Republic of Namibia

Ministry of Health and Social Services
Directorate of Special Programmes

National Guidelines for Antiretroviral Therapy

Sixth edition, August 2019

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FOREWORD

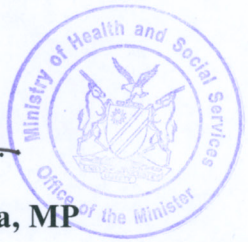
The HIV epidemic in Namibia is gradually being brought under control as demonstrated by results in the preliminary report of Namibia Population-Based HIV Impact Assessment (NAMPHIA), a cross-sectional household-based survey that was conducted in 2017. Currently, it is estimated that about 204,207 Namibians are living with HIV. According to the NAMPHIA preliminary report, HIV prevalence among adults aged 15-64 is 12.6% and the annual HIV incidence is 0.36%. This report, together with HIV programmatic data has shown that Namibia is one of the few African countries to meet the 2015 Joint United Nations Program on HIV and AIDS (UNAIDS) 90-90-90 targets before the set date of (2020) to control HIV and end AIDS epidemic globally by 2030.

The Government of the Republic of Namibia is committed to control the HIV epidemic and eventually end AIDS-related deaths by 2030. Interventions include providing quality and effective antiretroviral therapy and comprehensive HIV prevention services to all persons who are in need as stipulated in the National HIV policy of 2007.

Therefore, the Ministry of Health and Social Services (MoHSS) has developed ART Guidelines that are reviewed and updated from time to time whenever new scientific evidence emerge or new WHO Guidance become available. The aim is to ensure the quality of treatment, care and support for people living with HIV.

For Namibia to be able to control HIV and end AIDS by 2030, all stakeholders that deal with HIV service delivery in Namibia including People Living with HIV, Ministries offices and Agencies, the private sector and development co-operation partners need to work together and implement the National HIV Policy to ensure communities and individuals who have been affected by this disease get appropriate care and treatment. I also urge the HIV Think Tank and the Treatment Technical Advisory Committee to continuously follow ongoing scientific research on the management of HIV and update our guidelines timeously.

The Ministry has achieved great milestones in the fight against HIV and AIDS and this could have not been possible without the hard work of our health care workers, our patients and especially our development co-operation partners. Thank you very much for the continuous efforts and dedication to the fight against HIV in Namibia!



Dr Kalumbi Shangula, MP

Minister

PREFACE

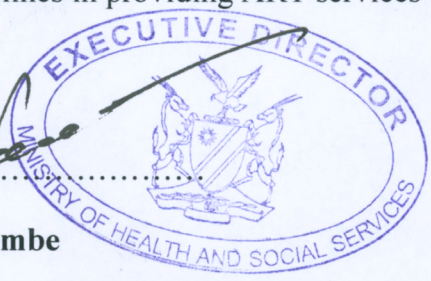
Namibia introduced free Anti-retroviral therapy (ART) in 2003. Subsequently, the Ministry of Health and Social Services (MoHSS) developed the ART Guidelines that has been guiding the provision of the ART service delivery in the country. Since then, these guidelines have been revised and updated several times whenever new compelling scientific evidence becomes available or when the World Health Organization (WHO) released new guidance. This is the 6th Edition. The provision of quality HIV services has been a fundamental principle of the National Strategic Framework for HIV and AIDS in Namibia and great milestones have been achieved as demonstrated by the Namibia Population-Based HIV Impact Assessment (NAMPHIA) 2017 and the recent HIV results of the programmatic data. According to this survey and the recent HIV programmatic data, 95% of all Namibians who are HIV positive know their status, 96% of those who are positive are on treatment and 94% of those who are on treatment are virally suppressed.

This 6th Edition of the National ART Guidelines has been updated to address clinical, operational and programmatic aspects of managing HIV disease and co-morbidities.

Major changes in these Guidelines include the following:

- Six new chapters on HTS, Care and support for adolescents living with HIV, Monitoring and Evaluation, Medicine Management and Patient Safety, Bio-Clinical Monitoring for patients on ART, Management Co-morbidities and other services have been added,
- The use of new medicines with better efficacy, tolerability, safety profile and affordability such as Dolutegravir and TAF have been added as part of first line of ART, and
- A section on strengthening of family planning services within ART settings has also been added.

My sincere gratitude and appreciation go to all the HIV experts who revised these Guidelines. The Ministry encourages programme staffs and partners to embrace operational research and learn from our own data to inform further implementation of the program. I would like to thank our Development co-operation Partners such as President's Emergency Plan for AIDS Relief (PEPFAR) for the ongoing technical and financial support as well as the UN family in Namibia, Offices Ministries and Agencies, Private Sector and all other stakeholders for their contributions to the fight against HIV and AIDS in Namibia throughout the years. These Guidelines are to be used by the public and private sector, health practitioners and professionals. I thereafter recommend that health care professionals and all community health care workers make use of these Guidelines in providing ART services to the communities in order to end AIDS in Namibia by 2030.



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Ben Nangombe

Executive Director

LIST OF ABBREVIATIONS

3TC	Lamivudine
ABC	Abacavir
ADLHIV	Adolescents Living with HIV
AFHS	Adolescent Friendly Health Services
AIDS	Aquired Immune Deficiency Syndrome
ALT	Alanine aminotransferase
ANC	Ante natal care
ART	Anti retroviral therapy
ARV	Antiretroviral
AST	Aspartate aminotransferase
ATV	Atazanavir
AZT	Zidovudine
BD	Twice Per Day
BMD	Body Mineral Density
BMI	Body Mass Index
CAGs	Community Adherence Groups
CCBHS	Comprehensive Community Based Health Services
CD4	Cluster of Differentiation 4
CHW	Community Health Worker
CVR	Cenicriviroc
CMV	Cytomegalovirus
CPT	Cotrimoxazole Preventive Therapy
CrAg	Cryptococcal Antigen
CrCl	Creatinine Clearance
CSF	Cerebrospinal Fluid
CXR	Chest X-Ray
DAOT	Directly Antiretroviral Observed Therapy
DBS	Dried Blood Spots
DNA	Deoxyribonucleic acid
DTG	Dolutegravir
DVT	Deep Vein Thrombosis
EFV	Efavirenz
ELISA	Enzyme-linked immunosorbent assay
ENF	Enfurvitide
ETR	Etravirine
ePMS	Electronic Patient Monitoring System
eMTCT	Elimination of Mother-to-Child Transmission
EVG	Elvitegravir
FARM	Fast Track Refill Model
FBC	Full Blood Count
FP	Family Planning
FTC	Emtricitabine
GMP	Growth Monitoring and promotion
Hb	Haemoglobin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
HCWs	Health Care Workers

HEI	HIV Exposed Infants
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
ICU	Intensive Care Unit
IDV	Indinavir
IM	Intramuscular
H	Isoniazid (INH)
IPT	Index Partner Testing
INSTI	Integrase Strand Transfer Inhibitor (Integrase Inhibitor)
IRIS	Immune Reconstitution Inflammatory Syndrome
IUCD	Intra Uterine Contraceptive device
IV	Intra venous
IVI	Intra venous injection
LFT	Liver function test
LPV/r	Lopinavir boosted with ritonavir
LPV/RTV	Equal doses of LPV and RTV
M	Months
MAC	Mycobacterium avium complex
MMD	Multi-Months Dispensing
MOTT	Mycobacterium other than tuberculoses
MUAC	Middle Upper Arm Circumference
MVC	Maraviroc
NAMPHIA	Namibia Population-based HIV Impact Assessment
NAT	Nucleic Acid Test
NEMLIST	Namibia Essential Medicine List
NIP	Namibia Institute of Pathology
NVP	Nevirapine
NRTI	Nucleoside reverse transcriptase inhibitor
NNRTI	Non-Nucleoside reverse transcriptase inhibitor
NTDs	Neural Tube Defects
OD or od	Once daily
Ols	Opportunistic infections
PCB	Patient Care Booklet
PCP	Pneumocystis jiroveci (carinii) pneumonia
PCR	Polymerase chain reaction
PEP	Post Exposure Prophylaxis
PI	Protease Inhibitor
PLHIV	People living with HIV
PML	Progressive multifocal leukoencephalopathy
PO	Per os (by mouth)
PrEP	Pre-exposure Prophylaxis
RAL	Raltegravir
RNA	Ribonucleic acid
RTV	Ritonavir
SJS	Steven Johnson's Sydrome
SMZ	Sulfamethoxazole
STAT	Immediately
STIs	Sexually Transmitted Infections
TAF	Tenofovir Alafenamide Fumerate
TAT	Turn-around Time

TB	Tuberculosis
TDF	Tenofovir Disoproxyl Fumerate
TDS or tds	Three times per day
TEN	Toxic epidermal-necrolysis
TLD 1	Tenofovir/Lamivudine/Dolutegravir First Line
TLD2	Tenofovir/Lamivudine/Dolutegravir Second line
TMP	Trimethoprim
TPT	Tuberculosis Preventive Therapy
ULN	Upper limit of normal
VL	(HIV) Viral Load
VZV	Varicella zoster virus
WBC	White Blood Count
WHO	World Health Organization
W	Weeks
XTC	Either 3TC (lamivudine) or FTC (Emtricitibine)

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

EXECUTIVE SUMMARY

INTRODUCTION	
Background	Namibia has made significant strides in responding to the HIV epidemic with 86% of PLHIV knowing their HIV status, 96% of the known HIV positives are on treatment and 91% of those on treatment are virally suppressed. Despite the progress, a high level of pre-treatment HIV drug resistance (exceeding the WHO threshold of 10%) has been observed prompting the review of the first line ART to include integrase inhibitors. Major changes to these guidelines include the addition of four new chapters i.*e. HIV Testing services, Bio-clinical Monitoring for patients on ART, Management of comorbidities and other services and Medicine management and patient safety*
Intended Users	The guidelines are intended for use by national HIV program managers, clinicians and other health service providers in both public and private sectors, managers of laboratory services, People Living with HIV and AIDS (PLHIV), community based organisations, national HIV treatment and prevention advisory bodies as well as international and bilateral agencies that provide financial and technical support.
Chapter 1: HIV TESTING SERVICES	
Comprehensive HTS includes the following:	Counselling (pre-test information and post-test counselling) Linkage to appropriate HIV services Coordination with lab services to support quality assurance practices Delivery of correct results
Point of Care Recency Testing (POC-RT) NEW	Recency testing is a disease surveillance testing methodology which provides insight into the timeline of an individual's HIV infection. It can be integrated during routine HTS *Benefits of Point of Care Recency Testing include:* Can be used to identify individuals who may qualify for further targeted testing It helps to track trends in recent infections to inform public health responses and prevention efforts Results may be used in mapping hot spots locations with high rates on new HIV infections or high-risk sub- populations
Index clients HIV testing	It is defined as a voluntary process involving testing sexual partners of HIV diagnosed clients and their exposed biological children and offering them HTS. It can be a part of Recency testing in order to trace and test sexual partners. The goal of Index client testing is to break the chain of HIV transmission by offering HTS to persons exposed to HIV and linking them to HIV treatment, if positive or to prevention services if negative such as PrEP, VMMC and other.
Use of Unique Patient Identifiers (NEW)	Unique identifiers are numeric or alphanumeric codes that help to identify individuals when accessing a variety of health services. The use of unique identifiers will help to track individuals seeking HIV care and other health services. It will also enhance person-centred monitoring as promoted by WHO and intended to shift the focus from measuring services provided, to monitoring people receiving HIV services and other health services and is critical in supporting data linkages and patient retention in care

Chapter 2: ANTIRETROVIRAL THERAPY FOR ADULTS AND ADOLESCENTS	
Re-testing for HIV prior to ART Initiation	All newly diagnosed HIV positive patients should be re-tested using the Namibia serial HIV rapid testing algorithm to verify their HIV positive status prior to enrolment for treatment.
When to start antiretroviral therapy in adults	All HIV positive adults irrespective of CD4 counts and WHO stage are eligible to start ART (Treat All). Patients should be initiated on ART immediately when they are ready, either on the same day or as soon as possible within one week.
Re-starting ART in patients who "default" and "Lost to Follow up".	Any patient who misses their clinic visit and interrupts treatment is defined as a "defaulter" Any patient who interrupts treatment for 30 consecutive days or more is defined as "lost to follow up" (NEW) Patients who return after being lost to follow-up and did not take ARVs for at least 6 months should have a CD4 test, assessed, managed for any co-infections and provided appropriate prophylaxis (NEW).
First-line ART for Adults and adolescents including Women of Child Bearing Potential	Preferred: TDF (or TAF) + 3TC (or FTC) + DTG (once daily FDC)* (TLD1) Alternate: TDF (or TAF) +3TC (or FTC) + EFV 400mg ABC+3TC+DTG** TDF (or TAF) + FTC (or 3TC) + ATV/r
Second-line ART for Adults and adolescents including Women of Child Bearing Potential	Failing first-line Regimen: TDF(or TAF) + 3TC + DTG or ABC + 3TC + DTG Preferred second-line Regimen: AZT + 3TC + ATV/r or (LPV/r) Failing first-line Regimen: TDF(or TAF) + 3TC + EFV or TDF + 3TC + ATV/r Preferred second-line Regimen: AZT + 3TC + DTG Failing first-line Regimen: AZT + 3TC + EFV or AZT + 3TC + ATV/r Preferred second-line Regimen: TDF (or TAF) + 3TC + DTG
Third line ART for adults and adolescents	Patients failing second line regimens should undergo an HIV resistance test following consultation with a specialist in order to determine the most effective 3rd line ART regimen.
Chapter 3: ELIMINATION OF MOTHER TO CHILD TRANSMISSION OF HIV	
Main strategies for eMTCT	Primary prevention of HIV infection. Prevention of unintended pregnancy in HIV infected women. Prevention of HIV transmission from HIV infected women to their infants. Provision of comprehensive care to mothers living with HIV, their children and families.
Testing of HIV negative women during pregnancy and breast-feeding period	All pregnant women, with the exception of known positives should be offered HIV testing and counselling services at their first antenatal visit, regardless of previous HIV negative results. On subsequent visits health workers should retest HIV-negative women as follows: after 3 months and at 36 weeks (unless already tested negative at 32-35 weeks) 6 weeks post-natal and 3 monthly during the breastfeeding period *(NEW)*
PrEP for Pregnant and Breast-feeding women	All HIV negative pregnant and breastfeeding women should be followed up until they stop breastfeeding. Those at substantial risk of HIV acquisition should be offered Pre-exposure Prophylaxis (PreP).
Viral Load algorithm for Pregnant &	For women already on ART: Check the most recent routine VL to ascertain if the VL is suppressed.

Lactating Women (NEW)	If a VL was not done within the last 3 months, repeat it at the first ANC visit and provide adherence counselling. If the VL was <40 copies/ml, repeat every 3 months until delivery, then at 6 weeks post-partum and thereafter every 3 months until the end of the breastfeeding period. if the VL was 40 to <1000 copies/ml, provide intensive adherence counselling and repeat according to the schedule above If the VL was/is >1000 copies/ml, intensive adherence counselling should immediately be done and the VL should be repeated in 6 weeks and every 3 months until delivery, then at 6 weeks post-partum, and thereafter every 3 months until end of breastfeeding period. If any repeat VL is >1000 copies, and adherence is good, manage as possible treatment failure and consult an HIV specialist / clinical mentor For women initiating ART during pregnancy, or in the breast-feeding period Do VL 3 months after initiation, then 3-monthly until delivery, then 6 weeks post-partum, and thereafter every 3 months until the end of the breastfeeding period. As with patients already on ART, if any VL result is >1000, appropriate action as discussed above should be taken. The above VL monitoring schedule will help to determine whether or not and when her breastfeeding infant can discontinue nevirapine prophylaxis. At the end of breastfeeding, the viral load monitoring schedule should revert to the non-pregnant adults schedule.
Definition of high-risk infants	High risk infants are defined as those: born to women with HIV infection who have received less than 4 weeks of ART at the time of delivery; or born to women with HIV infection with viral load >40 copies/ml in the 3 months prior to delivery or VL unknown or born to women with HIV infection with unknown VL born to women with HIV infection diagnosed during labour and delivery, post-partum or in the breastfeeding period
Definition of average risk infants	Infants born to HIV infected pregnant or breastfeeding women who do not fit into the above high risk category
Management of high-risk infants	High risk infants qualify for the following PACKAGE OF CARE: Nucleid Acid Test (NAT) DBS within 48 hours of birth after the infant's first bath, and labelled as a "fast-track" birth test with the name and telephone number of the district point person Dual infant prophylaxis to be given for the first 6 weeks of life as described below Intensified tracking including: maternity facility to record in a designated register the mother's contact details, a treatment supporter's contact details, anticipated PHC clinic to attend in 2 weeks for birth test result, anticipated PHC clinic to attend in 6 weeks point person in the district designated to review the maternity facility higher risk infant register on a weekly basis, follow-up with laboratory for the results, and inform both the 2-week and the 6-week clinic of results. If result is positive, additionally contact the mother to say the result of the birth test is ready and she should come to the clinic (confirm which clinic). The clinic should collect another DBS NAT sample to confirm HIV-positive status but should not wait for the result before initiating ART. The laboratory to immediately notify the point person for any positive NAT result

Infant prophylaxis for high risk infants	Infants prophylaxis for first 6 weeks NVP plus AZT for 6 weeks Infants prophylaxis after 6 weeks of age If breastfeeding AND mother's VL >40 or unknown, continue with NVP daily If NOT breastfeeding since birth or in last 4 weeks, OR mother's VL<40, discontinue infant prophylaxis
Infant prophylaxis for average risk infants	Infant prophylaxis for first 6 weeks NVP for 6 weeks Infants prophylaxis after 6 weeks of age If breastfeeding *AND* mother's VL ≥40 or unknown, continue with NVP daily If NOT breastfeeding since birth or in last 4 weeks, *OR* mother's VL<40, discontinue infant prophylaxis
Early infant diagnosis of HIV	All HEIs should have a NAT test done at 6 weeks of age, including those who had a negative birth NAT test. If the infant was tested and confirmed to be HIV-positive using NAT at or after birth (below 6 weeks), there is no need to repeat NAT at 6 weeks or later. A positive initial NAT followed by a repeat positive NAT confirms true HIV infection in the child. All HIV-exposed infants who initially tested NAT HIV negative at 6 weeks of age should have a repeat NAT done at 9 months of age. (NEW) If the result of the NAT is positive the infant starts ART and as usual a confirmatory NAT is performed at that time. If the HIV NAT result at 9 months is negative, a rapid antibody test should be done 3 months after the last exposure to breast milk or at 18 months, whichever is *later*. (NEW)
Indeterminate NAT Test results (NEW)	When NAT result is neither positive nor negative, but is "indeterminate" a health worker should send another NAT DBS sample 4 weeks from the initial NAT, labeling the sample "priority". If the 2nd specimen is "indeterminate", further review is needed by a team of clinical and laboratory specialists.

Chapter 4: ANTIRETROVIRAL THERAPY FOR INFANTS AND CHILDREN

When to start ART	ALL infants and childrenare eligible for ART and should be initiated on ART irrespective of CD4 count and clinical stage.
Which ARVs to initiate in infants, children and adolescents	Adolescents 20 to <30 kg-Preferred: ABC/3TC/DTG(1)(50mg); alternative Children 3 years and 10 to <20 kg- Preferred: ABC/3TC/DTG(1); alternative: ABC/3TC/EFV (if no prior PMTCT) Infants 4 weeks to 2 years old: Preferred: ABC/3TC/DTG(1); alternative: ABC/3TC/LPVr Neonates 2 to <4 weeks old: Preferred: AZT/3TC/LPVr Neonates <2 weeks old, premature or low birth weight: AZT/3TC/NVP - Seek specialist advice
ARV Formulations and recommended dosages (NEW)	Abacavir is now approved for use in infants 4 weeks of age and older who weigh at least 3 kg Dolutegravir 50 mg tablets are now recommended for children who weigh at least 20 kg Tenofovir 300 mg tablets are now recommended for adolescents who weigh at least 30 kg Atazanavir 200mg capsules (plus RTV 100mg) can now be used in children who weigh at least 10 kg and can swallow capsules whole Infants with TB/HIV co-infection are eligible for RAL 100mg scored chewable tablets for the duration of their TB treatment (until the paediatric DTG is available) if they weigh at least 6 kg

Second ARVs for children	If Failing 1st Line is ABC + 3TC + DTG(1); Preferred 2nd line: AZT + 3TC + (ATV+r or LPV/r); Alternative: AZT + 3TC + EFV (if cannot use PI and if no prior PMTCT) If prior PMTCT, genotype If failing 1st line is ABC + 3TC + LPVr (or ATV+r): Preferred 2nd line: AZT + 3TC + DTG(2); alternate: If <20 kg and appropriate DTG formulation not available, AZT + 3TC + (ATV+r or LPV/r If failing ABC + 3TC + EFV (or NVP); Preferred: AZT + 3TC + DTG(2); alternate: If <20 kg appropriate DTG formulation not available, AZT + 3TC + (ATV+r or LPV/r If failing AZT + 3TC + LPVr (or ATV+r); preferred: ABC + 3TC + DTG(2)
Chapter 5: BIO-CLINICAL MONITORING FOR PATIENTS ON ART	
Baseline clinical assessment and monitoring for adults and adolescents	Initial assessment: Take and record patient's Temp, Blood pressure, Weight, Height, MUAC etc Full medical history and physical examination for diagnosis and management of OIs, psychosocial and nutritional challenges. WHO staging Take baseline laboratory tests Initiate ART on same day of HIV diagnosis if ready Medicine counseling on benefits of taking ARVs, prophylaxis treatment, adherence requirements, possible adverse effects and when to return to the clinic and follow up visits Follow up visits: Take and record patient's Temperature, Blood pressure, Weight, MUAC etc Check if there are any pending previous laboratory results or if the patient is due for blood tests Assess for adherence to treatment and medicine side effects Assess for any new symptoms The patient's perception of how he/she is doing on therapy such as change in body weight and changes in frequency and severity of HIV-associated symptoms. Screen for alcohol and drug use and the impact these might have on adherence
Clinical assessment checklist for children	Assess for the following parameters: Growth Neurological and cognitive development WHO Clinical Staging Co-morbidities TPT eligibility Immunisation status Nutritional status Concomitant medications Disclosure status
Use of CD4 Lymphocyte Counts	CD4 testing is recommended at baseline to determine the degree of immune suppression If a patient has virologic failure or shows signs of clinical deterioration, a CD4 count should be taken
Use of Plasma HIV-RNA levels (viral load)	All patients initiating therapy will routinely have a viral load assay done at 6 and 12 months after beginning therapy and every 12 months thereafter *The following populations have a different VL schedule as follows:* Children/adolescents <19 years: VL every 6 months Pregnant women: every 3 months until delivery

	Breast-feeding women: 6 weeks after delivery then 3 monthly until end of breast feeding period; then reverting to an annual VL test
Chapter 6: CARE AND SUPPORT FOR ADOLESCENTS LIVING WITH HIV	
Promoting the uptake of services	The Child Care and Protection Act has made provision for adolescents aged 14 years upwards to access medical services including HTS without parental consent. This is envisaged to facilitate voluntary uptake of HTS among adolescents and subsequent linkage to treatment, care and support. Approaches recommended to educate, inform and mobilize adolescents for HTS include: Purposefully organized and targeted HTS campaigns. This could be facility or community-based outreach activities; including schools/colleges. Provider-initiated HTS coupled with other entry services such family planning services, VMMC and immunization campaigns Ensuring that all health facilities are oriented towards the adolescent friendly health services approach as per AFHS guidelines which includes flexibilities in clinic opening times.
Transition of adolescence to adulthood	Transition to adult care has been defined as 'the planned purposeful process that addresses the medical, psychosocial and educational/vocational needs of adolescents and young adults with chronic physical and medical conditions as they move from child-centred to adult-oriented health care systems. Adolescents are in transition from childhood to adulthood and it is a difficult period as they experience physical as well cognitive changes To facilitate adherence and retention in care, it is essential to screen for and treat mental health problems.
Chapter 7: MANAGEMENT OF COMORBIDITIES AND OTHER SERVICES	
Eligibility criteria for initiating and discontinuation of CPT	Adults (including pregnant women living with HIV): Initiate in all with severe or advanced HIV clinical disease (WHO stage 3 or 4) and/or with a CD4 count ≤350 cells/mm3. Lifelong CTX is given. Infants and childrenwith HIV: Initiate in all irrespective of clinical stage or CD4 cell count. Lifelong CTX is given. HIV-exposed infants: Initiate in all starting at 6 weeks of age. Stop once HIV has been ruled out TB/HIV co-infected: Initiate all HIV-infected patients with active TB disease regardless of CD4 cell count. Lifelong CTX is given.
TB screening and IPT	All PLHIV should be screened for TB including asking about TB exposure/contact history at each encounter with a health worker or visit to a health facility. TB-IPT is very effective in preventing TB disease in individuals who have latent TB infection. To be eligible for TB-IPT the HIV-positive individual must: Have no symptoms or signs of TB – such as cough, fever, weight loss, night sweats, fatigue, blood in sputum, chest pain, diarrhoea, shortness of breath, enlarged lymph nodes, loss of appetite (*NB: TB-IPT should not be given to patients who are unwell and where there is no explanation of the illness*) Not have current history of alcohol misuse Have no history of active liver disease, liver insufficiency, or jaundice Have no history of hypersensitivity to isoniazid Have no history of exfoliative dermatitis

	Be motivated for TB-IPT after being educated about the benefits, possible side-effects and risks.
TPT Regimens	Isoniazid given once daily for a period of 6 months (6H). IPT is now given for 6 months instead of 9 months as in the previous guidelines (NEW). Isoniazid and Rifapentine given in combination weekly for a total of 12 doses (3HP) (NEW) In special circumstances and in consultation with TB or HIV specialist Isoniazid and Rifampicin can be given daily for a three months period.
Use of Xpert MTB/RIF (NEW)	Xpert MTB/RIF should be used rather than conventional microscopy as the initial diagnostic test in adults and children suspected of having HIV-associated TB

Chapter 8: USE OF ANTIRETROVIRAL THERAPY FOR HIV PREVENTION

Definition of PrEP	PrEP is defined by WHO as the use of antiretroviral drugs before HIV exposure by people who are not infected with HIV in order to block or prevent the acquisition of HIV. Oral PrEP should be offered as part of the 'Combination Prevention' package that includes HIV Testing Services (HTS), male and female condoms, lubricants, ART for HIV-positive partners in sero-discordant couples, voluntary medical male circumcision (VMMC) and STI prevention and management.
Indications for PrEP	Any sexually active HIV-negative person at substantial risk of acquiring HIV. Those at high risk include but not limited to the following: HIV negative people in sero-discordant relationships with a partner who is not confirmed as virologically suppressed (i.e., partner has VL > 40 copies/ml) All HIV negative people in sero-discordant relationships (regardless of VL of the partner) who want to conceive Pregnant or breastfeeding HIV-negative women in sero-discordant relationships Those with partner(s) of unknown HIV status Those with recent/ recurrent STIs Those with multiple and/or concurrent sexual partners Those with history of inconsistent or no condom use Recurrent PEP users Those with history of sex whilst under the influence of alcohol or recreational drugs Injection drug users Those in abusive relationships Those who strongly feel at substantial risk of HIV infection.
Contraindications for PrEP	Unwilling to get tested for HIV HIV positive Signs and symptoms of HIV primary infection (characterized by flu-like symptoms) Adolescents weighing <35kg Adolescents aged <15 years who are not Tanner stage 3 or greater (should not get TDF) Abnormal CrCl<60ml/min Taking other nephrotoxic drugs, for example, aminoglycosides Known allergies to any of the PrEP drugs
PrEP ARV Regimen	Daily oral tenofovir/emtricitabine (TDF/FTC 300mg/200mg) or TDF/3TC as FDC is preferred
When to Stop PrEP	PrEP should be stopped: Whenever an HIV test is positive At client's request

	For safety concerns/ side effects (CrCl<60ml/Min) If risks of PrEP outweighs benefits
PEP regimens	Tenofovir 300 mg daily + emtricitabine 200 mg (or lamivudine 300 mg) FDC once daily for 28 days (low risk exposures). In case of high risk exposures; it is recommended to give TDF/3TC/DTG (NEW)
Procedures for PEP following occupational exposure	Draw baseline laboratory tests: HIV testing (with consent), HBsAg and Ab, and creatinine. If HIV negative, PEP should be initiated promptly, preferably within 1 - 2 hours post-exposure and especially if the source patient is HIV-positive or the patient's HIV status is unknown. For those whose results are positive for HIV, PEP should be discontinued immediately, and the clients linked into care for treatment Workers who are HIV-negative at baseline should repeat HIV-antibody tests at 6 weeks, 12 weeks, and 6 months
Comprehensive management of rape survivors	PEP regimens: Give expanded PEP regimens as above Presumptive STI prophylaxis cefixime 400 mg or ceftriaxone 250 mg IM STAT plus metronidazole 2 gram STAT plus azithromycin 1g STAT (adults) Emergency contraception, as soon as possible, within 120 hours (NEW): Ovral (norgestrel 500 mcg+ ethynyl oestradiol 50 mcg) given as 2 tablets STAT and 2 tablets 12 hours after the first dose. Levonorgestel 1.5mg STAT (given as 1 tablet containing 1.5mg or 2 tablets containing 0.75 mg each) – only available in the private sector in Namibia. A copper T IUCD. Hepatitis B immunoglobulin and hepatitis B vaccination should be started as soon as possible if the patient is not already immune A tetanus booster should be given. Counselling, medico-legal assessments

Chapter 9: DIFFERENTIATED SERVICE DELIVERY

Definition of Differentiated Care	Differentiated care is a client-centred approach that simplifies and adapts HIV services across the cascade to reflect the preferences and expectations of various groups of people living with HIV (PLHIV) while reducing unnecessary burdens on the health system. By providing differentiated care, the health system can refocus resources to those most in need.
Models of ARV Delivery in Namibia	Facility-based models Standard care (Main ART and NIMART sites) Fast-track ART refills model ART Adherence Groups (including Teen clubs) Out of facility models ART Outreach models Community ARV Refill Groups (CARGs)

Chapter 10: MEDICINES MANAGEMENT AND PATIENT SAFETY

Effective stock control system	3 main steps for an effective stock management system *Step 1*: Order ARVs based on patient number per regimen and correct pack size *Step 2*: Receive, verify and store ARVs under appropriate conditions *Step 3*: Dispense ARVs for up to 6 months and capture records on EDT
Multi-month dispensing (MMDs) of medicines	Multiple month dispensing (MMD) is one of the new service delivery models that aims to reduce clinic visits and ARV pick-up appointments for stable patients on ART A patient that meets the following basic eligibility criteria is eligible for MMD (NEW):

	is virally suppressed (less than 40 copies/ml on two previous consecutive tests), has no opportunistic infections (OIs) or other debilitating co-morbidities has been on ART for more than 12 months
Monitoring adverse drug reactions	ADRs that should be reported include all suspected adverse drug reactions, which are: All suspected reactions to new medicines - reactions to recently marketed medicines (on the market for less than five years) regardless of their nature or severity Unknown or unexpected reactions regardless of their severity i.e. not consistent with product information or labeling; Serious adverse drug reaction Unexpected therapeutic effects All suspected medicine interaction Product quality problems Treatment failure Medication errors

Chapter 11: MONITORING AND EVALUATION

Why M and E?	Monitoring the HIV programme by measuring key indicators and immediately feeding back to improve programme activities are essential to HIV programme success. The three major benefits include: It provides essential information for individual case management. It provides key information for managing the health facility (e.g. for ordering drugs and supplies or for making quality improvements). It provides information for operating and improving an HIV/AIDS program at the facility, district, national, and international levels
Quality Improvement practices	HIV care providers should integrate continuous quality improvement into routine service delivery. Namibia builds upon the QI framework and has the following components: Routine data collection, analysis and reporting to the next level by implementing weekly, monthly and quarterly data reviews Ensure that the testing sites have adequate infrastructure, technical expertise and QA and QI programs. Adopt site problem identification, prioritization, implementation of tests of change - -Plan, Do, Study, Act (PDSA) cycle guides, sustainable and ongoing change(CQI) Appoint a focal person to spearhead quality improvement teams at sites and integrate best practices. Strengthen the collaboration of multidisciplinary management teams at all levels Implement Data Quality Assessment for all core indicators on a routine basis

INTRODUCTION

Namibia has made significant strides in responding to the HIV epidemic with noticeable achievement on the UNAIDS Fast-track 90-90-90 targets by year 2020. According to the Namibia Population-based HIV Impact Assessment NAMPHIA (2017**); 86% of PLHIV know their HIV status, 96% of the known HIV positives are on treatment and 91% of those on treatment are virally suppressed**. Despite the progress, a high level of pre-treatment HIV drug resistance (exceeding the WHO threshold of 10%) has been observed prompting the review of the first line ART to include integrase inhibitors. In January 2019, the Namibia Treatment Advisory Committee resolved to introduce and transition HIV treatment towards Dolutegravir-containing regimens. The country officially introduced low dose Efavirenz 400mg-containing ARVs in September 2018 with approximately 60% of patients having transitioned to this ARV combination by the first quarter of 2019. Careful planning for the double transition is therefore needed to minimize potential losses and expiries of ARVs.

In December 2018, the World Health Organization released the Interim Guidelines with updated recommendations on first line and second line ARV regimens, Post-exposure prophylaxis and recommendations for early infant diagnosis. The MOHSS has revised its 5th National ARV Guidelines to incorporate new recommendations from the global normative guidance. These guidelines as the previous ones address clinical, operational and programmatic aspects of using ARV medicines for HIV treatment as well as for prevention. The guidelines are intended for use by national HIV program managers, clinicians and other health service providers in both public and private sectors, managers of laboratory services, People Living with HIV and AIDS (PLHIV), community based organisations, national HIV treatment and prevention advisory bodies as well as international and bilateral agencies that provide financial and technical support. These guidelines make reference other policies, guidelines and standards, and must therefore be used in tandem. The country will continue to implement the 'Treat All' recommendations with promotion of same day ART start.

Major changes to these guidelines include the addition of four new chapters' i.*e HIV Testing services, Bio-clinical Monitoring of patients on ART, Management of comorbidities and other services and Medicine management and patient safety*. The HTS chapter highlights main approaches to providing HTS services and the importance of linking patients tested to post-test HIV services. New interventions to testing including Recency Testing to determine recent HIV infections will aid mapping of hot spots locations and high-risk subgroups for better HIV prevention targeting efforts. Once fully operational; the use of unique patient identifiers will enhance patient-centred monitoring intended to promote monitoring people receiving HIV services rather than measuring services provided. The chapter on management of comorbidities consolidates the screening and management of common opportunistic infections and comorbidities that affect all HIV infected population groups. In order to strengthen aspects around adverse drug monitoring and management; a new chapter on medicine management and patient safety has been added. There is increasing interest in implementing patient-level data monitoring in addition to program level data management to inform both clinical management of individual patients and at national level to inform planning and decision-making to improve focus and direction of the national program. To address this need; key aspects of monitoring and evaluation including minimum set of indicators, quality assurance practices and surveillance interventions have been consolidated into a new chapter.

In order to strengthen the provision of comprehensive HIV prevention, treatment and care services in Namibia; the following interventions remain critical within the Namibian context:

A shift from HIV testing for coverage to targeted testing at community and facility levels and enhancing linkages to post-test HIV services

Provision of integrated patient-centred care where multiple health services are offered to a patient during the same visit by a single health worker or a clinical team

Mobilization and equitable distribution of resources across the public and the private sectors to support long-term program sustainability

Continuous patient counseling in order to ensure full understanding of ART, the importance of treatment adherence, timing of medication intake in relation to meals, psychosocial support, recording and reporting of adverse events associated with the intake of ARV medicines, and monitoring and management of medicine resistance.

Capacity to recognise and appropriately manage common HIV-related illnesses, opportunistic infections and adverse reactions to antiretroviral medicines (ARVs).

Reliable laboratory monitoring services including routine haematological and biochemical tests for the detection of medication toxicity and response to therapy.

Periodic quantification and forecasting of medicines and laboratory commodities for assurance of an adequate supply of quality medications, including medicines for treatment of opportunistic infections and other HIV-related illnesses.

Strengthen systems for pharmacovigilance and management of patients presenting with adverse drug reactions.

Availability of trained interdisciplinary health care teams, including doctors, pharmacists, nurses, social workers, and counselors.

Community involvement through awareness creation, mobilization, referral linkages and other collaborations.

Availability of appropriate care, support services and referral mechanisms in case of treatment failure.

Continuous improvement of guidelines in tandem with emerging scientific evidence and best practices in HIV prevention, treatment and care.

1 HIV TESTING SERVICES

1.1 Introduction

HIV testing is an entry point into all services and packages that are involved in the care and treatment of all who need HIV services. Ensuring that correct HIV test results are given is a priority and crucial component of the 5Cs for HTS and linkage to care. These Cs are Consent, Confidentiality, Counselling, Correct test results and Connection or linkage to prevention, care and treatment services. Increasing access to testing is essential to sustaining the UNAIDS 90-90-90 targets of which Namibia has exceeded these targets and is currently working towards the 95-95-95 goal. The onus is in developing strategies that increase access to HIV packages through testing.

Before a patient starts ART, it is important to have detailed discussions with him or her about their willingness and readiness to initiate ART, the ARV regimen, dosage and scheduling, the likely benefits and possible adverse effects and the required follow-up and monitoring visits.

This chapter summarizes some key protocols in the 2018 Namibia HIV Testing Services Guidelines and introduces new concepts that will increase testing services. The following areas are covered: definition of HIV Testing Services (HTS); HIV testing services in neonates, infants, children, adolescents and adults; point of care Recency testing (POC-RT); HIV self-testing (self-screening); index partner testing (IPT); linkage to care and use of unique patient identifiers.

According to the Namibia HTS National Guidelines (2018); HTS embraces the full range of services that should be provided together with HIV testing.

