

**RPM Plus Site Visit  
to the Tropical  
Diseases Hospital,  
Ho Chi Minh City,  
October 13, 2005:**

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***Report***

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*December 2006*

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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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## ACRONYMS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
CDC	U.S. Centers for Disease Control and Prevention
CPC	Central Pharmaceutical Company
FDC	fixed-dose combination
GoV	Government of Vietnam
HIV	human immunodeficiency virus
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
TDH	Tropical Diseases Hospital [HCMC]
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

### **TDH**

- Dr. Nguyen Tran Chinh, Deputy Director
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- Mr. Tran Thi Danh, Pharmacist
- Mr. Vo Xuan Phong, Pharmacist



## 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. It is also helping 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 demonstrated to assist in standardizing procedures to ensure quality and consistency of services, foster good dispensing practices, and promote accountability for ART programs.

### Key Findings and Recommendations

Topics	Findings	Recommendations
Status of the ART program	<p>ARV dispensing began in 2005</p> <p>Three sources of ARVs in stock on October 13, 2005—</p> <ul style="list-style-type: none"> <li>• U.S. President’s Emergency Plan for AIDS Relief (PEPFAR)-funded—in stock but dispensing not started yet</li> <li>• GoV-funded ARVs—approximately 200 patients</li> <li>• ESTHER-funded ARVs—49 patients</li> </ul>	<p>RPM Plus to make a follow-up visit after two months and then every six months to assist pharmacy to strengthen procedures and address challenges</p> <p>Harmonize procedures, forms, data collection, and reporting systems for all sources of ARVs as far as possible; consider including a representative of the pharmacy on the ART selection committee</p>
ARV medicine flow at the facility	<p>ARVs are delivered to and stored by the pharmacy—a nurse will dispense PEPFAR-funded ARVs at the ART outpatient clinic</p> <p>ARVs move through three different areas before being dispensed to the patient</p> <p>Stocks are held in two areas in the pharmacy</p>	<p>Consider options for simplifying ARV medicine flow, for example, dispensing ARVs directly to the patient at the dispensary</p>
Receiving ARVs at the site	<p>Central Pharmaceutical Company (CPC) No. 1 delivers directly to site</p> <p>Original delivery note is sent to the finance department</p>	

<b>Topics</b>	<b>Findings</b>	<b>Recommendations</b>
Inventory management and record-keeping at the ARV storage areas in pharmacy  <i>Pharmacy Storeroom</i>	Secured, air-conditioned ARV storage area with adequate space available  Official stock cards used (not seen)	Additional storage space will be needed for ART scale-up  Monitor temperatures of storage area and refrigerator routinely  Record batch number and expiry date when receiving ARVs  Check balance with physical stock once a month or when issuing or receiving ARVs
Inventory management and record keeping at the ARV storage areas in pharmacy  <i>Dispensary</i>	ARVs are stored in a non-air-conditioned area with very limited storage space  Unofficial (homemade) card used for recording daily issues  Official form for reconciling receipts and issues with physical count is completed every 10 days  Receipts not seen to be recorded on records kept  Balance not updated daily	Do not keep more than two weeks' supply of ARVs at the dispensary to minimize exposure to high temperatures  Additional storage space needed as a priority  Monitor temperatures of storage area and refrigerator routinely  Replace unofficial daily issues record with stock card  Use cards to record issues and receipts and keep a running balance to facilitate completion of the reconciliation report
Internal distribution of ARVs  <i>Issuing ARVs from pharmacy storeroom to the dispensary</i>	Unofficial (homemade) exercise book used (not seen)	Use a double copy official requisition book to track movement of ARVs from the ARV storage area to the dispensary  Document the unique requisition number when recording issues at the ARV storage area and receipts at the dispensary
Internal distribution of ARVs  <i>Issuing ARVs from dispensary to the ART outpatient clinic</i>	Official internal requisition book used  Exact quantity of ARVs needed to fill prescriptions for ART patients on that day is ordered  Requisition number and/or patient name/number not seen to be recorded on issues records at the dispensary  Pharmacy cross-checks quantity ordered with prescriptions provided	Document the unique requisition number and/or patient name/number when recording ARV issues at the dispensary

