

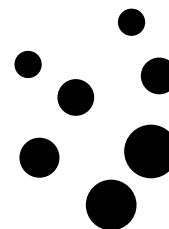
RETOOLING
TASK FORCE



ENGAGING STAKEHOLDERS FOR

RETOOLING TB CONTROL





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ABBREVIATIONS

ACT	artemisinin-based combination therapy
DOTS	internationally recommended strategy for TB control until 2005, and the foundation of WHO's new Stop TB Strategy in 2006
FBO	faith-based organization
FDC	fixed dose combination
GDF	Global Drug Facility
MDR-TB	multidrug-resistant tuberculosis
NGO	nongovernmental organization
RDT	rapid diagnostic test
NIP	national immunization programme
NTP	national tuberculosis programme
TB	tuberculosis
TB Alliance	Global Alliance for TB Drug Development
TFR	Task Force on Retooling
USAID	United States Agency for International Development
XDR-TB	Extensively drug-resistant tuberculosis
WHO	World Health Organization

1. INTRODUCTION

The Stop TB Partnership's Global Plan to Stop TB (2006-2015)¹ describes the principal strategies that will be used for TB prevention and control over the next 10 years. The plan addresses the challenges of expanding DOTS, and the threats of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB). Integral to this plan is the current development and future deployment of new medicines, new and improved tests for diagnosis and vaccines, as they become available. The Global Plan to Stop TB (2006-2015) estimated that there were 27 medicines, 15 diagnostics and 8 vaccines at various stages of development, ranging from product development to field trials. Since its publication, the number of candidate technologies has increased. The first of the new tools should be available in 2008.

Updating policies, programme guidelines and procedures for incorporating new tools, mobilizing resources and preparing for effective implementation takes time. Recognizing this, the Stop TB Partnership Task Force on Retooling (TFR) has developed a framework for catalysing the process in order to accelerate the introduction of new health technologies² within TB control programmes, targeted at global and national-level policy-makers and practitioners. One of the aims of the TFR is to stimulate discussions and planning for optimal, timely and appropriate adoption, introduction and implementation of these new TB technologies as they become available.³ This process has been termed "retooling".

One of the most important components of the process to accelerate the effective uptake of new TB technologies is analysing and engaging stakeholders at an early stage, even before the new technologies are ready for deployment. The process of engaging key stakeholders should include advocacy for timely TB technology evaluation and adoption at global and country level, and continue with activities that are required for programme introduction and implementation. The process of identifying and engaging stakeholders has been documented more explicitly in the corporate world, as well as in some public health reform and environment initiatives. Applying lessons learned from these areas may help to establish a structured and systematic approach to analysing and engaging stakeholders for accelerated adoption, introduction and implementation of improved TB technologies, resulting in better public health outcomes. For the methodology used, see *Annex 1*.

Objectives

The primary purpose of this document is to provide guidance to managers of national TB control programmes, national immunization programmes, and clinical laboratory and diagnostic services on identifying stakeholders and engaging them as contributors and beneficiaries in TB-control retooling. It also aims to inform members of the Stop TB Partnership, including advocacy and community-based organizations, donors, intergovernmental agencies, new product developers, national policy- and decision-makers, and academic and technical partners.

The document also provides simple tools for preparing a stakeholder engagement plan, and a list of suggested reading on the topic.

¹ Stop TB Partnership and WHO. *Global Plan to Stop TB 2006-2015*. Geneva, WHO, 2006 (WHO/HTM/STB/2006.35).

² The term "health technology" refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life (as defined by the Sixtieth World Health Assembly, May 2007).

³ Stop TB Partnership and WHO. *New technologies for TB control: a framework for their adoption, introduction and implementation*. Geneva, WHO, 2006 (WHO/HTM/STB/2007/40). Adoption is the multi-sector process resulting in an explicit global and/or country policy decision to access and use new and improved health technologies, including strategies for tuberculosis control. Introduction refers to the set of coordinated activities carried out to prepare for effective and sustainable access to the new and improved health technology. Implementation includes the activities that put into effect the policy and monitor and evaluate the progress of these activities and the impact on tuberculosis control.

2. WHO ARE THE STAKEHOLDERS?

Stakeholders are persons or groups who are directly or indirectly affected by TB-control retooling, those who may have an interest in retooling and/or the ability to influence its outcome, either positively or negatively.⁴ The wide range of constituencies includes individuals, groups, organizations and networks that are involved in TB product development, evaluation, manufacture, approval for marketing, supply, and use in both the public and private sectors. They also include those who decide on TB-control policy, manage TB-control programmes, provide technical and/or financial support for TB control and prevention, and people affected by the disease. *Boxes 1–3* provide illustrative lists of stakeholders at global, regional and country levels, as they relate to TB diagnostics, medicines and vaccines.

In identifying stakeholders, it is critical to understand:

- who or which organizations will implement the new TB-control technologies;
- who or which organizations will have influence and resources to support TB-control retooling;
- who or which organizations will be directly or indirectly affected by the new technologies;
- who or which organizations will support retooling with the new technology; who will resist it and why; and how resistance to change can be addressed;
- what can these organizations and individuals contribute to retooling; and
- what is the best way to leverage insights or assuage objections and concerns.

⁴ These definitions are adapted from: International Finance Corporation. *Stakeholder engagement: a good practice handbook for companies doing business in emerging markets*. Washington, D.C., International Finance Corporation, 2007.

CASE STUDY 1

Strengthening Laboratory Services and Introducing Liquid Culture Media and Drug Susceptibility Testing in Lesotho

The purpose of this case study is to illustrate the importance of partnerships in introducing diagnostic technologies in a national TB reference laboratory.

There is a growing concern with many countries facing extremely high rates of tuberculosis (TB) and HIV co-infection, and with the increase in multidrug-resistant (MDR) and extensively drug-resistant (XDR) infections. The World Health Organization (WHO) updated several policies to address these challenges and to improve the diagnosis of the deadly disease in countries that carry the greatest burden. In June 2007, WHO's Strategic and Technical Advisory Group for TB recommended that middle- and low-income countries use liquid culture and rapid species identification for culture and drug susceptibility testing (DST). The WHO made the recommendations with the recognition that retooling would require strengthening TB laboratory services.

Since late 2006, global and national partners had already been working to improve Lesotho's TB diagnostic capabilities, including strengthening the National TB Reference Laboratory (NRL). WHO recommended implementing the new technologies first in the country's national reference laboratory, and then to scale-up in a phased manner to the rest of the laboratory system. Partners in Health (PIH), with funding from the Open Society Institute, had established a partnership with the Ministry of Health and Social Welfare (MOH&SW) to launch a treatment program for MDR-TB. However, Lesotho lacked any capacity to diagnose MDR-TB.

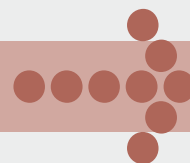
The Foundation for Innovative New Diagnostics (FIND) had signed a memorandum of understanding with the government in April 2007 to help prepare the laboratory system in Lesotho to introduce new diagnostic technologies. The collaborations between FIND and PIH provided an excellent opportunity to streamline the conventional culture and Drug Susceptibility Testing procedures (DST) and to pilot the introduction of liquid media for culture and DST.

The MOH&SW coordinated several levels of global and national support to rehabilitate the NRL and strengthen human resources capacity-building programs. It installed equipment purchased with funds from the Global Fund to Fight AIDS, Tuberculosis and Malaria, streamlined work-flow, and recruited additional technicians with funding provided by PIH and University Research Co., LLC (URC). WHO provided logistic support and appointed a country-based WHO medical officer to handle MDR TB cases. PIH provided logistics and financial assistance. FIND gave technical guidance and appointed an on-site technical expert for NRL renovation and supervision and provided a liquid culture system and rapid strip test to detect *M. tuberculosis*. The South African Medical Research Council, a WHO supranational reference laboratory, ensured external quality assurance for drug susceptibility testing.

