

**RPM Plus Site
Visit to Binh
Thanh District
Outpatient Clinic,
Ho Chi Minh City:**

***October 14, 2005:
Report***

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Helena Walkowiak
David Kuhl
Nguyen Anh Dao
Nguyen Viet Hung

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Helena Walkowiak
David Kuhl
Nguyen Anh Dao
Nguyen Viet Hung

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

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About RPM Plus

RPM Plus works in more than 20 developing and transitional 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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Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmplus@msh.org
Web: www.msh.org/rpmplus

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
CPC	Central Pharmaceutical Company
FDC	fixed-dose combination
FHI	Family Health International
GoV	Government of Vietnam
HIV	human immunodeficiency virus
IMPACT	Implementing AIDS Prevention and Care Project [FHI]
MSH	Management Sciences for Health
OI	opportunistic infection
PAC	Provincial AIDS Committee
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
RPM Plus	Rational Pharmaceutical Management Plus [Program]
SOP	standard operating procedure
USG	U.S. Government

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PAC, Ho Chi Minh City

- Dr. Than Thinh
- Dr. Huynh Thu Thuy, Program Officer, CDC
- Ms. Ma Bun Cam
- Ms. Nguyen Thi Thu Thao

FHI/IMPACT

- Dr. Rachel Burdon, Senior Technical Officer, Treatment and Care

Binh Thanh District Outpatient Clinic

- Dr. Nguyen Thanh Liem, Head of Outpatient Clinic
- Ms. Nguyen Thi Binh, ART Dispenser
- Dr. Ngo Thi Anh Dong, Adherence Counselor

EXECUTIVE SUMMARY

Management Sciences for Health’s (MSH) Rational Pharmaceutical Management (RPM) Plus Program is providing technical assistance to the Government of Vietnam (GoV), U.S. Government (USG), and local partners and stakeholders to procure and distribute antiretroviral medicines (ARVs) to USG-supported sites and to strengthen pharmaceutical management capacity to ensure continual and adequate availability of ARVs and other HIV/AIDS commodities, promote their appropriate use, and enhance the quality of pharmaceutical antiretroviral therapy (ART) services. Developing and implementing standard operating procedures (SOPs) for pharmaceutical management have been shown to help standardize procedures to ensure quality and consistency of services, to foster good dispensing practices, and to promote accountability for ART programs.

Key Findings and Recommendations

Topics	Findings	Recommendations
Status of the ART program	<p>Only one source of ARVs expected at time of visit</p> <p>U.S. President’s Emergency Plan for AIDS Relief (PEPFAR)-funded-ARV dispensing started in September 2005</p>	RPM Plus to make a follow-up visit after two months and then every six months to assist Binh Thanh District Outpatient Clinic to strengthen procedures and address challenges
ARV medicine flow at the facility	ARVs are delivered to, stored by, and dispensed by the pharmacy	
Receiving ARVs at the site	<p>Central Pharmaceutical Company (CPC) No. 1 delivers directly to Binh Thanh</p> <p>A representative from the pharmacy department at the District Health Center is present when the ARVs are delivered</p> <p>The pharmacy department staff at the District Health Center complete the financial reporting</p>	<p>An official form such as a financial receiving note can be used to facilitate financial reporting</p>
ARV storage and dispensing area at the pharmacy	Pharmacy is air-conditioned but air conditioning is turned off at night	<p>Additional storage space may be needed for scaling up</p> <p>Monitor temperature of storage area and refrigerator routinely, particularly at night when the air conditioning is turned off</p>

