole drug for treating VL
- Arginase inhibitors, 2-4 diaminopyridines, imipramine, aspartic peptidase inhibitors
Treatment of cutaneous leishmaniasis (CL). Susceptibility is different from diverse strains, drug choice should be guided by local epidemiology. CL due to *L. major* and *L. mexicana* is self-healing in around 50% of cases over a period of six to twelve months, but lesions due to *L. braziliensis* or *L. tropica* can last for several year and the efficacy of current drugs is very low. There is a need for a simple and efficacious treatment for CL with an acceptable side-effect profile. Proposals are topical treatment (paromomycin, AmB) or systemic treatment, especially using oral drugs. Currently however, there are not many options in the R&D pipeline. Current treatment options for PKDL are difficult to deploy and comply with, so there is an urgent need to identify better treatment options, especially in view of VL elimination programmes.

**Chagas disease**
The different *T. cruzi* genetic diversity with diverse susceptibility sustains the difficulty to find effective compounds. Chagas is endemic in Latin America with 11-18 million infected but is increasingly imported in North America (US and Canada) and Europe. Diagnostic and curative markers are difficult.

(i) Issues relating to drug efficacy
a. Benznidazole, first front line drug. Oral tablets for 1-2 months. Increasing adverse events especially allergic skin reactions. Resistance: naturally refractory strains in field. Lab studies indicate a central role of the nitroreductase that activates the drug in resistance (i.e. reduced nitroreductase, reduced drug activation). Possible tests: molecular status of nitroreductase gene?; possible fluorescent tests with fluorescent nitroheterocycles. Global shortage in 2011-2012. Now recovered through LAFEPE (Brazil) which re-started in 2012 and Laboratorio ELEA in Argentina that picked-up the production in 2011.

b. Nifurtimox (Bayer to WHO, 1 million tablets up to 2017). Resistance: naturally refractory strains in field. Lab studies indicate a central role of the nitroreductase (as for benznidazole). Possible tests: same as for benznidazole.

c. Fexinidazole. Also active against Chagas and less toxic. Resistance triggered through the same mechanism.

(ii) Challenges:
 a. National programmes asked to collect systematic information on adverse effects
 b. Global network of sentinel centres currently being designed

**Yaws**
Yaws is a non-zoonotic infection and sensitive to penicillin. An eradication programme is ongoing. In 1996-2003 the disease was eliminated from India with single shot of injected penicillin to affected persons. In 2012 WHO plans eradication campaign using single shot azithromycin. Pfizer has a donation programme till 2020 (for trachoma) but it will be necessary to find a donor for Yaws. Strategy is Total Community Treatment followed by Total Targeted Treatment. Surveillance is needed for (i) correct administration, (ii) emergence of treatment failure and (iii) molecular tests for resistance.
2.4.2 **Summary and recommendations for STAG in 2013**

2.4.3 **Achievements since establishment of WG**

(i) There are lots of data for monitoring efficacy and safety for Chagas and HAT (e.g. HAT SENTINEL) although less on Leishmania.

(ii) Laboratory resistance markers are advanced and efficacy studies have been implemented both in vitro (lab) and in vivo (field). Fluorescent microscopy is a good tool to spot rapidly whether resistance is occurring for some drugs.

(iii) New products are under development

2.4.4 **Future plan to fill the remaining gap**

(i) Improve the coordinated efforts towards elimination.

(ii) Set up dynamic modeling and predictive curve (especially for HAT and Chagas) based on data available following the example of PC diseases.

(iii) Make applicable lab markers and translate them for monitoring drug efficacy in the field.

(iv) Hasten the setting up of sentinel sites (HAT network should be reinvigorated) and standardized reporting system on efficacy and safety should be based on better technology (on-line mobile phone software).

(v) Develop clear monitoring guidelines and applicable recommendations for endemic countries (e.g. for Leishmaniasis the strategy of single-dose attack Ambisome as first line in Indian subcontinent might be reconsidered).

(vi) Develop appropriate markers to monitor treatment outcomes and therefore tools for monitoring drug failures/resistance.

(vii) Consider the implication of azithromycin donation (donated from Pfizer for trachoma but not for yaws) for yaws eradication. Define access to drug; establish the criteria for eliminating strategy. A special consideration in this area, should also be given to drug dosage: for jaws the recommended dose is of 30 mg/kg, the dosage utilized in the field for trachoma elimination (based on the use of a dose pole) is of 20 mg/kg up to a maximum of 1 g (4 tablets), this discrepancy could be of concern for the possible development of drug resistance.

2.5 **SubWG on DNDi and research on NTD drugs**

2.5.1 **Progress of ongoing work**

The DNDi objectives are (i) deliver 11 to 13 new treatments by 2018 for HAT, leishmaniasis, Chagas disease, malaria, paediatric HIV and specific helminth infections, (ii) establish a robust pipeline for future needs, (iii) use and strengthen existing capacity in disease-endemic countries.

(i) HAT

a. Clinical phase. Fexinidazole in Phase 2 trial with promising results. Oxaborole in Phase 1

b. Implementation phase. Studies on NECT are ongoing
(ii) Leishmaniasis
   a. **Pre-clinical phase.** New products with partners (i.e. Dundee University) are being developed. Nitroimidazoles are ready to go for clinical trials next year. Oral formulation of Ambisome for CL is under development.

   b. **Clinical phase.** The following drug combinations are being tested: Miltefosine + Ambisome (Africa); Ambisome +SSG (Africa); Ambisome + Glucantim (Brasil); Ambisome + Miltefosine (Asia); Ambisome + Paromomycin (Asia); Miltefosine + Paramomycin (Asia)

   c. **Implementation phase.** The following drug regimens are being tested in the field. Paromomicin +SSG (Africa); trials comparing single shot Ambisome vs drug combinations (Ambisome + Miltefosine; Ambisome + Paromomycin; Miltefosine + Paramomycin) (Asia).

