Supply Chain and Pharmaceutical System

Pharmacy Staff

Program at Assessment
One Pharmacy Technician from the Beira Central Hospital, Ms. Barbara Simao, will provide pharmacy support to the MTCT Plus and other Day Hospital (DH) activities. She will keep a regular, part-time (25%) schedule at the DH and be on call at other times of the day. Her work location in the Central Hospital directly adjacent to the DH and the fact that she carries a cell phone make this a feasible arrangement, at least for the start up months of the DH.

Three PLWHA trained and salaried by the program will serve as dispensers of the ARVs during the three month daily DOT phase of treatment.

Issues to Consider
1. As the patient load increases, more time will be required of the pharmacy technician, likely approaching full time.

Next Steps
1. No other pharmacy related staffing needs/issues identified or technical assistance requested at this time.

Forecasting Drug Requirements and Drug Procurement

Program at Assessment

FORECASTING
ARVs – Dr. Hoos has calculated the quantities of first line ARVs required for the first year of operations for 250 patients based on assumptions regarding the percentage of HIV positive mothers, children and partners who will meet the clinical criteria for ART. For second line ARVs the quantities are based on assumptions regarding percentage of clients who will be resistant to the first line regimen, will experience toxicity, etc.

Because of the delay in arrival of UNICEF procured drugs, HAI has estimated the quantities of ARVs required for the first month of operations.

OI drugs – HAI is estimating requirements for vitamin B6, multivitamins, cotrimoxazole, dapsone, INH and tuberculin skin tests. These items are for prophylaxis or testing. HAI has also estimated requirements for a number of drugs for treating opportunistic infections.

PROCUREMENT
The ARV drugs are being procured by UNICEF Copenhagen. Because of delays in this process, the site, after receiving authorization from the Secretariat, purchased a one month supply of ARV drugs through Wellworth, LDA, a local pharmaceutical importer and distributor. Those drugs were received at the site during the baseline assessment visit. The quantities received are shown in Table 1.
Table 1. ARV drug emergency purchase

<table>
<thead>
<tr>
<th>Item</th>
<th>Form</th>
<th>Quantity</th>
<th>Cost (meticals)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duovir</td>
<td>tablets</td>
<td>2,100</td>
<td>36,750,000</td>
</tr>
<tr>
<td>Nevirapine</td>
<td>tablets</td>
<td>2,100</td>
<td>18,375,000</td>
</tr>
<tr>
<td>Efivarence</td>
<td>tablets</td>
<td>270</td>
<td>5,700,000</td>
</tr>
<tr>
<td>Triamune</td>
<td>tablets</td>
<td>180</td>
<td>4,650,000</td>
</tr>
<tr>
<td>Zidovudine</td>
<td>100ml syrup/bottle</td>
<td>174</td>
<td>25,230,000</td>
</tr>
<tr>
<td>Nevirapine</td>
<td>100ml syrup/bottle</td>
<td>144</td>
<td>25,200,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td><strong>115,905,000</strong></td>
</tr>
</tbody>
</table>

At 24,000 metical/1US$ this emergency purchase was worth approximately $4,829.

Gtz has purchased the drugs listed in Table 2 for OI prophylaxis and treatment at the Day Hospital. The drugs are stored at the Beira Central Hospital drug storeroom awaiting installation of furniture at the Day Hospital. The Day Hospital will use these Gtz procured OI drugs for both MTCT Plus and other DH clients. MTCT Plus staff will monitor the consumption of these drugs and purchase drugs for OI prophylaxis and treatment for MTCT Plus clients in sufficient time to avoid stock outs.

Table 2. Gtz drugs purchased for use at the Beira Day Hospital

<table>
<thead>
<tr>
<th>Item</th>
<th>Dosage/Form</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metronidazole</td>
<td>250mg tablets</td>
<td>30,000</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>500mg capsules</td>
<td>14,400</td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>400/80mg tablets</td>
<td>28,800</td>
</tr>
<tr>
<td>Nystatin</td>
<td>100,000 units/ml oral drops in 300ml bottles</td>
<td>1,050</td>
</tr>
<tr>
<td>Ciprofloxacin hydrochloride</td>
<td>500 mg tablets</td>
<td>1,000</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>0.01g/g in 20g tubes</td>
<td>576</td>
</tr>
<tr>
<td>Acyclovir</td>
<td>200mg tablets</td>
<td>2,500</td>
</tr>
<tr>
<td>Albendazol</td>
<td>caplets</td>
<td>504</td>
</tr>
</tbody>
</table>

**Issues to Consider**

1. As the site gains experience in patient care it will accumulate data on actual ARV and other drug consumption. After 6-9 months of operation, the site should analyze the accumulated data and develop new site-specific assumptions on percentages of enrolled clients which will require ART, will be resistant to first line regimens, experience toxicity, require treatment for various OIs, etc. based on site specific experience. These assumptions should then be used to forecast future requirements for ARVs and OI drugs.

