2014

Clinical Management of HIV In Children and Adults

Malawi Integrated Guidelines for Providing HIV Services in:

- Antenatal Care
- Maternity Care
- Under 5 Clinics
- Family Planning Clinics
- HIV Exposed Child / Pre-ART Clinics
- ART Clinics

Applications and inquiries should be addressed to the Secretary for Health, P.O. Box 30377, Lilongwe 3, Malawi. We will be glad to provide the latest information on any changes made to the text, plans for new editions, and reprints and translations already available.

An electronic copy of this guideline is available on the website (www.hivunitmohmw.org) of the Department for HIV and AIDS of the Ministry of Health.

NOTE: The mention of certain manufacturers' products does not imply they are endorsed or recommended by the Ministry of Health in preference to others of a similar nature that are not mentioned.

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Foreword

This *2nd Edition* of the *Malawi Guidelines for Clinical Management of HIV in Children and Adults* will be implemented from April 2014. It replaces all previous editions of the Malawi Antiretroviral therapy (ART) and Prevention of Mother to Child Transmission (PMTCT) guidelines.

This document is written for medical doctors, clinical officers, medical assistants, nurses, midwives, health surveillance assistants (HSAs) and medical records clerks who are working in public and private sector health facilities in Malawi. It is designed to be a practical guide for implementation of integrated HIV Services.

The guidelines have been compiled by the joint Technical Working Groups for PMTCT, ART, HTC and Paediatric HIV under the leadership of the Department for HIV and AIDS of the Ministry of Health. The guidelines are based on ***Malawi's Revised Policy for PMTCT and ART*** which was endorsed by the Ministry of Health in June 2010 and which was prompted by the release of the 2010 Revision of the World Health Organisation (WHO) PMTCT and ART Guidelines. This 2nd Edition is an adaptation of the ***2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection***.

The protocols and policies presented in this document are adapted for health services in Malawi and follow a ***public health approach,*** aiming to provide the best possible services for the largest possible number of persons in need of these services.

This document defines the framework for Malawi's National HIV Programs. Considering public health benefits and risks, as well as funding and resource implications, **deviations from these guidelines are not supported by the Ministry of Health**.

The next (3rd) Edition of these guidelines is scheduled for release in **2015/2016**. Any updates or amendments to protocols and policies that are to be implemented between January 2014 and the release of the 3rd Edition of the guidelines will be communicated through an official MOH circular.

Acronyms and Abbreviations

3TC	Lamivudine
AAFB	Acid alcohol fast bacilli
ABC	Abacavir
ANC	Antenatal care
ARM	Artificial rupture of membranes
ART	Antiretroviral therapy
ARVs	Antiretroviral drugs
ATV/r	Atazanavir / ritonavir
AZT	Zidovudine
BCG	Bacille Calmette-Guérin
Benzyl pen	Benzyl penicillin
BF	Breastfeeding
BMI	Body mass index
CO	Clinical Officer
CPT	Cotrimoxazole preventive therapy
CSF	Cerebrospinal fluid
CTX	Cotrimoxazole
CXR	Chest X-ray
d4T	Stavudine
DBS	Dried blood spot
ddI	Didanosine
dl	decilitre
DNA-PCR	Deoxyribonucleic acid polymerase chain reaction
EFV	Efavirenz
EHP	Essential health package
EMB	Ethambutol
EPI	Extended Programme on Immunization
EPTB	Extra-pulmonary tuberculosis
FDC	Fixed dose combination
FP	Family planning
GIT	Gastrointestinal tract
H	Isoniazid
Hb	Haemoglobin
HCC	HIV Care Clinic
HIV	Human immunodeficiency virus
HTC	HIV testing and counselling
IEC	Information, Education and Communication
IM	Intramuscular
INH	Isoniazid
IPT	Isoniazid preventive therapy

Acronyms and Abbreviations

IRIS	Immune reconstitution inflammatory syndrome
ITN	Insecticide treated net
IV	Intravenous
KS	Kaposi sarcoma
LFT	Liver function test
LPV/r	Lopinavir/ ritonavir
M&E	Monitoring and evaluation
MA	Medical Assistant
MCH	Maternal and child health
MDR-TB	Multi-drug resistant tuberculosis
MOH	Ministry of Health
MUAC	Mid-upper arm circumference
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NS	Non-standard ART regimen
NVP	Nevirapine
OPD	Out-patient department
ORS	Oral rehydration solution
PCP	Pneumocycstis carinii (jiroveci) pneumonia
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PI	Protease inhibitor
PIFP	Provider initiated family planning
PITC	Provider initiated testing and counselling
PMTCT	Prevention of mother to child transmission
PO	Per os
PSHD	Presumed severe HIV disease
PTB	Pulmonary tuberculosis
PwP	Prevention with Positives
PZA	Pyrazinamide
R	Rifampicin
S	Streptomycin
SP	Sulphadoxine / pyrimethamine
STI	Sexually Transmitted Infections
TBT	Anti-tuberculosis treatment
TDF	Tenofovir disoproxil fumarate
TF	Therapeutic feeding
VIA	Visual inspection (of the cervix) with acetic acid
VL	Viral load
ZDV	Zidovudine

1 Introduction

In July 2013, the WHO released new ***Consolidated Guidelines for the Use of Antiretroviral Drugs for Treating and Prevention of HIV Infection***. The 2013 WHO guidelines advocate for the use of ARVs within a broad continuum of care and include guidance for implementation and M&E. This strategy of harmonization, integration and simplification follows the same principles that were introduced in the 1st Edition of the Malawi Guidelines in 2011.

2013 WHO recommendations include:

- Further expansion of ART eligibility: CD4 count threshold ≤500 cells/mm^3; universal eligibility for HIV infected pregnant and breastfeeding women, for children under 5 years, for patients co-infected with TB or severe chronic hepatitis B, etc. However, priority should be given to people with severe HIV disease and/or CD4≤350.
- Expanded use of ARVs for prevention of HIV infection (universal ART for pregnant / breastfeeding women and for discordant couples; pre- and post-exposure prophylaxis in certain situations)
- Use of simple, safer, once-daily, single-pill ARV regimens suitable for most patient groups.
- Use of viral load for monitoring ART success and diagnosing treatment failure.
- Expansion of HIV testing with linkage to prevention, care and treatment services.

Many of the 2013 WHO recommendations have already been part of the 2011 Malawi Clinical HIV Guidelines.

This ***2nd Edition of the Malawi Guidelines for Clinical Management of HIV in Children and Adults*** includes an adaptation of the 2013 WHO recommendations and several programmatic updates based on the experience of implementing the 2011 guidelines.

Between July 2011 and September 2013, Malawi's ART patient cohort has increased by 81,570 (**22%**) from 378,125 to **459,695**. With **over 500,000 patients in care** by September 2013 (including 46,419 patients in pre-ART), this 2nd Edition aims to balance the benefits of further acceleration of ART scale-up with the need for adequate quality of services and the increasing burden for the National Health System. Malawi's HIV Program remains firmly based on the public health approach, which seeks to provide the best possible services for the largest possible number of persons in need.

2 PMTCT strategy

Prong 1
- Primary prevention of HIV infection in parents

Prong 2
- Prevention of unintended pregnancies among HIV positive women

Prong 3
- Start of lifelong ART for HIV infected pregnant and breastfeeding women, regardless of CD4 count and/or clinical stage ('Option B+')
- Provision of nevirapine (NVP) prophylaxis for babies born to HIV infected mothers up to age 6 weeks
- Safe obstetric practices

Prong 4
- Provision of care, treatment and support for HIV-infected women, their children, and their families

Rationale for Lifelong ART for Pregnant and Breastfeeding Women (Option B+)

- **Increased access to ART:**
  - Because a positive HIV Antibody rapid test result in a pregnant woman is the only eligibility criterion for ART, antenatal clinics serve as an ideal entry point for ART.
  - High ANC attendance rates (97% in the 2010 Malawi DHS) and availability of HIV rapid testing at all ANC sites enables a high ART coverage of HIV infected women.
- **Reduction in post-partum mortality rates in HIV infected women:**
  - High mortality rates have been documented in post-partum women with high CD4 counts (>350 cells/mm³ in pregnancy) who were not on ART. [1,2]
- **Reduction of HIV transmission:** Maternal ART reduces viral load (VL) which:
  - Provides optimal protection during pregnancy, delivery and for subsequent pregnancies, especially given high fertility rates in Malawi.
  - Enables safe breastfeeding and avoids the need for extended infant HIV prophylaxis.
  - Reduces HIV transmission to sexual partners, especially for discordant couples.

[1] Hargrove JW, Humphrey JH. Mortality among HIV-positive postpartum women with high CD4 cell counts in Zimbabwe. AIDS 2010; 24(3):F11-4.

[2] Van Lettow M, Landes M, Bedell R, et al. Uptake and outcomes of a prevention-of mother-to-child transmission (PMTCT) program for 387 mother-child pairs in Zomba district, Malawi. XVIII International AIDS Conference 2010, Vienna

3 Summary of new policies and implementation plan

- The revised policies come into effect in **April 2014**.
- The policy changes will be communicated by circular to all District Health Offices and facilities.
- PMTCT/ART refresher trainings based on this 2nd Edition of the Clinical HIV Guidelines will commence in the first half of 2014.

Table 1: Summary of new and updated policies

	Definition of ART eligibility	*Page*
1.	Start all children under 5 years with confirmed HIV infection on ART, regardless of CD4 count and WHO clinical stage.	35
2.	Start all children (5 years +) and adults with confirmed HIV infection and CD4≤500 cells/mm^3 on ART.	35
3.	Repeat CD4 count every 3 months for pre-ART patients to decide when to start ART.	32
	Preventive services for HIV patients	
4.	For patients above 30kg, CPT can now be given as 1 tablet of cotrimoxazole **960mg** OD (24-hourly). Continue dosing based on weight under 30kg.	39
5.	Do not start Isoniazid Preventive Therapy (IPT) for HIV infected children under 5 years – all of these should be on ART.	41
6.	Give 1 tablet of pyridoxine 25mg **or 50mg** 24-hourly for all patients on IPT.	41
7.	Extend follow-up and repeat DNA-PCR before discharging children who started early on ART who have a negative rapid test and negative DNA-PCR at 12 or 24 month.	14
	Understanding ART regimens and formulations	
8.	Only **2** regimens are routinely used for ART initiation: Use **2P** for children under 25kg, **2A** for children/adults 25 – 35kg and **5A** for children/adults over 35kg.	43
9.	**1P** will no longer be available from mid 2014. Use the new alternative **0P (ABC/3TC + NVP)** for children who can't use **2P** or **4P**.	48
10.	Use the new alternative regimen **0P** or **0A (ABC/3TC + NVP)** for patients with contraindications or side-effects against TDF and AZT.	48
11.	TDF-containing regimens can be used for all patients above 35kg, regardless of age.	44
12.	Use EFV adult formulation (600mg) 24-hourly for patients weighing 35kg and above.	49
13.	Start TDF/3TC/EFV (**5A**) as early as possible in pregnancy – including in 1st trimester.	46
14.	**ATV/r** replaces **LPV/r** as the standard protease inhibitor in 2nd line regimens **7A** and **8A**. Use ATV/r for children and adults from 35kg, but continue using LPV/r for children under 35kg in regimen 9P. Use **double-dose LPV/r** instead of ATV/r if the patient is on rifampicin (TB treatment).	49

Prescribing and dispensing

15.	Dispense ARVs only in the original sealed container. Only exception: open containers to dispense the precise number of tablets needed for *Starter Packs*.	51
16.	Improvise a hardcover register to document ARVs dispensed to patients registered at another site (*Emergency Dispensing Register)*.	51

Starting ART / Continuing ART

17.	For confirmatory HIV testing: use the first and second rapid test in parallel (currently Determine + Uni-Gold).	55
18.	Children on paediatric 2nd line regimen (Regimen 9P) routinely change to standard adult 2nd line regimen (Regimen 7A) once they weigh over 35kg.	61
19.	95% dose adherence is now defined as missing **0-3 tablets** (assuming most patients are now on 5A with an average 8 week dispensing interval).	62

Post exposure prophylaxis (PEP)

20.	Use **TDF/3TC** as standard PEP regimen for patients weighing 35kg and above. Use **AZT/3TC** for patients under 35kg.	79

4 How to use these guidelines

These guidelines have been developed to standardise clinical management of HIV positive patients and of HIV exposed children using an integrated approach. They also incorporate relevant protocols from other national guidelines (TB, IPT, FP, STI and Reproductive Health).

Most clinical interventions for HIV patients are provided in different service delivery settings. The **standardised simplified protocols** for each intervention presented in this document will facilitate the job of the health workers and improve the standard of care for patients.

Key facts for providers and patients

- The most important information and key instructions are presented in a green box at the beginning of each section. It is appropriate and helpful to share this information with patients during Information, Education, and Communication (IEC) sessions, and in individual counselling.

Short bullet points and 'plain language' are used throughout this document to make the information as clear and as easily accessible as possible.

The standard package of clinical HIV interventions

Chapter 5 on page 10 shows **which** of the **clinical HIV interventions** should be provided in each of the regular service delivery points of the health system. It also defines the standard package of services and explains which interventions are appropriate for which patient groups and **when** to deliver them.

Protocols for how to deliver clinical HIV interventions

Chapter 6 on page 13 explains in detail **how** to deliver each of the HIV interventions. The protocols and directions are the same for *all* service delivery settings. This chapter also contains several checklists, tables and flow charts which can be laminated and used as job aids in the consultation room.

5 Integrating clinical HIV services

Clinical HIV services are an integral part of the essential health package (EHP). This section shows the **standard schedule** for the **minimum package of** clinical HIV interventions to be delivered within the established service points. **Table 2** on page **12** outlines the HIV interventions to be offered at various service delivery points. Refer to the page number for details on how to deliver the specific intervention.

5.1 Management of HIV exposed children

- Actively screen all children under 24 months for HIV exposure, particularly sick children seen at U1/U5 clinics, at OPD, NRU and on the paediatric ward (see Section 6.1 on page 14).
- Enrol all children born to and/or breastfeeding from HIV infected mothers as soon as possible.
- Do one DNA-PCR test as soon as possible from age 6 weeks. This will detect perinatal HIV infection and allow for ART initiation as early as possible.
- Visit schedule:
    - Monthly visits until age 6 months. Align with EPI vaccination visits.
    - 3 monthly visits from age 6 to at least 24 months. Most children are breastfed beyond 18 months and actual weaning can be difficult to confirm, so assume that all children are receiving breast milk until at least 18 months.
    - Schedule more frequent visits if the child is not doing well.
    - Discharge only after obtaining a negative HIV rapid test at least 6 weeks after stopping of breast feeding.

5.2 Pre-ART follow-up

- Enrol all children and adults who were found HIV positive but not yet eligible for ART in pre-ART.
- Visit schedule:
    - If IPT is started: review patient 1 month after starting IPT and then 2 months later (at month 3).
    - Give 3 monthly appointments thereafter
    - If IPT is not started: give 3 monthly appointments throughout.
    - Schedule more frequent visits if the patient is not doing well.
- Keep the patient in pre-ART until s/he starts ART.

5.3 The HIV Care Clinic (HCC) concept

- ***HCC*** is an integration in the same clinic setting for:
    - **HIV exposed children**
    - **pre-ART**
    - **ART**
- ***HCC*** is designed to facilitate clinical monitoring, preventive services and ART for family members affected by HIV.
- Family appointments can be given to encourage family members to attend together for HIV services.
- Family members can be seen in the consultation room at the same time or seen individually if there are sensitive issues to discuss.

Table 2: Integrated provision and scheduling of clinical HIV services

Interventions that are provided only under special circumstances are marked with brackets (●)

HIV Service	Page	Schedule	OPD	In-Patients	Fam Plan Clin	ANC	Maternity	Postnatal Clin.	U5 Clinic	HIV Care Clinic: Exp Child FUP	HIV Care Clinic: Pre-ART FUP	HIV Care Clinic: ART Clinic	HIV Care Clinic: TB Clinic
Diagnosing HIV infection and exposure	*13*	Ascertain current status at each visit	●	●	●	●	●	●	●	●	(●)	(●)	●
WHO clinical staging	*17*	When first found HIV+, then 3-monthly in pre-ART	●	●		●	●	●		●	●	●	●
Management of HIV-related diseases	*19*	When diagnosed	●	●		(●)	(●)			●	●	●	●
Standard monitoring of HIV patients	*23*	At every visit								●	●	●	●
CD4 monitoring for ART eligibility	*32*	Every 3 months									●		
Provider initiated family planning (PIFP)	*37*	At every scheduled visit									●	●	
Prevention with positives (PwP)	*38*	At every visit									●	●	
Cotrimoxazole preventive therapy (CPT)	*38*	At every scheduled visit				●	●			●	●	●	●
Isoniazid preventive therapy (IPT)	*40*	Dispense for 1, 2 and then 3 monthly thereafter									●		
Insecticide treated bed nets (ITN)	*42*	Dispense 1 ITN every 24 months				●			●	●	●	●	
Infant and child feeding counselling	*42*	At every visit	●			●	●		●	●	●	●	
Starting ART pregnant / BF women All others	*54*	As soon as possible Within 7 days of being found eligible for ART				●	●	●				●	●
Continuing ART	*60*	monthly for the 1st 6 months; 3 monthly thereafter				●		●				●	●
Management of labour and delivery	*75*	On admission					●						
Newborn and postnatal care	*75*	After delivery					●	●					
Initiating integrated mother/infant follow-up	*75*	At first opportunity when mother known HIV+					●	●	●				
Infant NVP prophylaxis	*76*	At first opportunity when mother known HIV+				●	●	●	●	(●)			
Post exposure prophylaxis (PEP)	*77*	As soon as possible after risk exposure	●				●						

6 Interventions

6.1 Diagnosing HIV infection and exposure

Key facts for providers and patients

- **Main** HTC Program goals:
    - **Identify as many** HIV **infected** people **as possible.**
    - Identify them **as early as possible** after getting infected.
    - **Enrol** them **into** pre-ART or ART **care** as **soon** as possible.
- Additional goal of HTC is to link HIV negatives to appropriate prevention services (VMMC, etc.) and to encourage retesting based on the client risk assessment.
- **PITC:** Ascertain HIV status for all patients attending health services (ANC, maternity, TB, STI, FP, U1 / U5, adult and paediatric wards).
- HTC is offered in various forms: client-initiated, community based, etc. Models of delivering HTC include: stand-alone, integrated, outreach, mobile, home-based, door-to-door.
- Remind patients during pre-test education (group or individual) that they can decline HIV-testing without any 'fear of punishment' by the health worker.
- Encourage patients to attend HTC with their sexual partner. Ensure that all children (including adolescents) of HIV infected parents are tested.
- All patients need a confirmatory HIV test to rule out any possibility of mix-up of test results or fraudulent access to ART (also see **Section 6.8.2** on **page 55**):
    - Either at enrolment into pre-ART follow-up,
    - Or before starting ART if the test to confirm was not done in pre-ART.
    - Children under 12 months starting ART with a positive DNA-PCR do not need another confirmatory test before starting ART, but all need a confirmatory rapid antibody test at age 12 and 24 months (see below).
- Enrol all children and adults with confirmed HIV infection for ART or for HIV care to ensure they can start ART as soon as they become eligible.
- Enrol all children born to and/or breastfeeding from HIV infected mothers (*'HIV exposed children'*) in the HIV Care Clinic and follow to at least age 24 months or longer if breastfeeding continues.
- From age 12 months, over 95% of children with a positive rapid test are confirmed HIV infected. Therefore, rapid testing should be used to determine universal eligibility for ART for children aged between 1 and 5 years.
- Examine all children under 12 months of age with confirmed HIV antibodies for clinical conditions that constitute *Presumed Severe HIV Disease (PSHD, see* **Table 4** *on* **page 18***)*. All of these need to start ART without delay.

Key facts for providers and patients

- All children in exposed child follow-up need (parallel) confirmatory rapid antibody testing at age 12 and 24 months to confirm / rule out HIV infection.
- Children who started ART under 24 months need a confirmatory antibody test at 24 months to rule out wrong initial diagnosis of HIV infection (wrong interpretation of PSHD symptoms; lab or documentation errors).
- **However:** when tested later, HIV infected children who start ART early can have:
    - A false negative rapid test because of very low antibody levels.
    - A false negative DNA-PCR while on ART.
- **Therefore:** Use DNA-PCR as 'tie-breaker' for a child who was **started on ART below age 24 month** and whose confirmatory **rapid antibody test** at age 24 months is **negative**.
    - Stop ART only if **DNA-PCR** comes back **negative**, too.
    - **Review every 4 weeks** and **repeat DNA-PCR at 8 weeks** after stopping ART.
    - Discharge only if repeat DNA-PCR is negative.

Routine ascertainment of HIV infection status for children and adults

- Ask every client at every visit about the most recent HIV test and review their health passport for previous HIV test results.
- Offer HIV testing to all patients attending health facilities for any reason, if:
    - never tested
    - tested negative more than 3 months ago (follow HTC risk assessment guidelines)
    - claims to have been tested any time in the past, but without documentation (being on ART counts as documented evidence)
- Routinely document HIV test results on page 6 of the patient's health passport unless the patient declines. For in-patients, also document test result in in-patient notes.

Routine ascertainment of HIV exposure status for children under 24 months

- Routinely ascertain the mother's HIV status for all children under 24 months of age seen at the U1 / U5 clinic, regardless of whether the child is healthy or sick:
    - Review mother's health passport (page 6) for the latest HIV test result
- Initiate a new HIV rapid test:
    - For the mother:
        - If she was not tested at least once during pregnancy or delivery
    - For the child:
        - If the mother is not available / has died
        - If the child is sick, even if the mother was tested negative during pregnancy or delivery. This is to rule out new HIV infection in the child.

- **Figure 1** on page 15 shows the conditions for testing of mother and/or child and the actions to be taken.