(iii) Chagas disease
   a. **Preclinical phase.** The following products are under evaluation: i) Nitroimidazole as a back up ii) Fexinidazole sulphone, iii) Nifurtimox enantiomer.

   b. **Clinical phase.** E1224 is in phase 2 trial. Nifurtimox pediatric formulation is in phase IIb/III (safety assessment). Results from the efficacy trial comparing posiconazole and benznidazole show higher efficacy for benznidazole.

   c. **Implementation phase.** Development of pediatric formulation of benznidazole (pharmacovigilance)

(iv) Filariasis
   a. **Preclinical phase.** Flubendazole
      i. Phase I DOLF: to develop an orally available formulation of flubendazole that duplicates the efficacy of parenteral dosing: macrofilaricidal: use in Loa areas; end-stage eradication; reduce time to elimination in new sites.

      ii. Phase II DNDI. Phase III DND /J&J engaged resources to look at safety and to a formulation that improve compliance and systemic effect. The amorphous solid dispersion (ASD) formulation provides excellent bioavailability in several animal species.

      iii. Progress:
          1. IND filing in early/mid 2014
          2. Priority is single oral dose (not much for compliance but for safety reasons)
          3. Case management vs MDA (but these are not mutually exclusive)
          4. Toxicology and PK/PD studies mainly completed
          5. Efficacy (in vivo and in vitro) studies ongoing at J&J

      iv. Additional studies : effect of flubendazole against microfilaria B. malayi and also against microfilaria Loa loa

   b. **Clinical phase.** Test on the use of Moxidectin as macrofilaricidal. Wolbachia project looking at efficacy of doxycycline.
3 Strengthening laboratory capacity for NTD control: on-going and future initiatives (cross cutting issues with the WG on Capacity Strengthening)

The Centre for Neglected Tropical Diseases (Liverpool, UK) supports 5 laboratories in Africa/Asia to strengthen M&E activities, and to accelerate LF and other NTD elimination towards 2020 (including STH and schistosomiasis). This activity is funded by DFID in order to strengthen the South-south collaboration. Inventory of needs have been developed, specifically on NTD diagnostics, infrastructure, and support to personnel. Since April 2012 a new system of laboratory evaluation has been established. The main areas of support are focused on (i) mapping and M&E activities, (ii) develop Quality Assurance, (iii) provide SOP for laboratory activities related to NTD control, (iv) process laboratory samples for operational research or M&E as required, (v) data management, and (vi) skills to provide technical support on NTD to neighbouring countries.

The 5 identified laboratories are:

1. Eastern and Southern Africa Centre of International Parasite Control (ESACIPAC), Kenyan Medical Research Institute, Nairobi, Kenya
2. Malaria Alert Centre, College of Medicine, Blantyre, Malawi
3. Noguchi Memorial Institute, University of Ghana, Accra, Ghana
4. MoH Laboratories, Bo and Makeni, Sierra Leone
5. MoH National Laboratory, Colombo, Sri Lanka

In addition, further support is planned for:

a. Centre Suisse de Recherches Scientifiques, Cotes d’Ivoire,
 b. NTD laboratory in DRC
 c. NTD laboratory in Ethiopia
 d. NTD laboratory in Ibadan University, Nigeria.

One of the aims of the WG on Capacity Strengthening (CS) is to build on the efforts of CNTD and to identify existing laboratories for becoming potential references lab in NTD endemic countries. An inventory of existing and potential references laboratories (including WHO CC) should be developed in consultation with CNTD and other relevant partners. Selection criteria and TOR should be laid down to define sub-regional labs, not limited to Africa. The technology transfer of APOC to 4 laboratories (MDRC in Ouagadougou, Burkina Faso, Noguchi Memorial Institute in Ghana, two other laboratories in Cameroon) and the TDR supports to other laboratories in Africa should be taken into considerations. Preference should be given to MoH laboratories to guarantee sustainability. Brazil should be considered as a potential resource for lusophone countries.
Conclusions and way forward
As shown from the progress in the different sub-working groups, much work has been done and achievements made. However, future plans indicate that more work is needed and efforts should be made to fulfil the gap to answer the original mission of this WG. The developments of predictive models that follow the path made by the Onchocerciasis group, the publication of SOP to assess drug efficacy for the different NTDs and their application/implementation at country level are among the necessary tools to ring the alarm bell in case of reduced anthelmintic drug efficacy. The next step would be to exclude confounding factors and to confirm (with molecular markers) the occurrence of drug resistance. Recommendations of the algorithm to follow after the alarm bell has rung needs still to be developed. In addition, a consensus must be reached on how to modify the PC deworming strategy in case drug resistance occurs. This WG therefore recommends to STAG to continue to work along these priorities and discuss the progress made in yearly meetings. This is important not only to guide NTD control in endemic countries, but also for the donors and the drug manufacturers involved in the drug donations both for monitoring donated drug efficacy and for developing new drug products. For these reasons it seems premature to end up this WG by merging it with other WGs (like CS and M&E) as it would difficult to keep the targets ahead. Some members of this WG are represented in other WG (Pat Lammie for M&E; Marco Albonico, Jozef Vercruysse and Bruno Levecke for CS group) and will serve as liaison and coordination in addition to the WHO secretariat.

