

## **Rational Pharmaceutical Management Plus**

### **Introduction of Antiretroviral Therapy in Mombasa, Kenya: Trip Report of Technical Assistance to Support Program Implementation, July 19 to August 13, 2003**

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November 2003

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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 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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## Acronyms

ADR	Adverse Drug Reaction
AFB	Acid Fast Bacilli [Culture]
AHFS	American Hospital Formulary Service
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral [Drugs]
CA	Cooperating Agency
CCC	Comprehensive Care Clinic [CPGH]
COPHIA	Community-Based HIV/AIDS Care, Support, and Prevention Program [Pathfinder]
CPGH	Coast Provincial General Hospital
DAART	Directly Administered Antiretroviral Therapy
DANIDA	Danish International Development Assistance [Agency]
DUR	Drug Utilization Review
FHI	Family Health International
ELISA	Enzyme-Linked Immunosorbent Assay
GOK	Government of Kenya
HIV	Human Immunodeficiency Virus
ICRH	International Centre for Reproductive Health
IMPACT	Implementing AIDS Prevention and Care Project [FHI]
KEMRI	Kenya Medical Research Institute
LFT	Liver Function Test
MIS	Management Information System
MOH	Ministry of Health [Kenya]
MSH	Management Sciences for Health
OHA	[USAID] Office of HIV/AIDS
PEP	Post Exposure Prophylaxis [for HIV]
PMO	Provincial Medical Officer [Coast Province]
QA	Quality Assurance
QC	Quality Control
REDSO	Regional Economic Development and Services Office for the Eastern and Southern Africa region [USAID]
RF	Renal Function
RPM	Rational Pharmaceutical Management Plus [Program]
SO4	[USAID/Washington] Fourth Strategic Objective
SOP	Standard Operating Procedure
TAP	Technical Assistance Partners [IMPACT/RPM Plus/Horizons]
USAID	U.S. Agency for International Development
U.S.HHS	U.S. Department of Health and Human Services
WHO	World Health Organisation



## **Background**

Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus (RPM Plus) Program has received funds from the United States Agency for International Development (USAID) under USAID's fourth strategic objective (SO4) funding to assist USAID Missions, cooperating agencies (CAs) and countries to assess the capacity of the local government to meet drug and other pharmaceutical needs in support of expansion of HIV/AIDS programs. This assistance may include identifying constraints and challenges, from a pharmaceutical management perspective. RPM Plus has received funding to collaborate with Family Health International (FHI)/Implementing AIDS Prevention and Care Project (IMPACT) and Population Council/Horizons to work with the Government of Kenya (GOK), USAID/Kenya, USAID/Washington and local partners to introduce antiretroviral therapy (ART) for selected communities of HIV infected individuals in the Mombasa District of Kenya's Coast Province, as part of a comprehensive package of prevention, care and treatment. The Mombasa ART Program will provide valuable implementation and operations research on how to safely and effectively deliver antiretrovirals (ARVs) and how to build capacity to expand access to treatment.

In September 2001, RPM Plus accompanied representatives from the USAID Office of HIV/AIDS (OHA), USAID/Kenya, to meetings with the Minister of Health, the Permanent Secretary for Health, the Minister of Public Health, the Director of Medical Services and the Chairman of the Pharmacy and Poisons Board of Kenya to discuss the Mombasa ART Program, drug registration, procurement and other drug management issues. RPM Plus also accompanied representatives from OHA, Kenya Mission, IMPACT, and Horizons on a site visit to Mombasa where the team met with the Provincial Medical Officer (PMO) for Mombasa, the Chief Administrator and Pathologist at Coast Provincial General Hospital (CPGH), and local partners.

In April 2002, RPM Plus along with FHI/IMPACT and Horizons participated in a workshop in Mombasa with local partners and GOK Ministry of Health (MOH) to finalize the proposal and to draw up a timeline for the assessment.

In September 2002, RPM Plus conducted an assessment of the capacity of the pharmaceutical management system and laboratory services to support the introduction of ART in 4 sites in Mombasa, in addition to assessing current access and use of ARVs in Mombasa city.

In November 2002, RPM Plus presented the results of a pharmaceutical management system and laboratory services assessment conducted from September 5 to 29, 2002 at a meeting of stakeholders. Invited participants included members of the Steering Committee and also other key stakeholders and partners, including representatives from the four sites.

In January 2003, RPM Plus met with the implementation team and key partners at each of the four sites present and solicited feedback on the results of the pharmaceutical management system and laboratory services assessment. In addition, RPM Plus in collaboration with FHI/IMPACT worked with the implementation team at CPGH to select and prioritize options and recommendations to develop an implementation plan in preparation for the start up of the Mombasa ART Program.

## **Purpose of Trip**

Helena Walkowiak traveled to Mombasa, Kenya from July 19 to August 13, 2003 to provide support for the implementation of the ART Program in Mombasa. An initial training was held at the end of March 2003 and ART was introduced at the first site, CPGH, in early June 2003. The purpose of Ms. Walkowiak's trip was to review and finalize pharmaceutical management systems and procedures, provide support as necessary to pharmacy and laboratory staff at CPGH, and to plan for ongoing activities. Ms. Christine Onyango, Program Associate for the RPM Plus/Nairobi Office, joined Ms. Walkowiak.

