

Technical Support to Second-line TB Drug Management, Moldova, October 4-6, 2006: Trip Report

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Printed: October 2006



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Supported by the U.S. Agency for
International Development

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 experts from Brazil and Moldova participated in the first Working Group (WG) meeting in charge of development and implementation of a Data Management Information Systems (DMIS) for MDR-TB drug management to strengthen the National Tuberculosis Control Program's (NTP) information system. As a result of this trip, the concept of the WG was officially validated and approved by the MoHSP with a matrix of responsibilities of all stakeholders and partners involved in the process of design and implementation of the new DMIS. The Moldavian technical team in charge of the surveillance system development and key specialists from the NTP discussed with RPM Plus experts the information to be collected, the DMIS database structure, and drafted the templates and forms expected to be used for data entry. It was agreed to develop a separate DMIS and integrate it with the current MoH systems for epidemiological TB control (SYMETA). The information collected during the trip will lead to the first version of the DMIS in Romanian to be posted online in early 2007 for stakeholder's testing on functionalities and final approval.

Recommended Citation

This report may be reproduced if credit is given to RPM Plus. Please use the following citation. Keravec, Joel; Seicas, Rita. Ricardo Memoria, Luis Gustavo Bastos 2006. *Technical Support to Second-line TB Drug Management, Moldova, October 4-6, 2006: Trip Report*. 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, TB, MDR-TB, DMIS, Second-line Drugs Management, GLC

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ACRONYMS

AFB	Acid-fast bacilli microscopy
AIHA	American International Health Alliance
Am	Amikacin
Amx/Clv	Amoxicillin/clavulanic acid
Cfx	Ciprofloxacin
Cm	Capreomycin
Cs	Cycloserine
GP	General Practice Medicine Office
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
DIP	Penitentiary Information Department
DMIS	Drug Management Information System
DOT	Directly Observed Therapy
DOTS	Directly Observed Therapy Short-course [WHO TB Control Strategy]
DOTS Plus	DOTS strategy for MDR-TB
DST	Drug Sensitivity Test
E&E	Bureau for Europe and Eurasia [USAID]
FDC	Fixed Dose Combination
FY	Fiscal Year
GFATM	The Global Fund to Fight AIDS, Tuberculosis & Malaria
IPP	Individual Patient Package
IPPS	Individual Patient Package Scheme
MDR-TB	Multi-Drug Resistant Tuberculosis
MOHSP	Ministry of Health and Social Protection
MOJ	Ministry of Justice
MOIA	Ministry of Internal Affairs
MSH	Management Sciences for Health
NTP	National Tuberculosis Control Program
PCU	Project Coordination Unit
PHC	Primary Health Care
PPI	Phtisio-Pneumology Institute “ <i>Chiril Draganiuc</i> ”
RPM Plus	Rational Pharmaceutical Management Plus Program [MSH]
SPCPHSM	Public Health and Sanitary Management Scientific Practical Center
SYMETA	TB/AIDS/STI Programs Monitoring and Evaluation System
TA	Technical Assistance
TB	Tuberculosis

TOT	Training of Trainers
USAID	United States Agency for International Development
WHO	World Health Organization
WG	Working Group

BACKGROUND

By definition, Multi-Drug Resistant Tuberculosis (MDR-TB) patients have developed resistance to at least isoniazid and rifampicin, currently the most powerful anti-TB medicines. The number of multidrug-resistant tuberculosis cases in many parts of the world is increasing due to poor treatment, noncompliance of patients, and poor access to pharmaceuticals. Moreover, the growing incidence of HIV/AIDS is expected to further impact the increasing number of MDR-TB patients. With the continues spread of MDR-TB, treatment costs will increase, additional global health resources will be required to combat TB, and patients will suffer for longer periods, or worse, die.

To confront this growing public health menace, the World Health Organization (WHO) and its partners have established the DOTS Plus strategy which provides technical support to countries and regions to build on existing DOTS programs (for primary TB). The WHO DOTS Plus strategy provides technical support through the Green Light Committee (GLC) and concessionary prices for second-line medicines needed to treat MDR-TB. Medicines to treat one MDR-TB patient can cost upwards of US\$ 10,000 or more per treatment if purchased on the open market. By purchasing through the GLC procurement agent, a country program can reduce costs to as little as US\$ 2,000 per patient.

