

WHO Training Course for TB Consultants: RPM Plus Pharmaceutical Management Session on TB/HIV in Sondalo, Italy July 04 – 08, 2006: Trip Report

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Strategic Objective SO5 TB

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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.

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Key Words

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ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
DOTS	WHO Strategy to break the transmission of Tuberculosis
GLRA	German Leprosy Relief Association
HIV	Human Immunodeficiency Virus
MSH	Management Sciences for Health
NGO	Non-governmental organization
RPM Plus	Rational Pharmaceutical Management Plus
TB	Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization

BACKGROUND

The growing HIV/AIDS pandemic is dramatically increasing the burden of TB cases worldwide, particularly in Sub-Saharan Africa, Eastern Europe and Asia. Comprehensive TB and HIV care and prevention rely on implementation of the WHO recommended strategy of TB control (DOTS strategy) and on HIV/AIDS care and prevention programme contributing both to strengthen national health system and health communities. In this process it has become increasingly clear that there is an urgent need for competent managers and consultants in the implementation of their TB/HIV collaborative activities within respective TB and HIV/AIDS program. The Core Group of the TB/HIV Working Group of the Stop TB Partnership recommended in February 2004 that WHO should conduct training to support country implementation of TB/HIV collaborative activities.

To respond to this recommendation, WHO's Stop TB and HIV/AIDS Departments in association with the WHO Collaborating Centre for Tuberculosis and Lung Diseases, S. Maugeri Foundation, Tradate, Italy and the University of Brescia (Italian Centre of Excellence for HIV/AIDS control activities) developed and organized three pilot courses. In April 2004 a one week course for TB/HIV Consultants was organized in Sondalo, Italy, followed in November of the same year by two courses for TB/HIV Managers in Addis Ababa, Ethiopia (conducted in collaboration with GLRA). The present course which focused on Eastern European countries was designed based on these experiences.

RPM Plus has been providing support for the pharmaceutical management session of the WHO TB training course using USAID funding. In 2006, RPM Plus received funds from USAID to continue supporting the pharmaceutical management sessions of the course.

Purpose of Trip

RPM Plus Senior Program Associate, Chinwe Owunna, traveled to Sondalo, Italy to facilitate the TB/HIV pharmaceutical management session at the WHO course for TB Consultants from July 04 – 08, 2006.

Scope of Work

To facilitate the pharmaceutical management session on TB/HIV collaboration for WHO TB consultant training course for Eastern European countries.

ACTIVITIES

The pharmaceutical management training materials were revised to incorporate differences between TB and HIV/AIDS supply management, and issues to consider when planning implementation of TB/HIV collaborative activities based on the WHO interim policy.

The very interactive course was attended by 18 participants from 9 countries in Eastern Europe and East Africa (See Annex 1 for list of participants). Participants shared country experiences on TB and HIV pharmaceutical management issues. The group activity also stirred up a lot of discussion and knowledge sharing amongst participants.

The course materials were based on an imaginary country called Fictitia. Course activities were based off of real country data incorporated into the Fictitia framework. Details of the pharmaceutical management session on TB/HIV collaboration can be found in annex 3.

Collaborators and Partners

The Course was facilitated by WHO Collaborating Centre for Tuberculosis and Lung Diseases, S. Maugeri Foundation, Tradate and Morelli Hospital, Sondalo, in collaboration with WHO/Geneva. Ggiovanni Battista Migliori, Director of the WHO Collaborating Center was the organizer and main facilitator of the course.

RPM Plus has funding from USAID for continuous support of the Sondalo courses in 2006.

