2nd Global GLC meeting
World Health Organization, Geneva, Switzerland, 28-29 February 2012
Meeting report
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Welcome of participants

Dr Mario Raviglione, Director, STB, WHO and Dr Lucica Ditiu, Executive Secretary, Stop TB Partnership, welcomed all the members to the second gGLC meeting. The global discussions on MDR-TB had now moved forwards from the earlier ones on procedural issues to the crucial topic of how the global framework and partners are to support the countries in their efforts to scale-up MDR-TB services and management. Members needed to focus on the important strategic issues such as: access to diagnostics; access to quality assured second line drugs (SLD) and the market dynamics related to SLDs; availability of the required funds at a time of a changing global financial environment; and human resources. All these issues were to be discussed during the meeting, and WHO is looking forward to the gGLC’s advice.

Dr Ditiu reminded the members that the eyes of the global community are now on the issue of MDR-TB, in particular on the access to treatment and scale-up of services for MDR-TB patients. Much however remains to be done and there are many unanswered questions. The ambitions of respective countries appear quite limited to date and few are aiming to achieve universal access to MDR-TB services by 2015, with the required human resources often lacking in-country. How should the global TB community respond to this and assist countries to scale-up? The advice of the gGLC is sought to help push this forwards.

Dr Raviglione also informed the members that, as of end May 2012, Dr Paul Nunn, Co-ordinator, MDR-TB/GLC Operations Unit, STB will be leaving WHO. There is on-going consultation with the STB Department and the HTM Cluster on the future positioning of the current MDR-TB/GLC Operations Unit. A recommendation is that it merges with the TB Diagnostics and Laboratory Strengthening Unit under Dr Karin Weyer. A final decision on this will made in the near future. On behalf of the gGLC members and members of the previous GLC, Dr Charles Daley, Chair, gGLC gave his thanks to Dr Paul Nunn on his global leadership in TB matters, over the years and in particular in relation to MDR-TB.

Declaration of Interests

Chuck Daley, Chair of the gGLC, thanked the speakers and introduced the participants. Interests were declared and discussed. No conflict of interest was identified.
Session 1 – Report back from the Secretariats

Objective: To follow up on recommendations made and action points agreed upon during the 1st gGLC meeting, and to review progress of MDR-TB management scale up in priority countries

Report from the gGLC Secretariat - Dr Susanne Carai, gGLC Secretariat, presented progress in implementing the recommendations and action points from the 1st gGLC, and outcomes of the 21st Stop TB Partnership Co-ordinating Board meeting

The rGLCs for the American, European and Western Pacific Regions are now fully operational. And the establishment of the rGLCs for the African, Eastern Mediterranean and South East Asian Regions is on track, with these 3 rGLCs expected to be operational by end Q2 2012. In 2011, 86 monitoring and technical assistance missions were carried out, with 97 second line drug (SLD) procurement orders reviewed by the gGLC and rGLC Secretariats during Q3-4 of 2011 (c.f. 70 in same period of 2010). The gGLC Secretariat plans to undertake country case studies in a number of countries (to be identified) in 2012 to understand the details of the progress and bottlenecks in the scale up of MDR-TB services in the identified countries. The methodology for the studies is under development.

Technical support: The gGLC Secretariat proposed to hold an additional gGLC meeting by telephone conference in Q2 2012 to discuss progress and next steps in relation to Technical Support, as there was not sufficient time to include this item in the agenda of the current meeting.

Second line drugs: There is now direct access to GDF for the procurement of QA SLDs. There is the possibility to procure partial regimens through GDF, with the proviso that GDF drugs are used only in conjunction with QA drugs. The volume of SLD orders through GDF has increased from USD $64 million in 2010 to USD $85 million i.e. a 30% increase. GDF updated on the follow-up of recommendations made during 1st gGLC meeting in more detail during Session 2. The work done since the 1st gGLC meeting on the issue of availability of clofazimine was summarized. An “SLD Market Access Improvement Initiative” has been established, involving many partners (including the GDF and the gGLC Secretariat), with a long term goal of all MDR-TB patients having access to quality assured SLDs at a cost that most countries can afford or one that donors are prepared to pay. The 1st meeting of the Task Force to develop a “roadmap for introduction on new drugs/regimens” will meet in April 2012 and 2 gGLC members are part of the Task Force.

Advocacy: Detailed presentations and discussions on the issues of the “Comprehensive advocacy strategy to support the expansion of DR-TB management”, and the proposal for WHO and partners to consider the organization of a follow up meeting to the high level ministerial meeting in Beijing (“Beijing II”) were had during Session 4. Work on the production of the 2012
WHO Annual MDR-TB progress report, together with a “Launching Strategy”, have begun with a tentative date in mid-2012 for publication.

Monitoring and Evaluation: The rGLCs are establishing a routine annual M&E mechanism, and 62 monitoring missions were conducted in 2011. Plans for the 2012 monitoring missions have been developed by all six regions. However timeliness of the submission of the reports remains an issue (11/62 reports not yet received). A progress report on MDR-TB will be presented to the WHA in May 2012.

Policy and Guidelines: Development of a “Companion manual” to the WHO 2011 update of PMDT guidelines to cover the ‘how to do’ elements to plan and implement PMDT activities is on track with a proposed publication date in Q3 2012. The MDR-TB Planning Tool, developed by WHO in partnership with PATH, was finalized in 2011 and is available at http://www.path.org/publications/files/TB_mdr-tb_planning_toolkit_v2.pdf.

Advice to funding agencies: This is on-going on a regular basis with the Global Fund and USAID. It is planned that in relation to the development of a “framework for the linkage of diagnosis, drugs and treatment services”, a proposal for SLD treatment will be submitted to UNITAID in 2012 to match the already submitted diagnostics proposal, once a call for letters of intent is made.

The major outcome of the 21st meeting of the Stop TB Partnership’s Coordinating Board, 30 January – 1 February 2012, was recognition that there was now a shift from procedural issues surrounding the setting up of the new framework to actually addressing the slow expansion of MDR-TB management worldwide. Further details are available at http://www.stoptb.org/about/cb/meetings/21/

Dr Carai concluded that the Global Framework to support scale-up of MDR-TB services is now established and working; the focus now is on providing the support to DR-TB services scale-up; and there needs to be discussion on how the evaluation of the global framework’s activities for supporting MDR-TB management scale-up is to be conducted (refer to Session 6).

