

**RPM Plus Site Visit
to Tam Binh Orphan
Center
Ho Chi Minh City,
October 14, 2005:**

Report

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Helena Walkowiak
David Kuhl
Nguyen Anh Dao
Nguyen Viet Hung

December 2006

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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
GoV	Government of Vietnam
HIV	human immunodeficiency virus
MSH	Management Sciences for Health
OI	opportunistic infection
PAC	Provincial AIDS Committee
Pact	Private Agencies Collaborating Together, Inc.
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
RPM Plus	Rational Pharmaceutical Management Plus [Program]
SOP	standard operating procedure
WWO	Worldwide Orphans Foundation

ACKNOWLEDGMENTS

MSH/RPM Plus would like to thank the staff of the Provincial AIDS Committee (PAC) of Ho Chi Minh City, Private Agencies Collaborating Together, Inc. (Pact), and Worldwide Orphans Foundation (WWO) for their support in facilitating the site visit. Special gratitude is offered to the staff from Tam Binh Orphan Center for their tireless and exceptional cooperation during the visit.

PAC, Ho Chi Minh City

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

Pact

- Dr. Diana Measham, Country Representative
- Ms. Nguyen Quynh Trang, Program Coordinator

Tam Binh Orphan Center

- Tran Ngoc Dung
- Nguyen Thi Kim Tien, Assistant Director
- Dr. Tho, ART Prescriber

Department of Labour, Invalid and Social Affairs

- Mr. Tai

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 (ARV) medicines 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>ART Program began in June 2005</p> <p>Have two sources of ARVs—</p> <ul style="list-style-type: none"> • U.S. President’s Emergency Plan for AIDS Relief (PEPFAR)-funded—stavudine liquid and efavirenz capsules • Worldwide Orphans Foundation (WVO)-funded ARVs—zidovudine, lamivudine, and nevirapine liquids 	<p>RPM Plus to make a follow-up visit after two months and then every six months to assist Tam Binh to strengthen procedures and address challenges</p> <p>Consider making capsules and tablets available in addition to liquids for older children—RPM Plus to monitor prescribing practices carefully to ensure accurate forecasting of long-term needs</p>
ARV medicine flow at the facility	<p>ARVs are delivered by CPC No.1 to the pharmacy department of the District Hospital.</p> <p>Tam Binh requisition from the District Hospital as needed—ARVs are received, stored, and dispensed by the nursing staff</p>	
Receiving ARVs at the site	<p>ARVs are delivered by CPC No.1 to the pharmacy department of the District Hospital who store ARVs on behalf of Tam Binh</p> <p>Tam Binh requisition ARVs from the District Hospital as needed</p> <p>Long delays experienced with clearing WVO ARVs at customs</p>	<p>Assist Tam Binh to clear WVO ARVs quickly and efficiently to avoid potential stock-outs and treatment interruptions</p>
Inventory management and record-keeping at the District Hospital	<p>Not visited by RPM Plus team</p>	<p>RPM Plus to visit District Hospital to identify challenges in receiving, storing, and issuing ARVs to Tam Binh</p>

Topics	Findings	Recommendations
Internal distribution of ARVs	System not known	Use a double copy requisition book to track movement of ARVs from the District Hospital to Tam Binh Document the unique requisition number when recording issues at the District Hospital and receipts at Tam Binh
ARV storage and dispensing area at Tam Binh Orphan Center	Nursing station does not have air conditioning Space for storage and dispensing adequate for now, but limited for scale-up	Additional storage space and a larger dispensing area will be needed for scale-up and for dispensing to pediatric clients in the community Do not keep more than two weeks' supply of ARVs at Tam Binh to minimize exposure to high temperatures; monitor temperatures of nursing station and refrigerator routinely Mark open bottles with date of opening
Record-keeping for ARVs at Tam Binh Orphan Center	Prescription written in individual patient books Inventory records: use separate books for receipts and issues; no running balance Patient book can be used as a longitudinal patient dispensing record Interim form in use to assist in aggregating consumption data for scale-up No software in use Numerous other records appear to be in use	Use one stock card or book to record both receipts and issues and keep a running balance; record patient name or number for each issue; check the balance with physical stock at least once a week Interim forms need to be replaced by a software that uses one entry at time of dispensing to collect data for inventory management, cross-checking prescriptions, and forecasting Software needs to capture daily issues to residents and monthly dispensing to clients in the community 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 Review and rationalize record keeping at Tam Binh

