World Health Organization

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

REPORT OF THE NINTH MEETING

9-11 November 2009
WHO Headquarters

Geneva, Switzerland

Secretariat:

WHO THE STOP TB DEPARTMENT

Printed by the WHO Document Production Services, Geneva, Switzerland

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WHO STRATEGIC AND TECHNICAL ADVISORY GROUP FOR TUBERCULOSIS (STAG-TB) 9-11 November 2009

The World Health Organization (WHO) recognizes its critical role in supporting urgent national efforts to enable universal access to treatment and care, so as to meet the Millennium Development Goal 6 target of reversing TB incidence, and the Stop TB 2015 targets of halving TB prevalence and mortality rates. The WHO Secretariat requires ongoing scientific, technical and strategic advice in TB care and control from its Strategic and Technical Advisory Group for Tuberculosis (STAG-TB), to help guide implementation of the Stop TB Strategy and the Stop TB Partnership's Global Plan to Stop TB, 2006-2015.

The ninth meeting of STAG-TB took place at WHO Headquarters from 9-11 November 2009. The meeting was organized by the WHO Stop TB Department (HTM/STB).

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.

Ninth meeting objectives:

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

1. MDR/XDR-TB response: Acting on Beijing and World Health Assembly recommendations
2. Policy change for improved quality and rational use of anti-TB drugs
3. TB diagnostics policy
4. Preparing for rapid policy review of new drugs
5. TB/HIV: from testing to assured care
6. Support to early case detection
7. Policy change to support Universal Health Coverage and implications for TB
8. Supporting implementation of the new infection control policy
9. Coordinating and consolidating technical assistance streams
10. Guiding action to promote ethical and rights-based approaches in TB prevention, care and control
11. Short updates and discussion on several other themes.

The meeting agenda as adopted is attached as **Annex 1**.

In 2009, STAG-TB was enlarged to 22 members, with a respective adjustment of its Terms of Reference to reflect this larger size; 7 members were newly appointed in 2009. Two of the 22 members were unable to attend as noted on the attached List of Participants, **Annex 2**. Dr Jeremiah Chakaya serves as Chair of the Group through 2010. Dr Paula Fujiwara serves as Vice-Chair for the period.

STAG-TB members were joined at the meeting by: the Chairs of Stop TB Partnership's DOTS Expansion Working Group (also Chair of STAG-TB), Multidrug-Resistant TB Working Group, and the New Diagnostics Work Group, and Chairs of several Stop TB Sub-Groups as well as the Green Light Committee and the Global Laboratory Initiative. Other participants included partners from donor and collaborating organizations and agencies; and WHO Stop TB Department staff from Headquarters, all 6 Regional TB Advisers and some other members of the network of TB staff working at regional and country level; representatives from other interested WHO Departments, including the HIV/AIDS Department and the Department of Essential Medicines and Pharmaceutical Policies, and the Special Programme on Tropical Disease Research and Training (TDR).

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 made by STAG-TB members. Stop TB Department staff and STAG Discussants served jointly as session rapporteurs (see **Annex 3**). Draft written recommendations from all sessions were reviewed and revised by STAG-TB members at the conclusion of meeting, and again via review of this report in draft form.

Following the meeting, STAG-TB conclusions and recommendations were presented by Dr Chakaya to Dr Hiro Nakatani, WHO Assistant Director-General for HIV, Tuberculosis, Malaria and Neglected Tropical Diseases. The meeting report will be posted on the WHO Stop TB Department website. It will also be circulated to all WHO Assistant

Directors-General, Directors, Regional Directors and Regional Communicable Disease Directors, WHO Representatives at country-level, and Regional TB Advisers.

STAG-TB conclusions and recommendations

For this written report, STAG-TB members summarized their overall concerns in the following statement, which also appears on the cover of this report.

The Introductory Session included a welcome and overview of STAG-TB objectives by Dr M. Raviglione, Director, WHO Stop TB Department, an introduction of all STAG-TB members, approval of the meeting objectives and the agenda, and opening remarks by the STAG-TB Chair, Dr. J. Chakaya. **Annex 4** provides the list of themes suggested by STAG-TB for the WHO Secretariat to consider in planning the 2009 meeting, with the reference to their coverage within the adopted 2009 agenda.

STAG-TB suggested that it would be valuable in 2010 to have a full summary of how 2009 recommendations were addressed during the interim by the WHO Secretariat.

Dr Raviglione offered a note of acknowledgement, in memoriam, of the extraordinary contributions of Sir John Crofton to global TB control, the medical sciences and public health. He then provided an overview presentation, on *TB prevention, care and control, 2010-2015: Framing global and WHO strategic priorities,* which highlighted the policy bottlenecks and opportunities that must be taken within the tuberculosis care and control realm, as well as within broader health systems, development and research agendas to respond effectively to the faces of the TB epidemic worldwide. Dr Raviglione presented a revised/updated WHO Stop TB Strategy framework, which will be elaborated in an update of the Stop TB Strategy document (WHO/HTM/TB/2006.368) (**see Annex 5**).

The following pages provide the conclusions and recommendations offered by STAG-TB. These conclusions and recommendations respond to the session summary sheets and advice requested from STAG-TB as posed by the WHO Secretariat in advance of the meeting, (please see http://www.who.int/tb/advisory_bodies/stag/en/index.html for access to the session summary sheets). For two sessions, STAG-TB was asked to review and consider endorsement of draft guidance and/or policies prepared as products of WHO expert consultations and/or Task Forces during 2009: Session 3 on diagnostics policy and Session 10a on guidance on ethics in TB care and control. Session 4 included lessons learned from the WHO Secretariat and Expert Group's experience in preparing the revision of the WHO TB Treatment Guidelines following new WHO Guidelines preparation guidance. Session 10b briefly introduced proposed work to be undertaken by a WHO as joint Secretariat with UNAIDS of a new Stop TB Partnership Task Force on TB and Human Rights.

Session 1: MDR/XDR-TB Response: Acting on Beijing and WHA Recommendations

STAG-TB:

- Appreciates the political commitment of high burden countries for the control of M/XDR-TB;

- Recognizes the positive momentum in countries' scale up of MDR-TB management, though current and predicted levels of MDR-TB treatment do not reach established targets;

- Recognizes the need to update the current business model of the Green Light Committee (GLC) in order to support countries for rapid scale up with quality-assured drugs, using both GLC and non-GLC procurement agents;

- Notes with concern the high demands, in terms of both financial and human resources, of the MDR/XDR scale-up and the need for countries to continue mobilization of resources for provision of universal access to free/equitable MDR-TB treatment and care, without diversion of resources from other TB control components;

- Stresses the need to establish the conditions required for the accelerated absorption of the funds already pledged by donors, such as the Global Fund, ensuring transparency and accountability.

STAG-TB recommends that WHO:

1. Pursue the integration of MDR-TB management into national TB control efforts, keeping the strengthening of basic TB control through quality DOTS as the prime objective, emphasizing the need to expand access to community-based care and to involve all health care providers, and taking into full consideration the social determinants of TB;

2. In collaboration with all partners and stakeholders, ensure that technical assistance needed by all countries for MDR-TB scale up is provided and WHO MDR-TB guidelines are properly implemented, including in MDR-TB treatment programmes that procure quality drugs outside of the GLC;

3. Systematically promote the social mobilization and empowerment of MDR-TB patients and affected persons in order to promote community stewardship of national MDR-TB treatment programmes;

4. Keep the ambitious goals of universal access to diagnosis and treatment of MDR-TB of the Global Plan 2006-2015, but take into consideration the TB case detection achieved by the country when assessing programme performance in diagnosing and enrolling MDR-TB patients on treatment. In view of the revised TB case detection target aiming at universal access, and considering that in some settings there has been a tendency to reduce efforts once 70% case detection has been achieved, harmonize any MDR-TB target with the universal case detection target for TB in general;

5. Explore options to replicate lessons learned in other successful emergency-level epidemic response programs, such as H1N1, to overcome barriers to access to diagnosis and treatment; e.g., expeditious and timely registration and importation license of diagnostics and drugs for MDR-TB.