The objectives of the 2nd gGLC meeting were presented, namely:

- To provide an update on the GDF and availability of SLDs
- To discuss how to increase availability and accessibility of SLDs
- To discuss strengthening MDR-TB Advocacy
- To review response to the “TDR-TB” event in India
- To provide advice on the evaluation of the new global framework
- To discuss revision of Global Fund indicators
- To review membership of the gGLC
Discussion

There was agreement on the proposal to hold an additional gGLC meeting by telephone conference in Q2 2012 to discuss progress and next steps in relation to Technical Support. A general point was raised that it is difficult for the gGLC members to stay “engaged” with just 2 face to face meetings per year, and additional meetings via teleconference etc., would be a good way to keep the members engaged. In addition, since the proposal to hold an additional meeting was prompted by the lack of time in the current meeting to accommodate all the proposed agenda items, there was discussion on whether the duration of the face to face meetings should be extended.

A number of the members re-iterated that the discussions of the gGLC needed to have a strategic focus, which required discussions and recommendations on prioritisation of areas should be targeted and focussed on where the greatest impact is anticipated.

Regional issues – Update from the Chairs from rGLC AMRO, rGLC EURO, rGLC WPRO

Dr Pepe Caminero, representative AMR rGLC, Dr Andrey Maryandyshev, Chair EUR rGLC, and Dr Lee Reichman, Chair WPR rGLC, provided updates on the activities of the respective rGLCs.

AMR rGLC: Dr Caminero informed the meeting that Dr Domingo Palmero had been selected as the Chair of the AMR rGLC, and that the call for applications of new members of the AMR rGLC would take place in the near future. An important issue raised by the AMR rGLC is in relation to the non-availability of second-line injectables and clofazimine. This issue was further discussed in session 2. Other issues raised by AMR rGLC relate to the use by countries of MDR-TB regimens that do not conform to WHO Guidelines – this issue was discussed further in session 5.

EUR rGLC: The EUR rGLC has now met 4 times (1 face to face meeting, 3 teleconference meetings) and the next meeting will be in early March. Priority activity in the region is seen as support to countries to update their respective MDR-TB expansion plans or MDR-TB components of NTP plans. This is anticipated to be completed by Sept 2012. As yet only 1 of the 11 priority countries in the region has not yet started implementing MDR-TB services. In the future the focus will be on monitoring of countries’ progress.

WPR rGLC: WPR rGLC has to date held one face-to-face meeting and two teleconferences. A number of important achievements, such as introduction of MDR-TB into insurance scheme coverage in China, banning of import and sales of anti-TB drugs in Cambodia, PMDT expanded in 5 countries; just started in Laos and PNG, etc. There have been PMDT missions to Papua & New Guinea, and Cambodia, with one to Vietnam planned for March. However there were delays in the review of monitoring missions - 4 months turnaround time for China report and 2 months for Cambodia mission report. Challenges and solutions in the areas of sustainability, case finding, laboratory, treatment and SLDs were presented.
Update from AFRO, EMRO & SEARO

An update on the African, Eastern Mediterranean and South-East Asian Regions was presented by Dr Tauhid Islam, gGLC Secretariat. The highlights of PMDT related activities, and monitoring and TA missions were presented. Details of progress for the establishment of the rGLCs in the respective Regions were presented, and the expected timelines for when each rGLC would be operational were given (AFR rGLC Q2 2012; EMR rGLC July 2012; and SEAR rGLC April 2012). The key challenges and ways forwards were presented for each of the three regions. Common challenges reported were: limited human resources to implement and scale-up MDR-TB services; financial constraints; and availability of QA SLDs with weak regulation of SLDs in the private sector.

Discussion

gGLC questioned the feasibility of implementing all the solutions proposed by the WPR rGLC. It was early days for the rGLCs and that the rGLCs were still “feeling their way” forwards on how they should work and their exact role. A strong recommendation of the gGLC members was that the rGLCs should focus on the big issues, particularly those issues that are common across the member countries of the respective region, and should not focus, or get bogged down on the minutiae of service implementation in any one country.

Also as the new global support framework has only been established and activities started in the last 6-8 months, the gGLC members felt that more time was needed for the new framework to be established and implemented, and for the people involved in the structures to gain more experience of its functioning, prior to any impact of the new framework being evaluated.

Conclusions and recommendations

The gGLC supports

- To add 1-2 teleconference meetings between the face to face meetings in order to address important matters that arise starting with a teleconference meeting in Q2 or Q3 2012 to discuss progress and next steps in relation to technical assistance.

The gGLC recommends

- The gGLC Secretariat to present the findings, outcomes and recommendations of the planned country case studies at the 3rd gGLC meeting in late 2012; and
- That consideration is given to extending the duration of the 3rd gGLC meeting to 2.5-3 days.
Session 2 - Availability of Second line anti-tuberculosis drugs

**Objective:** To provide an update on the Global Drug Facility and availability of SLDs

- Current status and future direction of the GDF
- Current availability of SLDs
- Update from the “SLD Access Improvement Initiative”

Dr Kaspars Lunte, GDF, presented an update showing that the value of SLDs procured had increased 37% to $78 million in 2011 compared to 2010. This represented about 19,500 patient treatments in 2011, up from 17,000. The average cost of a course was estimated to have fallen to $2,600. The gGLC pointed out that these numbers don’t add up. Clarification was promised and can be found in Annex 1.

Among drugs of particular interest to the gGLC, capreomycin has been difficult to obtain since the GDF’s warning of delivery delays in May 2011, but Vianex should be coming on stream at the end of February 2012. Invitations to bid for supplying linezolid have been issued for the first time and should be concluded early March 2012. The drug remains prohibitively expensive. The supply situation of clofazimine was presented, and was discussed in detail in Session 3. The production of thioacetazone has been discontinued by Bayer, while three sources were mentioned for imipenem/cilastatin. No significant price reductions were seen in the bidding process of August 2011 compared to the negotiations held with companies in 2009/2010 – yet the average price is said to have fallen significantly.

