

Technical Support to Second-line TB Drug Management, Romania, June 11-14, 2006: Trip Report

Joël Keravec
Rita Seicas

Printed July 2006



Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpplus@msh.org

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 and in-country partners, the Ministry of Health (MoH), National Tuberculosis Control Program (NTCP) and the National Health Insurance House (NHIH) are focusing their efforts on strengthening the drug management information system for the NTCP. RPM Plus conducted an evaluation with the NTP and main stakeholders for the potential implementation of a new Drug Management Information System (DMIS) developed by RPM Plus for second-line TB case management. Preliminary conclusions are highly favorable to the relevance of this project. Contacts for coordination of activities and initiatives in the field of information for TB were made with partners and stakeholders like GFATM. A working group of all stakeholders involved in the program was created, activities defined and a matrix of responsibilities agreed among all counterparts for the process of design and implementation of the new DMIS.

Recommended Citation

This report may be reproduced if credit is given to RPM Plus. Please use the following citation.

Keravec, J., R. Seicas. 2006. *RPM Plus Trip Report: Technical Support to Second-line TB Drug Management, Romania. June 11-14, 2006*. 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

Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmplus@msh.org
Web: www.msh.org/rpmplus.or

CONTENTS

Contents	iii
Acronyms	v
Background.....	1
Purpose of Trip	2
Scope of Work	2
Activities.....	3
Collaborators and Partners.....	7
Next Steps	9
Immediate Follow-up Activities	9
Recommendations.....	9
Agreement or Understandings with Counterparts.....	9
Important Upcoming Activities or Benchmarks in Program	9
Annex 1: Agenda	11
WHO Europe Region, Office for TB Control-Balkans	12
Annex 2: MDR-TB DRUGs Management context in romania	13

ACRONYMS

DMIS	Drug Management Information System
DOTS	WHO TB Control Strategy
DOTS Plus	DOTS strategy for MDR-TB
DOW	Doctors of the World
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
MDR-TB	Multi-Drug Resistant Tuberculosis
MOH	Ministry of Health
MSH	Management Sciences for Health
NHIH	National Health Insurance House
NIP "Marius Nasta"	National Institute of Pneumology "Marius Nasta"
NTCP	National Tuberculosis Control Program
PIU	Project Implementation Unit
RPM Plus	Rational Pharmaceutical Management Plus Program [MSH]
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 MDR-TB 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. If MDR-TB continues to spread, 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. Financial support is provided by the U.S. Agency for International Development (USAID).

In January 2005, RPM Plus conducted, with the participation of GLC and Partners in Health, a training course in Pharmaceutical Management for MDR-TB for staff from the National Institute of Pneumology “Marius Nasta” (NIP Marius Nasta), MOH and other key partners in the delivery of second-line medicines¹. The course materials were developed by RPM Plus and its partners, Partners in Health and GLC. The course was designed to provide technical information and to develop skills on specific managerial practices for managing a continual supply of quality MDR-TB medicines. In May 2005, the NTCP, using training materials provided by RPM Plus, undertook the Training of Trainers (TOT) on “Anti-Tuberculosis Drug Management” in order to keep to the schedule of activities planned under the GFATM project.

¹ Course on Pharmaceutical Management of Multidrug-resistant Tuberculosis: Trip Report Romania, January 24 - 28, 2005.

For the period 2006-2007, RPM Plus and in-country partners, the Ministry of Health (MoH), National Tuberculosis Control Program (NTCP) and the National Health Insurance House (NHIH) will focus on strengthening the drug management information system (DMIS) for the NTCP. For better coordination of all activities undertaken in the information field to strengthen diagnosis, treatment and MDR-TB case management, this new module for Drug Management Information will be developed and harmonized with other DMIS initiatives which may be currently developed with other key stakeholders and partners supported by other donors like 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 is as follows:

- Introduction of Senior Program Associate, Joël Keravec to USAID and in-country partners
- Review progress with on-going activity for the management of first-line anti-TB medicines
- Activity review and workplan definition for further strengthening of the pharmaceutical management of MDR-TB
- Present and demonstrate RPM Plus second-line TB Drug Management Information System to the NTP
- Initiate discussion with counterparts on a program of activities to be supported with the additional funding from USAID for strengthening the national tuberculosis control program
- Establish a workplan for the implementation of the system in Romania
- Brief/debrief the USAID Mission on the RPM Plus programming future planned funding with the USAID mission and counterparts in Romania

During his visit, Dr Joël Keravec was accompanied by Rita Seicas, Pharmacist and RPM Plus local consultant (based in Chisinau, Moldova). Rita Seicas will provide technical assistance to the NTP in Romania for this program.