<u>Session 2</u>: Policy change for improved quality and rational use of anti-TB drugs

STAG-TB:

- Acknowledges the contribution and collaboration of the Department of Essential Medicines and Pharmaceutical Policy and the Stop TB Department to help address the critical issues of ensuring quality and rational use of anti-TB drugs within the context of health system strengthening;

- Notes with great concern the availability of questionable quality anti-TB drugs in large segments of the health system;

- Recognizes the irrational use of anti-TB drugs, including as a result of their availability over the counter, often without prescription, and via providers operating outside national TB programmes;

- Emphasizes that substandard drug quality and irrational use of antimicrobial drugs pose ethical and public health threats; patients are entitled to receive the appropriate prescription of high-quality drugs, for the right indication, in an appropriate dosage, for an appropriate duration, and with appropriate patient information and support;

- Acknowledges that the problem of poor quality anti-TB drugs and irrational use of anti-TB drugs are a part of wider health systems problems that include poor drug quality, irrational use of drugs, and insufficient drug regulation;

- Recognizes that, despite two WHA resolutions and several positive examples from high-income countries of how rational use of drugs can be improved, very few resources have been mobilized and allocated and insufficient action has been taken by WHO and partners to promote rational use of drugs in low and middle-income countries.

STAG-TB recommends that WHO:

1. Help strengthen the evidence base concerning: characteristics of the anti-TB drug market, quality of anti-TB drugs on the market, anti-TB drug prescribing and dispensing practices, the link between poor quality anti-TB drug use and adverse treatment results (including drug-resistance development), and effective ways to improve quality and rational use.

2. Encourage comprehensive country-level actions to collect the appropriate data and improve drug quality including:
    a. Capacity strengthening of drug regulatory agencies;

b. Encouraging drug manufacturers to apply to the WHO Prequalification Programme and providing technical assistance to manufacturers to meet WHO quality standards;
c. Engaging with communities, civil society and activists to create demand for high-quality drugs;
d. Ensure that Member States take action on pharmaceutical companies known to produce substandard anti-TB drugs;

3. Encourage implementation and monitoring of coordinated and comprehensive country-level actions to improve rational use. This may include, based on country specific situation assessments, and as appropriate:

    a. Scaling up of public-private mix initiatives;
    b. Promoting use of, and training on national guidelines / international standards;
    c. Restricting prescription and dispensing rights to accredited providers only;
    d. Enacting and enforcing regulations against over-the-counter sales of anti-TB drugs;
    e. Scheduling of anti-TB drugs as restricted drugs or drugs with special reporting requirements for prescribers and pharmacies;
    f. Engaging with patients and their communities, civil society and activists in demand side interventions to improve rational use of anti-TB drugs;
    g. Developing approaches to engage major stakeholders such as, for example, pharmaceutical companies, professional associations and pharmacies, to curb unethical practises and promote rational use of anti-TB drugs.

4. Ensure that the work to improve quality and rational use of anti-TB drugs is incorporated into a significantly strengthened action framework to improve drug quality and rational use, as part of the broader agenda to strengthen health systems.

<u>Session 3</u>: Diagnostics policy

LED-based microscopy and other microscopy-enhancing methods

<u>On LED-based microscopy</u>

STAG-TB:

- Acknowledges a compelling evidence base and a large body of work demonstrating the superiority of direct fluorescent microscopy (FM) over direct light microscopy using Ziehl-Neelsen (ZN) staining in throughput, efficiency and improved sensitivity of diagnosis. STAG-TB also acknowledges the comprehensive evidence base presented for LED microscopy as a substitute for both conventional FM and direct ZN microscopy.

- Agrees that LED-based microscopy is an important development in direct fluorescent microscopy that facilitates identification of acid-fast bacilli in comparison with ZN, is cost-effective, utilizes low power systems and can be easily introduced in microscopy centres, including peripheral facilities. STAG-TB also agrees that sufficient training should be provided particularly in settings that have not used fluorescent microscopy

previously, and that internal quality control and external quality assurance systems ould have to be adapted to accommodate fading of fluorescent stains.

STAG-TB recommends that WHO:

1. Recommend conventional fluorescence microscopy be replaced by LED microscopy in all settings where fluorescence microscopy is now used, and that LED microscopy be phased in as an alternative for conventional ZN microscopy in both high- and low volume laboratories;

The switch to LED microscopy should be carried out through a carefully phased implementation plan, using LED technologies that meet WHO specifications;

Countries implementing LED should address the following issues:

- Training requirements, especially for laboratory staff unfamiliar with FM techniques;
- Validation during the introductory phase;
- Monitoring of trends in case-detection and treatment outcomes;
- Introduction of adapted systems for internal quality control and external quality assurance.

2. Develop and disseminate technical specifications for LED devices (including stand-alone LED microscopes and LED attachments to light microscopes) to guide countries, technical and funding agencies to purchase high-quality equipment;

3. Develop and disseminate standard operating procedures and a programme for external and internal quality assurance of LED microscopy;

4. Facilitate, with partners and technical agencies, a coordinated approach to standardised training on LED technology at country level;

On Same-day Diagnosis ('Front-loading')[1]

STAG-TB

- Acknowledges existing evidence that collecting two sputum samples in one day is equivalent, in terms of diagnostic accuracy, to existing conventional case-finding strategies, with a two specimen front-loaded approach providing the potential for initiation of anti-tuberculosis treatment on the first day;

- Acknowledges that significant organizational and programmatic changes would be required to optimize the advantages of a same-day diagnosis, and ensuring that laboratory results are received back at the health facility on the same day.

[1] 'Front-loading' or 'Same-day diagnosis' refers to consecutive sputum specimens from the same patient being examined - and results provided to health facilities - on the same day

STAG-TB recommends that WHO:

1. Recommend that implementation of a 'same-day diagnosis' strategy be preceded by a detailed situation assessment of the programmatic, logistic and operational implications at country level and supported by a carefully phased implementation plan.

2. With partners, should consider the following issues in a phased implementation plan:

    - Training of health personnel responsible for requesting sputum smear microscopy, instructing patients on sputum collection and staff responsible for registering patients and initiating TB treatment;
    - Alignment of sputum collection, microscopy reporting, and initiation of TB treatment as far as possible within existing human resource and laboratory work-load constraints;
    - Separation of coughing patients from other patient groups (especially those with HIV) to reduce the risks of TB transmission in health care settings.
    - Monitoring of patient drop-out between laboratory and treatment registers, and monitoring of trends in case-detection and treatment outcomes.

Non-commercial culture and drug-susceptibility testing (DST) methods

STAG-TB:

- Recognizes that current gold standards for culture and DST (conventional solid and automated liquid culture and DST systems, as well as molecular line probe assays) need to be phased in and scaled up as a matter of urgency and priority in addressing the MDR-TB epidemic;

- Recognizes that genotypic (molecular) methods have considerable advantages for scaling up programmatic management and surveillance of drug-resistant TB, particularly with regard to speed of diagnosis, standardized testing, potential for high-throughput, and biosafety;

- Recognizes that the use of rapid DST methods directly on sputum specimens constitutes the most important patient and public health benefit;

- Recognizes that the evidence-base for selected non-commercial culture and DST methods has been reviewed and the performance of these methods found to be acceptable under stringent laboratory protocols in reference/national laboratories in selected settings;

- Recognizes that non-commercial methods are less expensive, enable laboratories to be independent of single-test commercial providers, and may represent an incentive to commercial providers to lower prices; however, STAG-TB also recognises that non-commercial methods are prone to errors related to a lack of standardization and due to local variations in methodology;

STAG-TB recommends that WHO recommend a policy that:

1. Selected non-commercial culture and DST methods be used as an interim solution in resource-constrained settings, in reference laboratories or those with sufficient culture capacity, while capacity for genotypic and/or automated liquid culture and DST are being developed.

