

## **UNION World Congress on Lung Health October 31 – November 5, 2006: Trip Report**

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November 12, 2006



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Strategic Objective 5

This report was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

## About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

## Abstract

RPM Plus conducted a workshop titled “*Building Capacity in pharmaceutical management for TB, MDR and TB/HIV*” at the 37<sup>th</sup> annual International UNION World Congress on Tuberculosis and Lung Health held in Paris France.

## Recommended Citation

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Moore, Thomas, Andrey Zargorskiy, Edgar Barillas, Joel Keravec and Chinwe Owunna 2006. *Trip Report: Union World Congress on Lung Health, France October 29-November 5*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

## Key Words

Tuberculosis, Pharmaceutical Management, MDR-TB, TB/HIV, IUATLD, GDF, GLC

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## ACRONYMS

DOTS	Internationally recommended strategy for Tuberculosis
FDC	Fixed Dose Combination
GDF	Global TB Drug Facility/WHO
GLC	Green Light Committee/WHO
IUATLD	International Union Against Tuberculosis and Lung Diseases
MDR-TB	Multi-drug Resistant Tuberculosis
MSH	Management Sciences for Health
NTP	National Tuberculosis Program
RPM Plus	Rational Pharmaceutical Management Plus
TB	Tuberculosis
TB/HIV	Co-infection with tuberculosis and HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization



## BACKGROUND

Since 2000, RPM Plus has worked to bring the issues of pharmaceutical management to national agendas. Through regional and international venues, RPM Plus often works with partners like the Global TB Drug Facility (GDF) and other Stop TB working groups. Today all technical activities contribute to the Global Plan to Stop TB for 2006 – 2015.

MSH/RPM Plus, GDF and the Green Light Committee (GLC) believe that TB pharmaceutical management practices are becoming better understood within the TB community; however, some issues where the three health problems TB, multi-drug resistant TB (MDR-TB) and TB/HIV come together remain sticking points for national TB programs and good models are not presently available. Many national TB programs continue to encounter problems in providing quality TB medicines to patients when they need them. While lack of financial resources may be one constraint for procuring all TB medicines needed, national programs experience a host of other problems in pharmaceutical management.

For the fifth year MSH/GDF were asked by the UNION scientific committee to prepare and conduct a workshop for the UNION's World Congress on Tuberculosis and Lung Health. This report describes the topics and outcomes of the all day workshop.

### Purpose of Trip

The purpose of the trip was to:

- Conduct a TB pharmaceutical management workshop "*Building Capacity in Pharmaceutical Management for TB, MDR-TB and TB/HIV*" at the Union international congress
- Attend the 36th International UNION World Congress on Tuberculosis and Lung Health conference
- Discuss potential technical assistance and disseminate informational materials and tools developed by MSH/RPM Plus and partners on TB control and management



## ACTIVITIES

MSH/RPM Plus in collaboration with the GDF conducted a workshop at the 37<sup>th</sup> annual UNION World Congress on Tuberculosis and Lung Health.

### Objectives:

- To present relevant experiences from country programs
- To raise issues and allow participants to share both concerns and examples of successful interventions in their country programs
- To reach a consensus through open discussion on how to move beyond what is currently known about good TB pharmaceutical management to solving the more polemic issues related to TB, MDR-TB and TB/HIV
- To remind participants of a variety of resources and tools for managing the selection, procurement, distribution, quality control and rational use of TB medicines/commodities
- To disseminate the tools developed by RPM Plus and GDF over the course of the last 5 years

Experience from the USAID-supported Rational Pharmaceutical Management Plus Program, the Global TB Drug Facility (GDF) and the Green Light Committee Secretariat (GLC) were elaborated through discreet participatory sessions on operational research and workable interventions to help countries understand what others are doing and mechanisms available to them for promoting better management in their countries.

The target audiences included: managers of national TB programs (NTPs), managers of essential medicines and procurement departments, medicines policy makers, and TB donors/partners, including consultants who conduct program assessments on behalf of the GDF/GLC.

### Topics:

- Do TB Patient Kits Produce Better Results?
- What is the best way to quantify needs and to order 1<sup>st</sup> line TB medicines?
- Can there be a single TB and HIV medicines management system?
- What are the challenges to managing 2<sup>nd</sup> line TB medicines?
- What are the pharmaceutical implications for introducing new TB treatment mechanisms?
- Conclusions on outstanding TB pharmaceutical management issues, next steps and closing remarks

**Methodology:** Each topic was carried out as follows:

- 15 minute presentation of country experiences by a national representative
- 10 minute response by an expert from MSH, GDF, and GLC presenting the known bottlenecks with the TB pharmaceutical management topic and raising other polemic issues related to the topic
- 25 minutes of questions and comments by participants relating their experiences
- 10 minutes for reaching a final consensus of all present

Upcoming technical events and new developments involving GDF, GLC and MSH/RPM Plus were presented within each related topic.

