Republic of Namibia
Ministry of Health and Social Services

Pharmaceutical Services Division

STANDARD OPERATING PROCEDURES

DISPENSING ANTIRETROVIRAL MEDICINES

In collaboration with

Rational Pharmaceutical Management Plus Program, Namibia

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NAMIBIANS AND AMERICANS IN PARTNERSHIP TO FIGHT HIV/AIDS

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STANDARD OPERATING PROCEDURE DISPENSING ANTIRETROVIRAL MEDICATIONS TO A PATIENT

SOP No.: ARV 01/00	**No. of pages:** 41
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Purpose of SOP:
To describe the process to be followed when –

1. Dispensing ARV medications to a patient,
2. Counselling the patient on medication use,
3. Measuring and monitoring adherence to ARV therapy and
4. Maintaining complete and accurate records and appropriate reporting.

Responsibility:
Pharmacist or pharmacists' assistant responsible for dispensing ARV medications. In accordance with the Namibia ART guidelines, only pharmacists or pharmacists' assistants who have undergone training on the Namibia Guidelines for Antiretroviral Therapy may dispense ARVs.

References sources to be used for further information:

Namibia Guidelines for Antiretroviral therapy (latest edition)
Namibia Management of HIV Treatment guideline
Medicine Package Insert
South African Medical Formulary (SAMF) or British National Formulary (BNF)
Daily Drug Use

Resources:

Adult and Paediatric ARV Daily Dispensing Registers
ART Patient Dispensing Record
Patient Health Passport
ARV Medication Counselling Guideline
ART Patient Counselling Information (for side effects)
ARV Pill Count Form
Patient Case File

Note:

1. **ARV medication counselling, monitoring and measuring of adherence should be done at every visit, at the time of issuing the medication to the patient.**
2. **For the first visit, both patient and treatment supporter must be present when they collect the medication.**

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PROCEDURE A: DISPENSING TO NEW PATIENTS

Step	***Task***	***Reference/Notes***
1.	Pharmacist or Pharmacist' Assistant collects Patient ***Health Passport***	
2.	Confirm eligibility of new ARV patients	*Job Aid ART/JA 001*
3.	Evaluate prescription for validity, accuracy and potential interactions	*Job Aid ART/JA 002*
4.	Fill the prescription	*Job Aid ART/JA 003*
5.	Update ***ART Patient Dispensing Record, ARV Daily Dispensing Registers*** and ***Patient Health Passport***	*Job Aid ART/JA 004* *Job Aid ART/JA 005*
6.	Call patient to counselling room/window and introduce yourself giving your name and position	
7.	Counsel the patient as described in ***ARV Medications Counselling Guideline*** and ***Patient Counselling Information***	*Job Aid ART/JA 011* *Job Aid ART/JA 013*
8.	Record follow-up date in ***Patient Health Passport***	
9.	Communicate the follow-up date to patient and request them to bring ALL medication remaining during all follow-up visits.	The follow up date should be at least two days before the patient's medication is finished
10.	Confirm that patient understands.	Refer *ART/JA 011 Sections VIII and XI*

PROCEDURE B: FOLLOW-UP PATIENTS

Step	***Task***	***Reference***
1.	Designated pharmacy staff collects Patient ***Health Passport***	
2.	Ensure that patient file and laboratory results are available	
3.	Review laboratory results	*Job Aid ART/JA 012*
4.	Evaluate prescription for validity, accuracy and potential interactions	*Job Aid ART/JA 002*
5.	Review ***ARV Dispensing Record*** for previous quantities issued	
6.	Fill the prescription	*Job Aid ART/JA 003*
7.	Update ***ART Patient Dispensing Record, ARV Daily Registers*** and ***Patient Health Passport***	*Job Aid ART/JA 004* *Job Aid ART/JA 005*
8.	Call patient to counselling room/window and introduce yourself giving your name and position	
9.	Monitor adherence	*Job Aid ART/JA 008*
10.	Discuss side-effects experienced by patient and record significant side-effects, patient's complaints or own observations, relevant and significant lab results for monitoring efficacy or toxicity and any intervention recommended or made on ***Pharmacist' Notes***	
11.	Hand over medications to patient and reinforce medication information	How to take medication and storage; Refer *ART/JA 011 Sections VIII and XII*
12.	Agree on follow-up date with patient and record in ***Patient Health Passport*** and	The follow up date should be at least two days before the patient's medication is finished
13.	Communicate follow-up date to patient and request them to bring ALL remaining medications during follow-up visits.	
14.	Confirm that patient understands.	Refer *ART/JA 011Sections VIII and XI*

PROCEDURE C: MONTHLY REPORTING

Step	***Task***	***Reference/Notes***
1.	Complete the Monthly ART Services Report	*Job Aid ART/JA 006*
2.	Check completeness and accuracy of report	
3.	Fax report to ART Logistics Pharmacist	Mr. Idris Fax: 061 234136
4.	Fax copy of report to Regional Pharmacist	
5.	File report together with previous Monthly ART Services Reports	

PROCEDURE D: STOCK CONTROL OF ARV MEDICINES

Step	***Task***
1.	ARV Medicines should be kept in Locked cupboard at all times when not actually being dispensed.
2.	If possible ARVs that need to be stored between 2-8 °C should also be kept under lock and key. However if this is not possible (i.e. the fridge does not have a lock) then the fridge must be kept in an area where access can be controlled.
3.	Accurate stock records (e.g. stock cards or equivalent) must be kept of all ARV stocks at EVERY place where they are stored.
4.	All receipts of ARVs must be recorded in the stock card and copies of documents relating to receipts or issues to other facilities /departments must be filed.
5.	At the end of each day use either the ARV Daily Dispensing Register or the computerised ARV Dispensing Tool to calculate how many packs of each item have been dispensed.
6.	Write out the quantity of each ARV dispensed on the relevant stock card.
7.	Calculate the stock on hand for each ARV and write on the stock card on a daily basis.
8.	Regular checks should be made to ensure that the stock on hand of each ARV equates to the recorded stock on hand.

JOB AID **No: ART/JA 001**

CONFIRMING ELIGIBILITY OF ART PATIENT

a. If the hospital has an eligibility list, check if the patient is on hospital's eligibility list.

b. If there is no eligibility list, check CD4 Count and/or WHO Staging and eligibility for ART in accordance with the National Guidelines

c. Does patient have a Treatment Supporter?

d. If the patient does not meet the eligibility criteria, refer patient back to the treating doctor

JOB AID **No: ART/JA 002**

CHECKING VALIDITY AND ACCURACY OF PRESCRIPTIONS FOR ARV

a. Does prescription originate from this hospital? If yes, proceed to (b), if no and the patient is already on ART refer to section 2 below, (c) if no and the patient is not already on ART, follow-up with originating hospital.

b. Is the prescriber authorized to prescribe ARVs? If yes, proceed to (c), if no and the patient is already on ART proceed to (c), if no and the patient is not already on ART refer to ART doctors.

c. Check validity of the prescription by ensuring the that the it contains the following –
   i. Patient's full name
   ii. ARV Number
   iii. Weight in kg
   iv. Surface area in square meters for children
   v. Date prescription was written
   vi. Name, strength/concentration and dosage form of medication (Generic)
   vii. Frequency of administration
   viii. Quantity to be issued or duration
   ix. Prescriber's name and signature

d. Check the prescription for compliance with ART guidelines. If it does not comply refer to the prescriber for clarification **BEFORE** proceeding

e. Countercheck regimen and dose prescribed for accuracy (considering weight, height, age etc of patient). For paediatrics, refer to the dosing chart.

f. Check for drug-drug and/or drug-disease interactions using the medicine package insert, BNF or SAMF. If there are any interactions then assess the potential impact and contact the prescriber to discuss the prescription **BEFORE** proceeding

g. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies, before dispensing the prescription.