## **Scope of Work**

Scope of work for Helena Walkowiak

1. Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested.
2. Review the pharmaceutical management systems and procedures set up in place to support the introduction of ART at CPGH. Work with pharmacy and administrative staff to review and finalize standard operating procedures (SOPs), forms and registers and plan next steps.
3. Meet with Dr. Mandaliyia, Chief Pathologist and Chairman of the Scientific Committee for the Mombasa ART program, and with laboratory and senior staff from Port Reitz District Hospital, Bomu (Mkomani) Clinic and Magongo Clinic to finalize the results of the assessment for the four sites and to develop an implementation plan to strengthen the capacity of the laboratory services at CPGH. Work with Dr. Mandaliyia, the clinical team at CPGH and FHI to review the laboratory procedures and systems put in place to support the introduction of ART at CPGH. Plan next steps.
4. Meet with the RPM Plus laboratory consultant to review recommendations for strengthening laboratory services and plan for next steps.
5. Meet with the Steering and Scientific Committee to review progress and plan for next steps.
6. Interview candidates for a RPM Plus position to be based in Mombasa to provide direct technical assistance to sites and partners.
7. Meet with other key stakeholders, and local partners within the Kenyan Government, Ministry of Health, other cooperating agencies and partners to inform implementation of the ART Intervention Program, as appropriate.

## Activities

### **1. Participate in an arrival briefing and a departure debriefing for USAID/Kenya as requested.**

On July 31, 2003, briefed Cheryl Sönnichsen and Buck Buckingham of USAID/Kenya on the status of RPM Plus activities and next steps at a joint meeting with FHI/IMPACT and the International Centre for Reproductive Health (ICRH) – the local implementing partners of Horizons – held in Mombasa at the FHI Office. After the meeting, Ms. Walkowiak accompanied Ms. Sönnichsen and Mr. Buckingham to a meeting of the CPGH Eligibility Committee and then on site visits to the four implementing sites – CPGH, Port Reitz District Hospital, Bomu (Mkomani) Clinic and Magongo Municipal Clinic.

### **2. Review the pharmaceutical management systems and procedures set up in place to support the introduction of ART at CPGH. Work with pharmacy and administrative staff to review and finalize standard operating procedures (SOPs), forms and registers and plan next steps.**

A full report of progress to date is provided in Annex 1: *Introduction of Antiretroviral Therapy in Mombasa, Kenya: Update on Pharmacy and Laboratory Implementation Progress and Report of Visit to Provide Technical Assistance July 18–August 12, 2003*. This report was prepared for the PMO and for staff at all four sites.

Specific activities performed by Ms. Walkowiak during this trip contributed to progress to date for the pharmaceutical management system were:

- Meeting with the Chief Pharmacist and Pharmacy staff to review and address pharmacy issues around staff availability, infrastructure, management support, storage and security, dispensing and counseling issues. Roles and responsibilities of pharmacy staff for the ART Program were drafted, key responsibilities (e.g. issuing from the ARV bulk store and receiving into the outpatient pharmacy) separated and a weekly rota identifying staff members to perform key responsibilities initiated.
- With Dr Olwande, Pharmacist-in-Charge of the ART Program and administrative staff, extensive reviewing, testing and finalizing of SOPs, forms and registers for the ART Program.
- With Dr Olwande quantifying needs for the first USAID-funded procurement of ARVs.
- With Dr Olwande, discussions were held with CPGH HIV Paediatric Clinic to identify issues around dispensing ARVs to pediatric patients – due to start in October 2003.
- Review of procedures in place in the pharmacy department to prepack and manage supplies for the Directly Administered Antiretroviral Therapy (DAART) study.
- Meeting with the CPGH Comprehensive Care Clinic (CCC) coordinator, Dr Otieno, to obtain feedback on pharmacy issues that impact the working of the CCC and the ART program specifically.
- Meeting with the Dr Shikely, Chief Administrator, Dr Mwangi, Deputy Administrator and Dr Achola, Quality Committee to discuss operationalizing the Internal Audit

Committee. The SOP for performing internal audits was handed over to Dr Achola for testing.

- Review of the SOP for Adverse Drug Reaction (ADR) Monitoring and Reporting with Dr Mandaliyia, Chairman of the Scientific Committee and Dr Adungosi. The SOP was revised extensively for presentation to the Scientific Committee for policy decision-making.
- Meeting with the training manager from CPGH and pharmacy staff to develop a plan for ongoing training.

**3. Meet with Dr. Mandaliyia, Chief Pathologist and Chairman of the Scientific Committee for the Mombasa ART program, and with laboratory and senior staff from Port Reitz District Hospital, Bomu (Mkomani) Clinic and Magongo Clinic to finalize the results of the assessment for the four sites and to develop an implementation plan to strengthen the capacity of the laboratory services at CPGH. Work with Dr. Mandaliyia, the clinical team at CPGH and FHI to review the laboratory procedures and systems put in place to support the introduction of ART at CPGH. Plan next steps.**

A full report of progress to date is provided in Annex 1: *Introduction of Antiretroviral Therapy in Mombasa, Kenya: Update on Pharmacy and Laboratory Implementation Progress and Report of Visit to Provide Technical Assistance July 18–August 12, 2003*. This report was prepared for the PMO and for staff at all four sites.

Specific activities performed by Ms. Walkowiak during this trip that contributed to progress to date for the pharmaceutical management system were:

- Site visits were made to the laboratories at Port Reitz District Hospital, Bomu (Mkomani) Clinic and Magongo Municipal Clinic with Dr Mandaliyia, Chief Pathologist at CPGH and Chairman of the Scientific Committee to share and review the results of the assessment conducted in September 2002.
- With Dr Adungosi, FHI, a meeting was held with Dr Mandaliyia, and Mr Denje, Laboratory Supervisor at CPGH to review the results of the laboratory assessment for the four sites and to finalize the results based on the recent site visits. An Implementation Plan was developed for strengthening the laboratory at CPGH.
- Review of the laboratory procedures and systems put in place to support the introduction of ART at CPGH with Dr Mandaliyia, Mr Denje, Ms. Onyango and Dr Njagi, RPM Plus Consultant and planning of next steps.
- Meeting with the CPGH/CCC coordinator, Dr Otieno, to obtain feedback on laboratory issues that impact the working of the CCC and the ART program specifically.
- Meeting with the training manager from CPGH and laboratory staff to develop a plan for ongoing training.