Session leaders led the 10 minute discussion at the end of each topic including both participants and facilitators in the discussions which was aimed at gaining consensus on what works and the issues in TB pharmaceutical management still at hand.

The final session of the workshop consisted of a forum whereby the results of the 10 minute topic discussions were reviewed, major outstanding TB pharmaceutical management issues agreed upon and next steps elaborated to help national programs overcome these issues. See *Next Steps* in this report for a detailed description of the issues and who might be carrying out activities revolving around the suggested solutions.

The workshop was well attended with over 71 participants from all over the globe. See **Annex 1** for the workshop program, **Annex 2** for consensus reached on each topic discussion, **Annex 3** for a list of participants and **Annex 4** for participant evaluations.

Main tools disseminated during the workshop were:

- *Managing Pharmaceutical and Commodities: A Guide for National TB Programs*, 2005. MSH/RPM Plus

This guide is available in English, Spanish and French and provides national TB programs with a step-by-step approach to reviewing core components of pharmaceutical management for TB in their countries. Using checklists and decision trees, NTP central and district managers can identify and address key gaps in their systems related to TB medicines selection, procurement, distribution, use, management support and policy.

- *Pharmaceutical Management for TB: Assessment Manual*, 2004 MSH/RPM Plus

The assessment manual is an indicator-based guide for evaluating the status of the TB pharmaceutical sector and contains instructions, methodology, data collection sheets, how to input and analyze data and how to present findings. It is available in English, Spanish, Russian and French.

- *Operational Guide for National TB Programmes on the Introduction and Use of Fixed-Dose Combination Drug*, 2002 WHO, MSH/RPM Plus and partners

This Guide is available in English, Russian and French and is designed for use by national TB programs to use when switching from loose drugs to fixed-dose combination drugs recommended by WHO. It allows the TB program manager to think through all aspects including medicine selection, procedures development, training and phasing out of previously used loose medicines.

### **Workshop Evaluation:**

The workshop evaluation questionnaire was developed and analyzed by the UNION Congress secretariat. Of the more than 71 persons attending throughout the day a total of 31 participants completed the evaluation survey. The main findings include:

- 97% of respondents agreed that the workshop contents was interesting and well presented
- 90% stated they had the opportunity to participate fully in the discussion
- 55% reported that they would have like more presentations and topics
- 90% reported that the workshop met stated objectives
- 84% said the workshops were useful and relevant
- 94% agreed that the workshop title and description were in line with the course content
- 90% agreed that the workshop was related to conference theme

When asked if there are there any other topics they would like to be covered at a future conference, participants replied:

- Some logistics management training may be added
- Clinical trials for new regimens
- More country presentations
- For under developed countries and high burden countries of TB like Pakistan medical detailed pharmaceutical management for TB and TB-HIV if possible
- Countries experiences in procurement of drugs locally and quality assurance
- More countries experience
- More country examples - More on X-MDR treatment
- Global policy to countries that do not depend on GDF are need to buy medicines; how to guarantee manufactures' supply? Ex: Brazil
- Very goods speakers - Wrap up and summary was helpful!
- The role and perspective of the health facility manager health worker - actually responsible for implementing on site the drug programmes

In general, facilitators received very positive feedback from participants who said the workshop and tools will be very useful in their areas of work.

## **Collaborators and Partners**

StopTB/GDF



## NEXT STEPS

Participants and facilitators discussed at length the issues needing attention to further promote TB pharmaceutical management in national programs. The following lists the issues and needs, and indicates who might be completing the task.

- a) Need to develop specific *guidelines for using and switching to patient kit*

*Answer:* MSH plans to develop and disseminate these guidelines over the coming year.

- b) Spreadsheets do not solve anything; need *guidelines how to do calculations*, how to take into account weight band and side-effects and how to identify all of the stakeholders

*Answer:* MSH plans to discuss feasibility of developing and disseminating a reference guide over the coming year taking into account the variables encountered by national TB programs to help them do better TB quantification at all levels of the health system.

