

**Rational  
Pharmaceutical  
Management Plus  
Participation in the  
GFATM Procurement  
and Supply  
Management  
Workshop in Nairobi  
Kenya, February 19-  
25, 2006:**

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*Trip Report*

Management Sciences for Health  
is a nonprofit organization  
strengthening health programs worldwide.



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Shretta, Rima  
Ndyanabangi, Bannet

*March 2006*

**Rational Pharmaceutical Management Plus  
Participation in the GFATM Procurement and Supply Management  
Workshop in Nairobi Kenya, February 19-25, 2006: Trip Report**

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Rima Shretta  
Bannet Ndyanabangi

March 2006

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## **About RPM Plus**

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen pharmaceutical 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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## **Abstract**

RPM Plus participated in the Global Fund PSM Plan Development Workshop held in Nairobi, Kenya for Anglophone African countries during the week of February 19-25, 2006. RPM Plus staff interacted with the countries present at the workshop and with collaborating partners.

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**Key Words:** Malaria, Africa, PSM, Procurement Supply & Management, HIV

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## Acronyms

ACT	Artemisinin-based Combination Therapies
ADR	Adverse Drug Reaction
AIDS	Acquired Immune Deficiency Syndrome
AMDS	AIDS Medicines and Diagnostic Service
GFATM	Global Fund to Fight AIDS, Tuberculosis & Malaria
JSI	John Snow Inc.
ITNs	Insecticide Treated Nets
LLIN	Long Lasting Insecticidal Nets
MAC	Malaria Action Coalition
M&E	Monitoring and Evaluation
MMSS	Malaria Medicines and Supply Service
MSH	Management Sciences for Health
NMCP	National Malaria Control Program
PSM	Procurement and Supply Management
RBM	Roll Back Malaria
RDT	Rapid Diagnostic Test
RPM Plus	Rational Pharmaceutical Management Plus
TA	technical assistance
TB	Tuberculosis
TNF	Tanzania National Formulary
UNICEF	United Nations International Children's Fund
USAID	United States Agency for International Development
USD	United States Dollars
WBI	World Bank International
WHO	World Health Organization



## **Background**

In order to help countries receiving Global Fund grants meet the requirements set out by Global Fund for AIDS, Tuberculosis and Malaria (GFATM), a global partnership which includes World Bank, WHO,UNAIDS, UNICEF, USAID, MSH/RPM Plus, JSI/Deliver, GFATM and ESTHER was established to support the process of developing Procurement and Supply Management (PSM) plans.

The Global Fund and partners have already implemented a number of PSM workshops worldwide since 2004 both for Anglophone and Francophone African countries. With funding from global core funds HIV/AIDS (SO4) and Malaria, RPM Plus sent facilitators to the PSM workshop for Anglophone African countries. The workshop was held in Nairobi, Kenya from 19<sup>th</sup> to 25<sup>th</sup> February 2006. Other partners funded the participation of facilitators representing them at the workshop. Participant travel and accommodation fees were be covered by GF grants.

The main outcomes of the workshop were:

- Draft PSM plans for each country attending (HIV/AIDS, TB and malaria)
- Identify and discuss regional issues and approaches to PSM affecting implementation of GFATM grants in the East and Central African Region
- Identify key constraints and gaps in GFATM grant implementation related to PSM

### **Purpose of Trip**

Participate and facilitate at a workshop to draft PSM plans for Anglophone African countries receiving Global Fund grants.

### **Scope of Work**

- Participate and facilitate at the workshop to draft PSM plans for Anglophone African countries receiving Global Fund grants.
- Develop a plan to provide ongoing TA to the countries as they implement their PSM plans.
- Participate in a partners meeting to develop implementation and communication mechanisms for providing TA to the countries.
- Make presentations on forecasting and rational medicine use as requested by the organizers of the workshop
- Provide an arrival/departure briefing to USAID



## Activities

### **Participate in the workshop and provide facilitation as needed**

RPM Plus staff participated in the five-day workshop and provided technical assistance in the area of pharmaceutical management of HIV/AIDS, TB and malaria commodities during the sessions particularly in the areas of forecasting, quantification and rational medicine use.

A pre-workshop meeting was held for all facilitators on Sunday, February 19<sup>th</sup> during which the agenda for the week was reviewed and revised.

Day one focused on introducing the objectives of the workshop and an overview of the PSM plan, key principles for developing a PSM plan and detailed guidance for developing the plan. Presentations on product selection were made with perspectives on key issues for the selection of products for the three diseases.

This was followed by discussions and group work whereby the participants were divided into two groups. Countries that already had PSM plans that had been approved by the GFATM discussed their implementation status and associated issues and challenges. Those that did not have PSM plans ready used this time to work with their country counterparts to develop them.

Presentations on day two were on forecasting and diagnostics for HIV, TB and malaria for procurement and planning. A presentation was made by Rima Shretta of RPM Plus on key challenges for forecasting for TB, malaria and HIV with input from CHMP and Stop TB. This was followed by discussions on key issues in procurement and planning with regard to policies, systems, capacity and price monitoring. A presentation on operational principles for applying good pharmaceutical procurement for scaling up was made by UNICEF and WHO. This was followed by a general discussion on procurement with key discussants from UNDP, WBI and the Clinton Foundation. This was followed by presentations and discussions on distribution, stock management, inventory control and management of information systems. Participants were again divided into two groups for developing PSM plans and for troubleshooting for implementation issues particularly with regard to selection issues.