2. With due consideration of the above issues, endorse the selective use of one or more of the following non-commercial culture and DST methods:

   - Microscopically observed drug susceptibility (MODS), for rapid screening of patients suspected of having MDR-TB, under clearly defined programmatic and operation conditions, and once speciation concerns have been adequately addressed without compromising bio-safety;

   - The nitrate reductase assay (NRA), for screening of patients suspected of having MDR-TB, under clearly defined programmatic and operation conditions, and acknowledging that time to detection of MDR in indirect application would not be faster (but less expensive) than conventional DST methods using commercial liquid culture or line probe assays;

   - Colorimetric redox indicator (CRI) methods, as indirect tests on *M. tuberculosis* isolates from patients suspected of having MDR-TB, under clearly defined programmatic and operation conditions, and acknowledging that time to detection of MDR would not be faster (but less expensive) than conventional DST methods using commercial liquid culture or line probe assays.

STAG-TB recommends that WHO:

1. Outline the use of these methods in detailed, structured policy guidance;

2. Review existing documents on technical procedures, standard operating procedures, and biosafety requirements for these methods;

3. Develop and disseminate standardised methodologies as well as procedures for internal quality control and external quality procedures for these methods.

4. Monitor the adoption of such standardized methodologies and their impact on case detection.

Diagnostics Policy: Framework for adoption of new policies at various levels

STAG-TB acknowledges that:

- Successful DOTS expansion, as well as programmatic management of drug-resistant and HIV-associated tuberculosis (TB), require - at its core - increased access to TB diagnosis within a network of quality-assured laboratory services;

- Acid-fast sputum smear microscopy is simple, inexpensive and quickly detects infectious TB cases; however, direct smear microscopy is relatively insensitive, especially in patients with HIV-associated and extra-pulmonary disease. Moreover, microscopy cannot confirm *M. tuberculosis* or drug resistance, for which mycobacterial culture, identification and drug susceptibility testing (DST) are required;

- Current WHO policies call for country capacity to rapidly detect at least multidrug-resistant TB (MDR-TB), and for MDR-TB strains to be assessed for second-line drug resistance to identify patients with extensively drug-resistance TB (XDR-TB);

- Given available technologies, early TB case detection is best achieved through improved sputum microscopy at health centre level. For drug-resistant TB, appropriate laboratory diagnostic algorithms based on patient groups at greatest risk of drug-resistant TB (which includes HIV infection) enables the most cost-effective use of scarce laboratory and diagnostic resources;

- Developing a country-level policy framework for new TB diagnostics requires national TB programmes (NTPs) to assess:

  - Local epidemiology (TB, HIV, MDR-TB);
  - Priorities (risk groups) for case detection;
  - MDR-TB treatment policies;
  - Local laboratory capacity and networks;
  - Local laboratory human resources and skills base;
  - Financial resources;

- The landscape of new TB diagnostics is changing rapidly, and policy formulation therefore needs to be a dynamic and ongoing process, both at global and country level. STAG-TB believes that there remains a need for improved commercial and non-commercial testing modalities for diagnosis of TB;

- Local laboratory/diagnostic algorithms should start with screening policies to identify suspects and use microscopy services as the entry point. Implementation should be premised on the following considerations:

  - Liquid culture and molecular line probe assays are regarded as international gold standards, to be phased in without loss of existing solid culture and DST capacity;

  - Currently available technologies are not mutually exclusive. While molecular line probe assays and selected non-commercial culture and DST methods are suitable for direct application on smear-positive specimens, conventional culture capacity is required for smear-negative specimens while conventional DST capacity is needed to detect XDR-TB;

  - Rapid DST is essential for identifying patients at risk of MDR-TB, as the first priority in a screening strategy. Rifampicin resistance is a valid and reliable indicator/proxy of MDR-TB. Once MDR-TB has been confirmed, additional first- and second-line drug susceptibility results should be obtained based on current WHO recommendations and available laboratory capacity;

- Genotypic methods have considerable advantages for scaling-up programmatic management of drug-resistant TB, in particular with regard to speed, standardized testing, potential for high throughput, and biosafety. The ultimate aim should be to implement molecular assays such as the line-probe (or other well-validated and WHO-endorsed molecular platforms in the future) for rapid first-step identification of MDR-TB in the programmatic context. Rapid phenotypic DST methods therefore present an interim solution, especially in resource-constrained settings, while capacity for genotypic testing is being developed;

- None of the non-commercial culture and DST methods constitutes design-locked, standardized and quality-assured tests that are produced under international diagnostic standards. Performance is highly operator-dependent and good laboratory practice, good microbiological technique, and adequate quality assurance, supported by targeted training, are therefore imperative. Stringent laboratory protocols, standard operating procedures, and internal quality control mechanisms must be implemented and enforced;

- Conventional culture and DST systems/methods, as well as molecular line probe assays, are suitable for implementation at central/national reference laboratory level, with limited potential for decentralisation, given the need for appropriate infrastructure (especially with regard to laboratory biosafety and the need to avoid cross-contamination) and the technical complexity of available technologies/methods;

- Implementation of new technologies/methods for TB should be decided by Ministries of Health within the context of national strategic plans for laboratory strengthening;

- TB diagnostic capacity should be linked to drug access and programmatic capacity to ensure treatment of identified patients under appropriate standards of care.

STAG-TB recommends that WHO:

1. Provide countries with a feasible and affordable policy framework for adopting WHO approved diagnostics based on local resources and infrastructure;

2. Assist countries wishing to implement WHO-approved technologies/methods with technical advice and support.

3. With partners, conduct further operational research on the patient-important outcomes of new diagnostics and diagnostic approaches, especially in the following areas:

    a. Patient preferences on new approaches such as same-day diagnosis ('front-loading);
    b. Costs to patients and health services of new diagnostic algorithms;
    c. Patient drop-out during the diagnostic process;
    d. Improved patient outcomes as a result of rapid/early diagnosis.

Session 4: Preparing for rapid policy review of new drugs

STAG-TB:

- Acknowledges that new shortened first line treatment regimen(s) and new drugs may be available soon for the treatment of drug-sensitive TB (DS-TB) and drug-resistant TB (DR-TB), and that drugs that receive an indication for use in DR-TB may also be used off-label for the treatment of DS-TB after regulatory-authority approval;

- Recognizes this will have important implications for TB control programmes, particularly regarding patients' eligibility, programmatic feasibility and cost-effectiveness of newly-developed treatments; use of new drugs as part of FDCs to protect them; implications for large-scale use in terms of surveillance for implementation and development of resistance;

- Recognizes that it is essential to determine optimal regimens with any of the forthcoming newly developed or newly repurposed drug(s) for treatment of DS -TB and to define rational regimen(s) that incorporate(s) new drug(s) for DR-TB patients under programmatic conditions;

STAG-TB recommends that WHO:

1. Issue specific requirements on what evidence and information would be needed for WHO to develop policy recommendations related to new drugs/regimens for treatment of DS and DR-TB;

2. Engage in early dialogue with pharmaceutical companies developing new drugs to alert them on the importance of taking into account programmatic questions;

3. Help guide/promote the conduct of feasibility studies and as appropriate cost-effectiveness studies at an early stage in collaboration with partners (including the "Introducing New Approaches and Tools" subgroup of the Stop TB DOTS Expansion Working Group), in order to inform policy-making;

4. Pursue discussions with drug regulatory authorities so they are engaged early in addressing potential stumbling blocks in registration of new drugs within countries, and discuss strategies to ensure safe and appropriate use of new drugs being introduced in unregulated markets;

5. Actively promote collaboration and action by partners (i.e. pharmaceutical companies, regulatory authorities, research groups, technical partners, product development partnerships, and donors) so that appropriate drug regimens are utilized by programmes for the treatment of DS- and M/XDR-TB inclusive of the new drugs, and avoid irrational use of new drugs;

6. Issue clear policies to guide countries and partners on the introduction of new regimens for treatment of DS and DR-TB, in the next few years upon availability of evidence in support of use of such regimens;

7. Organize expert consultation(s) reviewing new drugs and regimens to inform timely development of treatment policy guidance to national health authorities - including assessing and promoting the evidence needed to consider treatment policy recommendations. This consultation would inform the Treatment Guidelines group and its decisions regarding revisions of such guidelines as appropriate;

8. Increase awareness and engagement of national authorities in the implementation of policies and guidelines for new TB treatment regimens at programmatic level (including development of national guidelines, training, drug quality, drug procurement, etc.), in collaboration with the Stop TB Partnership.

