

STANDARD OPERATING PROCEDURES FOR PHARMACEUTICAL SERVICES

Draft

Prepared for

ANTIRETROVIRAL THERAPY (ART) PROGRAMME COAST PROVINCIAL GENERAL HOSPITAL

In collaboration with

**Department of Pharmacy
Coast Provincial General Hospital
Ministry of Health, Kenya**



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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program works in more than 20 developing countries to provide technical assistance to strengthen drug 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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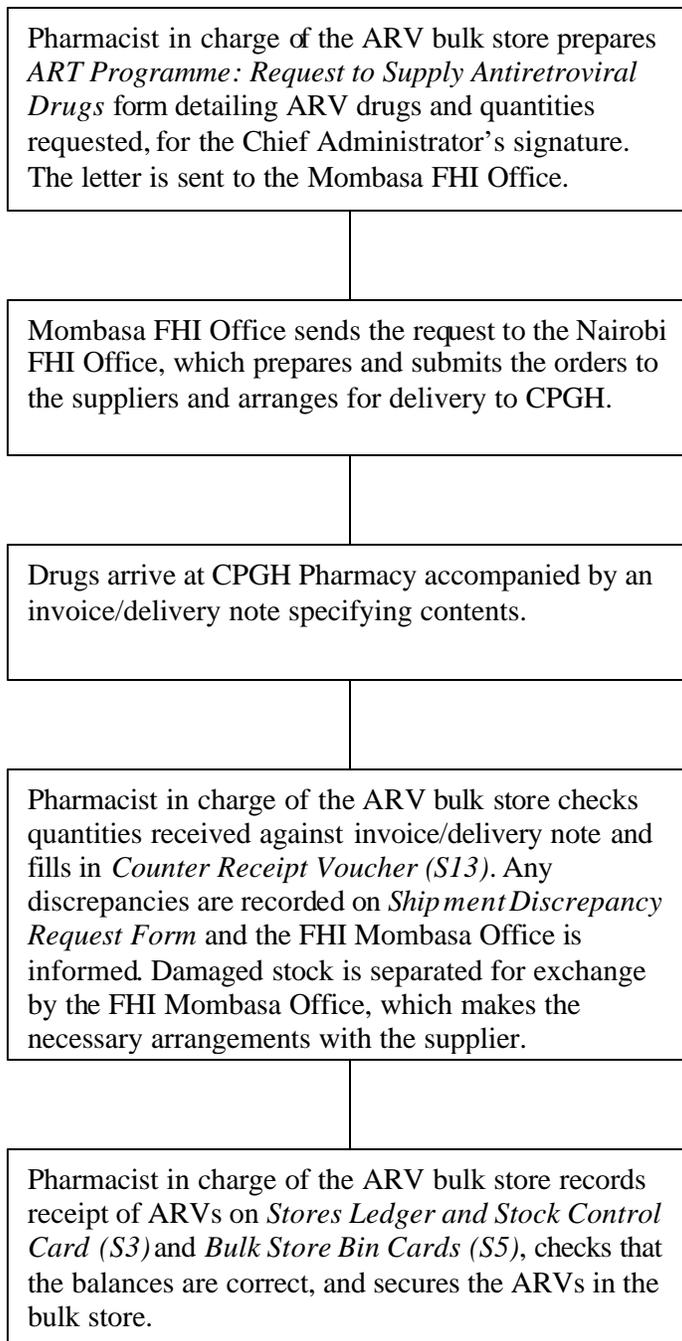
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ACRONYMS AND ABBREVIATIONS

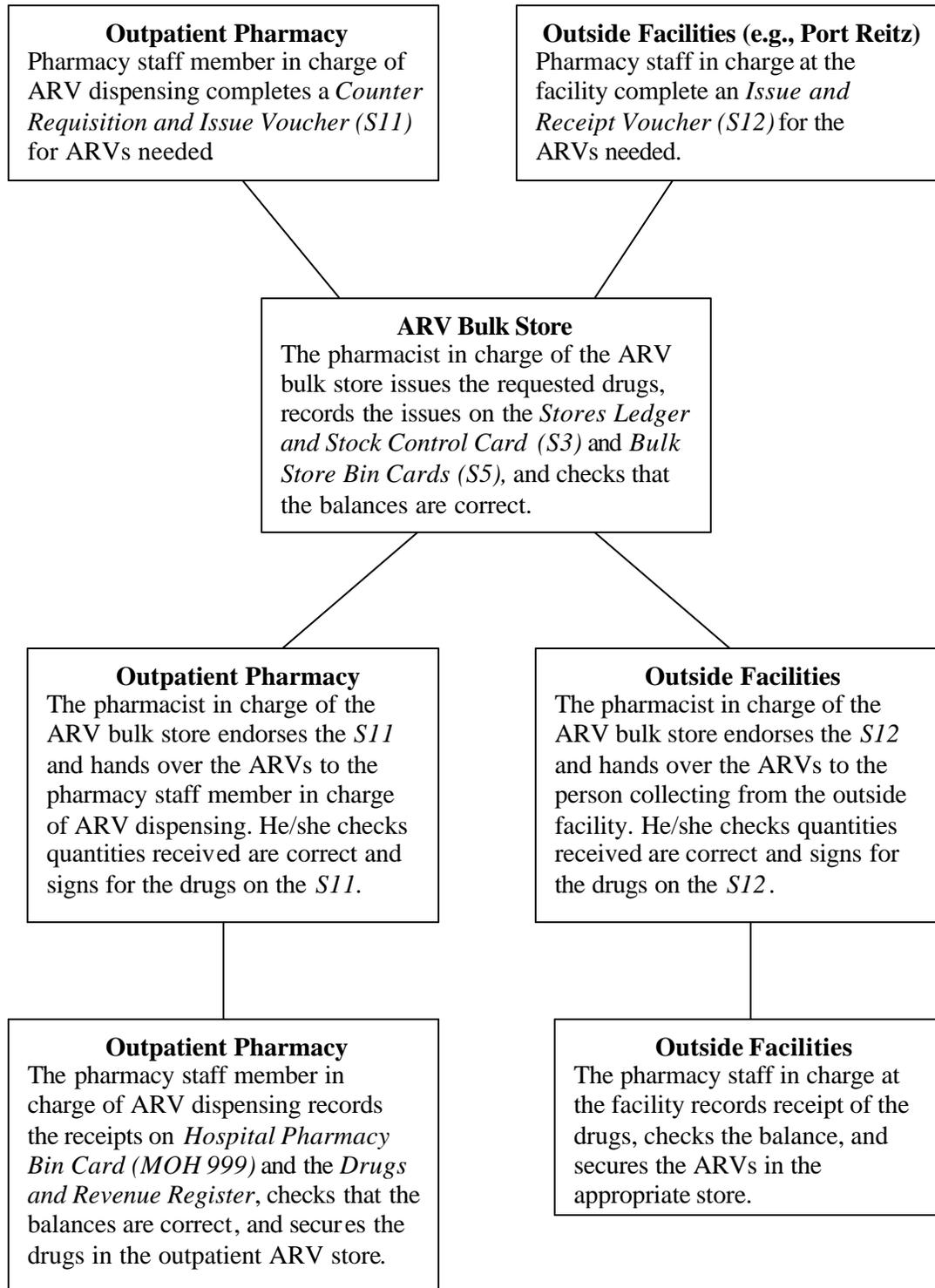
ADR	adverse drug reaction
ART	antiretroviral
ARV	antiretroviral therapy
AZT	zidovudine
B/F	Brought Forward
C/F	Carried Forward
CPGH	Coast Provincial General Hospital
DAART	Directly Administered Antiretroviral Therapy
DUR	drug utilization review
E.O.Q.	Economic Order Quantity
FEFO	first-expiry, first-out
FIFO	first-in, first-out
FHI	Family Health International
IMPACT	Implementing AIDS Prevention and Care (project) [FHI]
Ksh.	Kenya shilling
MOH	Ministry of Health
MSH	Management Sciences for Health
NFV	nelfinavir
RPM Plus	Rational Pharmaceutical Management Plus [Program]
SOP	standard operating procedure
TAP	Technical Assistance Partners [FHI]
ZDV	zidovudine

CPGH ANTIRETROVIRAL (ARV) DRUG MANAGEMENT FLOW CHARTS

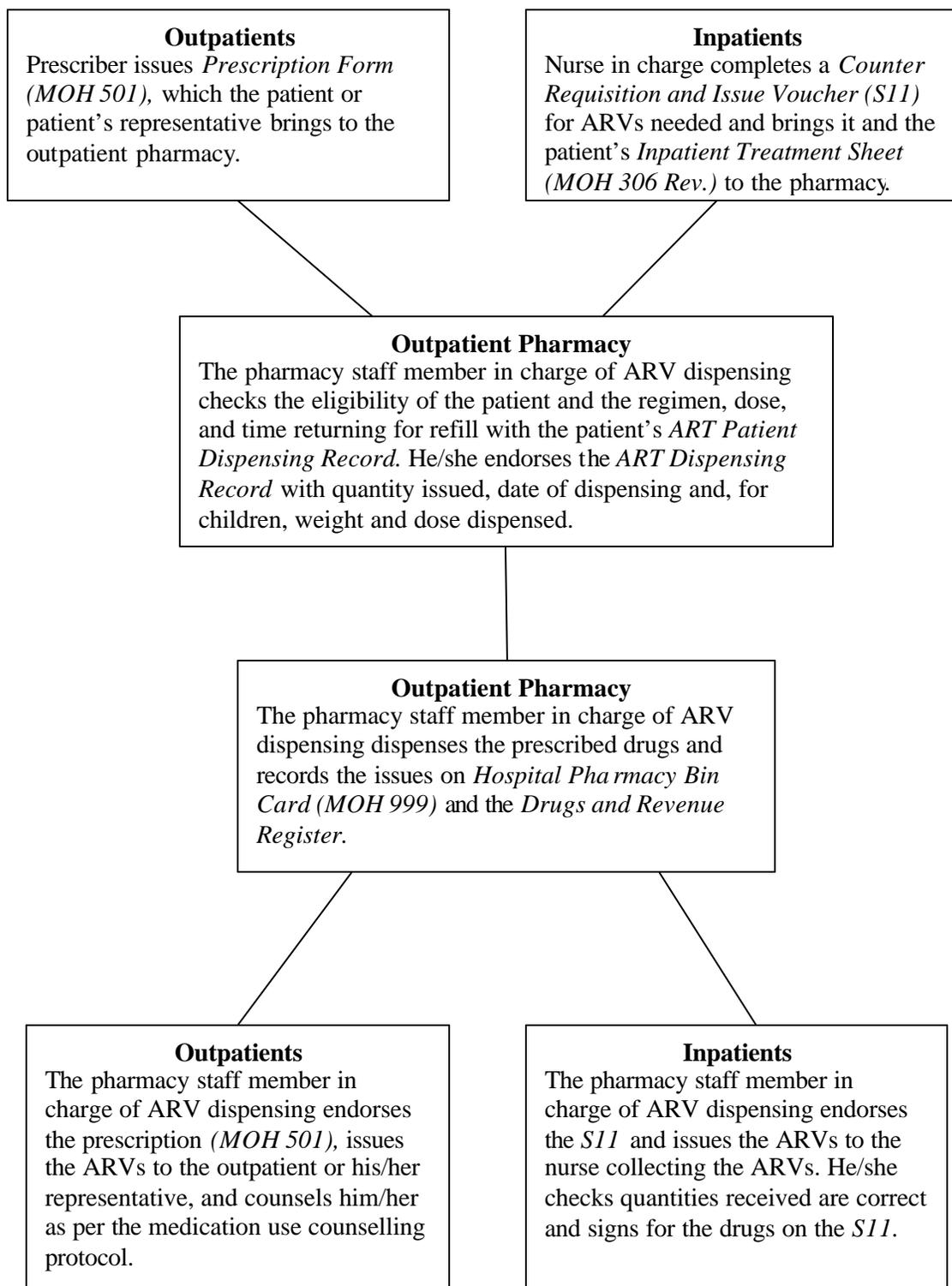
Requesting and Receipt of Antiretroviral Drugs



Issuing Antiretroviral Drugs from the ARV Bulk Store



Dispensing Antiretroviral Drugs from the Outpatient Pharmacy



ROLES AND RESPONSIBILITIES OF THE CPGH PHARMACY DEPARTMENT IN SUPPORT OF THE ART PROGRAMME

Pharmacist in charge of the ART Programme :

- Represents the pharmacy on the CPGH ART Eligibility Committee. As Secretary, takes the minutes of the meetings.
- Maintains a list of eligible patients.
- Maintains a signature file of doctors who are authorized to prescribe for ART patients.
- Works with the CPGH ART team and the CPGH training coordinator to organise continuing education on ART.
- Prepares and presents Adverse Drug Reaction (ADR) summary reports to the CPGH ART Eligibility Committee and makes recommendations on action to be taken.
- Assists in implementing prescribing and drug utilization reviews (DURs). Prepares ARV DURs for review by the CPGH ART Eligibility Committee.
- Carries out periodic spot checks of ARV storage and record keeping on wards at CPGH.
- Prepares the *ART Programme – Pharmacy Weekly Rota*. Assists the pharmacist in charge of the ARV bulk store in preparing and submitting the *ART Programme – Pharmacy Weekly Activity Report*.
- Liaises with the Directly Administered Antiretroviral Therapy (DAART) coordinator in support of the DAART study.
- Works with FHI/IMPACT to arrange exchange with suppliers of ARV drugs near expiry.
- Represents the pharmacy at other meetings relevant to the ART Programme as necessary.
- Maintains confidentiality and keeps patient information and records secure.

Pharmacist in charge of the ARV bulk store:

- Ensures that he/she or a designated proxy is available to receive or issue stock from the ARV bulk store at all times, when needed.
- Ensures that the ARV bulk store is kept locked at all times. Keeps the key to the ARV bulk store in his/her possession or hands it over to a designated proxy.
- Quantifies needs and requisitions ARVs from FHI. Periodically recalculates minimum, maximum, and safety stock levels. Alerts the pharmacist in charge of the ART Programme if stock has less than 8 months expiry to arrange for an exchange.

- Receives ARVs into the ARV bulk store. Completes and files the *S13* copies. Ensures all receipts of ARV stocks are entered in the *S3* and *S5* records at time of receipt. Completes and files a *Shipment Discrepancy Report* if discrepancies arise. Endorses and sends the original invoice/delivery note to FHI Mombasa Office with completed *Confirmation of Receipt of Supplies/Equipment* form together with the *CPGH/FHI ART Delivery Book*. If there are any discrepancies, attaches a copy of the *Shipment Discrepancy Report* to the original invoice/delivery note.
- Issues ARVs from the bulk store. Issues ARVs on first-expiry, first-out (FEFO), otherwise first-in, first-out (FIFO) basis. Ensures all issues of ARV stocks are entered in the *S3* and *S5* records at time of issue.
- Ensures that the stock balances on the *S3* and *S5* correspond to the physical stock in the ARV bulk store when receiving or issuing ARVs and when handing over responsibility to another staff member. Completes and files a *Stock Count Discrepancy Report* if discrepancies arise.
- Completes the temperature logs for the ARV bulk store twice daily and the ARV bulk store refrigerator once daily. Files temperature logs at the end of each month and opens up new logs for the coming month.
- Alerts the Pharmacist in Charge of the ART Programme, the Chief Pharmacist, and/or the Chief Administrator immediately if the temperature falls outside of acceptable limits.
- Prepares and submits the *ART Programme – Pharmacy Weekly Activity Report*.
- Maintains confidentiality and keeps patient information and records secure.

Pharmacy staff member in charge of dispensing ARVs from the outpatient pharmacy:

- Ensures that he/she or a designated proxy is available to issue stock to and counsel ART patients at all times during the rota period assigned.
- Ensures that the ARV cupboard is kept locked at all times. Keeps the key to the ARV cupboard in his/her possession or hands it over to a designated proxy.
- Once or twice weekly, checks the prescription records and the Eligibility List for new patients and requisitions sufficient ARVs for the next week from the ARV bulk store.
- Receives ARV stock into the outpatient pharmacy. Completes and files the *S11* copies. Ensures all receipts of ARV stocks are entered in the *MOH 999* and the *Drugs and Revenue Register* at time of receipt.
- Ensures that the stock balance on the *MOH 999* corresponds to the physical stock in the ARV cupboard when receiving stock. Completes and files a *Stock Count Discrepancy Report* if discrepancies arise.

- Issues ARVs on FEFO, otherwise FIFO, basis. Ensures all issues of ARV stocks are entered in the *MOH 999* and the *Drugs and Revenue Register* at time of issue. Endorses and files *S11* for issues to inpatients.
- Checks the validity of prescriptions with Signature Records held on file and eligibility of patients with the Eligibility List.
- Uses the *ART Patient Dispensing Record* to check:
 - for new prescriptions or changed regimens, that the prescription is in accordance with ART Programme standard regimens
 - for discrepancies in repeat prescriptions and that the dose prescribed is correct for the weight given for children and patients on stavudine (d4T)
 - that the collection time for a repeat prescription is appropriate
- Completes the *ART Patient Dispensing Record* and endorses the prescription with quantities given. Files all ART prescriptions on a daily basis in a separate register.
- Counsels outpatients or their representative s, covering all key counselling points and using the *Antiretroviral Therapy—Patient Counselling Information* table.
- Completes the temperature logs for the ARV outpatient pharmacy twice daily. Files temperature logs at the end of each month and opens up new logs for the coming month.
- Alerts the Pharmacist in Charge of the ART Programme, the Chief Pharmacist and/or the Chief Administrator immediately if the temperature falls outside of acceptable limits.
- Maintains confidentiality and keeps patient information and records secure.

Pharmacy staff member in charge of preparing prepacks for the DAART study:

- Before prepacking:
 - Ensures the workspace area is clear.
 - Checks that the stock bottle(s) contain(s) the correct drug, strength/concentration, and dosage form that is to be prepacked.
 - Checks that the expiry date is appropriate.
 - Inspects the medication from the stock bottle for broken or discoloured tablets or capsules. Inspects packaging containers to make sure they are clean and not damaged
 - Collects the appropriate number of labels for the number of prepacks needed.
 - Fills in the appropriate information on the labels.
 - Fills out the *ARV Prepacking Record*.
- After obtaining the necessary checks from the pharmacist in charge of checking, prepares and labels the prepacks .
- After obtaining a final check from the pharmacist in charge of checking:
 - Clears the workspace area and puts away all drugs, labels, and packaging materials.
 - Ensures all issues of ARV stocks are entered in the *MOH 999* and the *Drugs and Revenue Register* at time of issue.
 - Files away the *ARV Prepacking Record*.

Pharmacist in charge of checking prepacking for the DAART study:

- Before prepacking begins checks that:
 - The stock bottle(s) to be used contain(s) the correct drug, strength/concentration, and dosage form and the expiry date is appropriate.
 - Entries made in the *ARV Prepacking Record* are correct.
 - The correct labels have been selected and the information has been filled in correctly.
 - The number of labels and containers are the same and corresponds to the number of prepacks to be prepacked.

- Once prepacking is complete:
 - Checks 10% of the packages to ensure that the prepacks contain the correct drug, strength, dosage form, and quantity and are labelled correctly.
 - Checks that no excess labels or empty containers are left.
 - Checks that the number of capsules/tablets left in the bulk container(s) reconciles with the number expected.

- Completes the *ARV Prepacking Record*:
 - Initials the final prepacking check.
 - Initials the reconciliation check of bottles, labels, and drugs.
 - Signs as the verifying pharmacist that correct prepacking procedures have been followed.

**Coast Provincial General Hospital
Antiretroviral Programme**

Standard Operating Procedures

Pharmacy Department

Coast Provincial General Hospital	
Requesting Antiretroviral Drugs	
Number of pages: 2	Procedure number: 101
Issued by: Name: Title: Date:	Record of amendments Date: Type:

Objective:

To describe the procedure for requesting antiretroviral drugs from FHI/IMPACT for the ART Programme.

Responsibility:

- Pharmacist in charge of the ARV bulk store or his/her designated proxy
- Pharmacist in charge of the ART Programme

Resources:

Form used to request ARVs from FHI:

ART Programme: Request to Supply Antiretroviral Drugs

- Is a single page letter.

Procedure:

- The pharmacist in charge of the ARV bulk store or his/her designated proxy completes the *ART Programme: Request to Supply Antiretroviral Drugs* as described below.
- The pharmacist in charge of the ART Programme checks the request and forwards it through the Chief Pharmacist to the Chief Administrator for his/her signature.
- The Chief Administrator returns the signed letter to the pharmacist in charge of the ART Programme, who forwards it to the Mombasa ART Programme Technical Assistance Partners (TAP) Coordinator at the FHI Mombasa Office.

Steps for completing the *ART Programme: Request to Supply Antiretroviral Drugs*:

1. For each ARV preparation enter:
 - The number of packs in stock in the ARV bulk store
 - The number of packs requested
 - Date the delivery is needed by
2. Sign and record the date that the request was prepared.

Distribution:

- The original is forwarded to the Mombasa ART Programme TAP Coordinator at the FHI Mombasa Office.
- One copy of the completed and signed *ART Programme: Request to Supply Antiretroviral Drugs* is kept in the ARV bulk store.
- One copy of the completed and signed *ART Programme: Request to Supply Antiretroviral Drugs* is retained by the Chief Pharmacist.
- The *ART Programme: Request to Supply Antiretroviral Drugs* is used to check receipts of ARVs from FHI—to check for discrepancies between what was ordered and what is received and/or listed on the invoice.

Coast Provincial General Hospital ART Programme: Request to Supply Antiretroviral Drugs

To: Dr John Adungosi,
Technical Assistance Partners (TAP) Coordinator, Mombasa ART Programme,
FHI/IMPACT

Coast Provincial General Hospital requests the following supplies for the ART Programme:

Product	Form	Strength	Pack Size	# Packs in Stock in CPGH ARV Bulk Store	# Packs Requested	Date Needed By
Stavudine (d4T)	Capsules	30mg	56			
Stavudine (d4T)	Capsules	40mg	56			
Lamivudine (3TC)	Tablets	150mg	60			
Efavirenz (EFV)	Capsules	600mg	30			
Nevirapine (NVP)	Tablets	200mg	60			
Zidovudine (AZT, ZDV)	Tablets	300mg	60			
Zidovudine (AZT, ZDV)	Tablets	100mg	100			
Didanosine (ddl)	Tablets	200mg	60			
Didanosine (ddl)	Tablets	50mg	60			
Kaletra (Lopinavir/ritonavir)	Capsules	133.33/33.33mg	180			
Nelfinavir (NFV)	Tablets	250mg	270			
Indinavir	Capsules	400mg	180			
Stavudine (d4T)	Powder for solution	1mg/ml	200ml			
Lamivudine (3TC)	Oral solution	10mg/ml	240ml			
Nevirapine (NVP)	Oral suspension	10mg/ml	240ml			
Zidovudine (AZT, ZDV)	Syrup	50mg/5ml	240ml			
Didanosine (ddl)	Powder for solution	883mg/5ml	2g/4oz			
			4g/8oz			
Kaletra (Lopinavir/Ritonavir)	Solution	80/20mg/ml	160ml			

Request prepared by:.....

Date...../200....

Kindly confirm the receipt of this request and arrange for deliveries to be made to CPGH Pharmacy.

Yours sincerely,

.....

Date...../200....

Chief Administrator

Coast Provincial General Hospital	
Receipt of Antiretroviral Drugs at ARV Bulk Store	
Number of pages: 3	Procedure number: 102
Issued by: Name:	Record of amendments
Title:	Date:
Date:	Type:

Objective:

To describe correct antiretroviral drug receiving procedure at the ARV bulk store.

Responsibility:

Documentation and receipt of the ARVs will be performed by the receiving officer (the designated pharmacist in charge of the ARV bulk store or his/her designated proxy).

Resources:

Forms used for documenting receipt of ARVs:

Counter Receipt Voucher (S13):

- Is a serially numbered, single copy form.
- Is used for payment for goods delivered.
- Is also used to check entries on the invoice from the supplier.
- Is an important document to be kept under lock and key at the ARV bulk store.

Confirmation of Receipt of Supplies/Equipment

- Is a single page form.

CPGH/FHI ART Delivery Book

- Is a bound book

Forms needed to check receipt of ARVs:

- *ART Programme: Request to Supply Antiretroviral Drugs*

Procedure:

The receiving officer will:

- Meet with the delivery personnel and sign for the delivery
- Before signing, inspect and check the order against the invoice/delivery note and *ART Programme: Request to Supply Antiretroviral Drugs* and look for the following discrepancies:
 - Broken, cracked, or leaking bottles or bottles where seals are broken
 - Broken tablets
 - Drugs that arrive past their expiration date
 - Items that have no labels
 - Refrigerated items that arrive at room temperature or are warm
 - Inappropriate storage procedure during transportation of refrigerated items
 - Requirements from the tender that have not been met
 - Items listed on the invoice that are missing from the shipment
 - Items received that were not ordered or were not listed on the invoice
- Record all discrepancies on the *Shipment Discrepancy Report* as described in procedure 201: *Shipment Discrepancy Report*.