Section 2

1. If the patient comes to the ART clinic with a prescription from another health Facility, check the following;
   a. Is the patient transferring to your facility permanently? If yes, does the patient have a transfer letter? Or is the patient in transit?
   b. Does the passport have an appropriate ART number and valid facility code?
   c. Is the prescription valid and appropriate? (Check point C above)
   d. Has the prescription been filled already?
   e. Is the patient familiar with the medicines they are taking?
2. If you have uncertainties about the validity or appropriateness of the prescription then either refer the patient to the doctor for review or contact the facility where the prescription originated.

Note: It is not appropriate to refuse treatment to patients from other health facilities, but it is also *Your* responsibility to ensure that the patient is receiving the appropriate medicine based on their condition

JOB AID **No: ART/JA 003**

FILLING ARV PRESCRIPTIONS

1. Work should begin in a clean and clear workspace.

2. Retrieve the stock bottle from the ARV cupboard and match the following to the prescription:

   - Correct medicine
   - 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
   - Any cracks or chips in bottles
   - Expiration date

4. If any of the above are found, do not dispense medication from this container. Complete a Quality Assurance Notification Form and send the container back to Central Medical stores.

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

<u>Procedure for dispensing ARV tablets or capsules:</u>

1. Calculate quantity required for thirty (30) days and compare with the balance the patient has brought back

2. Issue whole packs (except for the initial 14-day treatment with NVP).

3. If necessary, count out desired number of tablets/capsules using a spatula or knife on a clean counting tray or clean sheet of paper. Avoid touching the medicines with hands, as contamination may result.

4. Recount number of tablets/capsules before packing them into the appropriate packaging

5. Label the package with appropriate label containing the following information
   a. Name of patient
   b. Quantity of medication issued
   c. Name, strength and dosage form of medication
   d. Batch number and expiry date
   e. Dosing instructions
   f. Date dispensed

6. Countercheck the dispensed product with the originating bottle (if applicable) and the passport to make sure that package and labelling contain the correct medicine, strength, quantity, dosage form, and directions for use.

Procedure for dispensing ARV liquids/powders:

1. Calculate the volume and number of bottles required for thirty (30) days. Use patient's weight from the passport and the dosing chart to confirm that the right dose is prescribed. If the right dose is not prescribed, refer to prescribing physician.

2. Reconstitute powders as per manufacturer's instructions, if required.

3. **Issue whole packs unless an exception is absolutely necessary.** If you need to dispense a partial 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 (you) while pouring so that you may check the label while pouring and, to ensure that the label does not become soiled and unreadable.

4. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the bottle:
    a. Name of patient
    b. Quantity of medication issued
    c. Name, strength/concentration and dosage form of medication
    d. Batch number and expiry date
    e. Dosing instructions
    f. Date dispensed

5. If the dose has changed since the last prescription, re-label previously issued bottles to reflect the new dose.

6. Countercheck the dispensed product to make sure that package and labelling contain the correct medicine, strength, quantity, dosage form, and directions for use.

JOB AID **No: ART/JA 004**

COMPLETING THE ARV PATIENT DISPENSING RECORD

Activity:	Creating or updating the ART Patient Dispensing Record Form
Completed By:	Pharmacist/Pharmacist's Assistant
Objective:	To keep track of ARV patient information and dispensing history
Resources:	*Patient Passport*
When to perform:	Every time ARVs are dispensed to patients

A: Enter Patient Demographic Details

Steps	Field/Data	Definition/Action
1	**ART No:**	Write the ART number of the patient. The ART number is the unique identification number assigned to the ART patient by the hospital
2	**Name of Facility:**	Write the name of the facility from which the medicine is being dispensed to the patient
3	**Name:**	Write the full name of the patient
4	**Date of Birth:**	Write the date of birth of the patient. If the exact date of birth is not known, determine an approximate year of birth and write in this column
5	**Sex:**	Tick the appropriate gender
6	**ARV Start Date:**	Write the date the patient was started on ARV treatment
7	**Physical Address:**	Write the residential address of the patient. Indicate any prominent landmarks that may aid in locating the residence. Confirm address at each visit and correct appropriately
8	**Telephone No:**	Write the telephone number of the patient (if available)
9	**Name of Doctor:**	Write the name of the doctor responsible for the patient's therapy
10	**Name, Address and Tel of Supporter:**	Write the name and address, and telephone number of the treatment supporter. Indicate any prominent landmarks that may aid in locating the residence. Confirm at each visit and correct appropriately. Write telephone number if available.
11	**Relationship:**	Write the relationship of the treatment supporter to the patient e.g. spouse, parent, friend, etc.

B: Enter Patient Medication Details

Steps	Field/Data	Definition/Action
1	**Allergies:**	Write any allergies patient is subject to
2	**Social Drug Use:**	Indicate patient's social drug usage by circling the appropriate status (Y/N) and date stopped if applicable
3	**Medication History:**	Write any medications that the patient is currently using for chronic or acute conditions. Also indicate any previous medications used in the previous 3 months
4	**Potential Interactions:**	Indicate any potential interactions between the ART regimen and current medications and communicate the same to the prescriber to change or modify the prescription if necessary
5	**Concomitant Disease(s):**	Indicate any other diseases the patient has (e.g. asthma, epilepsy)

Steps	Field/Data	Definition/Action
6	**ART Regimen:**	Enter the current ART regimen stating the names, dose and frequency of administration of each medicine. Use abbreviations for medicine names such as NVP/AZT/3TC. Refer to the ART Monthly Service report for regimen abbreviations.
7	**Start Date:**	Write the date on which the patient started on this regimen
8	**Stop Date:**	Write the date on which the patient stopped taking this medication if applicable
9	**Reason for stopping:**	Write the reason(s) for stopping this regimen if applicable
10	**New Regimen:**	Write the new regimen replacing the stopped regimen if applicable, in the form of the name, dose and frequency. Use abbreviations for medicine names such as NVP/AZT/3TC
11	**Start Date:**	Write the date the patient was started on this new/replacement regimen

C: Complete Patient Dispensing Record

Steps	Field/Data	Definition/Action
1	**Date:**	Enter the date of dispensing.
2	**Weight:**	Enter the weight of the patient. This information can usually be obtained form the patient passport. To avoid under-dosing for paediatric patients, update the paediatric weigh at each visit.
3	**Medication:**	Write the name of the ARV medication dispensed to the patient in the form of name and strength. Use abbreviations of medication names e.g. d4t 30
4	**Quantity Dispensed:**	Enter the quantity of the medication dispensed to the patient stating the unit of measure (e.g. 60 tabs, 180 mls)
5	**Adherence:**	For every revisit, conduct a pill count and enter the adherence score (Job Aid ART/JA 008).
6	**f/u Date:**	Calculate follow-up date as 28 days from current date or date last pill of previous dispensed medication is to be taken. If the f/u date falls on a weekend, set the f/u date for the Friday before the calculated date. Discuss the date with the patient (to confirm availability) and enter the follow-up/refill date in the column.
7	**Switch (✓)**	Place a ✓ mark if this regimen being dispensed is a switch from the one dispensed in the previous month. Also indicate if the switch is within first line or from first 1st to 2nd line. Refer to guidelines to see what first or 2nd line is.
8	**Pharmacist's Notes**	Record side-effects, patient's complaints and own observations and relevant and significant laboratory results for monitoring efficacy or toxicity Also enter any interventions recommended or made

ARV Patient Dispensing Record

ART No. _____ **Name of Facility:**

Name:	**Date of Birth:**	**Sex**: M ☐ F ☐	**ARV Start Date**:
Physical Address:		**Tel:**	**Doctor:**
Supporter Name and Physical Address:		**Tel:**	**Relationship:**

Allergies:	**Social Drug Use:**	**Date stopped:**	**Concomitant Medication:**	**Potential interactions:**	**Concomitant disease(s):**
	Alcohol Y N				
	Nicotine Y N				
	Others				

ART Regimen: *(name, dose and frequency)*	**Start date:**	**Stop Date:**	**Reason for Stopping:**	**New Regimen:**	**Start date:**
a.					
b.					
c.					
d.					

