Applications, comments 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.hiv.health.gov.mw) of the Dept. 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 to the 5th Edition

This 5th *Edition* of the *Malawi Guidelines for Clinical Management of HIV in Children and Adults* is implemented from January 2022. 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, laboratorians, 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, HIV testing and Paediatric HIV under the leadership of the Dept. 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 5th Edition is an adaptation of the latest WHO Recommendations[1].

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.

Universal ART eligibility for all PLHIV was introduced in the **2016** edition of these guidelines, following clear scientific evidence that patients should **start ART as soon as possible** after getting infected with HIV. **Patient benefits**: reduced risk of serious HIV-related illnesses that can occur even in the early stages of HIV infection when the CD4 count is still above 500. Early treatment benefits outweigh the risk of side effects because the regimens are easy to take and usually well tolerated.

[1] Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach (World Health Organization, July 2021).

Updated Recommendations on Service Delivery for the Treatment and Care of People Living with HIV (World Health Organization, April 2021).

Updated Recommendations on HIV Prevention, Infant Diagnosis, Antiretroviral Initiation and Monitoring (World Health Organization, March 2021).

Population benefits: successful ART greatly reduces the risk of onward transmission to sexual partners and from mother to child.

Malawi surpassed the UNAIDS 90-90-90 treatment targets in 2020. Aiming to eliminate HIV as a public health threat by 2030, the National Strategic Plan for HIV (2020-2025) includes the **95-95-95 treatment targets.** Malawi is very likely to achieve these even more ambitious targets ahead of schedule.

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**.

Acronyms and Abbreviations

3HP	3 months of Isoniazid and Rifapentine
3TC	Lamivudine
6H	6 months of daily isoniazid for TB preventive therapy
ABC	Abacavir
ANC	Antenatal care
ARM	Artificial rupture of membranes
ART	Antiretroviral therapy
ARVs	Antiretroviral medicines
ATV/r	Atazanavir / ritonavir
AZT	Zidovudine
B6	Pyridoxine
BCG	Bacille Calmette-Guérin
Benzyl-pen	Benzyl penicillin
BF	Breastfeeding
BMI	Body mass index
CO	Clinical Officer
MNCH	Maternal, neonatal and child health
CPT	Cotrimoxazole preventive therapy
CrAg	Cryptococcal antigen
CSF	Cerebrospinal fluid
CTX	Cotrimoxazole
CXR	Chest X-ray
DBS	Dried blood spot
DIC	Drop-in centre
dL	decilitre
DL	Detection limit (for viral load)
DNA-PCR	Deoxyribonucleic acid polymerase chain reaction
DSM-5	Diagnostic Statistical Manual for Mental Disorders, version 5
DTG	Dolutegravir
E	Ethambutol
EFV	Efavirenz
EMB	Ethambutol
eMTCT	Elimination of mother to child transmission of HIV
EPI	Extended Programme on Immunization
EPTB	Extra-pulmonary tuberculosis
FDC	Fixed dose combination
FP	Family planning
H	Isoniazid
Hb	Haemoglobin
HCC	HIV Care Clinic

Acronyms and Abbreviations

HIV	Human immunodeficiency virus
HTS	HIV testing services
IEC	Information, Education and Communication
IM	Intramuscular
INH	Isoniazid
INSTI	Integrase strand transfer inhibitor (ARV)
IPT	Isoniazid TB preventive therapy
IRIS	Immune reconstitution inflammatory syndrome
IV	Intravenous
KS	Kaposi sarcoma
LAM (urine-)	Mycobacterial lipoarabinomannan (LAM) antigen in urine
LFT	Liver function test
LPV/r	Lopinavir/ ritonavir
MA	Medical Assistant
MCH	Maternal and child health
MDR-TB	Multi-drug resistant tuberculosis
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	Pneumocystis carinii (jiroveci) pneumonia
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis for HIV using antiretroviral medicines
PHQ-9	Patient health questionnaire for depression screening
PI	Protease inhibitor (ARV)
PIFP	Provider-initiated family planning
PMTCT	Prevention of mother to child transmission
PO	Per os / orally/ by mouth
PrEP	Pre-exposure prophylaxis for HIV using antiretroviral medicines
PSHD	Presumed severe HIV disease
PTB	Pulmonary tuberculosis
PWID	People who inject drugs
PZA	Pyrazinamide
R	Rifampicin
S	Streptomycin
SP	Sulphadoxine / pyrimethamine
STI	Sexually transmitted infections

Acronyms and Abbreviations

SUD	Substance use disorder
TDF	Tenofovir disoproxil fumarate
TF	Therapeutic feeding
VIA	Visual inspection (of the cervix) with acetic acid
VL	Viral load
WLHIV	Women living with HIV
ZDV	Zidovudine

1 How to use these guidelines?

These guidelines standardise integrated clinical management of HIV infected patients and of HIV exposed infants using a public health approach. They also incorporate relevant protocols from other national guidelines (TB, FP, STI, PrEP, Malawi Standard Treatment Guidelines (MSTG), HIV Syphilis and Viral Hepatitis guidelines (HSVH), EID, VMMC, Cervical cancer 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 Patients and Providers

- The most important information and key instructions are presented in a 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 concise as possible.

The standard package of clinical HIV interventions

Chapter 4 on page 11 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

Chapters 5 – **23** (page **13** – **110)** explain in detail **how** to deliver each of the HIV interventions. The protocols and directions are the same for *all* service delivery settings. These chapters also contain several checklists, tables and flow charts which can be laminated and used as job aids in the consultation room.

2 Summary of key policies

Key Facts: Key policies

- All HIV infected people should **start ART as soon as possible** for their own health and to prevent on ward transmission of the virus.
- Rapid ART initiation should be offered on the same day to people who are ready to start.
- Serious HIV-related diseases can occur even in patients with high CD4 count (>500), without any previous symptoms. Rapid ART greatly reduces this risk.
- Current ART regimens are easy to take and rarely cause serious side-effects.
- **ART** for all HIV infected people is the **most effective HIV prevention method** available: Successful ART leads to very low levels of virus in the blood and in body fluids (viral suppression). Viral suppression greatly reduces the risk of sexual or mother-to-child transmission.

Table 1: Key new and existing policies

eMTCT Strategy		Page
New	Test all pregnant women and their sexual partners for hepatitis B at first antenatal visit unless they are already known to be hepatitis B positive. Link all hepatitis B positives for treatment eligibility screening.	**60**
New	In districts with high HIV incidence: Give an HIV self-test at discharge from maternity for sexual partners who don't come for professional testing to the facility. Re-test all breastfeeding women not known to be HIV positive at family planning/ MNCH/ EPI clinics between 6 to 9 months after delivery.	**108**
New	Give 6 weeks of AZT/3TC/NVP (2P) prophylaxis to high-risk HIV exposed infants; low risk infants receive 6 weeks nevirapine syrup as infant prophylaxis	**107**
HIV-related diseases		
Old	Short-course amphotericin B + flucytosine for induction phase treatment of cryptococcal meningitis.	
New	Single high dose liposomal amphotericin B + two weeks of flucytosine and fluconazole for treatment induction of cryptococcal meningitis for adults	**23**
Old	Amoxicillin 500mg 8-hourly for 5 days as standard treatment for mild to moderate community acquired pneumonia	
New	Amoxicillin 1000mg 8-hourly for 5 days as standard treatment for mild to moderate community acquired pneumonia	**27**
Old	No corticosteroids pre-medication before IV paclitaxel administration for KS	
New	Pre-medicate with corticosteroids before IV paclitaxel administration for KS	**30**

	HIV and COVID-19	Page
New	Don't use ARVs for HIV treatment for the prevention or treatment of COVID-19	**35**
New	Recommend full COVID-19 vaccination to all eligible PLHIV, including pregnant and breastfeeding women	**35**
	Standard monitoring of HIV patients	
New	Use semi-quantitative rapid CD4 count test for PLHIV initiating ART or with suspected clinical treatment failure where quantitative CD4 testing is not available.	**43**
	Preventive services for HIV patients	
New	Give 3HP to all PLHIV initiating ART (without contraindications) using a fixed-dose combination tablet of rifapentine/isoniazid.	**50**
	Management of non-communicable diseases in PLHIV	
New	Screen all ART patients 40+ years annually for diabetes using blood glucose testing.	**55**
New	Routinely screen all ART patients with treatment adherence challenges for depression and substance abuse.	**56**
	Understanding ART regimens and formulations	
Old	Stopping any NVP or EFV containing regimen requires giving a 7-day *'tail'* of the other 2 ARVs in the regimen	
New	No need for a 7-day tail after stopping NVP or EFV	**61**
	Prescribing and dispensing ARVs	
Old	Patients initiating standard or alternative first line ART must be reviewed clinically after 1 month and then every month for the first 6 months	
New	Patients initiating standard or alternative first line ART must be reviewed clinically at month 1, 2, 3 and 6 after initiation	**72**
	Continuing ART	
Old	Start / transition all children weighing 3 - 19.9kg to regimen 9P (ABC/3TC + LPV/r)	
New	Start / transition children weighing 3 - 19.9kg to regimen 15PP (ABC/3TC + DTG) using dispersible 10mg DTG tablets	**75, 82**
New	Intensive adherence support for patients with unsuppressed viral load must be provided by an experienced clinician or nurse, not by a lay provider	**84**
New	Emphatically welcome treatment interrupters to return to ART, either self-motivated or after active follow-up. Openly advertise at OPD and HTS that interrupters are welcome to restart ART at this facility.	**85**
Old	The first VL is scheduled 6 months after ART initiation for all ART patients. Thereafter, a new VL is scheduled every 12 months after the last test.	
New	For children on paediatric regimens, pregnant and breastfeeding women, a new VL is scheduled every 6 months after the last test.	**90**

Post exposure prophylaxis (PEP)		Page
Old	Four weeks of AZT/3TC is the standard paediatric PEP regimen	
New	Four weeks of ABC/3TC + DTG is the standard paediatric PEP regimen	**111**
Pharmacovigilance		
New	Use the mobile phone-based electronic reporting form (Medsafe-360 USSD platform) in addition to paper-based reporting of all suspected adverse drug reactions	**116**

3 Implementation plan

- The paediatric DTG policy was approved in March 2021, implementation started in June 2021, scaled up to all health facilities in October 2021.
- All other new policies in this guideline come into effect in January **2022**.
- The policy changes will be communicated to all public, CHAM and private facilities.
- Detailed implementation arrangements for NCDs including mental health will be shared in separate SOPs.
- Refresher trainings of health service providers in HIV clinical management based on this 5th Edition will commence in Q1 of 2022.
- All diagnostic and treatment commodities included in this guideline are already available in country or in pipeline.
- The next (**6th**) Edition of these guidelines is scheduled for release in **2024/25**. Any potential policy or protocol updates to be implemented before release of the next edition of the guidelines will be communicated.

4 Integrating HIV clinical services

HIV services are part of the 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.

HIV Care Clinic (HCC)

- ***HCC*** is an integration in the same clinic setting for:
    - **HIV exposed children**
    - **ART**
- Establish HCC services in ART and MNCH clinics.
- ***HCC*** is designed to facilitate clinical monitoring, preventive services and ART for family members affected by HIV.
- Make family appointments to encourage family members to attend clinic 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	Exp Child FUP	ART Clinic	TB Clinic	STI Clinic	Integr. outreach
Diagnosing HIV infection and exposure	**15**	Ascertain status at each visit	(●)	●	(●)	●	●	●	●	●	(●)	●	●	(●)
HIV-related diseases	**22**	When diagnosed	●	●		(●)	(●)		●	●	●	●		●
HIV and COVID-19	**35**	At every clinical review visit								●	●	●		●
Provider initiated family planning (PIFP)	**46**	At every scheduled visit									●			●
Cotrimoxazole preventive therapy (CPT)	**48**	At every scheduled visit				●	●			●	●	●		●
TB Preventive Therapy (TPT)	**50**	Dispense for 1, 2 and then 3 monthly thereafter									(●)			●
Infant and child feeding	**105**	At every visit	(●)			●	●		●	●	●			●
Starting ART	**74**	As soon as possible	(●)			●	●	●			●	●		
Continuing ART	**81**	Monthly for the 1st 3 months; 3-6 m. thereafter	(●)			●		●			●	●		●
Management of labour and delivery	**103**	On admission					●							
Newborn care and postnatal follow up	**104**	After delivery					●	●						
Integrated mother/infant follow-up	**104**	At first opportunity when mother known HIV+					●	●	●		●			
Infant HIV prophylaxis	**106**	At first opportunity when mother known HIV+				●	●	●	●	(●)				●
Pre-exposure prophylaxis (PrEP)	**109**	Dispense and test for HIV every 3 months			●								●	●
Post exposure prophylaxis (PEP)	**110**	As soon as possible after risk exposure	●				●						●	

5 eMTCT Strategy

Key Facts: eMTCT Strategy

- Dual elimination of mother-to-child transmission (EMTCT) of HIV and syphilis is a public health priority for Malawi.
- Commitment to the triple eMTCT of HIV, syphilis, and hepatitis B is forthcoming.
- Multiple strategies are available to prevent the transmission of HIV from mother to child and to reduce the HIV burden among mothers and their children.
- These strategies are grouped into the ***4 Prongs of the national PMTCT*** program.
- Implemented together, these strategies have resulted in a drastic reduction of HIV infections among children. Further scale-up is expected to virtually eliminate new paediatric HIV infections and AIDS deaths among children.
- Key interventions from all 4 PMTCT prongs are covered in these guidelines, but some medical and non-biomedical interventions are beyond the scope of this document and are covered in separate guidelines.

Prong 1: Primary prevention of HIV infection in the general population

- Behaviour change communication to reduce risky sexual contacts
    - Separate strategy
- Provision of condoms
    - **Section 11.1** Provider initiated family planning (PIFP)
    - Separate condom strategy
- Voluntary medical male circumcision for HIV negative men to reduce the risk of HIV acquisition and onward transmission
    - Separate MOH guidelines
- Scale-up of HIV testing in high-yield settings for early diagnosis and ART referral
    - **Section 6.1**: Routine ascertainment of HIV infection status for children and adults
- ART provision for all HIV infected adults and children, (regardless of CD4 count and/or clinical stage) to reduce morbidity and mortality and to prevent onward transmission
    - **Section 16.1**: When to start ART
    - **Section 18.7**: Achieving optimal adherence
- Viral load monitoring and timely switch to 2nd or 3rd line for patients on ART to ensure viral suppression and to reduce the risk of onward transmission
    - **Section 18.10**: Monitoring for treatment failure / HIV drug resistance
- Pre-exposure prophylaxis
    - **Section 22**: Pre-exposure prophylaxis (PrEP)
- Post-exposure prophylaxis
    - **Section 23**: Post exposure prophylaxis (PEP)

Prong 2: Prevention of unintended pregnancies among HIV positive women

- Provider initiated family planning in ART clinics
    - **Section 11.1** Provider initiated family planning (PIFP)
    - Separate MOH guidelines: National Sexual and Reproductive Health and Rights Policy

Prong 3: Preventing transmission of HIV from infected women to their children

- Provider initiated testing at MNCH settings for early HIV diagnosis and ART initiation
    - **Section 6.1**: Routine ascertainment of HIV infection status for children and adults
    - **Section 20.1**: HIV, syphilis and hepatitis B status ascertainment at maternity
- Initiation of lifelong ART for all HIV infected pregnant and breastfeeding women (regardless of CD4 count and/or clinical stage) to reduce the risk of transmission to the child.
    - **Section 16.1**: When to start ART
- Safe obstetric practices
    - **Section 20.3**: Reduce obstetric risk of HIV transmission
- Provision of infant HIV prophylaxis with 2P or Nevirapine
    - **Section 21.3**: Infant HIV prophylaxis
- Infant feeding advice to reduce the risk of transmission through breastmilk
    - **Section 21.2**: Infant and child feeding

Prong 4: Care, treatment and support for HIV-infected women and their children and families

- **Section 4**: Integrating HIV clinical services
- **Section 6.2**: Routine ascertainment of HIV exposure status for children under 24 months
- **Section 21.1**: Integrated mother/infant follow-up
- **Section 8**: HIV-related diseases
- **Section 11**: Preventive services for HIV patients
- **Section 11.2**: Cotrimoxazole preventive therapy (CPT)
- **Section 11.3**: TB Preventive Therapy (TPT)
- **Section 12**: Management of non-communicable diseases in PLHIV
- **Section 18.9**: Special treatment support for children and adolescents

6 Diagnosing HIV infection and exposure

Key Facts: HIV Testing Strategy

- **Main** HIV testing program goals:
    - Identify as **many** HIV infected people as possible.
    - Identify them as **early** as possible after getting infected.
    - Ensure they **start ART as soon as possible**.
    - Facilitate return to ART for patients who have discontinued ART.
    - Identify HIV negative high-risk people and link them to prevention services
- **Provider Initiated Testing:** Ascertain HIV status for all patients attending health services (OPD, ANC, maternity, TB, STI, FP, U1 / U5, adult and paediatric wards).
- 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 testing with their sexual partner. Ensure that all children, regardless of age (including adolescents) of HIV infected parents are tested. Ensure all siblings of HIV-infected children have been tested.
- 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.
- Examine all children under 12 months of age with confirmed HIV antibodies for clinical conditions that constitute *Presumed Severe HIV Disease* (PSHD, see **section 6.3** on page **19**). All these need to start ART without delay.
- All patients need a confirmatory HIV rapid test to rule out any possibility of clerical errors or fraudulent access to ART (also see **section 16.3** on **page 76**):
    - Before starting ART
    - All children under 24 months who start ART need a confirmatory DNA-PCR using a new DBS sample. This should be collected on the day of starting ART (also see **section 16.3.2** on **page 76**).
- See the **2022 Malawi Integrated HIV, Syphilis and Viral Hepatitis Testing Services Guidelines** for details.

6.1 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 before (follow risk assessment in HSVH testing guidelines)
    - claims to have been tested any time in the past, but without documentation (being on ART at a named facility counts as documented evidence)
    - there is clinical concern for HIV infection
- Do not test patients who are currently on ART as results may be false negative.
- 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.

6.2 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 is not known to be positive and has not been tested at delivery or thereafter.
    - 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. Mothers may have been recently infected themselves and the risk of onward transmission to the child is very high under these circumstances.
- There is no indication to routinely retest a child who has tested negative after the period of HIV exposure has ended, unless there is reason to believe a new exposure has happened (abuse, transfusion, cutting etc.)
- **Figure 1** on **page 17** shows the conditions for testing of mother and/or child and the actions to be taken.

Figure 1: Ascertainment of HIV exposure / infection in children under 24 months

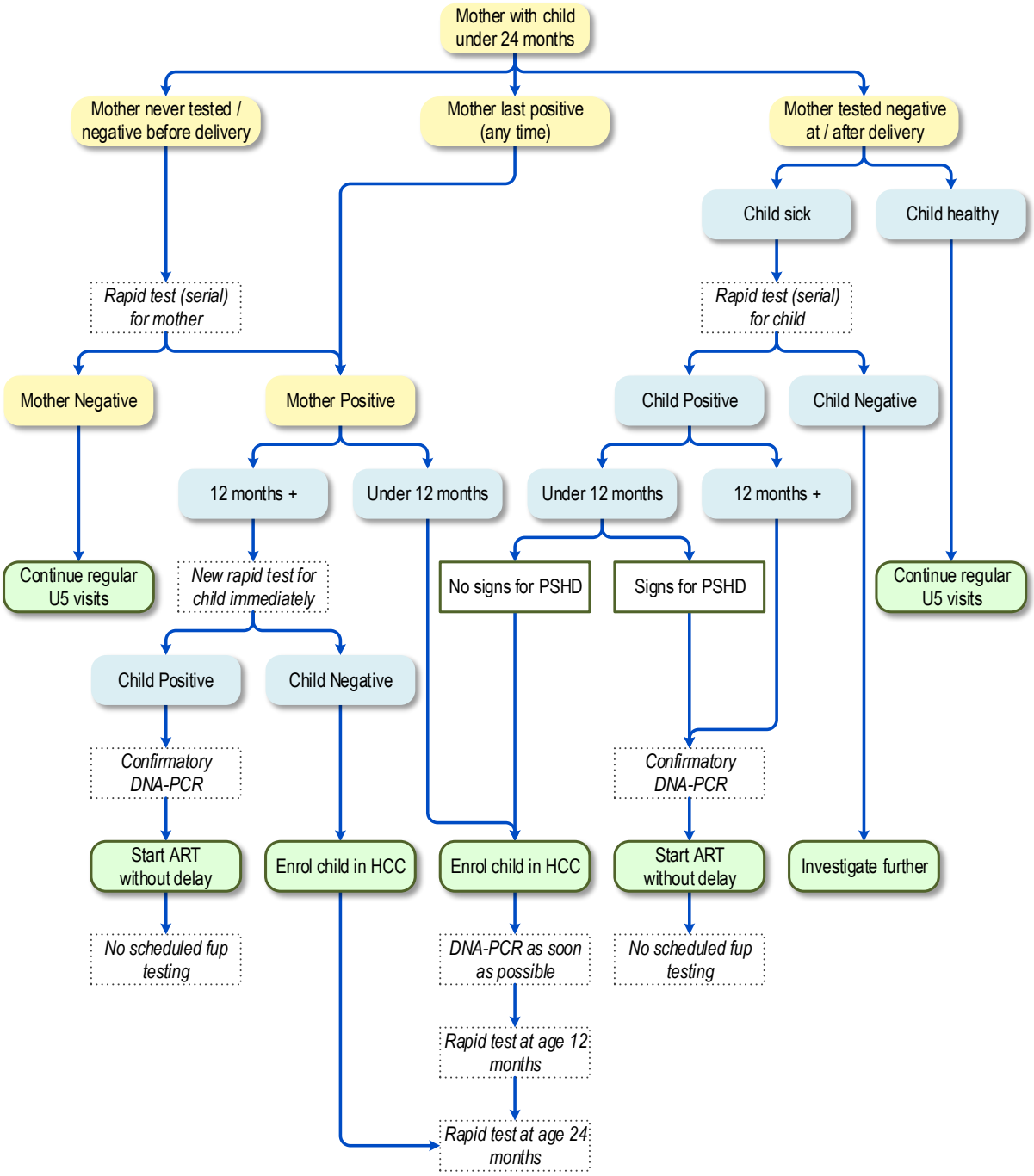

Table 3 on **page 18** shows the routine testing schedule for children under 2 years of age, the selection of the type of HIV test (DNA-PCR or rapid antibody test) depending on the child's age and the correct interpretation and action depending on the test result.

Table 3: HIV testing in children: 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. Confirmatory DNA-PCR at ART initiation.
	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 from HIV+ mother	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. Confirmatory DNA-PCR at ART initiation.
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 from HIV+ mother	Continue HCC, repeat rapid test at age 24 m.
			Positive	HIV Infected	Start ART. Confirmatory DNA-PCR at ART initiation.
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. Confirmatory (parallel) rapid test at ART initiation.

