STRATEGIC AND TECHNICAL ADVISORY GROUP
FOR TUBERCULOSIS
(STAG-TB)

REPORT OF THE ELEVENTH MEETING

20-22 June, 2011
WHO Headquarters

Geneva, Switzerland

The eleventh meeting of STAG-TB took place at WHO Headquarters on 20 to 22 June, 2011. The meeting was organized by the WHO Stop TB Department (HTM/STB) which provides the Secretariat for the STAG-TB.

**Overall objectives of STAG-TB:**

1. To provide to the Director-General independent evaluation of the strategic, scientific and technical aspects of WHO's Tuberculosis Area of Work;

2. To review progress and challenges in WHO's pursuit of its TB-related core functions:
   - Policies, strategies and standards;
   - Collaboration and support of countries' efforts;
   - Epidemiological surveillance, monitoring, evaluation and operational research;
   - Support to partnerships, advocacy and communications;

3. To review and make recommendations on committees, working groups etc.; and

4. To advise on priorities between possible areas of WHO activities.
Eleventh meeting objectives:

WHO asked STAG-TB to review and advise on the following nine areas of WHO global TB control policy, strategy, technical assistance and analytic work:

1. Restructuring and prioritization within core functions of the Stop TB Department
2. New structures for supporting Multidrug-Resistant TB (MDR-TB) scale-up – Headquarters and Regional Office roles
3. Progress on Xpert MTB/RIF diagnostic roll-out
4. Proposed revisions in TB and MDR-TB case definitions, given new molecular diagnostics
5. Development of TB screening guidance for early and improved case detection
6. Scaling-up community TB care and civil society engagement
7. Learning lessons in TB management in emergency and unstable populations
8. Process for new anti-TB drug policy development
9. Revising/updating the Stop TB Strategy.

The meeting agenda as adopted is attached as Annex 1. Annex 2 provides the list of participants.

Dr Jeremiah Chakaya served as Chair of the STAG-TB and the meeting for the fourth year.

STAG-TB members were joined at the meeting by the Chairs of some of the Stop TB Partnership's Working Groups and subgroups, invited technical experts, technical and development agency and civil society partners, as well as WHO staff from Headquarters and all Regions.

Each STAG-TB session began with an introductory presentation by WHO staff or other experts, followed by comments from STAG-TB members serving as discussants. Then there was open discussion for each session, and recommendations were made by STAG-TB members. WHO staff and STAG-TB discussants served jointly as session rapporteurs. Draft written recommendations from all sessions were reviewed and revised by STAG-TB members on the final day of the meeting, and again via review of this report in draft form.

Immediately following the meeting, STAG-TB conclusions and recommendations in full were presented by Dr Chakaya to Dr Hiroki Nakatani, Assistant Director-General, HIV/AIDS, Tuberculosis, Malaria, Neglected Tropical Diseases. Dr Nakatani received this draft recommendations on behalf of the WHO Director-General. The meeting report, will be posted on the WHO website: [http://www.who.int/tb/advisory_bodies/stag_tb_report_2011.pdf](http://www.who.int/tb/advisory_bodies/stag_tb_report_2011.pdf) and circulated to all WHO Senior Management and offices of the Organization.

STAG-TB Conclusions and Recommendations

The Introductory Session included, in addition to approval of the agenda, a short introductory video on the status of the TB epidemic and on WHO's recent actions in TB prevention, care and control. Also presented was a document providing an update on WHO actions taken on 2010 STAG-TB recommendations. See Annex 3.
Session 1: WHO Stop TB Department core functions, structure and priorities

The session provided an overview of the approved restructuring of the Department and the associated planned staff “reprofiling” to take place in mid-2011. The discussion of the core functions and structure of the Stop TB Department, and planned priorities based on core functions, continued during Session 4. The conclusions are noted here:

STAG-TB:
• Applauds WHO’s strategic direction and focus on “core business” to operate effectively in an environment of increasingly limited resources;
• Notes that Tuberculosis, including MDR-TB, is a global health security threat, that there are still major challenges ahead to achieve the Millennium Development Goal target of incidence reduction, Stop TB 2015 targets for halving TB prevalence and deaths, and that there is a new target to halve TB deaths in those living with HIV by 2015;
• Therefore, STAG-TB notes with grave concern the serious reductions in the staffing and financial resources of the Stop TB Department (STB) precisely at a time when Member States, which carry the largest burden of TB, HIV-associated TB, and MDR TB, are requesting additional policy guidance and technical support to implement life-saving interventions, promising new tools and monitor their impact.

STAG-TB urges:
• WHO to work with its partners to help reverse budget and full-time equivalent (FTE) staff reductions to WHO and to STB specifically. The successful interventions and updated policies promulgated by STB must be enhanced, not curtailed, if we are to meet 2015 targets and to succeed in the global elimination of TB as outlined in the Global Plan to Stop TB 2011-2015.
• WHO/STB and all Regional and Country Offices to:
  i. continue their efforts to prioritize within the stated core functions so as to use their limited human and financial resources most efficiently;
  ii. collaborate with partners to seek opportunities so that partners may pursue some activities no longer possible for WHO to pursue (e.g. at country level, and in management of Stop TB subgroups);
  iii. frame its medium-term resource mobilization strategy including outreach to new financial partners.

Session 2: New structures for supporting Multidrug-Resistant Tuberculosis (MDR-TB) management scale up, and WHO roles at HQ and at regional level

STAG-TB:
• Endorses the New Global Framework To Support Scale Up To Universal Access To Quality Management of Multidrug-Resistant Tuberculosis that was developed by Stop
TB partners through an inclusive and reiterative process over the past 20 months and the key issues on which WHO should focus;

- Emphasises that main focus should be the enhancement of country capacity to respond to the MDR-TB problem;
- Endorses the regional decentralization and the process for establishment of the global GLC;
- Urges WHO and partners to move immediately as planned on the 1st of July 2011 with the implementation of the new framework;
- Requests a full evaluation of the functioning of the new framework in one year’s time with particular attention to any negative unintended consequences, and requests adjustments to be made then if necessary;
- Recognizes that with the removal of the requirement of GLC approval for access to second line drugs, an important bottleneck has been removed. However STAG notes with concern the huge amount of work that will be necessary to address the other bottlenecks that have been identified, i.e.
  i. Insufficient country capacity;
  ii. Inadequate quality-assured second-line drugs;
  iii. Missing links with diagnostic capacity building at country level;
  iv. Insufficient funds to implement the new framework;
  v. Inadequate political commitment.
- Notes with great concern that funding for scale up of MDR-TB management is at risk of being decreased at a moment where it is most needed at all levels.

**STAG-TB** recommends that (priority ordering not undertaken):

1. WHO urgently works with the Stop TB Partnership Secretariat as requested in the transition plan to develop a global advocacy plan for MDR TB management scale up linked with the Stop TB Partnership’s global TB advocacy strategy;

2. WHO – using this advocacy strategy - works with all partners to raise the funds necessary to implement the new framework and specific Regional MDR-TB initiatives;

3. WHO and all partners support respective National TB Programmes to develop a country-by-country strategy including:
   a) Clear definition of roles and responsibilities of different partners;
   b) Advocacy to raise political commitment and adequate resources, particularly funding and human resources, through appropriate financial mechanisms;
c) Coordinated support to MDR-TB expansion plan development and implementation at national level to achieve universal access to timely diagnosis, treatment and care for all MDR-TB patients by 2015;

d) Identification of technical assistance needs and plans to address them;

e) Ensuring that no diagnosed patients have to wait for treatment and that sufficient drugs are available to complete treatment;

4. WHO works with the Global Drug Facility (GDF) and other partners to accelerate supply of quality-assured second-line drugs including the exploration of a humanitarian/global philanthropic push to solve the issue of manufacturing of and access to quality assured second-line drugs (SLDs);

5. Recommends WHO to work with the Global Fund (GF) to urgently finalize the streamlined process for the applicants as endorsed by the Stop TB Coordinating Board before the launch of the Global Fund Round 11;

6. Urges WHO to liaise without delay with the GF to fully understand the implications of the GF’s intention “to develop contracts with the regional GLC entities” and how this may affect the implementation of the new framework and its transition period.

3a: Progress on Xpert MTB/RIF diagnostic roll-out

STAG-TB acknowledges:

- The significant and rapid progress made by WHO-STB since STAG-TB 2010 in developing and disseminating policy guidance on implementation of Xpert MTB/RIF, gathering and sharing country experiences, and promoting awareness about the new technology.

