I. PURPOSE OF ASSESSMENT

There are two sections to this part of the MTCT Plus start-up assessment report. The first section on Pharmacy Management focuses on the facility where MTCT Plus services and products are to be provided. The persons responsible for ordering, receiving, storing, securing, dispensing and reporting on stock status and consumption of antiretroviral drugs and other MTCT Plus medicines at the site have been interviewed. The purpose of this part of the assessment is to document current pharmacy management procedures and capacity, and to identify areas that may need support to be able to ensure the consistent availability of quality products at the site for implementation of MTCT Plus services.

The second section on Supply Chain Management focuses on the forecasting, procurement and distribution system capacity for ensuring an adequate and timely supply of antiretroviral drugs and other HIV medicines to the facility. Donors, procurement agents, local suppliers (where applicable) and MTCT Plus program managers have been interviewed for this part of the
assessment. The purpose of this part of the assessment is to describe how antiretroviral drug requirements and other medicines for MTCT Plus services will be forecasted for procurement; to document the procedures and timeframes for ordering and receiving products from the MTCT Plus secretariat and suppliers; and to verify the in-country distribution system for receiving, storing and transporting MTCT Plus products to the facility.

II. SUMMARY OF PHARMACY AND SUPPLY CHAIN CAPACITY

In order for the MTCT Plus program to be able to ensure a full supply of antiretroviral drugs and other HIV medicines for treatment of enrollees, the program must be able to procure the right products in the right quantities and be able to deliver them to the right place, at the right time, in the right condition and at the right cost (the Six Rights of logistics). This implies that the program must have the forecasting, financing, procurement and distribution capacity for reliable and timely delivery of products to service providers, and be able to ensure the consistent availability and quality of products for end users at the service delivery site.

Within this context, the findings of this assessment indicate that the pharmacy procedures and capacity for managing antiretroviral drugs and other HIV related medicines at Moi Hospital and Mosoriot Health Center are adequate to meet current demand. However, technical assistance is needed and is already being provided to strengthen the areas of data collection and management in the pharmacy and ARV dispensary, coordination with clinicians for follow up of patients who do not return for re-supply of ARVs, and to address the need for additional storage space. The Eldoret MTCT Plus team has addressed these issues within the plans for expansion of the HIV Care Program at the hospital, which includes implementation of MTCT Plus services, and is actively working to resolve them in the short and intermediate term. (see section III. Pharmacy Management).

The forecasting and procurement procedures and timeframe, the supplier lead times and shipment delivery schedules, and the in-country storage and distribution system for MTCT Plus products supplied through UNICEF have not yet been clearly established. Therefore, it is not possible at this time to determine the appropriate stock levels and order intervals for the UNICEF storage facility in Nairobi nor the Eldoret MTCT Plus site. Additionally, there are considerable inefficiencies inherent in creating a parallel supply system for a limited number of products that will require separate forecasting, procurement, distribution, management and reporting systems. At this point, while Moi hospital may not have access to the lowest priced generic drugs available and needs to resolve the issue of delays in payment to suppliers, the hospital’s current tendering mechanism and proven supplier performance for delivery and quality of product seems to offer the most reliable alternative for procurement and distribution of these products in the short run. (see section IV. Supply Chain Management)

One cause for immediate concern is that the quantities of drugs forecasted to be supplied in the first quarterly UNICEF shipment for Eldoret may fall short for various reasons and it may be necessary to re-calculate the drug requirements and move up delivery of the second quarter shipment or request an additional shipment to avoid an interruption in the ARV drug supply for MTCT Plus patients (please see section IV. Supply Chain Management, A. Forecasting, page 8).

Specific issues to be addressed and next steps for supporting pharmacy management of the MTCT Plus products at the site and strengthening the supply chain to be able to ensure a reliable and timely supply of quality products to the facility are discussed within each section of the
III. PHARMACY MANAGEMENT

Findings

A. Antiretroviral treatment regimens and list of antiretroviral drugs and HIV medicines currently managed at Moi Teaching and Referral Hospital and Mosoriot Health Center.