Management Sciences for Health (MSH) and its Rational Pharmaceutical Management Plus Program (RPM Plus) are partners with the WHO Stop TB program and the GLC. One of the RPM Plus streams of activities is to provide support in pharmaceutical management of MDR-TB medicines in collaboration with the GLC and its partners.

In the coming years, 2007-2009, the Moldova National Tuberculosis Program (NTP), which is responsible for ensuring the continuous supply of drugs, plans to extend the number of multi-drug resistant tuberculosis (MDR-TB) patients to be treated within the DOTS Plus program from 200 patients to 600.

Since 2002, RPM Plus has been providing technical assistance (TA) to the NTP concerning the drug management for DOTS and DOTS-Plus program. In collaboration with the NTP manager, RPM Plus has drafted a management system for first- and second-line anti-TB drugs, which was already used for the planning and distribution of GDF drugs. Furthermore, RPM Plus has worked to strengthen the capacity of the NTP through several workshops, the latest of which took place in May and June 2006.

In 2007, RPM Plus and in-country partners, the Ministry of Health and Social Protection (MOHSP), the NTP and the Phtisio-Pneumology Institute “*Chiril Draganiuc*”(PPI) will be focusing on strengthening the second-line drug management information system (DMIS) to support the extension of the DOTS Plus project in Moldova. In order to improve the coordination of all activities undertaken in the information field to strengthen diagnosis, treatment and MDR-

TB cases management, the new applicative for Drugs Management Information will be developed and harmonized with other DMIS initiatives like the SYMETA (TB/AIDS/STI Programs Monitoring and Evaluation System), which may be currently developed with other key stakeholders and supported by partners such as the GFATM.

Purpose of Trip

Activity monitoring and workplan definition with NTP and counterparts for implementation of a new MDR-TB information system (DMIS) for diagnostic, treatment case management, provision and distribution of second-line drugs.

Scope of Work

Scope of work for Joël Keravec, Rita Seicas, Ricardo Memoria, and Luis Gustavo Bastos is as follows:

- Conduct the first meeting of the Working Group in charge of developing and implementation of an appropriate Data Management Information Systems (DMIS) for MDR-TB drug management.
- Follow-up on RPM Plus proposed DMIS model to study relevance of templates for data collection and harmonize the database with current templates and Drug Management (DM) procedures in use by the MDR-TB specialists in country.
- Discuss the guidelines for use and gather all the information needed to finalize the DMIS pilot model already developed by the Brazilian team and translated into Romanian.
- Interact with the technical team in charge of the development of the SYMETA surveillance system to finalize the design and upload the first beta version of the RPM Plus DMIS pilot data base in Romanian language to start the testing phase as soon as possible.
- Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova.

ACTIVITIES

RPM Plus Senior Program Associate Joël Keravec, MSH/RPM Plus consultant for Brazilian DMIS Ricardo Memoria (Software Development Specialist), MSH/RPM Plus consultant for Brazilian DMIS Luis Gustavo Bastos, Pneumologist (TB specialist), and MSH/RPM Plus Pharmaceutical consultant Rita Seicas (based in Chisinau) met all stakeholders and counterparts involved in MDR-TB case management. The first meeting of the WG, which is in charge of developing and implementing the Data Management Information Systems (DMIS) for MDR-TB drug management, was held at the Public Health and Sanitary Management Scientific Practical Center (SPCPHSM). Discussion was focused on the following points:

- Presentation of the current situation on SYMETA introduction at rayon level: results and challenges
- Short summary of RPM Plus last visits, presentation of the Brazilian DMIS and progress achieved towards the development of first DMIS model into Romanian
- Technical discussions among the experts to come up with a consensus on the new templates for information collection, data entry, information flows for the MDR-TB module
- Next steps to be followed

The agenda and the list of attendees at the first Working Group meeting in charge of developing and implementing the Data Management Information Systems (DMIS) for MDR-TB drug management are attached (Annex 2 and 3).

The first intermediate result of the DMIS implementation procedure is an official validation of the WG establishment (document reproduced in annex 4), with a clear matrix of roles and responsibilities. This WG is constituted of several entities like Ministry of Health and social Protection, NTP, IFP (National Reference for TB), National Health Insurance House, Scientific Practical Center of Public Health and Sanitary Management, TB/Aids Project coordination Unit, AHIA, MSH/RPM Plus.

