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MDR-TB scale-up workshop, 4-5 February 2010



Facilitator report
12 February, 2010

Facilitator report on the MDR-TB workshop held in Geneva on 4 and 5 February 2010

BACKGROUND AND CONTEXT

MDR-TB is a major and growing problem in the world. It is also a complex problem, and scaling up the world's capacity to diagnose and treat MDR-TB is challenging: diagnostic capacity issues (including drug sensitivity testing materials, labs, and reference labs) drug issues (including the right combinations of therapies, demand forecasting, procurement, quality and pricing), project and programme level capacity and human resource issues, and of course funding issues must all be solved simultaneously if countries are to scale-up their response effectively.

Alongside countries, many international organisations are involved in scale-up. Most feel that progress in scale-up needs to be faster than it is today, for example in order to meet the objectives set in Beijing and further discussed at the Pacific Health Summit in 2009. There is ongoing debate on how exactly to make this happen: a first workshop on this topic was held in October 2009, and this workshop follows on directly from that. Appendix 1 provides a list of participants.

WORKSHOP OBJECTIVES, AGENDA, AND APPROACH

The objective of this workshop was to build consensus on four issues:

1. The problem statement and objectives for scale-up of MDR-TB management
2. Strategy
 - What is required for countries to scale up
 - What the main barriers preventing this are
3. Organisation
 - What international support model is required to help countries overcome these barriers –and what does this imply for changes to the existing support model
 - How international efforts should be coordinated

4. What will happen after this workshop in terms of concrete actions?

Participants discussed and agreed on these objectives. The workshop agenda was adjusted during the course of the two days to better meet the needs of the debate and discussion, and the final version is shown below.

Agenda

Thursday		Friday	
Time	Agenda item	Time	Agenda item
0900 – 1000	<ul style="list-style-type: none">▪ Opening▪ Summary of interview findings	0830 – 0930	<ul style="list-style-type: none">▪ Review agenda▪ Proposed new model<ul style="list-style-type: none">– High-level assumptions / “commandments”– Proposed model– Specific functions– Other design questions
1000 – 1230	<ul style="list-style-type: none">▪ Country scale up model▪ Barrier analysis	0930 – 1100	<ul style="list-style-type: none">▪ Small-group problem-solving on contentious elements of the proposed new model
1330 – 1730 (with break)	<ul style="list-style-type: none">▪ “Clean sheet design”	1115 – 1300	<ul style="list-style-type: none">▪ Presentation of modifications to model and debate▪ Recap of agreements▪ Coordinating the international support model
1730 – 1800	<ul style="list-style-type: none">▪ Day 1 recap	1400 – 1700	<ul style="list-style-type: none">▪ Review and agreement on next steps: action, who is accountable, deadline
		1800	<ul style="list-style-type: none">▪ Closure

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The approach for preparing and facilitating the workshop included several elements:

- ¶ Pre-workshop interviews with participants to understand key issues and to subsequently test proposed workshop design and approach
- ¶ “Directive” facilitation of the workshop, with facilitators providing frameworks and draft starting points to discuss key issues
- ¶ Participants joining the debate as “TB leaders” rather than as representatives of their organisations, and also not discussing existing organisations (e.g., GDF, GLC) for the first day of the workshop
- ¶ The use of “Consensor”, an anonymous voting tool, to gauge participant views on particular propositions (e.g., degree of agreement with the conclusions reached at the end of a discussion) or to decide which issues to discuss in more depth.

SUMMARY OF INTERVIEW FINDINGS AND DISCUSSION

To prepare for the workshop, the facilitators conducted at least one (and usually two) in-depth discussions with participants to better understand their views on the objective of scale-up, the issues that needed to be discussed, and possible solutions. Although a few interviewees subsequently could not attend the workshop, and a few participants could not be interviewed in time, these interviews laid a solid foundation for the workshop and the topics covered.

