

TASK FORCE ON RETOOLING STOP TB PARTNERSHIP

Tuberculosis (TB) is a problem of global proportion that killed 1.6 million people in 2005. A mounting drug resistance problem, including multi-drug resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), coupled with a growing number of TB patients infected with HIV, is making the pandemic more threatening and more deadly, thus risking to compromise the progress in TB control achieved during the past decade.

Beyond current efforts to prevent, detect and cure TB, new technologies are needed to radically transform the fight against TB, to contain the threat of deadly drug-resistant strains such as MDR-TB and XDR-TB, and to seriously target elimination by 2050.

- Today's first line anti-TB medicines are **more than 40 years old** and must be taken for 6–9 months. Erratic or inconsistent treatment generates drug resistance.
- Today's most commonly used diagnostic tool, the light microscope, is **more than a century old** and is relatively insensitive (particularly in the presence of HIV co-infection), giving no indication of drug susceptibility.

- Today's vaccine, BCG, is **more than 85 years old** and provides only acceptable protection against the disseminated forms of disease among infants and very little, if any, protection beyond childhood.

Progress is being made in the development of new medicines, diagnostics and vaccines to combat the TB pandemic and eventually eliminate this deadly disease. The Global Plan to Stop TB, 2006–2015 (the Global Plan) estimated there were 27 medicines, 15 diagnostics and 8 vaccines at various stages in the production pipeline, ranging from product development to field trials. Since publication of the Global Plan in 2006, the number of candidate technologies has increased.

With the anticipated launch of the first of the new technologies within the next two years, the time is right to start preparing for the introduction of such technologies, and to minimize the delay between their licensure, availability and adoption. The goal is rapid and widespread of appropriate new technologies use in caring for people that need them most. This process is termed "Retooling".

The promise of new technologies

The Global Plan describes the principal strategies that will be used for prevention and control of TB over the next 10 years. Integral to this plan is the development and deployment of new and improved technologies – medicines, diagnostics and vaccines – as they become available. The plan also commits the Stop TB Partnership to implementation of the new WHO-recommended Stop TB Strategy, based on DOTS and including the International Standards for Tuberculosis Care.

The introduction of new technologies for TB control and prevention should be regarded as a means of improving the quality of care, by making available not only a wider choice of technologies to address unmet needs but also an opportunity to align the new technologies with the capacity of health systems to deliver care, the changing nature of the epidemic and the needs of communities with or at risk of TB.

The plans and investments made thus far to accelerate the development of new technologies have led to high expectations that these new technologies will provide national TB control programmes (NTPs) with better options and more choices to prevent, detect and treat TB. At the same time, making new

technologies available and accessible will require systems and procedures at global and country levels in order to rapidly and effectively assess these products and incorporate these new technologies where appropriate into TB control strategies and programmes.

The Task Force on Retooling

Previous experience with the introduction of new technologies to prevent and control malaria, hepatitis B and other communicable diseases 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 critical delay between evidence for and implementation of policy, the Stop TB Partnership Coordinating Board has established a Task Force on Retooling (Box 1) to develop a framework for catalysing policy-makers and practitioners at global and national levels towards accelerated introduction of new technologies into NTPs and national immunization programmes. One of its aims is to stimulate discussion and planning for optimal, timely and appropriate introduction, adoption and implementation of new technologies as they become available.

BOX 1

TASK FORCE ON RETOOLING:
PURPOSE AND ACTIVITIES**Purpose**

- To facilitate the introduction and adoption of new technologies, as they become available.

Activities

- Consolidating and sharing information from the working groups on drugs, diagnostics and vaccines on current product pipelines and timelines/milestones.
- Creating opportunities for consultative dialogue with stakeholders from high TB burden countries, including ministries of health, NGOs, affected communities, etc.
- Facilitating the mobilization of financial and human resources for country-level introduction and deployment.
- Consolidating relevant lessons learnt from other disease areas to inform TB-specific processes for adoption, introduction and implementation.
- Facilitating operational research on introduction of new technologies.
- Generating evidence to support the adoption of new technologies.
- Fast-tracking the incorporation of new technologies into WHO and national policies and guidelines.
- Enhancing communication among all working groups around the theme of retooling.

Framework for the adoption, introduction and implementation of new technologies

One of the first tasks of the Task Force on Retooling was to develop a framework for the adoption, introduction and implementation of new technologies. This document identifies key issues that need to be addressed to accelerate the adoption and implementation of new and improved technologies. It provides guidance on what actions are needed when improved existing and/or new medicines, diagnostics and vaccines become available.

This document is primarily intended to support NTPs, national immunization programmes and clinical laboratory and diagnostic services. It is also meant to inform Stop TB Partnership constituents, including advocacy and community-based organizations, donors, intergovernmental agencies, new product developers, national policy- and decision-makers, and academic and technical partners.

