

RETOOLING TASK FORCE

MEETING REPORT

PURPOSE OF THE MEETING: Status of the retooling task force's work plan for the year 2008

VENUE AND DATE: 15-16 January 2008, Crowne Plaza Hotel, Geneva, Switzerland.

PARTICIPANTS

RTF members Present

Mohamed Abdel Aziz, Rachel Bauquerez, Saidi Egwaga, Uli Fruth, Michel Gasana, Christy Hanson, Jean-François de Lavison, Barbara Laughon, David Lee, Vinand Nantulya, PR Narayanan, Ikushi Onozaki, Phillip Onyebujoh, Andrew Ramsay, Guy Stallworthy, Javid Syed, Francis Varaine, Karin Weyer, Jennifer Woolley

The RTF was pleased to welcome 2 new members to the Task Force: Dr PR Narayanan, NTP Manager in India and Michel Gasana, NTP manager in Rwanda.

RTF members Absent

Gillian Mann, Davide Manissero, Robert Matiru, Malebona Matsoso, Rosalind Vianzon, Nicole Schiegg,

External participants Present

Léopold Blanc, Isabelle Burnier, Marcos Espinal, Haileyesus Getahun, Mario Raviglione, Giorgio Roscigno, Mahnaz Vahedi, Diana Weil.

1. Introductions and Welcome

The Chairs welcomed all members of the Retooling Task Force (RTF) who were able to attend the meeting.

Marcos Espinal, Executive Secretary of the Stop TB Partnership, opened the meeting. He stated that we will not achieve the TB targets with the current tools available. New technologies are necessary to reach all the objectives established in Global Plan to Stop TB 2006-2015.

For the next six months, as diagnostics are already becoming available, Dr Espinal encouraged the RTF to prioritize diagnostic issues. Lessons learned from the recent Lesotho success story experience can be an opportunity for the RTF to build on. In addition, he reminded the RTF that the new drug-resistance surveillance report will be launched in February. The report will highlight the urgent need for new diagnostic tools especially at country level.

Dr Espinal reiterated the support from the Coordinating Board to the RTF and wished the task force a productive meeting.

2. Adoption of the agenda

The agenda was adopted.

3. Review of the recommendations from Cape Town and decisions on next steps

3.1 Consensus on definitions for adoption, introduction and implementation

David Lee of Management Science for Health (MSH) proposed definitions for adoption, introduction and implementation used in the retooling terminology as requested in the Cape Town forum. The RTF reinforced the fact that the definitions should target the NTPs but should also include the other stakeholders. It is imperative that the definitions are valid for both public and private sectors.

It was agreed that "Adoption" defines the notion of "evaluation and decision", "Introduction" describes the notion of "preparation" and "Implementation" identifies the "on going work".

The following definitions have been approved by the RTF:

Adoption

A 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.

Global and/or country policy decision to adopt a new and improved health technology follows an analysis of benefits, risks, and costs of the health technology and the health system's capacity to finance, manage and ensure its sustainable access and appropriate use. Communication of recommendations and policy decision is undertaken before introduction and implementation.

Introduction

The set of *coordinated activities* that is carried out to prepare for effective and sustainable access to the new and improved health technology.

Global and/or country introduction includes ensuring appropriate new technology regulation and registration, preparing phase-in/phase-out plans for procurement and logistics management, revising guidelines, tools, & training materials, financial resource mobilization, initiating staff training and advocacy, communication, social mobilization activities.

Implementation

The activities that put into effect the policy and monitor and evaluate the progress of these activities and the impact on tuberculosis control.

Implementation activities include the execution of a phase-in/phase out plan, on-going technical programme and supply management procedures, and monitoring and evaluation of programme implementation and new health technology performance.

Action items:

- Disseminate the definitions through the retooling website.
- Insert the definitions in the diagnostics checklist and the stakeholder engagement plan and use the definitions in future publications.

3.2 Discussion of the role of business sector in retooling

Jean-Francois de Lavison, current chair of the European Diagnostic Manufacturers Association (EDMA), presented some ideas for increasing the involvement of the private sector (PS) in retooling. He noted that during Coordinating Board (CB) meetings, the PS had the opportunity to meet some of the main partners of TB control and the Chairs and Secretaries of the working groups. He also highlighted a task force within EDMA that is focused on issues of retooling in developing countries.

Several innovations involving the PS were discussed, including:

- i) Organizing another meeting in May 2008, in conjunction with the next CB meeting, to facilitate the communication between the working groups, the RTF and some CEOs from the PS.
- ii) Identifying a focal point from different private sector companies to participate in relevant TB meetings. The private companies should include representatives of developing and low-income countries.
- iii) Working with the PS on innovative ways on how it can better support implementation and scale up at country level. It is also essential the PS is also engaged after sales and implementation.
- iv) Working with Business schools to develop different business models to accelerate retooling; Note: Guy Stallworthy of the Gates Foundation noted that his work on franchising may be able to explore some of these business model questions. He will report back to the RTF on progress.
- v) Investigating Advance Market Commitment (AMC) for TB tools
Note: It was agreed that Jennifer Woolley of Aeras, Christy Hanson of USAID, and Barbara Laughon of NIH would meet with Ruth Levine of Center for Global Development to discuss GAVI's work on AMC.
- vi) Request that EDMA consider how to provide information on how the PS engages in the absence of formal regulatory processes

Action Items:

- Participation of the retooling task force in a meeting between the WGs and the PS in May in Cairo to improve the dialogue between public health sector and business private sector. The list of the CEO present at the meeting will be provided to the RTF.
- Feedback on GAVI's role on AMC and guidance on the potential role of AMC for TB tools.
- Explore business models that can be used for TB/retooling.
- Follow-up on discussions regarding the regulatory issues for diagnostics (EDMA).