The first and second line regimens for antiretroviral therapy and single drug substitutes for toxicity that will be offered under the MTCT Plus program are described in Table 1: MTCT Plus Program, Antiretroviral Treatment Regimens. The antiretroviral drugs and other HIV medicines for prophylaxis of opportunistic infections currently available at Moi Teaching and Referral Hospital and Mosoriot Health Center are listed in Table 3: List of Current Suppliers and Prices for Antiretroviral Drugs and other Medicines for MTCT Plus Program. The range of products that will need to be available to provide MTCT Plus services includes 10 antiretroviral drugs, each with several different formulations, four drugs for prophylaxis of opportunistic infections, and vitamin supplements. Thus, a total of thirty or more products will be required to be able to meet the established treatment regimens for MTCT Plus services at the site.

B. Current procurement mechanisms and capacity for purchasing antiretroviral drugs and HIV medicines at the site.

Moi Teaching and Referral Hospital currently procures antiretroviral drugs and other HIV related medicines to support the ongoing HIV Care Program at the hospital and its satellite site, the Mosoriot Health Center. Antiretroviral drugs, currently all branded, have been available at the site since antiretroviral treatment services were initiated a year ago. The hospital tender board follows government regulations for awarding contracts which includes selection of suppliers based on product quality, lowest price, and supplier performance in terms of flexible delivery schedules and order fill rates. While the hospital tender board puts out to tender for all drugs, supplies, equipment and food needed for the hospital on an annual basis in June, the board may be convened at any time during the year to contract for additional drug purchases as needed.

Initially, hospital drug funds were used for monthly purchase of antiretroviral drugs from suppliers on a cash and carry basis. For the first several months that antiretroviral therapy became available, supply was regular and responsiveness of suppliers excellent with orders being received from Nairobi within 24 – 48 hours after placing the order. In August 2002, the hospital switched to payment of invoice within 30 days after receipt of delivery from the supplier. Delays in processing the invoice at the hospital led to a near stockout of antiretroviral drugs in November (stock levels of antiretroviral drugs had dropped to 6 days when delivery was finally received). Since then, the pharmacist responsible for ARVs regularly follows up on processing of invoice payment to suppliers at the hospital to avoid delays in product delivery although she admits that it would be easier if the suppliers were paid up front to ensure prompt delivery.

Other drugs that will be supplied by the MTCT Plus program for prophylaxis of opportunistic infections include Isoniazid for latent TB infection, co-trimoxazole for pneumocystis carinii
pneumonia, Fluconazole for prevention of cryptococcal meningitis, and multivitamins. The MTCT Plus program manager at Eldoret has already taken advantage of the Access to Medicines program to order Fluconazole through Pfizer’s guarantee of lifetime supply for free. Fluconazole tablets and pediatric suspension are ordered by e-mail and sent by DHL directly to the hospital from a Pfizer subsidiary in South Africa. Isoniazid 100mg tablets are provided for free from the government of Kenya TB program. Isoniazid in 300mg tablets is preferred for reducing the pill burden of HIV patients but is currently not available and significantly more expensive than the 100mg tablets. Dapsone is provided by the Leprosy program although the safety of using Dapsone for Kenyan patients (suspected toxicity?) has yet to be determined by the program manager. Generic co-trimoxazole and multivitamins are low cost drug items available locally that will be procured directly by the hospital.

C. Ordering, Receiving and Stock Management of Antiretroviral Drugs

One full time pharmacist is responsible for ordering and monitoring supplies of antiretroviral drugs at the Moi hospital pharmacy. She also counsels and dispenses ARV prescriptions to patients in a room specifically designated as the ARV dispensary. She fills out a requisition and issue form called the “Request for S11” (copy attached) which is used by all hospital dispensaries and in-patient wards that are directly supplied by the hospital pharmacy. The pharmacist determines the order quantity based on expected consumption and space available in the ARV dispensary. When she receives the quantities of drugs issued by the pharmacy, she updates the stock balance for each drug in the ARV dispensary by entering the quantity received and adding it to the stock balance in the Counter Book which is a type of stores ledger with separate pages for each drug. Every time drugs are received into or dispensed from the ARV dispensary, the Counter Book is updated for each drug (see dispensing section D. below).