In addition, it is proposed to STAG that a meeting to discuss back-up solutions in case resistance would emerge should be planned by WHO, involving also veterinary public health scientists. It is suggested also that the WG on CS should present to the STAG a clear proposal how to move forward within the laboratory reference network and a meeting to discuss and move forward on this specific issue should be called by WHO in the second half of 2013.
Chair: Dr. Sam Zaramba

Summary Points & Recommendations

Rapporteurs: Ms. Katie Zoerhoff, Dr. Reda M.R. Ramzy

**Introduction**
Welcome remarks by Dr. Savioli (Director, NTD, WHO, HQ) and Dr. Engels (Coordinator, NTD/PCT):
Dr. Savioli briefly discussed two recent issues of interest to NTDs. The first is a draft resolution to be adopted by the Sixty-sixth World Health Assembly. The resolution recommends to expand and implement interventions against neglected tropical diseases in order to reach the targets agreed by WHO and its partners in the London Declaration on Neglected Tropical Diseases and set out in WHO’s roadmap for accelerating work to overcome the global impact of neglected tropical diseases.

The other topic is the publication of a second WHO report on NTDs, “Sustaining the drive to overcome the global impact of neglected tropical diseases.” This report further elaborates concepts discussed in the roadmap, describes the need for sustainable progress, and examines the challenges in implementation encountered by member states, WHO and their partners.

Dr. Engels discussed the major outcomes based on the recommendations of the last M&E meeting in 2012. These include:

1. A working Group on Capacity Strengthening (WG CS) was established, its first meeting was convened on 6 – 7 December 2012. The WG CS priority activities were outlined in consultation with WHO regions. The overall working objectives of the WG CS is to expand managerial capacities for PC implementation & establish an NTD laboratory network to support national control programmes.
2. The Standard Operating Procedures for Monitoring Drug Efficacy of benzimidazoles and praziquantel were finalized (ready for transition to WG CS and WG M&E activities).
3. Work on mathematical models for predicting disease-specific impacts (STH) was commenced.
4. A Task Force for monitoring impact of preventive chemotherapy (PC) was established.
5. Work on tools to improve diagnostics for surveillance & scale-down of PC was initiated.
6. A provisional strategy for LF elimination in areas co-endemic with Loa loa was developed.
7. Practical definitions for control, elimination & eradication of NTDs were provided.
8. A scorecard for M&E of the NTD Roadmap was developed (for WHO internal use only).

Dr. Engels then highlighted the M&E priorities for 2013 as follows:

1. Monitoring scale-up of treatment coverage; there is a need to markedly improve reporting on outcomes of accelerated implementation of PC and change in trajectory by
   a) Significantly improving timeliness and completeness of implementation data;
   b) Improving data quality; by undertaking in-process assessments and evaluation of reported coverage (important for drug efficacy alert systems); and
c) Encouraging the use of mHealth to improve data transmission from peripheral sites to central levels.

2. Establish a laboratory network to support NTD control activities; and specially to roll-out application of Standard Operating Procedures for monitoring drug efficacy (benzimidazoles and praziquantel).

3. Strengthen surveillance for NTDs by
   a) improving diagnostic tools
   b) improving statistical sampling methods;
   c) defining cost-effective surveillance strategies for the scale-down phase of programmes; and
   d) further work on xenomonitoring for vector-borne diseases.

4. Advance efforts
   a) for integrated monitoring of co-implementation of LF, STH, SCH transmission assessments;
   b) harmonization of LF & ONCHO frameworks for mapping, impact evaluations, and programmatic decisions.

5. Consolidate evidence of enhanced outcomes and impact of preventive chemotherapy.

**Monitoring and Evaluation at Regional and National Levels**

Prof. Gyapong provided an overview of the preceding year’s activities and suggested activities for 2013 of the Subgroup 1: M&E of National Programmes: Responding to National Programme Needs.

A situation analysis was conducted for M&E and data management practices for NTDs. 17 participants from five WHO regions participated in the data management practices questionnaire.

Key results indicated:
1. Only four of the respondents had received data management training for NTDs in the past five years
2. Timeliness of reporting is a significant bottleneck issue. However, once the data are submitted, they appear to be completed.
3. There are no standardized tools/procedures for assessing data quality
4. Very few countries utilize an integrated NTD database in an appropriate software to host NTD data.

Three types of training workshops were held in 2012.
1. The first was a programme management training which included a series of workshops and meetings conducted, including on the use of the Tool for Integrated Planning and Costing (TIPAC) in AFRO. Then participant from countries developed and finalized multiyear National Plans of Action.
2. The second type of training focused on monitoring and evaluation. The training modules were developed in collaboration with partners (RTI, CDC, CNTD, and WHO-HQ). Four workshops (2 Anglophone, 2 Francophone) were conducted. During the workshop, participants were sensitized about a new Joint Request for Selected Medicines and Joint Reporting Form. Travel and accommodation of country participants was supported by CNTD. Participants drafted detailed multiyear M&E Plans of Action for their countries.
3. Three training workshops on transmission assessment surveys were held during 2012.
A working draft of Core Indicator Compendium is underway. This includes details of clear definitions of how to measure progress towards disease-specific control or elimination goals and serves as a reference document for health statistics. The draft is under technical review and editing for publication during 2013.