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*Executive Summary*

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<b>Topics</b>	<b>Findings</b>	<b>Recommendations</b>
ARV dispensing area at the ART outpatient clinic	ARVs are not routinely stored at the clinic	
	Space for dispensing ARVs at the outpatient clinic appears to be limited (actual dispensing not observed)	Larger, quieter dispensing area will be needed for scale-up
Record-keeping for ARV dispensing at the outpatient clinic	Official prescription form in use	Stamp prescription with source to be dispensed
	No inventory records used at clinic	Inventory records not needed at moment as no ARV stocks are held there
	Patient record book available—not known if it is used to cross-check prescriptions	Use patient-centered record book to cross-check prescription as an interim measure
	Interim forms not in use as yet to assist in aggregating consumption data for scale-up	Interim forms need to be replaced by a software that uses <b>one</b> entry at time of dispensing to collect data for inventory management, cross-checking prescriptions, and forecasting
	Ledger used to record ARV dispensing encounters consecutively; difficult to use this ledger to aggregate data for reporting	Software should be capable of aggregating and presenting data for monthly reporting for <b>all</b> sources of ARVs
	No software in use	Installing the software <b>is a priority</b> 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
		Computer with software will need to be installed at the ARV dispensing point (in the clinic); pharmacy will need access to enter receipts and issues and to collect consumption data collected by the software for reporting

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<b>Topics</b>	<b>Findings</b>	<b>Recommendations</b>
ARV dispensing and medication counseling at the ART outpatient clinic	No ART reference materials seen	Provide standard set of guidelines and reference materials
	Dispensing and medication counseling not observed	Minimize handling of ARV products by using gloves and/or tablet counters
	Plastic bags used to dispense GoV and ESTHER-funded ARVs—no gloves, tablet counters, dispensing aids seen	Use same containers for dispensing ARVs regardless of source—if pill counters are to be used for PEPFAR-funded ARVs, identify a mechanism to make them available for GoV and ESTHER-funded ARVs too
	Labels not used	Consider costs and benefits of using labels
	Dispensing and medication counseling done by nurse at ART clinic due to staffing constraints in pharmacy	Consider costs and benefits of expanding role of pharmacist in ARV dispensing, medication counseling, and potentially adherence monitoring
Pharmacy and ART outpatient clinic reporting for the ART program	Requisitioning and dispensing process causes delays for patients—patients face a long wait or return visit to collect ARVs in the afternoon	Make leaflets available at the dispensing point in addition to clinic
	No patient information leaflets seen at dispensing point	
Pharmacy and ART outpatient clinic reporting for the ART program	Interim reporting forms not yet used at time of visit	RPM Plus, PAC/Ho Chi Minh City, and CDC to monitor and assist site to address problems in completing and submitting the reporting forms to RPM Plus
	Workload implications of reporting and timeliness of forms reaching RPM Plus are potential concerns	
Other issues	Pharmacy staffing levels reported to constrain the pharmacist dispensing and providing medication counseling to ART patients	Consider the cost implications and benefits of expanding the role of the pharmacist to dispense, provide medication counseling and possibly monitor adherence for ART program in the long-term

## **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 TDH 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 TDH 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 ART program scale-up

### **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 TDH, 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	<ul style="list-style-type: none"> <li>• Medicines received</li> <li>• Dispensing not started at time of visit</li> </ul>	0 on October 13, 2005	Not known
GoV	Adult	<ul style="list-style-type: none"> <li>• Program started</li> </ul>	Approximately 200 on October 13, 2005	Not known
ESTHER	Adult	<ul style="list-style-type: none"> <li>• Program started</li> </ul>	49 on October 13, 2005	Not known
Out-of-pocket purchases	Adult	<ul style="list-style-type: none"> <li>• ART prescribing began 2004</li> <li>• Patients buy ARVs out of pocket</li> </ul>	Approximately 30 on October 13, 2005	Not applicable

- TDH commenced ART prescribing in 1995 using monotherapy for a study. Triple ART prescribing began in 2004.
- Only prescribe ART for adult patients—pediatric patients are transferred to Pediatric Hospital No. 1.
- Three sources of ARVs are prescribed at TDH—
  - PEPFAR-funded ARVs—single-drug branded products
  - GoV-funded ARVs—fixed-dose combination (FDC) locally produced generic products
  - Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau (ESTHER)-funded ARVs—some FDC locally-produced generic products and some single-drug products
- The ART selection committee does not have a pharmacy representative to report on stock status of each source of ARVs to the committee and report back to the pharmacy which source of ARVs a new patient is to receive.
- The pharmacy department prepares a monthly report for management (not seen) which is reported to include quantity in stock and expiry date of each ARV by source. The ART prescribers then decide which ARVs to dispense.
- Prescriptions for ESTHER-funded ARVs are endorsed with a stamp—do not have stamps ready for PEPFAR and GoV-funded ARVs as yet.