The ARV pharmacist monitors the stock levels in the pharmacy store to know when to re-order from suppliers. She maintains a minimum stock level of two months based on the last three months’ consumption and orders from suppliers as soon as stocks fall below two months supply. While a monthly ordering schedule has been established, supplier responsiveness allows the pharmacist to order as needed at any time stock levels fall below the 2 month supply level. Current ARV suppliers, Glaxo-Smith Klyne, Boehringer Ingelheim, and Phillips, a local agent, provide delivery of ARV drug orders directly to the hospital within 24 to 28 hours upon receipt of payment. (see section B. above).

All hospital drug orders are received in the Supply Head Office of the hospital. A hospital pharmacist is called to verify that the correct drug items, dosages and quantities have been received, the products have a minimum of 2 years of shelf life remaining, and that the drug packaging is intact upon visual inspection. Once received by the pharmacist, the drugs are moved to the Bulk Storage room where boxes are unpacked and any missing or damaged product is documented and the suppliers are contacted. While a quality assurance plan for routine sampling of products for quality testing does not exist, products of suspicious quality are sent out for testing. Due to time constraints, the consultant was unable to visit the Supply Head Office during this visit to verify the procedure for filing complaints and requesting product replacement from suppliers nor to follow up on the quality testing procedures.

All ordering, receiving and stock management procedures are recorded manually at this time. Pharmacy store staff commented on plans for computerization of the hospital pharmacy management system but the timeframe for implementation is unknown. Computerization of a
comprehensive data collection and reporting system for antiretroviral treatment and HIV care services to be linked to laboratory services and the pharmacy system for ARV drug dispensing will be funded and implemented through the Indiana University/Moi Hospital collaboration. Pharmacy supply and dispensing records will be linked to patient medical records to detect number of patients, prescribed treatment regimens, and changes in ARV regimens or single drug substitutions so that the pharmacy may monitor drug orders and supply levels to be able to ensure availability of the required drugs.

The pharmacy management component of the system will include dispensing, inventory, financing and identification of patients for follow up that did not fill their prescriptions or return for re-supply. The first site visit to begin implementation of this computerized data management system will be in early 2003. It is unclear at this time what pharmacy stock monitoring and consumption data will be collected, how it will be aggregated and reported from the Mosoriot health center, the Moi pharmacy store and the ARV dispensary, and how it will be linked to the patient medical records within the data management system. Computerized data management will also be required to relieve the ARV pharmacist of the paperwork load (the other hospital dispensaries have one trained full time person for transcribing stock movement and maintaining prescription registers) which will increase considerably as the number of patients on antiretroviral treatment increases and the need for a separate recording and reporting system for MTCT Plus products is implemented.

D. Dispensing

There are five categories of patients on antiretroviral drug treatment or pending initiation of treatment within the Moi hospital HIV care program. The patient categories include self-paying patients (current cost of treatment per patient is 5,250 Ksh per month, about US $70), 60 patients enrolled in a pilot program with cost of ARV drugs covered for a two year period, health care workers covered under the Moi hospital benefits plan (25 of these may be enrolled through the MTCT Plus program), MTCT Plus patients eligible to initiate treatment, and patients “Awaiting Assignment” who are clinically eligible for treatment but do not have the means to pay for the drugs. The largest number of patients on ARV drugs at this time is in the self-paying category. Estimates provided put the total number of patients currently receiving antiretroviral drugs at Moi hospital and Mosoriot health center at around 200. Verification of these figures from the Eldoret site for completion of the attached Table 2: Number and Category of Patients Receiving Antiretroviral Drug Treatment as of January 31, 2003 is pending.

The full time ARV pharmacist is supported by a floating pharmacist who rotates among the different hospital dispensaries and is available to relieve her in the ARV dispensary when needed. The pharmacist maintains a “Counter Book” for monitoring stock balances of each ARV drug in the dispensary and a Prescription Register for documenting the quantities of drugs dispensed to each patient. These are the two pharmacy records that will need to be incorporated into the computerized data management system.