2. The Day Hospital will begin seeing patients on February 10, 2003. It will be important to keep the site regularly updated on the progress of the UNICEF ARV drug procurements so HAI has sufficient advance notice in the event they have to make additional emergency ARV purchases.

3. Small scale, emergency drug purchases are usually more costly than larger scale, well planned, long-term purchases. Under normal circumstances, emergency purchases should be avoided. However, it would be beneficial to the overall MTCT Plus activity to monitor prices and lead times at Beira and other MTCT Plus sites authorized to make emergency purchases. These figures...
could then be compared to the prices and lead times experienced under the UNICEF global ARV procurement. If the price differentials were not great and if the lead times were shorter under local procurement arrangements, this option for procurement could be studied further. Because of the uncertainty in predicting both resistance to first line ART regimens and toxicity among users, the flexibility and agility of a procurement mechanism which does not require a long term commitment to fixed quantities of specific drugs and can deliver the required drugs on very short notice could be advantageous.

4. The Beira site has no budget for purchasing the tuberculin skin tests, and is requesting the MTCT Plus Secretariat to reimburse the site for these purchases.

5. Some staff of the Beira Central Hospital have received training under Pfizer’s Diflucan Partnership Program. However, no Diflucan (fluconazole) has been delivered to the hospital.

6. The Abacavir being purchased by UNICEF was not registered for use in Mozambique at the time of the site assessment.

Next Steps
1. The site has requested technical assistance in forecasting future drug requirements. This activity should take place in approximately six months -- late enough to ensure that the site will have accumulated significant consumption data and early enough for the new forecast to be fed into the UNICEF procurement cycle in time to ensure no interruption in ARV supply.

2. Secretariat to keep HAI updated on the status of UNICEF procurement for Mozambique, and if necessary authorize HAI to make additional emergency purchases with sufficient lead time to avoid stock outs of ARVs. UNICEF Mozambique, because of its close working relationship with Central de Medicamentos e Artigos Medicos and MEDIMOC, should keep HAI informed of progress on the in-country processes required for importation of the UNICEF procured ARVs.

3. Secretariat to advise Beira site whether or not TST costs will be reimbursed.

4. The Beira Central Hospital should follow up with the MOH Maputo on the schedule for delivery of the donated Diflucan to the BCH.

5. UNICEF Mozambique, as discussed in the February 6, MTCT Plus meeting at the Tivoli Hotel in Beira, will work with the MOH Maputo to ensure the early registration of Abacavir.

Receipt, Inspection, Storage and Security of Drugs

Program at Assessment

RECEIPT AND INSPECTION
On the evening of Thursday, February 6, 2003 representatives of the Sofala Provincial Health Office, MEDIMOC Beira, Beira Central Hospital, UNICEF Mozambique, Health Alliance International and the JSI baseline assessment team met at the Hotel Tivoli in Beira to clarify issues related to the importation of MTCT plus ARV drugs being procured for Mozambique by UNICEF Copenhagen on behalf of the MTCT plus Secretariat
The following points were made regarding receipt and inspection of the ARV drugs.

The ARV drugs are consigned to the MOH. The ARVs will be cleared through Customs by MEDIMOC Maputo and sent to MEDIMOC Beira. There are reportedly no duties levied on drugs. The payment for MEDIMOC’s services for clearing and distributing the ARVs will be included in the general payments from MOH to MEDIMOC for clearing all MOH consigned goods.

MEDIMOC Beira will notify the Beira Central Hospital (BCH) each time ARVs for MTCT Plus arrive in Beira. BCH will prepare an official request to MEDIMOC Beira for the ARVs, and based on this request MEDIMOC Beira will release the drugs to BCH. The ARVs will be received directly by the BCH Day Hospital, and will not be stored in the BCH general drug storeroom.

A committee comprised of the MTCT plus pharmacy technician, the HAI Mozambique HIV/AIDS coordinator, and the HAI clinical HIV/AIDS advisor will inspect each shipment of ARVs for conformance to invoice quantities and for any visual defects in product, labeling or packaging.

The MTCT plus pharmacy technician will enter the receipt of all ARVs on the appropriate stock cards at the Day Hospital.