**4. Meet with the RPM Plus laboratory consultant to review recommendations for strengthening laboratory services and plan for next steps.**

Dr. Ephantus Njagi Chomba (Dr. Njagi) has been assisting RPM Plus to strengthen the laboratory services at CPGH to support the introduction of ART as an RPM Plus consultant since June 2003. Dr. Njagi is a lecturer with the Department of Pathology, Section of Immunology, University of Nairobi. Ms. Walkowiak and Ms. Onyango accompanied Dr. Njagi on site visits to the laboratories at Port Reitz District Hospital, Bomu (Mkomani) Clinic and Magongo Municipal Clinic to meet management and laboratory staff and to review and update the results of the assessment conducted in September 2002. As noted above, meetings were also held with Dr. Adungosi, Dr. Mandaliya and Mr. Denje to review the laboratory procedures and systems put in place to support the introduction of ART at CPGH and to plan for next steps. Issues around setting up a contract with Kenya Medical Research Institute (KEMRI) to perform viral load testing and, training and setting up of the Partek CD4 CyFlow were identified as being of particular importance.

**5. Meet with the Steering and Scientific Committee to review progress and plan for next steps.**

The meetings of both the Steering and Scientific Committee were cancelled.

**6. Interview candidates for a RPM Plus position to be based in Mombasa to provide direct technical assistance to sites and partners.**

Ms. Walkowiak participated in interviews for an RPM Plus Senior Program Associate to be based in Mombasa. The job description is attached as Annex 2. The next step is to follow up on references before an offer is made.

**7. Meet with other key stakeholders, and local partners within the Kenyan Government, Ministry of Health, other cooperating agencies and partners to inform implementation of the ART Intervention Program, as appropriate.**

***PMO's Office on July 21, 2003***

Ms. Walkowiak and Dr. Adungosi attended a meeting with Dr. Mwanyumba in the absence of the PMO, to brief him on the objectives of the visit and to obtain approval for moving ahead on planned activities.

***CPGH Management Team on July 22 and July 23, 2003***

Ms. Walkowiak met with Dr. Shikelly, the Chief Administrator, Dr. Mwangi, the Deputy Administrator, Dr. Baya, the Chief Pharmacist and Dr. Mandaliya, the Provincial Pathologist to brief them on the objectives for the visit and to solicit feedback on progress to date.

***ICRH on July 24, 2003***

A meeting was held with Dr. Olwande, CPGH and ICRH to discuss start up issues related to the DAART study.

### ***USAID/REDSO on July 28, 2003***

Ms. Walkowiak accompanied Mr Gil Cripps from USAID/REDSO on his visit to CPGH to familiarize himself with the Mombasa ART Program. Mr Cripps briefly met with Dr. Shikely and Dr. Mwangi to discuss issues around introducing and scaling up ART.

### ***Municipal Council Medical Officer of Health and Deputy, Municipal Medical Officer of Health, Mombasa on July 30, 2003***

IMPACT and RPM Plus met with the recently appointed Municipal Council Medical Officer of Health – Dr. Chidagaya, and Municipal Medical Officer of Health, Mombasa – Dr. Were, to debrief them on the Mombasa ART Program. Copies of the proposal, assessment results and other key documents were provided. Some brief discussions were held on approaches to address the major issues identified that would constrain start up of the Mombasa ART Program at Magongo Municipal Clinic.

### ***CPGH Eligibility Committee Meeting on July 31, 2003***

Ms. Walkowiak attended the weekly meeting to review eligibility of new patients for the program.

### ***Magongo Clinic on August 1, 2003***

The staff at Magongo Municipal Clinic that attended the ART Program training at the end of March 2003 have all been transferred. Ms. Walkowiak met with Sister Jacinta Kyobe, the new Sister to brief her on the ART Program. Copies of the proposal, assessment results and other key documents were provided.

### ***Pathfinder/COPHIA on August 11, 2003***

Ms. Walkowiak and Dr. Adungosi met with John Waimiri from Pathfinder/COPHIA to follow up on discussions held in January 2003, on strengthening the pharmaceutical management system at Community Home Based Care Clinic at Bangladesh and to discuss possible interventions to address some of the major issues identified.

### ***FHI/IMPACT Nairobi on August 13, 2003***

A meeting was held with FHI staff in Nairobi to discuss issues around procurement of ARVs and equipment, and the contract for viral load testing.

## **Collaborators and Partners**

### ***USAID***

Cheryl Sönnichsen, USAID/Kenya  
Buck Buckingham, USAID/Kenya  
Gil Cripps, USAID/REDSO

### ***FHI***

Dr. John Adungosi, FHI/Mombasa  
John McWilliam FHI/Nairobi

Maina Kahindo, FHI/Nairobi  
Darsi Lotay, FHI Consultant

***ICRH***

Dr. Mark Hawken, ICRH/Mombasa  
Mr. Paul Munyao, ICRH/Mombasa

***Pathfinder/COPHIA***

Mr. J. Waimiri/Mombasa

***PMO's Office***

Dr. Mwanyumba

***ART Program Scientific Committee***

Dr. Mandaliyia (Chairman)

***Mombasa Municipal Council***

Dr. Chidagaya, Municipal Medical Officer of Health, Mombasa  
Dr. Were, Deputy Municipal Medical Officer of Health, Mombasa

***Site staff***

CPGH Management and Implementation Team  
Port Reitz District Hospital Management and Implementation Team  
Bomu (Mkomani) Clinic Management and Implementation Team  
Magongo Municipal Clinic Implementation Team

**Adjustments to Planned Activities and/or Additional Activities**

Meetings of the Steering Committee and Scientific Committee were both postponed. The policy decisions on the ADR Monitoring and Reporting system that needed to be made by the Scientific Committee in order to finalise the SOP were not made. A meeting is planned in the near future.