- Separate all damaged or expired medications and inform the FHI Mombasa Office, who will arrange for an exchange with the supplier.
- Send all refrigerated items directly to ARV bulk store refrigerator.
- Record all ARV items delivered (whether they were donated or purchased) on a *Counter Receipt Voucher (S13)*. An *S13* and directions for completing it are shown below.
- Check off each item received and endorse the invoice/delivery note with the quantity received and any discrepancies. Sign and date the invoice/delivery note.
- Complete *Confirmation of Receipt of Supplies/Equipment*. The pharmacist in charge of the ART Programme forwards it through the Chief Pharmacist to the Chief Administrator for his/her signature.
- The Chief Administrator returns the signed form to the pharmacist in charge of the ART Programme, who forwards it to the Mombasa ART Programme Technical Assistance Partners (TAP) Coordinator at the FHI Mombasa Office.

Steps for completing the *Counter Receipt Voucher (S13)*:

1. Enter Ministry (*of Health*) Dept./Branch (*Medical*) and Unit (*CPGH/ART*)
2. Record
 - Source of items(s)
 - Code number (number listed in the Kenya Essential Drug List that is specific to each drug, strength/concentration, and dosage form)
 - Description of item
 - Generic name
 - Strength/concentration
 - Dosage form
 - Unit of issue (e.g., number of tablets per package)
 - Quantity of units received
 - Value
 - Remarks (record *S3* number—specific to each drug, strength/concentration, and dosage form—and expiry date for each ARV preparation received)
3. The issuing officer (person delivering the items) and the receiving officer sign the *Counter Receipt Voucher (S13)*.

Steps for completing the *Confirmation of Receipt of Supplies/Equipment*:

1. For each ARV preparation received enter:
 - The product name, form, strength, and pack size
 - The number of packs requested
 - The number of packs received
 - Date the delivery is received
2. Sign and record the date that the request was received.

Steps for completing the *CPGH/FHI ART Delivery Book*:

1. For each delivery note/invoice sent to FHI enter:
 - No: The next consecutive number
 - Date the document is sent to FHI
 - Delivered to: FHI
 - Content: Invoice or Delivery Note and the document number
 - Signature of the person receiving the document
 - Date and time the document is received

Distribution:

- The original invoice/delivery note is sent to FHI Mombasa Office with the *Confirmation of Receipt of Supplies/Equipment* together with the *CPGH/FHI ART Delivery Book*. If there are any discrepancies, a copy of the *Shipment Discrepancy Report* is also attached to the original invoice/delivery note.
- The *S13* forms are stored in the ARV bulk store under the custody of the designated pharmacist. They are kept with the booklet containing the *Stores Ledger and Stock Control Card (S3)* forms.
- The completed *S13* is used to complete the *Stores Ledger and Stock Control Cards (S3)* and *Bulk Store Bin Cards (S5)* as described in procedure 103: *Record Keeping at ARV Bulk Store*.
- The information on the *S13* will be used to complete the *Antiretroviral Internal Audit Record* and to verify information on *Bulk Store Bin Cards (S5)* and *Stores Ledger and Stock Control Cards (S3)* as described in procedure 501: *Internal Audit of Antiretroviral Drugs*.

FORM: S13

**REPUBLIC OF KENYA
COUNTER RECEIPT VOUCHER**

Serial No:.....

Ministry.....Dept./Branch.....Unit:.....

Received the items listed below from (Source).....

Code No.	Item Description	Unit	Quantity	Value	Remarks

Order No. _____ Invoice No. _____ OR _____

Issuing Officer:.....Signature..... Designation:.....

Certified that the quantities received have been taken on-charge.

Receiving Officer:.....Signature..... Designation :.....

Account No:.....

Date:

GPK 090-1980bKS—5/2002

**Mombasa ART Programme :
Confirmation of Receipt of Supplies/Equipment**

To: Dr John Adungosi,
 Technical Assistance Partners (TAP) Coordinator, Mombasa ART Programme
 FHI/IMPACT
 P.O. Box 16981
 Mombasa
jadungosi@fhi.or.ke ; Tel: 041 314065/6, Fax: 041 228507, Cell: 0722 702573

This is to confirm the receipt of the following supplies and/or equipment provided by the Programme to Coast Provincial General Hospital/Port Reitz District Hospital/Bomu Medical Centre/Magongo Health Centre:

Product	Form	Strength	Pack/Item Size	Amount Requested	Amount Received	Batch Number of Stock Received	Expiry Date of Stock Received	Date Received

These items have been taken on-charge vide ref. nos:

.....

Received by:.....

.....

Date...../200...

(Name/Designation/Signature)

Yours sincerely,

.....

Chief Administrator/District MOH/Municipal MOH/Director, Bomu

Date...../200...

Coast Provincial General Hospital	
Record Keeping at ARV Bulk Store	
Number of pages: 7	Procedure number: 103
Issued by: Name: Title: Date:	Record of amendments Date: Type:

Objective :

To describe procedures for maintaining records for all activities that concern stock in the ARV bulk store.

Responsibility:

Documentation and recording of all ARV drug receipts and issues from the ARV bulk store is the responsibility of the pharmacist in charge of the ARV bulk store or his/her designated proxy.

Resources:

Forms used for record keeping of ARVs:

Stores and Ledger Stock Control Card (S3):

- Is a serially numbered single copy card bound in a booklet
- Must exist for each ARV preparation.
- Is used for checking physical stock against records in the ARV bulk store.
- Every receipt and issue must be entered at the time that stock is received or removed, without exception.

Bulk Store Bin Card (S5):

- Is a serially numbered single copy card.
- Must exist for each ARV preparation.
- Is used for ARV inventory control.
- Every receipt and issue must be entered at the time that stock is received or removed, without exception.
- A supply of S5 cards is to be kept as a stock item in the ARV bulk store in the custody of the pharmacist in charge of the ARV bulk store.

Forms needed to complete record keeping:

- *Counter Receipt Voucher (S13)*

Procedures:

- When ARV drugs arrive at the ARV bulk store, the receiving officer completes the *Counter Receipt Voucher (S13)* as described in procedure #102: *Receipt of Antiretroviral Drugs at ARV Bulk Store*.
- The information from the S13 is used to complete the *Stores Ledger and Stock Control Card (S3)*. An S3 and directions for completing the form are described below.
- The information from the S3 is used to complete the *Bulk Store Bin Card (S5)*. An S5 and directions for completing the form are described below.
- Receipts are to be entered in red ink and issues in blue or black ink.
- Cards must be used until all entries are completed on both sides of the card Balances from the completed card must be transferred to a new card.

- The designated pharmacy staff should check the physical count of each ARV preparation in stock any time there is a receipt or issue at the ARV bulk store to ensure that the physical stock balance corresponds with that shown on the *Bulk Store Bin Card (S5)*. If a difference is found, a *Stock Count Discrepancy Report* is completed as described in procedure 202: *Stock Count Discrepancy Report*.

Steps for completing the *Stores Ledger and Stock Control Card (S3)*:

1. Complete a separate *S3* for differing strengths/concentrations and units of issue (i.e., for each different pack size).
2. Record for a new card:
 - Item code number (number listed in the Kenya Essential Drug List that is specific to each drug, strength/concentration, and dosage form)
 - Description of item
 - Generic name
 - Strength/concentration
 - Dosage form
 - Unit of Issue : pack size (e.g., number of tablets per package)
 - Enter Ministry (*MOH*); Department (*Medical*); Location (*CPGH/ART*)
 - Card No.: for first card for a new item write *New*
3. Receipts: record when receiving stock
 - Date: of receipt
 - Voucher Number: the serial number from the corresponding *S13*
 - Supplier/Requisitioning Office : source of goods or supplier
 - Quantity: number of units received
 - Invoice Unit Price: the supplier's cost per unit in Kenya shillings (e.g., Ksh. 300 per 100ml bottle)
 - Value: total value in Kenya shillings
 - Balances
 - Quantity: new stock balance
 - Value: total value of stock in Kenya shillings
4. Issues: record when issuing stock
 - Date: of issue
 - Voucher Number: the serial number from the corresponding *S13*
 - Supplier/Requisitioning Office: department/unit requisitioning the drugs
 - Quantity: number of units ordered
 - Average Unit Price: average cost per unit in Kenya shillings (e.g., Ksh. 300 per 100ml bottle)
 - Value: total value in Kenya shillings
 - Balances
 - Quantity: quantity left in stock
 - Value: total value of stock remaining in Kenya shillings
5. Consumption Record: record
 - Monthly consumption: At the end of each month, calculate the monthly usage and record here. Do not count expired stock removed.
 - Annual Usage: At the end of each year, calculate the annual consumption and record here.
6. Forecast Requirements: record
 - Average Monthly Usage: Calculate from consumption records if usage is at steady state. If Programme is still scaling up, use current monthly usage.
 - Buffer Stock: safety stock to cater for any delays in the supply schedule
 - Reorder Levels: the stock level at which an order is to be placed

- Reorder Quantity: stock to be ordered if usage is at steady state. If Programme is still scaling up use current usage.
 - E.O.Q. (Economic Order Quantity): minimum order quantity
 - Size: dimensions of E.O.Q.
 - Weight: of E.O.Q.
 - Packaging: of E.O.Q.
7. Dues In: record details of outstanding orders placed by ARV bulk store
 - Date: of the order
 - Order: number
 - Quantity: ordered
 - Date received
 - Quantity received
 8. Dues Out: record details of outstanding requisitions to be filled by ARV bulk store
 - a. Date: requisition was received
 - b. Order: number
 - c. Quantity: to be supplied
 - d. Date issued
 - e. Quantity issued
 9. Lead time: Time between ordering and receiving drugs , should be recalculated every three months for the ART Programme. Record
 - Order: average time taken from when the pharmacist in charge of the ARV bulk store requests for an order to be made to when the supplier receives the order
 - Period: average time taken to receive this item in the ARV bulk store from when the supplier receives an order
 10. Stock Checks: record
 - Date : of stock check
 - Surp: any surplus—stock in excess of stock balance
 - Def: any deficit—stock shortage compared to stock balance
 - Initials : of person performing the stockcheck

Steps for completing the *Bulk Store Bin Card (S5)*:

1. Complete a separate bin card for differing strengths/concentrations and units of issue (i.e., for each different pack size)
2. Record for a new card:
 - Item Code No. (number listed in the Kenya Essential Drug List that is specific to each drug, strength/concentration, and dosage form)
 - Item Description:
 - Generic name
 - Strength/concentration
 - Dosage form
 - Unit of issue: pack size (e.g., number of tablets per package)
 - Storage requirements (e.g., refrigeration)
 - Ledger Card Number (the serial number from the corresponding S3 form)
 - Stock location (if another location is also used, the two should be frequently reconciled)
 - B/F from Card No. : for first card for a new item write *New*
 - Balance B/F (Brought Forward) is entered as the first entry in a new card. For a new product write *New*. When a set of columns is completed on one side, the Balance C/F (Carried Forward) is recorded in the next set of columns at the Balance B/F.

3. Record when receiving stock:
 - Date: (stock received)
 - Issue/receipt voucher no. :
 - The reference number of the voucher for goods received from the supplier, local purchase, or exchange
 - Expiry date of product for each receipt
 - Receipt: quantity received
 - Balance: calculated by increasing the previous balance for goods received
 - Initials: of person receiving stock
4. Record when issuing stock:
 - Date: (stock issued)
 - Issue/receipt voucher no.: the reference number of the voucher for goods issued to the different user departments or units or other facility sites
 - Issue: quantity issued
 - Balance: calculated by decreasing the previous balance for goods issued
 - Initials: of person issuing stock

Distribution:

- The *S3* cards are kept in a serialized booklet and are stored in the ARV bulk store under the custody of the designated pharmacist. The *S3* cards are kept with the *Counter Receipt Voucher (S13)* forms.
- The *S5* cards are kept with the goods in the ARV bulk store. Each *S5* bin card is kept on top on the stock of the corresponding item.
- Old cards must be retained for 5 years from date of last entry.
- The information on the *Bulk Store Bin Cards (S5)* and *Stores Ledger and Stock Control Cards (S3)* will be used to complete the *Antiretroviral Internal Audit Record* as described in procedure 501: *Internal Audit of Antiretroviral Drugs*.

FORM: S3

GOVERNMENT OF KENYA
STORES LEDGER AND STOCK CONTROL CARD

Serial No.

ITEM CODE No.

DESCRIPTION.....

UNIT OF ISSUE.....

MINISTRY

DEPT/BRANCH.....

LOCATION.....

Date	Voucher Number	Supplier or Requisitioning Office	RECEIPTS			ISSUES			BALANCES		Month/Year	CONSUMPTION RECORD			
			Quantity	Invoice Unit Price	Value	Quantity	Average Unit Price	Value	Quantity	Value		20.....	20.....	20.....	20.....
	B/F	Card No.									July				
											August				
											September				
											October				
											November				
											December				
											January				
											February				
											March				
											April				
											May				
											June				
											Annual Usage				
											<i>FORECAST REQUIREMENTS</i>				
												20.....	20.....	20.....	20.....
											Average Monthly Usage				
											Buffer Stock				
											Reorder Levels				
											Reorder Quantity				
											E.O.Q.	SIZE			
											WEIGHT	PACKAGING			
	C/F														

Coast Provincial General Hospital	
Internal Antiretroviral Drug Distribution	
Number of pages: 3	Procedure number: 104
Issued by: Name:	Record of amendments
Title:	Date:
Date:	Type:

Objective:

To describe the procedure for distributing antiretroviral drugs from the ARV bulk store to the outpatient pharmacy ARV stock or from the outpatient pharmacy ARV stock to the wards.

Responsibility:

Issuing:

- Pharmacist in charge of the ARV bulk store or his/her designated proxy

Receiving:

- Designated receiving officer: Designated Pharmacist or his/her designated proxy; the nursing officer in charge of the unit or his/her designated proxy

Resources:

Forms used to record ARV drug distribution:

Counter Requisition and Issue Voucher (S11):

- Is a serially numbered triplicate form.
- Is used for issue, delivery, and receipt of stock.
- Is used by the outpatient pharmacy to order from the ARV bulk store, and by wards and other departments to order from the outpatient pharmacy.
- Is kept in each department requiring its use. Additional supplies of the form can be requisitioned from the ARV bulk store.

Forms needed to complete internal drug distribution for issue of ARVs from the bulk store to the outpatient pharmacy:

- *Bulk Store Bin Cards (S5)*
- *Stores Ledger and Stock Control Card (S3)*
- *Hospital Pharmacy Bin Card (MOH 999)*
- *Drugs and Revenue Register*

Forms needed to complete internal drug distribution for issue of ARVs from the outpatient pharmacy to the wards:

- *Stores Ledger and Stock Control Card (S3)*
- *Medication Treatment Sheet (MOH 306 Rev.)*
- *Hospital Pharmacy Bin Card (MOH 999)*
- *Drugs and Revenue Register*

Procedure:

1. Procedure for the outpatient pharmacy to order and receive ARVs from the ARV bulk store:
 - Complete *Counter Requisition and Issue Voucher (S11)* as described below.
 - Make appropriate entries on the *Bulk Store Bin Cards (S5)* and the *Stores Ledger and Stock Control Card (S3)* as described in procedure 103: *Record Keeping at ARV Bulk Store* upon issue from the ARV bulk store.
 - Make appropriate entries on the *Hospital Pharmacy Bin Card (MOH 999)* and the *Drugs and Revenue Register* as described in procedure 106: *Record Keeping at the Outpatient Pharmacy* upon receipt of ARVs at the outpatient pharmacy from the ARV bulk store.

2. Procedure for the outpatient pharmacy to issue ARVs to wards:
 - Complete *Counter Requisition and Issue Voucher (S11)* as described below.
 - Receive completed *Medication Treatment Sheet (MOH 306 Rev.)* as described in procedure 108: *Issuing Antiretroviral Drugs to Inpatients*.
 - Ensure that the prescriber has signed the *Medication Treatment Sheet (MOH 306 Rev.)*.
 - Check that the patient is on the ART Programme eligibility list.
 - Make appropriate entries on the *Hospital Pharmacy Bin Card (MOH 999)* and the *Drugs and Revenue Register* as described in procedure 106: *Record Keeping at the Outpatient Pharmacy* upon issue to wards.

Steps for completing the *Counter Requisition and Issue Voucher (S11)*:

1. Designated person, authorised to requisition the stock, records:
 - Ministry (of Health) Depart./Branch (Medical) and Unit (e.g., CPGH/ART)
 - To (Issue point): e.g., ARV bulk store
 - Issue to (Point of use): receiving location (e.g., outpatient pharmacy)
 - Code No.: number listed in the Kenya Essential Drug List which is specific to each drug, strength/concentration and dosage form
 - Item Description:
 - generic name
 - strength/concentration
 - dosage form
 - Unit of Issue: the quantity in the container or pack size (e.g., 56 tablets per pack)
 - Quantity Required: the number of units of issue required (e.g., 10 packets of 56 tablets each)
 - Account No.: designated number if appropriate
 - Date: of requisition
 - Requisitioning Officer: name, designation, and signature
2. Designated person, authorised to issue the stock, records:
 - Quantity Issued: the number of units of issue which are actually issued
 - Value: of total amount of stock issued (calculated using average unit price)
 - Remarks/Purpose: expiry date of stock issued
 - Issued by: issuing officer's name and signature
 - Date: issued
3. Designated person authorised to receive the stock checks identity and quantity of ARV issued and records:
 - Received by: name, designation, and signature

Distribution:

The *Counter Requisition and Issue Voucher (S11)* is to be completed in triplicate:

- The original is kept by the ARV bulk store for stock issued to the outpatient pharmacy.
- For stock issued to inpatients, the original copy is retained by the outpatient pharmacy.
- Duplicate is retained by the initiating department.
- Triplicate remains in the *S11* book.

FORM S11

Serial No.....

REPUBLIC OF KENYA
COUNTER REQUISITION AND ISSUE VOUCHER

Ministry

Dept/Branch.....

Unit.....

To (Issue point).....

Please issue the stores listed below to (Point of use).....

Code No.	Item Description	Unit of Issue	Quantity Required	Quantity Issued	Value	Remarks/Purpose

Account No:

Date:

Requisitioning Officer:

Designation:

Sign:

Issued by:

Signature:

Date:

Received by:

Designation:

Sign:

Coast Provincial General Hospital	
External Antiretroviral Drug Distribution	
Number of pages: 4	Procedure number: 105
Issued by: Name:	Record of amendments
Title:	Date:
Date:	Type:

Objective :

To describe the procedure for distributing antiretroviral drugs from the ARV bulk store to the pharmacy of a peripheral facility (e.g., Port Reitz District Hospital, Magongo Municipal Clinic, and Bomu (Mkomani) Clinic).

Responsibility:

- Issuing officer: The pharmacist in charge of the ARV bulk store is responsible for filling out the *Issue and Receipt Voucher (S12)* as described below.
- Receiving officer: Pharmacy staff or the nurse in charge of the pharmacy at the peripheral site.
- Authorizing officer: Designated person at the peripheral facility.

Resources:

Forms used to record external antiretroviral drug distribution:

Issue and Receipt Voucher (S12):

- Is serially numbered, bound in a book. Each voucher has six pages, one original and five copies.
- Is used to transfer ARV stocks from CPGH to other peripheral facilities.

Forms needed to complete external drug distribution:

- *Bulk Store Bin Cards (S5)*
- *Stores Ledger and Stock Control Card (S3)*

Procedure:

- The peripheral facility shall produce a signed letter with an accompanying list of its consumption-based needs (including number of patients on each drug preparation and dose), signed by designated authorising officer.
- When the letter of request and list is received, the pharmacist in charge of the ARV bulk store will complete the *Issue and Receipt Voucher (S12)* for the peripheral facility as described below .
- Make appropriate entries to the *Bulk Store Bin Cards (S5)* and the *Stores Ledger and Stock Control Card (S3)* as described in procedure 103: *Record Keeping at ARV Bulk Store*.

Steps for completing the *Issue and Receipt Voucher (S12)*:

1. The pharmacist in charge of the ARV bulk store or designated proxy records :

Under Supplier/Issuing Office

- Name of Facility: requesting drugs
- Supplier/Issuing Office: *CPGH*
- Min./Dept: *Health/Medical*
- Address : of CPGH
- Issuing officer: pharmacist's name
- Designation and pharmacy stamp
- Merchant name/Address: is left blank

- Date: date stock issued
- Issue approved by: name of designated authorising officer signing letter of request
- Date: date of signed letter
- Stores packed by: issuing pharmacist's name
- Stores recorded by: issuing pharmacist's name
- Mode of transportation: record how ARVs were sent, or if collected, by whom
- Designation and pharmacy stamp
- L.P.O. No.: is left blank
- Delivery note: is left blank
- Invoice: is left blank

In grid:

- Item code: number listed in the Kenya Essential Drug List which is specific to each drug, strength/concentration, and dosage form
 - Description: of item
 - generic name
 - strength/concentration
 - dosage form
 - Unit: pack size of unit issued
 - Quantity Required/Ordered: number of packs ordered in letter of request
 - Quantity Issued/Received: number of packs actually issued
 - Quantity to follow: if applicable, number of packs to be issued at a later date
 - Rate: average cost per unit pack
 - Total value: of stock supplied
 - Stock Balance: CPGH stock balance
 - Ledger Folio No.: S3 number
 - Certified that the above items/s has/have been Received/Issued and recorded on Ledger/Inventory: signed by issuing pharmacist
 - Signature of Issuing Officer and Date
2. The requisitioning/receiving facility records upon receipt of ARVs:
Under Requisitioning/Receiving Office:
- Min./Dept.: e.g., Health /Port Reitz District Hospital
 - Indenting unit: *Pharmacy*
 - Address: of indenting unit
 - Receiving officer: name
 - Designation and stamp:
 - Reasons for demand: Write A
 - Indent approved by: the name of the designated authorising officer signing letter of request
 - Date: date of letter of request
 - Address for delivery: address of receiving facility
 - Receipt recorded by: name of person recording the receipt of ARVs
 - Chargeable to: is left blank
 - Vote/Head: is left blank
 - S/Head/Item No.: is left blank
 - Quantity Issued Received: number of packs received
 - Certified that the above items/s has/have been Received/Issued and recorded on Ledger/Inventory: signed by receiving pharmacist
 - Signature of Receiving Officer and Date

Distribution:

- The *S12* document has six pages.
 - The original is retained by CPGH ARV bulk store.
 - The receiving facility receives the second and third pages.
 - The fourth page is sent to the receiving facility's accounts department.
 - The fifth page is sent to the CPGH accounts department
 - The sixth page remains in the book.
- The *S12* will be filed together with the letter of request and accompanying needs list from the peripheral facility in the CPGH ARV bulk store.

REPUBLIC OF KENYA
ISSUE AND RECEIPT VOUCHER

Name of Facility:

Supplier/Issuing Office :				Requisitioning/Receiving Office:			
Min./Dept:	Issue approved by:	Min./Dept.:	Indent approved by:				
Address:	Date:	Indenting unit:	Date:				
.....	Stores packed by:	Address:	Address for delivery:				
Issuing officer:	Stores recorded by:				
Designation and stamp:	Mode of transportation:	Receiving officer:	Receipt recorded by:				
Merchant:	Designation and stamp:	Designation and stamp:				
Address:	L.P.O. No.:	Chargeable to:				
.....	Delivery note:	Reasons for demand (see note 4):	Vote/Head:				
Date:	Invoice:	S/Head/Item No.:				

Item	Item code	Description	Unit	Quantity Required/Ordered	Quantity Issued/Received	Quantity to follow	Rate	Total value		Stock Balance	Ledger Folio. No.	Remarks
								Sh.	Cts.			
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
								Total				

Certified that the above items/s has/have been Received/Issued and recorded on Ledger/Inventory

Signature of Issuing Officer and Date

Signature of Receiving Officer and Date

Coast Provincial General Hospital	
Record Keeping at the Outpatient Pharmacy	
Number of pages: 10 Issued by: Name: Title: Date:	Procedure number: 106 Record of amendments Date: Type:

Objective :

To describe the procedure for maintaining records of issues and receipts of ARV drugs at the outpatient pharmacy and of fees collected.

Responsibility:

Documentation and recording of all ARV receipts and issues from the ARV bulk store to the outpatient pharmacy is the responsibility of the designated pharmacist or pharmaceutical technologist in charge of dispensing ARVs or his/her designated proxy.

Resources:

Forms used for record keeping of ARVs in the outpatient pharmacy:

Hospital Pharmacy Bin Card (MOH 999):

- Must exist for each ARV preparation.
- Is a serially numbered, single-copy, loose-leaf form.
- Is used for ARV inventory control in the outpatient pharmacy.
- Entries must be made for every receipt and issue at the time that stock is received or removed, without exception.

Drugs and Revenue Register:

- Is a bound book of single-copy forms.
- Is used as a countercheck for inventory control of all ARVs issued from the outpatient pharmacy.
- Is also used as an accounting record of all fees collected or incurred

ART Patient Dispensing Record

- Is a single loose-leaf form.
- Has a summary reference page listing all patients and their ART regimens.
- Is used to check for discrepancies in repeat ART prescriptions and to check whether patients are using more or less medicine than is expected.