Executive Summary

Topics	Findings	Recommendations
Dispensing and medication counseling for ARVs at Tam Binh Orphan Center	No ART reference materials seen	Provide standard set of guidelines and reference materials
	Doses for residents are prepared in medicine pots	
	Only dispensing for one client in the community so far—issue original bottles	Plan for start-up of dispensing to pediatric clients in the community—containers, labels, dispensing procedure, and medication counseling
	Labels not seen	
Pharmacy reporting for the ART program	Interim reporting forms used at time of visit	RPM Plus, PAC, and WWO to monitor and assist site to address problems in completing and submitting the reporting forms to RPM Plus
	Staff report problems in preparing estimates of new patients to start ART by regimen	
	Workload implications of reporting and timeliness of forms reaching RPM Plus are potential concerns	Provide training and/or tools to assist site in preparing estimates of new patients to start ART by regimen
Other issues	Tam Binh prefer to use liquids even for older children	Cost implications of using liquids for all residents discussed

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. The development and implementation of 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.

Site Visit Objectives

In preparation for providing technical assistance to GoV to draft SOPs for ART pharmaceutical management, the RPM Plus team visited Tam Binh Orphan Center in Ho Chi Minh City to—

- Understand the roles and responsibilities of the staff in supporting pharmaceutical management for the ART program.
- Understand ARV medicine flow at the facility and identify forms and procedures used by the site 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 Tam Binh Orphan Center 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 Tam Binh Orphan Center, 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
WWO PEPFAR	Pediatric	WWO-funded ARVs received January 2005	20 at the end of September, 2005	40 children at end of December 2005
		PEPFAR-funded ARVs received September 2005 Issuing of ARVs began in June 2005		150 children at Tam Binh Orphan Center plus 50 in the community by the end of 2006

- WWO provides technical assistance to Tam Binh Orphan Center in support of the ART program partially with funding through Pact.
 - WWO fund for Tam Binh was established in 2004 primarily to provide ARVs for pediatric residents and training for staff.
 - WWO agreed to provide medicines for 20 patients for one year.
 - The first shipment, which was sufficient for three months, arrived in January 2005 but Tam Binh waited for the ARV national guidelines to be approved before beginning the program.
- Prescriptions are currently not endorsed with source of ARVs to be dispensed as only one source of each ARV medicine in stock at the moment—
 - WWO supplies zidovudine, lamivudine, and nevirapine liquids
 - PEPFAR supplies stavudine liquid and efavirenz 200 mg capsules

Recommendations

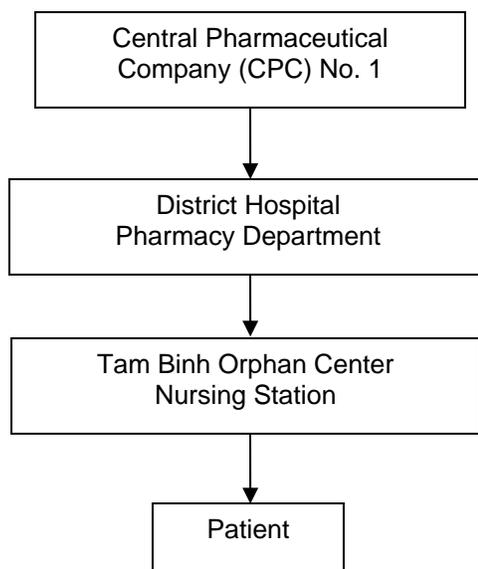
- As the PEPFAR-funded ARVs have recently been introduced at Tam Binh Orphan Center, a follow-up visit or contact should be made after two months and then every six months to assist the site to develop/strengthen procedures, address challenges, and monitor the impact of the ART program on the site.
- Consider if capsules and tablets should be made available in addition to liquids for older children.