6.3 Presumed severe HIV disease in infants (PSHD)

- Infants infected with HIV develop life-threatening HIV-related disease much more quickly than older children and adults.
- Conduct point of care DNA-PCR testing on site for timely clinical decision making, if available.
- However, it may take too long to **confirm HIV infection** in a sick infant using **DNA-PCR**.
- Under the age of 12 months, a positive **HIV rapid antibody test does not confirm HIV infection** because maternal antibodies pass through the placenta and remain in the baby's blood for several months.
- However, a positive rapid antibody test in an infant with the following clinical signs makes **severe HIV disease** (AIDS) very likely:

Table 4: Definition of presumed severe HIV disease (PSHD)

Infant with positive rapid antibody test PLUS:		
Combination of 2:	**OR**	**At least 1:**
• Oral thrush • Severe pneumonia • Severe sepsis		• Severe unexplained wasting / malnutrition not responding to treatment • Pneumocystis pneumonia • Candidiasis of oesophagus, trachea, bronchi or lungs • Cryptococcal meningitis • Cerebral Toxoplasmosis (from age 1 month)

- **Start ART** as quickly as possible for infants with PSHD – do not wait for a DNA-PCR result.
- Collect a DBS sample for DNA-PCR confirmatory testing on the day of starting ART (see **section 16.3** on **page 76**).

7 WHO Clinical Staging

Key Facts: WHO Clinical Staging

- Untreated HIV infection leads to a gradual destruction of the immune system.
- Different HIV-related diseases appear at different levels of immune suppression.
- Most of these diseases can also occur in HIV negative patients, but they are a lot more common and more severe in HIV infected patients.
- Actively search for and treat HIV-related diseases at ART initiation and at every follow-up visit. ART alone may not save the patient.
- Patients may have several HIV-related diseases at the same time. Write all diseases found on the ART Patient Card.
- 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 stage-defining conditions are specific to children under 15 years and others are specific to adults.
- 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 remains critical for identifying patients with advanced HIV disease and for general clinical care
- WHO clinical staging is mandatory for all HIV patients, regardless of CD4 count availability.
- Complete staging for every new HIV patient.

Table:5 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	• Upper 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

8 HIV-related diseases

Key Facts: HIV-related diseases

- Tuberculosis (TB) and cryptococcal meningitis (CM) are responsible for a large proportion of AIDS deaths.
- Many cases are either not diagnosed or diagnosed and treated late.
- Actively screen all PLHIV for CM and TB using clinical symptom checklists and the rapid diagnostic tests.
- Urine LAM (for disseminated TB) and CrAg (using serum/plasma/whole blood/CSF) tests are rapid, simple and cheap. A positive result is always an indication to treat.
- A patient on ART who develops a new or worsening HIV-related disease may not be adherent and/or have drug-resistant HIV. Do a targeted VL to rule out treatment failure. (See **section 18.10** on **page 88**).

8.1 Routine urine LAM and serum CrAg screening

- Routinely test **ALL children 5 years and above and adults** who meet the definition of advanced HIV disease using:
    - **Urine LAM** for disseminated TB and
    - **CrAG** for cryptococcal meningitis (CM) / subclinical cryptococcaemia (serum or whole blood).
- Patient groups with advanced HIV disease include:
    - All children <5 years old are considered to have advanced HIV disease until they are clinically stable with a suppressed VL on ART
    - CD4 < 200 cells/ml before ART initiation / while on ART.

      Note that a CD4 test result is not required to conduct urine LAM and CrAg testing if other criteria (see below) are met.
    - WHO stage 3 or 4
    - Every ART experienced patient with viral load 1000+ (on ART for > 1 year)
    - "Seriously ill" PLHIV:
        - All PLHIV admitted as in-patient
        - HIV infected patients with any of the following danger signs:
        - **Adults:** ≥30 breaths/min; heart rate ≥120 beats/min; unable to walk unaided; ≥39°C
        - **Children**: lethargy; unconsciousness; convulsions; unable to drink or breastfeed; repeated vomiting; fever ≥39°C; tachycardia; tachypnoea
- Document TB urine LAM and CrAg results in patient health passport and on ART patient card.

- Urine LAM result
    - **Positive:** treat for TB, regardless of other TB diagnostics (see **section 8.2.6** on page **26**)
    - **Negative**: does not rule out TB. Continue with TB investigations in symptomatic patients according to TB guidelines.
- Serum/Blood CrAg
    - **Positive:** Confirms Cryptococcocaemia but require CSF sample to confirm meningitis, assess for active meningitis signs, do lumbar puncture and CrAg on CSF, treat for active meningitis or give pre-emptive antifungal therapy (see **sections 8.2.1** and **8.2.2** on **page 23**).
    - **Negative:** does not rule out CM. Continue with CSF testing (CrAg, India ink, GXpert) and other investigations for patient with meningitis signs.

8.2 Management of HIV-related diseases

8.2.1 Cryptococcal Meningitis (CM)

Key Facts: Cryptococcal meningitis (CM)

- CM mortality is high. Early diagnosis and treatment are essential.
- The new treatment regimen with liposomal amphotericin B, flucytosine and fluconazole improves survival significantly and must be used whenever possible.
- Liposomal amphotericin B has much lower toxicity than the regular amphotericin B deoxycholate. This means it can be given at higher doses which is more effective.
- Liposomal amphotericin B and TDF can be used together if kidney function is monitored. Routine substitution to non-TDF-based ART regimen is unnecessary.

Clinical signs

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

Diagnosis / investigations

Lumbar puncture (LP) feasible / not contraindicated

Cryptococcal antigen (CrAg) rapid test or India Ink stain on CSF.

LP not feasible

CrAg rapid test on serum, plasma or whole blood.
Note: start CM treatment without delay for patients with acute meningitis signs + positive serum CrAg test, even if confirmation through CSF CrAg is not immediately possible.

Primary management

Admit

Daily therapeutic spinal tap if high intracranial pressure, severe headache or vomiting is present (up to 30 ml per puncture).
Do NOT give adjunctive corticosteroids during CCM treatment.
If not already on ART, start ART only 5 weeks after antifungal treatment initiation.
Do not interrupt ART if already on ART.

Before giving **Liposomal** Amphotericin B: Pre-hydrate and supplement electrolytes: 1000ml normal saline solution (weight-based for children) + Potassium 2 tabs 12- hourly + Magnesium trisilicate 1 tab 24-hourly. Give Magnesium trisilicate in the evening to avoid absorption interactions with DTG.

Induction phase

Recommended regimen: if all meds are available

Adults

Liposomal amphotericin B

10 mg/kg IV over 3 hours, single dose.

+ Flucytosine tabs

100mg/kg/day divided into 4 doses (6-hourly) for 14 days

+ Fluconazole tabs/IV

1200mg/day (24-hourly) for 14 days

Children

Liposomal amphotericin B

6mg/kg IV over 6 hours 24-hourly for 7 days.

+ Flucytosine tabs

100mg/kg/day divided into 4 doses (6-hourly) for 7 days

+ Fluconazole tabs

Start after the 7-day course of Liposomal amphotericin B + flucytosine is completed
12mg/kg (max 800mg) 24-hourly for 7 days

Alternative regimen 1: if liposomal amphotericin B is not available

Requires FBC monitoring: at baseline and 2-3 times in the second week of treatment.

Fluconazole tabs

Adult: 1200mg 24-hourly for 14 days
Child: 12mg/kg (max 800mg) 24-hourly for 14 days

+ Flucytosine tabs

100mg/kg/day divided into 4 doses (6-hourly) for 14 days

Alternative regimen 2: if flucytosine not available

Requires FBC, Creatinine and K+ monitoring: at baseline and 2-3 times in the second week of treatment.

Liposomal Amphotericin B

3-4 mg/kg IV over 6 hours 24-hourly for 14 days
Give up to 6 mg/kg for treatment failure or serious disease.

+ Fluconazole tabs

Adult: 1200mg 24-hourly for 14 days
Child: 12mg/kg (max 800mg) 24-hourly for 14 days

Consolidation phase

Fluconazole tabs for 8 weeks

Adult: 800mg 24-hourly
Child: 12mg/kg (max 800mg) 24-hourly

Maintenance phase

Fluconazole tabs, lifelong

Adult: 200mg 24-hourly
Child: 6mg/kg 24-hourly

8.2.2 Cryptococcocaemia

Clinical signs

Often no clinical signs. Note: the lack of meningitis signs does not rule out active CM.

Diagnosis / investigations

Serum CrAg test positive but CSF is negative for CrAg and/or microscopy (Indian ink).

Assess for meningitis signs. If positive, do full investigation and treatment for active CM (see **section 8.2.1**

Primary management

Fluconazole tablets

800 mg 24-hourly for 2 weeks, *then*
400 mg 24-hourly for 8 weeks, *then*
200mg 24-hourly for life

8.2.3 Toxoplasmosis

Clinical signs

New convulsions, possibly reduced consciousness, focal neurological symptoms

Very unlikely in patients with CD4 above 200 cells/ml

Diagnosis

Brain CT or MRI scan where possible.

Primary management

Clinical improvement on this treatment makes toxoplasmosis very likely.

Start ART after 4 weeks to prevent toxoplasmosis IRIS.

Recommended regimen

Cotrimoxazole tablets

Adult: 2 x 960 mg tabs 12-hourly for 6 weeks, *then*
1 x 960 mg tab 12-hourly for 3 months, *then*
1 x 960 mg tab 24-hourly for life

Child: **Call DHA for paediatric dosing**

Alternative regimen: if cotrimoxazole is not tolerated

Clindamycin tablets

600mg 6-hourly for 6 weeks

+ Pyrimethamine tablets

200 mg on day one
50mg 24-hourly for 6 weeks

8.2.4 Oral candidiasis

Clinical Signs

Multiple whitish or red patches anywhere inside mouth

Primary Management

Recommended regimen

Nystatin oral suspension

Keep in mouth as long as possible; apply to mother's nipples if breastfeeding

Adult: 4ml 6-hourly for 7-14 days

Child: 1ml 6-hourly for 7-14 days

Alternative regimen: if severe or no response to nystatin

Fluconazole tablets

Adult: 100 mg 24-hourly for 14 days

Child: 6mg/kg on day 1 then 3mg/kg daily for 14 days

8.2.5 Oesophageal candidiasis

Clinical signs

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

Primary management

Fluconazole tablets

Adult: 200mg 24-hourly for 14 days

Child: 12mg/kg day one then 6mg/kg for 14 days

8.2.6 TB

Clinical signs

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

Diagnosis / investigations

Clinical exam and history

Often difficult to confirm in PLHIV. Clinical diagnosis is critical, particularly in children with possible TB signs/symptoms and TB contact, even if investigations are not clear.

Xpert MTB-RIF

2x sputum

Also consider: ascites, CSF, lymph gland material, pleural or pericardial fluid

CXR

Microscopy

Fine needle aspiration of lymph nodes; CSF

Biochemistry

Pleural tap: straw coloured effusion? CSF

Urine LAM

See **section 8.1**on **page 22**

Focused Assessment with Sonography for HIV associated tuberculosis (FASH)
Test for COVID-19

Primary and secondary management

See National TB guidelines

8.2.7 Pneumonia

Clinical signs

Productive cough; chest pain; fever; tachypnoea / dyspnoea

Diagnosis / investigations

Infiltrations on CXR

Investigate for COVID-19 and TB, particularly if there is no improvement on standard antibiotic treatment.

Management: mild and moderate cases

Child: **See IMCI guidelines**
Adult, primary regimen:

Amoxicillin tabs
1000 mg 8-hourly for 5 days
If no improvement: secondary regimen

Doxycycline tabs
100 mg 12-hourly for 5 days
or Erythromycin tabs
500mg 6-hourly for 5 days

Management: severe cases

Child: **See IMCI guidelines**
Adult, primary regimen:

Amoxicillin + clavulanic acid
625mg tabs 8-hourly for 5-7 days
+ Macrolide antibiotic (erythromycin or azithromycin tabs)
If no improvement: secondary regimen

Ceftriaxone 2g IV + macrolide antibiotic or doxycycline
Add Gentamycin if no response.

8.2.8 Pneumocystis jirovecii pneumonia (PJP)

Clinical signs

Extreme shortness of breath; dry cough; +/- fever

Severe pneumonia in infants <12 months

Diagnosis / investigations

O_2 saturation: hypoxia, drop on exertion

CXR: Diffuse interstitial or hyperinflation; perihilar “batwing” infiltrates

Test for COVID-19

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

Primary management

Admit and give oxygen

Cotrimoxazole tablets 960mg

Adult: 120mg/kg/day, divided into 3 doses (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 5mg tablets

Give only if patient is hypoxic / in respiratory distress

Give 15-30 minutes before cotrimoxazole

Adult: 8 tablets 12-hourly for 5 days, then
8 tablet 24-hourly for 5 days, then
4 tablets 24-hourly for 11 days

Child: 2mg/kg 24-hourly for 7 days, then
1mg/kg 24-hourly for 7 days, then
0.5mg/kg 24-hourly for 7 days

Secondary management

Clindamycin

600mg 8-hourly for 21 days

+ Primaquine

30mg 24-hourly for 21 days

8.2.9 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 and refer to hospital

Child:

Benzyl Pen

50,000 IU/kg IV or IM stat

+ Gentamycin

7.5mg/kg slow IV / IM stat

Adult:

Chloramphenicol

1g IV or IM stat

+ Gentamycin

240mg slow IV or IM stat

Secondary management

Hospital level:

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 Chloramphenicol (if pneumococcal sepsis is suspected)
25 mg/kg IV 8-hourly (max. 1g per dose)

When stable continue to complete 10 days:

Amoxicillin
40 mg/kg/day, divided into 3 doses (8-hourly)
+ Ciprofloxacin
15 mg/kg 12-hourly

Adult:

Ceftriaxone
2g IV 24-hourly

When stable continue to complete 10 days:

Ciprofloxacin tablets
750 mg 12-hourly
+ Amoxicillin tablets
1g 8-hourly

8.2.10 Kaposi sarcoma

Clinical signs

Single or multiple purple patches or nodes, mainly mouth, skin, conjunctiva, lung, GI tract; +/- enlarged lymph nodes; +/- oedema / pleural effusions.

Children: presentation differs from adults. Enlarged lymph nodes in the neck, axilla, and inguinal regions are most common. Classic skin lesions are absent in nearly half. Adolescents similar to adults; may have woody oedema. CD4 count may be completely normal.

Diagnosis / investigations

Usually clear clinical picture

Adults: consider KS even without skin or oral lesions if no response to EPTB therapy within 4 weeks. Confirm with histology whenever possible.

Children: Look for firm, bulging, enlarged lymph nodes, woody oedema (hard, firm swelling) in the inguinal area / legs; darkened skin or mouth/palate lesions +/- subcutaneous nodules. Some children may have periorbital oedema and sub-conjunctival haemorrhage.

Primary management

All patients: ART, analgesia, symptomatic treatment

Child: Refer to oncology

KS treatment in children depends on severity of presentation; consult with paediatric specialist.

Adult: Delayed chemotherapy

For KS stage T0 (only skin KS without oedema). Start chemotherapy only if no improvement after 3 months on ART or if worsening of KS after ART initiation.

Note: If CD4 count result is not available, stage using T & S only to minimise treatment delays

Adult: Immediate chemotherapy

For KS stage T1 if: adult KS in mouth (other than hard palate) OR internal organs involvement (esp. lungs or GI tract) OR nodular skin KS OR oedema

Note: Ensure strictly IV injection as infiltration causes burns. Document therapy, disease extent, and response in health passport; examine for recurrence at every visit.

Recommended regimen for adults

Paclitaxel IV

Monitor FBC and LFT at baseline and before every paclitaxel infusion. Transfuse before paclitaxel dose if Hb <8 g/dl. Delay chemotherapy if absolute neutrophil count is below 500.

Monitor clinically for neuropathy and hepatitis.

Give chlorphenamine (Piriton) tablets 4mg + paracetamol 1gr + dexamethasone 12mg IV/PO 30-60 min before paclitaxel. Monitor for allergy / anaphylaxis (rare).

Paclitaxel vials must be stored in fridge.

Wear gloves, gown, and N95 mask when preparing.

Paclitaxel dosing and administration

Dose is based on body surface area m^2 (BSA). Read BSA from **Figure 8** on **page 130** or use online calculator. Round the dose to the nearest 5mg.

Dilute in 500ml normal saline solution, slow IV infusion (1-3 hours).

Paclitaxel regimen

100mg/m^2 BSA every 3 weeks.

Give 6 cycles. Stop if severe side-effects.

Refer to oncology if no improvement or severe side effects.

Alternative regimen

Bleomycin

Adult: 15 IU/m^2 IV every 3 weeks for 6 cycles

Child: 0.5 mg/kg IM every 3 weeks for 6 cycles

+ Vincristine IV

Adult: 2mg IV every 3 weeks for 6 cycles

Child: 0.05 mg/kg IV (max 2mg) every 3 weeks for 6 cycles

Review after every cycle:

Severe neuropathy / constipation: stop vincristine

Sign for lung fibrosis (incl. cough, shortness of breath): stop Bleomycin. Cumulative max. lifetime dose for Bleomycin is 400 units

Poor response: Refer for secondary management.

Secondary management

Oncology department

Doxorubicin or other drugs may be used according to oncology protocols.

8.2.11 Lymphoma

Clinical Signs

Swollen lymph nodes, weight loss, low-grade fever, night sweats, anaemia

Consider lymphoma if treatment for suspected lymph node TB shows no improvement after 4 weeks.

Management

Refer for lymph node biopsy, management in oncology department

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8.2.12 Cervical (pre-) cancer

Clinical signs

Possibly vaginal discharge, but often no early symptoms.

HIV infected women are at high risk of cancer from human papilloma virus co-infection. Screen actively every 12 months.

Diagnosis / investigation

Human papilloma virus (HPV) DNA test
Detects DNA from high-risk HPV types in vaginal and/or cervical samples
Recommended from 30 years of age
If positive, do VIA

Acetic acid visualisation (VIA)
Use good light source.
Expose cervix with Cusco speculum.
Apply 5% acetic acid to cervix with large cotton swab for 2 minutes.
Inspect cervix.

Pap smear
Scraping cells from the cervical surface for microscopy for signs of HPV infection and pre-cancerous or cancerous changes.

Primary management

Follow national cancer guidelines

Refer cervical cancer patients to central hospital for advanced treatment options or palliative care.

8.2.13 Herpes zoster (shingles)

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

If face affected (ophthalmic division of the 5th cranial nerve):

Refer to eye specialist
Monitor for secondary bacterial infection

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

8.2.14 Seborrhoeic dermatitis

Clinical signs

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

Primary management

Clotrimazole or Miconazole cream / ointment

Hydrocortisone 1% cream/ointment

Ketoconazole shampoo for scalp

Secondary management

Ketoconazole tablets
200 mg 12-hourly for 7 days
Flucloxacillin or Erythromycin
500mg 6-hourly for 7 days

8.2.15 Tinea corporis / cruris / pedis

Clinical signs

Round reddened plaques with scaly edge in multiple sites, possibly 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

8.2.16 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
Give non-sedating meds if available (cetirizine, loratadine)
Give sedating meds (chlorpheniramine) at bedtime
Skin emollients

Secondary management

Corticosteroid cream

8.2.17 Chronic diarrhoea

Clinical signs

More than 3 loose non-bloody motions per 24 hours for more than 4 weeks (adults) or 2 weeks (children)

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

Effective ART
Confirm VL suppression, do targeted CD4; consider if LPV/r is causing the diarrhoea.
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 6m – 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 6 months

8.2.18 Sexually Transmitted Diseases

Follow national STI management guidelines for syphilis screening and treatment of specific conditions.

9 HIV and COVID-19

Key Facts: HIV and COVID-19

- PLHIV are at increased risk of severe COVID-19, especially those with advanced HIV disease and older people and with NCDs and co-morbidities.
- PLHIV with COVID-19 often have other severe OIs that need diagnosis and treatment.
- Patients may avoid coming to health facilities during COVID-19 waves, leading to ART interruption.
- COVID-19 vaccination is safe and effective in PLHIV, those with low CD4 may have a weaker and more short-lived immune response.
- COVID-19 vaccine is safe in pregnancy and during breastfeeding period, there is an added advantage of antibody transfer to infants.
- HIV infection and ART do not change standard COVID-19 treatment protocols. There are no relevant drug interactions of standard ARVs with locally available and evidence-based treatments for COVID-19 (enoxaparin and dexamethasone).
- There is no evidence that any ARV used for treating HIV is effective for prevention and treatment of COVID-19.

COVID-19 prevention

- Recommend full COVID-19 vaccination to all eligible PLHIV, including pregnant and breastfeeding women.
- Emphasize importance of adhering to standard COVID-19 prevention measures e.g., proper wearing of face mask, hand washing, social distancing and avoiding overcrowded/closed spaces.

HIV and COVID-19 investigations

- Offer a COVID-19 test to all PLHIV with symptoms and/or signs of COVID-19.
- Ascertain current HIV status for all patients admitted for COVID-19 treatment.
- Investigate all PLHIV with COVID-19 for TB: Xpert MTB RIF, microscopy and urine TB LAM.
- Investigate all PLHIV with COVID-19 for OIs such as PJP and TB.
- Conduct a targeted HIV viral load for all COVID-19 in-patients without a viral load result in the last 3 months.

Preventing HIV service disruptions

- Inform all PLHIV accessing care about continued availability of HIV services during COVID-19 waves.
- Enrol all stable PLHIV into multi-months dispensation to decongest facilities and ensure uninterrupted availability of ARVs with patients.
- Do not prescribe ARVs for COVID-19 prevention and treatment.

10 Standard monitoring of HIV patients

Key Facts: Clinical monitoring

- Exposed children and ART patients need the same standard clinical assessment at every clinical visit.
- Check actively – do not rely on patients to report problems unprompted.
- The Standard Clinical Monitoring Checklist (**Table 7** on **page 38**) helps to find:
    - HIV-related diseases
    - ART failure
    - Drug side effects (ART, TB, CPT, TPT, etc.)
- It can be difficult to distinguish HIV-related diseases from side effects. An ambiguous symptom is likely a side-effect if it started / worsened after starting medication / improves after stopping.

10.1 Monitoring of nutritional status

- One of the simplest methods to detect HIV disease progression / ART failure.
- Investigate any patient with weight loss or children failing to grow/gain weight for TB.
- Assess for resistance to TB drugs, poor adherence, comorbid conditions if failure to gain weight is observed among PLHIV diagnosed with TB.
- Record length / height to the nearest cm at every visit (children) / once at enrolment (adults).
- Record weight in kg at every visit for children and adults.
- Use appropriate nutrition indicator for children and adults.