Apart from terizidone and ofloxacin, where there is only one supplier, there are at least 2, and often 3, for all the other major SLDs supplied by GDF. This is a significant improvement on 2010.

Members expressed concern for the GDF’s tough position on procurement of partial regimens and pointed out that whereas in the early 1990s problems surrounding the price, quality and amounts available for rifampicin had been addressed by WHO and the global community, the global mechanism for the supply of SLDs had only succeeded in preserving quality, but had not succeeded in reducing the price, nor increasing availability. One solution was to place responsibility for quality on the countries, rather than on the global mechanism.

Dr Sana Mostaghim presented the work of the Clinton Health Access Initiative and other stakeholders on the Second Line Drug Access Improvement Initiative (SLDAII), which has so far described the SLD market in unprecedented detail, and is exploring the possibility of a subsidy approach to the most expensive drugs, as one of 5 work streams. However, the solution to the problem of excessive cost of SLDs requires further work to avoid simply “rewording the status quo”. According to Dr Ditiu, Executive Secretary of the Stop TB Partnership, a request for proposals for drugs is expected in April 2012, which calls for a single large response from the TB community. She herself is the acting manager of the GDF, in the absence of Ms Bogren on sick
Conclusions and recommendations

The gGLC concluded
• That the high price of IQA drugs remains a major obstacle to increased supply.

The gGLC expresses concern
• About the failure of the market to provide uninterrupted supply of drugs
• That while quality was being maintained, the price was still too high and the amounts ordered insufficient
• That the policy of WHO/GDF for requesting partial regimens through GDF is too limiting and does not prevent countries to use drugs of unknown quality in their regimens

The gGLC requests
• GDF and STB to explore the feasibility for providing partial regimens to countries, e.g.
  — who commit to moving towards meeting international QA standards AND
  — who accept monitoring missions including the visit to SLD manufacturing facilities AND
  — who agree to submit samples to be tested

The gGLC expressed concern
• About the mathematics of the value of SLDs procured, compared to the number of treatments estimated, and the average price computed in the presentation by GDF.
  (Clarification provided by GDF can be found in Annex 1)

The gGLC requests
• That GDF check the calculations and return to the gGLC with their definitive figures and explanation of the methodology since funding agencies such as the Global Fund may use the average price computed as a benchmark.

The gGLC applauds the efforts
• Of the SLDAII to analyse the market and develop price-cutting strategies, and requests to be kept informed of progress.

The gGLC supported
• GDF’s role in influencing the market dynamics of SLDs, and requests
• That the GLC secretariat should closely collaborate with GDF in the preparation of any proposal to UNITAID, keeping the gGLC informed.
• The formation of an Advisory Group to support the Exec Sec while she is the a.i. Manager of the GDF, and requests that a member of the gGLC be included in that Advisory Group.
Session 3 - Improved access to Second line anti-tuberculosis drugs

Objective: To discuss how to increase availability and accessibility of SLDs

- Preferred injectable to feed into a price reduction strategy via consolidation policy
- Clofazimine: Current status and future prospects
- Results of drug quality survey in EURO member countries, and implications
- Heads up on US 2010 National TB Controllers Association survey

Preferred injectable to feed into a price reduction strategy via consolidation policy

Background

Dr Dennis Falzon, MDR/WHO, gave a presentation on the use of Parenteral drugs for the treatment of MDR-TB which was supplemented with information by Kaspars Lunte, GDF, from an availability point of view. The presentation can be found at: http://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx

The 2011 Update of the PMDT Guidelines recommends that an injectable should be included in the regimen without a clear superiority of either kanamycin (Km) or amikacin. The first choice is Km as it has been less costly. Capreomycin is recommended in case of resistance against Km. The use of streptomycin is not recommended.

Discussion

Currently Km is still the cheaper option. In case of resistance to one of the injectables – it was proposed to include a different injectable, however, given possible cross resistance it should not be counted as one of the four effective drugs needed to build a regimen.

At the moment there is not sufficient evidence to routinely recommend one injectable over the other. The factors that should be considered when selecting the injectable are: Cost, availability and cross resistance pattern. Programmatic issues such as registration of the drug in the country also need to be considered.

Conclusion and recommendations

The gGLC recommends
- No change in the present recommendation in relation to the use of injectables

The gGLC
- Does not support the preference of either amikacin or kanamycin for shaping market dynamics thus
- Advises WHO that no change in the present recommendation in relation to which injectable should be used can be made at this time until further information becomes available
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The current decision is based primarily on price and availability

The gGLC recommends

• To WHO and/ or partners to consider carrying out a systematic review to establish cross resistance among the injectables

**Clofazimine: Current status and future prospects**

Dr Ernesto Jaramillo, MDR/WHO, presented the Current status and future prospects of: Clofazimine- ensuring sustained supply...should we? The presentation can be found at: http://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx

**Background**

In the *WHO PMDT Guidelines* Clofazimine (Cfz) is considered a Group V drug and is not recommended routinely for the treatment of DR-TB as evidence on effectiveness has not been established in humans, but can be used when no other options are available and sustained supply is requested by countries.

Novartis is currently the only quality assured manufacturer of Cfz, however, it has not agreed to supply Cfz for treatment of drug resistant TB in view of lacking evidence of efficacy and safety in TB patients and liability issues in relation to off label drug use.

**Discussion**

It was felt to be essential to be able to collect data on the effectiveness and safety of Cfz. Joel Keravec reported from Brazil where data comparing regimens including Cfz used from 2000-2005 with regimens without Cfz from 2006-2011 was collected showing no significant difference. However the data has not yet been published.

Furthermore, it was felt to be important to gain insights in the drug interactions with antiretroviral drugs in HIV-TB patients.

Comments regarding the presented results of the meta-analysis (carried out for the 2011 update of the PMDT guidelines) on the effects of Group V drugs included the high likelihood of bias as Group V drugs were mostly used in difficult cases with severe resistance patterns.

