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CLINICAL TRIALS FOR DRUG RESISTANT TB URGENTLY NEEDED

On 10-12 June 2008, a workshop was held in Cambridge, MA, USA on clinical trials for drug-resistant tuberculosis. The workshop brought together scientists, practitioners and donors in the field of drug-resistant TB to discuss and finalize a strategic plan for designing, funding and conducting randomized clinical trials to test treatment regimens that can simplify and shorten those currently used.

The recommended treatment of MDR-TB with second-line drugs is long, complex and costly, and has a considerable rate of adverse effects. This is one of the factors hindering the global scale-up of MDR-TB management. The evidence base for these treatment regimens is weak. Most recommendations are based on observational studies and expert opinion. Randomized clinical trials for MDR-TB, the gold standard method for establishing effectiveness of drug treatment, have hardly been done. This was due to a lack of perceived epidemiologic significance of MDR-TB, lack of suitable trial sites, the heterogeneity of the patient population, absence of new anti-tuberculosis agents and limited political will.

Recent progress, including new epidemiologic evidence, policy changes, and advances in TB drug development, have improved the environment for embarking on trials of MDR-TB treatment. The Research Agenda for Scaling up Programmatic Management of Drug-resistant Tuberculosis (*PLoS Medicine*, July 2008), recently revised by the MDR-TB Working Group's Research subgroup, calls for clinical trials to identify optimal treatment protocols for drug-resistant tuberculosis. These trials should, in addition to the efficacy of new drugs, specifically address the



Participants at the workshop on clinical trials for drug resistant TB, Cambridge, MA.

optimal use of existing drugs. Provided that treatment efficacy is improved or at least maintained, shortening of the currently recommended second-line regimens and reduction of the number of drugs required potentially save scarce resources, improve treatment adherence, reduce toxicity and facilitate the scale up of treatment. In addition, there is no evidence base for preventive treatment of contacts of infectious patients



Participants write the Cambridge Declaration.

with drug-resistant TB. Therefore, well-designed clinical studies, including clinical trials, are needed to also develop effective strategies for preventive treatment of these contacts.

Clinical trials of drug-resistant TB will require substantial numbers of patients in different settings, and therefore multiple trial sites need to be involved.

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These may be clinical centers that have already been developed as clinical trials sites by existing consortia, as well as treatment centers of MDR-TB that can be developed into clinical trial sites, in particular if their treatment programmes have Green Light Committee (GLC) approval. Furthermore, since sponsoring of trials of existing drugs by pharmaceutical companies is unlikely, such trials require funding by other donors.

This calls for a coordinated effort to prioritize research questions, engage trial sites and advocate for funding.

Therefore, a Task Force was set up by the Working Group on MDR-TB in November 2007 (at the IUATLD Conference in Cape Town) to initiate a coordinated effort towards clinical trials for drug-resistant TB. It produced a document as a basis for a strategic plan that will be discussed and finalized at the workshop on Clinical Trials for Drug-Resistant Tuberculosis held in Cambridge, MA, USA, on 10-12 June. Hosted by Partners in Health and Harvard Medical School, the workshop was co-organized and co-sponsored by a number of other institutions involved in management and control of drug-resistant TB, including the Stop TB Partnership, Médecins Sans Frontières, the IUATLD, KNCV Tuberculosis Foundation, Treatment Action Group and the Potts Memorial Foundation.

Participants included researchers, tuberculosis control experts, representatives of MDR-TB treatment sites, treatment activists, and representatives of funding agencies and regulatory bodies. The participants discussed the priorities for clinical trials, and how these trials and other studies could be designed to address these priorities in an effective and efficient way. They elaborated on a process for site participation in clinical trials of drug-resistant TB and for engaging donors and collaborators from related fields, including animal studies and pharmacology. Finally they discussed regulatory issues and mechanisms for governance.

The Workshop culminated in the launch of an initiative to conduct the most important clinical trials and to mobilize the resources needed for these trials (see Cambridge Declaration). Its first step will be to finalize a comprehensive, strategic plan that outlines the issues discussed at the workshop. After endorsement by the Working Group in the second half of 2008, the plan will then be used as a roadmap to the development of, and funding for, clinical trials of drug-resistant TB. Two other steps of the initiative will be to develop study protocols for the priority trials, and to select sites to participate in these trials.

Contribution by **Frank Cobelens**, chair research subgroup of the MDR-TB WG.