10.1.1 Children 0-14 years

- Classify and manage wasting / malnutrition status according to ***Malawi Guidelines for Community Management of Acute Malnutrition (CMAM)***.
- Watch out for flattening of the growth curve (weight for age).

10.1.2 Non-pregnant adults 15 years and above

- Classify nutrition status according to BMI. Use standard MOH job-aids.
- Watch out for any weight loss over time. Review documented previous weight whenever available as reported weight loss can be unreliable.
- BMI under 17: Start TF for ‘moderate malnutrition’.
- BMI under 16: Start TF for ‘severe malnutrition’.

10.1.3 Pregnant and breastfeeding women

- Use MUAC instead of BMI.
- MUAC less than 22cm: start TF for ‘moderate malnutrition’.
- MUAC less than 19cm: start TF for ‘severe malnutrition’.

10.2 Standard clinical monitoring checklist

- Use the summary clinical monitoring checklist to actively screen every exposed child and ART patient for clinical symptoms at every clinical visit.
- Refer to **Table 7** on page 38 for more detailed screening instructions and interpretation of signs and symptoms for further management.

Table 6: Checklist for clinical monitoring of HIV exp. infants and ART patients

Ask for / Examine			
Appearance:	Weight loss / failure to thrive	N	Y
	Body shape change / breast swelling (men)	N	Y
	Swollen glands	N	Y
	Overweight	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 7: Detailed clinical monitoring list for HIV exp. and ART patients

Ask / Examine	Look for	Assess	Disease (most common)	Drug Side-Effects
Appearance	• Weight loss • Failure to thrive (failure to gain weight in children)	• 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 failure 5) Malignancy (lymphoma)	**Lactic acidosis due to ART** 1) AZT
	• Breast swelling (men) Body shape change	• Breast enlargement (gynaecomastia) • Slimming of cheeks • Slimming of forearms, buttocks and legs +/- protruding veins • Fattening of chest / belly / buttocks • Buffalo hump, swelling abdomen		**Gynaecomastia** 1) EFV **ART induced lipodystrophy** 1) AZT 2) 3TC 3) LPV/r 4) ATV/r 5) DRV + r
	• Overweight	• BMI >25 • Weight gain on thighs and trunk	1) Lack of physical activity, excess food intake 2) Metabolic syndrome	1) DTG
	• 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 • Reduced Glasgow Coma Scale (GCS) • Syncope		1) Meningitis (bacterial/ TB, cryptococcal) 2) Toxoplasmosis 3) HIV dementia	1) EFV 2) INH 3) DTG 4) Rifapentine

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) HCC	**Drug hepatitis** 1) NVP 2) EFV 3) PZA 4) Rifampicin (orange staining) 5) Rifapentine (orange stain.) 6) INH 7) Fluconazole 8) DRV/r 9) DTG **Hyperbilirubinaemia** 10) 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) EFV 4) Cotrimoxazole

Ask / Examine	Look for	Assess	Disease (most common)	Drug Side-Effects
Cough/ Flu like symptoms	• Any duration • Productiveness	• Weight loss/night sweats • Oxygen saturation • Fever • Lymphadenopathy • KS lesions • Nasal congestion	1) Pneumonia (bacterial) 2) TB suspect: circle on card 3) PCP 4) KS 5) COVID-19	**Hypersensitivity** 1) ABC 2) DRV/r 3) Rifapentine
Shortness of breath	• Specific breathing patterns • Chest in drawings	• Respiratory rate, pulse rate, Oxygen saturation, fever • Pulmonary and peripheral oedema	1) EPTB 2) Bacterial pneumonia 3) PCP 4) Heart failure 5) KS 6) Asthma 7) COVID-19	**Lactic acidosis due to ART** 1) 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 5) COVID-19	**Hypersensitivity** 1) ABC 2) EFV 3) RAL 4) ETV 5) DTG 6) Cotrimoxazole
		• More than 1 month	1) TB 2) Malignancies (lymphomas)	

Ask / Examine	Look for	Assess	Disease (most common)	Drug Side-Effects
Vomiting / abdominal pain	• Hydration status • Palpate abdomen	• Dehydration • Tenderness • Masses • Dilated abdominal veins	1) TB 2) NTS sepsis 3) Acute Gastro-enteritis 4) Malaria 5) Abdominal TB 6) Ulcer disease 7) CNS disease 8) Hepatoma	**Drug-induced hepatitis** 1) INH (nausea / anorexia early sign of INH hepatitis) **Drug-induced pancreatitis** 1) 3TC 2) RAL 3) ETV 4) DTG **Lactic acidosis due to ART** 1) AZT
Diarrhoea	• History • Blood in stool	• Less than 1 month	1) Salmonella 2) E. Coli 3) COVID-19 4) Amoeba/Shigella 5) HIV OI	**GI toxicity** 1) LPV/r 2) AZT 3) ABC 4) 3TC 5) DTG **Pseudomembranous enterocolitis** 1) Antibiotics
		• 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) Spinal TB	**Drug neuropathy** 1) INH 2) AZT 3) Vincristine 4) Paclitaxel 5) Metronidazole

Ask / Examine	Look for	Assess	Disease (most common)	Drug Side-Effects
Rash on arms, legs and trunk	• Skin lesions	• Purple lesions • Photo dermatitis	1) KS 2) Pellagra	1) INH
		• Blisters / vesicles	1) Shingles/ varicella zoster	**Stevens-Johnson Syndrome** 1) Cotrimoxazole 2) RAL
	• Generalized rash	• Maculo-papular	1) HIV associated rash (PPE) 2) Fungal skin infections 3) Molluscum contagiosum 4) Scabies	**Skin toxicity** 1) EFV 2) CTX 3) Fluconazole 4) DRV/r 5) ETV 6) DTG

10.3 CD4 count testing

Key Facts: CD4 count testing

- About 30% of PLHIV have a CD4 count <200 cells/ml at the time of starting ART and are therefore at high risk of TB, CM and other HIV-related diseases.
- Do **routine CD4 count** for all adults and children 5+ years before/when staring ART if CD4 testing is available at the site. However, do not delay ART initiation if CD4 machine is down / results are delayed or testing is currently not available.
- Do **Targeted CD4 count** for patients with suspected clinical and/or confirmed treatment failure (VL).
    - CD4 <200 cells/ml: Do routine urine LAM and serum CrAg for all adults and children 5 years and above (see **section 8.1** on **page 22**).
    - CD4 200+ cells/ml: no specific action
- Use point-of-care (POC) machines or semi-quantitative rapid CD4 count test kits.
- 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.
- Types of CD4 testing recommended in Malawi are:
    - **PIMA CD4 analyser**: POC test from a finger prick or venous whole-blood sample.
    - **VISITECT CD4** semi-quantitative test: lateral flow rapid test that shows if the CD4 count is above or below 200 cells/ml; will be prioritised for sites that do not have PIMA CD4 analyser.
- CD4 counts using PIMA CD4 analyser may fail or give wrong results unless the following protocol is used:
    - Collect a minimum of 2ml venous blood in tube with EDTA anticoagulant.
    - Immediately turn the tube upside down to mix the blood with EDTA. Do not shake vigorously
    - The sample must be processed in the lab within 6 hours or 48 hours, depending on the type of machine used.
    - Storing the tube at 2-8° C in the dark will extend the lifespan by a few hours
    - Protect the tube from hard vibrations during transport.

10.4 Collection of DBS samples for EID and VL

Key Facts: EID and VL testing

- 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). VL can also be tested using plasma samples.
- **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.
    - Use separate drying racks, clearly labelled ***EID*** and ***VL.***
- Pack DBS for EID and VL in separate plastic bags and envelopes.

Table 8: 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

11 Preventive services for HIV patients

Key Facts: Preventive services

- A simple standard package of preventive services is provided for all ART patients. This includes:
    1. Provider Initiated Family Planning
    2. Cotrimoxazole Preventive Therapy
    3. TB Preventive Therapy
- 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.)

11.1 Provider initiated family planning (PIFP)

Key Facts: Family planning

- Avoid unwanted pregnancies, regardless of HIV infection status.
- Use 'dual protection' – condoms alone are not enough for family planning as they must be used very consistently.
- Sex without condom is risky if the infected partner's viral load is not suppressed. Consistent condom use is especially important in the first 6 months after starting ART and/or if viral suppression is not confirmed (e.g., low adherence and/or treatment failure).
- Some hormonal contraceptives (the pill and implants) may be less effective with ARVs or TB treatment because of drug interactions.
- Depo-Provera® and Sayana Press® do not interact with ARVs or TB drugs but are generally slightly less effective in preventing pregnancy than implants.
- Intrauterine device, vasectomy and tubal ligation are safe to use with ART.
- 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 2% if the mother:
    - Starts ART as early as possible, best before conception
    - Is fully adherent to ART throughout pregnancy and breastfeeding

Implementing routine PIFP in HIV clinics

- Assume that all patients aged 15 years and above are sexually active.
- Offer FP to adolescents in a non-judgmental way. Do not let personal bias impact adolescent and young people's access to FP services.
- Offer condoms to all men and women aged 15 years and above:
    - Minimum of **30** male and/or female condoms
- Offer counselling on contraceptive methods. Refer to FP clinic if this is not feasible in the HCC setting.
- Offer at least Depo-Provera directly in the HCC (one-stop shop)
    - 1 Depo-Provera injection every 3 months
- Give patients the opportunity to refuse either method if they feel they don't need / want it.

11.2 Cotrimoxazole preventive therapy (CPT)

Key Facts: CPT

- CPT prevents Pneumocystis pneumonia (PJP), diarrhoea, malaria and other HIV-related diseases and prolongs survival.
- Start all the following on CPT:
    - HIV exposed children from age 6 weeks
    - HIV infected children from age 6 weeks
    - HIV infected adults
- Stop CPT in HIV exposed children when confirmed negative when discharged from exposed infant follow-up (following a negative HIV diagnostic test 6 weeks after stopping of breastfeeding).
- Provide CPT to all patients in HCC and ART follow-up.
- CPT is tolerated very well by most patients, can be taken at the same time with ART, TB treatment and TPT.
- CPT is safe in pregnancy.
- Do not combine CPT with SP – HIV positive pregnant women only take CPT (and ART).
- Children from 30kg and adults take one 960mg tablet of Cotrimoxazole 24-hourly.
- Dispersible paediatric tablets (120mg) are used for children under 14kg. Dosing of paediatric CPT and ART are both based on the same weight bands.
- CPT 960mg is usually available in blister-packs of 10 tablets – 3 strips are for a 30-day supply.
- Poor adherence to CPT is a warning sign for poor adherence to ART. Provide additional client-centred support to address barriers to adherence.
- Monitor toxicity and adverse reactions, especially for long term cotrimoxazole prophylaxis. See **section 24** for pharmacovigilance reporting.

Eligibility for 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 ARV prophylaxis.
    - Note: start HIV-exposed infants on CPT even if they did not receive ARV prophylaxis.
    - 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:
    - No contra-indication against CPT in the first trimester of 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.

CPT contraindications

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

CPT dosage and duration

- See **Table 16** on page **68** for dosing.
- HIV exposed children: stop CPT when confirmed HIV negative at least 6 weeks after stopping of breastfeeding.
- HIV infected children and adults: continue CPT for life unless there are severe side effects.
- Poor adherence to CPT will reduce the effectiveness of preventing HIV-related diseases, but it is less risky than poor adherence to ART.
- If pill burden is a challenge, particularly in adolescents, prioritize ART over CPT.

CPT intolerance

- Actively screen for potential CPT toxicity at every visit.
- Stopping CPT due to intolerance is not common.
- Document all serious side effects on the yellow pharmacovigilance forms and submit to PMRA or report using the MEDSAFE-360 USSD platform.

11.3 TB Preventive Therapy (TPT)

Key Facts: TB Preventive Therapy (TPT)

- A single course of TPT can prevent active TB in people who are at high risk:
    - HIV infected children, adolescents and adults
    - Children under 5 years – regardless of HIV status – who are household contacts of clients with bacteriologically confirmed TB (microscopy, gene Xpert or LF TB LAM): give IPT – 6H.
- HIV patients who have completed a course of TPT or TB treatment in the past do not need another course of TPT.
- Do not give TPT to a patient who has any signs suggestive of active TB: such patients need full investigation for TB and may require full TB treatment to avoid TB drug resistance.
    - New patients: Start TPT together with ART and CPT.
- Two alternative TPT options are similarly effective:
    - **3HP**: 3-month course of weekly doses of isoniazid + rifapentine
        - Preferred regimen for patients newly initiating ART
    - **6H**: 6-month course of daily dose of Isoniazid:
        - Use as an alternative regimen for those with contraindications to 3HP
        - Suitable for children and can be combined with all ART regimens
- Both 3HP and 6H should not be routinely given in pregnancy and 3 months postpartum due to increased risk of hepatotoxicity and potential adverse birth outcomes (low birth weight and preterm delivery).
- TPT is well tolerated by most patients. Most side effects are mild and disappear with time. Serious side effects are rare: hypersensitivity, neuropathy and severe hepatitis.
- Document all serious side effects on the yellow pharmacovigilance forms and submit to PMRA or report using the MEDSAFE-360 USSD platform.
- Stop TPT if any of the following are seen:
    - Nausea, vomiting, loss of appetite: early warning signs for hepatitis
    - Pellagra-type skin rash in sun-exposed areas and other severe skin rash
    - Yellow eyes
    - Dizziness / confusion / convulsions
    - Moderate numbness/burning pain and muscular weakness of legs and/or arms
    - Flu-like symptoms, syncope
- DO NOT RESTART TPT if any significant side effect is experienced.

Dispensing TPT

- Patients who have already completed a full course of TPT or TB treatment in the past are exempt.
- Emphasize adherence during treatment.
- Ensure proper documentation on patient card.
- Always give pyridoxine to prevent neuropathy. Don't prescribe TPT if pyridoxine is not available.
- Stop immediately if clients develop severe peripheral neuropathy, hypersensitivity reactions, gastrointestinal intolerance and hepatotoxicity.
- Report to the health facility immediately with nausea or loss of appetite. These are early warning signs of hepatotoxicity.

3HP

- Easier to complete due to short duration and fewer side effects.
- All clients newly initiated on ART (<3 months) in all districts are eligible for 3HP.
- Start 3HP at the same time as ART. If this was missed, start 3HP up to 3 months after ART initiation.
- Not suitable for patients on PI- and NNRTI-based ART regimens.
- Do not give 3HP to children on paediatric ART formulations (blue patient card).
- Women on hormonal contraception need to use condoms while on 3HP. Rifapentine reduces contraceptive effectiveness.
- 3HP reduces the effectiveness of malaria treatment, do not combine with LA.
- Check drug interaction job aid before starting any new drugs for someone on 3HP
- Give a single course of 12 weekly doses of rifapentine/isoniazid based on weight (see **Table 16 on page 68**).
- Give 1 daily tablet of Pyridoxine 24-hourly for 12 weeks. **Adults:** 25 or 50mg.
- Review patients at **month 1**, **2** and **3** after starting 3HP for side effects and adherence. Align ART appointments with 3HP dispensing and clinical review visits.

6H

- Offer 6H as an alternative TPT regimen to all ART clients with contraindications to 3HP.
- Give 1 daily dose of INH and pyridoxine for 6 months (cumulative total of at least 168 daily doses). Use weight-based dosing chart for children.
- Give 1 daily tablet of pyridoxine 24-hourly. **Adults:** 25 or 50mg. **Children <20kg**: about 1mg/kg
- Review patients at **month 1**, **2** and **3** after starting 6H for side effects and adherence. Align ART appointments with 6H dispensing and clinical review visits.

TPT completion and management of interruption

- Provide adherence support for clients to complete TPT course.

- **Table 9** shows the expected number of doses and the expected period to completion. It also shows the minimum doses and the maximum permissible period for a complete course of 3HP and 6H.
- 3HP requires completing 12 weekly doses, preferably without gap. A patient who interrupts:
    - Less than 1 month: continues the course. The course can be extended up to 120 days (4 months) in total. Ensure that at least 11 doses are taken.
    - More than 1 month: restarts the whole course, ignoring any doses that were taken before the interruption.
- 6H requires completing 182 daily doses, preferably without gap. A patient who interrupts:
    - Less than 2 months: continues the course. The course can be extended up to 239 days (8 months) in total. Ensure that at least 146 doses are taken.
    - More than 2 months: restarts the whole course, ignoring any doses that were taken before the interruption.

Table 9: Expected doses and duration for 3HP and 6H. Min. requirements for completion of course

TPT Regimen	Expected doses	Minimum doses	Expected duration	Max. duration
3HP	**12 doses**	11 doses	**84 days**	120 days
6H	**182 doses**	146 doses	**182 days**	239 days

TPT in Prisons

- Perform a thorough systematic symptom screen for TB among prisoners upon entry and every six months.
- Give 3HP to HIV-infected prisoners using the same eligibility criteria as for all other patients (see above).
- Provide enhanced adherence counselling for TPT regimen completion.

TPT Contraindications

Table 10: Contraindications for IPT and 3HP

IPT and 3HP	3HP
• Suspected or confirmed active TB • Prior adverse events or hypersensitivity to INH • Active hepatitis, hepatitis surface antigen positive, liver damage, heavy alcohol use • Severe or moderate peripheral neuropathy	• Prior adverse events or hypersensitivity to rifapentine, rifampicin or INH • PI- and NNRTI-based regimens must not be combined with 3HP • Active hepatitis, hepatitis surface antigen positive, liver damage, heavy alcohol use • Pregnant women or women planning to become pregnant during treatment

12 Management of non-communicable diseases in PLHIV

Key Facts: NCDs

- HIV infection is associated with higher triglycerides, lower HDL (good cholesterol) and hypertension. About 1/4 of adults ART patients from a study in Zomba had hypertension; about 4% had diabetes.
- DTG may increase risk of hyperglycaemia, particularly in patients with other risk factors for diabetes.
- The 4 NCDs with the highest burden among PLHIV cardiovascular disease (CVD), cervical cancer, depression, and diabetes.
    - CVD events are more common because of risk factors such as obesity and age
    - In 2021, about 1/4 of ART patients were 50 years +
- Routinely screen all ART patients in the following groups for NCDs:

Group	*Screen*	*When*
Adult 40 years +	Blood glucose, blood pressure	12-monthly
Women 15-49 years	Cervical cancer	12-monthly
Adolescents and adults with adherence challenges	Depression and substance abuse	Targeted

Integration of NCD management and ART

- Integrate HIV and NCD education in ART clinic health talks.
- Integrate NCDs screening and management in ART services whenever possible.
    - Refer NCD patients for end organ damage investigation.
- File ART and NCD patient cards at the ART clinic.
- Align ART and NCD clinic appointments if a full integration is not feasible.

12.1 Lifestyle modification to prevent NCDs

- Emphasize during group health education:
    - Don’t smoke
    - Aerobic exercise for at least 30 minutes on at least 3 days each week
    - Maintain a normal body weight (BMI 18.5 to 24.9).
    - Eat mainly fruits and vegetables
    - Limit animal fat (dairy, meat), processed and fast foods, sugar, salt
    - Reduce / abstain from alcohol

12.2 Detecting and managing high blood pressure

Key Facts: BP screening

- 1 out of 4 adults in Malawi have hypertension and over 75% of these have not been diagnosed.
- Even without hypertension, HIV patients have a higher risk of stroke.
- Managing all hypertensive ART patients can prevent many cases of stroke, heart and kidney failure and other complications.
- Screen all adults for hypertension:
    - Record BP on patient card header.
    - Check BP at least once a year for patients 30 years +.

Correct BP measurement method

- Make sure the patient is relaxed (rest at least 10 minutes after physical activity).
- Sit upright, remove clothing from upper arm that may restrict blood flow or interfere with BP cuff.
- Make sure BP cuff is the right size: check the arm circumference is within range shown on the cuff.
- If the initial reading is higher than **140** systolic and/or **90** diastolic:
    - Repeat reading twice. Wait for at least 5 minutes between readings.
    - Record the lowest reading

Classification	Systolic		Diastolic	Management
Mild	140-159	*and/or*	90-99	Try *lifestyle measures* alone, start stepped treatment if no normalization after 6 months
Moderate	160-179	*and/or*	100-109	*Lifestyle measures* + stepped treatment
Severe	>180	*and/or*	>110	Urgent treatment *Lifestyle measures* + stepped treatment

Management of hypertension

- Start management for hypertension if the lowest reading is higher than **140** systolic and/or **90** diastolic**.**
- Urgent treatment for severe hypertension if the repeat reading is **180** systolic and/or **110** diastolic.
- Screen for diabetes and symptoms and signs of end organ damage (eye, heart, kidney).
- *Lifestyle measures*: Eat more vegetables and fruits, less meat / fat, reduce salt, stop smoking, exercise regularly, normalize weight, limit or stop alcohol
- See latest ***Malawi Standard Treatment Guidelines*** for stepped anti-hypertension treatment.

12.3 Diabetes mellitus

Key Facts: Diabetes mellitus

- Unmanaged diabetes causes long-term damage to large and small blood vessels.
- It may lead to blindness, lower limb amputations, nerve damage, renal failure, heart attack and stroke.
- Insulin resistance can be caused by HIV infection and ARVs, particularly DTG, ATV/r, LPV/r and DRV.

Screening and Diagnosis

- Screen all of the following patient groups for diabetes using a random (non-fasting) blood glucose test. Screen at ART initiation and every 12 months thereafter.
    - Age 40 years +
    - Age under 40 years with any of the following risk factors:
        - Family history of diabetes
        - Hypertension
        - Dyslipidaemia (i.e., High triglycerides, high total cholesterol and low high- density-lipoprotein cholesterol)
        - Obesity (BMI > 30)
- Normal random blood sugar (RBS): below 200mg/dl (<11 mmol/L)
    - If patient is asymptomatic, repeat after 12 months
    - If patient is symptomatic (e.g., weight loss, polyuria, polydipsia), conduct fasting blood sugar (FBS) as soon as possible.
- Elevated RBS: 200mg/dl and above (>11 mmol/L)
    - Conduct FBS
- Elevated FBS: 126mg/dl and above (>7mmol/L):
    - Advise lifestyle modifications
    - Start DM treatment as per latest **Malawi Standard Treatment Guidelines**
        - Start Metformin at a low dose and increase gradually. Maximum dose for patients on DTG is 1000mg/day
    - Additionally, do the following:
        - Reinforce lifestyle interventions at every clinic visit
        - Educate HIV patients on metformin about the symptoms of lactic acidosis, including fatigue, weight loss, nausea, abdominal pain, dyspnea, and arrhythmia.