Dispensing Record *(use abbreviation and strength for medication e.g. NVP 200mg)*

Date:	**Weight:**	**Medication:**	**Qty Dispensed:**	**Adherence:**	**f/u date:**	**Switch (✓):**	**Pharmacist's Notes:**

Date:	**Weight:**	**Medication:**	**Qty Dispensed:**	**Adherence:**	**f/u date:**	**Switch (✓):**	**Pharmacist's Notes:**

JOB AID **No: ART/JA 005**

COMPLETING THE ARV DAILY DISPENSING REGISTER (ADULT AND PAEDIATRIC)

Activity:	Completing the Adult and Paediatric ARV Daily Dispensing Register
Completed by:	Pharmacist/Pharmacist's Assistant
When to complete:	Preferably filled immediately after dispensing medications to a patient. But in cases where there is shortage of man power to do this, it can be filled at the end of the day/working hours as convenient. It must be updated daily.
Purpose:	To capture and document data on, the quantity of ARVs dispensed to patients during the course of a day. This form is not meant to be prepared for each individual patient. Rather, the information about all patients is captured in the order the patients visit the pharmacy or ARVs are issued. This information is used for filling the *Monthly ART Services Report (ART/JA 006)* and for quantification/ordering purposes
Sources of data:	*ARV Patient Dispensing Recor*d (ART /JA 004)
Instructions:	At the end of each sheet, total each column in the *Total Dispensed* and *Total Number of Packs Dispensed* cells. If more than one sheet is used per month, at end of the month, add the total figures for each product from all sheets used and use this new total figure for quantification purposes and the *ART Services Monthly Report Form.* If the product available and dispensed is different from the ones listed in the table use the empty column headings to enter the product, strength and pack size as appropriate.

Steps	Field/Data	Definition/Action
1	**Name of Facility:**	Enter the name of the treatment facility
2	**Month and Year:**	Enter the Month and Year for the sheet. A new sheet must be started for each month
3	**Sheet No. for Month:**	Enter the sheet number for the current month (Note multiples sheets may be required per month)
4	**Date:**	Enter the date for the transaction in the appropriate column
5	**ART No:**	Write the ART number of the patient in the appropriate column. The ART number is the unique identification number assigned to the ART patient by the hospital and can be found in the *ARV Patient Dispensing Record* of the patient (ART/004).
6	**Sex**	Tick to indicate whether the patient is male or female

Steps	Field/Data	Definition/Action
	Reason for visit	A patient may visit the pharmacy with an ART prescription for one of the following reasons: *1.* New: *Refers to patients who have been prescribed ARV medicines for the first time to initiate ART.* 2. Refill: *Refers to patients who are already on ARV at this facility and are visiting the pharmacy for replenishment of their medications.* 3. Transferred in: *Refers to patients already registered at another facility and on treatment but have been transferred to the facility to continue with treatment and collection of medicines. These patients are therefore not new.* 4. Switch: *Refers to patients who are changing their previous regimen as shown in the list of regimens for reasons justified by the prescriber.* 5. In transit: *Refers to a patient registered and being treated at another facility but collecting medicine at your facility during this particular visit.* For each patient put a ✓ mark in the appropriate column.
7	**Regimen Number:**	Enter the Reference number of the regimen (as it appears in the list of regimens and regimen numbers job aid (ART/JA 007))
8	**Quantity of Medications Dispensed:**	Enter the number of tablets/capsules or volume of liquid (in bottles) dispensed to each patient under the relevant preparation. For example, if one bottle of Efavirenz 600mg is dispensed, enter **30** under the EFV 600 column for the patient. If three bottles of AZT oral liquid is dispensed, enter **3** under the AZT oral liquid 10mg/ml column for the patient.
9	**Total Patients:**	Count the number of ✓ marks per column and enter the total number of male and female patients
10	**Total Dispensed:**	Calculate and enter the total number of pills (for tablets and capsules) or bottles (for oral liquids) dispensed for each column.
11	**Pack Size:**	Use the information in this row to convert number of tablets and capsules dispensed to packs dispensed.
12	**Total Number of Packs Dispensed:**	To convert total tablets and capsules dispensed to total packs dispensed, divide the total number of tablets/capsules by the pack size. Round fractions to one decimal place (i.e. 10.4 instead of 10.36) Add all fractions together and round up to the nearest whole number at the end of the month after adding all sheets together.
13	**Page Summary of Regimens:**	For each Regimen Number, enter the total number of new, refill, switch, and transfer-in patients. Calculate the total of patients per regimen in the bottom row of this table for each sheet.

ADULT ARV Daily Dispensing Register

Name of Facility: _____ Month/Year: _____ Sheet Number for Month: _____

Date	ART No.	Sex		New (√)	Refill (√)	Switch (√)	Transfer In (√)	In-Transit (√)	Regimen Number	d4T 30/3TC tabs	d4T 40/3TC tabs	AZT/3TC tabs	NVP 200 tabs	EFV 200 caps	EFV 600 tabs	LVP/r 133/33mg caps	d4T 30 caps	d4T 40 caps	AZT 300 tabs	3TC 150 tabs	IDV 400 caps	ddi 150 tabs	ddi 100 tabs	TDF 300 tabs	RTV 100 caps	LPV/r 200/50mg tabs		
		Male (√)	Female (√)																								
Total Patients																											
TOTAL Dispensed																											
Pack Size										60	60	60	60	90	30	180	60	60	60	60	180	60	60	30	84	120		
Total Number Packs Dispensed																											

Page Summary of Regimens

Regimen Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
New Patients																			
Refill Patients																			
Switch																			
Transfer-In																			
Total for this Sheet																			

PAEDIATRIC ARV Daily Dispensing Register

Name of Facility: _____ Month/Year: _____ Sheet Number for Month: _____

Date	ART No.	Sex		New (√)	Refill (√)	Switch (√)	Transfer In (√)	In-Transit (√)	Regimen Number	EFV 50 Caps	EFV 200 caps	NVP 200 tabs	LVP/r 133/33mg	AZT 100 caps	AZT 300 tabs	d4T 15 caps	d4T 20 caps	3TC 150 tabs	EFV 50mg/ml	d4T Oral liq 1mg/ml	AZT Oral liq 50mg/5ml	3TC Oral liq 10mg/ml	NVP Oral 10mg/ml	LVP/r Oral liq 80/20mg/	LPV/r 200/50mg tabs			
		Male (√)	Female (√)																									
Total Patients																												
TOTAL Dispensed																												
Pack Size										30	90	60	180	100	60	60	60	60										
Total Number Packs Dispensed																												

Page Summary of Regimens

Regimen Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
New Patients																			
Refill Patients																			
Switch																			
Transfer-In																			
Total for this Sheet																			

JOB AID **No: ART/JA 006**

COMPLETING THE MONTHLY ART SERVICES REPORT

Activity:	Completing the Monthly ART Services Report Form
Completed by:	Pharmacist/Pharmacist's Assistant
When to complete:	At the end of each month
Purpose:	To document and report Monthly ART services provided including the characteristics of the patients served, the cumulative totals of new and continuing patients, distribution of patients by regimens, quantities of ARVs dispensed and the current stock status to Division: Pharmaceutical services.
Sources of data:	*ARV Patient Dispensing Record* *Adult and Paediatric ARV daily dispensing registers* *Stock Cards*
Instructions:	The report must be signed by the official preparing it and cross checked by the pharmacist in charge of ART or regional pharmacist. Copies of completed forms should be distributed to – - Division of Pharmaceutical Services (ART Logistics Pharmacist) - Regional Pharmacist - Facility HMIS Officer

Enter Product Details as described in the table below.