- Prescribing practices should be monitored carefully by RPM Plus to ensure that the long-term forecasting of needs of solid and liquid preparations for Tam Binh Orphan Center accurately reflects usage at the site.

2. ARV Medicine Flow at the Facility

Findings

- PEPFAR-funded ARVs are delivered by CPC No. 1 to the pharmacy department at the District Hospital. The District Hospital store the ARVs on behalf of Tam Binh Orphan Center who requisition stock from the District Hospital as needed.
- The ARVs are received, stored, and dispensed by the nursing staff at Tam Binh Orphan Center.
- Flow of PEPFAR-funded ARVs at Tam Binh Orphan Center—



3. Receiving ARVs at the Site

Findings

- Procedure—
 - CPC No. 1 delivers PEPFAR-funded ARVs to the pharmacy department at the District Hospital
 - District Hospital stores the ARVs on behalf of Tam Binh Orphan Center

- Tam Binh requisition stock from the District Hospital as needed
- Nursing staff check the order received and inspect the items for damage and expired stock
- ARV medicines are put into the cupboards at the nursing station and the receipt recorded in an inventory record book
- Tam Binh experienced long delays and difficulties with customs procedures when clearing and receiving WWO ARVs

Recommendations

- Tam Binh Orphan Center may need some assistance in completing the necessary paperwork and obtaining the necessary clearances when receiving the next shipment of WWO ARVs to avoid possible stock-outs and treatment interruptions.

4. Inventory Management and Record Keeping at the District Hospital ARV Storage Area

Findings

- Unfortunately the RPM Plus team did not have time to visit the ARV storage area at the District Hospital to observe inventory management and record-keeping for the ARVs.
- Tam Binh staff report that the stock cards are used to track the movement of ARVs at the District Hospital.

Recommendations

- RPM Plus to visit the District Hospital to understand systems used for receiving, storing, and issuing ARVs to Tam Binh and provide assistance to develop and strengthen procedures, address challenges, and monitor the impact of the ART program on the pharmacy.

5. Internal Distribution of ARVs

Findings

- Time was insufficient to discuss the mechanism for tracking the movement of ARVs from the ARV storage area at the District Hospital to Tam Binh Orphan Center.

Recommendations

- A requisition book should be used by Tam Binh to requisition ARVs from the District Hospital. The internal requisition book used by the pharmacy department at Viet Tiep Hospital can be used as a model if needed.
- Each requisition should have a unique number and a copy. Generally the department requisitioning ARVs keeps the book (and the requisition copy that remains in the book) and the department issuing ARVs retains the original which is detached from the book when the transaction is complete.
- Suggested procedure—
 - Tam Binh staff complete a requisition with name, strength, formulation and quantity of each ARV needed, signs, and dates the requisition.
 - The pharmacy staff responsible for issuing ARVs from the ARV storage area at the District Hospital endorses the requisition with quantities issued, signs, and dates the requisition.
 - At Tam Binh, the receiving 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 District Hospital and the receipt at Tam Binh.

6. ARV Storage and Dispensing Area at Tam Binh Orphan Center

Findings

ARV Storage and Dispensing Area Tam Binh Orphan Center		
Topics	For Current ART Patient Numbers/Stock	For ART Scale-Up
Organization	<ul style="list-style-type: none"> • Medicines are prepared for administration to residents on a counter at the nurses station • Medicines are stored in cupboards next to the counter • Cupboards are very full making it difficult to organize medicines with first expiry to front • Opened bottles of liquids not seen to be marked with date of opening 	NA