Thanks to the close collaboration among multiple stakeholders, Lesotho established a state-of-the-art mycobacteriology laboratory and rapidly introduced new TB diagnostic technologies needed to address the challenges posed by MDR- and XDR-TB.

For further reading visit: http://www.finddiagnostics.org/news/docs/lesotho_nov07.shtml

BOX 1 ILLUSTRATIVE LIST OF GLOBAL STAKEHOLDERS



Stop TB Partnership

- Task Force on Retooling, Research Working Groups (New TB Diagnostics, Drugs and Vaccines Working Groups), Implementation Working groups (DOTS Expansion, MDR-TB and TB/HIV Working Groups and Subgroups on laboratory capacity strengthening, on TB & Poverty), Advocacy, Communication and Social Mobilization Working Group

Intergovernmental agencies

- World Health Organization, United Nations Children's Fund (UNICEF) United Nations Development Programme (UNDP), Joint United Nations Programme on HIV/AIDS (UNAIDS), UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR).

International suppliers

- Stop TB Partnership's Global TB Drug Facility.
- Procurement agencies (e.g. Crown Agents, International Dispensary Association, GTZ), private health-care providers and institutions.

Advocacy and community-based organizations

- World Care Council, International Treatment Preparedness Coalition, RESULTS Educational Fund, Treatment Action Campaign (TAC), Treatment Action Group (TAG), Voice of America.

Professional organizations and technical partners

- International Union Against Tuberculosis and Lung Disease (the Union), US Centers for Disease Control and Prevention (CDC), KNCV (Royal Netherlands Chemical Society), Tuberculosis Foundation, German Leprosy and TB Institute (GLRA), Research Institute of Tuberculosis of Japan (RIT), the Jordanian Anti-Tuberculosis Association (JATA), National Institute of Allergy and Infectious Diseases (NIAD), Partners in Health (PIH), and others (e.g. American Thoracic Society, European Respiratory Society, other academic institutions).

Funding agencies

- Multilateral donors and development banks (Global Fund, World Bank); bilateral donors (CIDA, Danida, DFID, DGIS, Norad, Sida, USAID, etc.); US National Institutes of Health (NIH); European Developing Countries Clinical Trials Partnership (EDCTP); philanthropic and other funding organizations (Bill and Melinda Gates Foundation, Rockefeller Foundation, Open Society Institute, Wellcome Trust, etc.); Global Alliance for Vaccines and Immunization (GAVI); new financial mechanisms (UNITAID international purchase facility, International Finance Facility for Immunization, Advanced Market Commitments for Vaccines, etc.).

Nongovernmental organizations

- Médecins sans frontières (MSF), Pharmaciens sans frontières (PSF), others.

Private sector⁵

- Manufacturing companies (diagnostics, pharmaceuticals, vaccines).
- Private research and development (R&D) firms.
- Non-health enterprises.

Public-private partnerships

- Foundation for Innovative New Diagnostics (FIND), Global Alliance for TB Drug Development, Aeras TB Vaccine Foundation, others.

⁵ Subject to conflict of interest consultations

BOX 2 ILLUSTRATIVE LIST OF REGIONAL STAKEHOLDERS

Stop TB Partnership

- Stop TB Partnership for Europe and Central Asia.
- Meeting of national tuberculosis programme managers in the WHO Eastern Mediterranean Region.
- GDF regional focal points (based in AFRO, EMRO and WPRO, coming soon).

Intergovernmental agencies

- WHO regional offices for Africa, the Americas, South-East Asia, Europe, Eastern Mediterranean and Western Pacific, West Africa Health Organization (WAHO).
- International Red Cross and Red Crescent regional offices.

Funding agencies

- African Development Bank, Asian Development Bank, Inter-American Development Bank, Aga Khan Foundation.
- USAID regional missions (e.g. Central Asia).
- GFATM regional portfolio managers.

Academic, research and training institutions

- African Medical and Research Foundation.

BOX 3 ILLUSTRATIVE LIST OF COUNTRY STAKEHOLDERS

World health organization and united nations

- Interministerial groups led by WHO or the UN, such as the High Level Working Group (HLWG) on Tuberculosis in the Russian Federation.

National Stop TB partnerships

- Brazil, Ghana, Indonesia, Mexico, Russian Federation, Sudan, etc.

Ministry of health

- National TB control programme, national public health laboratory, national AIDS control council, joint HIV-TB committee, national immunization programme, department of planning, directorate of primary health care, health education department, provincial and district health officers, training department, medicines regulatory authority, pharmacy and essential medicines department.

Ministry of justice

- TB control in penitentiary system.

Ministry of finance

- Directorate of health budgets.

Ministry of education

- Academic, research and training institutions.
- Medical colleges, research institutes, training institutes.

Professional organizations

- Medical and paediatrics associations, nurses' association, pharmacists' associations, national TB/lung associations, laboratory technologists' associations.

State-owned enterprises

- Manufacturers of TB-control products.

Private sector health and non-health companies

- Manufacturers of TB-control products (diagnostics, medicines, vaccines), importers and wholesalers, hospitals and clinics, clinical diagnostic laboratories, faith-based organizations and NGOs, pharmacies and drug shops, traditional healers.
- Local enterprises committed to corporate social responsibility.

Decision-makers and opinion leaders

- National health policy-makers, academic and religious leaders, national "envoys" for TB (e.g. famous sportsmen, actors, etc.).

Community and patient advocacy groups

- Community-based organizations, patients' organizations, advocacy and community-based organizations.
- Civil society organizations.

Communications media

- Print media and journalists, television and radio stations.

Collaborating agencies

- Global Fund country coordinating mechanisms, collaborating partners, including multilateral (WHO, UNICEF, World Bank, etc.) and bilateral (United States Agency for International Development, United States President's Emergency Plan for AIDS Relief, United Kingdom Department for International Development, etc.).

3. WHY ARE STAKEHOLDERS ENGAGED?

Stakeholders are engaged to accelerate the effective uptake of new and improved technologies for TB control. *Box 4* lists some key components of the process. Stakeholders play key roles at every stage of the retooling process, at global and country levels. Stakeholder engagement is a broad and continuous process that encompasses a range of activities and approaches, and spans the entire period from adoption through introduction and implementation.⁴

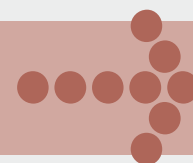
Stakeholder engagement aims to:

- obtain political support;
- mobilize participation in advocacy for the new and improved technology;
- leverage financial and/or technical resources, across the public and private sectors;
- obtain broader insights for designing appropriate ways to introduce the new and improved technology;
- provide opportunities for community participation in pilot and feasibility studies, determining acceptability of the new technology, and contribute to monitoring and evaluation activities, including reporting of drug- or vaccine-related adverse events;
- build relationships and trust; and
- establish partnerships to work together to achieve integration of the new technology into the TB control and prevention programme and effective implementation.

Obtaining political backing and support at the national and local levels is very important for the uptake and use of new technologies. For example, rapid diagnostic tests (RDTs) for malaria were successfully introduced as part of the malaria control programme in the Philippines, after obtaining appropriate political support.⁶ Key stakeholders such as the governor of a province or mayor of a local municipality gave their support by signing a memorandum of agreement for the deployment of RDT-trained personnel. Some municipalities adopted a resolution supporting the introduction of RDTs as part of the malaria control programme.