Day three focused on quality assurance, quality control, pre-qualification, pharmacovigilance and intellectual property rights. Presentations were made by WHO/QSM and WBI. Bannet Ndyabangi made a presentation on monitoring adherence and pharmacovigilance in ART programs. The afternoon sessions followed the same format as the previous days with a plenary session on the AMDS website.

Day four focused on identification and planning for technical assistance. Facilitators worked with countries on identifying needs for technical assistance using a template prepared by the workshop organizers. The rest of the day concentrated on PSM plan development. On day five, a review of the status of all the PSM plans was carried out

with a plan for the next steps that needed to occur for finalization. The roles of the PR and LFA were clarified and how funds would be disbursed was elucidated. In addition, an overview of technical assistance plans was presented. This was followed by a closing ceremony and concluding remarks.

At the end of each day, facilitators met to discuss progress on the PSM plans and the agenda for the following day. Facilitators were assigned to countries that needed continued assistance depending on areas of expertise needed.

### **Provide technical assistance during work sessions for country review of implementation**

TA was provided during the malaria, TB and HIV sessions for the country review of implementation. RPM Plus documents on the various aspects of implementation of malaria policy were shared with participants of countries.

### **Assist in facilitation and provide technical assistance for development of PSM plans**

RPM Plus staff assisted several countries in specific areas of their PSM plans including Namibia and Zambia.

### **Develop a plan to provide ongoing TA to the countries as they implement their PSM plans**

In addition to the technical assistance needs template provided by the workshop participants, RPM Plus distributed TA needs templates to key RPM Plus focus countries; namely Kenya, Tanzania, Uganda, Zambia, Ethiopia, Malawi, Namibia and South Sudan. Most of the countries needed to confer with their counterparts before submitting these forms back to RPM Plus. The status of the PSM plans at the end of the workshop are presented in Annex 2.

### **Participate in a partners meeting to develop implementation and communication mechanisms for providing TA to the countries**

A brief meeting was held among the facilitators to discuss how information collected on TA needs from the countries during the workshop would be shared amongst the partners and translated into action. Mechanisms for providing TA to countries were discussed. It was decided that information would be shared electronically amongst partners however, with regard to follow up action, it was decided that this issue was beyond the scope of the partnership present during the discussion and that it would need to be continued after the workshop.

**Make presentations on forecasting and rational medicine use as requested by the organizers of the workshop**

Rima Shretta and Bannet Ndyanabangi made presentations on forecasting and rational medicine use respectively.

**Provide an arrival/departure briefing to USAID**

Rima Shretta met with Sheila Macharia of USAID/Kenya to discuss the purpose of the visit and the mechanisms for providing TA to GFATM recipient countries.

**Collaborators and Partners**

- Representatives from World Bank, WHO, UNAIDS, UNICEF, USAID, MSH/RPM Plus, JSI/Deliver and GFATM
- USAID/Nairobi, Kenya
- Other conference participants



## Next Steps

### Immediate Follow-up Activities

- Complete trip report
- Continue to work with the Zambia NMCC to complete PSM plan for malaria
- Share recommendations on improvement of the PSM workshop process with partners

### Recommendations

1. Long term TA is required by countries to help them develop and formulate PSM plans. It is difficult for this process to occur at a workshop setting with limited number of individuals from the country present. It is recommended that one of two options be used a) Technical partners in collaboration with the GFATM can provide TA to specific countries over a period of time to develop PSM plans. The result of this TA may culminate in a workshop such as this where initial drafts have been prepared by relevant people with the processes of appropriate consensus building and buy-in having been achieved before-hand. The purpose of the workshop in this case would be to answer any concerns or questions that may have arisen during the process. Alternatively b) a workshop could be convened first, with the workshop focusing on providing the tools for countries to develop their PSM in-country with a variety of presentations from appropriate technical experts. Key point technical experts (from partners) would then be identified to follow up with specific countries to answer any queries and a timeline for final submission of the plans should be made.
2. The workshop should have presentations specifically for providing background information for participants in order to develop their PSM plans. Although the agenda was changed before the meeting to ensure that this occurred, workshop participants were not clear on the purpose of the presentations and in some cases had expectations beyond the scope of the presentations.
3. There is a need for clear tools to help countries quantify requirements and develop appropriate systems.
4. Drafts of the PSM plans should be shared amongst the facilitators prior to the workshop.
5. The GFATM proposals that the PSM plans were being developed for should be made available for reference for the participants and facilitators prior to the workshop. The division of labor in terms of facilitators (coaches) and PSM plan should be done prior to the workshop so that any data that is missing can be identified so that participants can access this before arriving at the workshop.