THE CAMBRIDGE DECLARATION: Towards Clinical Trials for Drug-Resistant Tuberculosis Cambridge, Massachusetts, USA, June 12, 2008

Because

- today millions of people are living with drug-resistant tuberculosis (TB),
- drug-resistant TB, which is transmissible and deadly, represents a public-health emergency,
- universal access to effective TB treatment is unachievable with current tools,
- inadequate treatment of drug-resistant TB leads to the emergence of extensively drug-resistant (XDR) TB, and
- there are huge gaps in our understanding of how to best treat drug-resistant TB, we express extreme concern that the best available treatments are of limited efficacy and are reaching only a small fraction of people who need them. The others are left to die, with no or inadequate treatment.

On June 10-12, 2008, stakeholders from communities, NGOs, governments, donors, industry, and academia met in Cambridge, Massachusetts, USA, and declared the formation of a movement that will:

- conduct priority clinical trials that test strategies in adults and children: to shorten and improve treatment for drug-resistant TB, and to prevent drug-resistant TB
- mobilize the resources needed for these trials
- build the capacity of trial sites
- report to stakeholders on progress made, and
- ensure that these efforts complement those of other groups, and address the critical unmet needs outlined above.

View all the signatories to the Cambridge Declaration by [clicking here](#).

For more information, to become a signatory, or to join protocol-writing groups, please contact: drtbworkshop@gmail.com

UPDATE FROM THE DRUG MANAGEMENT SUBGROUP (DMSG)

The Global Drug Facility (GDF) hosted a meeting in Mumbai, India June 2-5, 2008, with prospective suppliers of quality-assured 2nd line anti-TB drugs. The purpose of the meeting was to present potential suppliers with information on the growing demand for quality-assured 2nd line medications, to introduce GDF and IDA to the participants, explain how GDF and IDA work to supply medicines to GLC-approved projects. The meeting was attended by representatives from suppliers including Strides, Sandoz, Lupin, Svizera, MacLeods, Cadila, Eli Lilly, Micro Lab, Ranbaxy, Cipla, and Shrusti. GTZ, IDA, UNITAID, Proxy Labs, SGS (labs), Geis SDV, and Intertek also participated.

OUTCOME AND CONCLUSIONS?

The DMSG has been meeting monthly, seeking to increase the available supply of quality-assured 2nd line drugs for MDR-TB projects. Discussions have progressed with a number of suppliers for a variety of 2nd line drugs, but there are as yet no firm agreements with new producers to report. Later this month, the GDF will release figures showing the current supply and demand for each of the drugs in shortest supply, showing current and projected orders, the numbers of quality-assured suppliers and an estimate of the available supply for the remainder of 2008. The DMSC and the GDF have committed to provide this information quarterly to market participants, as a means of reporting to projects and to potential suppliers on the size of the market for important second line drugs.

The DMSC has also been working with consultants on estimates of global and country consumption of important 2nd line drugs. The sub-group will use this information to highlight the gaps between current demand and supply of 2nd line drugs around the world, to estimate what percentage of second line anti-TB drugs currently on the market are quality-assured. As concern about the rise of XDR-TB increases around the world, it will be increasingly important to monitor the volume of 2nd line drugs supplied, to track how much of this product is quality-assured, and to increasingly press for the use of these drugs in well-structured TB control projects, with adequate monitoring. Figures shown at the Second XDR-TB Task Force meeting held in Geneva, Switzerland, in April showed that there were some 47,000 MDR-TB patients reportedly on treatment in projects around the world, but that less than 10,000 of these patients are being treated in Green Light Committee-approved projects, while estimated global burden is around 490,000 cases. As countries continue to scale-up treatment of MDR-TB treatment patients, some will continue to do so outside the Green Light Committee (GLC). It will be very important, however, that countries structure their treatment projects in accordance with the WHO Guidelines for the programmatic management of drug-resistant Tuberculosis whqlibdoc.who.int/publications/2006/9241546956_eng.pdf and, as importantly, that they treat patients with quality-assured drugs.