<u>Session 5</u>: TB/HIV: From testing to assured care

STAG-TB:

- Recognizes the achievements in scaling up the implementation of collaborative TB/HIV activities, including HIV testing for TB patients and the access to ART in many high and low HIV prevalent countries;

- Recognizes the important role of integrated TB and HIV services to provide quality care for people living with HIV;

- Notes the importance of exploring the higher (national and sub-national in some cases) level integration of TB and AIDS control programme management based on the epidemiology of TB and HIV and country specific and local contexts;

- Notes that, despite considerable progress, more efforts are still urgently needed, particularly to reduce the high and early mortality and to prevent the incidence and transmission of TB among people living with HIV.

STAG-TB recommends that WHO:

1. Pursue support for integration of TB and HIV services at facility level and identify opportunities that could further strengthen the program response for TB/HIV. Notably TB and HIV laboratory services, and TB infection control would ideally be more closely integrated at programme management levels;

2. Encourage all countries to critically review their TB and HIV services and adapt unduly isolated services where these still remain as mainstay approaches for TB control programmes;

3. Develop innovative integrated service delivery models that effectively penetrate communities and reach patients with diagnosed and undiagnosed HIV and TB in the context of universal access, given that current evidence suggests that even primary care level services may not be sufficiently decentralized to achieve an acceptable rate of diagnosis and control in resource-poor communities;

4. Encourage Ministries of Health to take up the challenge of providing anti-retroviral therapy (ART) to all HIV-infected TB patients as part of their routine TB care activities and improve the quality of care of HIV-infected TB patients;

5. Document best practice models, especially those relating to areas where implementation has proved unusually challenging, such as infection control and isoniazid preventive therapy (IPT), or shows unusually high promise, such as decentralized ART and TB services at primary and community level;

6. Encourage countries to promote effective collaboration between TB and HIV/AIDS programmes at all levels of the health system. However, it is not yet advisable to promote a higher-level (national and sub-national in some cases) integration of TB and HIV/AIDS programmes, given the need to maintain sufficient expertise to be able to respond to a rapidly changing TB control environment.

Session 6: **Support to early case detection**

STAG-TB:

- Recognizes the importance of promoting increased and early case detection for making an accelerated impact on the incidence of TB in order to reach the MDG targets and move towards elimination;

- Emphasizes the importance of implementing and scaling-up approaches with proven impact on case detection, including increased diagnostic capacity with improved outreach; public-private mix approaches (PPM); the Practical Approach to Lung Health (PAL); contact investigations; and TB screening in HIV care settings;

- Notes with concern the findings in recent prevalence surveys and other data indicating that screening of TB suspects, as defined as people with chronic cough (2-3 weeks), has low sensitivity to identify cases of bacteriologically confirmed TB;

- Recognizes the need to seriously consider and improve the evidence base for more active case detection approaches among under-diagnosed groups and in additional TB high-risk groups and populations, such as the poor, diabetics, smokers, malnourished persons, children, elderly persons, migrants, prisoners, refugees, indigenous populations, and people living in urban high-density residential areas/locations, and informal settlements.

- Emphasizes the need for the approach to implementation and scaling up of early and increased case detection to be country-specific and based on country context and the local epidemiological profile;

- Recognizes that efforts towards increasing case finding must be matched with continued efforts to ensure diagnosis is linked to quality treatment.

STAG-TB recommends that WHO, working with partners:

1. Advocate and support countries to scale up, as a priority, proven approaches that help early and improved case detection, such as engaging all care providers, Practical Approach to Lung Health and systematic contact investigation;

2. Systematically review existing evidence, map experiences from countries and stimulate new research on the effectiveness and cost effectiveness of active case finding approaches, different screening methods, and use of different "TB suspect" definitions. Such analysis should consider impact on case detection, reduction of duration of infectiousness, treatment outcomes, and costs to programmes, patients, and society;

3. Further study approaches on how to create demand for TB services through community involvement;

4. Develop practical guidance for countries to implement evidence-based approaches for active case finding;

5. Promote and support the development of country-specific policy frameworks for early and increased case detection based on an assessment of epidemiological profile, risk groups, case detection barriers, and health systems context;

6. Assist countries in addressing the financial, human resource and other constraints in scaling up proven approaches for early and improved case detection.

<u>Session 7</u>: Policy change to finance Universal Health Coverage

STAG-TB:

- Expresses deep concern at the catastrophic costs documented to be borne by persons seeking TB care in many high TB burden settings, including the devastating burden of facing MDR-TB disease and long treatment;

- Acknowledges the profound impact of these costs borne by those affected by TB, as well as the financial barriers to accessing and fully utilizing TB services, especially for the most vulnerable;

- Recognizes the importance for the TB community to engage with others working to enable Universal Health Coverage, better social protection, and universal access to achieve the health MDGs;

- Notes the linked need for better financing for health service access, and for financing of quality programmatic support and quality services;

- Confirms that financial obstacles and burdens need to be addressed both through "upstream" attention on the social determinants of disease, and changing the "downstream" prevention, diagnosis and treatment pathway of those affected.

STAG-TB recommends that WHO:

1. Pursue with urgency support to countries to implement means to reduce patient costs, taking full consideration of primary and community care options, acting to reduce costs for the TB diagnostic process, and engaging with initiatives to eliminate overall health service fees.

2. Support countries to document patient direct & indirect cost burdens, using standardized methods, so as to arrive at the most effective policies to reduce and/or eliminate these burdens.

3. Continue inter-departmental collaboration so that TB examples are included in the problem identification and solution sections of the 2010 World Health Report on UHC;

4. Examine the policy implications and impacts of UHC models in different settings on TB care and control, including through "fund gap" analysis to examine where the patient and programmatic costs are being covered, where they are not yet benefitting and where there may be inefficiencies;

5. So as to provide policy guidance to programmes and their partners, rigorously document and assess the evidence on how various measures can help eliminate catastrophic costs and open up truly free TB care: e.g., various measures for earlier and quicker diagnosis; PPM, PHC and community care innovations; and partnering with social protection, food security and other schemes;

6. Involve patients/former patients in assessments and social mobilization.

<u>Session 8</u>: Infection control: from policy to implementation

STAG-TB:

- Acknowledges the development of the policy on infection control published by WHO, 2009, and agrees that encouraging countries to implement the policy is now the priority, for which effective managers, more technical support and more funding are required;

- Recognizes that TB infection control should be seen as a component of overall health systems strengthening, but recognizes that TB programmes, because *M. tb* is an airborne infection, also have specific responsibilities: infection control policies, strategies and a coordinating body in place at national level, a management plan and administrative controls at facility level, environmental controls and personal protection at least for MDR-TB hospitals/units, as well as early diagnosis and rapid initiation of treatment;

- Notes the critical role intersectoral collaboration will play in infection control, including with government departments of housing, environment, transport and other related departments, as well as health care workers' unions;

- And, notes as well the need to learn from examples of intra-sectoral collaboration within health (TB, HIV and other communicable diseases), as exemplified by the current system-wide efforts to control the influenza pandemic.

STAG-TB recommends that WHO:

1. Urgently assist NTPs and their partners to implement the infection control framework through:

    - collaboration with health programmes and their partners, notably, HIV and influenza control programmes, health care workers' unions, professional associations of ventilation engineers, and development of accreditation schemes to certify health facilities as "safe";
    - collaboration with Ministries of other sectors, including the justice system, housing, environment, and transport, to develop and implement broad policies that include infection control;
    - holding leaders at all levels accountable.