STAG-TB recommends that WHO:

1. Ensure collection of a minimum set of core data on country implementation of Xpert MTB/RIF, as recommended in the WHO Rapid implementation document, in order to gain evidence for scale-up and evaluate the interim diagnostic algorithms for consequent refinement;

2. Facilitate and promote the collection of evidence on logistical challenges (including information technology (IT) issues), to work with FIND and the manufacturer on addressing these challenges, and to evaluate the full costs of implementing Xpert MTB/RIF (including impact on patient outcomes) to ensure sustainability;

3. Assist Member States in integrating Xpert MTB/RIF into strategic national laboratory plans and to develop strengthened laboratory networks that utilize the advantages of various complementary WHO-endorsed diagnostic tests;

4. Facilitate the coordination of Xpert MTB/RIF roll-out among implementers, including countries and their partners;
5. Collaborate with Member States and implementing partners, including civil society, to further increase awareness among health care workers and patients about the benefits and limitations of Xpert MTB/RIF;

6. Promote strengthened drug resistance surveillance and accelerated access to drug susceptibility testing to ensure optimal treatment for patients diagnosed with rifampicin resistance using Xpert MTB/RIF;

7. Closely monitor whether the scale-up in diagnostics for DR-TB is being matched by treatment capacity.

3b: Proposed changes in TB case definitions and outcome definitions given new molecular diagnostics

STAG-TB acknowledges:

- The need to update definitions of cases and treatment outcomes for TB and drug-resistant TB in the context of new WHO-recommended rapid diagnostics;
- The need to simplify existing definitions of treatment outcomes for MDR-TB.

STAG-TB recommends that WHO:

1. Proceed with the proposed updating of case definitions, mindful of the following:
   - That changes should not compromise the monitoring of trends in TB (in particular trends in sputum smear-positive cases)* and drug-resistant TB at global and national levels;
   - That two case categories should be considered: (i) microbiologically diagnosed,** and (ii) clinically diagnosed (including suggestive histology) put on a full course of TB treatment. A category of "probable TB" for smear-positive TB is not recommended;
   - That the existing case definition for MDR-TB, recognizing the importance of MDR-TB for advocacy efforts to mobilize resources as well as for clinical management and research;
   - That there is need for a mechanism to allow reporting of the method of diagnosis after registration for culture-confirmed cases.

*To allow monitoring of trends in sm+ TB, reporting of confirmed cases may include disaggregation by method of diagnosis.

**Includes cases diagnosed by microscopy, culture or WHO-endorsed molecular tests

2. Simplifies the definitions of failure and treatment success for global surveillance of MDR-TB as proposed in the discussion paper, while also maintaining the distinction between cure and completed treatment for reporting of treatment outcomes at national level;
3. Continues to pursue the consultative/iterative process initiated in mid-May as proposed in the discussion paper, ensuring participation of all stakeholders and especially National TB Programmes, followed by piloting of revised recording and reporting forms in sites rolling out Xpert MTB/RIF before definitions are finalized;

4. Supports countries to implement the necessary changes to their recording and reporting systems, including by updating the WHO-recommended recording and reporting forms for paper-based use.

Session 4: STB/WHO Restructuring, Core Functions and Priorities
(see conclusions and recommendations under Session 1)

Session 5: Development of guidance on TB screening for earlier and full case detection

STAG-TB:

- Notes with concern that recent prevalence surveys in low and middle income countries show high burdens of undiagnosed active TB, indicating the need for more effective early case detection;

- Notes that countries are seeking advice on when, where, and how to screen for TB (perform active case detection), as well as guidance related to prioritization of risk groups and demarcation of program responsibilities;

- Recognizes that, while it is critical to continue to improve all aspects of "patient-driven TB detection"*, there is a need to develop guidelines on screening for active TB, to enhance early and expanded case detection;

- Notes that although important evidence on TB screening has emerged from a systematic review, recent research, and country experiences, funds must be secured to collect and evaluate essential data prior to finalization of guidelines;

- Recognises that terminology (e.g., TB screening vs. active case finding/detection and patient-driven TB detection vs. passive case finding) is an important consideration in efforts to improve acceptance among multiple stakeholders;

*STAG-TB suggests that the term "patient-driven TB detection" replace the term "passive case finding".

STAG-TB recommends that WHO, working with partners, develop guidelines on TB screening, while:

1. Linking to other relevant guidelines and frameworks focused on improving early case detection and on screening in specific risk groups (e.g., PLHIV and TB contacts).

2. Ensuring that bottlenecks for the implementation of essential interventions to minimize barriers to access and improve the quality of diagnosis, treatment, and care
are addressed before or in parallel to the introduction or expansion of screening activities.

3. Considering potential unintended consequences of screening including the detection of drug-resistant TB or other significant/life-threatening conditions (e.g., lung cancer, cardiovascular disease), cost and social burden, impact on health seeking behaviours, anxiety during prolonged evaluation, etc.

4. Commissioning and stimulating research (systematic reviews, operational research, mathematical modelling) to assess the impact, cost, and feasibility of different screening approaches from patient, provider, and societal perspectives;

5. Exploring potential roles of NTPs, health/social programmes, civil society, etc., in implementing different screening approaches in various health system contexts; and investigating TB screening as part of multi-disease control initiatives;

6. Continuing to engage all stakeholders as well as communication experts in determining the most appropriate terminology (screening vs. active case finding/detection) for the activity.

Session 6: Scaling up community-based care and civil society engagement

STAG-TB:

- Welcomes WHO’s efforts and vision to enhance the effective engagement of civil society organisations (CSOs) in TB prevention, treatment and care service delivery, research and advocacy including simplifying the guidance, standardising monitoring and evaluation (M&E), providing technical assistance to CSOs and reaching out to new stakeholders. It also acknowledges the recent progress made by WHO’s Stop TB Department within the context of broader WHO reforms;

- Emphasises the importance of effective and tailored engagement of civil society organisations in global and national TB prevention, treatment and care, and recognises the catalytic role of WHO to facilitate the linkage between National TB Programmes and CSOs particularly at country level;

- Supports the operational definition of CSOs for the planned WHO activities;

- Recognises the difficulty of modelling TB on other CSO responses to health and underlines the need to define a TB specific CSO engagement;

- Recognises that current global TB advocacy is limited in relation to CSOs’ engagement and underlines the importance of drawing lessons from and exploring synergies with ongoing efforts, such as the Stop TB Partnership (e.g. Advocacy, Communication and Social Mobilization (ACSM) Sub-group) and Public-Private/Public-Mix models (PPM) and PPM Sub-group efforts;

- Recognises the role of CSOs in providing technical assistance to Ministries of Health and WHO’s catalytic role to foster that engagement.
STAG-TB recommends WHO to:

1. Expedite the efforts to enhance the meaningful engagement of CSOs for TB prevention, treatment and care services including the simplification of guidance, and standardising M & E.

2. Reach out to new stakeholders and “natural allies” such as those engaged on lung health, HIV, non-communicable diseases (NCDs) and maternal and child health (MCH).

3. Prioritise enhanced TB case finding along with quality TB treatment and care services as central to these efforts and also mainstream advocacy and research-related activities.

4. Recognise the distinction between ‘Northern’ and ‘Southern’ CSOs. At the same time, promote linkages between the two groups and facilitate access to funding for smaller local NGOs.

5. Profile the role of CSOs in TB prevention, treatment, and care among donors, governments, and other stakeholders.

6. Enhance the capacity and knowledge of WHO's staff at all levels to ensure effective implementation and monitoring.

Session 7: TB management in emergency and unstable populations (preamble to be added)

STAG-TB:

- Acknowledges that there are rising numbers of settings in some regions where civil unrest and other emergency situations are creating significant challenges for public health action, including TB prevention, diagnosis and treatment efforts;

- Recognises that these situations are widely divergent, with a range of different underlying causes, as well as actors involved in addressing public health priorities in the face of such emergencies;

- Notes that, building on existing WHO guidance, there are opportunities for improving knowledge of how TB efforts are best addressed and obstacles overcome in different settings, and through specific approaches to collaboration across Government, UN agencies and the wide array of non-governmental partners that are engaged.

STAG-TB recommends:

1. As offered, WHO EMRO to convene a group of experts and stakeholders, along with WHO staff from different regions and from STB and PEC (Polio, Emergencies and Country Cooperation) which will:
• Review and assess the use, impact, lessons learnt, possible gaps, shortfalls, achievements and challenges encountered by applying WHO guidelines and documents on TB prevention, care and control contributions in complex emergency situations and unstable populations in recent years. It can due this while distinguishing between needs and responses for natural disasters, man-made disasters, complex emergencies, and chronic political country instability.

2. Report back to STAG-TB in 2012 on findings, and any recommendations on way forward.

Session 8. Development of policy recommendations on adoption of new anti-TB drugs

STAG-TB:

• Recognizes the impending approval of two new drugs for MDR TB treatment as soon as late 2012:

• Acknowledges and welcomes progress made at the WHO expert consultation held as planned in 2011 on new TB drug policy development;

• Notes with deep concern the need for all global stakeholders to help identify means to reduce the prohibitively high costs and prolonged preparatory phases required for randomized clinical trials, while still ensuring patient safety and scientific rigor, such that testing and introduction of new anti-TB drugs and other critical public health tools are expedited;

• Emphasizes that new first-line regimens recommended by WHO must be implementable in routine programme conditions in medium and high TB-burden settings;

• Endorses the establishment of a WHO task force to prepare a roadmap for the preparation of policy guidance on the rational introduction of new TB drugs and regimens.