⁶ Personal communication from Dr Raman Velayudhan, Scientist – Malaria, vector-borne and parasitic diseases, Office of the WHO Representative, Philippines (8 May 2007).

BOX 4 KEY ACTIONS IN THE TB CONTROL RETOOLING PROCESS



Before adoption, introduction and implementation

- Advance planning and preparation
- Operational research to guide retooling.

Adoption

- Analysis of need and evidence for change
- Evaluation of benefits and risks of the new technology
- Analysis of the health systems environment and capacity to adopt, introduce and implement the new technology
- Endorsement of the new technology, development and dissemination of new recommendations and policies.

Introduction and implementation

- Mobilization of financial and technical resources
- Product registration and regulation updating
- Programme guidelines and essential health technology lists updating, dissemination and health-worker and community-partners training
- Advocacy, communication and social mobilization
- Product supply management, including phase-in and phase-out planning
- Product quality and safety monitoring and evaluation
- Programme monitoring and evaluation.

CASE STUDY 2

Introduction of fixed-dose combination preparations (FDCs) in the national TB control programme

This case illustrates the importance of political support and contributions of global, regional and local stakeholders for effective retooling in TB control.

In 1999, following inclusion of the 4- and 2-drug fixed-dose combination preparations in the WHO Model List of Essential Drugs, the national TB control programme (NTP) introduced fixed-dose combination products (FDCs). The Philippine Coalition Against Tuberculosis (PhilCAT), a coalition of private-sector and nongovernmental organizations, supported the NTP.

Two divisions of the Department of Health, the Infectious Disease Office and the Centres for Health Development were given the task of implementing the transition from single-dose formulations to FDCs. The first step was to meet with the Philippines Bureau of Food and Drugs to provide information on the benefits of FDCs. Registration of FDCs took place within three months of this meeting. The Under-Secretary of the Philippines Bureau for International Health Cooperation facilitated rapid approval for procurement through the GDF, following advance notification by the NTP.

The NTP sought technical support from WHO (Regional Office for the Western Pacific and the country office). The Japanese International Cooperation Agency (JICA) provided financial support to develop guidelines for health professionals (physicians and nurses) and health workers (village volunteers and midwives). GFATM provided funds for policy development, training, roll-out of FDCs, and monitoring and evaluation. FDCs were implemented in two phases: a pilot period followed by nationwide expansion.

To facilitate the rapid implementation of FDCs by public-sector health workers in the field, the FDC guidelines were officially adopted through an NTP department circular in July 2003. Simultaneously, FDCs were promoted for use in the private sector through the Philippines initiatives on public–private mix for DOTS (PPMD). Use of FDCs for TB control was also included in the official Manual of Procedures used by all providers in the public programme and in the PPMD units.

Thanks to this process and the involvement of all key stakeholders, nationwide coverage for FDC utilization was achieved in two years.

Source: Dr Rosalind Vianzon, National TB Programme Manager, Department of Health, Manila, Philippines.

4. WHEN ARE STAKEHOLDERS ENGAGED?

Given past experience of significant delays between the global availability of new technologies for prevention and control in malaria, hepatitis B and other disease areas and their eventual adoption and introduction in countries, it is important to begin the stakeholder engagement process as early as possible. At the global level, the Stop TB Partnership, through its Task Force on Retooling, is already disseminating a framework for adoption, introduction and implementation, to stimulate discussions and advance preparation, anticipating the launch of several new TB tools that are in the pipeline. As the results of phase III clinical trials for medicines, demonstration studies under actual field conditions for new diagnostics, and/or field studies of new vaccines become available at global level, wide communication of findings will contribute to country-level planning for their evaluation and potential adoption and introduction. High-burden and high-incidence country stakeholders that participate in generating this evidence will have a head start in analysing the evidence for decision-making on adoption and introduction of the new technology.

As soon as a new technology is under serious consideration, stakeholders may be engaged. Local participation in the design and implementation of studies comparing alternative therapies creates ownership in results that supports the adoption of a new technology. Other tasks include analysis of health systems capacity and planning key actions needed for assessing, adopting, introducing and implementing the new technology. The stakeholder engagement process will span the stages of policy adoption, technology introduction, programme planning and programme implementation (*Case study 2*).

While it is desirable to engage stakeholders as early as possible, it is also important to carefully consider when this should occur, to avoid creating unrealistic, misleading or unmet expectations. Some stakeholders, particularly potential funders, may be engaged as early as one year ahead to ensure adequate financial support. Suppliers may be engaged as soon as it is likely that a new tool may be adopted, while providers are engaged when procedures, training materials and retraining are ready for implementation and supplies are assured.

CASE STUDY 3

Adoption of artemether-lumefantrine combination therapy in Nepal

This case study illustrates the contribution of local research to support decision-making in retooling.

Research in the past decade found that the efficacy of chloroquine and, more recently, sulfadoxine-pyrimethamine (SP) had fallen below levels deemed acceptable by WHO for the treatment of malaria in Nepal. In 2005, the Ministry of Health and Research Triangle International, with funding from USAID, conducted a single blind hospital-based study in Jhapa district, Nepal. The study compared the efficacy of Coartem[®] with the current first-line therapy (SP) for uncomplicated malaria, to determine whether artemether-lumefantrine (Coartem[®]), recommended by WHO, was an appropriate treatment option in Nepal.

The study was designed, planned and implemented in collaboration with staff from the Department of Health Services. In addition to confirming the efficacy of the new antimalarial combination treatment, the study focused on answering questions specific to the national situation: would the drug be acceptable, tolerated and feasible in the national setting. The principal investigator, from the Ministry of Health, oversaw implementation in the field, including hospitalization and clinical interventions, as well as laboratory services. The study was implemented in the government's Mecchi zonal hospital, by hospital staff with support from the government's malaria control programme for laboratory analysis. This was a critical aspect of the success of the study in persuading the medical community in Nepal of the appropriateness of the treatment: doctors observed for themselves the difference in clinical response between patients receiving SP or Coartem[®].

While both treatments were well tolerated, leading to a rapid resolution of malaria-associated symptoms, patients receiving Coartem[®] felt better much sooner (often within 12–24 hours), whereas SP patients suffered fever and headache for several days. Study doctors were overwhelmingly in favour of introducing Coartem[®] widely, which served as a strong influence on their peers in the Ministry.

Study findings were presented during a formal meeting at the Ministry of Health in December 2005, and were quickly adopted by the Ministry as an appropriate treatment option. Because the study was implemented almost entirely by the Ministry and other government partners, ownership of the results was also very clear. Instead of receiving and absorbing findings from outside, they were in a position to advocate for use of a proven technology. The findings provided a solid basis for policy formulation by the Government of Nepal and have been published in a peer-reviewed journal.

Source: Mary Linehan, Research Triangle International (see Thapa S et al. Comparison of artemether-lumefantrine with sulfadoxine-pyrimethamine for the treatment of uncomplicated falciparum malaria in eastern Nepal. *American Journal of Tropical Medicine and Hygiene*, 2007, 77:423-430).

5. HOW ARE STAKEHOLDERS ENGAGED?

The process of engaging stakeholders includes:

- establishing or identifying an existing working group;
- defining clear objectives for engaging the various stakeholders;
- conducting a stakeholder analysis;
- developing and implementing a plan for engaging each type of stakeholder (see *Box 5* for some guiding principles for stakeholder engagement);
- monitoring and evaluating the effectiveness of the stakeholder engagement plan; and
- providing timely feedback to all participants.

