

# Meeting Report

UNDP/World Bank/WHO Special Programme for Research & Training in Tropical Diseases (TDR)



## Recommendations

# Scientific Working Group on Tuberculosis

9-11 February 2000  
Geneva, Switzerland



[www.who.int/tdr](http://www.who.int/tdr)

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# SCIENTIFIC WORKING GROUP ON TUBERCULOSIS

## Executive Summary

### General Recommendations

TDR should adopt a three-pronged approach to tuberculosis (TB) research. It should focus on the **development of new tools** (diagnostics, drugs and vaccines), because that is the area of TDR's maximal comparative advantage, and on **health systems and services research** (HSSR), because that is the area of greatest neglect right now. **Research capacity strengthening** should aim specifically at supporting TDR's research in these areas. TDR steering committees should be strengthened with TB expertise and opened to TB applications.

### New Tools Development

#### First priority

TDR should further develop its ongoing **diagnostics** activities in TB, including expansion of the specimen bank. Since industry is already engaged, direct funding of research and development (R&D) by TDR is unnecessary. TDR should carry out an independent assessment of newly marketed tests and begin the process of **strengthening the capacity** for conducting field trials for new diagnostic agents as well as drugs.

#### Second priority

TDR should continue to work with the International Federation of Pharmaceutical Manufacturers Associations (IFPMA)/WHO Roundtable, Stop TB and the Global Alliance for TB Drug Development, and contribute to a market analysis for **anti-TB drugs**, a scientific blueprint for drug discovery and development, and detailed product profiles. TDR should lead efforts to harmonize regulatory pathways, support research in TB drug discovery, and work with industry to evaluate available antibiotics and 'off-the-shelf' drugs. Drug production by small pharmaceutical companies in the South should be encouraged. Of equal priority, TDR should help define **vaccine** product profiles, and work on specific topics such as animal models and correlates of protection. The experience and expertise of the TDR Steering Committee on the Immunology of Mycobacterial Diseases (IMMYC) should be retained, and TDR's discussions with the WHO Health Technology and Pharmaceuticals (HTP) cluster /Vaccines and Biologicals (VAB) department on integration of TB vaccine work through the inter-cluster vaccine research (IVR) initiative should be encouraged.

TDR is urged to hold a 'blue skies' meeting in the fall of 2000 to explore the possibility for much faster vaccine development. This could be combined with a joint IMMYC/IVR meeting and be coordinated with the US Department of Health and Human Services (DHHS) 'Blueprint for TB vaccine development' Task Force.

## Health Systems and Services Research (HSSR)

The Scientific Working Group (SWG) had insufficient time to define specific priorities in HSSR and recommended that TDR:

- Develop a conceptual framework for the research-control link and priority-setting to ensure a research agenda driven by expressed control needs.
- In the meantime review the preliminary ranking of research issues proposed by the SWG, and select one or two to be addressed immediately.
- Analyse how best to contribute to HSSR work within TB control programmes, especially in the highest burden countries, and institute appropriate capacity strengthening activities.
- Work closely with other WHO units involved with TB HSSR.

## Research Agenda Setting

TDR should play a role in the development of global TB research priorities. Through advocacy, partnerships and collaborating with Stop TB, TDR should work to increase the world's total investment in TB research. TDR should carefully coordinate its appeals for donor funds with those of the Stop TB Initiative. TDR should build on the Global Tuberculosis Research Initiative (GTRI) to achieve these aims. Specifically, GTRI should act as a forum for debate of TB research issues, for the clarification of the research needs of high TB burden countries, and to raise the visibility of TB research.



# SCIENTIFIC WORKING GROUP ON TUBERCULOSIS

## Introduction

The new administration at WHO has developed a new corporate strategy with a greater emphasis than before on research and establishment of the evidence base for health policy as well as for technical recommendations. In addressing the priorities for WHO, greatest importance will be attached to those diseases that create the greatest burden of ill-health amongst the poor. Within that area, priority will be accorded to the better use of existing tools.

Stop TB is an umbrella partnership, initiated and hosted by WHO, which will serve to increase awareness of the need for better control of tuberculosis and which aims to be the world's main conduit for fund-raising for TB issues, including research. Monies generated by Stop TB will largely be passed on to its partners, of which TDR is one, to carry out priority activities. However, TDR will need to demonstrate through its performance that it deserves this investment.

TDR is playing its full part in the new administration of WHO, and is itself undergoing a strategic review aimed at increasing the 'customer benefit' derived by the health systems in developing countries from the products produced by TDR. TDR is playing a full part in the development of the WHO-wide composite workplan for tuberculosis, coordinated by Stop TB, and the two organizations will be working closely together on resource mobilization.

The SWG felt that TDR should continue to operate by function, and to report by disease, while new TB-related activities are introduced. The projected balance of basic to applied research (more heavily weighted towards applied) reflects where TDR can most likely make a difference, but should be kept under constant review.