**Conclusions and recommendations**

The gGLC fully endorses

• The steps being taken by WHO to secure sustained supply of Cfz and requests WHO/ STP to pursue to secure sustained supply of Cfz despite absence of evidence on its efficacy in TB in humans
The gGLC recommends

- To WHO GDF to explore ways to make Cfz available for MDR/XDR TB immediately and update the gGLC
- To WHO/STP to present to Novartis satisfactory options to address the liability of the off label use and patient safety of Cfz in MDR-TB management
- GDF to continue exploring supply options through generic manufacturers

Results of drug quality survey in EURO member countries, and implications

Background

Dr Paul Nunn presented the results of the Survey of quality of anti-tuberculosis medicines. The presentation can be found at:
http://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx

The full report can be found at:

A peer reviewed article is currently being drafted.

Discussion

Queries regarding the sampling strategy were raised and discussed, as well as the fact that in the absence of dissolution results the rifampicin capsule results need careful interpretation. It was felt that it would be useful to analyse treatment outcomes of patients in countries included in the study to establish whether there is a correlation to the drug quality.

Conclusions and recommendations

The gGLC expressed concerns about the findings of the Quality Survey of EURO member countries and urges

- WHO to continue evaluating the quality of anti-TB drugs through additional studies like the Quality Survey of EURO member countries and these studies to include China, India, Philippines, Pakistan, Indonesia, South Africa (given the large number of patients and local manufacturers)
- WHO/EDM to provide more information and scientific data regarding the correlation between the bio-availability for rifampicin and other simpler tests directly on the medicine.

The gGLC recommends that

- Concerns around rifampicin be addressed in the planned peer reviewed publication because it may indicate problems with the bioavailability of rifampicin
Heads up on US 2010 National TB Controllers Association survey

Dr Lee Reichman provided a confidential heads up on the still unpublished results of the US 2010 National TB Controllers Association survey.

Discussion

It was felt that the survey report could serve as very good advocacy material.

Session 4 – Advocacy for MDR-TB management

Objective: To discuss strengthening MDR-TB Advocacy

MDR-TB Working Group perspective

Dr Ernesto Jaramillo, MDR, WHO, Secretariat of the MDR-TB working group, pointed out that the working group has not been very active in advocacy for TB. The World Health Assembly resolution makes the need for advocacy very clear to ensure that the countries honour the commitments made. The working group has been mostly constituted by implementers or technical people and there is very limited capacity for advocacy work in the MDR-TB working group.

Paul Thorn presented A framework to guide the advocacy work of the MDR-TB Working Group. The presentation can be found at https://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx

He presented the work that has been carried out in relation to a WHO/EURO inventory of potential MDR-TB advocacy partners with over 300 organizations and individuals approached and information for over 150 collected.

Discussion

It was suggested that the establishment of a new ACSM sub-group would not be useful but that an overall long-term proactive plan should be developed, enabling shorter-term intense reaction to exploitable events as they arise. The development of the advocacy approach to TB/HIV was felt to be a very strategic entry point to obtain support from the HIV community for TB/HIV activities, as well as to raise funds. Global and regional Advocacy should not be lumped together but have distinct objectives, plans and activities. It will be important to have a tool to measure numbers of patients diagnosed, numbers of patient treated and investments made by governments, in order to be able to hold governments accountable as otherwise the advocacy framework risks to be another document without impact.
Stop TB Partnership Perspective

- Introduction and (post-Bangkok Coordinating Board) direction
- Advocacy approach, activities, and opportunities for MDR-TB

Dr Lucica Ditiu stated that from a global level perspective geographic prioritization, i.e. big countries vs. other priority countries as well as thematic prioritization, i.e. quality of the drugs, access to drugs and/or research of new drugs, will have to be done as resources and capacities are limited. She felt that country level activities are important and encouraged the Regional GLCs to develop advocacy work plans that could be implemented in the partnership. The overall aim should be capacity building and empowerment so that sufficient people can speak about MDR TB in an educated manner to influence activities and policies.

Joel Spicer, Team leader Strategy and Advocacy, STP, gave a presentation on the STP perspective on MDR Advocacy and outlined the STP Advocacy Framework with the main pillars of:

1. Strengthen the architecture
2. Transform the conversation
3. Build the base

The presentation can be found at: http://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx

Given the limited capacities the proposed approach is to include MDR-TB advocacy in activities around TB, e.g. MDR-TB will be featured within the advocacy on tuberculosis in children around World TB Day. Joel Spicer referred to a presentation on marketing of TB that was made by the Private Sector Constituency (PSC) to the STB Coordinating Board that would need 2 million USD to implement the proposed PR approach. The presentation on Process and outcomes of Think Tank for TB Messaging can be found at: http://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx

Discussion

The gGLC reminded that during the last gGLC meeting the development of a comprehensive advocacy strategy on MDR-TB had been requested and expressed concern that yet the objectives had not been defined. The partnership pointed out that there are not sufficient resources within the partnership secretariat and that they were looking to the gGLC for strategic directions and prioritization on advocacy activities.

During the discussion it crystalized that the partnership had been looking at the gGLC for moving the advocacy work while the gGLC had been expecting the partnership to progress the advocacy agenda as put down in the transitional framework. The gGLC made clear that they were to provide recommendations, however not positioned to carry out the advocacy activities. The involvement of the regional GLCs to develop plans that meet the needs for each region was felt to be important and the chairs will revert back to their respective rGLCs with this request.
One – and maybe the most important - step is to hold countries accountable to the commitments made in the WHA resolution. WHO is publishing the annual Progress Report towards Universal Access to Diagnosis and Treatment of Multidrug- resistant and Extensively drugs- resistant Tuberculosis by 2015. The published data could be used by partners to produce “Report cards”. The Partnership Secretariat might be best positioned to contact partners. Furthermore, given the attention drug- resistant TB has shown to attract in the past, it might be worthwhile to leverage attention from these events towards TB rather than only using TB events to advocate for universal access to management of drug-resistant tuberculosis. An important activity that had been outlined in the Transition plan and that needs following up is the: Development of a “DR-TB Advocacy Manual” and work plan outlining the roll out of the manual. Conduct trainings on "Advocacy for DR-TB" in all regions

Beijing II?