**Next Steps**

1. The final report of the RPM Plus assessment will be finalized and disseminated by end of December 2003.
2. RPM Plus will work in collaboration with USAID/OHA, USAID/Kenya, partner cooperating agencies, the local government and local partners, to provide technical assistance to strengthen the pharmaceutical management system and the laboratory services at CPGH to support the introduction of ART as agreed in the implementation plans. The next steps for this are set out in Annex 1.
3. RPM Plus will plan to hold a joint meeting with IMPACT and Horizons in Mombasa in

October 2003 to discuss the management information needs and the monitoring and evaluation plan for the Mombasa ART Program

4. IMPACT and RPM Plus will plan to hold a meeting with Port Reitz District Hospital staff to develop an Implementation Plan to prepare for start up of the ART Program at this facility at the end of 2003.
5. IMPACT and RPM Plus will develop an ongoing training plan and map out the curricula. The curricula will be shared with TAP partners for comments to identify overlaps and to merge activities where possible. The ongoing training will commence in October 2003.

**Annex 1. Introduction of Antiretroviral Therapy in Mombasa, Kenya: Update on Pharmacy and Laboratory Implementation Progress and Report of Visit to Provide Technical Assistance July 18-August 12, 2003**

**Introduction of Antiretroviral Therapy in Mombasa, Kenya**

**Update on Pharmacy and Laboratory Implementation Progress**

**and**

**Report of Visit to Provide Technical Assistance**  
**July 18-August 12, 2003**

**Helena Walkowiak**

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## **Coast Provincial General Hospital**

### **Update on Pharmacy Implementation Progress**

Progress to date and next steps are reported for each of the key areas outlined in the CPGH Implementation Plan – developed January 2003.

#### **A. Policies and Standards**

##### **1. Guidelines**

###### **Progress to date:**

The following guidelines are now available in the Pharmacy

- Kenya ARV Therapy Guidelines: 2002 Edition
- Kenya Guidelines For Prevention & Management of Opportunistic Infections and Tumours in HIV/AIDS: 2002 Edition
- Scaling up Antiretroviral Therapy in Resource-limited Settings WHO 2002
- WHO Formulary 2003
- U.S. HHS Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents
- U.S. HHS Guidelines for the Use of Antiretroviral Agents in Paediatric HIV Infection

###### **Next steps:**

To assist CPGH Pharmacy to replace guidelines when updated copies are issued.

##### **2. Standard Operating Procedures (SOPs) for the ART Program**

###### **Progress to date and Next Steps:**

<b>Standard Operating Procedure for the ART Program</b>		<b>Status and Next Steps August 12, 2003</b>
102	Receipt of Antiretroviral Drugs at ARV Bulk Store	All these SOPs have been reviewed by CPGH Pharmacy.  Are ready to be presented to the Scientific Committee for approval early October 2003
103	Record Keeping at ARV Bulk Store	
104	Internal Antiretroviral Drug Distribution	
105	External Antiretroviral Drug Distribution	
106	Record Keeping at the Outpatient Pharmacy	
107	Issuing Antiretroviral Drugs to Outpatients	
108	Issuing Antiretroviral Drugs to Inpatients	
201	Shipment Discrepancy Report	

<b>Standard Operating Procedure for the ART Program</b>		<b>Status and Next Steps August 12, 2003</b>
202	Stock Count Discrepancy Report	CPGH Pharmacy.
302	Medication Error Reporting	Are ready to be presented to the Scientific Committee for approval early October 2003
401	Temperature Control	
403	Security of Antiretroviral Drugs	
	CPGH ART Drug Management Flow Charts <ul style="list-style-type: none"> <li>○ Requesting and Receipt of Antiretroviral Drugs</li> <li>○ Issuing Antiretroviral Drugs from the ARV Bulk Store</li> <li>○ Dispensing Antiretroviral Drugs from the Outpatient Pharmacy</li> </ul>	
109	Medication Use Counselling on Antiretroviral Therapy	Has been reviewed by CPGH Pharmacy. Next steps are for CPGH Pharmacy/RPM Plus, ICRH and FHI to harmonise information materials on side effects.  To be completed for presentation to the Scientific Committee for approval early October 2003
110	Prepacking Antiretroviral Drugs for the DAART Study	SOP and the form have been reviewed and an initial test completed. Final test will be done when DAART study is up and running.  Ready to be presented to the Scientific Committee for approval early October 2003 in its pre-test format
	Roles and Responsibilities of the CPGH Pharmacy Department in Support of the ART program <ul style="list-style-type: none"> <li>○ Pharmacist in charge of the ART Program</li> <li>○ Pharmacist in charge of the ARV bulk store</li> <li>○ Pharmacy staff member in charge of dispensing ARVs from the outpatient pharmacy</li> <li>○ Pharmacy staff member in charge of preparing prepacks for DAART study</li> <li>○ Pharmacist in charge of checking prepacking for DAART study</li> </ul>	All submitted for final review by CPGH Pharmacy Staff  Will be presented to the Scientific Committee for approval early October 2003

<b>Standard Operating Procedure for the ART Program</b>		<b>Status and Next Steps August 12, 2003</b>
501	Internal Audit of Antiretroviral Drugs	<p>Has been reviewed by CPGH Pharmacy, Deputy Administrator and Chairman of the Quality Committee</p> <p>Next step – the SOP and form will be tested by the Quality Committee in September.</p> <p>SOP and form will be revised and presented to the Scientific Committee for approval early October 2003</p>
502	ART Program: Pharmacy Activity Report	<p>Has been reviewed by CPGH Pharmacy</p> <p>Next step – the SOP and form will be tested by the CPGH Pharmacy in September 2003.</p> <p>SOP and form will be revised and presented to the Scientific Committee for approval early October 2003</p>
301	Antiretroviral Therapy Adverse Drug Reaction Monitoring and Reporting.	<p>SOP and forms have been drafted and reviewed by CPGH Pharmacy</p> <p>Next step - to be presented to Scientific Committee August 14, 2003 for policy decisions. SOP will be revised based on decisions and will be tested.</p> <p>Submission to Scientific Committee for approval may be delayed until November 2003 to allow adequate time for testing.</p>