Furthermore, a WHO-administered M&E SharePoint was established, with access by all M&E focal points in WHO and partner organizations. It serves as a working platform that has been used extensively for collaboration with partners in developing various M&E related products.

Prof. Gyapong suggested activities for 2013:
- Development of integrated national NTD databases (MS Access based);
- Targeted training for national NTD data managers, with a focus on programme management;
- Training for TAS for countries scaling-down and/or preparing to scale-down; and
- Development of tools for improving data quality, especially including a standardized data quality assessment protocol.

Participants representing WHO regional offices provided a comprehensive overview of M&E activities in their regions. These included number of endemic countries, distribution of NTDs, and M&E practices and needs. They also discussed program needs and challenges; common themes included strengthening M&E systems at all levels; increasing the capacity of countries to implement M&E for NTDs; improving transparency and uniformity of data; and data sharing and dissemination. Others issues comprised when to stop MDA and post-MDA surveillance; the cost of capacity building and implementing TAS; high cost of ICT cards; operational cost for TAS; and sustaining political commitment for NTD control/elimination.

The African Programme for Onchocerciasis Control (APOC) provided an update on its revised mandate from control to establishing a country-led systems capable of eliminating onchocerciasis as a public health problem in endemic countries by 2015, to: (i) Eliminating onchocerciasis in at least 80% of endemic countries in Africa by 2025; (ii) Collaborating with relevant programmes and partners to use CDTI to eliminate selected NTDs amenable to PC in onchocerciasis-endemic countries in Africa; and (iii) Collaborating with relevant programs to strengthen community health systems in onchocerciasis-endemic countries in Africa.

Given that LF and onchocerciasis have a number of commonalities and areas of collaboration, an inter-disciplinary team has been set up to improve collaboration between programs to eliminate the two diseases with three members from TCC and three from RPRG. This team held its first meeting in December, 2012 and identified the key priorities and key challenges as stopping IVM treatment and confirmation of focal elimination, maintaining government and NGDOs contribution, maintaining quality of data, and the expansion of treatment to all transmission zones (including Loa loa endemic areas) in order to achieve onchocerciasis elimination.

**Monitoring of disease-specific indicators—Progress reports and updates**

The sub-working group on disease-specific indicators met in October 2012 to review the current status of Transmission Assessment Surveys, to propose recommendations on how to scale-up these surveys, to discuss morbidity indicators for GPELF, to review the provisional strategy for MDA in LF-Loa co-endemic areas, and to re-visit the global burden of LF and consider how to revise the global estimates after 12 years of GPELF.

**GPELF Progress in Numbers, P. Lammie**

A country-by-country analysis was carried out to re-visit the global burden of LF. This preliminary analysis estimated 76.66 million cases prevented/cured including 56.13 million cases of mf, 3.70 million lymphoedema, and 16.83 million hydrocele, and the estimated current disease burden has been modified to 77.13 million. In 2013, the group will complete the detailed analysis to finalize
estimates of the new figures, which will be published in the Weekly Epidemiological Record (WER) and other sources.

**Strategy for Loa loa co-endemic areas, K. Ichimori**

A meeting on LF, malaria, and IVM was held in Accra during March 2012, where a provisional strategy for interrupting LF transmission in Loiasis-endemic countries was developed (Accra Strategy). This strategy was further refined in the sub-working group meeting in October 2012. It was proposed that where *Loa loa* infection is present based on RAPLOA and onchocerciasis is non-endemic or hypo-endemic (that is, less than 20% of nodule prevalence), mass drug administration could be implemented with albendazole alone (400 mg) once or twice a year, with twice a year being preferable.

**Morbidity management and disability prevention (MMDP) component in GPELF, P. Lammie**

Several steps for MMDP have been considered, including situation analysis, development of implementation policy and plan, operational action (including M&E), and reporting from NPELF to GPELF. It was determined that, at this time, national programmes should concentrate on collecting data on morbidity process indicators rather than on impact indicators, which can be developed in the future.

For individual treatment of clinical cases, any of the following regimens have been proposed and may be considered:

(i) a single dose of a combination of albendazole (400mg) and ivermectin (150-200μg/kg) in areas where onchocerciasis is co-endemic;

(ii) a single dose of a combination of albendazole (400mg) and DEC (6mg/kg) in areas where onchocerciasis is not present;

(iii) DEC (6mg/kg) for 12 days in areas where onchocerciasis is not present.

Additionally, for adults, doxycycline (200mg/day) for 6 weeks is under consideration as an alternative.

**Transmission Assessment Surveys (TAS), A. Yajima**

Several TAS trainings were held during 2012. An informal TAS meeting was held in September to discuss TAS-related issues, including the role of RPRG as a technical review group of TAS eligibility before TAS and to evaluate TAS results after TAS throughout the year on a virtual basis. Two WHO-TAS Training Manuals, a “Learner’s Guide” and “Facilitator’s Guide,” have been drafted. TAS training modules will be available in CD and downloadable online. TAS target populations and ICT needs have been projected based on past progress and country’s national plan up to elimination goal in 2020.

**NTD Tool Update, P. Lammie**

Programme needs for adequate tools change with progress across programme stages. An update on the current NTD tools for diagnostics and surveillance was provided:

- **ICT**: The technical problem with ICT has been described by many users. A new version developed by Alere (with support from BMGF) is being evaluated. Based on newly released data, the new version does not require cold chain, and lower cost. The test has comparable sensitivity and specificity to the original ICT in laboratory evaluation, but the test result is not stable at 24 hours. Field evaluation indicated that in most villages, the strip test version of the antigen test has greater sensitivity than the card test format. The next step is to determine sensitivity in low prevalence settings. A comparison between the old and new versions should start soon (April/May) to generate practical guidance on the use of the new test.

