

Agenda

March 21 - Morning

09.00	Administrative Session
09.15	The Year Ahead
09.45	Rio Forum Briefing
10.15	Coffee Break
10.45	M/XDR-TB Beijing Ministerial Meeting
12.00	Achieving Universal Coverage (TB-HIV)
12.30	Lunch

March 21 - Afternoon

14.00	Beyond Beijing: Pacific Health Summit
14.30	Research Movement
15.00	Coffee Break
15.30	Union Conference
16.00	Stop TB Partnership & McKinsey & Co.: Potential Joint Venture
16.45	Financial Crisis: Implications for TB & the Partnership
17.15	Retooling Task Force
17.45	Closing Session
18.00	Adjourn



RETOOLING TASK FORCE: Update on Progress

Introduction to Sub-group on INNOVATIVE NEW APPROACHES AND TOOLS



Rationale



Lessons learned

Lesson learned from previous experience with other communicable diseases show significant delays between the availability of new tools and use at country levels

Challenge to the TB community

Coordinated action by the Stop TB community at global and national levels for timely adoption and introduction of new tools as they become available

The Board's response

The Coordinating Board, Abuja, April 2006, established the Retooling Task Force



Goals



- Plan for adoption and introduction of new tools
- Create framework for policy-makers and practitioners to accelerate introduction of new tools
- Clarify processes to move from trials to policy and implementation
- Engage stakeholders working in TB control
- Learn from other disease communities
- Link all working groups around the theme of retooling

RTF: Phase I



Setting the foundation

Products

- **New technologies for TB control: a Framework on their Adoption, Introduction and Implementation**
 - Provide guidance on what actions are needed for adoption, access and proper use of tools as they become available
- **Engaging Stakeholders for Retooling TB Control**
 - Simple tools for conducting stakeholder analyses and preparing stakeholders engagement plan
- **Advocacy package**
 - Executive summary, FAQs, Overview on Retooling, Postcard
- **Diagnostic checklist**

Checklist of key actions to facilitate global and country stakeholder planning for timely assessment, adoption, introduction, and implementation of the WHO recommendation, as appropriate.



RTF: Phase II

Moving to country level



Retooling session in Cape Town

- Countries still lacking information on new tools in pipeline and recently endorsed by WHO
- Implementation / TA partners not prepared to support introduction of new tools