Topics	Findings	Recommendations
Record-keeping at the pharmacy	<p>Official prescription form in use</p> <p>Printed stock cards used</p> <ul style="list-style-type: none"> • Receipts—batch number and expiry date not seen to be recorded • Issues—patient's name/number do not appear to be recorded <p>No longitudinal patient dispensing record seen</p> <p>Interim forms in use to assist in aggregating consumption data for scale-up</p> <p>No software in use</p> <p>Record-keeping for ARVs and other medicines has a major impact on the pharmacy workload</p>	<p>Record batch number and expiry date when receiving ARVs</p> <p>Record patient name or number for each issue</p> <p>Establish a patient-centered record to track dispensing by patient and to cross-check prescription as an interim measure</p> <p>Interim forms need to be replaced by software that uses one entry at time of dispensing to collect data for inventory management, cross-checking prescriptions, and forecasting</p> <p>Installing the software is a priority to minimize workload due to record-keeping and catch up data entry; an interim stand-alone software package can be used while integrated systems are being developed and tested</p> <p>Review and rationalize record-keeping at the pharmacy</p>
Dispensing and medication counseling at the pharmacy	<p>No ART reference materials seen</p> <p>Plastic bags used by pharmacy staff; tablet counters do not appear to be used—fingers used to dispense medicines; patients are taught to refill and clean pill boxes themselves</p> <p>Lids on pill boxes reported to break easily</p> <p>Labels are used</p> <p>No patient information leaflets seen at pharmacy</p>	<p>Provide standard set of guidelines and reference materials</p> <p>Minimize handling of ARV products by using gloves, tablet counters, or tweezers</p> <p>More robust pill boxes needed</p> <p>Make leaflets available at the dispensing point in addition to clinic</p>
Pharmacy reporting for the ART program	<p>Interim reporting forms used at time of visit</p> <p>Staff report problems in preparing estimates of new patients to start ART by regimen</p> <p>Workload implications of reporting and timeliness of forms reaching RPM Plus are potential concerns</p>	<p>RPM Plus; PAC, Ho Chi Minh City; and FHI/IMPACT to monitor and assist site to address problems in completing and submitting the reporting forms to RPM Plus</p> <p>Provide training and/or tools to assist sites in preparing estimates of new patients to start ART by regimen</p>
Other issues	<p>Demand for ART at the clinic is very high</p>	

BACKGROUND

MSH/RPM Plus is providing technical assistance to the GoV and USG partners to procure and distribute ARVs to USG-supported sites. In addition, RPM Plus is working collaboratively with GoV, USG, and local partners and stakeholders to strengthen the pharmaceutical management capacity of referral, provincial, district, and other USG-supported sites to ensure continual and adequate availability of ARVs and other HIV/AIDS commodities, promote their appropriate use, and enhance the quality of pharmaceutical ART services. Developing and implementing SOPs for pharmaceutical management have been shown to help standardize procedures to ensure quality and consistency of services, to foster good dispensing practices, and to promote accountability for ART programs.

Site Visit Objectives

In preparation for providing technical assistance to GoV to draft SOPs for ART pharmaceutical management, the RPM Plus team visited Binh Thanh District Outpatient Clinic, Ho Chi Minh City, to—

- Understand the roles and responsibilities of the pharmacy staff in supporting the ART program
- Understand ARV medicine flow at the facility and identify forms and procedures used by the pharmacy staff for ordering, receiving, storing, internal distribution, record-keeping, and dispensing ARVs
- Solicit feedback on any problems or issues related to pharmaceutical management identified by Binh Thanh District Outpatient Clinic clinical and pharmacy staff during the start-up period of the ART program
- Explore staff concerns on the robustness of the current pharmaceutical management systems and procedures to support the scale-up of the ART program

Methodology

The RPM Plus team conducted semi structured interviews with key informants, observed operations and reviewed some records to prepare this report.

The members of the RPM Plus Team were—

- Helena Walkowiak, Senior Program Associate, RPM Plus, U.S. Office
- David Kuhl, Senior Technical Advisor, RPM Plus Vietnam Office
- Nguyen Anh Dao, Program Associate, RPM Plus Vietnam Office
- Nguyen Viet Hung, RPM Plus Information Technology Consultant, RPM Plus Vietnam Office

Caveats and Limitations

The information on which this report is based very often came from one source. Due to the limited time available for the visit and for interviews, RPM Plus staff did not have the opportunity to cross-check information. In addition, as the ART program is new to Binh Thanh District Outpatient Clinic, systems and forms are evolving and very often the staff interviewed were still uncertain about the final processes that would be put in place.