### Agreement or Understandings with Counterparts

RPM Plus will continue to work with the Zambia team to complete their PSM plans



## Annex 1. Workshop Agenda

### Procurement and Supply Management Workshop for Anglophone African Countries Nairobi, Kenya, 20 – 24 February 2006

**DAY 1: Monday 20 February 2006**

**Morning session moderated by Françoise Renaud-Théry, WHO AMDS**

- 08:30 – 09:00 Registration/Administrative/Housekeeping
- 09:00 – 09:30 Objectives, expected outcomes, and review of meeting agenda:  
Françoise Renaud-Théry, Aids Medicines and Diagnostics Services,  
WHO
- 09:30 – 10:00 The PSM plan: Key principles and overview E. Molari, GFATM
- 10:00 – 10:30 Guidance for developing the PSM plan: Introduction and Section 1  
E. Molari, GFATM (30 minutes)
- 10:30– 11:00 Tea/Coffee break
- 11:00 – 11:45 Opening Ceremony
- |                   |  |
|-------------------|--|
| Welcoming remarks | Dr Françoise Renaud-Théry                        |
| WHO Remarks       | Dr Peter Eriki, WR/Kenya                         |
| Official Opening  | Dr James Nyikal, Director of Medical<br>Services |
| Vote of Thanks    | Dr Vincent Habiyambere, WHO                      |
- 11:45-12:30 Discussion on the PSM Plan  
Discussants: E. Molari (GFTAM)

12:30 – 14:00 LUNCH

**Afternoon session moderated by Patrick Osewe, World Bank Institute**

- 14:00 – 15:15 Key issues in selection of products for HIV, TB, and Malaria for  
procurement
- Guidance for developing the PSM plan: Product selection, E. Molari, GFATM (10 minutes)
  - Product selection for TB, Malaria and HIV/AIDS: Key issues for procurement, Nienke Gruppelaar, IDA Foundation

(10 Minutes)

Discussion (55 Minutes)

Key discussants: MMSS, Lorenzo Witherspoon and Stop TB, Peter Ebling

Handouts and links to web sites to access detailed specifications for procurement (including for medical equipment) available in the workshop CD ROMs:

- WHO Treatment Guidelines on ARVS,
- ARV pediatric formulations
- Drugs for Opportunistic Infections and palliative care
- HIV testing, diagnostics and CD4
- TB drugs (Adults and pediatrics)
- Medicines, Diagnostics, Insecticides and nets for Malaria

15:15 – 15:30

Tea/Coffee break

15:30 – 17:30

a) Development of draft PSM plans

b) Working group on implementation issues  
Moderator: F. Renaud-Théry

18:00 - 20:00

Reception at the Stanley Hotel

**DAY 2:                    Tuesday 21 February 2006**

**Sessions moderated by Lorenzo Witherspoon, MMSS**

- 08:30 – 09:30            Key issues in forecasting medicines and diagnostics for HIV, TB and Malaria for procurement
- Guidance on Forecasting for developing the PSM plan, E. Molari, GFATM (10 minutes)
  - Key challenges for forecasting for TB, Malaria and HIV MSH/RPM Plus, Rima Shretta with CHMP and Stop TB, P. Ebling(10 minutes)
- Discussion (40 minutes)
- Forecasting tools available on workshop CD Rom (from CHMP, JSI, and Clinton Foundation)
- 09:30- 10:00            Key issues in procurement and planning: policies, systems, capacity and price monitoring:
- Guidance for developing the PSM plan, E. Molari, GFATM (10 minutes)
  - Operational principles for applying good pharmaceutical procurement for scaling : UNICEF, M. Banda and Regina Mbindyo WHO NPO Kenya (20 minutes)
- 10:00 – 10:30            Tea/Coffee break
- 10:30 - 11:30            Key issues in procurement and planning: policies, systems, capacity and price monitoring (cont.)
- Discussion (60 minutes)  
Discussants: Alfonso Fernandez de Castro UNDP, Patrick Osewe WBI, Kanika Bahl Clinton Foundation

**Sessions moderated by Rima Shretta, MSH RPM Plus**

- 11:30- 12:30            Key challenges in Distribution, Stock management, Inventory control and Management of Information System

- Guidance for developing the PSM plan, E. Molari, GFATM (10 minutes)
- Technical contribution: JSI/DELIVER, Y. Chandani (including Lessons Learned from Nigeria) (10 minutes)

Discussion (40 min.)

12:30 – 14:00

LUNCH

14:00– 15:15

Plenary discussion for sharing lessons learnt in forecasting, procurement and planning and distribution in scaling up PSM activities

15:15 – 15:30

Tea/Coffee break

15:30 – 17:30

- a) Development of draft PSM plans
- b) Working group: trouble shooting for implementation issues  
Selection of products: F. Renaud-Théry  
TB: Peter Ebling

**DAY 3:                      Wednesday, 22 February 2006**

**Sessions moderated by Marlon Banda, UNICEF**

08:30 – 10:00              Quality Assurance/Quality Control and Pre-qualification:

- Global Policy and Guidance for developing the PSM plan, E. Molari, GFATM (20 minutes)
- Technical contribution including HIV, TB and Malaria, Rutendo Kuwana, WHO/QSM consultant (20 Minutes)

Discussion (50 min)

10:00 – 10:30 Tea/Coffee break

10:30- 11:30              Rational drug use and Pharmaco-vigilance

- Guidance for developing the PSM plan, E. Molari, GFATM (10 minutes)
- Monitoring adherence and pharmaco-vigilance in ART programs: B. Ndyanabangi, MSH/RPM Plus with Shanti Pal, WHO/ QSM (15 minutes)

Discussion (35 minutes)

**Sessions moderated by S. Kinzett, JSI Kenya**

11:30– 12:30              Intellectual property Rights and regulatory issues for HIV medicines

- Guidance for developing the PSM plan, E. Molari, GFATM (10 minutes)
- Technical contribution: : Y. Nkrumah, WBI consultant (15 minutes)

Discussion (35 min.)