ACTIVITIES

RPM Plus Senior Program Associate Joël Keravec and RPM Plus Pharmaceutical Consultant Rita Seicas met all stakeholders and counterparts involved in MDR-TB case management to review on-going activities and propose new activities for strengthening second-line TB drug management. All meetings have been organized and facilitated thanks to the kind assistance of the National Professional Officer, WHO Europe Region, Office for TB Control-Balkans, Dr Cassandra Butu.

The detailed list of contacts met and the agenda of the meetings is presented in annex 1. The information presented below was obtained after extended discussions with the Professor Stoicescu, NTP manager, Dr. Iulia Husar, responsible for the Implementation Unit of Projects at the Institute of Pneumology "Marius Nasta," GLC Team leader Dr. Cristi Popa and GFATM projects team, Dr. Cristina Popa, Mariana Andrei, Dr Aurora Dragomiristeanu, Deputy director of the National Health Insurance House, Ms. Pascu (Director of SC Unifarm SA, company responsible for storage and distribution of all GLC drugs), key members of the Commission for Drugs Orders Evaluation and technicians of the Surveillance Unit for MDR-TB at the Institute of Pneumology "Marius Nasta," at the MOH, and with the National Professional Officer, WHO Europe Region, Office for TB Control-Balkans, Dr Cassandra Butu.

The National Tuberculosis Program (NTP) is currently implementing a DOTS Plus project, which was approved by the GLC in 2005. The current practice of data collection concerning MDR-TB patients is based on a recently developed DMIS managed at the MDR-TB Unit of the Institute of Pneumology "Marius Nasta" which provides general data on recruited MDR-TB patients, previous history of treatment, and current status as well as laboratory data. However, information on drug management is not included in this system. Data on second-line anti-TB drug management is collected and maintained at the different departments (pharmacy level, monitoring and evaluation department, warehouse, etc.), but it is not integrated into one system for the General TB Surveillance Unit DMIS of the MoH.

NTP and MOH plan to expand the DMIS database for management of MDR-TB and to integrate it with the current information systems on first-line TB management. A more detailed description on second-line drugs management issues is presented in annex 2.

Based on experience in this area, RPM Plus could provide technical assistance in development and establishment of DMIS to the NTP and MOH.

During these meetings, RPM Plus Senior Program Associate Joël Keravec presented and discussed with Romanian counterparts the management system currently used in Brazil, where RPM Plus has developed, field tested, and implemented a management information system for improving diagnosis, treatment, and management of MDR-TB cases.

The system consists of a computer application accessible through the Internet which could be used by designated judet level MDR-TB reference centers to register new patients and regularly report on case management throughout the treatment course. The monitoring of medicine stocks

is incorporated within the system, allowing the central administration of the program to track existing quantities of drugs, quantities consumed, and quantities needed for the next re-order period.

Following the discussions with key stakeholders involved in the implementation of DOTS Plus strategy along with the visit of the MSH RPM Plus Technical Coordinator in Romania, it was decided to build on the Brazilian experience and adapt this logical framework to the Romanian context for MDR-TB drug management. The discussion resulted in the decision to form a Working Group (WG) to study this potential DMIS implementation.

The purpose of establishing the WG is to form a unit to:

- coordinate the development and implementation of DMIS for MDR-TB,
- rationalize and optimize all counterparts initiatives and efforts undertaken in the TB information field
- avoid duplication/conflicts in the strategies to be followed and in the information templates used for data collection and regular reporting on first-line TB and MDR-TB.