Figure 1-1: Comprehensive HTS Services

1.2 HIV testing services in neonates, infants and children under 24 months

Testing children in this age category is not only a part of Namibia's elimination of Mother to Child Transmission of HIV (eMTCT) program, but follows the consenting procedures expressed in 'The Child Care and Protection Act (further elaborated upon in the section below). The technical details will be discussed in eMTCT Chapter 3.

It is important to note the following;

- Neonates from birth to 28 days and young infants <6 weeks old: higher- risk babies are offered NAT at birth (preferably within 48hrs) and if the result is positive, ART is commenced, whilst awaiting confirmatory test results.

- All exposed babies (regardless of classification of risk) are offered another NAT at 6 weeks or at the first presentation to a health facility after that time if that is beyond 6 weeks and also, if test results are positive, treatment is started whilst also awaiting confirmatory results.
- At 9 months of age, or at the first presentation to a health facility between 9 and 17 months, all babies who were previously NAT-negative will have NAT repeated
- At 18 months or 3 months after the cessation of breastfeeding whichever is *LATER*, the test offered will be the HIV rapid test which detects antibodies in the baby's system. The reason for this is that at that age all maternal antibodies will have been eliminated from the baby's bloodstream

For emphasis, an exposed baby is any baby born to an HIV positive mother, regardless of CD4 or viral load. These babies could be termed high risk or average risk. For further elaboration refer to Chapter 3.

1.3 HIV Testing services for adolescents and adults

The WHO defines adolescents as persons between the ages of 10-19 yrs of age. Adolescents may be further classified as young adolescents (10-14yrs) and older adolescents (15-19). With the recent coming into force of the Child Care and Protection Act the age of 'majority' has been reduced from 21 to 18 yrs. This Act also sets provisions for consent to medical interventions as well as HTS based on age and mental capacity/competence of adolescents and children.

Accordingly, children from the age of 14 years and above may consent to HIV testing without parental or guardian's permission, and those under 14 years of age may give consent, provided the person who conducts the pre-test counselling is satisfied that the child is of sufficient maturity to understand the benefits, risks and social implications of such a test.

A proper informed consent process and adequate pre- and post-test counselling procedures must be followed. HTS providers must therefore be responsive to the needs of their clients and not administer testing indiscriminately.

1.4 Optimized Provider Initiated Testing and Counselling

Provider initiated testing and counselling (PITC) services should be routinely offered by health care providers to persons attending health care facilities as a standard component of medical care.

Fundamentals of PITC:

- INFORM ALL (about the need for HIV testing)
- SCREEN ALL (for HTS eligibility)
- TEST ALL (eligible individuals)
- COUNSEL ALL (provide result-specific counselling)
- LINK ALL (to appropriate services)

1.5 Index Client HIV testing

It is defined as a voluntary process involving testing sexual partners of HIV diagnosed clients and their exposed biological children and offering them HTS. It can be a part of Recency testing (see above) in order to trace and test sexual partners. The goal of Index client testing is to break the chain

of HIV transmission by offering HTS to persons exposed to HIV and linking them to HIV treatment, if positive or to prevention services if negative such as PrEP, VMMC and others. (Refer to 2018 HTS Guidelines for more information). HIV testers should be mindful and highly uphold confidentiality concerns and cultural sensitivities in following up sexual partners of index clients. HTS providers are encouraged to show empathy and encouragement to clients. As with recency testing; trust and relationship building is paramount.

1.6 HIV Self Testing (HIV Self-screening)

HIV Self testing is an innovative approach involving self-determination of HIV status. It can be performed on self, using blood or saliva, in a private setting alone or with trusted person in attendance. Currently Namibia uses oral HIV testing (saliva) for screening.

The **benefits of self- screening** include: removal of self- stigma and empowering clients while enhancing health seeking behaviour and it is an ideal approach to testing for vulnerable and marginalized populations. Positive self-screening test should always be confirmed with the national algorithm on testing and followed by linkages to services such as ART, PrEP or VMMC as appropriate. It is not mandatory to confirm all negative self-test result unless there is an established element of risk. It is imperative to devise strategies to monitor, prevent, and mitigate any negative consequences of HIV self-screening, especially as they concern psychological and other issues.

1.7 Point of Care Recency testing (Recency Testing)

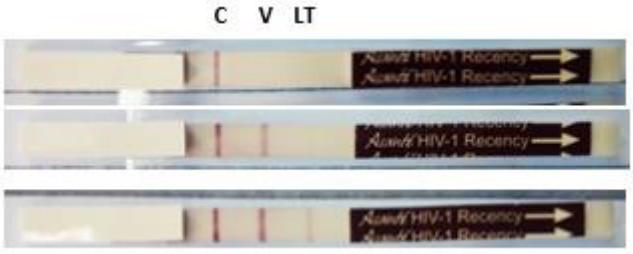
Recency testing (POC-RT) is a disease surveillance testing methodology which provides insight into the timeline of an individual's HIV infection. It is applicable to all individuals who are confirmed positive within the national HIV testing algorithm. Whilst the conventional Rapid test has lines (C and T), recency test has three lines i.e. Control line (C), Recent Infection (CV) and long term line (LT line)

C line = negative

CV Line = Recent infection (less than 1 year)

LT Line = Long term Infection (over 1 year)

Figure 1-2: Recency test lines



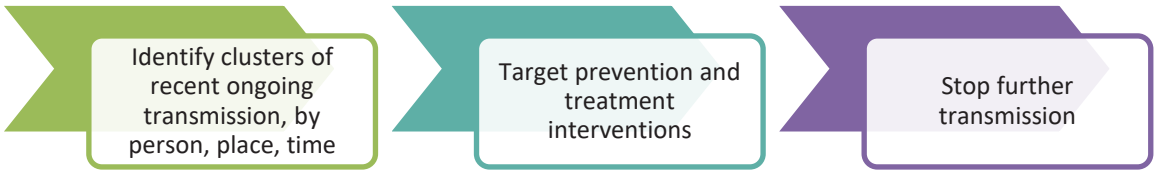
Benefits of Point of Care Recency Testing:

- It can be integrated into routine HTS
- Can be used to identify individuals who may qualify for further targeted testing

- It helps to track trends in recent infections to inform public health responses and prevention efforts
- Results may be used in mapping hot spots locations with high rates on new HIV infections or high-risk sub- populations

Recency testing involves building trust from the service providers who should establish sufficient rapport with clients to feel comfortable to disclose their personal sexual history including their current and past sexual partners. Recency testing cascade is shown in Figure 1-3Figure 1-3 below:

Figure 1-3: Recency testing cascade



1.8 Linkage to care

This is the process of connecting a client from the point of testing to services that are needed based on the results of the HIV test. Effective linkage from HIV testing to care ensures that people receive the support and information they need in order to improve their health and quality of life. Special effort should be placed to effectively link individuals who test positive in the community and re-test them prior to ART initiation.

If test results are confirmed positive, the client is offered **same day** access to Antiretroviral therapy (ART), where applicable, or as soon as possible within a week in order to maximize the benefits of ART. HIV infected people should be offered ongoing adherence counselling, bio-medical and psycho-social support, and condoms for dual protection of STIs and unintended pregnancies.

If an individual is HIV negative; they should be linked/referred to appropriate HIV prevention services including but not limited to PrEP, VMMC, psycho-social support, ongoing counselling and condoms.

1.9 Clients testing through community HTS

Where community testing is offered, a number of steps should be put in place to strengthen linkage. Community test and treat may be implemented through guidance from the Community Test and Treat SOP. When clients are tested and initiated on the same day even in the community, retention to care is high and the benefits are a lot. The Community Test and Treat SOP highlights what is required to implement test and treat in the community, linkage to care and use of ARV Starter Packs. The community HTS provider should keep a clear record of HIV-positive clients to be followed up. The HTS provider should contact or visit the referral sites to confirm enrolment within an agreed time (ideally within one month) or, with the client's consent, they may be followed up by phone or by a CHW or other community-based cadre.

1.10 Use of Unique Patient Identifiers

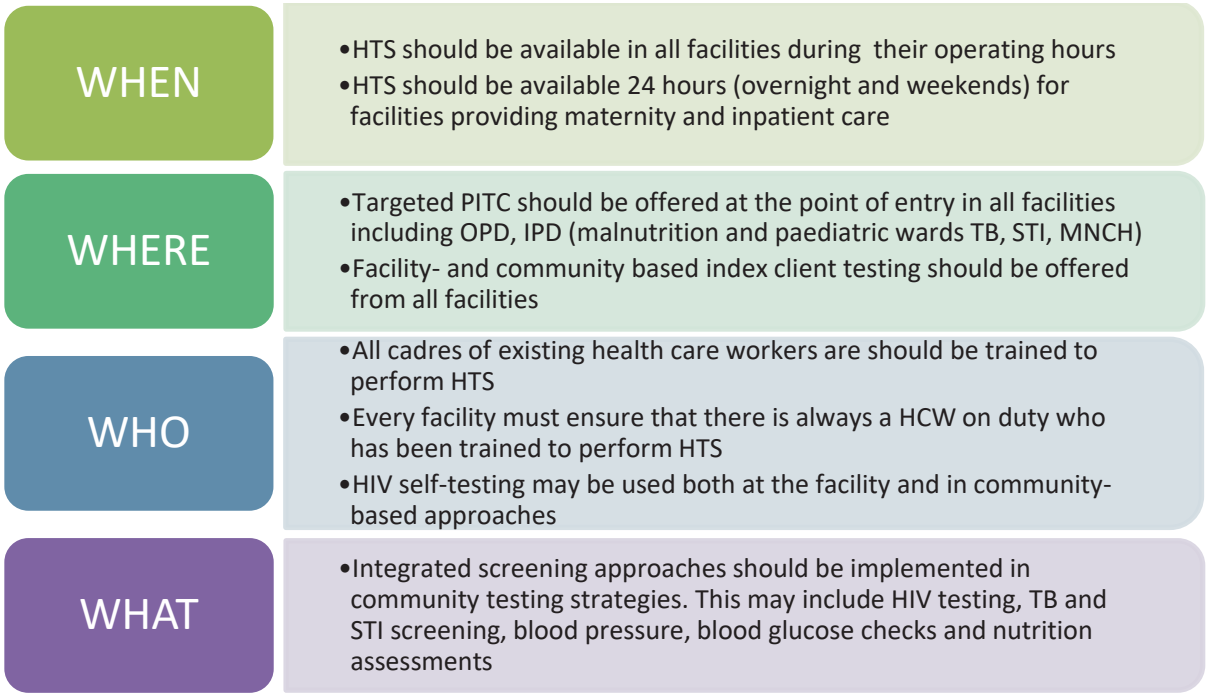
The country is planning to introduce unique patient identifiers within the health delivery system. Unique identifiers are numeric or alphanumeric codes that help to identify individuals when accessing a variety of health services. This code should be anonymous but linked to a secured database that has individuals' personal information. The use of unique identifiers will help to track individuals seeking HIV care and other health services. It will also enhance person-centred monitoring as promoted by WHO (2017) and intended to shift the focus from measuring services provided, to monitoring people receiving HIV services and other health services and is critical in supporting data linkages and patient retention in care. HIV patient records will contain unique identifiers and data will be shared within the HIV program with the anonymous coding linked to their health records.

Unique identifiers will be useful in managing patients who transfer in and out of health facilities without their health records. When the system of using identifiers is routinely used in Namibia; it will help reduce possible double counting of patients who receive HIV services at multiple service delivery points. The system will help improve efficiencies and effectiveness in case surveillance and patient monitoring in Namibia.

1.11 Summary of HIV Testing Services

Figure 1-4 below summarizes the HTS services to be provided in Namibia using the Four Building Blocks from the International AIDS Society Differentiated HIV Testing Framework (2018).

Figure 1-4: Summary of HTS Services in Namibia



2 ANTIRETROVIRAL THERAPY FOR ADULTS AND ADOLESCENTS

2.1 Assessment of HIV-positive adults

The MoHSS recommends re-testing of all newly diagnosed HIV positive patients to verify their HIV positive status prior to enrolment into treatment.

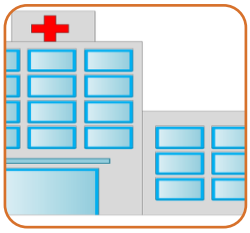
The patient should have the following taken:

- a complete medical history
- physical examination
- appropriate baseline laboratory tests
- rule out the presence of opportunistic infections and determine readiness to start ART

Figure 2-1: Readiness to start ART and maintain adherence

Patient and provider related

- Conduct adherence counseling on the day of enrolment and assess readiness of ART initiation. Patients who are ready should be started immediately.
- Provide follow up adherence counseling to those who are not ready until readiness is achieved.
- Conduct testing of sexual partners and biological children of index case and offer PrEP to the HIV-negative sexual partners.
- Encourage the patient to identify a family member, a friend, peer or community members for treatment support.
- Encourage the patient to develop a habit of using memory aids: such as timers/alarm clock/cell phone, written schedule, pill boxes.
- Counsel on planning travels ahead (as an example patients to carry enough medication and their health passport
- Educate patient regarding goals of therapy, proper dosing, medication interactions, food effects and side-effects.
- Educate patients about the importance of laboratory monitoring and the meaning of their test results.
- Provide counseling in the language of the patient/the language the patient understands
- Look out for active drug/alcohol use and untreated mental illnesses because they are associated with poor adherence.
- Assess for socio-economic factors that affect adherence and refer to line ministries
- Provide appropriate information about potential side-effects, encourage patients to report when they encounter side effects and manage them accordingly
- Monitor adherence and intensify management in periods of poor adherence.
- Ensure access at off-hours and weekends for questions or addressing problems.
- Involve entire health care team.
- Consider effect of new diagnoses and events on adherence.
- Consider patient's current medications and minimise adverse medicine interactions and reactions.
- Simplify regimen as much as possible regarding: dose frequency, pill burden, pill storage, and food requirements.



Health system related

- Provide training updates on adherence for all team members including community workers and utilise entire team to reinforce adherence.
- Educate volunteers, organisations of people living with HIV (PLHIV) and community representatives on importance of adherence.
- Develop systems to improve referral linkages and interactions between health facilities and community-based organizations
- Develop innovative approaches that address adherence

2.2 When to start antiretroviral therapy in adults and adolescents

All HIV positive adults irrespective of CD4 counts or WHO stage are eligible to start ART (Treat All). Patients should be initiated on ART immediately when they are ready, either on the **same day** or as soon as possible within one week. Absence of baseline test results should not delay the initiation of ART. However, in some cases ART initiation may be deferred due to some clinical indications as listed in Table 2-1 below:

Table 2-1: Medical indications to defer ART initiation

Reason	Action
Diagnosis of Cryptococcal Meningitis	Defer ART until 4-6 weeks after start of antifungal treatment. Earlier initiation has been shown to increase risk of death due to immune reconstitution inflammatory syndrome.
Serum or plasma cryptococcal antigen positive	Defer ART until 2 weeks after start of antifungal treatment (if meningitis is excluded on lumbar puncture then ART does not need to be deferred)
Diagnosis of any form of TB	Defer ART until 2-8 weeks after start of TB treatment. Earlier initiation has been shown to increase the risk of death due to immune reconstitution inflammatory syndrome.

For more details on management of co-morbidities refer to Chapter 7.

2.2.1 Re-starting ART in patients who "default" and "Lost to Follow-up"

Interruption of ART may result in viral load rebound and clinical progression of HIV. Any patient who misses their clinic visit and interrupts treatment is defined as a "defaulter". **Any patient who misses their clinic visit for 30 consecutive days or more is defined as "lost to follow up".** All defaulters and lost to follow-up patients should be traced, linked back to care and interviewed to assess for underlying reasons for treatment interruption. Efforts should be made to correct the circumstances leading to the lapse in treatment. Each case of lost to follow up, once returning to care, should be carefully evaluated before continuing treatment. Patients who are continuing treatment should receive continuous adherence counselling and close follow-up.

Patients who return after being lost to follow-up and did not take ARVs for at least 6 months should have a CD4 test assessed, managed for any co-infections and provided appropriate prophylaxis. The healthcare team should as much as possible try to reinstate the same treatment regimen on the same day. However if the patient is not ready to re-start ART, counselling should be provided to address the barriers. The HCW should ensure that clients who return to care after having defaulted should be welcomed back in a manner that is non-judgemental and non-discriminatory.

Facilities, as a routine practice, should print out on a weekly basis a list of patients who missed their appointments and contact the individuals as soon as possible. Health facilities should collaborate with community based organisations operating in their catchment areas to facilitate tracing of defaulters. The number of patients who are lost to follow up as well as the outcome of efforts of tracing such patients should be routinely reported. For further guidance and tools in reporting this indicator please refer to the SOPs for Tracing Patients Missing Appointments.

2.3 Adherence

2.3.1 Importance of adherence

The goal of ART is to achieve sustained and optimal viral suppression. Very high level of adherence is required to achieve this goal over time. This is promoted by proper on-going support, counselling and simplified well tolerated regimens.

2.3.2 Missed doses

Daily dosing regimen: If patient normally takes medication in the morning and misses a dose, take immediately as soon as it is remembered. Continue in the morning on the next day. If patient normally takes medication in the evening and misses the dose but then remembers in the morning of the next day, take immediately the missed dose. If remembered in the afternoon, take the missed dose immediately and skip the evening dose.

Twice daily regimen: If it is remembered in the morning, take the dose immediately and then continue with the evening dose as per normal schedule. If remembered in the evening, take dose immediately and then take the next morning one as per normal schedule.

2.3.3 Treatment supporters

A treatment supporter is someone at the patient's home, in the community, or at the workplace, who can accompany the patient to the health facility and assist with daily adherence to ART. The MoHSS advises that it is helpful for all patients to have a treatment supporter if possible. Absence of a treatment supporter, however, should not be a reason to deny treatment to a patient. Where possible, patients who are unable to identify a treatment supporter may benefit from having links to community-based organizations or support groups to provide treatment support.

2.4 Antiretroviral medications

There are currently six classes of antiretroviral agents as summarized in the Table 2-2 below:

Table 2-2: Classes of Antiretroviral medicines and mechanism of action

Antiretroviral medication classes	Mechanism of Action	Examples of ARVs*
Entry inhibitors	Prevents the virus from attaching to the host cell CD4 co-receptor CCR5	Maraviroc (MVR)
Fusion inhibitors	Block the virus from being able to merge with the host cell (i.e. CD4 cell) after binding	Enfuvirtide (ENF)
Integrase Strand Transfer Inhibitors (INSTIs)	Prevent the newly synthesized viral DNA from integrating into the host cell DNA	Raltegravir (RAL), Elvitegravir (EVG) and Dolutegravir (DTG)
Nucleoside/or Nucleotide Reverse Transcriptase Inhibitors (NRTIs).	Inhibit the transcription of viral RNA into DNA, which is necessary for reproduction of the virus	Tenofovir Disoproxyl Fumerate (TDF), Tenofovir Alafenamide (TAF), Zidovudine (AZT), Lamivudine (3TC), Abacavir (ABC) and Emtricitabine (FTC)
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)	Chemically different class from NRTIs, but also inhibit transcription of viral RNA into DNA.	Nevirapine (NVP), Efavirenz (EFV), Etravirine (ETV), and Rilpivirine (RPV)
Protease inhibitors (PIs)	Act on the viral enzyme that cuts long chains of virally produced amino acids into smaller proteins	Lopinavir (LPV), Ritonavir (RTV), Atazanavir (ATV), Darunavir (DRV)

**Not all of these medications are currently available in Namibia. The comprehensive list at the time of this printing is given here for completeness.*

2.4.1 Dolutegravir

Dolutegravir (DTG) is an Integrase Inhibitor which has a high genetic barrier to developing drug resistance. It has other advantages compared to most ARVs; including lower potential for drug interactions, a shorter median time to viral suppression. Adding to these benefits, it has also a long half-life, low cost and low dose mean that including this drug in a once-daily fixed-dose combination.

DTG is identified as a the most suitable regimen for adolescents and critically important given the demonstrated risk of suboptimal adherence compared with adults in some settings, which places them at high risk for treatment failure and developing drug resistance. In this context, a high value has been placed on more acceptable, effective, tolerable and forgiving regimens for adolescents. DTG is dosed as 50mg taken once daily. It is however dosed at 50mg twice daily in patients on Rifampicin and treatment experienced with known or suspected Integrase Inhibitors resistance mutations. A potential safety issue related to neural tube defects among infants born to women who were taking DTG at the time of conception has been identified from an analysis of an ongoing observational study in Botswana. Weight gain is another adverse effect that has been observed with the use of DTG in some studies.

2.4.2 Tenofovir Alafenamide (TAF)

Tenofovir alafenamide is a prodrug of the nucleotide analogue Tenofovir. It is predominantly metabolized intracellularly to Tenofovir which undergoes subsequent phosphorylation to yield the active Tenofovir diphosphate (TFV-DP). Administration of TAF results in higher concentrations of tenofovir in tissues but lower concentrations in plasma than does treatment with TDF; the clinical significance of this is not yet clear.

TAF is available as a FDC of TAF/FTC/DTG. TAF is approved for use in HBV infection. It has been associated with K65R and the K70E substitutions which lead to reduced susceptibility to ABC, TAF and TDF. Proximal tubular proteinuria and reduction in glomerular filtration rate (eGFR) are significantly less in TAF compared to TDF. It is associated with significantly less change in spine and hip bone mineral density (BMD) compared to TDF. There is currently no safety and efficacy data on the use of TAF in pregnant women and people with HIV/TB co-infection.

Use of Tenofovir Alafenamide (TAF)

TAF can be considered in elderly patients above 50 years, patients with CrCl 30 - 60 and HBV co-infected. Not to be given to patients with low CrCl < 30.

2.5 Recommended ART regimens in Namibia for Adults and Adolescents

Recommended ART regimens consist of a combination of 2 NRTIs plus an INSTI, NNRTI or a PI. For individuals who cannot tolerate the recommended regimens or who experience failure on the second line regimens, an HIV experienced provider or a clinical mentor should be consulted.

The first line and second line ART regimens for adults, adolescents ≥ 10 years who weigh at least 30 kg, and pregnant and breastfeeding women are listed in Table 2-3 below respectively.

Table 2-3: Recommended First Line ART regimens in Namibia

1st line ART	**Preferred 1st line Regimens**	**Alternative** 1st line Regimens[2]**
Adult males and adolescent boys ≥10 years and weighing at least 30kg Adult women and adolescent girls NOT of childbearing potential Women on reliable family planning and who choose to use DTG Pregnant (2nd and 3rd trimester) or breastfeeding	TDF + 3TC (or FTC) + DTG[1] **(TLD_1)***	TAF[2] +3TC (or FTC) + DTG[1] TAF +3TC (or FTC) + EFV 400mg ABC+3TC+DTG[3] TDF + FTC (or 3TC) + ATV/r AZT + 3TC + DTG[1]

Special Circumstances		
Women pregnant in first trimester **Or** Adult women and adolescent girls of childbearing age or potential who wish to become pregnant or who are not otherwise using or accessing consistent and effective contraception **AND** Have been fully informed of the potential increase in the risk of neural tube defects (at conception and until the end of the first trimester).	TDF + 3TC (or FTC) + DTG[1] **(TLD_1)**	TDF +3TC (or FTC) + EFV 400mg ABC+3TC+DTG[3] TDF + FTC (or 3TC) + ATV/r
Women pregnant in first trimester **Or** Adult women and adolescent girls of childbearing age **AND** do not wish to take DTG at that moment	TDF +3TC (or FTC) + EFV_{400}	TDF + FTC (or 3TC) + ATV/r

[1] TB patients on Rifampicin to receive DTG twice daily (b.d)
[2] TAF is not currently suitable for pregnant women, TB/HIV coinfected and CrCl<30
[3] ABC/3TC/DTG can be used from weights of 20kg.
**TLD_1 means patient is on TLD as first line*
***Alternative regimens should only be used if the preferred first line regimen is not an option*

TDF based regimens should be initiated on the same day of HIV diagnosis and the clinician should draw blood for baseline creatinine clearance to be reviewed within 2 weeks (NEW).

TDF can still be used in specific patients with renal insufficiency when its use is unavoidable (e.g. hepatitis B co-infection) but should be carefully monitored and the dosage should be adjusted according to the recommendations concerning use of TDF in renal failure in Table 2-4 below. Please refer to Appendix 5 for details on the appropriate dose adjustment of all NRTIs in case of renal failure.

Table 2-4: Recommendations for Tenofovir and TAF Dose Adjustment in Patients with Altered Creatinine Clearance[1]

Creatinine Clearance (ml/min)	Recommended Dosing of TDF 300 mg	Dosing of TAF/FTC/DTG
≥50	Every 24 hours	Every 24 hours
30-49	Every 48 hours	Every 24 hours
10-29	Twice a week	Not recommended
≤ 10	No recommendation available owing to a lack of pharmacokinetic data in this population	
Haemodialysis patients	Every 7 days or after a total of 12 hours of dialysis (administer following completion of dialysis)	

[1]Joel E. Gallant, MD, MPH (2005).Tenofovir and Renal Function: A Guide for Clinicians

2.6 Family Planning Consideration and Use of DTG

All women of childbearing potential and their partners have the right to choose the number, timing and spacing of their children and to decide on the use of FP methods, regardless of their HIV status or age. Women and their partners should be given adequate information to help them make an informed, voluntary choice of a contraceptive method. Please see Table 7-6 on contraceptive methods available in Namibia.

The following information should be provided about each contraceptive method:

- Correct usage
- How it works
- Common side-effects
- Health risks and benefits
- Signs and symptoms that would necessitate a return to the health facility
- Return to fertility after discontinuation
- Safer sexual practices to prevent STIs

Given the current recommendations to include DTG as part of antiretroviral therapy, counseling and provision of family planning services to women of childbearing potential should be strengthened using women centered approaches. Therefore, the overall approach of integrating FP services at point of care, should respond to **women's needs, rights, safety and preferences**. Care should be provided in a manner that respects the autonomy of women in decision making about issues pertaining to their own health. **Women should be given information and options to enable them to make informed choices**.

It is also important to note the following;

- Women on DTG who plan to get pregnant should discuss with their health care provider alternative antiretroviral treatment.
- Women's fertility intentions and FP status should be assessed at each treatment visit.

Table 2-5: List of contraceptive methods available in Namibia

Hormonal methods		**Effectiveness**
Intrauterine Device (IUD)	Intrauterine Contraceptive Device (IUCDs)	99% Effectiveness (**Reliable contraceptive**)
Progestin only Methods	Progesterone Only Injectables (POIs) Contraceptive Implants	99% if used correctly but less than 95% effectiveness on typical use **Reliable contraceptive**)
	Progestin Only Pills (POPs)	99% Effectiveness if used correctly but less than 95% effectiveness on typical use
Combined hormonal contraceptives	Combined Oral Contraceptives Combined Contraceptive Patch	95% Effectiveness
Non hormonal methods		**Effectiveness**
Intrauterine Device (IUD)	Copper IUD	99% (**Reliable contraceptive**)
Sterilization (Voluntary Surgical Contraception)	Vasectomy (Male Sterilization) Bilateral Tubal Ligation (Female sterilization)	99% (**Reliable contraceptive)**
Non-hormonal methods (barrier methods)	Male Condom Female Condom	98% if used correctly 95% if used correctly

Natural Family Planning (NFP) Methods	Abstinence Coitus Interruptus/ Withdrawal Lactational Amenorrhea Method (LAM) Fertility Awareness Methods (FAM)	60-73%

Table 2-6: Recommended Second line ART regimens in Namibia

Failing first-line Regimen	Preferred second-line Regimen
TDF(or TAF) + 3TC + DTG or ABC + 3TC + DTG	AZT + 3TC + ATV/r or (LPV/r)
TDF(or TAF) + 3TC + EFV or TDF + 3TC + ATV/r	AZT + 3TC + DTG*
AZT + 3TC + EFV or AZT + 3TC + ATV/r	TDF (or TAF) + 3TC + DTG**

TLD1: stands for first line regimen

*For HIV/TB coinfection on rifampicin based regimen, use LPV/R (super booster) instead of ATV/r and DTG ***B.D*** instead of DTG ***O.D***

** Maintain TDF in the second line for patients with chronic HBV coinfection

2.7 Third line ART for Adults and Adolescents

Third line regimens are complicated, more costly and should only be implemented following the recommendations and close supervision of HIV clinical mentors or specialist physicians. According to recent studies, most patients fail 2nd line ART in Namibia due to poor adherence[1].

Therefore, any decision to perform an HIV Resistance Test should be made in consultation with HIV clinical mentors or specialist physicians after ruling out poor adherence.

2.7.1 Reasons for changing antiretroviral therapy

Studies have shown that first line regimens give patients the best chance of long-term treatment success. ART may need to be changed due to therapy failure or medication toxicity, but there must be a very strong clinical justification for doing so.

2.7.2 Changing due to toxicity (ARV substitution)

If a change in ARV regimen is needed because of drug- induced toxicity, the offending medicine can be replaced with another medicine that does not have the same level of side-effects. This is further discussed in Section 10.6. When it is not possible to identify the offending medication, discussion with a HIV clinical mentor or specialist physician is recommended.

2.7.3 Changing due to treatment failure (ART Regimen Switch)

Treatment failure can be suspected clinically from patient's history and physical examination, immunologically from CD4 counts, and virologically by measuring viral loads. Clinical evidence of failure is indicated by HIV disease progression (e.g. emergence of new opportunistic infections) in a patient who had been clinically stable. Virological failure is defined as a viral load >1,000 copies/ml

[1] HIV1 drug resistance patterns among adult patients failing second line protease inhibitors containing regimens in Namibia, 2010-2015, Sawadogo et al

6 months after starting ART or viral rebound to >1,000 copies/ml on two consecutive measurements after a period of viral suppression. Please refer to Chapter 5 figure 5.3 for evaluating patients failing on treatment.

2.7.4 Transitioning adults to the new first line Fixed-dose Combination formulation

In order to take advantage of the new preferred first line regimen, it is important to consider whether the patient has virologic suppression on the current regimen before making a change. HCWs should carefully assess whether or not the patient is eligible for a direct substitution or if a regimen switch is required (Refer Table 2-7 and Table 2-8 below).

Non-thymidine analogues (e.g. ABC and TDF) have similar mutation patterns. However, changing from a thymidine analogue (eg. AZT) to a non-thymidine analogue or *vice versa* in the presence of virologic failure could compromise future 2nd line options – it would be essentially introducing one new ARV into a failing regimen. For this reason, results of the most recent viral load should be reviewed to inform the appropriate regimen change. **If the most recent VL was taken over 6 months previously; the same ARV regimen should be maintained until the next routine viral load test is performed (viral load tests SHOULD NOT be done solely for the purpose of transitioning patients)**.

Table 2-7: Transitioning patients on first-line regimen

Current ARVs	VL within last 6 months		
	VL < 40	VL 40 - 999	VL > 1000
TDF/3TC/EFV	TDF (or TAF) /3TC/DTG **(TLD1)**	Continue TDF/3TC/EFV. Repeat VL in 6 months and if remains the same, consult HIV clinical mentor or specialist physician.	Continue TDF/3TC/EFV. Assess adherence, consult HIV experienced provider or clinical mentor for possible switch to 2nd line regimen.
AZT/3TC/EFV	TDF (or TAF) /3TC/DTG **(TLD1)**	Continue AZT/3TC/EFV. Repeat VL in 6 months and if remains the same, consult HIV clinical mentor or specialist physician.	Continue AZT/3TC/EFV. Assess adherence, consult HIV experienced provider or clinical mentor for possible switch to 2nd line regimen.

**TLD1 means patients is on TLD as part of first line.*

Table 2-8: Transitioning patients on second-line regimen

Current ARVs	VL within last 6 months		
	VL < 40	VL 40 - 999	VL > 1000
TDF/3TC/AZT/PIs (*if AZT was part of first line*)*	TDF (or TAF) /3TC/DTG **(TLD2)****	Continue TDF/3TC/AZT + PIs. Repeat VL in 6 months and if remains the same, consult HIV clinical mentor or specialist physician.	Continue TDF/3TC/AZT + PIs. Assess adherence, consult HIV Clinical mentor or specialist for possible switch to 3rd line regimen.
TDF/3TC/AZT/PIs *(if TDF was part of first line)**	AZT /3TC/DTG	Continue TDF/3TC/AZT + PIs. Repeat VL in 6 months and if remains the same, consult HIV clinical mentor or specialist physician.	Continue TDF/3TC/AZT + PIs. Assess adherence, consult HIV Clinical mentor or specialist for possible switch to 3rd line regimen.

**Please consult when in doubt. Do not transition patient when not sure.*
***TLD2 means a patient is on TLD as part of second line.*

3 ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION OF HIV

3.1 Introduction

In the absence of antiretroviral medicines and with breastfeeding, published estimates of mother-to-child transmission (MTCT) of HIV range from 21% to 43% in various African settings. When it occurs, most transmission takes place during labour and delivery, followed by transmission in the uterus and through breastfeeding, depending on duration. The longer the child is breastfed, the greater the risk of HIV transmission.

All HIV negative pregnant and breastfeeding women should be followed up until they stop breastfeeding. Those at substantial risk of HIV acquisition should be offered Pre-exposure Prophylaxis (PrEP). Health care workers should encourage women to bring their partners for HIV testing.

Elimination of Mother to Child Transmission of HIV (eMTCT) includes 4 main strategies:

a. Primary prevention of HIV infection.
b. Prevention of unintended pregnancy in HIV infected women.
c. Prevention of HIV transmission from HIV infected women to their infants.
d. Provision of comprehensive care to mothers living with HIV, their children and families.

Figure 3-1: Timing of mother-to-child transmission with breastfeeding and no ARVs[1]

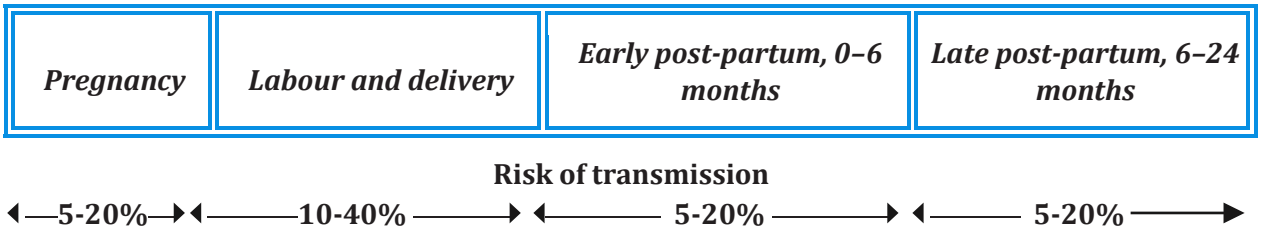


Table 3-1: Factors that increase the risk of mother-to-child transmission

Obstetrical	Maternal	Foetus/New-born	Viral
Episiotomy Invasive monitoring Instrumental delivery Rupture of membranes (ROM) >4 hours Antepartum and intra partum haemorrhage Amniocentesis	High viral load Low CD4 count Advanced disease Poor nutrition Breast condition STIs New HIV infection Maternal TB	Prematurity Multiple births Breastfeeding Mixed feeding Immature gastrointestinal tract Genetic factors Immature immune system	Viral type Viral resistance

[1] Adapted from Bertolli et al., Estimating the timing of mother-to-child transmission of human immunodeficiency virus in a breast-feeding population in Kinshasa, Zaire. J Infect Dis. 1996 Oct. 174(4): 722-6.)

3.2 HIV Screening during Antenatal and Postnatal Periods

All pregnant women, with the exception of known positives, should be offered HIV testing and counselling services at their first antenatal visit, regardless of previous HIV negative results. On subsequent visits health workers should retest HIV-negative women as follows:

- after 3 months and at 36 weeks (unless already tested negative at 32-35 weeks)
- 6 weeks post-natal, and;
- 3 monthly during the breastfeeding period

3.3 Use of Antiretrovirals (ARVs) During Pregnancy and Breastfeeding

3.3.1 Initiating ART in HIV Positive Pregnant Women

The goal of ART for HIV positive pregnant women is two-fold: to restore and maintain the mother's immune function and her general health and secondly, reduction in VL reduces the risk of HIV transmission during pregnancy, labour, delivery, breastfeeding and to the sexual partner.

- Lifelong ART is offered to pregnant/ breastfeeding woman on the same day of HIV diagnosis.
- All HIV infected pregnant/breastfeeding women should be screened for active TB– if TB suspected investigate before initiation of ART
- Ensure patient is counselled and given appropriate information on the importance of ART for her own health, prevention of transmission to her infant, adherence, side effects and follow-up care.
- Perform a physical examination and WHO clinical staging.
- Draw baseline laboratory HIV and ANC investigations and initiate the preferred first line regimen (or an alternative if there is a known contraindication to the preferred first line - discuss with HIV experienced provider or HIV clinical mentor)
- Make an appointment in 2-weeks' time to review laboratory results and for substantive intensive counselling on adherence and side effects.
- ART follow up and patient laboratory monitoring should be harmonized with ANC and Post-Natal Care (PNC) services.

Consult an HIV experienced provider or HIV clinical mentor if an HIV infected pregnant or breastfeeding woman has co-morbidities (diabetes, renal disease, neoplasia), severe adverse events or is on any regimen other than the recommended.

WHO now recommends the use of DTG-based regimens as the preferred first-line ARV drug for everyone living with HIV including pregnant and breast-feeding women. The prevalence of NTDs associated with using DTG at conception in the Botswana -Tsepamo study has declined although the prevalence difference remains higher than all other ARV drug exposures.