STORAGE
ARV drug storage space -- UNICEF Mozambique, at the February 6 MTCT plus meeting at the Hotel Tivoli, advised that both MEDIMOCs Maputo and Beira have special areas set aside for the secure storage of ARVs because of the very high cost of these items. They noted that BCH has the option of requesting all of the ARVs from MEDIMOC Beira at one time, or requesting only a portion of the ARVs in stock, such as a one month supply, at more frequent intervals, allowing the remainder of the stock to be held at the MEDIMOC Beira warehouse until needed by the Day Hospital.

The decision to request all or a portion of each shipment will depend on whether or not the Day Hospital has sufficient secure storage space for the ARVs. The locked cupboard area inside the DH pharmacy measures 390cm by 45cm by 60cm for a total volume of 1.1 cubic meters of lockable storage area. Neither the site staff nor the JSI team has information on the package dimensions of the ARVs UNICEF has ordered. Lacking this information, it is not possible to determine whether the DH lockable storage space is large enough to hold the ARVs on order from UNICEF.

The one month supply of ARV drugs procured by HAI through Wellworth, LDA have a total volume of 0.25 cubic meters, and will fit comfortably into the locked cupboard area of the DH pharmacy.

OI drugs storage space – The DH pharmacy has an open shelf above the locked cupboards and counter top area which runs the length of the pharmacy. This area would be suitable for storing non-ARV drugs and other items not requiring cold storage. There are approximately 1.8 cubic meters of storage space available on this upper shelf. Assuming that the small refrigerator will be placed on the pharmacy countertop and that one half of the counter top space will be needed for drug counting and packaging, another 0.8 cubic meter of space is available on the countertop for storage of OI drugs and other items not requiring cold storage. The infirmary has a locked cupboard area of approximately 0.5 cubic meter which could be used for consumable supplies.
and possibly for OI drugs, although it is not ideal for large quantities of drugs to be stored outside
the pharmacy.

These spaces add up to 3.1 cubic meters of non ARV storage volume. The OI drugs purchased by
Gtz listed in Table 2 above have a total volume of approximately 0.5 cubic meter, and can be
easily stored in the pharmacy open shelf space.

Cold storage space – HAI advised that two of the pediatric dosage ARV drugs and tuberculin skin
tests will require cold storage (2-8ºC). HAI has purchased a small refrigerator for the DH kitchen
with a cold storage volume of approximately 0.07 cubic meter. HAI plans to purchase a similar
size refrigerator for the pharmacy for maintaining cold storage for the few items requiring such
storage. Absent any package dimension information on the ARVs and TSTs, the purchase of a
small refrigerator seems in order. The Beira Central Hospital drug storeroom has a large
commercial type refrigerator with some unused capacity. However, the temperature reading on
the built in thermometer was 13ºC at the time of visit. Staff at the drug storeroom said this
thermometer is not working properly. The team placed a thermometer in the refrigerator and
obtained a reading of 55ºF, or 12.8ºC. The Day Hospital should not place items requiring cold
storage (2-8ºC) in this refrigerator.

SECURITY
The team reviewed physical storage facilities and procedures at the main Beira Central Hospital
drug storeroom and the physical storage facilities and planned procedures at the Day Hospital
pharmacy. It is planned that the MTCT plus provided ARVs will be received directly at the Day
Hospital facility.

The Day Hospital is newly renovated. The external door, internal doors and lockable cupboard
doors have very common types of locks. Doors and windows to the Day Hospital do not have
security bars. There is no burglar alarm system on the building, and such systems do not appear to
be used in the hospital compound or in Beira at large.

Issues to Consider

1. Because of the “zero tolerance” for stock outs of ARVs, it is critical that the shipments be
cleared through Customs and shipped to MEDIMOC Beira in a very timely fashion; that
MEDIMOC Beira give the BCH and MTCT plus program timely notice of the arrival of the
drugs, and that the BCH requisition the drugs in a timely fashion from MEDIMOC Beira.

2. It is important to obtain package dimensions for the various ARV drugs in order to be able to
state definitively whether the Day Hospital site has sufficient secure storage space, and to plan for
alternate secure storage arrangements if the Day Hospital space is not adequate.

3. MEDIMOC has both a private and a government personality. To know whether the
MEDIMOC warehouse is a viable alternative to storing all the ARV drugs at the Day Hospital,
the MTCT plus staff needs to gain a better sense of whether the ARVs will be safe if stored at
MEDIMOC. In the February 6 meeting UNICEF noted that MEDIMOC carries insurance on the
goods it handles, but seemed less certain as to whether that insurance actually pays out for goods
lost or damaged while in MEDIMOC’s possession. Does MEDIMOC’s insurance cover both
government stocks and MEDIMOC’s privately held stock, or just the privately held stock? The
MTCT plus ARVs are consigned to the MOH, and would in effect be government stock.
4. Beira experiences brief electric power outages daily. If these outages become more severe it could affect the viability of the products requiring cold storage.