BOX 5 GUIDING PRINCIPLES FOR STAKEHOLDER ENGAGEMENT



Transparency. Offer equal opportunity to access information and involvement, guided relevance, clarity in goals and procedures, accountability for decisions (rationale on why and how), and timeliness (stakeholders engaged early enough in the process).

Openness. Stakeholder involvement should be undertaken in a way that enables contribution of experiences, communication of expectations, knowledge and ideas for improving TB control and the design and delivery of the new technology.

Recognition of diverse capacity. As stakeholders have differing capacities and resources, measures should be taken to ensure effective participation.

Shared responsibility. All participants share responsibility for meeting the objectives and evaluating the results of the stakeholder engagement process.

Accountability. Commitments should be met and outcomes communicated.

Establishing a working group or identifying an existing one

The process begins with policy-makers establishing a working group, or a subgroup of an existing working group, with a clearly defined role and responsibility for engaging stakeholders in retooling TB control. For example, at global level, the Stop TB Partnership has already created a Task Force on Retooling (TFR), with broad representation. It includes experts, not necessarily working group members, designated by the chairpersons of the various Stop TB Partnership working groups; members from the key subgroups (laboratory strengthening, the Global TB Drug Facility, poverty), representatives from the national TB control programmes of high-burden countries, and representatives from the WHO Stop TB Department and other relevant departments within WHO. As appropriate, the TFR may allocate subgroup work on various aspects of the stakeholder engagement process.

At country level, the ministry of health or a relevant Stop TB Partnership member⁷ should establish a similar national task force or working group with broad representation. Membership might include representatives from the corresponding NTP and NIP, laboratories and other relevant departments of the ministry of health; the national reference laboratory; the HIV/TB programme; the ministry of finance; nongovernmental organizations and faith-based organizations, patient and community groups; equity advocacy groups; professional associations; suppliers (manufacturers, importers or distributors); private providers; communications media; academic or training institutions. Similarly, subgroups may take on responsibilities in the stakeholder engagement process.

The role of the task force is to facilitate the introduction and adoption of new tools as they become available. Its responsibilities include:

- developing a work plan and timelines;
- identifying relevant stakeholders and enhancing communication among them;
- creating opportunities for consultative dialogue with stakeholders from high-burden countries and high-incidence 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 learned from other disease areas to inform TB-specific processes for adoption, introduction and implementation;
- facilitating operations research on introduction of new tools, including the identification of appropriate pilot and scale-up areas in both easy and more difficult-to-reach populations; and
- fast-tracking incorporation of new tools in WHO and national policies and guidelines.

Roles and responsibilities may be defined for the national working group or for subgroups depending on the type of technology involved (e.g. one related to laboratory strengthening to prepare for new diagnostic tools, or immunization for new vaccines). For example, to facilitate adoption and implementation of artemisinin-based combination therapies (ACTs), the national malaria control programme of Zambia established subgroups to guide the process. With the engagement of various in-country and global stakeholders at different stages, it took two years to adopt the ACT policy and two years to implement it.⁸

Defining clear objectives for engaging the various stakeholders

As mentioned above, it is important to establish clearly the purpose of engaging the various stakeholders. The main objective is to accelerate the appropriate adoption, introduction and implementation of new and improved TB medicines, diagnostics and vaccines for improving TB case-detection and cure rates and achieving the World Health Assembly targets.

Specific objectives for engaging relevant individuals, groups or institutions will depend on their potential contribution to the retooling process, including:

- political support and decision-making;
- advocacy for the new and improved technology;
- provision of financial resources;
- planning and implementing retooling activities;
- provision of technical support;
- new technology supply management; and
- design and participation in operational research.

⁷ At present there are national Stop TB partnerships in Brazil, Canada, Ghana, Indonesia, Islamic Republic of Iran, Italy, Mexico, Pakistan, Russian Federation, Sudan, Uganda and the United States of America.

⁸ Mudondo C, Chanda P, Ndhlovu M. *Artemisinin-based combination therapy in Zambia: from policy change to implementation*. Geneva, WHO, 2005 (Roll Back Malaria).

Conducting a stakeholder analysis

The objectives of the stakeholder analysis are to:

- identify key stakeholders (including those not currently engaged in TB control);
- establish their potential roles in TB-control retooling (who they are and how they may contribute to retooling activities) based on the different key actions that are needed for global adoption and policy development, as well as for country adoption and implementation, as discussed in *New technologies for tuberculosis control: a framework for their adoption, introduction and implementation*;
- determine the level of commitment to retooling (extent of support or resistance to change and reasons for opposition, such as not being convinced of benefits or appropriateness to health-care system conditions, or reservations about sustainability owing to resource limitations);
- identify available resources (staffing, volunteers, money, technology, information, influence); and
- assess constraints (limitations, funding needs for stakeholder participation, lack of personnel, infrastructure, political barriers).

Annex 2 provides a sample matrix that may guide the systematic and structured analysis of stakeholders and assist in prioritizing activities. It includes a form that illustrates the structure of the analysis and an example of a completed form for potential adoption and introduction of a new medicine or treatment regimen.

In general, the stakeholder analysis process may follow these steps:

- compile and review existing information on the new technology;
- develop a list of all possible stakeholders that may be interested, benefit from or be opposed to the new technology;
- develop a list of priority stakeholders, with input from experts, regarding their level of influence or direct interest in the adoption or introduction of the new technology (stakeholders who are not organized or do not have the ability to affect positively or negatively the specific intervention should not be included);
- establish stakeholders' characteristics, based on their level of knowledge about the new technology, their position regarding its effective uptake, vested interests, alliances, ability to mobilize resources, and whether or not they have leadership;
- adapt questionnaires for interviewing priority stakeholders;
- analyse stakeholder information; and
- organize stakeholder data in a matrix.

Because stakeholders and their positions may change during the processes for introducing the technology, the analysis should be maintained as an ongoing process to allow for adjustments.

Developing and implementing a plan for engaging each type of stakeholder

Stakeholder engagement strategies or methods will range from simple information and communication (print, electronic, verbal) to consultation (soliciting stakeholder input) to participation (active involvement of stakeholders) and negotiations (e.g. establishing partnerships, memoranda of understanding), depending on the stakeholder involved and the specific purpose of the engagement.

Stakeholders may be engaged by disseminating printed information, involving the use of brochures, booklets, scientific or professional journal articles, press releases or newspaper articles. Stakeholder involvement in such activities is likely to be passive, although those who produce the information are actively engaged, e.g. publicity firms for media campaigns or journalists who produce news articles to assist in creating public awareness about availability or introduction of new TB tools.

Meetings and conferences also serve to disseminate and communicate information. When meetings are held as consultations, they may engage stakeholders in more active participation where their input is requested and taken into consideration in decision-making or planning.

Working groups and workshops are more appropriate forums to engage stakeholders in active participation, to develop action plans and operations research protocols for demonstration studies or field trials, and for programme monitoring and evaluation.

Surveys of policy-makers have the potential to provide strategic information on politically feasible means of distributing, targeting and financing the new tools.^{9,10,11} Policy analysis has the potential to identify crucial policy issues that may require consideration from multiple perspectives to overcome barriers to the successful introduction of new TB tools at least two years before introduction. Such methods were used for baseline policy-maker assessment in the case of hepatitis B vaccines and pneumococcal vaccines.¹²

The stakeholder analysis will provide information for the development of the plan to engage stakeholders, based on an understanding of the capacity and level of participation expected of the various stakeholders, the resources to be invested in engaging each type of stakeholder and the appropriate timing for that engagement.