- **CCA test for detection of schistosome antigen**: This CCA test is a urine-based test to detect circulating antigens, and antigen levels correlate with egg count. A multi-country evaluation was undertaken through SCORE project. The test is reliable for disease mapping before MDA. In settings where the prevalence of schistosomiasis is high, CCA can be used as an alternative to Kato Katz. It facilitates programmatic decision about implementing MDA. However, in settings where the
disease prevalence is low, the CCA assay may not be specific enough to make programmatic decisions.

- **The OV-16 Rapid Test:** Laboratory-based Ov16 antibody testing (Ov16-ELISA) was successfully used as a tool to support the onchocerciasis elimination program in the Americas. BMGF provided financial support to PATH to make this test applicable to field use. An OV-16 prototype test has now been evaluated. Relative to Ov16-ELISA (gold standard), the rapid test is >99% concordant. The overall sensitivity reached 89% and 97% specificity, indicating the test adequate for field testing. It would be valuable to use the OV-16 rapid test side by side with the ICT to facilitate assessment of LF and onchocerciasis where they overlap.

- **Antibody assay for trachoma:** Initial results have been published by Goodhew et al. (2012). The sensitivity reached >95% among PCR positive children. Preliminary results showed that in areas where transmission has been interrupted, children are antibody negative. The next steps are to analyze relationship between TF/II and antibody prevalence in children prior to MDA (i.e. disease mapping), then define utility of the antibody test for stopping MDA.

- **Antibody-based surveillance tools for LF:** A new recombinant antigen, Wb123, is specific for *W. bancrofti*. A standardized ELISA format is now being made available to regional laboratories by NIH. Three papers have been published to date in NTD PLoS. A rapid format test is being developed by PATH. For assessment of elimination, an “integrated TAS” can be used to assess LF, onchocerciasis, strongyloides, and trachoma transmission. Detection of antibody responses in children can be used as a measure of exposure to infectious diseases, as well as environmental antigens and vaccines. These responses can be used to monitor the impact of public health programs using a multiplex platform. The ultimate goal is to integrate surveillance for NTDs with routine health surveys by collecting blood spots for the multiplex as part of a DHS or malaria indicator survey.

### Filling the Gaps – Operational Research to Ensure the Success of the Neglected Tropical Disease Control and Elimination Programs, P. Lammie

A recently-awarded Bill and Melinda Gates Foundation grant enables the newly established Neglected Tropical Diseases Support Center (NTD-SC), as part of the Task Force for Global Health, to collaborate with the NTD community to address priority research gaps. Using the grant, NTD-SC will coordinate with partners to implement the research agenda for these diseases, while working with WHO to translate new solutions into program policy. The grant enables the NTD-SC to tackle the shared challenges facing NTD programs everywhere – challenges that prevent programs from scaling up to reach success or sustaining reduction of disease prevalence – to ensure achievement of NTD programs’ control and elimination goals. Participants at the meeting were encouraged to work with national programs to identify problems that should be addressed through operational research, and to communicate these with the NTD-SC.

### Measuring enhanced outcomes and impact: 2012 updates, A. Fenwick, C. Hanson

In 2012, a survey was conducted among national programs and donors to better understand the factors that could influence decision-makers’ willingness to prioritize NTDs, which indicated the need for better evidence related to the impact of NTDs in multiple sectors and improved framing of already-available data. A meeting was held in April, 2012 at Macalester College in St. Paul, Minnesota, US, to further elaborate the work required to build an evidence base in support of sound national and international policy decisions and to initiate action toward the compilation of this evidence. The need for a coordinated, multi-sectorial effort to systematically generate evidence to build political will was strongly expressed, and thus a Task Force for enhanced measurement of impact and outcomes of PC and control of NTDs (EMPaCT) was created. The objective of the Task Force is to generate an evidence base to support the mobilization of political will and sustain commitment to NTD control and elimination efforts at national and global levels. The Task Force
has four work streams to consolidate existing evidence and research needs for health, socio-economic status, education and water and sanitation (WASH). The Task Force will also serve as a hub for matching students from around the world, including those living in endemic countries, with research needs identified by national programmes and other partners. In 2013 the Task Force will publish a series of background review papers summarizing the current evidence on enhanced outcomes and impact of PC, develop standardized research protocols that can be used at national level to generate evidence required to confirm impact of PC and respond to countries strategic planning processes.

**Expert Committees: Report on M&E Activities and Priorities**

Monitoring and evaluation activities and priorities were presented by the Trachoma Expert Committee (TEC), Mectizan Expert Committee/Albendazole Committee (MEC/MAC), Children Without Worms (CWW) and Deworm the World (DtW). Challenges and priorities presented include promoting the use of mHealth for data capture during mapping and disease-specific assessments; adequately monitoring SAEs, particularly as programs scale-up with increased drug donations; improving diagnostics; clarifying M&E guidelines for mapping, implementation, and reducing treatment frequency; and defining clear appropriate indicators for use in scale-down phases.