Contribution provided by **Paul Zintl**, chair of the DMSG

SECOND WHO TASK FORCE ON XDR-TB MEETS TO ASSESS PROGRESS

The second meeting of the WHO Task Force on XDR-TB was held from April 9–10, 2008 in Geneva, Switzerland. Participants represented national programs, bilateral and multilateral agencies, international organizations, nongovernmental organizations, the pharmaceutical industry and academia. The objectives of the meeting were to review progress in implementing the recommendations of the first XDR-TB Task Force Meeting (Geneva, October 2006), to assess progress in implementing the Global MDR-TB and XDR-TB Response Plan 2007–2008 and to agree on steps to accelerate its implementation.



Participants at the XDR Taskforce meeting in Geneva, Switzerland

The meeting also reviewed new evidence as well as a draft of the updated WHO guidelines for the management of drug-resistant TB, sought ways to accelerate scale up of the response to MDR-TB and XDR-TB and looked at ways to mobilize more resources for universal access to MDR-TB diagnosis and treatment by 2015.

Major progress was reported on several fronts in particular, Peru had become the first low-resource setting reporting universal access to diagnosis and treatment of multidrug-resistant tuberculosis (MDR-TB).

The Global Laboratory Initiative was leading the strengthening of laboratory capacity and line-probe assays had been successfully evaluated in South Africa.

Epidemiological research indicated that poor TB control in KwaZulu Natal from 1994–2002, nosocomial spread, poor infection control, and misuse of ciprofloxacin were the most likely explanation for the outbreak of extensively drug-resistant TB (XDR-TB) in Tugela Ferry.

Evidence had emerged that MDR-TB could be managed in very difficult circumstances, such as settings with high HIV prevalence, but that it involved major ethical and legal

challenges. An overview of progress in 27 high-priority MDR-TB countries, however, showed enormous gaps, with the number of patients on treatment well below targets.

The Taskforce recommended that WHO and the Stop TB Partnership convene a meeting with high-level officials of all 27 high MDR-TB burden priority countries early in 2009, in order to discuss and identify the main factors hampering progress and foster and support the development of medium-term plans for scaling-up the programmatic management of MDR-TB that will address the obstacles to progress. It is essential that political commitment for the urgent scale-up of MDR-TB management is secured at all levels.

WHO was also tasked with producing training modules for the programmatic management of DR-TB and make them available as quickly as possible. Guidance on implementation of line-probe assays for MDR-TB within specific country settings and the ethical and legal issues to support patient-centered TB care, including community-based MDR-TB care raised by participants as a major issue to accelerate scale-up, was provided by STAG TB 2008.

DRUG MANAGEMENT STILL CRITICAL ISSUE FOR MDR-TB CORE GROUP

The Core Group of the MDR-TB Working Group met on April 10, 2008 in Geneva, Switzerland, to discuss progress, barriers and solutions to improve implementation of the MDR-TB Response Plan.

The Drug Management subgroup reported that they are now better informed of some of the more fundamental problems influencing drug procurement.

As the Drug Management subgroup increases its understanding of the market of second-line anti-TB drugs, more challenges become clear. For example, countries using local funds have political and legal reasons to prefer procuring these drugs from local producers or wholesalers, which are quite often lacking of the international best quality standards. Procuring outside the pooled procurement of GLC can have negative effects on the reduced prices obtained so far by GLC, and can also contribute to amplify resistance and create XDR-TB, due to the use of poor quality drugs.

The GDF received US \$30 million from UNITAID and US \$15 million from USAID. UNITAID funding is intended to create a stockpile of

drugs, as well as a revolving fund which can be used to purchase drugs in advance of country orders reducing the lead time to deliver a firm order. The Core Group hopes that this fresh funding to GDF will contribute to strengthen the current limited capacity of GDF to manage second-line drugs, especially in terms of workforce needed to handle the complex procurement of second-line anti TB drugs. This is essential to accelerate progress of response to dramatic crisis in drug procurement faced by the GLC-approved projects.

The Core Group also endorsed the use of a grid of 27 high MDR-TB burden countries based on country data submitted to WHO (which contains data on components of the Global MDR-TB Response Plan) to monitor progress and identify countries and areas to prioritize.

The WHO XDR-TB Task Force also recommended the creation of a task force to deal with the involvement of all health care providers in the response to MDR-TB and XDR-TB. The Core Group will now work the Public Private Mix (PPM) subgroup in this regard.

ACCELERATING THE UPTAKE OF NEW AND IMPROVED TUBERCULOSIS CONTROL TOOLS: THE STOP TB PARTNERSHIP'S TASK FORCE ON RETOOLING

Addressing the challenge of multi-drug resistant tuberculosis (MDR-TB) and extensively resistant tuberculosis (XDR-TB) requires the use of new and improved tools. The Global Plan to Stop TB predicts the availability of new drugs, diagnostics and vaccines by 2015. New diagnostics are already available and many more are in the development pipeline.