Appendix 2 lays out a high-level summary of interview findings, which were subsequently tested with participants using Consensor (also in Appendix 2). The results of this Consensor session were well aligned with pre-workshop interview findings, notably:

Areas of general agreement:

- ¶ Participants have good intentions and want a good workshop outcome
- ¶ The current support model for scale-up needs major change
- ¶ The need for clearer accountabilities, better coordination, and stronger operational capabilities to enable scale-up

Issues with mixed views –requiring further discussion:

- ¶ The degree of clarity on what countries need for sustainable MDR-TB management
- ¶ The main barriers to scale-up
- ¶ The model for and degree of coordination of international support

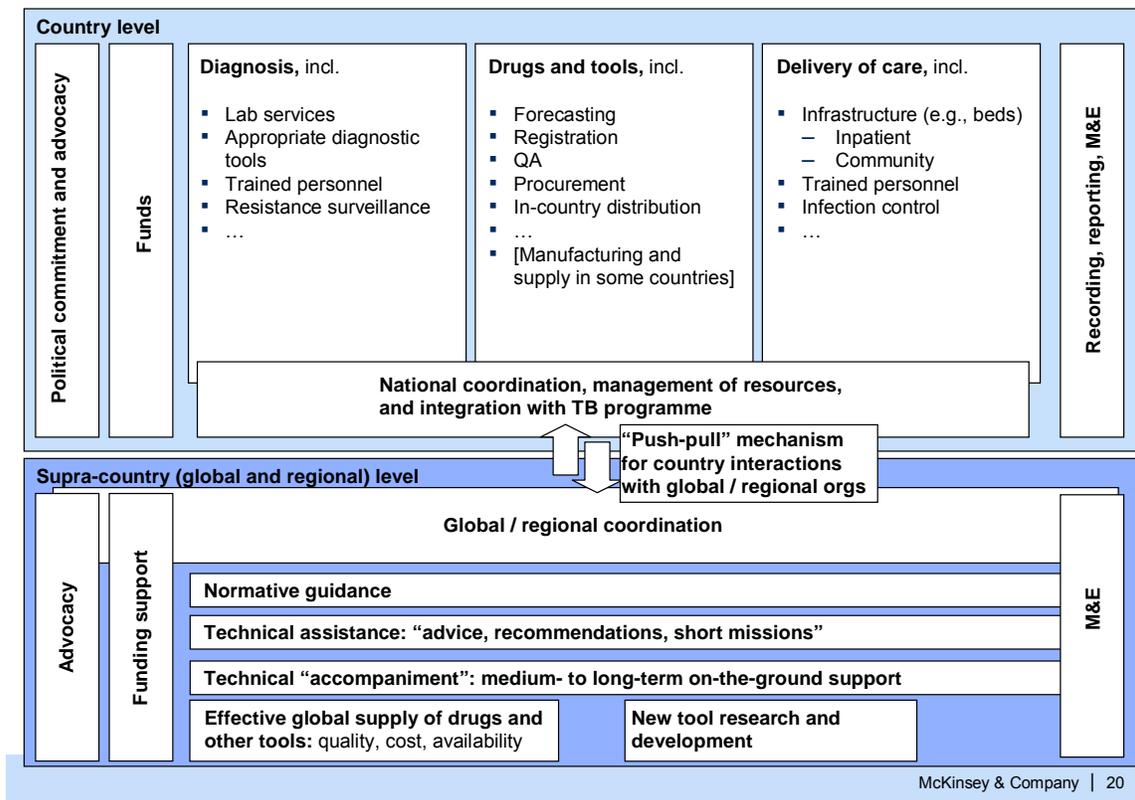
This discussion provided the opportunity to clarify terminology and the scope of the discussion: participants agreed to limit scope to “MDR-TB management”, which includes finding and diagnosing MDR-TB patients, notifying relevant authorities, and providing appropriate curative treatment. It was agreed that prevention of MDR-TB would be out of scope for this workshop –though clearly important.

The discussion also reaffirmed the vision of universal access to MDR-TB management, and almost all participants agreed that the 2015 targets set in Beijing, if achieved, would represent an outcome that they would be happy with.