**Strengthening laboratory capacity for NTD control: Ongoing and Future Initiatives, CNTD**

Impact assessments of interventions against NTDs require technical support through dedicated laboratories with well-trained staff and using appropriate equipment and standardized protocols for testing specimens and monitoring drug efficacy. The NTD department through its Working Group on Capacity Strengthening has commenced an initiative to establish a laboratory network to support NTD control and elimination goals. The overall objective is to strengthen capacity of existing laboratories in supporting national NTD control programmes. The Liverpool School of Tropical Medicine (LSTM) Capacity Strengthening Implementation Research Unit (CSIR) has designed a four-stage approach which it uses to monitor and evaluate capacity development of five laboratories in Ghana, Kenya, Malawi, Sierra Leone and Sri Lanka. CNTD supports these laboratories through the lymphatic filariasis (LF) elimination programme to contribute to their DFID-GSK funded Mass Drug Administration programme 2012-2015. Capacity strengthening plans incorporate activities at the levels of individuals, laboratories and an national/international context. This example is one of the approaches that the Working Group on Capacity Strengthening will expand upon as it works to establish a global NTD laboratory network. WHO and partners are invited to collaborate with CNTD on this effort.

**Perspectives on new diagnostics for NTDs, R. Peeling**

As the development of diagnostics “from bench to bedside” takes a substantial amount of time, requires significant resources, is often fragmented, and delays access to products which results in a disincentive to innovation, it is necessary to think about how the process can be accelerated and made more efficient, particularly within the timeline for elimination and control of targeted NTDs by 2020. Ideally, the diagnostic tools developed should be affordable (A), sensitive (S), specific (S), user-friendly (U), rapid and robust (R), equipment-free (E), and deliverable to field conditions (D) (i.e. ASSURED). However, all these features are practically impossible to combine into a single tool and compromises must be made between in order to develop affordable, accurate and simple products for use at field levels.

Moving forward, the NTD community should aim to refine target product profiles (TTPs), take an inventory of current diagnostic tools, evaluate existing tools against TPPs, develop a diagnostic toolkit and input data into models to inform policy. TPPs investigated for every stage should also be related to the level of endemicity in a population. Point of care (POC) testing results should be linked to national surveillance systems.
WG M&E recommendations and work plan priorities for 2013
The working group participants discussed the following recommendations:

1. **Strengthen the timeliness, completeness and quality of reported NTD data:**
   a. Develop an integrated NTD national database template, in order to facilitate integrated data storage, management, and analysis.
   b. Develop and field test a standard data quality assessment (DQA) protocol and tool for NTDs.
   c. Draft a protocol for evaluation of reported coverage.
   d. Establish consensus on mHealth tools and standards for data management in M&E of PC (using existing examples from ITI, NTD Support Center-Atlanta, RTI, etc.).
   e. Encourage use of standard Transmission Assessment Survey (TAS) eligibility and reporting form by national programs. The role of the RPRG should be expanded to provide a technical review of TAS eligibility before TAS and review TAS results throughout the year on a virtual basis.

2. **Implement specific capacity-strengthening efforts:**
   a. Continue roll-out new tools specifically including a national database template, Joint Request for Selected Medicines, and Joint Reporting Form.
   b. Develop and conduct a data management training workshops for training NTD data managers in best practices.
   c. Finalize and disseminate official WHO Transmission Assessment Survey training material.
   d. Conduct Transmission Assessment Survey training for countries scaling down/preparing to scale down.
   e. Participate in efforts to establish a laboratory network to support NTD control activities, to facilitate application of SOPs for drug efficacy. Liaise efforts of WG-CS, WG-MDE, and WG-M&E, and compile inventory of laboratories from all WHO regions that could potentially be part of such a network.

3. **Strengthen M&E of MMDP in GPELF**
   a. The recommendation for individual case-treatment guidelines should be finalized.
   b. Encourage government to strengthen MMDP activities, including data collection and M&E, within national programmes.
   c. Program managers should continue to include the morbidity data currently asked for in WHO annual reports to be reviewed by RPRG.
   d. MMDP technical meeting should be conducted in 2013 to discuss the new tools, evidence and approaches, such as specific surgical approaches for hydrocele.

4. **Advance integrated implementation, monitoring and evaluation efforts at country level**
   a. Promote implementation of provisional strategy for treatment of areas where loiasis is co-endemic with Lymphatic filariasis, and monitor impact.
   b. Extend CDTI model to strengthen integrated national NTD control and elimination programmes.
   c. Develop protocols for co-implementation of LF, STH, and schistosomiasis transmission assessments.
   d. Harmonize Lymphatic filariasis and onchocerciasis M&E frameworks.
   e. Promote data quality assessment as part of in-process monitoring, particularly during scale-up of PC treatments.
   f. Mobilize resources to support finalization and implementation of integrated national M&E plans.
5. **Endorse proposed modalities of EMPaCT Task Force**
   a. Request NTD STAG to endorse proposed modalities of EMPaCT Task Force, with expansion of its current mandate to cover all NTDs. Consequently, EMPaCT should work as an independent entity outside WG M&E Subgroup 3 but continue to provide relevant input to the group on evidence specifically related to the impact of preventive interventions.
   b. **Identify colleges and universities in endemic countries** to select students to participate in priority research opportunities identified by EMPaCT.
   c. **Translate** research concept notes **UN languages**
   d. **Liaise with UNDP, UNICEF, UNESCO, Global Program for Education (GPE)** to identify a coordinator for the education thematic area of work.
   e. Involve World Bank to incorporate indicators related to human development

6. **Strengthen end-stage strategies and surveillance methods for NTDs**
   a. Continue to improve **diagnostic tools and sampling frames.**
   b. Define cost-effective **surveillance strategies** for scale-down phase
   c. Conduct further work on **xenomonitoring** strategies for scale-down phase and post-treatment surveillance
   d. Finalize the **handbook of practical entomology for lymphatic filariasis** elimination.
   e. Accelerate access to **improved and affordable ICT tests** for use by national programmes

7. **Monitor utilization and expansion of drug donations in scaling-up deworming efforts**
   a. Resource mobilization for additional mapping, so that deworming can be expanded.
Notes on meeting of the Working Group on NZDs within the NTD Strategic and Technical Advisory Group (STAG)-WHO Headquarters, Geneva, 23 April 2012

Drs L. Savioli and F.X Meslin opened the meeting by welcoming participants and emphasizing on how important the Working Group was within the STAG. Prof. Malika Kachani, Chair of the working group welcomed members and thanked them for their contribution to the draft presentation which was to be discussed and finalised.