Key Objectives of WG:

- **Strategic objective:** Develop and implement an appropriate Data Management Information Systems for MDR-TB drug management.
- **Technical objectives:**
 - Optimize the current MDR-TB notification system
 - Define and test a model of MDR-TB health surveillance for patient management and appropriate data transfer at all levels (NTP, MoHF, judets, reference centers)
 - Maintain a MDR-TB case data base at central level
 - Define follow-up indicators for case management and standardized epidemiological and operational reports
 - Provide data for monitoring and operations research
 - Record and store data on distribution and use of medicines

Scope of work of WG

- Evaluate diagnosis, standard treatment guidelines (STGs) and practices for MDR-TB patient management
- Revise diagnosis, STGs and practices for MDR-TB patient management and notification
- Examine the current practice of data collection
- Identify needs of the NTP and MOH for the new DMIS
- Develop follow-up data sheets
- Define information flows and indicators for monitoring and standardized reporting
- Develop a DMIS logical framework for MDR-TB patient management harmonized with existing public health surveillance systems

- Undertake training workshops to implement the new model of MDR-TB patient management

Composition of Working Group:

- WG is a multidisciplinary group whose members are representatives of the organizations and institutions from different levels of the public and non-governmental sectors involved in implementation of the DOTS Plus strategy
- Proposed members of the WG are:
 1. **Conf. Constantin Marica**, NTP Manager/MoH
 2. **Dr. Iulia Husar**, Institute of Pneumology “Marius Nasta,” responsible for the Implementation Unit of Projects (IUP) GFATM
 3. **Dr. Cristi Popa**, MDR-TB drugs management expert, project coordinator DOTS Plus project, GFATM, phase 1
 4. **Horia Cocei**, System Administrator Surveillance Unit NTP, Institute of Pneumology “Marius Nasta”
 5. **Elena Pascu**, General Director JC “Unifarm,” responsible for storage and distribution of all GLC drugs
 6. **Dr. Cassandra Butu**, National Professional Officer, WHO Europe Region, Office for TB Control-Balkans
 7. TB Surveillance Unit Coordinator/MoH
 8. **Aurora Dragomiristeanu**, deputy director National Health Insurance House
 9. **Ady Popescu**, Responsible for anti-TB drugs, National Health Insurance House
 10. **Diaconu Ady, Lucian**, PMU-MOH
 11. **Rita Seicaș**, Consultant Pharmacist, Management Sciences for Health
 12. **Joël Keravec**, Senior Program Associate, Management Sciences for Health

Other participants may be invited to the team’s meetings as needed.

Matrix of Responsibilities - Role of members:

Representatives of MOH

- Follow-up for all steps of the development of the DMIS in close collaboration with the WG coordinator RPM Plus
- Approve all modules for the new developed DMIS and all drugs management procedures
- Validate the strategies for DMIS use at all levels and validate all training materials
- Coordinate the implementation of the system at all levels

Representatives of Institute of Pneumology “Marius Nasta” and Coordinators of DOTS Plus project

- Evaluate diagnosis, standard treatment guidelines (STGs) and practices for MDR-TB patient management
- Revise diagnosis, STGs and practices for MDR-TB patient management and notification
- Defining the necessity of the DMIS according to the recommendations of GLC, WHO and other international partners
- Revise the current system of data collection bases of MDR-TB
- Determine the needed data focusing on all aspects of the management of MDR-TB: Diagnosis, Recruitment, Treatment, Laboratory management, Drug supply management, Reports
- Define indicators and reports formats for management of MDR-TB
- Develop data collection and reporting flow
- Contribute to the development and validation of the training materials
- Monitor implementation of the new DMIS
- Maintain and update of the system

National Health Insurance House

- Revise diagnosis, STGs and practices for MDR-TB patient management and notification
- Defining the necessity of the integrated DMIS with current system
- Revise the current system of data collection bases of MDR-TB
- Determine the needed data focusing on all aspects of the management of MDR-TB
- Define indicators for management of MDR-TB
- Develop data collection and reporting flow
- Contribute to the development and validation of the training materials

PMU-MOH

- Provide assistance for development and implementation of new MDR-TB software
- Support in maintaining the DMIS
- Support in development of training materials