Adjustments to Planned Activities and/or Additional Activities

No adjustments were necessary

NEXT STEPS

RPM Plus will continue to conduct the TB and TB/HIV pharmaceutical management sessions of the WHO consultant training workshop. The date of the upcoming course in 2006 is:

1. September 27 – October 10: TB – HIV course. Edgar Barillas will facilitate the session.

ANNEX 1. AGENDA

Course Agenda: WHO Training on TB/HIV collaborative activities in Europe. 4-11 July 2006

Time	Tuesday 4	Wednesday 5	Thursday 6	Friday 7	Saturday 8	Sunday 9	Monday 10	Tuesday 11
8.30 - 10.30		<u>Unit 1:</u> Introduction & icebreaker <u>Unit 2:</u> Case study	<u>Unit 5, part 2:</u> Clinical management of TB	<u>Unit 8:</u> WHO interim policy and the European framework for TB/HIV	<u>Unit 12:</u> Monitoring & Evaluation for TB/HIV collaborative activities	Free time, social programme and plan writing	<u>Unit 15:</u> costing & budgeting for TB/HIV planning	<u>Unit 19:</u> Course evaluation & Closing <u>Departure to Tirano station</u>
10.30-11.00		Coffee	Coffee	Coffee	Coffee		Coffee	
11.00-13.00		<u>Unit 3:</u> Epidemiology of TB & HIV/AIDS <u>Unit 4:</u> Principles of TB & HIV/AIDS control	<u>Unit 6, part 1:</u> The WHO recommended strategy of HIV/AIDS control <u>Unit 6, part 2:</u> The clinical management of HIV/AIDS	<u>Unit 9:</u> Recording & Reporting	<u>Unit 12:</u> continue		<u>Unit 15:</u> continue <u>Unit 16:</u> Field visit	
13.00-14.30		Lunch	Lunch	Lunch	Lunch		Lunch	
14.30-15.30	<u>Arrival and registration</u>	<u>Unit 4:</u> Continue	<u>Unit 6, part 2:</u> Drug management	<u>Unit 10:</u> Surveillance of HIV prevalence among TB patients	<u>Unit 13:</u> Strengthening TB and HIV/AIDS collaboration	Free time, social programme and plan writing	<u>Unit 17:</u> Individual finalization of TB/HIV plans	
15.30 - 16.00	<u>Reading background documents</u>	Coffee	Coffee	Coffee	Coffee		Coffee	
16.00 - 18.00		<u>Unit 5, part 1:</u> The WHO-recommended strategy of TB control (DOTS)	<u>Unit 7:</u> Drug management	<u>Unit 11:</u> HDR for TB/HIV collaborative activities	<u>Unit 14:</u> how to prepare a plan		<u>Unit 18:</u> Discussion of selected TB/HIV plans	

ANNEX 2. LIST OF PARTICIPANTS

**WHO Training course on TB/HIV collaborative activities in Europe
Sondalo, 4 - 11 July 2006**

List of participants

	Name	Title / Institution	Phone / Fax number / Email
1	Dr. John Odhiambo Kembe Nairobi, Kenya	TB Program Team Leader PATH , Kenya ACS Plaza,4 th Floor,Lenana Road P.O.Box 76634 Nairobi, 00508, Kenya	Phone: +3877177/80/89 Fax: + 3877172 Mail address : jshauri@path.org
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13	<p>Dr.Olga Petrovna Frolova Moscow, Russian Federation</p>	<p>Head of TB/HIV Healthcare Center, Ministry of Health and Social Development of the Russian Federation, Head of Section for Anti-TB Service to the HIV patients, Research Institute of Phthisiopulmonology at the Sechenov Moscow Medical Academy</p>	<p>Tel./fax: 7 (095) 268 25 15 Mail address : opfrolova@mtu-net.ru</p>
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ANNEX 3. PRESENTATION ON PHARMACEUTICAL MANAGEMENT FOR TB/HIV

Drug management for TB and HIV/AIDS control
Document No. 4.3



WHO training course on TB/HIV collaborative activities in Europe

Slide 1

Objectives of the Unit

To describe the principles of TB and HIV/AIDS drug management:

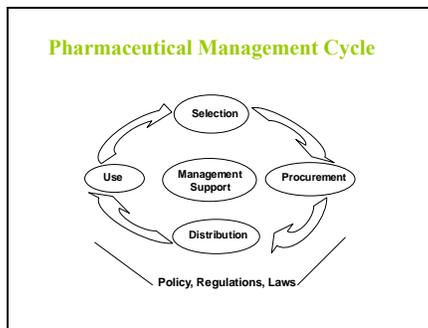
- to discuss the various aspects of TB/HIV drug management through a logical framework
- to identify the differences between procurement practices of TB and HIV/AIDS drugs
- to identify gaps and priorities in procurement of TB and HIV/AIDS drugs and propose solutions to facilitate the implementation of TB/HIV collaborative activities in drug management

Slide 2

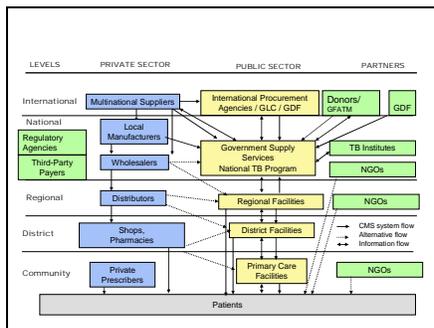
Pharmaceutical Management-defined

- Pharmaceutical management is a set of practices aimed at
 - Ensuring timely availability and appropriate use of safe, effective and quality medicines
 - Appropriate use of related supplies
 - Appropriate management of services for all health care settings

Slide 3



Slide 4



Slide 5

Standardized treatment regimens and uninterrupted drug supply are basic principles of the DOTS Strategy

- Political commitment to program including normative, financial, planning, surveillance, training and supervision functions
- Case detection among persons, presenting with symptoms, using low-cost tools
- **Standardized treatment with direct observation**
- **System for uninterrupted supply of quality TB drugs**
- Recording and reporting system allowing accountability and outcome evaluation

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TB Drug Supply (1)

- Estimation of drug needs (based on previous consumption and/or on notifications)
- Regimens are standardized
- FDC and /or blisters are recommended
- Use of patient kits
- Standardized recording and reporting system
- The cost of one first line regimen is about \$ 18
- Many suppliers available for quality TB medicines (limited pediatric drug suppliers)

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TB Drug Supply (2)

- GDF is fully operational to support procurement of quality drugs at the lowest possible price
- Low cost second line drugs are available for GLC programmes
- GDF and GLC convergence
- Convergence to occur in 2 phases
 - 1) Merging of procurement functions, as of January 2006
 - 2) Convergence of application process, reviews, monitoring and evaluation planned for 2007

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HIV Supplies Management (1)

- HIV-related drugs and diagnostics are ordinary supplies, but.....
- Scientific field is rapidly changing
 - Treatment is for life
 - Treatment or supplies interruptions have serious implications
 - The supply system has to cater for the different treatment regimens
 - changing percentages utilisation over time
 - ARVs are relatively expensive and in high demand.....

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HIV Supplies Management (2)

- ART receives high level Government and donor support and scrutiny
- Rapid scale-up of services
- ARVs and test kits may require cold storage
- ARVs often have short shelf lives
- Quantification and procurement is more cumbersome
- Global initiatives to improve access to ARVs (eg AMDS, TRIPS)

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Selection (1)

- Standardized treatment guidelines (STGs)
 - Evidence based
- Recommendations to shift from 1st to 2nd line *standardized* for TB , under constant revision for ARVs
- Greater need to change regimens for HIV/AIDS (failure or side effects) than for TB (30% vs 2%)
- Drugs for opportunistic infection and palliative care for HIV
- Drugs for adverse drug reactions associated with second line TB treatment

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Selection (2)

- More complicated for ART
 - ART HIV 2 infections
 - PI first line regimen
 - ART for TB co-infected patients
 - Interaction between rifamycins, PIs and NVP
 - ART for HBV and HCV
- Product issues
 - Cost of regimens
 - Shelf live (stability of products eg D4T liquid)
 - Storage requirements

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Procurement: quantification (1)