12:30 – 14:00              LUNCH

14:00– 15:15	Development of draft PSM plans (With participants from countries not developing PSM plans joining teams developing PSM plans for being familiarized in PSM plan development)
15:15 – 15:30	Tea/Coffee break
15:30 – 17:00	Continuation
17:00-17:45	Plenary presentation of AMDS web site and CD Rom: access to strategic information including HIV-related product selection, forecasting, Global Price Monitoring Mechanism, drug registration status, AMDS and AMDS technical partners tools and guidelines F. Renaud-Théry, AMDS  Questions and answers  Wrap up

**DAY 4: Thursday 23 February 2006**

08:30 – 09:30	PSM country coordination (10 minutes each) <ul style="list-style-type: none"><li>• Developing the PSM plan, E. Molari, GFATM</li><li>• Supporting national capacities and country coordination, UNICEF, M. Banda with F. Renaud-Théry, WHO AMDS</li></ul> Discussion moderated by Dr V. Habiyambere, WHO (40 minutes)
09:50 – 10:05	Tea/Coffee break
10:05- 11:00	Country teams working on identification and planning for technical assistance
11:00 - 12:30	PSM plans development
12:30 – 14:00	LUNCH
14:00– 15:15	PSM plans development
15:15 – 15:30	Tea/Coffee break
15:30 – 17:30	PSM plans development

**DAY 5: Friday 24 February 2006**

08:30 – 09:00	Administrative / Housekeeping
09:00 – 10:30	Review and finalization of PSM plans with GFATM feed-back
10:30 – 10:45	Tea/Coffee break
10:45 – 11:00	Overview of technical assistance plans R. Prohom, MMSS, P. Ebling Stop TB, F. Renaud-Théry, WHO
11:00 – 12:00	Overview of PSM plan development & Next steps: Process for PSM plans finalization and submission (roles of PR and LFA, Fund Disbursement) E. Molari
12:00 - 12:30	Closing ceremony
	Concluding remarks Dr Françoise Renaud-Théry, WHO AMDS WHO Remarks Dr Peter Eriki, WR/Kenya Official Closing Dr James Nyikal, Director of Medical Services
12:30 – 14:00	LUNCH

## Annex 2. Overview of PSM Plan Development Round 5, Phase 1

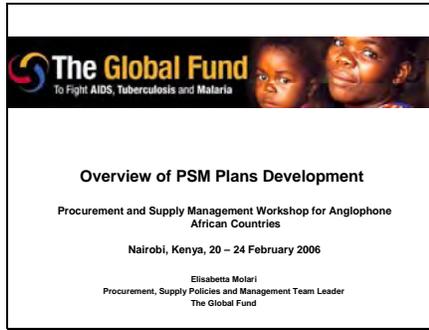
**Procurement and Supply Management Workshop for Anglophone African Countries  
Nairobi, Kenya 20/24 February 2006**

Country	Plan Finalized	Plan Not Finalized	Action/s
Botswana TB		X	<ul style="list-style-type: none"> <li>- Country to include the total value of procurement in the last 12 months.</li> <li>- Country to get final approval from MOH before submitting to PR.</li> <li>- Country to send to GFTAM the final version of the PSM approved by MOH by March 3rd.</li> </ul>
Equatorial Guinea Malaria	X		Submit plan to PR.
Gambia TB	X		Submit plan to PR.
Ghana TB	X		Submit plan to PR.
Ghana HIV	X		Submit plan to PR.
Lesotho HIV	X		<p>Submit plan to PR.</p> <hr/> <p>On the last day of the workshop Lesotho handed to the GFATM the preliminary draft of the PSM plan for Round 2 Phase 2 HIV/AIDS.</p> <ul style="list-style-type: none"> <li>- GFATM reviewed the preliminary draft plan and has provided a feedback to the country.</li> <li>- Country will send to GFATM the missing information and data of this preliminary draft plan as soon as possible.</li> </ul>
Malawi HIV	X		Submit plan to PR

Namibia TB		X	<ul style="list-style-type: none"> <li>- Country to determine list of non health products to be procured.</li> <li>- Country to send to GFTAM the final version of the PSM by March 3<sup>rd</sup>.</li> </ul>
Sudan North TB		X	<ul style="list-style-type: none"> <li>- Country to develop the plan and submit it to GFTAM by March 10<sup>th</sup>.</li> <li>- Country to inform GFATM with regard to the person/s responsible for developing the TB Plan by March 10<sup>th</sup>.</li> </ul>
Sudan North HIV		X	<ul style="list-style-type: none"> <li>- Country to include missing information.</li> <li>- Country to send to GFTAM the final version of the PSM by March 3<sup>rd</sup>.</li> </ul>
Sudan South TB/HIV		X	<ul style="list-style-type: none"> <li>- Country to include missing information.</li> <li>- Country to send to GFTAM the final version of the PSM by March 3<sup>rd</sup>.</li> </ul>
Zambia HIV		X	<ul style="list-style-type: none"> <li>- Country to include consumption data and other information requested by LFA by March 3<sup>rd</sup>.</li> <li>- Country to send to GFTAM the final version of the PSM by March 8<sup>th</sup>.</li> </ul>
Zambia Malaria		X	<ul style="list-style-type: none"> <li>- Country to include consumption data and other information requested by LFA by March 3<sup>rd</sup>.</li> <li>- Country to send to GFTAM the final version of the PSM by March 8<sup>th</sup>.</li> </ul>
Zimbabwe TB		X	<ul style="list-style-type: none"> <li>- Country to determine if drugs have to be procured.</li> <li>- Country to include missing information.</li> <li>- Country to send to GFTAM the final version of the PSM by March 3<sup>rd</sup>.</li> </ul>

