

Frequently Asked Questions



About Retooling for New TB Control Technologies

1 What is “retooling”?

“Retooling” is the process of introduction, adoption and implementation of new and improved diagnostics, medicines, and vaccines with the goal of maximizing their widespread use while minimizing delays. To be successful, the retooling process involves 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 technology.

2 Why are new technologies needed to control TB?

Today’s technologies for tuberculosis (TB) control—medicines, diagnostics, and vaccine—are decades old, and although they are still effective under some circumstances, improvements in these technologies or new technologies altogether would accelerate TB control efforts worldwide. For example—

- Current medicines must be taken for 6–9 months, which makes treatment adherence difficult for patients, thereby contributing to drug resistance. New medicines would potentially reduce treatment duration, require fewer pills, hasten patient cure and may be more effective in patients with multidrug-resistant (MDR) TB, extensively drug-resistant (XDR) TB or TB/HIV co-infection.
- Today’s most commonly used diagnostic tool, the light microscope, is relatively insensitive,

particularly in people co-infected with HIV, and does not detect all cases of TB, particularly those that are drug resistant. The goals for new diagnostics include being easier to use, greater sensitivity and accuracy, able to provide quicker results in the field, adaptable in resource constrained settings—especially in the presence of HIV co-infection and TB in children - and identifying drug resistance.

- The one vaccine available, Bacille Calmette–Guérin (BCG), provides protection against disseminated forms of disease in infants but little, if any, protection beyond childhood. New vaccine objectives are to prevent TB infection in all ages – including drug-resistant TB, prevent the progression of latent infection to active disease, and boost the conventional TB treatment regimen.

3 Who will benefit from new TB technologies?

New TB technologies will benefit everyone, especially TB patients. New TB drugs in the pipeline could shorten treatment regimens and make adherence to TB treatment easier for patients and providers. New vaccines are intended to provide better protection across age groups and protect against all strains of TB. New diagnostics are in development that could greatly improve diagnostic capabilities from the point of service in the field up to supranational reference laboratories. People for whom access to current services is difficult, such as those who

face geographic, economic and social barriers to access, and countries with limited resources for TB diagnostics and drug delivery will particularly benefit from these new technologies. In addition, because TB disproportionately affects the poor—especially young adults in their economically productive years—new TB technologies accessible to the poor have the potential to improve not only the health of patients, but also to strengthen the economic conditions of their families and communities.

4 What new TB technologies are being developed?

Progress is being made in the development of new medicines, diagnostics, and vaccines to combat TB and eliminate the disease. The Global Plan to Stop TB 2006–2015 estimated that in 2006, 27 medicines, 15 diagnostics, and 8 vaccines were in the production pipeline, but that number is constantly changing. These are in various stages/phases of development yet some are soon to be readied for implementation.

Research and development of new tools is ongoing, and it is expected that more candidates will be added to the pipeline. However, it is also expected that not all candidates will succeed and would therefore be removed from the pipeline. For a listing of new products in development, visit the Retooling Task Force website at <http://www.stoptb.org/retooling>.

5 How soon are new technologies expected to be available?

It is anticipated that in 2007–2008 the first new technologies available will be diagnostics appropriate for use in a reference laboratory, such as technologies for drug susceptibility testing (DST). Diagnostic tools to use in a peripheral laboratory will become available between 2008–2011; these include same-day smear microscopy and first-generation nucleic acid amplification. Examples of diagnostics that are simple enough to use at a clinic health post are urinary antigen detection and antibody assays. They

are scheduled for release between 2010–2012.

The first medicines in the research pipeline, which have the potential to help reduce the duration of the treatment regimen, are gatifloxacin and moxifloxacin. These may be available to add to TB treatment by 2010—other medicines are due to follow starting in 2011. A new TB vaccine regimen is anticipated to be ready for market by 2015.

6 If new technologies are still several years away, why do we need to talk about this now?

Past experiences with introducing new technologies for other public health programmes have shown significant lag time between the availability of new technologies at the global level and their eventual adoption and implementation at country level. With the anticipated launch of the first of the new diagnostics in 2007 or 2008, the time is right to prepare for their introduction and address any bottlenecks in their licensure, availability, and adoption. The goal of

this retooling process is the broad dissemination and use of appropriate new technologies as soon as they are ready, so they can quickly start helping the people who need them most. Creating policies, developing infrastructure, and stimulating health system and community readiness for new technologies can assist in shortening the time it takes for these technologies, once available, to get to the people in need of them.

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7 How will I know which new technologies are right for my country?

As new technologies become available, technical support and information will be provided to countries to assist them in determining which technologies are most appropriate based on the country's health systems, infrastructure and needs, and to assist

in procurement, introduction and adoption of the technology. There will also be policy statements and recommendations from credible international agencies to assist countries in the introduction, adoption and implementation processes.

8 What retooling efforts are being taken to facilitate the introduction of new TB technologies in control programmes?

The Stop TB partnership has organized seven Working Groups to coordinate effective action in TB prevention and control, which includes the development and deployment of new tools. The working groups cover DOTS expansion (with various specialty subgroups); MDR-TB; TB/HIV; new TB diagnostics; new TB drugs; new TB vaccines; and advocacy, communications, and social mobilization. In addition, the Stop TB Partnership Coordinating Board established a Task Force on Retooling to respond specifically to the need to prepare for the launch of new TB technologies.

The task force developed *New Technologies for TB Control: A Guide for their Adoption, Introduction, and Implementation*, which provides guidelines on what actions are needed to ensure that new TB tools are appropriately incorporated into TB control strategies and properly rolled out for use in the community. The purpose of the framework is to encourage policy makers and practitioners to accelerate the introduction of new tools into national TB control and immunization programmes.