COUNTRY SCALE-UP MODEL AND BARRIER ANALYSIS

The facilitators presented a draft model for “what would need to be in place for a country to manage MDR-TB effectively and sustainably”. This model was debated and adjusted to reflect the outcome of the discussions. The final model, which met with general agreement, is presented below:

What is required for countries to manage MDR-TB sustainably



Using this model, participants debated the *main* barriers to scale-up, with the test for main barrier being: “if all other barriers were removed, would this issue still be a barrier?” The six main barriers agreed were:

Country level: (1) weak political commitment (incl. advocacy), (2) low funding, (3) poor national coordination and management. (+ HR constraints in some countries)

Supra-country level: (4) poor coordination of global players, (5) weak supply mechanism for drugs and other tools

Country – supra-country interaction: (6) weak pull-push mechanisms and structures

Barriers (1), (2), and (3) were then discussed in greater detail. Participants were divided randomly into three sub-groups and asked to conduct a “clean sheet” redesign: describing the barriers, assuming no existing international organisations, and designing the international support that could help countries overcome these barriers. Sub-groups then presented their proposals in plenary, where these were debated. These debates generated a number of ideas about what the international support model would need to do, which fed into the materials for the second workshop day. Examples (non-exhaustive) of these ideas include:

Political commitment and advocacy:

- ¶ Greater focus on country leadership, beyond Minister of Health, with advocacy conducted by people who would be peers to those targeted
- ¶ Greater support for in-country patient activists and physician-activists

Funding:

- ¶ Demonstrating the lower total cost of early management of MDR-TB compared to waiting and treating when prevalence has increased

National coordination and management

- ¶ Creating incentives (e.g., performance transparency, recognition, support) to improve national coordination and management of resources
- ¶ Better aligning supra-country support models to reduce the administrative burden on national programmes, which are resource constrained

DAY 1 RECAPITULATION

At the end of day 1, most participants recognised that discussions were taking place in a constructive environment, and that progress was being made. Many were concerned that the pace of the discussions would need to be faster if we were to debate and resolve all the outstanding issues by end of day 2. Participants then asked for even more directive facilitation and provided a list of specific questions that they would like to see solved by the end of the workshop. These are laid out below:

10 issues that you want to address

1. What to do about non-GLC patients / countries?
2. How to provide quick assistance to countries asking for help?
3. How to stimulate more commitment at country level?
4. What are the complaints from countries that we need to address better?
5. What is the right balance of implementation quality vs. numbers treated?
6. How can we better tailor our response to the local context?
7. Do we need better / different “policing”?
8. What are the “10 big things / commandments” to turn the tide?
9. Do we need the GLC?
10. How to include the HBCs in the design and decision making process?

...+ 6 that we had raised: country ownership, normative guidance, programme quality accreditation, threshold for drug quality, sequencing, and accountability for support



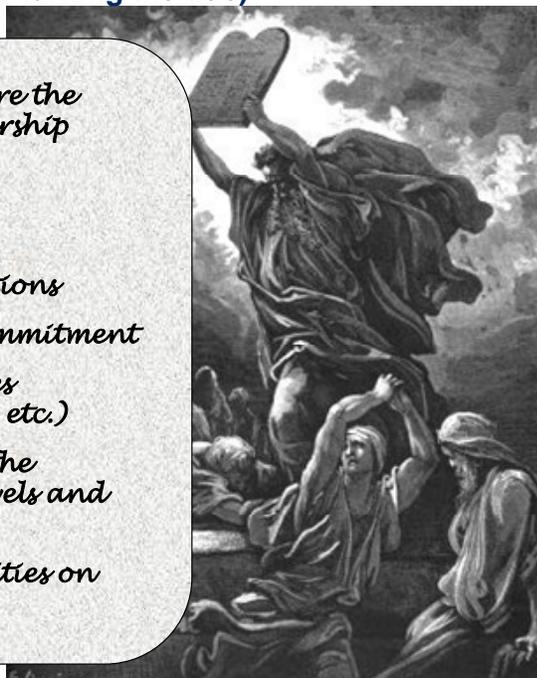
PROPOSED NEW MODEL FOR INTERNATIONAL SUPPORT

Building on the day 1 discussions, and responding to workshop participants' request for an even more directive approach that would ensure key issues were tackled in day 2, the facilitators built a proposed draft for what the international support model should look like to help countries accelerate scale-up of MDR-TB management. In order to further facilitate the debate, the high-level assumptions and specific design choices driving the model were also made explicit.