- Quantification more complicated for ART
 - Lack of historical data (inadequate DMIS)
 - Losses (Deaths, loss to follow-up)
 - Changes in regimens
 - Weight, pregnancy, treatment failures, ADRs, co-morbidities eg TB
 - Limited pediatric formulations
 - Changes in dose (weight, age)
 - wastage of liquids, inappropriate pack sizes
 - Short shelf life (mostly 2yrs at time of manufacture)

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Procurement: quantification (2)

Programmatic issues

- Push for rapid scale-up
 - Limited capacity to deliver services
 - Limited capacity of supply systems
- Availability and demand for HIV testing
 - Eg Opt-out in TB clinics
- Level of funding, donor restrictions
- Delays with disbursement of donor funds

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Procurement: tender methods

- Open tender: too long
- Restricted tender: market information on price & quality: www.who.int/medicines, www.accessmed-msf.org
 - Prequalified products "Access to HIV/AIDS drugs and diagnosis of acceptable quality" January 2004
 - Indicative price: "sources and prices of selected medicines and diagnosis for PLWHA" June 2003
 - Untangling the web of price reductions, December 2003

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Procurement

- ART supply issues
 - Oligopoly
 - Rapidly changing market
 - Prequalification or regulatory approvals
 - Unpredictable and long lead-times
 - Supplier preference for long term forecasts and assurances of procurement

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Distribution

- Port clearing (document, testing, taxes)
- Adequate storage
 - Security (ARVs expensive)
 - Good storage practice (temperature control)
- Good inventory management (register, bin card)
 - Monitor expiry dates
- Push or pull system (over-stocking or under-stocking)
- Transport (frequency, cold chain)
- Availability and distribution of INH for IPT

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USE

- CHW, home health care
- Dispensing (daily, weekly, monthly)
- Adherence monitoring systems
 - DOT, treatment buddy, pill counts
 - FDC (↓ pill burden)
- Patient education and support
 - Adverse drug effects
 - social and psychological support
- Irrational prescribing and use (waste resources)
- Treatment monitoring (cross resistance eg D4T and ZDV can ↓ ABC susceptibility)
- Lack of expertise in ART pediatric management

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Procurement: generic vs originator (1)

- TRIPS Agreement 1995 for ARVs (Trade Related aspects of Intellectual Property Rights) of the WTO
- Doha declaration 2001 (TRIPS and Public Health) = flexibilities like **Compulsory Licensing** is introduced to ensure that TRIPS agreement does not prevent members from taking measures to protect public health
- GOVERNMENT CAN ALLOW COMPANIES TO MAKE PATENTED PRODUCT UNDER LICENSE WITHOUT THE CONSENT OF THE PATENT OWNER FOR THE DOMESTIC MARKET (ARVs only)

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Procurement: generic vs originator (2)

- WTO member government decision of 30 August 2003. DOHA declaration effectively limited the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented.
The decision allows any member country to export pharmaceutical products made under compulsory license
23 countries announced to voluntarily refrain from use the system to import

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Making commodities available for countries : the WHO's AMD Service

- The AIDS Medicines and Diagnostics Service (AMDS) was launched in December 2003 as the access and supply arm of the 3 by 5 initiative.
- The objective of the AMDS is to expand access to quality, effective treatments for HIV/AIDS by improving the supply of antiretrovirals (ARVs) and diagnostics to developing countries

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Making commodities available for countries : the WHO's AMD Service

Partners group

- UN Agencies
 - WHO (EDM, EHT, CPS, Essential drugs and HIV RA in Regional offices), UNICEF, World Bank, UNAIDS, UNFPA, UNDP
- Technical organizations and donor agencies
 - CCAR, CHAI, CPA, Crown Agents, EPN, Esther, FIP, GFATM, IDA, JSI, MEDS, MSH
- Observers
 - MSF, US State Department (PEPFAR), USAID