## **Recommendations**

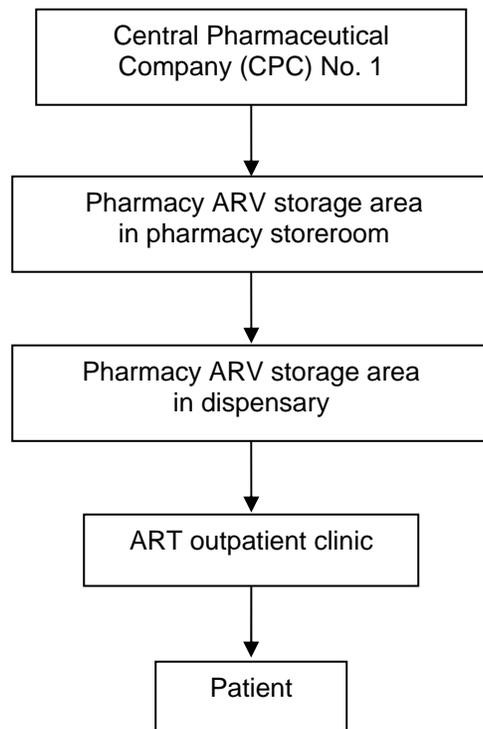
- As prescribing of the PEPFAR-funded ARVs has not yet started at TDH, a follow-up visit/contact should be made after two months and then every six months to assist the site to develop/strengthen procedures, address challenges, and monitor the impact of the multiple ART programs on the pharmacy and the nurse responsible for dispensing ARVs.
- The impact of managing three sources of different brands of ARVs on the pharmacy department and outpatient clinic can be minimized by—
  - Harmonizing procedures and forms/software used to receive, manage, issue/dispense, and report on ARVs as far as possible.
  - Establishing one record-keeping/software system that is able to track receipt, inventory, and consumption of ARVs by source.
  - Maintaining good communication between clinical and pharmacy services to ensure that the ART prescribers are aware of the stock situation at the pharmacy to aid selection of ARV source for new patients.
    - Pharmacy to continue to produce ARV monthly report for management.
    - Consider including a representative from the pharmacy department at ART selection committee meetings to provide a mechanism for site staff to discuss and resolve ART-related pharmaceutical management issues.
  - Maintaining good communication between prescribers and nursing staff responsible for dispensing ARVs to ensure that the dispensers know which source of ARVs a patient is selected to start on and should receive at each visit—
    - Stamps can be used by the prescriber to endorse the GoV and PEPFAR-funded ART prescriptions with source of medicines to be dispensed—the stamped prescriptions can be used as a cross-check with patient-centered records.

## **2. ARV Medicine Flow at the Facility**

### **Findings**

- The proposed flow of PEPFAR-funded ARVs at TDH is described in Figure 1 and is the same as that currently used for GoV and ESTHER-funded ARVs.
- ARVs are delivered to and stored by pharmacy.
  - PEPFAR-funded ARVs are delivered directly to TDH
  - GoV-funded ARVs are delivered to HCMC Health Services and then to the pharmacy at TDH

- ESTHER-funded medicines are ordered by TDH and delivered directly to the pharmacy
- ARVs are held in two storage areas in the pharmacy.
- PEPFAR-funded ARVs will be dispensed by a nursing staff member at the ART outpatient clinic—current procedure for GoV- and ESTHER-funded ARVs.
- It was reported that the outpatient clinic holds stocks of ARVs for the purposes of dispensing for ART patients at the clinic for that day only. It is understood that stocks of ARVs are not routinely held at the outpatient clinic.
- The ARVs must move through three different areas before being dispensed to patient. The paperwork to track the movement of ARVs between each area may prove to be considerable when the three ART programs scale up.