Up-date on MDRTB context:

The information presented below was obtained after extended discussions with Dr. Silviu Sofronie, Director of the Institute of Phtysio-pneumology “Chiril Draganiuc”(PPI); Dr. Dumitru Sain, NTP Coordinator; Liuba Nepoliuc, Chief of the MDR-TB ward at the PPI; Otilia Scutelnicuic, Chief of the Monitoring and Evaluation Department for National Programs; Valeriu Plesca, IT Specialist of the SPCPHSM; Victoria Vulpe, TB specialist, DMT at the PPI.

Currently only 122 MDR-TB patients are recruited in treatment from around 620 MDR-TB cases, where 102 patients are enrolled in the GLC cohort and 20 patients are covered from Ministry of Health and Social Protection sources.

The GLC enrollment decision is taken by the *DOTS-Plus Recruitment Committees* of the Institute of Phtysio-pneumology “Chiril Draganiuc”(IFP), which is also in charge of second-line drug management of patients treated during the intensive and continuous phase. The main

criterion for a patient to be enrolled in the GLC cohort is to be virgin of any previous MDR-TB treatment.

The total amount of second-line drugs available is insufficient to treat all diagnosed MDR-TB patients. Patients enrolled in the GLC cohort receive a regular treatment of second-line drugs (based on: Capreomicin 1,0 inj, Ethionamid caps.250 mg, Cicloserin tab.250 mg, Ofloxacin tab.200 mg and Pirazinamid tab.400mg. PAS, gran 4g. is a reserve drug). Patients not enrolled in GLC depend on other sources medicine resources (the MOHSP, National Health Insurance House and donations) to be treated on a regular basis. Unfortunately these other sources can not cover a regular supply of second-line drugs for the remaining patients (not enrolled in GLC cohort), and just a small percentage (9,42 %) of them receive the proper medicine (second-line drugs) with a risk of treatment disruption due to lack of drugs supply. MDR-TB patients not treated with any second-line anti-TB drugs receive a treatment based on first-line drugs. Currently, MDR-TB patients are treated by the MDR-TB ward of the IFP and at the Pruncul Prison Hospital of the Penitentiary Department. NTP plans to extend MDR-TB treatment in 3 more hospitals if the recently sent cohort extension application is approved by the GLC.

New MDR-TB cases notifications sent by TB physicians are analyzed by the Recruitment Committee at the IFP for further enrollment to GLC cohort and treatment perspectives.

Second-line drug management is assured by the NTP and Drug Management Team, however lack of management tools leads to missing information on drug stocks, past consumptions and consumptions projection.

The SYMETA is an Informational System for Monitoring and Evaluation of classical TB. It was developed by a third-part company and is now supported by the IFP. (Technical characteristics are as follows: Working environment: WEB / Desktop Computer Language: Microsoft / NET Web Server: Microsoft Internet Information Server / Database: Microsoft SQL-Server).

The system has no specific module for MDR-TB (although it was projected to be developed in a future version) and no specific functionality to handle drug management. The SYMETA is available to hospitals and its database is centrally managed by the IFP. The system is currently being decentralized at rayon level: each rayon manages its own local database and a synchronization command is available in the system, allowing each rayon to receive and send information from and to the Institute by the Internet. SYMETA is not a web based system, but uses internet for its data exchange. It is not yet available in all rayons for cost reasons and currently facing several challenges due to poor internet connection and lack of human computer skills in some rayons. Discussions held during the meeting to address these challenges were of great interest as lessons learned for the MDR-TB module strategy to be followed: partners are working together to address some remaining gaps, such as assessing the flow of pharmaceuticals among different health system levels, evaluating the sources of procurement, and finding solutions for weak training and supervision of data operators, poor Internet connections, lack of computer hardware infrastructure, and mistrust of computers by health teams. This working group experience for MDR-TB will facilitate the next phase of development for Moldova's DMIS, which will incorporate HIV/AIDS and sexually transmitted disease modules.

NEXT STEPS

Immediate Follow-up Activities

1. Adapting pilot system for data collection on Moldova framework.
2. Validation of the model for DMIS module.
3. Integration of the module with SYMETA system with support of GFATM and AIHA funds for final software development.
4. Assistance in development of Guide for MDR-TB case management and Guides for users.
5. Training for DMIS use at all levels.
6. Conducting an evaluation.

Recommendations

The SYMETA should continue to be built as an integrated system for TB and MDR-TB surveillance and drug management, even if MDR-TB will be first developed as a separate module.