Previous experience has shown that there is often a significant delay between the availability of new technologies at global level and their eventual adoption and implementation at country level. Recognizing this important delay between evidence for and policy implementation, the Stop TB Partnership established the Retooling Task Force (RTF) to develop a framework for catalyzing policy makers and practitioners at global and national levels towards accelerated introduction of new tools into national TB programmes. One of its aims is to stimulate discussion and planning for optimal, timely and appropriate adoption, introduction and implementation of new tools as they become available.

The Retooling Task Force (RTF) includes members of the product development, programme implementation, donor, scientific and patient advocacy communities. It serves as a bridge and communicator between Stop TB Partnership working groups, giving priority to seeking inputs from and providing information to disease-endemic countries regarding the need for and use of new tools.

Since 2006, the RTF has published a number of guidance documents and tools to facilitate the process of retooling at country level. These include *New Technologies for Tuberculosis Control: A Framework for their adoption, introduction and implementation*; *Engaging Stakeholders for Retooling TB Control*; a

Checklist of Key Actions for Use of Liquid Media for Culture and Drug Susceptibility Testing (DST); and an Advocacy Kit. The RTF also worked with the relevant Stop TB Partnership working groups to elaborate and communicate updates of the diagnostic, drug and vaccine development pipelines. These documents can be accessed on www.stoptb.org/retooling.

The RTF worked with the World Health Organization (WHO) to articulate the steps to global policy development in the context of retooling activities, specifically clarifying WHO's role in helping researchers to bring scientific findings into policy and practice. WHO has provided information for product developers regarding the procedures for generating and submitting evidence for Strategic and Technical Advisory Group for Tuberculosis (STAG) and WHO policy consideration (www.who.int/tb/en).

Retooling considerations have been incorporated into the WHO TB costing and budgeting tool for country planning and into

STAGES IN RETOOLING

Incorporating new and improved health technologies into tuberculosis (TB) control programmes is termed "retooling". It involves the adoption, introduction and implementation of new diagnostics, drugs, vaccines and strategies for TB control.

the planning framework for use in Round 8 Global Fund grant applications. This will facilitate appropriate country-level planning and budgeting for retooling activities, such as updating guidelines and registers for new case definitions or conducting field evaluations to demonstrate the country-specific relevance of a new tool. WHO has added three retooling indicators to the annual WHO Global TB survey, to monitor country preparedness and uptake of new tools and identify future needs for retooling.

RETOOLING FOR MDR-TB AND XDR-TB

There are several new diagnostic tools that are available or should become available during the next two years. WHO has already recommended the use of liquid culture and rapid species identification to address the needs for culture and DST and the use of molecular line probe assays for rapid detection of drug-resistant TB. Liquid culture systems reduce the time to get results from weeks to days, compared with solid media. Use of line probe assays may significantly reduce the demand on conventional culture and DST laboratory capacity. Detailed information on these and other diagnostic tools in the pipeline are provided on www.stoptb.org/retooling.

Therefore, it is critical that countries begin preparing for the analysis of benefits, costs, health system requirements and appropriateness of these and other diagnostics to improve detection and management of MDR-TB.

There are many factors to account for when considering new tools for TB diagnosis, many of which are described in the RTF guidance documents. Some of the key factors include the evidence base and need for field testing, programmatic readiness for and relevance of the tool, ease of the tool and the turnaround time for results, costs of the products required



Diagnosing TB with the fluorescent microscopy method. Mariamu Mzirai, Laboratory assistant at the Mwanayamala Hospital, Kinondoni Region Tanzania. Credit: Rachel Bauquerez

and their maintenance, regulatory and quality control measures, biosafety considerations, staff capacity and training capacity.

Recognizing the challenges of increasing laboratory capacity to diagnose not only patients with TB but also those with drug-resistant TB, the Stop TB Partnership Subgroup on Laboratory Capacity Strengthening and WHO have launched the Global Laboratory Initiative (GLI).