4. Vaccine and Drug focus: discussion of retooling priorities for next 6 months

Jennifer Woolley of Aeras and Uli Fruth, Secretariat of the Working Group on New TB Vaccines noted that in 2008, the priorities of the Working Group on New TB Vaccines related to Retooling include evaluating some of the economic aspects of new TB vaccines and initiating the development of target product profiles for new TB vaccines. On behalf of the WG, Jennifer and Uli requested RTF support to initiate development of target product profiles for new TB vaccines. The RTF reminded the New TB Vaccine WG that both the New TB Drug and New Diagnostics Working Groups undertook similar work¹ within their own workplans and agreed that this is not the mandate of the RTF. As done in other new tools WGs, the New TB Vaccine Working Group will also initiate the development of a "template procedure" for definition of product profiles based on existing experience (i.e. pneumococcal conjugate vaccine). Lessons learned from other vaccines programmes will be explored to evaluate if they could be valid for TB. Human resource needs are less likely to be a major issue for new vaccines, since the scheduled plan is to deliver

¹ The New TB Drugs Working Group has drafted an "Ideal TB Regimen Profile" that identifies basic requirements for drug development. For diagnostics, the Foundation for Innovative New Diagnostics (FIND) developed a "Customer requirement document" for each implementation level: health post, referral laboratory and microscopy level.

new TB vaccines through existing and future vaccination programmes. However, this can be modified depending on the product profile for Vaccines (i.e., pre or post-exposure, delivery mechanism, etc).

In response to a request from the Cape Town meeting for more accessible information on new tools, Jennifer reported that the Working Group is in the process of developing new materials for both global and country levels and requested assistance from the RTF to identify retooling community to receive this information and assistance in broader dissemination to this community. Specific audiences include product developers, national TB programmes and vaccine programmes, the private sector, donors and partners, and the implementation WGs. It was agreed that this need is not unique to the vaccine field. It is a need across the new tools and the RTF agreed that information dissemination should be a major focus of its activities in the coming months. The RTF will support the development of a strategic communications strategy, targeting various audiences and covering all pipelines. The communication strategy is described in more detail below.

Action items:

- Discuss with other vaccine development groups to understand their retooling experience, processes, successes and lessons learned.
- Contribute to the development of a communication strategy to disseminate information on new TB vaccines.

5. Implementation Working Groups

The RTF was pleased to note that retooling activities have been/are being incorporated into the workplans of the new tools WGs. However, more work is needed to clarify how retooling activities are relevant to the work of the implementation Working Groups. The RTF noted that it aims to also have retooling become an integral part of implementation. The RTF agreed to be more proactive in disseminating information to/through the implementation WGs and in working with these WGs to plan for retooling. In addition, the RTF agreed to become more involved in bringing retooling information to country level.

Action Items:

- Development of a communication strategy for the WGs and the countries, with full dissemination through the usual channels.
- Identify fora or set up meetings with the implementation WG chairs/core groups to introduce retooling and plan strategically for how the RTF can support their objectives, and how the WGs can take-up retooling issues in their plans.
- Initiate discussions with the TBTEAM to include the RTF in some review missions.

6. Field test the stakeholder engagement plan

Selection of countries should be based on those which planned to introduce liquid culture shortly. Tanzania and Rwanda showed their willingness during the meeting to be engaged in field testing. As retooling for liquid culture is in progress, it was proposed to include the engagement plan later in this process.

Action items:

- Finalize the engagement plan by including the Lesotho case study.
- Secretariat to check willingness of NTPs to undertake field tests in due time (proposed list of countries: Tanzania, Rwanda are in the process of introducing liquid culture - Others; Cambodia, Nigeria).
- Follow-up with the GLI where retooling for culture is planned with support from WHO (proposed countries: Côte d'Ivoire and Ethiopia).
- Define list of countries, which have already received money from the GF to initiate liquid culture implementation and target support for retooling.

- Translation of the stakeholder engagement plan in French (Rwanda, Côte d'Ivoire).
- Development of a cover letter explaining the background and purpose of the document.
- Propose a list of countries where the document will be tested, in conjunction with the on-going MDR-TB field testing.

7. Diagnostics-related needs as perceived by countries.

Dr S. Egwaga, NTP Manager from Tanzania, presented the retooling needs in the case of introduction of a new technology and also the adoption and monitoring process that the countries should follow. Dr Egwaga highlighted that introducing a new tool may have human resource, training, infrastructure, transport, maintenance and other financial and logistical implications. He encouraged the RTF to work with the new tools WGs to ensure that a comprehensive retooling 'package' is considered and made available to countries. He also highlighted the need to target stakeholders in the Ministry beyond the NTP and to include the private sector.