Source: Updated guidance on first-line and second-line antiretroviral regimens. Geneva, Switzerland: World Health Organization; 2019 (WHO/CDS/HIV/19.16)

3.3.2 Monitoring of Viral Load in pregnant and breastfeeding women

For women already on ART:	• Check the most recent routine VL to ascertain if the VL is suppressed. • If a VL was not done within the last 3 months, repeat it at the first ANC visit and provide adherence counselling. • If the VL was <40 copies/ml, repeat every 3 months until delivery, then at 6 weeks post-partum and thereafter every 3 months until the end of the breastfeeding period. • if the VL was 40 to <1000 copies/ml, provide intensive adherence counselling and repeat according to the schedule above • If the VL was/is >1000 copies/ml, intensive adherence counselling should immediately be given and the VL should be repeated in 6 weeks and every 3 months thereafter until delivery, then at 6 weeks post-partum, and thereafter every 3 months until end of breastfeeding period. If any repeat VL is >1000 copies, and adherence is good, manage as possible treatment failure and consult an HIV specialist / clinical mentor.
For women initiating ART during pregnancy, or in the breast-feeding period:	• Do VL 3 months after initiation, then 3-monthly until delivery, then 6 weeks post-partum, and thereafter every 3 months until the end of the breastfeeding period. As with patients already on ART, if any VL result is >1000, appropriate action as discussed above should be taken.

The above VL monitoring schedule will help to determine whether or not and when her breastfeeding infant can discontinue nevirapine prophylaxis. At the end of breastfeeding, the viral load monitoring schedule should revert to the non-pregnant adults.

3.3.3 Retention in care of mothers and HIV exposed children

Interruption of ART among HIV positive pregnant and breastfeeding mothers can result in increased viral load which increases the risk of HIV transmission. Similarly, interruption of HIV prophylaxis in HIV exposed children increases their risk of HIV acquisition. Efforts should be made to actively identify and trace mothers and HIV exposed children who miss their clinic visits or interrupt treatment. Follow-up appointments of mothers and HIV exposed children should be synchronized to avoid unnecessary visits to the facility. Health workers should support the formation of facility and community mother support groups.

3.3.4 HIV positive pregnant or breastfeeding women who refuse to commit to or who interrupt life-long ART

Refusal to commit to lifelong treatment: An HIV positive pregnant or breastfeeding woman might refuse initiation of lifelong ART after being given all the necessary information and reasonable counselling on the benefits. These women should be interviewed to assess the reasons behind their refusal to treatment. A multi-disciplinary team (health workers, social workers, community leaders, religious leaders) should be involved in counselling and addressing the barriers. Women should be reviewed at the facility on a monthly basis until they agree to start ART.

Interruption due to toxicity, stock outs or other factors: When a pregnant or breastfeeding mother interrupts ART it is important to determine an alternative ART regimen or solution, and counsel her on the need to continue treatment without interruption. Health care workers should consult an HIV experienced provider or clinical mentor if ART in a pregnant or breastfeeding woman needs to be interrupted or stopped.

3.4 Risk stratification for HIV exposed infants and Infant Prophylaxis

Infants should be managed according to risk-stratification (See Table 3-2).

It is important to differentiate the management of infants with high risk of HIV acquisition compared to those with average risk.

High risk infants qualify for the following 3-pronged PACKAGE OF CARE:

1. HIV Nucleic Acid Test (NAT) dried blood spot (DBS) within 48 hours of birth after the infant's first bath, and labelled as a "fast-track" birth test with the name and telephone number of the district point person.
2. Dual infant prophylaxis to be given as soon as possible after birth and within the first 72 hours for the first 6 weeks of life as described in Table 3-2 below.
3. Intensified tracking including:
   - maternity facility to record in a designated register the mother's contact details, a treatment supporter's contact details, anticipated Primary Health Care (PHC) clinic to attend in 2 weeks for birth test result, anticipated PHC clinic to attend in 6 weeks
   - point person in the district designated to review the maternity facility high risk infant register on a weekly basis, follow-up with laboratory for the results, and inform both the 2-week and the 6-week clinic of results. If result is positive, additionally contact the mother to say the result of the birth test is ready and she should come to the clinic (confirm which clinic)
   - laboratory to immediately notify the point person for any positive NAT test result

Table 3-2: Classification of infant risk and implications for infant prophylaxis regimen

Classification of risk	Risk criteria	Infant prophylaxis for first 6 weeks	Infant prophylaxis after 6 weeks of age
High risk of HIV transmission to infant	-Born to women with HIV infection who have received **less than 4 weeks of ART at the time of delivery;** -Born to women with HIV infection with VL **>40 copies/ml in the 3 months prior to delivery** -Unknown VL -Born to women with **HIV infection** diagnosed during labour and delivery, post-partum or in the breastfeeding period	NVP **plus AZT** for 6 weeks	**If breastfeeding AND mother's VL ≥ 40 or more or unknown**, continue with NVP daily **If NOT breastfeeding since birth or in last 4 weeks, OR mother's VL<40**, discontinue infant prophylaxis and continue to monitor mother's VL as prescribed
Average risk of HIV transmission to infant	All pregnant or breastfeeding women with HIV who do not fit into the high-risk category	NVP for 6 weeks	

Infants *who present to care more than 72 hours after birth* and who are breastfed should receive NVP prophylaxis. Note: such infants, even if high risk would not be eligible for dual prophylaxis.

In the event that the infant is *not* breastfeeding, ARV prophylaxis will not offer them protection and should not be given.
All infants should be assessed for risk of HIV transmission and even those who are high risk and present more than 72 hours should have an HIV NAT test immediately.

Simplified infant NVP and AZT dosing recommendations are given on **Table 3-3**: Simplified infant NVP and AZT dosing recommendations (eMTCT only)

. If NVP causes toxicity in the infant (or if NVP is not available), 3TC can be substituted only after discussions with an HIV experienced provider or clinical mentor.

Table 3-3: Simplified infant NVP and AZT dosing recommendations (eMTCT only)

Infant age	Dosing of NVP		Dosing of AZT (10mg/ml)
Birth to 6 weeks	**NVP 50mg Tablet***	**Alternative dose if there is NVP 200mg syrup**	
Birth weight 2000-2499g		**10 mg once daily** (1 ml of syrup once daily)	**10 mg twice daily** (1 ml of syrup twice daily)
Birth weight ≥ 2,500g		15 mg once daily **(1.5 ml of syrup once daily)**	15 mg twice daily **(1.5 ml of syrup twice daily)**
>6 weeks to <6 months	25mg (1/2 tablet) once daily	20 mg **(2 ml of syrup) once daily**	NA
6 months to <9 months	25mg (1/2 tablet) once daily	30 mg (3 ml of syrup) once daily)	NA
9 months to 4 weeks after the end of breastfeeding	40 mg once daily **(one 50 mg tablet once a day)**	4 ml of syrup once daily	NA

**NVP 50 mg dispersible tablet is now available for use in infants older than 6 weeks*

Single use of the dispersible NVP 50mg is recommended. Do not keep it in a reconstituted solution for longer than 24 hours because of formulation issues and sedimentation. Measuring amount to be taken using a syringe is not necessary.

For infants weighing <2000 g and older than 35 weeks of gestational age, the suggested doses are: NVP 2 mg/kg per dose once daily and AZT 4 mg/kg per dose twice daily. Contact an HIV clinical mentor or specialist paediatrician for dosing of premature infants younger than 35 weeks of gestational age.

3.5 Early Infant Diagnosis of HIV

It is important to identify young infants with HIV infection and enroll them in HIV care early because of the high mortality from untreated HIV in this age group. It is equally important to identify infants who are not HIV-infected in order to reassure their parent(s), discharge them from costly follow-up, and to measure the overall effectiveness of the eMTCT programme.

The Nucleic Acid Test (NAT) detects the genetic material of HIV rather than of anti-HIV antibodies, and therefore is not affected by the trans-placental transfer of maternal anti-HIV antibodies, unlike the HIV antibody tests. NAT specimens are collected using the dried blood spot (DBS) methodology.

A positive initial NAT followed by a repeat positive NAT confirms true HIV infection in the child.

Infants classified as having a high risk of HIV infection will receive a special package of care including being offered an HIV test within 48 hours of birth. Active tracing of infants found to be positive by birth testing is critical to ensure initiation of ART on time and to save lives. In addition, **any infant determined to be at high risk that missed the birth test for any reason, or whose mother is diagnosed during the post-partum period should have a NAT done at the first presentation to the health facility, not waiting until the infant is 6-weeks of age.**

All HEIs should have a NAT test done at 6 weeks of age, including those who had a negative birth NAT test. If the infant was tested and confirmed to be HIV-positive using NAT at or after birth (below 6 weeks), there is no need to repeat NAT at 6 weeks or later.

NEW!! NAT at 9 months, not rapid test

All HIV-exposed infants who initially tested NAT HIV negative at 6 weeks of age should have a **repeat NAT done at 9 months of age.** This is a change from the previous guidelines.

The reason for the change is that the rapid antibody test (RT) can be *negative* in infants <18 months of age, when NAT is positive. This was found in 15-40% of infants in Uganda and Kenya study. Therefore a RT is not a reliable screen to rule-out HIV infection in HIV-exposed infants.

The underlying cause of these "false-negative" RT tests is not yet clear but may include:

a. Delayed infant antibody development due to viral load reduction with maternal ART and infant prophylaxis;
b. ART provided soon after incident infection in the mother may result in lower antibody production in the mother and hence less placental transfer of antibody; and
c. Maternal infection in late pregnancy or post-partum can result in lack of passive placental antibody transfer, and infants produce antibody more slowly than adults.

If the result of the NAT is positive the infant starts ART and as usual a confirmatory NAT is performed at that time.

If the HIV NAT result at 9 months is negative, a rapid antibody test should be done 3 months after the last exposure to breast milk or at 18 months, whichever is ***later.*** This is also a change from the previous guidelines which stated that some infants who stopped breastfeeding earlier than 18 months, could have a RT to rule-out HIV infection 3 months after the cessation of breastfeeding, even if that was earlier than 18 months of age.

Since it is now known that a RT cannot rule-out HIV infection in infants <18 months, it is important to re-test at 18 months or older (if the infant has not yet completed at least 3 months since the cessation of breast-feeding. The infant should remain on cotrimoxazole and multivitamins until confirmed HIV negative. Infant prophylaxis with NVP is described in **Table 3-3**: Simplified infant NVP and AZT dosing recommendations (eMTCT only)

Indeterminate NAT test results: Occasionally a NAT result is neither positive nor negative, but is "indeterminate". If one indeterminate result is received, send another NAT DBS sample 4 weeks from the initial NAT, labelling the sample "priority". If the 2nd specimen is "indeterminate", further review is needed by a team of clinical and laboratory specialists. Until a final diagnosis is reached

the infant should remain on NVP and cotrimoxazole prophylaxis. If the 2nd result is positive, start ART and send confirmatory NAT as usual.

NEW!! Final HIV diagnosis by RT at 18 months or 3 months after end of BF whichever is *later*

HIV-negative HIV-exposed infant:

The parent(s)/guardian should be counselled that their infant is HIV-negative and the child can be discharged from HIV follow-up after 18 months of age if:

- HIV antibody test is negative and the child is at least 18 months old and has not been breastfed for the preceding 3 months.

Special situation:

Any HIV-exposed infant <18 months of age who presents for the first time to any health facility and has not had previous NATs, should have a NAT done at that visit.

Figure 3-2: Algorithm for early infant diagnosis of HIV using diagnostic Nucleic Acid Test (NAT) and Rapid Antibody tests for HIV-exposed infants

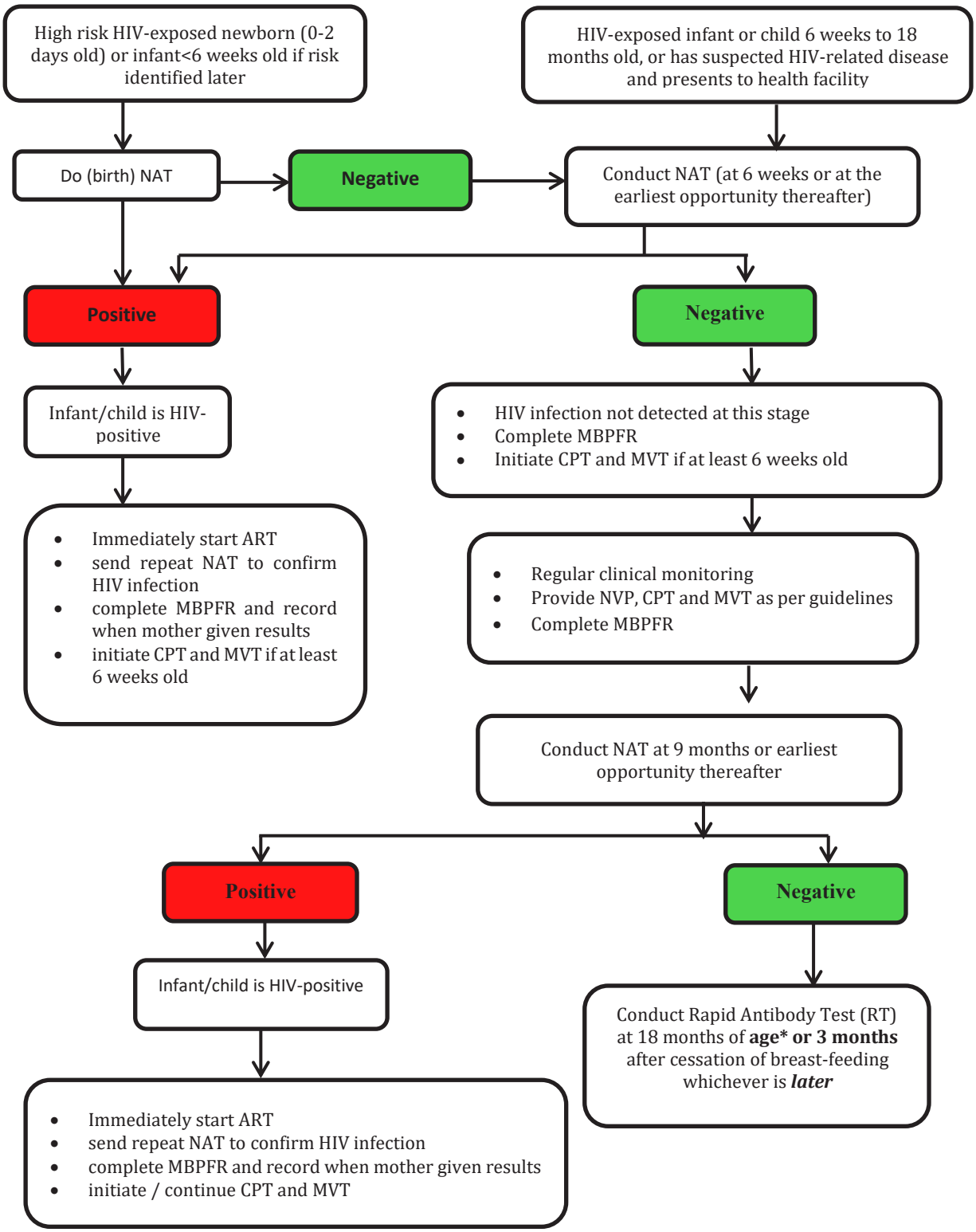


Table 3-4: Summary of Feeding Recommendations for HIV Exposed Infants and Young Children

	Mothers who are known to be HIV uninfected or whose HIV status is unknown	Mothers known to be HIV infected and whose infants are HIV uninfected or of unknown HIV status	Infants and young children known to be HIV infected
<6 months	Exclusive breastfeeding from birth until 6 months	Exclusive breastfeeding from birth until six months, with ARVs.	Exclusive breastfeeding from birth until six months.
≥ 6 months	Introduce appropriate complementary foods at 6months and continue to breastfeed for at least 24 months.	Introduce appropriate complementary foods at 6 months and continue breastfeeding for at least 24 months, continuing maternal ART and (if applicable) infant ARV prophylaxis	Introduce appropriate complementary foods at 6 months and continue to breastfeed for at least 24 months, with mother and child on ART

3.6 Reproductive considerations when one or both sexual partners are HIV positive

The success of ART has resulted in HIV- infected people living longer healthier lives and therefore having to make informed reproductive choices. However, it is important that those planning to have children do so carefully in consultation with health care providers to minimize the risk of infection to the sexual partner and their child. The first step towards addressing the issues of fertility and childbearing is to regularly and repeatedly raise these with HIV-positive patients, to understand their desires and related health care needs. Use of family planning services is important to avoid unplanned and unwanted pregnancies. Adherence to ART is critical to ensure suppressed viral load before getting pregnant.

If a Couple Wishes to Have a Child:

- Determine HIV status of both sexual partners – HIV counselling and testing is a prerequisite if the HIV status of both partners is not known.
- Counsel on the risks of MTCT
- Counsel and offer PrEP to the uninfected partner.
- Advise on use of family planning services including condoms
- Check CD4 or viral load (if on ART), screen for syphilis, other STIs, check haemoglobin and screen for cervical cancer (female)
- Identify and manage co-morbidities. For conditions with short-term management (e.g. TB or acute infections), recommend delay in attempts at conception until treatment is completed.

Table 3-5: Guidance for Couples who wish to have a child

Couples' HIV Status	ART Status of HIV infected individuals	Management
HIV Sero-Concordant Couple (Female and Male HIV-infected)	Both on ART Check for most recent viral load (repeat if not done in last 6 months)	*VL <40 copies/ml in both*: Advise couple on peri-ovulatory unprotected sexual intercourse within days 10-18 of her menstrual cycle for 3 months Emphasise consistent condom use outside this period
	One or both individuals not on ART Initiate ART according to guidelines and check VL after 6 months	*VL ≥ 40 copies/ml in one or both*: Evaluate and address inadequate adherence and other causes of failure Advise a delay in conception until the VL is <40 copies/ml
HIV Sero-discordant Couple (Male HIV-infected)	If Male is not on ART, initiate as soon as possible and check VL after 6 months If on ART check for most recent VL (repeat if not done in last 6 months)	Male's VL is <40 copies/ml: Check the female's: HIV antibody test (repeat if not done within last 3 months) Creatinine clearance (CrCL) If antibody test is negative and CrCl is normal, provide PrEP (Refer to PrEP chapter) Advise the couple on peri-ovulatory unprotected sexual intercourse within days 10-18 of female's menstrual cycle) for 3 months* Emphasise consistent condom use outside this period. Male's VL is ≥ 40 copies/ml: Evaluate and address inadequate adherence and other causes of failure. Advise a delay in conception until the VL is <40 copies/ml
HIV Sero-discordant Couples (Female HIV-infected)	If female is not on ART, initiate as soon as possible and check VL after 6 months If on ART, check for most recent VL (repeat if not done in last 6 months)	Female's VL is <40 copies/ml: Check male's HIV antibody test and if negative: Offer PrEP and advise on use of non-spermicidal condoms. If couple is unable or unwilling to use the artificial insemination method: Check CrCl If HIV antibody test is negative and CrCl is normal, provide PrEP (Refer to PrEP chapter) Advise the couple on peri-ovulatory unprotected sexual intercourse within days 10-18 of female's menstrual cycle) for 3 months* Emphasize consistent condom use outside this period. Female's VL is ≥ 40 copies/ml: Evaluate and address inadequate adherence and other causes of failure Advise a delay in conception until the VL is <40 copies/ml

*** In sero-discordant couples that mutually desire a pregnancy and the fertility procedure involves high HIV risk to the HIV negative partner, targeted counselling and appropriate options should be presented to the couple with their acknowledgement that they understand the process and risks of transmission to the negative partner.**

4 ANTIRETROVIRAL THERAPY FOR INFANTS AND CHILDREN

Many of the goals of HIV care and treatment in infants and children are similar to those in adults and are listed below:

- Undetectable viral load
- Durable suppression of HIV replication
- Restoration and/or preservation of immune function
- Reduction of HIV related morbidity and mortality
- Preservation of normal growth and development
- Safe and effective HIV disclosure to the child
- Improvement in quality of life for the child and family
- Successful transition to adolescent and adult HIV care

Preservation of normal growth and development, the need for disclosure of child's HIV status, and successful transition to adult HIV care are unique to paediatrics. In order for ART to be considered a success, growth and development must be monitored carefully and taken into consideration when managing such patients.

4.1 The natural course of HIV disease in children

Children may be infected with HIV during pregnancy, during delivery, or postnatally (through breastfeeding). Left untreated, the mortality rate from HIV is approximately 30% by age 1 year, 50% by age 2, and 60% by age 3. The mortality rate from untreated HIV is highest at < 18 months of age.

HIV RNA levels in perinatally infected infants not on ART are generally low at birth (i.e. <10,000 copies/ml), increase to high values by age 2 months and then decrease slowly after the first year over the next few years of life. This pattern probably reflects the lower efficiency of an immature but developing immune system in containing viral replication and possibly a greater number of HIV-susceptible cells in younger children.

CD4 T-lymphocyte counts and percentage values in healthy infants who are not infected with HIV are considerably higher than those observed in uninfected adults and slowly decline to adult values by age 5 years. (see Table 4.1). Although the CD4 absolute number that identifies a specific level of immune suppression changes with age, the CD4 percentage that defines each immunologic category is less variable. CD4 values at base-line will be used to assess the level of immunosuppression at diagnosis. In children it is more useful to note the CD4% vs the Absolute CD4 as it is less variable.

Table 4-1: HIV Paediatric immunological classification

Classification of HIV associated immunodeficiency	Age related CD4 values			
	≤11 months (%)	**12 – 35 months (%)**	**36 – 59 months (%)**	**≥ 5 years (cells/ mm³)**
Not significant	>35	>30	>25	>500
Mild	30-35	25-30	20-25	350-499
Advanced	25-29	20-24	15-19	200-349
Severe	<25	<20	<15	<200 or <15%

As with adults, progression of clinical HIV disease is determined through classification of associated illnesses and conditions into 4 clinical stages (See Appendix 2). These are similar to adult staging classification; however they include some conditions specifically targeting children such as stunting, unexplained parotid enlargement, symptomatic lymphoid interstitial pneumonitis, and others. It is important to be aware of and to record the child's stage of disease and to recognize co-existing conditions which need treatment.

4.2 Determination of HIV exposure in infants and diagnosis of HIV infection in children

4.2.1 Determining HIV-exposure status in infants

Most HIV positive women who are pregnant attend antenatal clinic (ANC). They either present to ANC as known positive pregnant women, or are tested at ANC and their HIV positive status is diagnosed. As noted in Chapter 3, all pregnant women who test HIV-negative during ANC and at delivery should be retested routinely during the breastfeeding period and some may be found to be HIV-positive. Infants of all of these mothers are "HIV-exposed".

Some infants may present to health facilities with signs and symptoms consistent with possible HIV-infection, and their HIV exposure status is unknown. The best test to screen for HIV-exposure in such infants is a rapid antibody test of the biological mother, and this should be done immediately. Appropriate actions can then be taken according to HIV-exposure status of the infant.

NEW!! Exposure status determined by NAT if mother not available for

If it is not possible to test the biological mother in this case, and the child is <18 months of age, a RT on the infant does not provide reliable information on whether or not the infant is HIV-exposed. Hence such infants should have a Nucleic Acid Test (NAT) to determine if HIV-infected. If this NAT is negative, in an infant with no history of PMTCT, the infant is HIV-negative. If the NAT is positive, the infant is HIV-positive and should be managed accordingly. Refer to Figuer 3-2 for early infant diagnosis.

4.2.2 Criteria for diagnosis or exclusion of HIV

HIV-positive children

Parent(s) should be counselled and a child should be clinically managed as being HIV-positive if:

- HIV NAT test is positive at any age, in symptomatic and asymptomatic infants or
- HIV antibody test is positive at ≥ 18 months, regardless of symptoms

Infants who test HIV positive with HIV NAT should have a confirmatory HIV test done, because otherwise life-long treatment will be given on the basis of a single blood test. A repeat HIV NAT (confirmatory test) must therefore be done for HIV-positive infants <18 months old at the same time as the baseline blood tests are taken, however ART should be commenced based on the first result - **do not wait for the results of the confirmatory HIV NAT to initiate ART.**

If the confirmatory test is positive, there is no need to ever repeat a diagnostic HIV test. If the confirmatory test result is indeterminate or negative, continue ART and consult a HIV experienced provider or clinical mentor.

As with adolescents and adults, children ≥18 months of age diagnosed with HIV by RT, should have a repeat RT before starting ART.

Serologic and/or NAT reversion can occur in HIV positive children who are confirmed HIV-positive and start ART early and whose viral load is persistently maximally suppressed (target not detected) through excellent adherence. This means that standard antibody tests (RT) and/or the NAT may give negative results while the child is actually HIV positive.

If ART is discontinued in that child, the HIV viral load will rebound and the child can become ill. There is no need to re-test a child who has been confirmed HIV-positive. However if the child is tested again for any reason, including as part of a testing campaign when older, for example, it is important for all health care workers and counsellors to be aware of this phenomenon to ensure that no child is inadvertently taken off treatment in the mistaken belief that the child is no longer infected with HIV.

In the rare event that a child was diagnosed HIV positive on the basis of a single HIV NAT (no confirmatory NAT result is found), a detectable viral load test result can serve as the confirmatory test. If all viral load results are undetectable (target not detected) in such children, and the HIV diagnosis is in doubt, **do not stop ART.** Consult a clinical mentor or HIV experienced provider before taking further action.

4.3 Counselling prior to starting ART

Children are dependent on their parents/caregivers for managing their ARV administration and for overall care and support. Therefore careful discussion about the illness and adherence counselling for the primary caregiver and at least one other treatment supporter should be done from the outset. Some parents may themselves be infected with HIV or may have other health or social challenges which might put maintenance of the child's care at risk, so there needs to be a "back-up" system in place.

It is important for children to initiate treatment ideally on the same day as diagnosis therefore counselling sessions should start immediately upon diagnosis. During counselling sessions it is very important to fully assess, discuss and address issues to do with adherence with caregivers and, if of appropriate age, with the children themselves. This is always essential, and can be particularly challenging if an HIV-infected child does not have any signs of HIV disease. Caregivers should be informed that at the start of ART, there is a need for more frequent visits, but that the frequency of visits will decrease once the child is stable on treatment.

Furthermore, HCWs should ask the caregiver which health facility would be most convenient for him/her to access HIV services for the child. Every effort should be made to enable caregivers and children to attend the same health facility.

4.4 When to start ART

All HIV positive neonates, infants and children are eligible for ART and should be initiated on ART irrespective of CD4 count and clinical stage ideally on the same day as diagnosis or within one week. Earlier treatment prevents progression of disease and therefor allows the child to grow and develop normally.

In special circumstances, such as showing TB symptoms, new diagnosis of TB or admission with severe malnutrition, ART initiation should be delayed. (see Chapter 7).

4.5 Recommended ART Regimens for Infants and Children in Namibia

The choice of ARVs in children depends upon age, weight, previous eMTCT nevirapine exposure and co-morbidities. Children who have had NVP as part of eMTCT may have HIV resistance mutations to NVP. Therefore initiating an ART regimen containing NNRTIs to those children would not be expected to be durable. It is preferable to use an age-appropriate fixed dose combination for any regimen if such a formulation is available. Oral liquid or syrup formulations should be avoided where possible, especially if dosage volumes are large. Where children use adult formulations, care must be taken to give the right dosage.

Table 4-2: Preferred first line ART regimens for infants and children in Namibia

Populations	Preferred 1st line regimen	Alternative 1st line regimen(s)	Special situations
Neonates <2 weeks old, premature or low birth weight	AZT/3TC/NVP - Seek HIV experienced provider or clinical mentor advice		
Neonates 2 to <4 weeks old	AZT/3TC/LPVr[b,c]		If infant anaemic, seek specialist advice
Infants 4 weeks to 2 years old	ABC/3TC/DTG(1)[b,c]	ABC/3TC/LPVr[d]	
Children 3 years and 10 to <20 kg	ABC/3TC/DTG(1)[b,c]	ABC/3TC/EFV (if no prior PMTCT)	ABC/3TC/LPVr, or ABC/3TC/ATV+r if prior PMTCT
Adolescents 20 to <30 kg	ABC/3TC/DTG(1)(50mg)[a,b]		ABC/3TC/ATV+ritonavir if SEs with DTG
For adolescents at least 30 kg, same as adults – *refer to chapter 2, section 2.5*			

[a] DTG as a single dose formulation
[b] When TAF is available for lower weight children this would be preferred over ABC (refer to Chapter 2 Section 2.4.2 for further explanation regarding TAF)
[c] When DTG available in appropriate formulation
[d] LPVr granules starting at 2 weeks or LPVr solution starting 42 weeks following the start of mother's LMP until 3 months old; when 10 kg and if can swallow tablets whole, can change to LPVr 100/25mg

- Abacavir is now approved for use in infants 4 weeks of age and older who weigh at least 3 kg
- Dolutegravir 50 mg tablets are now recommended for children who weigh at least 20 kg
- Tenofovir 300 mg tablets are now recommended for adolescents who weigh at least 30 kg
- Atazanavir 200mg capsules (plus RTV 100mg) can now be used in children who weigh at least 10 kg and can swallow capsules whole
- Infants with TB/HIV co-infection are eligible for RAL 100mg scored chewable tablets for the duration of their TB treatment (until the paediatric DTG is available) if they weigh at least 6 kg

4.6 Second line regimens

When considering switching to second line therapy in children, health care workers at the clinic should meet as a group to thoroughly review all aspects of the patient's case. In addition, it is recommended that a second opinion from an HIV expert may be sought although it is not mandatory.

The preferred second line regimens for children are listed in the Table 4-3 Table 4-3: The preferred second line regimens for children below.

Table 4-3: The preferred second line regimens for children

Failing first-line regimen	Preferred second-line Regimen	Alternative second-line regimens
ABC + 3TC + TLD(1)[a]	AZT + 3TC + (ATV+r[b] or LPV/r)	AZT + 3TC + EFV (if cannot use PI and if no prior PMTCT); If prior PMTCT, genotype
ABC + 3TC + LPVr (or ATV+r)	AZT + 3TC + TLD(2)[a]	If <20 kg and appropriate DTG formulation not available, AZT + 3TC + EFV
ABC + 3TC + EFV (or NVP)		If <20 kg and appropriate DTG formulation not available, AZT + 3TC + (ATV+r[b] or LPV/r)
AZT + 3TC + TLD(1)[a]	ABC + 3TC + (ATV+r[b] or LPV/r)	ABC + 3TC + EFV (if cannot use PI and if no prior PMTCT); If prior PMTCT, genotype
AZT + 3TC + LPVr (or ATV+r)	ABC + 3TC + TLD(2)[a]	If <20 kg and appropriate DTG formulation not available, ABC + 3TC + EFV
AZT + 3TC + EFV (or NVP)		If <20 kg and appropriate DTG formulation not available, ABC + 3TC + (ATV+r[b] or LPV/r)

[a] When appropriate formulations are available; DTG 50mg can be used from 20kg

[b] ATV (200mg) capsule with RTV boost can be used for children from 10kg if they can swallow the capsule whole.

[c] when TAF becomes available for children, where weight-appropriate replace ABC with TAF.

ABC/3TC/DTG$_2$ means patient is on ABC/3TC/DTG as second line

4.7 Transitioning infants and children to preferred ART regimens

HCWs should identify infants and children currently on AZT, NVP or LPV/r and should carefully plan a change to the currently preferred regimens according to the following guidance. When DTG formulations for children who weigh <20 kg are available, then transition to the preferred DTG regimens should also be planned. Table 4-4 and Table 4-5 summarizes the guidance on changing regimens

Table 4-4: Transitioning children safely to the new preferred first line regimen

	Last routine VL done within 6 months	
Current ARVs	**VL<40[a]**	**VL≥40**
ABC/3TC/PI	Change to ABC/3TC/DTG1	Continue ABC/3TC/PI while intensifying adherence counselling and follow-up, and evaluating for treatment failure and possible 2nd line if VL remains >1000 copies/ml
AZT/3TC/PI	Change to ABC/3TC/DTG1	Continue AZT/3TC/PI while intensifying adherence counselling and follow-up, and evaluating for treatment failure and possible 2nd line if VL remains >1000 copies/ml
ABC/3TC/EFV	Change to ABC/3TC/DTG1	Continue ABC/3TC/EFV (if on NVP change to EFV) while intensifying adherence counselling and follow-up, and evaluating for treatment failure and possible 2nd line if VL remains >1000 copies/ml
ABC/3TC/NVP	Change to ABC/3TC/DTG1	
AZT/3TC/EFV	Change to ABC/3TC/DTG1	Continue AZT/3TC/EFV (if on NVP change to EFV) while intensifying adherence counselling and follow-up, and evaluating for treatment failure and possible 2nd line if VL remains >1000 copies/ml
AZT/3TC/NVP	Change to ABC/3TC/DTG1	

If the most recent VL was taken more than 6 months previously; repeat the VL and determine potential transition to preferred regimens on receipt of that result. Viral load tests should not be done earlier than 6 months solely for the purpose of transitioning patients.

ABC/3TC/DTG$_1$ means patient is on ABC/3TC/DTG as first line

Table 4-5: Transitioning children safely to the new preferred second line regimen

Current ARVs	Last routine VL done within 6 months*	
	VL<40	VL>40
ABC/3TC/AZT/PI	***if ABC was part of first line, change to:*** AZT/3TC/DTG(2) ***if AZT was part of first line, change to:*** ABC/3TC/DTG(2)	Continue ABC/3TC/AZT/PI while intensifying adherence counselling and follow-up, and evaluating for treatment failure with possible 3rd line if VL remains >1000 copies/ml
ABC/3TC/AZT/EFV or NVP	***if ABC was part of first line, change to:*** AZT/3TC/DTG(2) ***if AZT was part of first line, change to:*** ABC/3TC/DTG(2)	Continue ABC/3TC/AZT/EFV or NVP (if cannot EFV contraindicated) while intensifying adherence counselling and follow-up, and evaluating for treatment failure with possible 3rd line if VL remains >1000 copies/ml

**If the most recent VL was taken more than 6 months previously; repeat the VL and determine potential transition to preferred regimens on receipt of that result. Viral load tests should not be done earlier than 6 months solely for the purpose of transitioning patients.*

4.8 Baseline clinical assessment

Careful baseline clinical assessment and follow-up is essential to managing HIV-infected infants and children and to monitoring the effectiveness of ART. Table 4-6 outlines essential items to be included in the baseline clinical assessment.

Table 4-6: Baseline clinical assessment for children following HIV confirmation

	Category	Action
☐	Growth parameters	Record weight, length/height, and head circumference (for <3 year olds). Plot on appropriate growth charts in the Paediatric Patient Care Booklet (PCB) and record the z-scores for weight-for-height (WFH), weight-for-age (WFA), height-for-age (HFA) and mid-upper arm circumference (MUAC). If child has acute malnutrition, take appropriate action (NACS, referral)
☐	Neurological and cognitive development	For <5 years old: assess developmental milestones achieved (see Developmental screening checklist, Table 4-7) For school-aged children: ask about grade at school and performance (e.g. results of last school report)
☐	WHO Clinical Staging	Determine WHO clinical stage by referring to WHO Clinical Staging of HIV in Infants and Children, Appendix 2
☐	Co-morbidities	Screen for active TB, other OIs
☐	TPT eligibility	Ask TPT screening questions and prescribe TPT if eligible, see Chapter 7, Management of Co-morbidities and Other Services
☐	Immunisation status	Review the vaccinations given as recorded in the health passport, and plan catch-up vaccinations if due (See Vaccination Schedule, Appendix 19)
☐	Nutritional status	Assess quality and quantity of intake in a typical day, ask what was eaten the previous day
☐	Concomitant medications	Ask about any other medications the child is taking, including traditional medications
☐	Preparedness for therapy	Assess child's and caregiver's preparedness for ART, the importance of starting on day of diagnosis, determine and help solve any immediate challenges to starting. Aim to start ART on same day or latest within one week.

☐	Disclosure status	Assess the disclosure status of the child. For children ≥6 years old, enrol in HIV disclosure activities and record at each visit on the appropriate form in the Paediatric Patient Care Booklet. Engage caregiver into discussions about disclosure until full HIV disclosure is achieved. (see section 4.8)

4.9 Growth monitoring and nutritional management

Growth monitoring

Monitoring growth, nutritional status, diet and nutrition-related symptoms, are critical in the early identification of malnutrition and poor growth. Growth failure may present as only a slight decline in normal growth rate, however if not adequately addressed this could lead to static (unchanging) growth or weight loss. Height (or length in infants), weight and head circumference (in children <3 years old) should be routinely measured, recorded and charted on the appropriate growth charts in the patient care booklet at every visit the child makes to the clinic. This is essential to ensure that doses of medication are escalated along with weight gain and to evaluate whether or not the child is growing and gaining weight normally.

In addition to lack of appropriate diet, HIV and other opportunistic infections can impact optimal growth for a child, leading to poor brain development, growth failure, and severe malnutrition. Other causes of growth failure such as superimposed infection (e.g. TB) and medicine intolerance need also to be considered.

4.10 Neurological and cognitive development

HIV can interfere with the normal neurological and cognitive development in a child. Therefore, it is very important that for children <5 years old, achievement of developmental milestones be monitored and recorded in the child's health passport and his/her patient care booklet. A child who is not achieving normal developmental milestones, or indeed who shows signs of regression after having achieved some, should be further assessed. Referral to a physiotherapist / occupational therapist (physical delay) or a social worker (cognitive delay) should be done as appropriate. Screening for normal neurological development need not take much time. A tool such as the one shown in Table 4-7 below offers a quick screen for assessing achievement of developmental milestones.

Table 4-7: Developmental Screening Checklist

Age	Developmental milestone
1 month	Raises head, makes crawling movements, alert to sound
2 months	Holds head at midline, lifts chest off table, smiles socially
4 months	Rolls front to back, laughs
6 months	Sits unsupported, babbles
9 months	Pulls to stand
12 months	Walks alone, uses single words
18 months	Can remove garment, scribbles, uses 6 words, runs
24 months	Can wash hands, jump up, combine words
36 months	Can put shirt on, speech is understandable, can balance on one foot
48 months	Can dress alone, draw a person, use complex speech, hop

4.11 Nutrient requirements of HIV-infected children

HIV infected children have greater energy needs compared to healthy non-HIV infected children. As with non-HIV infected growing children, they also have protein and micronutrient (e.g. iron and vitamins) requirement that must be met.