### **3. Generic Standard Operating Procedures for the Pharmacy**

**Progress to date:** None

**Next steps:**

RPM Plus will work with CPGH Pharmacy to start drafting generic SOPs in November 2003

### **B. Infrastructure/Equipment**

**Progress to date:**

- Lockable cupboards installed in ARV bulk store
- Sliding doors installed to be used as lockable cupboards for DAART prepacks
- Air conditioner installed in ARV bulk store

- Refrigerator purchased for ARV bulk store
- Cupboards grilled for security in outpatient pharmacy
- Booths installed for patient medication use counselling
- Thermometers purchased and temperature monitoring in place for ARV bulk store and refrigerator
- Handed over to CPGH – CPGH providing ongoing maintenance

#### **Next steps**

- CPGH to follow up on repairs/poor workmanship
  - Install more secure locks on cupboard in ARV bulk store
  - Stabilise cupboard in ARV bulk store
  - Sliding doors are jammed – plane down doors
  - Adjust locks on the grills of four cupboards in outpatient pharmacy - do not line up and they cannot be locked.
- Purchase thermometer for outpatient pharmacy and set up temperature monitoring

### **C. Human Resources - Training**

#### **Progress to date:**

- 2 pharmacists & 2 pharmaceutical technologists trained in April 2003 – 5 day training
- Topics have been identified by CPGH staff for ongoing training
- FHI and RPM Plus met with CPGH Training Officer to develop a plan and discuss logistics for ongoing training

#### **Next steps:**

- CPGH will provide the venue and organise the logistics.
- CPGH training officer will prepare and administer a questionnaire to identify priority topics for ongoing training for each cadre of staff and to get input on the best time to hold the trainings.
- Ongoing training will begin October 2003
- A repeat of the 5 day initial training is tentatively planned in 6 months – for new staff or staff that missed the initial training

### **D. Human Resources - Staffing**

#### **Progress to date:**

- Roles and responsibilities of pharmacy staff for the ART program have been drafted and are ready for review
- Key responsibilities (e.g. issuing from ARV bulk store and receiving into the outpatient pharmacy) have been separated
- Weekly pharmacy rota identifying staff members to perform key responsibilities has been initiated

**Next steps:**

- Stabilising staffing levels and increasing participation of a larger number of staff in ARV bulk store management, dispensing and counselling for ART patients and prepacking is key to the success of scaling up the ART Program
- Counselling ART patients can take 30 minutes for first visit and 10-15 minutes for ongoing visits – has implications for staffing as ART Program scales up.
- Organise a catch up workshop for staff who missed initial ART training

**E. Stores/Supply Management**

**Progress to date:**

- Record keeping for ARVs as per GOK MOH standard procedures are in place
- All records up to date as of August 9, 2003
- TA being provided to assist CPGH in quantifying requirements
- 1 request for procurement – for Nevirapine – has been submitted to FHI

**Next steps:**

- Develop a quantification methodology
- Train and hand over quantification to CPGH staff – by August 2004

**F. Use of ART**

**1. Prescribing and dispensing**

**Progress to date:**

- Dr. Olwande is a member of the Eligibility Committee and acts as Secretary. As a member is quickly able to update Eligibility List and to prepare for new patients
- The following books have been supplied to CPGH Pharmacy
  - AHFS Drug Information (2003)
  - Drugs in Pregnancy and Lactation
  - Martindale: The Complete Drug Reference (2002)
  - British National Formulary (March 2003)
- Pharmacy is now preparing for dispensing for paediatric patients – labels are being printed by ICRH and meetings have been held with Paediatric AIDS Clinic to discuss dispensing issues

**Next steps:**

- Pharmacy to produce a weekly list of availability of all drugs for CCC to assist prescribing
- Problems with availability of sequentially numbered prescriptions need to be addressed

**2. Medication Use Counselling**

**Progress to date:**

- Four staff members have been trained and are available to counsel patients on ART medication – rota provides details of availability and contact information
- SOP has been developed and counselling points to be covered decided on

**Next steps:**

- Pharmacy staff are often being asked about non-medication issues. FHI to prepare standard information for frequently asked questions to assist pharmacy staff
- CPGH/RPM Plus to work with ICRH/Horizons and FHI to harmonise information being given out on side effects
- RPM Plus to work with CPGH Pharmacy to develop standard information to be used for reference for drug interactions
- Pharmacy to work with FHI on developing patient information leaflets on ART
- Produce poster at Window 4 on ART Counselling
- Pharmacy to work on identifying strategies to improve patient flow at Pharmacy booths for non-ART patients to reduce crowding at the hatches.

**3. ADR monitoring and reporting system****Progress to date:**

- SOP and monitoring and reporting forms have been drafted and revised based on initial input from CPGH pharmacy and medical staff

**Next steps:**

- Present SOP to Scientific Committee August 14, 2003 for policy decisions.
- Revise SOP and forms based on decisions
- Test forms and SOP
- Develop training materials and deliver ADR training
- Submission to Scientific Committee for approval may be delayed until November 2003 to allow adequate time for testing.

**4. RDU monitoring and reporting****Progress to date:** None**Next steps:**

- Begin basic Drug Utilisation Reviews (DUR) in November 2003

**5. Dispensing for DAART study****Progress to date:**

- SOP and form has been developed – tested in August 2003
- Responsibilities for preparing prepacks and checking have been split
- CPGH ART Pharmacist and RPM Plus have accompanied DAART coordinator on visits to satellite units to advise on security of cupboards

**Next steps:**

- As DAART study has not started yet – there have only been a few patients to test the system – the SOP and forms need to be retested once the prepacking system is running at full scale
- DAART cupboard in CCC needs to be secured with a bar – ICRH following up
- As many of the ARVs are thermolabile, all DAART storage cupboards should have temperature monitoring – ICRH to follow up

## **G. MIS**

### **Progress to date:**

- Manual systems for inventory management and patient profiles have been set up and are up and running smoothly at current work level

### **Next steps:**

- In October 2003, RPM Plus/FHI will take a comprehensive look at the MIS for ART Program to identify strategies to improve efficiency in data collection and data quality and reporting.