The high-level assumptions were debated, modified, and agreed as below:

High-level assumptions underlying the proposed new model (The “big things / commandments” for turning the tide)

1. *True needs of MDR-TB patients are the focus of all actions by the Partnership*
2. *Create choices for countries on management and scale-up*
3. *Use a pull + push mechanism for country - supra-country interactions*
4. *Drive higher level of political commitment*
5. *Offer integrated support packages (the tools, TA, “accompaniment” etc.)*
6. *Coordinate intensively between the global, regional and country levels and between TB and MDR-TB*
7. *Confirm leadership accountabilities on global and country level*



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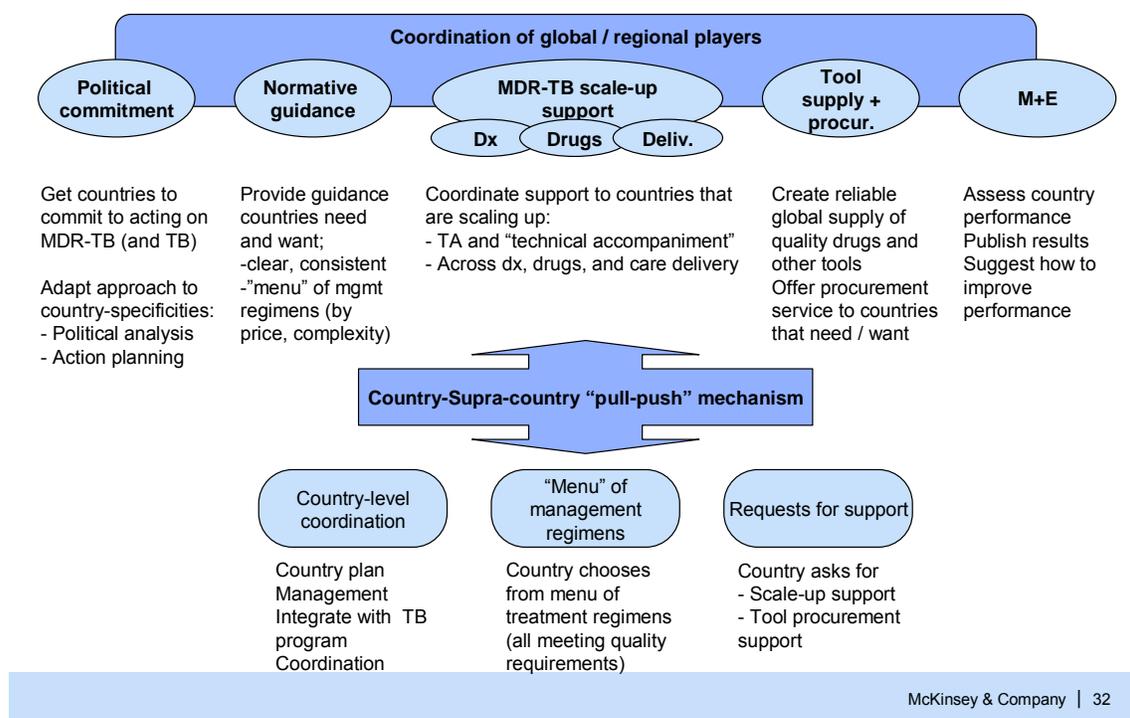
The first three assumptions reflect the necessary commitment of international organisations to engage with all countries trying to scale up MDR-TB management, to help them with their challenges –even if these countries are not currently pursuing the ‘most technical correct’ scale-up approaches, and to try to guide them towards better and better MDR-TB management. While this is, on one level, uncontroversial and clear, there was a view amongst some participants that this was not how international support was currently perceived by countries: categorization

of countries as “GLC or non-GLC countries” being one example. It was important, therefore, to assert these assumptions explicitly in the design of the model.