Paul Nunn gave a presentation on the High Level Ministerial meeting that took place in Beijing, China in 2009 with the question whether a ?Beijing II was warranted at this point in time. The presentation can be found at http://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx

Discussion

The Ministerial meeting in Beijing achieved consensus that MDR-TB has to be treated; the focus should now be put on the national level. It was felt that the most benefit would be obtained by activities at the Ministry of Health level and within National TB programmes to ensure that countries actually do what they committed to.

Conclusions and recommendations

The gGLC expresses concern

- That the advocacy activities related to MDR TB are currently vague, ill-defined and urgently need to be reconsidered and recalibrated.

The gGLC recommends

- That given the high media attention that DR TB has gained in the past - STP and the MDR-TB working group use MDR-TB both to gain traction for advocacy purposes for TB as well as integrating it into the TB advocacy framework
- That an MDR-TB Advocacy framework, a DR-TB Advocacy Manual and a work plan outlining the roll out of the manual be developed within 6 months. Trainings based on the manual will be developed in due course.
Mapping and piloting of country level advocacy activities in a number of high burden MDR-TB countries

To the rGLCs to adapt advocacy frameworks and plans for their respective regions

Giving preference to a series of country level advocacy activities to be implemented in a number of high MDR-TB priority countries rather than holding another meeting similar to the Ministerial meeting in Beijing in 2009

That a partner uses the data available in the WHO Global TB and MDR-TB progress report to develop “report cards”

Session 5 – “ Totally Drug Resistant Tuberculosis”? 

Objective: To review response to the “TDR-TB” event in India and the proposed next steps

Dr Paul Nunn presented the Background, response to date and major issues. The presentation can be found at:  
http://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx

Dr Karin Weyer, Coordinator, TBL, updated the gGLC committee on the Expert Group meeting on WHO Policy guidance on anti-tuberculosis drug susceptibility testing and Hain MTBDRsl second line drug molecular line probe assays to take place 19th to 21st March 2012. The following objectives of the meeting were outlined:

To review the evidence base for establishment or revision to critical concentrations for phenotypic drug susceptibility testing methods for first- and second-line drugs;

To review the evidence base and evaluate data from a systematic review on the reliability and reproducibility of WHO-endorsed phenotypic drug susceptibility testing methods for first- and second-line drugs using consensus critical concentrations;

To review the evidence base and evaluate data from a systematic review on the predictive value for multidrug-resistance when rifampicin resistance is found, from laboratory and epidemiological studies;

To evaluate data assessing the relationship between results of drug susceptibility testing to individual drugs and treatment outcomes with use of that drug;

To review available data from laboratory validation and field evaluation studies on the performance characteristics of Hain MTBDRsl® molecular line probe assays, for the diagnosis of second-line drug resistance;

To outline potential subject matters to be addressed by WHO in subsequent policy recommendations.
A Technical Consultation on “Totally Drug-Resistant TB”: diagnostic definition and treatment options will follow on 21-22 March, 2012 with the objectives to:

- Discuss the feasibility and implications of a definition to cover the most severe patterns of resistance and
- The need to provide specific guidance on treatment options for patients with XDR-TB with or without additional second line drug resistance.

This session aimed to establish the input the gGLC would like to provide via the Chair who will be participating in the WHO consultation.

Discussion

The gGLC congratulated WHO for the effective response to the “TDR event” in India and the media interest that was generated. Referring back to the previous session it was felt that these types of events need to be fully capitalized on for advocacy purposes. (TDR should be treated like Ebola, i.e. as a deadly disease: “X/TDR is Ebola with wings”)

The gGLC pointed out that if an additional definition for a form of drug resistant tuberculosis is to be established, the number of cases of “TDR-TB” occurring will be reported by country. It is therefore important to consider the implications in terms of expected actions to be taken, and the options and actions expected to be taken for treating them. Generally, it was felt to be imperative to stick to a minimum number of definitions in order to avoid further complication and possible confusion.

Lucy Chesire raised the question of what has happened with the “TDR” patients from India and whether they were started on treatment. The secretariat will follow up with the author who will attend the “TDR” consultation, and report back to the group.

The question was raised whether there would be a difference between people affected with XDR-TB and those with “TDR” in terms of prognosis - from the European region it was noted that in reality most patients with XDR die. Experience from Lesotho also shows that not a single patient with XDR TB has survived. It was agreed that one important factor to guide possible definitions would be the prognosis of the patient.

Summarizing, it was agreed that the criteria to be taken into account when discussing the need and feasibility of a new definition were:

- The clinical relevance, i.e. a clear difference in personal outcomes (prognosis) of any new definition from what already exists and
- The laboratorial reliability and
- The capacity in countries most affected (both laboratory/diagnostic capacity and management/treatment/reporting capacity)
It was also discussed whether or not patients with rifampicin mono-resistance or non-MDR poly-resistance with rifampicin should be treated differently from MDR-TB patients. In reality patients with rifampicin resistance are currently treated with a MDR-TB regimen (which sometimes additionally includes Isoniazid). While currently there may be not enough evidence, it would be important to determine what kind of data is needed in the literature to be able to make a better decision down the line.

Conclusions and recommendations

The gGLC recommends

- To consider the reliability of laboratory methods and differences in patient outcomes as criteria when discussing the possibility and need for additional definitions (including surveillance)
- WHO to review whether patients with rifampicin mono-resistance or non-MDR poly-resistance with rifampicin should be treated differently from MDR-TB patients

Discussion on Treatment duration

Dr Dennis Falzon gave a presentation on *Duration of regimen in MDR-TB treatment* outlining the evidence that led to the current recommendation concerning the treatment duration and addressing the question: *In patients with MDR-TB, is shorter treatment, compared with the duration currently recommended by WHO, more or less likely to lead to treatment success (and other outcomes).* The presentation can be found at: [http://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx](http://workspace.who.int/sites/PMDT/Global/2nd%20gGLC%20meeting/default.aspx)

Dr Chen-Yuan Chiang, IUATLD (The Union), gave a presentation, questioning whether duration of treatment in individualized approach is an adequate determinant of outcome. He pointed out that cases that died or were lost to follow up should not be included in the analysis because duration of treatment was not predetermined and was truncated by death or loss-to-follow-up. He further explained that excluding those who died or were lost to follow-up may not overcome the problem. He proposed that the GDG be presented with these issues and it should decide whether recommendations on treatment duration are to be maintained, modified, or withdrawn.