2. Design and pursue operational research to strengthen the weak evidence base for infection control interventions;

3. Develop the policy case for declaring TB an occupational disease for health workers;

4. Include support for an infection control component in national health plans and in all TB financing proposals, including those to the Global Fund.

<u>Session 9</u>: Coordinating and consolidating technical assistance streams

STAG-TB:

- Recognizes the substantial increase in funding for TB control, and that it has contributed to good progress; In order to operationalize the increasingly complex interventions of the Stop TB Strategy and use funds effectively, TBTEAM (the TB Technical Assistance Mechanism of the Stop TB Partnership that is managed by WHO), needs to expand as the main mechanism for significantly greater harmonization of short and long term technical assistance (TA) provided by increasing number of partners;

- Acknowledges that WHO Regional and Country Office networks, through supporting and advising Member States and partners to establish and maintain National TBTEAMs, are key to improving the National Authorities' role in coordinating and harmonizing TA for Stop TB Strategy implementation, including from GLC, GLI, infection control specialists, civil society and communities themselves;

- Urges that National TBTEAMs ensure the inclusion of TA plans within the national TB annual and medium term plan;

- Sees that it is essential for beneficiaries to provide regular feedback entry, on completion of missions or other TA, into the TBTEAM web tool; It ensures coordination and provides transparent sharing of information and forms the basis for a quality roster of TB experts.

STAG-TB recommends that WHO, in conjunction with partners, should:

1. Expand TBTEAM as the main mechanism for significantly increasing harmonization of short and long term technical assistance, and ensuring, as far as possible, that national authorities coordinate technical support between all suppliers, through the National TBTEAM;

2. Empower National TBTEAMs to develop the national TA plan and ensure its inclusion within the national TB annual and medium term plan, addressing both short term and long term TA needs and Global Fund related activities;

3. Build capacity in civil society, and promote involvement of the private sector, to act as technical partners of National TBTEAMs;

4. Ensure that TBTEAM should focus on at least the 22 high burden countries, the high MDR-TB burden countries, small countries with high TB incidence, and fragile states.

<u>Session 10</u>: Ethics and human rights-approaches in TB care and control

STAG-TB:

- Welcomes these initiatives, and recognizes that WHO guidance on ethics of TB care is a much needed contribution to fill a void in the tools to implement the Stop TB Strategy;

- Endorses the process followed in the development of the ethics guidance and the proposed next steps for finalization of the guidance and its dissemination;

- Acknowledges that this ethics guidance and the new task force on a rights-based approach to TB prevention, care and control present a major opportunity for involving patients and civil society in the response to the TB epidemic;

- Acknowledges the action taken to develop a human rights-based approach to TB prevention, care and control, given the urgent needs for the promotion and protection of the human rights of all those affected by TB, including highly vulnerable populations, patients, & health workers;

- Endorses the formation of the Stop TB Partnership TB and Human Rights Task Force, with joint secretariat at WHO and UNAIDS;

- Looks forward to reviewing the proposed draft products of the TB and Human Rights Task Force next year: including the policy framework, legislative review, strategic agenda, and advocacy efforts;

- Notes the value of promoting partner efforts, such as examples highlighted at this meeting: the Union's statement on recommendations for the diagnosis and treatment of TB in undocumented migrants; the take-up of the Patient's Charter for TB Care and Control and the UNAIDS HIV and Human Rights Reference Group discussions on TB/HIV-related rights concerns.

On the draft TB ethics and TB guidance document, STAG-TB recommends that WHO:

1. Improve the guidance by strengthening the section on health care worker and occupational health issues, in particular regarding the obligations of employers;

2. Put greater emphasis on the role of community-based MDR-TB care;

3. Exercise caution in the wording of the guidance and ensure that it does not give space for interpretations resulting in practices against ethics and human rights standards;

4. Spell out in more detail the options countries should consider for promoting accountability in the implementation of this guidance;

5. Ensure a wide dissemination of the final product and training, in particular among health care workers, patients, civil society and other stakeholders;

6. Develop case studies closely linked to guidance on other components of the Stop TB Strategy;

7. Together with the new effort on updating a rights-based approach to TB care and control, clearly and consistently articulate the roles and responsibilities of governments, multilateral agencies and all partners in achieving universal access to TB care in such a way that efforts do not restrict rights and liberties of the patients, and promotes the rights of all affected.

On the new TB and human rights work, STAG-TB recommends that WHO, with partners:

1. Pursue the proposed Task Force work plan, ensuring participation of diverse stakeholders, with added constituencies such as MDR-TB patients and former patients, professional regulatory groups, employee compensation authorities etc);

2. Explicitly link the guidance on ethical issues in TB care and control with the development of the rights-based approach, clarify their complementarity, and ensure cross-over participation in both task forces;

3. Ensure that the national-level audiences for these TB-specific tools and strategies can embed this work within broader health and human rights efforts, and continue to foster collaboration across fields at global level;

4. Explore early the official means to promote application of the approach, e.g. via World Health Assembly mechanisms.

<u>Session 11</u>: Top challenges in regional support for implementing the Stop TB Strategy

STAG-TB:

- Recognizes the increase in scope, nature and magnitude of the work of the National TB Programme (NTP) as a result of the rapidly expanding TB programme following the availability of Global Fund and other sources of financing;

- Recognizes that this increase requires strong technical, financial-administrative and managerial capacity in the central unit of the NTP;

- Recognizes the important role of WHO at country level in the provision and coordination of technical, financial-administrative and managerial support to the NTP.

On NTP management strengthening: STAG-TB recommends that WHO:

1. Document the evidence of gaps in implementation and help countries prioritize plans based on gaps identified, e.g. by better utilizing the recommendations of joint TB programme monitoring or supervision missions;

2. Document and disseminate good practice in management of NTPs;

3. Provide guidance to NTPs on the competencies required to effectively implement TB care in countries and in developing a comprehensive human resource plan, including in-service and other appropriate forms of training, and action-oriented performance appraisal;

4. Help leverage and build local capacity to support NTPs.

On WHO support: STAG-TB recommends that WHO:

1. Review the staffing situation and skill mix at WHO's Regional Offices in light of the requirements of country support;
2. Review current capacity of WHO and partners at country level, in consultation with countries, to deliver TA (technical, financial-administrative and managerial), and plans to build capacity to support countries, utilizing the existing mechanisms including TBTEAM.

Session 12: TB and Tobacco Control: Joining forces

STAG-TB:

- Acknowledges that a substantial TB burden is attributable to avoidable risk factors, such as tobacco smoking;
- Considers that ongoing joint TB-tobacco control activities represent a promising and appropriate platform to pursue joint approaches to address a number of TB determinants, such as alcoholism;
- Notes the need for the TB community to work in partnership with the tobacco control community in order to address the dual epidemic of TB & tobacco smoking;
- Recognizes that the lessons learnt from TB/HIV collaborative experiences can help promote joint TB/tobacco control activities' development.

STAG-TB recommends that WHO:

1. Clearly prioritize interventions tackling the various categories of TB determinants and risk factors with an eye on the specific needs of countries and regions;
2. Explore role of targeting tobacco users and those who are exposed to passive smoking for early TB case detection and TB prevention efforts;
3. Promote how DOTS services may be used as a model for long-term care associated with chronic conditions, such as diabetes;
4. Assess how TB determinants and risk factors could be included in TB surveillance activities for operational research purposes.

Session 13: Update: WHO Global Task Force on TB Impact Measurement

STAG-TB:

- Acknowledges the substantial amount of progress made by the Task Force in its 3 areas of work during the past year;
- Notes its concern about insufficient funding for prevalence surveys in several of the 21 global focus countries, including Kenya, Mali, Malawi, Mozambique, Sierra Leone and Uganda.