WHO Europe Region, Office for TB Control-Balkans

- Provide support in revising and updating of diagnosis, STGs and practices for MDR-TB patient management and notification

- Provide assistance in defining of indicators
- Support in development of training materials
- Support in conducting training

RPM Plus - MSH

- Coordinate and facilitate the activity of the WG for all steps needed by the program
- Define and monitor workplans and activities
- Provide a model software for management of MDR-TB Patients
- Provide support in updating and integration of MDR-TB software with current systems
- Provide assistance in elaboration of drug management component
- Coordinate the development of the DMIS
- Support in development of training materials
- Support in conducting training

Collaborators and Partners

1. **Conf. Dr. Contantin Marica**, Manager NTP/MoH
2. **Dr. Iulia Husar**, Director, Implementation Unit of Projects (IUP) GFATM – Institute of Pneumology “Marius Nasta”
3. **Dr. Cristi Popa**, MDR-TB drugs management expert, project coordinator DOTS Plus project, GFATM, phase 1
4. **Dr. Aurora Dragomiristeanu**, Deputy director of the National Health Insurance House
5. **Elena Pascu**, General Director JC “Unifarm”
6. **Dr. Cassandra Butu**, National Health Officer, WHO Europe Region, Office for TB Control - Balkans
7. **Ady Popescu**, Responsible for anti-TB drugs, National Health Insurance House
8. **Diaconu Ady**, Lucian, PMU-MOH

NEXT STEPS

Immediate Follow-up Activities

1. Officially nominate the members of the WG with all local counterparts
2. Organize the first meeting of the WG according to the Scope of Work presented in this report
3. Follow-up on RPM Plus proposed DMIS model to study relevance of templates, harmonize with current templates in use and translate data collection tool
4. Test the RPM Plus DMIS model by designing a new data base in Romanian language first and upload it to the Web for access by local counterparts
5. Recruit local consultant to assist the NTP and counterparts with the RPM Plus consultant from Moldova
6. Use this first pilot DMIS as a model to validate with all partners at all levels the procedures on data collection, epidemiological surveillance information reports, operational information reports and drugs management reports
7. Transfer the logics and the programming data of all DMIS pilot model functionalities expected to be transferred in the current TB information system for the development of the comprehensive MDR-TB module
8. Develop training courses, up-date educational manuals on MDR-TB and organize training workshops for decentralizing the use of the DMIS

Recommendations

The timeframe for implementation of the DMIS is short: it has to be fully implemented by September 2007. To gain time, RPM Plus suggests to articulate a task force using the current developers who were responsible for the design and realization of the DMIS in Brazil with the local technical counterparts and Romanian developers already involved in Data Management Projects for better efficiency in the development process.

Agreement or Understandings with Counterparts

The principle responsibilities of the WG has been discussed and need to be presented for final decisions to all stakeholders for the implementation steps of the new DMIS for second-line TB drug management. Since the NTP and MoH is passing through a period of change and structure reorganization due to the current health reform conducted by the MoH, further definitions need to be addressed before final nomination of the WG members. According to the WG scope of work, institutional agreements have been verbally assured for the continuation of the workplan, in accordance with the defined strategic and technical objectives.

Important Upcoming Activities or Benchmarks in Program

RPM Plus is also providing support to the Republic of Moldova NTP for strengthening second-line drug management of a GLC approved project. The Romanian program and workplan 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 language.

ANNEX 1: AGENDA

Management Sciences for Health Rational Pharmaceutical Program Plus

Mission to Romania – Final Agenda June 11-14, 2006

Participants:

Dr. Joël Keravec *Senior Program Associate, Management Sciences for Health/RPM Plus*
Ph. Rita Seicas, *Consultant, Management Sciences for Health /RPM Plus, Moldova.*