## **H. Monitoring and Evaluation/Performance Improvement**

### **Progress to date:**

- SOP and forms for internal audit (internal to CPGH but external to the pharmacy) have been developed.
- SOP and a Weekly ART Program: Pharmacy Activity report had been developed – provides information for performance monitoring. Also acts as a management tool – provides information on workload and administrative issues that are impacting the ART Program

### **Next steps:**

- CPGH to appoint 2 members of the Quality Committee and 1 administrative person to Internal Audit Committee
- Internal Audit Committee to test SOP and forms in September 2003.
- SOP and form will be revised and presented to the Scientific Committee for approval early October 2003
- ART Program Activity Report will be tested by the CPGH Pharmacy in September. SOP and form will be revised and presented to the Scientific Committee for approval early October 2003

## **Coast Provincial General Hospital**

### **Update on Laboratory Implementation Progress**

#### **A. CPGH Implementation Plan**

**Progress to date:**

- CPGH Implementation Plan has been finalized in August 2003

**Next steps:**

- Implementation of the plan will begin immediately

#### **B. Policies and Procedures**

##### **1. Guidelines**

**Progress to date:** None

**Next steps:**

- RPM Plus to work with CPGH Lab to identify and obtain a set of guidelines to be available for use by laboratory staff

##### **2. Standard Operating Procedures (SOPs) for the ART Program**

**Progress to date:**

- SOPs have been developed for:
  - Processing Chemistry Specimens
  - Criteria for rejecting chemistry specimens
  - Correcting erroneous reports
  - Alanine aminotransferase analysis by photometer 5010
  - Aspartate aminotransferase analysis by photometer 5010
  - Amylase analysis by photometer 5010
  - Total bilirubin analysis by photometer 5010
  - Total protein analysis by photometer 5010
  - Urea nitrogen analysis by photometer 5010
  - Creatinine analysis by photometer 5010
  - Chiron diagnostic 644 Na/K Analyser
  - Complete blood cell count by Coulter Analyser
  - Manual white cell differential count and platelet estimate
  - Sample preparation for CD4 T cell determination by Cytoflow
  - Refrigerator/freezer maintenance
  - Laboratory Critical/Panic Values
  - Thermometer quality control

**Next steps:**

- SOPs to be tested in September 2003
- SOPs to be prepared for
  - Sample preparation for Viral load

- CD4 T cell determination by Cytoscan
- AFB determination
- Generic laboratory SOPs – development to begin October 2003

### **C. Infrastructure/Equipment**

#### **Progress to date:**

- FHI has placed orders for
  - CD4 CyFlow (includes an initial supply of reagents and tubes)
  - Multichannel pipettes
  - Precision Pipettes

#### **Next steps**

- Repair Autolab (CPGH - filters on order and due to be replaced mid-September 2003). This will substantially decrease the workload currently involved in using the backup system
- FHI to order rotor for CCC to prevent blood samples from clotting
- Monitor need for other equipment/upgrades as program scales up

### **D. Human Resources – Training**

#### **Progress to date:**

- 4 technologists trained in April 2003 – 5 day training
- Topics have been identified by CPGH staff for ongoing training
- FHI and RPM Plus met with CPGH Training Officer to develop a plan and discuss logistics for ongoing training
- List of key books/reference materials have been identified

#### **Next steps:**

- CPGH will provide the venue and organise the logistics.
- CPGH training officer will prepare and administer a questionnaire to identify priority topics for ongoing training for each cadre of staff and to get input on the best time to hold the trainings.
- Ongoing training will begin October 2003
- A repeat of the 5 day initial training is tentatively planned in 6 months – for new staff or staff that missed the initial training
- Procure books/reference materials

### **E. Human Resources – Staffing**

#### **Progress to date:**

- Roles and responsibilities of ART Program Laboratory Coordinator have been developed by RPM Plus/CPGH
- Dr. Denje, laboratory supervisor has been identified to take on the duties initially

**Next steps:**

- CPGH Management to approve Dr. Denje, laboratory supervisor taking on the duties of ART Program Laboratory Coordinator
- Review additional workload 3 monthly

**F. Blood Specimen Collection****Progress to date:**

- Register has been set up to record all patients bled and samples collected
- Regular collection service has been established to bring samples to main lab and return results to CCC

**Next steps:**

- Improve labelling of samples
- Establish registers in each section of lab

**G. Testing****1. HIV Diagnosis****Next steps:**

- Shortages of HIV rapid kits and ELISA reagents are impacting the program and need to be followed up on

**2. Haematology and Clinical Chemistry****Next steps:**

- Purchase calibration reagents and institutionalise calibration

**3. CD4****Progress to date:**

- Contract has been set up with Aga Khan Hospital to perform CD4 testing in the interim

**Next steps:**

- Set up CD4 testing at CPGH – CyFlow – due to arrive mid-September 2003

**4. Viral Load****Progress to date:**

- Survey to identify appropriate facility has been performed. KEMRI has been identified for an initial 3 month contract – to continue based on performance
- FHI/RPM Plus have visited KEMRI to discuss contract and preparation of samples for testing.