Patients with a prescription for ARV drugs go directly from the clinician to the ARV dispensary. Patients covered under the MTCT Plus program or the pilot program may receive their drugs directly. For self-paying patients, the pharmacist calculates the cost of the ARV drugs according to the prescription for each patient. The patient then goes around the corner to make the payment at the pharmacy store and returns to the ARV dispensary with the pharmacy receipt. The Receipt Number and Prescription Number are entered into the Counter Book along with the date, the
patient’s name, the patient category (e.g. self-pay, pilot program, MTCT Plus), and the quantity of each drug dispensed and the stock balance is updated. This information is recorded separately for each drug dispensed on the corresponding pages in the Counter Book. At the end of the month, the ARV pharmacist adds up the total quantity of each drug dispensed during the month to monitor the consumption and compare against the stock levels in the pharmacy store to determine if it is time to place an order.

After dispensing the drugs to the patient and reviewing instructions on how to take them, (written instructions are provided where appropriate), the pharmacist completes the Prescription Register recording the date, patient’s name, prescription number and all the drug items and quantities that were dispensed to the patient that day.

Physicians from Moi hospital carry drugs to the Mosoriot health center on Wednesdays and Fridays for adult HIV clinic days and Thursdays for pediatric clinic days. Ten doses of each drug are left with the clinical officer at Mosoriot for dispensing to patients who may come for re-supply on other days of the week. Due to time constraints, the consultant was unable to verify how the stock movement from Moi hospital pharmacy store to Mosoriot is documented and to observe stock keeping and prescription registers and storage conditions at the health center.

The planned computerization of the stock keeping and dispensing records for ARV drugs will allow separate reporting of quantities of drugs dispensed to different categories of patients including MTCT Plus patients. At this time all patients are being treated with the same drugs purchased by the hospital according to the same basic regimen. While the first line regimen will remain the same for MTCT Plus and non-MTCT Plus patients (currently there is no alternate regimen for other patients), the actual drug products which will be dispensed to MTCT Plus patients will be separate items supplied by MTCT Plus funded procurement.

At this time it is unclear if the drugs for prophylaxis of opportunistic infections to be provided by the MTCT Plus program will be managed and dispensed by the ARV pharmacist together with the antiretroviral drugs or dispensed separately to patients directly from the pharmacy store. Another topic which was not addressed during this visit is the mode of dispensing for pediatric oral suspensions and availability of pre-measured syringes or dispensing units from suppliers.

E. Storage and Security

ARV drugs issued by the pharmacy store and received into the ARV dispensary are stored in a locked cabinet under the desk. Drugs that do not fit into the desk cabinet are currently stored on open shelves in the ARV dispensary (more locked cabinets for the ARV dispensary have been ordered). The door to the ARV dispensary is locked at all times that a pharmacist is not inside to attend patients. Storage conditions of the ARV dispensary aside from the need for more locked cabinets are very good. The ARV pharmacist noted that the available storage space in the dispensary, while adequate to meet current demand, will not be sufficient once enrollment of MTCT Plus patients (including health workers) picks up, along with the expected increase in the number of self-paying patients through the HIV Care Program.

While storage conditions in the pharmacy store are also very good, storage space is also limited and will be inadequate to meet the expected growth in demand for these drugs. ARV drugs are currently stored in large locked cabinets on the shelves. Stock management procedures to maximize storage space and product turnover in the pharmacy store include monthly ordering...
and a two to four month minimum stock level for most drug products. This indicates the need for flexible supplier delivery schedules to be able to provide frequent, small deliveries of product.

These storage constraints are expected to be resolved once the new HIV Care Center planned and funded by the Indiana University/Moi hospital collaboration has been built next to the hospital. The new center is designed to be able to serve up to 10,000 patients receiving HIV care and antiretroviral drug treatment. Construction is scheduled to begin this year.

Due to time constraints, the consultant was unable to verify the security measures for transfer and storage of drugs within the hospital from the Supply Head Office to Bulk Storage to the Pharmacy Store and the ARV dispensary, and for transport and storage of drugs for Mosoriot health center. It also remains to identify program staff who have authorized access to the ARV drugs and the procedures for designating alternates if the ARV pharmacist is not available.