Zimbabwe HIV		X	- Country to include missing information and verify consistency of numbers throughout the plan. - Country to send to GFTAM the final version of the PSM by March 3 <sup>rd</sup> .
Zimbabwe Malaria		X	- Country to include missing information and verify consistency of numbers throughout the plan. - Country to send to GFTAM the final version of the PSM by March 3 <sup>rd</sup> .
Total	6	10	

\* With the exception of Zambia which PSM Plans are related to Round 4, Phase 1. Furthermore, on the last day of the workshop Lesotho handed to GFATM the preliminary draft of Round 2, Phase 2 HIV/AIDS (see action/s column for details).



Overview of PSM Plan development

- Procurement value of R5 Phase 1PSM plans for NBI workshop (Feb 20-24 2006):
  - Total number of PSM plans: 16 (HIV, TB, Malaria and non medicinal products)
  - Procurement value for Year 1: \$85,720,727
  - Procurement value for year 2: \$65,500,089
  - **TOTAL VALUE: \$151,220,811**

Overview of PSM Plan development

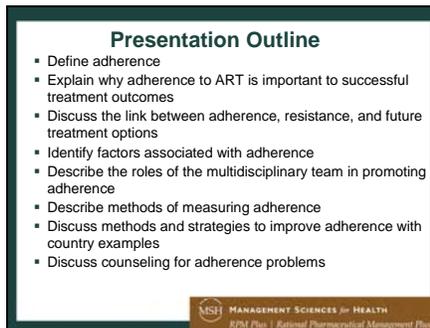
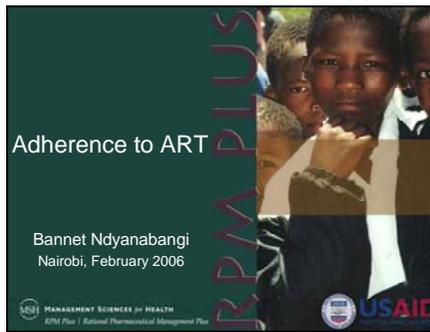
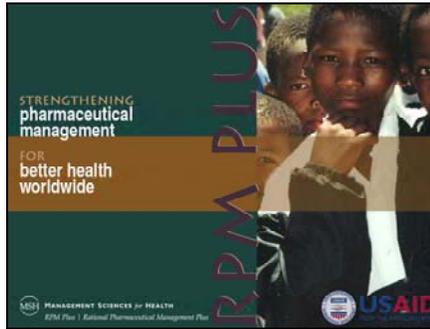
- Plans finalized: 8
- Draft Plans to be finalized in country: 8
- Next steps: Specific recommendations on actions to be taken by countries to finalize plans by first week of March

### Annex 3: Summary of Country Requests for Technical Assistance

Area	HIV	TB	MAL
Programme Management	3	2	1
Logistics Management and Information System	9	10	7
Procurement Methods	2	2	
Ensuring Rational Use of Pharmaceuticals	6	5	5
Forecasting	8	5	5
Product Selection	2	2	1
Inventory and Stock Management	6	6	4
Distribution	3	3	2
Quality Assurance & Quality Control	8	9	8
Intellectual Properties	5	3	4
Product Specification	3	3	1
Monitoring and Evaluation	2	3	2
Laboratory			
Strategic Planning	2	2	2
M&E	1	2	1
Laboratory	1	2	1
Coordination	2	1	
Condom prequalification	1		



## Annex 4. Adherence to ART Presentation



### Defining Adherence (1)

- Adherence is defined as the extent to which a client's/patient's behavior coincides with the prescribed health care regimen as agreed upon through a **shared** decision-making process between the client/patient and the health care provider. **Adherence involves a mutual decision-making process between client/patient and health care provider.**



### Defining Adherence (2)

- Patient takes medicines correctly: right dose, right frequency, and right time.
- Patient is involved in deciding whether or not to take the medicines.
- **Compliance is the patients'/clients' doing what they have been told by the doctor/pharmacist.**



### How Much Adherence Is Required for Optimal Results of ART?

% Adherence to PI Therapy	% of Clients/Patients with Virologic Failure
>95	21.7
90–94.9	54.6
80–89.9	66.7
70–79.9	71.4
<70	82.1

**Virologic failure** is defined as an HIV RNA level greater than 400 copies/ml at the last clinic visit.

Source: Paterson, D. L., et al. 2000. Adherence to Protease Inhibitor Therapy and Outcomes in Patients with HIV Infection. *Annals of Internal Medicine* 133:29–36.



## How much adherence is required? (2)

- Impact of adherence on viral load suppression could depend on drug combination **used in regimen** (PI or NNRTI) **and on whether** fixed-dose combination **used**.