Procedure:

- All receipts of stock from the ARV bulk store must be documented on *Hospital Pharmacy Bin Card (MOH 999)* and in the *Drugs and Revenue Register* as described below.
- All issues of stock, both to outpatients and inpatients must be documented on *Hospital Pharmacy Bin Card (MOH 999)* and in the *Drugs and Revenue Register* as described below.
- All issues must be recorded on the *ART Patient Dispensing Record* as described below.
- All entries must be completed at time of receipt or issue.
- Receipts on *Hospital Pharmacy Bin Card (MOH 999)* are to be made in red ink and issues in blue or black ink.
- All entries in the *Drugs and Revenue Register* are to be made in blue or black ink.

- Each *Hospital Pharmacy Bin Card (MOH 999)* must be used until all entries are completed on both sides of the card. Balances from the completed card must be transferred to a new card.
- The designated pharmacy staff should check the physical count of each ARV preparation in stock any time there is a receipt or issue at the outpatient pharmacy to ensure that the physical stock balance corresponds with that shown on the *Hospital Pharmacy Bin Card (MOH 999)* under remarks. If a difference is found, a *Stock Count Discrepancy Report* is completed as described in procedure 202: *Stock Count Discrepancy Report*.
- At the end of each day or when a new person takes over as the designated person to dispense ARVs, the person handing over must sign the *Drugs and Revenue Register* after his or her last entry.

Steps for completing the *Hospital Pharmacy Bin Card (MOH 999)*:

1. Complete a separate *MOH 999* for differing strengths/concentrations and units of issue (i.e., for each different pack size).
2. Record for a new card:
 - Hospital: *CPGH*
 - Description of item:
 - generic drug name
 - strength/concentration
 - dosage form
 - pack size
 - Unit of Issue : *1 tablet* or *1 capsule* or *1 ml*. If liquids are always issued in whole bottles, this can be the unit of issue (e.g., 240ml).
 - Code Number (number listed in the Kenya Essential Drug List which is specific to each drug, strength/concentration, and dosage form)
 - Remarks: record the balance brought forward or stock received for new product
3. Record when receiving stock:
 - Date: of receipt
 - Issue/Receipt Voucher Number: serial number from the *Counter Requisition and Issue Voucher (S11)*
 - From: *ARV bulk store*
 - Quantity: Record number of units (e.g., tablets; ml) received
 - Remarks: Record new stock balance (in units of issue)
4. Record when issuing stock:
 - Date: of issue
 - Issue/Receipt Voucher Number:
 - If issuing to wards, record inpatient number
 - If issuing to patient, record outpatient number
 - Issued:
 - To: record OP or IP/ward
 - Quantity issued
 - Issued by:
 - Name
 - Signature
 - Received by: For inpatients, signed by person receiving the drugs; for outpatients, name of prescribing doctor
 - Name
 - Signature
 - Remarks: Record new stock balance (in units of issue)

Steps for completing the *Drugs and Revenue Register*:

1. Record for each new page:
 - 1–20: record one ARV drug preparation name per numbered column
 - Balance B/F: record the balance brought forward or *new* for a new ARV preparation
2. Record when receiving stock (at top of page):
 - Quantity Received: in units of issue (e.g. , tablets ; capsules)
 - *SII* Number
 - Total in Hand: balance forward plus what was received
3. Record when issuing stock:
 - For each new day, enter date under Patient Name column and begin entries for that day on the next line. If page is used for more than one day, enter the new date on a new line.
 - OP. No./IP. No. : patient’s outpatient or inpatient number
 - Patient Name
 - Drug Code/Name: enter the number that corresponds to the drug at the top of the page (i.e., 1–20)
 - Drug Qty. : quantity of drug dispensed
 - Receipt #, Waiver #, Exempt: for USAID/FHI-funded drugs enter *Exempt*
 - Amt. (Shs.): If a fee is paid, enter the amount of total transaction in KSh.
 - Sign. of Issuing officer: signature of designated pharmaceutical technologist or pharmacist dispensing the prescription
4. Record when the page is complete (when no more space is left to enter either receipts or issues)
 - Quantity Used (at top of page): add up the number of units issued for each drug preparation
 - Balance (at top of page): calculate the balance (check that balance corresponds with physical stock count) and carry it forward to next page
 - Page Totals (at bottom of page)
 - Total Patients
 - Total Services: total number of items issued
 - Total Cash: receipts and number of corresponding items
 - Waivers: number of corresponding items
 - Exemptions: number of corresponding items

Steps for completing the *ART Patient Dispensing Record*:

1. For a new patient approved by the Eligibility Committee, record on the *ART Patient Dispensing Record* summary page :
 - ART Patient Record Number: fill in the next consecutive number
 - Patient’s Name
 - OP/IP Number: patient’s outpatient or inpatient number
 - Date Approved by Eligibility Committee
2. For a patient collecting his/her first prescription:
 - Check that the regimen follows the standard ART guidelines for the ART Programme. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription. Fill out a *Medication Error Report* as described in procedure 302: *Medication Error Reporting* for any errors discovered.
 - Record on the *ART Patient Dispensing Record* summary page:
 - Date Started on ART
 - Tick ARV drug preparations for current regimen in columns opposite Patient’s Name
 - For **adults** start a new *ART Patient Dispensing Record - Adults* for each patient and record:
 - ART Patient Record No: from summary page

- Patient's Name
 - IP/OP Number: patient's outpatient or inpatient number
 - Age
 - Sex
 - Allergies/ADR to ART
 - Date approved by the Eligibility Committee
 - Date started on ART
 - ART Regimen:
 - Date started on current regimen
 - Current regimen (drug name, form dose, frequency)
 - Dispensing Record:
 - Date: date first supply issued
 - No: days: number of days issued
 - DAART: tick if patient received the supply in prepacks for DAART
 - For **children** start a new *ART Patient Dispensing Record - Children* for each patient and record:
 - ART Patient Record Number : from summary page
 - Patient's Name
 - IP/OP Number: patient's outpatient or inpatient number
 - Age
 - Sex
 - Allergies/ADR to ART
 - Date approved by the Eligibility Committee
 - Date started on ART
 - ART Regimen:
 - Date started on current regimen
 - Current regimen: drug name, form and strength/concentration, and frequency
 - Dispensing Record:
 - Date: date first supply issued
 - Weight: current weight of patient in kg
 - Abbreviation of each drug name (e.g. , NVP) and current dose in ml for liquids, in mg for tablets
 - No: days: number of days issued
3. For a repeat issue:
- Check the summary page and find the ART Patient Record Number and pull the *ART Patient Dispensing Record* for that patient
 - Use the *ART Patient Dispensing Record* to countercheck the regimen and dose prescribed and that the patient is not collecting the prescription earlier or later than expected (by three or more days). For children, check current weight and that the dose is correct for current weight. Alert the prescriber/adherence nurse of any discrepancies before dispensing the prescription. Fill out a *Medication Error Report* as described in procedure 302: *Medication Error Reporting* for any errors discovered.
 - Record for **adults** :
 - Date: date of issue
 - No: days: number of days issued
 - DAART: tick if patient received the supply in prepacks for DAART
 - Record for **children**
 - Date: date of issue
 - Weight: current weight in kg
 - Abbreviation of each drug name (e.g. , NVP) and current dose in ml for liquids, in mg for tablets

- No: days: number of days issued
- Record for both **adults** and **children**: if the regimen has been changed
 - Date discontinued: above the previous regimen
 - Date started on current regimen
 - Current regimen (drug name, form dose, frequency)
 - Amend the Current ART Regimen on the summary page
- Record for both **adults** and **children**: if the regimen has been discontinued
 - Date ART stopped
 - Date discontinued: above the previous regimen

Distribution:

- The *MOH 999* forms and the *Drugs and Revenue Register* are kept with the ARVs in the outpatient pharmacy in a secure locked cupboard.
- Old *MOH 999* forms must be retained for 5 years from date of last entry.
- *ART Patient Dispensing Records* are kept in the pharmacy with the *Prescription Forms (MOH 501)*.
- The information from *MOH 999* and *ART Patient Dispensing Records* will be used to complete the *Antiretroviral Internal Audit Record* as described in procedure 501: *Internal Audit of Antiretroviral Drugs*.

DRUGS AND REVENUE REGISTER

Folio No.....

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
BALANCE B/F																				
QUANTITY RECEIVED S11.No																				
TOTAL IN HAND																				
QUANTITY USED																				
BALANCE																				

OP.NO./ IP.NO.	PATIENT NAME	DRUG CODE/ NAME	DRUG QTY.	RECEIPT # WAIVER # EXEMPT	AMT. (Shs.)	SIGN. OF ISSUING OFFICER	OP.NO./ IP.NO.	PATIENT NAME	DRUG CODE/ NAME	DRUG QTY.	RECEIPT # WAIVER # EXEMPT	AMT. (Shs.)	SIGN. OF ISSUING OFFICER

PAGE TOTALS	TOTAL PATIENTS	TOTAL SERVICES		TOTAL CASH (Receipts)		WAIVERS		EXEMPTIONS					
		Items	Kshs.	Items	Kshs.	Items	Kshs.	Items	Kshs.	Items	Kshs.	Items	Kshs.

ART Patient Dispensing Record – Summary Page

ART Patient Record Number	Patient's Name	OP/IP Number	Date Approved by Eligibility Committee	Date Started on ART	Current ART Regimen (✓ as appropriate)															
					d4T Cap 30mg	d4T Cap 40mg	3TC Tab 150mg	EFV Cap 600mg	NVP Tab 200mg	ddl Tab 50mg	ddl Tab 200mg	ZDV Tab 100mg	Kaletra Cap 133/33mg	NFV Tab 250mg	d4T oral soln 1mg/ml	3TC oral soln 10mg/ml	NVP oral susp 10mg/ml	ddl soln 88.3mg/5ml	AZT syr 50mg/5ml	Kaletra oral soln 80/20mg/ml
1																				
2																				
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19																				
20																				

ART Patient Dispensing Record – CHILDREN

ART Patient Record No:.....

Patient's Name:	Age:	Sex:	Date approved by Eligibility Committee:
IP/OP Number:	Allergies/ADR to ART:		Date started on ART:
			Date ART stopped:

ART Regimen (*Record drug name, form and strength/concentration & frequency – RECORD DOSE BELOW*)

Date started:	Date discontinued:	Date started:	Date discontinued:	Date started:	Date discontinued:
1.		1.		1.	
2.		2.		2.	
3.		3.		3.	

Dispensing Record (*Record date current weight, drug name, dose dispensed, and number of days dispensed*)

Date	Weight (Kg)	Drug	Dose (in ml)	No: days	Date	Weight (Kg)	Drug	Dose (in ml)	No: days	Date	Weight (Kg)	Drug	Dose (in ml)	No: days
		1.					1.					1.		
		2.					2.					2.		
		3.					3.					3.		
		1.					1.					1.		
		2.					2.					2.		
		3.					3.					3.		
		1.					1.					1.		
		2.					2.					2.		
		3.					3.					3.		
		1.					1.					1.		
		2.					2.					2.		
		3.					3.					3.		
		1.					1.					1.		
		2.					2.					2.		
		3.					3.					3.		

Coast Provincial General Hospital	
Issuing Antiretroviral Drugs to Outpatients	
Number of pages: 4	Procedure number: 107
Issued by: Name:	Record of amendments
Title:	Date:
Date:	Type:

Objective :

To describe correct procedures for issuing and dispensing antiretroviral drugs to outpatients. Good dispensing practices ensure that an effective form of the right drug is delivered to the right patient in the prescribed dosage and quantity, with clear instructions, and in a package that maintains the potency of the drug.

Responsibility:

- The authorized doctor/clinical officer is responsible for issuing the ART prescription (*MOH 501*)
- The designated pharmacist or pharmacy technologist is responsible for dispensing the ART prescription.

Resources:

Form used for issuing ARVs to outpatients :

Prescription form (MOH 501)

- Is a single-copy, loose-leaf form

Forms used to record issues of ARVs to outpatients:

- *Hospital Pharmacy Bin Card (MOH 999)*
- *Drugs and Revenue Register*
- *ART Patient Dispensing Records*

Procedure:

1. Authorized physician completes *Prescription Form (MOH 501)* for each eligible patient. A properly completed *MOH 501* for the ART Programme must have the following information:
 - CCC written or stamped at the top of the prescription
 - Patient's full name
 - Department
 - Number: Patient outpatient (OP) number
 - Date : date prescription was written
 - Generic name of drug, e.g. , lamivudine
 - Strength/concentration
 - Dosage form
 - Quantity to be issued or duration (maximum one month)
 - Frequency of drug administration (dosage)
 - Prescriber's signature
2. Upon receiving *MOH 501* the designated pharmacist or pharmacy technologist must:
 - Check that the patient's name on the prescription is for the outpatient or patient's representative bringing the prescription.
 - Check that the patient is on the Eligibility List and the prescriber is authorised to prescribe ARVs.

- Check that the regimen follows the standard ART guidelines for the ART Programme. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription.
 - Use the *ART Patient Dispensing Record* to countercheck the regimen and dose prescribed and that the patient is not collecting the ARVs earlier or later than expected. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription.
 - For adults on d4T (stavudine) **30mg**, ask the patient their current weight. If the patient weighs more than 60kg, alert the doctor that the dose needs to be increased to 40mg.
 - For children, ask for the patient's current weight and check that the doses are correct for the weight. Alert the doctor if the dose needs to be adjusted.
 - If the dose has changed, ask the patient or patient's representative for previously issued bottles for relabelling.
 - Fill out a *Medication Error Report* as described in procedure 302: *Medication Error Reporting* for any errors discovered.
3. Fill the prescription using the ARVs in the outpatient pharmacy stock as described below, and endorse the prescription with the quantities issued for each drug.
 4. Make entries in the *Hospital Pharmacy Bin Card (MOH 999)*, the *Drugs and Revenue Register*, and the *ART Patient Dispensing Records* as described in procedure 106: *Record Keeping at the Outpatient Pharmacy*.
 5. Counsel the patient on the use of the medication as described in procedure 109: *Medication Use Counselling on Antiretroviral Therapy*.

Procedure for dispensing ARVs:

1. Work should begin in a clear workspace.
2. Pull the stock bottle from the ARV cupboard and match the following to the prescription:
 - correct drug
 - strength/concentration
 - dosage form
3. Inspect the medication from the stock bottle. Look for the following:
 - broken or discoloured tablets or capsules
 - liquid medications that have changed colour or odour
 - bottles are free of cracks or chips
4. If any of the above are found, do not dispense them to patient. Complete a *Stock Count Discrepancy Report* as described in procedure 202: *Stock Count Discrepancy Report* and discard the items according to procedure 402: *Disposal of Antiretroviral Drugs*.
5. Inspect packaging container to make sure it is not damaged or soiled and that it is appropriate to drug product being packaged.

Procedure for dispensing ARV tablets or capsules:

1. Issue whole packs where possible.
2. If necessary, count out desired number of units using a spatula or knife on counting tray or clean sheet of paper. Avoid touching drug product with hands, as contamination may result.
3. Recount number of units before packing into the container.
4. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the package
 - Quantity
 - Batch No.
 - Expiry date

- Times at which the drug is to be taken
 - Patient's name
 - Date
5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and label contain the correct drug, strength, quantity, dosage form, and directions for use.

Procedure for dispensing ARV liquids/powders:

1. Reconstitute powders as per manufacturer's instructions, if required.
2. **Issue whole packs unless an exception is absolutely necessary.** If you need to dispense a part pack, make sure the bottle to contain the medicine is free of cracks or chips. If necessary, rinse bottles with clean water. Make sure that the label on the stock bottle is facing upward while pouring, to ensure that the label does not become soiled and unreadable.
3. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the bottle:
 - Quantity
 - Batch No.
 - Expiry date: Check the manufacturer's instructions for expiry dates of reconstituted medicines.
 - Dose
 - Frequency of administration
 - Times at which the drug is to be taken
 - Patient's name
 - Date
4. If the dose has changed since the last prescription, relabel previously issued bottles to reflect the new dose.
5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and label contain the correct drug, strength, quantity, dosage form, and directions for use.

Distribution:

- *Prescription Form (MOH 501)* is filed and kept for 5 years.
- The information from the *Prescription Forms (MOH 501)* will be used to complete the *Antiretroviral Internal Audit Record* as described in procedure 501: *Internal Audit of Antiretroviral Drugs*.

COAST PROVINCIAL GENERAL HOSPITAL
PRESCRIPTION FORM

NAME:
DEPARTMENT:
NUMBER:
DATE:

Doctors Name _____
Signature: _____

Coast Provincial General Hospital	
Issuing Antiretroviral Drugs to Inpatients	
Number of pages: 5	Procedure number: 108
Issued by: Name: Title: Date:	Record of amendments Date: Type:

Objective :

To describe correct procedures for issuing and dispensing antiretroviral drugs to inpatients. Good dispensing practices ensure that an effective form of the right drug is delivered to the right patient in the prescribed dosage and quantity, with clear instructions, and in a package that maintains the potency of the drug.

Responsibility:

- The authorized prescriber is responsible for prescribing ARV medication orders on the *Medication Treatment Sheet (MOH 306 Rev.)*.
- The nurse is responsible for recording administration of ARVs to inpatients on the *Medication Treatment Sheet (MOH 306 Rev.)*.
- The designated pharmacist or pharmacy technologist in charge of dispensing ARVs is responsible for issuing the ARV drugs to the ward.

Resources:

Forms used for issuing ARVs to inpatients:

Medication Treatment Sheet (MOH 306 Rev.):

- Is a record of all medication order(s) and medication administration including routine, ARVs, DDA, PRN and STAT orders
- All drugs administered to the patient must be recorded.
- *MOH 306 Rev.* should never be used for requisitioning medications for patients who have been discharged.

Forms used to record issues of ARVs to inpatients :

- *Hospital Pharmacy Bin Card (MOH 999)*
- *Drugs and Revenue Register*
- *ART Patient Dispensing Records*

Procedure:

1. Authorized physician writes the ARV order on the *Medication Treatment Sheet (MOH 306 Rev.)* (see steps for completing *MOH 306 Rev.* below).
2. The nurse brings *MOH 306 Rev.* and a *Counter Requisition and Issue Voucher (S11)* completed as described in procedure 104: *Internal Antiretroviral Drug Distribution* to the inpatient pharmacy.
3. Upon receiving *MOH 306 Rev.*:
 - Check that the patient is on eligibility list and the prescriber is authorised to prescribe ARVs.
 - Check that the regimen follows the standard ART guidelines for the ART Programme. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription.

- Use the *ART Patient Dispensing Record* to counter check the regimen and dose prescribed and that the nurse is not collecting the ARVs earlier or later than expected. Check the whole chart for drug interactions. Alert the prescriber of any discrepancies or problems before dispensing the ARVs.
 - For adults on d4T (stavudine) **30mg** ask for the patient's current weight and check that the dose is correct for weight. Alert the doctor if the dose needs to be adjusted.
 - For children, ask for the patient's current weight and check that the doses are correct for the weight. Alert the doctor if the dose needs to be adjusted.
 - If the dose has changed, ask the nurse to return previously issued bottles for relabelling.
 - Fill out a *Medication Error Report* as described in procedure 302: *Medication Error Reporting* for any errors discovered.
4. Fill the prescription using the ARVs in the outpatient pharmacy stock as described below. Inpatients should be issued with no more than a seven-day supply, although an exception can be made for ARV liquids when the smallest pack size can be issued
 5. Make entries in the *Hospital Pharmacy Bin Card (MOH 999)*, the *Drugs and Revenue Register*, and the *ART Patient Dispensing Records* as described in procedure 106: *Record Keeping at the Outpatient Pharmacy*.
 6. The designated pharmacy staff member completes the *Counter Requisition and Issue Voucher (S11)* and ensures the nurse receiving the drugs completes the *Counter Requisition and Issue Voucher (S11)* as described in procedure 104: *Internal Antiretroviral Drug Distribution*. Retain the original copy.
 7. The ARVs should be stored as per standard ward procedure for storing drugs in a secure, locked cabinet.
 8. On discharge, the patient should be issued with the drugs held on the ward. The nurse should check that the supply issued is labelled with the correct dose. In addition, a *Prescription Form (MOH 501)* should be issued by the authorized prescriber as described in procedure 107: *Issuing Antiretroviral Drugs to Outpatients*.
 9. The pharmacist in charge of wards and the nurse in charge of the ward should regularly review the *Medication Treatment Sheet (306 Rev.)* to ensure that all required information is being correctly recorded.
 10. For deceased patients, the ARVs should be returned to the pharmacy for either destruction or reuse if appropriate. If usable, the receipt of the ARVs should be entered into the *MOH 999* and the *Drugs and Revenue Register*. If the drugs are not usable they are removed for destruction as described in procedure 402: *Disposal of Antiretroviral Drugs*.

Procedure for dispensing ARVs:

1. Work should begin in a clear workspace.
2. Pull the stock bottle from the ARV cupboard and match the following to the prescription:
 - correct drug
 - strength/concentration
 - dosage form
3. Inspect the medication from the stock bottle. Look for the following:
 - broken or discoloured tablets or capsules
 - liquid medications that have changed colour or odour
 - bottles are free of cracks or chips
4. If any of the above are found, do not dispense them to patient. Complete a *Stock Count Discrepancy Report* as described in procedure 202: *Stock Count Discrepancy Report* and discard the items according to procedure 402: *Disposal of Antiretroviral Drugs*.

5. Inspect packaging container to make sure it is not damaged or soiled and that it is appropriate to drug product being packaged.

Procedure for dispensing ARV tablets or capsules:

1. Issue whole packs where possible.
2. If necessary, count out desired number of units using a spatula or knife on counting tray or clean sheet of paper. Avoid touching drug product with hands, as contamination may result.
3. Recount number of units before packing into the container.
4. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the package
 - Quantity
 - Batch No.
 - Expiry date
 - Times at which the drug is to be taken
 - Patient's name
 - Date
5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and label contain the correct drug, strength, quantity, dosage form, and directions for use.

Procedure for dispensing ARV liquids/powders:

1. Reconstitute powders as per manufacturer's instructions, if required.
2. **Issue whole packs unless an exception is absolutely necessary.** If you need to dispense a part pack, make sure the bottle to contain the medicine is free of cracks or chips. If necessary, rinse bottles with clean water. Make sure that the label on the stock bottle is facing upward while pouring, to ensure that the label does not become soiled and unreadable.
3. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the bottle:
 - Quantity
 - Batch No.
 - Expiry date: Check the manufacturer's instructions for expiry dates of reconstituted medicines.
 - Dose
 - Frequency of administration
 - Times at which the drug is to be taken
 - Patient's name
 - Date
4. If the dose has changed since the last prescription, relabel previously issued bottles to reflect the new dose.
5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and label contain the correct drug, strength, quantity, dosage form, and directions for use.

Steps for completing Medication Treatment Sheet (MOH 306 Rev.):

1. At the time of patient's admission, the admitting doctor should record:
 - Patient's full name (all names must be included to ensure proper identification of the patient)
 - Inpatient Number
 - Ward and Bed No.

- Allergies: to medications
 - Age
 - Sex
 - Name of Institution
2. All medication orders must be written on the *MOH 306 Rev.* by an authorised prescriber (doctor or clinical officer). The order should include:
 - Date and time the order was written
 - Drug name
 - Strength/concentration
 - Dose
 - Route of administration
 - Frequency of administration
 - Duration
 - Legible official name and signature and code of the prescriber
 3. When a drug is administered to a patient, the nurse or doctor administering the drug will write:
 - Date and time of administration
 - Her/His signature
 4. When an ordered drug for any reason cannot be administered, the nurse will write in the patient's nursing notes:
 - Name of the drug
 - Date and time the drug was to be administered
 - Reason why the drug could not be administered (e.g. , patient not on ward; stock unavailable)
 - Fill out a *Medication Error Report* as described in procedure 302: *Medication Error Reporting*

Distribution:

- *Medication Treatment Sheet (MOH 306 Rev.)* is filed in the inpatient records.
- *Counter Requisition and Issue Voucher (S11)* is completed in triplicate:
 - The original copy is retained by the outpatient pharmacy.
 - Duplicate is retained by the initiating department.
 - Triplicate remains in the *S11* book.

**MINISTRY OF HEALTH
MEDICATION TREATMENT SHEET**

Name:

Allergies:

Inpatient Number:

Age:

Sex:

Ward:

Bed No:

Name of Institution:

To be completed by clinician		To be completed by Clinician or Nursing Staff							
DATE	MEDICATIONS	TIME	DATE AND SIGNATURE						
		3AM							
		9AM							
		3PM							
		9PM							
		3AM							
		9AM							
		3PM							
		9PM							
		3AM							
		9AM							
		3PM							
		9PM							
		3AM							
		9AM							
		3PM							
		9PM							
		3AM							
		9AM							
		3PM							
		9PM							

**NOTE: USE RED PEN FOR DDA
ENTER YOUR SIGNATURE FOR EVERY DRUG GIVEN**

Coast Provincial General Hospital	
Medication Use Counselling on Antiretroviral Therapy	
Number of pages: 33	Procedure number: 109
Issued by: Name: Title: Date:	Record of amendments Date: Type:

Objective:

Describe the process for counselling a patient on the use of antiretroviral therapy.

Responsibility:

Medication use counselling will be the responsibility of the pharmacy staff member dispensing ARVs to the patient or his/her representative. These staff members include the pharmacist and pharmacy technologist who have completed the ART training.