**Issues to be Addressed**

- Limited storage space for ARV drugs in Moi hospital pharmacy store and ARV dispensary
- Increased workload of ARV pharmacist for maintaining manual stockkeeping and dispensing records to meet increased demand for ARV treatment services
- Increased workload of ARV pharmacist to maintain separate recording and reporting system for MTCT Plus procured products
- Need to establish maximum/minimum inventory control system to ensure full supply of all ARV drugs and other HIV medicines at Moi hospital and Mosoriot health center
- Design and standardization of stockkeeping and dispensing records, order calculation and monthly reporting forms to be incorporated into the computerized data management system for clinical, laboratory and pharmacy management of antiretroviral drug treatment services
- Integration of pharmacy records and reports for ARV drugs and HIV medicines into the already existing pharmacy management system to minimize duplication of effort and operation of parallel systems

**Next Steps**

- Describe how a maximum/minimum inventory control system works and discuss how it could be implemented to ensure full supply of ARV drugs and other HIV medicines at Moi hospital and Mosoriot health center
- Preparation of sample forms for stockkeeping and dispensing records, order calculation and monthly pharmacy reporting to be used manually or to be incorporated into the computerized data management system
- Communication and coordination between MTCT Plus secretariat data management staff and Indiana University health information specialists early on in the design of the computerized data management system to ensure MTCT Plus pharmacy reporting requirements can be met
- Verify procedures for tracking stock movement between Moi hospital pharmacy store to Mosoriot health center and for managing stocks of ARV drugs and HIV medicines at the health center
- Plan for implementation of standardized stock keeping and dispensing records to collect and aggregate pharmacy management data from Mosoriot health center into the new data management system
IV. SUPPLY CHAIN MANAGEMENT

Findings

A. Forecasting

The MTCT Plus Secretariat calculated the ARV drug order for the first 3 months based on the expectation that all 25% of the 250 enrollees for the first year and all 25 health care workers would initiate antiretroviral drug treatment in the first year. Therefore, in theory, the first order quantities should be sufficient to meet these needs and provide some buffer stock for 3 months since all 25% of enrollees and health workers would not be expected to initiate antiretroviral therapy within the first 3 months. Because the Eldoret MTCT Plus site has already been providing comprehensive HIV care and antiretroviral drug therapy for a year, they were permitted to begin enrolling patients retroactively and already have about 100 patients enrolled in the MTCT Plus program (confirmation on the number of these patients currently receiving antiretroviral drugs is pending) and the enrollment ceiling for Eldoret was raised to 350 patients.

This increase in number of enrollees and number of patients either already on ARV drugs or who will initiate ARV drug therapy, coupled with the fact that the calculation of first quarter shipment quantities did not take into account existing drug stocks at the site and initial quantities needed to fill the pipeline to cover UNICEF procurement and supplier lead times (still to be determined), is cause for concern that the quantities calculated for the Eldoret order may fall short of what is needed well before arrival of the second quarter shipment. It will be critical to closely monitor stock levels and consumption of the MTCT Plus products to assess what additional quantities of product may need to be ordered and when. Procedures for requesting early delivery of UNICEF shipments should be discussed with the MTCT Plus Secretariat and the Eldoret MTCT Plus site manager and pharmacist in case it becomes necessary to advance a delivery or place an additional order.

According to the MTCT Plus Secretariat, the estimate of drug quantities for the second quarterly shipment will be based on expected “failure rates”. It is not clear at this time how that will be calculated. It will be important to document the methodology and the assumptions for estimating the ARV drug requirements for the quarterly orders and for the yearly forecast of needs for Eldoret. The methodology should take into consideration expected and actual rates of enrollment, initiation of therapy, types of patients (index mothers, partners, HCWs etc), expected and actual numbers and rate of changes in drug regimens for single drug substitution (due to toxicity and resistance), and complete change of regimen to second line. This will take care of the estimate of quantities of drugs needed to meet patient demand on the clinical side.