Steps	Field/Data	Definition/Action
1	**Name of Facility:**	Enter the name of the treatment facility
2	**Reporting Month and Year:**	Enter the Month and Year for which the report is being compiled.
Part I: Patient Information:		
3	**New Patients**	These are patients who are receiving ARVs for the first time in the reporting month. They do not include patients who have been transferred in.
	Children < 13 years	Enter in the appropriate space the number of new male and female patients and add up these figures to obtain the total number of new patients under 13 years
	Adult ≥ 13 years	Enter in the appropriate space the number of new male and new female patients who are 13 years or older and add up these figures to obtain to total number of this category of patients.
4.	**Number of patients by Reason of visit:**	Enter in the appropriate space the total number of New, Refill, Switch and In Transit patients seen in the reporting month.
	New (starting this month)	Refers to patients who have been prescribed ARV medicines for the first time to initiate ART.
	Refill	Refers to patients who are already on ARV medicines at this facility and are visiting the pharmacy for replenishment of their medications

Steps	Field/Data	Definition/Action
	Switch	Switch: refers to patients who are changing their previous regimen as shown in the list of regimen for reasons justified by the physician.
	In Transit:	These are patients belonging to another ART site but collecting medication from the reporting site during the reporting month (e.g. patient on holiday etc.)
5.	**Total ART Patients for this month:**	Enter the total number of patients by the categories stated below in the appropriate space
	Cumulative from the previous month (A):	*Patients who were reported as Number on Active Treatment in the previous reporting month.*
	New (starting this month) (B):	*Patients receiving ARVs for the first time this month*
	Transferred in (C):	*Patients who have been transferred to the reporting facility from another facility, in the reporting month.*
	Transferred out (D):	*Patients who are transferred out of the reporting facility to another facility in the reporting month.*
	Stopped by Physician (E):	*Patients who have stopped taking their regular ARV medicines on the order of the physician in the reporting month.*
	Defaulted (F):	*Patients who fail to collect their medicines within one month after the next date of visit (Patients missing two consecutive visits)*
	Deceased (G)	*Patients who died during the reporting month only.*
	Number of active treatment = (A+B+C)-(D+E+F+G)	*This is the total number of patients currently on treatment at the facility. This number is calculated by the formula shown.*
PART II: Distribution of Regimens: (Adult and Paediatric Regimens)		
	Cumulative from last month (a)	For each regimen listed, enter the cumulative number of patients as recorded in last month's report.
	New this Month (b)	For each regimen listed, enter the total number of new adults and children seen in the reporting month.
	Transferred in (c)	For each regimen listed, enter the total number of adults and children seen in the reporting month that have been transferred from other facilities.
	Switch TO this regimen (d)	For each regimen listed, enter the total number of adults and children CHANGED TO this Regimen from their previous regimen in the reporting month.
	Switch FROM this regimen (e)	For each regimen listed, enter the total number of adults and children CHANGED FROM this regimen to other regimens during the reporting month.
	Transferred out (f)	For each regimen listed enter the total number of adults and children TRANSFERRED TO other facilities during the reporting month.
	Defaulted (g)	For each regimen listed enter the total number of adults and children who missed two consecutive appointments by the current reporting month.

Steps	Field/Data	Definition/Action
	Stopped by Physician (h)	For each regimen listed enter the total number of adults and children whose medication have been stopped by the doctor.
	Deceased	For each regimen listed enter the total number of adults and children who died in the reporting month ONLY
	Cumulative this Month = (a+b+c+d)-(e+f+g+h+i)	Use the formula provided in this column to determine the total number of adults and children who are on each regimen from the beginning of the program in your facility to the end of the reporting month. Enter the number in this column.
PART III: Monthly ART Stock Status Report:		
6	**Name of Facility:**	Enter the name of the treatment facility
7	**Reporting Month and Year:**	Enter the Month and Year for which the report is being compiled.
	SOH At the close of last month.	For each medication, enter the stock on hand by packs/bottles documented at the last day of the previous month.
	Quantity Received:	For each medication, enter the total quantity by packs/bottles received in the pharmacy in the reporting month from all sources (CMS, RMS, other facilities)
	Total Dispensed	For each medication, enter the total number of pack for tablets and capsules or bottles for liquid formulations dispensed to adults and paediatrics respectively in the appropriate column. If the medicine, formulation or pack size dispensed is not on the list, include the product dispensed with the correct pack size in the empty rows at the bottom of the form.
	Issued to other Health facility	For each medication, enter the total quantity, if any, by packs/bottles issued or supplied to other health facilities.
	Quantity Damaged, Lost or expired	For each medication, enter the total quantity by packs/bottles that was damaged, lost or expired in the reporting month.
	SOH at the end of this Month= (A+B)- (C+D+E+F)	For each medication calculate the SOH using the formula shown. Carry out a physical stock take to verify the calculated SOH. If the stock take value does not match the calculated SOH, indicate the counted physical value in this column and investigate the cause of the difference.
	Quantity on order	For each medication, enter the total quantity ordered from CMS or RMS previously but has not yet been received in the reporting month by packs/bottles. Do not indicate items that the CMS or RMS has indicated to be out of stock and will therefore have to be re-ordered.
	Quantity Short Dated	For each medication, enter the total quantity of products by packs/bottles that will expire in the next 6 months.

Ministry of Health and Social Services
Pharmaceutical Services Division
Monthly ART Services Report

Name of Facility: _____ **Reporting Month/Year:** _____

Part I: Patient Information

Fill Only the Unshaded Areas		Male	Female	Total
New Patients (Starting this month)				
Age Group	Children <13 years			
	Adult ≥ 13 years			
Number of Patients By Reason of Visit				
New (Starting this month)				
Refill				
Switch				
In Transit				
Total ART Patients For This Month				
Cumulative from the previous month (A)				
New (Starting this month) (B)				
Transferred In (C)				
Transferred Out (D)				
Stopped By Physician (E)				
Defaulted (F)				
Deceased (G)				
Number on Active Treatment including this month {=(A+B+C)-(D+E+F+G)}				

Part II: Distribution of Regimens

No	Regimen	Cumulative from last month (a)	New this month (b)	Transferred In (c)	Switch TO this regimen (d)	Switch FROM this regimen (e)	Transferred Out (f)	Defaulted (g)	Stopped by the Physician (h)	Deceased (i)	Cumulative this month =(a+b+c+d)-(e+f+g+h+i)
Adult Regimens											
1	D4T30/3TC/NVP										
2	D4T40/3TC/NVP										
3	AZT/3TC/NVP										
4	D4T30/3TC/EFV										
5	D4T40/3TC/EFV										
6	AZT/3TC/EFV										
7	D4T30/3TC/LPV-r										
8	D4T40/3TC/LPV-r										
9	AZT/3TC/LPV-r										
10	TDF/3TC/LPV-r										
11	AZT/3TC/IDV-r										
12	AZT/3TC/IDV-r										
13	TDF/3TC/EFV										
14	TDF/3TC/NVP										
15											
16											
17											
18	PEP: AZT/3TC										
	Total For Adults										

Ministry of Health and Social Services
Pharmaceutical Services Division

Monthly ART Services Report

Name of Facility: _____ **Reporting Month/Year:** _____

No	Regimen	Cumulative from last month (a)	New this month (b)	Transferred in (c)	Switch TO this regimen (d)	Switch FROM this regimen (e)	Transferred Out (f)	Defaulted (g)	Stopped by the Physician (h)	Deceased (i)	Cumulative this month =(a+b+c+d)-(e+f+g+h+i)
Paediatric Regimens											
19	D4T 15/3TC/NVP										
20	D4T 20/3TC/NVP										
21	D4T 15/3TC/EFV										
22	D4T 20/3TC/EFV										
23	D4T 15/3TC/LPV-r										
24	D4T 20/3TC/LPV-r										
25	D4T/3TC/NVP										
26	D4T/3TC/EFV										
27	D4T/3TC/LPV-r										
28	AZT 150/3TC/NVP										
29	AZT 100/3TC/NVP										
30	AZT 150/3TC/EFV										
31	AZT 100/3TC/EFV										
32	AZT/3TC/NVP$_{SOL}$										
33	AZT/3TC$_{SOL}$/EFV										
34	AZT/3TC/LPV-r										
35	AZT/3TC/LPV-r$_{SOL}$										
36											
37											
38											
39	PEP: AZT/3TC										
	Total For Paediatrics										