Retooling meeting with Working Groups

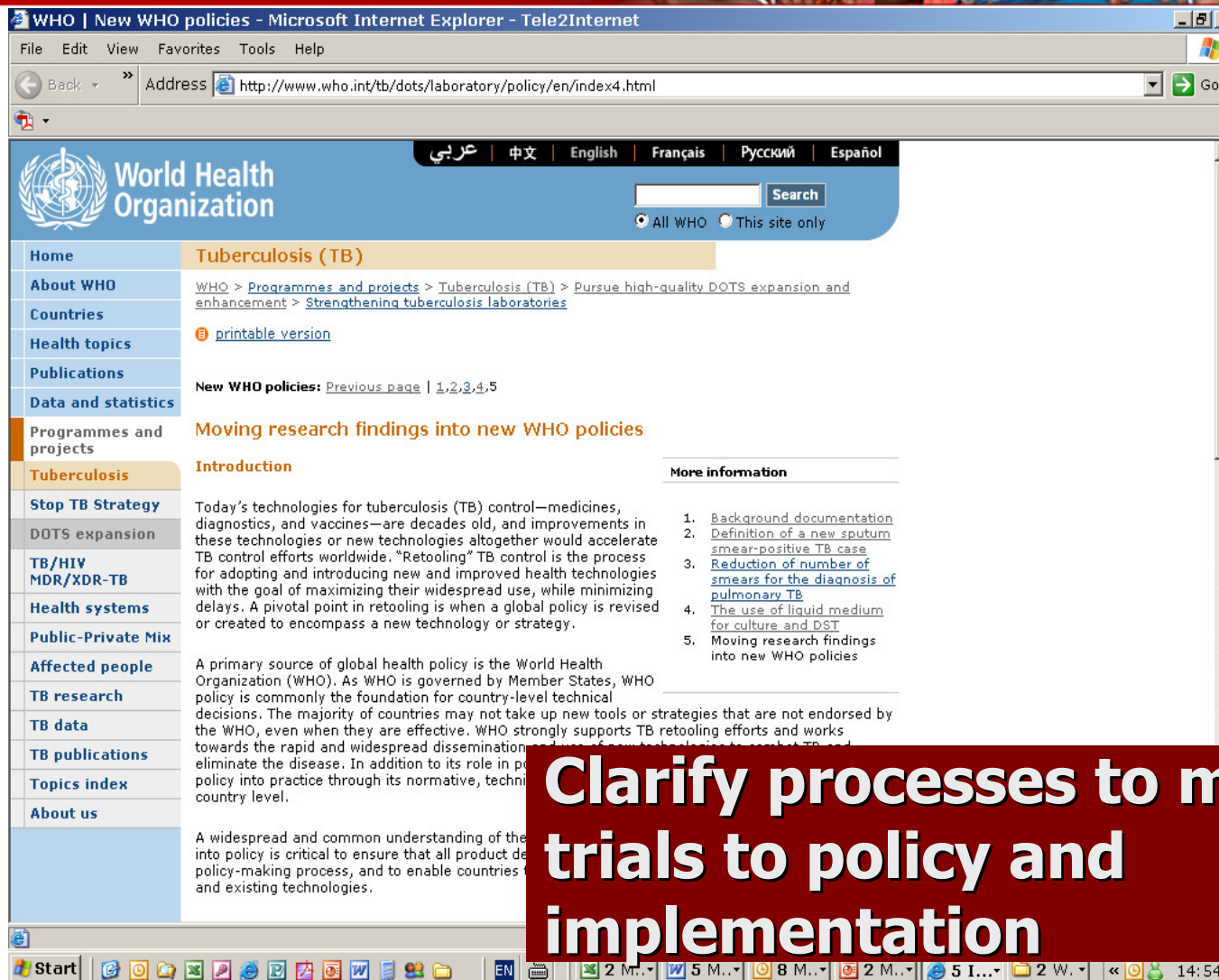
- Working groups may need support to take up retooling issues systematically
- Countries need information on programmatic aspects of retooling, e.g. HR/HS requirements, budgets, technical assistance

Task Force response / strategic direction

- **Mainstream retooling into working group activities**
- **Mainstream retooling in work of WHO and partners**
- **Address urgent communication / information needs**

Phase II activities (1)

Summary of WHO policy process to endorse new tools



The screenshot shows the WHO website in Microsoft Internet Explorer. The address bar displays <http://www.who.int/tb/dots/laboratory/policy/en/index4.html>. The page title is "WHO | New WHO policies - Microsoft Internet Explorer - Tele2Internet". The WHO logo and navigation menu are visible. The main content area is titled "Tuberculosis (TB)" and includes a sidebar with links to Home, About WHO, Countries, Health topics, Publications, Data and statistics, Programmes and projects, Tuberculosis, Stop TB Strategy, DOTS expansion, TB/HIV, MDR/XDR-TB, Health systems, Public-Private Mix, Affected people, TB research, TB data, TB publications, Topics index, and About us. The main text area is titled "Moving research findings into new WHO policies" and includes an "Introduction" section. The introduction text states: "Today's technologies for tuberculosis (TB) control—medicines, diagnostics, and vaccines—are decades old, and improvements in these technologies or new technologies altogether would accelerate TB control efforts worldwide. 'Retooling' TB control is the process for adopting and introducing new and improved health technologies with the goal of maximizing their widespread use, while minimizing delays. A pivotal point in retooling is when a global policy is revised or created to encompass a new technology or strategy. A primary source of global health policy is the World Health Organization (WHO). As WHO is governed by Member States, WHO policy is commonly the foundation for country-level technical decisions. The majority of countries may not take up new tools or strategies that are not endorsed by the WHO, even when they are effective. WHO strongly supports TB retooling efforts and works towards the rapid and widespread dissemination and use of new tools, thereby supporting TB control and elimination of the disease. In addition to its role in policy-making process, and to enable countries to implement policy into practice through its normative, technical, and financial support, WHO also plays a key role in endorsing new tools and technologies. A widespread and common understanding of the policy-making process, and to enable countries to implement policy into practice through its normative, technical, and financial support, WHO also plays a key role in endorsing new tools and technologies." The "More information" section lists five items: 1. Background documentation, 2. Definition of a new sputum smear-positive TB case, 3. Reduction of number of smears for the diagnosis of pulmonary TB, 4. The use of liquid medium for culture and DST, and 5. Moving research findings into new WHO policies.