5. Physical security for the drugs at the Day Hospital is not adequate at present.

**Next Steps**

1. UNICEF Mozambique will revise the paper flow and goods supply chain portion of their report, “Logistics Capacity Assessment for PMTCT + Programme in Dofala and Manica”, adding more details to the description of the steps in the paper flow process. UNICEF will disseminate the revised document to all parties to ensure a common understanding of the process and the roles of the various parties.

2. UNICEF Mozambique will track arriving ARV shipments and the pace of their clearance through Customs and shipment to MEDIMOC Beira to ensure that the drugs reach the Day Hospital MTCT plus site in a timely fashion.

3. UNICEF Mozambique will obtain package dimensions for the various ARVs being procured for the Beira site by UNICEF Copenhagen and pass this information on to JSI.

4. UNICEF Mozambique will look further into whether MEDIMOC’s insurance plan would cover the MTCT plus supplied ARVs, and advise HAI. If the volume of MTCT plus ARVs received is larger than can be stored at the DH pharmacy secure storage area, HAI and BCH staff should visit the MEDIMOC Beira facility to view the ARV secure storage area and in discussion with MEDIMOC management determine whether they are satisfied that MEDIMOC storage is sufficiently secure to provide a viable alternative.

5. MTCT plus staff will seek a backup cold storage arrangement, particularly for weekends, in the event that power outages worsen. The likely backup will be the hospital laboratory, which reportedly has generators for power outages.

6. HAI/BCH will place steel bar security gates on the main entry door to the Day Hospital and on the entry door to the DH pharmacy. They will also place steel burglar bars on the windows above each of these doors and on the external windows of the DH pharmacy, and place additional, stronger locks on the cupboards in the pharmacy and infirmary.

**Stock Management (Dispensing, Packaging and Labeling, Stock Taking, Stockkeeping Records and Reports)**

**Program at Assessment**

For patients newly started on HAART, the plan is that the pharmacy technician will pre-pack the ARVs prescribed by the physician in the patient’s clinical record for each patient at the start of each week. The tech will pack each of the two daily doses in separate, small “ziploc” type of bags. The bags have sun and moon markings, with the medicines in the sun marked bag to be taken in the morning and the moon marked bag in the evening. The pharmacy technician will then attach the daily dose for each patient, or three daily doses on Fridays, to a patient specific form.
showing the week of treatment and the days of the week. As noted earlier, three PLWHA trained and salaried by the program will dispense the ARVs to patients daily at the DH during the three month daily DOT phase of treatment. The pharmacy technician will give each of the three dispensers the forms and doses for the patients they will dispense to for that day. At each visit the dispensers will emphasize the importance of taking the ARVs without fail at the right time of the day. The patient will take each morning dose at the DH in front of the dispenser. The patient will take the evening dose at home and return the empty container in the morning. On Fridays the patient will be given the drugs for Friday and for the two weekend days, returning the containers on Monday morning.

When the patient shows up and receives the drugs for the day, the dispenser will mark the corresponding cell on the form, and return the form to the pharmacy technician at the end of the day. The pharmacy technician will then prepare the form with the next daily dose. This cycle will be repeated each day for 12 weeks. If a patient does not show up for the expected visit, the dispenser will mark the cell for that day indicating that the medicines were not taken, and return the form and the unused ARVs to the pharmacy technician. At the end of each week, the pharmacy technician will make entries into the respective ARV stock cards from the individual patient specific forms and update the running balance on the stock cards.

ART patients who have gone beyond the 12 week DOT period will be given a one month supply of ARVs. The site staff are still determining whether the pharmacy technician or the dispensers will dispense these ARVs and any medicines given for OI prophylaxis to the patients. In either case, the pharmacy technician will make an entry into the respective stock card at the same time the medicines are dispensed to the patients.

The HAI HIV/AIDS Clinical Advisor will at the end of each week on each ARV stock card enter the date, write “physical inventory” under the From/To column, conduct a physical count of each ARV, enter the count in the stock on hand column, and sign the card. The MTCT plus management team will investigate any discrepancies between the running balance total as calculated by the pharmacy technician and the physical count of stock as entered by the clinical advisor.