**Next steps:**

- FHI to set up viral load testing at KEMRI – August 2003
- RPM Plus to develop SOP for preparing and transporting samples for viral load testing

**5. Viral Resistance Testing**

**Progress to date:**

- Samples are being collected and stored for possible future testing

**H. MIS**

**Progress to date:**

- Lab request and reporting forms have been drafted

**Next steps:**

- Test Lab request and reporting forms
- In October 2003, RPM Plus/FHI will take a comprehensive look at the MIS for ART Program to identify strategies to improve efficiency in data collection and data quality and reporting

**I. Good Laboratory Practice**

**Next steps:**

- Adapt generic SOP for PEP for lab – include specific information on procedures to be followed for lab staff
- Set up an accident/incident register

**J. Monitoring and Evaluation/Quality Control**

**Next steps:**

- Develop a plan to strengthen QA/QC in lab

**K. Financing**

**Next steps:**

- Need to develop a policy for non ART Program patients seeking CD4 testing at CPGH

## **Implementation at Port Reitz, Bomu (Mkomani) Clinic and Magongo Clinic**

### **Update on Pharmacy and Laboratory Implementation Progress**

#### **A. Port Reitz**

##### **Progress to date**

- Site assessment was conducted in September 2002, results presented to site for feedback in January 2003.
- 1 pharmaceutical technologist and 1 lab technologist were trained in April 2003, 5 day training
- Follow on visit to the Pharmacy at Port Reitz was made for initial discussions on implementation of the ART program in July 2003.
  - Pharmacy has been renovated (by DANIDA)
  - New pharmacy storeroom has been set up (by DANIDA) and is now under the supervision of the drug inspector
- Two follow on visits to the laboratory were made in July/August 2003.
  - Laboratory has been renovated (by DANIDA)
  - Small colorimeter has been purchased with cost sharing funds for LFTs and RF

##### **Next steps**

- FHI will hold a meeting with the 4 sites to discuss issues around collaboration for the ART program e.g. transfer of specimens for laboratory testing, different cost sharing policies
- FHI and RPM Plus will meet with Port Reitz in October 2003 to develop implementation plan for introduction of ART
- CPGH training officer will prepare and administer a questionnaire to all sites to identify priority topics for ongoing training for each cadre of staff and to get input on the best time to hold the trainings.
- Ongoing training will begin October 2003
- A repeat of the 5 day initial training is tentatively planned in 6 months – for new staff or staff that missed the initial training
- Port Reitz staff will commence partnering assignments with CPGH in September 2003. Medical staff will work with Dr. Otieno, nursing staff with CCC staff, pharmacy staff with Dr. Olwande and laboratory staff with Mr Denje.

#### **B. Bomu (Mkomani)**

##### **Progress to date**

- Site assessment was conducted in September 2002, results presented to site for feedback in January 2003.
- 1 pharmaceutical technologist and 1 lab technologist were trained in April 2003, 5 day training

- Two follow on visits to the laboratory were made in July/August 2003.
  - No new equipment has yet been purchased and donors are still to be identified. (Bomu are requesting donations of a colorimeter and Autolab)

### **Next steps**

- FHI will hold a meeting with the 4 sites to discuss issues around collaboration for the ART program e.g. transfer of specimens for laboratory testing, different cost sharing policies
- FHI and RPM Plus will meet with Bomu staff in October 2003 to develop implementation plan for introduction of ART
- CPGH training officer will prepare and administer a questionnaire to all sites to identify priority topics for ongoing training for each cadre of staff and to get input on the best time to hold the trainings.
- Ongoing training will begin October 2003
- A repeat of the 5 day initial training is tentatively planned in 6 months – for new staff or staff that missed the initial training
- Bomu staff will commence partnering assignments with CPGH in September 2003. Medical staff will work with Dr. Otieno, nursing staff with CCC staff, pharmacy staff with Dr. Olwande and laboratory staff with Mr Denje.

## **C. Magongo**

### **Progress to date**

- Site assessment was conducted in September 2002, results presented to site for feedback in January 2003.
- 1 pharmaceutical technologist and 1 lab technologist were trained in April 2003, 5 day training – however, since then, the trained staff at Magongo have been transferred
- Municipal Council – health officer have all been replaced. FHI and RPM Plus met with the Medical Officer for Health (Dr. Chidagaya) and Deputy (Dr. Were) on ART Program.
- New Sister at Magongo has been briefed on ART program and provided with a copy of all assessment results
- Two follow on visits to the laboratory were made in July/August 2003.

### **Next steps**

- FHI will hold a meeting with the 4 sites to discuss issues around collaboration for the ART program e.g. transfer of specimens for laboratory testing, different cost sharing policies
- CPGH training officer will prepare and administer a questionnaire to all sites to identify priority topics for ongoing training for each cadre of staff and to get input on the best time to hold the trainings.
- Ongoing training will begin October 2003
- A repeat of the 5 day initial training is tentatively planned in 6 months – for new staff or staff that missed the initial training

### **List of RPM Plus meetings July 18 to August 9, 2003**

**July 21**

Meet FHI staff and John Adungosi – briefing  
Dr. Mwanyumba (in PMO's absence) – briefing  
Dr. Baya – briefing

**July 22**

Dr. Shikelly – briefing  
Dr. Baya, Caroline, Lawrence, (other pharmacist), Mwanburi – briefing and initial feedback  
Dr. Mandaliyia – briefing and timetable

**July 23**

Dr. Mwangi – briefing; internal audit; management issues  
Dr. Otieno – review of lab and pharmacy issues

**July 24**

ICRH – pharmacy & lab issues  
Pharmacy – ADR, counselling, repacking error report SOPs

**July 25**

Dr. Mwangi – review of Internal Auditing SOP  
Dr. Olwande – activity report, infrastructure, DAART storage in CCC

**July 28**

USAID/REDSO Gil Cripps – introduction to ART program  
CPGH lab review – Dr. Mandaliyia, Mr Denje, John Adungosi

**July 29**

CPGH lab review – Dr. Mandaliyia, Mr Denje  
Dr. Baya and pharmacy staff – briefing and initial feedback  
Dr. Shikelly – briefing  
Port Reitz, Bomu, Magongo – visits with Dr. Mandaliyia

**July 30, 2003**

Briefing of Municipal and Deputy Municipal Officer of Health  
Dr. Olwande – follow up on counselling and activity SOPs; review of ART bulk store SOPs