Determining the strategy for engagement of each type of stakeholder

One way of organizing the information derived from the stakeholder analysis is to map the different groups of stakeholders according to their level of power or influence, and the other according to their level of interest.¹³ This guides the strategy, ranging from simple information, communication and participation, to negotiation and partnership:

- high-power interested stakeholders should be fully engaged, and the working group should make the greatest efforts to satisfy these groups;
- high-power less interested stakeholders warrant enough effort to keep them satisfied, without insisting so much that they are put off or bored with the issue;
- low-power interested stakeholders need adequate information and monitoring just to ensure that no major issues arise; and
- low-power less interested stakeholders should not be burdened with information or demands, but their interest monitored.

The communication plan may have the following objectives:

- raise awareness;
- ensure that the new technology is understood as an improvement or as being beneficial to the health-care delivery system, enabling programme enhancement (for example, through being more cost-effective and/or reaching new, vulnerable sectors of the population);
- ensure that communications concerning key messages are consistent and that stakeholders have clarity around the different elements of the process of TB retooling, its implementation and what is required of them; and
- ensure that stakeholders are heard and that they have appropriate channels to communicate their ideas and concerns, raise issues, ask questions and obtain more information.

Stakeholder engagement is an iterative process that involves communicating, listening, consulting, engaging and partnering.

⁹ DeRoock D. The importance of engaging policy-makers at the outset to guide research on and introduction of vaccines: the use of policy-maker surveys. *Journal of Health, Population and Nutrition*, 2004, 22(3):322-330.

¹⁰ DeRoock D et al. Policymakers' views regarding the introduction of new-generation vaccines against typhoid fever, shigellosis and cholera in Asia. *Vaccine*, 2005, 23(21):2762-2774.

¹¹ Moree M, Ewart S. Policy challenges in malaria vaccine introduction. *American Journal of Tropical Medicine and Hygiene*, 2004, 71(Suppl.2):248-252.

¹² Mahoney R. Policy analysis: an essential research tool for the introduction of vaccines in developing countries. *Journal of Health, Population and Nutrition*, 2004, 22(3):331-337.

¹³ Health Canada, Health Products and Food Branch. *Public involvement framework*:

http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/pubs/piframework-cadrepp_e.pdf

Table 1 illustrates the selection of methods according to stakeholder engagement objective and stakeholder level of power and interest.¹⁴

Table 1 Stakeholder engagement: methods according to objective and level of power and interest

Low level of power and interest	Low level of power, some interest	Medium level of power and interest	Medium level of power, high interest	High level of power and interest
<i>Objective.</i> Inform or educate to raise public awareness	<i>Objective.</i> Gather information	<i>Objective.</i> Discuss	<i>Objective.</i> Engage	<i>Objective.</i> Partner
Consultation				
Information sessions, web-postings, social marketing, advertisement, promotional materials	Bilateral meetings, focus-group discussions, mail-outs requesting input (including e-mails), public meetings, publications, surveys, web-postings expecting feedback	Technical consultation, workshops, working groups including working committees, advisory committees	Advisory committees, dialogue, round tables, workshops and working groups	Sharing responsibilities for implementing aspects of policy or programme decisions

Stakeholder engagement plans should encompass all the stages of the involvement for each particular stakeholder. The plan should clearly articulate the consistency in messages at different stages, and how stakeholders will be kept engaged throughout the process of new tool introduction.

Annex 3 provides a sample structured form to guide preparation of the stakeholder engagement plan. It includes a form that illustrates the structure of an engagement plan and a corresponding example of a completed form for potential adoption and introduction of a new medicine or treatment regimen. The form may also be useful for monitoring purposes to ensure that proposed activities are carried out, and for assessing the need for adjustments. See also *Case study 3*.

¹⁴ Adapted from: Health Canada, Health Products and Food Branch. *Public involvement continuum: public involvement framework* (http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/pubs/piframework-cadrepp_e.pdf).

CASE STUDY 4

Introduction of fixed-dose combinations for TB in South Africa

This case study illustrates key elements in the stakeholder engagement process.

South Africa was one of the first countries that effectively adopted fixed-dose combinations (FDCs) for the treatment of tuberculosis as national policy in 1996. The policy change was not planned, but it was the end-result of a number of independent but interlinked activities and circumstances that led to the successful introduction and implementation of FDC-based treatment practices.

Role of multiple stakeholders

There was interaction among the four main stakeholders (industry, the clinical and scientific communities, the NTP and the Medicines Control Council) for over 10 years before practice became national policy in 1996. FDC-based treatment was already available prior to 1996, and was recognized by both manufacturers and the NTP as a simplified approach to TB therapy.

A number of groups came together to take a decision about the use of FDCs in the national programme (the Tuberculosis Research Institute of the Medical Research Council, the South African National Tuberculosis Association, and government TB officers, together with smaller but influential groups such as the Mine Medical Officers Association, academics at medical schools in the country, and medical staff at TB hospitals). The decision was based on publicized scientific discussions and other findings from the British Medical Research Council, the International Union against Tuberculosis and Lung Disease, the US Centers for Disease Control and Prevention, and the American Thoracic Society, in particular.

The NTP's TB Advisory Group incorporated the opinions of the clinical community in policy statements, which facilitated public procurement of locally manufactured FDCs. The Medicines Regulatory Authority of South Africa assured quality by instituting guidelines and licensing requirements for bioequivalence assessments, and creating clear principles for product registration.

Advocacy and communication

At the initial stages, manufacturers played a major role in promoting FDC use by printing and distributing attractive informative posters, leaflets and booklets, sponsoring sessions at scientific meetings, and assisting with organizing clinical discussions and workshops. Clinicians and government officials became fully informed of the advantages of FDC-based treatment regimens, and manufacturers gained by learning which formulations and drug quantities would be required in order to ensure uninterrupted supply.

The NTP and other government sources contributed significantly, in particular at the stage when fully FDC-based policies were issued, by ensuring wide consultation beforehand with stakeholders at all levels (clinical, general patient care, industry, regulatory, scientific and TB research community).

Source: Dr. Bernard Fourie, Chief Scientific Officer and Director of South African Operations. Medicine in Need, South Africa.

Monitoring and evaluating the effectiveness of stakeholder engagement

Stakeholder engagement requires following and monitoring. Questions should focus on the extent to which stakeholders were really engaged and the impact that the engagement had on facilitating the retooling process. See *Case study 4*.

Providing timely feedback to all participants

Stakeholder engagement is a continuous process which should include a plan for continued involvement or communication with the stakeholders, providing appropriate feedback on results of decision-making on adoption, status of plans for new tool introduction (e.g. registration, procurement, phase-in plan, phase-out plan), or programme implementation, and impact of new tool development, availability or uptake, and fully acknowledge stakeholder contributions to the retooling process.

CASE STUDY 5

Community engagement in home-based management (HBM) of fever in Rwanda

This case study illustrates how communities were engaged and the importance of evaluating the pilot phase when introducing a new health technology

In 2004, the Rwanda Integrated National Malaria Control Programme (INMCP) developed a strategy for home-based management of fever to enhance access to and timely treatment of malaria in children under five years of age. The strategy was based on the use of trained community volunteers, called *distributeurs*, to provide prepackaged treatment or referral to children with fever.

At six pilot health districts, the INMCP and its implementing NGO partners held public meetings to explain the proposed programme and discuss the criteria for being a *distributeur*. At these meetings, community members nominated and voted for their *distributeurs*; they were chosen on the basis of personal characteristics including integrity, self-respect, personal cleanliness and ability to participate in training. After the voting, the elected volunteer participated in training. Following the training, the local authorities officially announced the new services to the population during public meetings and community work days.