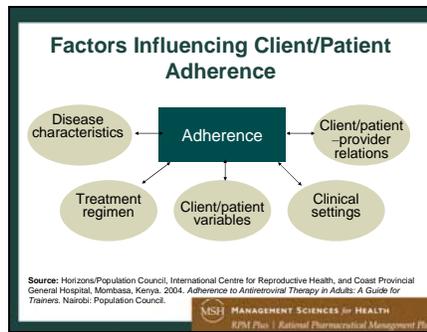
## Viral Load Suppression and Adherence NNRTI vs PI

Adherence by Pill Count, %	NNRTI Group, %	PI Group, %
94 to 100	-90	-65
74 to 93	-60	-60
54 to 73	-75	-30
0 to 53	-30	-12

- After a median 9.1 months of follow-up, most people on NNRTI therapy had a viral load below 400 copies/mL, even with adherence as low as 54%, while substantially fewer PI takers had viral loads that low if their adherence was shaky (Table)
- Source:** Bangsberg D, Wasser S, Gumbo D, Riley E. 85% adherence is not necessary for viral suppression to last than 400 copies/mL in the majority of individuals with NNRTI regimens. Program and abstracts of the 12th Conference on Retroviruses and Opportunistic Infections, February 22-25, 2005, Boston, Massachusetts. Abstract 616.

## Consequences of Poor Adherence

- For the individual—
  - Treatment failure
  - Drug resistance
  - More complex treatment, more toxicity, **more uncertain prognosis**
- From a public health perspective—
  - Transmission of resistant virus (subsequent ART failure)
- From a health economics perspective—
  - Negative impact on the established cost benefit of ART
  - Increased morbidity and mortality



- ### Methods of Measuring Adherence (1)
- Self-reporting
  - Pill counts
  - Pharmacy records
  - Provider estimate
  - Pill identification test
  - Electronic devices—MEMS (medication events monitoring system)
  - Biological markers—Viral load
  - Measuring medicine levels—TDM
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### Methods of Measuring Adherence (2)

Method	Advantages	Disadvantages	Potential Bias
Physician's assessment	<ul style="list-style-type: none"> <li>▪ Simple, cheap, requires no structured tool</li> </ul>	<ul style="list-style-type: none"> <li>▪ Subjective, inaccurate: estimates affected by doctor-patient relationship</li> </ul>	<ul style="list-style-type: none"> <li>▪ No particular bias</li> <li>▪ Study showed correct est. in only 40%</li> </ul>
Patient self-report	<ul style="list-style-type: none"> <li>▪ Simple, cheap, qualitative assessment possible</li> </ul>	<ul style="list-style-type: none"> <li>▪ Subjective, inaccurate: poor patient recall, lack of candor</li> </ul>	<ul style="list-style-type: none"> <li>▪ Overestimates adherence</li> <li>▪ Most widely used currently</li> </ul>
Pill counts	<ul style="list-style-type: none"> <li>▪ Simple, cheap, objective</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pill dumping, pill sharing, timing of doses unknown, bottles needed</li> </ul>	<ul style="list-style-type: none"> <li>▪ Overestimates adherence</li> </ul>

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Methods of Measuring Adherence (3)			
Method	Advantages	Disadvantages	Potential Bias
Pharmacy refill records	•Objective	•Pill dumping, pill sharing, timing of doses unknown; good records, patient tracking overtime needed	•Overestimates adherence
Drug level monitoring	•Objective	•Expensive, requires lab, invasive, unknown timing of doses; PK profile of population needed; short circulating times for most ARVs	•Can over- or underestimate depending on behavior immediately prior to test; genetic variations in drug metabolism
Electronic drug monitoring (EDM) - MEMS	•Objective, data on timing of doses, monitoring over longer periods	•Pill dumping, pill sharing, timing of doses unknown	•Underestimates adherence; taking out multiple doses for later use

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### Strategies and Tools to Enhance Adherence (1)

Pretreatment strategies—

- Identify the potentially nonadherent client/patient and address the barriers to adherence during counseling before first ARV prescription.
- Identify an adherence partner or buddy, or a peer educator.
- Ask the client/patient to demonstrate adherence ability.
- Identify reminders or tools to help in taking pills.

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### Strategies and Tools to Enhance Adherence (2)

Ongoing treatment strategies—

- Generate daily-due review and refill list, and “flag” absent clients/patients.
- Refer to community-based health care workers and NGOs.
- Use DAART or modified DOT (practiced at health centers, CBOs, or at client’s/patient’s home).
- Use incentives and enablers (e.g., having income-generating projects for caregivers, providing transport on clinic days, or providing food).

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### Strategies and Tools to Enhance Adherence (3): Example from Ghana\*

Patients qualifying for ART must satisfy two social criteria—

- Must complete 2–3 sessions of adherence counseling with adherence monitor.
- Must disclose to an adherence monitor (friend, family, or confidant of patient's choice).
- At pilot sites residence is verified.

\*Source: Amenyah, R., and K. Torpey. 2005. *The Challenges of Monitoring Antiretroviral Adherence: Strategies for Improved Patient Adherence to Therapy*. Presentation given at the 2005 Strategies for Enhancing Access to Medicines (SEAM) Conference, Accra, Ghana, June 18–20. Arlington, VA: Family Health International.



### Strategies and Tools to Enhance Adherence (4): Example from Ghana\*

Monitoring adherence at the sites—

- Routinely measure adherence using patient self-reports, pharmacy records, and pill counts.
- 7-day recall used for self-reports.
- Client exit interviews.
- Viral load measurements as surrogate marker.