**July 31, 2003**

Briefing of USAID/Kenya – Cheryl Sönnichsen and Buck Buckingham  
Eligibility Committee  
Visits to Port Reitz, Bomu, Magongo – Cheryl Sönnichsen and Buck Buckingham  
Dr. Olwande – SOPs

**August 1, 2003**

Briefing of Magongo – Sister

ICRH site visits – Magongo, Bomu, Port Reitz  
Dr. Olwande – SOPs and Quantification

**August 5, 2003**

ADR comments – Dr. Mandaliya  
Pharmacy SOP issues – Dr. Olwande  
ADR comments – Clinical Officer & Nurse

**August 6, 2003**

Meetings with Paediatric Clinic AIDS Clinic

**August 7, 2003**

Meeting with Dr. Achola  
Meeting with Pharmacy staff  
Meeting with Dr. Olwande

**August 8, 2003**

Visit with Mr Malika, Pharmacy Port Reitz

**August 11, 2003**

Meeting with COPHIA

**August 12, 2003 (pending)**

Meeting with CPGH Training Officer  
Scientific Committee meeting

**Annex 2. Center for Pharmaceutical Management Rational Pharmaceutical  
Management Plus. Position Description: Senior Program Associate,  
Mombasa ART Program**

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**POSITION DESCRIPTION**  
**Center for Pharmaceutical Management**  
**Rational Pharmaceutical Management Plus**

**TITLE:** Senior Program Associate, Mombasa ART Program  
**BAND:** 6  
**REPORTS TO:** Team Leader for the Mombasa ART Program  
**LOCATION:** Mombasa, Kenya

**OVERALL RESPONSIBILITIES:** The Senior Program Associate, Mombasa ART Program, is responsible for coordinating and managing field-based Rational Pharmaceutical Management (RPM) Plus assistance activities to build the capacity of the pharmaceutical management system and the laboratory services at selected sites in Mombasa district to support the introduction and scale up of antiretroviral therapy (ART). He or she acts as the primary liaison at the local level between RPM Plus and the Ministry of Health, staff at the ART sites, stakeholders, and RPM Plus' technical assistance partners (TAP). The Senior Program associate provides direct technical assistance to the sites and partners and manages ongoing training activities. This position is full time for four years, dependent on project funding, and is based in Mombasa, Kenya, with approximately 25% of time spent in Nairobi. This position reports directly to the Team Leader for the Mombasa ART Program, and is also supervised by the RPM Plus Regional Technical Advisor in the Nairobi Office.

**SPECIFIC RESPONSIBILITIES:**

1. Act as the primary RPM Plus liaison with staff from the ART Program sites, Ministry of Health, stakeholders, and TAP (FHI/IMPACT and Population Council/Horizons) in Mombasa. Represents RPM Plus on Steering and Scientific Committee meetings and on other committees as appropriate for the ART Program.
2. Communicate regularly with the Mombasa ART Program team and provides regular progress reports and updates on technical assistance activities to staff based in the Washington, DC, and Nairobi offices.
3. Collaborate with Mombasa ART site staff, stakeholders, local TAP counterparts, and RPM Plus staff in Nairobi and DC to identify priorities and develop strategies to support implementation of the ART program. Work with sites to develop site specific workplans. Assist the RPM Plus HIV/AIDS Team Leader in developing budgets and workplans for RPM Plus.
4. Coordinate and manage the implementation of RPM Plus capacity building strategies for the pharmaceutical management system and laboratory services at the local level.
5. Troubleshoot problems and facilitate progress as necessary. Provide support and oversight to RPM Plus consultants as necessary.

6. Provide direct technical assistance to strengthen the capacity of the pharmaceutical management system, as appropriate. The work will generally be performed in collaboration with other RPM Plus staff or consultants.
7. Work with site staff, stakeholders, and local TAP counterparts to coordinate the ongoing training program for laboratory and pharmacy staff. Assist in development of training materials and act as a trainer for the program. Take responsibility for logistics at the local level and conduct evaluations of training sessions.
8. Collect data and monitor results of RPM Plus activities for the Mombasa ART Program. Collect and report data on input, process, and output indicators on a regular basis; highlight significant constraints to progress and output; and use data gathered to present options and make decisions regarding implementation of activities in collaboration with the RPM Plus Team Leader. Coordinate the implementation of special studies, assessments, or evaluations conducted by RPM Plus staff and/or consultants. Coordinate data collection and dissemination with other partners.
9. Participate in documenting and disseminating results of the program, including lessons learned, tools, and methodologies, and deliver presentations at national and regional conferences as opportunities arise.
10. Participate in pharmaceutical and laboratory services assessments for scaling up the Mombasa ART Program. Contribute to developing detailed reports that define problems and gaps and recommend steps to remedy deficiencies.

**QUALIFICATIONS:**

1. Professional degree in a health related field required; physician, pharmacist or nurse qualification preferred.
2. Resident of Mombasa, Kenya preferred.
3. Significant work experience in providing clinical services in hospital and primary health care settings in the developing world. Experience in designing and implementing HIV/AIDS treatment and care programs preferred.
4. Knowledge and comprehensive understanding of Kenya's public sector health care system.
5. Significant experience in drug management, including supply chain management, dispensing drugs, and counseling patients.
6. Experience in developing training curricula and materials for pharmaceutical management and/or laboratory services and in organizing and delivering training for healthcare staff.
7. Experience in monitoring and evaluating programs and in implementing performance improvement programs/strategies.
8. Experience in implementing or backstopping USAID-supported projects preferred.
9. Strong organizational, administrative, and communications skills. Experience in developing workplans.
10. Willingness to be flexible and adapt to changing priorities and deadlines.

11. Strong English skills required, including ability to write lucid technical reports and documents, with fluency in Swahili strongly preferred.
12. Computer skills, including knowledge of Windows, Microsoft Word, Excel and Power Point.
13. Ability and availability to travel 25% of the time.

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