STAG-TB recommends that WHO:

1. Continue dialogue with drug developers so that WHO can:

   a) Define the evidence required by WHO to prepare clear policy guidance on the introduction and use of new drugs/regimens for TB and MDR-TB;

   b) Recommend preferred comparator and end points used in phase II and III licensure trials, both for drug susceptible and drug resistant TB;

   c) Propose best strategies for post-approval introduction of drugs so as to ensure affordability and access while also preserving drug efficacy;

   d) Encourage that newly developed products are made available to develop DST methods and to conduct studies in parallel to phase III trials, so as to generate evidence for combined regimens for drug susceptible and drug resistant TB.
2. Continue dialogue with regulators to inform their decisions on evidence required for approval and registration of TB drugs, and to encourage harmonization of requirements by major regulatory agencies.

3. Establish an expert committee to formally develop WHO guidance on the introduction of new TB drugs and recommended regimens.

Session 9: Revising/updating the Stop TB Strategy document

STAG-TB:

- Acknowledges the broad and ongoing commitment of National TB Programmes and partners to the Stop TB Strategy;

- Recognizes the need for national adaptation for a greater response from within and beyond the health sector, and prioritization of components, in keeping with the nature of local epidemics and contexts, to accelerate scaled-up implementation towards 2015 targets;

- Endorses the need to update the Stop TB Strategy document to reflect the changes made in the component phrasing in 2010, and to reflect more recent global health and poverty-alleviation agenda, technical policies, endorsed technologies, and the multisectoral approach including all stakeholders that must engage in TB prevention, care and support;

- Notes that this updated document must serve the dual need of assisting those currently implementing the Strategy, and of advocating for commitment to the Strategy by a much wider array of national and global stakeholders;

- Cautions that any updating the Stop TB Strategy should not lead to confusion by National TB Programmes, funders and partners and reaffirm that the fundamental components remain unchanged.

STAG-TB recommends that WHO:

1. In updating the document, include maintaining the “look” of the summary page, and ensure it is clear, succinct and readable. This should also ensure that the effort does not detract from other pressing priorities for WHO guidance and technical assistance;

2. Update the introductory context of the strategy, and relevant and necessary changes in the components and their explanations in line with recent recommended policies and tools;

3. Ensure that in the text, or an annex, that all adjustments made are clear and justified, so that National TB Programmes and all audiences can see what has, and has not, been changed;

4. Underscore the need for wider societal engagement in TB prevention, access to care, and effective treatment and patient support; in this, ensure that there is recognition of the roles of civil society, others outside government, and various actors within government; but avoid prescriptions given the country-specific nature of appropriate roles and capacities.
5. Pursue the plan for engaging partners in review of the updated document and for promoting the Strategy in 2012.

**FINAL SESSION:** This session included consideration of dates for the next STAG-TB annual meeting and proposed agenda topics.

**NEXT MEETING DATE:** The 12th STAG-TB meeting is proposed for 18-20 June 2012.

**STAG-TB 2012 agenda items** proposed by STAG-TB Members:

Each year, in addition to seeking feedback from STAG-TB on priority areas on which the WHO Secretariat seeks advice, agenda items proposed by STAG-TB members are also considered. The following concerns were proposed by STAG-TB members for consideration in planning the 2012 meeting agenda. Note: topics are noted in order of mention by STAG-TB members – no prioritization was done at the meeting; some topics were identified by multiple members.

1. TB/HIV Policy – status of implementation, including the 3 I’s.
2. Xpert MTB/RIF scale-up, assessment of any bottlenecks and lessons learnt, including attention on any concerns on gap between diagnostic and drug access.
3. Evaluation of the new framework for the GLC and MDR-TB scale up.
4. Update on efforts to support community participation in TB care, new partners and lessons learnt.
5. For improved case detection: what impact is being seen with implementation of new tools such as Xpert, community engagement, and prioritized intensified case finding/screening approaches?
6. TB surveillance and monitoring systems: how are new proposed new definitions being used?
7. Results from case studies and other measures to stop the uncontrolled availability of currently existing anti-TB drugs.
8. Target setting and universal access measures (overall, MDR-TB, TB/HIV etc.)
9. Update on new drug development and policy recommendations.
10. Across topics, is operational research delivering information needed?
11. How to provide guidance to national TB programmes facing budget reductions – how to target efforts to deliver more with less; and, how can we use “each other” to keep the agenda alive – measuring impact will be critical to ongoing financing.
12. TB in children: update on policy, diagnostic and treatment access.
13. Progress in ensuring social benefits and rights of patients.
Annex I

AGENDA
Strategic and Technical Advisory Group for Tuberculosis

Executive Board meeting room - 20 June
Salle A, 21-22 June

Monday, 20 June 2011

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
<th>Discussants</th>
</tr>
</thead>
</table>
| 9:00- 9:30 | Welcome  
Meeting Objectives  
Introduction of Participants  
Review of follow-up on 2010 Recommendations | H. Nakatani, ADG, HTM  
M. Raviglione, Dir, STB  
J. Chakaya, Chair  
D. Weil |  |
| 9:30 -10:00| 1. The TB Epidemic and WHO response: Core functions, structure and priorities | M. Raviglione |  |
| 10:00 -10:20| Coffee | | |
| 10:20 - 11:30| 2. New structures for supporting MDR-TB scale up - and WHO roles at Headquarters and at Regional level | P. Nunn | C. Daley  
G.B. Migliori |
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:30-13:00</td>
<td>3. a) Progress on Xpert roll-out</td>
<td>K. Weyer</td>
</tr>
<tr>
<td></td>
<td>3. b) Proposed changes in TB and MDR-TB case and outcome definitions</td>
<td>P. Glaziou</td>
</tr>
<tr>
<td></td>
<td>given new molecular diagnostics</td>
<td>D. Cirillo</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K. Castro</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mao tan Eang</td>
</tr>
<tr>
<td>13:00 - 14:00</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>14:00 - 15:30</td>
<td>4. Perspectives from STAG-TB and other partners on the revised WHO STB</td>
<td>M. Raviglione - Introduction</td>
</tr>
<tr>
<td></td>
<td>structure, functions and priority deliverables 2011-2012</td>
<td>J. Chakaya</td>
</tr>
<tr>
<td>15:30 - 15:50</td>
<td>Coffee</td>
<td></td>
</tr>
<tr>
<td>15:50 - 17:15</td>
<td>5. Early and increased case detection: TB screening evidence and</td>
<td>K. Lonnroth - Introduction</td>
</tr>
<tr>
<td></td>
<td>guidelines development</td>
<td>A. Shapiro</td>
</tr>
<tr>
<td></td>
<td></td>
<td>E. Corbett</td>
</tr>
<tr>
<td></td>
<td></td>
<td>M. van der Werf</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. Bloom</td>
</tr>
<tr>
<td>17:15 - 17:30</td>
<td>Day 1 Recommendations Wrap-up</td>
<td>Chair</td>
</tr>
<tr>
<td>17:45- 18:30</td>
<td>Reception - WHO/UNAIDS Building Cafeteria</td>
<td></td>
</tr>
<tr>
<td>18:30 -19:30</td>
<td>Session Reviews (First Day Rapporteurs and Discussants)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>STB Offices</td>
<td></td>
</tr>
</tbody>
</table>
**Strategic and Technical Advisory Group for TB**  
**STAG-TB**  

**Tuesday, 21 June 2011**

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speakers</th>
<th>Discussants</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00-9:30</td>
<td>Day 1 Review of Recommendations</td>
<td>Chair</td>
<td></td>
</tr>
<tr>
<td>9:30 - 10:30</td>
<td>6. Expanding the global TB response base: scaling up community TB care and civil society involvement</td>
<td>H. Getahun</td>
<td>L. Chesire</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>P. Das</td>
</tr>
<tr>
<td>10:30 - 10:50</td>
<td>Coffee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:50 - 12:15</td>
<td>7. WHO TB Regional Advisers' presentation - with a focus on TB management in emergency and unstable populations</td>
<td>M. Abdel Aziz, EMRO</td>
<td>S. Al Awaidy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>T. Lwin</td>
</tr>
<tr>
<td>12:15 - 14:00</td>
<td>Lunch</td>
<td>STAG-TB Members with STB Management Team</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>D-Cafeteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>T. van Shoen-Angerer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M. Murray</td>
</tr>
<tr>
<td>15.15 - 15:35</td>
<td>Coffee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15:35 - 16:45</td>
<td>9. Revising the Stop TB Strategy: Defining roles within and beyond the health sector</td>
<td>M. Uplekar</td>
<td>D. Barreira</td>
</tr>
<tr>
<td>Time</td>
<td>Topic</td>
<td>Speaker</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------</td>
<td>--------------------</td>
<td></td>
</tr>
<tr>
<td>9:00-11:30</td>
<td>Full review of final recommendations</td>
<td>Chair</td>
<td></td>
</tr>
<tr>
<td>11:30-11:45</td>
<td>Planning for next STAG-TB Meeting</td>
<td>D. Weil</td>
<td></td>
</tr>
<tr>
<td>11:45-12:00</td>
<td>Conclusions</td>
<td>J. Chakaya, H. Nakatani, M. Raviglione</td>
<td></td>
</tr>
</tbody>
</table>
Strategic and Technical Advisory Group for Tuberculosis (STAG-TB)