The mandate of RPM Plus was to understand and not assess the existing forms and systems although the team did solicit input from implementing staff on problems and issues that need to be addressed. As a result, the team observed and inventoried processes used and records kept, but did not assess the quality of operations and record-keeping. For example, we looked at whether a running balance was documented in stock records, but did not perform a physical count to check if the balance was correct.

FINDINGS AND RECOMMENDATIONS

1. Status of ART Program

Findings

Source of ARV Medicines	Client Type	Program Status	Number of Clients on ART	Target
PEPFAR	Adult	Dispensing started in September 2005	19 on October 14, 2005	140 at end of March 2006

- ARV dispensing commenced in September 2005.
- Only one source of ARV medicines expected—PEPFAR-funded ARVs—generally single-medicine branded products.
- IMPACT provides technical assistance to Binh Thanh District Outpatient Clinic to support ART program.
- Prescriptions are currently not endorsed with source of ARVs to be dispensed as only one source in stock at the moment.
- Medicines to prevent and treat opportunistic infections (OIs)—
 - Some donations received from local donors
 - Also receive OI medicines purchased with funds from the Global Fund for AIDS, Tuberculosis and Malaria
 - Some OI medicines are in short supply (e.g., fluconazole and acyclovir)

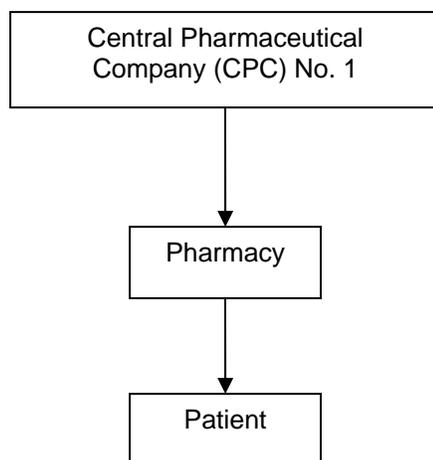
Recommendations

- As the ART program has just recently been introduced at Binh Thanh District Outpatient Clinic, a follow-up visit/contact should be made after two months and then at six-month intervals to assist the site to develop and strengthen procedures, address challenges, and monitor the impact of the ART program on the site.

2. ARV Medicine Flow at the Facility

Findings

- ARVs are delivered by CPC No. 1 directly to Binh Thanh District Outpatient Clinic.
- The ARVs are received, held by, and dispensed by pharmacy.
- Flow of PEPFAR-funded ARVs at Binh Thanh District Outpatient Clinic—



3. Receiving ARVs at the Site

Findings

- Procedure—
 - CPC No. 1 delivers PEPFAR-funded ARVs directly to Binh Thanh District Outpatient Clinic with—
 - One original and two copies of the CPC No. 1 Delivery Note
 - Copy of the Ministry of Health (MoH)-approved distribution plan
 - A representative of the pharmacy department from the District Health Center is present when the ARVs are delivered. The District Health Center agreed to let CPC No. 1 deliver directly to Binh Thanh as the pharmacy department did not have sufficient space to store the ARVs at the District Health Center and also to reduce the paperwork.
 - Pharmacy staff check the order received against the delivery note in the presence of a representative of the pharmacy department from the District Health Center and inspects the items for damaged and expired stock
 - If everything is in order the receiving pharmacy staff endorses the delivery notes and obtains the required signatures and stamps
 - CPC No. 1 driver waits for the delivery to be inspected and the documents to be signed
 - One signed and stamped delivery note is given to the CPC No. 1 driver
 - The original delivery note is kept by the District Health Center
 - One copy of the delivery note is kept at Binh Thanh
 - The pharmacy department at the District Health Center completes the financial reporting

- ARV medicines are put into the cupboards in the pharmacy and receipt recorded in inventory records
- No procedure for handling damaged or expired ARVs or delivery discrepancies has been developed as yet; so far, no damaged or expired ARVs have been received
- The site staff report that as of now, the procedure for receiving PEPFAR-funded ARVs is working well.