12.4 Mental health and psychosocial support

Key Facts: Depression

- One quarter of patients starting ART have some degree of depression.
- Depression affects ART adherence and retention.
- Mild and moderate depression can effectively be managed with counselling and support interventions; severe depression usually requires medication.
- Screen all PLHIV with poor adherence and retention challenges for depression and substance abuse.
- DTG may cause insomnia, headache and other neuropsychiatric side effects.

12.4.1 Depression screening and management

- Eligibility: screen all of the following patient groups routinely for depression:
    1. Returning to care after disengagement
    2. Known or suspected adherence problems
    3. High viral load

Patient Health Questionnaire (PHQ-2 and PHQ-9)

- **Pre-screening (PHQ-2):** ask all eligible patients aged 12 years + **the first 2 questions** from the PHQ.
    - Score and add up the responses (range: 0–6)
    - Patients with a PHQ-2 score **above 0** need the full set of questions (PHQ-9)
- **Full screening (PHQ-9):** ask all patients with a PHQ-2 score above 0 **all 9 questions**
    - Refer all patients with a score of 5 and above to a trained mental health counsellor.

Table 11: Patient Health Questionnaire for depression screening (PHQ-2 and PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following?		Not at all	Several days	More than half days	Nearly every day
1	Little interest or pleasure in doing things	0	1	2	3
2	Feeling down, depressed, or hopeless	0	1	2	3
3	Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4	Feeling tired or having little energy	0	1	2	3
5	Poor appetite or overeating	0	1	2	3
6	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7	Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8	Moving or speaking so slowly that other people could have noticed? Or the opposite: being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9	Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
	Total Score	**0**	**+**	**+**	**+**

Scores	Depression Severity	Action
0 - 4	None-minimal	Patient may not need depression treatment.
5 - 9	Mild	Use clinical judgment about treatment, based on patient's duration of symptoms and functional impairment.
10 - 14	Moderate	
15 - 19	Moderately severe	Treat using antidepressants or psychotherapy or a combination.
20 - 27	Severe	Treat using antidepressants with or without psychotherapy.

Suitable antidepressants for patients on ART

- The preferred antidepressant for patients on DTG, ATV/r, LPV/r and DRV + r is **citalopram**.
- Check **Table 28** on **page 131** for interactions between ARVs and common antidepressants, and recommended management.

12.4.2 Substance use disorder in PLHIV

Key Facts: Substance use disorder (SUD) in PLHIV

- People who inject drugs are at high risk of acquiring and transmitting HIV, Hepatitis B, C and other blood borne diseases.
- Alcohol and substance abuse are likely to affect ART adherence and retention.
- Liver damage from alcohol is a major risk factor for drug toxicity (DTG, INH, ATV/r, etc.) and a contraindication for starting TPT.

Screening for substance use disorder (SUD)

- Screen all PLHIV with history/physical examination suggestive of substance abuse using the DSM-5 screening criteria (see **Table 12** below).
- Ask initial questions to quickly assess for potential risk using the recommended single-item alcohol and drug screening questions.
- SUD is confirmed if a patient has significant impairment or distress from their pattern of drug use **and** had **at least 2** of the DSM-5 symptoms in the last 12 months.
- Refer all patients with SUD for an in-depth assessment and management to a mental health clinic.

Table 12: DSM-5 Substance use disorder criteria

	Which of these criteria apply in the last year?
1	Taking the substance in larger amounts or for longer than you're meant to.
2	Wanting to cut down or stop using the substance but not managing to.
3	Spending a lot of time getting, using, or recovering from use of the substance.
4	Cravings and urges to use the substance.
5	Not managing to do what you should at work, home, or school because of substance use.
6	Continuing to use, even when it causes problems in relationships.
7	Giving up important social, occupational, or recreational activities because of substance use.
8	Using substances again and again, even when it puts you in danger.
9	Continuing to use, even when you know you have a physical or psychological problem that could have been caused or made worse by the substance.
10	Needing more of the substance to get the effect you want (tolerance).
11	Development of withdrawal symptoms, which can be relieved by taking more of the substance.
	Total Score

Syringe (needle) exchange program for people who inject drugs (PWID)

- Enrol PWID for harm reduction and HIV prevention services at Drop-in Centres (DICs)
- Record age, sex, residential area and group members in an improvised register
- Ascertain HIV status of all group members
    - Link HIV negative members to combined HIV prevention services e.g., PrEP
    - Link HIV positive members to ART
- Link PWID with mental health experts for counselling and opiate substitution therapy
- Dispense single-use syringes in exchange for used syringes in DICs

12.5 Cervical cancer screening in WLHIV

Key Facts: Cervical cancer

- WLHIV are at-higher risk for human papilloma virus (HPV) disease such as cervical cancer and genital warts.
    - Screen all WLHIV annually for cervical cancer
    - Screen and treat precancerous lesions at the same visit. Pathology confirmation is not necessary
    - Thermocoagulation is the most common treatment but may not be definitive requiring annual follow up.
- HPV vaccine is very safe and effective in preventing HPV infection and disease
    - Vaccinate before start of sexual activity
    - All girls aged 9-14 years are eligible

How to screen for cervical cancer

- Screen all WLHIV at enrolment into care and annually thereafter:
    - Visual inspection using acetic acid (VIA)
    - Patients with pre-cancerous cervical lesions should be managed according to latest Malawi cervical cancer guidelines.

13 HIV and viral hepatitis

Key Facts: Viral hepatitis

- Around 8% and 1% of older adults in Malawi may be infected with hepatitis B and C, respectively.
- Hep B is mostly transmitted during childbirth and in early childhood. Early infection carries a high risk of liver cirrhosis and cancer later in life.
- Hep B and C can also be transmitted sexually, through blood products and sharing of contaminated needles.
- HIV and HBV/HCV coinfection accelerates progression to liver disease.
- Hep B and C liver damage increases the risk of ARV drug toxicity.
- Hep B vaccine is currently available as part of the EPI for:
    - Infants at age 6, 10 and 14 weeks together with DPT vaccine
    - All health care workers
- The addition of a Hep B birth dose vaccination (together with BCG and OPV0) is planned. It can effectively eliminate transmission of Hep B from mother to child.

Routine viral hepatitis screening

- Routinely screen all the following groups with a rapid test for Hepatitis B surface antigen (HBsAg):
    - Antenatal women above 20 years at the first visit
    - STI patients
    - People starting PrEP
    - Blood donors
    - Female sex workers
    - Prisoners

Management of co-infection with HIV and hepatitis B

- HepB HIV co-infected patients are appropriately treated for both with TDF-based ART
- Determine HepB treatment eligibility for all HBsAg positive and HIV negative patients
    - About 5% of HBsAg positive people need TDF/3TC lifelong treatment for chronic HepB
    - Refer to VH clinical guidelines for more information

14 Understanding ART regimens and formulations

Key Facts: ART regimens

- 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 a 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 possibly for life if they are fully adherent. All 1st line regimens:
    - Are easy to prescribe and easy to take.
    - Have a low risk of serious side effects. Do not require lab monitoring for toxicity.
    - There are **8 different** regimens used as **1st line**
        - **Two** are standard for **initiating ART** depending on patient age and weight (see **Table 15** on **page 66**).
    - Transition patients with significant side effects to an alternative regimen without delay. Choose the regimen by **substituting** only the ARV responsible for the side effects.
- **2nd Line regimens** are for patients with confirmed treatment failure on 1st line regimen. Moving from 1st to 2nd line ART is called **switching**. 2nd line regimens:
    - Contain protease inhibitors (PI) or integrase strand transfer inhibitors (INSTI).
    - PI- and INSTI-based regimens may be used as 1st or 2nd line. It is therefore no longer possible to distinguish 1st and 2nd line regimens without knowing the patient's regimen history.
    - There are **8 different regimens that may be used as 2nd line**. The appropriate 2nd line regimen is determined by the 1st line regimen that the patient was taking when failing. Patients suspected to fail on a PI- or INSTI-based regimen need genotyping to confirm the presence of drug resistant virus before switching to 2nd or 3rd line.
- **3rd Line regimens** are for patients with confirmed treatment failure on 2nd line regimen. This requires confirmation of drug resistant virus using genetic testing in the lab. 3rd line can only be initiated by a specialised ARV clinician upon authorization of the national HIV Drug Resistance Committee. 3rd line regimens are:
    - Expensive
    - Can have more side effects and are more difficult to take.
- It is no longer recommended to give a 7-day NRTI **"tail"** when stopping ART in patients on EFV-based regimens. The risk of developing EFV resistance due to the longer half-life is now considered insignificant.

Key Facts: Dolutegravir (DTG)

- DTG may be used in 1st, 2nd and 3rd line ART regimens.
- The benefits of DTG outweigh any potential risks, including for **women who may get pregnant** while on ART:
    - Faster and more durable viral suppression
    - Lower risk of maternal OIs and death
    - Reduced risk of HIV transmission to sexual partners and to the child
    - The potential risk of neural tube defects is now considered very low.
- **Note: regimen 13A can only be used from 30kg+** as TDF-dose is too high for smaller children.
- **(Relative) Contra-indications** for DTG-based regimens:
    - Renal failure: creatinine clearance <30ml/min
    - Sev. liver damage: ascites; albumin <2.8g/dL; tot. bilirubin >50mmol/L; encephalopathy
- Potential **side-effects** (rare). Submit ADR reporting form for all suspected side-effects
    - Insomnia, headache, agitation
    - Nausea, diarrhoea
    - Skin rash
    - Weight gain, hyperglycaemia
    - Hepatitis/jaundice (uncommon)
- DTG can cause **obesity** in some patients, requiring a regimen substitution.
    - Unwanted weight gain can undermine motivation for ART adherence
    - Obesity can cause diabetes, hypertension and the long-term consequences
    - This potential side effect has not yet been seen in children.
- DTG can potentially cause or worsen **hyperglycaemia**
    - Monitor blood glucose every 12 months in patients 40 years+
    - In patients with newly diagnosed or worsened hyperglycaemia on DTG-based regimen: substitute DTG for EFV or other alternative regimen and check if glucose improves
- Important DTG **drug-interactions**:
    - Rifampicin (TB treatment): double daily DTG-dose (see **section 17** on **page 80**).
    - Drugs with iron, magnesium, calcium, zinc (FeFo, multi-vitamins, antacids, etc.) reduce DTG absorption: take DTG 2 hours before or 6 hours after taking such drugs.
    - Metformin (diabetes): limit daily dose to 1000mg, confirm effective glucose control.
    - NVP, ETR (ARVs): do not combine with DTG
    - Carbamazepine, phenytoin, phenobarbitone, sodium valproate: **avoid DTG.**

14.1 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 13: Classification of ARVs

Mode of action	Biochem. structure	Abbrev.	ARVs	Dosing interval
Reverse **T**ranscriptase **I**nhibitors	**N**ucleosides	***NRTI***	**AZT**	***12****-hourly*
			3TC, ABC	***12****- or* ***24****-hourly*
			Entecavir (ETV)*	***24****-hourly*
	Nucleotide	***NtRTI***	**TDF**	***24****-hourly*
	Non-**N**ucleosides	***NNRTI***	**NVP**	***12****-hourly*
			EFV	***24****-hourly*
Protease **I**nhibitors		***PI***	**ATV/r**	***24****-hourly*
			DRV	***12****-hourly*
			LPV/r	***12****-hourly*
Integrase **S**trand **T**ransfer **I**nhibitor		***INSTI***	**DTG**	***24****-hourly*
			RAL	***12****-hourly*

**ETV is used for treating chronic HepB (not HIV). Needed for HIV/HepB co-infected patients who cannot take TDF/3TC containing ART (e.g. children under 30kg, patients with renal insufficiency)*

14.1.1 Regimen names

- **Table 15** on **page 66** shows the standard ART regimens for Malawi.
- ART regimens and formulations are numbered and coded to ease M&E and supply management:
    - Old regimens that are no longer used are omitted from **Table 15**. This explains the gaps in the number sequence.
    - Most PI- and INSTI-based regimens may be used as 1st or 2nd line. It is therefore no longer possible to distinguish 1st and 2nd line regimens without knowing the patient's regimen history.
    - **Regimen 13** is the standard 1st line regimen for men and women weighing 30+ kg.
    - The 4 remaining NNRTI-based regimens are only used as alternative 1st line (Regimen 4, 5, 16, 17).
    - **Regimen 12** is the standard 3rd line regimen.

- ART regimen formulation codes
  - "**A**" is added to the regimen number for adult formulations (e.g., Regimen 13A)
  - "**P**" is added for paediatric formulations (e.g. Regimen 9P).
  - "**PP**" is added for regimens that are made up of 2 separate tablets when both tablets are paediatric formulations. For example, Regimen 15PP contains ABC 120mg/3TC60mg (paediatric) + DTG 10mg (paediatric).
  - "**PA**" is added for regimens that are made up of 2 separate tablets when one is paediatric and the other is adult formulation. For example, Regimen 15PA contains ABC 120mg/3TC60mg (paediatric) + DTG 50mg (adult).

- Fixed dose combinations (FDC) are shown with a slash (e.g., TDF **/** 3TC **/** DTG).
- Combinations made up of separate 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 effective even when drug-resistant HIV is present.

14.1.2 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 30kgs. The standard adult formulation (TDF 300mg) can be used from 30kg.

14.1.3 Choosing ART regimen, formulation and dosage

Start regimen

- Select **Regimen 13 or 15** to start patients on ART, based on weight.
- Use alternative 1st line regimens if the patient has any contraindications for the standard regimen.

Table 14: Selection of ART regimen for initiation

Weight (kg)	Regimen	Conditions / Instructions	ART patient card
Under 3kg	-	No routine ART. Consult DHA in special cases.	
3 – 19.9kg	**15PP**	Use paediatric ABC/3TC+ paediatric DTG 10mg.	paediatric
20.0 – 24.9kg	**15PA**	Use paediatric ABC/3TC tablet + adult DTG 50mg.	paediatric
25.0 - 29.9kg	**15A**	Use adult ABC/3TC tablet + adult DTG 50mg.	adult
30kg +	**13A**	TDF/3TC/DTG 300/300/50mg	adult

14.1.4 Initial prescriber level

- All MOH-certified PMTCT/ART providers are authorized to start any of the eight 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 and 3rd line regimens can also be made by Level 1 providers. See details in **section 14.2** on **page 69**.

14.1.5 Contraindications

- Most contraindications are not absolute for a specific regimen: balance risks, benefits and alternatives. A suitable alternative regimen can be chosen from **Table 15**. 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).

14.1.6 Adverse events / side effects

- Choose the appropriate alternative regimen for patients with:
    - Contraindications
    - Moderate to severe side-effects (immediately)
    - Troubling side effects that did not improve within 2 weeks with symptomatic treatment.
- Use **Alt. 2** if **Alt. 1** can't 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.

14.1.7 Dosing and frequency

- **Table 16** 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 and ATV/r tablets must be **given whole** (not split or crushed or chewed).

Table 15: Standard ART Regimens (all strengths in mg)

Regi-men	Formulation: Paed. + Paed.	Formulation: Paed. + Adult	Formulation: Adult	Used for ART initiation	Line	Prescri-ber level	Relative Contraindications	Possible adverse reaction	If confirmed, use: Alt 1	If confirmed, use: Alt 2
4	**AZT** 60 / **3TC** 30 + **EFV** 200	**AZT** 300 / **3TC** 150 + **EFV** 200	**AZT** 300 / **3TC** 150 + **EFV** 400	No	1st	1	• Anaemia <8g/dl • History of psychosis	• Anaemia, vomiting, appetite loss	5, 17	13, 15
								• Lipodystrophy, lactic acidosis	5, 17	13, 15
								• Hepatitis, rash[1], psychosis, gynaecomastia[2]	14	13, 15, 11
								• Treatment failure	13	15, 9, 10
5			**TDF** 300 / **3TC** 300 / **EFV** 400	Alternative if (relative) DTG contra-indications	1st	1	• History of psychosis • Renal failure	• Renal failure	17[3]	4, 15[3], 14
								• Hepatitis, rash[1], psychosis, gynaecomastia[2]	7	13, 15, 14
								• Persistent dizziness, visual disturbances	13	7, 15, 14
								• Treatment failure	14	8, 11
7			**TDF** 300 / **3TC** 300 + **ATV/r** 300/100	No	2nd	2	• Renal failure • Rifampicin or rifapentine[4] • Pre-existing jaundice or hepatitis[5]	• Renal failure	15[3]	11, NS
								• Jaundice[6]	13	10, NS
								• Treatment failure[7]	(12)	
8			**AZT** 300 / **3TC** 150 + **ATV/r** 300/100	No	2nd	2	• Anaemia <8g/dl • Patient on rifampicin or rifapentine[4] • Pre-existing jaundice or hepatitis[5]	• Anaemia, vomiting, appetite loss	15	9, 13, NS
								• Lipodystrophy, Lactic acidosis	15	9, 13, NS
								• Jaundice[6]	11	14, 13
								• Treatment failure[7]	(12)	
9	**ABC** 120 / **3TC** 60 + **LPV/r** 100/25	**ABC** 600 / **3TC** 300 + **LPV/r** 100/25	**ABC** 600 / **3TC** 300 + **LPV/r** 200/50		1st or 2nd	1	• ABC hypersensitivity	• Fever, body pains, vomiting, cough[8]	10, 11	14, 13, 8
								• Diarrhoea, vomiting, dizziness, headache	15	7
								• Treatment failure[7]	(12)	
10			**TDF** 300 / **3TC** 300 + **LPV/r** 200/50	No	2nd	2	• Renal failure	• Renal failure	9[3]	14, 15[3], 8
								• Diarrhoea, vomiting, dizziness, headache	7	13, 14, 15
								• Treatment failure[7]	(12)	
11	**AZT** 60 / **3TC** 30 + **LPV/r** 100/25	**AZT** 300 / **3TC** 150 + **LPV/r** 100/25	**AZT** 300 / **3TC** 150 + **LPV/** 200/50	No	2nd	2	• Anaemia <8g/dl	• Anaemia, vomiting, appetite loss	9	13, 15
								• Lipodystrophy, lactic acidosis	9	13, 15
								• Diarrhoea, vomiting, dizziness, headache	8	14
								• Treatment failure[7]	(12)	
12	**DRV** 150 + **r** 50 + **DTG** 10 (± NRTIs)	**DRV** 150 + **r** 50 + **DTG** 50	**DRV** 600 + **r** 100 + **DTG** 50 (± NRTIs)	No	3rd	2	• Epilepsy[9] • (Hepatitis B or C)[12] • Patient on rifampicin or rifapentine[4]	• Diarrhoea, vomiting, headache, dizziness, insomnia[10], obesity, diabetes[11], hepatitis[12]	NS	
								• Neuropathy	NS	
								• Rash, jaundice	NS	

Regi-men	Paed. + Paed.	Formulation Paed. + Adult	Adult	Used for ART initiation	Line	Prescri-ber level	Relative Contraindications	Possible adverse reaction	If confirmed, use Alt 1	Alt 2
13			**TDF** 300 / **3TC** 300 / **DTG** 50	**Standard for all patients 30 kg+**	**1st** or **2nd**	**1**	• Renal failure • Uncontrolled diabetes • Epilepsy9 • (Hepatitis B or C)[12]	• Renal failure	**15**[3]	**14**
								• Diarrhoea, vomiting, headache, dizziness, insomnia[10], obesity, diabetes[11], hepatitis[12]	**5**	**7**
								• Hepatitis	**10**	**5, NS**
								• Treatment failure[7]	**(8)**	**(11)**
14	**AZT** 60 / **3TC** 30 + **DTG** 10	**AZT** 60 / **3TC** 30 + **DTG** 50	**AZT** 300 / **3TC** 150 + **DTG** 50	**No**	**1st** or **2nd**	**1**	• Anaemia <8g/dl • Epilepsy9 • (Hepatitis B or C)[12]	• Anaemia, vomiting, appetite loss, lipodystrophy, lactic acidosis	**13**	**15**
								• Renal failure	**15**[3]	**17**[3]
								• Diarrhoea, vomiting, headache, dizziness, insomnia[10], obesity, diabetes[11], hepatitis[12]	**4**	**8, 11**
								• Hepatitis	**4**	**11**
								• Treatment failure[7]	**(7)**	**(9, 10)**
15	**ABC** 120 / **3TC** 60 + **DTG** 10	**ABC** 120 / **3TC** 60 + **DTG** 50	**ABC** 600 / **3TC** 300 + **DTG** 50	**Standard for all patients below 30 kg**	**1st** or **2nd**	**1**	• ABC hypersensitivity • Epilepsy9 • (Hepatitis B or C)[12]	• Fever, body pains, vomiting, cough[8]	**13**	**14**
								• Diarrhoea, vomiting, headache, dizziness, insomnia[10], obesity, diabetes[11], hepatitis[12]	**17**	**4, 9, NS**
								• Treatment failure[7]	**(8)**	**(11, 7)**
17	**ABC** 120 / **3TC** 60 + **EFV** 200	**ABC** 600 / **3TC** 300 + **EFV** 200	**ABC** 600 / **3TC** 300 + **EFV** 400	**No**	**1st**	**1**	• ABC hypersensitivity • History of psychosis	• Fever, body pains, vomiting, cough[8]	**5**	**13, 4, 14**
								• Hepatitis, rash[1], psychosis, gynaecomastia[2]	**15**	**16, 9, 7, 8**
								• Treatment failure	**14**	**8, 11**

[1] 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.
[2] EFV can cause breast enlargement in children and men (one side or both sides). This may resolve spontaneously while continuing EFV, but substitution is usually needed (and effective).
[3] Patients with CrCl <50 ml/min need lower dose 3TC but full dose ABC. Combine ABC/3TC paed tabs and ABC (single) tabs for the correct dose. Call HIV Dept. logistics hotline for ABC single tabs.
[4] Do not combine ATV/r with rifampicin (TB treatment) or rifapentine (TB preventive therapy using 3HP).
[5] Do not start patients with pre-existing jaundice or suspected hepatitis on ATV/r and LPV/r.
[6] 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.
[7] Treatment failure on ATV/r, LPV/r, DRV and DTG-based regimens need confirmation of resistance mutations by genotyping before switch can be considered.
[8] 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.
[9] DTG should not be combined with standard antiepileptic drugs: carbamazepine, phenobarbital, phenytoin and sodium-valproate. Use alternative anti-epileptic if available. Otherwise consider non-DTG based regimen or combine phenobarbital or carbamazepine with double dose of DTG. Check VL 6-monthly to confirm VL suppression.
[10] DTG is very well tolerated. Mild headache, insomnia, nausea and diarrhoea usually subside without regimen change.
[11] DTG may rarely cause hyperglycaemia and obesity. Use alternative regimens if lifestyle changes are unsuccessful. Check if hyperglycaemia improves on alternative regimen.
[12] DTG and RAL may worsen liver damage (alcohol, viral Hepatitis B or C, etc.) and rarely cause hepatotoxicity. Check transaminases before and after starting DTG in patients with known Hep B/C.