Figure 1: Flowchart for routine ascertainment of HIV exposure / infection in children under 24 months

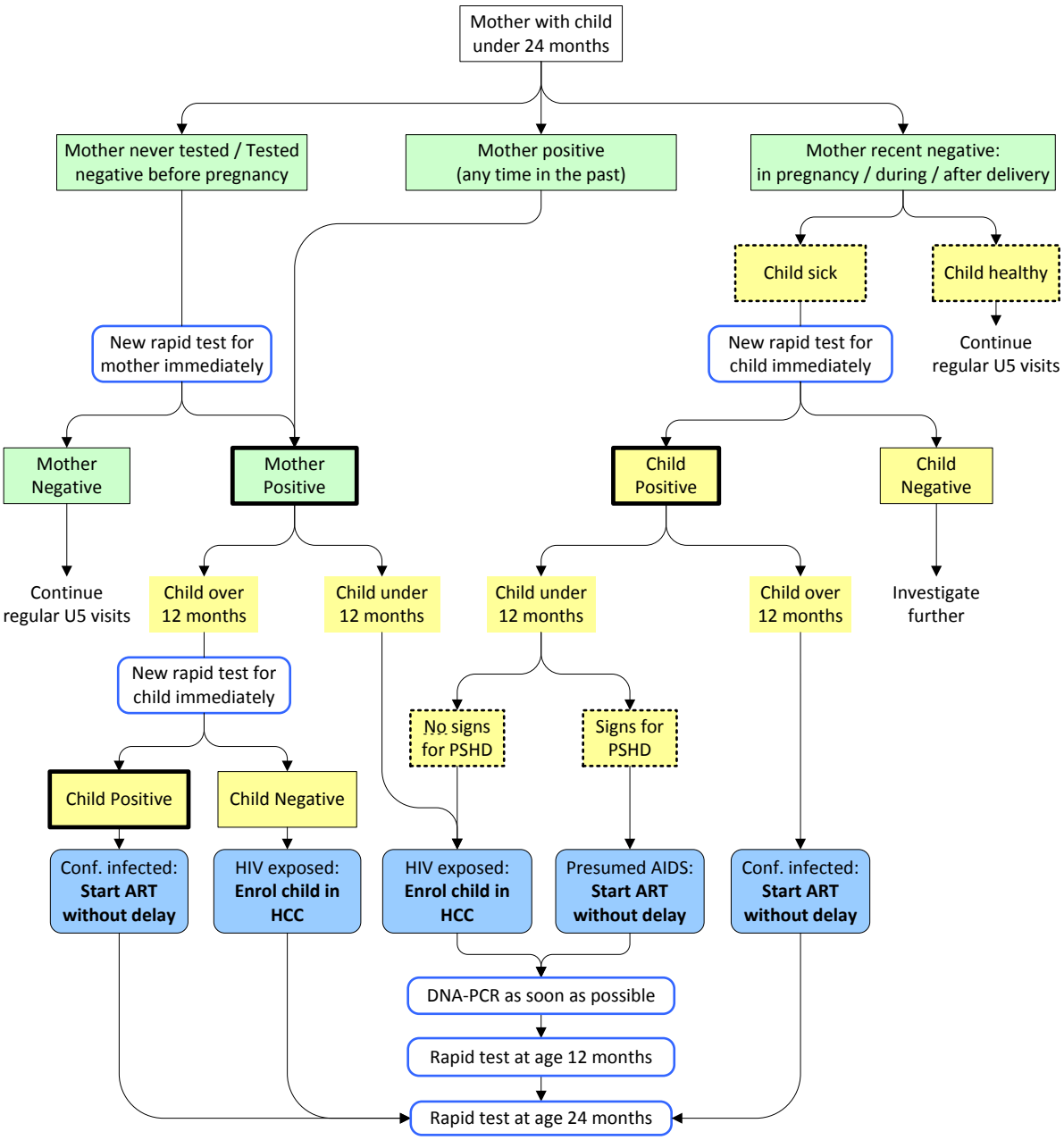


Table 3 on page 16 shows the routine testing schedule for children under 2 years of age, the selection of the type of HIV test (DNA-PCR or rapid antibody test) depending on the child's age and the correct interpretation and action depending on the test result.

Table 3: Schedule of HIV testing in children in HCC or ART follow-up: Choice of type of test, interpretation of results and follow-up management

Age (months)	Test	Schedule	Result	Interpretation	Action
Under 12	DNA-PCR (if available)	First opportunity from age 6 weeks	Negative	Not infected, but at risk of infection if breastfeeding	Continue HCC. Do rapid test at age 12 months.
			Positive	HIV infected	Start ART. Confirm with rapid test at 12 and 24 months.
	Rapid antibody	Immediately if signs of PSHD identified ***OR*** If mother's HIV status cannot be ascertained	Negative	Not infected, but at risk of infection if breastfeeding	Treat condition. Continue HCC. Repeat rapid test at age 12 and 24 months.
			Positive	Possibly HIV infected if no PSHD symptoms	Enrol in HCC. Do DNA-PCR at first opportunity.
				Likely AIDS if symptoms for PSHD	Start ART. Confirm with rapid test at 12 and 24 months.
12 to under 24	Rapid antibody	From age 12 months ***OR*** If mother's HIV status cannot be ascertained	Negative	Not infected, but at risk of infection if breastfeeding	Continue HCC, repeat rapid test at age 24 m. If on ART don't stop unless confirmed by negative DNA-PCR.
			Positive	HIV Infected	Start ART. Confirm with rapid test at 24 months.
24 and above	Rapid antibody	From age 24 months but ensure that BF stopped at least 6wks ago	Negative	Not infected	Discharge child from HCC.
			Positive	HIV Infected	Start ART for all U5 (any clinical stage / CD4). If already on ART, continue ART. If 5 years+, continue pre –ART in HCC until ART eligible.

6.2 WHO clinical staging

Key facts for providers and patients

- Untreated HIV infection leads to a gradual destruction of the immune system.
- Different HIV-related diseases appear at different levels of immune suppression.
- HIV-related diseases are grouped into 4 WHO clinical stages that correlate with disease progression and prognosis of survival:
    - Stage 1: Asymptomatic
    - Stage 2: Mild
    - Stage 3: Advanced
    - Stage 4: Severe
- Many patients have several HIV-related diseases from different stages.
    - List all conditions on the *ART Patient Card.*
    - The most severe condition determines the WHO clinical stage.
- Most WHO stage defining conditions apply to all ages, but some are only for children under 15 years and others are only for adults.
- Patients in WHO stage 3 or 4 are always eligible to start ART. Other conditions apply to patients in stage 1 or 2 (see Section 6.4.5 on Page 35).
- WHO clinical staging requires confirmed HIV infection.
- An infant aged under 12 months with only a positive HIV rapid antibody test can NOT be given a WHO clinical stage because HIV antibodies in infants do not confirm HIV infection.
- However, an infant with HIV antibodies and specific clinical conditions is very likely to have AIDS and needs to start ART without delay (see definition of *Presumed Severe HIV Disease* below).
- WHO clinical staging is mandatory for all HIV patients, including those who are universally eligible for ART (confirmed infected children under 5 years, pregnant or breastfeeding women) or those with a CD4 count result.
- Keep blank (pre-) *ART Patient Cards* at OPD. Complete staging for every new HIV patient.

Table 4: WHO clinical staging for children and adults with confirmed HIV infection and definition of presumed severe HIV disease for infants

	Adults and Children	Adults only (15 years or older)	Children only (below 15 years)
1	• Asymptomatic • Persistent generalized lymphadenopathy		
2	• Respiratory tract infections, recurrent (sinusitis, tonsillitis, otitis media, pharyngitis) • Herpes zoster • Angular cheilitis • Oral ulcerations, recurrent • Papular pruritic eruptions / Fungal nail infections	• Moderate weight loss <10%, unexplained • Seborrhoeic dermatitis	• Hepatosplenomegaly, persistent unexplained • Lineal gingival erythema • Wart virus infection, extensive • Molluscum contagiosum, extensive • Parotid enlargement, persistent unexplained
3	• Fever, persistent unexplained, intermittent or constant, >1 month • Oral hairy leukoplakia • Pulmonary tuberculosis (current) • Tuberculosis (PTB or EPTB) within the last 2 years • Anaemia, unexplained < 8 g/dl • Neutropaenia, unexplained < 500 /mm^3 • Thrombocytopaenia, chronic < 50,000 /mm^3	• Severe weight loss >10% and/or BMI <18.5kg/m^2, unexplained • Diarrhoea, chronic (>1 month) unexplained • Oral candidiasis • Severe bacterial infections (pneumonia, empyema, pyomyositis, bone/joint, meningitis, bacteraemia) • Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis • Hepatitis B or C infection	• Moderate unexplained wasting / malnutrition not responding to treatment (weight-for-height/ -age 70-79% or MUAC 11-12cm) • Diarrhoea, persistent unexplained (14 days or more) • Oral candidiasis (from age 2 months) • Acute necrotizing ulcerative gingivitis or periodontitis • Lymph node tuberculosis • Bacterial pneumonia, severe recurrent • Symptomatic lymphoid interstitial pneumonitis • Chronic HIV-associated lung disease including brochiectasis
4	• Pneumocystis pneumonia • Candidiasis of oesophagus, trachea, bronchi or lungs • Extrapulmonary tuberculosis • Kaposi's sarcoma • HIV encephalopathy • Cryptococcal meningitis or other Extrapulmonary cryptococcosis • Disseminated non-tuberculous mycobacterial infection • Cryptosporidiosis, chronic with diarrhoea • Isosporiasis >1 month • Disseminated mycosis (coccidiomycosis or histoplasmosis) • Symptomatic HIV-associated nephropathy or cardiomyopathy • Progressive multifocal leukoencephalopathy • Cerebral or B-cell non-Hodgkin lymphoma	• HIV wasting syndrome (severe weight loss + persistent fever or severe weight loss + chronic diarrhoea) • Bacterial pneumonia, recurrent severe • Chronic herpes simplex infection (orolabial, genital / anorectal >1 month or visceral at any site) • Cytomegalovirus infection (retinitis or infection of other organs) • Toxoplasmosis of the brain • Non-typhoidal Salmonella bacteraemia, recurrent • Invasive cancer of cervix • Leishmaniasis, atypical disseminated	• Severe unexplained wasting / malnutrition not responding to treatment (weight-for-height/ -age <70% or MUAC <11cm or oedema) • Bacterial infections, severe recurrent (empyema, pyomyositis, bone/ joint, meningitis, but excluding pneumonia) • Chronic herpes simplex infection (orolabial or cutaneous >1 month or visceral at any site) • Cytomegalovirus infection: retinitis or other organ (from age 1 month) • Toxoplasmosis of the brain (from age 1 month) • Recto-vaginal fistula, HIV-associated **Presumed Severe HIV Disease in infants <12 months *(PSHD)*** Positive antibody (rapid) test *PLUS* one or several of the highlighted clinical conditions in the WHO staging list *OR* combination of at least 2 of the following: • Oral thrush • Severe sepsis • Severe pneumonia

6.3 Management of HIV-related diseases

Use the following list to identify and manage the main HIV-related diseases seen in Malawi. A more detailed discussion is available in the *Management of HIV Associated Diseases* guidelines.

Oral candidiasis

Clinical Signs

Multiple whitish or red patches anywhere inside mouth

Primary Management

Nystatin oral suspension

Treat for 7-14 days; keep in mouth as long as possible; apply to mother's nipples if breastfeeding

Adult: 4ml 6-hourly
Child: 1ml 6-hourly

Secondary Management

3 Alternative treatment options if severe or no response to nystatin:

Fluconazole tablets

Treat for 14 days
Adult: 100 mg 24-hourly
Child: 6mg/kg on day 1 then 3mg/kg daily

Ketoconazole tablets

Do not give with NVP
Adult: 200mg 24-hourly for 14 days
Child: 5mg/kg 24-hourly for 14 days

Miconazole gum patch or gel

Use for children > 4 months and adults
Treat with 1 patch 24-hourly for 14 days

Oesophageal candidiasis

Clinical signs

Retrosternal pain on swallowing; infants and children refusing to eat; +/- oral thrush

Primary management

Fluconazole tablets

Treat for 14 days
Adult: 200mg 24-hourly for 14 days
Child: 12mg/kg day one then 6mg/kg

Chronic diarrhoea

Clinical signs

More than 3 loose non-bloody motions per 24 hours for more than 2 weeks

Diagnosis / investigations

Based on response to stepwise empirical treatment:

Step 1 treats: isospora, cyclospora, bacterial

Step 2 treats: giardia, clostridium, amoeba, microsporidium

Step 3 treats: microsporidium, helminths

Primary management

ORS (Thanzi)

drink 5ml/kg 4-hourly and after every episode of diarrhoea.
drink 5ml doses every 5 min if vomiting occurs

IV Fluids

if severe de-hydration

Loperamide tablets

Adult: 2mg after every loose stool (max 12mg in 24 hours)
Child: Do NOT use for children

Step 1: Cotrimoxazole tablets

Adult: 960mg 8-hourly for 7 days
Child: 80 mg/kg 8-hourly for 7 days

Zinc tablets

Give for 10 days
Child 0-6mths: 10 mg 24-hourly
Child 6mths – 5 yrs: 20 mg 24-hourly

Secondary management

Continue with step 2 and 3 if no improvement

Step 2: Metronidazole tablets

Adult: 800mg 8-hourly for 7 days
Child: 15mg/kg 8-hourly for 7 days

Step 3: Albendazole tablets

Adult: 400mg 12-hourly for 14 days

TB

Clinical signs

Very variable: Persistent fever / drenching night sweats; weight loss; failure to thrive; cough; anaemia <8g/dl; enlarged nodes; meningitis signs

Diagnosis / investigations

TB case / TB suspect in household; 2x sputum for AAFB; Gene-Xpert; CXR; fine needle aspiration nodes (for microscopy); pleural tap

for biochemistry: straw coloured effusion?; lumbar puncture: CSF for biochemistry, microscopy

Primary management

1st Line TB treatment

Consider presumptive TB treatment in HIV patients with suspected TB

New smear-positive or negative PTB:

Intensive phase: 2 RHZE
Continuation phase: 4 RH

TB Meningitis:

Intensive phase: 2 SRHZ
Continuation phase: 7 RH

Secondary management

Relapse/ return after default/ treatment failure/ recurrent TB

Admit for Intensive phase: 2 SHRZE (in hospital)
1 RHZE
Continuation phase: 5 RHE

Chronic/MDR-TB

Specialised treatment

Kaposi sarcoma

Clinical signs

Single or multiple purple patches or nodes, mainly mouth, skin, conjunctiva, lung, GI tract; +/- enlarged nodes; +/- Oedema

Diagnosis / investigations

Usually clear picture; children often present with lymphadenopathy only; consider KS even without skin or oral lesions if no response to EPTB therapy within 4 weeks

Primary management

For all patients:

Analgesia
Symptomatic treatment
ART

For KS stage T0 (skin KS without oedema):

Delayed chemotherapy if no improvement after 3 months on ART

For KS stage T1 (KS in mouth or internal organs, nodular skin KS, skin KS with oedema):

Immediate chemotherapy

Contraindications for chemotherapy: Severe PN; Hb<10g/dl; platelet count <50/mm^3; jaundice; pregnancy

1st Line: Vincristine

Each cycle consists of 6 doses; ensure strictly IV injection as infiltration causes burns; document therapy and response in health passport; examine for recurrence at every visit

Adult: 2mg vincristine IV
Child: 0.05 mg/kg vincristine IV (max 2mg)

Review after every cycle:

Severe neuropathy / constipation: stop
Lesions cleared: stop
Good response but residual lesions: continue next cycle
Poor response: Start 2nd line chemotherapy

1) Initial cycle:
1 dose every 7 days for 6 weeks
2) Second cycle:
1 dose every 14 days for 12 weeks
3) Final cycle:
1 dose every 28 days for 6 months

Secondary management

2nd Line: vincristine + bleomycin

Cumulative max. lifetime dose for bleomycin is 400 units for adults and 17 doses for children; stop bleomycin immediately if any sign for lung fibrosis (incl. cough, shortness of breath) are seen; give one combined dose every 14 days until cumulative max. dose is reached or until response is achieved; refer for 3rd line chemotherapy (doxorubicin) if poor response

Adult: 15 units bleomycin IM / IV / SC **plus** 2mg vincristine IV
Child: 0.5 mg/kg bleomycin IM **plus** 0.05 mg/kg vincristine IV (max 2mg)

Cervical cancer

Clinical signs

No early symptoms therefore active 12-monthly screening needed; abnormal vaginal discharge

Diagnosis / investigations

Acetic acid visualisation (VIA)

Use good light source
Expose cervix with cusco speculum, visualise cervix after washing for 2 minutes with a large cotton swab immersed in 4% acetic acid

Primary management

Surgical, depending on stage

Shingles (Herpes zoster)

Clinical signs

Grouped blisters in one patch; intense pain / burning; +/- fever; +/- body pains; lesions do not usually cross the body's mid-line

Primary management

Analgesic Ladder
Rigorous pain control

Acyclovir tablets
Must be started before blisters burst
Adult: 800mg 5 times per day for 7 days
Child: 20 mg/kg 8-hourly for 7 days

If face affected:
Refer to Eye specialist
Monitor for secondary bacterial infection

Seborrhoeic dermatitis

Clinical signs

Greasy, scaly rash in axilla, groin, scalp, neck, face

Primary management

Clotrimazole or Miconazole cream / ointment

Secondary management

Ketoconazole tablets
200 mg twice daily for 7 days

Tinea corporis / cruris / pedis

Clinical signs

Round reddened plaques with scaly edge in multiple sites, poss. widespread

Primary management

Whitfield's ointment
Clotrimazole cream or Gentian-Violet paint
Apply twice daily for 3-4 weeks

Secondary management

Griseofulvin tablets
Adult: 500 mg 12-hourly for 4-6 weeks
Child: 20mg/kg per day for 4-6 weeks

Pruritic papular eruptions

Clinical signs

Severe itching, evenly distributed normal- or dark-coloured papules on trunk, arms or legs, often scratch-lesions

Primary management

Calamine Lotion
Antihistamines

Secondary management

Corticosteroid cream or tablets
Metronidazole tablets
250mg 12-hourly for 7-14 days

Pneumocystis carinii (jiroveci) pneumonia (PCP)

Clinical signs

- Extreme shortness of breath; dry cough; +/- fever
- Severe pneumonia in infants <12 months

Diagnosis / investigations

O_2 saturation: hypoxia

CXR: Diffuse interstitial or hyperinflation; bats wing shadow

Treat empirically for PCP any HIV exposed or confirmed infected infant presenting with severe pneumonia

Primary management

Admit
Oxygen
Cotrimoxazole tablets
Adult: 4 x 480mg 8-hourly for 21 days
Child: 80mg/kg 8-hourly for 21 days
Lifelong maintenance (CPT)
IV Cotrimoxazole if unable to swallow and NGT impossible to place

Prednisolone tablets:
Give 15-30 minutes before cotrimoxazole
Adult: 8 tablets 12-hourly for 5 days
8 tablet 24-hourly for 5 days
4 tablets 24-hourly for 11 days
Child: 2mg/kg 24-hourly for 7 days
1mg/kg 24-hourly for 7 days
0.5mg/kg 24-hourly for 7 days

Secondary management

Clindamycin
300mg 6-hourly for 3 weeks
plus
Primaquine
30mg 24-hourly for 3 weeks

Cryptococcal meningitis

Clinical signs

Slow onset severe headache; confusion; convulsions; +/- fever; +/- neck stiffness

Diagnosis / investigations

CSF India ink stain; cryptococcal antigen in serum or CSF

Primary management

Admit

Daily therapeutic spinal tap (up to 20ml per puncture)

Fluconazole tablets

Adult: 1200mg 24-hourly for 14 days
400mg 24-hourly for 42 days
200mg 24-hourly for life

Child: 12mg/kg 24-hourly for 2 weeks
6mg/kg 24-hourly for life

Secondary management

Amphotericin B

Specialised sites only

Adult and Child: 0.7-1mg/kg IV over 6 hours 24-hourly for 14 days

Follow acute treatment with Fluconazole for life

Fluconazole tablets

Adult: 400mg 24-hourly for 42 days
200mg 24-hourly for life

Child: 6mg/kg 24-hourly for life

Pneumonia

Clinical signs

Productive cough; chest pain; fever; tachypnoea / dyspnoea

Diagnosis / investigations

Infiltrations on CXR

Primary management

Child:

Mild: Tachypnoea but no dyspnoea

(See IMCI guidelines)

Adult:

Mild to moderate presentation:

Amoxicillin tablets

500mg 8-hourly for 5 days

Doxycycline or Erythromycin if no response

Secondary management

Severe presentation:

Chloramphenicol + Benzyl Penicillin
Add Gentamycin if no response

Sepsis

Clinical signs

Severe illness; fever (can be absent, especially in children); fast heart rate; fast breathing

Diagnosis / investigations

+/- Malaria parasites; do not rule out sepsis if malaria parasites are seen; blood culture for culture and sensitivity (if available)

Primary management

Health Centre Level:

Immediate presumptive treatment
Referral to hospital

Child:

Benzyl Pen 50,000 IU/kg IV or IM stat +
Gentamycin 7.5mg/kg slow IV / IM stat +
Quinine 10mg/kg IM stat

Adult:

Chloramphenicol 1g IV or IM stat +
Gentamycin 240mg slow IV or IM stat +
Quinine 1200mg IV in 5% dextrose over 4 hours

Secondary management

Hospital management:

Neonate:

Benzyl Pen 50,000 IU/kg IV 8-hourly +
Gentamycin 7.5 mg/kg IV 24-hourly

Child:

Gentamicin 7.5.mg/kg 24-hourly + **Benzyl Pen** 50,000 IU/kg IV 8-hourly

OR

Ceftriaxone 50-100 mg/kg IV 24-hourly

OR (if pneumococcal sepsis suspected)

Chloramphenicol 25 mg/kg IV 8-hourly (max. 1g per dose)

When stable continue to complete 10 days:
Amoxicillin 40 mg/kg 12-hourly +
Ciprofloxacin 15 mg/kg 8-hourly

Adult:

Ceftriaxone 2g IV 24-hourly

When stable continue to complete 10 days:
Ciprofloxacin 500 mg tablets 12-hourly +
Amoxicillin 500 mg tablets 8-hourly

6.4 Standard monitoring of HIV patients

Key facts for providers and patients

- All patients in HIV Care (exposed infants, pre-ART, ART) need the same standard clinical assessment at every visit.
- Check actively – do not rely on patients to report problems unprompted.
- The Standard Clinical Monitoring Checklist (Table 6 on Page 28) helps to find:
  - HIV-related diseases
  - WHO clinical stage
  - ART treatment failure
  - Drug side effects (ART, TB, CPT, IPT, etc.)
- It can be difficult to distinguish HIV-related diseases from drug side effects. An ambiguous symptom is likely a side-effect if it started or worsened after the start of medication / improves after stopping.