Recommendations

- Review procedures after six months when ARV orders become larger to check if revisions are needed (e.g., CPC No. 1 driver waiting during what may become a lengthy receiving process).
- Consider using a standard form to facilitate the reporting of shipment discrepancies.

4. ARV Storage and Dispensing Area at the Pharmacy

Findings

Pharmacy ARV Storage and Dispensing Area		
Topics	For Current ART Patient Numbers/Stock	For ART Scale-Up
Organization	<ul style="list-style-type: none"> • Neat and tidy • Organized with first expiry to front • Opened bottles marked with date of opening 	NA
Space	<ul style="list-style-type: none"> • Quiet room • Adequate cupboard space with room for expansion for ARV storage • Dispensing space is adequate 	<ul style="list-style-type: none"> • May need more cabinet space and dispensing space for scale-up in the long term
Security	<ul style="list-style-type: none"> • Adequate • Locked cupboards in secured room 	<ul style="list-style-type: none"> • Adequate
Air conditioning	<ul style="list-style-type: none"> • Adequate • Turned off at night • Also has a dehumidifier 	<ul style="list-style-type: none"> • Adequate
Temperature monitoring of storage area	<ul style="list-style-type: none"> • Thermometer seen but no chart monitoring temperature observed 	NA
Refrigerator	<ul style="list-style-type: none"> • Adequate 	<ul style="list-style-type: none"> • Adequate
Temperature monitoring of refrigerator	<ul style="list-style-type: none"> • Not seen 	NA

Recommendations

- Additional storage space will probably be needed for scale-up.
- Temperature charts can be used to monitor if the routine temperatures in the pharmacy and the refrigerator are appropriate for the products, particularly at night when the air-conditioning is turned off.
- A chart to monitor expiry date of ARV products may be useful.

5. Record-Keeping at the Pharmacy

Findings

- Records were all neat, legible, and tidy. ARV records are kept in plastic folders.
- Prescription—
 - Official prescription form in use
 - Only one source of ARVs available at present so prescription is not stamped/ marked with source
 - The ART prescriptions are filed separately to facilitate auditing issues
- Inventory records—
 - To track consumption by product and monitor losses and wastage
 - Printed stock cards (the kho) used
 - Record date, quantity in or out, and balance
 - Balance reported to be checked at the end of the day
 - Patient name/number do not appear to be recorded for issues
- Longitudinal patient dispensing record—
 - To facilitate pharmaceutical care to patient—to cross-check medicines and doses prescribed and to identify source of medicines to be issued
 - None seen
- Record to assist in aggregating consumption data by regimen and product dispensed—
 - To forecast needs, the pharmacy will need to look at consumption patterns by regimen and also by product dispensed, e.g., to distinguish between consumption of 30 mg and 40 mg stavudine capsules for adults and between solid preparations and liquids for pediatrics

- Interim forms prepared by RPM Plus are available and staff have been trained to use them (not seen)
 - Daily ART Service Register for adult patients
 - Daily ART Service Register for pediatric patients
 - Daily ART Service Register for prevention of mother-to-child transmission
- Software—
 - No software is in use at the moment to facilitate the collection and analysis of dispensing data for ARVs
- Other records used—
 - Several books and registers appeared to be in use for recording issues for different kinds of medicines
 - Ledger used to record ARV dispensing—date, patient name, gender, ID code, diagnosis, medicine, and quantity given, and fees paid are recorded. Each dispensing encounter is recorded consecutively so it is not easy for staff to aggregate data for reporting, e.g., on consumption patterns by regimen and product dispensed
- Impact of ARV record-keeping on the workload of the pharmacy—
 - Pharmacy staff reports that record-keeping for the ART program is a major burden
 - The record-keeping at the pharmacy for ARVs and other medicines takes a total of two hours every day to complete; lack of familiarity with the RPM Plus forms contributes to the problem.
 - Binh Thanh Health Service Center staff requested software to assist with record-keeping at the pharmacy