The *Antiretroviral Therapy – Patient Counselling Information* table, *Antiretroviral Therapy – Technical Side Effect Information* table, the *Antiretroviral Therapy – Technical Drug Interaction Information Presented by ARV Drug* table, and the *Antiretroviral Therapy – Technical Drug Interaction Information Presented by Interacting Drug* table should be updated annually under the supervision of the Chief Pharmacist at CPGH. The pharmacist should check the references noted in the tables and send any changes to the pharmacy contact at each ART site using this SOP.

Resources:

Form used for counselling patient or his/her representative:

Antiretroviral Therapy – Patient Counselling Information

- Is a table of ARV drug information used to counsel patient or his/her representative

Antiretroviral Therapy – Technical Side Effect Information

- Is a table of technical information on ARV drug side effects to inform pharmacists and prescribers

Antiretroviral Therapy – Technical Drug Interaction Information Presented by ARV Drug

- Is a table of technical information on ARV drug interactions that can be searched by ARV drug to inform pharmacists and prescribers

Antiretroviral Therapy – Technical Drug Interaction Information Presented by Interacting Drug

- Is a table of technical information on ARV drug interactions that can be searched by drugs that can potentially interact with ARV drugs to inform pharmacists and prescribers

Resources used to prepare drug information tables:

Overview of Antiretroviral Agents

- Available online through the U.S. Dept. of Health and Human Services at:
<http://www.aidsinfo.nih.gov/drugs/> (originally referenced 9/03)

Scaling up ART in Resource Limited Settings

- Available online through the World Health Organization at:
<http://www.who.int/docstore/hiv/scaling/guidelines.pdf>) (originally referenced 9/03)

Procedure:

- Dispense the medications as described in procedure 107: *Issuing Antiretroviral Drugs to Outpatients*.
- Counsel the patient or his/her representative using the guidance below and insert the information from the *Antiretroviral Therapy – Patient Counselling Information* table for each drug that the patient is taking.
- Counsel the patient or his/her representative at Window 4 of the pharmacy.

Counselling Points for Patients on ART:

1. **Introduce yourself:** Give your name and position (pharmacist or pharmaceutical technologist).
2. **Identify who is being counselled:** Is the person picking up the medicines the patient or caregiver or a representative?
3. **Check what the patient or his/her representative already knows about the medicines:** Ask the patient or his/her representative questions to see how much they already understand about the medications:
 - a. *What did the doctor/nurse tell you the medication was for?*
 - b. *How did the doctor/nurse tell you to take the medicines?*
 - c. *What other information did the doctor/nurse tell you about taking this medication?*
4. **Make sure the patient or his/her representative understands how the se medications work:**
 - a. *These medicines (**together**) are used to suppress the infection caused by the human immunodeficiency virus (HIV). HIV is the virus responsible for acquired immune deficiency syndrome (AIDS).*
 - b. *The medicines you are receiving to treat your HIV infection will not cure or prevent HIV infection or AIDS; however, they will help keep HIV under control and appear to slow down the destruction of the immune system, the body's defence against diseases. This may help delay the development of problems usually related to AIDS or HIV disease.*
 - c. *These medicines will not keep you from spreading HIV to other people.*
 - d. *People who receive these medicines may continue to have problems usually related to AIDS or HIV disease.*
5. **Check for questions and concerns:** *Do you have any questions or concerns, before I continue?* If you cannot address the patient's or his/her representative's questions or concerns, seek the advice of the doctor/nurse.
6. **Give medicine name and describe appearance:** Tell the patient or his/her representative the names of the medicines they are receiving. As you say the name (use the abbreviation) of the medicine, point to the name on the package label. Open the package and show the patient or his/her representative a tablet, or show the patient a picture of the tablet from a poster or other aid you keep in the pharmacy. Refer to *Antiretroviral Therapy – Patient Counselling Information* table.

7. **Give route of administration:** For example, “You should take these medicines by mouth with a glass of water.”
8. **Give directions:** Explain to the patient or his/her representative the directions they should follow (number of pills or amount of fluid) to take and when to take the medication. Refer to *Antiretroviral Therapy – Patient Counselling Information* table. Explain that the medicines must be taken regularly, exactly as directed, and not to miss any doses:
- These medications are meant only for you. Do not share these medications with others.*
 - These medications work best when there is a constant amount in the blood. To help keep the amount constant, do not miss any doses.*
 - Take the medicine exactly as the doctor/nurse told you. You should not take more of it or take it more often than the doctor/nurse has said.*
 - If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. You should not take your missed dose and your next dose at the same time (or two doses at the same time).*
Give the patient a scenario and ask him what he would do. Make up an example that is based on the drugs the patient is receiving.
For example, the patient is supposed to take his/her medication at 8 in the morning and 8 at night. The patient remembers at 10 in the morning that he or she forgot the morning dose, what should the patient do? (Correct answer: patient should take the morning dose because it is not too close to evening dose). What if the patient remembered that he or she forgot the morning dose at 6 in the evening, what should the patient do? (Correct answer: the patient should not take the forgotten dose but should take their evening dose as scheduled).
 - Keep taking the medication, even if you start to feel better. You will need to be on these or similar medications for the rest of your life.*
 - If you don’t take these medicines exactly as the doctor/nurse told you, they may not work. This is dangerous, because there are only a limited number of drugs that can be used to treat patients with HIV infections if these stop working.*
 - Don’t stop taking these medicines without checking with your doctor/nurse first.*
9. **Give information on the side effects of the medicines:**
Refer to *Antiretroviral Therapy - Patient Counselling Information* table (the most common side effects are listed in **boldface** type).
- Side effects to report at the next visit:** *These side effects usually do not need medical attention and go away during treatment as your body adjusts to the medicine. However, talk with your doctor if these side effects continue or are very bothersome.*
 - Side effects to report immediately:** *Check with your doctor **immediately** if you have the following side effects.*
10. **Taking other medicines/herbs/local medicine and drug interactions:** Ask the patient or his/her representative if the patient has any drug allergies. If the pharmacy keeps this information on file, double-check that the information is accurate. Ask the patient or his/her representative if the patient is taking any other medicines at the moment and check for interactions using the *Antiretroviral Therapy – Technical Drug Interaction*

Information Presented by Interacting Drug table. Inform the prescriber of any interactions identified.

Tell the patient:

- a. *Some medicines are not safe to take while you are taking ARV drugs. Give the specific information listed in the “Drug Interactions” column of the Antiretroviral Therapy – Patient Counselling Information table.*
- b. *You may or may not be able to tell if the other medicines are causing a problem.*
- c. *It is always best to check with your doctor before starting any new medicines (this includes herbals and vitamins).*
- d. *Avoid alcohol while taking ARV drugs.*

11. Storage :

- a. *Store the medication in a place where children cannot reach it.*
- b. *Store the medication in a cool and dry place. Do not store the medication in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to not work as well.*

12. Check the understanding of the patient or his/her representative : by asking them to repeat back to you key information. Remind them of information they left out. You can say something like:

- a. *Can you repeat back to me the information I shared with you, so that I know if I missed telling you any important information.*

Or

- b. *That was a lot of information. Just to make sure I covered all the information and you understood all of it, can you repeat back what we have covered?*

13. Final check for questions and concerns: *Do you have any questions or concerns?* If you cannot address the patient/caregiver’s questions or concerns, seek the advice of the doctor/nurse.

Antiretroviral Therapy – Patient Counselling Information

(Most common side effects are listed in **boldface** type.)

Description	Directions	Side Effects	Drug Interactions						
<p>Stavudine (d4T), Zerit®</p> <p>40mg capsule (dark orange)</p> <hr style="border-top: 1px dashed black;"/> <p>30mg capsule (light orange and dark orange)</p> <hr style="border-top: 1px dashed black;"/> <p>1mg/ml oral solution</p>	<ul style="list-style-type: none"> • This medication can be taken with or without food. <p>Take 1 capsule twice a day</p> <hr style="border-top: 1px dashed black;"/> <p>Take 1 capsule twice a day</p> <hr style="border-top: 1px dashed black;"/> <p>Children: (dose twice daily)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">$<30\text{kg}$</td> <td style="width: 50%;">1mg/kg/dose</td> </tr> <tr> <td>30–60kg</td> <td>30mg/dose</td> </tr> <tr> <td>Max. dose $>60\text{kg}$</td> <td>40 mg/dose</td> </tr> </table>	$<30\text{kg}$	1mg/kg/dose	30–60kg	30mg/dose	Max. dose $>60\text{kg}$	40 mg/dose	<p>Report immediately:</p> <ul style="list-style-type: none"> • Tingling, numbness, or pain in the hands/feet • Unusual tiredness, weakness, or muscle pain • Nausea, vomiting, or diarrhoea • Severe abdominal pain • Fever, chills, or rash <p>Report at next visit:</p> <ul style="list-style-type: none"> • Headache or difficulty sleeping 	*
$<30\text{kg}$	1mg/kg/dose								
30–60kg	30mg/dose								
Max. dose $>60\text{kg}$	40 mg/dose								
<p>Lamivudine (3TC), Epivir®</p> <p>150mg tablet (white diamond shaped)</p> <hr style="border-top: 1px dashed black;"/> <p>10mg/ml oral solution</p>	<ul style="list-style-type: none"> • This medication can be taken with or without food. <p>Take 1 tablet twice a day</p> <hr style="border-top: 1px dashed black;"/> <p>For children: (dose twice daily)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;"><30 days</td> <td style="width: 50%;">2mg/kg/dose</td> </tr> <tr> <td>>30 days or <60 kg</td> <td>4 mg/kg/dose</td> </tr> <tr> <td>Max. dose >60 kg</td> <td>150mg/dose</td> </tr> </table>	<30 days	2mg/kg/dose	>30 days or <60 kg	4 mg/kg/dose	Max. dose >60 kg	150mg/dose	<p>Report immediately:</p> <ul style="list-style-type: none"> • Tingling, numbness, or pain in the hands/feet • Unusual tiredness, weakness or muscle pain • Nausea, vomiting, or diarrhoea • Severe abdominal pain • Fever, chills, or rash <p>Report at next visit:</p> <ul style="list-style-type: none"> • Dizziness, headache, or difficulty sleeping 	*
<30 days	2mg/kg/dose								
>30 days or <60 kg	4 mg/kg/dose								
Max. dose >60 kg	150mg/dose								

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Description	Directions	Side Effects	Drug Interactions												
<p>Efavirenz (EFV), Stocrin®</p> <p>200mg capsule (gold)</p> <hr style="border-top: 1px dashed black;"/> <p>600mg capsule (yellow, capsular-shaped)</p>	<ul style="list-style-type: none"> • This medication can be taken with or without food. • Avoid high-fat foods. <p>Take 3 capsules at night</p>	<p>Report immediately:</p> <ul style="list-style-type: none"> • Rash • Nausea, vomiting, diarrhoea • Severe abdominal pain • Severe depression or thinking you don't want to live anymore <p>Report at next visit: (These side effects are rather common but tend to go away after about a month.)</p> <ul style="list-style-type: none"> • Dizziness, headache, difficulty sleeping or concentrating <p>**Inform patients that sometimes the drug causes abnormal or bad dreams, but that this should resolve within 2–4 weeks.</p>	<p>There can be life-threatening problems if you take certain medicines with efavirenz.</p> <p>The birth-control pill may not work effectively while taking efavirenz. Always use a barrier backup birth-control method (for example, a condom).</p>												
<p>30mg/ml syrup</p>	<p>Children**: (dose once daily)</p> <table border="0"> <tr> <td>10–15kg</td> <td>270mg</td> </tr> <tr> <td>15to<20kg</td> <td>300mg</td> </tr> <tr> <td>20 to <25kg</td> <td>360mg</td> </tr> <tr> <td>25 to <33kg</td> <td>450mg</td> </tr> <tr> <td>33 to <40kg</td> <td>510mg</td> </tr> <tr> <td>Max dose> 40kg</td> <td>600mg</td> </tr> </table> <p>** These doses are for the syrup. Children who take the capsule will have a slightly lower total mg dose because of formulation issues.</p>			10–15kg	270mg	15to<20kg	300mg	20 to <25kg	360mg	25 to <33kg	450mg	33 to <40kg	510mg	Max dose> 40kg	600mg
10–15kg	270mg														
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CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Description	Directions	Side Effects	Drug Interactions
<p>Nevirapine (NVP), Viramune®</p> <p>200mg tablet (white, oval)</p>	<ul style="list-style-type: none"> This medication can be taken with or without food. <p>Take 1 tablet once a day for the first 2 weeks of therapy, then take 1 tablet twice a day</p>	<p>Report immediately:</p> <ul style="list-style-type: none"> Rash or fever Muscle weakness or aches Yellow colour to skin or the whites of eyes Unusual tiredness or weakness Severe nausea, vomiting, or diarrhoea 	<p>*</p> <p>The birth-control pill may not work effectively while taking nevirapine. Always use a barrier backup birth control method (for example, a condom).</p>
<p>50mg/5ml oral suspension (white to off-white)</p>	<p>4 mg/kg once a day for 2 weeks. Thereafter, maintenance dose: Children > 2 months to < 8 years: 7 mg/kg twice a day. Children > 8 years: 4mg/kg twice daily. Maximum recommended dose: 400mg/day</p>	<p>Report at next visit:</p> <ul style="list-style-type: none"> Headache 	
<p>Zidovudine (AZT, ZDV) Retrovir®</p> <p>300mg tablet (white, round)</p>	<ul style="list-style-type: none"> Preferably should be taken at least 2 hours before or 2 hours after a meal. Suggest patients take with food (light, low-fat meal) if nausea and vomiting are a problem. <p>Take 1 tablet twice a day</p>	<p>Report immediately:</p> <ul style="list-style-type: none"> Fever or chills Sore throat Pale skin, unusual tiredness or weakness, shortness of breath, rapid heart beat 	<p>*</p>

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Description	Directions	Side Effects	Drug Interactions
50mg/5ml syrup (colourless to pale yellow)	Children: (dose twice daily) <4 weeks 4mg/kg/dose 4 weeks–13 years 180mg/m ² /dose >13 years 300mg/dose Dose for prophylaxis (full-term new born): 2 mg/kg orally every 6 hours starting with 12 hours of birth and continuing for 6 weeks.	Report at next visit: <ul style="list-style-type: none"> • Nausea, headache, or difficulty sleeping 	

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Description	Directions	Side Effects	Drug Interactions						
<p>Didanosine (DDI) or Videx®</p> <p>200mg tablet (off-white to light orange/yellow, round)</p> <p>50mg tablet (off-white to light orange/yellow, round)</p> <p>10mg/1ml oral suspension</p>	<ul style="list-style-type: none"> Should be taken at least 2 hours before or 2 hours after a meal. Avoid drinking alcohol. Chew tablets and take with full glass of water. <p>For patients >60 kg Take the prescribed dose twice a day</p> <p>For patients <60 kg Take the prescribed dose twice a day</p> <p>Children: (dose twice daily)</p> <table border="0"> <tr> <td><3 months</td> <td>50mg/m²/dose</td> </tr> <tr> <td>>3 months to <13 years</td> <td>90mg/m²/dose</td> </tr> <tr> <td>Max. dose >13 years or ></td> <td>60kg 200mg/dose</td> </tr> </table>	<3 months	50mg/m ² /dose	>3 months to <13 years	90mg/m ² /dose	Max. dose >13 years or >	60kg 200mg/dose	<p>Report immediately:</p> <ul style="list-style-type: none"> Changes in vision Tingling, numbness, or pain in the hands/feet Unusual tiredness, weakness, or muscle pain Nausea, vomiting, or diarrhoea Severe abdominal pain Fever, chills, or rash <p>Report at next visit:</p> <ul style="list-style-type: none"> Anxiety, headache, or difficulty sleeping 	<p>*</p> <p>There are many drugs that interact with didanosine; be especially careful to report any unusual symptom to your doctor when you start new drugs.</p>
<3 months	50mg/m ² /dose								
>3 months to <13 years	90mg/m ² /dose								
Max. dose >13 years or >	60kg 200mg/dose								
<p>Lopinavir/Ritonavir (LPV/RTV), Kaletra®</p> <p>133.3mg/33.3mg capsule (orange)</p> <p>400mg/100mg/5ml oral solution</p>	<ul style="list-style-type: none"> Should be taken with food. <p>Take 3 capsules twice a day</p> <p>Children: (dose twice daily)</p> <table border="0"> <tr> <td>>6 months to 13 years</td> <td>225mg/m² LPV/ 57.5mg/m² ritonavir</td> </tr> <tr> <td>Max. dose >40kg</td> <td>400mg LPV/100mg ritonavir</td> </tr> </table>	>6 months to 13 years	225mg/m ² LPV/ 57.5mg/m ² ritonavir	Max. dose >40kg	400mg LPV/100mg ritonavir	<p>Report immediately:</p> <ul style="list-style-type: none"> Unusual tiredness, weakness, or muscle pain Nausea, vomiting, or diarrhoea Severe abdominal pain Fever, chills, or rash Yellow colour to the skin or the whites of eyes <p>Report at next visit:</p> <ul style="list-style-type: none"> Headache or difficulty sleeping 	<p>*</p> <p>There can be life-threatening problems if you take certain medicines with lopinavir/ritonavir.</p>		
>6 months to 13 years	225mg/m ² LPV/ 57.5mg/m ² ritonavir								
Max. dose >40kg	400mg LPV/100mg ritonavir								

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

*All patients should be counselled about drug interactions as follows for each ARV drug:

- *Some medicines are not safe to take while you are taking ARV drugs. Give the specific information listed in the “Drug Interactions” column of this table*
- *You may or may not be able to tell if the other medicines are causing a problem.*
- *It is always best to check with your doctor before starting any new medicines (this includes herbals and vitamins).*
- *Avoid alcohol while taking ARV drugs.*

References:

Side Effects/Drug Interactions: Overview of Antiretroviral Agents. Available online through the U.S. Dept. of Health and Human Services at:

<http://www.aidsinfo.nih.gov/drugs/>

Dosing/Drug Interactions: Scaling up ART in Resource Limited Settings. Available online through the World Health Organization at:

<http://www.who.int/docstore/hiv/scaling/guidelines.pdf>)

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Antiretroviral Therapy – Technical Side Effect Information

(Clinically severe side effects are listed in **boldface** type.)

ART Drug	Side Effect	Considerations
Stavudine (d4T), Zerit®	Common: <ul style="list-style-type: none"> • Peripheral neuropathy (PN) • Headache • Insomnia • Rash • Diarrhoea • Nausea/vomiting • Lipodystrophy Rare: <ul style="list-style-type: none"> • Pancreatitis • Lactic acidosis with hepatic steatosis 	<ul style="list-style-type: none"> • Additional risk factors for pancreatitis include female gender, obesity, and prolonged nucleoside exposure. Suspend stavudine in patients with suspected lactic acidosis or pancreatitis. If pancreatitis remits, reinstitute stavudine with extreme caution only if necessary, but not in combination with other drugs known to cause pancreatitis (especially didanosine or hydroxyurea). Reinstitution of stavudine is not recommended after confirmed lactic acidosis. • Additional risk factors for PN include advanced HIV disease, history of neuropathy, and concurrent neurotoxic drug therapy. Interrupting treatment with stavudine may cause PN to resolve. Some patients tolerate stavudine resumption at a decreased dose (approximately ½ original dose) after PN resolution. If PN returns again, permanent discontinuance of stavudine should be considered.
Lamivudine (3TC), Epivir®	Common: <ul style="list-style-type: none"> • Dizziness • Headache • Insomnia • Fatigue • Nausea • Rash Rare: <ul style="list-style-type: none"> • Lactic acidosis with hepatic steatosis (less common than with stavudine) • Peripheral neuropathy (less common than with stavudine) 	<ul style="list-style-type: none"> • Additional risk factors for pancreatitis include female gender, obesity, and prolonged nucleoside exposure. Suspend lamivudine in patients with suspected lactic acidosis or pancreatitis. If pancreatitis remits, reinstitute lamivudine with extreme caution only if necessary, but not in combination with didanosine. Reinstitution of stavudine is not recommended after confirmed lactic acidosis. • Additional risk factors for PN include advanced HIV disease, history of neuropathy, and concurrent neurotoxic drug therapy. Interrupting treatment with lamivudine may cause PN to resolve. Some patients tolerate lamivudine resumption at a decreased dose after PN resolution. If PN returns again, permanent discontinuance of lamivudine should be considered.

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ART Drug	Side Effect	Considerations
<p>Efavirenz (EFV), Stocrin®</p>	<p>Common:</p> <ul style="list-style-type: none"> • Central nervous symptoms (esp. abnormal or bad dreams, dizziness, headache, somnolence, insomnia, confusion, difficulty concentrating) • Mild rash • Nausea/anorexia/vomiting • Diarrhoea <p>Rare:</p> <ul style="list-style-type: none"> • Severe rash • Suicidal ideation • Visual disturbances • Gynaecomastia • Tinnitus • Increased transaminase levels 	<ul style="list-style-type: none"> • CNS symptoms are very common and have been reported to occur in at least 50% of patients. These symptoms were reported to be severe in 2% of patients, and 2% of patients discontinued therapy as a result. Symptoms usually began during the first or second day of therapy and resolve after the first 2–4 weeks of therapy. Dosing at bedtime is recommended to improve tolerability. This drug has been shown (in clinical use) to often cause abnormal or bad dreams. Typically the bad dreams resolve within 2–4 weeks. Warning patients ahead of time may encourage compliance. • In most patients, mild rash resolves within 1 month with continuing efavirenz therapy. Efavirenz may be reinitiated in patients interrupting therapy because of mild rash. Severe rash (Stevens-Johnson syndrome) is rare, but the efavirenz should be permanently discontinued.
<p>Nevirapine (NVP), Viramune®</p>	<p>Common: Headache</p> <p>Rare: Rash Hepatitis, including hepatic necrosis Lipodystrophy</p>	<ul style="list-style-type: none"> • Patients experiencing a mild rash during the 14-day lead-in period should not have their dose increased until the rash resolves. Patients experiencing a severe rash should have nevirapine discontinued immediately. Stevens-Johnson syndrome has been reported. Women have a higher risk of rash. • Monitor patients intensively during the first 12–16 weeks of therapy to detect potentially life-threatening hepatotoxicity or skin reactions. Most cases occur within the first 4–6 weeks of therapy. • If severe hepatic, skin, or hypersensitivity reactions occur, nevirapine should not be restarted.

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

ART Drug	Side Effect	Considerations
Zidovudine (AZT, ZDV) Retrovir®	Common: Nausea/anorexia Headache Insomnia Malaise Asthenia Rare: Bone marrow suppression Anaemia Neutropenia Lactic acidosis with hepatic steatosis Myopathy	<ul style="list-style-type: none"> • Although many references recommend that zidovudine be taken on an empty stomach, nausea and vomiting may result, which may deter patients from taking the drug. Suggest patients take with food (light, low-fat meal) if nausea and vomiting are a problem. • Myopathy has been associated with prolonged therapy. • Reduction in haemoglobin may occur as early as 2–4 weeks after the start of therapy. Neutropenia usually occurs after 6–8 weeks. Significant anaemia and or neutropenia may require a dose interruption until evidence of marrow recovery has occurred.
Didanosine (DDI) or Videx®	Common: <ul style="list-style-type: none"> • Anxiety • Headache • Insomnia • Diarrhoea • Nausea Rare: <ul style="list-style-type: none"> • Pancreatitis • Peripheral neuropathy • Lactic acidosis with hepatic steatosis • Retinal changes and optic neuritis 	<ul style="list-style-type: none"> • Additional risk factors for pancreatitis include female gender, obesity, and prolonged nucleoside exposure. Didanosine should be withheld if pancreatitis is suspected, and discontinued if pancreatitis is confirmed. The manufacturer suggests discontinuing didanosine in patients who require life-sustaining treatment with other drugs known to cause pancreatitis. Pancreatitis is dose related (increased dose, increased chance for pancreatitis).

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

ART Drug	Side Effect	Considerations
Lopinavir/ Ritonavir (LPV/RTV), Kaletra®	Common: <ul style="list-style-type: none"> • Headache • Insomnia • Abnormal stools • Diarrhoea • Weakness/tiredness • Nausea • Rash Rare: <ul style="list-style-type: none"> • Pancreatitis • Increased bleeding in haemophiliac patients • Elevated transaminase enzymes • Fat redistribution and lipid abnormalities • Hyperglycaemia • Asthenia 	<ul style="list-style-type: none"> • Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risk of cardiovascular events and pancreatitis. Interventions may include dietary modification, lipid-lowering agents, or discontinuation of lopinavir/ritonavir. • Cases of worsening glycaemic control among patients with pre-existing diabetes and cases of new-onset diabetes, including diabetic ketoacidosis, have been reported. • Monitor patients with pre-existing (or at risk for) transaminase elevations for further elevations.

References:

Guidelines for the Use of Antiretroviral Agents. Available online through the U.S. Dept. of Health and Human Services at:
<http://www.aidsinfo.nih.gov/guidelines/>

Scaling up ART in Resource Limited Settings. Available online through the World Health Organization at:
<http://www.who.int/docstore/hiv/scaling/guidelines.pdf>

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Antiretroviral Therapy – Technical Drug Interaction Information Presented by ARV Drug

(Drugs with clinically severe interactions are listed in **boldface** type.)