Assumptions 4 to 7 then inform how the international support model acts and is coordinated.

The proposed model, summarised in the figure below, was presented, and each function explained, making the design choices for each function (not shown here) also explicit. The elements of the model are *functions* not structures or organizations.

Proposed model: overview



The main differences between this proposed model and the existing international support architecture were summarised as follows:

- ¶ A more effective “pull-push” mechanism to allow a richer debate between countries and international organisations on countries ‘wants’ and ‘needs’, resulting in tailored international support which responds to country ‘wants’ and ‘needs’ and also urges, incentivises, and supports countries to improve MDR-TB management, based on M&E “rating” (see below)

- ¶ A powerful function to help increase country political commitment –not just to conduct advocacy—with sufficient resource to conduct country-specific political analysis and action planning
- ¶ A fundamental shift in the role of M&E and technical support, towards a more support, “rating” countries performance on MDR-TB and encouraging and supporting them to work to improve their rating

Using Consensor, participants all agreed or strongly agreed with the high-level model presented. Each function was then discussed in turn, and the level of agreement assessed by Consensor:

- ¶ *Political commitment*: proposal agreed to by 18/20 voters, with the design option to decide the goal and intensity of scale-up support on a country-by-country basis as a function of that country’s level of political commitment, recognising that without political commitment, sustainable scale-up would be challenging
- ¶ *Normative guidance*: proposal agreed by majority of voters
- ¶ *MDR-TB scale-up support (across diagnostics, drugs, and care delivery)*: the main debate here was on whether international partners should be accountably “narrowly” for their own work (e.g., scale-up of diagnostic capacity) or “broadly” for their work *and* for the final outcome (i.e., number of patients treated for MDR-TB). The majority of participants supported the function and “broad” accountability (15 agree, 2 disagree, 3 no opinion/unsure)
- ¶ *Tool support and procurement*: while there was good agreement on the goal of this function (improve access to drugs and other tools for countries who need/want to access global supply), there was less agreement on how best to do this. Specific questions included the quality of drugs that would be offered and the mechanisms that would lead to best prices for these drugs and other tools. This function was thus selected for further debate
- ¶ *Monitoring and Evaluation*: the broad agreement here (17/20) was to replace the current binary system (Green Light or none) with an evaluation approach that provides a ‘rating’ for countries, makes that information visible, and encourages and supports countries to improve their ‘rating’. This has implications for GLC, which were further debated
- ¶ *The Country-Supra-country “pull-push” mechanism*: the three elements of this “pull-push” function were agreed, and the question for debate was on how strong the coordination of supra-regional coordination should be

- ¶ *Global / regional (supra-country) coordination:* Participants were mostly in favour of an “Air Traffic Control” model which makes the country activities of international organisations visible to all and helps them to coordinate, and also identifies potential coordination problems, flags them for resolution by parties involved, and where required, escalates the issue to the STB Coordinating Board for resolution

Having agreed the general shape of the model and the non-contentious functions, participants then agreed four functions that required further debate, which took place in sub-groups and in plenary. These were (1) the “pull-push” function, (2) the global tool supply function –focusing on drugs, (3) country-level coordination, and (4) implications for the GLC (initiative, mechanism, and committee). The results of these debates, including both sub-group and subsequent plenary discussions) are captured below.

1- Country-supra-country “pull-push” mechanism

The fundamental goals of this mechanism were re-affirmed: simplifying interactions, improving responsiveness to country wants and needs, and tailoring international support. The main elements included:

- ¶ Reforming the current functions of GLC into a global approach that (i) rates or ranks countries’ performance on MDR-TB management, (ii) offers appropriate technical assistance to improve this rating / ranking, and (iii) does the above on a more decentralized (e.g., regional) basis
- ¶ Supporting countries in expanding beyond pilot mode
- ¶ Providing incentives for countries to adopt and share successful approaches to scale-up

Many of these issues were reviewed in the plenary session on GLC

2- Tool support and procurement

The sub-group began by discussing and agreeing on relevant terminology for drug quality and which terms were clearly and objectively defined (e.g., WHO-PQ, SNRA, “Interim Approval”) and which were not (“strict” regulatory authorities). This allowed the discussion to continue using a shared and commonly understood lexicon.