9 Who should be involved in retooling?

At the global level, the Stop TB Partnership is leading efforts in retooling, as mentioned above. Other intergovernmental organizations, such as United Nations agencies, and funding agencies, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria have a vested interest in assuring that new public health technologies are optimized. Other global stakeholders include pharmaceutical and laboratory suppliers and manufacturers, professional and advocacy organizations, and product development partnerships, such as the Global Alliance for TB Drug Development, the Foundation for Innovative New Diagnostics and Aeras Global TB Vaccine Foundation.

In countries, the main constituents for the retooling process are national TB programmes, national immunization programmes and government authorities because they will have the primary responsibility for incorporating new tools into their programmes for the benefit of their citizens. Additional country-level stakeholders come from across public and private sectors and include health care providers and their professional bodies, community-based groups and people living with TB, donors, and academic and research institutions.

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What are some of the key actions that countries will need to take to develop retooling policies and implement the retooling process?

Actions that countries need to take in the **policy development** stage include identifying and engaging key partners and stakeholders in the retooling process, analyzing the capacity of the country's health care system to manage and use the new technology, and determining the costs and benefits of adopting and implementing a new technology.

In the **implementation** stage, countries need to address technical considerations, such as product registration and new or updated treatment guidelines. Operational issues include planning the phase-out of products being replaced, managing the supply and distribution of the new product, and monitoring the

quality and use of the new technology. In addition, a monitoring and evaluation system needs to be put in place early in the process, so the resulting data can be used to guide any changes in how retooling is implemented. National programmes may initiate operational research activities to optimize the use of these new technologies within their healthy systems

The framework document "New Technologies for TB Control" includes three separate annexes that illustrate key actions to take when introducing and implementing new medicines, diagnostics, and vaccines.

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What is expected of me?

Programme managers should be abreast of developments in the pipeline of new technologies and communicate them regularly to decision-makers; gather the necessary information to analyze the need for changes, the benefits and harm, costs, training needs and health system capacity to incorporate the new technologies. They must plan ahead and prepare for timely implementation of the new technology, if adopted. Plans should include capacity building and financing strategies.

Policymakers should assess the needs for improving TB control, the benefits, harm, costs and the readiness or capacity of the health system to incorporate the new tools as they become available. Based on these analyses, they must decide whether or not to adopt the tool and, once adopted, fully support their introduction and implementation of the technologies into the TB programme. Policymakers should engage key stakeholders and encourage their endorsement of the new policies and explore opportunities to leverage funds for their implementation.

Donors should provide appropriate technical and financial assistance to countries for retooling activities, as needed. They should coordinate their support and help countries establish an inclusive process to facilitate coordination, communication, and collaboration among stakeholders.

Activists should keep abreast of developments, inform their constituencies about the development of new technologies and communicate potential barriers and "enablers" to the public health sector to facilitate effective and efficient roll out of the new technologies and strategies. They can also advocate for timely adoption and introduction and contribute to monitoring progress in implementation.

Multilateral agencies and implementing partners should provide support for coordination and technical assistance to countries and programmes to assess the need for retooling, and plan, implement, monitor and evaluate the uptake of new tools.

12 We already have a system in place for TB control. Won't changing it be complicated and expensive?

The cost of introducing changes that improve TB control may be offset by the benefits of significantly increased number of lives saved and productivity of the country's citizens in the long term. The Stop TB Partnership is facilitating technical and financial

support to assist countries in addressing the challenges of strengthening health systems and help ensure that the retooling process will be operationally feasible.

13 How much will these new technologies cost? Will it be more expensive than what we are currently using?

It is difficult to predict the cost of new technologies when they are still in the development stages. However, several of the organizations that are working on new technologies, particularly the product development partnerships such as the Global Alliance for TB Drug Development, Aeras Global TB Vaccine Foundation and the Foundation for Innovative New Diagnostics, are committed to developing technologies that are affordable, accessible, acceptable and readily available especially for low-resource settings.

There are also several potential sources of funding and support for the procurement and distribution of new TB control technologies, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNITAID, the Global Drug Facility and others. Information and assistance in obtaining financial support will be provided when new technologies are available for introduction.

14 How can we get the new technologies once they are available?

The new technologies may be procured in various ways, including the Global Drug Facility (GDF) for tuberculosis (TB) and traditional commercial channels.

Regardless of the mechanism, new technologies should always be procured from certified and reliable suppliers of high-quality products reliable suppliers.

FAQs

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15 How can my country learn about, get involved in and benefit from clinical trials and development of new technologies?

The purpose of the Task Force on Retooling is to provide information and assistance in adopting new technologies once they become available. The Stop TB Partnership has specific Working Groups focused on the development of these new technologies. These Working Groups can provide information and assistance to countries that want to get involved in the clinical and product development processes.

For more information about the Working Groups:

Working Group on New TB Drugs: http://www.stoptb.org/wg/new_drugs/

Working Group on New TB Diagnostics: http://www.stoptb.org/wg/new_diagnostics/

Working Group on New TB Vaccines: http://www.stoptb.org/wg/new_vaccines/

16 What other information on retooling is available and where can I get it?

In addition to the new technology framework mentioned in Question 8, the Stop TB Task Force on Retooling is continuing to support retooling efforts with plans to publish the following:

- A stakeholder engagement plan
- A detailed checklist and timelines for adoption and implementation of new diagnostics
- Monitoring and evaluation indicators
- 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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