Eleventh Meeting
20-22 June 2011, WHO Headquarters, Geneva, Switzerland

List of Participants

**STAG-TB Members 2011**

**Dr Salah Al Awaidy**
Director
Department of Communicable Disease Surveillance & Control
Ministry of Health
Oman

**Dr Draurio Barreira**
General Coordinator
National TB Control Program
Ministry of Health
Brazil

**Dr Amy Bloom**
Senior Technical Advisor
Bureau of Global Health,
Office of HIV/AIDS
US Agency for International Development
USA

**Dr Kenneth Castro**
Director, Division of TB Elimination Centers for Disease Control and Prevention
USA

**Dr Jeremiah Muhwa Chakaya**
(STAG-TB Chair)
Technical Expert, National Leprosy and TB Programme
Ministry of Health
Kenya

**Ms Lucy Chesire**
Executive Director
TB ACTION Group
Kenya

**Dr Gavin Churchyard**
Chief Executive Officer
Aurum Institute for Health Research
South Africa

**Dr Daniela Cirillo**
Head
Emerging Bacterial Pathogens Unit
San Raffaele del Monte Tabor Foundation
San Raffaele Scientific Institute
Italy

**Dr Elizabeth Corbett**
Reader in Infectious and Tropical Diseases
London School of Tropical Medicine & Hygiene
and MLW Research Programme
Malawi
Dr Charles L. Daley
Head, Division of Mycobacterial and Respiratory Infections
National Jewish Medical and Research Center
USA

Dr Pamela Das
Executive Editor
The Lancet
United Kingdom

Dr Thandar Lwin
Programme Manager
National TB Programme
Department of Health/
Ministry of Health
Myanmar

Prof Vladimir Malakhov (unable to attend)
National Center for External Quality Assessment in Laboratory Testing of The Russian Federation
Russian Federation

Dr Mao Tan Eang
Advisor to the Minister of Health
Director, National Center for Tuberculosis and Leprosy Control
Ministry of Health
Cambodia

Dr Giovanni Battista Migliori
Director
WHO Collaborating Centre for Tuberculosis and Lung Diseases
Fondazione Salvatore Maugeri
IRCCS
Italy

Dr Megan Murray
Assoc. Professor of Epidemiology
Harvard University
School of Public Health
Department of Epidemiology
USA

Dr Yogan Pillay (unable to attend)
Deputy Director General
Strategic Health Programmes
Department of Health
South Africa

Dr Minghui Ren (unable to attend)
Director-General
Department of International Cooperation
Ministry of Health
People’s Republic of China

Dr Rajendra Shukla (unable to attend)
Joint Secretary
Ministry of Health & Family Welfare
India

Dr Marieke van der Werf
Head, Unit Research
Senior Epidemiologist
KNCV Tuberculosis Foundation
The Netherlands

Dr Rosalind G. Vianzon (unable to attend)
National TB Programme Manager
National Center for Disease Control and Prevention
Department of Health
Philippines

Dr Tido Von Schön-Angerer
Executive Director
Campaign for Access to Essential Medicines
Medicins sans Frontières
Switzerland
Stop TB Partnership Working Group Chairs

Dr Jeremiah Muhwa Chakaya
Chair, DOTS Expansion Working Group
(See under STAG-TB Members)

Dr Richard O'Brien
Chair, Global Laboratory Initiative Working Group
Foundation for Innovative New Diagnostics
USA

Dr Aamir Khan
Chair, MDR-TB Working Group
Executive Director
MDR-TB Control Program
Indus Hospital Research Center
Pakistan

Dr Giorgio Roscigno
Chair, New Diagnostics Working Group
Chief Executive Officer
Foundation for Innovative New Diagnostics
Switzerland

Dr Mel Spigelman
Chair, New Drugs Working Group
President and Chief Exec. Officer
Global Alliance for TB Drug Development
USA

Temporary Advisers

Dr Jaap Broekmans
Former STAG-TB Chair
Chair, WHO Global Task Force on TB Impact Measurement
Former Executive Director KNCV
Netherlands

Dr Dyah Erti Mustikawati
National TB Program Manager
Ministry of Health
Republic of Indonesia

Other Participants

Dr Nils Billo
Executive Director
International Union against Tuberculosis and Lung Disease

Dr Raquel Child
Director
UNITAID
Switzerland

Mr William Coggin
Senior Technical Officer, TB/HIV
Office of the US Global AIDS Coordinator
USA

Prof. Francis Drobniewski
Director, Health Protection Agency
National Mycobacterium Reference Unit
Institute for Cell and Molecular Sciences,
United Kingdom

Ms Fran Du Melle
Director, International Activities
American Thoracic Society
USA

Ms D'Arcy Richardson
TB Team Leader
PATH
USA

Dr Peter Gondrie
Executive Director
KNCV Tuberculosis Foundation
The Netherlands
Dr Philip Hopewell
Professor of Medicine
Div. of Pulmonary and Critical Care
San Francisco General Hospital
USA

Dr Emma Huitric
Scientific Officer for Tuberculosis
European Centre for Disease Prevention and Control (ECDC)
Office of the Chief Scientist
Sweden

Ms Blessina Amulya Kumar
Stop TB Partnership Co-chair
Community Treatment Action Group
India

Dr Eugene McCray
Chief, International Research & Programs Branch
Division of TB Elimination
Centers for Disease Control and Prevention
USA

Dr Ya Diul Mukadi
Senior Technical Advisor
Bureau of Global Health
Office of Infectious Diseases
US Agency for International Development
USA

Dr Joshua Obasanya
National TB Programme
Nigeria

Dr Sai Pothapregada
Senior M&E Officer
The Global Fund to Fight AIDS, Tuberculosis and Malaria
Switzerland

Ms Lisa Regis
Portfolio Manager, Tuberculosis
UNITAID
Switzerland

Dr Suman Jain
Senior M&E Officer
The Global Fund to Fight AIDS, Tuberculosis and Malaria
Switzerland

Dr Adrienne Shapiro
Department of Epidemiology
Johns Hopkins School of Public Health
Center for TB Research
Johns Hopkins School of Medicine
USA

Dr Akira Shimouchi
Vice Director
Department of International Cooperation
Research Institute for TB (RIT)
Japan Anti-TB Association
Japan

Dr Stephen Bertei Squire
Senior Lecturer
EQUI TB Knowledge Programme
Liverpool School of Tropical Medicine
UK

Dr Javid Syed
TB/HIV Project Director
Treatment Action Group
611 Broadway, Suite 308
New York, NY 10012
USA

Dr Maarten van Cleeff
Project Director TBCTA
KNCV Tuberculosis Foundation
The Netherlands

Dr Wanda Walton
Chief, Communications, Education and Behavioural Studies Branch - Division of Tuberculosis Elimination
Centers for Disease Control and Prevention (CDC)
USA
### WHO Staff (Regional/Country Offices)

#### AFRO
Dr Bah Keita, TB Programme Manager  
Dr Daniel Kibuga (Brazzaville)  
Dr Abera Bekele Leta (Ethiopia)  
Dr Gani Akorede Alabi  
Dr Ayodele Awe (Nigeria)  
Dr Samson Kefas (Swaziland)  
Dr Wilfred Nkhoma (Zimbabwe)

#### AMRO
Dr Mirtha del Granado, TB Regional Adviser  
Dr Yamil Silva

#### EMRO
Dr Jaouad Mahjour  
Dr Mohamed Abdel Aziz, TB Regional Adviser  
Dr Martin van den Boom  
Dr Syed Karam Shah  
Dr Sevil Huseynova (Iraq)  
Dr Ireneaus Sindani (Somalia)  
Dr Aayid Munim (Sudan)  
Dr Philip Ejikon (South Sudan)

#### EURO
Dr Masoud Dara, TB and M/XDR-TB Programme Manager  
Dr Ogtay Gozalov  
Dr Kristin Kremer

#### SEARO
Dr Khurshid Hyder, Regional Adviser  
Ms Eva Nathanson (WHO Myanmar)  
Dr Mohammed Akhtar (WHO Nepal)

#### WPRO
Dr Catharina van Weezenbeek, Team Leader, STB and Leprosy Elimination  
Ms Keri Lijinsky  
Dr Fabio Scano (China)