Table 16: Standard pack sizes and dosing of Paediatric and Adult formulations of ARVs, TPT and CPT

Drug	Tablets per tin		3 – 3.9 kg		4 – 5.9 kg		6 – 9.9 kg		10 – 13.9 kg		14 – 19.9kg		20 – 24.9kg		25 – 29.9kg		30 – 34.9 kg		35 – 39.9 kg		40 – 49.9 kg		50 kg +	
	Paed.	Adult	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
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	1	1
ABC / 3TC	60	60	1	0	1	0	1 ½	0	2	0	2 ½	0	3	0	1	0	1	0	1	0	1	0	1	0
LPV / r liquid / tabs	60	120	*1ml*	*1ml*	*1.5ml*	*1.5ml*	2	1	2	1	2	2	2	2	3	3	3	3	2	2	2	2	2	2
LPV/r granules (sachets)	120		2	2	2	2	3	3	4	4	5	5	6	6										
EFV	90	30							0	1	0	1 ½	0	1 ½	0	2	0	2	0	1	0	1	0	1
ATV / r		30															0	1	0	1	0	1	0	1
TDF / 3TC		30															0	1	0	1	0	1	0	1
TDF / 3TC / EFV		30																	0	1	0	1	0	1
TDF / 3TC / DTG		30/90															1	0	1	0	1	0	1	0
DTG	90	30	½	0	½	0	1½	0	2	0	2½	0	1	0	1	0	1	0	1	0	1	0	1	0
DRV[2]	240	60									2½	2½	2½	2½	2½	2½	3	3	1	1	1	1	1	1
r	60	60									1	1	1	1	1	1	1	1	1	1	1	1	1	1
CTX 120	1000		0	1	0	1	1	1	1	1	2	2	2	2										
INH 100	100		0	½	0	½	0	1	0	1 ½	0	2	0	2 ½										
CTX 480		1000					0	½	0	½	0	1	0	1	0	2	0	2	0	2	0	2	0	2
CTX 960		1000									0	½	0	½	0	1	0	1	0	1	0	1	0	1
INH 300 (daily for IPT)		672									0	½	0	½	0	1	0	1	0	1	0	1	0	1
INH 300 (weekly for 3HP)*		672											0	1	0	1 ½	0	1 ½	0	2	0	2	0	3
RFP 150 (weekly for 3HP)*		24											0	3	0	4	0	5	0	5	0	5	0	6
INH 300 / **RFP** 300 (3HP)*		36															0	3	0	3	0	3	0	3

[2] DRV and r can be given as once daily dosing for patients **without** any HIV drug resistance against DRV. Follow the advice from the national 3rd line committee for each specific patient.

14.2 Choosing regimen and time of starting in special situations

Table 17: Choosing ART regimen and timing of initiation in special situations

Condition	Timing for ART initiation	3-19.9kg	20-24.9kg	25-29.9kg	30kg+
Anaemia (<8g/dl)	• As soon as possible	**15PP**	**15PA**	**15A**	**13A**
Active TB	• Pulmonary and extra-pulmonary TB (except meningitis): within 14 days of diagnosis. • TBT + ART can be started on the same day if the patient is stable. Don't delay TBT or ART • Delay ART initiation by 5 weeks after starting treatment for TB meningitis to reduce IRIS risk.	See **section 17** on **page 80**			
Cryptococcal meningitis	• Delay ART initiation by 5 weeks after starting treatment for acute CM to reduce IRIS risk.	**15PP**	**15PA**	**15A**	**13A**
Jaundice	• Refer to District / Central Hospital for lab monitoring • After investigation and stabilisation	**15PP**	**15PA**	**15A**	**13A**
Renal failure	• Refer to District / Central Hospital for lab monitoring • Start within 7 days of diagnosis	**15PP**	**15PA**	**15A**	**15A**
Psychiatric history	• As soon as possible • Reliable guardian needed	**9P**	**9P**	**9P**	**7A**
Epilepsy	• As soon as possible • Reliable guardian needed	**4P**	**4P**	**4P**	**5A**

14.3 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, ABC) or NNRTIs (EFV) may need a NS regimen.
- Consider ATV/r or LPV/r for substitution of DTG, and EFV.
- Contact the DHA for availability of non-standard ARVs (see **section 26** on **page 123**).
    - Provide patient history, indication and proposed regimen.

15 Prescribing and dispensing ARVs

Key Facts: Prescribing and dispensing ARVs

- 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.
    - DTG (regimen 12, 13, 14, 15) can disturb sleep and should therefore preferably be taken in the morning.
    - EFV (regimen 4 and 5) can cause dizziness, especially in the first 4 weeks. This is less troublesome when taken before bed.
- **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 halfway** 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 the patient or his registered guardian/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).

15.1 Rules for prescribing and dispensing of ARVs

ARVs for treatment of HIV (ART)

- Only MOH-certified clinical ART providers are authorized to **prescribe** ART: Medical Doctors; Clinical officers; Clinical technicians; Medical Assistants; Registered Nurses; Nurse/Midwife Technicians.
- Only health workers and qualified pharmacy personnel are allowed to **dispense** ARVs.
- ARVs may be dispensed at MOH-certified static ART clinics and in outreach locations. Outreach clinics must be staffed by certified ART providers. ARVs must not be distributed outside of these settings.
- Only the patient or his individual registered guardian/treatment supporter are allowed to **collect** ARVs.

ARVs for PEP

- PEP needs to be started as soon as possible after high-risk exposure. Such events are often managed under challenging circumstances (e.g., rape, accidents).
- Non-health professionals (e.g., police officers) are allowed to dispense the initial dose of PEP without prior confirmation of HIV negative status under the following circumstances:
    - Received PEP training by a MOH certified ART provider.
    - Under regular supervision by ART clinic staff
    - District pharmacy in charge is responsible for supplying and accounting for ARVs given to e.g., *Victim Support Units* and must provide active support with ARV stock management.

Emergency dispensing to patients from another PMTCT/ART site

- In an emergency, patients are allowed to collect one month of ARVs from any ART clinic in Malawi under the following conditions:
    - The patient must show 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 an improvised *Emergency ARV Dispensing Register*. Document date, original ARV registration number, original facility name, patient name and contact details, ARV name and quantity dispensed, reason for emergency dispensation and staff name.
    - Instruct patient to return to their ART clinic of registration as soon as possible to ensure the patient is not recorded as lost to follow-up.

15.2 Determining quantities to be dispensed and next appointment

- **Table 18** on **page 73** shows the number of tablets to be supplied for appointment intervals of 4, 8, 12 or 24 weeks for the total number of tablets taken of each ARV per day (paediatric and adult formulations).
    - Use **Table 16** to add up the 'total tablets taken per day' for each ARV contained in the regimen. For example: a child of 10kg on ABC/3TC + DTG (Regimen 15PP) takes **2** paediatric tablets of ABC/3TC and **2** paediatric tablets of DTG in the morning.
    - Note: regimens that are given in 2 or more different tins may not be used up at the same time. For example, children on 15PP will finish ABC/3TC long before DTG because DTG is supplied in 90 tabs tins. Make sure the patient / guardian comes back for a refill before running out of either ARV to avoid that only part of the regimen is taken.
    - 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 16**). 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 and always making sure they have all drugs not just some (15PP in particular).
- 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.

15.3 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 4, 12 or 24 weeks.
- Patients initiating standard or alternative first line ART must be reviewed clinically at month 1, 3 and 6 after initiation.
- Thereafter, stable and adherent patients can be given up to 24-week (**6-month**) appointments.
- In exceptional cases (e.g., international travel), up to **12 months** of ARVs can be dispensed.
- Patients starting 2nd or 3rd line ART must be seen every 4 weeks for the first 3 months. Thereafter, patients who are stable and adherent can be given up to 12-week appointments.
- Align dispensing of CPT and TPT with ART, exposed child follow-up and ANC 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 18: 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 ABC/3TC and DTG making up Regimen 15

Dispens. interval	Total tabs taken per day	Supply needed								Total tabs **USED** in interval - Adherence	
		Actual tabs *	*Multiples of full tins*								
			Tins of 30		Tins of 60		Tins of 90		Tins of 120		
			tabs	**tins**	tabs	**tins**	tabs	**tins**	tabs	**tins**	**Perfect** 100%	**Good** 95% – 105%
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*
24 weeks	1	**170**	180	**6**			180	**2**			168	160 – 176
	2	**338**					360	**4**			336	319 – 353
	3	**506**					540	**6**			504	479 – 529
	4	**674**					720	**8**			672	638 – 706
	5	**842**					900	**10**			840	798 – 882
	6	**1010**					1080	**12**			1008	958 – 1058

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

16 Starting ART

Key Facts: Starting ART

- ART does not cure HIV infection.
- ART stops the virus from multiplying, which allows the immune 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. All patients need effective support:
    - Identify a reliable guardian / treatment supporter who needs to attend ART education.
    - Link with patient / peer support group
- Successful ART leads to very low levels of virus in blood, semen and vaginal fluids. A suppressed VL effectively eliminates the risk of sexual or mother-to-child transmission. However, condom use is important
    - In the first 6 months after starting ART
    - Later if adherence is not good and/or viral suppression has not been confirmed.
- All patients need a confirmatory HIV test before starting ART (see **section 16.3** on **page 76**) to rule out any possibility of mix-up of test results or fraudulent access to ART.
- 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 ARVs 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).
    - Ask for consent for active follow-up at the time of starting ART.
    - Patients can withdraw consent at any time.
- A small number of ART patients develop serious side-effects. Educate all patients about the important signs to look out for (see *Key facts* for **section 16.4.1** on **page 78**)

16.1 When to start ART

Key Facts: Starting ART

- Start ART as soon as possible:
    - For all children and adults with **confirmed HIV infection**
    - For infants with **presumed AIDS** (following definition of PSHD).
- **All** patients need a confirmatory HIV test before starting ART. The standard (blood-based) HIV testing algorithm, performed by a trained HTS provider at the same health facility where ART is started, counts as the confirmatory HIV test. A new confirmatory test is only needed for patients who were initially diagnosed elsewhere (community, another health facility).
- Explain the benefits of immediate ART for the patient's **own health**, and for **prevention** of onward transmission to sexual partners and from mother to child. This understanding is key for patient motivation and good adherence.
- Patients may not be ready to start ART immediately.
    - Allow for reflection time if the patient is unsure and/or wants to discuss with family.
    - Schedule a follow-up appointment not further than 2 weeks.
    - Delay ART initiation by 5 weeks for patients treated for cryptococcal or TB meningitis (see **section 14.2** on **page 69**) due to the risk of IRIS (see **section 18.12** on **page 100**).
- Initiate / transition all children from 3kg+ to a DTG-based regimen.
    - **15PP** (paed ABC/3TC + paed DTG) for **3 – 19.9 kg**
    - **15PA** (paed ABC/3TC + adult DTG) for **20 – 24.9kg**
    - **15A** (adult ABC/3TC + adult DTG) for **25 – 29.9kg**
        - Confirm undetectable VL in the last 6 months before making this transition.
- Monitor weight and routinely move children to **13A** once they have reached **30kg+**
- Collect routine VL samples 6-monthly for all children on paediatric regimens (blue patient card) and for pregnant or breastfeeding women.

16.2 Record keeping

- PMTCT/ART nurse or clinician: fill ART patient card s 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.

16.3 Confirming HIV infection

- All patients need a confirmatory HIV antibody test to rule out a mix-up of test results or fraudulent access to ART:
    - Before starting ART
    - All children under 24 months who start ART need a confirmatory DNA-PCR using a new DBS sample or POC test. This should be collected on the day of starting ART.
    - The standard (blood-based) HIV testing algorithm, performed by a trained HTS provider at the same health facility where ART is started, counts as the confirmatory HIV test. A new confirmatory test is only needed for patients who were initially diagnosed elsewhere (community, another health facility).
- 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.

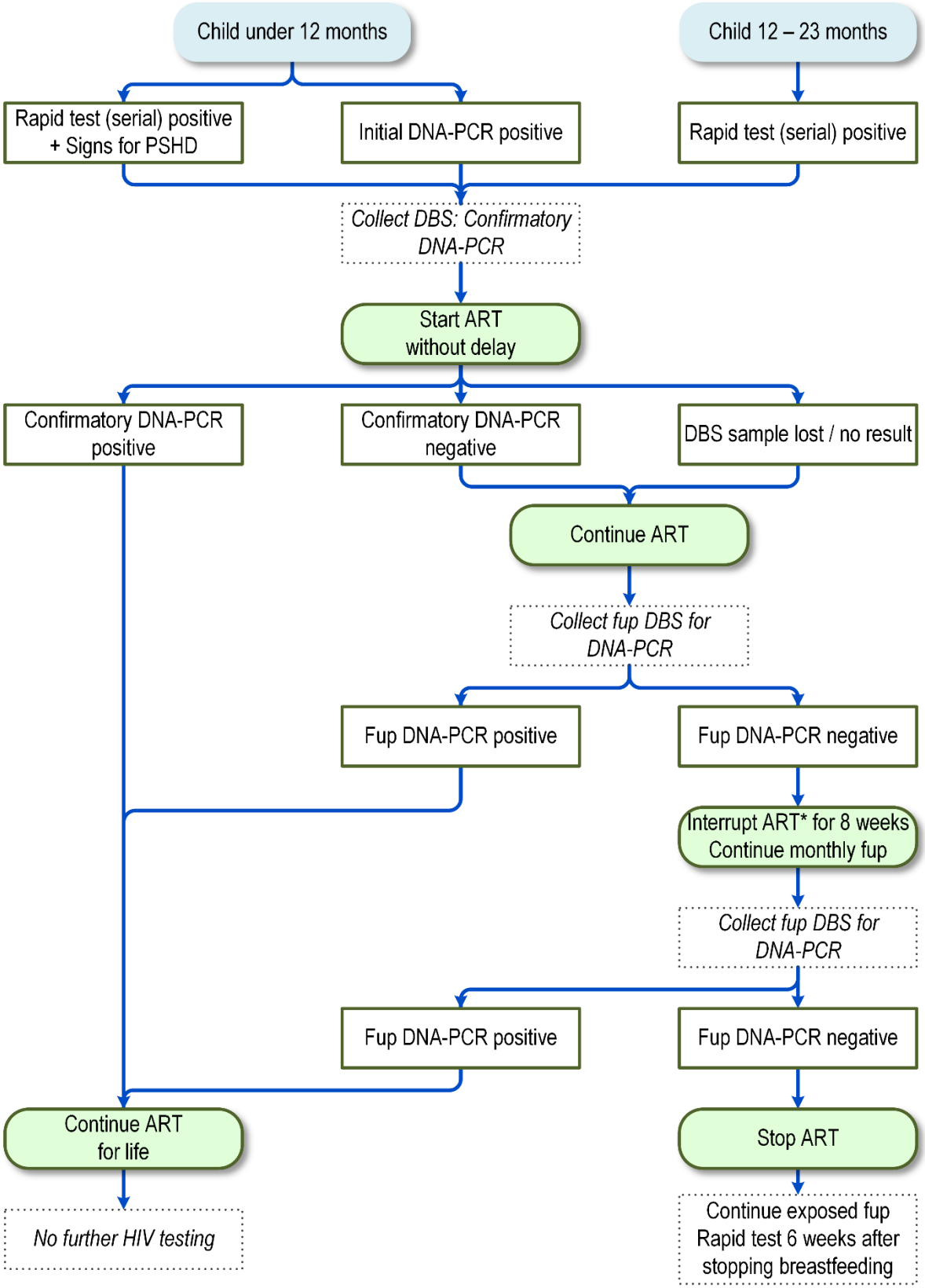
16.3.1 Confirmatory testing for adults and children 2 years and above

- Place a dedicated HIV testing provider to the ART clinic to do confirmatory testing. Ensure that all Quality Assurance protocols for HIV testing (proficiency testing, quality control) are being followed.
- Follow the national HIV testing guidelines.

16.3.2 Confirmatory HIV testing for children under 2 years

- All children to be started on ART under the age of 2 years need a confirmatory DNA-PCR.
- Collect the DBS sample on / before the day of initiation.
- Don’t delay ART initiation - don’t wait for the confirmatory PCR result before starting ART.
- Refer to **Figure 2** on **page 77** for the schedule of follow-up testing and the correct action based on the results.

Figure 2: Confirmatory HIV testing for children under 2 years



16.4 Preparing the patient for ART

- Start ART as soon as possible after testing positive.
- Offer pregnant women to start ART on the same day of diagnosis.
- 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.).
- Identify 2 or more guardians for all children to support adherence and retention.
- Ask all patients to attend the initial group counselling and/or the ART initiation visit with a named guardian/treatment supporter.
    - Another patient can be appointed as the *named treatment supporter* if the patient is unable to identify a suitable guardian.

16.4.1 Mandatory patient education when starting ART

Key Facts: ARV side effects

- A small number of patients on ART develop significant side-effects.
- Most side-effects are mild and disappear while ART is continued.
    - DTG can **disturb sleep**, but this is rare when taken in the morning and usually settles by itself.
- Some side-effects require a regimen change.
- 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**
    - Severe **skin rash** with blisters, involving eyes, mouth or genitals

- 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 on the same day as 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 16.3** on **page 76**).

ART group counselling

- Use the latest version of the MOH ART flip chart.
- Share "Key facts for providers and patients"
- Explain the standard VL monitoring schedule (see **page 88**). Ask the patients to help remember when VL is due.

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

16.4.2 Baseline and routine lab investigations

- If CD4 testing is available at the site: do baseline CD4 count for all adults and children 5+ years before/when staring ART. However, do not delay ART initiation if CD4 machine is down / results are delayed or testing is currently not available. See **section 10.3** on **page 43**
- Use point-of-care (POC) machines or semi-quantitative rapid CD4 count test kits.
- Do routine urine LAM and serum CrAg for patients with advanced HIV infection (see **section 8.1** on **page 22**).
- 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.
- Monitor VL according to the standard schedule (see **section 18.10** on **page 88**).

17 Combining ART and TB treatment

Key Facts: ART and TB treatment

- Each year, 12,000 (1.2%) of the 986,000 HIV infected Malawians develop active TB and 4,200 die from TB[3].
- The risk of active TB is high for the first 6 months on ART and remains elevated for life.
- Most HIV patients with TB do not have typical TB symptoms (productive cough). Many 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.

Selecting ART regimen and adjusting dosage

- See **Table 28** on **page 131** for a detailed list of potential drug interactions
- ATV/r, LPV/r and DRV have significant interactions with rifampicin. Do not combine if possible.
- DTG-based ART regimens (**13, 14, 15**) are a good combination with TB 1st line treatment.
- However, the **daily DTG dose needs to be doubled** while on rifampicin-containing TB treatment:
    - Adults take the regular DTG-containing regimen in the morning and one additional tablet of DTG 50mg in the evening (after 12 hours)
    - Children on paediatric DTG 10mg formulation take regular DTG dose in the morning and an additional DTG dose in the evening (after 12 hours)
    - Continue with double-dose DTG for 7 days after the last dose of rifampicin.
- DTG-based regimens are the best option for patients previously on 6A, 7A, 10A and 11A who need TB treatment.
- Patients with ART failure (see **section 18.10.2**on **page 89**) may develop active TB. In this case, 2nd line ART needs to be combined with TB treatment.
    - **Preferred:** Use **13A, 14A** or **15A** (with double dose DTG) while on TB treatment.
    - **Alternative:** Use LPV/r-based 2nd line regimens (**9A**, **10A**, **11A**) for patients who cannot use **13A, 14A or 15A**.
        - Double the daily dose of LPV/r (4 tablets of LPV 200mg / r 50mg every 12 hours) for the duration of rifampicin treatment.
        - For children who can swallow whole tablets (without crushing or chewing), boost LPV/r with additional LPV/r. Children who cannot swallow tablets whole should not take LPV/r in combination with TB treatment as this will result in development of PI resistance.

[3] 2021 Global tuberculosis report (WHO)

18 Continuing ART

18.1 Confirming adherence to appointment

- On the patient card, look at the *Next Appointment Date* given from 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.*

18.2 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 for children based on *CMAM* guidelines. Children should grow. If not gaining weight or height investigate further.
- Investigate any consistent weight loss over 2 or more consecutive visits. Remember to confirm that the weighing scale is correctly calibrated and any heavy clothing was removed.

18.3 Monitoring for 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 20** on **page 96** 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 side-effects Yes / No on the patient card and specify new side effects under *Notes*.
- Change the ART regimen if medically indicated (see below).
- Write any new HIV-related disease under *Notes* on the back of the patient card/EMR

18.4 Indications for interrupting or stopping ART

- Stop ART in patients with chronic poor adherence. Consider stopping if intensive counselling has 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

18.5 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 insomnia/headache after starting a regimen with DTG. However, substitute with an alternative drug if symptoms have not disappeared after a month.

Change dosage and formulation:

- Review current weight for children and adjust dosing if necessary. (See **Table 16** on **page 68**).
- 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.

Change ART regimen:

- Use **Table 15** on **page 66** 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.
- Adjust regimen and formulation according to current weight:
    - Transition all children on regimen **9P** to **15PP**
    - Move to **15PA** when they reach 20kg
    - Move to **15A** when they reach 25kg
    - Move to **13A** once they **weigh over 30kg**. This is to reduce the pill burden and benefit from optimised treatment regimens.
- Add any new regimen to the *ART Regimens* history section on the card header and specify any non-standard regimen here.
- Multiple contraindications / side-effects may require NS regimen (see Section **14.3** on **page 69**)

18.6 Routine TB screening (*intensified case finding*)

- 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
- **Children:** in addition to the above, ask about the following signs. Investigate for TB if any are present:
    - Unresolved pneumonia
    - Frequent hospitalization/ illness
    - TB contact

- 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 presumptive*** if one or several of the 4 signs are positive.
        - Thoroughly investigate further (full clinical exam, sputum for Xpert, chest x-ray, fine needle aspirate, TB urine Lam if indicated, FASH, etc.)
        - Interrupt TPT until active TB has been ruled out
    - ***TB confirmed*** if the patient has a current confirmed episode of TB (clinical or lab diagnosis).
        - Always confirm if the patient is currently taking and adherent to TB treatment – initiate TB treatment without delay or provide intensive adherence support.
        - Classify ***on TB treatment*** or ***not on treatment.***

18.7 Achieving optimal adherence

Key Facts: ARV adherence

- Repeated skipping of individual doses or repeated longer interruptions inevitably lead to development of HIV drug-resistance.
- Children and adolescents on ART need special support (see **page 86**).