Discussion

Part of the members felt that the section on treatment duration should be revised and rewritten as evidence had been misinterpreted. The question was raised whether the gGLC should recommend to WHO to call a meeting of the PMDT Guideline Development Group to review this issue.
Dr Karin Weyer emphasised that there were two possible reasons for WHO to change WHO guidelines: 1) New evidence becomes available or 2) there was a flaw in the analysis that was carried out to establish the recommendations. If there are concerns that the second reason does apply here, the issue will be addressed – if this includes going through the guideline review process, this will be done. However, a recommendation and way forward is needed on how to do this most efficiently without embarking on an expensive two year process which may terminate with the same recommendation and very low evidence taking into account the fact that every WHO guideline has to undergo in any case the review process every 3 to 5 years. It has to be considered what the potential gain vs. loss of a revised recommendation is and what the implications at the country level would be.

Conclusions and recommendations

The gGLC recommends

- That WHO revisits the recommendations on treatment duration by calling for a small Working Group to study if (i) there is a flaw in the analyses that led to the current recommendations, and (ii) if this is the case, what steps to take, taking into account the implications at country level, including communication. The target date is the evening of the 21st March. Members to be C-Y Chiang, C Daley, D Falzon, D Menzies, M Rich, H Schünemann, WHO biostatistician not previously involved.

- That the WHO Companion Manual to the 2011 update of the PMDT Guidelines interprets fully how the findings from the analysis used for the 2011 Update should be applied in the field, considering the conditional nature of these recommendations.

Session 6 – Evaluation of the Global Framework

Objective: To provide advice on the evaluation of the new global framework for supporting MDR-TB management scale up

Dr Carai presented an outline for evaluation of the new framework firmly based on the process and outcome indicators in the Global Plan to Stop TB 2011-2015. The gGLC agreed that this issue was timely and unanimously expressed a desire to focus on outcome indicators, with an evaluation to be carried out around 2014 to give time for the new framework to have achieved something. Joel Keravec expressed the importance of learning from similar activities, notably the recent 10 year analysis of GDF’s missions to 24 countries. The Chair emphasised the importance of including the rGLCs in the process.
Conclusion and recommendations

The gGLC agreed that

- The development of an evaluation plan with details of the methodology should continue by email exchange, led by the Secretariat (S. Carai and D. Falzon) together with members of the gGLC (J.Keravec, CYC and M. Rich). It should be structured around the objectives of the new framework, focus on outcome indicators as well as process indicators, making full use of the data published in the WHO Global Control Report. A draft should be presented at the next meeting of gGLC.
- Joël Keravec to share the analysis of 10 years of GDF mission reports on drug management of FLDs

Session 7 – Global Fund indicators

Objective: To discuss revision of Global Fund indicators

Background

Sarah Royce raised the concern regarding the recently posted 4th edition of the Global Fund (GF) Monitoring and Evaluation Toolkit, which can be found at: http://www.theglobalfund.org/en/me/documents/toolkit/

This would require two changes: 1. Add an indicator: “MDR-TB cases notified” and 2. Change the name of the second MDR-TB indicator to “confirmed MDR-TB cases enrolled in treatment.”

Discussion

GF is already notified about the 2nd point. Agreed by GF that it is a typo and should be corrected ‘notified’ and ‘enrolled’ both indicators are important. Confirmed MDR cases exclude mono resistant and high risk group (non-confirmed) MDR cases, so may have implication in funding. Implications of these indicators are not directly linked with MDR-TB scale up (thus not very much related to gGLC mandate). As GF management has been changed, there is a disease specific committee; there is good opportunity to collaborate with GF

Conclusions and recommendations
The gGLC agrees with the concern but as this is not a major issue related to MDR-TB scale up effort (thus not related with the mandate) – gGLC will not communicate officially to GF this issue.

The gGLC recommends

- That the gGLC secretariat contacts the GF to request that the title of Indicator 2 be changed from "notified" to "enrolled"

Session 8 - gGLC membership

Objective: To review the membership of the gGLC

The vacancy recently created by the resignation of one of the members of the gGLC and the opportunities this represented for filling not only this vacancy but also strengthening representation in other areas were presented by Dr Carai. Members indicated NTP management as the most important area to fill, and also paediatrics, nursing, SLD market dynamics, and national MDR-TB focal point experience.

The gaps in the skill set of the current gGLC were felt to be, as a priority, an NTP Manager of a high MDR TB burden country, and also (in no particular order), paediatrician, nurse, market dynamics expert, MDR TB focal point of a high MDR TB burden country.

The GLC concluded

- That it should wait until the representatives of the 3 remaining rGLCs were identified; then re-list the missing skills, review the last set of applicants to see if suitable candidates are on that list, and if necessary the secretariat to prepare a call for nominations at that point

Other business

- The next gGLC meeting will be held in October 2011. The gGLC Secretariat will send out a doodle poll to establish the date.
- A teleconference will be held as soon as possible.
Agenda