WHO | New WHO policies - Microsoft Internet Explorer - Tele2Internet

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Address <http://www.who.int/tb/dots/laboratory/policy/en/index4.html> Go

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Moving research findings into new WHO policies

Introduction

Today's technologies for tuberculosis (TB) control—medicines, diagnostics, and vaccines—are decades old, and improvements in these technologies or new technologies altogether would accelerate TB control efforts worldwide. "Retooling" TB control is the process for adopting and introducing new and improved health technologies with the goal of maximizing their widespread use, while minimizing delays. A pivotal point in retooling is when a global policy is revised or created to encompass a new technology or strategy.

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More information

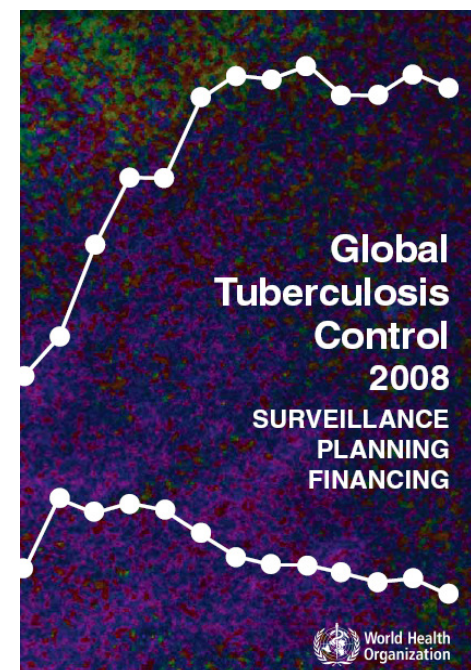
1. Background documentation
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3. Reduction of number of smears for the diagnosis of pulmonary TB
4. The use of liquid medium for culture and DST
5. Moving research findings into new WHO policies

Clarify processes to move from trials to policy and implementation

Phase II activities (2)

Retooling questions included in WHO global monitoring

- Retooling questions included in the WHO Annual Global Survey
- Global TB report with progress report on implementation activities



Phase II activities (3)

Retooling activities included in guidelines for Global Fund applicants

- Encourage countries to budget retooling activities
 - Introduction of liquid culture and rapid speciation test
 - Uptake of new case definition

The screenshot displays the WHO website's Tuberculosis (TB) page. The header features the WHO logo and a language selection bar with options: عربي, 中文, English, Français, Русский, and Español. A search bar is also present. The left sidebar contains a navigation menu with links such as Home, About WHO, Countries, Health topics, Publications, Data and statistics, Programmes and projects, Tuberculosis, Stop TB Strategy, DOTS expansion, TB/HIV MDR/XDR-TB, Health systems, Public-Private Mix, Affected people, TB research, TB data, TB publications, Topics index, and About us. The main content area is titled 'Tuberculosis (TB)' and includes a breadcrumb trail: WHO > Programmes and projects > Tuberculosis (TB) > Pursue high-quality DOTS expansion and enhancement. Below this, there is a link to a 'printable version' and a section titled 'Preparing round 8 TB proposals to submit to the Global Fund'. A 'Queries' section provides contact information for technical queries. An 'Events and missions' section lists links to a provisional list of R8 applicant countries and round 8 information meetings. A 'Tools' section recommends the use of specific tools for preparing Global Fund Round 8 TB Proposals, including an overview presentation and a Stop TB Planning Matrix and Frameworks Tool. The Windows taskbar at the bottom shows the Start button, various application icons, and the system clock displaying 16:52.

Phase II activities (4) Retooling in Tanzania



Background

- Case detection rate: 45%
- Introducing MGIT, Hain and widespread use of LED
- Moving from 3 to 2 smears for diagnosis
- No standard EQA system currently operational
- TB programme: pathfinder within MOH
 - Pushed lab services to periphery, innovator

Priority

- Ensure that the introduction of new tools is catalytic and does not overburden the health system
- Model coordinated technical assistance
 - GLI, FIND, RTF, new diagnostics working group, donor

Phase II activities (5)

New Diagnostic Technologies for TB Control

An informal inventory for National TB Programmes and partners of new or improved TB diagnostics in process of development or those available and endorsed by WHO for immediate use.