18.7.1 Routine adherence support

- The following patient groups are at high risk for poor adherence (and interruption of treatment) and need special attention: children, adolescents, previous LTFU, depression, new ART initiation (particularly in pregnancy or breastfeeding women), excessive alcohol use, living far from clinic, seasonal workers.
- Ask at every clinical assessment visit:
    - What challenges have you had taking your ARVs?
    - What days / time of day are you most likely to forget taking your meds? (Weekends, weekdays, mornings, evenings?)
- Remind patients of the importance of perfect adherence at every clinic visit:
    - Initial ART counselling
    - Follow-up group counselling
    - Start *intensive adherence counselling* (**IAC**) if any sign for poor adherence (see **page 84**)
- Give **practical strategies** 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.

18.7.2 Intensive adherence counselling

Indications

- Questionable or confirmed poor adherence noted at regular visit / late for appointment
- Low level viraemia, or VL result 1000+ copies/ml (see **page 90**).

Step-by-step guide

- Intensive adherence support for patients with unsuppressed viral load must be provided by an experienced clinician or nurse, not by a lay provider
- Ask both patient and the treatment supporter to attend.
- Explain the information presented in the boxes with **Key facts**:
  - Starting ART (**page 74**)
  - Achieving optimal adherence (**page 83**)
  - Monitoring for treatment failure / HIV drug resistance (**page 88**)
- Routinely screen and manage depression and substance use disorder using PHQ-2 and DSM-5 (see **section 12.4** on **page 56**)
- Make a (verbal) ***contract*** with the patient and the treatment supporter:
  - "We will check your VL again in 3 months."
  - "We will work together to help you remember to take your tablets as prescribed. This will help us find out if your current ARVs are still able to make your ***VL undetectable***."
- Look for specific problems / situations that get in the way of good adherence. Ask for:
  - Frequent travel / boarding school
  - Conflicts at home / lack of privacy / stigma
- Agree on an action plan and write instructions in health passport: select the most suitable **practical strategies** from **page 83**. Review specific strategies for children / adolescents (**page 86**)
- Consider giving monthly appointments until follow-up VL is due (after 3 months of good adherence).
  - Do pill count and assess adherence closely at each follow-up visit
  - Review action plan: what has worked – what has not? Revise plan if necessary.

18.8 Welcoming patients back to care after treatment interruption

Key Facts: ART treatment interruption

- Treatment interruptions are common, and many patients need active support to return to ART.
- Most treatment interrupters feel more comfortable returning to ART via the HTS program and many do not disclose previous ART use out of fear of reprisals.
- Judgemental and derogatory comments from health workers are a significant barrier for treatment interrupters to return to care. Do not judge/criticize/shame.
- Emphatically welcome treatment interrupters to return to ART, either self-motivated or after active follow-up.
- Openly advertise at OPD and HTS that interrupters are welcome to restart ART at this facility.

Confirmatory HIV testing before ART re-initiation

- Patients who interrupted ART less than 3 months ago:
    - With documentation of HIV+ status: no need for confirmatory HIV testing before ART re-initiation.
    - Without documentation of HIV + status: routinely do confirmatory HIV test before ART re-initiation.
    - If confirmatory inconclusive: collect a DBS sample and send to National HIV Reference Laboratory (NHRL).

ART re-initiation

- Offer individual counselling to establish the reasons behind the disengagement. (See **section 18.7.1** on **page 83** for steps for individual counselling)
- Screen for advanced HIV disease (AHD). See **section 8.1, page 22** and **section 10.3, page 43**
- Screen for mental health disorders using PHQ-2 and DSM 5 screening tools. See **section 12.4 , page 56**
- Follow the routine ART initiation protocol. See **section 16.4 , page 78**
- Collect VL sample at 6 months after ART restart/re-initiation
- Encourage the patient to visit with his/her treatment supporter at the next appointment.

18.9 Special treatment support for children and adolescents

Key Facts: Supporting children / adolescents

- Good adherence is particularly challenging for children and adolescents
- Dependence on caregivers, often in difficult home environment
- Need to adjust ARV dose by body weight
- Developmental and psychosocial changes
- Guardians may falsely assume that older children are independent and no longer need treatment support:
    - Explain to guardian that they are part of their child's "treatment team". Their role will change but they will be needed through adolescence and into early adulthood.

- Ask at every visit:
    - Who is responsible for supervising the taking of ARVs?
    - Who stands in for the guardian if s/he is away? Identify at least 2 guardians
    - How do you give the tablets?
- Discuss possibility of selecting a trusted teacher or fellow student as treatment supporter for children attending boarding school. Feasibility depends on each school but may be considered.
    - Offer to transfer the child to the most convenient ART site closest to school or dispense ARVs for 6 months to allow refill during school holidays.
- 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. However, pay attention to weight bands and avoid MMS when dose adjustment is likely at next visit.

18.9.1 Managing the disclosure process

- Explain to the parent that disclosure is a gradual process. Assure the parent that you will work through this process together.
- 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 in an age-appropriate way.
- 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 may 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'.
- Full disclosure can begin as early as 8-10 years.

By age 11-13 years:

- Add more information gradually. By age 11-13 years the child should know that s/he has HIV. Also, all 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:

- Invite open dialogue about 'teenage challenges' that can get in the way of good adherence:
    - Low self-esteem, pill fatigue, frustration about the need for ART
    - Conflicts at home / at school
    - Relationships
    - Alcohol / drug abuse
- Encourage to join an "*ART Teen Club*" where available. Provide extra support for patients transitioning from a *Teen Club* to the adult clinic.
- Eligibility criteria for joining an *ART Teen Club* include:
    - Confirmed HIV infection
    - Fully disclosed
    - Aged between 10 – 19
    - Guardian consent
- Offer condoms and other FP methods; explain use on penis model; give at least 20 condoms
- Explain: Do not have penetrative sex without condom. HIV like other infections can travel in semen and vaginal fluid and infect the other person.
- Explain: It is still possible for you to have children when you want to. The risk of passing HIV to your partner or to your baby is very low if your VL is undetectable.
- Explain: Where to access STI treatment, family planning services and help in case of sexual assault.

18.10 Monitoring for treatment failure / HIV drug resistance

18.10.1 Viral load (VL) testing

Key Facts: Viral load testing

- VL is the best test to monitor success/failure of ART
  - VL = number of viral particles per ml of blood.
  - More virus ⇨ faster destruction of CD4 cells ⇨ more severe immunosuppression
- The VL monitoring schedule is designed to detect adherence problems and potential ART failure early while avoiding unnecessary tests to save cost.
- Collect the first scheduled VL **6 months** after starting ART. Normally, patients are expected to have an undetectable VL at this time. If the VL is detectable, possible causes are:
  - Most likely a sign of poor adherence.
  - Patients who were infected with drug-resistant HIV.
  - Patients who developed drug-resistance from previous ARV use (e.g., infants who received NVP prophylaxis).
- Patients who have suppressed viral load at 6 months and are adherent and clinically well have a low risk of ART failure. Therefore, routine VL monitoring is scheduled approximately **every 12 months.**
- **Children on paediatric regimens, pregnant and breastfeeding women** require **6 monthly** VL monitoring because a high VL is common in these groups and has severe implications.
- Collect missed VL tests at the next regular visit.
- Do additional targeted VL tests outside of this schedule when suspecting ART failure.
- Explain the standard VL monitoring schedule to every patient. Ask the patient to help remember when VL is due.
  - Explain (example): “You had your viral load drawn in November. Therefore, every November ASK your provider for your viral load test to be done.”
- Actively communicate (phone / home visit) any detectable VL results (above detection limit, even if <1000) to patients as soon as the result is received at the site. Call for an early appointment.
- **DBS** and **plasma** VL samples produce different results in the low ranges below 839 copies/ml:
  - DBS results are usually not quantifiable below 839 copies/ml. (Some labs may produce an actual readout above 400 copies/ml from DBS). A DBS result <839 copies/ml means that some viruses have been detected, but it is not possible to determine if this VL is in the very low range below 200 copies/ml or higher.
  - Plasma results are usually quantified above 40 copies/ml.
  - Both DBS and plasma results of <LDL mean that no virus has been detected, i.e., the VL is undetectable or fully suppressed.
  - Plasma is the gold-standard for viral load testing. Collect plasma samples if feasible.

Key Facts: ART failure and drug resistance

- ARV drug resistance starts gradually with low level viraemia 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- or third-line regimen that still works.
- Although DTG has a high barrier to resistance development, some cases with DTG resistance have emerged.
- HIV drug resistance usually affects different ARVs of the same class (cross resistance).
- ***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.

18.10.2 Clinical screening and diagnosis of treatment failure

- **Suspect ART failure** if both of the following clinical conditions are met:
    - On ART for at least 12 months
    - New HIV-related disease / unexplained weight loss / failure to thrive
- For all **suspected ART failure** cases, look for indications for poor adherence in the last 6 months
    - Adherence was good:
        - Do a targeted VL, where available use a point-of-care VL testing platform such as Gene Xpert or refer to have this done immediately.
    - Known current poor adherence:
        - Start intensive adherence counselling (see **page 84**)
        - Do a targeted VL after 3 months if adherence was satisfactory.
- See **Figure 3** on **page 93** for the interpretation of VL results.

18.10.3 Protocol for Drug resistance testing referrals.

- Patients on DTG- and PI-based regimens who don't re-suppress below 1000 copies/ml after an initial high VL despite good adherence need a genotype sample for resistance testing.
- Contact the National HIV drug resistance (HIVDR) Expert Committee (either through DHA or sending an email to 3rdlineart@lighthouse.org.mw) for a copy of the HIVDR testing application form (see **Form 1** on **page 132** in the Appendix). You can also access the application forms through your district ART coordinator.
- Follow the instructions on the application form and ensure that the application form is completely filled before sending it to the expert committee.
- The expert committee will advise if a genotype sample needs to be collected. Genotyping is only possible if the current VL is 1000+ and will be more reliable from 5000+.

- The genotype result can only be interpreted correctly if the patient has been taking their ARVs consistently for 2-3 months before the sample was collected.
- Maintain the current regimen until genotyping results are available.
- Follow the regimen recommendations from the National HIVRDR expert committee.

When to do VL

- See **Figure 4** on **page 102** for the alignment of the VL monitoring schedule and 6 months dispensing.

Children on paediatric ARV formulations (blue patient card), pregnant and breastfeeding women

- The first VL is scheduled at 6 months after ART initiation or re-initiation. Aim for 6-monthly routine VL monitoring thereafter. Revert to 12-monthly monitoring when the patient is on adult ARV formulations (yellow cards) and no longer pregnant / breastfeeding.
- Routinely collect the next VL sample when 5 months or more have elapsed since the last VL sample was collected.

All other patients

- The first VL is scheduled at 6 months after ART initiation or re-initiation. Aim for 12-monthly routine VL monitoring thereafter.
- Routinely collect the next VL sample when 11 months or more have elapsed since the last VL sample was collected.

All patient groups

- Don't delay a scheduled/routine or targeted viral load sample collection because of (suspected) poor adherence.
- Ascertain good adherence in the last 3 months before taking the follow-up sample after a first high VL and IAC.
    - Review pill counts and doses missed carefully.
    - Trust the patient if they insist that adherence was good. Do not rely on pill count alone.
- Delay collection of follow-up sample after IAC ONLY if poor adherence is confirmed and if the patient is still clinically stable.

Interpreting and acting on VL results

- See **Figure 3** on **page 93** for indication, interpretation and action from VL testing.

Table 19: Classification of DBS and plasma VL results

Sample type	Suppressed	Low-level viraemia	Viraemia 1000+
DBS	<LDL	<400 <550 <839 Any value 400-999	1000+
Plasma	<LDL <20 <30 <40 <150 Any value 20-199	Any value 200-999	1000+

Successful ART

Finding	**Routine** or **targeted / repeat** VL "*suppressed*"
Interpretation	Successful ART
Action	Praise the patient and encourage further good adherence. Continue the same regimen. Offer 6 month dispensing if otherwise eligible. Next routine VL after 6 months for children on paediatric regimens, pregnant and breastfeeding women; after 12 months for all other patients

Potential treatment failure

Finding	**Routine, Targeted/ repeat or Follow-up** VL: *"low-level viraemia"*
Interpretation	Potential treatment failure
Action	Deliver one quality session of intensive adherence counselling and depression screening (see **section 12.4.1** on **page 56**) at the same visit when returning the result to the patient. Provide additional IAC sessions at 1-month intervals for patients with specific adherence problems. Enter in "*Detectable Viral Load*" register (green cover, prev. "High VL register"). Continue same ART regimen. Give a regular 3-month appointment. Collect repeat VL sample after 3 months of good adherence. **Collect the next VL after 6 months if follow-up result is still *"low-level viraemia"*.**

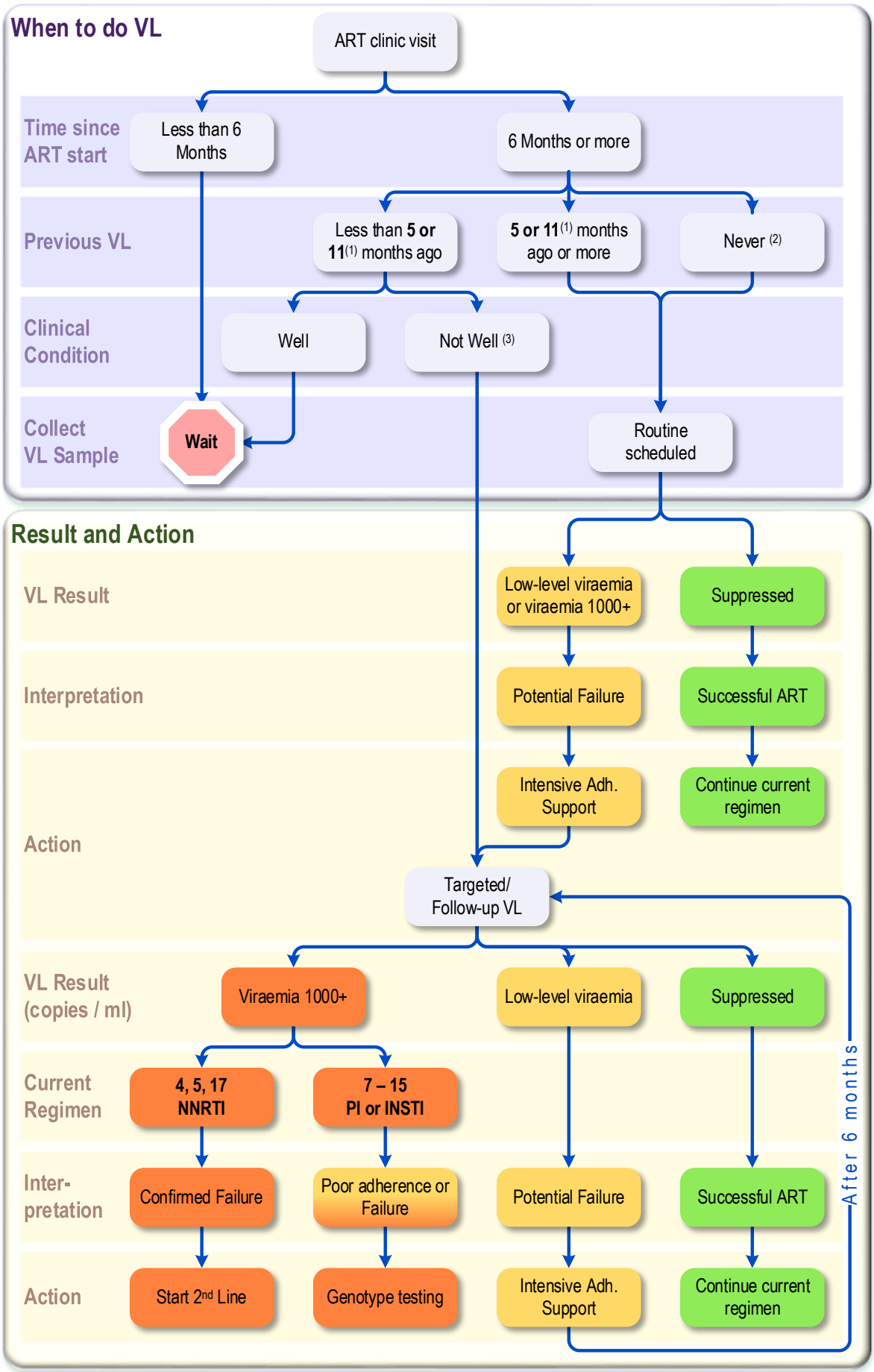
Confirmed treatment failure

Finding	**Targeted / repeat** VL: *"viraemia 1000+" AND* Patient is **on NNRTI-based regimen (4, 5, 17)** *AND* **good adherence** in the 3 months before sample collection
Interpretation	The virus is likely resistant to the current ART regimen.
Action	Deliver one quality session of intensive adherence counselling at the same visit when returning the result to the patient. Provide additional IAC sessions at 1-month intervals for patients with specific adherence problems. Enter in "*Detectable Viral Load*" register (green cover, prev. "High VL register"). Consult certified 2nd Line Prescriber for initiation of 2nd line ART without delay. 'Reset the clock' for routine VL monitoring: **6 months** after switch to 2nd line and **every 12 months** thereafter.

Poor adherence or treatment failure

Finding	**Targeted / repeat** VL: *"viraemia 1000+" AND* Patient is **on PI- or DTG-based regimen (7, 8, 9, 10, 11, 12, 13, 14, 15, 16)**
Interpretation	High VL on these regimens can be adherence problems / poor absorption or drug-resistant virus. Need HIV drug resistance testing to confirm resistance before changing regimen.
Action	Deliver one quality session of intensive adherence counselling at the same visit when returning the result to the patient. Provide additional IAC sessions at 1-month intervals for patients with specific adherence problems. Enter in "*Detectable Viral Load*" register (green cover, prev. "High VL register"). Collect DBS or plasma sample for genotyping. Continue current regimen until genotyping results are available. Give a regular 3-month appointment. Select ART regimen based on resistance profile. 'Reset the clock' for routine VL monitoring: **6 months** after switch to 2nd or 3rd line and **every 12 months** thereafter.

Figure 3: Indication, interpretation and action for routine scheduled and targeted VL testing



(1) For **children on paediatric regimens (blue patient card), pregnant and breastfeeding women:** a new VL is scheduled **every 6 months** after the last test. Use 5-month cut-off for these priority patient groups.
All **other patient groups**: a new VL is scheduled **every 12 months** after the last test. Use 11-month cut-off.

(2) Includes: VL never tested, sample rejected, result lost or declared missing

(3) Any of the following: Significant weight loss, failure to thrive, new / worsening HIV-related disease (susp. or confirmed)

18.11 Updating follow-up outcome

- 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.
- Loss to follow-up ('default'):
    - 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 20: Symptom-based identification and management of side-effects

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Body pains, weakness			
AZT, 3TC	Severe anaemia: Hb <7 g/dl	Stop AZT, consider transfusion	Substitute AZT, continue ART without gap
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	Don't re-start ART before lactic acid <2mmol/l Can restart ART with AZT after suspected LA Never give AZT after confirmed LA Can use ABC or TDF containing regimen
Fever			
Onset independent of drugs: Bacteraemia, malaria, TB	FBC, MPs, blood culture, urine dipstick, Xpert, chest x-ray, urine LAM		
Onset within 8 weeks of starting drugs: ABC, NVP, EFV, rifapentine	ABC, NVP or EFV hypersensitivity: Body pains, vomiting, diarrhoea, abdominal pain, sore throat, cough, shortness of breath, rash, jaundice Rifapentine hypersensitivity: flu like symptoms, fever, headache, sudden collapse (syncope)	Any suspected hypersensitivity: Stop all ART and TPT immediately, treat at hospital Don't re-start 3HP (rifapentine) after suspected hypersensitivity	Do not re-start before symptoms have resolved Never use NVP or ABC again Replace NVP with EFV and ABC with TDF Never restart TPT
Slimming: **Cheeks, forearms, buttocks, legs (often prominent veins) Fattening: Back of neck ('buffalo hump'), breast, stomach, and waist**			
AZT, LPV/r, 3TC, TDF, HIV EFV	Lipodystrophy (from ART / HIV itself)	Reassure patient Substitute likely causative ARV	
DTG	Metabolic syndrome (obesity)	Reduce calorie intake, increase physical activity	Substitute DTG to EFV or ATV/r if severe and no improvement

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Breast swelling / enlargement: one- or both-sided, in males or children			
EFV, ketoconazole, cimetidine, omeprazole, spironolactone, isoniazid, testicular tumours, physiological in adolescence and middle-aged/elderly testosterone deficiency (HIV), AZT, LPV/r	Gynaecomastia: palpate enlarged breast gland Lipodystrophy: accumulation of fat (from ART / HIV itself)	Reassure patient Substitute EFV with DTG in ART regimen.	Consider surgery for extreme gynaecomastia
Upper GI symptoms: Nausea, vomiting			
AZT, LPV/r, 3TC, DTG Drug-induced hepatitis	Lactic acidosis? (see '*Body pains and weakness*') Jaundice? (see 'Yellow eyes')	Determine liver enzymes 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 continue the same ART regimen If persistent, substitute
Skin Rash			
Onset before starting drugs: Seborrhoeic dermatitis ("bumpy itch") Pruritic papular eruption	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/papular rash not involving mouth, eyes, and genitalia No fever, body pain, weakness, etc.	Continue EFV, reassure: initial rash mostly resolves. Adults only: Promethazine 25mg 12-hourly Adults or children (lower dose): Chlorpheniramine (Piriton) 10 mg 8-hourly	Switch to DTG based regimen

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Lower GI symptoms: Diarrhoea, lower abdominal pain			
Onset before ART initiation: HIV-induced	Stepwise empirical treatment	Stepwise empirical treatment of chronic HIV diarrhoea (see page 26)	
Onset within 6 weeks of starting drug: LPV/r, AZT, 3TC, DTG	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			
3TC	Pancreatitis Serum amylase >1.5 times above upper normal limit	Stop all ART immediately Treat at hospital	Restart ART after complete remission Call DHA for guidance
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 ARV drug that was the suspected cause Reinitiate ART one month after jaundice is resolved, and LFT <2.5 of upper normal limit
Yellow eyes			
Viral hepatitis, alcohol, ATV/r, NVP, INH, Rifapentine, EFV, ABC, severe malaria, Cancer Rifapentine can stain eyes/body fluids orange	LFT and ultrasound scan to differentiate: Viral hepatitis, cirrhosis, drug hepatitis, primary liver cancer, metastases	Discontinue ART and TPT immediately if jaundice develops after start. See notes below **Table 15** on **page 66** for patients on ATV/r. Identify cause and manage accordingly (LFT, ultrasound, hepatitis serology). Reassure patients for orange discolouration of eyes and body fluids	Never re-start the ARV or TPT that was the suspected cause. Re-initiate ART 1 month after jaundice has resolved and LFT <2.5 times upper normal limit

Cause (in order of likelihood)	**Diagnosis**	**Primary Management**	**Secondary Management**
Swollen face and eyelids, particularly in the morning/tiredness, too much or too little urine			
Onset before starting drugs HIV, diabetes, hypertension	Confirm nephropathy with serum creatinine, serum albumin and protein in urine	Identify cause and manage accordingly. Stop all nephrotoxic drugs. Consult specialist physician	Adjust ART dosage according to creatinine clearance
Onset within 1 year of starting drugs: TDF	Confirm nephropathy with serum creatinine, serum albumin and protein in urine	Admit to hospital Substitute TDF to ABC without gap	Adjust ART dosage according to creatinine clearance
Drowsiness, confusion, nightmares, insomnia, psychosis			
EFV, DTG	Neuropsychiatric EFV or DTG toxicity	Drowsiness/ bad dreams usually disappear after a few weeks without the need to discontinue ART. Take EFV before bed. Take DTG in the morning. Confusion / psychosis: replace EFV or DTG with PI immediately	If intolerable beyond 2 weeks: replace EFV with DTG replace DTG with PI
Leg pain, numbness or burning, inability to walk			
Onset before starting drugs: HIV neuropathy Onset or worsening after starting drugs INH, vincristine, paclitaxel Onset independent of drugs Alcohol, diabetes	Mild peripheral neuropathy (PN): no sleep disturbance	Amitriptyline 25 mg nightly for 4 weeks Pain control using WHO analgesic ladder	If no improvement after 4 weeks: stop amitriptyline, continue analgesics
	Moderate PN: sleep disturbance	Stop responsible drug WHO analgesic ladder	
	Severe PN: severe pain, muscular weakness		

18.12 Immune reconstitution inflammatory syndrome (IRIS)

Key Facts: IRIS

- 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 immune 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 other causes for worsening have been ruled out.
- Patients who start ART with very advanced AIDS are at a higher risk of developing IRIS.