Agreement or Understandings with Counterparts

WG with all members has been officially approved and signed by MOHSP Vice Minister, Dr. Boris Golovin. The Ministry of Health has also significantly increased funding for procuring TB drugs in 2007.

Key stakeholders agreed on the first drafts for data collecting forms and on the logical structure of DMIS.

The information flow for drugs management was extensively discussed and is still to be finalized after WG's stakeholders consensus.

Important Upcoming Activities or Benchmarks in Program

RPM Plus is also providing support to the Romanian NTP for strengthening second-line drug management on a GLC approved project. Both Romania and Moldova programs and workplans will benefit from all activities and synergies carried out in the region, especially during the design and testing phases of the new DMIS in Romanian. A panel for a cross-cutting look and experience sharing on MDR-TB management systems between Brazil, Moldova and Romania was submitted to the next Global Health Council.

ANNEX 1: PROGRAM

Management Sciences for Health Rational Pharmaceutical Program Plus

Mission to the Republic of Moldova - October 04-6, 2006

Participants:

1. Dr. Joel Keravec Senior Program Associate, Management Sciences for Health/RPM Plus
2. Ph. Rita Seicas, Consultant, Management Sciences for Health /RPM Plus, Moldova.
3. Ricardo Memoria Lima, IT specialist , Consultant, Management Sciences for Health/RPM Plus /Brazilian office
4. Dr. Luis Gustavo Do Valle Bastos, TB Consultant, Management Sciences for Health/RPM Plus /Brazilian office

October 4 , Wednesday			
Institution, program	Name and position	Suggested duration	Purpose:
Scientific Practical Center of Public Health and Sanitary Management	Members of the WG (Annex 3)	10.30 am- 01.00 pm	<ul style="list-style-type: none"> • Summary of the last trip visit to Moldova; • The Brazilian experience on MDR-TB data management; • Translated version of software ; • The next activities for the implementation of the DMIS on MDRTB; • Working Group approach: purpose, objects and roles/ responsibilities
	Lunch	01.00 pm - 02.30 pm	
Scientific Practical Center of Public Health and Sanitary Management	Otilia Scutelnicuic Chief Monitoring and Evaluation of the National Program Department Valeriu Plesca Specialist IT	02. 30 pm – 08.00 pm	Integration with SYMETA: technical aspects of the system; structure, informational flow, forms of the system and data entry fields. Logic bases of the Brazilian system

October 5, Thursday			
Institute of Ftisiopneumology „Chiril Draganiuc,, NTP: Drug Management Team (DMT), Monitoring and Evaluation Department Scientific Practical Center of Public Health and Sanitary Management	Dr. Dumitru Sain, NTP Coordinator Liuba Nepoliuc Chief of the MDRTB ward Victoria Vulpe TB doctor, DMT Ecaterina Axenti- TB doctor, Monitoring and Evaluation Department Felicia Lupacescu Chief Org/Method Department	9.30 am-6.00 pm	Data collection forms, Current practice of data collection of the NTP; Requirements of the NTP for the new system; determine the flows for drugs management; data entry fields; Brazilian data bases: forms, flow, frequency, reports.
	Otilia Scutelnicuic Chief Monitoring and Evaluation of the National Program Department Valeriu Plesca Specialist IT		
	Lunch	02.00 pm - 03.30 pm	
October 6, Friday			
Institution, program	Name and position	Suggested duration	Purpose:
Institute of Ftisiopneumology NTP	Dr. Silviu Sofronie, Director of the Ftisiopneumology,, Institute C. Draganiuc Dr. Dumitru Sain, NTP Coordinator	10.00 -11.00 am	Discussed on the following topics: <ul style="list-style-type: none"> • Next activities in development and implementation of the DMIS • Development of the national guidelines for strengthening MDR-

			TB diagnosis, treatment and case management <ul style="list-style-type: none"> • Trainings
Rita Seicas, Ricardo Memoria Lima, Luis Gustavo:			
Institute of Ftysiopneumology	Liuba Nepoliuc Chief of the MDR-TB ward	9.30-11.00.am	<ul style="list-style-type: none"> • DOTS Plus pilot project: treatment of MDRTB and data collection practice; updated record tool. • Sources of the drugs supply
Joel Keravec:			
USAID Mission Chisinau Office	Michael C. Burkly Diana Cazacu Project Management Assistant	12.00-02.00 pm	Briefing-debriefing Strategic discussion for workplans and activities on RPM Plus continuing support for strengthening 2 nd line drugs management RPM Plus programming future planned funding with the USAID mission and counterparts in Moldova