## New Tools Research and Development

### *General Recommendations*

The Group agreed that the need is clear, and the time scientifically and technically opportune, for TDR to engage in research targeted at the development of new affordable tools (diagnostics, drugs, vaccines) for control of TB, with new diagnostics as first priority. TDR should work to ensure that any products are affordable and accessible by the poor in disease endemic countries. Research capacity strengthening is especially important in these activities.

## ***Basic and Strategic Research***

The SWG recommended to open the relevant steering committees (on pathogenesis and genomics) to TB applications, and to strengthen their membership with TB expertise. Specific suggestions were: for the Pathogenesis Committee\* to pass high-quality but non-funded proposals from principal investigators in TB-endemic countries to Research Capability Strengthening (RCS) for re-review; and for the Genomics Committee\* to take a leading role in coordination of focused genomics and post-genomics activities, including curation of genome databases, the specimen bank, web sites, etc. Fostering support for sequencing of mycobacterial strain variants should also be considered. RCS activities to be encouraged under the genomics heading should specifically include training in bioinformatics and related activities.

## ***Product Research and Development***

**First Priority: development of ongoing diagnostics in DRD (Diagnostics R&D),** with the aim of replacement or supplementation of the sputum smear test. There is no need to fund R&D, since industry is already engaged. However, DRD should act as a coordination/evaluation focus for activities such as: developing product specifications (minimum and ideal), developing protocols for testing new tools against such specifications, encouraging and facilitating independent assessment of newly marketed tests, and making recommendations based on the results. These activities should be carried out with particular regard to the needs of, and in collaboration with, TB-endemic countries in the South.

G. Roscigno suggested an industry consortium might be formed for supporting some RCS activities, e.g. the development of diagnostic testing and clinical trial sites. The PRD/DRD specimen bank (currently about 8000 specimens, from 4 different countries) should be expanded to cover more countries, especially in Asia. Product Research and Development (PRD) should play a proactive role in assuring the development of ethical protocols, including specimen collection protocols. Additionally, PRD/DRD should address tests for rapid detection of rifampicin resistance, for the detection of latent TB infection, and for diagnosis in the presence of HIV co-infection.

**Second priority: TB drug development.** PRD should work through the IFPMA/WHO Roundtable and TB Drug Development Alliance, to contribute to the production of a pharmaco-economic report on the TB drug market and a scientific blueprint for TB drug discovery and development. Again in collaboration with these partners, PRD should work to develop product profiles and lead efforts to harmonize regulatory pathways.

In addition, PRD should support new TB drug discovery, and initiate discussions with industry to encourage and, where appropriate, participate in the evaluation of 'off-the-shelf' drugs and available antibiotics, including reformulated products.

Such work could include development of relevant animal models and definition of surrogate markers for sterilizing activity.

The production of new or available TB drugs by small pharmaceutical companies in TB-endemic countries in the South should be encouraged. RCS must engage in the development of clinical trial sites in these countries.

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\* now re-named the Pathogenesis and Applied Genomics Committee

**Third priority: promotion of TB vaccine R&D**, with emphasis on advocacy and coordinating development of clear product profiles, relevant animal models and definition of surrogate markers of protection. The experience and expertise of IMMYC should be retained, and TDR's discussions with HTP/VAB on integration of TB vaccine work through IVR should be encouraged. It was recommended that TDR open communication with the Sequella Foundation and other key vaccine researchers to develop effective collaboration. A potential product would be development of the criteria for candidate selection at the predevelopment/development interface, and selection of one candidate for TDR to pursue.

TDR was also urged to hold a 'blue skies' meeting in the fall of 2000 to explore the possibility for much faster vaccine development. This could be combined with a joint IMMYC/IVR meeting and be coordinated with the US DHHS 'Blueprint for TB vaccine development' Task Force. WHO could host the meeting with multiple sponsors and a broad spectrum of participants. Full use should be made of RCS opportunities, especially in planning and preparing sites for clinical trials and studies to test clinical correlates of protection.

In conclusion, the SWG reaffirmed that effective control of TB will require new, improved diagnostics, drugs and vaccines. TDR's first priority should be in capacity building, coordination\*\* and advocacy in all product areas. The next priority is to further develop its ongoing diagnostics activity. Finally, TDR should become involved in both drug and vaccine activities, but it was felt premature to prioritize these. For drugs, TDR is well positioned because of its experience in drug development for other indications. Also, the time lines for drug development are expected to be shorter than for vaccines, so a new drug is likely to have a more rapid impact. However, the potential impact of a new vaccine is greater and it is important that WHO is perceived as being involved.