### WHO Headquarters Staff

#### HIV, TB and Malaria Cluster (HTM)
Dr Hiroki Nakatani, Assistant Director-General

#### Stop TB Department (STB)
Dr Mario Raviglione, Director  
Ms Diana Weil, Coordinator, Policy and Strategy  
Mr Glenn Thomas  
Ms Melina Abrahan  
Ms Sara Faroni

#### Stop TB Strategy (TBS/STB)
Dr Léopold Blanc, Coordinator  
Dr Daniel Chemtob  
Mr Jacob Creswell  
Dr Haileyesus Getahun  
Dr Knut Lonnroth  
Dr Delphine Sculier  
Dr Mukund Uplekar  
Ms Lana Velebit  
Ms Monica Yesudian

#### TB Operations & Coordination (TBC/STB)
Dr Paul Nunn, Coordinator  
Ms Luz Baclig  
Ms Karin Bergstrom  
Ms Annemieke Brands  
Dr Angelito Bravo  
Dr Susanne Carai  
Ms Ines Garcia Baena  
Dr Dennis Falzon  
Dr Malgosia Grzemska  
Dr Christian Gunneberg  
Ms Andrea Godfrey  
Dr Tauhidul Islam  
Dr Azizkhoon Jafarov  
Dr Wieslaw Jakubowiac  
Dr Ernesto Jaramillo  
Ms Soleil Labelle
Annex II

Dr Pierre-Yves Norval  
Dr Salah Ottmani  
Dr Fraser Wares  
Dr Matteo Zignol  

**TB Monitoring and Evaluation (TME/STB)**

Dr Katherine Floyd, Coordinator  
Mr Christopher Fitzpatrick  
Dr Philippe Glaziou  
Dr Ikushi Onozaki  
Ms Andrea Pantoja  
Dr Charalampos Sismanidis  
Mr Hazim Timimi

**TB Laboratory Strengthening (TBL/STB)**

Dr Karin Weyer, Coordinator  
Dr Christopher Gilpin  
Dr Jean Iragena  
Dr Fuad Mirzayev  
Mr Wayne Van Gemert

**Stop TB Partnership Secretariat (TBP/STB)**

Dr Lucica Ditiu, Executive Secretary  
Mr Nejib Ababor  
Ms Shirley Bennett  
Ms Caroline Bogren  
Ms Raegan Boler  
Mr Vittorio Cammarota  
Ms Hélène Castel  
Ms Young-Ae Chu  
Mr Thierry Cordier-Lassalle  
Mr Jacob Creswell  
Mrs Andrea de Lucia  
Ms Jenniffer Dietrich  
Mr Allan Esser  
Mr Argimiro Garcia Montes  
Dr Giuliano Gargioni  
Ms Julia Geer  
Ms Henriikka Huttunen

Ms Annette Kasi Nsubuga  
Ms Paloma Lerga  
Dr Christian Lienhardt  
Mr John Loeber  
Mr Kaspars Lunte  
Mr Richard Maggi  
Ms Judith Mandelbaum-Schmid  
Ms Elisabetta Minelli  
Ms Elena Mochinova  
Mrs Daniela Mohaupt  
Mr Samuel George Nuttall  
Ms Maria Monika Patyna  
Dr Suvanand Sahu  
Mr Joel Spicer  
Mr Anant Vijay  
Ms Anne Zeindl-Cronin

**Representatives from other departments**

**Emergency Preparedness and Institutional Readiness (EPC)**

Dr Rudi Coninx

**HIV Department**

Dr Reuben Granich

**The Special Programme for Research and Training in Tropical Diseases (TDR)**

Dr Shenglan Tang

Anna ted: vi
STAG-TB 2010 Meeting

Actions taken on STAG-TB Meeting Recommendations
(Noted in blue)

Session 2. Scaling up MDR-TB treatment: revising strategies and roles in supporting countries

Actions taken on Session 2 recommendations below are addressed in Session 2 in STAG-TB 2011 Meeting

STAG-TB recommends that WHO, in cooperation with partners:

1. Pursue a revised and rebranded approach to care and control of DR-TB that mainstreams DR-TB into TB control and:
   a. prioritizes the building of national and regional capacity and strengthens the roles of WHO and partners in the coordination and provision of technical assistance;
   b. strengthens country ownership, leadership and accountability of programmes;
   c. ensures strengthening of human resources capacity;
   d. promotes inclusion of all partners including civil society and the private sector;
   e. establishes a comprehensive monitoring and evaluation system;
   f. ensures expanded capacity for laboratory diagnosis, including provision of new tools, and the tight linkage of case management to it;
   g. promotes operational research and advocacy as tools for scaling up the response to DR-TB;

2. Mobilizes resources and develops capacity to ensure TBTEAM and other mechanisms, at national, regional and Headquarters (HQ) levels are able to absorb the increased responsibilities they are expected to hold in coordination of technical assistance under the revised approach;

3. Ensures acceleration of a quality-assured supply of second-line drugs;

4. Encourages WHO to reinforce its monitoring and evaluation of DR-TB scale up in countries;

5. Ensures that the mechanisms developed align with the strategies, policies and needs of countries and donors;

6. Identifies effective country-specific mechanisms of DR-TB care and control, including successful models for provision of care and involvement of private-sector providers, and promotes their adoption in similar settings.
Session 3. Preparing for rapid policy review of new drugs

STAG-TB recommends that WHO:

1. Continues dialogue with regulatory authorities, ensuring the contribution of experienced regulators from countries with both low and high burdens of TB. This dialogue should explore possibilities for:
   - harmonizing the registration of anti-TB drugs,
   - including regulators from high-burden countries in the review carried out by stringent national regulatory authorities,
   - deploying strategies to ensure rapid registration of new medicines and promoting their rational use;

2. Expands the aims of the planned expert meeting to include establishing criteria to guide the drug development process towards the use of new drugs for treatment of DS-TB and DR-TB, including addressing critical issues related to the drug development pathway, clinical trial design and the need for combination therapy;

3. Develops a set of criteria to recommend for optimal use of anti-TB drugs in various programmatic settings, with clearly established timelines and priorities for public health, ensuring proper, equitable and cost-effective access;

4. Assists countries to develop mechanisms for compassionate use and expanded access to new drugs in the context of legislation and national regulatory structures;

5. Pending the results of clinical trials, organizes a meeting with partners to consider the risks and benefits of using fluoroquinolones as first-line drugs within shortened treatment regimens.

Actions taken (will be further addressed in Session 8):

1. Dialogue with regulatory authorities has continued through discussions with several (incl. MHRA, EMEA, FDA, MCC), as well as with the Critical Path to TB Drug Regimen.

2. An Expert Meeting was organized on the 9th-10th June 2011 to address points 2 to 5. The specific objectives of this meeting are:

   (i) To advise WHO on the necessary evidence and information that will be needed to develop recommendations related to the use of new drugs/regimens for the treatment of DS and MDR-TB;

   (ii) To advise WHO on the development of a policy document to guide countries on the introduction and use of new drugs/regimens for DS and MDR-TB in various settings;

   (iii) To review the current WHO guidance on compassionate use of drugs for MDRTB management and advise WHO on the need to revise this and develop mechanisms
for compassionate use and expanded access of new TB drugs in the context of legislation and regulatory structures of the countries.

3. This expert meeting will be preceded by a meeting of experts with drug developers on the 8 June 2011. The Objective is to facilitate exchange of information between drug developers and the WHO on the state of development of new TB drugs and plans for their introduction in the market, and the potential implications for WHO action.

Session 4. Diagnostics policies (A): commercial serodiagnostics

STAG-TB recommends that:

1. WHO pursues a policy that current commercial TB serodiagnostic tests should not be used in individuals with suspected active pulmonary or extrapulmonary TB, irrespective of their HIV status;

   This recommendation also applies to childhood TB, based on the generalization of data derived from adults (while acknowledging the limitations of microbiological diagnosis in children);

   This recommendation also applies to the use of commercial serodiagnostic tests as add-on tests in smear-negative individuals given the high risk of false-positives and the consequent adverse effects;

2. WHO provides a strong message to the TB scientific community and research funding agencies that further targeted research is needed to develop an accurate, simple serodiagnostic test for TB and strongly recommends that proof-of-principle studies be followed by evidence produced from prospectively implemented and well designed evaluation and demonstration studies, including assessment of patient impact.

**Actions taken:** WHO Policy Statement completed, cleared by GRC, final editing underway. Expected date of issue: July 2011

Session 4. Diagnostics policies (B): use of commercial IGRAs in low-income and middle-income countries

STAG-TB:

- Acknowledges the large body of work and compelling evidence base demonstrating the poor performance of current commercial IGRAs in low-income and middle-income countries (typically high-TB settings and/or high HIV-burden settings) and the adverse impact of misdiagnosis and wasted resources on patients and health services when using these tests for the diagnosis of active TB disease;

- Acknowledges the large body of work and compelling evidence base to discourage the use of IGRAs for the detection of latent TB infection (LTBI) in
adults, children, health-care workers, contacts and those involved in outbreak investigations in low-income and middle-income countries (typically high-TB\textsuperscript{1} settings and/or high-HIV burden settings), acknowledging the difficulty in obtaining high-quality data on the diagnosis of LTBI in the absence of a reference standard;

- Endorses the findings of the WHO Expert Group\textsuperscript{1} and supports the strategic approach to develop “negative” WHO policy recommendations to discourage the use of commercial IGRAs in low-income and middle-income countries (typically high-TB\textsuperscript{2} settings and/or high-HIV burden settings).