**Figure 1. Flow of PEPFAR-funded ARVs at Tropical Disease Hospital**

***Recommendations***

- Consider simplifying ARV medicine flow by having the ARVs dispensed at the dispensary if staffing allows.

### **3. Receiving ARVs at the Site**

#### ***Findings***

- Procedure—
  - CPC No. 1 delivers PEPFAR-funded ARVs directly to the pharmacy with—
    - One original and two copies of the CPC No. 1 Delivery Note
    - Copy of the Ministry of Health-approved distribution plan
  - The pharmacy storekeeper checks the order received against the delivery note and inspects the items for damaged and expired stock.
  - If everything is in order, the pharmacy storekeeper endorses the delivery notes and obtains the necessary 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 forwarded to the finance department. It is understood that the pharmacy does not prepare or receive a copy of a financial receiving note.
  - One copy of the delivery note is filed in the pharmacy.
  - ARVs are put onto the shelves in the storeroom and receipt recorded in inventory records.
- No procedure for handling damaged, expired, or delivery discrepancies of ARVs has been developed as yet. So far no damaged or expired ARVs have been received but the pharmacy plans to use the system that exists for returning other medicines for ARVs, should the need arise.
- The pharmacy storekeeper reports that so far 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; for example, the CPC No. 1 driver waiting during what may become a lengthy receiving process.
- Consider requesting that a copy of the financial receiving note be sent to the pharmacy storeroom; it can be filed with the relevant delivery note for each order.
- Consider using a standard form to facilitate the reporting of shipment discrepancies.

#### 4. Inventory Management and Record-Keeping at the Pharmacy ARV Storage Areas

##### A. Pharmacy Storeroom

###### *Findings*

<b>ARV Storage Area in Pharmacy Storeroom</b>		
<b>Topics</b>	<b>For Current ART Patient Numbers/Stock</b>	<b>For ART Scale-Up</b>
Organization	<ul style="list-style-type: none"> <li>• PEPFAR-, GoV-, and ESTHER-funded ARVs are all kept on separate shelves in separate areas</li> <li>• Very neat and tidy</li> <li>• Organized with first expiry to front</li> </ul>	NA
Space	<ul style="list-style-type: none"> <li>• Adequate shelf space with room for expansion</li> </ul>	<ul style="list-style-type: none"> <li>• More shelf space will need to be allocated for ARVs—some unused shelf space probably available</li> </ul>
Security	<ul style="list-style-type: none"> <li>• Adequate</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate</li> </ul>
Air-conditioning	<ul style="list-style-type: none"> <li>• Adequate</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate</li> </ul>
Temperature monitoring of storage area	<ul style="list-style-type: none"> <li>• Not seen</li> </ul>	NA
Refrigerator	<ul style="list-style-type: none"> <li>• Not seen</li> </ul>	<ul style="list-style-type: none"> <li>• Not seen</li> </ul>
Temperature monitoring of refrigerator	<ul style="list-style-type: none"> <li>• Not seen</li> </ul>	NA

- Record-keeping
  - Official inventory records in use—stock cards
  - Due to time constraints, the RPM Plus team was unable to look at the stock cards entries so we are unable to comment on record-keeping for receipts, issues, and checking of balances

###### *Recommendations*

- Check that the record-keeping for ARVs includes the following details—
  - For receipts—
    - Record the date, supplier, delivery note number, and quantity received for each product; recalculate the balance
    - Record the batch number and expiry date to facilitate tracking and implementation of product recalls

- For issues—
  - Make the entries at the time of issuing stock to the dispensary
  - Record the date, internal requisition number (see below), quantity issued, and recalculate the balance
- The balance—
  - Can be checked with the physical stock once a month or at the time of receipt or issue
  - Making a notation in the record that the balance is correct can help 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
- Temperature charts can be used to monitor if the routine temperatures in the pharmacy and the refrigerator (if there is one) are appropriate for the products held
- A chart to monitor expiry date of ARV products may be useful