Secretariat

- AMDS unit of HIV Department of WHO

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What the AMDS will offer

- To manufacturers: necessary forecasting information of volumes to be produced.
- To buyers (Governments, NGOs): intelligence to make informed choice on procurement
- Technical country support to the pharmaceutical management cycle

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What the AMDS can provide to countries

- Guidance on selection of core ARVs.
- Guidance on legal issues of importation of generic medicines
- Pre-qualification of drugs and diagnostics
- Information on product specification to be used in tenders
- Guidance and training in local production and quality assurance

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Making commodities available for countries : the WHO's AMD Service (1)

Progress so far:

- Procurement of drugs/diagnostics on competitive basis through the AMDS supply partners UNICEF, IDA, and WHO/CPS.
- Clarity on procurement
- As of mid-2004 20 countries used AMDS, estimate of 50 by the end of 2005

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Making commodities available for countries : the WHO's AMD Service (2)

Progress so far

- Technical support (Myanmar, Vietnam, Sudan, ...)
- Procurement of drugs/diagnostics on competitive basis through the AMDS supply partners UNICEF, IDA, and WHO/CPS.
- Example of CIPLA AIDS medicines (lamivudine and zidovudine/lamivudine) delisted from and then reinstated in the list of pre-qualified medicines during 2004

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Factors to Consider when implementing TB/HIV collaborative activities (1)

- Does a TB/HIV coordinating committee exist?
- What new intervention medicines and supplies will be required?
- Who will fund and manage new intervention drugs?
 - Quantification (method, data availability)
 - Procurement (what program?)
 - Distribution (what program or channel?)

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Factors to Consider when implementing TB/HIV collaborative activities (2)

- How will treatment be provided?
 - Referrals?
 - One stop service?
- Access of new intervention medicines?
 - TB treatment provided at lowest level
 - HIV treatment at higher level health facilities
- Inclusion of new intervention drugs in TB and HIV program STGs

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Factors to Consider when implementing TB/HIV collaborative activities (3)

- Drug management information system requirements? (reporting and recording)
 - What information is needed?
 - How will information be collected and used?
- What pharmaceutical management indicators will be monitored?
 - Eg, % of HIV patients on IPT
 - How to monitor indicators

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Factors to Consider when implementing TB/HIV collaborative activities (4)

- How will treatment compliance and adherence be monitored?
 - What adherence monitoring methods are feasible in your setting?
 - How will it be implemented and monitored?
- Human resources capacity
- Pharmaceutical supply system capacity
 - Eg, appropriate storage capacity

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Introduction to the exercise for Unit 6

1) The following table lists the ART regimens prescribed and reported from the 20 Raions delivering ART in Fictitia. For each regimen, indicate in the *Comments* column:

- if it is a WHO-recommended first- or second-line regimen.
- if you notice irrational prescribing or suboptimal use of ARVs in any regimen.

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Sample Comments on ART Regimens

ART Regimen	Comments
ZDV/3TC/EFV	WHO-recommended first-line therapy
ZDV/3TC/NVP	WHO-recommended first-line therapy
ZDV/3TC/IDV	Unboosted PI (no ritonavir)
ZDV/3TC/ABC	Three NRTIs – less effective
PI regimen	Single therapy?? Unsure
d4T/ddI/NVP	d4T/ddI no longer recommended due to risk of high toxicity

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Table 1

ART Regimen	Comments
ddl/ABC	Dual therapy
TDF/ZDV/3TC/LPV/r	Added benefit of third NNRTI is questionable
ABC(s)/3TC(s)/NVP(s)	ABC not recommended as first-line unless to replace NVP for rifampicin-based TB treatment in children under 3 or weighing less than 10 kg
d4T(s)/3TC(s)/EFV	Recommended first-line therapy; EFV not recommended for children under 3 or weighing less than 10kg

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Introduction to the exercise for Unit 6

2) List possible reasons why stock-outs or medicine shortages can occur in a pharmaceutical system (eg, HIV test kits were out of stock twice in 2004 in Fictitia for 2 weeks and 1.5 months respectively)

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