6.4.1 Monitoring of nutritional status

- One of the simplest methods to detect HIV disease progression / ART treatment failure.
- Record length / height to the nearest cm at every visit (children) / once at enrolment (adults).
- Record weight in kg to the nearest 100g at every visit (children and adults).
- Use appropriate nutrition indicator for children and adults.

Children 0-14 years

- Classify wasting / malnutrition status according to weight-for-height form **Figure 2** on page 25.
- Watch out for flattening of the growth curve (weight for age).
- Weight-for-height less than 80% (below green curve in **Figure 2**) and/or MUAC less than 12cm:
  - Investigate for TB
  - Refer / admit for Therapeutic Feeding
  - Start ART if no response to TF after 3 weeks (WHO stage 3)

Non-pregnant adults 15 years and above

- Classify nutrition status according to BMI from **Figure 3** on page 26
- $$BMI = \frac{weight(kg)}{height(m) \times height(m)}$$

- Watch out for any weight loss over time.
    - Review documented previous weight whenever available as reported weight loss can be unreliable.
    - Investigate any weight loss for TB.
- Weight loss >10% and/or BMI under 18.5 (below green curve in **Figure 3**).
    - Investigate for TB.
    - Start ART if weight loss unexplained (WHO stage 3).
- BMI under 17 (below yellow curve in **Figure 3**).
    - Start TF for 'moderate malnutrition'.
- BMI under 16 (below red curve in **Figure 3**)
    - Start TF for 'severe malnutrition'.

Pregnant and lactating women

- Use MUAC instead of BMI.
- Universally eligible for ART if confirmed HIV infection.
- MUAC less than 22cm: start TF for 'moderate malnutrition'.
- MUAC less than 19cm: start TF for 'severe malnutrition'.

Figure 2: Weight for Height classification of wasting / malnutrition for children 0 - 14 years

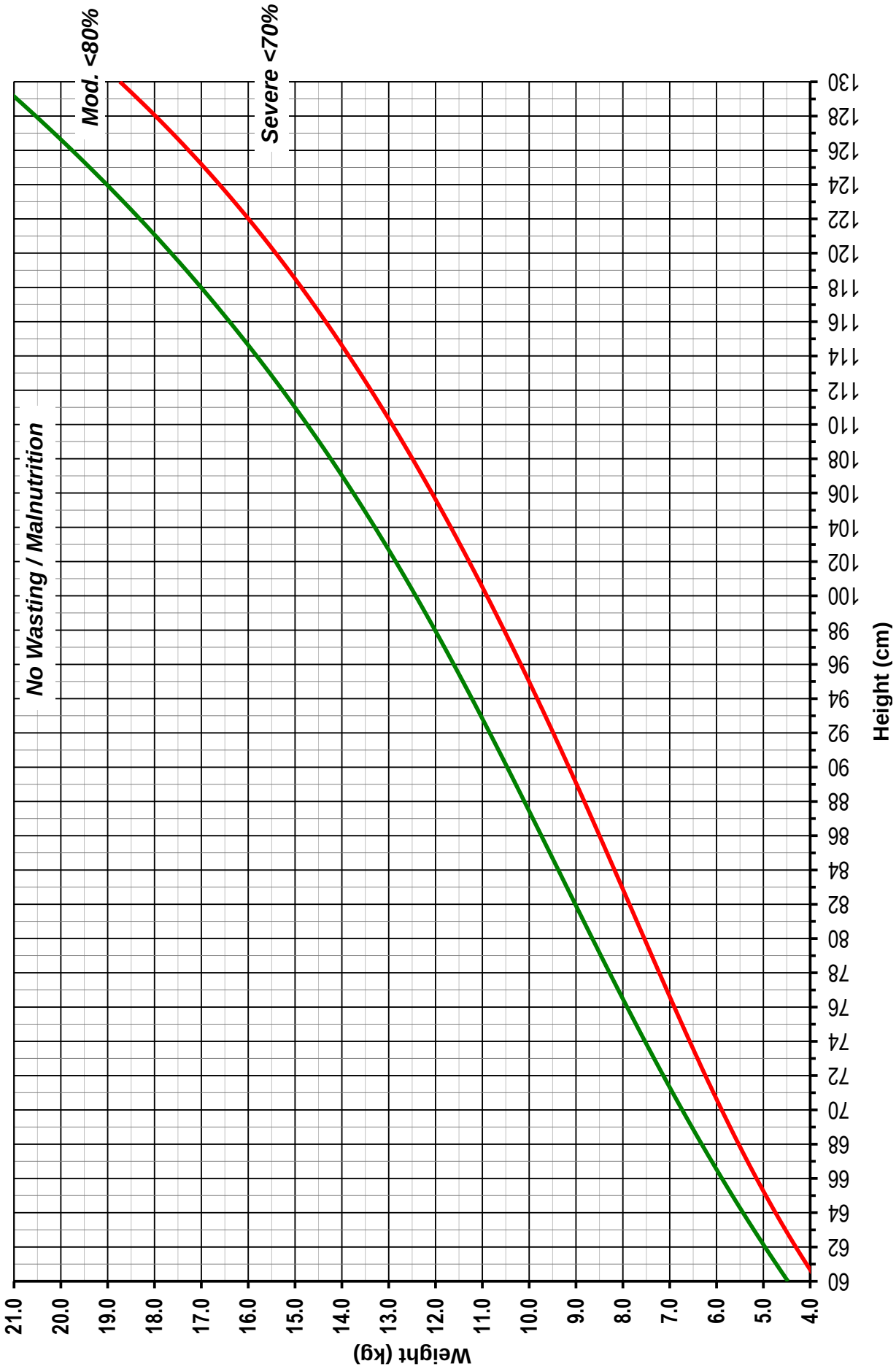
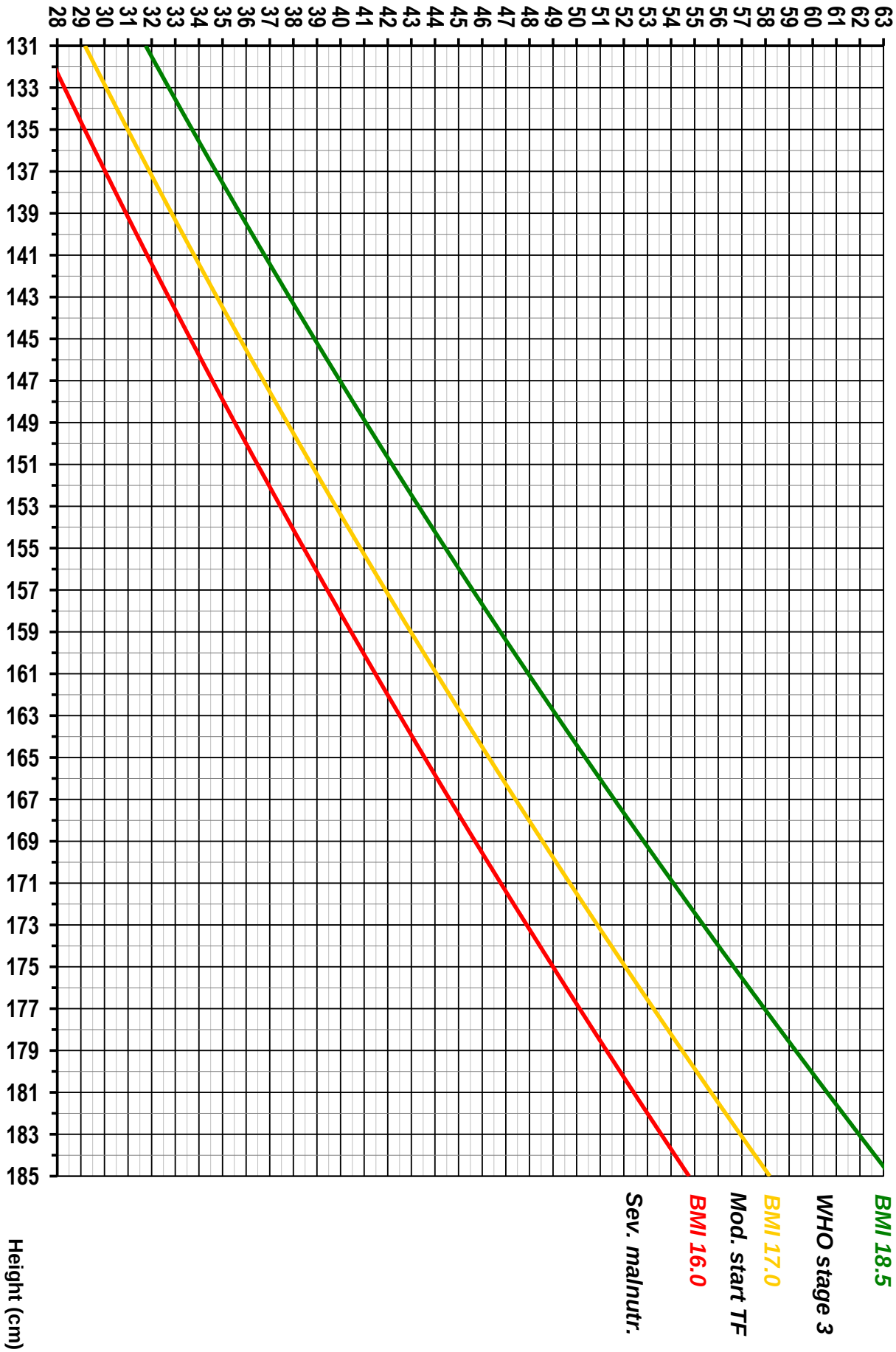


Figure 3: BMI classification of malnutrition for non-pregnant adults 15 years +



6.4.2 Standard clinical monitoring checklist

- Use the summary clinical monitoring checklist to actively screen every HIV patient (exposed child, pre-ART and ART) for clinical symptoms at every visit.
- Refer to **Table 6** on page 28 for more detailed screening instructions and interpretation of signs and symptoms for further management.

Table 5: Checklist for clinical monitoring of HIV exp. children and (pre-) ART patients

Ask for / Examine			
Appearance:	**Body shape change**	**N**	**Y**
	Malnutrition	**N**	**Y**
	Swollen glands	**N**	**Y**
Headache / confusion / dizziness		**N**	**Y**
Yellow eyes		**N**	**Y**
Mouth sores		**N**	**Y**
Cough		**N**	**Y**
Shortness of breath		**N**	**Y**
Fever / night sweats		**N**	**Y**
Vomiting / abdominal pain		**N**	**Y**
Diarrhoea		**N**	**Y**
Leg pain / numbness / weakness		**N**	**Y**
Rash on arms, legs or trunk		**N**	**Y**

Table 6: Detailed clinical monitoring list for HIV exp. and (pre-) ART patients

Ask / Examine	Look for	Assess	Disease (most common)	Drug Side-Effects
Appearance	• Weight loss • Failure to thrive	• Weight loss: trend from patient card / health passport • BMI (adults) • Weight for height, weight for age, MUAC (children)	1) TB 2) Chronic diarrhoea 3) Malnutrition 4) ART treatment failure 5) Malignancy (lymphoma)	**Lactic acidosis due to ART** 1) d4T 2) ddI 3) AZT
	• Body Shape	• Slimming of cheeks • Slimming of forearms, buttocks and legs +/- protruding veins • Fattening of chest / belly / buttocks • Buffalo hump • Breast enlargement (gynaecomastia)		**ART induced lipodystrophy** 1) d4T 2) AZT 3) 3TC **Gynaecomastia** 1) EFV
	Swollen glands	• Cervical / axillary lymphadenopathy	1) PGL 2) EPTB 3) Lymphoma 4) KS (+/- skin lesions) 5) BCG adenitis	
Headache, confusion, dizziness	• Neck stiffness • Nausea / vomiting		1) Meningitis (bacterial/ TB, cryptococcal) 2) Toxoplasmosis HIV dementia	1) EFV

Ask / Examine	Look for	Assess	Disease (most common)	Drug Side-Effects
Yellow eyes	• Yellow sclera	• Jaundice	1) Viral hepatitis 2) Alcoholic hepatitis 3) Malaria 4) Cancer 5) Hep B-IRIS	**Drug hepatitis** 1) NVP 2) EFV 3) PZA 4) Rifampicin 5) INH 6) Fluconazole **Hyperbilirubinaemia** 7) ATV/r
Mouth sores	• Mucosa lesions	• Whitish patches • Painful red patches	1) Oral thrush 2) Oral hairy leukoplakia	
		• Purple lesions	1) KS	
		• Ulcerations	1) Acute ulcerative stomatitis/ gingivitis/ periodontitis 2) Herpes simplex 3) Angular cheilitis 4) Aphthous ulcers	**Hypersensitivity** 1) ABC 2) NVP 3) Cotrimoxazole
Cough	• Duration • Productiveness	• Less than 2 weeks • Fever • +/- Productive	1) Pneumonia (bacterial) 2) TB suspect: circle on card 3) PCP	**Hypersensitivity** 1) ABC
		• More than 2 weeks • Fever / night sweats	1) TB suspect: circle on card 2) KS	

Ask / Examine	Look for	Assess	Disease (most common)	Drug Side-Effects
Shortness of breath	• Observe breathing • Pleural effusion	• Pleural effusion	1) EPTB 2) Bacterial pneumonia 3) Heart failure 4) KS	
		• No pleural effusion	1) Bacterial pneumonia 2) PCP 3) TB +/- pneumo-thorax	**Lactic acidosis due to ART** 1) d4T 2) ddI 3) AZT
	• Conjunctiva	• Pale conjunctiva	1) HIV anaemia 2) Chronic severe malaria 3) Nutritional anaemia	**Anaemia** 1) AZT
Fever / night sweats	• History / Duration • Current temperature	• Less than 1 month	1) URTI / viral 2) Sepsis 3) Malaria 4) TB	**Hypersensitivity** 1) ABC 2) NVP 3) Cotrimoxazole
		• More than 1 month	1) TB 2) Malignancies (lymphomas)	
Vomiting / abdominal pain	• Hydration status • Palpate abdomen	• Dehydration • Tenderness	1) TB 2) NTS sepsis 3) Acute Gastro-enteritis 4) Malaria 5) Abdominal TB 6) Ulcer disease 7) CNS disease 8) Hepatoma	**Drug-induced pancreatitis** 1) d4T 2) ddI 3) 3TC **Lactic acidosis due to ART** 1) d4T 2) ddI 3) AZT

Ask / Examine	Look for	Assess	Disease (most common)	Drug Side-Effects
Diarrhoea	• History • Blood in stool	• Less than 1 month	1) Salmonella E. Coli Amoeba, Shigella 2) HIV / OI	**GI toxicity** 1) LPV/r 2) NVP 3) AZT 4) ABC 5) 3TC Antibiotics: Pseudo-membranous enterocolitis
		• Longer than 1 month	1) HIV / OI 2) Abdominal TB	
Leg pain, numbness, weakness	• History • Neurological exam	• Sleep disturbance (moderate) • Motor involvement (severe)	1) HIV peripheral neuropathy 2) EPTB	**Drug neuropathy** 1) d4T 4) INH 2) ddI 3) AZT 5) Vincristine 6) Metronidazole
Rash on arms, legs and trunk	• Skin lesions	• Purple lesions	1) KS	
		• Blisters/ vesicles	1) Shingles/ varicella zoster	Stevens-Johnson Syndrome 1) NVP 2) Cotrimoxazole
	• Generalized rash	• Maculo-papular	1) HIV associated rash (PPE) 2) Fungal skin infections 3) Molluscum contagiosum 4) Scabies	**Skin toxicity** 1) NVP 2) EFV 3) CTX 4) Fluconazole

6.4.3 CD4 monitoring for ART eligibility

Key facts for providers and patients

- CD4 counts are the most direct routine measure for HIV immune suppression, but can be influenced by several factors:
    - Gender, time of day, physical exercise, pregnancy, smoking, etc.
- CD4 counts do not replace clinical staging.
- Use CD4 counts only to monitor ART eligibility in patients who would otherwise not be eligible. CD4 counts are not needed for the following patients:
    - Age under **5** years
    - WHO clinical stage 3 or 4
    - Pregnant or breastfeeding
- Do not use CD4 counts for routine monitoring of patients on ART.
- CD4 counts must not be used to delay or cancel ART initiation in patients who are otherwise eligible (pregnant or breastfeeding, age <5 years, WHO clinical stage 3 or 4).
- Repeat CD4 counts for patients aged 5+ years in pre-ART follow-up every 3 months.
- CD4 counts may fail or give wrong results unless the following protocol is used:
    - Collect a minimum of 2ml venous blood in tube with anticoagulant (EDTA)
    - Immediately turn tube upside down to mix the blood with the EDTA. Do not shake the tube vigorously.
    - The blood must be processed in the lab within a short time (6 hours for PARTEC machines; 48 hours for FACS count machines).
    - Storing the tube at 2-8°C in the dark will extend the life-span by a few hours.
    - Protect the tube from hard knocks / shaking during transport.

CD4 monitoring of patients in HIV Care Clinic follow-up

- Routinely perform clinical monitoring for all HIV exposed children and pre-ART patient at every HCC visit (see Table 6 on Page 28). This covers WHO clinical staging and identification of HIV-related diseases and potential drug toxicity
- Every 3 months (at every 3-monthly visit), do routine CD4 count for patients with confirmed HIV infection (pre-ART patients) who are not otherwise eligible for ART.
    - Give CD4 count result to the patient at the next scheduled visit (after 3 months). Giving an extra (earlier) appointment for picking up of CD4 results is usually too burdensome for the patient. Consider giving the result by phone.
    - Stop CD4 monitoring once a patient has CD4 results or a clinical condition which makes them eligible for ART.

6.4.4 Collection of DBS samples for EID and VL

Key facts for providers and patients

- Diagnosing HIV infection in infants and detecting treatment failure in patients on ART is done by testing for HIV genetic material in a blood sample.
- This requires making millions of copies of the genetic material so that there is enough to be measured. This method is called polymerase chain reaction (PCR). PCR is very sensitive and it can be disturbed by tiny amounts of dirt or contact with other samples.
- PCR testing is only done in special labs, making it necessary to prepare dried blood spot (DBS) samples that can be kept at normal temperature for several weeks.
- Carefully follow the protocol when preparing DBS samples. Most steps are the same, but there are some **important differences between** DBS for **EID** and **VL** (shown below).
- **Never** allow EID samples to **touch or mix** with VL samples as this will lead to false positive EID results:
    - Use separate rooms or at least separate tables within one room.
    - Allocate different staff for collection of DBS for EID and VL.
    - Schedule different days / time for collecting EID and VL samples.
    - Use separate drying racks, clearly labelled ***EID*** and ***VL.***
    - Pack DBS for EID and VL in separate plastic bags and envelopes

Materials needed	EID	VL
1. Gloves	✓	✓
2. Alcohol swab	✓	✓
3. Gauze	✓	✓
4. Lancet	✓	✓
5. Sharps bin	✓	✓
6. Biohazard waste bag	✓	✓
7. Capillary tube	✗	✓
8. DBS card	✓	✓
9. Drying rack	✓	✓
10. Zip-lock bags x 2	✓	✓
11. Sachets with desiccant x 3	✓	✓
12. Marker pen	✓	✓
13. Envelopes	✓	✓

Table 7: Summary protocol for preparation of DBS samples for EID and VL

	Early Infant Diagnosis (EID)	Viral Load (VL)	Caution
Getting ready	• Label DBS card with patient name, ID and date • Wash hands, put on gloves, wash powder off gloves (unless powder-free)		• Hold the filter paper card only at the edges • Never touch the area near the circles
Sample collection	• Infants <9kg: select left or right side of the sole under the heel • Children under 2 years >9kg: select heel or side of big toe • From age 2 years and adults: select side of fingertip, preferably ring finger • Position down, warm up, squeeze intermittently		
	• Wipe with alcohol swab, dry for 30 sec • Press lancet on skin, prick, dispose into sharps bin • Wipe away first drop of blood with sterile gauze, wait for large drop of blood to appear		• Avoid excessive squeezing of heel / toe / finger
	• Drip one free drop of blood directly onto filter paper	• Dip capillary into blood drop and fill to black line (50 micro litres) • Hold tip of the capillary at a slight angle in the centre of the circle on the filter paper	• Don't allow the finger / toe to touch the filter paper • Apply blood only on one side of filter paper • Don't rub or scratch filter paper with capillary
	• Let the blood soak into the paper to fill the whole circle • Repeat this procedure until all **5 circles** are filled		• Don't re-apply more blood to the same circle
Drying	• Slot filter paper into drying rack • Dry in protected area at room temperature for at least 3 hours (best overnight)		• Don't touch/ smear/ allow to touch other objects • Protect from sunlight, heat, dust, insects, rodents
Packing	• Put each filter paper card into a separate zip-lock bag • Put 3 sachets with desiccant into each zip-lock bag • Squeeze out air and seal zip-lock bag • Use marker pen to label the zip-lock bag and envelope, including **'EID'** or **'VL'** • Insert zip-lock bags and specimen forms in this envelope and seal		• Don't pack filter paper cards before completely dried • Don't combine EID and VL samples in same envelope
Storage, transport	• Store envelopes in cool dry place		• Keep away from sunlight

6.4.5 Definition of ART eligibility

Key facts for providers and patients

- All patients need to be assessed clinically, regardless of other criteria that may make them eligible to start ART (CD4 count results, universal eligibility based on age, pregnancy or breastfeeding).
- Patients always remain eligible to start ART if they have satisfied eligibility criteria once.
- *Universal ART eligibility* is limited to certain patients for certain time periods:
    - Children aged 5 years and above are NOT universally eligible to start ART (see Section 6.4.5).
    - HIV infected women who did not start ART while pregnant or breastfeeding need to be in WHO stage 3 or 4 or have a CD4 count below the threshold in order to start ART.
- Use the flowchart in **Figure 4** on page 36 to classify the *Reason for starting ART.* Some patients may be eligible for ART on the basis of different conditions. In this case, WHO clinical stage 3 and 4 are considered to 'override' other eligibility criteria.

Infant under 12 months

- **Universal ART:** Confirmed HIV infection (DNA-PCR needed), regardless of WHO stage and CD4 count or CD4 %.
- **Presumed severe HIV disease (PSHD):** HIV antibodies (HIV rapid antibody test) and PSHD-defining clinical conditions (see WHO Clinical Staging Chart).