## **B. Dispensary**

### *Findings*

<b>ARV Storage Area in Dispensary</b>		
<b>Topics</b>	<b>For Current ART Patient Numbers/Stock</b>	<b>For ART Scale-Up</b>
Organization	<ul style="list-style-type: none"> <li>• ARVs are kept on a crowded shelf in a very crowded room at the back of the dispensary</li> <li>• Space restrictions do not allow the pharmacist to organize the ARVs easily</li> </ul>	NA
Space	<ul style="list-style-type: none"> <li>• Storage space is inadequate</li> </ul>	<ul style="list-style-type: none"> <li>• More space will need to be allocated for ARVs</li> <li>• Pharmacy staff hope to have a separate ARV storage area eventually</li> </ul>
Security	<ul style="list-style-type: none"> <li>• Adequate</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate</li> </ul>
Air-conditioning	<ul style="list-style-type: none"> <li>• No air-conditioning</li> </ul>	<ul style="list-style-type: none"> <li>• May need to plan for air-conditioned storage space in the future</li> </ul>
Temperature monitoring of storage area	<ul style="list-style-type: none"> <li>• Not seen</li> </ul>	NA
Refrigerator	<ul style="list-style-type: none"> <li>• Not seen</li> </ul>	<ul style="list-style-type: none"> <li>• Not seen</li> </ul>
Temperature monitoring of refrigerator	<ul style="list-style-type: none"> <li>• Not seen</li> </ul>	NA

- Record-keeping
  - Two sets of inventory records in use—
    - Homemade daily record of issues—used to assist in completing official form mentioned below; pharmacy staff record date and issues only—no internal requisition numbers seen to be recorded (see below)
    - Official form for reconciling receipts and issues with physical count—completed every 10 days

### *Recommendations*

- Additional storage space for ARVs in the dispensary is a priority. Organizing the different sources of ARVs is particularly important to avoid dispensing errors and to facilitate dispensing of shortest dated stock first.
- A larger dispensing space will be needed for scale-up.
- As the ARV storage room in the dispensary is not air-conditioned, it is recommended that the dispensary keeps no more than two weeks supply of ARV stocks to minimize exposure to higher than recommended temperatures. The pharmacy may need to plan for an air-conditioned storage space in the dispensary for the future.
- Temperature charts can be used to monitor if the routine temperatures in the storage area and the refrigerator are for the products held.
- An alternative to renovating a space in the dispensary could be to issue ARVs directly from the pharmacy storeroom to the ART outpatient clinic although careful consideration should be made of the advantages and disadvantages.
- Record-keeping—replace the home-made records by official stock cards to facilitate record-keeping. Check that the record-keeping for ARVs includes the following details—
  - For receipts—
    - Record the date, internal requisition number (see below), and quantity received from the pharmacy storeroom; recalculate the balance
    - Record the batch number and expiry date to facilitate tracking and implementation of product recalls
  - For issues—
    - Make the entries at the time of issuing stock to the ART outpatient clinic
    - Record the date, internal requisition number (see below) or patient name/number, quantity issued and recalculate the balance

- The balance—
  - The official reconciliation form can be completed from the stock cards
  - Making a notation on the stock card that the balance is correct can help staff to look for errors if they know the last date when the balance was correct
- Temperature charts can be used to monitor if the routine temperatures in the ARV storage area in the dispensary and the refrigerator are appropriate for the products held.

## **5. Internal Distribution of ARVs**

### ***A. Issuing ARVs from the Pharmacy Storeroom to the Dispensary***

#### *Findings*

- Dispensary uses an exercise book (homemade record) to order and receive GoV- and ESTHER-funded ARVs from the storeroom (not seen).
- Book stays in the dispensary and it is understood that no record of the requisition is kept in the pharmacy storeroom.
- Internal requisition number not observed to be recorded when issuing stock from storeroom or receiving stock at the dispensary.