**Actions taken:** WHO Policy Statement completed, under review by GRC.  
Expected date of issue:  July 2011

**Session 4. Diagnostics policies (C): Xpert MTB/RIF system**

**STAG-TB:**

- Acknowledges the transforming potential of this new technology and the solid evidence base to support its widespread use for detection of TB and rifampicin resistance. STAG-TB also acknowledges the need for access to this innovation in individuals at risk of TB and MDR-TB in resource-constrained settings.

STAG-TB therefore supports the Expert Group\textsuperscript{3} findings that:

1. Xpert MTB/RIF should be used as the initial diagnostic test in individuals suspected of having MDR-TB\textsuperscript{4} or HIV-associated TB;

2. Xpert MTB/RIF may be considered as a follow-on test to microscopy in settings where MDR-TB or HIV is of lesser concern, especially in further testing of smear-negative specimens.

STAG-TB acknowledges the major resource implications associated with this recommendation.

**Remark:** These recommendations also apply to children, based on the generalization of data from adults and acknowledging the limitations of microbiological diagnosis of TB (including MDR-TB) in children;

\textsuperscript{1} Report of the WHO Expert Group on use of interferon-γ release assays (IGRAs) in tuberculosis control in low- and middle-income settings, 20-21 July, 2010

\textsuperscript{2} No globally agreed definition for high TB incidence/burden is available; selected systematic reviews used arbitrary cut-offs of 100 per 100 000 population for stratified analyses. All used World Bank income stratification as proxy.

\textsuperscript{3} Report of WHO Expert Group on Automated nucleic acid amplification technology for simultaneous and rapid detection of tuberculosis and rifampicin resistance: Xpert MTB/Rif system, 1 September, 2010.

\textsuperscript{4} MDR-TB includes retreatment failures, chronic cases, non-converting cases (by month 3), relapses and return after default, contacts of confirmed MTB-TB cases, exposure in institutions with high rates of MDR-TB (prisons, areas where drug resistance is highly prevalent, etc.; see Guidelines for the programmatic management of drug-resistant tuberculosis: emergency update 2008. Geneva, World Health Organization, 2008 (WHO/HTM/TB/2008.402)].
Remark: Access to conventional microscopy, culture and drug-susceptibility testing (DST) is still needed for infection control, monitoring of therapy, for prevalence surveys and/or drug-resistance surveillance, and for recovering isolates for DST other than rifampicin (including second-line anti-TB drugs);

Remark: These recommendations apply to the use of Xpert MTB/RIF in sputum specimens (including pellets from decontaminated specimens), as data on the utility of Xpert MTB/RIF in extrapulmonary specimens are still limited;

Remark: These recommendations support the use of one sputum specimen for diagnostic testing, acknowledging that multiple specimens increase the sensitivity of Xpert MTB/RIF but have major resource implications for both health systems (cartridge costs) and patients (costs of visits to health services).

STAG-TB recommends that WHO:

1. Proceeds with detailed policy guidance on the use of Xpert MTB/RIF;

2. Develops a global strategy for rapid uptake of Xpert MTB/RIF in a systematic and phased approach, including mechanisms to monitor and assess the roll-out of Xpert MTB/RIF, with a clear plan to document the impact on case detection, MDR response scale-up and cost-effectiveness;

3. Proceeds with a Global Consultation on the implementation considerations for scale-up of Xpert MTB/RIF under routine programme conditions (including diagnostic algorithms, logistics, procurement and distribution, quality assurance, and waste disposal);

4. Assists countries with technical support and planning for inclusion of Xpert MTB/RIF in revised diagnostic algorithms.

Furthermore, STAG-TB:

1. Encourages donors and funding agencies to support global uptake of Xpert MTB/RIF technology through public health services or other mechanisms that explicitly promote access by the poor;

2. Encourages further and continuing research for the development of a simple point of care test for the diagnosis of TB especially in low-bacillary samples, e.g. children and HIV-infected individuals;

3. Encourages further development of other equivalent or more sensitive test platforms for the diagnosis of TB and DR-TB.

Above covered in Session 3a, STAG-TB 2011
Session 5. Early and increased case detection

STAG-TB recommends that WHO, working with countries and partners:

1. Elevates advocacy for PPM to the ministerial level, to promote it as an essential intervention to strengthen broader health systems, improve access to TB diagnosis and ensure quality of TB care provision;

2. Mainstreams PPM also as part of MDR-TB response and TB/HIV collaborative activities; seek collaboration with other health programmes as an integrated approach to private sector engagement;

3. Pursues regulatory approaches such as certification and accreditation of care providers as a way to ensure rational use of anti-TB drugs and promote International Standards of TB Care;

4. Continues with ACF systematic review, with clarification of case-detection strategies and terminology, and prioritizing recommendations of high-risk persons, groups and communities where increased case detection will be beneficial;

Actions taken:
- ACF systematic review has been completed, and a draft report will be presented in Session 5 of STAG-TB 2011 meeting.

5. Takes the following steps while awaiting the results of the current systematic review on ACF to:
   - compile a global inventory of ACF approaches being already implemented by countries, including prevalence surveys and related projects
   - plan to convene an Expert Group to examine available evidence, and develop a framework for designing ACF approaches and make recommendations on their implementation.

Actions taken:
- A scoping meeting was held on 31 May and 1 June, to define content of guidelines on TB screening, in line with GRC requirements. Further analytical work will be required before recommendations and guidelines can be developed. Further outcomes presented in Session 5 at 2011 meeting. As a part of the meeting preparations, an attempt was made to identify key ongoing ACF activities, and invite representatives of those to the meeting. However, no comprehensive mapping of initiatives has been done. This will be relevant after the scope of the guidelines has been defined and it should include TBREACH and GF funded activities.
Session 6. WHO TB/HIV policy: from interim to definite

STAG-TB recommends that WHO:

1. Includes, in the updated policy guidance, collaboration between TB and HIV programmes and other line ministries at national, regional and state levels, and integration of TB and HIV services, to provide patient-centred care at facility and community levels. In particular, WHO should recommend that TB and HIV laboratory and drug procurement services collaborate more closely at programme management levels;

- Recommendations under the objective A. Establish and strengthen the mechanisms for integrated TB ad HIV services delivery of the updated policy include that:
  - AIDS and TB programmes or their equivalents should create and strengthen a joint national TB/HIV coordinating body, working at regional, district and local levels, with equal or reasonable representation of the two programmes, including representatives of people at risk of and affected by TB and HIV and other line ministries (e.g. working on prison, harm reduction or mining health services)
  - AIDS and TB programmes should describe models to deliver client-centred integrated TB ad HIV services at facility and community levels compatible to national and local contexts
  - AIDS and TB programmes should ensure that there is sufficient capacity in health care delivery (e.g. laboratory, drugs and referral capacity, private sector involvement, focus on special populations such as people who use drugs and prisoners) for effective implementation and scale-up of collaborative TB/HIV activities

2. Includes guidance on antiretroviral therapy (ART) for TB prevention; recognize the evidence for early initiation of ART for TB patients with HIV; and the need for definite TB screening for PLHIV at first care contact using the most sensitive available technologies;

- Following the recommendation of STAG, WHO has commissioned a systematic and GRADE review including data from large multicentre cohorts was conducted to explore the role of earlier initiation of ART, i.e. at CD4 350-500 cells/mm$^3$, to prevent TB in people living with HIV. The Policy Updating Group discussed the inclusion of a separate recommendation on initiating ART among PLHIV at CD4 count 351-500 cells/mm$^3$. While the Group agreed on the role of earlier initiation of ART for the prevention of TB and other clinical conditions, the inclusion of a separate recommendation on earlier initiation of ART with CD4 cell count between 351 and 500 cells solely as a means of TB prevention was agreed to be beyond the scope of the TB/HIV policy document. The Group recommends that the next revision of the WHO guidelines should address this issue specifically in light of its implication on TB risk reduction and other clinical conditions. The policy document emphasised the earlier initiation of ART among people living with HIV in line with WHO and national guidelines. The policy updated also included a systematic review on the best models for the delivery of integrated TB
and HIV services which has identified five models for integration, although they are not exhaustive or prescriptive.

3. Provides guidance to countries on how to adapt global policy and targets to national and regional ones, and on how to implement collaborative TB/HIV activities at programme and service delivery levels;

   - A section on the adaptation of the policy at regional and country level is included as well as a section on settings national targets for nationwide scale-up of collaborative TB/HIV activities is now included in the TB/HIV policy.