The RTF was asked to better advocate and promote available TB technologies in the pipelines to countries. WHO's role within the partnership is to make sure that countries know new technologies are available. As not only NTPs are needed to implement new technology, clear coordination at country level is needed. This will involve decision-makers across different teams.

Action items

- Better advocate and promote TB pipelines developed by the WGs, at country level.
- Disseminate the checklist with the stakeholder engagement plan to the relevant entries: NTPs, MoH and academic institutions for further disseminate.
- Development of a letter of recommendation to be included with the sending of the document.
- Work with new tools WGs to revise product profiles to include the operational considerations; i.e. a full package of information about the requirements for implementing a new tool.

8. Role of WHO in promoting policy change and retooling - Lesotho case study

Dr M. Raviglione, Director of the Stop TB Department, provided an overview of the role of WHO and its advisory body (STAG) in retooling. Specifically, he defined the evidence requirements and processes needed prior to the consideration of policy recommendations by STAG for any new or improved diagnostics technologies.

Dr Raviglione also presented the Lesotho case study, where liquid culture has been successfully introduced, showing the great value of a partnership work, including the Ministry of Health, WHO, Partners in Health, FIND and TDR. WHO emphasized the need to focus on the benefit of the use of the technology, and not on the product itself. Success stories with solid examples of partnership and strong benefit to the patients should be publicized.

It was highlighted that the retooling process has weak points in the chain such as the lack of regulatory authorities for new diagnostics. This was discussed by the RTF members who agreed that this is beyond the mandate of the RTF.

Action items:

- Develop and disseminate concise information on the process for seeking and gaining endorsement of new tool by STAG / WHO.
- Promote the policy process developed by WHO.
- Identify the entry point (e.g. WHO?) for product developers to share information on new tools and seek consideration of their evidence.
- Refer the absence of any global diagnostics regulatory authority to WHO for consideration of next steps.

9. Diagnostic checklist: discussion on dissemination plan

For the diagnostics checklist to be useful for countries (e.g. to facilitate retooling for liquid culture), it needs to be presented as part of an overall retooling package that supports policy changes, implementation considerations, and stakeholder engagement. At the same time, the role of the diagnostics checklist should not be overemphasized; i.e. it is not a laboratory strengthening tool, but it has implication for quality. NTPs will play a key role for a broad dissemination, which will help to reach all stakeholders to lead to greater sense of partnership, including public and private laboratories. The RTF agreed that the checklist must be disseminated in conjunction with other RTF tools and links to technical assistance.

Action items:

- Development of a cover letter explaining the background and purpose of the document.
- Provide the checklist to the NTPs and TB focal points.
- Development of a cover letter to be attached to the diagnostics checklist.
- Develop a two page document to include retooling in the GF planning framework (SDA 1.5 Management and Supervision and 1.2 Diagnostic).
- Define list of countries, which have already received money from the GF to initiate liquid culture implementation.
- Present one pager about RFT at PEPFAR meetings.
- Launch country-level retooling pilots.

10. TBRM and Retooling

During the last retooling meeting, the task force's members welcomed the creation of the TB Research Movement (TBRM) and proposed a meeting with TBRM to discuss collaboration between the RTF and the TBRM. However, as the TBRM is in transition, the RTF has not had the opportunity to setup a plan of action with the TBRM. During the coming months, the RTF's members wish to liaise closely with the TBRM to ensure that the action plan of the TBRM takes into account research needs related to retooling. In the meantime, the RTF's members request that TDR and others conducting research related to retooling continue to update the RTF on this work.

Action item:

- Hold a discussion between the Stop TB Partnership, RTF and TDR to define research priorities in support of retooling and a process for promoting the completion of this research agenda.

11. WHO Global Survey and Retooling

WHO is collecting and analyzing TB data on an annual basis through a very comprehensive survey. With the arrival of new diagnostics technologies, the RTF would like to include retooling indicators in the next annual WHO Global Survey.

In this purpose, the RTF developed the following three indicators:

- a. Is your country preparing with partners to introduce any new tools?
- b. In the past 2 years (or in the fiscal years..), was your country involved in a formal evaluation or analysis of a new and improved technology/strategy?
- c. Does the introduction of a new diagnostic tool require regulatory approval?

Action item:

- Initiate discussions with the WHO/TME team to include the following retooling indicators in the annual country questionnaire.

12. Consideration for other technologies for retooling

Francis Varaine of MSF gave an overview of the existing TB diagnostics technologies that have already been adopted or are under evaluation by MSF. The process of retooling within MSF appears evidence-based and rapid. The RTF expressed interest in learning more about how evidence is considered and the field experiences of MSF in retooling

Action items:

- Learn from MSF the process they use to introduce existing tools.
- Ask the New TB Diagnostics Working Group to follow-up with MSF and the core group as they consider the information to be included in product profiles and standard product evaluations.