Ministry of Health and Social Services
Pharmaceutical Services Division

Monthly ART Services Report

Name of Facility: _____ _____ **Reporting Month/Year:** _____

Part III: Monthly ART Stock Status Report

Description	Pack Size	SOH at the close of last month (A)	Qty Received (B)	Total Dispensed		Issued to other Health Facility (E)	Qty Damaged /Expired (F)	SOH at the end of this month {=(A+B)-(C+D+E+F)}	Qty on Order	Qty Short Dated (<6 months)
				Adults (C)	Paeds (D)					
3TC + AZT	60									
D4T 30 + 3TC	60									
D4T 40 + 3TC	60									
3TC 150mg	60									
AZT 100 mg	100									
AZT 300mg	60									
D4T 15mg	60									
D4T 20mg	60									
D4T 30mg	60									
D4T 40mg	60									
EFV 50mg	30									
EFV 200mg	90									
EFV 600mg	30									
NVP 200 mg	60									
TDF 300 mg	30									
LPV/r (133.3+33.3mg)	180									
LPV/r (200/50mg) tabs	120									
DDI 25 mg	60									
DDI 100mg	60									
DDI 150mg	60									
IDV 400 mg	60									
DDI 8mg/ml	200ml									
Ritonavir 100mg	84									
AZT 10mg/ml	100ml									
AZT 10mg/ml	240ml									
3TC 10mg/ml	100ml									
3TC 10mg/ml	240ml									
NVP 10mg/ml	100ml									
NVP 10mg/ml	240ml									
D4T 1mg/ml	200ml									
LPV/r (80+20)mg/ml	60ml									

N:B- SOH = Stock on Hand. Carry out a Physical Stock take to verify SOH. If the stock take value does not match the calculated SOH, Indicate the counted Physical stock under SOH and investigate cause of difference.

	Name	Signature	Date
Prepared by:			
Checked by:			
Distributed by:			

JOB AID No: ART/JA 007

LIST OF REGIMENS AND REGIMEN NUMBERS

a) These are the regimen numbers to be used for when entering a patient's regimen on the daily dispensing registers
b) Adult regimens are numbered from 1-18 with four blank rows for any regimen used but unlisted.
c) Paediatric regimens are numbered from 19-33 with four blank rows for any other regimen used but not listed on the table.

Adult Regimen		**Paediatric Regimen**	
Regimen Number	***Regimen***	***Regimen Number***	***Regimen***
1.	D4T30/3TC/NVP	19.	D4T15/3TC/NVP
2.	D4T40/3TC/NVP	20.	D4T20/3TC/NVP
3.	AZT/2TC/NVP	21.	D4T15/3TC/EFV
4.	D4T30/3TC/EFV	22.	D4T20/3TC/EFV
5.	D4T40/3TC/EFV	23.	D4T15/3TC/LPV-r
6.	AZT/3TC/EFV	24.	D4T20/3TC/NVP
7.	D4T30/3TC/LPV-r	25.	D4T/3TC/NVP
8.	D4T40/3TC/LPV-r	26.	D4T/3TC/EFV
9.	AZT/3TC/LPV-r	27.	D4T/3TC/LPV-r
10.	TDF/3TC/LPV-r	28.	AZT/3TC/NVP
11.	AZT/3TC/IDV-r	29.	$AZT/3TC/NVP_{SOL}$
12.	TDF/3TC/EFV	30.	AZT/3TC /EFV
13.	TDF/3TC/NVP	31.	$AZT/3TC_{SOL}$/EFV
14.		32.	AZT/3TC/LPV-r
15.		33.	$AZT/3TC/LPV\text{-}r_{SOL}$
16.		34.	
17.		35.	
18.		36.	
		37.	

JOB AID No: ART/JA 008

ADHERENCE MONITORING

<table>
<tr><th>Steps</th><th>Task</th><th>Reference/Notes</th></tr>
<tr><td>1.</td><td>Check and obtain the previous medication containers from the patient. Confirm with the patient that all the previous medication issued has been brought back.</td><td></td></tr>
<tr><td>2.</td><td>Count medication returned and record on the Pill Count Form.</td><td>Job Aid ART/JA 009</td></tr>
<tr><td>3.</td><td>Record patient's adherence score on the ART patient Dispensing as per the table below (Good, Fair and Poor).
Adherence score -
<table>
<tr><td>Adherence</td><td>%</td><td>Missed doses per month (BD doses only)</td></tr>
<tr><td>Good</td><td>≥ 95 %</td><td>≤ 3 doses</td></tr>
<tr><td>Fair</td><td>85 -94%</td><td>4 – 8 doses</td></tr>
<tr><td>Poor</td><td>< 85%</td><td>≥ 9 doses</td></tr>
</table></td><td></td></tr>
<tr><td>4.</td><td>Ask the questions from the self- evaluation form and fill in the form. File the form with the ARV Patient Dispensing Record.</td><td>Job Aid ART/JA 010</td></tr>
<tr><td>5.</td><td>Compare adherence score with the patient's CD4 count change/ trend and weight changes and alert the prescriber of discordant pattern.</td><td></td></tr>
<tr><td>6.</td><td>Discuss patient's experience with ART, adherence score and identify patients with problems. Plan interventions with patient and provide support.</td><td></td></tr>
</table>

JOB AID No: ART/JA 009

COMPLETING THE PILL COUNT FORM

Activity:	Completing the Pill Count Form
Completed by:	Pharmacist/Pharmacist's Assistant
Purpose:	To monitor the level of adherence to therapy
When to perform:	At each patient visit
Resources:	*ARV Patient Dispensing Record*
Instructions:	At each follow up, record the number of pills that should remain, count the number of pills returned and record the number of pills remaining. The difference signifies the number of pills missed. File this form with the Patient Dispensing Record

Enter Product Details

Steps	Data	Action
1	**Patient Name:**	Enter the name of the patient
2	**ART Number:**	Enter the ART number of the patient
3	**Date:**	Enter the date of the transaction
4	**No of Pills:**	
	- **Expected:**	For each medication that the patient is taking, enter the number of pills **EXPECTED** to be left in the container
	- **Actual**	For each medication that the patient is taking, enter the **ACTUAL** number of pills left in the container
5	**Signature:**	Pharmacy staff responsible to sign or initial the form

ARV PILL COUNT FORM

Patient's Name: ______________________________ **ART Number:** ________________________

1	2	3																		
Date	**No. of Pills**	**AZT**	**AZT/3TC**	**D4T 30/3TC**	**D4T 40/3TC**	**D4T 30mg**	**D4tT 40mg**	**DDI 100mg**	**DDI 150mg**	**DDI150mg**	**EFV 600mg**	**IDV 400mg**	**NVP 200mg**	**LPV/r tabs**	**RTV caps**	**3 TC 150mg**	**TDF 300mg**			**Signature**
	Expected																			
	Actual																			
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JOB AID No: ART/JA 010

COMPLETING THE PATIENT SELF EVALUATION FORM

Activity:	Completing the Patient Self Assessment Form
Completed by:	Pharmacist/Pharmacist's Assistant
Purpose:	To evaluate and record patients' adherence to medications
When to perform:	**For the first 3 months the patient is on treatment, perform the evaluation at each visit. If adherence and comprehension is good, perform every 3 months**
Resources:	*ARV Patient Dispensing Record*
Instructions:	This form should be filled at each follow-up visit. Ask the patient the questions and indicate the answers on the form. File the form with the Patient Dispensing Record

Steps	Data	Action
1	**Patient Name:**	Enter the name of the patient
2	**ART Number:**	Enter the ART number of the patient
3	**Date:**	Enter the date of the visit
4	**HIV medication**	Ask the patient what medication they are taking and record their response on the form. The patient may say the names or describe the medicine. (column 1)
5	**No of pills per day**	For each medicine, ask the patient how many they take in a day and record the answer next to the appropriate medicine. (column 2)
6	**No of times per day and time taken**	Ask the patient how many times they take each medicine and at what times and record the answer next to the appropriate medicine. (columns 3 and 4)
7	**Last dose taken**	Ask the patient when did they take the last dose before coming to the hospital and record the date and time the last dose was taken. If only the time is recorded, it is assumed that the last dose was taken on the day of the hospital visit.
8	**Missed doses**	Ask the patient if they have missed any doses in the last month and how many doses. Record their answer in column 7.