Child 12 – 60 months

- **Universal ART:** Confirmed HIV infection (HIV rapid antibody test or DNA-PCR), regardless of WHO stage and CD4 count.

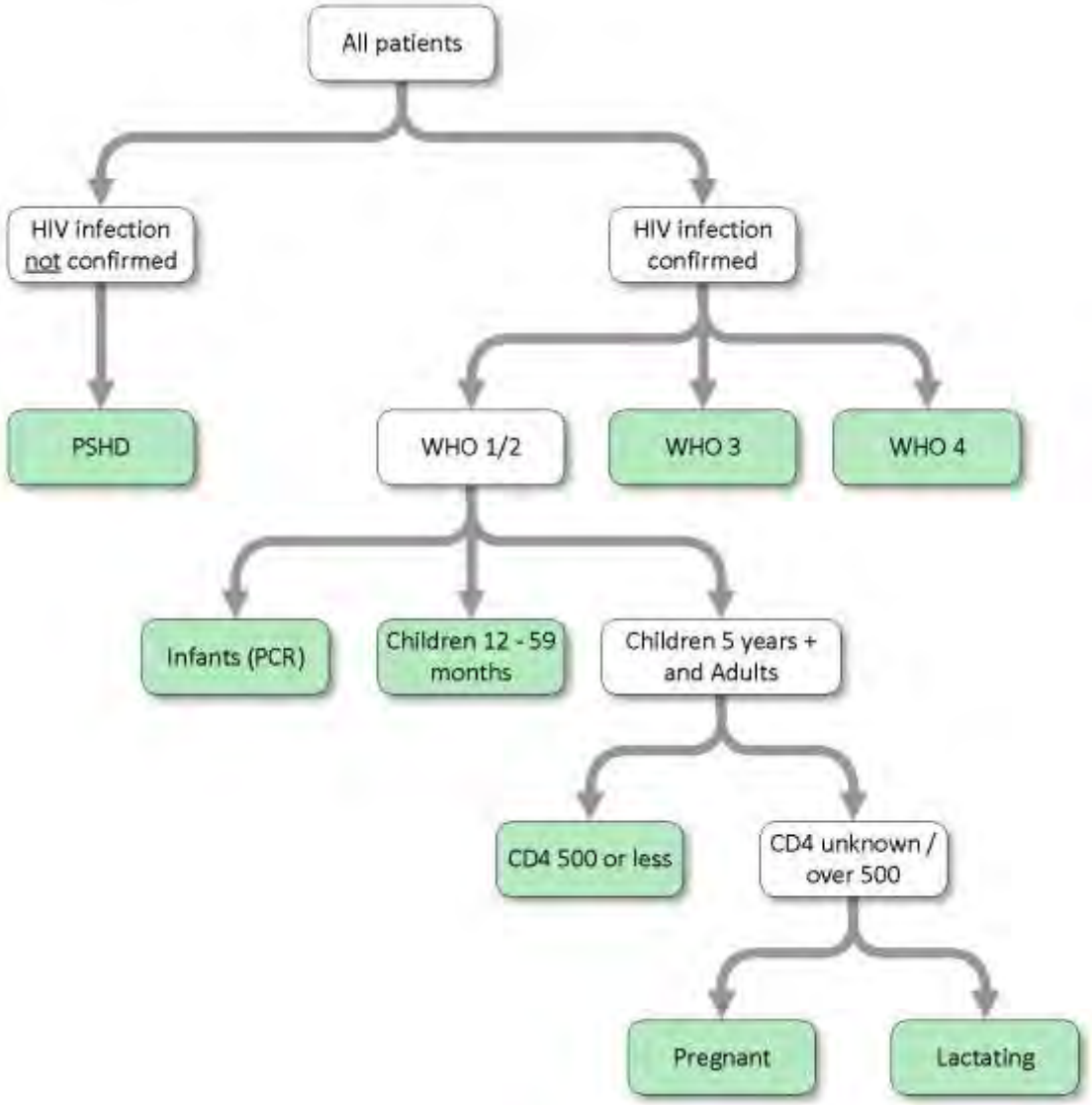
Child 5 years + and Adult

- Confirmed HIV infection (HIV rapid antibody test) **and**
    - Pregnant or breastfeeding women (regardless of the age of the child) regardless of WHO stage and CD4 count

      OR
    - WHO stage 1 or 2 and CD4 ≤500 cells/mm^3

      OR
    - WHO clinical stage 3 or 4 regardless of CD4 count

Figure 4: Flowchart for classification of *Reason for Starting ART* (shaded boxes) based on the hierarchy of ART eligibility criteria



6.5 Preventive services for HIV patients

Key facts for providers and patients

- A simple standard package of preventive services is provided for all patients in HIV Care (exposed children, pre-ART children and adults) and ART Clinics. This includes:
    1. Provider Initiated Family Planning (condoms + Depo-Provera)
    2. 'Prevention with Positives'
    3. Cotrimoxazole Preventive Therapy
    4. Isoniazid Preventive Therapy (not for patients on ART)
    5. Insecticide Treated bed Nets
- This package effectively reduces:
    - HIV transmission to sexual partners
    - HIV transmission from mother to child by preventing unwanted pregnancies
    - Serious HIV-related diseases (TB, diarrhoea, pneumonia, malaria, etc.)
    - HIV disease progression, deferring the need to start ART

6.5.1 Provider initiated family planning (PIFP)

Key facts for providers and patients

- Avoid unwanted pregnancies, regardless of HIV infection status.
- Unprotected sex is a risk for discordant and concordant HIV infected couples.
- Couples should use dual protection – condoms alone are not enough for family planning as they have to be used very consistently.
- The 3-monthly injection (Depo-Provera), intrauterine contraceptive device, tubal ligation and vasectomy are safe with TB treatment and ART. Advise women that other hormonal contraceptives (pill, implants) may become less effective with ARVs or TB treatment.
- Encourage HIV positive women to make an informed choice about pregnancy. Health workers should not actively discourage pregnancy as the risk of transmitting HIV to the baby is less than 5% if the mother :
    - Starts ART as early as possible
    - Is fully adherent to ART throughout pregnancy and breastfeeding

Implementing routine PIFP in HIV clinic

- Assume that all patients aged 15 years and above are sexually active.
- Offer condoms to all men and condoms and Depo-Provera to all women age 15 years and above:
    - Minimum of **30** male and/or female condoms

  - 1 Depo-Provera injection every 3 months
- Give patients the opportunity to refuse either method if they feel they don't need / want it.
- Refer clients to FP clinics for further counselling or for other FP methods.

Giving Depo-Provera

- Depo-Provera has no relevant drug interactions with ART and/or TB treatment.
- Inject 1 vial (150mg) in the deltoid muscle.

Contraindications

- Jaundice
- Possibility of current pregnancy
- Suspected or known breast cancer

6.5.2 Prevention with positives (PwP)

- Assess and counsel at every visit for:
  - High risk sexual activity
  - Partner's and children's HIV status (See Section 6.1 on Page 13)
  - Disclosure to partner/ guardian/ treatment supporter
  - Signs and symptoms of STIs
  - Pregnancy status
  - Adherence to ART and other medications (See Section 6.9.6 on Page 61);
  - Abuse of alcohol and other substances
  - Positive living (nutrition, alcohol and smoking cessation)

6.5.3 Cotrimoxazole preventive therapy (CPT)

Key facts for providers and patients

- CPT prevents PCP pneumonia, diarrhoea, malaria and other HIV-related diseases and prolongs survival.
- Start all HIV exposed and infected children from age 6 weeks and adults regardless of clinical stage or CD4 count on CPT.
- Provide CPT to all patients in HCC and ART follow-up.
- Continue CPT for life for all HIV positive patients.
- Stop CPT in HIV exposed children when confirmed negative after stopping of breastfeeding (when discharged from exposed infant follow-up).
- CPT is tolerated very well by most patients, can be taken at the same time with ART, TB treatment and IPT and is safe in pregnancy.

Key facts for providers and patients

- Do not combine CPT with SP – HIV positive pregnant women only take CPT (and ART).
- Children from 30.0kg and adults take one 960mg tablet of cotrimoxazole 24-hourly.
- Dispersible paediatric tablets (120mg) are used for children under 14.0kg. Dosing of paediatric CPT and ART is both based on the same weight bands.
- CPT is usually available in blister-packs of 10 tablets – 3 strips of 10 tabs are enough for a 30 day supply.
- Poor adherence to CPT is a warning sign for poor adherence to ART.

Eligibility and when to start CPT

- All infants born to HIV infected mothers (without confirmed HIV infection) from age 6 weeks:
    - Aim to start CPT straight after the infant has finished NVP syrup.
    - Note: having taken NVP prophylaxis is NOT a condition for starting CPT.
    - Keep the infant on CPT until s/he is confirmed HIV-negative and is discharged from HCC follow-up (around age 24 months).
- Confirmed HIV infected children from age 6 weeks and adults:
    - Regardless of CD4 count or clinical stage.
    - No contra-indication against CPT in the first trimester of pregnancy.
    - Start CPT as soon as possible in pregnancy.
    - Do not give SP to HIV infected pregnant women on CPT.
    - If SP has already been taken, wait for 14 days before starting CPT.

Contraindications

- Jaundice
- Renal failure
- Suspected allergy to any of the following sulfonamide drugs (skin rash, mucosal ulceration, severe anaemia, leukopenia)
    - Cotrimoxazole
    - Sulfadoxine / Pyrimethamine (SP)

Table 8: Dosage of Cotrimoxazole Preventive Therapy

Weight	960mg tablets	480mg tablets	120mg dispersible tabs	Syrup
less than 6kg		¼ tab **24**-hourly	**1** tab **24**-hourly	**2.5**ml **24**-hourly
6.0 – 13.9kg		½ tab **24**-hourly	**2** tabs **24**-hourly	**5**ml **24**-hourly
14.0 – 29.9kg	½ tab **24**-hourly	**1** tab **24**-hourly		
30kg +	**1** tab **24**-hourly	**1** tab **12**-hourly		

When to stop on CPT

- HIV exposed children: when confirmed HIV negative at age 24 months (or when confirmed HIV negative at least 6 weeks after stopping of breastfeeding).
- HIV infected children and adults continue CPT for life, unless severe side effects develop.
- Poor adherence to CPT will reduce the effectiveness of preventing HIV-related diseases, but it is less risky than poor adherence to ART.

6.5.4 Isoniazid preventive therapy (IPT)

Key facts for providers and patients

- Daily IPT can prevent TB in people who are at high risk of developing TB.
- Give IPT to the following:
  - HIV infected children and adults who are not on ART, regardless of WHO clinical stage or CD4 count.
  - Children under 5 years (HIV negative or unknown HIV status) who live with a patient with pulmonary TB (sputum smear negative or positive) who has not yet completed 2 months of TB treatment.
- Start IPT at enrolment for pre-ART follow-up and continue for as long as the patient is in pre-ART follow-up. Stop IPT when ART is started.
- Do not give IPT to a patient who has any signs suggestive of active TB: such patients need full investigation for TB and combination TB treatment if confirmed to avoid TB drug resistance.
- IPT is well tolerated and can be taken with CPT and in pregnancy.
- Stop IPT if any of the following are seen:
  - Severe skin rash
  - Yellow eyes
  - Dizziness / confusion / convulsions
  - Severe numbness/burning pain and muscular weakness of legs and/or arms

Eligibility for IPT

HIV infected patients are eligible to start IPT if they fulfil all of the following conditions:

- Age 5 years + (as all children under 5 years with confirmed HIV infection should be on ART).
- Not on ART
- Active TB ruled out. Use the standard TB screening questions below:
    - Current cough: any duration, productive or non-productive
    - Unexplained weight loss (adults)
    - Failure to thrive and/or malnutrition (children)
    - Fever and/or night sweat

IPT contraindications

- Suspected or confirmed active TB
- Active hepatitis
- Severe peripheral neuropathy

IPT dosage and duration

- Provide IPT during pre-ART visits. One extra visit is needed 1 month after starting IPT.
- Review patients at month **1**, **3** and **6** after starting IPT for any side-effects.
    - IPT initiation: Give INH and pyridoxine for 1 month.
    - 1 Month IPT review: Give INH and pyridoxine for 2 months.
    - From 3 Month IPT review: Continue giving INH and pyridoxine for 3 months.
- Give 1 tablet of pyridoxine 25 or 50mg 24-hourly to children and adults who are taking IPT.
- Stop IPT when the patient starts ART, regardless of how long IPT has been taken.

Table 9: Dosage for Isoniazid Preventive Therapy

Weight	Target dose (OD)	INH 100mg tabs	INH 300mg tabs
Under 10kg	100mg	**1** tab 24-hourly	
10- 13.9 kg	150mg	**1 ½** tabs 24-hourly	**½** tab 24-hourly
14- 19.9 kg	200mg	**2** tabs 24-hourly	
20- 24.9 kg	250mg	**2 ½** tabs 24-hourly	
25 kg or above	300mg	**3** tabs 24-hourly	**1** tab 24-hourly

6.5.5 Insecticide treated bed nets (ITN)

- Dispense 1 ITN to each patient at enrolment into the HIV Care / ART clinic
- Dispense 1 replacement ITN every 2 years and document this on the (pre-) ART patient card

6.5.6 Infant and child feeding counselling

Key facts for providers and patients

- Feeding recommendations are the same for all infants, regardless of HIV exposure or HIV infection status.
- Give only breast milk up to age 6 months.
- Gradually start complementing breastfeeding with suitable hygienically prepared foods from age 6 months (such as Likuni Phala, fruits, vegetables, beans, ground nuts and soya).
- Stop breastfeeding around age 24 months.
- Stop breastfeeding gradually over a period of 1 month (no *rapid cessation*).

Additional key messages for health workers and patients

- Replacement feeding (formula) is **NOT** recommended unless women are unable to breast feed.
- Monitor weight, height and MUAC according to schedule using standard MOH charts and intervene if no adequate weight-gain.
- Give only medicines prescribed by a health professional.
- Start breastfeeding immediately after birth. Explain and observe optimal breastfeeding:
    - Empty both breasts properly to avoid breast engorgement.
    - Ensure proper attachment and positioning to minimize nipple cracks and fissures.
    - Watch out for signs of breast infection (pain, swelling, heat, redness)
        - Don’t feed baby from infected breast.
        - Express infected breast to avoid engorgement. Discard expressed milk – do not feed to baby.
        - Go to health facility for treatment.

6.6 Understanding ART regimens and formulations

Key facts for providers and patients

- ART requires combining **3 different ARVs** that act differently to avoid development of drug-resistant HIV.
- Use only the standard ARV regimens for the specified patient groups shown in these guidelines. Other ARV combinations may cause more side effects or lead to drug-resistant HIV. Non-standard (NS) regimens can only be prescribed by specialists for complicated cases.
- Do not change ART regimens without clear medical indication. Unnecessary regimen changes spoil future treatment options.
- **1st Line regimens** are the best. Patients can remain on the same 1st line regimen for many years if they are fully adherent. All 1st line regimens:
    - Are easy to prescribe and easy to take.
    - Have a low risk of side effects.
    - Require no lab monitoring for toxicity.
    - There are **7 different 1st line** regimens:
        - **2** are used for **initiating ART** depending on patient weight (see Table 11 on Page 48). Both are fixed-dose combinations: only 1 type of tablet is taken.
        - Move all patients with significant side effects to an alternative 1st line regimen without delay. Alternative regimens are chosen by **substituting** only the ARV responsible for the side effects.
    - All children started on Regimen 2 continue on the same regimen after their 15th birthday. Change to adult formulation (2A) above 25kg. Continue on 2A for life unless they develop toxicity or fail.
- **2nd Line regimens** are a lifeline for patients who have confirmed treatment failure on 1st line regimen (usually due to poor adherence in the past). Moving from 1st to 2nd line ART is called **switching**. 2nd line regimens:
    - Contain a completely different class of ARVs (protease inhibitors)
    - Are more complicated to prescribe and take
    - Can have more side effects
    - There are **3 different 2nd line** regimens. The appropriate 2nd line regimen is determined by the 1st line regimen that the patient was taking when failing.
- **3rd Line regimen** is 'salvage therapy' and a last resort for patients failing on second line in spite of good adherence. This requires confirmation of drug resistant virus using genetic analysis in the lab. 3rd line can currently only be initiated on a study basis by a specialised expert ARV clinician.
    - Very expensive
    - Can have more side effects and be difficult to take.
    - Currently not supplied in the National Program.

6.6.1 Classification of individual ARVs

- Main classification is based on **mode of action** against HIV replication.
- Sub-classification is based on **biochemical structure** of the drug.
- Only ARVs with the same dosing interval are available as fixed-dose combinations.

Table 10: Classification of ARVs

Mode of action	Biochem. structure	Abbrev.	ARVs	Dosing interval
Reverse **T**ranscriptase **I**nhibitors	**N**ucleosides	***NRTI***	**d4T, AZT**	***12**-hourly*
			3TC, ABC	***12**- or **24**-hourly*
			TDF	***24**-hourly*
	Non-**N**ucleosides	***NNRTI***	**NVP**	***12**-hourly*
			EFV	***24**-hourly*
Protease **I**nhibitors		***PI***	**ATV/r**	***24**-hourly*
			LPV/r	***12**-hourly*

6.6.2 Choosing ART regimen, formulation and dosage

Regimen Names

- **Table 11** shows the standard ART regimens for Malawi.
- Regimens are numbered for ease of reference:
  - Regimen 0 – 6 are 1st line regimens, including alternative 1st line regimens.
  - Regimen 7 – 9 are 2nd line regimens.
  - An "**A**" is added to the regimen number for adult formulations (e.g. Regimen 1A) and a "**P**" is added for paediatric formulations (e.g. Regimen 3P).
- Fixed dose combinations (FDC) are shown with a slash (e.g. AZT **/** 3TC **/** NVP).
- Combinations made up of different tablets are shown with + (e.g. AZT/3TC **+** EFV).
- **3TC (lamivudine)** is the backbone in **ALL** 1st and 2nd line regimens because it is extremely well tolerated and remains active even with drug-resistant HIV is present.

Paediatric / Adult Formulations

- Most regimens are suitable for children and adults and are available as both adult and paediatric strength tablets, but:
  - TDF may affect growing bones and is not given to children under 35kg.

Start Regimen

- Start patients under 35kg on Regimen **2** and patients above 35kg on Regimen **5**. Start on alternative 1st line regimen if the patient has any contraindications for Regimen 2 or 5.

Initial Prescriber Level

- All MOH-certified PMTCT/ART providers are authorized to start any of the seven 1st line regimens, but only experienced ART staff (certified Level 2 providers) are authorized to initiate 2nd line regimens. However, follow-up prescriptions for 2nd line regimens can also be made by Level 1 providers. See details in Section 6.6.3 on page 50

'Starter Pack'

- Regimens with NVP (regimen **0, 1, 2** and **6**) need to be *phased in* to avoid potentially severe hepatitis or skin toxicity. During the first 2 weeks, the NVP-containing FDC is taken only once daily (before bed). The other 2 ARVs are taken in the morning to achieve 12-hourly dosing from the first day.
- *Starter packs* are dispensed as a 2-week supply of one pack of the triple ARV fixed-dose combination (with NVP) plus one pack of the other 2 ARVs in combination (without NVP). Dispense the required number of tablets in labelled tablet dispensing bags.
- *Starter packs* are needed for all patients starting Regimen **0, 1, 2** or **6:**
    - For the **first time** (new ART initiation)
    - After interrupting ART for more than **14 days** (re-initiation / re-start)
- *Starter packs* are **NOT** given when changing without interruption from an EFV-containing regimen (3, 4 or 5) to regimen 0, 1, 2 or 6. This is because patients on EFV already excrete NVP faster.

Tail needed

- NVP and EFV remain in the body much longer than the other ARVs. Stopping any 1st line regimen due to side-effects (or due to patient's decision, etc.) therefore requires giving a 7-day '*tail*' of the other 2 ARVs in the regimen to avoid exposing the virus to only NVP or EFV, which would risk development of NVP- and EFV-resistant HIV and spoil future treatment options.
- However, do **NOT** give a *tail* in case of severe potentially life-threatening side effects (lactic acidosis, pancreatitis), but stop all ARVs immediately.

Contraindications

- Most contraindications are not absolute for a specific regimen: balance risks, benefits and alternatives. Usually, a suitable alternative regimen can be chosen from Table 11. The following conditions are absolute contraindications:
    - Patients who developed severe toxicity to any specific ARV (hepatitis or Stevens - Johnson syndrome from NVP or EFV, severe anaemia from AZT, ABC hypersensitivity) must **NEVER AGAIN** be given a regimen containing the responsible ARV.
    - Do not use **TDF**-containing regimens in severe **renal failure** (creatinine clearance <50ml/min).

Adverse Events / Side Effects

- Chose the appropriate alternative regimen from **Alternative 1** for patients with:
    - Contraindications
    - Significant side-effects (immediately)

  - Troubling side effects that did not improve within 2 months with symptomatic treatment.

- Use **Alt. 2** if **Alt. 1** cannot be used due to previous toxicity or other specific contraindications.
- The appropriate 2nd line regimen depends on the 1st line regimen the patient was on when confirmed with treatment failure. Only certified **Level 2 ART providers** can initiate 2nd line.

Dosing and Frequency

- **Table 12** shows the number of tablets to be taken by children and adults once or twice per day.
- 10 weight-bands are used to determine the number of paediatric tablets to be given.
- Most paediatric formulations are **tablets** that can be crushed if necessary. The only exceptions are:
  - LPV/r for children **under 6kg** requires **liquid suspension** (80/20mg per ml).
  - LPV/r and ATV/r tablets must be **given whole** (not split or crushed).

Rationale for using Regimen 5A for pregnant and breastfeeding women

- 5A is the regimen of choice for universal ART for all HIV-infected pregnant and breastfeeding women (PMTCT 'option B+').
  - Other regimens with NVP can cause severe toxicity in patients with high CD4 counts. Other patient groups do not start ART with such high CD4 counts.
  - TDF is more suitable than AZT for B+ women because it does not cause anaemia, which is a particular risk in pregnancy.

Use of EFV in women of reproductive age

- EFV is recommended in pregnancy, including in the 1st trimester. Compared with NVP, EFV provides better long-term viral suppression, has fewer adverse events and less risk of resistance.[3]
  - Start 5A as early as possible in pregnancy – including in the first trimester.
  - Don't change regimen if a woman got pregnant while on an EFV-containing ART regimen.