ANNEX 2: MEETING AGENDA

MSH/RPM Plus and Working Group Meeting Agenda on the Development and Implementation of the Data Management Information Systems (DMIS) for MDR-TB Drug Management

1. Presentation of SYMETA's implementation process throughout the country for TB monitoring: results, challenges and lessons learned
2. Summary of RPM Plus last trip visit to Moldova
3. Presentation of the Brazilian experience with MDR-TB
4. The Working Group Approach: validation of the Working Group concept and the member's roles and responsibilities matrix
5. Next Steps

ANNEX 3: LIST OF ATTENDEES

MSH/RMP Plus and Working Group Meeting October 4, 2006

1. **Raisa Flocea** – senior specialist, General Department of the MOHSP
2. **Petru Crudu** - Deputy Director, Public Health and Sanitary Management Scientific Practical Center
3. **Otilia Scutelnicuic**, Chief, Monitoring and Evaluation of the National Program Department, Public Health and Sanitary Management Scientific Practical Center
4. **Valeriu Plesca**, IT specialist, Monitoring and Evaluation of the National Program Department, Public Health and Sanitary Management Scientific Practical Center
5. **Ana Volcov** , doctor, Monitoring and Evaluation of the National Program Department, Public Health and Sanitary Management Scientific Practical Center
6. **Valentin Martalog** – Deputy Director, PPI (Phtisio-Pneumology Institute “*Chiril Draganiuc*”
7. **Dumitru Sain** – NTP coordinator
8. **Victoria Vulpe** – TB specialist, Drug Management team, Phtisio-Pneumology Institute “*Chiril Draganiuc*”
9. **Liubovi Nepoliuc**, Chief, MDRTB ward, PPI Ftiziopneumology Institute „Chiril Draganiuc”
10. **Victor Burinschi**, TB/AIDS Coordinator PCU "TB/AIDS Program"
11. **Rita Seicaș**, Consultant, Management Science for Health
12. **Joel Keravec**, Senior Program Associate, Management Science for Health
13. **Viorel Soltan**, Director of the project, American International Health Alliance (AIHA)
14. **Valeriu Crudu**, Laboratory and surveillance specialist, AIHA
15. **Ricardo Memoria**, IT Consultant and Software Development Expert
16. **Luis Gustavo Valle Bastos**, MDRTB specialist

ANNEX 4: WORKING GROUP APPROVED BY MOHSP



MINISTERUL SĂNĂTĂȚII ȘI PROTECȚIEI
SOCIALE AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОЙ ЗАЩИТЫ
РЕСПУБЛИКИ МОЛДОВА

DISPOZIȚIE
РАСПОРЯЖЕНИЕ

24.11.06 Nr. 374-d
mun. Chișinău

„Cu privire la elaborarea și implementarea Sistemului Informațional de Monitorizare și Evaluare (SIME) pentru TB MDR”

Întru îmbunătățirea managementul cazurilor de TB-MDR și practicilor de colectare și administrare al datelor informaționale pentru TB-MDR în conformitate cu cerințele OMS inclusiv și GLC și prevederile Programului Național de Control al Tuberculozei pentru anii 2006-2010.

APROB:

1. Componența nominală a Grupului de Lucru pentru coordonare a procesului de elaborare și implementare al Sistemului Informațional de Monitorizare și Evaluare (SIME) pentru TB MDR (Anexa nr. 1).
2. Regulamentul Grupului de Lucru pentru coordonare a procesului de elaborare și implementare al Sistemului Informațional de Monitorizare și Evaluare (SIME) pentru TB MDR (Anexa nr. 2).

DISPUN:

1. Membrii Grupului de Lucru pentru coordonare a procesului de elaborare și implementare al Sistemului Informațional de Monitorizare și Evaluare (SIME) pentru TB MDR vor participa la realizarea prevederilor regulamentului în conformitate cu atribuțiile aprobate.

Controlul executării Dispoziției în cauză se atribuie Șefului Direcției Generale Sănătate a MSșiPS, Dl Liviu Vovc.

Viceministru

Boris Golovin

1



**MINISTERUL SĂNĂTĂȚII ȘI PROTECȚIEI
SOCIALE AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
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