

# OVERVIEW OF RETOOLING PROCESS

Although progress in controlling tuberculosis (TB), including increased case detection and treatment success rates, has been encouraging, challenges such as drug resistance and TB/HIV co-infection threaten further advances. Today's medicines, diagnostics, and vaccines are decades old. Fortunately, improvements in current approaches and promising new technologies, developed to address the current constraints to TB care and control, are in the pipeline.

**"Retooling"** is the process of introduction, adoption and implementation of new and improved technologies - diagnostics, medicines, and vaccines - with the goal of maximizing their widespread use and minimizing delays to roll-out. To be successful, the retooling process will need to involve the participation of a wide range of stakeholders at the global and country levels and the consideration of a number of key components, including an assessment of a country's capacity to adopt and implement a new or improved technology.

## Retooling TB Control and Developing Related Policies

Introduction, adoption and implementation of new technologies for TB control involves changing global recommendations and national policies. These changes require:

### ***Awareness of and information about technologies in the pipeline***

It is important to be aware of technologies in the pipeline, when they are expected to be available for market, and how the technologies' product profiles fit with the needs, infrastructures and programmes in place in the countries where the technologies will be used.

### ***Analysis of the benefits and risks of the new technology***

Determining the risks and benefits of a new technology requires a careful examination of the evidence, which should include not only the *safety* and *efficacy* of a new technology based on controlled clinical trials, but also on evidence of the *effectiveness* and *efficiency* of a new technology under actual use conditions.

The benefits and risks of these new technologies should also be analyzed from the perspective of improvement to the quality of public health services, which would lessen the impact of TB as a public health concern.

### ***Analysis of health systems' capacity to adopt, introduce, and implement the new technology***

This analysis requires understanding the different sectors of health systems, including the public, not-for-profit private, and for-profit sectors, since capacity differs both between sectors (intersectoral) and between different levels within a given sector (intrasectoral). It is important to analyze the existing infrastructures and understand their capacity for retooling. For example, diagnostic tools that require users to have a high degree of skill or a sophisticated infrastructure may only be suitable for use at higher level health facilities. On the other hand, simplified diagnosis and treatment would also benefit lower-level facilities. At the country level, evaluating the health system's capacity to take full advantage of the new TB technology will determine the inputs needed for success.

### ***Development, endorsement, and dissemination of the new recommendations and policies***

If the analyses of needs and evidence related to the risks and benefits of the new technology and health system capacity demonstrate improvements in effectiveness and/or efficiency, recommendations at the global level and policies at the country level will be revised to reflect the new technology.

At the global level, WHO will include appropriate new technologies in revised guidelines and recommendations for countries. At the country level, governments have to decide whether to endorse a new technology, and if so, whether to develop a new policy or revise the existing policy. Countries will need to plan ahead in order to ensure timely implementation.

Once policy makers have decided to adopt a new TB control technology, the new technology must be introduced and rolled-out in both the public and the private sectors, including faith-based or secular nongovernmental organizations and the for-profit sector.

To accelerate and evaluate the introduction of new technologies, technical and operational activities ranging from the training of health workers, to securing and distributing new commodities, need to take place. These activities are elaborated in Stop TB Partnership retooling framework.

## INTRODUCING AND IMPLEMENTING NEW TECHNOLOGIES FOR TB CONTROL

### 1. TECHNICAL ACTIVITIES

- Registration of products and revision of regulations
- Development/update of program guidelines, the essential medicines list and/or the essential medical devices and supplies list, and recording and reporting forms
- Dissemination of guidelines and training of health workers and community partners who provide TB care
- Advocacy, communication, and social mobilization targeting the community
- Monitoring and evaluation of implementation process
- Product quality and safety surveillance

### 2. OPERATIONAL ACTIVITIES

- Development of a transition plan that includes the phasing-out of technologies being replaced and the phasing-in of these new technologies. This will guide the user on how to manage products currently in use that are to be replaced by new technologies for eventual mainstreaming of the new technology into existing program conditions
- Management of new product supply
  - Availability in the public and private sectors
  - Development of a phase-in or rollout plan
  - Forecasting of demand and quantification
  - Procurement
  - Distribution
  - Inventory management

## Moving Forward with Retooling

Retooling involves individuals and organizations from the community to the global level, including community-based advocacy organizations and health care providers, national TB control programmes, national immunization programmes, governmental agencies in endemic and donor countries, product development organizations, and global and multilateral agencies.

The Stop TB Partnership Coordinating Board has established a Task Force on Retooling, which has developed a retooling framework to guide policy makers and practitioners as they introduce new technologies into national TB and immunization programs. In addition, Stop TB Working Groups will facilitate collaboration to:

- Keep stakeholders informed about products in the development pipeline
- Strengthen frameworks and processes for product regulation and registration, particularly for diagnostics and drugs
- Strengthen pharmaceutical management and laboratory infrastructure and services
- Ensure the availability and access to quality assurance systems (QAS)
- Increase capacity to conduct operations research to guide adoption, introduction, and implementation
- Facilitate the development of policies at country level
- Address human resource capacity strengthening
- Mobilize financial resources

Stop TB Partnership members will work together to develop and widely disseminate practical guidance documents and training materials on:

- Stakeholder engagement
- International standards and related guidance documents for assessing and regulating diagnostics
- Methodologies for evaluating product options
- Product-specific road maps for adoption and introduction
- Product-specific materials for advocacy, communication, and social mobilization
- Monitoring and evaluation, including indicators for adoption, introduction, and implementation of new TB tools
- Documentation of best practices and lessons learnt for sharing amongst agencies/countries

Additional information on the retooling process can be found at [www.stoptb.org/retooling](http://www.stoptb.org/retooling)

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