The framework identifies challenges to retooling and proposes key steps for facilitating appropriate and timely adoption and implementation. It also provides an overview of technical and operational considerations for retooling at global and national levels.

The annexes summarize the technologies in the development pipeline. They provide an illustrative list of key actions for the adoption and implementation of new technologies in each technology category, and an illustrative generic timeline or sequencing of key tasks for adoption, introduction and implementation. A list of suggested further reading is also provided.

Specific information included in the framework is described below.

Systemic and programmatic readiness for change. The wide array of products in the development pipeline with different expected dates of availability requires systems that can manage ongoing change and enable rapid integration of newly available technologies at both global and national levels. A new technology may be rapidly superseded by a newer one within a short time-span, where appropriate evidence exists to support it. The level of incremental improvement afforded by the new technology, and the projected availability of the next incremental improvement, will play a role in decisions regarding investment of resources to support its adoption. The anticipated sequence of new technology availability may also impact the resources that are allocated for the implementation of the newly adopted technology.

Policy-makers and decision-makers at global and national levels will need to stay abreast of the status of the product pipeline, and to update other stakeholders on new advances that are likely to become marketed and on the approximate time frame. They will also need to consider differences in national environments and of the potential roles of the product types (medicines, diagnostics, vaccines); how they can be used together; or potential modification of diagnostic or treatment algorithms when developing recommendations and policies. They will want to ensure the participation of other programmes, such as the global Expanded Programme on Immunization, the national immunization programme, and reproductive and child health programmes, in planning and implementation.

The timely and appropriate adoption, introduction and implementation of new and incrementally improved technologies for TB control face many significant challenges:

- weak or non-existent legal and regulatory frameworks;
- inadequate capacity to manage laboratory and diagnostic services;
- inadequate capacity to manage pharmaceutical supply;
- inadequate infrastructure, equipment and support services;

- human resource constraints, in terms of sufficiency and adequacy of health workers, particularly in the public sector;
- resistance to change;
- misappropriation of resources;
- country-specific regulatory requirements;
- lack of leadership; insufficient capacity to manage change; and
- financial constraints.

These challenges may be addressed by:

- engaging stakeholders from the beginning of the policy analysis process (for adoption) and throughout introduction and implementation;
- advanced planning and preparation, both globally and nationally; and
- conducting operational research to guide adoption, introduction and implementation.

Adoption and development of new policy.

Although the development of recommendations on the use of new or improved technologies for TB control at the global level and the development of new policies for these technologies at the country level are separate processes, the essential components of these processes are the same. Ideally, these two processes should take place simultaneously. However, it is likely that some countries may decide to proceed with adoption and implementation without waiting for global recommendations, while others will decide to

wait until guidance is available through widely accepted international organizations with a mandate for setting normative standards and providing technical assistance, such as WHO or the International Union Against Tuberculosis and Lung Disease.

The essential and interlinked components of a process for adoption of new technologies and a subsequent change in global recommendations and national policies include:

- stakeholder participation in the development of recommendations and policies;
- analysis of the needs and evidence for change;
- analysis of the risks and benefits of the new technology and of the health system environment and capacity to adopt, introduce and implement the new technology; and
- development and endorsement of the new recommendations and policies and their wide dissemination.

Introduction and implementation of new technologies.

The key components of a process for implementing policy changes in both the public and the private sector, including not-for-profit institutions such as faith-based or secular nongovernmental organizations and the for-profit sector, can be divided into technical considerations, operational considerations, and monitoring and evaluation.

Technical considerations relate to registration of products and revision of regulations; demonstration projects; development or updating of programme guidelines, essential medicines, medical devices and related supplies lists, and recording and reporting forms; dissemination of guidelines and training of health workers and community partners providing TB care; and advocacy, communication and social mobilization.

Operational considerations include the management of technologies currently in use that are to be replaced by new technologies (phase-out plan); management of supply of new technologies; addressing availability in public and private sectors; development of a phase-in or roll-out plan; quantification and demand forecasting; procurement, distribution and inventory management; and ensuring quality of products and services and their safety.

Monitoring and evaluation of the adoption, introduction and implementation of new technologies will provide important lessons for the uptake of incrementally improved technologies.

Future work of the Task Force on Retooling

In addition to the framework described above, the Task Force will also work with key policy-makers and stakeholders to understand and further delineate all aspects of adoption and implementation of new technologies to combat TB. In the future, it expects to produce additional documents to support retooling efforts, including a stakeholder engagement plan, detailed illustrative timelines for adoption and implementation for each new technology, monitoring and evaluation indicators, and pipeline updates for medicines, diagnostics and vaccines.

This document is also available in Arabic, Chinese, French, Spanish and Russian.

For further information on the task force and its products, please consult our website at <http://www.stoptb.org/retooling>.

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