Involvement of political leaders and communities at an early stage created a sense of ownership. In particular, allowing communities to elect the person they wanted to be their *distributeur* enabled the communities to choose the person they felt was most competent to take on that responsibility. As a result, community members had no initial hesitation in seeking care from their *distributeurs*, since they trusted them already.

Two years later, the INMCP conducted an evaluation of the pilot phase that included review of existing surveillance and service data, reports of previous evaluations from partner agencies and the INMCP; assessment of community practices, perceptions and opinions regarding the HBM programme; evaluation of knowledge, practices and opinions of health workers (*distributeurs*, health centre and district health staff); assessment of pharmaceutical management and management information systems; and investigation of other potential care providers (traditional healers, traditional birth attendants, and formal and informal private drug sellers). The comprehensive evaluation included in-depth interviews (community leaders, health centre staff, *distributeurs*, private providers), focus-group discussions (community health workers, caregivers), record reviews and stock inspections at health facility and *distributeur* levels).

The evaluation found that communities were pleased with *distributeurs* and their services. Caregivers now preferred taking their sick children to *distributeurs*, resulting in a significant increase in the percentage of children brought for care within 24 hours; *distributeurs* showed strong knowledge of correct management of childhood fever and records suggested appropriate dispensing; sick children were almost always appropriately treated. The evaluation provided insights into possible ways of maintaining the already high motivation of *distributeurs* and the need to ensure the sustainability of the programme as it is scaled up.

Source: USAID, BASICS, MSH/RPM Plus. *External evaluation of the pilot phase of the home-based management of malaria programme in Rwanda*. Final report, February 2007.

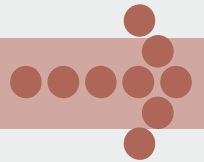
6. CONCLUSION

The degree of acceleration of adoption, introduction and implementation of new improved tools for TB control will depend on the extent to which the global and country Stop TB partners engage stakeholders at the relevant levels (*Box 6*). This will be greatly facilitated by creating national task forces or working groups on retooling, and systematically structuring an approach to: identifying stakeholders; defining their potential roles; identifying the resources they can contribute; understanding the dynamics among them; creating an engagement and follow-up plan; and tracking this engagement throughout the adoption, introduction and implementation process.

BOX 6 PITFALLS TO AVOID

Common issues that may adversely affect the success of stakeholder engagement include:

- inviting only stakeholders who agree with a proposed plan;
- selecting only stakeholders from the organization that is directly involved (e.g. ministry of health);
- inviting a number of stakeholders that is insufficient to ensure representation of different perspectives;
- inviting stakeholders to a preliminary briefing, but thereafter not including them in decision-making, planning or project design;
- including stakeholders who may not be at the appropriate level in a community or organization to contribute to the project or take decisions; and
- creating expectations about the project at the onset, and then providing little or no follow-up about the results of the initiative.



ANNEXES

Annex 1 Methodology

A systematic search for stakeholder-related documents was made using PubMed. The criteria for searching articles included country-level stakeholder engagement related to “retooling” and/or timely adoption, introduction and implementation of new technologies. The search was limited to articles describing experience in developing country settings. The term “stakeholder” was separately combined with each of the following key words: engagement, involvement, mapping, guide, assessment, tuberculosis, malaria, vaccines, HIV, AIDS. The search was repeated, combining the term “policy-makers” with each of the key words. A systematic search was also performed to identify generic stakeholder engagement documents that may help describe the process for retooling.

Although many articles were found on stakeholder engagement related to public health programme implementation, health system reforms, care and treatment, community interventions, waste management, environment and others, few articles were found on stakeholder engagement specifically related to the theme of “retooling.” A list of key references related to retooling was provided in a previous publication.¹⁵ Some articles were found on stakeholder engagement specifically related to vaccines and they are cited in this document but none were found on diagnostics.

There are a few published examples of stakeholder engagement for country-level policy adoption and introduction of new medicines. However, these articles are limited to describing policy adoption or why there were delays in introducing new medicines. Another article describes how effective, multistakeholder engagement led to successful scale-up of health commodities, but not the adoption and introduction aspects of new technologies.¹⁶ Therefore, the search was widened by using a general Internet search engine (Google) with the same combination of key words. The criteria for searching articles from the general Internet search engine were that articles had to be from a country’s TB programme, national and international technical and consulting agencies, and NGOs.

The Internet was also searched for documents describing a general framework on stakeholder engagement and many such documents were found. WHO has compiled a list of resources on stakeholder analysis for partnership management.¹⁷ The framework for stakeholder engagement is drawn from these and other publications found through a general search.

An attempt was made to identify and summarize case studies of successful ventures that demonstrated effective stakeholder engagement for adoption and introduction of new technologies from TB and other disease areas. The literature was searched for articles describing country-level stakeholder engagement experiences in introducing TB fixed-dose combination preparations (FDCs). No published documents were found through either PubMed or a general Internet search.

WHO global tuberculosis control reports from 2000 to 2007 were reviewed to identify countries that successfully introduced FDCs. Attempts were made to contact the respective national tuberculosis programme managers from countries that were listed as having successfully adopted and introduced FDCs. However, usable responses could not be obtained. Other case studies that are described in this document were developed through literature synthesis, phone interviews and e-mail communications.

¹⁵ Stop TB Partnership and WHO. *New technologies for tuberculosis control: a framework for their adoption, introduction and implementation*. Geneva, WHO, 2007 (WHO/HTM/STB/2007/40).

¹⁶ Magesa SM et al. Creating an «enabling environment» for taking insecticide treated nets to national scale: the Tanzanian experience. *Malaria Journal*, 2005, 4:34.

¹⁷ <http://www.who.int/management/partnerships/stakeholders/en/index.html>

Annex 2 TB retooling: proposed form for stakeholder analysis

A. Sample form

Name of stakeholder (organization, group or individual at national, regional or local level)	Stakeholder description (primary purpose, affiliation, funding)	Potential role in retooling activity (vested interest in the activity)	Level of knowledge of new tool (specific areas of expertise)	Level of commitment (support or oppose new tool, to what extent, and why)	Available resources (staff, volunteers, money, technology, information, influence)	Constraints (limitations, need funds to participate, lack of personnel, political or other barriers)
Government sector						
Ministry of health (various departments)						
Ministry of finance (health budgets)						
Political sector						
National policy-maker						
Municipality						
Commercial sector						
Manufacturer						
Supplier						
Other civil society target audiences						
Community-based organization						
Patient organization						
International donors						
Global Fund country coordinating mechanism (CCM)						
Bilateral aid agency						

Adapted from: MEASURE Evaluation. *Stakeholder engagement: an assessment and implementation tool for identifying stakeholders in a data collection initiative and engaging them as contributors and beneficiaries*. Data demand and information use, part 2: strategies and tools (<http://www.cpc.unc.edu/measure>).

B. Example of a completed form

The following completed stakeholder analysis form for adoption and introduction of a new medicine or treatment regimen is provided as an example only. It does not portray the actual situation in any given country.