The RTF recently coordinated a joint country mission with the GLI and the New TB Diagnostic Working Group to support Tanzania's ambitious plans to retool its diagnostic algorithm and incorporate several new tools, including screening for MDR-TB among retreatment cases. The Tanzania National Tuberculosis and Leprosy Programme (NTP) has actively coordinated the support of multiple donors to attain treatment success rates of 81%. NTP plans to increase current case detection from 45% to 70%.

Recent Tanzanian laboratory services improvement included renovating the Central TB Reference Laboratory (CTRL) at Muhimbili Medical Centre, Dar es Salaam; building a new laboratory at Kibongo National Tuberculosis Hospital, and introducing LED fluorescent microscopes and services in some diagnostic centres. The International Union Against Tuberculosis and Lung Disease and the Foundation for Innovative New Diagnostics provide on-going technical assistance to the CTRL.

The joint mission, NTP and CTRL used the retooling diagnostics checklist to comprehensively define and review activities for introducing LED microscopy, liquid media for culture and DST, line probe assay and its corresponding external quality assurance (EQA) systems. The mission also provided recommendations, some of which were incorporated into the U.S. Agency for International Development's plans to support the NTP and CTRL.

The RTF will continue to support the work of the GLI as it takes on more issues of retooling. For additional information on the retooling task force, please contact: The Stop TB Partnership Retooling Task Force [stoptbretooling@who.int].

COMMUNITY BASED MDR-TB TREATMENT - WILL IT WORK? EXPERTS RESPOND TO THE QUESTION:

"What do you think are the crucial components to creating a successful community based MDR-TB treatment program?"



"MDR-TB is a devastating disease: difficult to diagnose and long to treat, with side effects due to drugs, requiring constant support. How long can a patient stay in a hospital, isolated and far from the family and the community?"

Therefore, community-based MDR-TB treatment may be the best option in many circumstances when the patient who is not too sick can be discharged home. In a model program in Lesotho, for non-contagious patients still needing close doctor supervision and coming from far away, hostels near the hospital have been created where relatives may be hosted. For patients who can be supervised daily in their treatment by a health worker, care can be provided in the community. The crucial thing is to ensure strong psychological support and the best care, daily, guaranteeing that treatment is closely monitored, as mistakes are often fatal with this disease."

Dr. Mario Raviglione,
Director, Stop TB Department, WHO



Given the fear and stigma surrounding XDR-TB, full discussion and consensus between community representatives, the public health folk involved, the local/district TB programme, and staff

from the health facilities seems crucial to me. And this doesn't stop once the treatment programme begins, but needs to feedback to the community as it goes on. The concept is immensely challenging, but so much more humane than locking people up in what is effectively a prison, away from their homes and relatives, and all that makes life bearable."

Dr. Paul Nunn,
Coordinator, Stop TB Department, WHO



"Communities have the potential to push health authorities and policymakers to provide free and high quality MDR-TB diagnosis and care to all TB patients at increased risk of drug-resistant TB. This potential for political pressure is still underutilized. Furthermore, involvement of local NGOs and volunteers offers major opportunities for patient centered care and improved case-holding. However, decentralizing and involving the community does not mean the health authorities can sit back. They need to offer supportive supervision, facilitate cross referral in case of side effects and monitor closely. Effective health education and training, taking into account cultural sensitivities and realities are crucial. Ideally, we should benefit from some simple qualitative research or input from medical anthropologists when designing community MDR-TB programs and related training/IEC materials."



Kitty Lambregts,
Chair, MDR-TB Working Group

"An individualized, comprehensive approach tailored to each patient's clinical, socioeconomic and emotional situation is needed. Treatment

must include Directly Observed Comprehensive Care and not just the provision of medicine. Care provided within and with the community by involving community promoters, leaders, grassroots organizations, and families. Care must be provided in each patient's home. It must be close to a patient's habitat, lifestyle, routine. This approach costs less, is more convenient and saves time. It enhances patient and family involvement in the treatment process and facilitates a more individualized, comprehensive approach (tailored to each patient's situation). Community based care would also facilitate contact tracing and timely diagnosis of TB and MDR-TB and brings healthcare workers closer to patients and the community allowing for identification of other health issues (not just TB)."

Jaime Bayona,
Director of Socios en Salud/Partners in Health, Peru

INDONESIA PREPARES FOR THE FIRST MDR-TB CONTROL PROGRAMME THROUGH GLC!