\*Source: Amenyah, R., and K. Torpey. 2005. *The Challenges of Monitoring Antiretroviral Adherence: Strategies for Improved Patient Adherence to Therapy*. Presentation given at the 2005 Strategies for Enhancing Access to Medicines (SEAM) Conference, Accra, Ghana, June 18–20. Arlington, VA: Family Health International.



### Strategies and Tools to Enhance Adherence (5): Example from Ghana\*

Monitoring adherence: key outcomes—

- Adherence according to self-reports high.
- Nov. 2003–Jan. 2004 client exit interviews among 25 randomly selected patients showed none of the patients missed their drug; only delays reported.
- Delays attributed to food not being ready in time and to forgetting.

\*Source: Amenyah, R., and K. Torpey. 2005. *The Challenges of Monitoring Antiretroviral Adherence: Strategies for Improved Patient Adherence to Therapy*. Presentation given at the 2005 Strategies for Enhancing Access to Medicines (SEAM) Conference, Accra, Ghana, June 18–20. Arlington, VA: Family Health International.



## Strategies and Tools to Enhance Adherence (6): Example from Ghana\*

Monitoring adherence: key outcomes—

- Of 132 patients seen May 2003–Dec. 2003, only 1 had medications discontinued as a result of poor adherence.
- 27 of 36 patients (75%) who had been on treatment for more than 4 months had undetectable viral load (UDVL).
- Percentage increases to almost 90% if 6 months of treatment is used as cutoff point.

\*Source: Amenyah, R., and K. Torpey. 2005. *The Challenges of Monitoring Antiretroviral Adherence: Strategies for Improved Patient Adherence to Therapy*. Presentation given at the 2005 Strategies for Enhancing Access to Medicines (SEAM) Conference, Accra, Ghana, June 18–20. Arlington, VA: Family Health International.

## Strategies and Tools to Enhance Adherence (7): Example from the Khayelitsha cohort, Western Cape, S. Africa\*

**Promoting Adherence**

- Disclosure
- Pill boxes
- Support groups
- Treatment assistants
- Trust in clinic staff and belief in treatment efficacy

**Associated with Poor Adherence**

- Competing priorities – changes in social circumstances/employment
- stress/depression
- New partners/ non-disclosure
- Men leaving alone
- Alcohol

More than 75% of patients still in care after 48 months, 16% on second line.

\*Source: MSH, presented at ICASA, Abuja, Nigeria, 2005. Abstract No.

## Adherence Counseling: Multidisciplinary Team

Same message from all!



Source: Horizons/Population Council, International Centre for Reproductive Health, and Coast Provincial General Hospital, Mombasa, Kenya, 2004. *Adherence to Antiretroviral Therapy in Adults: A Guide for Trainers*. Nairobi: Population Council.

### Adherence Counseling: Purpose

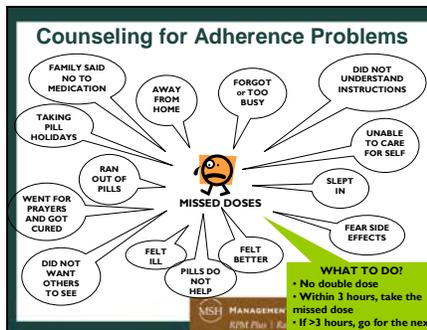
- Help clients/patients develop an understanding of their treatment and its challenges.
- Prepare clients/patients to initiate treatment.
- Provide ongoing support for clients/patients to adhere to treatment over the long term.
- Help clients/patients develop good treatment-taking behavior.
- Help clients/patients set goals for their treatment.

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### Adherence Counseling: Nature

- Needs to occur before and be ongoing throughout treatment period sessions.
- Involves highly personal and intimate matters and behavior.
- Requires recognition of barriers to and challenges of adherence.
- Needs reinforcement or constructive intervention as appropriate.
- Avoids negative-messaging, judgmental attitudes, and "pill policing."
- Encourages participation by family and friends.

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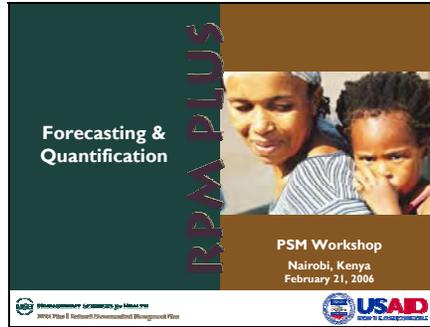
### Recap on Adherence to ART

- Excellent adherence is key to successful ART programs.
- The consequences of poor adherence are poor health outcomes and increased health care costs.
- Adherence is a dynamic process that needs to be followed up.
- Client/patient-tailored innovative interventions are required **and must fit** into the sociocultural context of each setting.
- Family, friends, and community are key factors in improving adherence.
- A multidisciplinary approach toward adherence is needed.