To strengthen the Task Force work, STAG-TB recommends WHO, with partners:

1. Include experts in surveillance and TB epidemiology from outside the NTP in workshops and country missions in which surveillance data are assessed and estimates of disease burden updated
2. Help countries to transition to electronic recording and reporting systems, and related assessments of whether TB surveillance should be integrated into general (or infectious disease) information systems
3. Produce a second edition of the guidelines on disease prevalence surveys, to better address topics such as data management, data analysis and training of those responsible for data collection

Session 14: STAG-TB Meeting 2010: Dates, process and suggested themes

At the meeting the WHO Secretariat proposed dates for the 10th meeting of STAG-TB: Monday to Wednesday, 21-23 June 2010 which were noted by STAG-TB Members. **Note**: Subsequent to the meeting, the WHO Secretariat has determined that given planned policy development time requirements in 2010, new dates are proposed: **27-29 September 2010.**

STAG-TB members offered the following themes for consideration as agenda items for the June 2009 meeting. STAG-TB acknowledged that the agenda needs to include WHO requests for advice on new priority concerns, as well as follow-up to priority themes addressed in previous meetings. STAG-TB recommended, and the WHO Secretariat concurred, that the themes addressed should be more restricted in number in 2010 to allow more ample discussion and time for development of recommendations, reinforced by early distribution of background material before the meeting.

Topics proposed are presented in the order they were raised, and have not been prioritized. Some points below consolidate similar ideas offered by multiple STAG-TB members. The WHO Secretariat will consider these suggestions in developing the agenda for the 2010 meeting.

1. Follow-up on ethics guidance roll-out, and draft products of the TB and Human Rights Task Force;
2. Diagnostics follow-up, including: monitoring/assessment of impact on case detection and on patient outcomes; progress made in modification of the GRADE approach to assessing diagnostics; progress on how diagnostics are being rolled-out at country level and are their any policy questions that have been missed so far; state of quality of diagnostic tests in the field; and, overall what is progress and challenges on steps being taken to address the severe laboratory capacity constraints in Africa;
3. Universal Health Coverage advances and other efforts to reduce patient catastrophic costs;
4. Review of prioritization of recommendations made this year and actions taken; related assessment of the relative impact on TB care outcomes and TB control impact of the large number of interventions being proposed to be supported, in order to add prioritization process;
5. How is the promoting research component of the Stop TB Strategy being pursued, and how can WHO and partners help get findings into practice, including work ongoing on new drugs policies;
6. What is the progress on PPM scale-up and how to further facilitate this;
7. Rational prioritization of intensified case detection approaches; examples of progress made in countries on early and expanded case detection; and how is internet recording and reporting helping, including related concern of MDR-TB treatment enrolment;
8. Steps taken to improve anti-TB drug management at country level, both for first-line and second-line drugs as well as to strengthen the GLC mechanism;

9. How is support progressing to increase NTP and civil society capacity to make progress on MDR-TB response;
10. How can we best measure the impact of NTP interventions on patients, as well as on overall control of the TB epidemic.
11. Where are we relative to 2015 targets?
12. Where are we on coherent approaches to supporting the role of communities across all the interventions proposed, and provide case studies on what works.
13. Progress in TB/HIV service integration and programme discussions and progress.

Annex 1

World Health Organization

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

Ninth Meeting, 9-11 November 2009
Salle A, WHO Headquarters **Geneva, Switzerland**

AGENDA

MONDAY 9 NOVEMBER

9:00 **Introduction**

- **Welcome & introduction of members** — **M. Raviglione**
- **Meeting objectives** — **J. Chakaya, Chair**
- **Approval of agenda**

High-level policy changes needed to reach 2015 targets — **M. Raviglione**

9:30 **1. MDR/XDR-TB Response: Acting on Beijing and WHA Recommendations** — **E. Jaramillo**

Discussant: R. Shukla

Discussion

10:30 **Coffee**

10:50 **2. Policy change for improved quality and rational use of anti-TB drugs** — **E. Nathanson**

A. Regulatory issues: quality, prequalification and prescription status — **A. van Zyl**

B. Promoting rational use of antibiotics — **K. Holloway/M. Uplekar**

Discussants: K. Castro, R.V. Asokan

Discussion

12:00 Lunch

13:00 3. TB diagnostics policy K. Weyer

A. GRADE process for evaluation of new diagnostics M. Pai
B. LED-based microscopy and other microscopy-enhancing methods
C. Non-commercial culture and drug susceptibility testing methods
D. Framework for adoption of new policies at various levels

Discussants: V. Malakhov, F. Drobniewski

14:20 Coffee

14:40 4. Preparing for rapid policy review of new drugs C. Lienhardt

And, lessons learnt from revision of treatment guidelines M. Grzemska

Discussants: S. Al Awaidy, W. El-Sadr

15:40 5. TB/HIV: From testing to assured care H. Getahun

Discussant: E. Corbett

16:40 6. Update: Support to early case detection, including via contact investigation and the Practical Approach to Lung Health L. Blanc

Discussant: Mao Tan Eang

17:30 Wrap-up for Day 1 J. Chakaya

17:45 Reception D Building Cafeteria

18:30-19:15 Break-out groups for recommendations from Day 1
Chair, STAG-TB Day 1 discussants and rapporteurs

TUESDAY 10 NOVEMBER

9:00 **Review of recommendations from day 1** **J. Chakaya**

9:30 **7. Policy change to finance Universal Health Coverage** **D. Weil**

A. Strategies for health financing & social protection **D. Evans**

B. Catastrophic costs of TB and its care **K. Lonnroth**

C. Linking UHC and TB control to reach the vulnerable **D. Weil/B. Squire**

Discussant: Y. Kasetjaroen

10:30 **Coffee**

10:50 **8. Infection Control: from policy to implementation** **P. Nunn**

Discussant: Y. Pillay

11:50 **9. Coordinating and consolidating technical support streams** **P. Nunn**

Discussant: P. Suarez

12:45 **Lunch**

P. Fujiwara, STAG-TB Vice Chair: Chair, Sessions 10, 11, 12, 13

13:45 **10. Ethics and human rights approaches in TB care and control**

A. Review of draft guidance on ethical issues in TB prevention, care and control **A. Reis/E. Jaramillo**

Discussant: O. Akanni, F. Ahmed

Discussion

B. A rights-based approach to TB care and control: Stop TB Task Force, policy paper & strategic agenda **D. Weil/A. Reid**

C. Case example: UNION statement on undocumented migrants **E. Heldal**

Discussants on B & C: C. Gordon, L. Vianzon

Discussion

15:00 **Coffee**

15:20 **11. Top challenges in Regional support for implementing the Stop TB Strategy** **Regional Advisers**

Discussants: TAG Chairs

16:30 **12. Update: TB and Tobacco Control: Joining forces** **M. Raviglione, D. Bettcher**

Discussant: M. Murray

17:00 **13. Update: Progress on Impact Measurement** **A. Bierrenbach**

Discussant: M. van der Werf

17:30 **Wrap up - Day 2** **J. Chakaya, P. Fujiwara**

17:45-18:30 **Break-out groups for recommendations from Day 2** **Chair, Vice-Chair, STAG-TB discussants and rapporteurs**

WEDNESDAY 11 NOVEMBER

9:00 **Overall review of STAG-TB recommendations** **J. Chakaya**

10:20 **Coffee**

10:40 **Review continues**

11:30 **Proposed date for interim update call (January 2010), 2010 STAG-TB meeting date and agenda** **J. Chakaya**

11:45 **Final remarks** **J. Chakaya, M. Raviglione**

12:00 **Close**

Annex 2

Strategic and Technical Advisory Group on Tuberculosis
(STAG-TB)
Ninth Meeting

9-11 November 2009, WHO Headquarters, Geneva, Switzerland

List of Participants

STAG-TB Members 2009

1. **Mr Faruque Ahmed**
   Director
   BRAC Health Program
   Bangladesh

2. **Ms Olayide Akanni**
   Executive Director
   Journalists Against AIDS (JAAIDS) in Nigeria
   Nigeria