Name of stakeholder (organization, group or individual at national, regional or local level)	Stakeholder description (primary purpose, affiliation, funding)	Potential role in retooling activity (vested interest in the activity)	Level of knowledge of new tool (specific areas of expertise)	Level of commitment (support or oppose new tool, to what extent, and why)	Available resources (staff, volunteers, money, technology, information, influence)	Constraints (limitations, need funds to participate, lack of personnel, political or other barriers)
Government sector						
Ministry of health National TB programme (NTP)	Department that steers and directs NTP implementation and spearheads the retooling process	Formulates policies and guidelines Pilot-tests new treatment regimen to advance implementation in selected sites	High level of expertise in operational implementation of new treatment regimen relative to NTP	Strongly supports adoption, introduction and implementation of the new treatment regimen	NTP organizational infrastructure NTP staff and coordinators available at various levels of health-care system	Insufficient funds for information dissemination Lack of funds to conduct feasibility studies Lack of funds for pilot-testing and roll-out
National essential medicines list committee	Group of technical experts who evaluate and approve the new medicine or treatment regimen for use in public sector	Includes new medicine in the national essential medicines list	High level of knowledge and experience in evaluating requests for new medicines, based on the national context Medium to low level of knowledge of international situation	Some members support retooling, but there are concerns about costs and a few members wish to see local data	Committee members appointed on an ad hoc basis	Revision process takes place every two years Limited information resources Needs additional funding to carry out deliberations and relevant consultations
National medicines regulatory authority	Agency that evaluates, approves and licenses new medicines	Fast-track evaluation and registration of new medicine; approval of new indication for an existing licensed product	Medium level of experience in evaluation of new products, usually based on registration in industrialized countries of origin	Supports retooling, but concerns about lack of local safety and efficacy data, although local clinical trials are not legally required	Evaluation and approval committee members from academia and health professions	Technical evaluation committee meets on a quarterly basis Technical and administrative staff are insufficient and overworked
Ministry of finance (health budgets)	Agency that facilitates development and review of budget and provides public funds	Prioritizes review and approval of retooling budget	Expertise in financial planning for new treatment regimen	Variable, may be opposed to adoption of new treatment regimen if costs are significantly increased	Funds to support implementation of new treatment regimen	Insufficient funds to cover potential increase in costs of new treatment regimen

Name of stakeholder (organization, group or individual at national, regional or local level)	Stakeholder description (primary purpose, affiliation, funding)	Potential role in retooling activity (vested interest in the activity)	Level of knowledge of new tool (specific areas of expertise)	Level of commitment (support or oppose new tool, to what extent, and why)	Available resources (staff, volunteers, money, technology, information, influence)	Constraints (limitations, need funds to participate, lack of personnel, political or other barriers)
Political sector						
National policy-maker	Individuals who mobilize high-level political will Individuals who ensure appropriate financing	Champions change and improvements in social conditions	No knowledge, but would need to understand cost implications	Would need to identify champion	News conferences, high-level commitments; statements and declarations at key policy events	May not see retooling TB control as critical to political platform
Municipality	Local government unit that ensures appropriate financing for health care	Promotes the need to improve local health conditions Shows leadership Supports necessary programmatic changes	No knowledge, but may be relevant to help with a social mobilization campaign at local level (radio, TV, print news)	Would need to engage high-level representation (e.g. mayor)	Local media; commitments and declarations; support on World TB Day	May have competing issues to promote (education, social welfare)
Commercial sector						
Manufacturer	Enterprise that manufactures pharmaceutical products	Produces new treatment regimen	Expertise in product formulation requirements, and quality assurance	Depends on potential financial benefit	Marketing support (e.g. patient and physician information materials)	Need commitment to demand forecast
Supplier	Supply agency that imports and distributes medicines and other essential health supplies	Appropriate packaging and supply chain	Packaging according to NTP guidelines (e.g. blister packs); understanding of supply chain	Level of commitment depends on potential financial benefit or other products through the same supply chain	Marketing support; assistance with demand forecasting	Need commitment to reliable demand forecasting

Name of stakeholder (organization, group or individual at national, regional or local level)	Stakeholder description (primary purpose, affiliation, funding)	Potential role in retooling activity (vested interest in the activity)	Level of knowledge of new tool (specific areas of expertise)	Level of commitment (support or oppose new tool, to what extent, and why)	Available resources (staff, volunteers, money, technology, information, influence)	Constraints (limitations, need funds to participate, lack of personnel, political or other barriers)
Service providers Service delivery nongovernmental organization (NGO)	NGO that provides integrated primary health care in five districts: clinics plus community outreach Country office of an international NGO funded by bilateral donors and philanthropic organizations	Adopts and implements new treatment regimen	Several medical doctors and nurses on staff with sound knowledge of current TB protocols. No knowledge of new regimen or of the results of its clinical trials	Senior management encourages innovation Community-level staff concerned about need to change record-keeping systems and patient-education materials Overall, the organization is supportive if made aware of compelling evidence about improved patient outcomes and cost-effectiveness	Medical doctors, nurses and community health workers on staff; numerous community health volunteers Some funds available for operations research	Need to consult with NGO headquarters Medical director before switching to new regimen Need permission of bilateral donor to use funds to procure new regimen Transition will take several months because of need to revise materials and train staff Initial stock of new treatment regimen would avoid procurement delays, but there are concerns about what to do with unused stock

Name of stakeholder (organization, group or individual at national, regional or local level)	Stakeholder description (primary purpose, affiliation, funding)	Potential role in retooling activity (vested interest in the activity)	Level of knowledge of new tool (specific areas of expertise)	Level of commitment (support or oppose new tool, to what extent, and why)	Available resources (staff, volunteers, money, technology, information, influence)	Constraints (limitations, need funds to participate, lack of personnel, political or other barriers)
Other civil society target audiences						
Community-based group (e.g. home-based care)	HBC group providing care to PLWAs and other chronically sick people	Generates awareness among volunteers and patients Supports patients Collects medicines; observes treatment; identifies side-effects and refers for care; keeps records Patient surveys on attitude to new regimen	Very limited technical knowledge of the technology High level of awareness of problems faced by patients and any cultural or religious considerations	Level of commitment may depend on degree of benefit to patients (e.g. speed of recovery) and consequently impact on their own work	Limited, but may be able to mobilize volunteers	Lack of funds Attitude of government towards community-based organization engagement Availability of volunteer time
Patient organization	People diagnosed with TB or with prior experience of TB	Newly diagnosed members may be involved in clinical or operational research trial May help recruit people to trials and support them Members who have been involved in trials may also become advocates for new regimen	Limited technical knowledge High level of knowledge concerning how new and prior regimens affect health and livelihoods	High level of commitment if new regimen saves time, travel and medical costs May have some initial resistance owing to fear of new medicines	Limited personal resources Current patients form a substantial resource for operational research	Lack of funds
International donors						
Global Fund country coordinating mechanism (CCM)	Multi-stakeholder committee charged with overseeing implementation of Global Fund TB project	Approves NTP proposal to use Global Fund grant to procure new regimen (or new diagnostic)	Low level of knowledge of new regimen CCM includes several medical doctors but not up to date with current medicines research	Some members are strongly committed to new regimen, a few are opposed because it has not been demonstrated efficacious in this country, and a majority have no strong opinions on the subject	Key gatekeeper for use of Global Fund grant, which represents 80% of funds for TB control in the country	Vocal opposition to new regimen from two members (chair of medical research council and of paediatricians' society)
Bilateral aid agency	Donor or loan agency	Influences policy Funds field trials, cost-effectiveness analysis, introduction and scale-up of new technology	Limited technical knowledge	Strongly committed to improve efficiency of programmes, wants results	Financial resources Potentially, human resources to influence policy	Need to understand field relevance of new technology Need to see how new technology will impact their desired results Need evidence to enable funding shift

Annex 3 TB retooling: stakeholder engagement plan

A. Sample form

Stakeholder organization, group or individual	Potential role in new tool introduction	Engagement strategy	Follow-up strategy and plans for feedback or continued involvement	Timing of engagement
Government sector				
Ministry of health (various departments)				
Ministry of finance (health budgets)				
Political sector				
National policy-maker				
Municipality				
Commercial sector				
Manufacturer				
Supplier				
Community-based group (HBC)				
Patient organization				
International donors				
Global Fund CCM				
Bilateral aid agency				

Adapted from: MEASURE Evaluation. *Stakeholder engagement: an assessment and implementation tool for identifying stakeholders in a data collection initiative and engaging them as contributors and beneficiaries*. Data demand and information use, part 2: strategies and tools (<http://www.cpc.unc.edu/measure>).