On the pharmacy supply side, the actual and expected rates of consumption for each of the drugs (actual rates of consumption for each drug will come from the prescription register, expected rates will come from clinicians and program manager) will need to be compared against the current stock levels to estimate how long supplies will last. The quantities of drugs needed to cover the procurement and supplier lead times (from the time the drugs are ordered until they are actually delivered, received into the pharmacy and available for dispensing), must also be calculated and included in the procurement request.
B. Procurement Planning/Shipment Delivery

At the time of the visit, the MTCT Plus program staff had not been informed of expected shipment delivery dates, nor provided any information on the drug items or quantities of the MTCT Plus products being procured through UNICEF for the site. MTCT Plus staff were expecting a box of drugs to be “dropped off” at the hospital one day. Inquiries since the visit have confirmed that the MTCT Plus program is moving ahead with centralized UNICEF procurement of ARV drugs through IDA Copenhagen for several MTCT Plus sites. Procurement for the first quarterly shipment to cover drug needs for the first line regimen of ARVs for adults and children plus some single drug substitutions for toxicity for 3 months has been completed. For Eldoret, the order will include several generic drugs and only a couple of branded drugs (nevirapine and lamivudine from Ranbaxy, brand name stavudine from Bristol Myer Squibbs and oral suspensions from Cipla). In the short term, the MTCT Plus Secretariat will be placing the orders for the sites to facilitate the procurement and distribution process for getting the drugs flowing to the sites. Later on, these functions (forecasting, procurement and distribution of the drugs) can be devolved to those sites where the capacity exists and where pharmacy stock management (ordering, dispensing, storage, security etc) is good.

The MTCT Plus program manager discussed the possibility of using Moi hospital's already established mechanisms for contracting suppliers and receiving product from Nairobi based suppliers for future procurement and distribution of the ARV drugs for the MTCT Plus enrollees since ARVs are already being procured for all the other patients under treatment through the HIV care program at the hospital. In order to determine which procurement and distribution system may be most favorable, the costs and quality of the drugs, the timeliness of delivery of orders, and responsiveness of UNICEF will need to be compared to the performance of current suppliers to determine whether it is worthwhile to establish and maintain a parallel procurement and distribution system for the MTCT Plus antiretroviral drugs. Specifically, the MTCT Plus program manager proposed whether some economies of scale could be achieved by utilizing UNICEF for procurement of lower priced generic drugs for those products in low demand at the site and utilize the hospital’s more flexible tendering system for procurement and distribution of ARV drugs for the basic regimens.

C. In-country Storage and Distribution

The UNICEF Kenya Country Office will be responsible for customs clearance and reception at the port of entry, storage at the UNICEF storage facility in Nairobi (Transami), and transport to Eldoret. To minimize administrative burden and be able to ensure a timely response to site requests for release of drugs from storage, UNICEF Kenya prefers to limit deliveries from suppliers to annual or semi-annual shipments and to receive quarterly letters of request from the site. The site's order will be reviewed, approved by UNICEF, and sent to the storage facility to be prepared for delivery. UNICEF officials confirmed that, while they cannot process more than quarterly letters of request to the storage facility, monthly deliveries to Eldoret may be arranged so that less stock will need to be kept at Moi pharmacy store. UNICEF requires that the letters of request include a detailed description of each drug item, the quantity requested for the 3-month period, and the monthly delivery schedule.
Issues to be addressed