4. Raises the need for global commitment to TB/HIV collaborative activities and recommends the inclusion of a TB/HIV session at the next meeting of the WHO HIV-STAC and the participation of selected STAG-TB members to this meeting;

   - Following the recommendation of STAG, a TB/HIV session was included at the WHO HIV-STAC meeting in February 2011 to which STB director and other staff participated. The report of the STAC-HIV noted:
     - STAC-HIV acknowledges the exemplary collaboration and work of the Stop TB and HIV/AIDS Departments of WHO that has resulted in encouraging scale-up of collaborative TB/HIV activities. In addition STAC-HIV recommended that WHO applies and adapts the TB-HIV collaborative model to other programmes with links to HIV, such as maternal, newborn and child health and sexual and reproductive health as appropriate.

5. Seeks endorsement from UNAIDS for the updated policy.

   - UNAIDS representative is included in the Policy Updating Group and endorsement will be sought when the document is finalized. The document is expected to be published in November, 2011 and launched at the planned Stop TB Partnership TB/HIV Working Group meeting in China.

**Session 7: Universal Access: definition and strategy**

**STAG-TB recommends that WHO:**

1. Establishes a Task Force, including Members of STAG-TB, the WHO TB Impact Measurement Task Force, and other experts on TB implementation, health equity, health system strengthening;

   The aims of the Task Force should include:
   a) proposing a definition of universal access applicable for TB prevention, care and control;
   b) reviewing TB indicators and targets on universal access, including those developed by Stop TB Partnership working groups to be released shortly in the revised Global Plan to Stop TB;
c) proposing any new indicators and global target(s), as appropriate, and providing guidance on target-setting at the country level;

d) recommending if and how universal access should be advocated for within global and national health agendas;

2. Reports back to STAG-TB at its 2011 meeting or earlier on the recommendations of the Task Force and on WHO's next steps based on these findings, including producing policy and operational guidance on any proposed revision of indicators and target-setting;

3. Informs the Stop TB Partnership’s Coordinating Board of the results, which may have implications for the pursuit of the Global Plan to Stop TB, 2010–2015 and on global advocacy for TB and the health-related Millennium Development Goals.

**Actions taken:**
For follow-up: the priority from October 2010 to June 2011 has been ensuring progress in the three strategic tracks of work already defined by the Global Task Force on TB Impact Measurement as necessary to ensure the best possible assessment of whether the 2015 impact targets are achieved; and the annual monitoring of the global TB epidemic and progress in TB care and control and associated production of the annual WHO report on TB control. In addition, many of the targets included in the Global Plan to Stop TB 2011-2015, as developed by the Stop TB Working Groups and TME (and (launched in October 2010 - one month after the 2010 STAG-TB meeting) are already consistent with the concept of “universal access” (UA).

Other steps taken include:
- discussions among WHO staff and Jaap Broekmans (Chair, Global Task Force on TB Impact Measurement) were held in early 2011. It was agreed that, as a first step, it would be helpful to contact senior figures working in the field of HIV (since it is here that the concept of UA was first emphasized), to explore their views on the value of the concept of "universal access" for both target setting and advocacy.

It was also agreed that if their feedback was positive, the next step would be to identify a consultant (possibly a STAG member or member of the Global Task Force on TB Impact Measurement) to prepare a discussion paper addressing points a) to d) in recommendation 1. This discussion paper would then serve as the basis for a meeting of the (to-be-established) Task Force on UA.

A few senior figures working in the field of HIV were then contacted. Their feedback can be summarized as follows:
- UA is a useful concept when framed as a broad goal/aspiration (as opposed to a specific target) that is not time-bound. If UA is time-bound (as it was originally for HIV, in 2010) then the goal may be forgotten once the target year has passed;
- the broad goal of UA can however, as noted at the STAG-TB meeting in 2010, be linked to specific indicators and ambitious time-bound targets for these indicators (e.g. targets that lead to progress towards UA), which may vary by country and over time;
- the global targets agreed for ARV and prevention of mother-to-child transmission were intervention coverage of 80% (considered a proxy for UA) while for most prevention interventions current targets for coverage range from 65-80%.
• UA encourages all national AIDS programmes to provide services to reach all people in need;
• there has been a commitment to UA by the G8 and backing away from this would be a mistake;
• UA is a multi-faceted concept that includes the availability, affordability and acceptability of services;
• the main criticisms or concerns were that actually defining and clarifying what was meant by UA was difficult, and that UA did not encourage prioritization because so many things could be seen to contribute it;
• It was noted that there is a vacuum in terms of targets after the MDG target year of 2015 (this was a general comment, not specific to either HIV or TB).

This feedback suggests that UA is a concept/goal worth exploring further in the context of TB, and that it could be linked to the indicators and ambitious targets that have been set in the Global Plan to Stop TB 2011–2015. It will also inform the process of beginning to determine appropriate post-2015 targets.

The next steps are to identify a suitable consultant to prepare a background discussion paper, and to seek volunteers/nominations for the Task Force. The timing of this work could be best linked to serious consideration of a target framework for TB beyond 2015. Initiation of work on this topic has been discussed by the secretariat of the Global Task Force on TB Impact Measurement. Given the need to prioritize the main mandate of this Task Force’s work - ensuring the best-possible assessment of whether the 2015 impact targets are met and monitoring of progress in the interim - the indicative start date is 2012.

Session 8. Report from the WHO regional offices on management of change

STAG-TB recommends that WHO, in collaboration with partners:

1. Assists countries with “change management” by:
   1. Providing effective communication strategies on innovations

PAHO/AMRO
- Supranational and national laboratory network meeting to define the steps of Xpert implementation at country level
- Regional TB meeting with NTPs and indigenous leaders to discuss TB control strategies and share experiences among countries

EMRO
- Wide and immediate distribution of technical documents and reports from relevant meetings, such as the Xpert consultations, and recent scientific articles
- Inclusion of new interventions and tools in the EMRO Region STB Strategy 2011-2015
- Communicating the new methods of estimating TB burden and strengthening TB surveillance systems including the CAPTURE TB study
- Supporting countries in adapting CAPTURE TB study protocols and implementing the studies in EMR countries: Egypt, Syria, Djibouti, Yemen(pilot and expanded), Pakistan(pilot), and Iraq
- Developing and presenting a comprehensive web-based surveillance system during NTP managers meeting and training NTPs in eligible EMR countries on the system
- Translating research results into policy and practice of the programmes such as innovative PPM models, innovative interventions to improve DOT and reduce defaulting, etc
- Introducing of new tools in TBREACH and other proposals.

SEARO
- Wide distribution of technical documents, TB TWG meeting reports, updated information on Xpert MTB-RIF to all countries in SEAR
- Developed Regional advocacy, communications and social mobilization (ACSM) framework and distributed to the countries in SEAR.

WPRO
- Wide and immediate distribution of technical documents and reports from relevant meetings, such as the Xpert consultations
- Inclusion of new interventions and tools in the Western Pacific Region STB Strategy 2011-2015
- Advocating for introducing of new tools in TBREACH and other proposals
- Created “STOPTB Cambodia website and communication tool” and he is communicating all developments with all national partners. Very much liked by partners at both national and regional level.

2. Offering differentiated support and addressing country specific needs and opportunities, ranging from countries that need special attention to countries that have the potential to set an example

AFRO
- Capacity building through Regional training course on TB/HIV and MDR-TB in African region
- Capacity building and development of country plans on TB prevalence survey in African region

AMRO
- Infection control evaluation of priority countries (Guyana done) and preparation of action plan (Guyana; action plan written in process of implementation).
- Laboratory network evaluation in priority countries (Honduras and Nicaragua this year) and preparation of action plan for strengthening the laboratory network.

EMRO
- Development of annual TB report to share situation analysis including the inventories of the following:
  - Inventory of the status of the M&E, recording and reporting system and surveillance systems, DOTS, laboratory, drug supply and management system, high risk groups, MDR-TB, infection control, in countries to inform future TA needs and GF proposals
  - success stories from countries with other countries (and partners), and challenges
- Development of country specific national TA plans based on national strategic plans and GF proposals
- Developing work plans for countries according to their epidemiological categories during the NTP managers’ meeting: high burden; intermediate burden and countries under elimination
- Capacity building and support for drug resistance surveys infection control, monitoring and evaluation, operational research, and drug management
- Support to the introduction and development of nationally adapted PAL indicators to boost PAL implementation.
- Infection control evaluation of priority countries (Guyana done) and preparation of action plan (Guyana; action plan written in process of implementation).
- Laboratory network evaluation in priority countries (Honduras and Nicaragua this year) and preparation of action plan for strengthening the laboratory network.