(Interacting drugs under each ARV drug are listed in decreasing order of clinical significance.)

ARV Drug	Severity and Interacting Drug(s)	Nature of Reaction	Considerations
Stavudine (d4T), Zerit®	Didanosine with or without hydroxyurea Alcohol, asparaginase, azathioprine, estrogens, frusemide, lamivudine, methyldopa, nitrofurantoin, pentamidine, ribavirin, sulphonamides, sulindac, tetracyclines, thiazide diuretics, valproic acid, zalcitabine	Lactic acidosis, pancreatitis (potentially fatal)	<ul style="list-style-type: none"> • Use with caution and only if potential benefit outweighs potential risk. Suspend stavudine in patients with suspected lactic acidosis or pancreatitis. If pancreatitis remits, reinstitute stavudine with extreme caution only if necessary, but not in combination with didanosine or hydroxyurea. • Reinstitution of stavudine is not recommended after confirmed lactic acidosis.
	Chloramphenicol, cisplatin, dapsone, didanosine, ethambutol, ethionamide, hydralazine, isoniazid, lithium, metronidazole, nitrofurantoin, phenytoin, ribavirin, vincristine, zalcitabine	May cause or exacerbate peripheral neuropathy (PN)	<ul style="list-style-type: none"> • Avoid unnecessary use of interacting drugs. Interrupting treatment with stavudine may cause PN to resolve. Some patients tolerate stavudine resumption at a decreased dose after PN resolution. If PN returns again, permanent discontinuance of stavudine should be considered.
	Zidovudine	Metabolism of stavudine reduced	<ul style="list-style-type: none"> • Concomitant use is not recommended.

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

ARV Drug	Severity and Interacting Drug(s)	Nature of Reaction	Considerations
Lamivudine (3TC), EpiVir®	Alcohol, asparaginase, azathioprine, estrogens, frusemide, hydroxyurea, methyldopa, nitrofurantoin, pentamidine, ribavirin, stavudine, sulphonamides, sulindac, tetracyclines, thiazide diuretics, valproic acid, zalcitabine	Lactic acidosis, pancreatitis (potentially fatal)	<ul style="list-style-type: none"> • Use with caution and only if potential benefit outweighs potential risks. Suspend lamivudine in patients with suspected lactic acidosis or pancreatitis. If pancreatitis remits, reinstitute lamivudine with extreme caution only if necessary, but not in combination with didanosine. • Reinstitution of stavudine is not recommended after confirmed lactic acidosis.
	Chloramphenicol, cisplatin, dapsone, didanosine, ethambutol, ethionamide, hydralazine, isoniazid, lithium, metronidazole, nitrofurantoin, phenytoin, ribavirin, stavudine, vincristine, zalcitabine	May cause or exacerbate PN	<ul style="list-style-type: none"> • Avoid unnecessary use of interacting drugs. Interrupting treatment with lamivudine may cause PN to resolve. Some patients tolerate lamivudine resumption at a decreased dose after PN resolution. If PN returns again, permanent discontinuance of lamivudine should be considered.
	Sulphamethoxazole/trimethoprim	May decrease clearance of lamivudine by 30%	<ul style="list-style-type: none"> • Monitor patient for toxicity associated with lamivudine.

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

ARV Drug	Severity and Interacting Drug(s)	Nature of Reaction	Considerations
Efavirenz (EFV), Stocrin®	Astemizole, cisapride, ergot derivatives, midazolam, terfenadine, triazolam (potentially any drug metabolized by CYP3A4)	May cause life-threatening adverse events such as cardiac arrhythmias, prolonged sedation, or respiratory depression	<ul style="list-style-type: none"> • Concomitant use is not recommended.
	Warfarin	Clinical effects of warfarin increased or decreased	<ul style="list-style-type: none"> • Monitor warfarin level closely.
	Alcohol, psychoactive drugs, especially midazolam and triazolam	Prolonged sedation	<ul style="list-style-type: none"> • Avoid concomitant therapy or monitor patient very closely.
	Ethinyl estradiol (hormonal contraceptives)	Increased ethinyl estradiol level (clinical effect unknown)	<ul style="list-style-type: none"> • Addition of a reliable barrier contraception method recommended.
	Lopinavir/ritonavir	Plasma concentrations of lopinavir/ritonavir are decreased	<ul style="list-style-type: none"> • Avoid unnecessary use or monitor efficacy of protease inhibitor and consider dose adjustment if indicated.
	Rifabutin or rifampicin or rifapentine	Rifabutin concentration may be decreased Rifampicin may decrease efavirenz concentration	<ul style="list-style-type: none"> • Monitor patient for rifabutin efficacy. May consider increasing rifabutin dose to 400–650mg QD or 600mg 3 times a week. Rifapentine is not recommended.
	Phenobarbital or St. John's Wort [<i>Hypericum perforatum</i>]	Decreased efavirenz concentration	<ul style="list-style-type: none"> • Administer with caution. Monitor patient for loss of virologic response and resistance (due to decreased efavirenz).
	Clarithromycin (possibly erythromycin)	Plasma concentration of clarithromycin may be decreased (erythromycin has not been studied)	<ul style="list-style-type: none"> • Monitor patient for clarithromycin (erythromycin) efficacy or use alternative agent. Concomitant use is not recommended.
Nevirapine	Studies have not been performed	<ul style="list-style-type: none"> • Concomitant use is not recommended. 	

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

ARV Drug	Severity and Interacting Drug(s)	Nature of Reaction	Considerations
Nevirapine (NVP), Viramune®	Rifampicin or rifabutin or rifapentine	Increased levels of rifampicin and rifabutin, and/or decreased levels of nevirapine	<ul style="list-style-type: none"> Dosage adjustments or therapeutic substitutions may be necessary. Effect is more pronounced with rifampicin, and thus co-administration of rifampicin and nevirapine is not recommended. Rifapentine is not recommended.
	Ethinyl estradiol (hormonal contraceptives)	Decreased contraceptive concentration	<ul style="list-style-type: none"> Hormonal contraceptives should not be used as the primary means of contraception.
	Lopinavir/ritonavir	Decreased levels of lopinavir/ritonavir	<ul style="list-style-type: none"> Administer with caution. Monitor patient for loss of virologic response and resistance (due to decreased lopinavir/ritonavir).
	Ketoconazole	Reduced ketoconazole concentration, increased nevirapine concentration	<ul style="list-style-type: none"> Monitor patient for ketoconazole efficacy; co-administration is not recommended.
	Cimetidine, macrolide antibiotics (clarithromycin, erythromycin), any drug metabolized by CYP3A4	Nevirapine may lower other drug concentration, or nevirapine concentration may be increased	<ul style="list-style-type: none"> Dosage adjustments may be necessary.
	Prednisone or Prednisolone	Increase incidence and severity of rash	<ul style="list-style-type: none"> Monitor patient.
	Methadone	Decreased methadone concentration	<ul style="list-style-type: none"> May need to retitrate methadone dose to effect.
	St. John's Wort [<i>Hypericum perforatum</i>]	Decreased nevirapine concentration	<ul style="list-style-type: none"> Monitor patient for loss of virologic response and resistance (due to decreased nevirapine).

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

ARV Drug	Severity and Interacting Drug(s)	Nature of Reaction	Considerations
Zidovudine (AZT, ZDV) Retrovir®	Cytotoxic agents, radiation, bone marrow depressants such as ganciclovir or interferon-alpha	Increased histologic toxicity of zidovudine	<ul style="list-style-type: none"> • Monitor patient carefully.
	Cidofovir + Probenecid (probenecid is causative drug)	Increased zidovudine concentrations, patients may develop myalgia, fever, and rash	<ul style="list-style-type: none"> • On days that cidofovir, probenecid, and zidovudine are co-administered, zidovudine should be temporarily discontinued or zidovudine dose should be reduced by 50%.
	Doxorubicin, ribavirin, stavudine	Drugs may antagonize one another.	<ul style="list-style-type: none"> • Concomitant use is not recommended.
	Acetaminophen, aspirin, atovaquone, benzodiazepines, cimetidine, indomethacin, morphine, sulphonamides, valproic acid	May increase zidovudine concentration or other drug concentration	<ul style="list-style-type: none"> • Monitor patient for drug toxicity.
	Rifampicin	Decreased zidovudine level	<ul style="list-style-type: none"> • Monitor patient for loss of virologic response and resistance (due to decreased zidovudine).
	Acyclovir, clarithromycin, fluconazole, methadone, nelfinavir, phenytoin, ritonavir	Theoretically may interfere with zidovudine level, but no specific data to support	<ul style="list-style-type: none"> • Monitor patients carefully.

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

ARV Drug	Severity and Interacting Drug(s)	Nature of Reaction	Considerations
Didanosine (DDI) or Videx®	Alcohol, asparaginase, azathioprine, estrogens, frusemide, hydroxyurea, lamivudine, methyldopa, nitrofurantoin, pentamidine, ribavirin, stavudine, sulphonamides, sulindac, tetracyclines, thiazide diuretics, valproic acid	Increased risk of pancreatitis	<ul style="list-style-type: none"> Avoid concomitant use or use with extreme caution. Manufacturer suggests discontinuing didanosine in patients who require life-sustaining treatment with other drugs known to cause pancreatitis. Didanosine should be suspended if pancreatitis is suspected and discontinued if pancreatitis is confirmed.
	Chloramphenicol, cisplatin, dapsone, ethambutol, ethionamide, hydralazine, isoniazid, lithium, metronidazole, nitrofurantoin, phenytoin, ribavirin, stavudine, vincristine, zalcitabine	Increased risk of peripheral neuropathy	<ul style="list-style-type: none"> Avoid concomitant use or use with extreme caution.
	Tenofovir disoproxil fumarate	Increased absorption of didanosine	<ul style="list-style-type: none"> Co-administration should be undertaken only with extreme caution, and patients monitored closely for didanosine-related toxicities. Consider decreasing didanosine dose.
	Allopurinol	Increased toxicity of didanosine	<ul style="list-style-type: none"> Concomitant use is not recommended.
	Ganciclovir Itraconazole, ketoconazole	Increased toxicity of didanosine Decreased concentration of itraconazole or ketoconazole	<ul style="list-style-type: none"> Monitor patient for increased toxicity of didanosine. Avoid concomitant use if possible; therapy failure with itraconazole or ketoconazole is possible. Manufacturer recommends itraconazole or ketoconazole be administered at least 2 hours prior to didanosine.
Protease inhibitors	Potential decreased effect of protease inhibitors if taken at the same time.	<ul style="list-style-type: none"> Separate dosing of protease inhibitors and didanosine. 	

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

ARV Drug	Severity and Interacting Drug(s)	Nature of Reaction	Considerations
Didanosine (DDI) or Videx® (continued)	Dapsone	Treatment failures with dapsone (for pneumocystis carinii pneumonia prevention) have occurred	<ul style="list-style-type: none"> • Avoid concomitant use. Manufacturer suggests separating doses by 2 hours.
	Fluroquinolones, tetracyclines	Decreased effect of fluroquinolone or tetracyclines	<ul style="list-style-type: none"> • Separate dosages of drugs by at least 2 hours.
	Methadone	Decreased didanosine concentration	<ul style="list-style-type: none"> • Monitor patient for loss of virologic response and resistance (due to decreased didanosine).
Lopinavir/ Ritonavir (LPV/RTV), Kaletra®	Astemizole, cisapride, ergot derivatives, flecainide, midazolam, pimozide, propafenone, rifampicin, terfenadine, triazolam (any drug metabolized by CYP3A4 or CYP2D6)	May cause life-threatening adverse events such as cardiac arrhythmias, prolonged sedation or respiratory depression	<ul style="list-style-type: none"> • Concomitant use is not recommended.
	Atorvastatin, cerivastatin, lovastatin, simvastatin	Increased risk of myopathy or rhabdomyolysis	<ul style="list-style-type: none"> • Concomitant use is not recommended.
	Ethinyl estradiol (hormonal contraceptives)	Decreased contraceptive concentration	<ul style="list-style-type: none"> • Hormonal contraceptives should not be used as the primary means of contraception.

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

ARV Drug	Severity and Interacting Drug(s)	Nature of Reaction	Considerations
Lopinavir/ Ritonavir (LPV/RTV), Kaletra® (continued)	Amiodarone, amprenavir, atovaquone, bepridil, carbamazepine, clarithromycin, cyclosporine, delavirdine, desipramine, dexamethasone, didanosine, efavirenz, felodipine, indinavir, itrac onazole, ketoconazole, lignocaine, methadone, metronidazole, nevirapine, nicardipine, nifedipine, oral contraceptives, phenobarbitone, phenytoin, quinacrine, rifabutin, rifapentine, saquinavir, sirolimus, tacrolimus, theophylline, voriconazole, warfarin	Increased or decreased other drug concentration	<ul style="list-style-type: none"> • Monitor patient for signs of toxicity or efficacy of other drug. • Do not exceed 200mg ketoconazole daily. • Consider decreasing rifabutin to 150mg QOD. • Monitor anticonvulsant levels. • Methadone dose may need to be increased. • Bepridil is not recommended.
	St. John's Wort [<i>Hypericum perforatum</i>]	Decreased lopinavir/ritonavir concentration	<ul style="list-style-type: none"> • Monitor patient for loss of virologic response and resistance (due to decreased lopinavir/ritonavir). Concomitant use is not recommended.
	Sildenafil	Increased sildenafil	<ul style="list-style-type: none"> • Co administration is not recommended. Expect increased risk of hypotension, syncope and visual changes.

Reference:

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Antiretroviral Therapy – Technical Drug Interaction Information Presented by Interacting Drug
(Clinically severe interactions are listed in **boldface** type.)

Key: *Concomitant use is not recommended		M: Monitor patient carefully			R: Recommendation or suggested action		
ARV Agent	Didanosine (DDI) or Videx®	Efavirenz (EFV), Stocrin®	Lamivudine (3TC), Epivir®	Lopinavir/Ritonavir (LPV/RTV), Kaletra®	Nevirapine (NVP), Viramune®	Stavudine (d4T), Zerit®	Zidovudine (AZT, ZDV) Retrovir®
Interacting Drug							
Acetaminophen (see Paracetamol)							? Zidovudine M
Acyclovir							M
Alcohol	*Pancreatitis (potentially fatal)	*Prolonged sedation	*Lactic acidosis, pancreatitis (potentially fatal)			*Lactic acidosis, pancreatitis (potentially fatal)	
Allopurinol	*Didanosine toxicity						
Amiodarone				M			
Amprenavir				M			
Asparaginase	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	
Aspirin							? Zidovudine M
Astemizole		*Life-threatening adverse events: cardiac arrhythmias		*Life-threatening adverse events: cardiac arrhythmias			
Atorvastatin				*Increased risk of myopathy			
Atovaquone							? Zidovudine M

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Key: *Concomitant use is not recommended		M: Monitor patient carefully			R: Recommendation or suggested action		
ARV Agent	Didanosine (DDI) or Videx®	Efavirenz (EFV), Stocrin®	Lamivudine (3TC), Epivir®	Lopinavir/Ritonavir (LPV/RTV), Kaletra®	Nevirapine (NVP), Viramune®	Stavudine (d4T), Zerit®	Zidovudine (AZT, ZDV) Retrovir®
Interacting Drug							
Azathioprine	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	
Benzodiazepines							? Zidovudine M
Bepridil				*			
Carbamazepine				M anticonvulsant levels			
Cerivastatin				*Increased risk of myopathy			
Chloramphenicol	Peripheral neuropathy M		Peripheral neuropathy M			Peripheral neuropathy M	
Cimetidine					R: Dose adjustments may be necessary		? Zidovudine M
Cisapride		*Life-threatening adverse events: cardiac arrhythmias		*Life-threatening adverse events: cardiac arrhythmias			
Cisplatin	Peripheral neuropathy M		Peripheral neuropathy M			Peripheral neuropathy M	
Clarithromycin		*? Clarithromycin concentration M		M	R: Dose adjustments may be necessary		M
Cyclosporine				M			

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

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ARV Agent	Didanosine (DDI) or Videx®	Efavirenz (EFV), Stocrin®	Lamivudine (3TC), Epivir®	Lopinavir/Ritonavir (LPV/RTV), Kaletra®	Nevirapine (NVP), Viramune®	Stavudine (d4T), Zerit®	Zidovudine (AZT, ZDV) Retrovir®
Interacting Drug							
Dapsone	*Peripheral neuropathy Dapsone treatment failure reported		Peripheral neuropathy M			Peripheral neuropathy M	
Delavirdine				M			
Desipramine				M			
Dexamethasone				M			
Didanosine			Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M	M		Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M	
Doxorubicin							*
Efavirenz				M			
Ergot derivatives		*Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression		*Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression			
Erythromycin		? (potentially) Erythromycin concentration M			R: Dose adjustments may be necessary		
Estrogens	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal)			Lactic acidosis, pancreatitis (potentially fatal)	

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

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Interacting Drug			M			M	
Ethambutol	Peripheral neuropathy M		Peripheral neuropathy M			Peripheral neuropathy M	
Ethinyl estradiol (hormonal contraceptives)		*Use alternative birth control		*Use alternative birth control	*Use alternative birth control		
Ethionamide	Peripheral neuropathy M		Peripheral neuropathy M			Peripheral neuropathy M	
Felodipine				M			
Flecainide				*Life-threatening adverse events: cardiac arrhythmias			
Fluconazole							M
Fluoroquinolones	? Effect of fluoroquinolones R: separate doses by at least 2 hours						
Frusemide	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	
Ganciclovir	M R: didanosine toxicity possible						? histologic toxicity M

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Key: *Concomitant use is not recommended		M: Monitor patient carefully			R: Recommendation or suggested action		
ARV Agent Interacting Drug	Didanosine (DDI) or Videx®	Efavirenz (EFV), Stocrin®	Lamivudine (3TC), Epivir®	Lopinavir/ Ritonavir (LPV/RTV), Kaletra®	Nevirapine (NVP), Viramune®	Stavudine (d4T), Zerit®	Zidovudine (AZT, ZDV) Retrovir®
Hydralazine	Peripheral neuropathy M		Peripheral neuropathy M			Peripheral neuropathy M	
Hydroxyurea	*Pancreatitis (potentially fatal) Peripheral neuropathy		Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M			Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M	
Indinavir				M			
Indomethacin							? Zidovudine M
Interferon-alpha							? Histologic toxicity M
Isoniazid	Peripheral neuropathy M		Peripheral neuropathy M			Peripheral neuropathy M	
Itraconazole	*Itraconazole failure reported			M			
Ketoconazole Lamivudine	*Ketoconazole failure reported Pancreatitis (potentially fatal) Peripheral neuropathy M			R: Do not exceed 200mg ketoconazole daily	*?? Ketoconazole, ? Nevirapine	Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M	
Lignocaine				M			

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

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Interacting Drug							
Lithium	Peripheral neuropathy M		Peripheral neuropathy M			Peripheral neuropathy M	
Lopinavir/ritonavir		? Lopinavir/Ritonavir concentration M			?Lopinavir/ritonavir concentration M		
Lovastatin				*Increased risk of myopathy			
Methadone	? Didanosine concentration M			R: Methadone dose may need to be ?	R: Methadone dose may need to be ?		M
Methyldopa	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	
Metronidazole	Peripheral neuropathy M		Peripheral neuropathy M	M		Peripheral neuropathy M	
Midazolam		*Life-threatening adverse events: prolonged sedation		*Life-threatening adverse events: prolonged sedation			
Morphine							? Zidovudine M
Nelfinavir							M
Nevirapine		*		?Lopinavir/ritonavir concentration M			

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

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Interacting Drug							
Nicardipine				M			
Nifedipine				M			
Nitrofurantoin	Pancreatitis (potentially fatal) Peripheral neuropathy M		Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M			Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M	
Paracetamol							? Zidovudine M
Pentamidine	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	
Phenobarbitone		? Efavirenz concentration M		M anticonvulsant levels			
Phenytoin	Peripheral neuropathy M		Peripheral neuropathy M	M anticonvulsant levels		Peripheral neuropathy M	M
Pimozide				*Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression			

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

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Prednisone/ Prednisolone					? Incidence/ severity of rash		
Probenecid							? Zidovudine R: discontinue or reduce zidovudine dose temporarily M
Propafenone				*Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression			
Quinacrine				M			
Ribavirin	Pancreatitis (potentially fatal) Peripheral neuropathy M		Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M			Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M	*
Rifabutin		?Rifabutin concentration M R: consider increasing dose to rifabutin 400- 650mg daily		R: Consider ?rifabutin to 150mg every other day	? Nevirapine concentration OR ?? Rifabutin concentration M		

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

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Rifampicin		? Efavirenz concentration		*Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression	*? Nevirapine concentration OR ? Rifampicin concentration		? Zidovudine M
Rifapentine		*		*	*		
Ritonavir							M
Saquinavir				M			
Sildenafil				*? Hypotension/ syncope			
Simvastatin				*Increased risk of myopathy			
Sirolimus				M			
St. John's Wort		*? Efavirenz concentration		*? Lopinavir/ ritonavir concentration	*? Nevirapine concentration		
Stavudine	Pancreatitis (potentially fatal) Peripheral neuropathy M		Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M				*? Stavudine metabolism
Sulphamethoxazole/ trimethoprim			? Lamivudine clearance M				

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

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Sulphonamides	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	? Zidovudine M
Sulindac	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	
Tacrolimus				M			
Tenofovir disoproxil fumarate	*Monitor patients for didanosine toxicity						
Terfenadine		*Life-threatening adverse events: cardiac arrhythmias		*Life-threatening adverse events: cardiac arrhythmias			
Tetracyclines	Pancreatitis (potentially fatal) ? Effect of tetracyclines R: separate doses by at least 2 hours		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	
Theophylline				M theophylline levels			
Thiazide diuretics	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

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Interacting Drug							
Triazolam		*Life-threatening adverse events: prolonged sedation		*Life-threatening adverse events: prolonged sedation			
Valproic acid	Pancreatitis (potentially fatal) M		Lactic acidosis, pancreatitis (potentially fatal) M			Lactic acidosis, pancreatitis (potentially fatal) M	? Zidovudine M
Vincristine	Peripheral neuropathy M		Peripheral neuropathy M			Peripheral neuropathy M	
Voriconazole				M			
Warfarin		M warfarin level					
Zalcitabine	Pancreatitis (potentially fatal) Peripheral neuropathy M		Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M			Lactic acidosis, pancreatitis (potentially fatal) Peripheral neuropathy M	
Zidovudine						*? Stavudine metabolism	

References:

Guidelines for the Use of Antiretroviral Agents. Available online through the U.S. Dept. of Health and Human Services at: <http://www.aidsinfo.nih.gov/guidelines/>

Scaling up ART in Resource Limited Settings. Available online through the World Health Organization at: <http://www.who.int/docstore/hiv/scaling/guidelines.pdf>

This information sheet is current as of September 29, 2003. It should be revised annually under the supervision of the Chief Pharmacist at CPGH. The pharmacist should check the references above and send any changes to the pharmacy contact at each ART site using this SOP.

Coast Provincial General Hospital	
Prepacking Antiretroviral Drugs for the DAART Study	
Number of pages: 3	Procedure number: 110
Issued by: Name:	Record of amendments
Title:	Date:
Date:	Type:

Objective:

To describe correct and safe prepacking procedures for antiretroviral drugs.

Responsibility:

- Designated pharmacist in charge of checking prepacking for the ART Programme or his/her proxy (pharmacist) will be responsible for verifying that correct prepacking procedures are followed.
- Designated pharmacy staff (pharmacist or pharmacy technologist) for prepacking will be responsible for prepacking of ARVs.
- The same person will not be responsible for both activities.

Resources:

Forms used for prepacking ARVs:

ARV Prepacking Record

- Is a single loose-leaf form

Procedure:

1. Only one drug product should be prepacked at any one time in a work area. Work should begin in a clear workspace area.
2. When removing the stock bottle(s) from storage, double check that the stock bottle(s) contains the correct drug, strength/concentration, and dosage form that is to be prepacked. Check that the expiry date is appropriate.
3. Inspect the medication from the stock bottle. Look for broken or discoloured tablets or capsules. If any of the above are found, do not dispense them to patient. Complete a *Stock Count Discrepancy Report* as described in procedure 202: *Stock Count Discrepancy Report*. Discard the items according to procedure 402: *Disposal of Antiretroviral Drugs*.
4. Inspect packaging containers that will be given to the patients to make sure they are clean, not damaged, and appropriate for the drug product being packaged.
5. Collect the appropriate number of labels for the number of prepacks needed.
6. Fill in the labels as appropriate with:
 - Quantity
 - CPGH Prepacking Batch No.
 - Expiry date: 6 months from the date of prepacking for loose capsules or tablets, or the expiry date, whichever is less. For blister-packed ARVs use the manufacturer's expiry date.
 - Times of day that the medicine should be taken (may be left blank if prepacks are being prepared in advance)
 - Patient name (may be left blank if prepacks are being prepared in advance)
 - Date of dispensing (may be left blank if prepacks are being prepared in advance)
7. Fill out the *ARV Prepacking Record* as described below.
8. Before the prepacking begins, the pharmacist in charge of prepacking will check that:
 - The stock bottle(s) contain(s) the correct drug, strength/concentration, and dosage form.
 - The expiry date is appropriate.