- c) *Need more information on models* for collaborative pharmaceutical management of TB/HIV medicines and commodities

*Answer:* MSH will continue its current technical activity of studying how selected countries are collaborating on pharmaceutical management of TB/HIV medicines and commodities and will present the findings at appropriate international and national events.

- d) Many challenges for supply of 2<sup>nd</sup> line TB medicines such as lengthy GLC approval process, long lead-time for receiving medicines, short shelf-life of medicines, not using standardized treatment regimens because of poor understanding of resistance pattern in countries.

*Answer 1:* GLC and GDF have merged and will pre-qualify suppliers and attempt to reduce lead times of medicine procurement through creation of a buffer stock supply; GLC will still promote use of WHO regimens for MDR-TB treatment by national TB programs to help standardize a smaller variety of medicines needed.

*Answer 2:* MSH/RPM Plus and GLC will finalize its report of the global study recently conducted on availability and use of 2<sup>nd</sup> line medicines which will serve to inform producers of the size of the market and which drugs and formulations are needed. It is expected that the supply issue will improve once this information has been disseminated.

*Answer 3:* The global study findings should increase the speed for transfer of technology that is currently underway by big Pharma companies to countries such as China.

- e) New TB treatment mechanisms are needed such as sachets instead of tablets and FDCs for 2<sup>nd</sup> line treatment to promote compliance in adults and children, but the biggest underlying problem is still poor TB pharmaceutical program management

*Answer:* MSH/RPM Plus will still provide capacity-building technical activities throughout the coming year in appropriate regions.



## ANNEX 1. WORKSHOP PROGRAM

### Building Capacity in Pharmaceutical Management for TB, MDR-TB and TB/HIV

**How the proposed workshop is related to the UNION conference theme:** Pharmaceutical management is a primary component of any capacity-building program, and national programs should be familiar with the contrast in managing medicines and commodities for treating DOTS, DOTS-Plus and TB/HIV patients.

**Target audience:** Managers of NTPs, managers of essential medicines and procurement departments, medicines policy makers, and TB donors/partners, including consultants who conduct program assessments on behalf of the GDF.

**Goal:** Through open discussion reach a consensus on how to move beyond what is currently known about good TB pharmaceutical management to solving the more polemic issues related to TB, MDR-TB and TB/HIV

**Underlying theme:** MSH and GDF believe that TB pharmaceutical management practices are becoming better understood within the TB community; however, some issues where the three health problems come together remain sticking points for national TB programs and good models are not presently available

#### Objectives:

- To remind participants of a variety of resources and tools for managing the selection, procurement, distribution, quality control and rational use of TB medicines/commodities
- To present relevant experiences from country programs
- To raise issues and allow participants to share both concerns and examples of successful interventions in their country programs

<b>Time</b>	<b>Topic</b>	<b>Session Leader/Presenter/Responder</b>
8:30 – 9:00	Introduction	Leaders: <b>Thomas Moore</b> and <b>Edgar Barillas</b>
9:00 – 10:15	<b>Topic 1:</b> Do TB Patient Kits Produce Better Results?	Leader: <b>Andrey Zagorskiy</b> Presenter: <b>Kenya – Dr. Joseph Sitienei</b> Responder: <b>Hugo Vrakking</b>

10:15 – 11:15	<b>Topic 2:</b> What is the best way to quantify needs and to order 1 <sup>st</sup> line TB medicines?	Leader: <b>Adam Thomas</b> Presenters: <b>Edgar Barillas</b> <b>Homero Hernandez</b> Responder: <b>Chinwe Owunna</b>
11:15 – 11:30		
11:30 – 12:30	<b>Topic 3:</b> Can there be a single TB and HIV medicines management system?	Leader: <b>Andrey Zagorskiy</b> Presenter: <b>Chinwe Owunna</b> Responder: <b>Thomas Moore</b>
12:30 – 14:00		
14:00 – 15:15	<b>Topic 4:</b> What are the challenges to managing 2 <sup>nd</sup> line TB medicines?	Leader: <b>Adam Thomas</b> Presenters: <b>Robert Matiru</b> <b>Fabienne Jouberton</b> <b>Philippines</b> <b>IDA</b> Responder: <b>Fabienne Jouberton</b>
15:15 – 16:15	<b>Topic 5:</b> What are the pharmaceutical implications for introducing new TB treatment mechanisms?	Leader: <b>Robert Matiru</b> Presenter: <b>Joel Keravec</b> Responder: <b>Andrey Zagorskiy</b>
16:15 – 17:15	Decisions, conclusions and closing remarks	Leader: <b>Thomas Moore</b> Responders: <b>All facilitators and participants</b>