Findings and Recommendations

Space	<ul style="list-style-type: none">• Cupboards are full of medicines— not much room for expansion• One week's supply kept at Tam Binh and the rest at the District Hospital due to shortage of space• Have adequate supply for preparing medicines for issue to residents at the moment	<ul style="list-style-type: none">• May need to plan for an upgrade for scaling up especially if Tam Binh will be dispensing to children in the community• More storage and dispensing space will be needed
Security	<ul style="list-style-type: none">• Probably adequate	<ul style="list-style-type: none">• Probably adequate
Air conditioning	<ul style="list-style-type: none">• None	<ul style="list-style-type: none">• May need to plan for upgrade in future
Temperature monitoring of storage area	<ul style="list-style-type: none">• Not seen	NA
Refrigerator	<ul style="list-style-type: none">• Seen	<ul style="list-style-type: none">• More refrigerated space may be needed for scale-up
Temperature monitoring of refrigerator	<ul style="list-style-type: none">• Not seen	NA

Recommendations

- Additional storage space and a larger dispensing area will be needed for scale-up, especially if Tam Binh will routinely be dispensing ARVs for children in the community.
- Because air conditioning the nursing station is difficult, it is recommended that Tam Binh keeps no more than two weeks supply of ARV stocks to minimize exposure to higher than recommended temperatures.
- Temperature charts can be used to monitor if the routine temperature in the nursing station and the refrigerator is appropriate for the products held.
- A chart to monitor expiry date of ARV products may be useful.

7. Record-Keeping for ARVs at Tam Binh Orphan Center

Findings

- Prescription—
 - Prescriptions are written in individual patients books
 - Only one source of ARVs available at time of visit so prescription is not stamped/marked with source at present
- Inventory records—
 - Purpose—to track consumption by product and monitor losses and wastage

- Appear to have one book for receipts and one book for issues—no running balance
- Inventory books not seen
- 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
 - Individual patient books can be used to cross-check prescriptions
- Record to assist in aggregating consumption data by regimen and product dispensed—
 - Purpose—to forecast needs, Tam Binh will need to look at consumption patterns by regimen and also by product dispensed; for example, to distinguish between consumption of solid preparations and liquids for pediatrics
 - Not known if interim form Daily ART Service Register for Pediatric Patients prepared by RPM Plus is available and if staff have been trained to use it (not seen in use)
- Software—
 - No software is in use at the moment to facilitate the collection and analysis of dispensing data for ARVs
- Other records used—
 - Numerous other records appear to be in use
- Impact of ARV record keeping on the workload of the nursing staff—
 - Tam Binh staff report that record keeping for the ART program is not too problematic at the moment but will be difficult as the number of ART patients scales up

Recommendations

- Prescription—
 - 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—
 - Use one stock card or book to record both receipts and issues and keep a running balance
 - For receipts at Tam Binh—

- Record the date, internal requisition number, batch number, and expiry date of product received to facilitate tracking and implementation of product recalls; recalculate the balance
- For issues at Tam Binh —
 - Ideally, the entries should be made at the time of issuing stock to the residents, but should at a minimum be done daily as the program scales up
 - Record the date, the patient name or number, quantity issued, and recalculate the balance; including the patient's name or number will create an audit trail
- Checking the balance—
 - Suggest checking the balance of liquids when a new bottle is opened and correcting for wastage/losses
 - An alternative is to check the balance with the physical stock once a week (increase to daily as patient numbers increase) or at the time of receipt of ARVs from the District Hospital
 - 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
- Longitudinal patient dispensing record—
 - The individual patient books can be used to track ARV dispensing by patient as an interim measure. However, software will be needed before the facility reaches its end of 2006 target of 200 pediatric patients
- Record to assist in aggregating consumption data by regimen and product dispensed—
 - Interim RPM Plus form will need to be replaced by a software before the facility reaches its end of 2006 target of 200 patients
- Software—
 - Although Tam Binh Orphan Center will be dispensing ARVs to some children in the community, for the majority of resident patients, doses will be issued from stock bottles
 - 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