Summary of technologies			Estimated costs			
Technology	Description	Product	Training ²	Infrastructure	Equip.	Consumable
Endorsed by WHO						
Liquid culture	Commercial broth-based culture systems detect TB bacteria (in up to 960 cultures at a time); can be configured for DST.	BacT/ALERT 3D; MGIT; MGIT-DST	Extensive	■■■	High	High
Molecular line probe assay	Strip test simultaneously detects TB bacteria and genetic mutations that indicate isoniazid and/or rifampicin resistance.	GenoType® MTBDR and MTBDRplus; INNO-LiPA Rif.TB	Extensive	■■ to ■■■■	High	High
Strip speciation	Strip speciation test detects a TB-specific antigen from positive liquid or solid cultures to confirm the presence of TB bacteria in culture samples.	Capilia TB Rapid Diagnostic Test	Minimal	■■	Low	Medium
Other technologies under development or piloting phases						
Colorimetric redox indicators	Technique indicates isoniazid and rifampicin resistance in culture samples after incubation with redox dyes.	Non-commercial method (Resazurin)	Moderate	■■	Low	Medium
Front-loaded smear microscopy	Technique aims to decrease workload and increase the complete diagnosis by collecting specimens in one day.	Molecular line probe assay				Year available for adoption
Interferon gamma release assay	Blood test detects immune responses to proteins to indicate TB infection.	Strip test simultaneously detects TB bacteria and genetic mutations that indicate isoniazid and/or rifampicin resistance.				
LED fluorescence microscopy	Technological improvement aims to increase the sensitivity by introducing fluorescent microscopes with light-emitting diodes.	Advantages: Studies and implementation projects in diverse geographical and epidemiological settings have confirmed that line probe assays show excellent correlation with conventional DST methods and are highly sensitive and specific for detecting rifampicin resistance. Studies have also shown such assays perform well when used directly on smear-positive sputum specimens (with sensitivity exceeding 97% and specificity exceeding 98%), confirming their value in rapid screening of patients suspected of MDR-TB. While molecular methods are not yet sufficiently developed to fully replace conventional methods for culture and DST, implementation of such assays may reduce the demand for sophisticated and expensive conventional laboratory infrastructure, especially in high MDR-TB burden settings. There is the potential for savings in overall TB diagnostic cost if such assays are judiciously introduced in screening algorithms for detection of MDR-TB.				
Liquid culture	Manual liquid culture technique uses basic laboratory equipment (e.g. inverted light microscope) and microscopy skills to detect TB bacteria.	Considerations: While specificity is excellent for isoniazid resistance, sensitivity estimates are modest and highly variable. Geographical variation in prevalence of mutations associated with rifampicin - and in particular with isoniazid resistance - may result in varying performance of line probe assays in different epidemiological settings. Introduction of line probe assays should be preceded by an assessment of sensitivity and specificity of these assays in a representative collection of MDR- and non-MDR isolates at country or at regional level. Line probe assays are as complex to perform as conventional culture and DST methods and require skilled and well-trained laboratory personnel, as well as adequate laboratory space and design to reduce the risk of false-positive results. Line probe assays do not eliminate the need for conventional culture and DST capability, as culture remains necessary for definitive diagnosis of TB in smear-negative patients, while conventional DST is required to diagnose XDR-TB. Problems with contamination may be experienced, especially when newly-trained staff perform the assay.				
Solid culture	Solid culture technique measures nitrate reduction to indicate rifampicin resistance.	Requirements: Processing of smear-positive specimens for direct testing should be performed in a BSL-2 level laboratory, whereas performing line probe assays on positive cultures requires BSL-3 laboratory infrastructure and equipment, including a class I or class II microbiological safety cabinet equipped with uninterrupted power supply (UPS), autoclave, screw-topped tubes and bottles, pipetting aids, disposable transfer loops and personal protective equipment such as gloves, gown/lab coat, respirator and eye protection. Laboratory technicians require training in either BSL-2 or BSL-3 safety precautions (depending on the procedure) and supervised training in how to perform the line probe assay. Reagents used in line probe assays must be refrigerated or frozen, while amplification and hybridization procedures must be conducted under closely monitored temperature conditions. Line probe assays require specific equipment for molecular procedures, such as a thermal cycler, shaking platform and water bath, heating block, sonicator, micro centrifuge and tubes, fridge, freezer, micropipettes and pipette tips, and PCR tubes. UPS is required during PCR amplification and use of the automated hybridization systems to avoid interruption of the procedure and subsequent loss of results. The laboratory must be designed to address the risk of amplicon contamination. Certain equipment such as incubators and automated hybridization systems are product-specific. Manual line probe assay systems are appropriate for use in laboratories processing small numbers of specimens. Technical support from test distributors is required to address hardware problems and to assist with troubleshooting related to unusual results and contamination. Establishing a long-term support agreement with an international supplier is critical.				
	Solid culture technique uses a standard microscope to detect TB bacteria and indicate isoniazid and rifampicin resistance.					