♦ Eldoret MTCT Plus site unaware of expected delivery date, drug items and quantities being shipped for first quarterly shipment from UNICEF
♦ Lead time required for customs clearance, reception and transfer to UNICEF storage facility in Nairobi and time for product to be transported to Eldoret is not known
♦ If stocks are low and storage space is available at Moi hospital, can UNICEF arrange for transport directly to Eldoret from Nairobi airport and bypass storage facility in Nairobi to speed up delivery?
♦ First quarter shipment quantities based on drug requirements estimated to meet demand for 250 enrollees for a 3 month period did not take into current stock levels at the site and initial quantities needed to fill the pipeline to cover procurement and supplier lead times
♦ The methodology for forecasting and quantifying requirements for antiretroviral drugs and other HIV medicines at Eldoret MTCT Plus site is not clearly established nor documented
♦ The procurement and distribution system(s) to be used for ensuring supply of ARV drugs and HIV medicines to Moi hospital/Mosoriot health center for the MTCT Plus program in the short run and in the long run have not been determined
♦ The recommendation for establishing a maximum/minimum inventory control system to ensure full supply of ARV drugs and other HIV medicines at Moi hospital and Mosoriot health center has not been agreed upon with program management and pharmacy staff
♦ The quality assurance mechanisms for documentation of quality testing and filing complaints and requests for product replacement from MTCT Plus suppliers has not been verified and communicated to the Eldoret MTCT Plus site
♦ The security measures in place for UNICEF customs clearance, reception, storage and distribution of antiretroviral drugs in-country have not been confirmed

Next Steps

The responses and the information gathered in the following next steps will be critical for making informed decisions about which system to use for procurement and distribution of ARV drugs and other HIV medicines, how to forecast requirements to meet expected demand, what stock levels and order intervals to establish at the site, how to calculate the quantity of drugs to order, and the best system for recording, monitoring and reporting on stock levels and consumption.

MTCT Plus Secretariat:
♦ MTCT Plus Secretariat to communicate with IDA Copenhagen, with UNICEF Kenya Country Office and Eldoret MTCT Plus site to confirm expected delivery date for first quarterly shipment to include information on drug items and quantities being shipped
♦ MTCT Plus Secretariat to ensure all suppliers and products to be provided by the MTCT Plus program are currently registered for use in country by the national drug regulatory authority
♦ MTCT Plus Secretariat and Eldoret MTCT Plus site to verify who will be responsible for forecasting and quantifying drug requirements for procurement and document the forecasting methodology to be used for estimating the quantities needed of each drug for MTCT Plus program
MTCT Plus Secretariat to establish timeframe for submission of drug requirements to MTCT Plus secretariat for products to be procured through UNICEF mechanism

MTCT Plus Secretariat to determine procurement lead time from submission of requirements to confirmed purchase of drug orders

MTCT Plus Secretariat to determine supplier lead time for shipment of product to Nairobi and supplier delivery schedules

MTCT Plus Secretariat to verify quality assurance mechanisms for quality testing and filing of complaints and requests for product replacement with MTCT Plus suppliers

UNICEF Kenya Country office:

UNICEF Kenya Country Office to verify the lead time for customs clearance, reception and transport of MTCT Plus products to UNICEF storage facility in-country

UNICEF Kenya Country Office and Eldoret MTCT Plus site to coordinate delivery of products from UNICEF storage facility in Nairobi to Moi hospital in Eldoret according to stock levels and storage capacity at Eldoret

UNICEF Kenya Country Office to confirm if MTCT Plus products may be transported directly to Eldoret from Nairobi airport to bypass storage facility in Nairobi and speed up delivery if needed

UNICEF Kenya Country Office to verify security measures in place for customs clearance, reception, storage and distribution in-country of MTCT Plus antiretroviral drugs procured by UNICEF

Moi Teaching and Referral Hospital/Eldoret MTCT Plus site:

Develop and document forecasting methodology for estimating drug requirements for ARV drugs and other HIV medicines at Moi hospital and Mosoriot health center to include data sources, assumptions and formulas

Complete data in Table 2: Number and Category of Patients Receiving Antiretroviral Drug Treatment as of January 31, 2003 to help estimate current drug needs

Complete information in Table 3: List of Current Suppliers and Prices for Antiretroviral Drugs and other HIV Medicines for MTCT Plus Program, January 2003 to be able to compare product and shipment delivery costs between current suppliers and UNICEF procured products for the MTCT Plus program

Compare performance of current supplier with UNICEF delivery schedules, product quality and product security to determine which procurement and distribution system(s) will be used for MTCT Plus products and the other ARV drug and HIV medicines in use at Moi hospital

Conduct stocktaking of antiretroviral drugs and other HIV medicines for HIV care program, review past consumption and calculate number of months of stock on hand for each drug. Include stock in hospital pharmacy store, ARV dispensary and at Mosoriot health center in Stock on Hand. Complete data for Table 4: Stock on Hand and Consumption of Antiretroviral Drugs and other HIV related Medicines, January 2003. This will determine how long current stocks will last and if incoming shipment of MTCT Plus products will cover the additional lead times needed for procurement and delivery of the second quarter shipment of antiretroviral drugs.
♦ Provide technical assistance to all areas listed under Next Steps as requested

Johnnie ??????????????????????????