## **Health Systems and Services Research**

Major issues discussed include the following:

- The priority-setting process for TB research in TDR should be driven by the needs of TB control.
- Both short-term and longer-term research needs should be identified and addressed.
- The two WHO units most involved with TB HSSR, i.e. Intervention, Development and Evaluation\*\*\* (IDE) of TDR and the unit for Strategy Development for Endemic, Bacterial and Viral Diseases (EBV), should collaborate to ensure that selected research priorities are addressed adequately. Epidemiology, modelling and surveillance remains the responsibility of departments other than TDR.
- While operational (problem-solving) research is a priority for TB control programmes, this is not an area where TDR has historically focused its efforts.
- If operational research capacity building is to be taken on by TDR, it will need to be coordinated with training in other TDR areas and diseases.
- Generation of competitive proposals will require TDR to assist in protocol development and also to focus initially on commissioned research.

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\*\* with IFPMA, the Global Alliance for TB Drug Development, Sequella Foundation, National Institutes of Health (NIH) USA, Centers for Disease Control and Prevention (CDC) USA, and other key potential industrial and academic partners

\*\*\* now renamed Intervention Development and Implementation Research

- The term 'HSSR' was thought to be too narrowly focused on issues related to national TB programme (NTP) functioning (and in particular operational research). A broader perspective was called for, that would consider factors outside the programme that influence TB control (community demand, social/economic/political context, etc.).
- The facilitation of post-regulatory assessment should have a strong RCS component.
- The future Steering Committee on Strategic Social, Economic and Behavioural Research (SEB) has a potentially important role to play in investigating some of these broader issues, and its trans-disease focus will allow for identification of cross-cutting and global issues.

## Specific Recommendations

- The group produced a preliminary ranking of research issues and questions that should be addressed by TDR, and recommended that TDR take responsibility for further refining and prioritizing the research issues to be addressed in the immediate term (2000-2001).
- TDR should develop a conceptual framework to be used as a mechanism for longer-term priority-setting, that would ensure a need- and impact-driven research agenda.
- The group stressed the need for operational research to support the day-to-day implementation of TB control programmes. However, the capacity for this type of research does not currently exist at country level, and is particularly weak in the 22 high burden countries. The group recommended that TDR consider how best to contribute to operational research capacity building in these countries.

## Research Agenda Setting

TDR should play a role in the development of global TB research priorities. Through advocacy, partnerships and collaborating with Stop TB, TDR should work to increase the world's total investment in TB research. TDR should carefully co-ordinate its appeals for donor funds with those of the Stop TB Initiative. TDR should build on the GTRI to achieve these aims. Specifically, GTRI should act as a forum for debate of TB research issues, for the clarification of research needs of high TB burden countries, and to raise the visibility of TB research.

## Annex I

### RESEARCH ISSUES/QUESTIONS GENERATED BY GROUP 2 (HSSR)

Following is the detailed list of priority research questions generated by the group. Those in italics are the topics that were ranked highest with regard to both their potential impact on TB control and TDR's comparative advantage to address them.

#### Basic Social, Economic and Behavioural Research

- Studies to identify needs and opportunities for increasing political will for TB control: What are the factors/processes that influence the creation of political commitment for TB control?
- Studies to examine the impact of TB and TB control on poverty: What are the contributions of TB control to poverty alleviation?
- *Studies to identify needs and opportunities for ensuring equity in TB control: To what extent do sex differences in case notification rates reflect gender-related differences in access to TB care? How can effective TB care be ensured for marginalized populations?*
- What is the relation between infection and transmission? Studies to provide better data used for modeling purposes (not really SEB, but basic research).
- *What are the implications of health systems research for TB control? National public health regulations: What are their effects on TB control? What models of health legislation/regulation can support TB control?*
- What can be learned from specific country successes and failures?
- What are effective models of drug procurement?

#### Intervention Development and Evaluation

##### Studies to improve NTP management

- How can NTP staff be motivated to perform optimally?
- How can programmes retain good people (service providers and researchers) in poor resource settings?
- How should/do countries develop human resources capacity for disease control?
- How do programme structure and management relate to programme performance? (evaluation of managerial interventions, e.g. supervision mechanisms).

##### Studies to develop & evaluate alternative TB care delivery strategies

- *How can demand for services be increased?*
- *How can case detection rates be improved?*
- *What are the major sources of diagnostic delay, and how can these be addressed? (both patient and health system sources of delay)*
- *How can treatment adherence be improved? (in particular, could the use of fixed-dose combinations improve adherence?)*
- *What are alternative strategies for TB control in differing health system environments? What alternative treatment delivery mechanisms might be developed?*
- What is the impact of information, education and communication on TB-related health seeking behaviour and treatment adherence?
- To what extent are current control strategies supported by evidence from research (establish evidence base and guidelines for the type of evidence needed to assess new interventions, such as efficacy, effectiveness, cost-effectiveness, feasibility, sustainability)?

**Studies to develop and evaluate new treatment regimens**

- What methodologies could be developed to assess treatment efficacy in multi-drug resistance?
- What is the efficacy of intermittent treatment regimens, specifically in HIV patients?
- What is the impact of co-trimoxazole prophylaxis in the management of HIV infected adults and children with TB?
- What are the optimal approaches to diagnosis and treatment of extra-pulmonary disease in HIV infected patients?

## Annex 2

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