## **ANNEX 2. CONSENSUS REACHED ON EACH WORKSHOP TOPIC**

### **Topic 1: Do TB Patient Kits produce better results?**

- 1) Cannot prove they increase the cure rate
- 2) It does produce better results in terms of pharmaceutical management provided that there is better planning in:
  - a) Handling excess drugs
  - b) Providing for more space
  - c) Transportation may need to be altered because of size of order
  - d) Consideration of which weight band to use
  - e) Need to develop specific guidelines for patient kits

### **Topic 2: What is the best way to quantify needs and to order 1<sup>st</sup> line TB medicines?**

- 1) Ordering in complete treatments important for pharmaceutical management
- 2) Health facilities should report to central level on stock position of drugs
- 3) Keep track of consumption at primary-level; it is cost-effective for time invested since better controls inventories
- 4) Quantification spreadsheet issues:
  - a) GDF spreadsheet tailored for GDF ordering only
  - b) Do NTPs need guidelines and spreadsheet for quantification?
  - c) With several players involved in quantifying drugs, makes it difficult to use a single spreadsheet
  - d) Spreadsheets don't solve anything; need guidelines how to do calculations, how to take into account weight band and side-effects and how to identify all of the players (stakeholders)

### **Topic 3: Can there be a single TB and HIV medicines management system?**

- 1) There is insufficient evidence on best way for the TB/HIV medicines management teams to collaborate
- 2) Need more information to have conclusive outcomes
- 3) Joint system and collaboration could be the solution

### **Topic 4: What are the challenges to managing 2<sup>nd</sup> line TB medicines?**

- 1) Challenges:
  - a) Lengthy approval of proposal
  - b) Long lead-time
  - c) Short shelf-life
  - d) Combination of empiric and individualized treatment make quantification difficult
- 2) Facing the challenges:
  - a) Changing of regimens over time
  - b) Transferring of technology
  - c) Creation of buffer stocks
  - d) Understanding market demand so producers will fill market

- e) Merger of GLC-GDF?
- f) Issue of quality assurance

**Topic 5: What are the pharmaceutical implications for introducing new TB treatment mechanisms?**

- 1) Based on previous experience, process may be lengthy
- 2) Would like to have FDC for 2<sup>nd</sup> line treatment
- 3) May not produce desired results
- 4) Key issues to improving detection and curing patients are still because of poor program management
- 5) Other technologies should be considered such as the dosage forms sachets

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## ANNEX 4.WORKSHOP EVALUATIONS BY PARTICIPANTS

### EVALUATION WORKSHOP

Date: Wednesday, 1st November 2006 (08:30-17:00, Room 362/363)

Title: 5. Building capacity in pharmaceutical management for TB, MDR-TB and TB-HIV

Section: Tuberculosis

Coordinator: Thomas Moore (USA)

No. of evaluation forms collected: 31							
General Practitioner: 2    Specialist: 15    Graduate Student: 4 Program Implementor)							
1 = Strongly agree    2 = Agree    3 = Neither agree nor disagree    4 = Disagree    5 = Strongly disagree							
		1	2	3	4	5	No reply
1.	The postgraduate course content was interesting and well presented	14	13	3	0	1	0
2.	I had the opportunity to participate fully in the discussion	14	12	2	2	1	0
3.	I would have liked more presentations (if so, please state what topics you would have liked to hear	3	6	8	9	1	4
4.	The postgraduate course met the stated objectives	13	15	0	2	1	0
5.	The postgraduate course materials were useful and relevant	14	11	1	2	1	2
6.	The postgraduate course title and description were in line with the course content	12	14	3	1	1	0
7.	The postgraduate course was related to the conference theme	15	11	2	2	1	0

Are there any other topics that you would like to be covered at a future conference:

- Some logistics management training may be added.
- Clinical trials for new regimens.
- More country presentations.
- For under developed countries and high burden countries of TB like Pakistan medical detailed pharmaceutical management for TB and TB-HIV if possible.
- Countries experiences in procurement of drugs locally and quality assurance.
- More countries experience.
- More country examples - More on X-MDR treatment.
- Global policy to countries that not depend to GDF are .... need to buy medicines. How guarantee manufactures supply? Ex: Brazil
- Very good speakers - Wrap up and summary was helpful!
- The role and perspective of the health facility manager health worker - actually responsible for implementing on site the drug programmes.