B. Example of a completed form

The following completed stakeholder engagement plan is provided to illustrate some possible activities related to the adoption and introduction of a new medicine or treatment regimen. They may or may not be relevant, depending on the specific country situation.

Stakeholder organization, group or individual	Potential role in new tool introduction	Engagement strategy	Follow-up strategy and plans for feedback or continued involvement	Timing of engagement
Government sector Ministry of health National TB programme (NTP)	Assess the benefits and risks of new medicine or treatment regimen to decide on adoption Coordinate the engagement of key stakeholders for evaluation and adoption of the new medicine or treatment regimen, as appropriate Formulate policies and guidelines on the new medicine or treatment regimen Pilot-test new treatment regimen to advance implementation in selected sites	Stay informed of developments in the pipeline (through Stop TB Partnership communications, publications, conferences) Conduct regular reviews of pipeline updates Participate in workshops and meetings for design of operations research to address implementation issues Plan phased implementation, including selection of initial (pilot) sites, performance of baseline or rapid assessments, monitoring and evaluation Plan roll-out or scale-up, including expansion of coverage, engagement of additional stakeholders (e.g. private-sector providers)	Conduct periodic monitoring and evaluation of progress in introduction and implementation Hold regular meetings and provide updates to key stakeholders Share experiences during forums and conferences Review progress in formulation of revised policies, guidelines and standards Review progress in phased implementation, from pilot to roll-out	As soon as there is sufficient evidence to suggest that a new medicine or treatment regimen warrants or is undergoing appropriate clinical trials to determine clinical or programmatic benefits Before the new medicine or treatment regimen is available, as the NTP may be involved in research to assess its appropriateness to the country situation
National essential medicines list committee	Include the new medicine or treatment regimen in the national essential medicines list	Provide evidence of benefits of new medicine or treatment regimen in TB control (through written or face-to-face communication methods) Invite the NEML to participate in design or approval of relevant research on the new medicine or treatment regimen	Provide regular updates of progress of ongoing relevant research	As soon as evidence is available for evaluation of the benefits and risks of the new treatment regimen
National medicines regulatory authority	Fast-track evaluation and registration of new medicine or approval of new indication for an existing licensed product	Hold meeting to discuss role of the new medicine or treatment regimen in TB control Submit written request for fast-tracking evaluation and approval of new product or new indication for a product that is already registered	Contribute data on safety and effectiveness of new medicine or treatment regimen, as gathered through programme monitoring	As soon as decision is taken to adopt the new treatment regimen (if the product is not already approved for marketing)
Ministry of finance (health budgets)		Provide information on the cost-benefit of the new treatment regimen	Provide updates in regular reports on budget implementation	As soon as a decision is taken to adopt a new treatment regimen

Stakeholder organization, group or individual	Potential role in new tool introduction	Engagement strategy	Follow-up strategy and plans for feedback or continued involvement	Timing of engagement
Political sector				
National policy-maker	Catalyse high-level political will and commitment	Approach through leadership structure (e.g. the Prime Minister or President) or known health champions Involve in a key stakeholder meeting	Hold regular briefings (2–4 times per year) to update key leaders on progress and challenges	As soon as decision is taken to adopt a new treatment regimen
Municipality	Finance and support programmatic change	Have local representative of NTP meet with municipal leadership	Update local leadership at monthly council meetings	When plans are being developed to phase in the new treatment regimen
Commercial sector				
Manufacturer	Manufacture new treatment regimen Finance and conduct marketing and promotional activities to encourage uptake of new treatment regimen	Clearly define and distribute (publish) desired timing of change; manufacturing process and tender requirements Include in procurement document, a requirement for marketing support	Meet with current and potential interested manufacturers Facilitate contact with WHO prequalification process and GDF	As soon as decision is taken to adopt a new treatment regimen
Supplier	Manage supplies for phase-in/phase-out of new/old treatment regimens	Develop joint plans for phase-in of new treatment regimen and phase-out of old treatment regimen Provide reliable estimates of product requirements (for both phase-in and phase-out)	Hold regular meetings with current and new suppliers to ensure smooth transition of product	As soon as a decision is taken to adopt the new treatment regimen
Service providers				
Service delivery nongovernmental organization (NGO)	Operations research to understand implications for staff training, logistics and patient education Eventual adoption and implementation Post-introduction surveillance	Provide scientific evidence for new regimen Meet with senior management to discuss potential role, assess opportunities and constraints, and clarify expectations on both sides	Regular feedback during meetings of TB technical working group	As soon as NTP management has decided to proceed with adoption of new treatment regimen

Stakeholder organization, group or individual	Potential role in new tool introduction	Engagement strategy	Follow-up strategy and plans for feedback or continued involvement	Timing of engagement
Other civil society target audiences				
Community-based group, home-based care (HBC)	Generate awareness among volunteers and patients Provide support to the sick – collecting medicines; observing treatment; identifying side-effects and referring to care; record-keeping Collaborate with patient surveys on attitude to new treatment regimen	Identify HBC groups in each region/district/ subdistrict NTP representative should call a meeting of HBC coordinators If they are not already engaged in supporting TB patients, explain nature of TB and why treatment is crucial Explain purpose of new treatment regimen and how it differs from old Ask if they would be willing to engage in the retooling process and explain what would be required Provide guidelines on what they need to do for the process (identification of patients; research; support to sick) and how they link with NTP (contact at local health facility or with district TB representative) Provide supplies required (research materials, stationary, etc.)	Periodic assessment and evaluation Regular meetings and updates Sharing of experiences during forums and conferences	When government has taken a decision to conduct a clinical trial with the new treatment regimen During research phase to assess feasibility of adoption Throughout adoption process As soon as supply of new treatment regimen is assured
Patient organization	Involve people living with TB in clinical research or operational research trial May help recruit people to trials and support them Members who have been involved in trials may also become advocates for new regimen	As for HBC groups	Review of reports sent in Follow up meetings at district/ subdistrict/health-centre level with HBC coordinators to assess whether desired role is being fulfilled and to ensure any required materials are available	When government has taken a decision to conduct a clinical trial with the new treatment regimen During research phase to assess feasibility of adoption Throughout adoption process As soon as supply of new treatment regimen is assured
International donors				
Global Fund country coordinating mechanism (CCM)	Endorse request to the Global Fund to include new treatment regimen in procurement plan and budget realignment to provide for associated training and patient education	Arrange for international expert to present scientific evidence for new treatment regimen at CCM meeting Approach key CCM members individually to inform and obtain support	Provide routine reports on progress of adoption and scale-up as part of Global Fund project reporting	As soon as it is anticipated that the new treatment regimen will be adopted, to ensure that funds will be available to support implementation
Bilateral aid agency	Funding of the introduction and scale-up Influence on policy decisions (government willingness to adopt new tool)	Provide scientific evidence base and any cost-effectiveness analysis	Engage in policy discussions Share evidence from trials Understand planning/budgeting cycle and provide proposals one year before funding is required	Initiate discussions at least one year before new treatment regimen is to be introduced to enable budgeting

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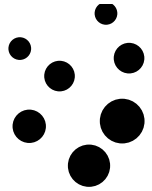
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RETOOLING
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