[3] Use of efavirenz during pregnancy: a public health perspective. Technical update on treatment optimization. Geneva, World Health Organization, 2012 (www.who.int/hiv/pub/treatment2/efavirenz/en, accessed 2 December 2013).

Table 11: Standard ART 1st line (Regimen 0 - 6) and 2nd Line (Regimen 7 - 9)

Regi-men	Paediatric Formulation	Adult Formulation	Used for ART initiation 'Start regimen'	Initial pre-scriber level	Starter pack	'Tail' needed	Contraindications	Possible adverse event	If confirmed, use Alt 1	If confirmed, use Alt 2
0	**ABC** 60mg / **3TC** 30mg + **NVP** 50mg	**ABC** 600mg / **3TC** 300mg + **NVP** 200mg	**No**	**1**	**Yes**	**Yes**	• ABC hypersensitivity • Jaundice / hepatitis	• Fever, body pains, vomiting, cough [4] • Hepatitis, rash • Lipodystrophy, Lactic acidosis • Treatment failure	**2** **ABC/3TC+EFV** **5** **7**	**6, 5, NS** **5, 4** **6, NS** **8**
1	**d4T** 6mg / **3TC** 30mg / **NVP** 50mg	**d4T** 30mg / **3TC** 150mg / **NVP** 200mg	**No**	**1**	**Yes**	**Yes**	• Jaundice / hepatitis	• Neuropathy • Hepatitis, rash • Lipodystrophy, Lactic acidosis • Treatment failure	**2, 5** **5, 4** **5** **7**	**0, 6** **NS** **NS** **9**
2	**AZT** 60mg / **3TC** 30mg / **NVP** 50mg	**AZT** 300mg / **3TC** 150mg / **NVP** 200mg	• Standard for children and adults under 35kg	**1**	**Yes**	**Yes**	• Anaemia <8g/dl • Jaundice / hepatitis	• Anaemia • Hepatitis, rash • Lipodystrophy Lactic acidosis • Treatment failure	**0 or 5** **4** **5** **7**	**6** **5, 3** **NS** **9**
3	**d4T** 6mg / **3TC** 30mg + **EFV** 200mg	**d4T** 30mg / **3TC** 150mg + **EFV** 600mg	**No**	**1**	**No**	**Yes**	• History of psychosis	• Neuropathy • Hepatitis, rash[5], psychosis, gynaecomastia[6] • Lipodystrophy, Lactic acidosis • Treatment failure	**5** **0, 6** **5** **7, 9**	**4, NS** **NS** **6**
4	**AZT** 60 mg / **3TC** 30mg + **EFV** 200mg	**AZT** 300 mg / **3TC** 150mg + **EFV** 600mg	**No**	**1**	**No**	**Yes**	• History of psychosis • Anaemia <8g/dl	• Anaemia • Lipodystrophy, Lactic acidosis • Hepatitis, rash[5], psychosis, gynaecomastia[6] • Treatment failure	**5, 0** **5** **2, 0** **7**	**3, 6** **6** **9**
5		**TDF** 300mg / **3TC** 300mg / **EFV** 600mg	• Standard for children and adults 35kg +	**1**	**No**	**Yes**	• History of psychosis • Renal failure • Child under 3 years [7]	• Renal failure • Hepatitis, rash[5], psychosis, gynaecomastia[6] • Persistent dizziness, visual disturbances • Treatment failure	**0** **6** **6** **8**	**2 (adj dose)** **0, 2** **0, 2** **NS**
6		**TDF** 300mg / **3TC** 300mg + **NVP** 200mg	**No**	**1**	**Yes**	**Yes**	• Jaundice/Hepatitis • Renal failure • Child under 3 years	• Renal failure • Hepatitis, rash • Treatment failure	**0** **5** **8**	**2 (adj dose)** **NS** **NS**

3TC = Lamivudine **ABC** = Abacavir **ATV / r** = Atazanavir/ Ritonavir **AZT** = Zidovudine **d4T** = Stavudine **EFV** = Efavirenz **LPV / r** = Lopinavir / Ritonavir **NVP** = Nevirapine **TDF** = Tenofovir

[4] Fever, body pains, vomiting, cough / sore throat and breathing problems can be due to life-threatening ABC hypersensitivity (rare). Stop all ARVs immediately. Never re-start ABC.

[5] Mild skin rash and/or dizziness and nightmares are common after starting EFV. This usually resolves by itself and is not usually a reason to interrupt or change regimen.

[6] EFV can cause breast enlargement in children and men (one side or both sides). This may resolve spontaneously while continuing EFV, but NVP substitution is usually needed (and effective).

[7] Regimen 5A and TDF 300mg/3TC 300mg can be used from 35kg. Paediatric formulation for TDF is currently not available in the national program.

Regimen	Paediatric Formulation	Adult Formulation	Used for ART initiation 'Start regimen'	Initial prescriber level	Starter pack	'Tail' needed	Contraindications	Possible adverse event	If confirmed, use Alt 1	If confirmed, use Alt 2
7		**TDF** 300mg / **3TC** 300mg + **ATV/r** 300/100	No	2	No	No	• Renal failure • Patient on rifampicin [8] • Pre-existing jaundice or suspected hepatitis [9]	• Renal failure	8	NS
								• Nausea, vomiting	NS	
								• Jaundice [10]	TDF/3TC +LPV/r	
8		**AZT** 300mg / **3TC** 150mg + **ATV/r** 300/100	No	2	No	No	• Anaemia <8g/dl • Patient on rifampicin [8] • Pre-existing jaundice or suspected hepatitis [9]	• Anaemia	7	9
								• Nausea, vomiting	NS	
								• Jaundice [10]	AZT/3TC + LPV/r	
9	**ABC** 60mg / **3TC** 30mg + **LPV/r** 100/25		No	2	No	No	• ABC hypersensitivity	• Fever, body pains, vomiting, cough [4]	7	8
								• Diarrhoea, vomiting	NS	

Table 12: Standard pack sizes and dosing of Paediatric and Adult formulations used in standard 1st and 2nd line ART regimens

ARV	Tablets per tin Paed.	Tablets per tin Adult	3 – 3.9 kg AM	3 – 3.9 kg PM	4 – 5.9 kg AM	4 – 5.9 kg PM	6 – 9.9 kg AM	6 – 9.9 kg PM	10 – 13.9 kg AM	10 – 13.9 kg PM	14 – 19.9kg AM	14 – 19.9kg PM	20 – 24.9kg AM	20 – 24.9kg PM	25 – 29.9kg AM	25 – 29.9kg PM	30 – 34.9 kg AM	30 – 34.9 kg PM	35 – 39.9 kg AM	35 – 39.9 kg PM	40 kg + AM	40 kg + PM
d4T / 3TC	60	60	1	1	1	1	1 ½	1 ½	2	2	2 ½	2 ½	3	3	1	1	1	1	1	1	1	1
d4T / 3TC / NVP	60	60	1	1	1	1	1 ½	1 ½	2	2	2 ½	2 ½	3	3	1	1	1	1	1	1	1	1
NVP	60	60	1	1	1	1	1 ½	1 ½	2	2	2 ½	2 ½	3	3	1	1	1	1	1	1	1	1
AZT / 3TC	60	60	1	1	1	1	1 ½	1 ½	2	2	2 ½	2 ½	3	3	1	1	1	1	1	1	1	1
AZT / 3TC / NVP	60	60	1	1	1	1	1 ½	1 ½	2	2	2 ½	2 ½	3	3	1	1	1	1	1	1	1	1
ABC / 3TC	60	60	1	1	1	1	1 ½	1 ½	2	2	2 ½	2 ½	3	3	0	1	0	1	0	1	0	1
LPV / r	60	120	*1ml*	*1ml*	*1.5ml*	*1.5ml*	2	1	2	1	2	2	2	2	3	3	3	3	2	2	2	2
EFV	90	30							0	1	0	1 ½	0	1 ½	0	2	0	2	0	1	0	1
ATV / r		30																	0	1	0	1
TDF / 3TC		30																	0	1	0	1
TDF / 3TC / EFV		30																	0	1	0	1

[8] Do not combine ATV/r with rifampicin (TB treatment). Substitute to LPV/r for the duration of TB treatment.
[9] Do not start patients with pre-existing jaundice or suspected hepatitis on ATV/r. Use LPV/r instead.
[10] ATV/r can cause jaundice. Mostly, this is only of cosmetic concern. Refer jaundice to a specialist for LFT. If only indirect bilirubin is raised, continue ATV. Stop ATV/r if LFT cannot be done.

6.6.3 Choosing regimen and time of starting in special situations

Table 13: Choosing ART regimen and timing of initiation in special situations

Condition	Timing of ART initiation	Weight	
		Less than 35kg	35kg +
Anaemia (<8g/dl)	• Within 7 days of diagnosis	**0P**	**5A**
Active TB	• Within 14 days of diagnosis • TBT + ART can be started on the same day if the patient is stable • Don't delay either TBT or ART	**Under 3 yrs: 2P** **3 yrs +: 4P / 4A**	**5A**
Jaundice	• Refer to District or Central Hospital • After investigation and stabilisation	**4P / 4A**	**5A**
1st trimester pregnancy	• As soon as possible		**5A**
In labour (new HIV+)	• As soon as possible		**5A**
Renal failure	• Refer to District or Central Hospital • Start within 7 days of diagnosis	**0P / 0A**	**0P / 0A**
Psychiatric Illness (history)	• As soon as possible • Reliable guardian needed	**2P / 2A**	**6A**

6.6.4 Non-standard (NS) ART regimens

- Only expert ART clinicians can initiate NS regimens.
- Patients with multiple contraindications and/or adverse reactions against all standard NRTIs (TDF, AZT, d4T) or NNRTIs (NVP, EFV) may need a NS regimen.
- Consider ABC / 3TC for substitution of TDF/3TC, AZT/3TC and d4T/3TC.
- Consider ATV/r or LPV/r for substitution of NVP and EFV.
- Contact the Department for HIV and AIDS for availability of adult formulation ABC/3TC and other non-standard ARVs (see **Section 8** on page **89**).
    - Provide patient history, indication and proposed regimen.

6.7 Prescribing and dispensing ARVs

Key facts for providers and patients

- ARVs should be taken after the same number of hours every day (e.g. every 12 or every 24 hours). Most ART regimens can be taken in the morning, at noon or at night and it does not matter if they are taken before, after or with food.
- **Missing a dose**: what to do if a patient remembers to take his ARVs late? If the patient remembers:
    - **Less than half-way** to the next scheduled dose: take the missed dose immediately, and take the regular next dose at the normal time.
    - **More than half way** to the next scheduled dose: skip the missed dose and take the regular next dose at the normal time.
- Dispense ARVs only in the original sealed container. Only exception: open containers to dispense the precise number of tablets needed for *Starter Packs.* [11]
- Only the patient or his registered guardians/treatment supporter is allowed to collect ARVs.
- In an emergency, patients are allowed to collect ARVs from any ART clinic in Malawi following special rules (see below).

Rules for ARV dispensing

- All certified clinical PMTCT/ART providers are authorized to prescribe and dispense ART (Doctors, Clinical officers, Medical Assistants, Registered Nurses, Nurse/Midwife Technicians)
- Only the patient or his registered guardians/treatment supporter is allowed to collect ARVs.

Emergency dispensing to patients from another PMTCT/ART site

- In an emergency, patients are allowed to collect ARVs from any ART clinic in Malawi under the following conditions:
    - The patient must present an ART identity card or the health passport with ARV dispensing information.
    - If in doubt about a patient's authenticity, confirm by calling the site where the patient is registered.
    - Document emergency ARV dispensing in the patient's health passport.
    - ARV dispensed to patients registered at another site must be recorded in the *Emergency ARV Dispensing Register.* Improvise a hardcover register: Date, original ARV registration number, original facility name, patient name and contact details, ARV name and quantity dispensed, reason for emergency dispensation, staff name.
    - Instruct patient to return to their ART clinic of registration as soon as possible to ensure the patient is not recorded as defaulter.

[11] To prevent crumbling of tablets in plastic bags; to prevent mixing of different batches of drugs with different expiry dates; and to ensure hygiene and avoid contamination.

Determining quantities to be dispensed and next appointment

- **Table 14** on page 53 shows the number of tablets to be supplied for appointment intervals of 2, 4, 8 or 12 weeks for the total number of tablets taken of each ARV per day (paediatric and adult formulations).
    - Use **Table 12** to add up the 'total tablets taken per day' for each ARV contained in the regimen. For example: a child of 15kg on AZT/3TC/NVP (Regimen 2) takes **2½** paediatric tablets in the morning and **2½** tablets in the evening, adding up to **5** total tablets per day.
    - The *Actual number of tablets needed* is the minimum number of total tablets the patient needs to take home to cover the time to the next appointment. (Total tablets = tablets remaining from the previous visit **+** tablets newly dispensed). The number needed includes an extra 2-day supply to act as a safety-buffer. The total tablets must meet or exceed the *Actual number of tablets needed*.
    - Different ARVs come in tins of 30, 60, 90 or 120 tablets (see **Table 12**). Given that only full tins should be dispensed, the number of tablets needed is *rounded up* to multiples of full tins.
    - *Rounding up* may result in a considerable *over-supply.* For some regimens and dosages, perfectly adherent patients will be left with more than half a tin of ARVs at their next appointment. Explain this to the patient / guardian and emphasize the importance of keeping the next appointment.
    - The number of tablets expected to be used in the interval is shown for 'perfect adherence' (100%) and for 'good adherence' (95%-105%).
    - Calculate the number of tablets used by subtracting total tablets remaining at the current visit from total tablets available at the end of the previous visit.

Appointment / dispensing interval

- Give next appointment date at least 2 days before ARVs would be finished to allow for the safety buffer.
- Take account of the weekly ART clinic schedule (e.g. Mondays + Wednesdays) when giving the next appointment. Appointments are usually given for 2 weeks (starter pack), 4, 8 or 12 weeks.
- Patients initiating standard or alternative first line ART have to be reviewed clinically after **2 weeks** if they have been given a starter pack / otherwise after **1 month** and then every month for the first 6 months.
- Thereafter, give 12-week (**3-month**) ART appointments for all stable and adherent patients.
- In exceptional cases (e.g. international travel), up to **6** or even **12 months** of ARVs can be dispensed.
- Patients starting 2nd line ART have to be seen every 4 weeks for the first 6 months. Thereafter, patients who are stable and adherent to 2nd line ART can be given up to 8-week appointments.
- Align dispensing of CPT with ART visits.
- Push back appointment date to allow patients to use up accumulated 'hanging' tablets, e.g. give an appointment after 5 instead of 4 weeks.

Table 14: Quantity of ARVs to be supplied by visit interval and daily dose

Note: *supply and consumption must be calculated separately for each component in the regimen.*
Example: separate calculation for AZT/3TC and AZT/3TC/NVP making up a starter pack of Regimen 2

Dispens. interval	Total tabs taken per day	Supply needed								Total tabs **USED** in interval - Adherence	
		Actual tabs *	*Multiples of full tins*							**Perfect**	**Good**
			Tins of 30		**Tins of 60**		**Tins of 90**		**Tins of 120**		
			tabs	**tins**	tabs	**tins**	tabs	**tins**	tabs **tins**	100%	95% – 105%
2 weeks	1	***16***	30	**1**	60	**1**	90	**1**		14	*14 – 14*
	1 ½	***24***			60	**1**	90	**1**		21	*20 – 22*
	2	***32***			60	**1**	90	**1**		28	*27 – 29*
	2 ½	***40***			60	**1**				35	*34 – 36*
	3	***48***			60	**1**				42	*40 – 44*
	4	***64***			120	**2**				56	*54 – 58*
	5	***80***			120	**2**				70	*67 – 73*
	6	***96***			120	**2**				84	*80 – 88*
4 weeks	1	***30***	30	**1**	60	**1**	90	**1**		28	*27 – 29*
	1 ½	***45***					90	**1**		42	*40 – 44*
	2	***60***			60	**1**	90	**1**		56	*54 – 58*
	3	***90***			120	**2**			120 **1**	84	*80 – 88*
	4	***120***			120	**2**			120 **1**	112	*107 – 117*
	5	***150***			180	**3**				140	*133 – 147*
	6	***180***			180	**3**			240 **2**	168	*160 – 176*
	8	***240***			240	**4**				224	*213 – 235*
	9	***270***			300	**5**				252	*240 – 264*
8 weeks	1	***58***	60	**2**	60	**1**	90	**1**		56	*54 – 58*
	1 ½	***87***					90	**1**		84	*80 – 88*
	2	***116***			120	**2**	180	**2**		112	*107 – 117*
	3	***174***			180	**3**			240 **2**	168	*160 – 176*
	4	***232***			240	**4**			240 **2**	224	*213 – 235*
	5	***290***			300	**5**				280	*266 – 294*
	6	***348***			360	**6**			360 **3**	336	*320 – 352*
	8	***464***			480	**8**				448	*426 – 470*
	9	***522***			540	**9**				504	*479 – 529*
12 weeks	1	***86***	90	**3**	120	**2**	90	**1**		84	*80 – 88*
	1 ½	***129***					180	**2**		126	*120 – 132*
	2	***172***			180	**3**	180	**2**		168	*160 – 176*
	3	***258***			300	**5**				252	*240 – 264*
	4	***344***			360	**6**				336	*320 – 352*
	5	***430***			480	**8**				420	*399 – 441*
	6	***516***			540	**9**				504	*479 – 529*

** Actual tabs needed includes a 2-day safety-buffer*

6.8 Starting ART

Key facts for providers and patients

- ART does not cure HIV infection.
- ART stops the virus from multiplying, which allows the body's defence system to recover.
- The virus will 'wake up' as soon as ART is interrupted and it will learn how to evade ART. This means that ART may no longer work for this patient.
- Once started, ART must be taken every day for life.
- Patients on ART can still pass on HIV to others and must use condoms.
- From July 2011, all patients (incl. pregnant women tested on the same day of starting ART) need a confirmatory HIV test to rule out any possibility of mix-up of test results or fraudulent access to ART:
    - Either at enrolment into pre-ART follow-up, or before starting ART if the confirmatory test was not done in pre-ART.
    - Children under 12 months starting ART with a positive DNA-PCR do not need another confirmatory test before starting ART, but all need a confirmatory rapid antibody test at age 12 and 24 months (see **Section 6.1** on **page 13**).
- ARVs must not be dispensed outside of certified PMTCT/ART facilities (static or outreach) and must not be shared, sold or passed on to others.
- Bring back any remaining ARV tins and tablets at every clinic visit to allow the provider to count them.
- Return unused ARVs (e.g. after a patient's death) to the clinic for proper disposal.
- Patients who are late for their ART appointment will be actively followed from the clinic (home visit, phone, guardian).
- All patients are asked for consent for active follow-up at the time of starting ART. Patients can withdraw consent at any time.
- A small number of patients on ART develop side-effects:
    - Most side-effects are mild and disappear while ART is continued.
    - Some side-effects require a regimen change.
    - EFV can cause bad dreams and dizziness in the first few weeks of treatment, but this usually disappears by itself and it is important to continue treatment.
    - Very few patients develop serious side effects. Stop all drugs immediately and present to the hospital if any of the following conditions are seen:
        - Yellow eyes / hepatitis
        - Severe stomach pain and vomiting
        - Shortness of breath
        - Severe skin rash with blisters, involving eyes, mouth or genitals

6.8.1 Record keeping

- PMTCT/ART nurse or clinician: fill ART patient cards immediately when ART eligibility is established (do not delegate this to HSA). For this reason, keep blank ART treatment cards at OPD, ANC, maternity, wards, etc.
- Dispensing of ARVs must be recorded on the patient treatment cards.
- Complete ART treatment cards before giving out the first supply of ARVs.
- Patients should only be entered in the ART register when receiving their first supply of ARVs.

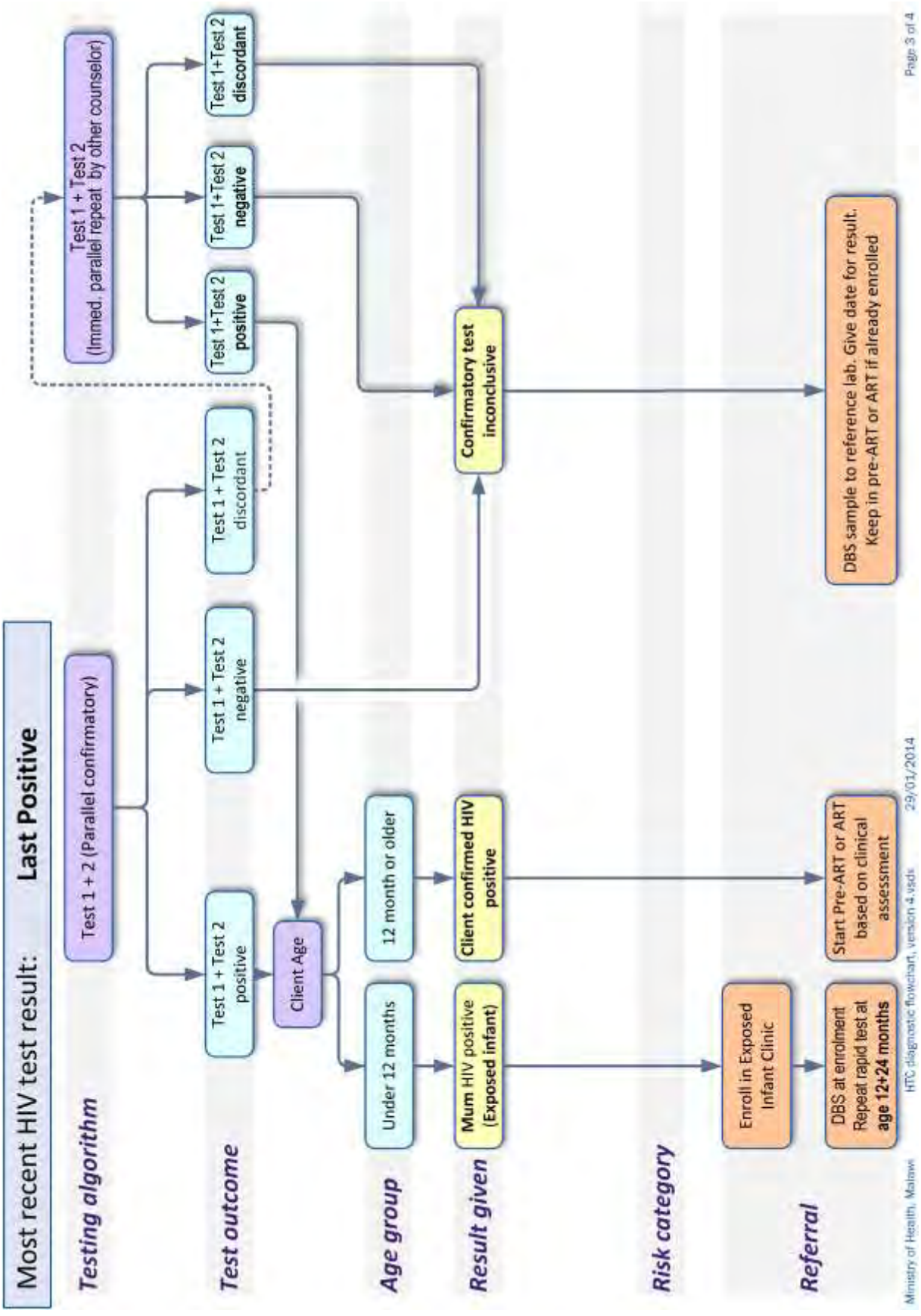
6.8.2 Confirming HIV infection

- All patients need a confirmatory HIV antibody test to rule out any possibility of mix-up of test results or fraudulent access to ART. This also applies to pregnant and breastfeeding women who have been tested on the same day of starting ART:
    - Either at enrolment into pre-ART follow-up,
    - Or before starting ART if the confirmatory test was not done in pre-ART.
    - Children under 12 months starting ART with a positive DNA-PCR do not need another confirmatory test before starting ART, but all need a confirmatory rapid antibody test at age 12 and 24 months (see **Section 6.1** on **page 13**).
- Do not delay ART initiation if HIV test kits are not available for the confirmatory test, but do confirmatory test at the next scheduled visit as soon as testing is available.