#### *Recommendations*

- Use an official requisition book to track movement of ARVs—the book used by wards and departments to requisition supplies from the dispensary would be appropriate. Use a different book for each source of ARVs.
- Each requisition should have a unique number and a copy. The department requisitioning ARVs (that is, the dispensary) should keep the book, and the requisition copy that remains in the book. The department issuing ARVs (the pharmacy storeroom) should retain the original which is detached from the book when the transaction is complete.
- Suggested procedure—
  - The pharmacy staff member responsible for ordering ARVs at the dispensary completes a requisition with name, strength, formulation, and quantity of each ARV needed, signs and dates the requisition
  - The pharmacy storekeeper responsible for issuing ARVs from the ARV storeroom endorses the requisition with quantities issued, signs and dates the requisition
  - The receiving pharmacy staff checks the ARVs received for discrepancies, signs and dates the requisition if all is correct

- The unique requisition number should be documented when recording the issue at the pharmacy storeroom and the receipt at the dispensary to facilitate tracking and auditing of ARVs.
- The same procedure should be used for all sources of ARVs.

***B. Issuing ARVs from the Dispensary to the ART Outpatient Clinic***

*Findings*

- On the morning of the ART clinic, the nurse responsible for dispensing ARVs calculates how much of each ARV product will be needed to dispense for all the patients collecting ARVs that day.
- The nurse uses an official requisition book issued to the ART outpatient clinic to requisition the exact amount of GoV- or ESTHER-funded ARVs needed from the dispensary. Separate books are used for the two sources of ARVs.
- Neither the internal requisition number nor patient name/number was seen to be recorded on the inventory record when issuing ARVs from the dispensary.
- Pharmacy reconciles the prescriptions received with the quantity ordered as a cross-check and keeps the prescriptions.

*Recommendations*

- Use an official requisition book to requisition PEPFAR-funded ARVs from the dispensary as for GoV- and ESTHER-funded ARVs.
- Either the internal requisition number or the individual patient name/number should be documented on the inventory record when recording issues at the dispensary to facilitate tracking and auditing of all sources of ARVs. Recording the patient name/number will also assist in the aggregation and reporting of consumption at the dispensary.
- File the ART prescriptions separately to facilitate auditing of ARV issues.

## 6. ARV Dispensing Area at the ART Outpatient Clinic

### Findings

Topics	Outpatient Clinic ARV Dispensing Area	
	For Current ART Patient Numbers/Stock	For ART Scale-Up
Organization	<ul style="list-style-type: none"> <li>• ARVs are not routinely stored at the ART outpatient clinic</li> <li>• Dispenser requisitions exactly the amounts needed on the day of the clinic</li> </ul>	NA
Space	<ul style="list-style-type: none"> <li>• ART outpatient clinic was observed to be very busy</li> <li>• Dispenser was not dispensing ARVs during the visit to the clinic; however, it appears that—                             <ul style="list-style-type: none"> <li>○ The nurse dispenses ARVs at an open table in the waiting area</li> <li>○ Space for dispensing ARVs is limited</li> </ul> </li> <li>• It is not clear if the same dispensing area is used for both the GoV- and ESTHER-funded ARVs and where dispensing of PEPFAR-funded ARVs will be done</li> </ul>	<ul style="list-style-type: none"> <li>• Larger dispensing space in a quiet area will probably be needed for ART scale-up</li> </ul>
Security	<ul style="list-style-type: none"> <li>• Inadequate but not necessary as ARVs are not stored at the clinic</li> </ul>	NA
Air-conditioning	<ul style="list-style-type: none"> <li>• None but not necessary as ARVs are not stored at the clinic</li> </ul>	NA
Temperature monitoring of storage area	<ul style="list-style-type: none"> <li>• Not necessary</li> </ul>	NA
Refrigerator	<ul style="list-style-type: none"> <li>• Not seen but not necessary as ARVs are not stored at the clinic</li> </ul>	NA
Temperature monitoring of refrigerator	<ul style="list-style-type: none"> <li>• Not necessary</li> </ul>	NA

- The lack of secured, air-conditioned space appears to be the main constraint to storing ARVs at the ART outpatient clinic.
- The lack of staff and space for dispensing directly to patients appears to be the main constraint to dispensing ARVs directly from the dispensary.
- The current system of having the dispensary store the ARVs and the outpatient clinic requisition ARVs for dispensing on the day of the clinic appears to result in long waits or necessitates return visits for the patient (see next section).

### *Recommendations*

- A larger, quieter area for dispensing ARVs at the outpatient clinic will probably be needed for scale-up.
- Significant renovations would be needed if a decision is made to store ARVs at the ART outpatient clinic.