At every visit, check with the caregiver about the availability of food in the household and also ask about the meals provided to the child, for example, the previous day. Use the opportunity to suggest including nutrient rich options that are likely to be available in the household (see list below).

Strategies to meet nutrient requirements:

Dietary adjustments and meal plans to include energy-giving foods such as mahangu, maize, rice, potatoes, cassava and wheat. Adoption of food preparation methods that add more energy, for example sweetening porridge or adding nuts and oil during preparation of meals.

Increase frequency of meal intake in a day or consumption of snacks between meals.

- protein rich options such as beans, eggs, meat and fish
- micronutrient rich foods such as oranges, mangoes, pawpaw, guava, baobab, tomatoes, spinach, pumpkin, carrots, melons, and locally available fruits

4.12 Nutrition Assessment, Counselling and Support (NACS)

Nutrition assessment is an analysis of an individual's medical and diet history, laboratory values, and anthropometric measurements to identify nutritional risk or malnutrition and identify underlying causes so that appropriate nutrition intervention can be planned and initiated. See Appendix 9.

NACS is an approach designed to:

a. Provide food and nutrition services as part of care and treatment on an outpatient basis, with strong links to community service
b. Prescribe food to malnourished target individuals for a limited time, based on clear admission and discharge criteria to improve nutrition and health outcomes.

Health workers should encourage mothers and caregivers to routinely bring their children to the facility for assessment and be counselled/educated using appropriate guidelines. Any child who is identified as malnourished should receive the therapeutic food products as per the national guidelines.

Severe Malnutrition in HIV-infected children

Severe malnutrition is a life-threatening condition in HIV infected children and requires urgent therapeutic feeding (WHO 2009). For the management of moderate and severe malnutrition in HIV positive children and adolescent, refer to Appendixes 7 and 8.

All newly diagnosed HIV-positive children with severe malnutrition should be treated according to national guidelines. If the child is otherwise clinically well and has a good appetite, ART should be initiated while at the same time providing nutritional support.

If the child has severe acute malnutrition with any medical complications including poor appetite or is <6 months of age, he/she should be admitted to hospital. The Namibian "Inpatient Management of Severe Acute Malnutrition" Guidelines (2016) provide guidance on the management of such patients. ART initiation is essential and should be initiated as soon as possible after stabilization of metabolic complications and sepsis. This would be indicated by return of appetite and resolution of severe oedema.

4.13 Adherence and missed doses

The goal of ART is to achieve sustained and optimal viral suppression. Very high level of adherence is required to achieve this goal over time. This is promoted by proper ongoing support, counselling and simplified well tolerated regimens.

Adherence to medication is the single most important factor predicting success of antiretroviral therapy. It should therefore be addressed at each visit to the clinic and in all encounters with health care workers. Pill (and liquid) counts should be routinely done as well as discussions specifically targeting any possible barriers to adherence.

If a child misses a dose of antiretrovirals:

Daily dosing regimen
If patient normally takes medication in the morning and misses a dose, take immediately as soon as it is remembered. Continue in the morning on the next day. If patient normally takes medication in the evening and misses the dose but then remembers in the morning of the next day, take immediately the missed dose. If remembered in the afternoon, take the missed dose immediately and skip the evening dose.

Twice daily regimen:
If it is remembered in the morning, take the dose immediately and then continue with the evening dose as per normal schedule. If remembered in the evening, take dose immediately and then take the next morning one as per normal schedule.

4.14 Disclosure of HIV status

Disclosure of HIV status to children is challenging for parents/ caregivers and health care workers alike. Disclosure is a process rather than a single event. It starts with a relationship of trust that caregivers and/or HCWs build with the child in which the child is always told the truth, in a positive and supportive way. However, age-appropriate partial or full disclosure is essential if sustained adherence to medication is to be achieved, especially as children grow into young adolescence as shown in table 4-8.

A booklet called *"Why I take my medicines"* is available in clinics in several local languages and should be used to guide HIV disclosure to children.

Further guidance on age appropriate disclosure for infants and children is clearly stipulated in the National Guidelines on ALHIV 2019.

Table 4-8: Age Appropriate disclosure partial and full disclosure guidance

Age characteristics	Stage of Disclosure	Provider Action
0 - 4 years	No disclosure	At this stage no disclosure is done since the child is too young to understand about HIV
5 - 8 years	Partial disclosure	At this age the child can understand a lot. Define the virus as a germ and the CD4 as the soldier in the body that keep fighting and one has to take the drugs to strengthen the soldiers in the body

9 to 12 years	Full disclosure	Full disclosure is important since most children at this stage are able to understand more about HIV and would have heard about HIV as part of formal education at school. Follow the following stages in the disclosure process Stage 1 Assessing the child social support system to ensure availability of sufficient support once disclosure is completed Stage2 Assess the child's prior knowledge e about HIV/ AIDS including information given at school, any myths and misconceptions. Offer or reinforce accurate in formation Stage 3 Use an imaginary exercise or story to assess child's reaction to disclosure of HIV status Stage4 Tell the child about their HIV status. Support parents to disclose to the child and clarify the mode of infection. Address immediate reaction and concerns a child might have
	Post-disclosure (1-2 weeks after full disclosure)	Find out from the parent/guardian if they have observed anything after disclosure, e.g. change in behaviour: Introduce the child to tell their story and emerge as a hero (a comic book may be a useful aid) Link the child to a support group or with an older child who has been disclosed to NB: Find out how the child is doing at every visit after full disclosure

4.15 Immunizations in HIV positive infants and children

It is essential that all children receive the full schedule of immunisations to ensure their protection against vaccine-preventable diseases. Clinicians should determine the immunisation status on a regular basis and plan catch-up vaccinations if applicable.

All HIV-exposed infants should receive the birth vaccinations including BCG unless they are very sick and require, for example, intensive care, in which case they should receive the birth schedule as soon as possible.

If an infant or child has severe immunosuppression (as defined in Table 4-1) or signs of severe HIV infection, consider delaying live attenuated vaccinations (e.g. Measles Rubella, Rotavirus, and OPV) and discuss with a HIV experienced provider or clinical mentor paediatrician or physician. Follow the infant or child closely and ensure that the delayed vaccinations are eventually given when the infant / child is stable.

The Namibian Vaccination schedule, according to the National Expanded Programme on Immunisation (EPI) Guidelines is provided in Appendix 17.

4.16 Model Centres for Paediatric ART services

Unlike adults, a higher proportion of infants and children are experiencing viral failure due to a number of factors prompting the national ART program to consider setting up clinics dedicated to providing high quality services to infants and children LHIV. As children survive longer, treatment

strategies improve and better drugs become available, the complexity in clinical management of children living with HIV increases which necessitates ongoing training of clinicians caring for these population.

In order to improve the care for infants and children LHIV in Namibia, the MoHSS is committed to:

- Develop model clinical care centres that aim at providing high quality and comprehensive services to CLHIV
- The centres will address training gaps in paediatric ART through attachments of newly employed HCW and student doctors and nurses.

Existing sites will be selected and capacitated to become model clinics for Paediatric ART having met the following criteria:

- Availability of well trained and experienced staff committed to provide essential package of comprehensive services. Staff can be trained on the job.
- Availability of adequate space needed to create child friendly environment.,
- The potential of the site to be a referral centre for tertiary care in Paediatric HIV care, support and treatment
- Availability of laboratory facilities necessary for routine investigations and diagnosis of opportunistic infections
- The willingness to be repositories of information related to care and Paediatric HIV and to continually improve care through a process of quality monitoring and operational research.
- The commitment to scale up capacity in Paediatric HIV by actively engaging in training and mentoring activities.

5 BIO-CLINICAL MONITORING FOR PATIENTS ON ART

5.1 Introduction

Following HIV diagnosis and initiation of ART, clinical and laboratory monitoring are important in assessing individuals for the existence of co-infections, NCDs and other co-morbidities that may affect the response to treatment. Patients taking ART require close monitoring to assess their adherence to treatment, tolerance to their medication, medicines side effects, and the efficacy of treatment. This chapter provides guidance on what health workers have to do for the initial evaluation of patients following an HIV positive diagnosis and follow up clinical assessments and laboratory investigations, across all HIV infected populations including adults and adolescents, pregnant and breast-feeding women and children.

5.2 Baseline Clinical Assessment and Monitoring of PLHIV

5.2.1 Adults and Adolescents

Once ART has started, a reasonable schedule for clinical monitoring includes follow-up visits two and six weeks after initiation (which will also be useful to evaluate and reinforce adherence to antiretroviral therapy), and thereafter a minimum of once every three months until stable (including clinical and laboratory monitoring). Regular visits with trained nursing staff, which can be combined with medication dispensing, are encouraged to monitor and reinforce adherence and identify problems requiring referral. At each visit, inquiries should be made with respect to the following aspects:

Table 5-1: Actions during follow-up visits

Issue/Category	Actions
☐ Initial ART clinic visit assessment	Take and record patient's Temp, Blood pressure, Weight, Height, MUAC etc Full medical history and physical examination for diagnosis and management of OIs, psychosocial and nutritional challenges. WHO staging Take baseline laboratory tests (Refer to table 5.2) Initiate ART on same day of HIV diagnosis if ready Medicine counselling on benefits of taking ARVs, prophylaxis treatment, adherence requirements, possible adverse effects and when to return to the clinic and follow up visits
☐ Follow up ART visit assessment	Take and record patient's Temperature, Blood pressure, Weight, MUAC etc Check if there are any pending previous laboratory results or if the patient is due for blood tests Ascertain if adherence ≥95%? If not, find out why not and discuss what steps can be taken to improve adherence. Are there any new symptoms that may be related to medication side-effects? Are there any new symptoms that may be related to HIV disease progression or opportunistic infections? The development of significant opportunistic infections (OIs) while on ART may indicate clinical failure, but early in treatment may also be attributable to Immune Reconstitution Inflammatory Syndrome (IRIS) The patient's perception of how he/she is doing on therapy such as change in body weight and changes in frequency and severity of HIV-associated symptoms. Screen for alcohol and drugs use and the impact these might have on adherence Assess for eligibility for appropriate model of differentiated care (Refer to Chapter 9)

5.3 Laboratory Monitoring of PLHIV

Specific laboratory investigations are recommended as the basic level of care that is necessary to safely start ART. Laboratory tests are also needed to monitor response to treatment and to identify potential toxic reactions which might trigger changes in ARV regimens according to the national guidelines. These tests should be performed at the initial clinic visit and at follow-up visits as indicated in Table 5.2 below. Experience in some sites has shown that laboratory results are often not available at the time patients are seen for their follow-up visits, causing delays in taking appropriate management decisions for the patient. Sites should therefore implement 'Point of Care' testing where feasible and/or schedule patient visits in a way that allows for the patient to receive results in a timely manner. Efforts should be stepped up to improve laboratory specimen handling practices; access to results and improved turn-around times (TAT) by increasing access to testing services and availability of terminals or SMS printers at health facilities.

Table 5-2: Laboratory assessment for children, adolescents, adults pregnant and breast feeding women for ART initiation and monitoring

Phase of HIV management	Tests	Frequency
At initial clinic visit	CD4	Once
	HBsAg	Once; if positive, repeat after 6 months. If HBsAg is reactive, then the lab will automatically do ALT
	CrAg[1]	Once if CD4<200
	Hb	Once
	CrCl	Once if TDF will be included in the regimen
	HIV NAT[5] repeat	Once if <18 months old - Do not wait for result to initiate ART
Treatment monitoring	VL	6 M, 12 M (then every 12 months) [for children and pregnant women see below [2]]
	CrCl	6 W, 6 M, 12 M (then every 12 months) if on TDF
	Hb	2 W, 6 W, 3 M if on AZT. No need to repeat Hb after three months if there is no anaemia.
HBsAg positive	ALT	2 W, 6 W, 3 M (then every 12 months if the second HBsAg remains positive)
Suspected treatment failure	VL	repeat VL after 3 months of good adherence to treatment and once OIs are excluded
Virological failure	1) CD4[3]	after three months of suspected virologic failure
	2) HIV Drug Resistance	Children <10 years old who have been on a PI as part of 1st line with eMTCT NVP exposure in infancy Before Switching to a 3rd line regimen all ages
Secondary fluconazole prophylaxis following cryptococcal meningitis	CD4[4]	6-monthly while on fluconazole prophylaxis until 2 consecutive values >200 cells/mm^3

[1]CrAg: plasma Cryptococcal Antigen: lab will do this automatically for patients with CD4<200

[2] Children and adolescents under 19 years routine VL every 6 months; pregnant women 3 monthly until delivery and BF women 6 weeks after delivery then 3 monthly until end of breast-feeding period

[3]Check CD4 count to assess immunological status and inform clinical management (e.g. assess for possible OIs)

[4]Check CD4 count to determine when fluconazole prophylaxis can safely be stopped

[5]Confirmatory NAT done when the initial one is positive

Other laboratory tests may be indicated based on the suspicion of a medication toxicity (such as signs of liver toxicity or rash with NVP, signs of glucose intolerance if on PIs, etc) or clinical disease progression. Additional baseline and routine laboratory monitoring may be needed if the patient has existing co-morbidities such as diabetes. Appendix 3 provides a summary of the routine monitoring laboratory tests to be done based on the ARV regimens used.

Without delaying same day ART initiation; it is important for a healthcare worker to rule out underlying renal insufficiency before a client is initiated on TDF containing regimens. Once blood for serum creatinine has been collected together with other baseline tests, ART should be initiated on the same day unless there are other reasons to defer starting therapy. The health worker should ensure that creatinine results are available on the next follow up visit (after 2 weeks) and that creatinine clearance is calculated using the formula shown below.

Figure 5-1: Formula for the calculation of creatinine clearance in adults and adolescents ≥18 years old

The formula to calculate the creatinine clearance in men is as follows:

$$\frac{(140 - \text{age in years}) \times \text{weight in kg} \times 1.22}{\text{Serum creatinine in micromoles/L}}$$

Multiply the answer above by 0.85 for creatinine clearance in women

Note: If the creatinine clearance at baseline is <60ml/minute an alternative to TDF should be included in the ART regimen unless the patient is co-infected with HBV. In such cases TDF and TAF (if available) may be considered. Other alternatives may include ABC and AZT. See Table 2-4 for TDF and TAF dose adjustments in patients with altered creatinine clearance.

The Swartz equation shown in

Figure 5-2 is for calculating creatinine clearance for all children younger than 19 years of age.

Figure 5-2: Creatinine Clearance calculation for use in children <19 years old[1]

SCHWARTZ equation

$$\text{CrCl (ml/min/1.73m}^2) \approx [\text{length (cm)} \times k \times 88.4]/\text{serum creatinine (mmol/l)}$$

k = 0.45 for infants 1 – 52 weeks
k = 0.55 for children 1 – 13 years old
k = 0.55 for adolescent females 13 – 18 years old
k = 0.7 for adolescent males 13 – 18 years old

[1] Schwartz, GL et. al. A simple estimate of glomerular filtration rate in children derived from body length and plasma creatinine. Pediatrics 1976, 58:259-263

Table 5-3: Normal GFR in children and young adults[1]

Age (gender)	Mean GFR ± SD (ml/min/1.73m^3
> 8 weeks and <2 years (males and females)	95.7 ± 21.7
2 - 12 years (males and females)	133 ± 27.0
13 - 21 years (males)	140 ± 30.0
13 - 21 years (females)	126 ± 22.0

5.3.1 CD4 Lymphocyte counts

CD4 levels are important markers of immune function. CD4 testing is recommended at baseline to determine the **degree of immune suppression**. If a patient has virologic failure or shows signs of clinical deterioration, a CD4 count should be done.

5.3.2 Plasma HIV-RNA levels (viral load)

Routine viral load (VL) monitoring is recommended to facilitate earlier detection of treatment failure. VL levels should reach undetectable levels by 6 months of therapy in fully adherent patients. All patients initiating therapy will routinely have a viral load assay done at 6 and 12 months after beginning therapy and every 12 months thereafter. The following populations have a different VL schedule as follows:

- Children/adolescents <19 years: VL every 6 months
- Pregnant women: every 3 months until delivery
- Breast-feeding women: 6 weeks after delivery, then 3 monthly until end of breast feeding period; then reverting to an annual VL test

The aim of performing a VL test is to identify patients who are having sub-optimal responses to ARV therapy earlier and whose immunologic and clinical responses may not have deteriorated at this stage. These patients persistently have VLs > 40 copies per ml. Such patients must undergo intensive adherence counselling and support to avoid further failure, to achieve viral suppression and to prevent the emergence of ARV resistant virus and the necessity to switch to second line treatment. In addition, routine viral load measurements will allow analysis of the ART program at the population level.

VL assays are also recommended for patients already on treatment who are showing evidence of immunologic and or clinical failure. The test should be repeated in this category of patients 6 months after changing therapy, to evaluate response to the new regimen and to evaluate the level of adherence in this group of patients.

5.3.3 Viral Load Results Interpretation

In the Namibian context, the following operational definitions are used to interprete viral load results;

- Treatment failure is VL results > 1000 copies/ml
- Low level viremia is VL results between 40-1000 copies/ml
- Virological suppression is VL results < 40 copies/ml or target not detected (TND)

5.3.4 Ensuring Specimen Integrity For Plasma Viral Load Testing

Blood specimens must reach the laboratories **within 6 hours to ensure the validity of VL results,** specimens reaching the laboratory for processing after 6 hours will be rejected. Facilities with

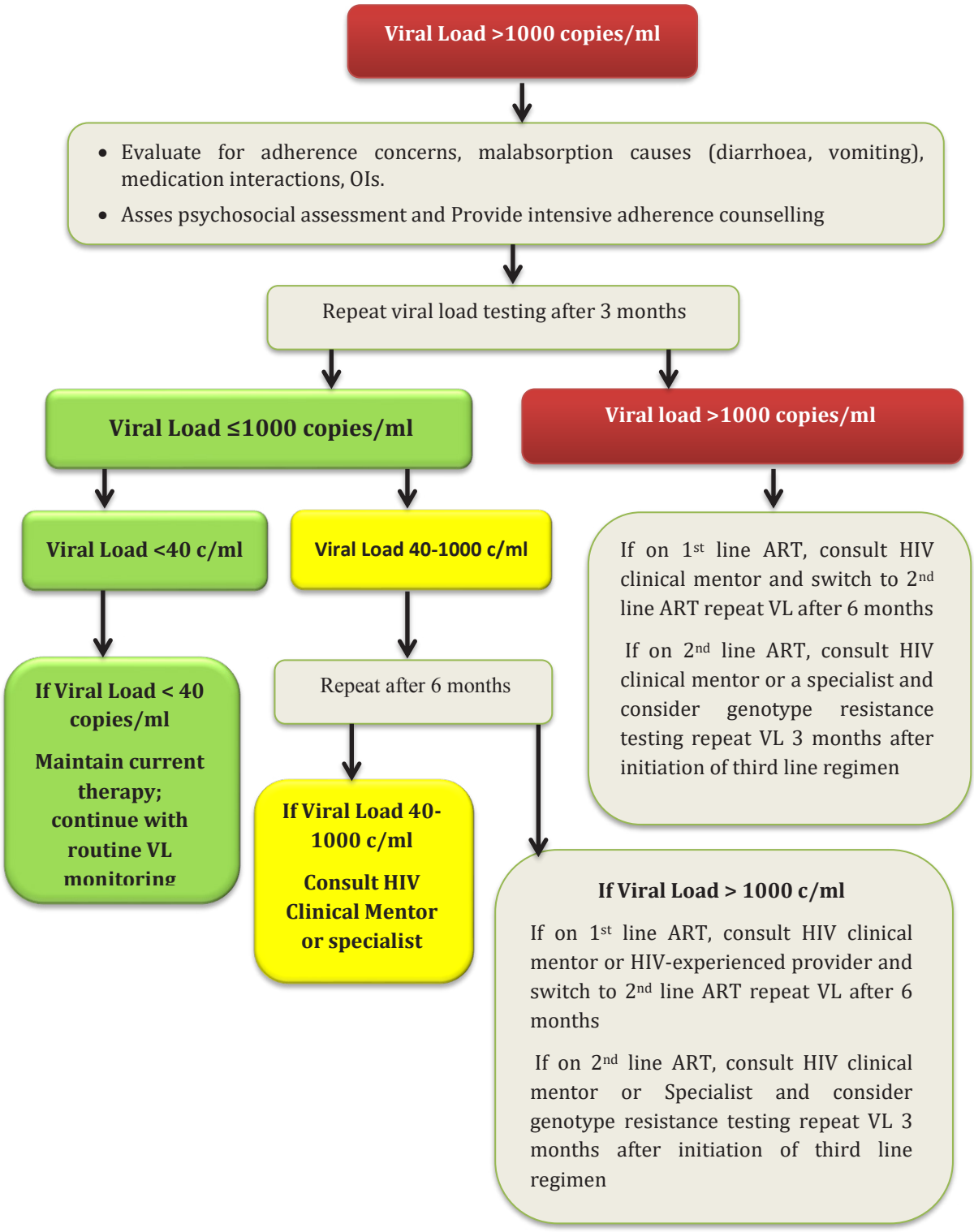
[1] Ref: National Kidney Foundation / KDOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification (2002), National Kidney Foundation, Inc

centrifuges will need to spin samples as soon possible while awaiting collection. HCWs should use the SOPs for processing of samples at facility level.

5.3.5 Point of Care Viral Load Testing

Timely access to VL results is crucial for patient management, hence utilization of point of care VL testing platforms when available should be considered as a way to improve access and potentially cut costs.

Figure 5-3: Algorithm for evaluating suspected treatment failure



***Assess for drug to drug interactions, food drug interactions, check for hepatitis C coinfection**

Before any change is made due to failure, the circumstances contributing to the failure (e.g. poor adherence, medication interactions, and malabsorption) should be thoroughly investigated and corrected before a new regimen can be started. Each case should be discussed with an HIV experienced provider or Clinical Mentor.

After a switch from first line to second line or from second line to third line, a VL should be done after 6 months to assess response to treatment, followed by routine yearly viral load testing.

5.3.6 Resistance testing

Although management of patients would be easier if resistance testing was done prior to selection of a second line regimen, this is costly and **should not** be done routinely. Resistance testing provides identification of HIV mutations that may have been selected and which might be causing virological failure in a patient who is adhering well to ART. A Specialist or Clinical Mentor can give approval for HIV resistance testing on an individual patient basis.

5.3.7 Eligibility For HIV Resistance Testing

- A patient who has failed a second line regimen and needs a third line regimen.
- Children who have either been exposed to NVP for eMTCT and have failed a protease inhibitor as a first line regimen.
- Patients switched to multiple first line regimens in the presence of high viral load.

5.3.8 Ordering of HIV Resistance Tests

Ordering an HIV genotype resistance test should be done using the specific form for that purpose (See Appendix 18. On this form, patient's medication history, the indications for doing the test and the name of the authorized HIV specialists/mentor who attended to the patient should be specified. Without a fully completed form, the laboratory will not accept the sample for testing.

5.3.9 Interpreting HIV Resistance Results

Interpreting results of resistance testing is complex and should be analysed in conjunction with the ART history of the patient, noting that it may only provide full information about resistance to the current regime the patient is on. Mutations selected by a previous regimen that the patient was taking may be "archived" (still present but not in high enough quantity to be detected by the resistance test) and if that ARV is given again, the mutation will become more prominent and the ARV will not be effective. Interpretation of results should be done in consultation with a specialist.

The MoHSS has established HIV DR Central Clinical Committee (HIV DR CCC). The HIV Drug Resistance Central Clinical Committee (HIV DR CCC) meets regularly to review cases and recommends the clinical management of such patients. Health care workers should consult the committee through their clinical mentors:

- When they have received the genotype HIV resistance results done in consultation with the HIV specialist/mentor
- To propose or design the available third line regimen
- To discuss the proposed third line regimen to the HIV DR CC
- To switch and close monitoring of patients on third lines regimen as per the Guidelines

5.4 Laboratory Monitoring in Patients Restarting ART after "Default" and "Lost to follow up"

Patients who return after being lost to follow up and did not take ARVs for at least **6 months; they should have a CD4 test done, assessed, managed for any co-infections and provided appropriate prophylaxis.**

After ART re-initiation, do a VL after 6 months and then at 12 months following the routine monitoring schedule if suppressed. If the VL is not suppressed after 6 months, the SOP for high VL monitoring should then be followed.

6 CARE AND SUPPORT FOR ADOLESECENTS LIVING WITH HIV

6.1 Introduction

WHO defines adolescents as children between the ages of 10-19 years. They may be further classified as younger adolescents (10-14 years) and older adolescents (15-19 years). Namibia has adopted this definition for adolescents. Furthermore, the Child Care and Protection Act No. 3 of 2015, Section 10 (1) made provisions for the age of majority at 18 years. Additionally, the Act has made provisions for individuals at the age of 14 years or older to consent to receive medical or surgical interventions without the permission of a caregiver/parent. Any adolescent from the age of 14 years and above can consent to having an HIV test and HIV treatment (the Child Care and Protection Act No. 3 of 2015, Section 221(2).

6.2 Overview of Adolescence issues

Adolescents continue to be vulnerable to HIV infections amidst all efforts to control the epidemic in this sub-population. Adolescent girls living in generalized HIV epidemics have an even higher risk for acquisition or transmission of HIV through sexual transmission. Access to and uptake of HIV testing services (HTS) by adolescents is significantly lower than for adults. Between 2005 and 2012, HIV-related deaths among adolescents increased by 50%, while the global number of HIV-related deaths fell by 30% (UNAIDS).

This increase in adolescent HIV-related deaths was attributed to;

- Poor prioritization of adolescents in national HIV plans
- Inadequate provision of accessible and acceptable HTS services
- Lack of adolescent friendly treatment services and support for adolescents to remain in care
- Poor adherence to ART
- Poor linkage and retention in care
- ART coverage rates for adolescents are generally lower than for other age groups
- Lower viral load suppression rates

Failure to address these challenges may lead to treatment failure, emerging drug resistance, and high likelihood of increasing morbidity and mortality rates associated with HIV.

Data from NAMPHIA shows that HIV incidence is 0.36% (0.59%in females and 0.13% in males) in the 15-49 years sub-population, translating to fewer new HIV infections. In 2017, 4500 new HIV infections were recorded, of which 500 were in children. The viral load suppression among young people aged 15-24 years living with HIV is lower at 65.4 percent for females and 60.7 percent for males against the adult viral load suppression of 92.5 per cent for females and 86.3% for males (NAMPHIA, 2018). The National Guidelines on Adolescents Living with HIV (ALHIV) of 2012 was reviewed in 2019 and provides strategic guidance for the provision of multi-sectoral services for ALHIV. To meet the objective of delivering comprehensive adolescent-focused clinical and Community based HIV services to ALHIV, this section summarizes key interventions to be promoted and implemented.

6.3 Promoting the uptake of HIV Testing Services

The following approaches are recommended to educate, inform and mobilize adolescents for HTS:

- Purposefully organized and targeted HTS campaigns. This could be facility or community-based outreach activities including schools and colleges.
- Provider-initiated HTS coupled with other entry services such as family planning services, Voluntary Medical Male Circumcision (VMMC), STI's and immunization campaigns
- Ensuring that all health facilities are oriented towards the Adolescent- Friendly Health Services (AFHS) approach as per AFHS guidelines which include flexibilities in clinic opening times.

6.4 Treatment, clinical care and integrated services

6.4.1 Treatment

ART coverage in Namibia among adolescents is lower compared to the national target. ART should be provided to all ALHIV regardless of their WHO clinical stage or CD4 cell count. However, due to complexities and multiple factors that affect adolescents; treatment readiness of the adolescents and their caregivers will determine ART initiation. Normally, the adolescent ART regimens are similar to those recommended for adults (Refer to the adult ART Regimen in Chapter 2 of this guideline). It is essential to also note that some adolescents living with HIV may be stunted or underweight and hence medicine dosage may require adjustments accordingly (See adult and paediatric, adolescent ART sections).

6.4.2 Clinical Care

Adolescents face many challenges related to their rapid period of growth resulting in changes in their biological, physiological, neuro-developmental, social and behavioural characteristics. However, this population seems to be under-served in many settings and across the HIV cascade. They have significantly worse access to ART services, high risk of loss to follow up, sub-optimal adherence, increased needs for psychosocial support and sexual reproductive health services. They therefore require comprehensive health care and social services to meet their unique challenges. Older adolescents (15-19 years) adhere less to the medications compared to the younger adolescents (10-14 years) who generally are still receiving support from their care- givers.

Due to the multi-faceted care that this population requires; these guidelines therefore recommend that adolescents who are unstable (e.g. those with high VL, social challenges) may be seen more frequently for clinical consultations, care and support. Adolescent who meet eligibility criteria for DSD services may be recommended for appropriate DSD models such as Multi-Month Dispensing. Refer to DSD Chapter 9 for more clarifications.

6.4.3 Integrated Services and Collaboration with Other Stakeholders

Some adolescents may require referral to other services depending on their needs. It is not uncommon for ALHIV to live in difficult environments sometimes away from their biological parents as in child-headed families or in extended families. Health workers should refer to the Ministry of Gender Equality and Child Welfare (MGECW) services any child <18 years old with insufficient care and support that results in poor adherence, defaulting visits and ART, VL failure (after attempts at the clinic have failed). A child suspected of being in need of protective services (professionals) as contemplated in Section 132 (2) of the Child Care Protection Act, Act No. 3 of 2015 may be directly referred to MGECW using attached specified Form 13 A (Refer to Appendix 14).

6.5 Adherence to ART

Adherence to antiretroviral therapy appears to be poorer during adolescence for many ALHIV. ALHIV face multiple barriers to adherence to ART;

- Bereavement of their parents impacting their support systems.
- Treatment fatigue especially among older adolescents who have been taking ARVs since early childhood and they may not find any reason to continue taking their tablets.
- Pill burden to some ARVs where the dosing is more than one tablet
- Medication side effects e.g. abdominal upset due to LPV/r may lead to some of these adolescents to start skipping doses of particular ARVs.
- Issues surrounding non-disclosure specifically when they enter into new relationships with the opposite sex may lead them to either stop or not taking their medications accordingly fearing to be stigmatized by their partner.

Counselling on adherence should explore on specific reasons that may contribute to poor adherence. Particular attention should be paid in assessing adherence at every visit and to provide adherence support.

6.6 Disclosure of HIV status for adolescents living with HIV

It is important to systematically disclose HIV status to adolescents living with HIV (ALHIV) from an early age so that they fully understand and engage in their care and it also minimizes accidental disclosure. For younger adolescents, disclosure should be a gradual and ongoing process, while for older adolescents full disclosure may be applied with or **without the assistance from their caregivers and is dependent on the readiness of the adolescent.**.

Table 6-1: Roles and responsibilities of parents and health care workers

	Roles and responsibilities
Parents and guardians	• Seek support from the clinical team to inform the adolescents of their HIV infection • Adherence support
Health care workers including Social Workers	• Health workers should not assume that adolescents are aware of their HIV status • Counsel parents, guardians and adolescents on the need for disclosure • Conduct age appropriate disclosure (refer to Table 4-8) • Should purposefully support facility-based and home-based disclosure • Facilitate access to a wide range of care and support services, including sexual and reproductive health and rights

Health care workers including Social workers should be cognisant of adolescents' cognitive and emotional development during the disclosure process. (MoHSS 2019). Refer to Namibia Guidelines for ALHIV (2019) for further guidance on age-appropriate disclosure actions. The "ARVs and Healthy Me" booklet is available in clinics and in several languages. This is a tool that may support adolescents' understanding and acceptance once HIV status has been disclosed.

Adolescents living with HIV should be empowered to disclose their HIV status to family members, friends or significant others safely on a voluntary basis.

6.7 Mental health and psychosocial support

Adolescents are in transition from childhood to adulthood and it is a difficult period even for those without HIV. They experience physical as well cognitive changes and maturation. Changes in their bodies may affect their emotions and behaviours. HIV is an added burden and adolescents who have previously adhered to therapy from childhood often start to default taking their medicines in their adolescence. Health Care workers should anticipate this and discuss it with adolescents and caregivers as part of the treatment plan. In addition, comprehensive sexuality education should be provided as indicated.

Activities that can help to identify and address mental health and psychosocial issues include

- Train health providers to screen adolescents for potential symptoms of mental health problems;
- Effective communication skills and building trust between health providers, care givers and adolescents are the first steps towards creating a supportive environment;
- Mental health promoting activities should be incorporated in individual and group activities for adolescent support groups.

6.8 Teen Club- A Service Delivery Model of Care for Adolescents Living with HIV in Namibia

Teen clubs are a peer-based psychosocial support group intervention for ALHIV, with the ultimate goal of improving their health, well-being and HIV outcomes as well as supporting healthy transition into adulthood.

Teen Clubs provide safe and welcoming space where ALHIV are empowered to gain knowledge, develop life skills and learn to take responsibility for their health including improving their adherence to ART. They also improve their self-esteem, learn how to cope with the challenges of living with HIV and build strong supportive peer relationships through the teen clubs.

Teen Club meetings takes place, usually on a monthly or quarterly basis taking into account school schedules, distances to facilities to prevent members from missing school and avoid frequent visits to facilities which may result in increased transport costs. To facilitate attendance and reduce transport costs, in most facilities Teen Club meetings are scheduled to coincide with the adolescent's review dates or ART refill clinic visits.

Further guidance on Teen club implementation is found in the National Guidelines on ALHIV 2019/2023 as well as in the Teen Club Starter Pack.

6.9 PrEP for adolescents at high risk of HIV acquisition

Adolescents at substantial risk of HIV acquisition should be considered for PrEP (See Chapter 8 on PrEP).

6.10 Voluntary Medical Male Circumcision (VMMC)

VMMC should be part of health promotion activities aimed at encouraging the uptake of VMMC services.

6.11 Cervical cancer prevention and screening

It is known that cervical cancer is caused by infection with human papilloma virus (HPV). Considering the high risk of cervical cancer among women living with HIV it is recommended that HPV vaccine when available may be provided to all girls aged 9-19 years living with HIV. It is important to administer the vaccine *before* sexual debut, as it provides the greatest amount of protection against acquiring HPV once sexually active. All girls aged 9 to 19 years should receive HPV vaccine regardless of their HIV status. The HPV vaccination schedule has 3 doses with second dose administered 1-2 months after the first dose and third dose given 6 months after the first dose.

It is important that teenagers do not undergo cervical cancer screening with PAP or VIA, as it will likely result in high false positive results.

6.12 Sexual and Reproductive Health

Adolescents in HIV and ART care should be provided with age and developmentally appropriate sexual and reproductive health information and services. Health workers should assess adolescent's maturity and knowledge and provide services including screening, prevention and treatment of STIs accordingly (Refer to STI Guidelines). Specific information and services to be given to adolescents to include:

- Discuss with adolescents the advantages of delayed sexual debut;
- The right to delay marriage and to refuse unwanted sexual advances.
- Adolescents should be provided with accurate sexual and reproductive health information, services for STI prevention, diagnosis and treatment and information on where to seek help in cases of sexual assault
- For sexually active adolescents; dual protection with a condom should also be discussed and safe sex with consistent condom use encouraged. PrEP should also be offered to HIV negative partners of ALHIV.
- It is important to provide individual family planning counselling and methods to prevent unintended pregnancy; where possible family planning commodities including emergency contraception should be made available in the clinic where the adolescent is receiving ART.
- If applicable, partner testing and disclosure should be encouraged

Sexually active adolescents should be educated on the benefits of good adherence to treatment and subsequent reduction of HIV transmission risk.

6.13 Transitioning to adulthood

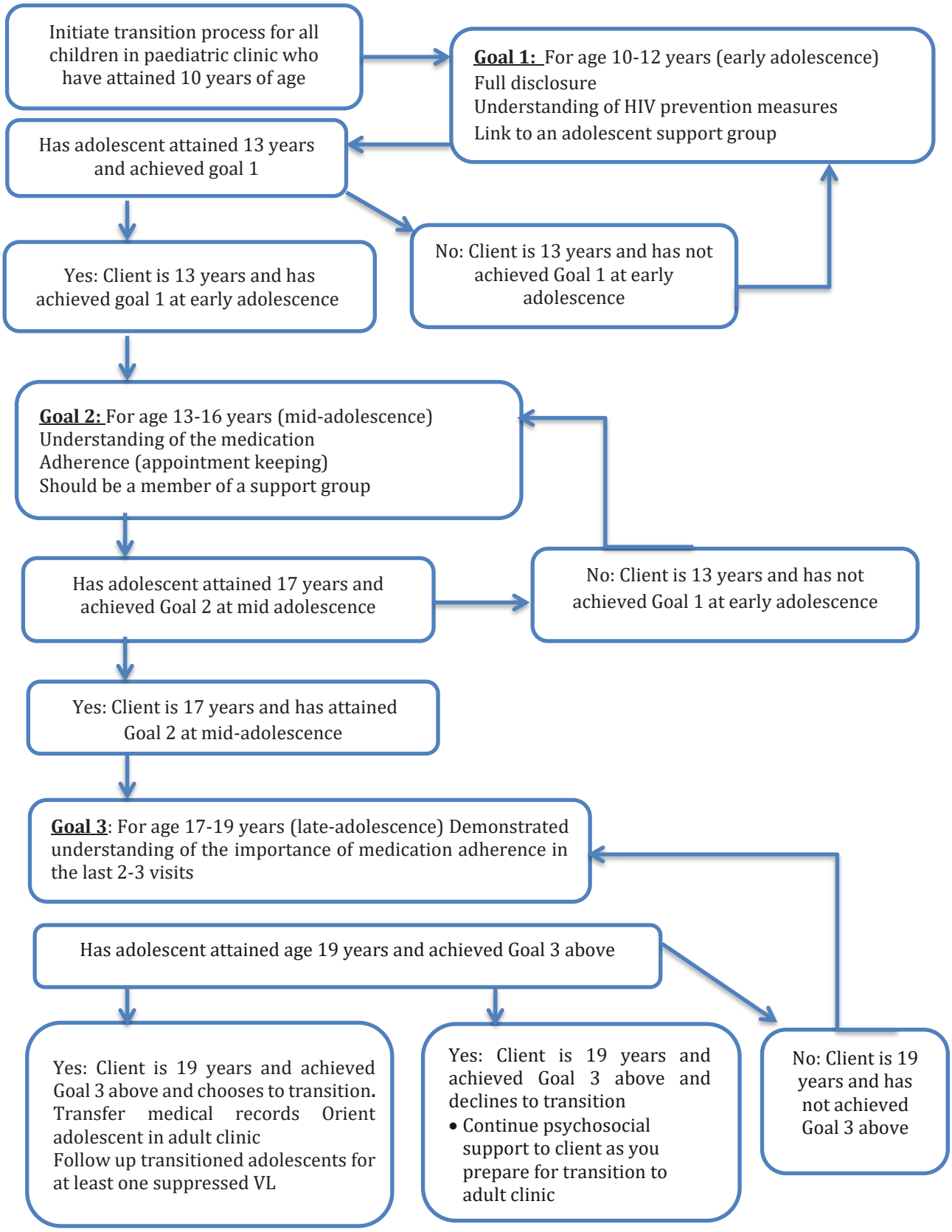
This process involves preparing the adolescent to take control of their own treatment and be less dependent on their caregiver. Transition to adult care has been defined as *'the planned purposeful process that addresses the medical, psychosocial and educational/vocational needs of adolescents and young adults with chronic physical and medical conditions as they move from child-centred to adult-oriented health care systems.'* (UNICEF, 2016)

Planning and problem-solving skills, treatment literacy, self-confidence and a therapeutic relationship with members of the health care team are important for adolescents on ART to achieve good adherence to therapy as they transition into adulthood. **Service providers should encourage mature adolescents (in consultation with caregivers) to attend clinic visits alone where**

appropriate. As a last step to transitioning to adult care, adolescents should be familiarized with the adult care setting and procedures.