PATIENT SELF EVALUATION FORM

Patient's Name: ______________________________ **ART Number:** ___________________

I. What HIV medication are you taking? How many pills per day? How many times per day? And at what time of the day do you take each of your medicines?

Date: __________________________

1	2	3	4	5	6	7
HIV Medication	**# of pills per day**	**# of times per day**	**Time of day to be taken**	**How is medication taken (e.g. with meals)**	**When was last dose taken?**	**How many doses were missed in the last month**

Date: __________________________

1	2	3	4	5	6	7
HIV Medication	**# of pills per day**	**# of times per day**	**Time of day to be taken**	**How is medication taken (e.g. with meals)**	**When was last dose taken?**	**How many doses were missed in the last month**

Date: __________________________

1	2	3	4	5	6	7
HIV Medication	**# of pills per day**	**# of times per day**	**Time of day to be taken**	**How is medication taken (e.g. with meals)**	**When was last dose taken?**	**How many doses were missed in the last month**

Date: __________________________

1	2	3	4	5	6	7
HIV Medication	**# of pills per day**	**# of times per day**	**Time of day to be taken**	**How is medication taken (e.g. with meals)**	**When was last dose taken?**	**How many doses were missed in the last month**

JOB AID **No: ART/JA 011**

ARV MEDICATION COUNSELLING

I. **Welcome patient and introduce yourself**

II. **Identify who is being counselled:** Determine if the person picking up the medicines is the patient or treatment supporter

III. **Discuss the goal of therapy:** Explain aim of the treatment
ART can:
a. *Improve quality of life*
b. *Reduce HIV-related morbidity and mortality*
c. *Restore the functioning of the immune system*
d. *Maximally suppress the viral load*

IV. **Discuss how the 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.*
e. *Inform the patient that the medicines are life-long*

V. Explain adherence:
Adherence is taking the medication exactly as directed. This is important because missing even a few doses in a month can lead to the treatment not working for you.
a. *Adherence is taking the medications exactly as directed without missing doses.*
b. *These medications work best when there is a constant amount in the blood therefore missing doses (even a few) can lead to the medication not working for you. This is called treatment failure*
c. *Not taking the medication correctly can also result in the HIV virus changing so that the medication can no longer suppress it effectively. This is called resistance.*

VI. **Discuss how adherence will be monitored:** The methods that will be used for measuring adherence are Pill Count and Patient Self Evaluation Form
a. *You should bring all the remaining medications every time you come for a refill or an appointment at the clinic. Your medication will be counted/ measured against what was given to you to give an idea of how well you are taking your medicines.*
b. *At each visit, you will be asked some questions on how you are taking your medication. You will also be asked to identify your medication.*

VII. **Design a medication-taking plan with the patient:**
a. Give the name of the medicine and show the patient what the medication looks like
b. Instruct the patient how to take the medicine (for example "take one tablet by mouth every 12 hours with a full glass of water half an hour before meals.)
c. Check for any food restrictions or requirements.

d. Help the patient to identify how best to take their medication with minimum disruptions to their schedules.
e. Provide tips/advice on how to minimise missing doses (e.g. set alarm, associate pill taking with normal routine activities).

VIII. **Give medication information:** Explain that the medicines must be taken regularly, exactly as directed, and not to miss any doses:

a. *These medications are meant only for you. Do not share these medications with others.*
b. *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 medication at the same time each day.*
c. *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.*
d. *If you miss a dose, take it as soon as you remember.. 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 her/him what she/he would do. Make up an example that is based on the medicines 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).

e. *If you vomit the medicine within 30 to 1 hour minutes of taking it, take another dose immediately.*
f. *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.*
g. *If you don't take these medicines exactly as the pharmacist/doctor told you, they may not work. This is dangerous, because there are only a limited number of medicines that can be used to treat patients with HIV infections if these stop working.*
h. *Don't stop taking these medicines without checking with your doctor/pharmacist/nurse first.*

IX. **Confirm patient understands:**

a. Find out if the patient understands the information given by asking an open-ended question, such as "*I know that I just gave you a lot of information, just to make sure that I told you everything that I needed to, would you please repeat the information?*"
b. Ask patient to recap on how the medicines should be taken by asking an open-ended question such as "*how would you take these medicines*?"
c. Ask if patient has any questions, concerns or requires clarification and address these

X. **Give information on the side effects of the medicines:** Refer to *Antiretroviral Therapy - Patient Counselling Information* table (Annex 1- the most common side effects are listed in **boldface** type).

a. **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.*
b. **Side effects to report immediately:** *Check with your doctor* ***immediately*** *if you have the following side effects.*
c. **Long term effects:** *Some side-effects develop over time. It is important that you attend all your appointments with the doctor and for taking blood.*

XI. **Discuss medicine interactions:** Refer to BNF/SAMF or Medicine Package Insert
Tell the patient:

a. *Some medicines are not safe to take while you are taking ARV medicines.* Give the specific information listed in the "Medicine 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 or pharmacist before starting any new medicines (this includes herbals and vitamins).*
d. *Avoid alcohol while taking ARV medicines.*

XII. **Storage**: Refer to Medicine Package Insert and/or Manufacturer's label…

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.*
c. *If medication has to be stored in the fridge, give alternative area of storage if they do not have a fridge.*

XIII. **Check the understanding of the patient or his/her representative**: by asking them to repeat back to you key information. Remind them of any information they left out. Use open-ended questions such as:

a. *How will you use this medication?*
b. *How will you store this medication?*
c. *How will you remind yourself to take the medication?*
d. *What will you do if you miss a dose?*

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

XV. **Communicate follow-up date to patient and request the patient to bring his/her medication containers along at the next visit. (**The follow up date should be at least two days before the patient's medication is finished).

JOB AID NO: ART/JA 012

LABORATORY MONITORING PARAMETERS

This Job Aid is meant to be a guide of the parameters to be monitored in regimens containing specific medicines.

1. Check the laboratory results of the patient against the normal values indicated in the laboratory report or table below.
2. If any abnormal result requiring action is noted, consult with the doctor and concur on the action to be taken if any.
3. Note significant or abnormal results in the patient's records under "**Pharmacist's Notes**" and the action taken for reference and further monitoring during subsequent visits.