<i>June 12, Monday</i>		
Institution / Program	<i>Name and position</i>	<i>Suggested duration – Topics discussed</i>
Institute of Pneumology “Marius Nasta”	Prof. Ioan Paul Stoicescu <i>NTP manager</i>	11.30 am-04.00 pm
	Dr. Iulia Husar, <i>Director IUP - GFATM</i> Dr. Cristi Popa and Dr. Cristina Popa <i>Coordinator and Team leader -Implementation Unit of Projects (IUP) – GFATM-</i>	Briefing Presentation of RPM Plus DMIS Evaluation of the relevance of the DMIS model in the Romanian context Strategic discussion for workplans and activities First conclusions and next steps for stakeholders support and participation to the WG
	<i>Chief Pharmacist of the Hospital Pharmacy</i>	
	Dr. Cassandra Butu, <i>National Professional officer, WHO Europe Region, Office for TB Control-Balkans</i>	
<i>June 13, Tuesday</i>		
<i>Institution, program</i>	<i>Name and position</i>	<i>Suggested duration</i>
PMU-MOH	Dana Podaru Diaconu Ady- Lucian <i>Surveillance Unit Officers</i>	10.00. -12.30 a.m. Presentation of RPM Plus DMIS Evaluation of the relevance of the DMIS model in the Romanian context
	Dr. Cate Johnson <i>Director, Democratic and Social Sector Reform Bureau</i>	01.30 -02.20 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
USAID Romania	Alina Panait <i>Health Specialist</i>	

		funding with the USAID mission and counterparts in Romania
National Health Insurance House	Dr. Aurora Dragomiristeanu <i>Chief physician, Deputy General Director</i> Alin Stanescu <i>Counselor</i> Ady Popescu <i>Responsible for anti-TB drugs</i>	03.30-04.30 pm. Briefing Presentation of RPM Plus DMIS Evaluation of the relevance of the DMIS model in the Romanian context Strategic discussion for workplans and activities First conclusions and next steps for stakeholders support and participation to the WG
June 14, Wednesday		
WHO Europe Region, Office for TB Control-Balkans	Dr. Cassandra Butu, <i>National Professional Officer, WHO Europe Region, Office for TB Control-Balkans</i>	9:00 – 10:00 Global context of TB control activities Meeting with GFATM representatives
Institute of Pneumology “Marius Nasta”, Bucuresti	Horia Cocei <i>System Administrator Surveillance Unit NTP</i>	10.00 -11.30 am Presentation of current TB DMIS Evaluation of the relevance of the DMIS model in the Romanian context Strategic discussion for workplans and activities
MDRTB Center Bucuresti	Adrian Constantinescu <i>Computer Operator</i>	12.00-01.00pm Presentation of current TB DMIS Evaluation of the relevance of the DMIS model in the Romanian context
JC “Unifarm“ Public State Warehouse (DOTS Plus Project Partner for MDR-TB drugs)	Elena Pascu <i>General Director</i>	02.00-02.45 pm Strategic discussion for workplans and activities on specific drugs management issues
Institute of Pneumology “Marius Nasta”, Bucuresti	Pr Stoicescu, <i>NTP Manager</i> Dr. Cristi Popa, Dr. Cristina Popa, <i>Implementation Unit of Projects (IUP) GFATM</i> Dr. Iulia Husar, <i>Director</i>	02.45-04.00 pm Final debriefing on mission and conclusions and next steps for stakeholders support and participation to the WG

ANNEX 2: MDR-TB DRUGS MANAGEMENT CONTEXT IN ROMANIA

I. General Background for TB and MDR-TB in Romania

1) *TB related Health System Structure*

The Romanian administrative structure is divided into 41 counties or *judets* and the Bucharest municipality. In turn, the Bucharest municipality is divided into six administrative districts. The central unit for TB is located at the “Marius Nasta” Institute, in Bucharest. Patients are treated and drugs are distributed at the dispensary level. There are a total number of 190 TB dispensaries, where each county has more than one dispensary (about 3-5). Each dispensary has one pharmacy. The TB hospital system consists of 70 units. Currently there is a restructuring of the public health system, reorganizing regional hospital references and TB hospitals direction teams.

2) *Main particularities of TB teams organization:*

Family doctors have an active role: identify suspect patients (TB suspects and contacts), send them to TB dispensary for diagnosis, ensure DOT treatment, and prescription.

Anti-TB drugs are not sold through the pharmacy, except rifampicin and quinolones which are used by other health service.