The HAI HIV/AIDS Manager will at the end of each month on each ARV stock card enter the date, write “physical inventory” under the From/To column, conduct a physical count of each ARV, enter the count in the stock on hand column, and sign the card. The MTCT plus management team will investigate any discrepancies between the running balance total as calculated by the pharmacy technician and the physical count of stock as entered by the HAI HIV/AIDS Manager.

For non-ARV medicines, at the end of every month the clinical advisor will conduct the physical inventory and enter it on the respective stock cards, and the MTCT plus management team will reconcile any differences between the running balance and the physical count.

The clinical advisor will use the information on the ARV stock cards to report ARV monthly consumption and stock balances to the MTCT plus Secretariat.

The HAI HIV/AIDS Manager will select a random sampling of entries from each ARV stock card at least once a month and compare these to the relevant patient clinic records to ensure that the ARVs are reaching the intended clients and that there is no leakage of ARVs from the system.
The site staff and assessment team discussed the type of packaging for the one month patient ARV supply. The site staff are interested in knowing more about packaging options (pill boxes, blister packs or one month supply of each medicine in a separate bottle), packaging costs (reusable pill box versus throw away blister pack), and likely impact of packaging on facilitating patient adherence.

**Issues to Consider**

1. There is a need to carefully review the proposed flow of ARV drugs within the Day Hospital and settle upon a model to be used at the commencement of services. If necessary, this model can be modified after the site has gained several months of experience in dispensing ARVs.

2. A decision has not yet been made on the packaging for the one month ARV supply to be given to patients after the DOT phase of care. More information is needed on packaging options and costs in order to make this decision, but this information is not readily available at the site.

**Next Steps**

1. Site staff will prepare a drug flow chart with a narrative detailing how the drugs will move within the Day Hospital from the pharmacy to the patient and the records and reports to be completed at each step of the process.

2. The JSI IQA group will research available packaging and costs and advise the site of its findings. The site can then make a decision on the packaging to be used for the one month patient supply of ARVs.

**Inventory Control System**

**Program at Assessment**

For Mozambique the estimated annual quantities of ARV drugs required have been divided into four equal quarterly shipments. In a mature program with the drug supply pipeline already established and holding the prescribed stock levels, this type of shipment schedule would be okay. In a brand new program such as MTCT plus this shipping schedule will likely result in stock outs of ARVs, and force the sites to frequently resort to emergency purchases.

The program should design an inventory control system with established maximum and minimum stock levels for the MTCT program ARV pipeline, and then put sufficient stock into the pipeline at the start to keep the drugs flowing smoothly rather coming in spurts with no drugs available at certain times. The challenge is to set maximum and minimum stock levels which will protect the sites from stock outs, but which will not result in the sites having more stock than they can store securely or more stock than they can use before reaching the expiry dates of the drugs.

To determine the proper maximum and minimum stock levels for the Beira site, it is necessary to know the frequency with which the site will be sent ARVs. This is known as the review period, and for the Beira site this is quarterly under the UNICEF contract. It is also necessary to know the lead times for all the steps in forecasting, procuring, shipping, receiving, and distributing to sites. These lead times are not presently known because the UNICEF ARV procurement mechanism is being used for the first time. Even when average lead times are known it is necessary to add in a level of safety stock when computing desired max/min stock level,
particularly when doing ART. This is because of variation in how fast the steps can be undertaken, and the unforeseen situations which always arise. The minimum stock level for the Beira site should be the lead time stock plus the safety stock. If the lead time were estimated to be three months, and one opted to have another three months stock as safety stock, the minimum stock level would be six months. Maximum stock level is the minimum stock level (six months) plus the review period stock level (three months) which equal a maximum stock level of nine months.

**Issues to Consider**

1. With the lead times not known, but based on UNICEF experience in Mozambique, UNICEF Mozambique at the February 6 Hotel Tivoli meeting suggested a maximum stock level of 9-12 months. JSI based on its global experience suggested a 6-9 month maximum. To be sure of adequate supply, MTCT plus in forecasting the quantities to order assumed that all 250 patients would be enrolled from the first day of the program. This will not actually happen, but by so assuming there is a “safety stock” factor already built into the quantities UNICEF was asked to purchase. Based on this discussion the assessment team recommends to the Secretariat that nine months be used as the maximum stock level at the outset, at least for the first line ARVs, and this maximum level be adjusted upwards or downwards as necessary based on actual ARV consumption and lead time experience.

**Next Steps**

1. The Secretariat, JSI, and UNICEF Copenhagen will discuss the merits of increasing the maximum stock level for the Mozambique program.