3. **Dr Salah Al Awaidy**
   Director
   Department of Communicable Disease Surveillance & Control
   Oman

4. **Dr R. V. Asokan**
   Indian Medical Association
   RNTCP National Coordinator
   India

5. **Dr Kenneth Castro**
   Director, Division of TB Elimination
   Centers for Disease Control and Prevention
   United States

6. **Dr Jeremiah Muhwa Chakaya**
   STAG-TB Chair
   Technical Expert
   National Leprosy and TB Programme
   Ministry of Health
   Kenya

7. **Dr Elizabeth Corbett**
   Reader in Infectious and Tropical Diseases
   London School of Tropical Medicine & Hygiene and MLW Research Programme
   Malawi

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

9. **Dr Wafaa El-Sadr**
   CIDER
   Mailman School of Public Health
   Columbia University
   USA

10. **Dr Paula I. Fujiwara, STAG-TB Vice Chair**
    Director, Dept of HIV and Senior Advisor
    The Union
    France

11. **Mr Case Gordon**
    World Care Council
    France

12. **Prof Vladimir Malakhov**
    National Center for External Quality Assessment in Laboratory Testing
    of Russian Federation
    Russia

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

14. **Dr Megan Murray**
    Associate Professor of Epidemiology
    Harvard University School of Public Health
    Department of Epidemiology
    United States of America

15. **Dr Yogan Pillay**
    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
    China

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

17. **Dr Rajendra Shukla**
    Joint Secretary
    Ministry of Health & Family Welfare
    India

18. **Dr Pedro Guillermo Suarez**
    TB & TB-HIV/AIDS Division
    Center for Health Services
    Management Sciences for Health
    USA

19. **Dr Rosalind G. Vianzon**
    National TB Programme Manager
    National Center for Disease Control and Prevention
    Department of Health
    The Philippines

    Prof Wang Longde (unable to attend)
    Dean, School of Public Health
    Peking University
    China

20. **Dr Yuthichai Kasetjaroen**
    Director
    Bureau of Tuberculosis
    Ministry of Health
    Thailand

WHO Regional Tuberculosis Advisory Group Chairs (TAG)

AMRO

Dr Kenneth Castro
(see under STAG-TB Members)

EMRO

Dr Donald Enarson (unable to attend)
Senior Adviser
The Union
France

EURO

21. **Dr Einar Heldal**
Norway

SEARO

22. **Dr P.R. Narayanan**
India

WPRO

Dr Jaap Broekmans (unable to attend)
Former Executive Director KNCV
Netherlands

Stop TB Partnership Working Group Chairs & Sub-Group Chairs

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

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

23. **Dr Giorgio Roscigno**
Chair, New Diagnostics Working Group
Chief Executive Officer
Foundation for Innovative New Diagnostics
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24. **Dr Madhukar Pai**
Co-chair, New Diagnostics Working Group
Assistant Professor
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McGill University
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25. **Dr. Kitty Lambregts van Weezenbeek**
Chair, MDR-TB Working Group
KNCV Tuberculosis Foundation
The Netherlands

Dr Michel Greco (unable to attend)
Chair, Vaccines Working Group
Independent Vaccine Expert
France

Dr Diana Havlir (unable to attend)
Chair, TB/HIV Working Group

26. **Dr Salmaan Keshavjee**
Chair, Green Light Committee
Assistant Professor of Social Medicine and Medicine, Harvard Medical School
Senior TB Specialist, Partners In Health
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27. **Dr John Ridderhof**
Chair, Global Laboratory Initiative
Associate Director for Laboratory Science
National Center for Preparedness, Detection and Control of Infectious Diseases, CCID
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28. **Dr Philip Hopewell**
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29. **Dr Stephen Bertei Squire**
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Temporary Advisers

30. **Dr Roberto Tapia-Conyer**
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Mexico

31. **Dr Joseph Amon**
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32. **Dr Mohammed Aziz**
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33. **Dr Amy Bloom**
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34. **Ms Celina D'Costa Menezes**
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37. **Ms Erin Howe**
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42. **Dr Mahfuza Rifat**
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43. **Dr Akira Shimouchi**
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44. **Dr Maarten van Cleeff**
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54. Dr Amal Bassili
55. Dr Philip Ejikon (Southern Sudan)
56. Dr Sevil Huseynova (WHO Iraq)
57. Mr Wasiq Khan
58. Dr Syed Karam Shah (WHO Afghanistan)
59. Dr Ridha Jebeniani (WHO Djibouti)
60. Dr Peter Metzger (WHO, Pakistan)
61. Dr Ireneaus Sindani (WHO, Somalia)
62. Dr Bashir Suleiman (WHO Somalia)
63. Aayid Munim

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SEARO

67. Dr Nani Nair, Regional Adviser
68. Dr Douglas Fraser-Wares (WHO, India)
69. Dr Suvanand Sahu (WHO, India)
70. Dr Mohammed Akhtar (WHO, Nepal)

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71. Dr Pieter van Maaren, Regional Adviser
72. Dr Nobuyuki Nishikiori
73. Dr Daniel Sagebiel
74. Dr Fabio Scano (WHO China)
75. Dr Xuejing Wang (WHO China)
76. Dr Woojin Lew (Philippnes)
77. Dr Linh Nhat Nguyen (Fiji, Pacific Island)
78. Dr Rajendra Yadav (Cambodia)

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HIV, TB and Malaria Cluster (HTM)

Dr Hiroki Nakatani, Assistant Director-General**(unable to attend)**

Stop TB Department (STB)

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79. Dr Mario Raviglione, Director
80. Ms Diana Weil, Coordinator, Policy & Strategy
81. Mr Glenn Thomas
82. Ms Melina Abrahan

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83. Dr Léopold Blanc, Coordinator
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85. Ms Annemieke Brands
86. Mr Jacob Creswell
87. Dr Malgosia Grzemska
88. Ms Catherine Lijinsky
89. Dr Knut Lonnroth
90. Dr Pierre-Yves Norval
91. Dr Ikushi Onozaki
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93. Dr Mukund Uplekar
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98. Dr Dennis Falzon
99. Dr Haileyesus Getahun
100. Dr Christian Gunneberg
101. Dr Ogtay Gozalov
102. Mr Jean de Dieu Iragena
103. Dr Tauhidul Islam
104. Dr Wieslaw Jakubowiak
105. Dr Ernesto Jaramillo
106. Dr Fuad Mirzayev
107. Ms Eva Nathanson
108. Mr Martins Pavelsons
109. Ms Rose Pray
110. Dr Delphine Sculier
111. Mr Wayne Van Gemert
112. Dr Karin Weyer
113. Dr Matteo Zignol

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114. Dr Katherine Floyd, Coordinator
115. Dr Ana Bierrenbach
116. Mr Christopher Fitzpartrick
117. Ms Ines Garcia Baena
118. Dr Philippe Glaziou
119. Dr Timizi Ahzim Bakir

Stop TB Partnership Secretariat

120. Dr Marcos Espinal Fuentes, Executive Secretary
121. Ms Raegan Boler
122. Mr Nejib Ababor
123. Mr Vittorio Cammarota
124. Ms Hélène Castel
125. Ms Young-Ae Chu
126. Mr Thierry Cordier-Lassalle
127. Ms Andrea de Lucia
128. Ms Jenniffer Dietrich
129. Mr Allan Esser
130. Dr Giuliano Gargioni
131. Ms Julia Geer
132. Mr Homero Hernandez
133. Ms Henriikka Huttunen
134. Ms Annette Kasi Nsubuga
135. Dr Christian Lienhardt
136. Mr John Loeber
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138. Mr Richard Maggi
139. Ms Judith Mandelbaum-Schmid
140. Ms Elisabetta Minelli
141. Ms Elena Mochinova
142. Mr Thomas Moore
143. Ms Paloma Lerga
144. Ms Maria Monika Patyna
145. Ms Maria Sarquella
146. Ms Anahitta Shirzad
147. Mr Holland Sillas
148. Mr Anant Vijay
149. Ms Anne Zeindl-Cronin