A TB team consisting of two specialists - family doctor or pneumologist and nurse, and sometimes with the assistance of a social worker – care for TB patients. Three thousand family doctors have been trained and there is currently a plan to train another 1,500 from a total of 12,000 family doctors. Training is focused on doctors from rural area.

TB patients receive social support in the form of food vouchers in only two areas: Bucharest and Constanta. A developed legal basis for such support does not exist, even if ensuring TB patients with social support is a vital issue in some cases.

3) *Laboratory network:*

It is composed of:

- Central Level: National Reference Laboratories (Bucharest and Cluj-Napoca) in charge of DST, culture, microscopy testing
- Second level: 70 laboratories in charge for microscopy/Drug Sensitivity Test (DST)
- Third level: 190 laboratories in charge for microscopy

There are two levels for ensuring the quality of laboratory activities:

- *internal control*, where TB laboratory from one county is checked by the TB laboratory from others. The National Reference Laboratories is responsible for checking the quality of the judet laboratories.
- *external control* is undertaken by the supranational laboratory from Stockholm. The results of external control for first-line treatment is 90-95% of concordance.

After the WHO laboratories network mission recommended the reduction of the number of laboratories performing DST, one laboratory per 2-3 judet began carrying out DST. Formal recognition from public health system and funding for laboratory exams is minimal, except for funding hospital beds. The NTP made proposals at high levels to change the financing principle for the TB program.

4) DOTS coverage:

DOTS is implemented in the large towns, however the total DOTS percentage of coverage is still difficult to estimate in the country.

5) Summary on MDR-TB Epidemiological Data:

In 2005:

25000 new TB cases

5000 relapses => 10,7 % MDR-TB in all previous treated patients

1000 MDR-TB patients treated in the normal structure of TB ambulatories
(MDR-TB definition used in Romania follows the WHO definition

IR 140

According to the national resistance survey conducted in 2003-2004 a total of 2,9 % primary MDR-TB was reported.

II. Drugs Management for MDR-TB in Romania

1. National Context for MDR-TB Drug management

With the assistance of the Global Fund and MSH, the NTP developed a Drug Management for Anti-Tuberculosis Guide. The Guide was distributed to participants who attended training sessions held by the NTP which focused on a multidisciplinary group of specialists involved in providing MDR-TB treatment: TB doctors, family doctors, pharmacists, and a specialist from the National Insurance Company. Around 300 have been trained thus far and as of now, the NTP has held 12 regional meetings for DM activities. In addition, with WHO support, a CD consisting of training materials on all aspects of TB including drug management has been developed.

In 2004 Romania sent the application to GLC for access to second-line anti-tuberculosis drugs. In order to provide MDR-TB treatment, two MDR-TB Centers were created: one at the "Marius Nasta Institute," Bucharest (50 beds) and the other in the TB hospital located in Bisericani, in the eastern part of the country (70 beds). Currently, there are 200 patients from all over the country enrolled in DOTS Plus Project and other 200 will be integrated soon.

Each facility has a MDR-TB Commission for Treatment and Management in charge of selection and inclusion of patients, including defining treatment regimens. MDR-TB Commission for Treatment and Management is composed of 12 specialists from different departments.

Here is the scheme of patient's recruitment in MDR-TB treatment:

- A. TB doctors from the dispensary prepare documents and send to TB Commission for examination (Bucharest or Bisericani)
- B. Hospitalization for 4-6 months until conversion, if there is a decision of the TB Commission. If it is necessary, the patient might be hospitalized for up to eight months.
- C. After conversion, treatment is continued at the ambulatory level.

2. Treatment regimens:

The treatment of MDR-TB patients is based on an individual regimen determined by the TB commission. Until the culture result is available, the treatment of patients begins with the empirical scheme, following previous data on treatment: history, received drugs, and origin of contact.

3. Procurement of drugs:

For MDR-TB patients recruited in the DOTS Plus project cohort, drugs are procured by the NTP through the grant from the Global Fund to Fight AIDS, TB and Malaria, with the approval of the Green Light Committee mechanism.

The estimated quantity is based on the number of predicted MDR-TB patients for treatment and a list of second-line anti-TB drugs selected by the NTP.