Indonesia is making final preparations for the programmatic management of MDR-TB. The programme has been designed in true public private partnership (PPM). From the very beginning the National TB Programme (NTP) has closely collaborated with the specialists in the national respiratory referral hospital 'RS Persahabatan', and with the national laboratory and MDR-TB working groups. KNCV Tuberculosis Foundation and the SRL (supranational laboratories), Institute of Medical and Veterinary Science (IMVS, Australia) offered technical assistance within the USAID funded TBCAP programme. In February 2008, the Green Light Committee (GLC) application was approved.

The pilot programme is of major importance to Indonesia, a high MDR-TB burden country that has only limited access to second line drugs. In fact, PAS, Ethionamide and Cycloserin are not available, nor in the private, nor in the public market. As a consequence, physicians treat MDR-TB with inadequate regimens with just Quinolones and or Kanamycin. Obviously, these erratic MDR-TB treatment regimens often fail and have the potential to create XDR-TB. In fact, as preliminary data show, resistance to Ofloxacin is already a major problem in one third of hospital based MDR-TB cases (data from survey in two hospitals).

The MDR-TB control design that resulted from this PPM initiative, is innovative and focuses on smooth referral and cross referral between the designated hospitals and labs, the NTP and the community. All procedures are described in detail in the programme manual and the related standard operating procedures and are agreed upon by all partners.

Case-finding will target all patients at increased risk of MDR-TB, such as patients reporting previous TB treatment in either public or private sector, and

diagnosis will be free of charge to both NTP and public and private hospital clients that meet these 'suspect criteria'. Thus, private physicians in the designated hospitals will be fully involved in identifying MDR-TB cases, provided that they refer suspects to the designated (externally quality controlled laboratory). Second line drug susceptibility testing (SL-DST) to Ofloxacin and Kanamycin is part of the routine. In addition, all suspects will be referred for molecular DST within the context of an operational research project that aims at assessing the validity and operational feasibility of rapid molecular DST in the Indonesian context.

Patients will be treated with one of the 4 standardized regimens, based on the drug-resistance pattern (including SL-DST). Given the widespread use of Ofloxacin, the Indonesian experts have decided to use Levofloxacin instead of Ofloxacin..

All MDR-TB patients will be hospitalized for 2-4 weeks in the MDR-TB ward of Persahabatan hospital. This initial hospitalization will serve to build capacity for the early identification and management of side effects. After all, Indonesian clinicians do not yet have

any experience with PAS, Ethionamide and Cycloserin. This period is also used for intensive health education of patients and family-members, for preparation of the health centers involved in ambulatory treatment (refresher course for the staff, infection control, etc.) and for the selection and training of a community or family DOT supporter. Whereas all health centers (puskesmas) are involved in case-finding, only some are selected for treatment delivery. Assuring easy access for all patients, though concentrating treating experience and creating some ambulatory 'centers of excellence'.

Upon release of the patient from the hospital, the puskesmas staff will visit the patient in the hospital to receive the last patient specific instructions and to meet the patient and his family DOT provider. In general, the selected puskesmas will provide DOT during the intensive phase of treatment. During that period the family DOT supporter will be closely involved. After all, he or she will mainly manage the last continuation phase of treatment. However, during the whole treatment, the hospital MDR-TB team and the Clinical Expert Committee will monitor the patient monthly.

Based on the experiences during the first phase of the pilot and depending on available donor support, Indonesia plans to scale up with two more sites per year and cohort expansion in the successful sites.

We will keep you informed!

Jane Soepardi, manager of the National TB Programme, Indonesia

Kitty Lambregts-van Weezenbeek, KNCV Tuberculosis Foundation

INTERNATIONAL CENTER FOR TUBERCULOSIS INAUGURATED IN MAKATI, PHILIPPINES ON WORLD TB DAY

On Monday, March 24, 2008, World TB Day, the Tropical Disease Foundation, in partnership with the Ayala Corporation, Angelo King Foundation, World Lung Foundation and other major donors celebrated the grand opening of the International Center for Tuberculosis (ICT). The state-of-the-art facility will more effectively combat multi-drug resistant (MDR-TB) TB by providing research, training and a steady supply of much-needed medications to the Filipino public and across the region. The center is the first of its kind in Asia.

The building will house a TB Treatment Center, a TB laboratory, and a training center. The world-class TB center, a five-storey facility, is located in Makati City, Philippines. A flagship project of the Tropical Disease Foundation (TDF), it will soon be a major venue for training on diagnosis and treatment of patients with multidrug-resistant TB, or MDR-TB.