The following algorithm provides specific goals that should be achieved by adolescents throughout the transition process. Younger adolescents (10-12 years) should achieve all Phase 1 goals before transitioning to Phase 2 goals (13-16 years). All goals indicated under phase 3 should be fulfilled prior to transitioning to adult care. For details, refer to figure 6.

Figure 6-1: Adolescent Transition Implementation Algorithm



7 MANAGEMENT OF CO-MORBIDITIES AND OTHER SERVICES

7.1 Introduction

This chapter will focus on the prevention, screening, diagnosis and management of various co-infections including opportunistic infections in PLHIV. The guidelines will include some common non- communicable diseases, mental illnesses and nutritional requirements for PLHIV. Comprehensive services for PLHIV include screening and management for Non-communicable diseases (NCDs), Opportunistic infections (OIs), cervical cancer and STIs, provision of family planning services, preventive services such as VMMC, condom provision and psychosocial support services.

7.2 Management of Opportunistic Infections

Opportunistic infections (OIs) are medical conditions that occur more frequently and are more severe in people with weakened immune systems, including PLHIV. OIs are less common now due to universal access to ART in Namibia. However, many people with HIV still develop OIs due to delayed ART initiation and treatment failure. Prophylaxis and early treatment of OIs has been clearly shown to prolong and improve the quality of life for PLHIV.

7.3 Prophylaxis for Opportunistic infections

7.3.1 Cotrimoxazole Preventive Therapy (CPT)

Cotrimoxazole {sulfamethoxazole (SMZ) plus trimethoprim (TMP)} has been shown to have protective effects against pneumocystis pneumonia, toxoplasmic encephalitis, malaria episodes, bacterial infections including bacterial pneumonia, diarrhoea and bacteraemia, and it may reduce diarrhoea from Isospora sp. Cotrimoxazole also reduces morbidity and mortality in TB patients who are co-infected with HIV.

7.3.2 Eligibility for CPT

Figure 7-1: Eligibility criteria for initiating and discontinuation of CPT

Population	CPT Initiation Criteria	CPT Discontinuation Criteria
Adults and adolescents (including pregnant women living with HIV)	Initiate in all with severe or advanced HIV clinical disease (WHO stage 3 or 4) and/or with a CD4 count ≤350 cells/mm3.	Lifelong
Infants and childrenwith HIV	Initiate in all irrespective of clinical stage or CD4 cell count.	Lifelong
HIV-exposed infants	Initiate in all starting at 6 weeks of age	Stop once HIV has been ruled out
TB/HIV co-infected	Initiate all HIV-infected patients with active TB disease regardless of CD4 cell count	Lifelong

Figure 7-2: Dosing of CPT in Children

Weight (kg)	Once daily cotrimoxazole dosage (SMZ/TMP)			
	Tablets (dispersible) 100mg/20mg	Suspension (200/40mg)/5ml	Tablets 400/80 mg	Tablets 800/160mg
3-5.9 kg	1	2.5 ml	-	-
6-13.9 kg	2	5 ml	½ tablet	-
14-24.9 kg	4	10 ml	1 tablet	½ tablet
≥25 kg	-	-	2 tablets	1 tablet

Figure 7-3: Cotrimoxazole adjustment in case of renal insufficiency

If a patient has renal insufficiency; cotrimoxazole doses should be adjusted as follows:

- CrCl 15-30ml/min: decrease CTX dose by 50%
- CrCl <15ml/min: do not use or discontinue CTX

In the event of severe renal, liver or BM suppression, discontinue CPT until the clinical situation has improved.

7.3.3 Use of Dapsone for PCP Prophylaxis

Patients with known allergy or those who develop allergy to Cotrimoxazole and whose CD4 count is <200 cells/mm^3 should be given Dapsone 100mg once daily as an alternative. When dapsone (as a substitute for CPT) is being used as PCP prophylaxis, it is only recommended for patients in WHO Stage 4 and/or absolute CD4 count <200 cells/µL (or CD4 % < 14%), and should be discontinued once a patient achieves a CD4 count of > 200 cells/µL for at least 6 months. Dapsone will contribute to anaemia in most patients, and causes haemolytic anaemia in some patients, so patients should have a baseline Hb before starting dapsone and Hb monitored every 1-2 weeks for the first couple of months.

If a patient started Cotrimoxazole at a CD4 level of > 200 cells/mm^3 and developed severe reaction such that desensitization cannot be attempted, then stop cotrimoxizole and do not give Dapsone.

NOTE: Dapsone is useful in the prevention of Pneumocystis Jirovecii Pneumonia (PCP). PCP is commoner at a CD4 levels less than 200 cells/mm^3. Moreover, Dapsone has major bone marrow suppressive effects. Hence, the benefit of providing Dapsone to patients with CD4 count more than 200 cells/mm3 will not outweigh the risk of toxicity.

7.4 TB/HIV Collaborative Activities

The close association between TB and HIV is well-established. TB is the most common OI in individuals who are HIV-positive in Namibia. In 2018, a total of 8,100 TB cases were notified of which 99% had documented HIV status of which 35% were HIV positive. The goal of TB/HIV collaborative activities is to reduce the burden of TB and HIV in populations affected by both diseases by expanding the scope of TB and HIV programmes.

7.4.1 TB Infection Control (TB IC)

Each health care facility should have a TB infection control plan that includes administrative control measures, environmental controls and personal protective equipment. A triage system should be put in place to identify presumptive TB cases and minimize diagnostic delays. Health care workers should be offered HIV testing and counselling services and those who test HIV positive should be provided with ART and TB Preventive Therapy (TPT) if they are eligible.

7.4.2 TB screening and TB Preventive Therapy (TPT)

Individuals with both HIV infection and latent TB have a 5-10% risk of developing active TB each year, compared to HIV-negative individuals, whose lifetime risk is 10%. The combination of HIV and TB is one of the major causes of death in Namibia. TPT in combination with ART is very effective in preventing active TB disease in individuals who have latent TB infection by 60 to 90%. .

All PLHIV should be screened for TB including asking about TB exposure/contact history at each encounter with a health worker or visit to a health facility.

Infants (<1 year of age) should be given preventive treatment only if they have a history of household contact with a TB case and active TB has been excluded in investigations.
All PLHIV including children above 1 year of age should be given TPT once TB disease is excluded.

For all children <5 years old (whether HIV positive or negative) and all HIV-positive infants and children(regardless of age) who have had contact with someone with infectious TB, and infants born to mothers with untreated pulmonary TB disease, supervised isoniazid preventive therapy (TB-TPT) should be given once active TB disease has been excluded.

TPT ideally should be started on the same day that ART is initiated.

PLHIV who has already completed a course of TPT and is subsequently exposed to a patient with bacteriologically confirmed pulmonary TB, consider giving another course of TPT after every episode of exposure. TB patients who have completed a course of anti-TB treatment and who have not previously started TPT should be initiated on TPT immediately after completing TB treatment.

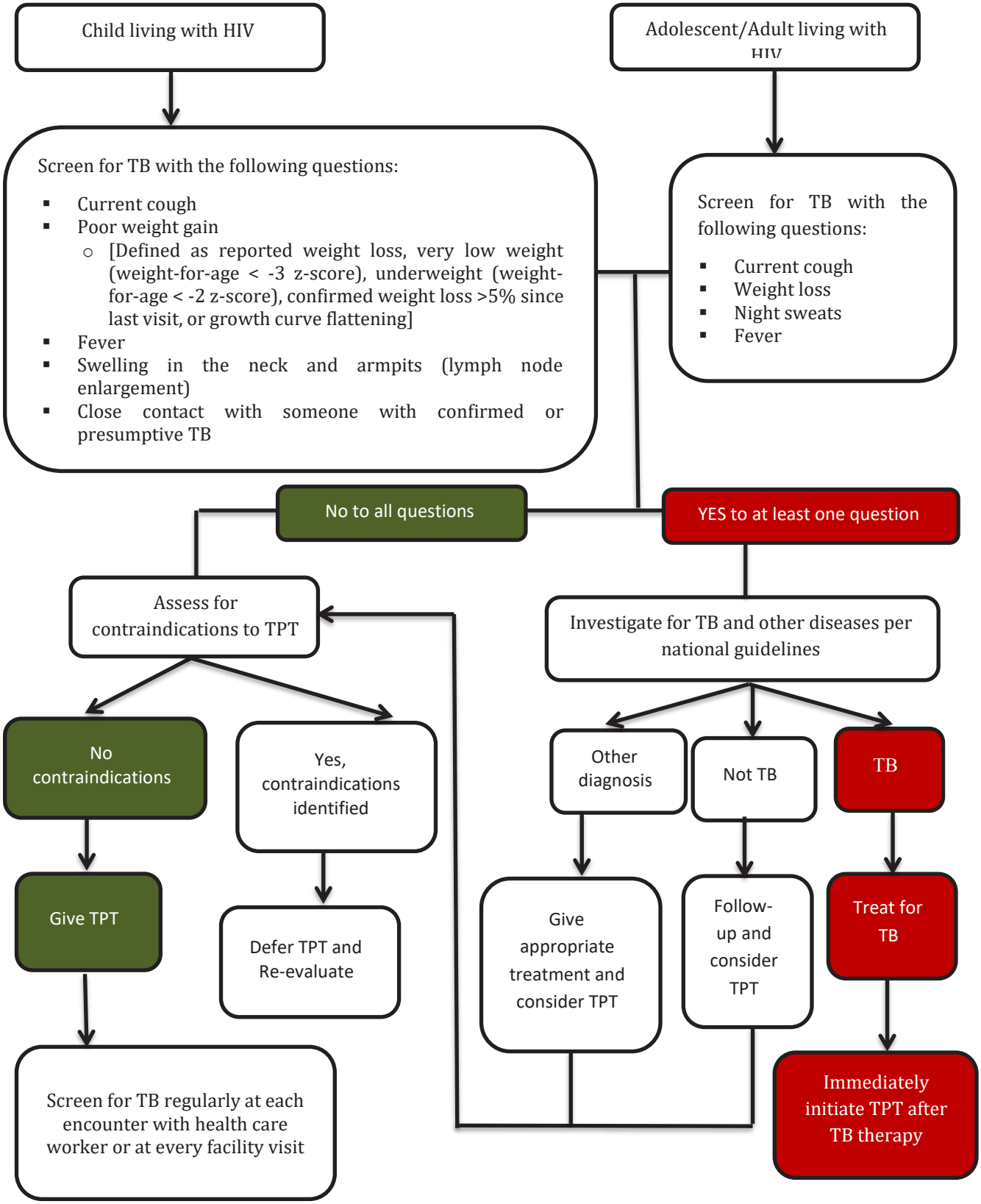
See **Figure 7-4**, below for algorithm for TB screening and TPT among children, adults and adolescents living with HIV.

7.4.3 TB Screening among PLHIV

Screening for TB amongst adults and children should be done according to the algorithm below.

It will be particularly important in children to enquire carefully about exposure to someone in, or often visiting, the household with a chronic cough, or active TB.

Figure 7-4: Algorithm for TB screening and TPT among children, adults and adolescents living with HIV



Answers to the TB screening questions and follow-on evaluations/decisions should be recorded in the appropriate page of the paediatric patient care booklet.

Figure 7-5: Considerations for TPT

- **All PLHIV must be routinely screened for active TB. TPT should be initiated in all PLHIV where active TB disease has been excluded.**
- **For newly diagnosed PLHIV it is encouraged to start same day ART and TPT initiation if eligible.**
- **PLHIV who are close contacts of patients with infectious TB should receive TPT even if they have completed a previous course of TPT.**

Patients should be motivated for TPT after being educated about the benefits, possible side-effects and risks.

7.4.4 Contraindications for TPT

Signs and symptoms of TB (*NB: TB-TPT should not be given to patients who are unwell and where there is no explanation of the illness*)

- History of active liver disease, liver insufficiency, or jaundice
- History of hypersensitivity to isoniazid or any other agent used for TPT
- History of exfoliative dermatitis

7.4.5 Precautions

- Persons starting TPT must be made aware of the possible side-effects of Isoniazid and Rifamycins (rifapentine and rifampicin). Isoniazid-induced hepatitis will present with nausea and vomiting accompanied by passing dark urine and/or generalised itching. Peripheral neuropathy manifests as burning sensation, numbness or tingling in feet and/or hands. If these symptoms develop, the patient must stop taking TPT and report immediately to the nearest health facility for assessment and management. Refer to the National Guidelines for the Management of Tuberculosis.
- Rifapentine may cause orange/red discolouration of body fluids. The colour will fade over time; just reassure the client.
- Health workers should always check clients for signs and symptoms of hepatitis, neuropathy and skin itching when they come to collect TPT.

7.4.6 TPT regimens

The recommended TPT regimens are;

- Isoniazid given once daily for a period of 6 months (6H). **IPT is now given for 6 months** instead of 9 months as in the previous guidelines. All patients who previously were prescribed 9 months IPT and has taken 6 months IPT should be stopped and considered as TPT completed.
- Health care workers should ensure that the outcome is updated in the ePMS as "TPT Completed".
- Isoniazid and Rifapentine given in combination weekly for a total of 12 doses (3HP)
- In special circumstances and in consultation with TB or HIV specialist Isoniazid and Rifampicin can be given daily for a three months period.

After establishing TPT eligibility, the following regimens can be administered (Table 7-1), depending on availability, patients current ART regimen and age.

Table 7-2 can be used to calculate the dosage of various TPT medications in children and adolescents.

Table 7-1: TPT regimens

ART regimen	Preferred Regimen	Alternative
On Efavirenz and Raltegravir based Regimen	6H	*3HP (for adults and children >2 years) 3HR (in children only)
On DTG based regimen and fully VL suppression	6H	*3HP (for adults and children >2 years) 3HR (in children only)
On DTG not fully VL suppressed or no evidence of suppression	6H	
Pregnant women	6H	
Children <2 years	6H	3HR
PI based regimen	6H	

**3HP should not to be used in; pregnant women, children <2 years, patients who are on PI containing regimen and, for patients on DTG containing regimen with high VL.*

Table 7-2: Recommended dosages of TPT regimens

Drug regimen	Dose per kg body weight	Maximum dose	Pyridoxine
Isoniazid alone, daily for 6 months	Adults, 5 mg/kg Children, 10 mg/kg (range, 7–15 mg) 4-6.4 kg = 50 mg 6.5-9.9 kg =100 mg 10-13.9 kg=150mg 14-19.9 kg=200mg 20-24.9 kg=250mg >25 kgs=300mg	300 mg	Adults and children 12 years and older 25 mg daily Children 5 to 11 years of age 12.5mg daily Children <5 years of age not routinely given
Weekly rifapentine plus isoniazid for 3 months (12 doses)	Individuals aged ≥ 12 years: Isoniazid: 15 mg/kg Individuals aged 2–11 years: Isoniazid: 25 mg/kg **Rifapentine:** 10.0–14.0 kg = 300 mg 14.1–25.0 kg = 450 mg 25.1–32.0 kg = 600 mg 32.1–50.0 kg = 750 mg > 50 kg = 900 mg	Isoniazid, 900 mg Rifapentine, 900 mg	Adults and children 12 years and older 50 mg daily Children 5 to 11 years of age 25mg daily Children <5 years of age not routinely given
Daily isoniazid plus rifampicin for 3 months	**Isoniazid**: Adults, 5 mg/kg Children, 10 mg/kg (range, 7–15 mg) **Rifampicin:** Adults, 10 mg/kg Children, 15 mg/kg (range, 10–20 mg)	Isoniazid, 300 mg Rifampicin, 600 mg	Adults and children 12 years and older 25 mg daily Children 5 to 11 years of age 12.5mg daily Children <5 years of age not routinely given

Temporary TPT interruption, although not ideal, is acceptable, as long as the patient completes:

- 6H – Completes 6 months of treatment within 9 months period
- 3HP – Completes 12 doses within 16 weeks

In non-adherent patients, prophylaxis should be discontinued. Pyridoxine should be given along with isoniazid to prevent isoniazid associated neuropathy.

7.4.7 Follow-up of patients on TPT

Review patients on TPT as appropriate and review/reinforce adherence

- Screen for active TB during each clinic visit using intensive case finding (ICF) form
- Update patient care booklet and TPT clinic register record at every visit and document outcome on completion of therapy
- Monitor for TPT adverse effects
- Isoniazid and rifampicin should be discontinued in symptomatic patients with ALT/AST more than three times the upper limits of normal.
- Children under 5 years receiving isoniazid do not require pyridoxine.

7.4.8 Recording and reporting

All details of the person receiving TPT must be recorded as required in TPT register and in the patient care booklet. In addition, either the TPT identity card should be attached to the patient's passport or details of TPT provision should be in the patient's passport.

- Clinicians should list isoniazid in the list of medications prescribed in the health passport and the PCB for patients on TPT.
- Facilities with Pharmacy staff should keep TPT, dispense and record in the EDT
- In facilities without Pharmacy staff, health care workers should ensure that TPT prescribed and dispensed is recorded in the ePMS and EDT.

7.4.9 TB diagnosis for PLHIV

Any PLHIV found to have symptoms of TB following routine screening and at any time should be tested using Gene Xpert MTB/RIF according to national algorithm for the laboratory diagnosis of TB. In PLHIV tested Gene Xpert MTB/RIF negative but presumptive TB, a specimen may be sent for mycobacteria culture. In severely ill* regardless of CD4 PLHIV, or those with low CD4 (≤100) or bedridden with negative Gene Xpert MTB/RIF, a urine sample for TB-LAM test should be done. Although a positive TB–LAM confirms TB, however negative LAM test doesn't rule out TB. TB-LAM should not be used as screening test for TB.

Severely ill is defined based on 4 danger sign: respiratory rate >30/min, temperature >39□C, heart rate >120/min and unable to walk unaided.

7.4.10 HIV Treatment in Adults co-infected with TB

ART should be initiated as soon as possible in all TB/HIV co-infected patients with active TB (within 2-8 weeks after the commencement of TB treatment). Do not wait until 8 weeks as treatment outcomes are better if ART is initiated as soon as possible. HIV-positive TB patients with profound immunosuppression (such as CD4 counts less than 50 cells/mm^3) should receive ART within the first two weeks of initiating TB treatment.

Table 7-3: HIV Treatment in adults co-infected with TB

Preferred 1st line ART regimen	**TDF + FTC (or 3TC) + DTG (at 50mg twice daily)**
Alternate 1st line ART regimen	TDF + FTC (or 3TC) + EFV (at **400mg once daily**) (this is a change from the previous guidance which recommended increasing the dose to 600mg with TB treatment).

For PLHIV on a boosted PI regimen	***Option 1:*** Substitute rifampicin in the TB treatment with rifabutin ***Option 2:*** If Rifabutin is unavailable or contraindicated, maintain rifampicin in TB treatment and use PI based regimen super boosted with ritonavir.* TDF or AZT + 3TC with LPV/r 400mg+ritonavir 400 mg BD (LPV/RTV) or **(LPV/r 800 +ritonavir 200mg BD)** *Note: ATV/r is contraindicated in patients with TB/HIV co-infection*

*Lopinavir/ritonavir needs to be "super-boosted" with ritonavir. This means adding additional ritonavir to bring the dose of ritonavir equal to that of lopinavir.

7.5 Children with TB and HIV co-infection

Infants and children with HIV should be screened for TB including asking about TB exposure/contact history at each encounter with a health worker.

Bacteriological confirmation should be sought whenever possible. Sputum can be collected from most children using direct expectoration (older children), gastric aspirates or sputum induction. For a description of specimen collection in children, see the National Guidelines for the Management of Tuberculosis.

Gene Xpert MTB/Rif is the preferred initial diagnostic test over DM and Culture and DST for sputum and other specimens. It is important to remember that a negative Xpert MTB/Rif, DM or culture test result does not rule out TB.

7.5.1 When to start ART in HIV/TB co-infected infants and children

Initiation of ART in children co-infected with TB follows the same approach as described for adults above (See section 7.4)

HCWs should be aware that starting ART soon after the start of TB treatment does carry a risk of Immune Reconstitution Inflammatory Syndrome (IRIS). However, there is ample evidence that mortality from delaying the start of ART in TB co-infected infants and children greatly outweigh the risk from IRIS (see 3.9 section for the management of IRIS).

7.5.2 ART regimens for children with TB being treated with rifampicin-based regimen

Table 7-4: Initiating ART for infants and Children currently on TB treatment

<4 weeks old	**Seek specialist advice**
4 weeks to <3 years old or weight <10 kg	ABC/3TC + DTG bd If DTG not available: ABC + 3TC + RAL *or* ABC + 3TC + super-boosted lopinavir/ritonavir (LPV/r + R)* *NB: Switch to standard ART regimen two weeks after competing* rifampicin-based *TB treatment*

3 years old and weight 10 kg to <20 kg	ABC + 3TC + DTG bd *If DTG not available and If the child has had NO previous eMTCT/PMTCT NVP exposure:* ABC+ 3TC + EFV *if DTG not available and the child has had previous eMTCT/PMTCT NVP exposure:* ABC + 3TC + RAL **or** ABC + 3TC + super-boosted lopinavir/ritonavir (LPV/r + R) * *NB: two weeks after TB treatment is completed, change to the standard ART regimens*
Adolescents 20 to <30 kg	**ABC + 3TC + DTG bd** **if no DTG available**, *And If the child has had NO previous eMTCT/PMTCT NVP exposure* ABC + 3TC + RAL (if RAL available) ABC + 3TC + super-boosted lopinavir/ritonavir (LPV/r + R)*
≥30 kg and at least 10 years old:	TDF + 3TC + DTG bd If DTG not available, TDF + 3TC + EFV

* Lopinavir/ritonavir needs to be "super-boosted" with ritonavir. This means adding additional ritonavir to bring the dose of ritonavir equal to that of lopinavir.

7.5.3 Initiating TB treatment on infants and children currently on ART

Start TB treatment and adjust ART as in Table 7-4; always changing back to the standard ART regimen two weeks after completion of TB treatment.

Remember: Two weeks after TB treatment with rifampicin is completed, the child should change to the usual first line regimens, or to the regimen he/she was taking before starting TB treatment if the child has been given a triple NRTI regimen or super-boosted lopinavir/ritonavir.

7.6 Pneumocystis Pneumonia (PJP)

Pneumocystis pneumonia is caused by Pneumocystis jirovecii, a ubiquitous organism that has been classified as a fungus. The previously used name Pneumocystis carinii is no longer used after a taxonomy reclassification when it became clear that *P. jirovecii* infects humans and *P. carinii infects rats.* It is an AIDS defining illness (WHO stage 4). Before ART area and *PCP* prophylaxis, PCP occurred in up to 80% of patient.

Currently, the risk factors of PJP include severely immuno-compromised patients (CD4<200) who are either unaware of their HIV infection or are not engaged in care (defaulters).

7.6.1 Symptoms and signs

- Dry cough
- Dyspnoea (worsens with exercise, walking, speaking)
- High fever
- Malaise
- Tachypnoea
- Tachycardia
- Cyanosis
- Few chest signs (auscultation may be normal)

The diagnosis of PCP should be considered among differentials in patients with CD4 < 200 presenting with above signs and symptoms.

7.6.2 Management of PJP

Figure 7-6: Management of PJP

- Cotrimoxazole (TMP/SMX):
  - 20 mg of TMP/SMX per kg body weight based on TMP, IV or po divided in 3-4 doses per day x 21 days
- Steroids (In patients with severe hypoxia (Room air Pa02 value ≤ 8 kPa/ ≤ 70mmHg)
  Prednisone:
  - 40 mg po Bd x 5 days (days 1-5)
  - Then 40 mg po od x 5 days (days 6-10)
  - Then 20 mg po od x 11 days (days 11-21)

Alternatives for patients with severe CTX allergy include TMP + dapsone or clindamycin + primaquine.
PJP prophylaxis: CTX 2 tablets (960 mg)/day lifelong for all HIV positive patients.

7.7 Management of Cryptococcal Disease

Cryptococcal meningitis (CM) is a leading cause of mortality among HIV-infected adults with severe immunosuppression. Early identification of asymptomatic patients and provision of presumptive therapy for patients with a positive cryptococcal antigen test remarkably improves outcomes for these patients. HIV-positive adults with CD4 count <200 cells/mm^3 should be screened for cryptococcal antigenemia.

There are insufficient data to recommend routine cryptococcal screening of HIV-positive children in whom the incidence of CM is much lower; however, HIV-positive adolescents with severe immunosuppression may be at risk.

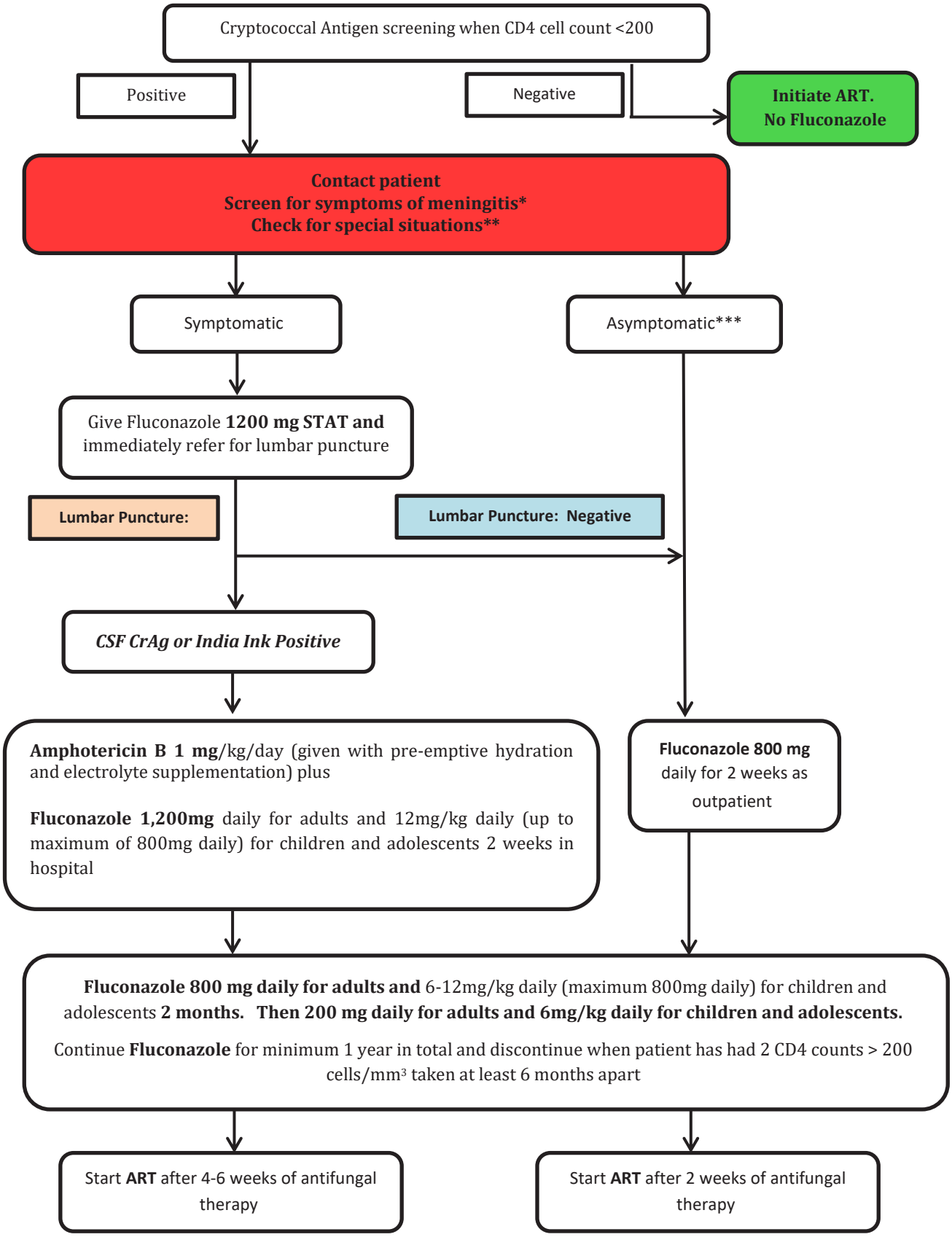
Patients diagnosed with and treated for cryptococcal meningitis should receive secondary prophylaxis with fluconazole 200mg daily for at least one year. This should only be stopped after 2 successive CD4 count results at least 6 months apart are >200 cells/mm^3.

Figuer 7-7 below**,** shows the current recommended management protocol for HIV-positive patients with positive cryptococcal antigen test.

See section 2.2 on timing of ART Initiation in patients with cryptococcal meningitis.

Immediate ART initiation is not recommended in HIV-infected patients with symptoms suggesting cryptococcal meningitis due to the high risk of IRIS that may be life threatening. ART should be started 4-6 weeks after induction and consolidation anti-fungal regimen.

Figure 7-7: Screening and pre-emptive treatment for Cryptococcal Meningitis



**Symptomatic for meningitis if either headache or confusion is present*
***Special situations include: prior cryptococcal meningitis; pregnancy or breastfeeding mother*
****A lumbar puncture may be considered if available*

Source WHO. The diagnosis, prevention and management of cryptococcal disease in HIV-infected adults, adolescents and children. March 2018

7.8 Liver disorders

7.8.1 Hepatitis B Virus (HBV)

All PLHIV should be assessed at enrolment into HIV care for hepatitis B surface antigen (HBsAg). Lamivudine (3TC), Emtricitabine (FTC) and tenofovir (TDF or TAF), all have antiviral effects on HBV, and TDF or TAF plus [3TC or FTC] should be used together to effectively suppress HBV replication. Caution should be exercised when stopping ART in HBV/HIV co-infected patients due to risk of rebound Hepatitis B viral DNA leading to liver damage. It is important to maintain both TDF or TAF and FTC or 3TC when switching regimens due to HIV treatment failure as HBV resistance to lamivudine develops within two years in 50% of HIV/HBV co-infected patients on lamivudine-containing ART without tenofovir. Patients with HIV/HBV coinfection on ART require close monitoring for clinical signs and symptoms of hepatotoxicity and laboratory monitoring of ALT.

All patients in whom HBsAg is reactive (positive):

- Do ALT at ART initiation 2, 6, and 12 weeks, and then yearly thereafter if the repeat HBsAg result remains positive at 6 months.
- Chronic Hep B is defined as persistent HBsAg for more than 6 months.
- Elevated ALT arising during therapy may have many causes, and needs to be carefully evaluated for each patient.

Children with chronic HBV/HIV co-infection who weigh ***at least 17 kg and are at least 2 years old*** should receive TDF/XTC as part of their ART according to the paediatric dosage schedule Appendix 13. Such children should be routinely screened for renal function.

Children ***<2 years old or <17 kg*** should have the standard preferred first line NRTIs (ABC/3TC) as part of their ART regimen and should transition to TDF/FTC when eligible by age and weight.

Table 7-5: Common causes of liver disease among HIV-positive persons in Namibia

Category of liver disease	General etiology	Specific etiology	Notes
Hepatocellular Disease (ALT or AST)	Medication toxicity	ARV's: NVP>>RTV>EFV NNRTIs and PIs	
	Lactic acidosis with steatohepatitis	AZT	
	Acute viral hepatitis	Hepatitis A,B, E	Self-limited
	Chronic viral hepatitis	Hepatitis B,C	With abrupt withdrawal of TDF or 3TC, or with development of resistance to anti-hepatitis B medicines ALT may rise
	Immune Reconstitution Inflammatory Syndrome	Immunologic response to hepatitis B	If severe may have to stop ART temporarily
	Alcoholic liver disease	Alcoholic steatosis, acute alcoholic hepatitis	Reduce or eliminate alcohol use

Jaundice Bilirubin	Severe liver insufficiency	Any cause	High direct bilirubin, ALT/ AST, low albumin, prolonged prothrombin time, may have ascitis, encephalopathy, GI bleeding
	Severe malaria	Haemolysis rather than hepatitis	High indirect bilirubin with anaemia and positive malaria smear
	Biliary tract obstruction	Common bile duct stones, pancreatitic cancer, mass in porta hepatis	High direct bilirubin, alkaline phosphatase, normal ALT/AST, sonogram helpful
	Medication toxicity	Atazanavir	Causing mild, symptomatic indirect hyperbilirubinaemia in up to 10% of patients.
Infiltrative liver disease	Infections	Extra-pulmonary or disseminated TB, MOTT	High alkaline phosphastase, other LFTs nearly normal, hepatomegaly
	Immune Reconstitution Inflammatory Syndrome	Hepatoma, lymphoma, liver metastasis	See section 1.18.1
	Malignancies		Sonogram helpful, liver biopsy diagnostic

7.9 Immune reconstitution

Improvement in a patient's condition in response to antiretroviral therapy (immune reconstitution) is quantitative (CD4 response) and qualitative (antigen/microbe-specific). The clinical impact of immune reconstitution has been demonstrated by:

- The safety of discontinuing prophylaxis for selected OIs.
- The control of several chronic, untreatable opportunistic infections.
- An impressive decline in virtually all HIV-associated complications except lymphomas and liver disease.
- An inflammatory response ascribed to immunologic reactions to selected microbial antigens.

Chronic, relatively untreatable infections that can be controlled with immune reconstitution include molluscum contagiosum, progressive multifocal leukoencephalopathy (PML), cytomegalovirus infections (CMV), cryptosporidiosis, and microsporidiosis.

7.9.1 Immune Reconstitution Inflammatory Syndrome (IRIS)

This relatively common syndrome results from a dramatic increase in the inflammatory response to antigens from previous, partially treated or latent infections in HIV patients shortly after initiating ART. It usually occurs in the first few weeks after a patient starts therapy.

Common risk factors for IRIS are;

- Rapid decline in viral load (especially in the first three months after ART initiation)
- Low baseline CD4 count (especially <50 cells/mm3) and rapid increase after initiating ART
- Initiation of ART soon after initiation of treatment for opportunistic infection (OI)
- Disseminated versus localized OI
- ART-naïve patient

Although patients with IRIS appear as though ART is failing (clinical deterioration), these patients are actually undergoing robust improvements in their immune systems. Examples of infections or conditions which have been associated with IRIS include tuberculosis, MAC, cryptococcal meningitis, herpes zoster; PML, CMV vitritis, and Kaposi Sarcoma. Recommendations for management vary by pathogen and clinical expression, but most involve medications directed against the pathogen with or without corticosteroids.

7.10 Non-Communicable HIV-associated diseases

7.10.1 Renal diseases

In patients with renal insufficiency or renal failure, ARV dosages need to be adjusted for some medicines on the basis of creatinine clearance (see Appendix 5). Discuss with colleagues or where possible consult with an HIV specialist before starting ART in a patient with renal failure or when renal failure develops in a patient on ART. Figure 5-1 and

Figure 5-2 contains the formula for the calculation of CrCl.

7.10.2 Common cardiovascular diseases

Non-communicable diseases also affect HIV-infected patients. These diseases include hypertension, diabetes mellitus, and ischaemic and rheumatic valvular heart disease. Generally, cardiovascular conditions particularly pericarditis and dilated cardiomyopathies may be HIV, OI, or medication-related.

Some ARVs, especially PIs, may cause hypercholesterolemia and in the long term could result in premature onset of coronary artery disease or stroke. Therefore, there should be constant screening of such complications of treatment as indicated.

Increased vasculitic events have been noted in HIV patients leading to strokes, peripheral arterial occlusions and other vaso-occlusive events.

At every clinical visit, the patients should be assessed and educated on risk reduction for cardiovascular diseases, by:

- Weight measurements and BMI calculation
- Blood pressure assessment
- Random blood sugar every 6 months for patients with established risk of cardiovascular diseases
- Random Blood cholesterol once a year for all patients on ART and fasting lipogram for at risk patients (PLHIV and Hypertension, PLHIV with Diabetes, PLHIV with history familial dyslipidaemia)
- CVD risk reduction counselling- Refer to Namibia Standard Treatment Guidelines (STG) section on Hypertension

7.10.3 Depression

PLHIV are at high risk of mental, neurological and substance-use disorders. Depression is one of the commonest mental health problems among PLHIV including adolescents LHIV.

Depression is a mood disorder that causes a persistent feeling of sadness and loss of interest. Screening for depression may support adherence to ART, retention in care and viral load suppression and improve the quality of life amongst PLHIV.

Health care workers should screen for the following signs and symptoms of depression in PLHIV.