Recommendations

- Prescriptions—
 - When more than one source of ARVs become available, stamps can be used by the prescriber to endorse the ART prescriptions with source of medicines to be dispensed—can be used as a cross-check with pharmacy records.
- Inventory records—
 - For receipts at the pharmacy—
 - Record the supplier and delivery note number in addition to date and quantity received for each product

- Record the batch number and expiry date to facilitate tracking and implementation of product recalls
- For issues at the pharmacy—
 - Ideally, the entries should be made at the time of dispensing stock to the patient, but at a minimum should be done daily as the program scales up
 - Record either the patient name or number in addition to date and quantity issued; including the patient's name or number will create an audit trail
- Checking the balance—
 - Making a notation in the record that the balance is correct can help pharmacy staff to look for errors if they know the last date when the balance was correct
 - A stock discrepancy form can be used to facilitate the recording and reporting of stock discrepancies that cannot be resolved
- Longitudinal patient dispensing record—
 - A patient-centered form can be used to track ARV dispensing by patient as an interim measure; however, software will be needed before the facility reaches its March 2006 target of 140 adult patients
- Record to assist in aggregating consumption data by regimen and product dispensed—
 - Interim RPM Plus forms will need to be replaced by software before the facility reaches its March 2006 target of 140 adult patients
- Software—
 - A software package that allows staff to enter data for inventory management, pharmaceutical care, and forecasting all at time of dispensing is needed to reduce the impact of ART record-keeping on the workload of the pharmacy
 - The software should aggregate and report data in a format that facilitates reporting of workload, consumption, and data for forecasting
 - Installing software is a priority to minimize workload due to record-keeping and catch up data entry; an interim stand-alone software package can be used while integrated systems are being developed and tested
- Impact of ARV record-keeping on the workload of the pharmacy—
 - The pharmacy would benefit from a review and rationalization of kept records

- Providing software to assist with the reporting at Binh Thanh should be made a priority to reduce the impact of record-keeping for ARVs and other medicines on the pharmacy workload

6. Dispensing and Medication Counseling for ARVs at the Pharmacy

Findings

Topics	Observations/Information Reported
Reference materials on ART	<ul style="list-style-type: none">• None seen at pharmacy
Container	<ul style="list-style-type: none">• Plastic bags are used for dispensing ARVs at the pharmacy• Each patient is given a pill box by the adherence counselor who teaches the patient how to fill it• Adherence counselor also provides instructions to the patient on how to clean the box• Lids have broken on some of the boxes• Adherence counselor reports that so far all patients have remembered to bring their pill boxes back to the clinic
Labels	<ul style="list-style-type: none">• Waterproof labels seen on pill boxes
Dispensing process	<ul style="list-style-type: none">• Prescription received and checked• No patient-centered record observed to be available for cross-checking prescription• Tablet counters seen but dispensers use fingers to place capsules into bags• Records made at the end of the day
Patient flow	<ul style="list-style-type: none">• Patient observed to be seen by—<ol style="list-style-type: none">(1) Receptionist(2) ART doctor(3) Pharmacy staff(4) Adherence counselor• Rooms are close to each other and patient flow well organized• Corridors and waiting areas may get crowded as program scales up
Medication counseling area at pharmacy	<ul style="list-style-type: none">• Medication counseling given in the pharmacy• Encounter is confidential• Room is quiet