- The entry in the *ARV Prepacking Record* is correct
 - The correct labels have been selected and that the information filled in correctly.
 - The number of labels and containers are the same and corresponds to the number of prepacks to be prepacked.
9. Count out correct number of units (tablets or capsules) using a spatula or knife on counting tray or clean sheet of paper. Avoid touching drug product with hands, as contamination may result.
 10. Recount number of units before packaging to reduce error risk.
 11. Once prepacking is complete, the pharmacist-in-charge of prepacking will check 10% of the packages to make sure that:
 - The prepacks contain the correct drug, strength, dosage form, and quantity.
 - The prepacks are labelled correctly.
 - No excess labels or empty containers are left.
 - The number of capsules/tablets left in the bulk container(s) reconciles with the number expected.
 12. Clean the area and put away all drugs, labels, and packaging materials.
 13. Prepacks should be stored under cool, dry conditions in a locked cabinet until the medicines are dispensed.

Steps for completing the *ARV Prepacking Record*:

- Before beginning prepacking, the staff member prepacking records:
 - CPGH Batch No.
 - Drug Name
 - Drug Strength and Form
 - Manufacturer Name
 - Manufacturer Batch No.
 - Manufacturer Expiry Date
 - Date of Prepacking
 - Prepack Expiry Date
 - Number of units (tablets/capsules) per prepack
 - Number of units (tablets/capsules) removed for prepacking
 - Number of prepacks to be prepared
- Before the prepacking begins, the pharmacist-in-charge of prepacking checks the products, labels, containers, and initials:
 - Label check
 - Product check
- When prepacking is complete, the staff member prepacking records:
 - Number of units (tablets/capsules) used for prepacking
 - Number of units (tablets/capsules) remaining
 - Signs as the prepacker
- After the reconciliation check of bottles, labels, and drugs, and the final check of 10% of the prepacks, the pharmacist-in-charge of prepacking:
 - Initials the Final prepacking check
 - Initials the Reconciliation check of bottles, labels, and drugs
 - Signs as the verifying pharmacist that correct prepacking procedures have been followed

Distribution:

- Form should be filed in the Pharmacy and kept for 2 years

**Coast Provincial General Hospital
ARV Prepacking Record**

CPGH Batch No.		Drug Name		Drug Strength & Form		Manufacturer Name		Manufacturer Batch No:	Manufacturer Expiry Date:	
Date of prepacking		Prepack expiry date		No. units/prepack		No. units removed for prepacking		No. units used for prepacking	No. of units remaining	
No. prepacks to prepare		Label check		Final prepacking check		Reconciliation check of bottles, labels & drugs		Prepacker's signature:		
		Product check			Verifying pharmacist's signature:					
CPGH Batch No.		Drug Name		Drug Strength & Form		Manufacturer Name		Manufacturer Batch No:	Manufacturer Expiry Date:	
Date of prepacking		Prepack expiry date		No. units/prepack		No. units removed for prepacking		No. units used for prepacking	No. of units remaining	
No. prepacks to prepare		Label check		Final prepacking check		Reconciliation check of bottles, labels & drugs		Prepacker's signature:		
		Product check			Verifying pharmacist's signature:					
CPGH Batch No.		Drug Name		Drug Strength & Form		Manufacturer Name		Manufacturer Batch No:	Manufacturer Expiry Date:	
Date of prepacking		Prepack expiry date		No. units/prepack		No. units removed for prepacking		No. units used for prepacking	No. of units remaining	
No. prepacks to prepare		Label check		Final prepacking check		Reconciliation check of bottles, labels & drugs		Prepacker's signature:		
		Product check			Verifying pharmacist's signature:					

Coast Provincial General Hospital	
Shipment Discrepancy Report	
Number of pages: 3	Procedure number: 201
Issued by: Name: Title: Date:	Record of amendments Date: Type:

Objective:

To describe the procedure for documenting any discrepancies between the shipping invoice and the shipment received.

Responsibility:

Receiving officer (the designated pharmacist in charge of the ARV bulk store or his/her designated proxy) and a witnessing pharmacy staff member.

Resources:

Forms used for recording shipping discrepancies

Shipment Discrepancy Report

- Is a duplicate form.

Forms needed to complete *Shipment Discrepancy Report*:

- *Counter Receipt Voucher (S13)*
- Shipment invoice

Procedure:

1. Errors in shipment must be recorded on the *Shipment Discrepancy Report*. Errors in shipping may include the following:
 - Damaged products, including:
 - Broken, cracked, or leaking bottles or bottles where seals are broken
 - Broken tablets
 - Drugs that arrive past their expiration date
 - Items that have no labels
 - Refrigerated items that arrive at room temperature or are warm
 - Inappropriate storage procedure during transportation of refrigerated items
 - Requirements from the tender that have not been met
 - Items listed on the invoice that are missing from the shipment
 - Items received that were not ordered or were not listed on the invoice
2. The form should be completed by the receiving officer and should be witnessed by another pharmacy staff member.

Steps for filling out the *Shipment Discrepancy Report*:

1. Record:
 - Date: date of shipment
 - Received by: name of receiving officer
 - Witnessed by: name of witnessing pharmacy staff member
 - Invoice number
 - Transport Company: name of transport company
 - Vehicle Reg. No.: delivery vehicle registration number
 - Driver Name
 - Number of boxes received
 - No. of Other Containers Received

- For each item that is damaged, missing, or incorrect, fill out:
 - Serial No. : found on the *S13* where the product is recorded (if you are reporting items missing from the shipment, this will be left blank)
 - Item Description
 - generic drug name
 - strength/concentration
 - dosage form
 - Code No.: number listed in the Kenya Essential Drug List which is specific to each drug, strength/concentration and dosage form
 - Unit: unit of issue (i.e., number of tablets per package)
 - Quantity Broken, Quantity Missing, Quantity in Error: items broken/missing/issued in error
 - Comments: describing nature of error (i.e., broken bottles, expiration date for drugs delivered expired, missing drugs, or drugs received that were not ordered or not listed on invoice, etc.)
- 2. Signatures of receiving officer and witnessing pharmacy staff member

Distribution:

- Give the original copy of the *Shipment Discrepancy Report* to the Chief Administrator and keep one copy on file with the *Counter Receipt Voucher (S13)* for this shipment in the ARV bulk store.
- The information on the *Shipment Discrepancy Report* will be used to complete the *Antiretroviral Internal Audit Record* as described in procedure 501: *Internal Audit of Antiretroviral Drugs*.

**Coast Provincial General Hospital
SHIPMENT DISCREPANCY REPORT**

Date:

Received by:

Witnessed by:

Details of Shipment

Invoice Number:

Transport Company: Vehicle Reg. No.:

Driver Name:

No. of Boxes Received: No. of Other Containers Received:

Details of Discrepancies

Breakages:

Serial No.	Item Description	Code No.	Unit	Quantity Broken	Comments

Items Missing:

Item Description	Code No.	Unit	Quantity Missing	Comments

Items Issued in Error:

Serial No.	Item Description	Code No.	Unit	Quantity in Error	Comments

Any other discrepancies or comments:

Signature of receiving officer:

Signature of witness:

Coast Provincial General Hospital	
Stock Count Discrepancy Report	
Number of pages: 3	Procedure number: 202
Issued by: Name:	Record of amendments
Title:	Date:
Date:	Type:

Objectives:

- To describe the procedure for documenting any discrepancies between physical counts of the ARVs held at the ARV bulk store and the quantity recorded on the *Bulk Store Bin Card (S5)*.
- To describe the procedure for documenting any discrepancies between physical count of the ARVs held at the outpatient pharmacy and the quantity recorded on the *Hospital Pharmacy Bin Cards (MOH 999)*.
- To describe the procedure for documenting any discrepancies between the records of ARV stock issued and stock received during transfer of stock from the ARV bulk store and the outpatient pharmacy.

Responsibility:

- The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and a witnessing pharmacist.
- The designated pharmacy staff member in charge of the outpatient pharmacy or his/her designated proxy and a witnessing pharmacist.
- The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and the designated pharmacy staff member in charge of the outpatient pharmacy or a witnessing pharmacist.

Resources:

Form used to record stock count discrepancy:

Stock Count Discrepancy Report

- Is a duplicate form.

Forms needed to fill complete *Stock Count Discrepancy Report*:

- *Bulk Store Bin Card (S5)*
- *Stores Ledger and Stock Control Card (S3)*
- *Hospital Pharmacy Bin Cards (MOH 999)*
- *Drugs and Revenue Register*

Procedure:

- A *Stock Count Discrepancy Report* is completed when a physical count in the ARV bulk store is different from the count recorded on the *Bulk Store Bin Card (S5)* or when the physical count of ARVs kept in the outpatient pharmacy is different from the count recorded on the *Hospital Pharmacy Bin Cards (MOH 999)*.
- It can also be used to record broken or damaged tablets/bottles that cannot be dispensed to patients.
- Countercheck any discrepancy in the ARV store on the *Bulk Store Bin Card (S5)* with the corresponding *Stores Ledger and Stock Control Card (S3)*.
- Countercheck any discrepancy in the outpatient pharmacy on the *Hospital Pharmacy Bin Cards (MOH 999)* with the *Drugs and Revenue Register*.

- Give a full explanation for any discrepancy reported (e.g., circumstances where a drug preparation was lost, discovery of drugs or drug packaging that are damaged or expired and must be destroyed, or the accidental loss of drug via spillage, etc.).

Steps for completing the *Stock Count Discrepancy Report*:

1. Record:
 - Date
 - Serial No.: from *S5* or *MOH 999*
 - Item Code No.: from *S5* or *MOH 999*
 - Bin Card No. : from *S5* or *MOH 999*
 - Unit of Issue
 - Item Description:
 - generic name
 - strength/concentration
 - dosage form
 - Location: *ARV bulk store* or *outpatient pharmacy*
 - Recorded Count: the count recorded on *S5* or *MOH 999*
 - Physical Count
 - Difference: between the recorded count and the physical count
 - For the ARV bulk store record:
 - Count recorded on corresponding *Stores Ledger and Stock Control Card (S3)*
 - For the outpatient pharmacy record:
 - Count recorded in *Drugs and Revenue Register*
 - A complete explanation of the discrepancy, including reason for discrepancy (expiration of product, damaged product, spillage, etc.)
2. The form should be signed and dated by both the person performing the physical count and a witness:
 - The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and a witnessing pharmacist.
 - The designated pharmacy staff member in charge of the outpatient pharmacy or his/her designated proxy and a witnessing pharmacist.
 - The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and the designated pharmacy staff member in charge of the outpatient pharmacy or a witnessing pharmacist.

Distribution:

- Give the original copy to the Chief Administrator and keep one copy on file with the *Bulk Store Bin Cards (S5)* in the ARV bulk store or the *Hospital Pharmacy Bin Cards (MOH 999)* in the outpatient pharmacy.
- The information on the *Stock Count Discrepancy Report* will be used to complete the *Antiretroviral Internal Audit Record* as described in procedure 501: *Internal Audit of Antiretroviral Drugs*.

Coast Provincial General Hospital Stock Count Discrepancy Report

Date: Serial No:

Item Code No: Bin Card No:

Unit of Issue: Item Description:

Location:

Discrepancy Description	
Recorded Count: Physical Count: Difference:	
Count recorded on corresponding <i>Stores Ledger and Stock Control Card (S3)</i> :	Count recorded on corresponding <i>Drugs and Revenue Register</i> :
Details and Explanation of Discrepancy	
<input type="checkbox"/> Damaged	Details of damage/breakage and cause :
<input type="checkbox"/> Expired Date of shipment: Date of expiry:	Details of expired stock and quantity removed:
<input type="checkbox"/> Accidental loss	Details and explanation:
<input type="checkbox"/> Unknown	Details and explanation:

.....
Pharmacy staff member in charge: Name and Signature

.....
Date

.....
Witnessing pharmacist: Name and Signature:

.....
Date

Coast Provincial General Hospital	
Antiretroviral Therapy Adverse Drug Reaction Monitoring and Reporting	
Number of pages: 14	Procedure number: 301
Issued by: Name: Title: Date:	Record of amendments Date: Type:

Objectives:

The purpose of the ART Adverse Drug Reaction (ADR) Monitoring and Reporting procedure at CPGH is twofold:

- To minimize adverse outcomes by early detection of ADRs in individual ART patients
- To continuously improve treatment approaches, policies, procedures and training by analysis of aggregate ADR data from ART patients

Policy:

ADR identification, reporting, and review is an essential component of the ART Programme patient care at CPGH and contributes to optimal outcomes and patient safety. All ART patients' ADRs will be reported on an ADR form. The forms will be reviewed, compiled, examined for trends, reported, and appropriate actions will be taken in response to the ADR report.

Note: During the first three months of ART ADR monitoring and reporting, all ADRs, regardless of severity or causality, will be recorded on ADR forms to instil a notification culture within the Programme.¹ The ADR form will be used to report on ADRs to ART and other drugs used in the Programme

Definitions:²

Adverse drug reaction: a response to a medicine that is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or the modification of physiological function

Serious adverse drug reaction: any reaction that is fatal, life-threatening, permanently/significantly disabling, requires or prolongs hospitalization, causes a congenital anomaly, or requires intervention to prevent permanent impairment or damage

Responsibility:

The role of core team members is listed in Table 1.

Table 1: Role of Core Team Members

Core Team Member	Role in ADR Monitoring, Reporting, and Review
Triage nurse ART nurse Nutritionist Pharmacist Pharmaceutical technologist Laboratory technologist	<ul style="list-style-type: none"> • Understand the definition of an ADR. • Understand what signs or comments from patients might indicate ADRs. • Refer all patients with suspected ADRs to the Medical Officer (MO)/ Registered Clinical Officer (RCO). • Laboratory technologist will consider ADR referral for patients with unscheduled labs or abnormal lab values for blood sugar, CBC, LFTs, bicarbonate, chloride, lipid levels, and will refer patients with suspected ADRs to the MO/RCO. The laboratory technologist will refer to the ADR document <i>Estimating Severity Grading</i> for guidance in determining suspect lab values for a possible ADR referral. • If the laboratory technician suspects an ADR, he/she will immediately request that a fresh blood specimen to be collected as soon as possible.
Registered Clinical Officer and Medical Officer	<ul style="list-style-type: none"> • Understand the definition of an ADR. • Assess patients for ADRs on all routine visits using <ul style="list-style-type: none"> ○ Objective Evidence (labs, vital signs, and physical exam) ○ Subjective Evidence (patient counselling) • Evaluate and treat patients when appropriate. • For an initial period the RCO will refer all patients with suspected ADRs to the MO. At a period to be determined by the ART Eligibility Committee, the RCO will only refer to the MO patients with suspected serious ADRs, ADRs that require treatment, or complicated, unclear, or unusual cases. • Counsel the patient regarding when to return to the clinic for an extra visit to assess the ADR, changing drug therapy, etc. • Counsel the patient regarding the signs that the reaction has abated or accelerated and what to do in each case. • Document suspected ADR in a progress note in medical record. • Write the name of the drug suspected of causing the ADR that falls into the probability categories definite or probable in red pen/red sticker on the cover of medical record. • Complete one ADR form for each ADR and place the original form in the record. • Ensure that a duplicate copy of the ADR form is received by the pharmacist in charge of the ART Programme. • Refer to the document <i>Estimating Severity Grading</i> for guidance in determining severity.

Core Team Member	Role in ADR Monitoring, Reporting, and Review
ART nurse	<ul style="list-style-type: none"> • Understand the definition of an ADR. • Initially counsel all patients regarding the possibility of ADRs. Inform patients of signs and symptoms that may indicate an ADR. • Instruct patients that in the event of an ADR, they should return to the clinic immediately if the reaction is life-threatening or contact the MO/RCO as soon as possible in all other instances. • Continually screen patients for ADRs according to Standard Operating Procedures. • For an initial period, only the MO will complete the ADR form. Refer all patients with suspected ADRs to the MO/RCO. • After a period to be determined by the ART Eligibility Committee, complete first section of one ADR form for each ADR reported. Refer patients with suspected ADR to the MO/RCO with the ADR form. • Work with the pharmacist in charge of the ART Programme and the Records Officer to ensure the original ADR form is placed in the patient's record.
Pharmacist Pharmaceutical technologist	<ul style="list-style-type: none"> • Understand the definition of an ADR. • Counsel all patients regarding the possibility of ADRs. Inform patients of signs and symptoms that may indicate an ADR. • Instruct patients that in the event of an ADR, they should return to the clinic immediately if the reaction is life-threatening or contact the MO/RCO as soon as possible in all other instances. • For an initial period, only the MO will complete the ADR form. Refer all patients with suspected ADRs to the MO/RCO. • After a period to be determined by the ART Eligibility Committee, complete one ADR form for each ADR reported. Refer patients with suspected serious ADRs or patients requiring treatment to the MO/RCO.

Core Team Member	Role in ADR Monitoring, Reporting, and Review
Pharmacist in charge of the ART Programme or designated deputy	<ul style="list-style-type: none"> • Work with the Records Officer and the nursing staff to make sure that the original ADR form is placed in the patient record and the duplicate is received by the pharmacist. • Work with the MO/RCO to calculate the probability that an ADR was caused by a specific drug using the (modified) Naranjo Method³ and complete the <i>ART ADR Report</i>. Refer ADR reports to the ART Eligibility Committee for review. • Maintain a file of all completed ADR forms and relevant reports. • Review ADR forms on an ongoing basis and alert the ART Eligibility Committee of unusual trends or findings. • Provide verbal feedback at ART Eligibility Committee meetings, or written feedback to staff regarding outcomes of referred ADRs (to encourage continued reporting). • Prepare <i>ADR Summary Report</i>. • Present to the ART Eligibility Committee, the <i>ADR Summary Report</i> and findings.

Procedure:

• **Staff ADR Education**

1. Orientation for all core team members includes a session describing the importance, definition, flow, and recognition of ADRs.
2. In addition, specific instruction regarding ADR form completion will be provided for the RCO/MO.
3. Education regarding report generation, report assessment, and Uppsala Monitoring Centre/manufacture reporting will be provided for the pharmacist in charge of the ART Programme.
4. The ART Eligibility Committee will be responsible for ensuring the staff receives ongoing education, as appropriate, based on pertinent information gleaned in the ADR reports.

• **ADR Form Completion and Actions on an Individual Level**

For an initial period, to be determined by the ART Eligibility Committee, all suspected ADRs will be referred to the MO and only the MO will complete the ADR form.

The ART Eligibility Committee will determine when selected ADRs will not need to be referred to the MO and can be dealt with by the RCO.

Similarly, the ART Eligibility Committee will determine when staff other than the MO and RCO can complete the ADR form and which ADRs they should refer to the MO or RCO.

I. ADR Flow (for the initial period)

1. Patient presents with clinical symptoms or signs or staff member (triage nurse, ART nurse, nutritionist, pharmaceutical technologist, and laboratory technologist) suspects an ADR. (If patient initially presents to MO with ADR complaint, MO will proceed with step 3 below.)
2. Patient is referred to the MO.
3. The MO:
 - o Counsels patient
 - o Records suspected ADR both in a progress note and in red pen/red sticker on the front of the record, when warranted
 - o Treats patient
 - o Records suspected ADR on *ART ADR Form* and documents actions taken (Part A)
 - o Places the original form in the record.
 - o Gives a carbon copy of the *ART ADR Form* to pharmacist in charge of the ART Programme or to the ART nurse to give to the pharmacist
4. The Pharmacist in charge of the ART Programme :
 - o Works with the Records Officer to ensure that one copy of the *ART ADR Form* is placed in patient's record.
 - o Reviews the *ART ADR Form*
 - o Works with the MO to complete the form and to assign a probability category as outlined in Section II below
 - o Generates an *ART ADR Report* which is attached to the *ART ADR Form*.
 - o Refers the report to the ART Eligibility Committee
5. The ART Eligibility Committee:
 - o Reviews the *ART ADR Report* and the ADR probability estimation
 - o Decides to take appropriate actions in response to ADRs and/or *ART ADR Reports* as outlined in Section III Table 2

II. ADR Probability Estimation

The probability that an ADR was caused by a specific drug will be determined using the (modified) Naranjo Method.³

ADR Probability Score			
Answer the questions, circle the pertinent score, sum all responses to give a total score, and choose the corresponding probability category.	Yes	No	Do not know
1. Are there previous conclusive reports on this reaction?	+1	0	0
2. Did the adverse reaction appear after the suspected drug was administered?	+2	-1	0
3. Did the adverse reaction improve when the drug was discontinued?	+1	0	0
4. Did the adverse reaction reappear when the drug was readministered?	+2	-1	0
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0
6. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0
7. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0
8. Was the adverse reaction confirmed by any objective evidence?	+1	0	0
Total			

Probability Category: Definite ≥ 9 , Probable 5–8, Possible 1–4, Doubtful ≤ 0

III. ADR Actions on an Individual Level

Possible actions that could be taken by ART Eligibility Committee to an *ART ADR Report* on an individual level are outlined in Table 2.

Table 2: ADR Actions on an Individual Level

ADR Form Field Response	Possible Actions
<p>Serious ADRs associated with ADR Probability Category Definite or Probable</p> <ul style="list-style-type: none"> • not listed in the product labelling <p>or</p> <ul style="list-style-type: none"> • occurring in drugs less than 5 years old since first approved by the Pharmacy and Poisons Board 	<ul style="list-style-type: none"> • Refer the patient to the ART Programme Consultant Team for further assessment • Notify the Scientific Committee. The Scientific Committee could decide to inform the Steering Committee who may <ul style="list-style-type: none"> ○ Notify the Pharmacy and Poisons Board ○ Notify the manufacturer
<p>Serious ADRs associated with ADR Probability Category Definite or Probable listed in the product labelling</p>	<ul style="list-style-type: none"> • Refer the patient to the ART Programme Consultant Team for further assessment • Notify the Scientific Committee
<p>Grade 1 and 2 ADRs associated with ADR Probability Category Definite or Probable not listed in the product labelling</p>	<ul style="list-style-type: none"> • Refer the patient to the ART Programme Consultant Team for further assessment • Notify the Scientific Committee
<p>ADRs occurring when the intended medications were not taken at the intended dosages</p>	<ul style="list-style-type: none"> • The MO/RCO/RNO will contact the ART nurse, and take appropriate action (ensure patient receives additional counselling, etc.)

• **ADR Summary Report and Actions on an Aggregate Level**

I. ADR Flow

1. Pharmacist in charge of the ART Programme
 - Reviews the *ART ADR Forms* and *ART ADR Reports* and prepares the *ADR Summary Report* at the end of each month
 - Looks for unusual trends.
 - Reviews the *Actions Taken* section of the reports submitted to ensure that appropriate actions have been taken as decided by the ART Eligibility Committee based on the outline in Table 2
 - Presents the *ADR Summary Report* to the ART Eligibility Committee at the first meeting of each month
 - Reports on unusual trends
 - Reports on inappropriate actions taken

2. The ART Eligibility Committee
 - Reviews the *ADR Summary Report* and if necessary, the raw data
 - Decides to take appropriate actions in response to *ADR Summary Reports* and/or on unusual trends and/or inappropriate actions taken (possible actions are outlined in Section III Table 3)
 - Forwards the *ADR Summary Reports* and presents the findings to the Scientific Committee
3. The Scientific Committee reviews the *ADR Summary Reports* and decides on appropriate action to be taken (possible actions are outlined in Section III Table 3)

II. Steps for Completing the *ADR Summary Report*

The *ADR Summary Report* is a compilation of the data elements on the *ART ADR Form* and *ART ADR Report*.

The *ADR Summary Report-Part I* includes:

1. ADR Rate Per Total ART Patients
 - Calculated by dividing the total number of ADRs for the month by the total number of patients receiving ART
2. Total number of ADRs: reported by
 - Age group
 - ADR probability category
 - Actions taken
 - Patient outcomes from ADR
 - Interventions required from ADR
3. Suspected Drugs: names of the specific drugs

The *ADR Summary Report-Part II* includes:

4. Reports by each ARV drug used in the ART Programme
 - ADR Rate Per Total ART Patients Taking the Drug
 - Calculated by dividing the total number of ADRs for an individual drug for the month by the total number of patients receiving the ARV drug
 - Total ADRs: reported by suspected drug by
 - Age group
 - ADR probability category
 - Actions taken
 - Patient outcomes from ADR
 - Interventions required from ADR
 - ADRs reported

The *ADR Summary Report-Part III* includes:

5. Reports for a specific side effect for an ARV drug used in the ART Programme if deemed necessary to determine trends
 - ADR Rate Per Total ART Patients Taking the Drug
 - Calculated by dividing the total number of a specific ADR for the month by the total number of patients receiving the ARV drug
 - Total ADRs: reported by suspected drug by
 - Age group
 - ADR probability category
 - Actions taken
 - Patient outcomes from ADR
 - Interventions required from ADR

III. ADR Actions on an Aggregate Level

Once ADR data has been collected for 6 months, it may be useful for the ART Eligibility Committee and/or the Scientific Committee to set numerical thresholds for specific data elements as triggers for action.