- sadness
- loss of interest in pleasurable or fun activities

- tiredness
- trouble focusing or concentrating
- unhappiness
- anger
- irritability
- frustration
- sleep issues (too much or too little)
- no energy
- craving for unhealthy foods
- anxiety
- isolation

The PHQ-9 is a multipurpose instrument can be considered for screening, diagnosing, monitoring and measuring the severity of depression. See Appendix 20.

Depression should be managed according to standard national treatment guidelines, and patients should be offered or appropriately linked to mental health services.

Treatment involves a combination of **cognitive/behavioral therapy and medication.** Exclude any other causes of depression: hypothyroidism, Parkinson's syndrome, Efavirenz intolerance (associated with insomnia, nightmares, loss of memory), recent family death, etc. Pharmacological treatment is often needed and speeds recovery. Many patients benefit from **3-6-month course** of therapy, but some will need longer-term treatment. Medication is encouraged for those with suicidal ideation, repeat episodes of depression and insufficient response to psychological support alone. All patients on anti-depressant medication also benefit from psychological support, and combination therapy is highly recommended.

7.10.4 Substance Abuse Disorders

Use of alcohol or other drugs is a common reason for poor adherence. Management involves regular support counseling. Co-morbid depression or anxiety should be diagnosed and treated.

7.10.5 Acute Psychosis

Symptoms include: restlessness, agitation, shouting, aggressive and violent behavior, running away, destructive to property, setting fire to house and property, illogical, irrational and irrelevant talk, sees and hears voice from nowhere, and poor hygiene.

Management

- Brief history taking from relative
- Physical examination if possible.
- Look and note injuries.

Drug Treatment

- Inj. Haloperidol 5mg I/M.
- Inj. Diazepam 5-10mg I/M; repeat inj if necessary after 4-6 hrs.

Once patient is calm and cooperative do thorough physical examination and laboratory investigations including radiological investigation. Start Oral treatment with Haloperidol 5mg twice daily or Risperidone 2mg – 4mg daily orally in divided doses.

7.11 Nutrition

7.11.1 Food and medication interactions

Due to the effect of HIV on the immune system, persons infected with HIV are more prone to opportunistic infections than healthy individuals. Furthermore, a low CD4 count and/or high viral load greatly increases one's chances of developing these infections. Antiretroviral therapy provides

the body with tremendous benefit in suppressing the viral load thereby increasing the CD4 levels, and reducing the chances of developing opportunistic infections. Special nutrition considerations must be taken when pr**escribing ART to clients.**

To minimise the negative effects of food-medication interactions and to maximise the benefits of available medications and nutrients, it is important to understand food and medication interactions and how to manage them to improve the health of the client. Foods and medications can interact in a number of ways that result in both positive and negative health and nutritional outcomes in people living with HIV. Some interactions between medications and food are as follows:

- The effect of certain foods on how medicine works in the body (how medicines are absorbed, metabolised, distributed, and excreted).
- The effect of certain medicine on how food is used in the body (how nutrients from foods are absorbed, metabolised, distributed, and excreted).
- The side-effects of a medication, which, in turn, can affect food intake and nutrient absorption.
- Side-effects caused by combinations of certain medications and foods.

Most ARVs can be taken with or without food. Proper nutrition management interventions can help alleviate some of these negative effects and can help people living with HIV maintain adequate food and nutrient intake.

7.11.2 The effects of food on medications

Food can enhance or inhibit the absorption, metabolism, distribution, and excretion of medication, and therefore, affect the medication's efficacy and the overall health of the individual. High fatty food increases the bioavailability of TDF and absorption of PIs. Even if the clinical significance with regard to ARV effectiveness of this is not clear, patients should be counselled to reduce consumption of high fat diet.

7.11.3 Nutrition-related side-effects of medications and food

Medications may cause side-effects that affect food intake and nutrient absorption in the following ways:

- Side-effects of medication, such as taste changes, loss of appetite (i.e. anorexia), nausea, bloating, heartburn, vomiting and diarrhoea reduce food intake or nutrient absorption.
- Reduced food intake and poor nutrient absorption can lead to weight loss.
- Weight loss leads to further weakening of the immune system.
- A weakened immune system allows HIV to progress to AIDS more rapidly.

However most patients recover quickly and do well on ARV medications.

While ARVs contribute to improved nutritional status, they occasionally create nutritional problems, which require nutritional and other life-style interventions.

- **High blood cholesterol:** Nutritional counselling to reduce dietary fat intake and limiting saturated and trans- fat intake, increase daily vegetable and fruit intake, and regular exercise should be promoted.
- **High triglycerides:** Nutritional counselling to limit saturated and trans- fats intake (low density lipoproteins), moderation in carbohydrate intake and an increase in intake of whole grain cereals, fruits and vegetables. Regular exercise is a vital supportive measure.
- **Peripheral neuropathy:** This is not uncommon condition and is often described as numbness, tingling, and burning sensation in the toes, feet, fingers or hands. It might be attributed to HIV, medical treatment or nutritional deficiencies. Thus the cause must be

determined in order to provide specific treatment. The condition is usually treatable and reversible. Supplementation with vitamin B is only useful where nutritional deficiency is considered likely.

- **Diabetes:** Some PIs and NRTIs can affect carbohydrate metabolism which may cause insulin resistance and thus, increases patient's risk of developing diabetes. Relevant lifestyle advice should be given.

Proper nutrition management can help maintain food intake, compensate for nutrient losses, prevent weight loss and improve the condition of the patient. Proper nutritional management can also improve adherence to the regimen. When not properly managed, side-effects often lead to the interruption of treatment and contribute to poor adherence. Therefore, nutrition counselling should be provided to all clients on ART from the start of therapy. Health workers and counsellors should provide clients with dietary guidance that is specific to the patient's situation.

7.11.4 Nutrient requirements for people living with HIV

Nutritional assessment, counselling, support, and monitoring are essential components when providing care to HIV patients. Clinical and dietary assessment at enrolment and during management helps in determining additional contributory factors to poor response to therapy. This can promote timely and appropriate interventions. Meal planning should correspond to nutritional requirements of the ARV regimen and should be feasible for clients.

There should be counselling sessions provided by healthcare workers (HCW) to patients and household members if possible, that is directed at helping them to understand the impact of therapy on nutritional status and vice versa. HCWs should also work with patients to identify feasible options.

To provide counselling for clients on antiretroviral therapy, health workers should:

- Always promote and encourage optimal nutrition intake with a variety of foods every day.
- Discuss ART and food interactions with the client before they begin treatment.
- Ask the client about food availability and access at the household level. Address such issues with referrals to community- based projects, or other assistance.
- Use the Food and Medication Intake Form to assist in counselling the client on the importance of food intake with ART.
- Identify medications that have special food interactions
- Identify potential nutrition-related side-effects with ART and provide counselling on management of side-effects.

Malnutrition among PLHIV manifests most commonly as weight loss and wasting in adults. Weight loss among PLHIV occurs due to reduced intake (starvation), malabsorption and sudden increase in energy expenditure, problems with utilization or a combination of these factors. Therefore, a key objective of nutrition, care and support for PLHIV is to prevent weight loss and maintain nutritional status within the normal range.

Good nutrition management can help maintain food intake, compensate for nutrient losses, prevent weight loss and improve the condition of the patient. Proper nutritional management can also improve adherence to the regimen. For these reasons, nutrition counselling should be provided to all clients on ART from the start of therapy.

Increased energy needs

Asymptomatic adult PLHIV require additional 10% energy foods while symptomatic adult PLHIV require an additional 20-50% depending on disease stage. To achieve the additional energy needs, PLHIV should be counselled and educated on consumption of a variety of foods. Strategies to meet increased energy requirements of PLHIV include:

- Dietary adjustments and meal plans of regular energy giving foods such as mahangu, maize, rice, potatoes, cassava, wheat.
- Adoption of food preparation methods that add value for example sweetening porridge or adding peanut butter, and frying potato chips raises their energy values several folds.
- Consumption of snacks between meals.

Protein needs

According to WHO, there is insufficient evidence to support increased protein requirements for PLHIV. However, the quality of protein with respect to adequacy of essential amino acids is important. PLHIV should therefore be encouraged to consume foods rich in both animal protein (dried small fish, chicken, Mopani worms, fillet and beef) and plants source protein (soya, lentil seeds, beans, groundnuts and peas).

Micronutrient needs

Adequate micronutrient intake is achievable through consumption of a healthy balanced diet including plenty of fruits and vegetables. Current evidence does not support increased micronutrient needs above 1 Recommended Daily Allowance (RDA) for PLHIV compared to non-HIV infected individuals. Therefore, PLHIV should be encouraged to consume plenty of fruits (such as oranges, mangoes, pawpaw, guava, apples, and baobab) and vegetables (such as spinach, amaranthus, cauliflower).

Water requirement

Water consumption is an integral part of good nutritional practices. A daily fluid intake of 2 litres, equivalent to 8 glasses of about 250 ml is required. PLHIV must take adequate amount of clean and safe water to avoid dehydration and aid transport of nutrients, removal of wastes (such as medication by-products), assist metabolic activities, provide lubrication to moving parts and helps regulate body temperature. In the absence of clean safe water, point-of-use water treatment should be provided to the patients.

S*e*vere acute malnutrition in HIV positive adults

PLHIV are at greater risk of malnutrition (under-nutrition) than non-HIV-infected adults. This manifests as wasting, weight loss and/or reduced immunity and is usually as a result of deficiency in macro- and micronutrients. Prevention or treatment of moderate and severe malnutrition is essential in HIV infected adults. All HIV infected adults attending the ART clinic should regularly undergo nutrition assessment (weight, height, BMI or MUAC) for categorization of their nutritional status. Health care workers should integrate NACS into HIV Clinic care.

Patients who received therapeutic food supplements and have improved nutritional status should be referred and linked to community-based support services through regional councils and other line Ministries. Furthermore, they should be adequately counselled/educated on nutrition using appropriate guidelines. For the management of moderate/severe malnutrition in HIV positive adults refer to Appendix 8.

Supplements

Traditional therapies and remedies for PLHIV should be discouraged. Considerations when discussing supplements with clients should include:

- Multi-vitamins should be used as prescribed by a health worker, they offer most of the micronutrients needed and no extra supplements are necessary.

- Other supplements including traditional herbs and remedies that claim to boost the immune system or cure disease should be discouraged as they have potential adverse medicine interactions with ARVs.

7.12 Family Planning

All women of child bearing potential and their partners have the right to choose the number, timing and spacing of their children and to decide on the use of FP methods, regardless of their HIV status or age. Women and their partners should be given adequate information to help them make an informed, voluntary choice of a contraceptive method. Table 7.8 has the list of contraceptive methods available in Namibia.

Table 7-6: List of contraceptive methods available in Namibia

Hormonal methods		**Effectiveness**
Intrauterine Device (IUD)	Intrauterine Contraceptive Device (IUCDs)	99% Effectiveness (**Reliable contraceptive**)
Progestin only Methods	Progesterone Only Injectables (POIs) Contraceptive Implants	99% Effectiveness if used correctly but less than 95% effectiveness on typical use **Reliable contraceptive**)
	Progestin Only Pills (POPs)	99% Effectiveness if used correctly but less than 95% effectiveness on typical use
Combined hormonal contraceptives	Combined Oral Contraceptives Combined Contraceptive Patch	95% Effectiveness
Non hormonal methods		**Effectiveness**
Intrauterine Device (IUD)	Copper IUD	99% (**Reliable contraceptive**)
Sterilization (Voluntary Surgical Contraception)	Vasectomy (Male Sterilization) Bilateral Tubal Ligation (Female sterilization)	99% Effectiveness **(Reliable contraceptive)**
Non-hormonal methods (barrier methods)	Male Condom Female Condom	98% if used correctly 95% if used correctly
Natural Family Planning (NFP) Methods	Abstinence Coitus Interruptus/ Withdrawal Lactational Amenorrhea Method (LAM) Fertility Awareness Methods (FAM)	60-73%

The following information should be provided about each contraceptive method:

- Correct usage
- How it works
- Common side-effects
- Health risks and benefits
- Signs and symptoms that would necessitate a return to the health facility
- Return to fertility after discontinuation
- Safer sexual practices to prevent STIs

In 2019, WHO recommended DTG-based regimens as a preferred first-line ART for everyone living with HIV. **The prevalence of NTDs associated with using DTG at conception in the Tsepamo study has declined and the benefits of giving DTG-based regimens to women of child bearing potential outweigh the risks.**

Therefore, the overall approach of integrating FP services at point of care, should respond to **women's needs, rights, safety and preferences**. Care should be provided in a manner that respects the autonomy of women in decision making about issues pertaining to their own health. **Women should be given information and options to enable them to make informed choices**. It is also important to note the following;

Adolescent girls and women of childbearing potential:

- Who currently do not want to become pregnant and women who are breastfeeding SHOULD be offered a pregnancy test first before receiving the preferred regimen containing DTG together
- Women's fertility intentions and FP status should be assessed at each treatment visit.
- There is a potential for reduced efficacy of long-acting progestogen-only implants when a woman is also on ART containing NNRTIs and dual protection should be adequately addressed.
- Central Medical Stores should quantify contraceptive commodities based on the needs of PLHIV in ART sites to ensure appropriate ordering and distribution of contraceptives.

7.13 Cervical Cancer and HIV

Women living with HIV are 4-5 times more likely to develop cervical cancer compared to HIV negative women and have a 40% higher risk of mortality from cervical cancer. Despite being on treatment and achieving viral suppression the risk is still higher than in HIV negative women. Most cases of invasive cervical cancer, almost all of which are caused by the human papillomavirus (HPV), are preventable.

According to the Namibia cancer registry, cervical cancer is the 2nd most prevalent cancer. Therefore, cervical cancer screening programmes need to be integrated in the pre-existing HIV services to enable early detection and treatment.

HIV positive women are at higher risk of:

- Infection with Human Papilloma Virus (HPV), the causative agent for cervical cancer.
- Having pre-cancerous lesions (2-6 times) depending on degree of immune suppression
- Developing cervical cancer
- Early progression to invasive cancer
- Presenting with late disease with poor prognosis

As part of clinical monitoring **cervical cancer screening is recommended** for all HIV positive women regardless of viral load suppressions status.

Frequency of screening

- Annual screening if using PAP smear method
- yearly screening if using VIA method or HPV triage test

All women with abnormal screening results should be referred for further evaluation and treatment as appropriate. **Cervical Cancer screening should be integrated into the HIV care and treatment clinics** in order to ensure convenience to clients and early diagnosis of pre-cancer lesions.

7.14 Kaposi sarcoma

Kaposi's sarcoma (KS) is the most common malignancy in patients with HIV infection. HIV associated KS does not have a preferential pattern of localization and may affect all skin and mucous membranes. Lymph nodes and internal organs such as stomach, gut, lung or liver may also be involved. The progression of HIV-associated KS is variable: the tumours can remain unchanged for months to years, or grow rapidly within a few weeks and disseminate.

Typical findings at manifestation are:

- asymptomatic purple macules or nodules
- haemorrhage
- central necrosis and ulceration
- wood hard oedema (lymphoedema)
- In the oral cavity, the hard palate is frequently affected.
- purplish erythema and progress to plaques and nodules that ulcerate
- KS lesions may also involve the external genitalia

Diagnosis of KS is usually made based on clinical findings. However, in all inconclusive or questionable cases a histologic diagnosis is recommended. Differential diagnosis includes other neoplasia such as cutaneous lymphomas or angiosarcoma, but also infectious diseases such as syphilis and bacillary angiomatosis. In all cases of KS do complete examination and investigations as needed.

Treatment. Start all patients on ART and refer for biopsy. With viral suppression and immune reconstitution, many KS lesions stabilize or even resolve completely without specific treatment. In contrast, children with KS almost always need chemotherapy in addition to ART. Patients with KS should be referred to an oncologist to determine regimen and timing of chemotherapy.

8 USE OF ANTIRETROVIRAL DRUGS FOR HIV PREVENTION

8.1 Introduction

This chapter contains guidance on the use of ARVs for HIV prevention as Pre-Exposure and Post-Exposure Prophylaxis as recommended by WHO.

8.2 Oral Pre-Exposure Prophylaxis (PrEP)

PrEP is defined as the use of antiretroviral drugs before HIV exposure by people who are not infected with HIV in order to block or prevent the acquisition of HIV. Oral PrEP should be offered as part of the 'Combination Prevention' package that includes HIV Testing Services (HTS), male and female condoms, lubricants, ART for HIV-positive partners in zero-discordant couples, voluntary medical male circumcision (VMMC) and STI prevention and management.

8.2.1 HIV Risk Assessment and Clinical Eligibility Criteria for PrEP

8.2.1.1 Indications for PrEP

Any sexually active HIV-negative person is at risk of acquiring HIV. Those at substantial risk include but are not limited to the following:

- HIV negative people in zero-discordant relationships with a partner who is not confirmed as virologically suppressed (i.e., partner has VL > 40 copies/ml)
- All HIV negative people in zero-discordant relationships (regardless of VL of the partner) who want to conceive
- Pregnant or breastfeeding HIV-negative women in zero-discordant relationships
- Those with partner(s) of unknown HIV status
- Those with recent/ recurrent STIs
- Those with multiple and/or concurrent sexual partners
- Those with history of inconsistent or no condom use
- Recurrent PEP users
- Those with history of sex whilst under the influence of alcohol or recreational drugs
- Injection drug users
- Those in abusive relationships
- Those who strongly feel at substantial risk of HIV infection.

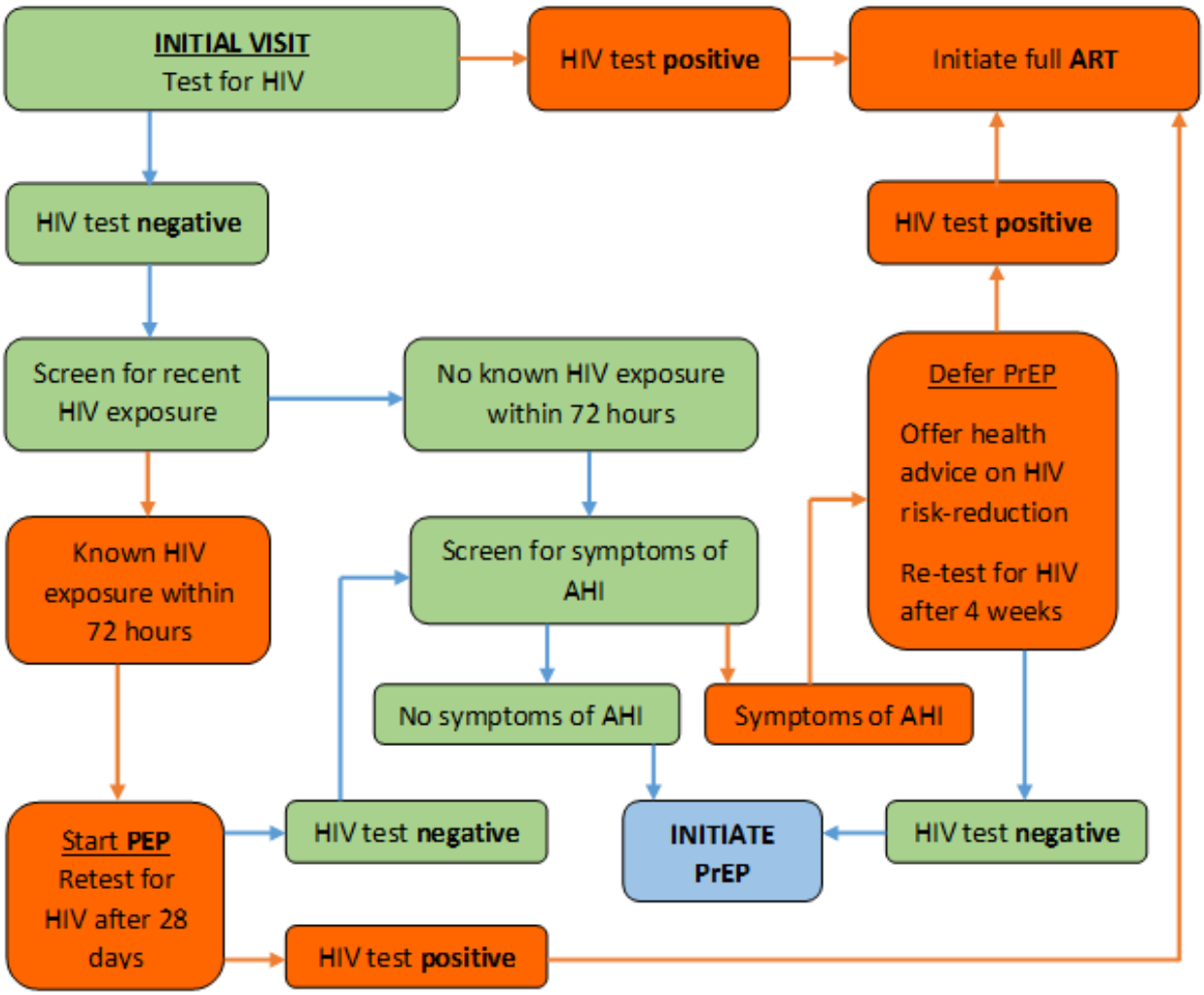
8.2.1.2 Contraindications to PrEP use

Despite being at substantial risk, some clients will not be eligible for PrEP if they have any of the following:

- Unwilling to get tested for HIV
- HIV positive
- Signs and symptoms of HIV primary infection (characterized by flu-like symptoms)
- Adolescents weighing <30kg
- Adolescents aged <15 years who are not Tanner stage 3 or greater (should not get TDF)
- Abnormal CrCl<60ml/min
- Taking other nephrotoxic drugs, for example, aminoglycosides
- Known allergies to any of the PrEP drugs

Note: It is critically important to take a thorough history (particularly sexual) to determine PrEP eligibility. Use the algorithm below to initiate PrEP in clients with recent HIV exposure and/or symptoms and signs of acute HIV infection (AHI):

Figure 8-1: PrEP initiation algorithm for clients with recent HIV exposure



8.2.2 PrEP Initiation and Follow-up

The recommended regimens for use in Namibia are:

- TDF/FTC (300mg/200mg), one tablet taken once a day, **OR**
- TDF/3TC (300mg/300mg), one tablet taken once a day.

The table below outlines the recommended procedures for PrEP initiation and follow up.

Table 8-1: Summary of pre-exposure prophylaxis visits and procedures

Visit	Recommended Procedures	Tests
Screening and PrEP initiation (including restart)	• Assess HIV risk - thorough sexual and social history • Medical history and physical examination to determine clinical eligibility • Provide STI treatment if indicated • Educate about the risks and benefits of PrEP • Educate client about PrEP side-effects and management • Educate client about signs and symptoms of acute HIV infection • Contraceptive counselling and offer services • Discuss with client on the adoption of healthy lifestyles such as avoiding alcohol, tobacco and recreational drugs • Provide condoms and lubricants • Refer HIV-neg men aged 10-49 yrs. for VMMC • Provide **one-month** supply of PrEP and arrange follow up visit	• HIV test • CrCl • HBsAg • RPR
One-month follow-up	Same as at PrEP initiation visit **PLUS**: • Assess tolerability, side effects and effective use (adherence) • Actively manage side effects • Provide 2-month prescription and follow up date	• HIV test
Three-month follow-up and 3-monthly maintenance visits	• Repeat procedures done at one-month follow-up • Provide 3-month prescription and follow up date	• HIV test
Summary of schedule for repeating lab tests: • HIV test – **Initiation, M1, M3, then 3-monthly afterwards** • CrCl – **Baseline, M6, then annually afterwards** • HBsAg – **Baseline and M6 (if positive at baseline)**		

8.2.3 Counselling and key messages for PrEP

- PrEP is highly effective in preventing HIV infection only when taken daily as prescribed.
- Advise use of condoms for 7 days after starting PrEP for clients engaging in receptive anal sex and 21 days for clients engaging in receptive vaginal sex. It takes about **7 days** for anal sex and **21 days** for receptive vaginal sex for PrEP to achieve protective levels.
- If the client misses a PrEP dose on a given day and realises this on that same day, they should take the pill as soon as they remember. If the client does not remember until the next day, there is no need to take two pills on that day.
- The ARV combination for PrEP is different from the regimen(s) for full ART (for treatment). Clients must be discouraged from exchanging or sharing their medication with friends or family members who might also be taking ARVs.
- Minor side effects associated with PrEP use (such as nausea, abdominal cramping, vomiting, dizziness, headache, and fatigue) typically arise within the first 2 weeks of PrEP use and are self-limiting, often disappearing in the next few weeks.
- PrEP is safe for use in pregnancy and during breastfeeding, and has not been shown to have any significant interactions with contraceptives or other hormonal therapy.
- PrEP does not protect against STIs or pregnancy.

8.2.4 Stopping PrEP

PrEP is meant to be used intermittently during periods of perceived high HIV acquisition risk, rather than continually and lifelong, as is the case with ART. PrEP should be stopped:

- If a PrEP user tests HIV positive (refer for full ART)

- If there is evidence of kidney impairment (CrCl <60ml/min) – manage accordingly or consult/refer
- When a PrEP user considers themselves to be no longer at substantial risk of HIV infection (offer appropriate medical advice)
- If risks of PrEP outweigh benefits for any reason

PrEP users should ideally discontinue prophylaxis in consultation with the HCW. For maximal protection, PrEP must be continued for 28 days after last potential exposure to HIV. After discontinuation of PrEP, key populations and HIV-negative individuals whose partners are known to be HIV-positive (or have unknown status) should be re-tested for HIV at least annually. Clients who have discontinued PrEP but become at substantial risk again and meet eligibility criteria should be restarted on prophylaxis, following the same procedures outlined in Table 8.1 above.

8.2.5 Notes for Implementing PrEP

- Medical officers and nurses trained in either NIMART or PrEP can prescribe and dispense PrEP medicines. All healthcare workers can provide other PrEP services such as creation of awareness and demand for PrEP, and HIV risk assessment.
- PrEP initiation should preferably take place on the same day of HIV risk assessment and clinical eligibility screening.
- Clients must be educated about the potential major PrEP side-effect of renal impairment, and be advised to seek urgent medical attention if they experience the related signs and symptoms (reduced urine output, puffy face and swelling of the lower limbs, confusion and trouble thinking clearly, and unexplained shortness of breath).
- Clients who test HIV positive while on PrEP must be immediately initiated on full ART and monitored according to the schedule outlined in the ART chapters in these guidelines.
- MOHSS has put in place a system for recording and reporting PrEP use.

8.3 Post-Exposure Prophylaxis (PEP)

Post-exposure prophylaxis (PEP) is defined as the use of antiretroviral drugs by HIV negative people to prevent acquisition of HIV after exposure.

8.3.1 Prophylaxis after occupational exposure to HIV

Risk of infection

Health care workers have a low but measurable risk of HIV infection after accidental exposure to blood or body fluids from an HIV infected individual. The average risk of HIV infection after a single percutaneous exposure is 0.3%.

Table 8-2: Assessment of exposure risk

Low risk exposure	High risk exposure
Exposure to a small volume of blood	Exposure to large volume of blood or potentially infectious fluids eg. Contaminated blood transfusion
An injury with a solid needle	Injury with a hollow bore needle
Any superficial injury or mucocutaneous exposure	Deep and intensive injury
	Source patient has advanced HIV disease or high viral load

8.3.2 Recommendations for Post-Exposure Prophylaxis

a. Draw baseline laboratory tests of the exposed: HIV testing (with consent), HBsAg and Ab, creatinine. Drawing these tests and waiting for the results must not delay starting PEP.
b. Determine the pregnancy status (and gestational age) in women of childbearing potential. For use of DTG during pregnancy (Refer to Section 2.6)
c. Determine the HIV and the hepatitis B status of the source. If known HIV positive, trace the latest VL blood test result whenever possible.
d. Classify the exposure either as low or high risk and offer PEP accordingly.
e. PEP is recommended to exposed healthcare workers after occupational exposures (percutaneous or trans-mucous membrane) to blood or other potentially infectious body fluids. For exposures with negligible risk (intact skin contact with blood), PEP is not justified. The exposed health worker has the right to decline PEP without risk of losing eventual compensation if infection develops.
f. PEP should be initiated promptly, preferably within 1 - 2 hours post-exposure. The longer it takes to initiate PEP, the higher the risk of contracting HIV following exposure. PEP is not offered at more than 72 hours after exposure.
g. Considering the importance of early initiation of PEP and the high prevalence of HIV among hospitalized patients, **it is recommended to initiate PEP immediately if the source patient is HIV-positive or the patient's HIV status is unknown**. If results of the HIV zero-status of the source patient later become available, decisions about discontinuation of PEP can be made on a case-by-case basis.
h. Baseline tests for PEP:
    - HIV rapid test
    - HBsAg
    - HBsAb
    - Creatinine clearance
i. Workers with occupational exposures to HIV should receive follow-up counselling and medical evaluation. For those whose results are positive for HIV, PEP should be discontinued immediately, and the clients offered treatment.
j. The schedule for repeating HIV test in workers who are HIV-negative at baseline is as follows:
    - at 6 weeks
    - at 12 weeks
    - at 6 months
k. Exposed workers should be counselled to observe precautions to prevent possible secondary transmission (for example to their sexual partner or from mother to child) until they are found to be HIV-negative 6 months following the exposure.
l. Counselling and monitoring for medication toxicities; if subjective or objective toxicity is noted, ARV substitution should be considered with expert consultation, and further diagnostic tests may be indicated.
m. Relative contraindications of PEP include significant renal or liver impairment and severely ill workers. When in doubt about the use of PEP, urgent consultation from a specialized physician or referral centre can be sought, but care must be taken not to unduly delay the initiation of treatment when indicated. It may be necessary to begin PEP while awaiting this consultation.
n. Health workers who become infected with HIV despite taking PEP should receive appropriate medical care.
o. At 20-40%, the risk of transmission of hepatitis B from a percutaneous exposure is significantly greater than the risk for transmission of HIV. Ensure to get the hepatitis B Ab titre of the health care worker. Hepatitis B vaccination series with hepatitis B

immunoglobulin (HBIG) must be provided for all unvaccinated, non-immune health care workers following sharps injuries or exposure to infected materials.

8.3.3 Recommended PEP regimens

Table 8-3: Summary of PEP recommendations

Risk stratification	PEP regimens	
	Preferred regimen	**Alternative regimens**
High risk exposure	TDF/3TC/DTG[1, 2]	TDF/XTC + DTG[2] **OR** RAL **OR** a PI[3] AZT/3TC + DTG[2] **OR** RAL **OR** a PI[3] ABC/3TC + DTG[2] **OR** RAL **OR** a PI[3]
Low risk exposure	TDF/FTC (3TC)	AZT/3TC ABC/3TC

[1] The preferred regimen is a fixed-dose combination of TDF, 3TC and DTG (TLD). If the FDC is not available, the preferred regimen will be TDF/XTC + DTG.

[2] Consider double dosing DTG (50 mg twice a day) in clients taking CYP450 inducers, e.g., Rifampicin

[3] The preferred PI is ATV/r, with LPV/r and DRV/r as alternatives

8.3.4 PEP regimens when the source patient has been on ART

If the source patient has been on ART and there is reason to believe the regimen is failing (i.e. clinical progression, poor immunological response, documented elevated viral load), viral resistance should be suspected. In this instance, consideration must be given to the source patient's ART regimen, and ARVs with a different resistance profile should be used for PEP:

Table 8-4: Determining PEP regimen if source patient failing on ART

Source patient's ARV regimen	Recommended PEP regimen for exposed health worker
TDF (or ABC)-based NRTI backbone	AZT-based NRTI backbone
AZT-based NRTI backbone	TDF (or ABC)-based NRTI backbone
NRTI (EFV or NVP)-based regimen	Use DTG or PI as 3rd drug
PI-based regimen	Use DTG as 3rd drug
DTG-based regimen	* Consult Clinical Mentor

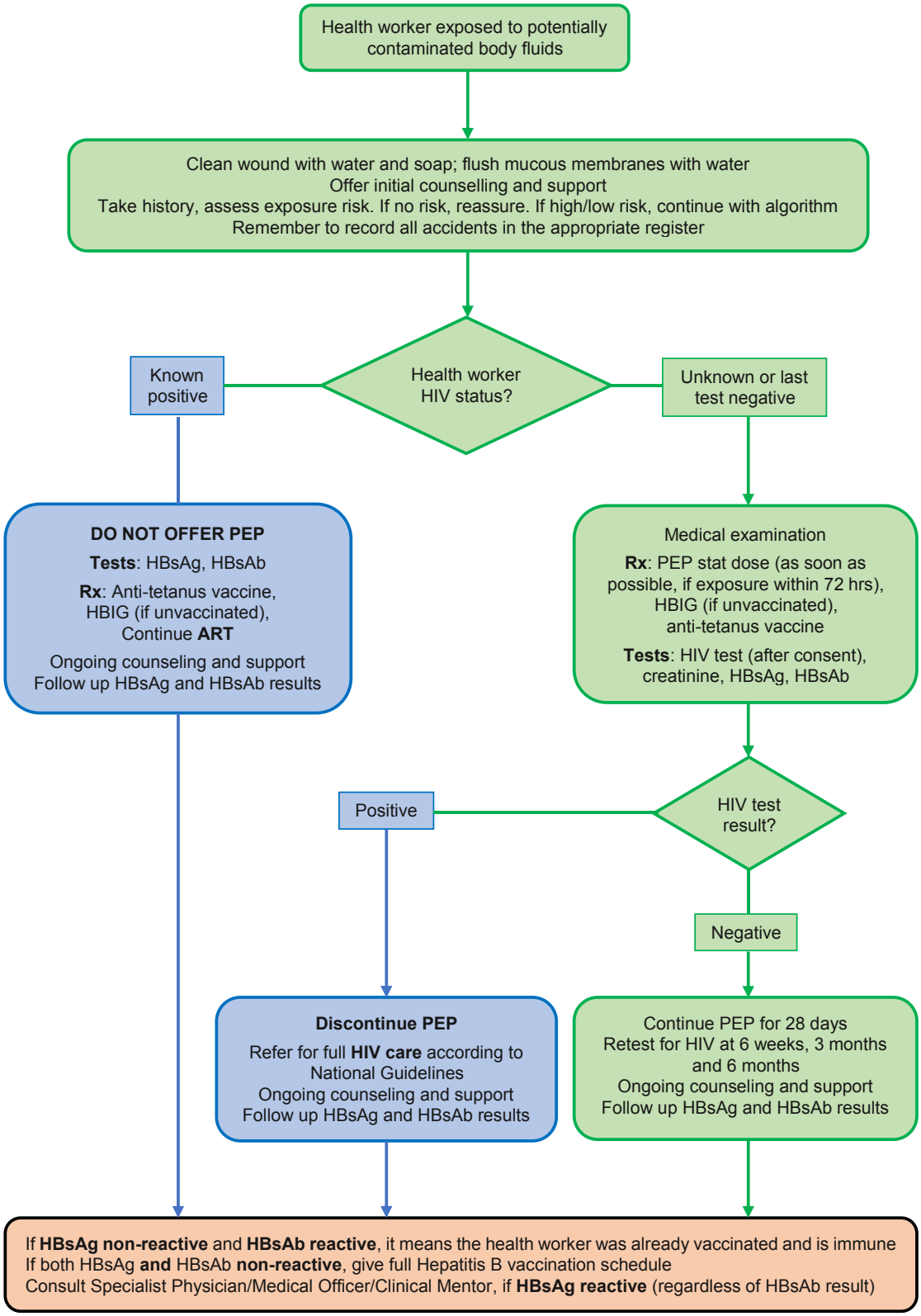
8.3.5 Accompanying measures

To ensure that the risk of occupational exposure is minimized and PEP is administered according to the guidelines, it is recommended that the following measures be taken at all facilities in the country:

- Infection control committees should be put in place.
- Strict attention should be given to the correct handling of sharps and all contaminated materials through standard precautions (e.g., no recapping or bending of needles, disposal of all sharps in solid containers, etc.).
- Staff should be fully informed about the measures to be taken following exposure to a potentially infectious body fluid. Each health facility should establish and disseminate clear procedures to ensure appropriate management following an occupational exposure.

- Monitoring of all potential exposures. For each incident, the facility supervisors should investigate the circumstances and report the findings and proposed measures to the infection control committee in order to avoid recurrence. Risks for support staff (cleaners, porters, etc.) should be minimized. Registration of accidents should be standardized and they should be regularly reported by all relevant health facilities.
- Antiretroviral medications for PEP should be made available on a 24-hour basis (for example through casualty services).
- All employees of health facilities should be vaccinated against HBV and tetanus.

Figure 8-2: Algorithm for PEP after occupational exposure



8.3.6 Prophylaxis after rape

All women, men and children presenting to a health facility after being raped should be counselled by the examining health care worker about the potential risks of HIV transmission post-rape. If the rape survivor presents within 72 hours of being raped, post-exposure prophylaxis (PEP) should be offered to prevent HIV transmission.

8.3.7 Issues to be addressed during counseling

The following issues should be addressed during counseling:

- The risk of HIV transmission is not known, but it exists.
- It is important to start PEP as soon as possible.
- For each rape survivor, blood and urine will be taken routinely to screen for syphilis, HIV and existing pregnancy.
- It is the survivor's choice to receive PEP and to have HIV testing. However, it is important for the survivor to know her/his HIV status prior to starting PEP.
- PEP will be offered if the possible risk for HIV transmission is established, the rape occurred within a period of 72 hours, and the rape survivor is HIV-negative (or results are not immediately available).
- The efficacy of PEP in preventing HIV sero-conversion in cases of sexual assault is not known.
- The common side-effects of the medicines should be explained, with particular reference to feelings of fatigue, nausea, headache, and flu-like symptoms.
- PEP should be discontinued immediately if the baseline HIV test of the survivor is confirmed to be positive, in which case the survivor will be linked to full ART care.
- The importance of adherence to treatment should be emphasized.
- Survivors should be counselled to observe precautions to prevent possible secondary transmission (for example to their sexual partner or from mother to child) until they are found to be HIV-negative 6 months following the exposure.