Topics	Observations/ Information Reported
Content of medication counseling at pharmacy	<ul style="list-style-type: none">• Pharmacy staff is responsible for counseling on how to take medicines, how to store them, how to recognize the pills and doses, and when to take the medicines• Adherence counselor is responsible for reiterating instructions on doses and times of administration for each ARV, provides information on side effects and storage, teaches the patient to fill the pill box, issues the adherence card, and monitors adherence; also organizes group meetings on adherence• Counseling given during three encounters observed. Pharmacy staff—<ul style="list-style-type: none">○ Gave directions on how to take medicines○ Gave instructions on taking before or after food○ Gave additional instructions for some medicines on being cautious when driving○ Asked if the patient had any questions and responded to issues raised
Patient Information Leaflets	<ul style="list-style-type: none">• None seen at pharmacy

- Adherence counselor reports that Binh Thanh would like to use the pill boxes to assist non-ART patients to adhere to medicines and asked if it would be possible to obtain additional supplies.

Recommendations

- Reference materials—
 - Provide a standard set of reference materials and clinical guidelines for the dispenser
 - Identify a mechanism to keep the materials updated
- Container for liquids—
 - Investigate the availability of more robust pill boxes
 - Plan for start up of dispensing to pediatric clients; decide if original bottles will be dispensed or if medicine bottles will be needed so the pharmacy can dispense precise quantities to facilitate adherence monitoring
- Labels—
 - Labels will also be needed for pediatrics if medicine bottles are used to dispense precise quantities
- Dispensing process—
 - Tablet counters and using tweezers/gloves to dispense and load the pill boxes can minimize contamination during dispensing

- Patient information leaflets—
 - Make information leaflets available at the dispensing point in addition to the clinic

7. Pharmacy Reporting for the ART Program

Findings

- Each facility receiving PEPFAR-funded ARVs completes two report forms to facilitate forecasting of ARV medicine needs and one order form at the end of each month. The three interim forms are—
 - ARV patient reporting form
 - ARV stock/usage reporting form for health facility
 - ARV ordering and receipt form for health facility
- The forms need to reach RPM Plus by the tenth of each month to ensure that orders are dispatched promptly.
- Binh Thanh District Outpatient Clinic had completed the forms for the first time at the time of the site visit and reported that they had encountered some difficulties with filling the forms and preparing the estimates of new patients.
 - The clinic staff reported that it was difficult to estimate the number of patients who would start on each regimen two months in advance.
 - The pharmacy staff in charge of dispensing ARVs also reported that considerable time was needed to aggregate the data for completing the forms.
 - Binh Thanh staff requested that software to assist in the process be made available as soon as possible.

Recommendations

- The RPM Plus team to work with to work with PAC, Ho Chi Minh City; and FHI/IMPACT to monitor and if necessary, address site problems in completing the reports and delays in the reports reaching RPM Plus by the tenth of each month.
- As mentioned previously, software to aggregate and report data in a format that facilitates reporting for ARV medicines will reduce the workload for the pharmacy considerably.
- The software will be needed before the facility reaches its March 2006 target of 140 adult patients.

- Provide training on preparing estimates and/or a workbook to help site staff in preparing forecasts of new patients starting ART by regimen.

8. Other Issues Discussed

Availability of ARVs

The head of Binh Thanh District Outpatient Clinic informed RPM Plus team that the clinic currently has 1,000 active patients and many new patients come to the clinic every day. Of the 600 patients who have had a CD4 test done, 40 percent (240 patients) have a CD4 of less than 200. The patients cannot afford to buy ARVs in the private sector so the clinic is under great pressure to provide ARVs. The main problem the clinic faces is having enough ARVs to meet the need.

NEXT STEPS

- The site visit report will be shared with the staff at Binh Thanh District Outpatient Clinic, PAC/Ho Chi Minh City and FHI/IMPACT for review and comments.
- The findings and recommendations in this report will be aggregated with the reports from the other seven ART sites visited by the RPM Plus team in October 2005, and shared with site staff, implementing agencies and stakeholders.
- RPM Plus will work with site staff, implementing agencies, and key stakeholders to identify how current procedures and tools could be harmonized to facilitate the development of SOPs for pharmaceutical ART services. Lessons learned and best practices identified from the sites visited can be used to improve current practices.