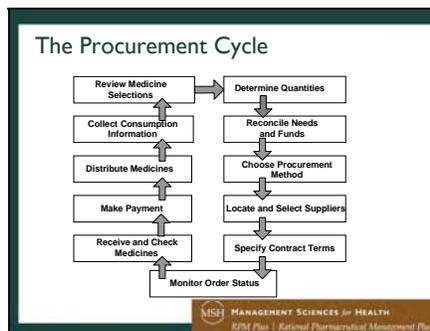
# Annex 5. Forecasting and Quantification Presentation



### Presentation Outline

- Definition
- Quantification methods
- Assumptions
- Special considerations for quantifying antimalarials, ARVs and anti-TB medicines

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### Introduction/Definitions

- Forecasting of medicines involves estimating how much of a specific commodity is needed
- Quantification of medicines involves estimating how much of a specific commodity is needed; what financial means are required to obtain it and adjustments according to budget available

### Critical Issues in Quantification

1. Developing the medicine list (selection)
2. Preparing an action plan for quantification
3. Using centralized or decentralized quantification
4. Using manual or computerized methods for quantification
5. Estimating time requirements, including procurement period, stock-outs, safety stock
6. Filling the supply pipeline

### Critical Issues in Quantification (2)

7. Considering the impact of lead time at all levels
8. Adjusting for program growth and for losses due to waste and theft
9. Cross-checking estimates produced with previous years of alternative methods
10. Estimating total procurement cost
11. Adjusting and reconciling final quantities in accordance with available funds

## Quantification Methods

- Consumption
- Morbidity
- Adjusted consumption
- Service-level extrapolation

## Comparison of Methods

	Consumption	Morbidity	Adjusted Consumption	Service-Level Extrapolation
Use	Established supply systems	New programs	Comparison areas	Estimating budget needs
Data	<ul style="list-style-type: none"> <li>• Inventory records</li> <li>• Pipeline requirements</li> <li>• Unit medicine costs</li> <li>• Lead time</li> <li>• Wastage</li> </ul>	<ul style="list-style-type: none"> <li>• Service population</li> <li>• Attendance</li> </ul>	<ul style="list-style-type: none"> <li>• Comparison area with good consumption and population data</li> </ul>	<ul style="list-style-type: none"> <li>• Use by service levels and facility type</li> <li>• Average medicine cost per attendance</li> </ul>
Implementation Requirements	<ul style="list-style-type: none"> <li>• Accurate consumption data</li> <li>• Regular updates</li> </ul>	<ul style="list-style-type: none"> <li>• Accurate attendance data</li> <li>• Standard treatments</li> <li>• Computer analysis for large database</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate comparability of facilities, morbidity, and treatment practices</li> </ul>	<ul style="list-style-type: none"> <li>• Variable facility use, attendance, treatment patterns, supply system efficiency</li> </ul>

## Quantifying Commodities

- Preferred methods
  - Morbidity, particularly for new treatments
  - Consumption (if accurate data are available)
- Population or conditions to treat (adjust for growth)
  - Endemic areas, epidemics, refugee populations
  - Special groups (Pregnant women or women likely to become pregnant; Children)
- Need to ensure supply through continued demand
- Need to use appropriate data sources
- Financing
  - Major purchasers mainly using donor funding
  - Public and not-for-profit sector demand increasing relative to private sector demand; likely to continue be the main market for most people in the short term

### Special Considerations for Quantifying Antimalarial Commodities

- Population or conditions to treat?
  - Uncomplicated malaria
    - First-line treatment
    - Second-line treatment
  - Severe malaria
  - IPT
  - RDTs
  - Insecticide-treated nets
  - Other
- Fevers used as proxy for incidence
- First-line treatment failures do not always receive second-line treatment immediately

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### Challenges in Quantifying Antimalarial Commodities

- ACTs
  - Short shelf life (24 months); ordering cycle (usually 12 months) may have to be adjusted
  - Little experience with quantification or use
    - Highly effective, may affect the quantity of second-line treatments required because treatment failures are fewer
    - Progression to severe malaria?
    - Need to monitor consumption closely and track stocks to ensure stocks do not run out or expire and to facilitate future forecasting
  - High cost; Higher chance of leakage
  - Lack of availability in private sector may affect utilization of public sector
  - ACTs are new products; imperfect market

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### Challenges in Quantifying ARVs and HIV/AIDS Commodities

- Need to ensure continuous supply of other related supplies e.g rapid tests, CD4, lab reagents/consumables
  - Percentage of people who agree to be tested
- High cost; higher chance of leakage
- New products
- Data on toxicity and treatment failure (conversion to 2<sup>nd</sup> and 3<sup>rd</sup> line)
- Treatment interruption can lead to resistance and viral explosion
- Flow of patients in and out of therapy
- Growth trends of patients on treatment
- Multiple treatment regimens
- PMTCT
  - Data on pregnant women
- Pediatric patients (average weight needed)
- Need data on occurrence of OIs

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### Challenges for Quantifying Anti-TB Products

- Data on number of patients at all levels
- Data on number of patients in each category of treatment
- Data on MDR inadequate
- Different quantities needed depending on source (e.g. GDF etc)
- Lack of data on treatment in the private sector

### Quantification Tools Available

- Quantimed (MSH)
- Antimalarial Cost Estimation Tool (WHO)
- ARV Forecasting Tool (CHMP, Clinton Foundation)
- CD4 Procurement Forecasting Tool
- Adult HIV Forecasting Diagnostics
- Infant HIV Diagnostics Procurement Forecasting tool
- CD4 full cost model

Tools are only as good as the data that is entered

### Summary – Quantification

- Needed for:
  - Planning, budgeting, and ordering
- Critical issues:
  - Must first have good selection of drugs
  - Decide who will quantify; centralized vs. decentralized activity
  - Tools to use - manual vs. computerized
  - Knowledge of lead times, stock-outs, safety stock, growth, losses, existing stocks
  - Reconcile quantities needed with budget