Survivors presenting more than 72 hours after the rape should be counselled about the possible risk of HIV transmission. It should be explained that it is highly unlikely that PEP started >72 hours after the rape will have impact on preventing HIV infection. Use shared decision-making with the survivor to determine whether HIV post-exposure prophylaxis is appropriate. If a rape survivor becomes pregnant as a result of the rape, she should be counselled on the option of termination of the pregnancy as per provisions of the Abortion and Sterilization Act, 1975 (Act No. 2 of 1975).

8.3.8 Procedures for administering PEP for rape survivors

- Lab tests:
  - HIV test
  - RPR
  - Pregnancy test
  - Hepatitis B antibody test

Note:

It may be difficult to obtain informed consent for HIV testing shortly after the rape. Explain the importance of an HIV test. If the survivor presented within 72 hours, offer a 3-day PEP starter pack and give a return appointment at the ARV clinic within three days. This will hopefully give the survivor time to think further about consenting to testing. The remainder of the 28 day PEP regimen should be given at this visit if the survivor is HIV negative or still refuses to be tested for HIV. ***In situations where the survivor of rape is unlikely to return for their test results and for re-supply of drugs; the health care work may use his/her own discretion on a case by case basis to issue a full one month supply of PEP drugs to the client.***

- Survivors who are either known to be HIV-positive or found to be HIV-positive at baseline should be appropriately counselled and referred to an ART-clinic for long-term management of HIV infection.
- Relative contraindications to the use of PEP include significant renal or liver impairment. When in doubt about the use of PEP, urgent consultation with a specialist physician or referral centre

can be sought, but care must be taken that this consultation does not unduly delay the initiation of treatment when indicated. It may be necessary to begin PEP while awaiting this consultation.

- Monitoring for toxicities due to PEP:
  - ALT and CrCl at baseline
  - Repeat after 2 weeks (or when symptoms occur)
  - If subjective or objective toxicity is noted, ARV substitution should be considered with expert consultation, and further diagnostic tests may be indicated.
- HIV serology should be done at 6 weeks, 12 weeks and 6 months. Rape survivors who become infected with HIV should receive appropriate medical care.

8.3.9 PEP regimen after rape

Rape should be considered **high risk exposure**.

Adults:

The recommended PEP regimen following rape is TDF/3TC/DTG for 28 days. See

Table 8-3 for alternative regimens. If the perpetrator is known to have a high viral load on ART, refer to Table 8.4 for choice of ARV regimen to use. If the survivor is an adolescent girl or a woman, information must be provided on the risks (including the potential risks of neural tube defects) and benefits of DTG. For women and adolescent girls who do not want to take emergency contraception or DTG, a boosted PI should be used as an alternative to DTG.

Children < 10 years old

Child survivors who are <10 years old or weigh <30 kg cannot use TDF for PEP because lower dose formulations are not available in Namibia. The regimen to be used must comprise of an NRTI backbone of AZT/3TC (or ABC/3TC if AZT cannot be used) and a 3rd drug. Choice of 3rd drug depends on the survivor's actual age and weight:

Table 8-5: Choice of 3rd drug by survivors age and weight

NRTI backborne	Age	Weight	Choice of 3rd drug (in order of preference)
AZT/3TC (preferred) ABC/3TC (alternative)	<3 years	<10 kg	RAL **OR** LPV/r
	3 – 6 years	≥10 kg	RAL **OR** LPV/r OR EFV
	≥6 years	≥15 kg	RAL **OR** LPV/r OR ATV/r
		≥20 kg	DTG[1] **OR** RAL OR LPV/r OR ATV/r

* Refer to dosing charts for appropriate weight-dependent doses!

** If the perpetrator is known to have a high viral load on ART, refer to Table 8.4 for choice of ARV regimen to use.

[1] Children weighing ≥20 kg can be given the adult dose of DTG (50mg once a day). Younger children weighing <20 kg can be given DTG if appropriate formulations are available.

Comprehensive management

It is strongly suggested that PEP be administered only in the context of a comprehensive support programme for rape survivors. This should encompass the following:

- STI treatment: presumptive treatment should be given in the form of cefixime 400 mg or ceftriaxone 250 mg IM STAT **plus** metronidazole 2 gram STAT **plus** azithromycin 1g STAT .
- Emergency contraception, as soon as possible, within 120 hours:

- **Ovral** (norgestrel 500 mcg+ ethynyl oestradiol 50 mcg) given as 2 tablets STAT **and** 2 tablets 12 hours after the first dose.
- **Levonorgestel** 1.5mg STAT (given as 1 tablet containing 1.5mg or 2 tablets containing 0.75 mg each) – only available in the private sector in Namibia.
- A **copper T IUCD**.

- Hepatitis B immunoglobulin and hepatitis B vaccination should be started as soon as possible if the rape survivor is not already immune, and no later than 21 days after the incident. If the results of the HBsAb test are non-reactive vaccinate at 0, 1, and 3 to 6 months.
- A tetanus booster should be given.
- Counselling of the rape survivor, identification of support needs, and necessary referrals should be done.
- In cases where rape survivors have severe bleeding, the issue of proper nutrition with regards to foods that are high in iron, folate, riboflavin, vitamin A and vitamin B12 to avoid developing anaemia should be emphasized.
- In subsequent visits, issues relating to stress management should be discussed as part of the support programme. Since stress may cause illness related to physical and mental exhaustion, the survivor should be made aware of stress indicators such as general irritability, trembling, pain in the neck or back and changes in appetite or sleeping patterns.
- Medico-legal assessment of injuries.
- Completion of appropriate registers.

It is recognized that children who experience rape need ongoing, comprehensive support. Where there is any suggestion that a child has been raped, the case should be referred to an experienced pediatrician. Full assessment of physical injuries must be performed, STI prophylaxis will need to be adjusted using pediatric doses, and psychological and emotional support must be initiated systematically.

8.4 Post-exposure prophylaxis in other situations

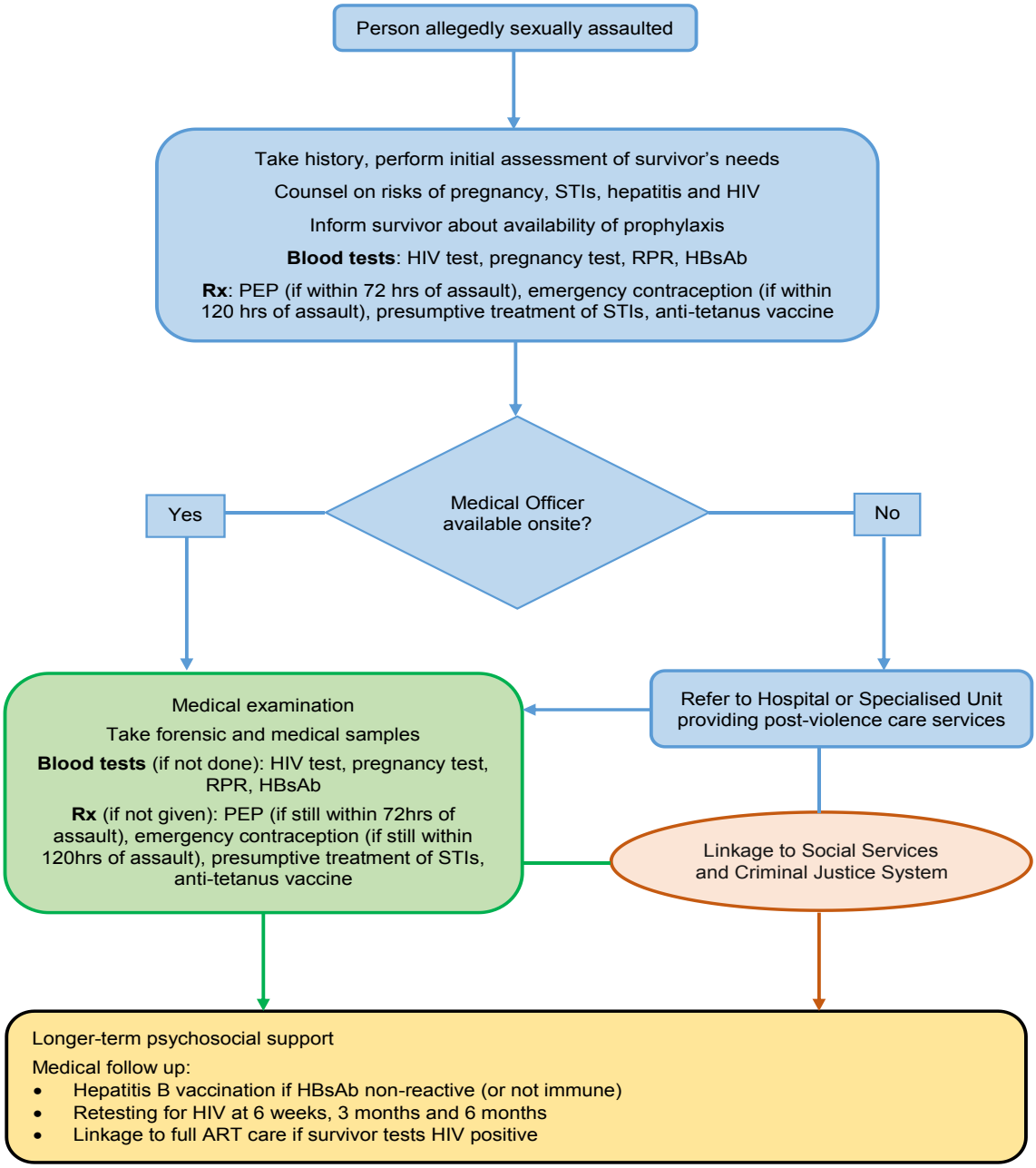
8.4.1 Accidental sexual exposure

It is recognized that clients sometimes present to health facilities after having had unprotected sex (or 'burst condom') with a partner of known HIV positive status or unknown serostatus. If the client presents within 72 hours, clinicians should offer PEP, but counseling concerning correct condom use and risky behavior is essential. PEP regimen is the same as for rape. For repeated accidental sexual exposure, offer PrEP and discuss with the client that they need to take it for as long as he/she is experiencing repeated HIV exposure.

8.4.2 Accidents

Where there is exposure to blood or body fluids such as at the scene of a motor vehicle accident or injuries caused by human bites, clinicians should assess the level of exposure risk. The occupational exposure algorithm (Figure 8.3.1.1) can also be used in these situations.

Figure 8-3: Algorithm for PEP for Rape Survivor



***Note**: Usually, survivors will report to the police before coming to the health facility. However, a police report **is not** a prerequisite to receiving essential emergency post-violence care at a health facility. PEP and emergency contraception are more effective when given early. These must be given as soon as possible, before referral to the police and/or to a higher level of care. Nevertheless, due caution must be taken not to contaminate or destroy crucial evidence.*

9 DIFFERENTIATED SERVICES DELIVERY

9.1 Introduction

This chapter aims at providing guidance to programme managers and service providers on the "Differentiated service delivery" models based on the WHO differentiated implementation framework (section 9.1.1).

Differentiated care is a client-centered approach that simplifies and adapts HIV services across the cascade to reflect the healthcare needs, preferences and expectations of various groups of people living with HIV (PLHIV) while reducing unnecessary burdens on the health system. The health system can refocus resources to those most in need by providing differentiated care. As summarized in Figure 9-1 and 9.1.3, WHO has grouped patients into four categories below:

- People presenting "well" (early disease)
- People with 'advanced' disease
- Clinically Stable
- Clinically unstable

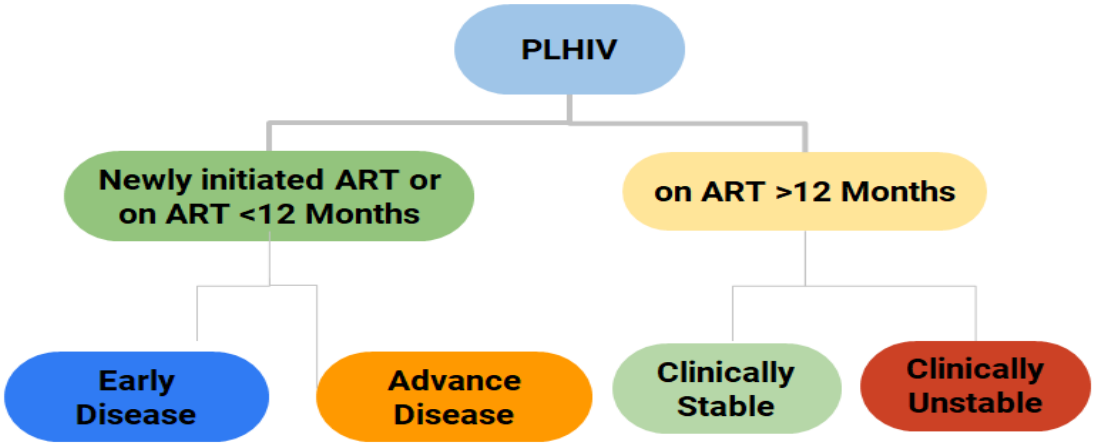
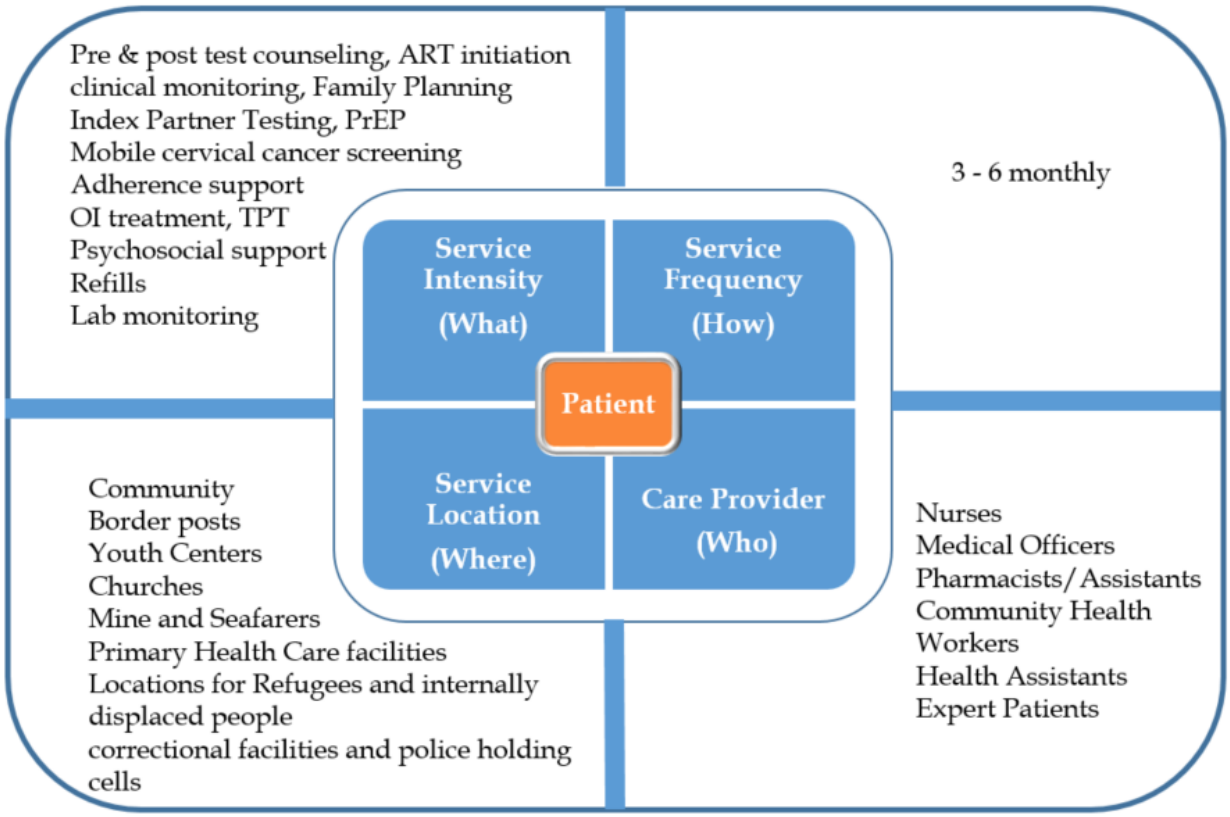


Figure 9-1: WHO classification of patients

People Presenting As Early Disease ("Well")	• Clients with early HIV disease • Enrolled on care but have no OIs • Relatively have high CD4 counts
Clinically Stable patients	• A patient is considered clinically stable if they have been on **ART for >12 months**, is **virally suppressed** with a viral load of (<40 copies/mL) from the recent viral load results within the past 12 months. The patient **should not have any current adverse drug reactions** (ADRs); **no current illness/ conditions** such as malnutrition, mental health condition, alcohol and or substance abuse or any other condition that requires frequent clinic visits. The patient should have a **good understanding of lifelong adherence**. • Children 2 years and older who meet the above description whose parents and or guardians are part of DSD models may have their child/children seen with them in any DSD models. • **Pregnant and breastfeeding women** who were stable on ART before the current pregnancy and are virally suppressed.

People Presenting As Advanced Disease	• Late HIV disease • Immunologically compromised • Require more intense care and regular follow up • Clinical for reducing morbidity and mortality
Clinically Unstable patients	• All general adult patients, children < 2 years, pregnant and breastfeeding who did not meet the above criteria. However, clinician's discretion, informed by patient's informed decision should guide the decision to determine the appropriate DSD care model for this group of patients, mainly facility-based models.

Figure 9-2: Implementation Framework for Differentiated Service Delivery Models



9.2 Key considerations and special populations

Children under 2 years of age, this population needs more frequent clinical consultations and refill visits due to weight changes and need for medication dosage adjustments, hence they may not be sent into out-of facility models or have more than 3 months of ART refills.

Children 2 years and older; this group could be considered for DSD based on the clinician's discretion and the parent or guardian's informed decision.

Adolescents: consider 2 clinical visits per year, this will provide sufficient opportunity for a clinician to identify and assess adherence, any newly arising psychosocial issues, mental health conditions, sexual and reproductive health needs. Clinical consultations should be scheduled during school holidays. Where possible adolescent- friendly services hours could be considered to support adolescents access to services after school hours.

Pregnant and breastfeeding women: Pregnant and breastfeeding women who have been stable on ART before falling pregnant, consider 3-month clinical visits with 3- monthly refills. It is emphasized that pregnant and breast-feeding women should maintain their scheduled ANC visits.

Cross-border, Migrant and Displaced patients - It is recommended that this population should have an annual clinical consultation and receive 6 monthly medicines refills. Where applicable they could be enrolled in community-based models.

People in correctional facilities: It is recommended that they have 3 monthly clinical consultations and refills.

Mines workers and seafarers: Consider annual clinical visits and 6 monthly medicines refills. Where applicable they could be enrolled in Community-based models in Namibia closer to where they live.

Other Key populations (FSWs; MSMs, LGBT): This population can be enrolled in any DSD models of their choice based on clinical eligibility.

Clinically unstable patients on ART: This group of patients should be carefully screened; taking into consideration the risks versus the benefits of keeping the patient in the standard care model or enrolling them in a differentiated service delivery model care. Providers should take note that some patients are unstable because they are not able to travel to the facility for the follow-up care. For patients with clearly treatment failure and alcohol or substance abuse leading to being unstable; these groups of patients must be seen at the facility.

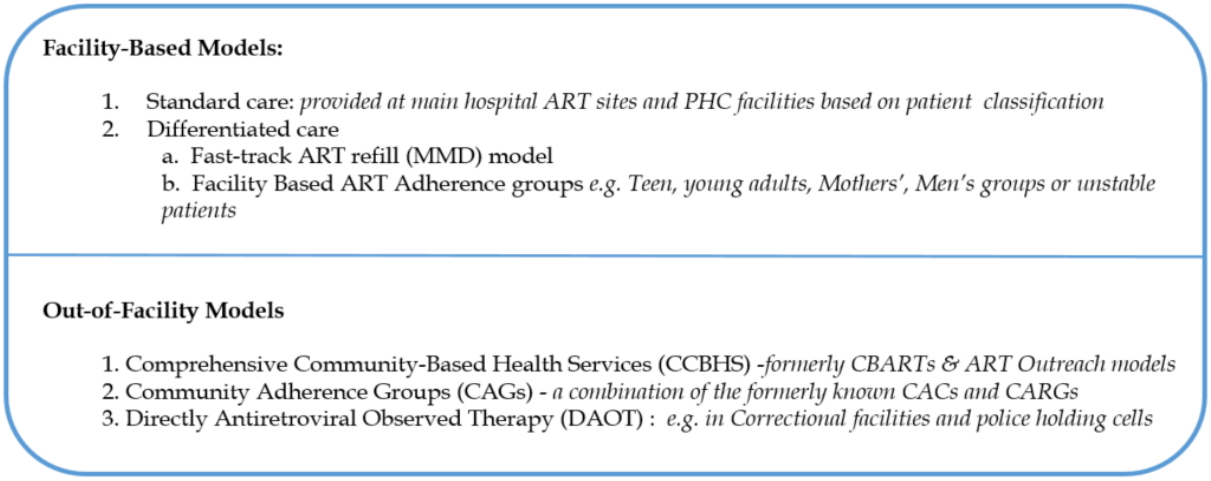
Newly HIV diagnosed in Out-of-facility models: For patients tested and newly diagnosed with HIV in Community-based Testing outreach programs or other out-of facility models; or tested in the past but still pre-ART when seen in an out-of-facility model, consider providing Pre-pack ARVs for 1 month, do baseline investigations and actively link the patient to the nearest facility for further management until they are stable to be down referred back to out-facility models. Patient records should be managed accordingly. For all newly HIV diagnosed patients; trace index partners as per the national guidelines for index partner testing.

Pre-Exposure Prophylaxis (PrEP): For patients seen in Comprehensive Community-based model with perceived high risk of contracting HIV, consider providing PrEP as per national Guidelines for PrEP and actively link them to the nearest facility. Patient monitoring and records should be managed accordingly.

PEP: For patients seen in Comprehensive Community-based model in need of PEP, consider providing PrEP as per the national Guidelines for PrEP and actively link to the nearest facility. Patient monitoring and records should be managed accordingly.

9.3 Type of differentiated HIV Service Delivery Models in Namibia and packages of service

Figure 9-3: Type of differentiated Service Delivery Models



Please refer to section 10.2.3 for more detailed information on dispensing

Facility teams are encouraged to modify or create new approaches that are responsive to the needs of their patients, communities and facility.

9.3.1 Definitions

Facility- Based

Fast Track Refill Model (FARM): FARM means issuing multi-months ARV refill to stable patients for up to 6 months depending on stock availability and the ability of the patient to store the medicines under optimal storage conditions.

Facility Based ART Adherence Groups: Led by expert clients: Adherence groups established in health facilities can be used as ARV drug distribution platforms reducing the burden on facilities.

Out of Facility

Comprehensive Community Based Health Services (CCBHS): This refers to places were community-based antiretroviral therapy is carried out. These are places in the community where on a pre-defined schedule; a team from the hospital carries out appropriate examinations and provides ART refills to patients who have gathered there for that purpose.

Community Adherence Groups: CAGs are self-forming groups of HIV-positive persons (who are on ARVs), living in the same community and organized in groups of 5-15 members. These members take turns to pick up ARVs at the health facility and distribute them among the other group members in the community. The members of the CAGs manage their own health and share experiences about living positive with HIV.

Community Based Client Led ARV Distribution Groups: These are self-formed PLHIV support groups whereby 5-15 people are trained, mentored and supported to enable them to collect and distribute ARVs medicine. Health facilities make special arrangements with such groups making sure client monitoring and data is not compromised.

Directly Observed Antiretroviral Therapy (DOAT)

DOAT means the patient takes their medication every day under the observation of a health care worker or a trained officer e.g. in Correctional Facilities and Police Holding Cells.

Table 9-1: Facility based models

Models	Criteria	Care Provider	Services Intensity & Frequency
Fast Track Refill Model (FARM)	• 18 years & above • VL of <40 copies/ml in two previous consecutive tests • No Opportunistic Infections (OIs) • On ART > 12 months, • On 1st or 2nd line ART • Not pregnant or breastfeeding • capacity to store and take care of medicines appropriately • On appropriate OI prophylaxis	• Nurses • Pharmacist	• Consultation and VL test once per year • Blood tests to be done one month prior to scheduled consultation date • One year prescription • ART refill every 6 months, client must go direct to the pharmacy for refill if no complain
Facility Based ART Adherence groups (Teen group, Young Adults, Mothers', Men's groups, etc.)	• Stable and Unstable patients	• Doctors • Nurses • Health Assistants • Pharmacists • Pharmacist Assistants • Social Workers	• Follow-up and refill is up to 3 months (depending on facility and team arrangements) • ART follow up and adherence counseling • Health education (alcohol, drugs misuse, nutrition) & SRH information • Creational activities • Life skills • Career guidance • Educational positive living • Family Planning • Psychosocial support • Cervical cancer screening • Disclosure to partners & PrEP services (HTS) • Index Partner solicitation and testing

Table 9-2: Out of Facility based Models

Models	Criteria	Care Provider	Services	Frequency of visit
Comprehensive Community-Based Health Services (CCBHS)	• All clients regardless of VL results or duration of being on ART • Willingness • No children > 2 years	• Minimum • NIMART Nurse • Health Assistants • Pharmaceutical personnel • If need be: • Mentors • Doctors • CHW • TB Field promoter • Social worker	• Minimum • HTS & PrEP • VMMC (referral) • ART Initiation & follow up • TB screening & TPT • Pediatric disclosure • Nutritional assessment and growth monitoring • NCDs screening • Family planning • If need be: • ANC & PNC • Immunization • Psychosocial support	Monthly (strictly)
Adolescents and young adults groups in CCBHS	• 10 to 19 years old and 20 to 24 years old • Fully disclosed to (teens) • On ART for 6 months • Irrespective of VL test result • Guardians 'consent (teens) • Willingness	• Friendly NIMART Nurse • (Ped trained) • HAs • Pharmacy personnel • Social workers • Mentors	• ART follow up and adherence counseling • Health education & SRH information (age) • Family Planning • Recreational activities • Psychosocial support • Health education (alcohol, drugs misuse, nutrition) & SRH information • Creational activities • Life skills	Monthly

			• Career guidance • Educational positive living • FP • Psychosocial support • Cervical cancer screening • Disclosure to partners & PrEP services (HTS)	
CAGs	• Patient must be: • ≥18 years of age • On ART for >12 months • Virally suppressed (two most recent consecutive viral loads should be <40 copies/mL) or target not detected (TND) • No signs of opportunistic infections (no current active Tuberculosis) • No medical condition requiring regular clinical consultations • Had at least two ART visits at the facility in case of transfer in clients • Clinicians confirm the client's eligibility for membership • Membership is voluntary	• Peer Educators/ Expert Patients • Community Health Workers	• Pill pick up • H/E • Support group activities	• Minimum 1 clinical visit every 12 months for each CAG member • 3 monthly pill pick up
Directly Antiretroviral Observed Therapy (DAOT) for correctional Facilities and Police Holding Cells	• For patient in Correctional facilities and Holding cells where keeping of large qualities of medications is limited • For patients in institutions with mental conditions • For seriously ill patients • Patients on TB DOT can also benefit from DAOT	• Nurses • Correctional Officers	• Services provided is based on the patients' WHO classification • ARVs are administer daily or based on the institution's policy and directives	As per patient classification

The following standard practices are recommended for dispensing of ARV across the differentiated care sites:

Table 9-3: Dispensing ARV medicines

Models	Clinical Consultation	Prescription	Dispensing duration	Collection or pick up point
Standard Care	Annually*	6 monthly	3-6 month	Facility level pharmacy
Fast track & MMD	Annually*	6 monthly	3-6 month	Facility level pharmacy
Adherence clubs & CCBS	Annually*	6 monthly	3-6 month	Adherence clubs CCBHS site
DAOT	1-12 Months	1-6 monthly	1-3 month	Police Holding Cells & Correctional Facility' Mental institutions

Note: * Frequency of consultation, Prescription and dispensing duration depends on whether the patient is stable or unstable.

9.3.2 Considerations for down-referral and up-referral to and from facility-based care

Down-referral: This refers to patients being invited and enrolled to receive care in an out- of- facility site after ART initiation and in some cases a suitable period of observation on treatment.

Up-referral: Patients receiving care in an out-of facility models being referred back to the facility (hospital/Health Centre/Clinic). This may be because of poor adherence, treatment failure or having symptoms of other conditions, e.g. tuberculosis or related to patient's preference. The reason for down-referral must documented.

Take appropriate actions and treat for the confirmed diagnoses, if the patient is seriously ill consider referral back to the hospital/facility based model. Any child, adolescent, or pregnant or breastfeeding woman receiving care through ART differentiated care should be referred for intensified care if they have:

- An acute illness requiring more frequent clinical management, including but not limited to developing a co-morbidity or co-infection, an adverse drug reaction or malnutrition in children;
- VL above a 1000 copies/ml;
- Psychosocial related issue/s or mental health disorders requiring more intense support/management.
- Harmful drug or alcohol use that affects adherence to ART
- As per patient's preference

Routine ARV refills

Unless there are special circumstances, health care workers involved in dispensing of ARVs should dispense 3-6 months' supply of ARVs to stable patients. Special considerations will be made to clients on a case by case basis (patients who will be at sea or abroad for more than 6 months) e.g. migrant workers, students and soldiers.

In transit patients

All in transit patients that visit ART sites including out-of-facility models should be supplied with ARVs ideally for 3-6 months based on prescription schedule in their health passport at the sites they are visiting. Documentation is critical. All recommendations for in-transit patients apply as per national guidelines.

9.3.3 Managing Quality Improvement for DSD

Quality of care provided to patients under DSDs should not be compromised at any point. All patients must be managed according to the ART guidelines and receive all services regardless of the point of service delivery, please refer to the SOP for DSD.

9.3.4 Monitoring and Evaluation

The monitoring and evaluation framework for differentiated service delivery will be nested in the existing monitoring and evaluation platforms for HIV care and treatment services. Each care and treatment model will have a few additional paper-based and electronic tools. There is need for quality assurance to ensure clients in differentiated service models receive quality service and monitored similarly to patients under routine facility-based care.

10 MEDICINES MANAGEMENT AND PATIENT SAFETY

10.1 Introduction

The uninterrupted availability of medicines is an essential part of any health care system, but even more critical to the success of any HIV treatment program with the aim of achieving and maintaining durable undetectable viral suppression among PLHIV. Ensuring an effective ARV medicine supply management system is one of the critical sub-components of the strategy to control the HIV pandemic. The non-availability of ARVs to PLHIV can contribute to the emergence of HIV drug resistance requiring more costly and complex therapies to manage patients. Moreover, it undermines the credibility of the health system from the perspective of the patient and the community. In addition, new medicines are being introduced into the HIV treatment program whose safety is not well documented; therefore the need for patient safety monitoring is paramount.

Pharmacy staff and other health-care workers responsible for medicines supply and dispensing at all levels should be familiar with all the pharmaceutical management tools namely;

- Managing Pharmaceutical Stores Manual
- Procurement SOPs
- Pharmaceutical Standard Operating Procedures
- Electronic Dispensing Tool (EDT)
- Manual and Electronic Stock Card Tools (FESC)
- Pharmaceutical Management Information Dashboard System
- Adverse Drug Reaction Reporting Tools

This chapter only highlights some of the most critical aspects as they relate to the management of ARVs and related health commodities as well as patient safety. Pharmacy staff and other health-care workers should take the responsibility for the provision of an uninterrupted supply of medicines and monitoring and reporting of patient safety.

10.2 Stock management

The most important tool for effective stock control is the proper maintenance of up-to-date stock cards, whether manual or electronic. A proper stock control system which is documented by the effective use of stock cards deals with three main steps in the medicine supply cycle at facility level:

Figure 10-1: Facility level medicine supply cycle

10.3 Ordering of ARVs medicines and related supplies

Medicines need to be ordered at regular intervals as determined by the ordering schedule prescribed by the central or regional medical depots. The quantity of ARV medicines required by a health facility is directly related to the number of ART patients registered at the facility. Therefore, any increase or decrease in the number of ART patients registered at the facility will necessitate adjustments in future orders for ARVs. If **too much** of an item is ordered, then medicines which might be needed urgently elsewhere will pile up on shelves and eventually expire. In such instances of overstocking; pharmacy staff should liaise with neighbouring facilities to redistribute the medicines. If **too little** is ordered, then patients may fail to access the right quantities of the required medicines. During periods of transition to new optimal ARV medicines and formulations, staff responsible for ordering must carefully quantify the requirements for new medicines being phased in and old formulations that are being phased out and then order appropriately.

Figure 10-2: Forecasting and supply planning by the CMS

Proper forecasting and supply planning should be done by the CMS and adhere to set timelines (Pipeline)

- Orders must be based on number of patients and their respective ART regimens
- Consider whether a product is being newly introduced, being scaled up or being phased out
- Know when the order is to be placed and then make sure that the orders are completed and submitted on time according to applicable standard operating procedures
- Ensure products are ordered using the correct pack sizes

10.4 Receiving and storage of ARVs

ARVs are supplied along with other medicines but have a separate delivery note against which the shipment should be verified at the time of receipt. During verification, the consignment should be checked to ensure conformity with ordered quantities. If there are any problems with the quantity, type, expiry date or condition of any items received then staff should immediately contact the supplying facility by telephone to report the problem. In addition, Goods Discrepancy Report Form should be completed; with one copy kept at the facility for future reference while another copy sent to the supplying facility. Like other medicines, ARVs should be stored below 25°C and those that require cold storage like Lopinavir/ritonavir oral solution should be stored in a refrigerator until dispensed.

10.5 Dispensing of ARVs

The following standard practices are the general recommendations for dispensing of ARVs at health facilities and at community outreach sites.

- The duration of all routine refill prescriptions for ARVs must be based on a monthly cycle of **28 days** (four-week cycle) in order to have a consistent appointment schedule
- The dispensing of ARVs must also follow the prescribed 28-day cycle and multiples of four-week cycles in case of multiple month dispensing
- The pill count and dispensed quantities must be well documented in the patient's health passport and also be captured on the EDT
- The patient follow-up appointment date must be clearly indicated in the patient passport
- Dispensers are encouraged to dispense full unopened patient packs/bottles whenever possible
- Prescribers must facilitate the dispensing of full packs of medicine when determining appointment dates
- Dispensers should counsel patients on what to do if they experience side effects or adverse reactions
- Dispensers should counsel caregivers on the correct administration of child-friendly formulations such as dispersible tablets and granules
- Medicines for prophylaxis against opportunistic infections such as TB preventive therapy and co-trimoxazole prophylaxis should be refilled along with the routine ARV refills.

10.6 Multiple month dispensing

Multiple months dispensing (MMD) is one of the new service delivery models that aim to reduce clinic visits and ARV pick-up appointments for clinically stable patients on ART. It entails moving to, or expanding the national approach to providing 3 months to up to six months' supply of ARVs. The rationale for multiple month dispensing is to:

- Reduce patient visits to health facilities and the resultant decongestion at facilities
- Improve adherence by reducing the frequency of visits to health facilities
- Enable health facilities to manage the higher number of patients expected from the implementation of Test and Start
- Reduce patient costs to access ARVs, for example, travel costs to visit health facilities

- Improve the efficiency of the supply chain

Figure 10-3: Basic eligibility criteria for MMD

A patient that meets the following basic eligibility criteria is eligible for MMD:
- is virally suppressed (less than 40 copies/ml on two previous consecutive tests),
- has no opportunistic infections (OIs) or other debilitating co-morbidities
- has been on ART for more than 12 months

Once clinicians are satisfied that the patient meets these basic criteria, they will prescribe for up to 12 months and the pharmacy will dispense ART for 3-6 months according to patient individual characteristics and give a follow up date.

Table 10-1: Follow-up after initial MMD dispensing

Guidance on MMD
• Clinicians assess eligibility of patients for MMD based on the criteria stipulated above • Clinicians and health assistants should provide adequate counselling • Pharmacy staff should dispense up to 3- 6-month supply of ARVs for patients that qualify for MMD depending on stock availability at the pharmacy • Clinicians and pharmacy staff should double check adherence measures including pill counts and viral load suppression and ascertain that the client is stable • Pharmacy staff should counsel patients on proper storage conditions for medicines and including safety (out of reach of children). Patients should be educated on good medicines storage practices • In all cases, the pharmacy staff must maintain an accurate electronic record of the quantity of ARVs dispensed and give an appropriate follow-up date • Dispensed ARVs should have a remaining shelf life of at least 6 months
Exclusion criteria for MMD
• Severe malnutrition • Repeated or frequent incidents of lost medicines by the client • Inability to store medicines under appropriate storage conditions • Occurrence of adverse drug reactions that require regular monitoring • Evidence of non-adherence to treatment such as increasing viral load • Any patient presenting with advanced disease • Any patient requiring medical supervision

The Pharmacy staff will then dispense a multi-month refill for up to 6 months depending on stock availability and the ability of the patient to store the medicines under adequate storage conditions.

For purposes of making it easier for the pharmacy and clients to manage their stock:

- New packaging of ARVs in 90-tablet bottles (and even 180-tablet bottles) is now available in the market. Once these are made available by CMS, they will be the preferred pack sizes for multi-month dispensing
- Carton-less containers will also be introduced to save cost and storage space
- As these packages are introduced, pharmacy staff should treat the new pack sizes as a separate line items or products when forecasting and generating orders for their health facilities.
- Pharmacists and other health care workers should inform patients about the benefits of the 90-tablet or 180-tablet bottles to enhance user acceptance.

Cross-border, displaced ART patients who meet the "stable patient" criteria are also eli

10.7 Supply chain implications for MMD

It is important to note that patients will consume the same quantities of ARVs in a year whether they are re-supplied monthly or less frequently. This is true regardless of whether health staff dispense one bottle per month, three bottles every three months, four bottles every four months or six bottles twice a year. Over the long term, once multiple month dispensing becomes the norm, no additional quantities are required in the delivery system (central medical stores, regional medical stores and facility level in aggregate) to meet the forecast consumption of the stable patient population. However, the quantities of ARVs in stock at facilities will need to be adjusted upwards by the facility for the initiation of multiple month dispensing. Currently, most stable patients in Namibia receive three month refills of ARVs at every visit.