She reminded members of the objective of the meeting which was to finalize a report in form of a presentation to the STAG meeting which was going to be held the following day.

An agenda for the day’s proceedings and discussions was tabled for adoption. Presentations were made by members following the agenda followed by comments and questions.

1. NZDs surveillance

Prof. Sarah Cleaveland introduced the first topic on NZDs surveillance and gave an overview of the challenges and opportunities in the surveillance of NZDs.

She made an in-depth analysis on the following issues:

- Reversing the cycle of NZD neglect.
- Purposes of collecting data for surveillance.
- Challenges in responding to outbreaks of zoonotic diseases.
- Early detection and early response to control; delays in reporting outbreaks especially in Africa and Asia.
- Under-reporting as a challenge in surveillance of neglected zoonoses (example of human febrile illness in Tanzania) with some insights on incentives and dis-incentives to reporting for communities.
- Perpetuation of inequities in geographical reporting in global surveillance of zoonoses: identifying areas where zoonoses are endemic and surveillance capacity is limited.
- Building capacity in laboratory and technical competencies: case-scenario of Kenya on inclusion of zoonotic diseases demonstrating challenges in investment on diagnostic capacity and importance of integration between veterinary and medical sector.
- Common elements in surveillance of emerging and endemic zoonoses.

Questions and comments

- Comments were made on the feasibility of identifying sentinel areas and carrying out pilot studies on community engagement as a proof of concept.
- The importance of buy-in and integration with different ministries and stakeholders was also emphasized.
- The group should advocate use of the OIE system of surveillance and reporting and encourage a paradigm shift to all stakeholders involved.
- A point was raised on the huge heterogeneity of diseases and the limitations in use of animal species as indicator for zoonoses.
- Several points from Sarah’s presentation were included in Dr Kachani’s presentation for STAG.
1.1. Surveillance in echinococcosis and cysticercosis

Prof. Phil Craig made a presentation on surveillance of echinococcosis and *Taenia solium* cysticercosis.

The issues below were emphasized in his presentation;
- Focus was put on surveillance of *E. granulosus* (including Genotypic variation ) and *T. solium*.
- Tools for cystic echinococcosis surveillance and control in dogs, livestock and humans were highlighted.
- Tools for *T. Solium* cysticercosis/taeniasis surveillance and control in pigs and humans were highlighted.
- It was noted in the presentation that proofs of concept of combinations of control strategies for both cystic echinococcosis and *T. Solium* cysticercosis are still lacking.

Approaches to control of neglected diseases
- Consideration should be taken whether human or animal is source of infection and the reservoir.

Questions and comments
- Issues on genotype differences and across-host infection and in relation to vaccine efficacy was raised.
- Safety and efficacy issues related to the use of praziquantel versus niclosamide for preventive chemotherapy in areas of schistosomiasis, STH and cysticercosis co-endemicity were mentioned.
- The use of Ag-ELISA for human cysticercosis diagnosis was added to the presentation as a useful tool.
- It was noted that guidelines for surveillance of NCC in affected communities in developing countries were missing.

2. Public health and socio-economic burdens of NZDs

2.1 Burden of Parasitic Zoonoses

Prof. Paul Togerson made a presentation on the global burden of surveillance of echinococcosis and *Taenia solium* cysticercosis.

- Burdens of NZDs and parameters considered in building a DALY score for cystic echinococcosis, alveolar echinococcosis, HAT, zoonotic leishmaniasis, etc.
- Burden of epilepsy due to neurocysticercosis and burdens of zoonotic food-borne trematodes (fasciolosis, chlonorchiasis and opisthorchiasis) were highlighted.
- The estimated burdens of zoonotic schistosomiasis, toxocariasis, trichinellosis, trypanosomiasis, leishmaniasis, toxoplasmosis (congenital), intestinal protozoa, brucellosis, bovine tuberculosis and anthrax were noted.
- Cost-effectiveness of interventions for rabies, HAT, brucellosis and echinococcosis were shown.

Questions and comments
Questions on integrated control not being applied to NZDs was raised (at public health level, bringing diseases control managers together) and cost-effectiveness of integrated control needing to be elucidated.
2.2. Rabies

Prof. Cleaveland made a presentation on global surveillance of rabies and the current challenges. Issues related to under-reporting of the disease were raised. Cost-effectiveness of different strategies were discussed. The effectiveness of legislations in rabies control and prevention was also discussed.

Questions and Comments

- The Group strongly agreed that rabies should be considered as public good to make prevention and control sustainable.