The sub-group then agreed on three questions to be address, and developed proposals for each, as follows:

(a) How to help countries assess the quality of drugs they purchase / use? Four options proposed to address this:

- ¶ Expansion of national and regional capacity for quality control
- ¶ A project to map the quality of MDR-TB drugs currently in use
- ¶ A project to measure cure rates achieved with different drugs (to confirm that high-quality drugs do indeed have better cure rates, in response to country challenges on this topic)
- ¶ White list and black list for drugs and manufacturers

Implicit in all of these options is the recognition that many countries are already purchasing second-line drugs and scaling up their programs as they see fit. It is important therefore to make it explicit that the international community recognises and accepts this, and that it will help all countries.

(b) What level of quality is appropriate to maintain as minimum standards for global supply mechanisms such as GDF? After debating the terminology, the sub-group agreed that only the following drugs should be used for a global supply mechanism:

- ¶ WHO-PQ and SNRA-approved drugs
- ¶ Drugs on the “Interim Approval” pathway

(c) What type of global supply mechanism would best be able to supply the above quality drugs at low prices and good availability? The sub-group explored a range of possible options here, including

- ¶ Intentionally creating a supply oligopoly and working closely with it
- ¶ Tendering for treatment regimens rather than for individual drugs
- ¶ “Rating” procurement agencies so that countries can choose from a range of “approved” procurement agencies to work with
- ¶ Funding an ‘advanced purchase commitment’ for second-line drugs
- ¶ Forecasting global demand for second-line drugs
- ¶ Building and maintaining a stockpile of second-line drugs

After debating these options, the sub-group agreed that there was not enough information available on the supplier landscape and the market dynamics of second-line drugs to offer a fact-based recommendation on which option to

pursue. For example, it was clear that a ‘stockpile’ would likely “waste” drugs as it continually renewed its stock. But would the stockpile’s guaranteed demand help lower prices enough to outweigh the cost of the “waste”?

The sub-group then agreed that an analysis of the supplier landscape would be required to choose the right option. This analysis should not be a “boil the ocean” effort lasting a year, but rather a focused one that (i) tests for particular hypothesis (e.g., stockpile or not) and (ii) also identifies short-term solutions that can be implemented in time to serve the larger number of patients who are being diagnosed via the diagnostics scale-up effort.

3- Country-level coordination

This sub-group debated different options for improving the in-country coordination of international partner activities, and developed an approach which includes:

- a) Standardized approach to identifying country needs through a questionnaire-template and an outside-in needs assessment (building on the Monitoring and Evaluation ranking scheme)
- b) Identification of a country focal point in the Partnership to serve as main contact for the recipient country stakeholder
- c) Identification of the recipient country stakeholders (e.g.; NTP, Minister of Health)
- d) Definition of a standardized country action plan, using a “menu-based” template covering the full range of country actions in which the actions can be defined based on identified country needs (see (a)), ownership and timing
- e) Monitoring and evaluation of country successes based on (a) and (d); reporting of best practices to the global Monitoring and Evaluation team.

4- Implications for GLC initiative, mechanism, and GL committee

In plenary session, the group recognised that the model above, proposed and broadly agreed, did not explicitly have a “GLC”, thought it did have the four functions of the current GLC:

1. Assessment/evaluation/approval/“greenlighting” (exact term debated) ...represented as “assess country performance” under the M&E function
2. Input into normative guidance
3. Monitoring and evaluation

4. Coordination of technical assistance

Consequently, participants then discussed at length the implications of moving to this model for the GLC *as it is today* –recognizing the original purpose of Green Light Committee and its evolution to this day. Specific elements of the debate included:

- ¶ Should countries be “assessed/evaluated/greenlighted” at all?
- ¶ Should countries be “assessed/evaluated/greenlighted” before receiving international donor support for scale-up? If yes, who does perform this function: donors themselves or another body, on behalf of donors?
- ¶ Which of the four “GLC” functions should happen at global vs. regional level?