Day 1

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<th>Session</th>
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<td>Welcome of participants</td>
<td>L. Ditiu, M. Raviglione</td>
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<td>Declaration of Interests</td>
<td>C. Daley, Chair gGLC/ S. Carai, gGLC Secretariat</td>
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<tr>
<td>09.30 – 10.30</td>
<td>Session 1</td>
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<tr>
<td></td>
<td>Objective: To follow up on recommendations made and action points agreed upon during the 1st gGLC meeting, and to review progress of MDR-TB management scale up in priority countries</td>
<td>S. Carai, gGLC Secretariat</td>
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<td>Report from the gGLC Secretariat:</td>
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<td></td>
<td>• Progress in implementing recommendations and actions points from 1st gGLC meeting, and outcomes of 21st Stop TB Partnership Co-ordinating Board meeting</td>
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<td>Regional issues – Update from the Chairs</td>
<td>J. Caminero for D. Palmero</td>
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<td></td>
<td>• rGLC AMRO</td>
<td>A. Maryandyshev</td>
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<td></td>
<td>• rGLC EURO</td>
<td>L. Reichman</td>
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<td></td>
<td>• rGLC WPRO</td>
<td>T. Islam, gGLC Secretariat</td>
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<td></td>
<td>• AFRO/EMRO/SEARO related issues, including update on establishment of rGLCs</td>
<td>C. Daley, Chair gGLC</td>
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<td>10.30 – 11.00</td>
<td>Coffee</td>
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<td>11.00 – 13.00</td>
<td>Session 2</td>
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<td></td>
<td>Objective: To provide an update on the Global Drug Facility and availability of SLDs</td>
<td>L. Ditiu, a.i. GDF</td>
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<tr>
<td></td>
<td>• Current status and future direction of the GDF</td>
<td>K. Lunte, GDF</td>
</tr>
<tr>
<td></td>
<td>• Current availability of SLDs</td>
<td>S. Mostaghim, CHAI</td>
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<td></td>
<td>• Update from the “SLD Access Improvement Initiative”</td>
<td>C. Daley, Chair gGLC</td>
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<tr>
<td>Time</td>
<td>Session 3</td>
<td>Session 4</td>
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<tr>
<td>14.00 – 15.30</td>
<td>Objective: To discuss how to increase availability and accessibility of SLDs</td>
<td>Objective: To discuss strengthening MDR-TB Advocacy</td>
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<td>• Preferred injectable to feed into a price reduction strategy via consolidation policy</td>
<td>• MDR-TB Working Group perspective</td>
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<td></td>
<td>• Clofazimine: Current status and future prospects</td>
<td>• Stop TB Partnership perspective</td>
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<td></td>
<td>• Results of drug quality survey in EURO member countries, and implications</td>
<td>o Introduction and (post-Bangkok Coordinating Board) direction</td>
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<td></td>
<td>• Heads up on US 2010 National TB Controllers Association survey</td>
<td>o Advocacy approach, activities, and opportunities for MDR-TB</td>
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<td>Discussion</td>
<td>• Beijing II?</td>
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<tr>
<th>Time</th>
<th>Coffee</th>
<th>Session 3 continued</th>
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<tr>
<td>15.30 – 16.00</td>
<td></td>
<td>Discussion continued</td>
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<tr>
<td>16.00 – 16.45</td>
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<td>Proposed next steps and recommendations</td>
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<tr>
<th>Time</th>
<th>Wrap up Day 1</th>
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<tr>
<td>17.45 – 18.00</td>
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15.30, MDR/GLC and GDF
15.30, MDR/GLC
15.30, MDR/GLC
L. Reichman, Chair WPRO
C. Daley, Chair gGLC

16.00, C. Daley, Chair gGLC

16.45, P. Thorn, E.Jaramillo, MDR - Working Group
L. Ditiu, STP
J. Spicer, STP Secretariat
P. Nunn, MDR/GLC

17.45, C. Daley, Chair gGLC
## Day 2

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Description</th>
<th>Presenter(s)</th>
</tr>
</thead>
</table>
| 09.00 – 10.30 | **Session 5** | Objective: To review response to the “TDR-TB” event in India and the proposed next steps  
• Background, Response to Date and Major Issues  
Discussion | P. Nunn, MDR/GLC |
| 10.30-11.00 | Coffee    |                                                                              |                                       |
| 11.00 – 12.00 | **Session 5 continued** | Discussion continued  
Proposed next steps | C. Daley, Chair, gGLC |
| 12.00 – 13.00 | **Session 6** | Objective: To provide advice on the evaluation of the new global framework for supporting MDR-TB management scale up  
• Approach to the evaluation of the global framework  
Discussion | S Carai, gGLC Secretariat  
C. Daley, Chair, gGLC |
| 13.00 – 14.00 | Lunch     |                                                                              |                                       |
| 14.00 – 14.45 | **Session 7** | Objective: To discuss revision of Global Fund indicators                   | C. Daley, Chair, gGLC |
| 14.45 – 15.30 | **Session 8** | Objective: To review membership of the gGLC  
Ensuring representation of all “Technical areas” and “constituencies” on the gGLC | S. Carai, gGLC Secretariat  
C. Daley, Chair, gGLC |
| 15.30 – 16.00 | Coffee    |                                                                              |                                       |
| 16.00 – 17.30 | Summary of recommendations, next steps and closing | C. Daley, Chair gGLC |
List of participants

**gGLC Members**

1. **José Caminero Luna** (also designated representative, AMR rGLC)
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   IUATLD Servicio de Neumologia
   Hospital de Gran Canaria "Dr Negrin"
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3. **Chen-Yuan Chiang**
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   75006 Paris
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4. **Daniela Maria Cirillo***
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   San Raffaele Scientific Institute
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   ITALY

5. **Charles Daley** (Chair)
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6. **Joel Keravec**
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7. **Michael Rich**
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   LESOTHO
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11. Aamir Khan*  
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12. Sana Mostaghim  
William J. Clinton Foundation  
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13. Paul Thorn  
Director  
TB Survival Project  
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UK

*attended by Skype
Annex 1
GDF comments in response to the summary recommendation of the 2nd gGLC meeting in respect to SLDs:

Dr Kaspars Lunte, GDF, presented an update showing that the value of SLDs procured had increased 37% to $78 million in 2011 compared to 2010. This represented about 19,500 patient treatments in 2011, up from 17,000. The average cost of a course was estimated to have fallen to $2,600. The gGLC pointed out that these numbers don’t add up. Clarification was promised.

The gGLC expressed concern

• about the mathematics of the value of SLDs procured, compared to the number of treatments estimated, and the average price computed in the presentation by GDF.

The gGLC requests

• that GDF check the calculations and return to the gGLC with their definitive figures and explanation of the methodology since funding agencies such as the Global Fund may use the average price computed as a benchmark.