18.12.1 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.
- Remember that in case of any CNS infections (e.g., cryptococcal and TB meningitis cerebral toxoplasmosis) ART should be started 5 weeks after initiating treatment of CNS infection.
- Consider TB treatment failure if worsening occurs after more than one month on TB treatment.
- Admit severe cases to hospital.
- NSAIDs may be given in mild and moderate cases. Consider prednisolone (e.g., 1mg/kg for 2 weeks then 0.5mg/kg for 2weeks) only in severe IRIS.

19 Differentiated ART services

Key Facts: Differentiated ART services

- Different patient groups need different HIV services. Adapt the interval and range of services to suit current needs of each patient.
- DSD can reduce the burden of unnecessary clinical visits, allowing health workers to spend more time with unstable patients who need thorough review and management.
- DSD must be safe, feasible, cost-effective and have a clear benefit for patients and the health system.

- A stable patient is defined as meeting all the following criteria:
    - On the current ART regimen for 6 months+ without any significant side effects
    - No opportunistic infections
    - Latest VL was within the last 12 months and was suppressed (see **Table 19** on **page 90**)
    - Not pregnant or breastfeeding
- Offer approved MoH DSD models to all eligible patients but ensure they are returned to regular clinical services if they become unstable.
    - 3- or 6-months ART dispensing *(See eligibility criteria below)*
    - Teen Clubs (see **section 18.9.1** on **page 87** for eligibility criteria)
    - Outreach and mobile clinics delivered by a certified ART-provider
    - Drop-in-Centres for key and marginalised populations
- Unstable patients are defined as presence of any of the following:
    - Latest VL result: low-level viraemia or viraemia 1000+
    - Current WHO clinical stage 3 and 4 conditions
    - CD4 count of 200 and below in the last 6 months
- See **sections 8.1** (**page 22**) and **18.10** (**page 88**) for management of patients at risk / with advanced illness. Patient with advanced illness must be managed within the clinic settings.

19.1 Six months ARV dispensing (6MD) visits

Facility criteria

- Facilities can provide 6MD when they meet the facility criteria:
    - Stable and reliable stock management for all HIV related commodities.
    - Secure storage space for additional large volumes of commodities: identify and organize room for storage in advance before the stocks arrive.
    - Ample current stocks for each ARV and other drugs needed (CPT, fluconazole, etc.) to avoid the need for rationing supplies for other patients.

Patient criteria

- Routinely give 6MD appointments for stable and adherent patients. Patients must meet all the following criteria:
    - At least 24 years old; ages 18-24 are eligible if they have a dedicated treatment supporter recognised by the clinic.
    - On ART treatment for at least 6 months
    - On the current ART regimen for at least 3 months
    - Not on TPT (IPT or 3HP)
    - No current ARV side effects
    - No opportunistic infections
    - Suppressed VL, collected in the last 12 months
    - No pending VL result
    - Not pregnant or breastfeeding
- **Figure 4** shows how to align 6MD appointments with the standard VL monitoring schedule.
- **Figure 5** shows an example for aligning the enhanced 6-monthly VL monitoring with the dispensing visit schedule for a woman initiating ART in the 2nd trimester of pregnancy.
- Plan ahead: give a shorter appointment to maintain around 12 months between collection of VL samples.

Figure 4: Alignment of 6 months dispensing with 12-monthly VL monitoring

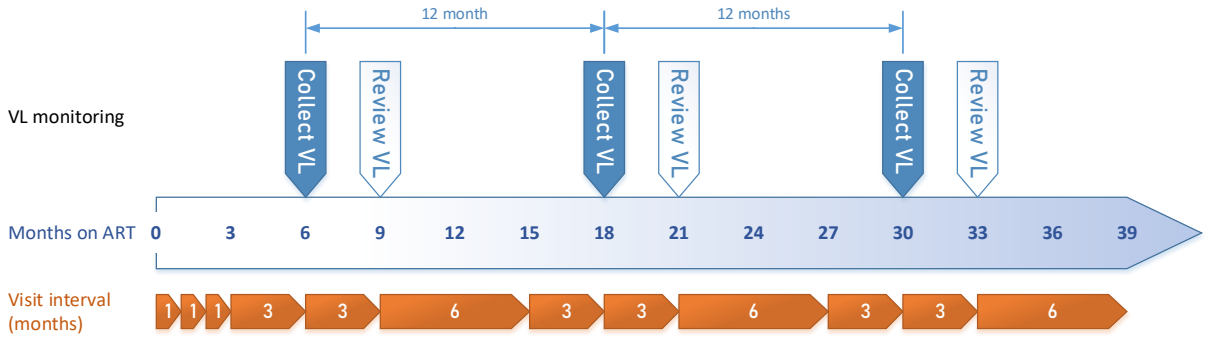
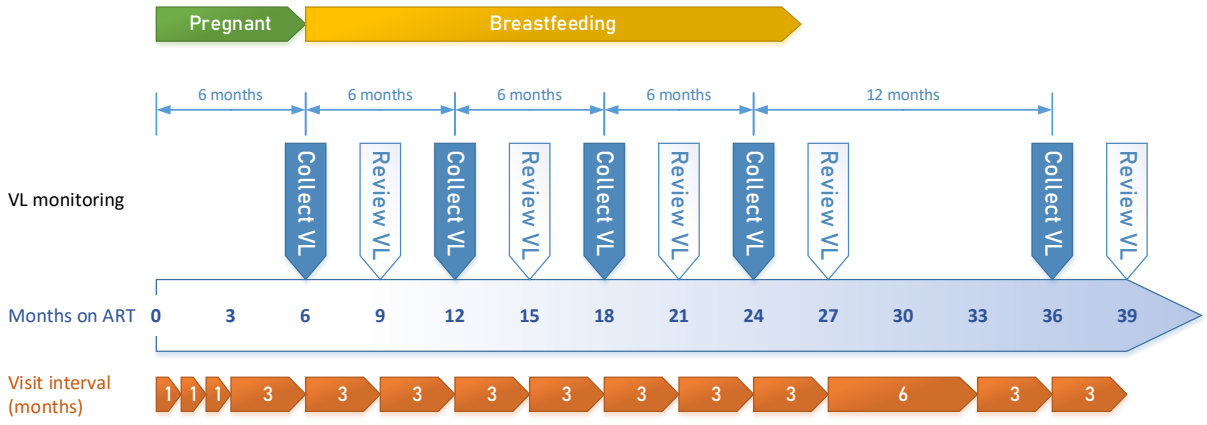


Figure 5: Alignment of enhanced 6-monthly VL monitoring for pregnant and breastfeeding women with dispensing visit schedule



20 Management of labour and delivery

20.1 HIV, syphilis and hepatitis B status ascertainment at maternity

- Review HIV testing page in health passport on admission.
- Provide new HIV test for all women, who are:
    - Not already known to be HIV positive
    - Never tested or tested negative any time in the past, even if this result is from the last trimester. Maternal seroconversion during pregnancy is associated with high MTCT risk, so immediate HIV diagnosis and ART initiation are critical.
- Provide syphilis and hepatitis B tests for women who were not tested during pregnancy.

20.2 ART provision at maternity

- 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/DTG (Regimen 13A) as soon as possible, during labour or after delivery.
    - Deliver individual ART counselling and IEC before discharge.
    - Treat women with syphilis as per Malawi STI treatment guidelines.
    - See the section on **HIV and viral hepatitis** on **page 60** for management of HIV/viral hepatitis coinfection.

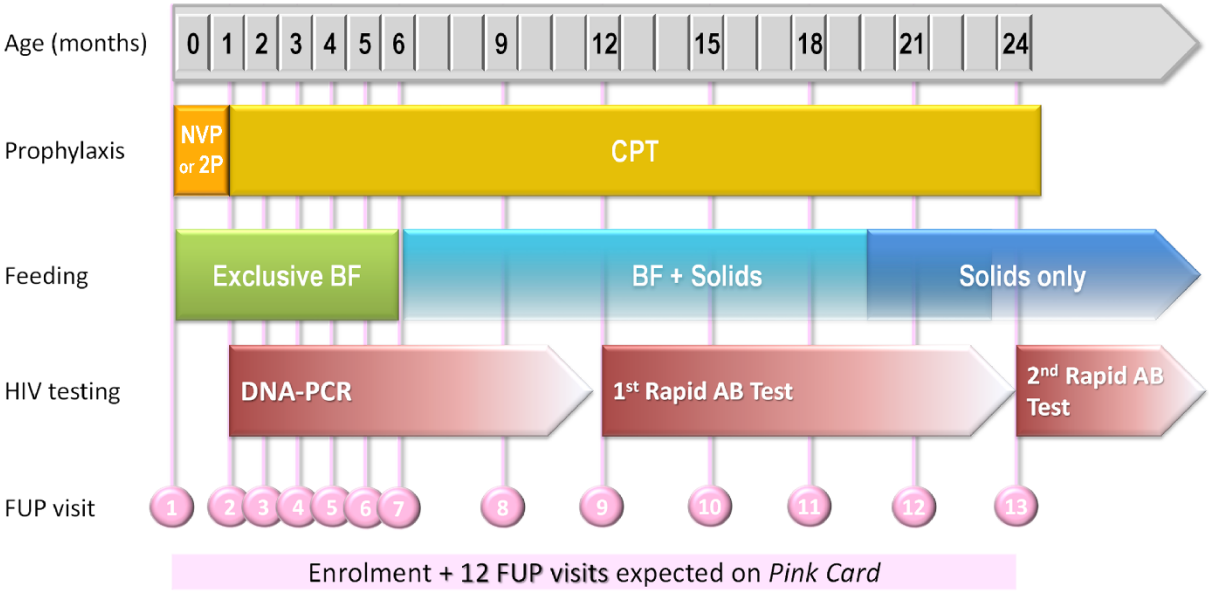
20.3 Reduce obstetric risk of HIV transmission

- Use a partograph 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.
- Do not suction a new-born with a naso-gastric tube unless there is meconium-stained liquor.
- Immediately after birth, wipe the new-born dry with a towel to remove maternal body fluids.

21 Newborn care and postnatal follow up

- Follow regular post-natal care.
- Give all regular EPI vaccinations to all babies born to HIV infected mothers (as for all other infants).
- Give HIV self-test (s) for all sexual partners on discharge from maternity, instruct HIV positive sexual partners to return for immediate ART initiation.
- Offer HTS to all women not known to be HIV positive at 6-9 month FP/EPI visit
- See **Figure 6** below for the standard schedule of HIV exposed child follow-up: infant prophylaxis, CPT, feeding and HIV testing

Figure 6: Standard follow-up schedule for HIV exposed children



21.1 Integrated mother/infant follow-up

- Ensure continued follow-up for HIV infected mothers and babies. Schedule mothers and babies together on the same clinic day, as well as other family members if desired.
- Women in outreach and mobile ART services and in DICs should return to regular ART clinic for the duration of pregnancy and breastfeeding.
- Enrol baby in HCC before discharge from post-natal ward:
    - Fill Exposed Child patient card, enter in HCC register.
- Mothers on ART before delivery:
    - Confirm next ART appointment.
    - Synchronise mother's ART appointment with baby's first HCC visit. Aim for first HCC visit at post-natal visit or first vaccination visit.

- Mother initiated ART in labour:
    - Fill ART patient card and enter in ART register.
    - Write baby's HCC registration number and date of birth on mother's ART card.
    - 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.

21.2 Infant and child feeding

Key Facts: HIV-exposed infant feeding

- 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).
- Aim to stop breastfeeding around age 22 months, so that the final HIV test can be done at age 24 months (6 weeks after breastfeeding has stopped).
- Stop breastfeeding gradually over a period of 1 month (no *rapid cessation*).

- 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. Refer to latest Malawi Standard Treatment Guidelines

21.3 Infant HIV prophylaxis

Key Facts: Infant prophylaxis

- Daily infant ARV prophylaxis shields the baby from HIV infection during the riskiest time.
- Give infant prophylaxis for the same duration regardless of the mother's ARV regimen.
- Infants of women with unsuppressed VL are at high risk of MTCT (see criteria below)
- Select the infant prophylaxis regimen based on risk:
    - **Low risk:** NVP syrup 24-hourly for 6 weeks
    - **High risk:** AZT/3TC/NVP (2P) ¼ tablet 12-hourly for 6 weeks
- For NVP Syrup
    - Store NVP syrup bottles + 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.

21.3.1 Selecting regimen and dispensing infant prophylaxis

- Dispense NVP syrup or 2P tablets based on maternal risk assessment and birth weight (see below and **Table 21** on **page 107**)
- As soon as the mother is known to be HIV-infected at ANC (or maternity):
    - Demonstrate how to give ARV prophylaxis to the baby.
    - Dispense the total amount needed for the 6-week course to take home.
    - Unopened bottles of NVP syrup or 2P 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 estimated delivery date.
    - Ask at every following visit if the 2P or NVP syrup and the syringes are still available. Replace without delay any items that may have been lost or spoilt.

High risk infant prophylaxis

- Infants with any of the following conditions are at **high risk**
    - Mother initiating or re-starting ART in 2nd or 3rd trimester, at maternity or post-partum
    - Mother interrupted ART in pregnancy
    - Mother with known low-level viraemia or viraemia 1000+ during pregnancy/ delivery or within the first 4 weeks post-partum
- Dispense **1 tin of 60 tabs of 2P** to take home.
- Give ¼ tablet of 2P (AZT/3TC/NVP) 12-hourly for 6 weeks. Explain:
    - Dissolve the ¼ tablet in a clean spoon with some expressed breastmilk.
    - Ensure the entire amount is actually swallowed.
    - Give ¼ of the split 2P tablet in the morning and the other ¼ in the evening to average out the daily dosing. This is because splitting 2P tablets into quarters may not be very accurate.
    - Note: Minimum birth weight for 2P infant prophylaxis is 3000g. Use NVP syrup for smaller high-risk babies.

Low risk infant prophylaxis

- Infants without any of the high-risk conditions listed above.
- Dispense **2 x 100ml-bottles of NVP syrup** with dosing syringe to take home.
- Give 1.5 ml NVP syrup 24-hourly. Give 1.0 ml to babies below 2000g birth weight.

21.3.2 Dosing

- The dose of NVP syrup or 2P tabs remains the same for the whole 6-week period – do not change the dose according to age or body weight.
- Use the standard dose (1.5ml NVP syrup or ¼ tablet of 2P) if birth weight is unknown (home birth, no scale).
- Give ¼ tablet of 2P to high-risk infants **weighing 3kg or above** twice daily for 6 weeks
- Give NVP syrup to high-risk Infants **weighing less than 3kgs** once daily for 6 weeks

Table 21: Dosing of NVP syrup (10mg/ml) and 2P tabs (AZT/3TC/NVP) for infant prophylaxis

Birth weight	Low risk		High risk	
2500g or less	**1.0 ml NVP**	24-hourly	**1.0 ml NVP**	24-hourly
2500 -3000g	**1.5 ml NVP**	24-hourly	**1.5 ml NVP**	24-hourly
3000g or above	**1.5 ml NVP**	24-hourly	**¼ tab 2P**	12-hourly
unknown	**1.5 ml NVP**	24-hourly	**¼ tab 2P**	12-hourly

21.3.3 Timing and duration

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

21.3.4 Postnatal HIV testing

Key Facts: MTCT during postnatal period

- Around ⅓ of all remaining infant infections in 2021 are from women who are newly infected during breastfeeding period. Almost all these women have tested HIV negative in ANC and maternity and are not in follow up.
- The main aim is to prevent new infection of the mother by testing and ART initiation of infected sexual partners.
- This can be achieved through promotion of HIV self-testing and timely ART initiation of sexual partners.
- Early diagnosis and treatment of these newly infected breastfeeding mothers and enrolment of the infant into exposed child follow up can reduce the risk of infant transmission.

- Give HIV self-tests to all women at discharge from maternity / post-natal care for their sexual partners.
    - Advise the partner to self-test and/or come to the facility for HTS before resumption of sex.
    - Advise all HIV positive partners to start ART without delay and use condoms for the first 6 months on ART
- Retest all breastfeeding women who are not known to be HIV positive between 6-9 months postpartum at FP/MNH/EPI clinics or any health service delivery point.
- Initiate all HIV positives on ART and enroll the infant in HCC.
- Counsel on HIV risk reduction, offer condoms and PrEP for high-risk women.

22 Pre-exposure prophylaxis (PrEP)

Key Facts: Pre-exposure prophylaxis

- PrEP is being rolled out as a public health intervention for HIV prevention in Malawi.
- Offer PrEP as an additional primary prevention method for HIV negative persons who are at substantial risk of acquiring HIV (see separate PrEP guidelines). Emphasize the need for combination with other HIV prevention methods such as consistent condom use, VMMC, etc.
- PrEP involves:
    - Taking one daily fixed-dose combination tablet of ARVs (TDF/3TC)
    - HIV testing every 3 months before any drug refill
    - STI screening before any drug refill
    - Adherence support
    - Renal function monitoring before initiation then annually
    - Baseline testing for HepB infection
- Eligibility criteria for PrEP:
    - At substantial risk of acquiring HIV
    - Willingness to take daily PrEP as prescribed
    - Confirmed HIV Negative
    - No signs of acute HIV infection (AHI)
    - Above 15 Years of age
    - Body weight 30kg+
    - eGFR >60ml/min, no renal disease
    - No Contraindications to TDF/3TC
- TDF/3TC is the preferred PrEP regimen for Malawi.
    - Tenofovir/emtricitabine (TDF/FTC) can be given as an alternative.
- The following tests need to be conducted before an individual is initiated on PrEP:
    - HIV test
    - Serum creatinine test
    - Hepatitis B surface antigen
- More details on PrEP are included in the PrEP guidelines for Malawi

23 Post exposure prophylaxis (PEP)

Key Facts: Post-exposure prophylaxis

- HIV infection can be prevented after a high-risk contact with fluids from an HIV infected person.
    - Remove immediately as much as possible of the body fluid.
    - Immediately give a 30-day supply of PEP and start taking it as soon as possible.
    - Assess risk and test for HIV 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 accessible 24/7, e.g., at maternity or other well-advertised locations.
- Offer STI treatment and emergency contraception, 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 22** on **page 111**).
- Offer PrEP to all people at substantial ongoing risk of sexual HIV acquisition. Discourage repeated use of PEP as it is less effective.

Classification of risk

- Use **Table 22** 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. The source person could be newly infected himself and may be in the window period.

Table 22: Classification of risk of transmission after exposure to HIV

	Substance	Type of contact	Source person
Risk	• Blood • Semen • Vaginal fluid • Cerebral-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 22**).
- 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 HIV testing is not immediately available (no test kits, night, etc.). Do HIV testing 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 perform HIV testing 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 23: Post exposure prophylaxis regimens

Weight	Standard	Alternative
3.0 – 19.9 kg	**15PP:** **ABC** 120mg / **3TC** 60mg +DTG 10mg	**AZT** 60mg / **3TC** 30mg
20 – 24.9 kg	**15PA:** **ABC** 120mg / **3TC** 60mg + DTG 50mg	**AZT** 60mg / **3TC** 30mg
25 – 29.9 kg	**15A:** **ABC** 600mg / **3TC** 300mg +DTG 50mg	**AZT** 300mg / **3TC** 150mg
≥ 30.0 kg	**13A:** **TDF** 300mg / **3TC** 300mg / **DTG** 50mg	**AZT** 300mg / **3TC** 150mg

- See **Table 16** on **page 68** for weight-based dosing

PEP follow-up

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

Additional prevention measures after rape / sexual exposure

- Give emergency contraception (EC) within 72 hours if needed (see **Table 24**)
    - 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 25**
- Follow latest *National Guidelines for Provision of Services for Physical and Sexual Violence*

Table 24: 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 25: 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 g per day)	2g stat
Nystatin pessaries	N/A	100,000 units 12 hourly for 7 days

24 Pharmacovigilance

Key Facts: Pharmacovigilance

- Pharmacovigilance: detect, assess, understand and prevention of adverse effects or any other drug related problems.
- Adverse drug reactions (ADRs) can be detected by either a patient, guardian or health worker.
- Report all suspected ADRs (minor or serious) to the National Pharmacovigilance Centre within 48 hours using standardized reporting tools: Fill the **ADR Reporting Form (Version 1.1) and submit details via the Medsafe-360 USSD platform.**
- Serious ADRs (e.g., death) must be reported within 24 hours.
    - Death; life-threatening; disability; hospitalization/prolonged hospitalization; congenital anomaly; or any other important medical event.
- The Pharmacovigilance Centre is based at the Pharmacy and Medicines Regulatory Authority (PMRA). PMRA is in charge of collecting, follow-up and aggregation of ADR reports.

24.1 Detection of suspected Adverse Drug Reactions

24.1.1 Definitions

Adverse Event (AE)

- Any untoward medical occurrence in a patient. It does not necessarily have a causal relationship with any medicine administered.