Programmatic management of drug-resistant TB (PMDT) is a priority of the World Health Organization and the Stop-TB Partnership MDR-TB Working Group. The operation of the ICT will help in the scale up of PMDT to respond to the public health threat from severe forms of MDR-TB and extensively drug-resistant TB (XDR-TB). The ICT will assist the Philippines and other countries by providing training courses and field and bench experience in the laboratory, which it will supplement with monitoring, supervision and consultation services.



STOP TB PARTNERSHIP COORDINATING BOARD SAYS MDR-TB PRIORITY AREA

The Stop TB Partnership Coordinating Board met in Cairo, Egypt from May 6-7, 2008. The key area of discussion was about the external evaluation of the Stop TB Partnership's effectiveness. Findings indicate that the Partnership is working well and doesn't need much 'fixing'. In addition, the Board decided to delay any decisions concerning representation of different constituencies and working groups.

The urgency of MDR/XDR was brought to the fore at a number of junctures. Ken Castro, U.S. Centers for Disease Control and Prevention, gave an excellent overview of the second meeting of the WHO Task Force on XDR-TB held in Geneva in April 2008. He also highlighted the importance of the Task Force recommendation of holding a Ministerial meeting with the 27 high burden MDR-TB countries in 2009, as a very important step to secure greater political engagement, which was endorsed by the co-ordinating board.

Importantly, a long discussion was held on the problems with drug procurement for second line drugs. The Global Drug Facility (GDF) provided a concise update and analysis on efforts to address the drug supply crisis, and inputs from many around the table illustrated a desire to seek a solution without delay. It was suggested that a meeting of the GDF, MDR-TB Working Group, the Drug Procurement subgroup, the Global Fund and UNITAID could come up with proposals for high level action that the Coordinating Board could undertake to move this issue forward.

For those seeking to rapidly scale-up MDR-TB and XDR-TB, the Coordinating Board meeting was a step in the right direction.

Contribution provided by **Case Gordon**

UPCOMING EVENTS

WHO-KNCV REGIONAL TRAINING ON TB CONTROL PROGRAM MANAGEMENT

When: November 4-11, 2008

Where: Warsaw, Poland

For more information:
tuberculosis@euro.who.int

WHO EURO, KNCV,
WHO Collaborating Centre

European TB course for programme
managers

WHO TRAINING COURSE ON IMPLEMENTING THE STOP TB STRATEGY (MDR/XDR, TB/HIV, PPM)

When: November 3-15, 2008

Where: Sondalo, Italy

For more information:
www.euro.who.int/tuberculosis

Email: tuberculosis@euro.who.int

WHO Collaborating Centre

Global TB course

WORKING GROUP ON MDR-TB OF THE STOP TB PARTNERSHIP

The Core Group and the subgroups of the WG will meet 14 October in Paris. More information to follow soon.

CONFERENCE ON TB CONTROL IN CENTRAL ASIA

When: November

Where: Tashkent, Uzbekistan

For more information:
www.euro.who.int/tuberculosis

Email: tuberculosis@euro.who.int

WHO EURO, KfW

Annual conference on TB control for five
central Asian republics.

THE TRAINING COURSE FOR MDR-TB CONSULTANTS

When: December 1-5 2008

Where: Lima, Peru

WHO and the MDR-TB Working Group in collaboration with the Peru National TB Programme and Socois en Salud, will run an intensive one week MDR-TB course for selected consultants that will support operations of the Green Light Committee.