HIV/AIDS Department

150. Dr Teguest Guerma, Director, A.I.
151. Dr Siobhan Patricia Crowley, Coordinator A.I.
152. Dr Rueben Granich

Other WHO Departments

Medicines Policy, Essential drugs and Traditional Medicine

153. Dr Kathleen Holloway
154. Dr A. van Zyl

Health Systems Financing

155. Dr David Evans, Director

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

156. Dr Soumya Swaminathan, Coordinator
157. Dr Philip Onyebujoh

Ethics, Equity, Trade and Human Rights

158. Marie-Charlotte Bouesseau, Coordinator
159. Mrs Helena Nygren-Krug, Coordinator
160. Dr Andreas Reis

Tobacco Free Initiative

161. Dr Douglas Bettcher, Director
162. Dr Armando Peruga, Coordinator
163. Dr Dungbo Fu

Annex 3 : STAG-TB 2009 support

STAG-TB Chair, 2008-2010: J. Chakaya, Technical Expert, National Leprosy and TB Programme, Kenyan Ministry of Health, and Kenyan Medical Research Institute

Vice-Chair: P. Fujiwara, Senior Technical Advisor, International Union Against Tuberculosis and Lung Disease (The Union)

STAG-TB coordinator and overall rapporteur: D. Weil, HTM/STB

Session rapporteurs:

Session 1: R. Shukla (STAG-TB), W. Van Gemert, E. Jaramillo, HTM/STB

Session 2: K. Castro/R.V. Asokan (STAG-TB), E. Nathanson, M. Uplekar HTM/STB

Session 3: V. Malakhov, F. Drobniewski (STAG-TB), K. Weyer, HTM/STB

Session 4: S. Al Awaidy, W. El Sadr (STAG-TB) C. Lienhardt, HTM/STB

Session 5: E. Corbett (STAG-TB), H. Getahun, HTM/STB

Session 6: Mao Tan Eang (STAG-TB), J. Creswell, L. Blanc, HTM/STB

Session 7: J. Kasetjaroen (STAG-TB), D. Weil, HTM/STB

Session 8: Y. Pillay (STAG-TB), T. Islam, P. Nunn, HTM/STB

Session 9: P. Suarez (STAG-TB), P.Y. Norval, P. Nunn, HTM/STB

Session 10: O. Akanni, F. Ahmed, L. Vianzon, C. Gordon (STAG-TB), E. Jaramillo, D. Weil HTM/STB, A. Reis, IER/ETH

Session 11: K. Castro, E. Heldal, P.R. Narayanan (TAG Chairs), Akihiro Seita (EMRO), Pieter van Maaren (WPRO)

Session 12: M. Murray (STAG-TB), S. Ottmani HTM/STB

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ANNEX 4 - WHO Secretariat response to STAG-TB recommendations for 2009 agenda

In the 2008 meeting, STAG-TB members offered the following themes for consideration as agenda items for the June 2009 meeting:

Some points consolidate similar ideas offered by multiple STAG-TB members. Topics are presented in the order they were first raised, and have not been prioritized. Understanding that the themes are too numerous for consideration at one meeting, the WHO Secretariat will make clear how it has worked from this draft list in devising the final proposed agenda for 2009.

1. TB prevention, care and control in the human rights context -- working with many other interested agencies, such as UNAIDS (Session 10)

2. The impact of TB on health care workers; the role of National TB Programmes in helping overcome the human resources crisis, including approaches to capacity development (Stop TB HRD subgroup formed with WHO secretariat - also see CDROM, Session 10 on ethical issues related to health care workers and TB)

3. Financing trends for HIV/TB joint interventions, for TB research and development, and for increasing national-level commitments to TB control (Global TB Control Report 2009 and Update, December 2009)

4. Reporting on follow-up on major areas of recommendations from the 8th meeting, and presentation from WHO Regional TB Adviser(s) on the application of recommendations at regional/country level (various sessions, including RO presentation - Session 11)

5. Progress on implementation of rapid drug susceptibility tests and related "retooling", second-line drug susceptibility testing, lab strengthening and quality assurance (Sessions 1 and 3)

6. National TB Programme management capacity and approaches to overcoming limitations, as well as capacity of civil society partners (Session 9)

7. Measures to improve overall TB drug supply system capacity at country-level (Sessions 1 and 2)

8. Improving local and international technical assistance capacity, and the impact of Global Fund processes on technical assistance (Session 9)

9. Progress on developing an alternative ("category two") retreatment regimen (Session 4)

10. Methods to reduce the burden on patients of service visits (Session 7)

11. Progress on surveillance systems certification and improvements (Session 13)

12. Follow-up at country level on the HIV/TB Global Leaders' Forum and the planned MDR-TB high-level meeting (Sessions 1 and 5)

13. Progress on MDR-TB surveillance, analysis of MDR-TB treatment outcomes, development of Centres of Excellence in MDR-TB management, and MDR-TB community-care models. (Session 1)

14. Experiences in linking national government action with NGO efforts in TB prevention, care and control (Session 6)

15. Progress in measuring effectiveness of public-private mix models of TB care (STB publications 2009)

16. How to improve earlier diagnosis of smear-negative and extrapulmonary TB? (Session 6)

17. What are the synergies in response to the three diseases by the Global Fund? (Session 11)

18. Intensified TB case finding approaches -- results of proposed analyses (Session 6)

Annex 5

THE STOP TB STRATEGY

VISION	**A TB-free world**
GOAL	To dramatically reduce the global burden of TB by 2015 in line with the Millennium Development Goals and the Stop TB Partnership targets
OBJECTIVES	• Achieve universal access to quality diagnosis and patient-centred treatment • Reduce the human suffering and socioeconomic burden associated with TB • Protect vulnerable populations from TB, TB/HIV and drug-resistant TB • Support development of new tools and enable their timely and effective use • Protect and promote human rights in TB prevention, care and control
TARGETS	• MDG 6, Target 8: Halt and begin to reverse the incidence of TB by 2015 • Targets linked to the MDGs and endorsed by Stop TB Partnership: – 2015: reduce prevalence of and deaths due to TB by 50% – 2050: eliminate TB as a public health problem

COMPONENTS

1. **Pursue high-quality DOTS expansion and enhancement**
   - **a.** Secure political commitment, with adequate and sustained financing
   - **b.** Ensure early case detection, and diagnosis through quality-assured bacteriology
   - **c.** Provide standardized treatment with supervision, and patient support
   - **d.** Ensure effective drug supply and management
   - **e.** Monitor and evaluate performance and impact
2. **Address TB/HIV, MDR-TB, and the needs of poor and vulnerable populations**
   - **a.** Scale-up collaborative TB/HIV activities
   - **b.** Scale-up prevention and management of multidrug-resistant TB (MDR-TB)
   - **c.** Address the needs of TB contacts, and of poor and vulnerable populations
3. **Contribute to health system strengthening based on primary health care**
   - **a.** Help improve health policies, human resource development, financing, supplies, service delivery, and information
   - **b.** Strengthen infection control in health services, other congregate settings and households
   - **c.** Upgrade laboratory networks, and implement the Practical Approach to Lung Health (PAL)
   - **d.** Adapt successful approaches from other fields and sectors, and foster action on the social determinants of health
4. **Engage all care providers**
   - **a.** Involve all public, voluntary, corporate and private providers through Public-Private Mix (PPM) approaches
   - **b.** Promote use of the International Standards for Tuberculosis Care (ISTC)
5. **Empower people with TB, and communities through partnership**
   - **a.** Pursue advocacy, communication and social mobilization
   - **b.** Foster community participation in TB care, prevention and health promotion
   - **c.** Promote use of the Patients' Charter for Tuberculosis Care
6. **Enable and promote research**
   - **a.** Conduct programme-based operational research
   - **b.** Advocate for and participate in research to develop new diagnostics, drugs and vaccines