Medicine	**Parameter and Monitoring Frequency**	**Normal Values**	**Result Interpretation/ Toxicity**	**Action to be taken**
All	Full blood count with Differential Count. To be monitored at baseline and every 3 months	1.White blood cells 4.0-11.0 $x10^9$/l. 2. Red cell count 4.2-6.5 $x10^{12}$/l 3. Haemoglobin 12-18.8g/dl 4. Haematocrit 40.0-54.0% 5. Neutrophil 2.0-7.5$x10^9$/l 6. MCV 80-99.9fl 7. MCHC 27-31.0% 8. Platelets 140-440 $x10^9$/l	For patients on AZT monitor more frequently (monthly) if Hb<9g/l. Serious toxicity indicated by Hb level≤6.5 g/l. Monitor neutrophil count monthly if <1000cells/mm^3. Serious toxicity indicated by neutrophil count below 500cells/mm^3	It is recommended that AZT or any other bone marrow suppressing medicine be discontinued if Hb levels is < 6.5g/l or the total neutrophil count is <500cells/mm^3
All	CD4 count. To be monitored routinely every six months to determine efficacy of regimen.	Normal values in adults range from 500-1800cells/mm^3. In children CD4% is a more useful indicator and normal values should be > 25%.	CD4 count typically increases by ≥ 50cells/mm^3 after 4-8 weeks of successful viral suppression with ART and increases an additional 50-100cell/mm^3 per year on ART thereafter. A rising trend indicates that the treatment is working and the patient's immunity is being restored. A falling trend indicates treatment failure.	If CD4 count or CD4% falls then further investigation needs to be done. It may mean the patient is not adhering to treatment or it may mean there is resistance to current treatment and a change in regimen is needed.

Medicine	Parameter and Monitoring Frequency	Normal Values	Result Interpretation/ Toxicity	Action to be taken
All	Serum Creatinine Recommended to be monitored at baseline and if renal insufficiency is present/ suspected. Urine dipstick recommended at baseline and every six months for patients on Tenofovir.	53-115umol/l but value will be age, weight and sex dependent. Calculate Creatinine clearance (ClCr) using the formula: ClCr (ml/min)= (140-age) x wt (kg) x 1.22 / Serum creatinine (umol/l) For females multiply above by 0.85.	A highly elevated serum creatinine level is indicative of renal insufficiency and possible reduced elimination of medicines excreted renally especially NRTIs ddI/ d4T, 3TC and TDF.	If serum creatinine is high, calculate creatinine clearance for patient and adjust dose in consultation with the doctor especially if ClCr is < 50ml/min. Refer to appendix 2 of the ART guidelines for the recommended dose adjustments for the various levels of renal insufficiency.
Nevirapine	Alanine Aminotransferase (ALT) Monitor for possible hepatotoxicity at 2,4 6 weeks, 2 months and thereafter 6 monthly if no problem	< 40u/l This is the upper limit of normal (ULN) but value is lab dependent. Confirm the value indicated as ULN by your laboratory.	> 175-350u/l or 5x the upper limit of normal indicates toxicity.	Repeat ALT regularly if higher than 2.5x ULN and stop or change Nevirapine if > 5x ULN. Stop all medicines if ALT> 10x ULN and consult specialist physician for further management.
NRTIs especially ddI, d4T, 3TC, ddC	Amylase To be monitored only when clinically indicated for suspected pancreatitis.	Up to 200u/l. Please confirm the levels indicated as normal by your laboratory.	Serious toxicity indicated by amylase level > 2.5x upper limit of normal. Patients with continuously elevated amylase level should be monitored closely.	Discontinue causative medicine if Amylase is > 2.5x ULN. Patients experiencing pancreatitis should never receive the causative medicine again.
NRTIs	Lactate, Blood PH, Bicarbonate level To be monitored only when clinically indicated for suspected lactic acidosis (Pt with lethargy, abdominal pain, hyperventilation, cyanosis)	**Lactate:** usually < 1mmol/l but variable **PH:** 7.38-7.42	Lactic acidosis is characterized by low PH and low bicarbonate. Plasma lactate > 5mmol/l or greater than 2x ULN. PH < 7.25 Bicarbonate < 21mEq/L. Lactic acidosis should be suspected in any patient having unexplained acidosis	Immediate discontinuation of NRTIs and immediate admission of patient to hospital for therapy to correct acidosis if patient is very ill. Once levels normalize, it is recommended to switch the patient to other NRTIs which have a reduced risk of causing

Medicine	Parameter and Monitoring Frequency	Normal Values	Result Interpretation/ Toxicity	Action to be taken
				lactic acidosis e.g. AZT, 3TC, ABC, TDF but not ddI, ddC or d4T.
Protease Inhibitors	Blood glucose Baseline and yearly thereafter only for patients on PIs	4-8mmol/l	Random blood sugar > 11mmol/l on at least two occasions or fasting blood sugar > 8mmol/l are warning signs.	Action will depend on case by case review. Seek specialist opinion.
Protease Inhibitors	Cholesterol/ triglycerides Baseline and yearly thereafter only for patients on PIs.	**Total cholesterol** Desirable < 5.18mmol/l-6.2mmol/l **HDL Cholesterol** Desirable > 1.04mmol/l Acceptable 1.04-1.56mmol/l **Total cholesterol:HDL** ratio of less than 5:1 **Fasting triglyceride levels** < 1.7mmol/l	Signs of toxicity are: Total cholesterol > 6.2mmol with HDL cholesterol < 1.04mmol/l Total cholesterol: HDL ratio more than 5:1 Fasting triglyceride levels of > 2.15mmol/l	Consult specialist Physician for further management especially for patients with increased coronary heart disease risks.

JOB AID No: ART/JA 013

ANTIRETROVIRAL THERAPY – PATIENT COUNSELLING INFORMATION

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

Description	Directions	Side Effects	Medicine Interactions
Stavudine (d4T), 40mg capsule (dark orange)	• This medication can be taken with or without food. Take 1 capsule twice a day	**Report immediately:** • **Tingling, numbness, or pain in the hands/feet** • Unusual tiredness(fatigue) weakness or muscle pain • Severe abdominal pain with nausea and vomiting **Report at next visit:** • **Headache or difficulty sleeping** • **Nausea, vomiting, diarrhoea** • **Fever, Rash** • **Changes in the distribution of fat**	• Should never be used with zidovudine (AZT) • Avoid combination with ddI especially in pregnancy • Caution when using with other medicines causing peripheral neuropathy such as isoniazid, chloramphenicol, ethambutol, ethionamide
30mg capsule (light orange and dark orange)	Take 1 capsule twice a day		
15mg Capsules 20mg Capsules 1mg/ml oral Solution	Children: (dose twice daily) <30kg 1mg/kg/dose 30–60kg 30mg/dose Max. dose >60kg 40 mg/dose The oral solution should be kept in a fridge after reconstitution.		
Lamivudine (3TC), 150mg tablet (white diamond shaped)	• This medication can be taken with or without food. Take 1 tablet twice a day	**Report immediately:** • Tingling, numbness, or pain in the hands/feet • Unusual tiredness(fatigue) weakness or muscle pain • Severe abdominal pain with nausea and vomiting **Report at next visit:** • **Dizziness, headache, or difficulty sleeping** • **Nausea, vomiting, diarrhoea**	
10mg/ml oral solution	For children: (dose twice daily) <30 days 2mg/kg/dose >30 days or <60 kg 4 mg/kg/dose Max. dose >60 kg 150mg/dose		

Description	Directions	Side Effects	Medicine Interactions
		• **Rash**	
Indinavir (IDV), 400mg Capsules	Take 2 capsules three per day on an empty stomach (1 hour before and 2 hours after food). Take the medicine with plenty of fluids (about 2 litres per day) Or 2 capules two times daily together with Ritonavir 100mg twice daily. No food restrictions are necessary with this combination.	**Report immediately:** • Severe side or back pain. • Blood in urine, dark yellow or brown urine, paleness and unusual bleeding • Yellowing of the skin **Report at next visit:** • **Dizziness, headache, abdominal pain, nausea, vomiting, metallic taste,** diarrhoea, change in body fat distribution	Indinavir is an inhibitor of cytochrome P450 3A4 (CYP3A4), and may alter serum concentrations of other medicines metabolized by this pathway, including certain benzodiazepines, cholesterol-lowering agents, ergot derivatives, rifampin, phosphodiesterase type 5 (PDE5) inhibitors (sildenafil, tadalafil), and others. Because indinavir is also metabolized by CYP3A4, medicines that affect this enzyme system, such as ketoconazole, rifampin, and rifabutin may significantly affect indinavir levels. Separate dosing by 2 hour if coadministered with didanosine
Efavirenz (EFV), 200mg capsule (gold)	• This medication should be taken preferably on an empty stomach. If it must be taken with food, avoid high-fat foods. Take 3 capsules at night	**Report immediately:** • **Pruritis/Rash** • **Nausea, vomiting, diarrhoea** • Severe abdominal pain • Severe depression or thinking you don't want to live anymore **Report at next visit:** (These side effects are rather common but	Coadministration of efavirenz with medicines primarily metabolized by CYP2C9, CYP2C19, and CYP3A4 may result in altered plasma concentrations of the coadministered medicine. Astemizole, cisapride, ergot alkaloids and derivatives, midazolam, or triazolam should not be used concomitantly with efavirenz.