After the presentation on rabies the Chair proposed to amend the Agenda by omitting the presentation on “Human-animal-ecosystem interface for NZDs” in order to have more time to finalize the presentation for the STAG meeting. This was agreed by members. Prof. Samson Mukaratirwa was requested to give an overview “Review of the detailed NZDs roadmap for high-priority neglected zoonotic diseases for 2012-2020” before discussing the final presentation. Prof. Mukaratirwa referred members to the recent report on “Interagency meeting on planning the prevention and control of neglected zoonotic diseases” held in July 2011 for the detailed information regarding the road map for high-priority neglected diseases and the financial requirements needed for the control and prevention activities thereof. Members recommended adjustments on the presentation to make it more specific on the short-term objectives.

3. Final Discussions and comments to the draft presentations

The Chair introduced the draft presentation based on contributions from members of the Working Group. It was agreed that the presentation should be shortened by removing slides on individual diseases and the option of taking one disease (rabies) as an example was agreed. The presentation was revised and updated based on the new information from previous presentations and discussions. It was agreed that the introduction slides should emphasize the inherent characteristics of NZDs and their importance to communities. A slide giving information on the global burden of high-priority NZDs was also added.

4. Conclusion of the meeting

The Chair concluded the meeting by thanking all members of the Working Group and reiterated that their contributions to the NTD-STAG was very much appreciated. Dr Meslin made the final remarks and the meeting was closed.
Joint Message/Statement from USAID and DFID to the Meeting of the Sixth Strategic and Technical Advisory Group on Neglected Tropical Diseases

(Emily – first slide from the capacity building working group)

We would like to take this opportunity to thank the NTD stag for the opportunity to provide a few words from DFID and USAID.

Progress since the London Declaration on NTDs

The UK has launched a programme to complete the global mapping of trachoma. It has agreed to programmes that take an integrated approach to tackling NTDs in Nigeria and South Sudan. It has also helped the World Health Organisation strengthen its NTD staffing and coordination, and resources to tackle Kala-azar. This is in addition to the UK’s on-going NTD programmes on guinea worm and the 5 PCT diseases.

The US, through USAID, has continued to expand its support for integrated NTD programs. As of 2012 USAID is currently supporting 25 countries in Africa, Asia and Latin America. In addition, new initiatives have been launched to support global capacity building and complete disease mapping of the five PCT diseases in coordination with DfID and other partners. Support to WHO HQ and WHO Regions also continued with a focus on M&E and capacity building.

The draft resolution on NTDs proposed by the 132nd session of the WHO Executive Board will be submitted for adoption to the 66th WHA in May 2013. The US and UK support this resolution, particularly the importance of national ownership and improving the capacity to implement and monitor integrated NTD programmes.

The Challenge

(Chris)
Since January 2012 NTDs have seen a significant increase in resources and welcome attention to the fight against NTDs. However with this comes the need to make the best use of the increased resources, coordinate the increase in activities, and communicate the results with increased scrutiny. We also are aware that there is still a significant funding gap, and there is more that can be done to broaden the donor base.

Increased funding – though funding has increased the need is still great so there is a need to make good use of the available resources. This challenges us all to ensure we are making the best possible use of the resources available, and we are achieving results.

The draft resolution for adoption at the WHA recognises that integrated implementation of NTD programmes is highly effective and contributes to stronger health systems and the achievement of targets. Activities should build on one another, with integration of activities where appropriate to deliver more efficient and effective interventions. However it is important to see the evidence of integration on the ground. This involves integration of medicines as they are distributed, integration of NTD activities with the health system, integration with other sectors such as WASH and education, and integration of planning and implementation for organisations that are focussing on diseases that can be tackled together.
Increase in partners and activities at the global, regional and national levels means that strong coordination of activities at global, regional, national and sub-national levels, with leadership from WHO and Ministries of Health, clear prioritisation of the needs, and coordination of all those organisations involved, is absolutely key. Coordination means avoiding overlap and building synergies. We encourage WHO to continue efforts to engage partners, such as was demonstrated in the meeting to plan expansion of Preventive Chemotherapy Interventions in Geneva in December.

Increasing commitment at the national level for integrated NTD programmes – means that there is a need for the human resources to deliver the programmes. Now is the time to ensure that rapid and coordination capacity building efforts are identified and implemented. There are numerous efforts to build capacity which need to be harmonised and accelerated, but the current capacity building initiatives run the risk of not meeting the demand that is there.

Drug donation programmes have eliminated the pharmaceutical barrier. It is therefore necessary to have the appropriate guidelines and tools freely available, so we can support programmes in their efforts to deliver programmes and document where they have reached control or elimination goals. Critical disease guideline gaps remain that need to be urgently filled.

Whilst quality medicines are now available at scale, drugs can also be procured from a variety of other sources with potential for varying quality. It is necessary to ensure that prequalified manufacturers are identified and encouraged for use by governments and organisations working outside the scope of the drug donation programmes.

Increased visibility and scrutiny means that there is an increased need to demonstrate results, with an impact on those infected or at risk from NTDs. This means ensuring that programmes have strong monitoring and evaluation built in, as well as clear lines of accountability. It also means communicating the results that programmes achieve, whether an individual’s story or the impact of NTD programmes on the affected populations.

This meeting

(Emily)
We would like to raise these points, because if the status quo continues in its current direction, we will not be able to reach the 2020 goals outlined in the WHO roadmap for implementation.

Many of the barriers at the global level have been removed with the provision of donated medicines and committed funding. We require accelerated implementation to meet the goals, with much more focus on the delivery at the country level. In order to achieve this, we require integration where appropriate, strong leadership and coordination, accelerated capacity building, the finalisation of the key guidelines and tools and document and communicate the results that are achieved through this.