Product information: GenoType® MTBDR and MTBDRplus (<http://www.hain-lifescience.com/>); INNO-LiPA Rif.TB (<http://www.innogenetics.com/>)
Current known developers: GenoType® MTBDR and MTBDRplus (Hain Lifescience GmbH in collaboration with FIND); INNO-LiPA Rif.TB (Innogenetics NV)

Phase II activities



Other activities

- **Ensured availability of updated pipelines for new diagnostics, drugs and vaccines**
- **Checklist for introduction of liquid culture**
 - Recently field tested in Tanzania

Evolution



- **The RTF has fulfilled its original mandate**
- **Rather than satisfy information needs at country level, this work has generated more interest and demand from countries for support**
- **Specific focus needed to accelerate uptake and avoid delays.**
- **Countries are requesting support that is beyond the mandate of a task force.**
- **Cross-cutting issues**
- **DEWG best forum for coordinating a response that draws from all WGs but which maintains its focus on serving the needs of the NTPs and implementing partners.**

Sub-group: Innovative New Approaches & Tools



- **Mission: holistic support to countries to ensure that they receive relevant and timely information and technical assistance to enable the rapid evaluation and introduction of new tools, policies and approaches for TB prevention and control.**
- **Not a replacement for work on new tools working groups or GLI**
- **Extension of the groups' mandates firmly into programmes (NTP and immunization)**
 - **Activities to be jointly planned**

Sub-group: Innovative New Approaches & Tools



Objectives

- Solicit information from NTPs, national immunization programmes, and other implementing partners on the challenges being faced with evaluating, adopting, introducing or implementing new tools or approaches as an integral part of accelerating progress toward the MDGs
- Prioritize and coordinate a concerted response to the operational challenges identified including:
 - Ensure that relevant technical assistance and training is provided to countries or made available within countries with respect to “retooling”; including ensuring that strategic planning, resource mobilization, and routine monitoring and supervision includes consideration of new tools and approaches (note: to be coordinated with TB TEAM and other implementation WGs), and building capacity for ‘retooling’ among technical assistance partners
 - Formulate and include guidance related to the introduction of new tools and approaches in upcoming technical guidelines, training materials, operational tools (e.g. budgeting tool) and policies of WHO and other normative bodies; develop other guidance as requested by countries or implementing partners (e.g. guide to select tools appropriate to specific epidemiological and health system contexts)
 - Coordinate the compilation and dissemination of information on emerging new tools and approaches, as requested by countries and in a manner consistent with national planning for attaining the StopTB partnership goals (note: to be coordinated with other WGs)

Sub-group: Innovative New Approaches & Tools



Objectives

- Set priorities for operational and evaluation research that will facilitate the widescale implementation of new approaches and tools; notably research that can generate evidence of the impact of new tools/approaches on case detection, case management and equitable access under field conditions; advocate for and coordinate the implementation of priority research
- Advocate for the appropriate uptake of new tools and approaches at the country level which may include working with local TB control and immunization programs.
- Track progress in the uptake and expansion of new policies and approaches, coordinating with countries, implementing partners, and WHO regional offices to promote the expansion of these new tools
- Facilitate an expanded membership of the DEWG to include immunization programme implementers particularly from endemic countries as new vaccine introduction becomes imminent, enabling comprehensive planning for TB prevention as well as control.

Next steps



- Meeting of interested parties in Rio
- Election of chair
- Selection of home for secretariat
- Steering committee
 - 1 member of core group from each WG
- Process for workplan development with other WGs

For further information

Website: www.stoptb.org/retooling

Email: stoptbretooling@who.int