<table>
<tr><th>Description</th><th>Directions</th><th>Side Effects</th><th>Medicine Interactions</th></tr>
<tr><td>600mg tablets
(white, capsular-shaped)</td><td>Take 1 tablet at night</td><td rowspan="2">tend to go away after about a month.)
Dizziness, headache, difficulty sleeping or concentrating

**Inform patients that sometimes the medicine causes abnormal or bad dreams, but that this should resolve within 2–4 weeks.</td><td rowspan="2">The birth-control pill may not work effectively while taking efavirenz. Always use a barrier backup birth-control method (for example, a condom). This is very important because EFV can potentially cause problems with the development of a fetus.</td></tr>
<tr><td>Paediatric formulations
30mg/5ml syrup
50mg capsules
200mg capsules</td><td>Children (dose once daily). Children who take the capsule will have a slightly lower total mg dose because of formulation issues

<table>
<tr><th>Wt band</th><th>Syrup</th><th>Cap/ tablets</th></tr>
<tr><td>10-15kg</td><td>270mg</td><td>200mg</td></tr>
<tr><td>15-<20kg</td><td>300mg</td><td>250mg</td></tr>
<tr><td>20-<25kg</td><td>360mg</td><td>300mg</td></tr>
<tr><td>25-<32.5kg</td><td>450mg</td><td>350mg</td></tr>
<tr><td>32.5kg-<40kg</td><td>510mg</td><td>400mg</td></tr>
<tr><td>>40kg</td><td>Max dose 600mg</td><td>600mg</td></tr>
</table></td></tr>
<tr><td>Nevirapine (NVP)

200mg tablet
(white, oval)</td><td>• This medication can be taken with or without food.

Take 1 tablet once a day for the first 2 weeks of therapy, then take 1 tablet twice a day</td><td rowspan="2">Report immediately:
• 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

Report at next visit:
• Headache
• Stomach Pain, Nausea, diarrhoea</td><td rowspan="2">Nevirapine is metabolized by and induces the activity of CYP3A isoenzymes.
This may result in lower/higher plasma concentrations of concurrently administered medicines that are extensively metabolized by CYP3A
NVP ↓the level of estrogens in birth-control pills and they may not work effectively while taking NVP; additional barrier contraceptives are recommended. NVP ↓the levels of ketoconazole, Rifampicin and St</td></tr>
<tr><td>50mg/5ml oral suspension
(white to off-white)</td><td>4 mg/kg once a day for 2 weeks. Thereafter, maintenance dose:
Children > 2 months to < 8 years: 7 mg/kg twice a day.</td></tr>
</table>

Description	Directions	Side Effects	Medicine Interactions
	Children > 8 years: 4mg/kg twice daily. Maximum recommended dose: 400mg/day		Johns Wort ↓NVP levels.
Zidovudine (AZT, ZDV) 300mg tablet (white, round)	• Can be taken without regard to food, however suggest that patient take with food (light, low fat meal) if nausea and vomiting are a problem Take 1 tablet twice a day	**Report immediately:** • Fever or chills • Sore throat • Pale skin, **unusual tiredness or weakeness**, shortage of breath, rapid heart beat. • Muscle pain and weakness. **Report at Next visit:** • Headaches, nausea and vomiting	Antagonistic effect if used together with stavudine. Concurrent use of blood dyscrasia-causing medications, other bone marrow depressants eg ganciclovir, cytotoxic agents may cause an additive or synergistic myelosuppression requiring dosage reduction of either or both medicines
Paediatric formulations: 50mg/5ml syrup (colourless to pale yellow) 100mg capsules	Children: (dose twice daily) <4 weeks 4mg/kg/dose 4 weeks–13 years 240mg/m^2 twice daily >13 years 300mg/dose Dose for prophylaxis (full-term newborn): 2 mg/kg orally every 6 hours starting with 12 hours of birth and continuing for 6 weeks.		
Lopinavir/Ritonavir (LPV/RTV), Aluvia®	• Should be taken with food.	**Report immediately:** • **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	Lopinavir/r is an inhibitor of the P450 isoform CYP3A in vitro. Coadministration of lopinavir/r and medicines primarily metabolized by CYP3A may result in increased plasma concentrations of the other medicine, which could increase or
250mg/50mg tablet (brown/orange)	Take 2 tablets twice a day		

Description	Directions	Side Effects	Medicine Interactions
400mg/100mg/5ml oral solution	Children: (6 months-12 years) 7-15kg 12/3 mg/kg twice daily 15-40kg 10/2.5mg/kg twice daily	of eyes **Report at next visit:** • **Headache or difficulty sleeping**	prolong its therapeutic and adverse effects eg antiarrhymics. Lipid lowering medicines (Atorvastatin) antifungals, Itraconazole and Ketoconazole. Always refer to drug-drug interaction tables.
Didanosine (DDI)	• Should be taken at least 30 minutes before or 2 hours after a meal as food decreases absorption. • Didanosine formulations contain buffering agents or antacids. • When administering chewable tablets, at least two tablets should be administered to ensure adequate buffering capacity (i.e if the dose is 200mg, two 100mg tablets should be administered.	**Report immediately:** • 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 **Report at next visit:** • **Anxiety, headache, or difficulty sleeping**	There are many medicines that interact with didanosine; be especially careful to report any unusual symptom to your doctor when you start new medicines. Presence of food in the GI tract decreases the rate and extent of absorption of oral didanosine. Antacids increase the oral bioavailability of didanosine. Buffer in ddI may reduce absorption of quinolones or tetracyclines and doses should be separated by at least 2 hours There is an increased risk of pancreatitis if combined with stavudine Avoid concomitant use with medicines known to cause peripheral neuropathy or pancreatitis.
50mg tablet (off-white to light orange/yellow, round) 200mg tablet (off-white to light orange/yellow, round)	For patients >60 kg 250mg/ day in 1-2 divided doses For patients <60 kg 400mg /day in 1-2 divided doses		
8mg/1ml oral suspension	Children: (dose twice daily) <3 months 100mg/m^2/day in 1-2 divided doses >3 months to <13 years 240mg/m^2/day in 1-2 divided doses		

Description	Directions	Side Effects	Medicine Interactions
Tenofovir (TDF) 300mg tablets (White)	This medication can be taken with or without food. Take one tablet once daily Tenofovir is not approved for children under the age of 18 years	**Report Immediately** • Severe abdominal pain with nausea and vomiting • Unusual tiredness, weakness or muscle pain • Fast shallow breathing/ shortness of breath **Report at next visit** • **Abdominal discomfort** • **Diarrhoea**, **intestinal gas** • Dizziness, **headache** • **Rash**	TDF significantly ↑ ddI levels if administered together and predispose to ddI toxicity (peripheral neuropathy and pancreatitis). If used together, the dose of ddI may need to be reduced