V. OTHER ISSUES AND OBSERVATIONS

A. Timing and Schedule of the Site Visit

The timing of this start-up assessment visit following on the heels of the one week MTCT Plus site training created an additional burden on clinicians and pharmacy staff who had a backlog of patients and were more pressed for time than they might have been otherwise. Due to time constraints, some key pharmacy assessment activities could not be completed as documented within this report. Nonetheless, all MTCT Plus staff interviewed were extremely cooperative and patient, knowledgeable about the areas for which they were being interviewed, and clearly dedicated to their work within the hospital HIV Care Program.

The original two days allotted for the site visit did not include time for interviews to assess supply chain management issues with the UNICEF Kenya Country Office staff in Nairobi who will be key to coordinating the procurement, delivery and in-country reception, storage and distribution of MTCT Plus products to the Eldoret site. An additional day for interviews with UNICEF was required and needed to be arranged before departure for Kenya. For future site visits, it will be critical to meet with donors, procurement agents, suppliers and other in-country collaborators who will be responsible for coordinating the forecasting, procurement, delivery, customs clearance, storage and distribution of the MTCT Plus products for the site.

B. Recommended Pharmacy Assessment Activities for Future Site Visits

In general, the two days allotted for completing both the general site assessment and the pharmacy and supply chain assessment were inadequate to be able to conduct a thorough review of all pharmacy procedures for stock management and reporting on ARV drugs and HIV medicines at Moi hospital and Mosoriot health center. Specific pharmacy assessment activities that could not be completed during this initial visit and that are recommended for future site visits include;
- review of transaction documents for ordering and receiving from suppliers (visit the Supply Head Office)
- clarification of how routine drug order quantities are calculated
- documentation of the forecasting methodology for estimating ARV drug requirements for procurement (data sources, assumptions, formulas)
- conduct on-site stock taking of a few randomly selected products to compare physical stock balances with inventory records (counter book, bin cards)
- crosscheck consumption data from prescription registers against pharmacy and dispensary stock balances to determine months of stock on hand at time of visit (see Table 4: Stock on Hand and Consumption of Antiretroviral Drugs and Other HIV Related Medicines, January 2003)
- cross check ARV dispensing register against clinician records to assess linkage between patient visits and pharmacy records as part of individual patient care and follow up
- confirm data collection and reporting system for tracking stock movement between Moi hospital pharmacy and Mosoriot health center and for recording and reporting drug consumption and stock balances at Mosoriot health center
- review procedure for recording losses and adjustments to inventory (for damaged, defective, expired or missing product) and requesting product replacement from suppliers
- review procedure for identifying and documenting products to be sent for quality testing
verify security measures for transfer and storage of antiretroviral drugs within the hospital from the Supply Head Office to Bulk Storage to the Pharmacy Store and the ARV dispensary, and for transport and storage of drugs for Mosoriot health center. Identify staff who have authorized access to these drugs and procedures for designating access.

C. Relationship between Assessment Team and MTCT Plus site staff

Initial suspicion of the assessment team and fears that findings from the start-up assessment visit might delay program implementation dissipated after this first site visit. By the end of the visit, the members of the assessment team were seen as collaborators and supporters rather than detractors and a good rapport and working relationship was established with the MTCT Plus staff. The groundwork has been laid for a productive and beneficial partnership with common goals for the future of the program. The MTCT Plus staff at Moi hospital and Mosoriot health center are an outstanding group of dedicated, hard working professionals and it was a pleasure and privilege to work with them.