## **7. Record-Keeping for ARV Dispensing at the ART Outpatient Clinic**

### ***Findings***

- Nurse was not dispensing ARVs during the visit to the clinic so information is based on what was reported.
- Prescription—
  - Official prescription form in use
  - No stamps for prescriber to endorse prescriptions with the source of GoV- and PEPFAR-funded medicines
- Inventory records—
  - Purpose—to track consumption by product and monitor losses and wastage
  - No ARV inventory records reported to be used at the clinic
- Longitudinal patient dispensing record—
  - Purpose—to facilitate pharmaceutical care to patient, to cross-check medicines and doses prescribed, and to identify source of medicines to be issued
  - A patient record book was reported to be available but it is not certain if it is used for the purposes of cross-checking the prescription
- Record to assist in aggregating consumption data by regimen and product dispensed—
  - Purpose—to forecast needs, the pharmacy will need to receive information on consumption patterns by regimen and also by product dispensed at the clinic; for example, 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 not yet in use as dispensing of PEPFAR-funded ARVs had not begun at the time of the site visit. The interim forms include—
    - 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—
  - Ledger used to record ARV dispensing—date, patient name, age, medicines, and quantity given are recorded; each dispensing encounter is recorded consecutively so it is not easy for staff to aggregate data for reporting, for example, on consumption patterns by regimen and product dispensed

### **Recommendations**

- Prescription—
  - As the nurse will soon have three different sources of ARVs available for dispensing, stamps can be used by the prescriber to endorse the PEPFAR-funded ART prescriptions with source of medicines to be dispensed—can be used as a cross-check with the patient record book
- Inventory records—
  - Inventory records are not currently needed to manage ARVs at the ART outpatient clinic as no stocks are held there; the dispensary staff cross-check the quantity ordered by the ART outpatient clinic with the prescriptions received
  - Pharmacy is also responsible for reporting inventory
- Longitudinal patient dispensing record—
  - A patient-centered record book can be used to cross-check prescriptions as an interim measure. However, software will be needed as the program scales up, particularly as the site will be managing three sources of ARVs
- Record to assist in aggregating consumption data by regimen and product dispensed—
  - Not clear if the nurse has been trained on how to complete the interim RPM Plus forms
  - Interim RPM Plus forms will need to be replaced by a software at the program scales up, particularly as the site will be managing three sources of ARVs
- Software—
  - A software package that allows one entry at the time of dispensing to collect data for inventory management, pharmaceutical care, and forecasting is needed to reduce the

impact of ART record-keeping on the workload of both the pharmacy and the nurse responsible for dispensing ARVs

- The software should aggregate and report data in a format that facilitates reporting for all sources of ARVs for the purposes of reporting workload, consumption, and data for forecasting
- 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
- The computer and software will probably need to be installed at the ART outpatient clinic as that is where the dispensing is done; however, the pharmacy will also need to have access to input ARV receipts and issues, and to review and report consumption data collected by the software

## **8. ARV Dispensing and Medication Counseling at the ART Outpatient Clinic**

### ***Findings***

- The nurse was not dispensing ARVs during the visit to the clinic so information is based on what was reported for GoV- and ESTHER-funded ARVs.

<b>Topics</b>	<b>Observations/Information Reported</b>
Reference materials on ART	<ul style="list-style-type: none"> <li>● None seen at ARV dispensing area</li> </ul>
Container	<ul style="list-style-type: none"> <li>● Plastic bags are used to dispense GoV- and ESTHER-funded ARVs</li> </ul>
Labels	<ul style="list-style-type: none"> <li>● None used</li> </ul>
Dispensing process	<ul style="list-style-type: none"> <li>● Dispense ARVs on Thursdays at present</li> <li>● Doctor writes the ARVs to be dispensed on a prescription form and also in the patient's book in the morning</li> <li>● Nurse collects all the prescriptions, aggregates ARV requirements, and orders the medicines and quantities needed in the internal requisition book</li> <li>● Nurse takes the prescriptions and requisition book to the dispensary and collects the ARVs</li> <li>● Nurse dispenses the ARVs to the patients in the afternoon</li> <li>● Existing workload at the pharmacy was reported to be the main constraint to expanding the pharmacist's role to dispense ARVs</li> </ul>
Patient flow	<ul style="list-style-type: none"> <li>● Patients come in the morning for examination and then can wait for an hour or more to get their ARVs</li> <li>● It was also reported that some patients come in the morning for examination and then return in the afternoon to collect the ARVs</li> </ul>
Medication counseling area at the ART outpatient clinic	<ul style="list-style-type: none"> <li>● Not observed</li> </ul>