- However, the software will also need to be able to capture data for twice daily issues to residents from a stock bottle
- The software should aggregate and report data in a format that facilitates reporting of 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
- Impact of ARV record-keeping on Tam Binh Orphan Center workload—
 - Tam Binh would benefit from a review and rationalization of records kept at the nursing station
 - Providing software to assist with the reporting at Tam Binh Orphan Center should be made a priority to reduce the impact of record-keeping for ARVs and other medicines on the nursing staff

8. Dispensing and Medication Counseling for ARVs at Tam Binh Orphan Center

Findings

Topics	Observations/Information Reported
Reference materials on ART	<ul style="list-style-type: none"> ● None seen at nursing station
Container	<ul style="list-style-type: none"> ● Issuing doses to residents <ul style="list-style-type: none"> ○ Dose is put in a measuring cup ● Dispensing to patients in the community <ul style="list-style-type: none"> ○ Only one patient so far ○ Give original bottles
Labels	Not seen
Dispensing process	<ul style="list-style-type: none"> ● Issuing doses to residents <ul style="list-style-type: none"> ○ Prescription is written in patient's book ○ Not known if prescription is crosschecked with previous entries ○ Nurse measures doses and puts in medicine cups ○ Nurses give morning doses ○ Babysitter give evening doses ● Dispensing to patients in the community <ul style="list-style-type: none"> ○ Process not formalized yet
Patient flow	<ul style="list-style-type: none"> ● Dispensing to patients in the community <ul style="list-style-type: none"> ○ Process not formalized yet
Medication counseling area	<ul style="list-style-type: none"> ● Dispensing to patients in the community <ul style="list-style-type: none"> ○ Process not formalized yet
Content of medication counseling	<ul style="list-style-type: none"> ● Dispensing to patients in the community <ul style="list-style-type: none"> ○ Process not formalized yet
Patient information leaflets	<ul style="list-style-type: none"> ● Dispensing to patients in the community <ul style="list-style-type: none"> ○ Process not formalized yet

Recommendations

- Reference materials—
 - Provide a standard set of reference materials and clinical guidelines for the nursing staff
 - Identify a mechanism to keep the materials updated
- Container—
 - Plan for start-up of dispensing to pediatric clients in the community
 - For liquids, decide if original bottles will be dispensed or if medicine bottles will be needed to allow the pharmacy to dispense precise quantities to facilitate adherence monitoring
 - For solid preparations, decide if plastic bags or pill boxes will be used
- Labels—
 - Labels will be needed for pediatrics if medicine bottles are used to dispense precise quantities of liquids
- Dispensing process—
 - A procedure for dispensing and providing medication counseling to pediatric clients in the community will need to be developed
- Patient information leaflets—
 - Make information leaflets available at the dispensing point for patients in the community

9. 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.

- Tam Binh Orphan Center 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 site staff reported finding it difficult to estimate the number of patients who would start on each regimen two months in advance.
 - Tam Binh staff report that reporting for the ART program is not too problematic at the moment but will be difficult as the number of ART patients scales up.

Recommendations

- The RPM Plus team to work with PAC, Ho Chi Minh City; WWO; and Pact 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 site considerably.
- The software will be needed before the facility reaches its end of 2006 target of 200 paediatric patients.
- Provide training on preparing estimates and/or a workbook to help site staff in preparing forecasts of new patients starting ART by regimen.

10. Other Issues Discussed

ARV Dispensing for Pediatric Patients

- Tam Binh Orphan Center currently provide ARVs to 20 residents
 - Three are newborn
 - Five are two-years-old
 - Twelve are between the ages of four and nine
- All children are given liquids with the exception of those children who are on efavirenz 200 mg capsules
- Tam Binh Orphan Center staff prefer to use liquids even for older children—syrups were reported not to cause problems with nausea and vomiting
- Cost implications of using liquids for all residents was discussed with the site staff

NEXT STEPS

- The site visit report will be shared with the staff at Tam Binh Orphan Center, WWO, Pact, and PAC, Ho Chi Minh City, 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.