The quality of second-line drugs for the DOTS Plus project is assured through the procurement process of the International Agency and selected and approved by the GLC to supply drugs.

Additional sources of second-line anti-TB drugs for MDR-TB patients that are not in the DOTS Plus cohort are drugs procured through tender organized by the Ministry of Health and the National Insurance House. Tender is supposed to be organized once per year. Last year, however, the MoH and NIH decided not to organize tender and to instead procure anti-TB drugs at the price of last year's tender,

4. Drug registration:

According to the national law, import and use of non-registered drugs is prohibited. From the list of drugs provided by the GLC mechanism, only Capreomycin and PAS are not registered in the country. These drugs are used specifically for patients from the cohort of the DOTS Plus project. However, the MOH issued special authorization to allow for the importation of certain unregistered drugs procured with financial support by GFATM to ensure the needs of health programs. In order to record drugs provided by the IDA, the manufacture/origin of drugs would have to be changed and different registration would be needed.

5. Importation and Customs Clearance:

Procedures are harmonized with NIH and MoH, without any problem reported on this issue since the DOTS plus has been initiated.

6. *Central storage:*

- For Second-line anti-TB drugs funded by GFTAM

Second-line anti-TB drugs received from the procurement agent of the GLC – IDA are stocked at “Unifarm,” **Public State Warehouse (DOTS Plus Project Partner for MDR-TB drugs)** which has been contracted for drug storage, evidence, issue and transportation service. Unifarm receives a report on drugs, quantity and expiration date on a monthly basis.

- For First- and Second-line anti-TB drugs funded by NIH

First- and second-line anti-TB drugs are stocked at the warehouse of the supplier winning the tender. According to the GLC requirements, the stock lasts for six months and is distributed monthly to the pharmacies of the TB dispensaries at the county level. The stock at the pharmacy is for one month for second-line anti-TB drugs while for first-line, it is up to three months.

7. *Transfer of stock to health facilities*

- For Second-line anti-TB drugs funded by GFTAM

Based on the pharmacy order from the local level, Unifarm sends second-line drugs to outpatient clinics for a period of three months for each patient. All orders are checked by the Coordinator of the DOTS Plus project.

- For First- and Second-line anti-TB drugs funded by NIH

First- and second-line anti-TB drugs procured by the National Health Insurance House are distributed on a monthly basis.

8. *Delivery to Patient and use*

Drugs for inpatients are dispensed from the pharmacy to the MDR-TB ward on a weekly basis. Drugs for outpatients are dispensed under DOT by the TB or family doctors in rural areas. TB patients visit the TB cabinet/family doctor once per week and receive one DOT dose while the other doses are self-administered at home.

9. *Information Systems and Data Management*

A new system/software has been developed but does not currently have all the pertinent information. Each patient is monitored with an excel sheet to register history of drugs administered, results on conversion, resistance observed and DST results. Based on the gathered data, the treatment is defined for each individual by the committee.

Up until now, out of 200 patients being treated, updated information on 60 patients is presently in the database. According to the DOTS coordinator of the DOTS Plus program, the system does not provide data on drug movement. At the Institute pharmacy, software designed for accountability of this unit exists. However, the software cannot provide all the needed data on drug supply throughout the country. The same type of software is used by the Joint Company “Unifarm.” (JC Unifarm)

An information system at the Surveillance Unit where epidemiological data is collected also exists. The system is used within three levels: primary unit, judet and central level. The data from Laboratories is part of this system and includes direct access to the unit. Data is introduced by dispensaries and laboratories allowing for double verification. Reports can be generated at all three levels. The pharmacies are not part of this system/software.

The National Health Insurance House (NHIH) has software for all medicines – including for first- and second-line TB drugs procured by the NIH. Yet it is not integrated with all relevant levels on a comprehensive scale for drugs information management making it difficult to understand the true management picture.

The NTP with the assistance of MSH/RPM Plus developed and proposed a new DMIS which has not been yet incorporated by the NIH. The NIH is working on improving the current software and agreed to formulate one integrated system.

All pharmacies of the TB dispensaries are equipped with computers.