Testing protocol for confirmatory HIV test

- Attach a dedicated HTC counsellor to the HCC / ART clinic to do confirmatory testing. Ensure that all Quality Assurance protocols for HTC (proficiency testing, quality control) are being followed.
- **Use the first and second rapid test in parallel** (currently Determine + Uni-Gold) for confirmatory HIV testing. Review Figure 5 for the correct algorithm and interpretation of results:
- Test 1 and Test 2 are **both positive**:
    - Record ***'Confirmatory Positive'*** result in the **MOH HTC register** (Version 3, January 2013)
    - Record confirmatory HIV test results on pre-ART or ART patient card.
    - Enrol in pre-ART / Start ART
- Test 1 and Test2 are **discordant**:
    - Review testing protocol, quality control, expiry date and condition of test kits. Do immediate (parallel) repeat. Use different (experienced) HTC staff if possible.
        - Both positive: see above
        - Discordant or both negative: see below
- Test 1 and Test2 are **both negative**:
    - Record ***'Confirmatory Inconclusive'*** in HTC Register.
    - Collect DBS blood sample and send to reference lab and/or send patient to referral hospital to repeat regular HIV testing and for review by an experienced ART clinician.
    - Give follow-up appointment to review lab test result.

Figure 5: Testing algorithm for confirmatory HIV testing



6.8.3 Preparing the patient for ART

- Patients who are clinically stable should start ART no later than 7 days after being found eligible.
- Pregnant women should be offered to start ART on the same day.
- Confirm that patient (or parent/guardian if patient is <15 years) understands implications of ART and is committed to lifelong adherence.
- Identify long-term treatment support for patients who are unable to take responsibility for their own treatment (persons with mental disability or drug-addiction, etc.).
- Ask all patients to attend the initial group counselling and/or the ART initiation visit with a named guardian/treatment supporter.
    - If the patient is unable to identify a suitable guardian, another patient can be used as the named treatment supporter.

Mandatory IEC procedures when starting ART

- All patients must receive individual counselling at ART initiation.
- Women starting ART in labour can receive individual ART counselling after delivery.
- In addition, all patients should attend an ART group counselling session. Recommended practice:
    - Attended group counselling between 1 to 5 days before the day of ART initiation.
    - But: group counselling can be attended on the same day as ART initiation to avoid delay beyond 7 days.
    - Pregnant women may attend the group counselling at the next scheduled visit to ensure they can start ART on the same day.
    - Ask patients to attend with their named guardian (also see Section 6.8.2 on page 55).

ART group counselling

- Use standard ART flip chart (to be updated).
- Share “Key facts for providers and patients”

Individual ART counselling

- Confirm that patient and guardian have understood the following:
    - Commitment to lifelong adherence
    - Dosage and interval of taking ARVs
    - Potential side-effects
    - Date of next appointment

6.8.4 Baseline and routine lab investigations

- The national program does not require:
    - Routine baseline lab investigations before starting ART or routine investigations for ART toxicity.

- Routine scheduled CD4 monitoring of patients on ART is not supported.

- Use targeted investigations if clinically indicated.
- Scheduled VL monitoring is being rolled out (see **Section 6.9.10** on page **65**).

6.8.5 Combining ART and TB treatment

Key facts for providers and patients

- Each year 27,000 (3%) of the 900,000 HIV infected Malawians develop TB.
- 2 out of every 3 TB patients in Malawi are HIV infected.
- The risk of developing TB remains high for the first 6 months on ART.
- Most HIV patients with TB do not have typical TB symptoms (productive cough) and most are sputum smear negative.
- HIV infected TB patients must start ART and TB treatment as soon as possible. The long term outcome is poor if only one treatment is taken.
- There is no problem with taking ART Regimen 5A at the same time as TB treatment.

- Certain combinations of ARVs and TB drugs increase the risk of side-effects or reduce each other's effectiveness (due to faster excretion).
- The following table shows the relevant interactions.
  - **Green:** Combination causes no problems
  - **Yellow:** Combination causes usually no problems but monitor patient for possibly increased side-effects or adjust dosage as shown
  - **Red:** Do not combine without specialist advice

Table 15: Relevant interactions between ARVs and TB drugs

	Isoniazid	Rifampicin	Streptomycin	Ethambutol	Pyrazinamide
TDF	OK	OK	renal toxicity	OK	OK
AZT	OK	OK	OK	OK	OK
3TC	OK	OK	OK	OK	OK
d4T	neuropathy	OK	OK	OK	OK
EFV	OK	OK	skin rash	OK	hepatitis
NVP	skin rash	start NVP full dose, hepatitis	skin rash	OK	hepatitis
ABC	OK	OK	OK	OK	OK
ATV/r	OK	no experience (don't combine)	OK	OK	OK
LPV/r	OK	major dose adjustment	OK	OK	OK

Combining Second Line ART with TB Treatment

- Patients with ART failure (see 6.9.9 on page 60) may develop active TB. In this case, second line ART may need to be combined with TB treatment.
- Do not combine ATV/r with rifampicin-containing TB treatment. Give LPV/r instead of ATV/r for the duration of TB treatment and move (back) to ATV/r once TB treatment has been completed.
- Double the daily dose of LPV/r (4 tablets of LPV 200mg / r 50mg every 12 hours) for the duration of rifampicin treatment.

6.9 Continuing ART

6.9.1 Confirming adherence to appointment

- On the patient card, look at the *Next Appointment Date* given at the previous visit to confirm that the patient is not late.
- The patient is likely to have missed doses if s/he is more than 2 days late. Compare and validate with *Pill Count* and the reported number of *Doses Missed.*

6.9.2 Monitoring height and weight

- Record current weight (and height for children under 18 years).
- Look for weight changes compared with previous measurements. Patients are expected to normalize their weight in the first 6-12 months on ART.
- Classify nutrition status based on weight for height (children) or BMI (adults).
- Investigate any consistent weight loss over 2 or more consecutive visits. Remember to confirm that the scale is correctly calibrated and any heavy clothing was removed.

6.9.3 Monitoring for new HIV-related diseases and drug side-effects

- Use the standard clinical monitoring checklist for HIV patients to actively screen for symptoms of HIV-related diseases and/or drug side effects.
- Use the syndromic guide shown in **Table 16** on page 70 to identify the likely cause of symptoms and to choose the right primary and secondary management.
- A symptom that could be caused by an HIV-related disease or by a side-effect is more likely a side-effect if it started or worsened after the start of medication.
- Circle all symptoms that are likely drug side-effects on the patient card.
- Change the ART regimen if medically indicated (see below).
- Write any new HIV-related disease under *Notes* on the back of the patient card.

6.9.4 Indications for interrupting or stopping ART

- Stop ART in patients with chronic poor adherence. Consider stopping if 3 intensive counselling sessions have failed.
- ART should be stopped abruptly and completely if any of the following severe side-effects are suspected:
    - Lactic acidosis
    - Pancreatitis
    - Severe hepatitis
    - Stevens-Johnson syndrome

- Stopping ART in patients with less severe toxicity against EFV or NVP (skin rash, psychiatric effects) should be done by giving a 'tail' of the other 2 ARVs for 7 days to prevent 'monotherapy' due to the long half-life of NVP and EFV (see **Table 11** on page 48).

6.9.5 Selecting regimen and formulation for continuation

- Don't change regimen without clear medical indication. Unnecessary changes spoil future treatment options.

Do NOT change ART regimen:

- If a patient has moderate dizziness / drowsiness / nightmares in the first 2-4 weeks of starting a regimen with EFV (Regimen 3, 4 or 5. Also see footnote on page **48**).
- All children on Regimen 2 continue on the same regimen after their 15th birthday. These patients continue on Regimen 2A through adolescence and adulthood unless they develop toxicity or fail.

Change dosage and formulation:

- Review current weight for children and adjust dosing if necessary. Children on 1st line regimens change to adult formulation and dosage when their weight is over 25kg (see **Table 12** on page **48**).
- Start a new *ART Patient Card – Adult ARV Formulations* for children who change from paediatric to adult ARV formulation. File together with the old card in the same polythene sleeve.

Change ART Regimen:

- Use **Table 11** on page 48 to select the appropriate alternative regimen. Change patients with significant side-effects immediately. Change patients with troubling side-effects that did not improve after 2 months of symptomatic treatment.
- Children who were on paediatric 2nd line regimen (Regimen 9P) routinely change to standard adult 2nd line regimen (Regimen 7A) once they **weigh over 35kg**. This is to reduce the pill burden while continuing on an equally effective regimen.
- Add any new regimen to the *ART Regimens* history section on the card header and specify any non-standard regimen here.
- Patients with multiple contraindications and/or side-effects may need a NS regimen (see Section 6.6.4 on page 50)

6.9.6 Routine TB screening

- Screen all patients at each visit for signs of active TB using 4 standard screening questions
  - Cough of any duration
  - Fever
  - Night sweats
  - Weight loss / failure to thrive / malnutrition

- Classify screening outcome as follows:
    - ***TB not suspected*** if none of the 4 signs are positive. In this case, the patient is very unlikely to have active TB.
    - ***TB suspected*** if one or several of the 4 signs are positive and thoroughly investigate further (full clinical exam, sputum for AAFB, chest x-ray, fine needle aspirate, etc.)
    - ***TB confirmed*** if the patient has a current confirmed episode of TB (clinical or lab diagnosis). Always confirm if the patient is currently taking TB treatment – initiate TB treatment without delay or provide intensive adherence support. Classify ***on TB treatment*** or ***not on treatment.***

6.9.7 Achieving optimal adherence

Key facts for providers and patients

- Patients must take more than 95% of doses at the prescribed interval for life to prevent HIV drug-resistance. Repeated skipping of individual doses or repeated longer interruptions inevitably lead to development of HIV drug-resistance.
- **Example:** HIV drug-resistance will develop if a patient on Regimen 5A (TDF/3TC/EFV) continues to skip more than **3 tablets** in every **8 week** period.
- Children and adolescents on ART need special support.

Routine and targeted adherence support

- Ask at every visit:
    - Have you had any problems taking your ARVs? Can you explain what problems?
    - Were there any days when you did not manage to take all of your tablets at the right time? (Weekends, weekdays, mornings, evenings?)
- Remind patients of the importance of perfect adherence at every clinic visit:
    - Initial ART counselling
    - Follow-up group counselling
    - Individual counselling if any sign for poor adherence
- Give practical advice how to achieve optimal adherence:
    - Build ARVs into the daily routine (e.g. before washing the face, after evening meal)
    - Ask family or friends to remind
    - Set a daily alarm on the cell phone
    - Keep a ‘drug diary’ and mark every tablet taken
- Encourage honest dialogue. Avoid giving the impression of ‘policing’ the patient. Work with patients to help them achieve good adherence.
- Poor adherence always has valid reasons and most can be resolved: vomiting, transport problems, domestic problems, (perceived) side effects, psychological problems, wrong understanding, etc.

6.9.8 Special treatment support for children and adolescents

- Ask at every visit:
    - Who is responsible for supervising the taking of ARVs?
    - Who stands in for the guardian if s/he is away?
    - How do you give the tablets?
- Select a teacher or fellow student as treatment supporter for children attending boarding school.
    - Offer to transfer the child to the most convenient ART site closest to school.
    - Children (just like any other patients) who are adherent and stable on ART can be given 3 months of drug supply or more if necessary.

Managing the disclosure process

- Remind parents / care givers at every clinic visit that it is very important to talk to the child about their HIV infection and ART status.
- Don't isolate the child behind a "wall of secrecy and silence". Remember the child probably knows more than you think.
- Never lie or make up stories about the child's HIV infection and the drugs they are taking (e.g. misrepresenting ARVs as TB drugs or vitamins). Lies will eventually come out and undermine trust and make the child feel guilt, shame and will damage self-esteem and lead to poor adherence.
- Ask parents at every visit how far they have come in the disclosure process.
- Encourage parents to talk directly to their child in the environment they feel most comfortable. Offer to take part in the discussion if parents are uncomfortable doing this on their own.

From age 5-7 years:

- Explain that the child has a germ that requires taking drugs every day to keep the germ 'asleep'.

By age 11-13 years:

- Add more information gradually. By age 11-13 years, all of the following should have been explained:
    - Touching, cuddling and kissing are safe.
    - Sharing soap, towel, plates and cutlery is safe.
    - Don't share needles or razor blades. HIV and other diseases can travel in traces of blood and infect the other person.

From puberty / adolescence:

- Offer condoms; explain use on penis model; give at least 20 condoms
- Explain: Don't have penetrative sex without condom. HIV can travel in semen and vaginal fluid and infect the other person.
- Explain: It is still possible for you to have children later in life. The risk of passing HIV to your partner or to your baby is very low if you are taking your ARVs every day as prescribed.

6.9.9 Keeping track of the number of months since ART initiation

- Needed to determine when blood samples for routine VL monitoring are to be drawn.
- Calculate and document on the ART patient card the number of months since the patient first started ART. Simply calculate the number of months since first ART initiation, ignoring any potential gaps (periods of stopping / defaulting).
- Electronic medical record systems give automatic reminders when scheduled VL samples are due.

6.9.10 Monitoring for treatment failure / HIV drug resistance

Key facts for providers and patients

- ARV drug resistance starts gradually and the virus will still be partly suppressed for many months. Emerging drug-resistant virus does not cause any immediate clinical symptoms.
- HIV will grow resistant to more and more ARVs if a patient continues to take a failing ART regimen for several months. Accumulated multiple ARV resistance can make it difficult to find a second line regimen that still works.
- HIV drug resistance usually affects different ARVs of the same class.
- ***Example:*** HIV that has grown resistant to EFV will also be resistant to NVP, even if the patient has never taken NVP before.
- Drug resistant virus can be transmitted to other people.
- ***Example:*** About 5% of Malawians who got newly infected with HIV in 2009 acquired virus with some level of drug-resistance against d4T/3TC/ NVP.

Clinical suspicion and diagnosis of treatment failure

- **Suspect ART failure** if both of the following clinical conditions are met:
    - On ART for 12 months or more
    - New WHO clinical stage 3 or 4 condition
- For all **suspected ART failure** cases, look for indications for poor adherence in the last 6 months
    - Adherence was good:
        - Do a targeted VL or refer to have this done immediately.
    - Adherence was questionable:
        - Start intensive adherence support
        - Do a targeted VL after 3 months if adherence was satisfactory.
- See **Figure 6** on **page 67** for the interpretation of VL results.

Intensive adherence counselling and support

- Use ART diary, alarm clock, etc.
- Identify, counsel and educate effective guardian / treatment supporter
- Give monthly appointments, do pill counts and deliver adherence counselling.

Viral load (VL) testing

Key facts for providers and patients

- VL is the best measure for the level of progression of HIV infection.
  - VL = number of viral particles per ml of blood.
  - More virus ⇨ Faster destruction of CD4 cells ⇨ More severe immunosuppression.
- VL testing is expensive.
- VL testing uses an advanced lab method (RNA-PCR) on a blood sample. It can be done from:
  - Dried blood spot (DBS): Transport in plastic bag with desiccant at ambient temperature, sample viable for 3 months or more (see Section 6.4.4 on page 33).
  - Blood plasma: Transport in cooler box to lab within 24 hours.
- VL is required to confirm suspected ART failure (clinical and/or CD4-based).
- Routine VL monitoring is being scaled up gradually from 2011 to 2015.
- The VL schedule is designed to detect ART failure early while avoiding unnecessary tests to save costs:
  - Patients harbouring drug-resistant HIV when starting ART may have a high VL after **6 months** on ART. This can be from infection with drug-resistant HIV or after taking sdNVP. Otherwise, a high VL at 6 months is an important sign for poor adherence.
  - After that, patients who are adherent and clinically well have a low risk of ART failure. Therefore, routine follow-up VLs are done at **2 years**, **4 years**, **6 years**, **etc**. after ART initiation.
  - Do additional targeted VLs outside of this schedule when suspecting ART failure.

When to do VL

- **Routine scheduled** VL is done for all patients at specific times after ART initiation:
  - At 6 months, 2 years, 4 years, and every 2 years thereafter.
  - Collect catch-up VL sample at the next opportunity if the regular schedule was missed. Continue with the regular schedule (determined by the time since ART initiation).
- **Targeted/Repeat**
  - **Only** for patients who have received intensive adherence support.
  - **Only** if we are confident adherence in the last 3 months was good.
  - Mandatory before starting 2nd line ART to confirm suspected ART failure.

Interpretation of VL

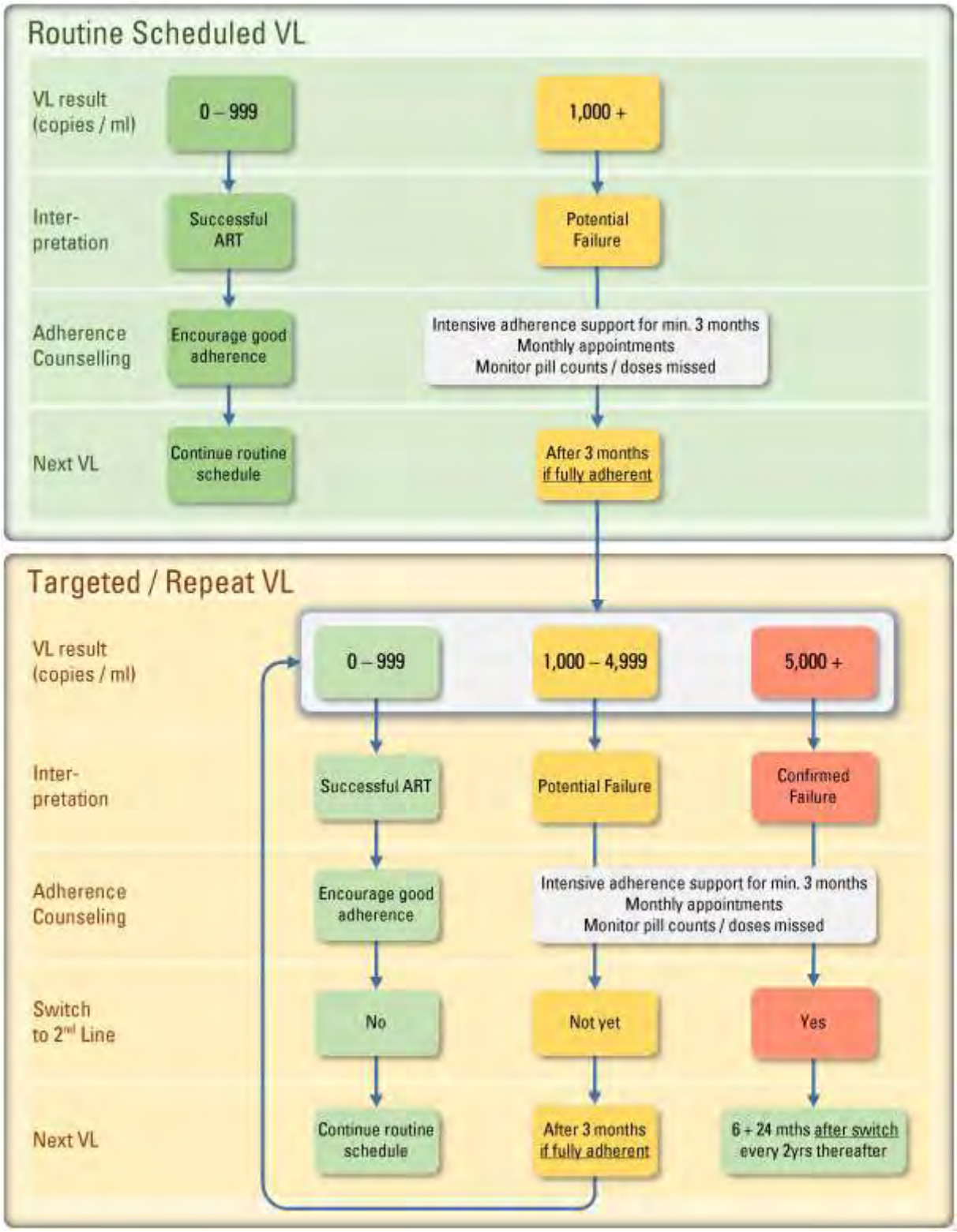
- **Routine scheduled** and **Targeted / Repeat VL** are classified and interpreted differently!

Start 2nd line ART only if:

1. Patient has already received intensive adherence support for at least 3 months.
2. Adherence in the 3 months before drawing the Targeted / Repeat VL was good.
3. Targeted / Repeat VL is 5,000 or higher.
4. Patients with good adherence and 2 or more follow-up results of 1,000 – 4,999 are likely to have drug-resistant virus. Discuss with senior clinician and consider starting 2nd line.