Adverse drug reaction (ADR)

- An unintended noxious response to a medicinal product

Suspected adverse drug reaction

- May present as a new sign, symptom, abnormal laboratory finding or specific disease
- Suspected, but not confirmed to be caused by any medicine administered. Common causes of AEs include advancement/complication of the underlying disease, manifestation of a new disease, or indeed the medicine administered.
- Healthcare workers must report all suspected ADRs to the National Pharmacovigilance Centre at Pharmacy and Medicines Regulatory Authority (PMRA)

Side effect (SE)

- An unintended effect of a medicinal product occurring at doses normally used in humans, which is related to its pharmacological properties.
- All ADRs are AEs, but not all AEs are ADRs. All AEs and ADRs are harmful, but SEs can be either harmful or beneficial.

Safety signal

- An ADR which was previously either unknown or poorly documented in terms of its distribution, severity, incidence or clinical presentation.
- It is not possible, especially at bed side, to determine whether an individual case constitutes a safety signal.
- Pharmacovigilance aims to detect safety signals for period evaluation of the benefit-risk balance of the medicine.

24.1.2 When to suspect an ADR

- An ADR should be suspected when any of the following AE criteria are met:
  a) Medicines with a known high risk for ADRs
  b) Medicines with narrow therapeutic index or potential for multiple interactions.
  c) Sudden discontinuation of therapy or change of regimen
  d) Dose reduction indicated
  e) Prescription of ADR management medications: e.g., corticosteroids, adrenaline, vitamin K, dextrose 50%, antihistamines, etc.
  f) In-patients with abnormal lab results
  g) Development of a new AE on long-term medication

24.2 How to report a suspected ADR

- **Who**: any health workers must report suspected ADRs.
- **What**: any of the following conditions must be reported to the National Pharmacovigilance Centre:
  - Well-known side effect or ADR of the medicine given. This allows the DHA and PMRA to compare the incidence rate of the reaction to the documented rate by the manufacturer.
  - Non-serious ADRs: a change in the incidence rate, distribution or clinical presentation of the reaction may constitute a safety signal.
  - Rare ADRs: rare ADRs are commonly not documented as they were not seen in clinical trials. A rare ARD may constitute a safety signal.
- **How:** Fill the standard paper reporting form (Suspected **ADR Reporting Form, version 1.1**). Whenever possible, also submit the report via cell-phone to the **Medisafe-360 USSD platform**.
  - Send the paper ADR reporting form to the **district pharmacovigilance focal person** for submission to the National Pharmacovigilance Centre
  - The pharmacovigilance focal person is responsible for collecting and summarising all ADRs to the District Health Management Team (DHMT). S/He collaborates with district program coordinators (ART, TB, Malaria, Family planning, etc.)

Using the paper ADR Reporting Form

- Fill all mandatory fields for each section:

Section	Details
1	Patient name, age, birth date, gender, etc.
2	AE description, date of onset, action, lab results, outcome + date (e.g. death)
3	Suspected medicine generic and brand name, batch number
4	Other medicines taken, incl. herbal remedies
5	Reporters name and contact details

Using the Medsafe-360 USSD platform

- Can be accessed toll-free from any basic or smart-phone (Airtel or TNM) by dialling ***360#**
- Mirrors the paper ADR reporting form
- Respond to the questions in sequence using the number-pad or keyboard of your phone

24.3 How to handle serious ADRs

- Report immediately to the next level using the easiest and fastest mode of communication (phone, email, SMS).
- Submit a written report within 24 hours of the event.
- Manage clinically according to treatment guidelines.

25 Monitoring and evaluation

Key Facts: Monitoring & Evaluation

- 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 many facilities, but electronic systems for monitoring are used at sites with many patients.
- Reporting is done monthly for ANC, maternity and exposed child follow-up and quarterly for ART (see **Table 26** on **page 119**)
- Cohort analyses are needed to report outcomes of patients in ANC, exposed child 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 is integrated into the regular Health Management Information System. Monthly / quarterly facility reports are entered directly into the District Health Information System at the District Health Offices for national reporting.

25.1 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 under 5 clinics.

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 (PrEP, 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.

- **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).

Lost to follow-up ('defaulted')

- 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 exp. children): 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' when the next cohort analysis is done if they return to the clinic and continue 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 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').

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. It is practically too complicated to consider varying intervals when analysing adherence. Therefore, 3-monthly visits are assumed for all patients for reporting.
- Patient who are supposed to take 1 tablet per day (e.g., Regimen 13A) and who have missed more than 5 tablets are classified as 'less than 95% adherent'.
- Patients who are supposed to take 2 tablets per day (e.g., Regimen 4A) and who have missed more than 10 doses are classified as 'less than 95% adherent'.

Table 26: 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 • TPT started / completed • 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

25.2 Manual 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.

25.3 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, unless they have died. Therefore, the records of all patients ever registered must 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 26** lists the primary follow-up outcomes used for the different reports.
- For ART only, deaths are further classified according to 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 26** 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** (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.

25.4 Record keeping and filing

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.

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[4] in each register: Continue using the same row for returning transfers and re-starts after default or stop.

[4] 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 to separate the quarters when adding 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.

Use of patient cards

- Each patient has only one patient card at any one time (Exposed child, 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.

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 ARV formulation** cards into different files.

25.5 Ensuring adequate data quality

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

26 Supply Management

Key Facts: HIV Program Supply Management

- The HIV program requires uninterrupted supply of large amounts of HIV related commodities (ARVs, test kits, OIs/STI drugs, condoms, lab reagents and supplies).
- A dedicated HIV Program Logistics Team (HIV Logistics), working under MOH Depts. for Health Technical Support Services and for HIV/AIDS actively coordinates procurement, supply planning and distribution of HIV related commodities, technical support and system strengthening to all health facilities providing ART services.
- Stock-outs lead to 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. Minimum stock levels for HIV commodities are:
    - 6 months at the central warehouse
    - 2 months at the health facilities
- **Responsibilities:**
    - All health workers: fill standard MOH forms, patient cards, registers, reporting forms
    - Pharmacy in-charge: manage and account for all commodities received
    - District Health Management Teams: coordinate and supervise
    - HIS Officer: ensure quality paper / EMR data as this guides supply management
- **Contact HIV Logistics** by email (hivdeptlogistics@gmail.com) or call toll-free on working days (7:30 – 16:30):
    - **5 91 91** (from Airtel phone)
    - **68 82** (from TNM phone)
- Call HIV Logistics for help and get an **authorization code before** any of the following transactions with ARVs, test kits and all other HIV related commodities:
    - 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 (suspected) side effects.

27 HIV commodity supply cycle

- **Table 27** shows the different commodity groups currently managed by the HIV Program.

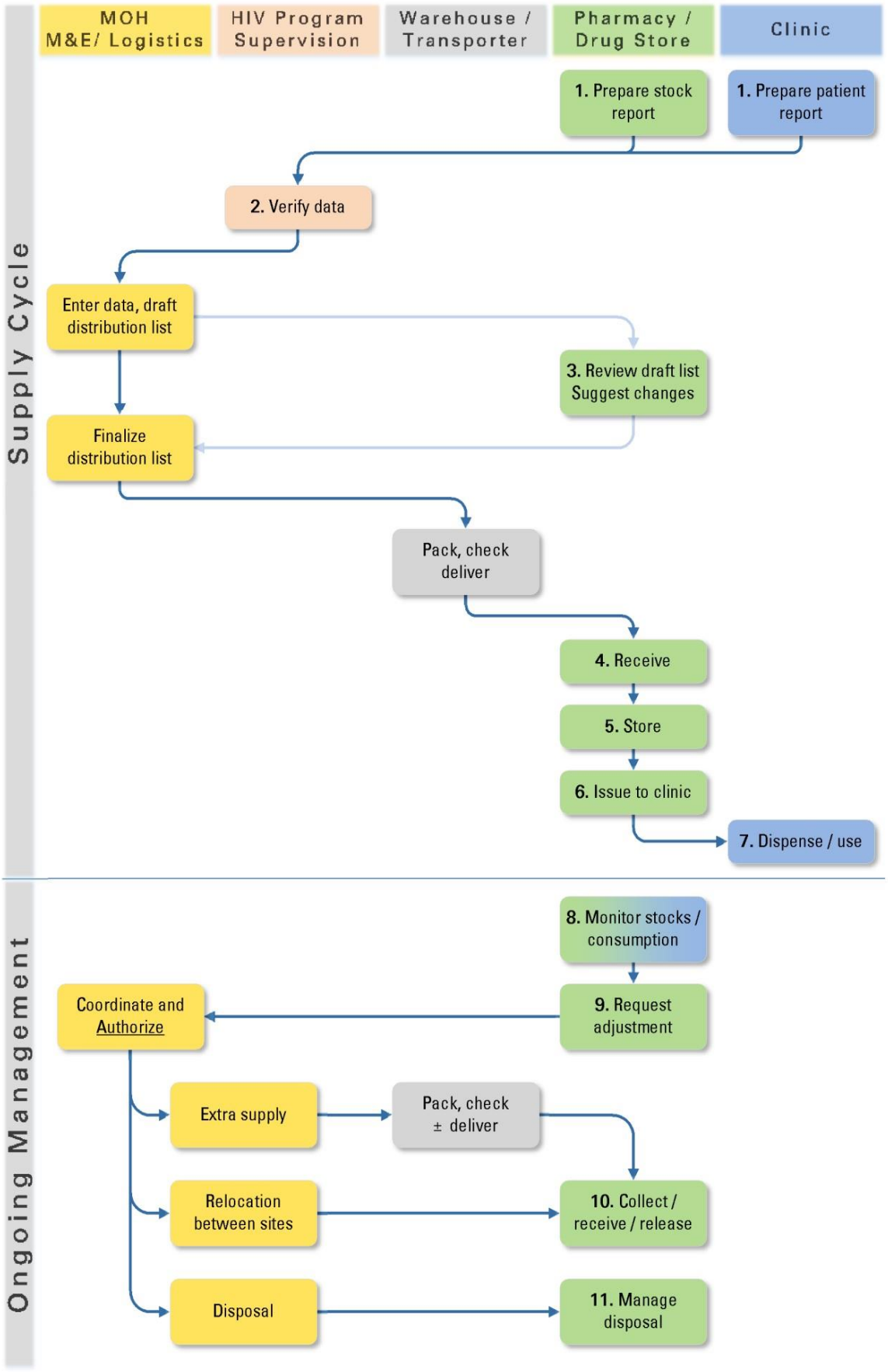
Table 27: Drugs and supplies managed by the HIV Program

Commodity group	Examples	Supply*
ARVs	(All ARVs, incl. PEP, PrEP and infant prophylaxis)	**E**
OI prophylaxis	Cotrimoxazole for CPT	**E**
TPT	Isoniazid, Rifapentine + pyridoxine for TPT	**E**
OI treatment	Cotrimoxazole, other antibiotics, fluconazole, chemotherapy	**S**
STI	Standard/alternative antibiotics, acyclovir, clotrimazole	**S**
Cervical cancer	Cervical cancer screening tools	**S**
VMMC	Shang rings and conventional circumcision kits	**E**
PIFP	Condoms	**S**
AHD	Serum CrAG, PIMA beads	**S**
Analgesic	Morphine, codeine	**S**
DBS, plasma kits	For EID and VL samples	**E**
Rapid tests	HIV, viral hepatitis 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 every 2 months 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 **2-monthly supply cycle** and the **ongoing management** following the 11 steps in **Figure 7** below.

Figure 7: Flowchart for HIV commodity supply management



1. Prepare stock/patient report (Pharmacy/drug store-in-charge & clinician)

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

2. Verify data (HIV program supervision & team)

- 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.
    - Verify completeness of stock cards, relocation books, delivery notes/goods received notes and requisition and issue vouchers (RIVs).
    - Patient data by reviewing patient cards and registers.
- Check that the stock report filled during supervision is complete and accurate. The supervision team and the pharmacy in-charge are responsible for confirming this by signing the form.

3. Review of draft distribution list (HIV logistics and M & E teams)

- **2-monthly consignments** are calculated by *HIV Logistics* from patient numbers and stock reports collected at the last supervision visit.
    - All HIV related commodities should be about **2 MOS** (months of stock, see below).
    - Consignments are scheduled to arrive every 2 months.
    - Facilities should have about **2 MOS** remaining when the new consignment arrives bringing the total available stock to about **4 MOS**.
- HIV Logistics will circulate the *draft distribution list* to anyone registered with their email address. To register, send an email request to hivdeptsupplychain@hivmw.org. Anyone can also subscribe for an automatic notification by email and/or SMS whenever a distribution list is posted for review on the HIV Dept. website (www.hiv.health.gov.mw).
- Review and confirm that the items and quantities are correct and adequate for you. Submit any suggested changes (by email, SMS or phone) with justification before the deadline shown on the draft list.

4. Receive consignment (Pharmacy-in-charge)

- 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 batch number and 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 facility/Pharmacy In-Charge will be held responsible for any discrepancies noted later.

5. Store (Pharmacy-in-charge)

- 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 (Pharmacy-in-charge)

- The user units/departments will request for commodities from the store using *Requisition and Issue Vouchers*.
- Ensure that the facility in-charge or assigned designated approves the request for commodities
- The Pharmacy/stores in-charge assess the stocks and issues accordingly.
- 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 (Clinician)

- 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.
    - Using the adverse drug reaction form (ADR) ensure that all ADR related issues are documented and reported to HIV Dept. and PMRA
- Account for all HIV commodities dispensed. Specify type and quantity:
    - On *patient master cards* (ART, Exposed child).
    - *Dispensing registers* for ARVs, OIs/STI and special drugs.
    - *Daily Activity Registers (DAR)* for HIV test kits.
- The *DAR* is used for tracking use of test kits.
    - Keep a separate register at all places where testing is done.
    - Use separate registers for the different types of tests (Determine, Uni-Gold, and other test kits).
    - Test kits *used for clients* must match entries in the HIV testing 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 HIV testing report by adding numbers from all DAR used at the facility.

8. Monitor stocks/consumption (Pharmacy-in-charge)

- 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 or any other special scenarios such as clinic closure, fire, theft etc.

- **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 transition to alternative regimens or switching to 2nd line or 3rd line regimens.
  - Rapid scale up 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 or 6).
- Commodity **excess:** more than **4 MOS**, especially if units will expire before they can be used:
- Contact *HIV Logistics* for to request stock relocation (see below).

9. Request adjustment (Pharmacy-in-charge & HIV logistics)

- 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 another 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.
  - File the Registration Forms in the pharmacy to account for all commodity transactions.
- **Caution**: Never relocate or dispose HIV commodities without *authorization code*. In exceptional circumstances (threating 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 (Pharmacy-in-charge)

- 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 blue copy of the form to the facility receiving the relocated commodities.
    - Retain the pink copy of the form for collection by Ministry of health-HIV logistics.
    - The receiving facility must enter the commodities on the stock cards in the pharmacy and issue as per the issuing procedure (as above 6).

11. Disposal (Pharmacy-in-charge)

- Update the stock card by subtracting off the expired quantity.
- Separate expired commodities from usable stock.
- Notify HIV logistics, get Authorization code and fill the registration form for relocation and disposal.
- Update the Health facility expired commodity list.
- Contact the District Pharmacist and arrange for transfer of expired items for controlled destruction.

28 Appendix

Figure 8: Body surface area estimation for calculation of paclitaxel dose

BSA	Height in cm																									
Weight in kg	140	142	144	146	148	150	152	154	156	158	160	162	164	166	168	170	172	174	176	178	180	182	184	186	188	190
36	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4
38	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
40	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5
42	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5
44	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
46	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6
48	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6
50	1.4	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
52	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7
54	1.4	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7
56	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
58	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
60	1.5	1.5	1.5	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8
62	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8
64	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8
66	1.6	1.6	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9
68	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9
70	1.6	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9
72	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9
74	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0
76	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0
78	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
80	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1
82	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1
84	1.8	1.8	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1
86	1.8	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1
88	1.8	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2
90	1.9	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2
92	1.9	1.9	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2
94	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2
96	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3
98	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3
100	2.0	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3
102	2.0	2.0	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3
104	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
106	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4
108	2.0	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4
110	2.1	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4
112	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4
114	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.5
116	2.1	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.5	2.5
118	2.1	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.5	2.5	2.5	2.5
120	2.2	2.2	2.2	2.2	2.2	2.2	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.5	2.5	2.5	2.5	2.5

Table 28: Interactions between ARVs and other common drugs

Green: Combination causes no problems

Yellow: Usually no problems. Monitor for possibly increased side-effects or adjust dosage as shown

Red: Do not combine without specialist advice

Drug Name	Treatment	3TC	ABC	ATV/r	AZT	CTX	DRV	DTG	EFV	LPV/r	TDF
Amitriptyline	Depression										
Amphotericin B	CM										1
Artesunate	Malaria										
ASAQ	Malaria										
Bedaquiline	TB			2			2		2	2	
Bleomycin	KS										
Citalopram	Depression										
Delamanid	TB										
Ethambutol	TB										
Fluconazole	CM										
Flucytosine	CM										
Fluoxetine	Depression			3						3	
Glibenclamide	Diabetes			4			4			4	
Isoniazid	TB										
Levofloxacin	TB										
Linezolid	TB										
LA	Malaria										
Metformin	Diabetes						5	6			
Moxifloxacin	TB										
Paclitaxel	KS										
Paroxetine	Depression										
Pyrazinamide	TB										
Pyridoxine	TB										
Rifampicin	TB			2			2	7		2	
Rifapentine	TB			2			2		2	2	
Sertraline	Depression										
SP	Malaria					2					
Vincristine	KS										

[1] Monitor for renal toxicity
[2] Significant interaction. Do not combine.
[3] Monitor for increased fluoxetine side-effects.
[4] Monitor closely for hypoglycaemia.
[5] Monitor for increased metformin side-effects.
[6] Maximum metformin dose is 1000mg.
[7] Double DTG dose (see details in **section 17** on **page 82**)

Form 1: HIV Drug resistance testing application form

3rd line ART Expert Committee Malawi- Application form

Patient details

First Name		Surname	
ART-ID Number		Gender	M F
VL sample ID		DOB	Age, if DOB is not available:_____

Facility details

ART Clinic	
Clinician's Name	
Clinician's Tel. Number	
Clinician's Email Address	

Current clinical status and history

WHO stage at start of treatment	
Current WHO stage (+ defining condition)	
Weight	Height
ART Interruptions?	Y N If yes, Date: Reason:
History of serious side effects	Peripheral Neuropathy Y N Jaundice Y N Lipodystrophy Y N Kidney failure Y N Psychosis Y N Gynecomastia Y N Anemia Y N Others:
OI in the last 6 month?	Y N If yes, Date: Diagnosis:
Significant diarrhea or vomiting?	Y N Details:
Alcohol or drug consumption?	Y N Details:
Traditional medicine?	Y N Details:
Current co-medications (Antiepileptic, Steroids, Warfarin, Statins)?	Y N Details:
Other current clinical problems?	Y N Details:

Pregnancy Section (Fill for females only)

Is the patient currently pregnant?	Y N If yes, week of pregnancy?
Is the patient breastfeeding?	Y N

Pediatric section (Fill for children < 3 years)

Has mother had single dose NVP? Y N	Has mother had PMTCT? Y N
Was baby given NVP? Y N	Is the child able to swallow tablets? Y N

Treatment History

Please specify the complete ART history, when which drugs were started, changed or stopped, particularly specify if patient was on dual or mono ART. State all CD4 and VL monitoring results. If specific dates are not available provide the (approx.) month and year.

ART drugs		Start date		Stop date	Reason for changes (toxicities?)

Monitoring date	**CD4**	**VL**	Reason for detectable VL (Non-adherence, treatment break)	Weight (kg)

TB treatment			Start date	Stop date	Reason for changes (toxicities?)
Reg. 1	Reg. 2	MDR			

Adherence section (Patient adherence in the last 3 visits)

Scheduled visit date:	Actual visit date:	Pill count (%)
Scheduled visit date:	Actual visit date:	Pill count (%)
Scheduled visit date:	Actual visit date:	Pill count (%)

Adherence questions (circle answer)

Do you ever forget to take your medicine?	Y N
Are you careless at times about taking your medicine?	Y N
Sometimes if you feel worse, do you stop taking your medicines?	Y N
Thinking about the last week. How often have you not taken your medicine?	Never 1-2 3-5 >
Did you not take any of your medicine over the past weekend?	Y N
Over the past 3 months, how many days have you not taken any medicine at all?	< 2 days > 2 days

Laboratory section (compulsory)

Creatinine	HepB Ag neg pos not tested	
Hb	ALT	Bilirubin

Important note:
While this form is processed, keep the patient on his current treatment regimen. It may still confer some benefit to the patient and resistance testing can only be done while patient is on treatment !!!

For internal use: Patient assigned to

1)
2)
3)

Form 2: Suspected adverse drug reaction reporting form

Version: 1.1

Quality Medicines for Malawi

REPORT OF SUSPECTED ADVERSE DRUG REACTIONS

Pharmacy and Medicines Regulatory Authority

Safety Yellow Form
Identities of reporter and patient will remain strictly confidential

1. PATIENT INFORMATION

Names:		Age:	Gender ☐ Male ☐ Female	Weight (kg):
Patient Reference No:		DOB:	If female, Date of last menstruation:	Height (cm):

2. ADVERSE EVENT INFORMATION

Type of report: ☐ Initial ☐ Follow up
Date of onset of reaction: ___ /___ / ____

Description of suspected reaction(s) and any treatment given: *Use additional sheets if needed*	Action Taken
	☐ Drug withdrawn ☐ Dose increased ☐ Dose reduced ☐ Dose not changed ☐ Unknown

Do you consider the reaction to be serious? ☐ Yes / ☐ No
If yes, please indicate why: ☐ Death ☐ Life-threatening ☐ Disability ☐ Caused or prolonged hospitalization
☐ Congenital anomaly/birth defect ☐ Other medically important reaction

Outcome: ☐ Recovered ☐ Recovering ☐ Not recovered ☐ Recovered with sequelae ☐ Unknown ☐ Died
If died, date of death: __/__/__ Autopsy done: ☐ Yes ☐ No ☐ Unknown

Comments: Event subsided/ abated after medication use stopped (de-challenge)? ☐ Yes ☐ No ☐ Unknown
Event reappeared after re-introduction (re-challenge)? ☐ Yes ☐ No ☐ Unknown

Relevant Laboratory Tests	**Test Date**	**Results**

RELEVANT MEDICAL HISTORY: including pre-existing medical conditions (allergies, previous exposure, alcohol use, baseline test results/ lab data)

3. SUSPECTED DRUG (S) - *Enter Fixed Dose Combinations as a single medicine*

Drug (Brand if known) & strength	Batch no.	Dosage	Route	Date Started	Date Stopped	Indication

4. OTHER DRUG(S) *Include self-medication and herbal remedies taken in the last 3 months prior to reaction*

Drug (Brand if known) & strength	Batch no.	Dosage	Route	Date Started	Date Stopped	Indication

5. REPORTER INFORMATION

Names		Qualification		Tel.	
Health Facility		District		Date	
Signature		E-mail			

This report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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