**THE CAMBRIDGE DECLARATION:
Towards Clinical Trials for Drug-Resistant Tuberculosis
SIGNATORIES, 23 June 2008**

1. Ms. Paula Akugizibwe, AIDS and Rights Alliance for Southern Africa, Namibia
2. Mr. Sidney Atwood, Brigham and Women's Hospital, USA
3. Dr. Jaime Bayona, Socios En Salud-Sucursal Peru, Peru
4. Dr. Mercedes Becerra, Harvard Medical School, USA
5. Dr. Cesar Bonilla, National Health Strategy for TB Prevention and Control, Peru
6. Dr. Maryline Bonnet, Epicentre / Médecins Sans Frontières, Switzerland
7. Dr. William Burman, Denver Public Health, USA
8. Dr. Peter Cegielski, U.S. Centers for Disease Control and Prevention, USA
9. Dr. Richard Chaisson, Johns Hopkins University School of Medicine, USA
10. Dr. Frank Cobelens, KNCV Tuberculosis Foundation, The Netherlands
11. Dr. Theodore Cohen, Brigham and Women's Hospital, USA
12. Dr. Margareth Dalcolmo, Centro de Referência Prof. Hélio Fraga, Brazil
13. Dr. Charles Daley, National Jewish Medical and Research Center, USA
14. Dr. Manfred Danilovits, Tartu University Lung Clinic, National Tuberculosis Program, Estonia
15. Mr. Karel De Beule, Tibotec, Belgium
16. Dr. Victor De Gruttola, Harvard School of Public Health, USA
17. Dr. Mary Ann DeGroot, Colorado State University, USA
18. Dr. Ashwin Dhamadhikari, Brigham & Women's Hospital, USA
19. Ms. Nancy Dianis, Westat, USA
20. Dr. Kelly Dooley, Johns Hopkins University School of Medicine, USA
21. Dr. Kathleen Eisenach, University of Arkansas for Medical Sciences, USA
22. Dr. Gerald Friedland, Yale University School of Medicine, USA
23. Dr. Robert Gerety, Medicine in Need, USA
24. Dr. Abdul Hamid Salim, Damien Foundation, Bangladesh
25. Mr. Mark Harrington, Treatment Action Group, USA
26. Dr. Martin Hirsch, Harvard Medical School, USA
27. Dr. Timothy Holtz, U.S. Centers for Disease Control and Prevention, USA
28. Dr. Robert Horsburgh, Boston University School of Public Health, USA
29. Dr. Gary Horwith, Sequella, Inc., USA
30. Dr. Frauke Jochims, Médecins Sans Frontières, Switzerland
31. Dr. Salmaan Keshavjee, Harvard Medical School, USA
32. Dr. Michael Kimerling, University of Alabama at Birmingham School of Medicine, USA
33. Dr. Kitty Lambregts, KNCV Tuberculosis Foundation, The Netherlands, and MDR-TB Working Group of the Stop TB Partnership, Switzerland
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35. Dr. Christian Lienhardt, International Union Against Tuberculosis and Lung Disease, France
36. Dr. Pushpa Malla, National Tuberculosis Centre, National Tuberculosis Program, Nepal
37. Dr. William Mac Kenzie, U.S. Centers for Disease Control and Prevention, USA
38. Dr. Charles Mgone, European and Developing Countries Clinical Trials Partnership, Netherlands
39. Dr. Fuad Mirzayev, World Health Organization, Switzerland
40. Prof. Denis Mitchison, St. George's Hospital, UK
41. Dr. Carole Mitnick, Harvard Medical School, USA
42. Dr. Edward Nardell, Brigham and Women's Hospital, USA
43. Dr. Eric Nuemberger, Johns Hopkins University School of Medicine, USA
44. Mrs. Carol Nyirenda, Treatment Advocacy and Literacy Campaign, Zambia
45. Dr. Thomas Nyirenda, European and Developing Countries Clinical Trials Partnership, South Africa
46. Ms. Lesley Odendal, Treatment Action Campaign, South Africa
47. Dr. Charles Peloquin, National Jewish Medical and Research Center, USA
48. Dr. Sergey Popov, Russia Moscow Medical Academy, Russia
49. Dr. Alexander Pym, Medical Research Council of South Africa, South Africa
50. Dr. Lee Reichman, University of Medicine and Dentistry of New Jersey, USA
51. Dr. Hind Satti, Partners In Health, Lesotho
52. Dr. Rajeswari Ramachandran, Tuberculosis Research Centre, India
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56. Dr. Alexander Sloutsky, Massachusetts State Laboratory Institute, USA
57. Dr. Thelma Tupasi, Tropical Disease Foundation, Philippines
58. Dr. Frank van Leth, KNCV Tuberculosis Foundation, The Netherlands
59. Mr. Wim Vandeveld, European AIDS Treatment Group, Belgium
60. Dr. Francis Varaine, Médecins Sans Frontières, France
61. Dr. Andrew Vernon, U.S. Centers for Disease Control and Prevention, USA
62. Dr. Tido von Schoen-Angerer, Médecins Sans Frontières, Switzerland
63. Dr. Charles Wells, Otsuka America Pharmaceutical, Inc., USA
64. Dr. Matteo Zignol, World Health Organization, Switzerland