- Reset the clock for routine VL monitoring: 6, 24 months, etc. after switch to 2nd line.

Figure 6: Interpretation of routine scheduled and targeted VL results



6.9.11 Updating follow-up outcomes

- Regularly review all patient cards and keep an appointment register to identify patients who are overdue for their appointment as soon as possible.
- Try to contact the patient or the named guardian by phone or by home visit from 2 weeks after the missed appointment. Confirm from ART Patient Card that consent was given for home visit.
    - Patient is alive: counsel to return to the clinic as soon as possible and continue treatment.

  - Patient has stopped, died or transferred out: update outcome and date of outcome on patient card and in register.

- 'Defaulter' tracing is expensive and time-consuming. Prioritize patients on ART and HCC patients who are eligible to start ART.
- Loss to follow-up:
  - Patient is overdue for the appointment and is not known to have stopped ART, died or transferred to another facility.
  - Classify as 'defaulted' if the patient has run out of ARVs 2 or more months ago (based on the number of tins given at the last visit).
- Patients who are alive but known to have stopped ART (for any reason) should be classified as 'stopped' and not as 'defaulted'.
- Ask guardians to notify the clinic if an ART patient has died. Bring back the patient health passport and/or ART ID and any remaining ARVs.

Table 16: Symptom-based identification and management of ARV side-effects

Body pains, weakness

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
AZT, 3TC	Severe anaemia: Hb <7 g/dl	Stop AZT, consider transfusion	Substitute AZT, continue ART without gap
d4T, ddI, AZT	Lactic acidosis (LA): shortness of breath, nausea Serum lactate: suspect: 2-5 mmol/l, confirmed: ≥5 mmol/l	*Any suspected LA:* Stop all ART immediately IV fluids, treat at hospital	Do not re-start ART before lactic acid <2mmol/l Can re-start ART with AZT after suspected LA Never give d4T, AZT, ddI after confirmed LA Can use ABC or TDF containing regimen

Fever

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Onset independent of drugs: Bacteraemia, malaria	FBC, MPs, blood culture, urine dipstick		
Onset within 8 weeks of starting drugs: ABC, NVP, EFV	ABC/NVP/EFV hypersensitivity: Body pains, vomiting, diarrhoea, abdominal pain, sore throat, cough, shortness of breath, rash, jaundice	Any suspected hypersensitivity: Stop all ART immediately, treat at hospital	Do not re-start before symptoms have resolved Never use NVP or ABC again Replace NVP with EFV and ABC with TDF

Slimming: Cheeks, forearms, buttocks, legs (often prominent veins) Fattening: Back of neck ('buffalo hump'), breast, stomach, and waist

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
d4T, ddI, AZT, LPV/r, 3TC, TDF, HIV EFV	Lipodystrophy (from ART / HIV itself) Gynaecomastia (from EFV)	Reassure patient Substitute likely causative ARV	Consider surgery for extreme gynaecomastia

Skin Rash

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Onset before starting drugs: Seborrhoeic dermatitis ("bumpy itch")	HIV-related skin rash	Adults only: Promethazine 25 mg 12-hourly Adults or children (lower dose): Chlorpheniramine (Piriton) 10 mg 8-hourly Calamine lotion	Consider scabies, etc.
Onset within 8 weeks of starting drugs: NVP, ABC, Cotrimoxazole, EFV	Mild hypersensitivity Macular/popular rash not involving mouth, eyes, and genitalia No fever, body pain, weakness, etc.	Continue EFV containing regimen, reassure: initial EVF rash mostly resolves spontaneously. Continue on half dose NVP (if on NVP starter pack) for further 2 weeks Adults only: Promethazine 25mg 12-hourly Adults or children (lower dose): Chlorpheniramine (Piriton) 10 mg 8-hourly Calamine lotion	If no improvement on half dose NVP, stop NVP Substitute to EFV once rash has resolved. If patient unable to take EFV, consult with ART specialist for alternatives

Upper GI symptoms: Nausea, vomiting

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
AZT, LPV/r, d4T, 3TC	Lactic acidosis ? (see '*Body pains and weakness*') Jaundice? (see 'Yellow eyes')	Adults only: Promethazine 25 mg up to 12-hourly Adults or children (lower dose): Chlorpheniramine (Piriton) 10 mg up to 8-hourly-oral rehydration solution(ORS)	If no lactic acidosis: try to continuing the same ART regimen If persistent, substitute

Lower GI symptoms: Diarrhoea, lower abdominal pain

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Onset before ART initiation: HIV-induced	Stepwise empirical treatment	Stepwise empirical treatment of chronic HIV diarrhoea (see page 19)	
Onset within 6 weeks of starting drug: LPV/r, AZT, d4T, 3TC	Drug toxicity	For adults only: Loperamide 2 mg 8-hourly (mainly for LPV/r induced diarrhoea)	Try to continue same ART regimen If persistent substitute

Severe upper abdominal pain, nausea and vomiting

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
d4T, ddI, 3TC	Pancreatitis Serum amylase >1.5 times above upper normal limit	Stop all ART immediately Treat at hospital	Restart ART after complete remission Use TDF- or AZT-containing regimen
NVP, EFV, alcohol, viral hepatitis	Acute fulminant liver failure Liver function tests	Discontinue ART immediately Treat at hospital Identify cause and manage accordingly	Never re-start NVP or EFV if this was the suspected cause Reinitiate ART one month after jaundice is resolved, and LFT <2.5 of upper normal limit

Yellow eyes

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Viral hepatitis, alcohol, ATV/r, NVP, INH, EFV, ABC, severe malaria, cancer	LFT and ultrasound scan to differentiate: Viral hepatitis, cirrhosis, drug hepatitis, primary liver cancer, metastases	Discontinue ART immediately if jaundice develops on ART. See footnote **10** on page **49** if patient is on ATV/r. Identify cause and manage accordingly (LFT, ultrasound, hepatitis serology).	Never re-start NVP or EFV if this was the suspected cause. Re-initiate ART 1 month after jaundice has resolved and LFT <2.5 times upper normal limit.

Swollen face and eyelids, particularly in the morning/tiredness, too much or too little urine

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Onset before starting drugs HIV, diabetes, hypertension	Confirm nephropathy with serum creatinine	Identify cause and manage accordingly	Adjust ART dosage according to creatinine clearance
Onset within 1 year of starting drugs: TDF, streptomycin	Confirm nephropathy with serum creatinine	Admit to hospital Substitute TDF to AZT (or d4T) without gap Stop streptomycin	Adjust ART dosage according to creatinine clearance

Drowsiness, confusion, nightmares, psychosis

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
EFV	Neuropsychiatric EFV toxicity	Usually disappears by itself without the need to discontinue ART Take EFV before bed	If intolerable replace EFV with NVP

Leg pain, numbness or burning, inability to walk

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Onset before starting drugs: HIV neuropathy Onset or worsening after starting drugs d4T, ddI, INH, vincristine Onset independent of drugs Alcohol, diabetes	Mild peripheral neuropathy (PN): no sleep disturbance	Amitryptiline 25 mg nocte for 4 weeks Pain control using WHO analgesic ladder	If no improvement after 4 weeks: stop amitryptilline, continue analgesics Substitute d4T with AZT or TDF without gap
	Moderate PN: sleep disturbance	Both: Substitute d4T with AZT or TDF without interruption of ART (gap) WHO analgesic ladder	
	Severe PN: severe pain, muscular weakness		

6.9.12 Immune reconstitution inflammatory syndrome (IRIS)

Key facts for providers and patients

- A small number of patients may get worse in the first 6 months after starting ART.
- The most common causes for this are (in the order of likelihood):
    - Undiagnosed / untreated OI, mainly TB
    - Poor adherence to ART
    - Drug-resistant TB (if on TB treatment)
    - IRIS
- IRIS is an over-aggressive response of the body's defence system caused by a sudden recovery on ART.
- IRIS appears as a severe bout / worsening of an OI:
    - TB
    - Cryptococcal meningitis
    - Herpes zoster
    - KS
    - Hepatitis
- IRIS should only be considered if the more common causes for worsening have been ruled out.
- Patients who start ART with very advanced AIDS are at a higher risk of developing IRIS.

Management of IRIS

- Confirm that ART is actually taken as prescribed.
- Continue ART if ART toxicity has been ruled out as the underlying cause.
- Treat the OI.
- Consider TB treatment failure if worsening occurs after more than one month on TB treatment.
- Admit severe cases to hospital.
- Seek specialist advice on whether NSAIDs and/or prednisolone should be given.

6.10 Management of labour and delivery

Ascertain HIV status

- Review HIV testing page in health passport on admission.
- Offer PITC[12] if never tested or tested negative more than 3 months ago.

Provide ART

- Mothers already on ART: continue the same ART regimen at regular prescribed intervals. Pregnancy / breastfeeding are no indication to change women from any previous ART regimen.
- HIV positive mothers not yet on ART / who interrupted / stopped ART: emergency ART initiation
    - Start lifelong TDF/3TC/EFV (Regimen 5A) as soon as possible, during labour or after delivery.
    - Deliver individual ART counselling and IEC before discharge.

Reduce obstetric risk of HIV transmission

- Use a partogram to allow early detection and management of prolonged labour.
- Artificial rupture of membranes (ARM) increases the risk of HIV transmission.
    - ARM is not indicated if labour is progressing well.
    - If prolonged labour due to poor uterine contraction: perform ARM at ≥6cm cervical dilation and augment with oxytocin (pitocin).
- Do not perform routine episiotomy except for specific obstetric indications (e.g. vacuum extraction).
- Avoid frequent vaginal examinations.
- Do not 'milk' the umbilical cord before cutting.

6.11 Newborn and postnatal care

- Follow regular post natal care.
- Do not suction with a naso-gastric tube unless there is meconium-stained liquor.
- Immediately after birth, wipe the baby dry with a towel to remove maternal body fluids.
- Give BCG and oral polio vaccine after birth to all babies born to HIV infected mothers (as for all other infants).

6.12 Initiating integrated mother/infant follow-up

- Ensure continued follow-up for HIV infected mothers and babies.
- Enrol baby in HCC before discharge from post natal ward:
    - Fill Exposed Child patient card, enter in HCC register.

12 There is no general time limit for offering PITC. Consider that other important interventions such as C-section or tubal ligation are also offered with emergency counselling very late in labour.

- Mothers on ART before delivery:
    - Confirm next ART appointment.
    - Synchronise mother's ART appointment with baby's first HCC visit. Aim for HCC enrolment at post-natal visit or first vaccination visit.
- Mother initiated ART in labour:
    - Fill ART patient card and enter in ART register.
    - Give regular 4 week ART + HCC appointment.
- If mother wants to continue HCC and ART at another facility:
    - Record 'transfer out' in HIV clinic and ART register and give mother her ART patient card and the baby's Exposed child card.

6.12.1 Infant NVP prophylaxis

Key facts for providers and patients

- NVP syrup is given to all babies born to HIV infected mothers.
    - NVP syrup shields the baby from HIV infection during the most risky time.
    - Give NVP syrup to the baby 24-hourly for 6 weeks.
    - All babies should take NVP syrup for the same duration regardless of the mother's ARV regimen and regardless if the mother was taking ARVs at all.
- Store NVP syrup bottles and syringe: dark, cool, clean and dry and out of children's reach.
- Use an old syrup bottle filled with water to show how to draw 1.5ml of syrup in the syringe.
- Hand out one example syringe where the 1.5ml line has been marked with a pen.
- Squirt the syrup in the back of the infant's mouth between the cheek and the gum to ensure it gets swallowed (use cup to demo).
- Rinse the dosing syringe carefully with clean water after every use and let dry.
- Bring back to the health facility at the 6 week vaccination visit all NVP bottles (whether used or unused). The nurse will check if the right amount was used.

Prescription and dispensing of NVP prophylaxis

- When to dispense NVP syrup for infant prophylaxis to take home:
    - At ANC (or maternity) as soon as the mother is known to be HIV-infected.
    - Unopened bottles of NVP syrup have a long shelf-life. Therefore never delay dispensing until later in pregnancy. Make sure the expiry date is at least 2 months after the EDD.
    - Ask at every following visit if the NVP syrup and the syringes are still available. Replace without delay any items that may have been lost or spoilt.
- Dispense **3** x 25ml-bottles of NVP syrup (with dosing syringe included).

Dosing

- The dose of NVP syrup remains the same for the whole 6 week period – do not change the dose according to age or body weight, etc.
- Use the standard dose (1.5ml) If birth weight is unknown (home birth / no scale).

Table 17: Dosing of NVP syrup for infant prophylaxis

Birth weight	NVP syrup (10mg per ml)
2500g or less	**1.0 ml** 24-hourly
Over 2500g / unknown	**1.5 ml** 24-hourly

Timing and duration

- Start giving NVP syrup to the baby as soon as possible after birth. The earlier the start, the more effective.
- NVP syrup can be started anytime between birth and 4 weeks of age if the mother presents late. Starting NVP prophylaxis later is less effective and may cause drug-resistant HIV if the baby is already infected (and needs to start ART).
- Stop giving NVP syrup when the infant is 6 weeks old. The infant will receive less than 6 weeks of prophylaxis if NVP syrup has been started late.

6.13 Post exposure prophylaxis (PEP)

Key facts for providers and patients

- HIV infection can be prevented after a high risk contact with body fluids from an HIV infected person.
    - Remove immediately as much as possible of the body fluid.
    - Immediately give a 3-day supply of PEP and start taking it as soon as possible.
    - Do assessment of risk and HIV test as soon as possible. Continue a 30-day course of ARV prophylaxis (PEP) if exposure is classified as 'risk' and exposed person is HIV negative.
- PEP, if taken correctly, reduces the risk of infection by 80%.
- ARVs taken for PEP are usually well tolerated.
- Keep ARVs for PEP at maternity for 24-hour access and at other well-advertised locations in every facility.
- Offer STI treatment and emergency contraception, when indicated, for rape victims accessing PEP.
- The risk of getting infected may be high or low, depending on the type of substance and contact. However, PEP should always be started if there is a possible risk of transmission (see classification in **Table 18** on page 78).

Classification of risk

- Use **Table 18** to find out if the exposure is a possible risk for infection.
- Obtaining a new HIV test from the source person can help to reassure that the risk is low, but PEP should still be given if the test result is negative as the person could be newly infected himself and may be in the window period.

Table 18: Classification of risk of transmission after exposure to HIV

	Substance	Type of contact	Source person
Risk	• Blood • Semen • Vaginal fluid • Cerebro-spinal fluid • Pleural fluid • Amniotic fluid • Synovial fluid • Ascites fluid	• Skin penetrated with contaminated needle (hollow or non-hollow) • Large amount of substance on mucous membrane • Sexual intercourse no condom • Risk substance on lacerated skin / open wound	• Regardless of known/unknown HIV status
No Risk	• Urine • Stool • Pus • Tears • Saliva • Sputum • Nasal secretions	• Risk substance on intact skin	

Immediate measures

- Remove infectious substance.
    - Wash exposed wounds and skin sites thoroughly with soap.
    - Flush mucous membranes with water.
    - Do not use bleach, antiseptics or other caustic substances.

Eligibility to start PEP (ARV prophylaxis)

- Any exposure classified as risk in the last 72 hours (see **Table 18**).
- Never refuse PEP on moral judgement about the kind of exposure (accident, negligence, rape, 'burst condom').
- New HIV test is mandatory to confirm negative HIV status,
    - BUT: Don't delay starting PEP if HTC is not immediately available (no test kits, night, etc.). Do HTC as soon as possible.
- PEP is safe in pregnancy and breastfeeding.
- Severe anaemia (<8g/dl) is contraindication for AZT/3TC.
- Severe renal failure is contraindication TDF/3TC.

How to start PEP

- Start taking PEP as soon as possible after high risk exposure, ideally within 2 hours.
- Starting PEP more than 72 hours after exposure is not effective and should not be done.
    - However, still do HTC at baseline, at 3 and 6 months.
- Explain dosage and importance of adherence.
- Mild side effects (nausea, etc.) are not a reason to stop PEP.
- Advise to return immediately if serious side effects are suspected.
- Advise all exposed adults to practice safe sex until confirmed HIV negative at 3 months.
    - Give 30 condoms and re-supply as requested.
- Do not stop breastfeeding.
- Write case details in PEP register (improvised).

Table 19: Post exposure prophylaxis regimens and dosage (number of tabs taken)

	Standard					Alternative			
Weight	**AZT** 60mg / **3TC** 30mg		**AZT** 300mg / **3TC** 150mg		**TDF** 300mg / **3TC** 300mg	**d4T** 6mg / **3TC** 30mg		**AZT** 300mg / **3TC** 150mg	
3.0 – 5.9 kg	1	1				1	1		
6 – 9.9 kg	1½	1½				1½	1½		
10 – 13.9 kg	2	2				2	2		
14 – 19.9 kg	2½	2½				2½	2½		
20 – 24.9 kg	3	3				3	3		
25 – 34.9 kg			1	1				1	1
≥ 35.0 kg					0 1			1	1

PEP follow-up

- At 30 days: (after completing ARV prophylaxis)
    - Assess adherence
    - Give 60 condoms
- At 3 months and 6 months: repeat HTC

Additional prevention measures after rape / sexual exposure

- Give emergency contraception (EC) within 72 hours if needed (see **Table 20**)
    - Repeat dose if vomiting occurs within 1 hour of taking EC.
    - Explain that next menstrual period should occur before or around the expected time.
- Consider giving presumptive treatment for STIs using **Table 21**

Table 20: Regimens and dose for emergency contraception

Contraceptive drug	Immediately	After 12 hours
Postinor 2 (750µg levonorgestrel)	2 tablets	
OR		
Lo-Feminal or Microgynon	4 tablets	4 tablets

Table 21: Dosing of standard presumptive STI treatment after sexual exposure

STI drug	Child <15 years	Adult
Benzathine pen. vials	50,000 IU/kg IM stat (max 2.4 million IU)	2.4 Mega Units IM stat
Gentamicin vials	7.5 mg/kg IM stat (max 240mg)	240mg IM stat
Erythromycin tabs	12.5 mg/kg 6-hourly for 14 days (max 500 mg per dose)	500mg 6-hourly for 7 days
Metronidazole tabs	5 mg/kg 8-hourly for 7 days (max 2 grams per day)	2g stat
Nystatin pessaries	N/A	100,000 units 12 hourly for 7 days

7 Monitoring and Evaluation

Key facts for providers and patients

- The HIV program relies heavily on accurate and timely data for planning, reporting to donors and for drug procurement and distribution.
- Data analysis and reporting is done from patient cards and clinic registers at most facilities, but electronic systems for monitoring will increasingly be used at sites with many patients.
- Reporting is done monthly for ANC, maternity and exposed child follow-up and quarterly for pre-ART and ART (see Table 22 on page 84)
- Cohort analyses are needed to report outcomes of patients in ANC, exposed child, pre-ART and ART follow-up. Cohort reports look at the current / latest status of all patients enrolled in follow-up and require a review of all patient records to classify primary and secondary outcomes before data can be aggregated for reporting.
- Reports from facilities are to be completed within 5 working days after the end of the reporting period.
- HIV Program reporting will be further integrated into the regular Health Management Information System. Monthly / quarterly facility reports will be entered directly into the District Health Information System at the District Health Offices for national reporting.

7.1 Definitions

PMTCT site

- A facility is counted as a PMTCT site if they have initiated on ART at least one pregnant or breast feeding woman during the reporting period.
- Depending on the mode of integration of PMTCT/ART interventions into the general health services, ART may be initiated in any of the following service points: ART, ANC, maternity, post-natal or U5 clinic.

ART site

- A facility is counted as an ART site if they had retained at least one patient alive on ART at the end of the reporting period.

ART status at registration

- Refers to the patient's status at the time of first registration at this ART clinic – this status will never change as long as the patient remains at this clinic.
- **First time initiation:** Never taken ART (triple ARV combination treatment) in the past. Having taken ARVs for prophylaxis (PEP, single dose nevirapine, AZT combination prophylaxis for PMTCT) does NOT count as having taken ART and is ignored for the *ART status at registration*.

- **Re-initiation**: Received ART (triple ARV combination for treatment) from another ART site in the past but has NOT been taking it for 2 weeks or more as of the day of registering at this clinic. Patients who have interrupted for 2 weeks or more need to take a starter pack for re-initiation (if started on a regimen containing NVP).
- **Transfer in**: Received ART from another ART site in the past and is currently taking ART or has interrupted for less than 2 weeks. Count as *Transfer In* regardless if the patient brings his old Patient Card or not ('official' or 'unofficial' transfer).

Defaulted / Lost to follow-up

- Patients are counted as 'defaulted' in the cohort report if they have not returned to the clinic and are not known to have transferred out, stopped or died.
- The following times apply in the different clinics:
    - HCC (HIV exposed children and pre-ART patients): 2 months after the *Next Appointment Date* given at the last visit.
    - ART: 2 months after the patient is expected to have run out of ARVs.
- Patients may revert to 'alive on ART' at the next cohort analysis if they return to the clinic and continue (pre-)ART

ART stop

- Patients are counted as 'stopped' if they are last known to be alive and have stopped taking ART. Stop is used regardless:
    - of the reason the patient has stopped (clinician's or patient's own decision).
    - if the ART interruption is intended to be permanent or temporary.
    - of the duration of the ART interruption at the time of doing the cohort analysis.
- Patients may revert to 'alive on ART' at the next cohort analysis if they re-start ART.

Died

- Patients are counted as 'died' if there is a reliable report about the patient's death. 'Died' is used regardless:
    - of the cause of death (HIV- or non-HIV related disease, accident, suicide or homicide).
    - if the patient was on ART or not at the time of death.

ART re-start

- Interrupted ART for more than 2 months while registered at the respective ART site. Update the number of re-starts in the ART clinic register whenever the patient re-started ART after defaulting or stopping for more than 2 months (i.e. returns after 'defaulting'). Patients who have interrupted for 2 weeks or more need to take a starter pack for re-initiation (if started on a regimen containing NVP).

ART adherence level

- Reporting of adherence levels is based on a classification of the number of doses missed at the last visit before the end of the quarter evaluated.