Suggested trends and actions for the data fields appearing on the *ADR Summary Report* and the *ART ADR Form* appear in Table 3 below. This table is not all-inclusive; it merely provides a starting point for the ART Eligibility Committee and/or the Scientific Committee and/or Steering Committee to use when evaluating the *ART ADR Reports*.

Table 3: ADR Actions on an Aggregate Level

Trends	Possible Actions
<p>An increase in suspected/probable ADRs associated with a specific age group, gender, pregnancy status, drug class or particular drug</p> <p>Serious ADRs associated with ADR Probability Category Definite or Probable</p> <ul style="list-style-type: none"> • not listed in the product labelling <p>or</p> <ul style="list-style-type: none"> • occurring in drugs less than 5 years old since first approved by the Pharmacy and Poisons Board <p>Appropriate actions are not being taken in response to suspected ADRs as decided by the ART Eligibility Committee and/or based on the outline in Table 2.</p>	<ul style="list-style-type: none"> • Notify the Scientific Committee • Drug may be used cautiously in particular groups with extra patient monitoring (lab or clinic visits) required • Drug may not be given to particular groups • Drug may be removed from treatment plan • ADR may be reported to the manufacturer and/or the Pharmacy and Poisons Board by the Steering Committee on the recommendation of the Scientific Committee • ART Eligibility Committee and/or Scientific Committee will investigate possible causes of this increase and take appropriate corrective or preventative actions • Notify the Scientific Committee • Drug may be used cautiously with extra patient monitoring (lab or clinic visits) required • Drug may be removed from treatment plan • ADR may be reported the manufacturer and/or the Pharmacy and Poisons Board by the Steering Committee on the recommendation of the Scientific Committee • A training session could be organised • Discuss with individual prescribers

Distribution:

- A copy of the *ART ADR Form* is kept in the patient record and a duplicate copy is kept on file in the Pharmacy with a copy of the *ART ADR Report*.
- The *ADR Summary Reports* are held on file in the Pharmacy.
- All reports are kept in a confidential file.

References:

1. Safety Monitoring of Medicinal Products. Pg. 20. The Uppsala Monitoring Centre/World Health Organization. 2000.
2. Safety Monitoring of Medicinal Products. Pg. 8. The Uppsala Monitoring Centre/World Health Organization. 2000.
3. Naranjo, et al. A method for evaluating the probability of adverse drug reactions. *Clinical Pharmacology Therapeutics*, 1981; 30:239-245.

Antiretroviral Therapy Adverse Drug Reaction (ADR) Form

Please place original form in the patient records and return duplicate to ART pharmacist

Patient	Patient Name					Reporter	Reporter's Name, Title, Signature		
	Patient ID No.						Clinician's Name (if not the reporter)		
	Age	Gender M / F	Pregnant YES/NO	Weight	Height				

Suspected Drug	Suspected Drug Name and Batch No.	Daily Dose	Route	Start Date	Stop Date	Indication
	1. _____	_____	_____	_____	_____	_____
	Other drug(s) taken in the last 3 months. (Continue on back if needed)					
	2. _____	_____	_____	_____	_____	_____
	3. _____	_____	_____	_____	_____	_____
	4. _____	_____	_____	_____	_____	_____
	5. _____	_____	_____	_____	_____	_____
	6. _____	_____	_____	_____	_____	_____
	7. _____	_____	_____	_____	_____	_____
	8. _____	_____	_____	_____	_____	_____
9. _____	_____	_____	_____	_____	_____	
Were the intended medications taken at intended dosage? Yes No (circle one)						

Reaction	Tick all boxes that describe the ADR.					
	? Pain/tingling/numbness in extremities	? Chills/fever	? Unusual fatigue			
	? Abdominal or back pain	? Insomnia	? Unusual bruising/bleeding			
	? Nausea/vomiting/diarrhoea	? Rash	? Other _____			
	? Anxiety, depression	? Headache	_____			
	? Persistent muscle pain/weakness	? Dizziness	_____			
Date ADR Started: ____/____/____ Date ADR Stopped: ____/____/____						
Describe additional details (nature, localisation, results of tests, course, risk factors):						

Severity	Tick the grade of severity of the ADR.	
	? Grade 1: Mild	transient or mild discomfort, no limitation in activity, no medical intervention/therapy required
	? Grade 2: Moderate	mild to moderate limitation in activity; some assistance may be needed, no or minimal medical intervention/therapy required
	? Grade 3: Severe	marked limitation in activity, some assistance usually required, medical/intervention/therapy required, hospitalisation possible
	? Grade 4: Life Threatening	extreme limitation in activity, significant assistance required, significant medical intervention/therapy required, hospitalisation or hospice care probable

Outcome	Tick all applicable boxes for sections A, B and C.		
	A-Action Taken	B-Patient Outcomes from ADR	C-Interventions Required
	? Discontinued suspected drug	? Symptoms resolved/improved	? Patient counselled
	? Decreased dose	? Permanent/significant disability	? Drug required to treat ADR
	? Other _____	? Congenital abnormality	? Additional clinic visit
_____	? Life-threatening	? Additional labs	
_____	? Patient death	? Hospitalisation	
	? Other _____	? Other _____	

Antiretroviral Therapy Adverse Drug Reaction (ADR) Report

Complete one report per ADR form submitted and attach to duplicate copy of Antiretroviral Therapy ADR Form.

Patient Name:	Patient ID No.:	Symptoms that describe the ADR:
Date ADR Reported:	ADR form No.:	

Drug Name	Dose & Frequency	Drug Given at Correct Dose Yes/No	Start Date	Stop Date	ADR Listed in Labelling Yes/No	Drug Is <5 Years Old	Batch No.	Probability Score	Probability Category	Comments

Date presented to the Eligibility Committee	Action Taken
--	---------------------

Adverse Drug Reaction Summary Report – Part II

<i>Drug Name:</i>								
<i>Year : 200</i>	<i>June</i>	<i>July</i>	<i>August</i>	<i>Sept</i>	<i>October</i>	<i>Nov</i>	<i>Dec</i>	<i>Total</i>
ADR Rate Per Total ART Patients Taking the Drug								
Total ADRs								
Age<1								
Age 1– 12								
Age >12								
# Pregnant Patients								
Males								
Females								
ADR Probability Category								
Definite								
Probable								
Possible								
Doubtful								
Actions Taken								
Discontinued Suspected Drug								
Decreased Dose Suspected Drug								
Other								
Patient Outcomes from ADR								
Symptoms Resolved/Improved								
Permanent/Significant Disability*								
Congenital Abnormality*								
Life-threatening*								
Patient Death*								
Other								
Interventions Required from ADR								
Patient Counselling								
Drug Required to Treat Reaction								
Additional Clinic Visit								
Additional Labs								
Hospitalisation*								
Other								
ADRs Reported								

Adverse Drug Reaction Summary Report – Part III

<i>Drug Name:</i>				<i>ADR:</i>				
<i>Year : 200</i> _____	<i>June</i>	<i>July</i>	<i>August</i>	<i>Sept</i>	<i>October</i>	<i>Nov</i>	<i>Dec</i>	<i>Total</i>
ADR Rate Per Total ART Patients Taking the Drug								
Total ADRs								
Age<1								
Age 1–12								
Age >12								
# Pregnant Patients								
Males								
Females								
ADR Probability Category								
Definite								
Probable								
Possible								
Doubtful								
Actions Taken								
Discontinued Suspected Drug								
Decreased Dose Suspected Drug								
Other								
Patient Outcomes from ADR								
Symptoms Resolved/Improved								
Permanent/Significant Disability*								
Congenital Abnormality*								
Life-threatening*								
Patient Death*								
Other								
Interventions Required from ADR								
Patient Counselling								
Drug Required to Treat Reaction								
Additional Clinic Visit								
Additional Labs								
Hospitalisation*								
Other								

Coast Provincial General Hospital	
Medication Error Reporting	
Number of pages: 3	Procedure number: 302
Issued by: Name: Title: Date:	Record of amendments Date: Type:

Objectives:

To describe the procedure for reporting medication errors. *Medication Error Reports* are used to make improvements in the medication systems (i.e., design, method of administering medication, training, supervision and monitoring).

Responsibility:

Any hospital health care worker that recognizes a medication error.

Resources:

Form used to record a medication error:

Medication Error Report:

- Is a single loose-leaf form.
- Should be used at all locations where patients receive medications (e.g., outpatient department, wards, theatres, x-ray department).
- Each ward and department should obtain forms from the ARV bulk store.
- Will be used to make improvements in the medication systems, i.e., design, method of administering medication, training, supervision and monitoring.
- There will not be any legal consequences to recording an error.
- Is not part of the patient's medical record.

Procedure:

1. Use the *Medication Error Report* to report :
 - Incorrect drug administered to patient
 - Omitting an ordered dose
 - Incorrect time of administration
 - Incorrect dose
 - Incorrect dosage form
 - Unauthorized prescriber
 - Administration of expired drug
 - Administration of medication to the wrong patient
 - For the ART Programme, to keep a record of prescribing errors
2. Serious medication errors should be investigated by the appropriate person in charge of the concerned department and by the Chief Administrator. This could include the nurse in charge of the unit, the Head of Clinical Services, and/or the Chief Pharmacist

Steps for completing the *Medication Error Report*:

Record:

- Date and time of error: fill in date and time at which error was made , if known
- Location of error: state the location(s) at which the incident occurred (e.g. , ward name)
- Patient's name, IP/OP number, and diagnosis
- Responsible doctor informed at (time/date):
By: name and position of person who informed the doctor

- Staff involved:
 - Positions of staff who were, in any way, involved in the medication error
 - Names of persons to whom error was immediately reported
- Full description: provide a full description of error, including the name of the drug(s) concerned, dosage, route of administration, how the error occurred, and immediate consequences
- Patient's status: indicate what the status of the patient was following the medication error
- Counter measures taken: describe any measures that were taken to counter the effect of the medication error (e.g., gastric lavage)
- Comments/review by responsible doctor
- Comments by other responsible person in charge
- Signature and position of staff completing report
- Date of report: date report prepared

Distribution:

- Original report is forwarded to the responsible person in charge who discusses it with the doctor/nurse in charge and makes relevant comments indicating an opinion on why the error occurred. Comments from other hospital staff are included as appropriate.
- The completed report is forwarded to the Chief Administrator who decides on appropriate action to be taken to prevent a repetition of the error, if any.
- A duplicate copy is given to the Chief Pharmacist.
- All reports are kept in a confidential file.

**Coast Provincial General Hospital
Medication Error Report (Confidential)**

1. Date and time of error: _____
 2. Location of error: _____
 3. Patient's name, IP/OP number and diagnosis: _____
 4. Responsible doctor informed at (time/date): _____
By: _____
 5. Staff involved: _____

 6. Full description (e.g., drug, dosage, route, consequences): _____

 7. Patient's status: _____

 8. Counter measures taken: _____

 9. Comments/review by responsible doctor : _____

 10. Comments by responsible person in charge : _____

 11. Comments in responsible charge: _____

- Signature: _____ Date of report: ____/____/_____
Position: _____

Coast Provincial General Hospital	
Temperature Control	
Number of pages: 5	Procedure number: 401
Issued by: Name:	Record of amendments
Title:	Date:
Date:	Type:

Objective:

To describe procedures to ensure that antiretroviral drugs are stored at appropriate temperatures to maintain the quality of the products.

Responsibility:

- Designated pharmacist in charge of the ARV bulk store or his/her designated proxy
- Designated pharmacy staff member in charge of dispensing for the outpatient pharmacy or his/her designated proxy

Resources:

Forms used for temperature control:

Temperature Control Log: ARV Bulk Store

Temperature Control Log: ARV Bulk Store Refrigerator

Temperature Control Log: Outpatient Pharmacy ARV Store

Procedure:

1. Monitor the temperature of the ARV bulk store and the outpatient pharmacy TWICE daily. Monitor the temperature of the ARV bulk store refrigerator ONCE daily.
2. Complete the *Temperature Control Log: ARV Bulk Store*, *Temperature Control Log: ARV Bulk Store Refrigerator*, and the *Temperature Control Log: Outpatient Pharmacy ARV Store* as described below.
3. Acceptable limits for the ARV storage areas are:
 - ARV bulk store and outpatient pharmacy temperature 18–25°C
 - ARV bulk store refrigerator temperature 2–8°C
4. Report temperatures not within acceptable range to the ART Pharmacist or his/her proxy IMMEDIATELY.
5. Check to ensure that the ARV bulk store air-conditioning system is working effectively on a regular basis.
6. Report any problems with the air-conditioning system to the ART Pharmacist or his/her proxy IMMEDIATELY.
7. The ART Pharmacist or his/her proxy should inform the Chief Pharmacist and alert the Deputy Administrator and/or Chief Administrator of the need to take immediate action to repair the air conditioning and/or cool the storage area.
8. The ART Pharmacist is responsible for following up on repairs/action to be taken on a daily basis.

Steps for completing *Temperature Control Log: ARV Bulk Store*

- A.M./P.M. Time: Enter the time the temperature is checked
- Recorded temp (°C): write down the temperature
- Acceptable Yes(✓)/No:
 - ✓ if the temperature is within the acceptable range
 - Write NO if the temperature is outside of the acceptable range
- Initials

Steps for completing *Temperature Control Log: ARV Bulk Store Refrigerator*

- Time: enter the time the temperature is checked on that day
- Recorded temp (°C): write down the temperature
- Within acceptable range:
 - ✓ if the temperature is within the acceptable range
 - Write NO if the temperature is outside of the acceptable range
- Initials

Steps for completing *Temperature Control Log: Outpatient Pharmacy ARV Store*

- A.M./P.M. Time: enter the time the temperature is checked
- Recorded temp (°C): write down the temperature
- Acceptable Yes(✓)/No:
 - ✓ if the temperature is within the acceptable range
 - Write NO if the temperature is outside of the acceptable range
- Initials

Distribution:

- The logs in use are pinned up in the relevant area.
- Completed logs are kept on file in the ARV bulk store.
- The information on the temperature logs will be used to complete the *Antiretroviral Internal Audit Record* as described in procedure 501: *Internal Audit of Antiretroviral Drugs*.

**Coast Provincial General Hospital
Temperature Control Log: ARV Bulk Store**

Month/Year:/200__

Acceptable temperature range +18-25°C

Date	A.M. Time	Recorded Temp (°C)	Acceptable Yes(✓)/No	Initials	P.M. Time	Recorded Temp (°C)	Acceptable Yes(✓)/No	Initials
1								
2								
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**Coast Provincial General Hospital
Temperature Control Log: ARV Bulk Store Refrigerator**

Month/Year:200__

Acceptable Range 2-8°C

Day	Time	Recorded Temp (°C)	Within Acceptable Range Yes(✓)/No	Initials
1				
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31				

**Coast Provincial General Hospital
Temperature Control Log: Outpatient Pharmacy ARV Store**

Month/Year:/200__

Acceptable temperature range +18-25°C

Date	A.M. Time	Recorded Temp (°C)	Acceptable Yes(✓)/No	Initials	P.M. Time	Recorded Temp (°C)	Acceptable Yes(✓)/No	Initials
1								
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Coast Provincial General Hospital	
Disposal of Antiretroviral Drugs	
Number of pages: 3	Procedure number: 402
Issued by: Name:	Record of amendments
Title:	Date:
Date:	Type:

Objectives:

To describe the procedure for accounting for damaged or expired drugs, or patient returns of antiretroviral drugs that are set aside for disposal.

Responsibility:

- The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and a witnessing pharmacy staff member.
- The designated pharmacist in charge of dispensing ARVs from the outpatient pharmacy or his/her designated proxy and a witnessing pharmacy staff member.

Resources:

Forms used for recording the removal of ARVs for disposal

ART Programme: Notification of ARVs Set Aside for Disposal

- Is a single-page form

Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O. 58)

- Is a single-page form

Other forms used in recording the removal of ARVs for disposal

- *Stock Count Discrepancy Report*

Procedure:

- The pharmacist in charge of the ARV bulk store:
 - Separates damaged or expired ARVs and makes the necessary adjustments to the *Stores Ledger and Stock Control Card (S3)* and *Bulk Store Bin Cards (S5)* as described for issuing stock in procedure 103: *Record Keeping at ARV Bulk Store*.
 - Completes a *Stock Count Discrepancy Report* as described in procedure 202: *Stock Count Discrepancy Report*.
- The pharmacist in charge of dispensing ARVs from the outpatient pharmacy:
 - Removes damaged or expired ARVs for storage in the ARV bulk store.
 - Makes the necessary adjustments to the *Hospital Pharmacy Bin Card (MOH 999)* and the *Drugs and Revenue Register* as described for issuing stock in procedure 106: *Record Keeping at the Outpatient Pharmacy*.
 - Completes a *Stock Count Discrepancy Report* as described in procedure 202: *Stock Count Discrepancy Report*.
- Keep all stock set aside for destruction, including patient returns, separate from other stock in the ARV bulk.
- Complete the *ART Programme: Notification of ARVs Set Aside for Disposal* as described below.
- The pharmacist in charge of the ART Programme checks the notification and forwards it through the Chief Pharmacist to the Chief Administrator for his/her signature.

- The Chief Administrator returns the notification to the pharmacist in charge of the ART Programme who forwards it to the Mombasa ART Programme Technical Assistance Partners (TAP) Coordinator at the FHI Mombasa Office.
- The FHI TAP coordinator inspects the drugs set aside for destruction and signs and dates the verification.
- Complete the *Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O. 58)* as described below and submit the *F.O. 58* to the Board of Survey.
- The Board of Survey is convened and boards the drugs. A list of drugs and value is sent to the Permanent Secretary for Health who authorises the destruction of the ARVs.

Steps for completing ART Programme: Notification of ARVs set aside for disposal

1. Record:
 - Date set aside
 - Location: *ARV bulk store* or *outpatient pharmacy*
 - Bin card number: from *S5* or *MOH 999*
 - Item description:
 - generic name
 - strength/concentration
 - dosage form
 - Unit of issue
 - Quantity set aside for disposal
 - A complete explanation of the reason why the drugs were set aside for disposal (damaged product, expiration of product, unusable patient returns, etc.)
2. The form is signed and dated by both the person setting aside the stock for disposal and a witnessing pharmacist.

Steps for completing Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O.58)

1. Record:
 - Ministry of: *Health*; Department: *Medical*; Station: *Coast Provincial General Hospital*
 - Complete the table:
 - Column 1: Item No.
 - Column 2: Article: generic name; strength/concentration; dosage form
 - Column 3: Quantity: write in quantity to be destroyed
 - Column 4: Date of Purchase: write date the product was delivered to CPGH
 - Column 5: Original value: insert value if known
 - Column 6: State whether Unserviceable or Surplus: *Unserviceable*
2. Signature and Official Designation of Officer-in-Charge of Stores: Sign; state position and date the form

Distribution:

Art Programme: Notification of ARVs Set Aside for Disposal

- The original is forwarded to the Mombasa ART Programme TAP Coordinator at the FHI Mombasa Office.
- One copy of the completed and signed *ART Programme: Notification of ARVs Set Aside for Disposal* is kept in the ARV bulk store.
- One copy of the completed and signed *ART Programme: Notification of ARVs Set Aside for Disposal* is retained by the Chief Pharmacist.

Coast Provincial General Hospital ART Programme: Notification of ARVs Set Aside for Disposal

To: Dr John Adungosi,
Technical Assistance Partners (TAP) Coordinator, Mombasa ART Programme,
FHI/IMPACT

Coast Provincial General Hospital wishes to notify you that the following antiretroviral drug purchased by FHI for the Mombasa ART Programme has been set aside for disposal.

Date set aside:	Location:	Bin card number:
Item description:	Unit of issue:	Quantity set aside:
Details and Explanation		
<input type="checkbox"/> Damaged	Details of damage/breakage and cause	
<input type="checkbox"/> Expired Date of shipment: Date of expiry:	Details of expired stock and explanation:	
<input type="checkbox"/> Patient returns Patient's name: Date dispensed:	Details and explanation:	
<input type="checkbox"/> Other	Details and explanation:	
..... Pharmacy staff member in charge of ARV bulk store: Name and Signature	 Date
..... Witnessing Pharmacist: Name and Signature:	 Date

Please arrange to authenticate the ARV drugs set aside for disposal
Yours sincerely,

..... Date...../200....
Chief Administrator

Verified by:
..... Date...../200...
FHI TAP Coordinator

REPORT OF THE BOARD OF SURVEY ON STORES (UNSERVICEABLE AND SURPLUS TO REQUIREMENTS)

Ministry of Department Station.....

N.B.-Column Nos 1 to 6 to be completed by the Department prior to the assembly of the Board

1 ITEM No.	2 ARTICLE	3 QUANTITY	4 DATE OF PURCHASE	5 ORIGINAL VALUE	6 State whether Unserviceable or Surplus	7 BOARD'S REPORT ON CONDITION	8 RECOMMENDATION OF BOARD FOR DISPOSAL	9 ESTIMATED LOCAL SALEABLE VALUE IF SALE IS RECOMMENDED	10 REMARKS		
<p>.....<i>Signature and Official Designation of Officer- in-Charge of Stores</i>..... Date.....Station</p>						<p style="text-align: center;">DECISION OF: -</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;"> <p>ACCOUNTING OFFICER <i>Accounting Officer</i> Date.....</p> </td> <td style="width: 50%; text-align: center;"> <p>TREASURY <i>For Minister for Finance</i> Date.....</p> </td> </tr> </table>				<p>ACCOUNTING OFFICER <i>Accounting Officer</i> Date.....</p>	<p>TREASURY <i>For Minister for Finance</i> Date.....</p>
<p>ACCOUNTING OFFICER <i>Accounting Officer</i> Date.....</p>	<p>TREASURY <i>For Minister for Finance</i> Date.....</p>										

Coast Provincial General Hospital	
Security of Antiretroviral Drugs	
Number of pages: 1	Procedure number: 403
Issued by: Name: Title: Date:	Record of amendments Date: Type:

Objective:

To describe correct security measures and responsibilities to decrease the risk of diversion of antiretroviral drugs.

Responsibility:

- Designated pharmacist in charge of the ARV bulk store or his/her designated proxy.
- Designated pharmacy staff member in charge of dispensing ARVs in the outpatient pharmacy or his/her designated proxy.

Procedure:

Storage of ARVs in the ARV bulk store:

1. All ARVs will be stored separately from other stock in a *locked* cupboard in the ARV bulk store.
2. Keep the door to the ARV bulk store and the cupboard(s) locked at all times.
3. Only the designated pharmacist in charge should have access to the ARV bulk store.
4. The designated pharmacist in charge of the ARV bulk store will:
 - Keep the key to the ARV bulk store and cupboard in his/her possession at all times whilst in the pharmacy
 - Never leave the key outside of his/her direct control (e.g., the key should never be hung on the wall)

Storage of ARVs in the outpatient pharmacy:

1. All ARVs will be stored separately from other stock in a *locked* cupboard in the outpatient pharmacy.
2. The cupboard(s) should be locked at all times.
3. Only the designated pharmacist or pharmaceutical technologist should have access to the ARV cupboard(s) in the outpatient pharmacy.
4. The designated pharmacist in charge of dispensing ARVs in the outpatient pharmacy will:
 - Keep the key to the ARV cupboard in the outpatient pharmacy in his/her possession at all times.
 - Never leave the key outside of his/her direct control (e.g., the key should never be left on the dispensing counter)

Storage of ARVs on the wards:

1. All ARVs will be stored in a *locked* drug cupboard as per normal nursing procedures.
2. The cupboard(s) should be locked at all times.
3. Only the designated authorised nursing staff should have access to the cupboard where the ARVs are stored.
4. The designated nurse in charge of the ward will:
 - Keep the key to the drug cupboard in his/her possession at all times.
 - Never leave the key outside of his/her direct control (e.g., the key should never be hung on the wall)

Coast Provincial General Hospital	
Internal Audit of Antiretroviral Drugs	
Number of pages: 14	Procedure number: 501
Issued by: Name: Title: Date:	Record of amendments Date: Type:

Objective:

To describe the procedure to perform a monthly audit on storage, prescribing, and dispensing of antiretroviral drugs. The results of the internal audit will monitor the integrity of the ART Programme in regard to the correct management of the ARVs. Results of the internal audit will be recorded for use in the external audit.

Responsibility:

Internal audit of ARVs will be performed by the CPGH Audit Team once a month. The members of the CPGH Audit Team will be appointed by the Chief Administrator.

Source of Information:

Forms used for performing and recording the internal audit:

- *Detailed Description of Indicators Definition and Calculations* will be used to assist the audit team in gathering the necessary information and making the correct calculations.
- The data from the monthly audit will be documented in the *ART Internal Audit Record*.