GDF would like to clarify the following:

1. The mathematics for average cost of patient treatment in 2011:

   As presented, the total Ex Works value for all product lines procured in 2011 was USD 137 million, out of which 78 million USD was SLDs.

   However, the average cost of treatment in 2011 is calculated by GDF from the value of SLDs delivered with all fees included during the year divided by the number of patients treatments effectively delivered in 2011.

   The numbers are as follows:

   - All fee included value of SLDs delivered 2011 = 50 859 286 USD
   - Number of patient treatments delivered in 2011 = 19 592

   Calculation of average cost of patient treatment delivered in 2011 is 50 859 286 USD /19 592 = 2,595 USD, as presented.

2. About the discrepancy between GDF and gGLC calculation:

   The reason why the estimation from the gGLC “don’t add up” with GDF calculations is because it divides the value Ex Works of SLDs procured during the same year – i.e. $78 m - by the number of patient treatments delivered i.e. the 19,592 patient treatments, estimated for 2011.

---

1 Procured- Products bought: ordered and pre-paid (no orders can be placed without payment in place), but not necessarily delivered during the reporting period.
Ex Works value of products ordered doesn't reflect real value of amount delivered during the reporting period (related costs such as transportation, procurement fee, quality control, consolidation, etc are not accounted), but also since one can't compare value of products procured that are covering multiple staggered deliveries scheduled beyond the reporting year as to maximize shelf life of product- to product value delivered during the year meant to treat patient during that same period.

4. About using this estimate for “Planning purposes for Funding Agencies such as the Global Fund”.

It should be noted that GDF current method (based on system data for values and delivery dates) is used mainly to assess cost trends - since the notion of average patient treatment cost doesn't explain the large variety of regimen and their respective treatment costs which can be better appreciated by the high and low range calculated during the same period, see Table 1 below.

The Programs and Funding agencies shall not be recommended to use this value – since it doesn't reflect the patient regimen used in a specific program, but to use instead the GLC calculation spreadsheet for the exact calculation of the number of basic units of SLDs and respective cost per specific regimen.

5. Important reduction in total EXW cost of treatment per patient.

Due to constant striving to reduce the costs of treatment per patient, GDF would like to highlight important reduction in total EXW cost of treatment per patient achieved in 2011 versus the costs as reported for the year 2010.

In 2011, GDF was able to provide lower drug treatment cost using new treatment algorithm, the costs were decreased by 2.5% using high range and decreased by significant -16% for the low range treatment, which is important success due to change of the duration of the active phase from 6 to 8 months of duration.

Indicative calculation based on standard approach, however, the data in various countries might vary due to chronic cases or changes in the duration of the treatment phases which might increase real the costs on the ground.
Table 1 High and Low range drug treatment cost in 2011 (using new treatment algorithm), in USD:

<table>
<thead>
<tr>
<th>Treatment algorithm</th>
<th>EXW Cost of Intensive phase treatment per patient</th>
<th>EXW Cost of Continuation phase treatment per patient</th>
<th>Total EXW Cost of treatment per patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>High range 12 Cm Pto Cs Mxf PAS / 12 Pto Cs Mfx PAS</td>
<td>$5,385.30</td>
<td>$2,505.30</td>
<td>$7,890.60</td>
</tr>
<tr>
<td>Low range 8Am Eto Cs Lfx / 16 Eto Cs Lfx</td>
<td>$1,042.61</td>
<td>$1,027.30</td>
<td>$2,069.90</td>
</tr>
</tbody>
</table>

The examples of low and high range have been updated according to the current treatment regimens used by the programs and the latest treatment guidelines.

Table 2 MDR TB Patient treatments supplied by GDF, by WHO regions

<table>
<thead>
<tr>
<th>Year Supplied</th>
<th>AMRO</th>
<th>EURO</th>
<th>AFRO</th>
<th>SEARO</th>
<th>WMHO</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>3,494</td>
<td>9,383</td>
<td>10,960</td>
<td>12,420</td>
<td>10,502</td>
<td>46,870</td>
</tr>
<tr>
<td>2009</td>
<td>4,294</td>
<td>10,054</td>
<td>11,240</td>
<td>13,425</td>
<td>11,502</td>
<td>59,516</td>
</tr>
<tr>
<td>2009</td>
<td>5,294</td>
<td>10,054</td>
<td>11,240</td>
<td>13,425</td>
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<td>59,516</td>
</tr>
<tr>
<td>2011</td>
<td>7,294</td>
<td>10,054</td>
<td>11,240</td>
<td>13,425</td>
<td>11,502</td>
<td>59,516</td>
</tr>
<tr>
<td>2012</td>
<td>8,294</td>
<td>10,054</td>
<td>11,240</td>
<td>13,425</td>
<td>11,502</td>
<td>59,516</td>
</tr>
</tbody>
</table>

Table 3 Order Value overview

<table>
<thead>
<tr>
<th>2010</th>
<th>2011</th>
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<tbody>
<tr>
<td>Value Products Procured Exworks</td>
<td>$ 56 891 631</td>
</tr>
<tr>
<td>Value Products Procured All Fee Included</td>
<td>$ 63 873 068</td>
</tr>
<tr>
<td>Value Product delivered Exworks</td>
<td>$ 35 755 281</td>
</tr>
<tr>
<td>Value Products delivered All Fee Included</td>
<td>$ 40 380 872</td>
</tr>
</tbody>
</table>
GDF Key Achievements 2011

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2011</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of countries serviced (all product lines)</td>
<td>93</td>
<td>101</td>
<td>+8%</td>
</tr>
<tr>
<td>Value of Products Ordered (EXW, all product lines)</td>
<td>USD 112m</td>
<td>USD 137m</td>
<td>+22%</td>
</tr>
<tr>
<td>Value of 2nd line drugs procured</td>
<td>USD 57m</td>
<td>USD 78m</td>
<td>+37%</td>
</tr>
</tbody>
</table>

Estimated MDR TB patient treatments delivered per year through GDF

Estimated MDR TB patient treatment costs

Consolidation of orders contributes to price containment

The access to SRS enabled the completion of orders and serviced urgent orders in more than 47 countries (just for the period of Jan-Jun 2011)