- The translation of the number of doses missed into adherence % depends on the number of days since the last visit. In practice, it is too complicated to consider varying intervals when analysing cohort adherence. Therefore, 2 monthly visits are assumed for all when classifying adherence for reporting.
- Patient who are supposed to take 1 tablet per day (e.g. Regimen 5A) and who have missed more than 3 tablets are classified as 'less than 95% adherent'.
- Patients who are supposed to take 2 tablets per day (e.g. Regimen 1A) and who have missed more than 6 doses are classified as 'less than 95% adherent'.

Table 22: Overview of M&E systems for integrated HIV program reporting

Service	M&E tools		Report cycle	Report elements			
	Patient card	Register		New registrations	Cohort outcomes		
					Definition of cohort	Primary outcomes	Secondary outcomes
ANC	–	ANC Clinic Register	Monthly	New first visits	• Registration group (6 months after first ANC visit)	–	(Final status at end of ANC) • HIV test status • On ART
Maternity	–	Maternity Register	Monthly	New deliveries	–	–	–
ART	ART Patient Card (separate cards for Paediatric and Adult Formulations)	ART Clinic Register	Quarterly	Patients newly registered at ART clinics	• Cumulative (all ever registered) • Registration group (survival analysis)	• Alive on ART • Died • Defaulted • Stopped ART • Transferred out	• ART regimen / formulation • Adherence level • Side effects • TB status • On CPT • Using FP
Pre-ART	HIV Care Patient Card, Pre-ART Child/Adult	HIV Care Clinic Register	Quarterly	Patients newly registered at HCC	• Cumulative (all ever registered)	• Alive in pre-ART care • Started ART • Transferred out • Defaulted • Died	• TB status • On IPT • On CPT • Using FP
Exposed child FUP	HIV Care Patient Card, Exposed Child Under 24 Months	HIV Care Clinic Register	Monthly	Patients newly registered at HCC	• Birth cohort: children who (would) have turned 2, 12 and 24 months of age	• Alive in exp. child FUP • Discharged uninfected • Started ART • Defaulted • Transferred out • Died	• Age when received DNA-PCR result • Latest HIV status

7.2 Reporting of registration data

- For all new patients registered, baseline data (such as age at registration, sex, pregnancy status, clinical stage, etc.) are recorded on patient treatment cards and copied into the clinic register.
- These details do not change over time and tallying of these data needs to be done only once when reporting on new patients registered during the reporting month or quarter.
- *Page summaries* in the clinic registers are filled as soon as each page is full. Count the number of circled values for each column on the page.
- **Monthly** or **quarterly registration reports** are obtained by adding the page summaries from each page in the respective reporting month or quarter.
- **Cumulative registration reports** are obtained by adding the data from the new monthly or quarterly registration report to the data from the previous cumulative registration report.
- Data elements in most sections should add up to the respective total number of patients registered.
    - Males, non-pregnant females and pregnant females must add up to the total number registered.
    - Age groups must add up to the total number registered.
    - ART status (first time initiations, re-initiations, and transfer ins) must add up to the total number registered.
- Some registration data (such as the number of patients with KS at the time of ART initiation) are counted separately and are not part of a section. These data elements are not expected to add up to the total number registered.

7.3 Reporting of cohort outcomes

- *Cohort analyses* are needed to measure outcomes of patients in follow-up.
- In principle, the outcome status of any patient ever registered can change at any time. Therefore, the records of all patients ever registered have to be reviewed each time a cumulative cohort outcome analysis is done. Current outcome data cannot be obtained by addition from the previous quarterly outcome data.
- Patient outcomes are considered as of the last day of the reporting period. Any events (e.g. death) that happened after that day are ignored in the respective cohort analysis, but will be counted in the next report.

Primary follow-up outcome

- The primary outcome shows if a patient has been retained alive in care or if he has dropped out and why.
- The primary outcome categories must add up to the total patients registered in the cohort.
- Table 22 lists the primary follow-up outcomes used for the different reports.
- For ART only, deaths are further classified according the time after ART initiation. The categories used are: death within 1st, 2nd, 3rd month after ART initiation or after 3rd month of ART initiation.

Secondary outcome

- Secondary outcomes are the latest treatment details among the patients retained alive in care.
- Secondary outcomes are counted directly from the cards of the patients retained alive in care, usually by looking at the last visit before the end of the month or quarter evaluated. This visit might be several months before the end of the quarter, for example if the patient is on long ARV dispensing intervals (as long as the patient is still classified as 'retained alive in care' at the end of the quarter evaluated).
- Each set of secondary outcome categories must add up to the total number of patients retained alive in care.
- Table 22 shows the secondary outcomes used for the different reports

Definition of cohorts for different program reports

- 3 slightly different methods are used to define cohorts for outcome analyses:
- **Cumulative cohort** (Pre-ART and ART): Follow-up status of all patients ever registered at the respective clinic. The number of patients with adverse follow-up outcomes (death, default, etc.) inevitably increases over time. The number of patients retained in care is calculated by subtracting all patients with adverse follow-up outcomes from the total patient ever registered.
- **Registration group cohort** *'Survival analysis'* in ART: Follow-up status of patients registered during the quarters that ended 12, 24, 36, 48 and 60 months ago (ART). *ANC cohort outcomes:* final status as of the last ANC visit for the women who started ANC 6 months ago. This method standardises follow-up times and makes outcome data comparable between sites and over time.
- **Birth cohort** (HIV exposed child follow-up): Follow-up status of children who (would) have turned 2, 12 and 24 months old. Patient cards are filed in batches by month and year of birth (birth cohorts) and only the cards of children born 2, 12 and 24 months ago are pulled out for reporting. Outcomes are counted separately for the 2-, 12- and 24-month birth cohort. Reporting is done monthly and a different birth cohort is covered in each reporting month. This method standardises ages and is used for children enrolled in HIV exposed child follow-up.

7.4 Record keeping and filing

7.4.1 Confidentiality of patient records

- All patient cards and clinic registers are property of the MOH and may only be kept at the respective facility or at the National Archives.
- Patient cards and clinic registers must be kept in a locked room and are only to be accessed by clinic staff responsible of providing the respective service and by the national supervision team. Patients and named guardians have access to their own patient card.

7.4.2 Use of clinic registers (ANC, Maternity, HCC, ART)

- Keep patient registration for each different service centralized in each facility: Use only one set of registers in each facility.
- Each patient has only one row[13] in each register: Continue using the same row for returning transfers and re-starts after default or stop.

[13] In the ANC register, each woman has one separate section with rows for each subsequent visit.

- Turn to a new page when starting to register patients in a new quarter. Leave any unused rows at the bottom of the previous page empty. This is necessary to separate the quarters when adding up page totals.
- Assign continuous registration numbers (by sequence of registration). Take care not to duplicate registration numbers.
    - Continue assigning cumulative registration numbers in the HCC- and ART-Register. These number series are never re-started.
    - Re-start assigning registration numbers annually for the ANC- and Maternity Register. Re-start with number 1 on the 1st of July.

7.4.3 Use of patient cards

- Each patient has only one patient card at any one time (Exposed child, pre-ART, ART). Attach another patient card once the old card is full.
- Patient cards are filed in polythene sleeves in lever arch files, up to 100 cards per arch file.
- Separate filing systems are used for the different types of patient cards:

Exposed Child Under 24 Months Cards

- File in batches by year and month of birth.
- Within each birth month, sort in ascending order by HCC registration number.
- Do not remove the cards of children who have started ART, died, defaulted or transferred out from this filing system.
- Files with birth cohorts who (would) have now reached at least age 3 years can be removed from the clinic for archiving.
- File DNA-PCR results in the polythene sleeve together with the 'pink card'.

Pre-ART Child / Adult Cards

- File cards in ascending order by HCC registration number.
- Prepare separate filing systems for **ACTIVE** (retained in pre-ART care) and **INACTIVE** patients (started ART, transferred out, defaulted, died).
- One arch file can hold approximately 100 cards.
    - Label the **ACTIVE** files with HCC numbers 1-100, 101-200, 201-200, etc.
    - Label the **INACTIVE** files with HCC numbers 1-200, 201-400, 401-600, etc.
- Each time the quarterly cohort analysis is done, update in the HCC register the outcome for patients who have dropped out of pre-ART (started ART, transferred out, defaulted or died). Straight after this, move these cards of from the **ACTIVE** to the **INACTIVE** filing system.

ART Patient Cards, Paediatric and Adult ARV Formulations

- File ART Patient Cards in ascending order by ART registration number.
- Prepare separate filing systems for **ACTIVE** (retained in ART) and **INACTIVE** patients (stopped ART, transferred out, defaulted, died).

- One arch file can hold approximately 100 cards.
    - Label the **ACTIVE** files with ART numbers 1-100, 101-200, 201-200, etc.
    - Label the **INACTIVE** files with ART numbers 1-200, 201-400, 401-600, etc.
- Each time the quarterly cohort analysis is done: update in the ART register the outcome for patients who have dropped out of ART (stopped ART, transferred out, defaulted or died). Straight after this, move these cards of from the **ACTIVE** to the **INACTIVE** filing system.
- Do not separate **Paediatric** and **Adult** cards into different files.

7.5 Ensuring adequate data quality

- Use only the standard national reporting forms.
- The clinic's own analysis and reports are checked by the PMTCT/ART supervision team each quarter from primary records.
- Copies of the checked reports are kept at the clinic.

8 Supply Management

Key facts for providers

- The HIV program requires an uninterrupted supply of huge amounts of very expensive drugs and lab supplies. In 2014, Malawi will spend over USD 100 million (MKW 43 billion) for HIV commodities.
- Commodity stock-outs lead to an interruption of life-saving health services. ARV stock-outs are especially serious because patients who interrupt treatment can develop drug-resistant HIV which can be transmitted to others.
- **Responsibilities:**
    - All health workers: support supply management by filling the standard MOH forms, patient cards, registers and reporting forms.
    - Officer in-charge of pharmacy: manage and account for all commodities received.
    - District Health Management Teams: coordinate and supervise.
- A dedicated HIV Program Logistics Team (**HIV Logistics**) working under MOH Depts. for Health Technical Support Services and for HIV and AIDS actively coordinates procurement, supply planning and distribution of drugs and lab supplies for the HIV and STI Programs.
- Contact HIV Logistics by email (**hivdeptlogistics@gmail.com**) or call **toll-free** on working days 7:30 – 17:00:
    - **5 91 91** (from Airtel phone)
    - **68 82** (from TNM phone)
    - **8000 80 89** (from MTL phone)
- Ask HIV Logistics for help and get an **authorization code before** any of the following transactions with ARVs and HIV test kits:
    - Getting additional supplies from warehouse.
    - Moving stocks from / to another facility.
    - Disposing expired / spoiled stocks.
- **Notify** HIV Logistics about (even if suspected):
    - Damaged or inappropriate stocks received.
    - Serious side effects.

8.1 HIV commodity supply cycle

- Table 23 shows the different commodity groups currently managed by the HIV Program.

Table 23: Drugs and testing supplies managed by the HIV Program

Commodity group	Examples	Supply*
ARVs	(All ARVs, incl. PEP and infant prophylaxis)	**E**
OI	Cotrimoxazole for CPT	**E**
	Isoniazid + pyridoxine for IPT	**E**
	Cotrimoxazole, other antibiotics, fluconazole, chemotherapy	**S**
STI	Standard / alternative antibiotics, acyclovir, clotrimazole	**S**
PIFP	Condoms, Depo-Provera	**S**
Analgesic	Morphine, codeine	**S**
DBS kits	for EID and VL samples	**E**
Tests	HIV and syphilis rapid test kits	**E**

Supply*: **E** = item managed exclusively through HIV Program. **S** = items supplemented by HIV Program in addition to essential medicine supplies.

- HIV commodities are delivered in the last month of each quarter from a central warehouse (Lilongwe) directly to all facilities.
- Distribution lists for all facilities are calculated based on the patient and stock reports collected during quarterly HIV Program supervision and reported through the Logistics Management Information System.
- Actively support the **quarterly supply cycle** and the **ongoing management** following the 11 steps in **Figure 7**.

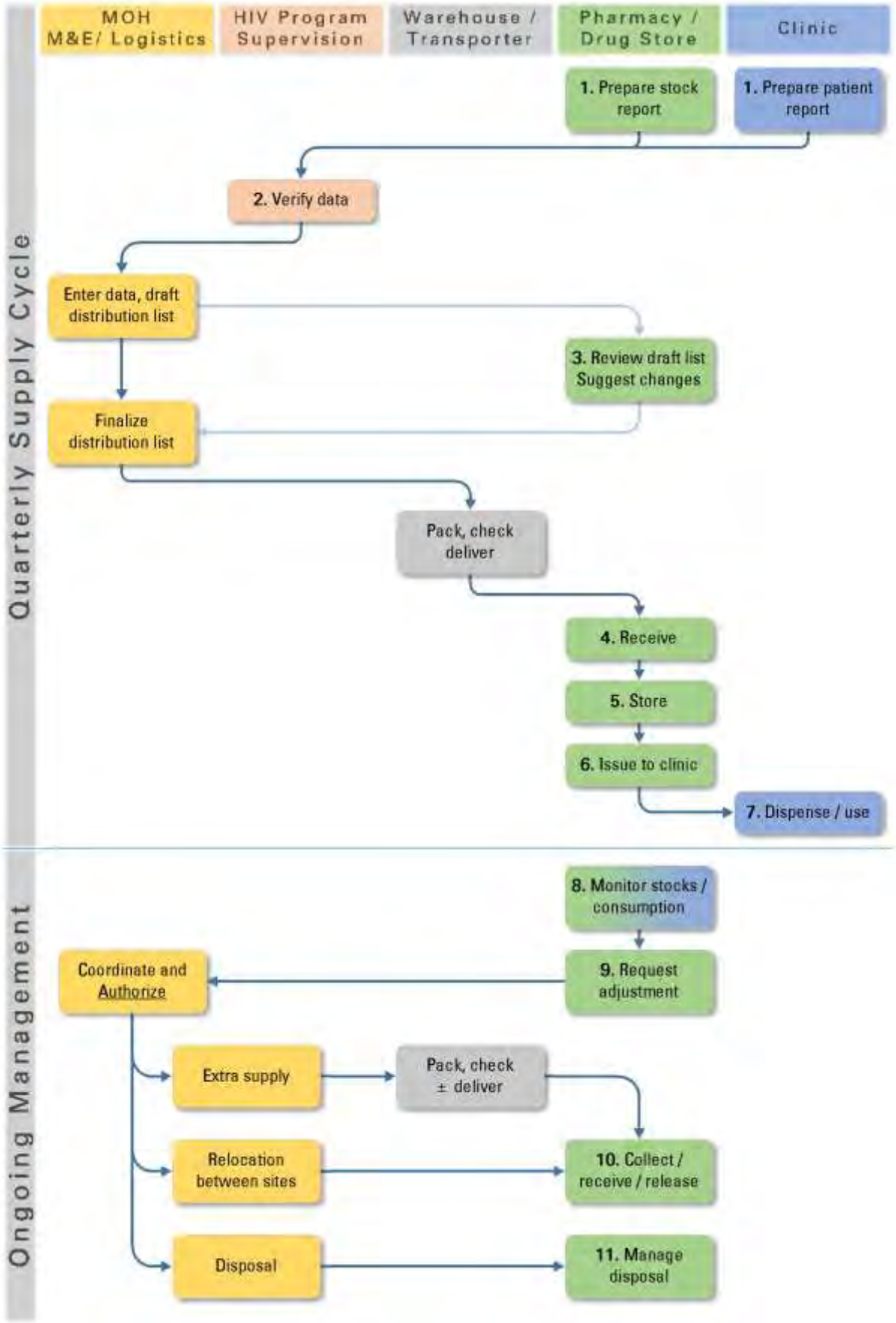
1. Prepare stock / patient report

- Confirm each commodity is sorted by expiry date.
- Do physical count of stock on hand (SOH). Exclude any units that may have already expired.
- Ensure all available stock is counted, including in bulk store, at the clinic / HTC rooms, etc.

2. Verify data

- Ensure all storage areas and patient records / registers are accessible on the day of supervision.
- The HIV Program supervision team will work with facility staff to verify:
    - Stock reports by doing a physical count.
    - Patient report by reviewing patient cards and registers.
- Check that the stock report filled during supervision is complete and accurate. The supervision team and the In-Charge of pharmacy are responsible for confirming this by signing the form.

Figure 7: Flowchart for HIV commodity supply management



3. Review draft distribution list

- **Quarterly consignments** are calculated by *HIV Logistics* from patient numbers and stock reports collected at the last supervision visit.
    - All ARVs and HIV test kits included should be about **3 MOS** (months of stock, see below).
    - Consignments are scheduled to arrive in the last month of each quarter
    - Facilities should have about **2 MOS** remaining when the new consignment arrives (site-level buffer). This should bring the total to about **5 MOS**.
- HIV Logistics circulate the *draft distribution list* to all members of the **Logistics Group** on the HIV Department website. Anyone can register with this group with his / her email on this website.
- Review and confirm that the items and quantities are correct and adequate for you. Submit any suggested changes (by email, SMS or phone) before the deadline shown on the draft list.

4. Receive consignment

- Inspect the entire consignment in the presence of a witness designated by DHMT/ facility In-Charge:
    - Physically count all re-packed / loose units. Originally sealed boxes do not need to be opened for counting of units. Add up total units received for each item.
    - Check expiry date for all items.
    - Write physical count for each item into the respective box on the *delivery note*. Write 0 (zero) for any items not received – don't leave any boxes empty.
- Sign, date and stamp the *delivery note* to confirm receipt of the items as indicated.
- The person signing on the delivery note is accountable for all items s/he has signed for. The In-Charge of pharmacy / facility will be held responsible for any discrepancies noted later.

5. Storage

- Immediately move all items received to a secure storage area (clean, dry, cool and off the floor).
- Enter quantity and date of receipts on *stock cards* without delay.
- Arrange items by expiry date to make it easy to follow the *First Expiry -First Out* principle (*FEFO*).

6. Issue to clinic

- Fill *Requisition and Issue Vouchers* for all commodity requests from the clinic.
- Always follow the *FEFO* principle.
- Immediately update *stock card* when moving items out of the pharmacy.
- Limit the amount of stock stored at the clinic to 1 week consumption.

7. Dispense / use

- Ensure that the patient has fully understood:
    - How and when to take their drugs.

  - Possible side-effects; which side-effects require coming to the health facility.

- Account for all HIV commodities dispensed. Specify type and quantity:
  - On *patient master cards* (ART, pre-ART, Exposed child)
  - *Dispensing registers* for special drugs (Diflucan)
  - *Daily Activity Registers (DAR)* for HIV test kits.
- The *DAR* is used for tracking use of HIV test kits.
  - Keep a separate register at all places where HTC is done.
  - Use separate pages for the different types of tests (Determine, Uni-Gold).
  - Test kits *used for clients* must match entries in the HTC Register.
  - The DAR includes sets of 3 carbonated sheets: keep white sheet at facility; send blue sheet to DHO; retain pink/yellow sheet for collection by HIV Logistics (MOH).
  - Fill monthly summary on HTC report by adding numbers from all DAR used at the facility.

8. Monitor stocks / consumption

- Do a **physical stock count** for all items (in store and at the clinic) and update stock cards:
  - On the last working day of each month.
  - When handing over pharmacy management to another staff member.
  - Whenever discrepancies are noted.
- **Calculate** average monthly consumption (**AMC**) and months of stock (**MOS**) for all ARVs and HIV test kits after doing the monthly physical count:

$$\mathbf{AMC} = \frac{\text{units used in last 3 months}}{3} \qquad \mathbf{MOS} = \frac{\text{stock on hand}}{\text{AMC}}$$

- Be alert: commodity shortages can be anticipated before they happen:
  - Large number of transfers in.
  - Patients moving to 2nd line or alternative regimens.
  - Rapid growth through new initiations.
- As soon as commodity **shortage** is **suspected or noticed**:
  - Contact *HIV Logistics* for additional supply (see below).
  - Inform all relevant staff members.
  - Prioritize use (e.g. HIV test kits for sick patients needing to start ART, women at ANC and maternity, etc.).
  - Shorten supply interval (e.g. give ARVs for 1 month instead of 3).
- Commodity **excess:** more than **5 MOS**, especially if units will expire before they can be used:
  - Contact *HIV Logistics* to request stock relocation (see below).

9. Request adjustment

- Call *HIV Logistics* as soon as possible if **shortage**, **excess** or **expiry** is noted.
- Before calling, prepare the following information:
    - Number of tins / bottles / tests remaining.
    - Expiry date
    - Number of patients on this regimen / approximate AMC.
    - When additional stocks are needed / to be sent to other site.
    - If own transport can be organized.
- *HIV Logistics* will:
    - Review the information and find out the reason for the problem.
    - Coordinate: **extra allocation from the warehouse**, **relocation of stocks between sites**, or register **disposal of expired commodities**.
    - Send a unique ***Authorization Code*** for each item by SMS or phone.
- Confirm receipt of authorization codes by sending 'OK' by SMS or by calling *HIV Logistics*.
- Fill a ***Registration Form for Relocation or Disposal of HIV Commodities*** for each adjustment.
    - Write the authorization code for each item on the form.
    - Keep Registration Forms in the pharmacy to account for all commodity transactions.
- Never relocate or dispose HIV commodities without *authorization code*. In exceptional circumstances (threatening stock-out and no phone coverage / no answer), stocks may be relocated and notification and *authorization codes* must be obtained at the earliest opportunity.

10. Collect / receive / release stock (from adjustment)

- When collecting extra consignments from the warehouse:
    - Ask for the size of the consignment and make sure it can be safely transported (security, sun/rain protection, etc.). Partial collection will not be allowed.
    - Make specific appointment and get directions from *HIV Logistics*.
    - Bring ID (passport, driving license, etc.) and official facility stamp.
    - Inspect the whole consignment. The collecting officer and a witness must fill, sign and stamp the delivery note as usual.
    - There is no need to fill a *Registration Form for Relocation* for extra allocations from the warehouse.
- Relocating stocks between facilities:
    - Fill a *Registration Form for Relocation* and write the *authorization code* for each item.
    - Keep the white copy of the form at the facility releasing the stock. This is mandatory to account for commodities given away to another site.
    - Give the pink copy to the facility receiving the relocated commodities.

11. Manage disposal

- Separate expired commodities from usable stock as soon as possible.
- Notify HIV Logistics, get ***Authorization Code*** and fill ***Registration Form for Disposal***
- Contact the District Pharmacist and arrange for transfer of expired items for controlled destruction.

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Second Edition | Feb 2014 | Ministry of Health, Malawi