Forms used to calculate internal audit data:

- *ART Patient Dispensing Records*
- Authorised prescribers' signature record
- *Bulk Store Bin Cards (S5)*
- *Counter Receipt Vouchers (S13)*
- *Hospital Pharmacy Bin Cards (MOH 999)*
- Patient eligibility list
- *Prescription Forms (MOH 501)*
- *Shipment Discrepancy Report*
- *Stock Count Discrepancy Report*
- *Stores Ledger and Stock Control Cards (S3)*
- Temperature logs in ARV bulk store, ARV bulk store refrigerator, and outpatient pharmacy

Procedure:

- The audit team will use the *Detailed Description of Indicators Definition and Calculations* to calculate data for the internal audit.
- The audit team can either perform the audit at a scheduled time or with no notice.
- The indicators for the audit are the following:

Prescriptions and Prescription Records:

1. Percentage of ART prescriptions issued to eligible patients out of all ART prescriptions issued during the last month
2. Percentage of ART prescriptions dispensed to eligible patients out of all ART prescription dispensed during the last month
3. Number of ART prescriptions dispensed that do not correlate with the authorised prescriber's signature on file during the last month

4. Number of times a patient was dispensed an early or late refill on an ART prescription by 3 or more days during the last month

ARV Bulk Store Stock:

5. Percentage of ARV preparations for which *Bulk Store Bin Cards (S5)* are kept updated out of total ARV preparations currently held in the ARV bulk store during the last month
6. Number of ARV preparations out of stock at least once in the ARV bulk store during the last month
7. Number and percentage of ARV preparations for which the recorded stock count on the *Bulk Store Bin Cards (S5)* corresponds to the physical count of ARV preparations held in the ARV bulk store at time of audit
8. Number of discrepancies between the *Bulk Store Bin Cards (S5)* and the physical count that were not accounted for and documented during the last month
9. Number of discrepancies between records of stock issued and stock received during transfer of stock from ARV bulk store to the outpatient pharmacy during the last month that were not accounted for and documented
10. Temperature log in ARV bulk store completed twice daily during the last month as described in procedure 401: *Temperature Control*
11. Number of days where temperature in ARV bulk store was outside of acceptable limits during the past month
12. Temperature log in ARV bulk store refrigerator completed daily during the last month as described in procedure 401: *Temperature Control*
13. Number of days where temperature in ARV bulk store refrigerator was outside of acceptable limits during the past month

Outpatient Pharmacy ARV Stock:

14. Percentage of ARV preparations for which *Hospital Pharmacy Bin Cards (MOH 999)* are kept updated out of total ARV preparations currently held in the outpatient pharmacy during the last month
15. Number and percentage of ARV preparations for which the recorded stock count on the *Hospital Pharmacy Bin Cards (MOH 999)* corresponds to the physical count of ARV preparations held in the outpatient pharmacy at the time of audit
16. Number of discrepancies between the *Hospital Pharmacy Bin Cards (MOH 999)* and the physical count in the outpatient pharmacy that were not accounted for and documented during the last month
17. Temperature log in outpatient pharmacy completed twice daily during the last month as described in procedure 401: *Temperature Control*
18. Number of days where temperature in outpatient pharmacy was outside of acceptable limits during the last month

Security:

19. Door to the ARV bulk store is locked at time of audit
20. Key to the door of the ARV bulk store is kept with the pharmacist in charge of ARV bulk store or his/her designated appointee at time of audit

Distribution of Report:

- The data from the monthly audit will be documented in the *ARV Internal Audit Record*
- The *ARV Internal Audit Record* will be shared with the ART Committee and the Chief Administrator monthly, who will decide on the action(s) to be taken to correct any areas of concern.
- The data from the *ARV Internal Audit Record* will be used in the external audit.

Detailed Description of Indicators Definition and Calculations for ARV Internal Audit

Sr No.	Indicator Definition and Calculation	Possible Use and Expectations
<i>Calculated on a Monthly Basis</i>		
Prescriptions and Prescription Records		
1.	<p>Definition: Percent age of ART prescriptions issued to eligible patients out of all ART prescriptions issued during the last month</p> <p>Calculation: Number of ART prescriptions for eligible patients issued in the last month/total number of ART prescriptions issued in the last month × 100</p> <p>Source of data: <i>Prescription Forms (MOH 501)</i> and patient eligibility list</p>	<p>Use: Monitors adherence to ART prescribing procedures— monitors prescribing for patients who have not been approved as eligible by ART Committee</p> <p>Expectation: 100% is desired</p>
2.	<p>Definition: Percent age of ART prescriptions dispensed to eligible patients out of all ART prescriptions dispensed during the last month</p> <p>Calculation: Number of ART prescriptions dispensed to eligible patients during the last month/total number of ART prescriptions dispensed during the last month × 100</p> <p>Source of data: <i>ART Patient Dispensing Records</i> and patient eligibility list</p>	<p>Use: Monitors adherence to ART dispensing procedures— monitors whether prescriptions are being dispensed for patients who have not been approved as eligible by ART Committee</p> <p>Expectation: 100% is desired</p>
3.	<p>Definition: Number of ART prescriptions dispensed that do not correlate with the authorised prescriber's signature on file during the last month</p> <p>Source of data: <i>Prescription forms (MOH 501)</i> and authorised prescribers' signature record</p>	<p>Use: Monitors adherence to ART dispensing procedures— monitors whether forged prescriptions are being issued and dispensed</p> <p>Expectation: None is desired</p>
4.	<p>Definition : Number of times a patient was dispensed an early or late refill on an ART prescription by 3 or more days during the last month</p> <p>Source of data: <i>ART Patient Dispensing Records</i></p>	<p>Use: Monitors proper use of medications by patients— monitors if patients are using more or less medicine than is expected</p> <p>Expectation: Zero is desired</p>
ARV Bulk Store Stock		
5.	<p>Definition: Percent age of ARV preparations for which <i>Bulk Store Bin Cards (S5)</i> are kept updated out of total ARV preparations currently held in the ARV bulk store during the last month</p> <p>Calculation: Number of ARV preparations that have <i>Bulk Store Bin Cards (S5)</i> kept updated at the ARV bulk store in the last month/total number of ARV preparations currently held in stock at the ARV bulk store in the last month × 100</p> <p>Source of data: <i>Bulk Store Bin Cards (S5)</i></p>	<p>Use: Monitors adherence to stock keeping procedures— monitors if inventory records in ARV bulk store are kept up to date</p> <p>Expectation: 100% is desired</p>

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Sr No.	Indicator Definition and Calculation	Possible Use and Expectations
Calculated on a Monthly Basis		
ARV Bulk Store Stock		
6.	<p>Definition: Number of ARV preparations out of stock at least once in the ARV bulk store during the last month</p> <p>Source of data: <i>Bulk Store Bin Cards (S5)</i></p>	<p>Use: Monitors adherence to inventory control/ procurement procedures</p> <p>Expectation: Zero is desired</p>
7.	<p>Definition: Number and percentage of ARV preparations for which the recorded stock count on the <i>Bulk Store Bin Cards (S5)</i> corresponds to the physical count of ARV preparations held in the ARV bulk store at time of audit</p> <p>Calculation:</p> <ul style="list-style-type: none"> • Number of ARV preparations for which the recorded stock count on the <i>Bulk Store Bin Cards (S5)</i> corresponds to the physical count held in the ARV bulk store at the time of audit • Number of ARV preparations for which the recorded stock count on the <i>Bulk Store Bin Cards (S5)</i> corresponds to the physical count held in the ARV bulk store at the time of audit/total number of <i>Bulk Store Bin Cards (S5)</i> held at the ARV bulk store at the time of audit × 100 <p>Source of data: <i>Bulk Store Bin Cards (S5)</i></p>	<p>Use: Monitors adherence to inventory control procedures in ARV bulk store—monitors accuracy of inventory record keeping in ARV bulk store</p> <p>Expectation: All <i>Bulk Store Bin Cards</i> and 100% are desired</p>
8.	<p>Definition: Number of discrepancies between the <i>Bulk Store Bin Cards (S5)</i> and the physical count that were not accounted for and documented during the last month</p> <p>Source of data: <i>Bulk Store Bin Cards (S5), Shipment Discrepancy Report, and Stock Count Discrepancy Report</i></p>	<p>Use: Monitors adherence to inventory control procedures in ARV bulk store—monitors whether discrepancies are accounted for and an explanation given</p> <p>Expectation: Zero is desired</p>
9.	<p>Definition: Number of discrepancies between records of stock issued and stock received during transfer of stock from ARV bulk store to the outpatient pharmacy during the last month that were not accounted for and documented</p> <p>Source of data: <i>Stores Ledger and Stock Control Cards (S3), Bulk Store Bin Cards (S5), Counter Receipt Vouchers (S13) and Stock Count Discrepancy Report</i></p>	<p>Use: Monitors adherence to inventory control procedures on transferring stock—monitors whether discrepancies are accounted for and an explanation given</p> <p>Expectation: Zero is desired</p>
10.	<p>Definition: Temperature log in ARV bulk store completed twice daily during the last month as described in procedure 401: <i>Temperature Control</i></p> <p>Source of data: ARV bulk store temperature log</p>	<p>Use: Monitors adherence to procedures to maintain quality of ARV medicines</p> <p>Expectation: Yes is desired</p>
11.	<p>Definition: Number of days where temperature in ARV bulk store was outside of acceptable limits during the past month</p> <p>Source of data: ARV bulk store temperature log</p>	<p>Use: Monitors problems with temperature control in ARV bulk store</p> <p>Expectation: Zero is desired</p>
12.	<p>Definition: Temperature log in ARV bulk store refrigerator completed daily during the last month as described in procedure 401: <i>Temperature Control</i></p> <p>Source of data: ARV bulk store refrigerator temperature log</p>	<p>Use: Monitors adherence to procedures to maintain quality of ARV medicines</p> <p>Expectation: Yes is desired</p>

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Sr No.	Indicator Definition and Calculation	Possible Use and Expectations
Calculated on a Monthly Basis		
ARV Bulk Store Stock		
13.	<p>Definition: Number of days where temperature in ARV bulk store refrigerator was outside of acceptable limits during the past month</p> <p>Source of data: ARV refrigerator temperature log</p>	<p>Use: Monitors problems with temperature control in ARV bulk store refrigerator</p> <p>Expectation: Zero is desired</p>
Outpatient Pharmacy ARV Stock		
14.	<p>Definition: Percent age of ARV preparations for which <i>Hospital Pharmacy Bin Cards (MOH 999)</i> are kept updated out of total ARV preparations currently held in the outpatient pharmacy during the last month</p> <p>Calculation: Number of ARV preparations that have <i>Hospital Pharmacy Bin Cards (MOH 999)</i> kept updated at the outpatient pharmacy in the last month/total number of ARV preparations currently held in stock at the outpatient pharmacy in the last month × 100</p> <p>Source of data: <i>Hospital Pharmacy Bin Cards (MOH 999)</i></p>	<p>Use: Monitors adherence to stock-keeping procedures—monitors if inventory records in outpatient pharmacy are kept up to date</p> <p>Expectation: 100% is desired</p>
15.	<p>Definition: Number and percentage of ARV preparations for which the recorded stock count on the <i>Hospital Pharmacy Bin Cards (MOH 999)</i> corresponds to the physical count of ARV preparations held in the outpatient pharmacy at the time of audit</p> <p>Calculation:</p> <ul style="list-style-type: none"> • Number of ARV preparations for which the recorded stock count on the <i>Hospital Pharmacy Bin Cards (MOH 999)</i> corresponds to the physical count held in the outpatient pharmacy at the time of audit • Number of ARV preparations for which the recorded stock count on the <i>Hospital Pharmacy Bin Cards (MOH 999)</i> corresponds to the physical count held in the outpatient pharmacy at the time of audit/total number of <i>Hospital Pharmacy Bin Cards (MOH 999)</i> for ARVs held in the outpatient pharmacy at the time of audit × 100 <p>Source of data: <i>Hospital Pharmacy Bin Cards (MOH 999)</i></p>	<p>Use: Monitors adherence to inventory control procedures in outpatient pharmacy—monitors accuracy of inventory record keeping in pharmacy</p> <p>Expectation: All bin cards and 100% are desired</p>
16.	<p>Definition: Number of discrepancies between the <i>Hospital Pharmacy Bin Cards (MOH 999)</i> and the physical count in the outpatient pharmacy that were not accounted for and documented during the last month</p> <p>Source of data: <i>Hospital Pharmacy Bin Cards (MOH 999)</i> <i>Stock Count Discrepancy Report</i></p>	<p>Use: Monitors adherence to inventory control procedures in outpatient pharmacy—monitors whether discrepancies are accounted for and an explanation given</p> <p>Expectation: Zero is desired</p>
17.	<p>Definition: Temperature log in outpatient pharmacy completed twice daily during the last month as described in procedure 401: <i>Temperature Control</i></p> <p>Source of data: Hospital pharmacy temperature log</p>	<p>Use: Monitors adherence to procedures to maintain quality of ARV medicines</p> <p>Expectation: Yes is desired</p>

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Sr No.	Indicator Definition and Calculation	Possible Use and Expectations
Calculated on a Monthly Basis		
Outpatient pharmacy ARV stock		
18.	<p>Definition: Number of days where temperature in outpatient pharmacy was outside of acceptable limits during the last month</p> <p>Source of data: Hospital pharmacy temperature log</p>	<p>Use: Monitors problems with temperature control in outpatient pharmacy</p> <p>Expectation: Zero is desired</p>
Security		
19.	<p>Definition: Door to the ARV bulk store is locked at time of audit</p> <p>Source of data: Observation by Audit Committee</p>	<p>Use: Monitors adherence to inventory management procedures—monitors security of ARV bulk store</p> <p>Expectation: Yes is desired</p>
20.	<p>Definition: Key to the door of the ARV bulk store is kept with the pharmacist in charge of ARV bulk store or his/her designated appointee at time of audit</p> <p>Source of data: Observation by Audit Committee</p>	<p>Use: Monitors adherence to inventory management procedures—monitors security of ARV bulk store</p> <p>Expectation: Yes is desired</p>

ARV Internal Audit Record

To be completed using *Detailed Descriptions of Indicators Definitions and Calculation*

Prescriptions/Prescription Records:

- Percentage of ART prescriptions issued to eligible patients out of all ART prescriptions issued during the last month

July	August	September	October	November	December	January	February	March	April	May	June
%	%	%	%	%	%	%	%	%	%	%	%
Comments or actions taken (date each entry):											

- Percentage of ART prescriptions dispensed to eligible patients out of all ART prescription dispensed during the last month

July	August	September	October	November	December	January	February	March	April	May	June
%	%	%	%	%	%	%	%	%	%	%	%
Comments or actions taken (date each entry):											

- Number of ART prescriptions dispensed that do not correlate with the authorised prescriber's signature on file during the last month

July	August	September	October	November	December	January	February	March	April	May	June
Comments or actions taken (date each entry):											

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

4. Number of times a patient was dispensed an early or late refill on an ART prescription by 3 or more days during the last month

July	August	September	October	November	December	January	February	March	April	May	June
Comments or actions taken (date each entry):											

ARV Bulk Store Stock:

5. Percentage of ARV preparations for which *Bulk Store Bin Cards (S5)* are kept updated out of total ARV preparations currently held in the ARV bulk store during the last month

July	August	September	October	November	December	January	February	March	April	May	June
%	%	%	%	%	%	%	%	%	%	%	%
Comments or actions taken (date each entry):											

6. Number of ARV preparations out of stock at least once in the ARV bulk store during the last month

July	August	September	October	November	December	January	February	March	April	May	June
Comments or actions taken (date each entry):											

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

7. Number and percentage of ARV preparations for which the recorded stock count on the *Bulk Store Bin Cards (S5)* corresponds to the physical count of ARV preparations held in the ARV bulk store at time of audit

July	August	September	October	November	December	January	February	March	April	May	June
/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %
Comments or actions taken (date each entry):											

8. Number of discrepancies between the *Bulk Store Bin Cards (S5)* and the physical count that were not accounted for and documented during the last month

July	August	September	October	November	December	January	February	March	April	May	June
Comments or actions taken (date each entry):											

9. Number of discrepancies between records of stock issued and stock received during transfer of stock from ARV bulk store to the outpatient pharmacy during the last month that were not accounted for and documented

July	August	September	October	November	December	January	February	March	April	May	June
Comments or actions taken (date each entry):											

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

10. Temperature log in ARV bulk store completed twice daily during the last month as described in procedure 401: *Temperature Control*

July	August	September	October	November	December	January	February	March	April	May	June
Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Comments or actions taken (date each entry):											

11. Number of days where temperature in ARV bulk store was outside of acceptable limits during the past month

July	August	September	October	November	December	January	February	March	April	May	June
Comments or actions taken (date each entry):											

12. Temperature log in ARV bulk store refrigerator completed daily during the last month as described in procedure 401: *Temperature Control*

July	August	September	October	November	December	January	February	March	April	May	June
Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Comments or actions taken (date each entry):											

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

13. Number of days where temperature in ARV bulk store refrigerator was outside of acceptable limits during the past month

July	August	September	October	November	December	January	February	March	April	May	June
Comments or actions taken (date each entry):											

Outpatient Pharmacy ARV Stock:

14. Percentage of ARV preparations for which *Hospital Pharmacy Bin Cards (MOH 999)* are kept updated out of total ARV preparations currently held in the outpatient pharmacy during the last month

July	August	September	October	November	December	January	February	March	April	May	June
%	%	%	%	%	%	%	%	%	%	%	%
Comments or actions taken (date each entry):											

15. Number and percentage of ARV preparations for which the recorded stock count on the *Hospital Pharmacy Bin Cards (MOH 999)* corresponds to the physical count of ARV preparations held in the outpatient pharmacy at the time of audit

July	August	September	October	November	December	January	February	March	April	May	June
/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %	/ %
Comments or actions taken (date each entry):											

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

16. Number of discrepancies between the *Hospital Pharmacy Bin Cards (MOH 999)* and the physical count in the outpatient pharmacy that were not accounted for and documented during the last month

July	August	September	October	November	December	January	February	March	April	May	June
Comments or actions taken (date each entry):											

17. Temperature log in outpatient pharmacy completed twice daily during the last month as described in procedure 401: *Temperature Control*

July	August	September	October	November	December	January	February	March	April	May	June
Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Comments or actions taken (date each entry):											

18. Number of days where temperature in outpatient pharmacy was outside of acceptable limits during the last month

July	August	September	October	November	December	January	February	March	April	May	June
Comments or actions taken (date each entry):											

CPGH ART Programme Standard Operating Procedures: Pharmacy Department

Security:

19. Door to the ARV bulk store is locked at time of audit

July	August	September	October	November	December	January	February	March	April	May	June
Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Comments or actions taken (date each entry):											

20. Key to the door of the ARV bulk store is kept with pharmacist in charge of ARV bulk store or his/her designated appointee at time of audit

July	August	September	October	November	December	January	February	March	April	May	June
Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
Comments or actions taken (date each entry):											

Coast Provincial General Hospital	
ART Programme : Pharmacy Activity Report	
Number of pages: 5	Procedure number: 502
Issued by: Name:	Record of amendments
Title:	Date:
Date:	Type:

Objective:

To describe the procedure to prepare the weekly *ART Programme—Pharmacy Weekly Activity Report*.

The objectives of the report are:

- To monitor the integrity of the ART Programme in regard to the correct management of the ARVs—inventory management, breakages and losses, and record-keeping procedures.
- To serve as a management reporting tool on ART Programme activity, status of ARVs in stock and on order, and administrative and maintenance problems that are affecting the ART Programme.

Responsibility:

The pharmacist in charge of the ARV bulk store prepares the *ART Programme—Pharmacy Weekly Activity Report* with assistance from the pharmacist in charge of the ART Programme.

Source of Information:

Forms needed:

ART Programme—Pharmacy Weekly Activity Report

- Is a three-page report.

ART Programme—Pharmacy Weekly Rota

- Is a single-page form.

Forms used to prepare the activity report :

- *ART Patient Dispensing Records*
- *ARV Prepacking Record*
- *Bulk Store Bin Cards (S5)*
- *Hospital Pharmacy Bin Cards (MOH 999)*
- *Prescription Forms (MOH 501)*
- *Shipment Discrepancy Report*
- *Stock Count Discrepancy Report*
- Temperature logs in ARV bulk store, ARV bulk store refrigerator , and outpatient pharmacy

Procedure:

- The pharmacist in charge of the ARV bulk store prepares the *ART Programme—Pharmacy Weekly Activity Report* with assistance from the pharmacist in charge of the ART Programme.
- The pharmacist in charge of the ART Programme prepares the *ART Programme—Pharmacy Weekly Rota* , which is attached to the report.

Distribution:

- The report is submitted to the Chief Pharmacist for his/her signature and comments.
- The report is submitted to the Chief Administrator.
- The copy of the report is held on file in the Pharmacy.

COAST PROVINCIAL GENERAL HOSPITAL

ART PROGRAMME – PHARMACY WEEKLY ACTIVITY REPORT		
Report submitted for week ending		200
1	Number of prescriptions dispensed for new ART patients in the last week	
2	Number of repeat prescriptions dispensed for ART patients in the last week	
3	Number of prepacks prepared for DAART patients in the last week	
4	Number of DAART patients counselled by pharmacy staff in the last week	
5	Number of ARV preparations out of stock in the ARV bulk store <i>(list below and indicate date and action taken to resolve stock outs)</i>	
6.	Current levels of stock held in the ARV bulk store attached	Yes/No
7.	Number of ARV preparations on order <i>(list below with date ordered from FHI)</i>	
8.	Number of ART preparations with less than 6 months expiry <i>(If any, list below and date FHI alerted to arrange for exchange of stock)</i>	
9.	All <i>Bulk Store Bin Cards (S5)</i> in the ARV bulk store are up to date	Yes/No
10.	All recorded stock counts on <i>Bulk Store Bin Cards (S5)</i> of all ARV preparations held in the ARV bulk store correspond with physical count <i>(If no, give details of discrepancies below and date and action taken)</i>	Yes/No
11.	All <i>Hospital Pharmacy Bin Cards (MOH 999)</i> for ARVs held in the outpatient pharmacy up to date	Yes/No
12.	All recorded stock counts on <i>Hospital Pharmacy Bin Cards (MOH 999)</i> of all ARV preparations held in the outpatient pharmacy correspond with physical count <i>(If no, give details of discrepancies below and date and action taken)</i>	Yes/No
13.	Number of breakages, shortages, and other discrepancies not reported in items 10 and 12 <i>(Give details and date and action taken)</i>	

ART PROGRAMME – PHARMACY WEEKLY ACTIVITY REPORT Report submitted for week ending _____ 200_		
14.	Temperature log in ARV bulk store up to date	Yes/No
15.	Number of days temperature in ARV bulk store was outside acceptable limits in the last week	
16.	Temperature log in ARV bulk store refrigerator up to date	Yes/No
17.	Number of days temperature in ARV bulk store refrigerator was outside acceptable limits in the last week	
18.	Temperature log in the outpatient pharmacy (ARV stock cupboard) up to date	Yes/No
19.	Number of days temperature in outpatient pharmacy (ARV stock cupboard) was outside acceptable limits in the last week	
20.	Are there any problems with equipment/storage cupboards or storage conditions that are affecting the ART Programme? <i>(If yes, give details and date and action taken/requested to resolve the problem)</i>	Yes/No
21.	Are there any other issues that are affecting the ART Programme (e.g., staffing, prescription forgeries, prescriptions for ineligible patients, etc.)? <i>(If yes, give details and date and action taken/requested to resolve the problem)</i>	Yes/No
22.	ART Programme Pharmacy Staff Rota attached for following week	Yes/No
Report prepared by..... Date.....200_		
Report seen by Chief Pharmacist..... Date.....200_ Comments/Action taken:		
Report received by Chief Administrator.....Date.....200_ Comments/Action taken:		

Current stock levels of stock held in the ARV bulk store

Date _____/200__

Product	Form	Strength	Pack Size	# Packs in stock
Stavudine (d4T)	Capsules	30mg	56	
Stavudine (d4T)	Capsules	40mg	56	
Lamivudine (3TC)	Tablets	150mg	60	
Efavirenz (EFV)	Capsules	600mg	30	
Nevirapine (NVP)	Tablets	200mg	60	
Zidovudine (AZT,ZDV)	Tablets	300mg	60	
Zidovudine (AZT,ZDV)	Tablets	100mg	100	
Didanosine (ddI)	Tablets	50mg	60	
Didanosine (ddI)	Tablets	200mg	60	
Kaletra (Lopinavir/Ritonavir)	Capsules	133.33/33.33 mg	180	
Nelfinavir (NFV)	Tablets	250mg	270	
Indinavir	Capsules	400mg	180	
Stavudine (d4T)	Powder for solution	1mg/ml	200ml	
Lamivudine (3TC)	Oral solution	10mg/ml	240ml	
Nevirapine (NVP)	Oral suspension	10mg/ml	240ml	
Zidovudine (AZT,ZDV)	Syrup	50mg/5ml	240ml	
Didanosine (ddI)	Powder for solution	883mg/5ml	2g/4oz 4gm/8oz	
Kaletra (Lopinavir/Ritonavir)	Solution	80/20mg/ml	160ml	

COAST PROVINCIAL GENERAL HOSPITAL

ART PROGRAMME – PHARMACY WEEKLY ROTA

For week beginning _____ 200__

	Monday	Tuesday	Wednesday	Thursday	Friday
Dispensing & counselling ART patients	Morning	Morning	Morning	Morning	Morning
	Afternoon	Afternoon	Afternoon	Afternoon	Afternoon
Prepacking for DAART patients	Prepacking Checking				
ART Bulk Store				

ART Pharmacy Staff

Contact telephone number

Dr Caroline Olwande
 Dr Lawrence Nzumbu
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 Pharmacy
 Pharmacy