SEARO
- Inventory of the alignment of laboratory and PMDT scale-up plans in Bangladesh, India, Indonesia, Myanmar, Nepal
- Inventory of the status of infection control in HBCs in SEAR to inform future TA needs and GF proposals
- Addressed TA needs on NSP to Bhutan and development of country specific national TA plans based on national strategic plans and GF proposals
- Documented success stories in Bangladesh, Bhutan and Nepal

WPRO
- Inventory of the alignment of laboratory and PMDT scale-up plans in key countries to inform future TA needs and GF proposals.
- Inventory of the status of infection control in key countries to inform future TA needs and GF proposals
- Inclusion of intermediate TB burden countries (addressing their specific needs) in TA by WPRO (for instance Malaysia, Japan)
- Sharing success stories from countries with other countries (and partners)
- Development of country specific national TA plans based on national strategic plans and GF proposals

3. Facilitating joint programme reviews to guide and monitor progress on national and regional objectives

AFRO
- Supported six countries to conduct TB control programme reviews (Lesotho, Mauritania, Mozambique, Nigeria, Sierra Leone and Zambia)

AMRO
- Regional meeting with the participation of TAC members and partners:
  - TB low prevalence countries - TB elimination strategies
  - MDR-TB priority countries for expanding MDR-TB control – Expansion MDR-TB Plans, Xpert implementation
  - TB control in prisons – share experiences among countries and improve TB control
  - TB/VIH collaborative activities – evaluation of the implementation of collaborative activities
EMRO
- Joint monitoring missions in Pakistan, Afghanistan, Iran, UAE, in 2010 and Lebanon in 2011
- Training on M&E to monitor and evaluate programme performance for Iraq, Jordan, OPT, Tunisia, UAE
- Technical assistance in developing M&E plans for Yemen, OPT, Morocco, Egypt

SEARO
- TB Technical Working Group meeting in SEAR
- Joint monitoring missions in Bangladesh, Bhutan and Sri Lanka

WPRO
- Technical Advisory Group meeting
- Reviews on progress in the field of intensified case-finding (Philippines, Vietnam)
- Review of TB programme in Japan and Shanghai

4. Supporting the establishment of national strategic and technical advisory groups to assist national TB control programmes to introduce and evaluate new tools and strategies within a comprehensive programme framework

AFRO
- Supported six countries to conduct TB control programme reviews (Lesotho, Mauritania, Mozambique, Nigeria, Sierra Leone and Zambia)

AMRO
- Laboratory working group – for giving technical assistance to priority countries and carry out evaluations of countries needs
- MDR-TB expert group – for giving technical assistance to priority countries

EMRO
- Assisting countries in developing national strategic plans during an inter-country workshop followed by in-house review
- Assisting countries in developing M&E frameworks within their M&E plans addressing the introduction and evaluation of new tools through well defined indicators
- Engaging regional and international consultants in providing TA to countries during the process of introduction and evaluation of the new tools.

SEARO
- DOTS-Plus Committee for PMDT strengthened in Bangladesh, India, Indonesia, Myanmar and Nepal in SEAR
- Multiple Technical Working Group established/strengthened in SEAR countries (e.g. PPM, TB-HIV)
- Technical Advisory Working Group initiated to implement EXPAND TB PROJECT in Indonesia and Myanmar in SEAR

WPRO
- Multilateral Technical Advisory Groups, for instance in the field of prison TB
- Development of national strategic plan in PNG
STAG-TB recommends that WHO:

1. Establishes and/or strengthens strategic and technical advisory groups in every region to regularly provide guidance on technical and strategic matters including internal (WHO) and external advocacy (See above);

2. Ensures collaboration across all bodies and teams (e.g. Global Laboratory Initiative (GLI), Innovative New Approaches and Technologies (INAT)) to assist countries in introducing and scaling up use of new diagnostics and other tools; (ongoing)

3. Assists countries in:
   - developing a regulatory framework to protect existing and new drugs and to prevent the emergence of more drug resistance (rational use)
   - building capacity to manufacture new drugs and tools in compliance with international standards (focus on large high-burden countries)
   - building capacity to prioritize and implement operational research


STAG-TB recommends that WHO:

1. On revision of the draft framework:
   a. Emphasizes that TB/DM collaboration should be developed within a framework of health systems strengthening and TB co-morbidities respectively, and be seen as a step towards generally improved collaboration between communicable and non-communicable disease programmes;
   b. Clearly delineates the responsibilities for TB and DM care by the respective control programmes and primary health services providers;
   c. Further guides countries on the relevance of pursuing TB/DM collaboration, according to TB and DM epidemiology and health systems infrastructure;
   d. Clearly states the need for monitoring and evaluation and operational research as a complement to clinical trials;
   e. Guides countries on where and how to mobilize resources;
   f. Ensures engagement of all relevant partners;

2. On implementation of the framework and associated operational research:
   a. Identifies and supports pilot implementation and operational research in selected sites, starting in countries with high burdens of TB and DM, a well-functioning TB control programme, and a sufficiently well-developed infrastructure for DM care;
   b. Advocates for resources from funding agencies to support TB/DM collaboration and research.

Actions taken: Framework revised and finalized. With partners in process of roll-out and promotion (including meetings in China, India etc.)
Session 10. Supporting access to, and quality of, TB care for women and children

STAG-TB:

- Recognizes the importance of prioritizing advocacy for increased access to TB prevention and care among women and children worldwide as part of a broader maternal and child health (MCH) agenda and to capitalize on the renewed global interest through engagement of "MCH champions";

- Applauds the renewed attention on women and children's health and calls for attention to the full spectrum of women's health issues, including, but not exclusively, reproductive health.

STAG-TB recommends that WHO:

1. Pursues collaborative activities within and beyond WHO towards mainstreaming TB control into existing maternal and child health initiatives (e.g. Safe Motherhood programmes and Prevention of Mother-to-Child Transmission of HIV (PMTCT) initiatives) to include key partners (e.g. UNICEF) and links with community initiatives and women's health support groups (e.g., White Ribbon Alliance);

2. Provides guidance and technical support for the introduction and evaluation of TB screening at PMTCT clinics;

3. Promotes and technically supports relevant operational research related to women's health, maternal and child health and TB prevention, care and control;

4. Promotes and technically supports relevant childhood research activities that will address:
   a. the needs for better diagnostics tools and treatment, including ensuring the inclusion of children in clinical trials and multicentre studies of new diagnostics and new drugs (including the development of new fixed-dose combination formulations);
   b. MDR-TB among children and the development of paediatric formulations.

Actions taken:

Re Women and Children:

1. WHO has been raising the profile of TB within the UNAIDS Treatment and TB/HIV technical Working Group to ensure the inclusion of TB prevention, diagnosis and treatment services in the work of other UN agencies particularly UNICEF. WHO has also prioritised women and children as a theme for the upcoming one day symposium at the 2011 Union Lung Conference, in which presentations from maternal health stakeholders will be included. Reaching out particularly for organisations working on maternal health is also included in WHO’s work with community and civil society organisations.

2. The WHO guidelines on PMTCT has included a TB chapter and underlines the importance of TB screening in line with the new WHO policies on TB screening and
preventive therapy. Furthermore, the integrated patient monitoring system of PMTCT developed by the Global Fund, WHO, UNAIDS and UNICEF has included TB screening and IPT indicators.

3. WHO has commissioned an extensive systematic search to review the evidence about mainstreaming TB prevention, diagnosis and treatment into maternal health services and inform possible policy and programme activities.

4. Presentation on women and TB at a session targeting UN delegates and others, with TB partners, and sponsored by the Global Alliance on Women's Health and facilitated by the Eli Lilly MDR-TB Partnership (first time an the Alliance had addressed TB).

Re Children:

1. WHO, the Childhood TB subgroup of the DOTS Expansion Working Group of the Stop TB Partnership, and European Centre for Disease Control (ECDC) organized an international meeting on childhood tuberculosis, in a joint effort to highlight the current situation and to move the agenda forward in order to achieve a concerted advocacy approach. The meeting was held on 17-18 March 2011 in Stockholm and was attended by a wide range of participants, including researchers, paediatricians, community representatives, civil society organizations, staff from ECDC, WHO/HQ and WHO/EURO.

   The objectives of the meeting were to:
   - Identify and highlight the gaps, challenges and needs in childhood TB control.
   - Prepare the scientific rationale for the need of advocacy and to identify the key areas where more advocacy and targeted engagement with stakeholders is needed.
   - Reach a consensus on how to advocate for childhood TB control in light of the MDG 4 for child survival and how to bring forward the voice of the children.

   At the end of the meeting a call to action was launched and it was posted for signature on the Stop TB Partnership website.

2. WHO Stop TB Department and Department of Essential Medicines and Pharmaceutical Policies are planning a two-day meeting of experts on access and availability of TB and other medicines for children. The focus will be a review and finalization of technical strategies needed to encourage the production and supply of appropriate, quality fixed-dose combination drugs. The proposed dates and venue are 14-15 July 2011 at the WHO in Geneva.

3. WHO Stop TB Department, TDR and the childhood TB subgroup are working jointly with MSF on proposing a standard case definition for TB in children for the purpose of research studies (clinical trials). This will be discussed at the Paediatric TB Diagnostics Workshop organized by NIH on 28-30 June 2011.