Further debate and discussion led to a broad consensus, which we summarize:

- ¶ The nature of the efforts of the Partnership on MDR-TB scale-up should explicitly shift from a *controlling* to a *supporting* mode
- ¶ The fundamental role of the M&E function should therefore be to *support* country scale-up efforts. The M&E function should devise and use a system for “rating” countries’ scale-up efforts using a standardized scale – and explicitly move away from a binary system (Green Light or not)
- ¶ Donors will continue to want an “independent technical expert opinion” on the technical merits of scale-up applications they receive from countries as part of their decision-making process. They would prefer to seek this expert opinion from a consistent global body, rather than to each form their own separate technical review panels. Therefore a secondary role of the M&E function would be to use its ‘rating’ approach to perform this service for donors –with the expectation that over time, as more countries scale up effectively and sustainably, the need for this secondary role will decrease
- ¶ This M&E function could be decentralized (e.g., to the level of WHO regions). Decentralization could have two major benefits: it would increase total global capacity for M&E, and it would allow the function to be conducted by experts who are closer to the countries they are working with and thus would have a better sense of the issues at hand. It could also have downsides, including inconsistencies in approach across different regions. Therefore, the process of decentralizing this function would need to be carried out gradually and with care. This process would include:

- (a) ensuring that M&E processes are well-designed and working well at the global level before they are decentralized
 - (b) ensuring consistency of M&E and “rating” approach between regions
 - (c) ensuring clear organizational accountability (e.g., would the regional M&E function be an advisory body to WHO, as GLC currently is?)
 - (d) determining the roll-out path (e.g., decentralize to one region every three months)
- ¶ The other GLC functions then get mainstreamed into their corresponding functions in the new model –Normative Guidance, MDR-TB Scale-up Support, and Tool Supply/Procurement

CONCLUSIONS AND NEXT STEPS

Participants agreed that the model described above, with the further specifications on particular functions and on the changes to GLC, was a good base from which to proceed, with the goal of having the new international support model fully functional by the end of 2010.

Facilitators then raised the question of accountability for taking this work forward. Mario Raviglione volunteered to coordinate the overall effort, and to set up the next meeting of this group, via teleconference in ~ 6 weeks. Task forces were then set up to take forward the issues raised in this workshop. Further task forces will likely need to be set up, once the overall transition plan is developed.

Task forces, owners, and main tasks were agreed as follows:

MDR-TB Scale-up Support function (Paul Nunn)

- ¶ Define spectrum of services and “minimum standards”
- ¶ Assess pros and cons of global vs. regional support model and make recommendation
- ¶ Create templates to identify country needs and actions taken

Tool Supply and Procurement function (Tom Moore and Bernard Fourie)

- ¶ Make recommendation on best option to help countries assess drug quality
- ¶ Create terms of reference for a focused analysis of the supplier landscape for second-line drugs (this may also include analysis of current level of drug quality and current cure rates, as discussed in the sub-group)
- ¶ Identify short-term opportunities to improve global supply of quality drugs, in light of MDR-TB diagnostics scale-up

Monitoring & Evaluation function (Ernesto Jaramillo) and GLC transition (Kitty Lambregts) [facilitator note: combined, because interlinked]

- ¶ Design criteria for rating country MDR-TB performance, and define rating scale
- ¶ Redefine the activities of the M&E function with respect to its fundamental role (rating countries to help them scale up) and its secondary role (providing an independent expert opinion to donors evaluating country applications for scale up –currently provided by)

- ¶ Assess the advantages and disadvantages of decentralization of the two M&E roles, and if deciding on decentralization, develop a road map that addresses the issues raised in the sub-group discussion
- ¶ Define the transition model from the current GLC to the future model, including communication planning

There was considerable discussion on the role of appropriate incentives in making the new model work effectively. The collective decision was to allow each of the above task forces to first work independently on incentives for their particular function, and then to review these and decide if an overarching ‘incentives’ task force is required.