<b>Topics</b>	<b>Observations/Information Reported</b>
Content of medication counseling at the ART outpatient clinic	<ul style="list-style-type: none"><li>• Not observed</li><li>• Not known if any adherence monitoring (e.g., pill counts) are done at the clinic</li><li>• Existing workload at the pharmacy was reported to be the main constraint to expanding the role of the pharmacist to provide medication counseling on ART</li></ul>
Patient information leaflets	<ul style="list-style-type: none"><li>• Not known if leaflets are available in the ART dispensing area at the time of the clinic</li></ul>

- The lack of secured, air-conditioned space appears to be the main constraint to storing ARVs at the ART outpatient clinic.
- The lack of staff and space for dispensing directly to patients appears to be the main constraint to dispensing ARVs directly from the dispensary.
- The current system of having the dispensary store the ARVs and the outpatient clinic requisition ARVs for dispensing on the day of the clinic appears to result in long waits and/or necessitates return visits for the patient.
- The nurse responsible for dispensing ARVs did not attend the RPM Plus training on dispensing ARVs.

### **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—
  - The dispenser will need training if pill boxes are to be used for dispensing PEPFAR-funded ARVs
  - It is recommended that dispensing for all three sources of ARVs be harmonized as much as possible including using the same type of container, whether plastic bags or pill boxes
- Labels—
  - Consider cost implications and benefits of labeling medicines with name and dose to be taken to facilitate adherence
- Dispensing process—
  - Tablet counters and tweezers/gloves should be made available, if not already used, to count and dispense ARVs to minimize contamination during dispensing

- Consider the cost implications and benefits of expanding the role of the highly trained pharmacy staff to dispense ARVs
- Medication counseling—
  - Consider the cost implications and benefits of expanding the role of the highly trained pharmacist to play a greater role in medication counseling and possibly adherence monitoring for ART
- Patient information leaflets—
  - Consider if information leaflets need to be made available at the dispensing point

## **9. Pharmacy and ART Outpatient Clinic Reporting for the ART Program**

### ***Findings***

- Each facility receiving PEPFAR-funded ARVs will need to complete 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.
- The pharmacy and the ART outpatient clinic had yet to complete the forms for the first time at the time of the site visit so the procedures had not been tested.
- The pharmacy department produces a monthly ARV inventory report for the management.
- As the responsibility for ARV inventory management rests with the pharmacy while the ART outpatient clinic staff are responsible for ARV dispensing, completion of the forms may need some coordination and support.
- Producing the estimates of new patients two months in advance may be difficult with the current record-keeping systems—it may not be easy to extract data on current prescribing patterns from the existing records.

### ***Recommendations***

- The RPM Plus team to work with PAC, Ho Chi Minh City; and CDC 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 ARVs will reduce the workload for the pharmacy and the ART outpatient clinic considerably.
- One software program should be used to collect and aggregate data and facilitate reporting for all sources of ARVs. Ideally, the same procedure and form should be used for reporting for all sources of ARVs held at the facility.

## **10. Other Issues Discussed**

### ***Human Resources and the Role of the Pharmacist in the ART Program***

The deputy directors of TDH estimate that HIV/AIDS is responsible for approximately 33 percent of the current workload at TDH and that this workload is likely to increase. The skills of the highly trained pharmacy staff are currently underutilized in supporting the ART program mainly due to staffing constraints and some infrastructural issues.

TDH and implementing partners may wish to consider the cost implications and benefits of expanding the role of the pharmacist to play a greater role in dispensing, medication counseling, and possibly adherence monitoring for ART in the long-term. For example, the benefits of dispensing ARVs directly from the dispensary include simplifying ARV medicine flow at the facility and reducing the waiting time and/or return visits made by patients to collect their medication.

## NEXT STEPS

- The site visit report will be shared with the staff from the pharmacy department at TDH, PAC/Ho Chi Minh City, and CDC 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.