CLOSURE OF THE WORKSHOP

The Consensor tool was used to answer anonymously two questions:

1. Do we agree that we have achieved the objectives of the workshop?

Strongly agree	6
Agree	11
Don't know	4
Disagree	2
Strongly disagree	0

2. Are we happy with the decisions we have taken?

Strongly agree	3
Agree	8
Don't know	5
Disagree	0
Strongly disagree	0

Appendix 1: Workshop participants

Workshop participants

	First name	Surname	Role	Organization
1	Mohammed	Abdel Aziz		Global Fund
2	Amy	Bloom	Participant	US Agency for International Development (USAID)
3	Jeremiah	Chakaya	Chair of the DOTS Expansion Working Group	Kenya Medical Research Medicine (KEMRI)
4	Peter	Cegielski	Participant	Division of TB Elimination, US CDC
5	Bernard	Fourie	GDF Business Advisory Committee	Medicine in Need (MEND)
6	Myriam	Henkens	GLC Member	MSF International
7	Kitty	Lambregts	Chair – MDR-TB Working Group	KNCV Tuberculosis Foundation
8	Carole	Mitnick	Participant	Partners in Health
9	Lisa	Regis	TB Portfolio manager	UNITAID
10	Owen	Robinson	Coordinator Clinton HIV/AIDS Initiative	Clinton Foundation
11	Paul	Thorn	Vice-Chair - MDR-TB Working Group	TB Survival Project
12	Léopold	Blanc	Coordinator - TBS	WHO
13	Mirtha	Del Granado	WHO/AMRO TB Regional Adviser	WHO
14	Wieslaw	Jakubowiak	GLC Secretariat	WHO
15	Ernesto	Jaramillo	DR-TB team	WHO
16	Pierre-Yves	Norval	TBTEAM	WHO
17	Paul	Nunn	Coordinator - TBC	WHO
18	Mario	Raviglione	Director - STB	WHO
19	Karin	Weyer	Coordinator - TBL	WHO
20	Marcos	Espinal	Executive Secretary	Stop TB Partnership
21	Kaspars	Lunte	Global Drug Facility	Stop TB Partnership
22	Thomas	Moore	Global Drug Facility	Stop TB Partnership
23	Arjen	Iwema	Facilitator	McKinsey & Co.
24	Steve	Davis	Facilitator	McKinsey & Co.
25	Farhad	Riahi	Facilitator	McKinsey & Co.
Regrets				
26	Giorgio	Roscigno	Chair	Foundation for Innovative New Diagnostics (FIND)
27	Salmaan	Keshavjee	Chair, Green Light Committee	Partners in Health
28	Michael	Kimerling		Bill & Melinda Gates Foundation

Appendix 2: summary of interview findings and Consensor questions

Summary of interview findings

1. Universal consensus: (a) Good intentions (b) "TB leader" mindset
2. General consensus: what problem that we are trying to solve, but *different views on right target for 2015*
3. Consensus at high level on "what is required for countries to scale up", but *different levels of detail and different emphases*
4. Universal consensus that different countries have different scale-up needs, but *still need consensus on specific scale-up models for different types of country*
5. Range of views on how much the 'international support model' needs to change
6. Universal consensus on need for better coordination of international support, ...but
 - *Differing views on the 'strength' of coordination required*
 - *Differing views on the underlying drivers of poor coordination & what to improve*

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Consensor session questions

Vote!

1. Everyone here today has good intentions
2. We have consensus on the goal for scale-up by 2015
3. We have consensus that the goal is feasible
4. We have consensus on what countries need to have for sustainable MDR-TB management
5. We have consensus on what the major barriers to scale-up are
6. Our current international support model is the best one for scale-up
7. Our current model needs to be changed radically for scale-up
8. Accountabilities in our current scale-up model are clear
9. Our current level of coordination is appropriate
10. We need a centralised, strongly controlled model of coordination
11. We have the operational capabilities and capacity today to provide the support countries need
12. I believe that we can make major progress on these issues in this workshop

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