At the initiation of multiple months dispensing, stock on hand at facility level will need to be higher than usual during the period of transition from three months to six months dispensing. Analysis shows that the maximum additional stock required at a health facility prior to initiation of MMD when moving from three months to six months dispensing is 1.5 months of stock.

The additional stock needs to be available only for the initial three months after which the quantity dispensed to all ART patients should settle down to the same level as before. This additional 1.5 months of stock needs to be pre-positioned at health facilities prior to implementation of 6 monthly dispensing.

In transit patients

All in-transit patients that visit ART sites should ideally be supplied with ARVs for no more than one month at the ART sites they are visiting. A patient who is planning to be in-transit at another facility for more than one month should obtain a transfer-out letter from the original facility and be officially transferred in to the new facility. The transit facility should request transfer letters from the original sites. With MMD, we anticipate there will less need for in-transit refills.

Other recommendations

Pill counts should be done routinely for all patients at each encounter with a health worker and the number of remaining pills should be entered in the appropriate data capturing tools and the health passport. Left over medicines should be given back to the patient to continue using unless they are soiled, broken or expired, in which case they should be discarded; in both cases, this should be recorded in the data capturing tool. ARVs should be dispensed in their original packaging at all times; addition or removal of tablets is not recommended. For deceased patients, relatives or treatment supporters should be encouraged to return medicines to the nearest pharmacy/dispensary for safe disposal.

10.8 Monitoring Patient Safety during ART

This guideline introduces the routine use of new medicines such as dolutegravir and tenofovir alafenamide whose safety profile is not well documented. Therefore, pharmacovigilance activities should be incorporated in the ART program to ensure patient safety.

Definitions:

The following definitions have been adapted from the Namibia *National Guidelines for Medicine Safety Surveillance* published by the Namibia Medicines Regulatory **Council (NMRC).**

Pharmacovigilance (PhV): is the science and activities relating to the detection, assessment, understanding, and prevention of adverse events (AEs) or any other possible medicine-related

problems; recently, its concerns have been widened to include herbals, traditional and complementary medicines, blood products, biologicals, vaccines and medical devices.

Adverse Drug Reaction (ADR): a noxious and unintended response to a medicine that occurs at a dose normally used in humans for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function; the term AMR should be reserved for harmful or seriously unpleasant effects that call for a reduction in the dosage, a withdrawal of the medicine, and/or a forecast of hazard from future administration.

Adverse event: Any negative or harmful occurrence that takes place during treatment, that may or may not be associated with a medicine. *Note*. A fall could be such an event that may – or may not – have any association with a medicine.

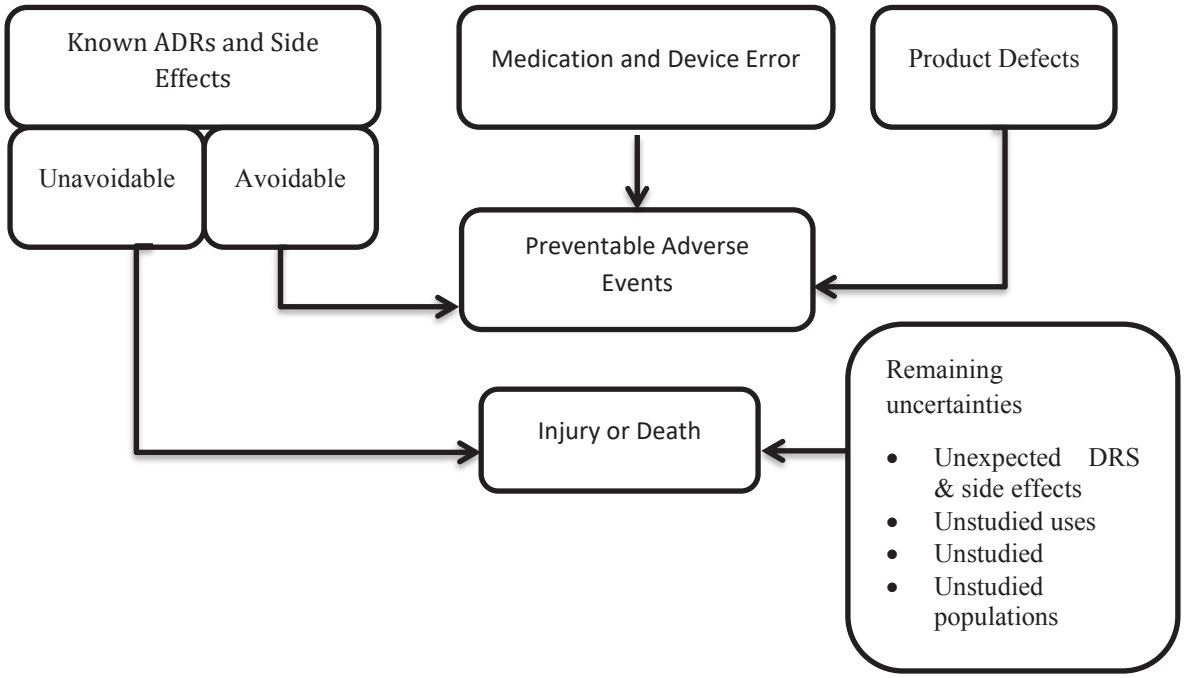
Medication error: any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer; such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use

Serious adverse event: any untoward occurrence that is life threatening or fatal, causes or prolongs hospital admission causes persistent incapacity or disability, causes misuse or dependence, and causes a congenital anomaly or birth defect.

Side effect: any unintended effect of a pharmaceutical product occurring at doses normally used in man, which is related to the pharmacological proprieties of the medicine.

Medicine safety surveillance*:* the processes involved in the collection, collation, analysis, and dissemination of data and other activities carried out in relation to safeguarding the safety and effectiveness of pharmaceuticals and related products.

Figure 10-4: Schematic presentation of preventable and unavoidable adverse events (Source: National Guidelines for Medicine Safety Surveillance)



10.9 Monitoring Adverse Drug Reactions

ADR reports, for the most part, are only suspected associations. A temporal or possible association is sufficient for a report to be made. Reporting an ADR does not imply a causal link.

ADRs that should be reported include all suspected adverse drug reactions, which are:

- **All suspected reactions to new medicines -** reactions to recently marketed medicines (on the market for less than five years) regardless of their nature or severity
- Unknown or unexpected reactions regardless of their severity i.e. not consistent with product information or labeling;
- Serious adverse drug reaction
- Unexpected therapeutic effects
- All suspected medicine interaction
- Product quality problems
- Treatment failure
- Medication errors

10.9.1 Adverse Reactions Associated with Antiretroviral Medicines

No medicine is 100% safe. Antiretrovirals, like other medicines, may cause adverse drug reactions (ADRs). This section provides information on the ADRs associated with ARV medicines, and the recommended clinical management. Like all medication toxicities, antiretroviral toxicities are categorized according to severity. The categories are: mild (grade 1), moderate (grade 2), severe (grade 3), life-threatening (grade 4) and death related to the adverse reaction (grade 5).

Some toxicities are class-related while others are related to one particular ARV. The frequency and severity of class related toxicities also vary among medicines within the same class. **Clinicians working with patients on ART should be aware of the common and serious adverse reactions associated with these medications and to immediately report any medicine adverse reactions to the Therapeutics Information and Pharmacovigilance Center (TIPC) using the appropriate form**. See Appendix 10 for the Adverse Medicine Reaction Reporting Form. Some serious ART-related toxicities are summarized in Table 10.1 below along with ART management recommendations. Management of specific toxicities is in the following section.

Table 10-2: ARV-Associated Adverse Medicine Reaction and Recommended ARV Substitution

Adverse Medicine Reaction	Associated agent(s)	Common signs	Clinical management /ARV Substitution
Potentially fatal adverse effects			
Renal toxicity (renal tubular dysfunction)	TDF	Often asymptomatic, occasionally decreased urine output, Fluid retention, causing swelling in your legs, ankles or feet	If HBV-co-infected, decrease dose of TDF according to the dose adjustment table for renal insufficiency (Appendix 5). If not HBV co-infected, change TDF to ABC Do not initiate TDF at an estimated glomerular filtration rate of <50 mL/min, uncontrolled hypertension, untreated diabetes or kidney failure
Hematological toxicity (bone marrow suppression: macrocytic anemia or neutropenia)	AZT	Dizziness, syncope, palpitations, chest pain, shortness of breath, pale skin, menorrhagia in females, inability to	Patients initiating AZT require Hb to be monitored for the first 3 months. a) Substitute AZT with TDF if Hb falls below 8mg/dl or more than 25% within the first 3 months of treatment or

		concentrate, cold hands and feet	b) Substitute AZT with TDF if more than 3 months after start of treatment, if recent VL in last 6 months is <40 copies/ml
Toxic epidermal necrolysis (TEN) or Steven's Johnsons Syndrome	NVP, EFV-less commonly RAL DRV/r	Diffuse, moist desquamation, maculopapular rash involving mucous membranes. Skin peeling leading to formation of painful sores, flu-like symptoms	Stop immediately. Never re-challenge. After resolution, resume ART with a boosted PI instead of an NNRTI
Skin rash with or without hypersensitivity reaction	ABC DTG	Pyrexia and rash, malaise, nausea, headache, myalgia, arthralgia, diarrhea, shortness of breath , systemic anaphylaxis, arthralgia	Stop Immediately. Never re-challenge. After resolution, resume ART with TDF. If cannot use TDF, and if <3 months since start of ART, use AZT or consult an HIV specialist
	RAL		Stop Immediately. Never re-challenge. Substitute with non- INSTI.
	NVP EFV-less commonly		For mild to moderate rash, substitute NVP with EFV
Lactic acidosis	All NRTIs (particularly AZT)	Gradual onset of nausea/emesis, unexplained weight loss, fatigue, dyspnoea (late) motor weakness, and may include mental status changes and organ failure.	Stop immediately After resolution, check latest VL; if done < 6 months *prior to* the adverse event and if VL was <40copies/ml, resume ART with TDF; if cannot use TDF, give ABC. If VL was not suppressed, discuss with an HIV specialist
Hepatotoxicity; Hepatitis	All ARVs (particularly ATV/r)	Jaundice due to unconjugated hyperbilirubinaemia, hepatomegaly, elevation of liver enzymes, darkened urine and stool, abdominal pain, diarrhoea, nausea, vomiting & pyrexia	Jaundice is clinically benign but potentially stigmatizing. Reassure the patient and substitute ONLY if adherence is compromised. If ALT is >5 times the upper limit of normal, discontinue ART and monitor. After resolution, restart ART, replacing the causative drug.
Electrocardiographic abnormalities	ATV/r LPV/r	PR and QRS interval prolongation; Concomitant use of other drugs that may prolong the PR or QRS intervals	Use with caution for people with pre-existing conduction disease or taking concomitant drugs that may prolong the PR or QRS intervals.
Disabling adverse effects			
Peripheral neuropathy	All NRTIs	Distal extremity painful dysesthesias, allodynia, severe burning pain, pins and needles sensations	Symptomatic treatment
Osteonecrosis/ Osteoporosis	Origin uncertain (TDF, PIs)	Bone pain or tenderness, limited range of motion, joint stiffness, or limping, muscle spasms, progressive bone damage leading to bone collapse, neck or low back pain, loss of height, stooped posture	Manage osteoporosis

Male gynaecomastia	EFV, PIs	Significant enlargement of breasts; painful breast tissue	Substitute EFV with DTG or boosted PI
Neuropsychiatric changes	EFV, RAL, DTG	Abnormal dreams, Depression, suicidal ideation, or mental confusion; Insomnia especially in females older than 60 years using DTG	Dreams are usually self-limited, without the need to discontinue ART. New onset depression, psychiatric illness or suicidal ideation replace EFV with a PI, For insomnia with DTG, consider morning dose or substitute with EFV, boosted PI or RAL.
Long-term adverse effects			
Lipoatrophy and lipodystrophy	NRTIs d4T> AZT All PIs and EFV INSTI (RAL, DTG)	Significant loss of subcutaneous fat; abnormal fat distribution	Replace suspected ARV with less toxic agent
Dyslipidemia	All NRTIs, All PIs and EFV DTG	Asymptomatic	Consider replacing the suspected ARV. *NB: currently lipids and cholesterol not monitored routinely in the state sector*
Insulin resistance; pancreatitis	All PIs AZT	Polyuria, polydipsia, polyphagia, unexplained weight loss, and fatigue or weakness	Substitute with another therapeutic class (DTG or RAL).
Myopathy	AZT, RAL	Muscle pain, weakness, rhabdomyolysis	Do CPK. If elevated stop the ARV and discuss with a clinical mentor or specialist

10.10 Medicine safety surveillance methods

10.10.1 Spontaneous surveillance

Also known as spontaneous reporting systems: a system whereby case reports of adverse medicine events are voluntarily submitted by health professionals, patients, and pharmaceutical manufacturers to the national medicine regulatory authority/TIPC. Voluntary, passive reporting of suspected adverse events during routine clinical practice should be done using the safety yellow forms (see Appendix 10).

10.10.2 Active surveillance

Active surveillance safety studies are usually conducted for the purpose of identifying previously unrecognized safety concerns (hypothesis ***generation), investigating potential and identified risks (hypothesis*** testing to substantiate a causal association) or confirming the known safety profile of a medicinal product under normal conditions of use. They may also be conducted to quantify established adverse reactions and to identify risk factors.

10.10.3 Reporting on new medicines

The introduction of new medicines in the population requires active surveillance as the safety profile has not been fully established. There is also need to identify risk factors, confirm signals, determine incidence, prevalence and severity of adverse events. New medicines including dolutegravir (DTG) and tenofovir alafenamide (TAF) will be monitored through an active surveillance system.

Possible sources of data for active surveillance of DTG

- PCB active surveillance register
- Maternity register
- P-tracker

- EDT

10.10.4 How to report

Medicines safety reporting forms can be obtained from the pharmacy or the NMRC website. Fill in the reporting form as completely as possible, using a separate form for each patient and fax or email it to the Therapeutics Information and Pharmacovigilance Centre (TIPC). The success of the program depends on the quality and accuracy of the information sent in by the reporter.

Fax/Fax2Mail/Email to:
Therapeutics Information and Pharmacovigilance Centre (TIPC)
Tel: (061) 203 2406/ 203 2312
Fax: (061) 226631
Fax2Mail: 0886606781
Email: info.TIPC@mhss.gov.na

Therapeutics Information and Pharmacovigilance Centre (TIPC): is the MOHSS official Centre for provision of unbiased therapeutic information and pharmacovigilance services to health care workers and the general public in Namibia.

10.11 Considerations when changing therapy

Substitution of ARVs should not be delayed in cases of severe adverse medicine reactions in order to avoid harm and poor adherence to treatment, which will ultimately lead to drug resistance and poor treatment outcome. When an ARV must be stopped due to intolerance or mild to moderate toxicity, and the offending agent can easily be identified, simple substitution with another ARV in the same class may be done without stopping treatment. For example, a patient taking a TDF-containing regimen who develops renal insufficiency can have the TDF replaced by TAF or ABC.

In situations where the adverse reaction is mild or moderate (grade 1 or 2), but the substituting medicine can cause similar reactions, it is advisable to withdraw the causative agent and allow the adverse reaction to resolve before substituting. If immediate substitution is done, the reaction may worsen and both medicines will be lost from the regimen, hence narrowing future treatment options for the patient.

When NNRTIs (NVP or EFV) must be stopped, and the patient is on AZT, patients should discontinue the NNRTI first and continue with the NRTIs at their usual dosage for 14 days. This will decrease the risk of developing NNRTI (cross-) resistance. If the patient is taking either TDF or ABC with an NNRTI, the whole regimen can be stopped at the same time.

If cross-reaction is not expected, then immediate substitution may be made following grade 1 and 2, and higher grade reactions. For example, when a patient develops serious CNS symptoms associated with EFV, an immediate replacement with DTG can be made.

Patients with severe life-threatening toxicity on EFV (or NVP), such as symptomatic hepatitis, Stevens - Johnson syndrome or Toxic Epidermal Necrolysis, should stop all medications immediately. When the toxicity has resolved and the patient has recovered, ART can be restarted without using an NNRTI, to avoid recurrence of the toxic event. A regimen that combines 2 NRTIs with a PI can safely be stopped at once.

11 MONITORING AND EVALUATION (M&E)

11.1 Introduction

Monitoring the HIV programme by measuring key indicators and immediately feeding back to improve programme activities are essential to HIV programme success. This requires an effective patient monitoring system integrated within prevention, care and treatment at the health facility.

Patient monitoring is an important part of high quality patient care. Monitoring involves documenting all patient encounters by keeping regular and accurate records of key aspects of the care and treatment that are offered. This makes it possible to capture the history of a patient or group of patients over time and across different clinical sites and to collect data for reporting on and evaluating patient care at regular intervals.

In the context of facility-based HIV care, monitoring offers three major benefits:

a. It provides essential information for individual case management.
b. It provides key information for managing the health facility (e.g. for ordering drugs and supplies or for making quality improvements).
c. It provides information for operating and improving an HIV/AIDS program at the facility, district, national, and international levels.

Figure 11-1: Monitoring related definitions

Patient monitoring is the routine collection, compilation, analysis and use of individual patient data or a group (cohort) of patients for decision- making. Data is collected over time and across service delivery points. The information can be paper based or electronic. This is also called "patient tracking" and it provides important information for patient management.

Patient Management is the relationship between providers on a clinical team and the individual patient. It involves generating, planning, organizing, and administering medical and nursing care services for patients, assisted by written records. It is also called "clinical management" or "clinical monitoring."

Programme Monitoring is on-going collection of priority information about a programme to determine if it is operating according to plan. It provides ongoing information on programme implementation and functioning. It is performed at facility, district and national levels.

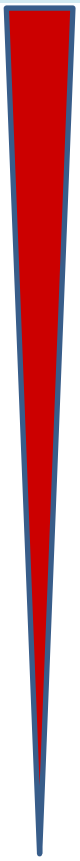
Source: Consolidated guidelines on person-centred HIV patient monitoring and case surveillance. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

11.2 Routine data collection in Namibia

Information necessary for individual patient management exists in both paper and electronic forms. Clinician need to be conversant with the use of registers, patient care booklets, other paper records as well as the electronic registers. Electronic systems are not end repositories of individual patient data; rather, they are the starting point for aggregation of patient level data to different reporting levels starting from facility to national and global levels.

Table 11-1: Levels of data collection in the Namibia HIV patient monitoring system

Level of data collection	Monitoring tool	Purpose	Quantity
Patient	PCB/ Health passport	Patient management	More
Facility and Community	Facility registers logbook/Community registers Monthly summery report Longitudinal registers Electronic Database	Clinical team management of groups of patients, case review, audits, drug supply management, facility-level indicators (e.g. programme, QI, HIVDR EWI)	
District	District summary indicators Electronic Database	Indicators for district, regional and national planning and reporting	
Regional	Regional summary indicators Electronic Database	Indicators for regional and national planning and reporting	
National	National summary indicators Electronic Database	Summary indicators for national planning and reporting and action	
Global	Global summary indicator Electronic Database	Summary indicators for global reporting planning, and action	Less



11.3 Minimum dataset in the HIV patient monitoring

The minimum dataset contains a core set of demographic, clinical and laboratory data. The minimum dataset provides a comprehensive assessment of all people living with HIV enrolled in HIV care. The primary purpose of the minimum dataset is to standardize patient information with a simplified and harmonized set of essential data elements corresponding to core patient management and programme monitoring functions. It enables programme staff to compare data across populations, time, geographical areas and settings, and provides data for clinical teams to monitor the quality of care longitudinally and along the cascade of HIV services. In Namibia, HIV clinicians should record patient information in the Patient Care Booklet (PCB) and fill all the essential data elements as listed in Appendix 21.

11.4 Namibia Standardized data collection and reporting tools by service delivery area

Paper based and electronic data collection and reporting tools form the critical foundation of all M&E. These tools are source of data for monthly summary reporting at the lower level, as well as in-depth high level data analysis at national level. HIV care providers are therefore expected to familiarize with all the monitoring and reporting tools used in the Namibia HIV program and report regularly based upon the stipulated reporting frequency (Appendix 22).

11.5 Data Quality

The goal of M&E is to produce data that can be used to document progress towards program objectives and improve. However often times data is not timely, credible, accurate, and complete due to inefficient M&E system. Data must be of high quality to inform health policy, programs and resource allocation.

Table 11-2: Characteristics of quality data

- Completeness: The proportion of stored data considered as providing all relevant data elements at a required point in time (from 0-100%)
- Timeliness: The degree to which all data represent reality at the present time
- Uniqueness: Data are free of unnecessary duplicated records or elements
- Accuracy: The extent to which the recorded data correctly describe the truth (reality) of the health event at a given point in time
- Validity and legitimacy : Data are recorded meaningfully for a specific element and comply with coding standards or rules
- Reliability and consistency: Data are recorded in the expected manner, and can be interpreted in the same manner across follow up measures for the same patient/s

** Reference: The Six Dimensions of EHDI Data Quality Assessment, CDC*

11.6 Improving Data Quality

Data quality is not the sole responsibility of data clerks or other designated staff. All HCP have a fundamental role and responsibility in improving the quality of data at facility level, where much critical patient information is actually generated.

Regular data review meetings with feedback to data personnel and program managers should be conducted at all levels in order to improve the quality and accuracy of routine program data.

11.7 Core indicators covered by the patient monitoring system

Analysis of data for monitoring and/or programme evaluation begins with aggregation of patient level data into smaller units, thereby simplifying and reducing information into a single, measurable variable. Such variable that measure one aspect of performance is called an indicator. Indicators measure progress program/project towards targets.

Appendix 23 includes a list of key indicators that measure and monitor programme performance, from facility to national level.

11.8 National Strategic Framework Indicators and Targets

Namibia aims to achieve the following six priority impact results by 2020, while laying strong foundation to eliminate AIDS by 2030.

Table 11-3: National Strategic Framework Indicators and Targets

Priority 1	**HIV new infections reduced by 75%**
Priority 2	**HIV related deaths reduced by 75%**
Priority 3	**Elimination of MTCT to less than 2%**
Priority 4	**100% of newly identified PLHIV enrolled and retained on ART**
Priority 5	**TB/HIV mortality reduced to 21 per 100,000 population by 2021**
Priority 6	**Domestic contribution towards the national multi-sectoral HIV and AIDS response increased to 80%**

The NSF monitoring will be an on-going process and will be conducted at national, regional, district and community levels. In order to ensure the quality of data collected, common indicators and pre-designed standard tools will be used.

11.9 Uses of facility level data

11.9.1 Monitoring Drug Resistance

HIV drug resistance poses a significant threat to the success of the national HIV program. Drug resistance results in more rapid virologic failure among people receiving ART and increases the need for second and third-line regimens, which may be associated with greater toxicity, adverse events, poorer adherence and higher costs. Drug resistance may also negatively affect the ability to prevent HIV transmission using ARV-based pre- or post-exposure prophylaxis or topical microbicides. Surveillance of drug resistance should be an integral component of national HIV programme. Surveillance data should inform the selection of first- and second-line regimens for ART, as well as ARV drugs for eMTCT, to optimize treatment outcomes within a public health approach.

11.9.1 Monitoring early warning indicators for HIV drug resistance

Early warning indicators use existing clinic and pharmacy records to assess the factors associated with the emergence of HIV drug resistance at the level of ART programmes and clinics.

These factors include

- ART prescribing practices
- Drug supply continuity
- Adherence to ARV drug regimens measured by on-time pick-up of ARV drugs
- Retention in care
- Viral load suppression

Monitoring of early warning indicators is integrated into the national monitoring and evaluation system and provides the information needed to address practices that may lead to poor outcomes and HIV drug resistance.

11.10 Research and Evaluation

Although programme monitoring is an integral part of tracking NSF programme results, additional research and evaluation are required to measure high level impact. Programme evaluation will focus

on assessing the effectiveness and efficiency of the response towards achieving planned results and the impact the response has made.

11.10.1 Cross-sectional surveys of acquired HIVDR (ADR) in adults and children on ART

The WHO generic protocol for monitoring acquired HIV drug resistance uses a standardized survey methodology to assess population-level virologic suppression at the national level and the emergence of HIV drug resistance among populations receiving treatment. Performed regularly at representative sites, these surveys provide evidence for action at the programme and clinic level to minimize HIV drug resistance. They also provide evidence to optimize the selection of first- and second-line ART regimens.

11.10.2 Cross-sectional surveys to monitor pre-treatment HIV drug resistance

The WHO generic protocol for surveillance of pre-treatment HIV drug resistance provides a nationally representative estimate of HIV drug resistance in populations initiating ART. Performed regularly at representative ART clinics, these surveys support national, regional and global decision-making regarding the choice of first-line regimens.

11.10.3 Transmitted HIV drug resistance surveys (TDR)

The WHO generic protocol for surveillance of transmitted HIV drug resistance provides estimates of transmitted HIV drug resistance in recently infected populations, and the results should contribute to ART policy decisions, including guidelines on ART regimens and HIV prophylaxis.

11.10.4 Surveillance of HIVDR in children less than 18 months of age

Retrospective cross-sectional survey using remnant DBS from HIV-infected children diagnosed with HIV by EID at age less than 18 months that has been stored at EID laboratories.

11.10.5 Surveys to monitor HIV incidence and prevalence of suppressed viral load

A Population-based HIV Impact Assessment (PHIA) survey that was conducted in 2017 in Namibia was aimed at examining the distribution of HIV disease, assessing the coverage and impact of HIV services at the population level, and measuring HIV-related risk behaviors using a nationally-representative sample of adults and children. PHIAs are instrumental in tracking progress towards reaching the 90-90-90 Fast Track targets by 2020.

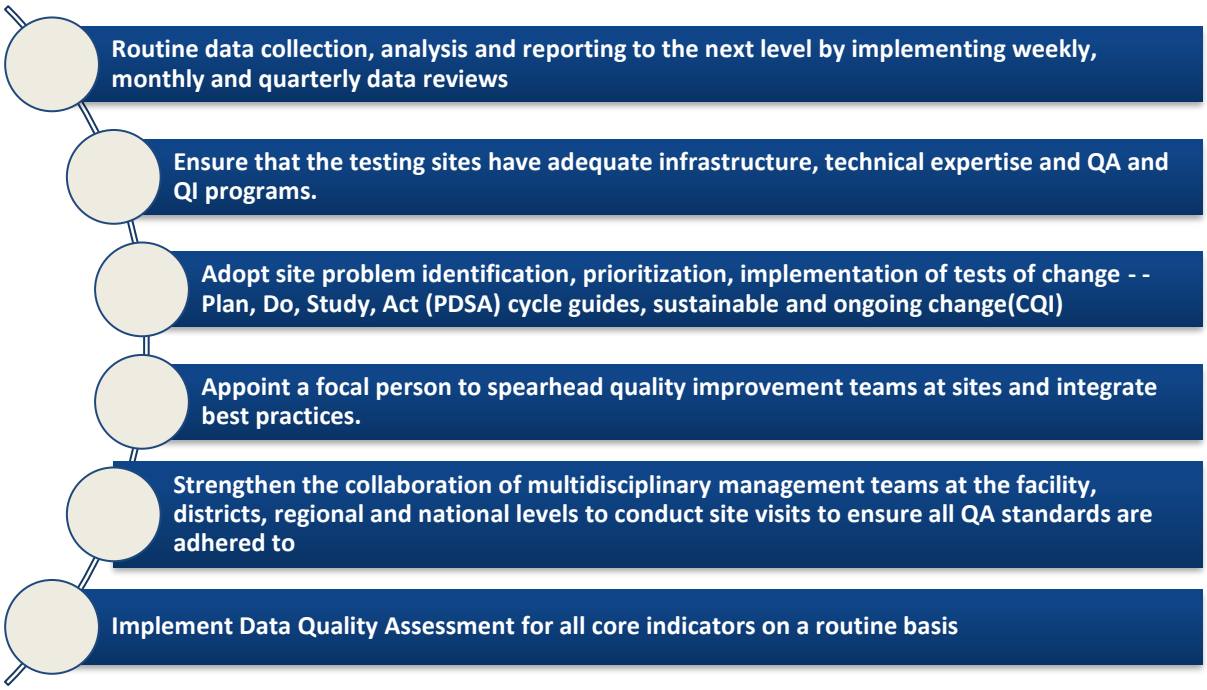
11.11 Recency testing

HIV recency testing is a disease surveillance testing protocol which provides insight in to the time lines of an individual's HIV infection. Refer to section 1.8.

11.12 HIVQUAL

This section focuses on key principles, approaches, and interventions highlighting the quality assurance and quality improvement practices based on implementation and program experience. Quality of care emphasizes that services should be effective in achieving the desired health outcomes and that health care practices should be people-centered and safe. HIV care providers should integrate continuous quality improvement into routine service delivery. Namibia builds upon the QI framework and has the following components:

Figure 11-2: Components of QI framework



12 APPENDIXES

12.1 Appendix 1: WHO Clinical Staging of HIV disease in Adults And Adolescents (2007)

Clinical Stage 1 • Asymptomatic • Persistent generalized lymphadenopathy
Clinical Stage 2 • Unexplained[1] moderate weight loss (under 10% of presumed or measured body weight)[2] • Recurrent upper respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis) • Herpes zoster • Angular cheilitis • Recurrent pruritic ulcerations • Seborrhoeic dermatitis • Fungal nail infection
Clinical Stage 3 • Unexplained[1] severe weight loss (over 10% of presumed or measured body weight)2 • Unexplained[1] chronic diarrhoea for longer than one month • Unexplained[1] persistent fever above 37.6°C (intermittent or constant, for longer than one month • Persistent oral candidiasis • Oral hairy leukoplakia • Pulmonary tuberculosis (current) • Severe bacterial infections (e.g. pneumonia, empyema, pyomysitis, bone or joint infection, meningitis, bacteraemia) • Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis • Unexplained[1] anaemia (below 8 g/dl), neutropenia (below 0.5 x 109/L) or chronic thrombocytopenia (below 50 x 109/L
Clinical Stage 4[3] • HIV wasting syndrome • Pneumocystispneumonia • Recurrent severe bacterial pneumonia • Chronic herpes simplex infection (orolabial, genital, or anorectal of more than one month's duration or visceral at any site) • Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) • Extrapulmonary tuberculosis • Kaposi's sarcoma • Cytomegalovirus infection (retinitis or infection of other organs) • Central nervous toxoplasmosis • HIV encephalopathy • Extrapulmonary cryptococcosis including meningitis • Disseminated non-tuberculous mycobacteria infection • Progressive multifocal leukoencephalopathy • Chronic cryptosporidiosis (with diarrhoea) • Chronic isosporiasis • Disseminated mycosis (coccidiomycosis or histoplasmosis) • Recurrent non-typhoidal Salmonella bacteraemia • Lymphoma (cerebral or B cell non-Hodgkin) or other solid HIV-associated tumours • Invasive cervical carcinoma • Atypical disseminated leishmaniasis • Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy

[1] *Unexplained refers to where the condition is not explained by other conditions.*

[2] *Assessment of body weight among pregnant woman needs to take into consideration the expected weight gain of pregnancy.*

[3] *Some additional specific conditions can also be included in regional classifications, such as the reactivation of American trypanosomiasis (meningoencephalitis and/or myocarditis) in the WHO Region of the Americas, and penicilliosis in Asia*

12.2 Appendix 2: WHO Clinical Staging of HIV in Infants and Children (2007)

Stage 1 (Asymptomatic)

- Asymptomatic
- Persistent generalised lymphadenopathy

Clinical Stage 2 (Mild)

- Unexplained persistent hepatosplenomegaly
- Papular pruritic eruptions
- Angular cheilitis
- Extensive wart virus infection
- Extensive molluscum contagiosum
- Recurrent oral ulcerations
- Unexplained persistent parotid enlargement
- Lineal gingival erythema
- Herpes zoster
- Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)
- Fungal nail infections

Clinical Stage 3 (Advanced)

- Unexplained moderate malnutrition or wasting not adequately responding to standard therapy
- Unexplained persistent diarrhoea (14 days or more)
- Unexplained persistent fever (above 37.5 ºC, intermittent or constant, for longer than one month)
- Persistent oral candidiasis (after first 6-8 weeks of life)
- Oral hairy leukoplakia
- Acute necrotizing ulcerative gingivitis/periodontitis
- Lymph node TB
- Pulmonary TB
- Severe recurrent bacterial pneumonia
- Symptomatic lymphoid interstitial pneumonitis
- Chronic HIV-associated lung disease including bronchiectasis
- Unexplained anaemia (< 8.0 g/dl), neutropaenia (< 0.5 x 109/L) or chronic thrombocytopaenia (< 50 x 109/L)

Clinical Stage 4 (Severe)

- Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy
- Pneumocystis pneumonia
- Recurrent severe bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)
- Chronic herpes simplex infection (orolabial or cutaneous of more than one month's duration, or visceral at any site)
- Extrapulmonary TB
- Kaposi sarcoma
- Oesophageal candidiasis (or candida of trachea, bronchi or lungs)
- Central nervous system toxoplasmosis (after one month of life)
- HIV encephalopathy
- Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, with onset at age over 1 month
- Extrapulmonary cryptococcosis (including meningitis)
- Disseminated endemic mycosis (histoplasmosis, coccidiomycosis)
- Chronic cryptosporidiosis (with diarrhoea)

- Chronic isosporiasis
- Disseminated non-tuberculous mycobacteria infection
- Cerebral or B cell non-Hodgkin lymphoma
- Progressive multifocal leukoencephalopathy
- Symptomatic HIV-associated cardiomyopathy or nephropathy

12.3 Appendix 3: Routine Laboratory monitoring by regimen

Regimen	W 2	W 6	M3	M6	M9	M12	M15 & every 6 months thereafter	M18 & Every 6 months thereafter	M24 & Every 12 months thereafter
TDF/[FTC or 3TC]/DTG		***CrCl***		***CrCl*** ***VL***		***CrCl*** ***VL***		***VL if<19y[1]***	***CrCl*** ***VL***
TDF/[FTC or 3TC]/EFV		***CrCl***		***CrCl*** ***VL***		***CrCl*** ***VL***		***VL if<19y[1]***	***CrCl*** ***VL***
AZT/3TC/DTG	***Hb***	***Hb***	***Hb***	***VL***		***VL***		***VL if<19y[1]***	***VL***
AZT/3TC/EFV	***Hb***	***Hb***	***Hb***	***VL***		***VL***		***VL if<19y[1]***	***VL***
TDF/[FTC or 3TC]/AZT/ LPV/r	***Hb[2]***	***Hb[2]*** ***CrCl***	***Hb[2]***	***CrCl*** ***VL***		***CrCl*** ***VL***		***VL if<19y[1]***	***VL*** ***CrCl***
ABC/3TC/EFV				***VL***		***VL***		***VL if<19y[1]***	***VL***
ABC/3TC/LPV/r				***VL***		***VL***		***VL if<19y[1]***	***VL***
ABC/AZT/3TC/LPV/r	***Hb[2]***	***Hb[2]***	***Hb[2]***	***VL***		***VL***		***VL if<19y[1]***	***VL***
ABC/AZT/3TC/EFV	***Hb[2]***	***Hb[2]***	***Hb[2]***	***VL***		***VL***		***VL if<19y[1]***	***VL***
Special situations									
HBsAg positive at diagnosis	***ALT***	***ALT***	***ALT***	***Repeat HBsAg***	***ALT[3]***		***ALT[3]***	***ALT[3]***	

Notes:

[1]Viral Load testing at 6 months and 6 monthly thereafter only for children <19 years old

[2]Only do Hb if patient has NOT had AZT in first line

[3]Continue to monitor ALT only if repeat HBsAg is positive

Any other Lab test can be requested as clinically deemed necessary

12.4 Appendix 4: Summary information on Antiretroviral formulations for adults

ARV	Formulation /Strength	Dose for adults*	Special Considerations	Side effects and adverse effects
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)				
Zidovudine (AZT)	Tablets: 300mg, 100mg FDC: AZT/3TC 300/150mg; AZT/3TC/NVP 300/150/200mg	300 mg bd	With or without food	Anaemia, neutropenia, Gastrointestinal intolerance, Headache, insomnia, myopathy Lactic acidosis with hepatic steatosis (rare)
Abacavir (ABC)	Tablet: 300mg FDC: ABC/3TC 600/300mg	600 mg od (or 300 mg bd if part of an FDC)	With or without food	Hypersensitivity reaction (can be fatal) Fever, rash, fatigue, nausea, vomiting, anorexia Respiratory symptoms (sore throat, cough) Lactic acidosis with hepatic steatosis (rare)
Lamivudine (3TC)	Tablet: 150mg FDC: AZT/3TC 300/150mg; ABC/3TC 600/300mg; TDF/3TC 300/300mg	150 mg bd (or 300 mg od if given with TDF or ABC)	With or without food	Minimal toxicity Lactic acidosis with hepatic steatosis (rare)
Emtricitabine (FTC)	FDC: TDF/FTC 300/200mg; TAF/FTC/DTG 25/200/50mg	200 mg od	With or without food	Headache, nausea, skin rash and discoloration Lactic acidosis with hepatic steatosis(rare)
Nucleotide Reverse Transcriptase Inhibitor (NtRTIs)				
Tenofovir disoproxil umarate (TDF)	Tablet: 300 mg	300 mg od	Take with food	Abdominal pain, anorexia, asthenia, diarrhoea, dizziness, dyspnoea, flatulence, headache, hypophosphatemia, lactic acidosis, nausea,

ARV	Formulation /Strength	Dose for adults*	Special Considerations	Side effects and adverse effects
	FDC: TDF/3TC 300/300mg; TDF/3TC/EFV 300/300/400mg; TDF/3TC/DTG 300/300/50mg			pancreatitis, renal impairment, rash, vomiting, lactic acidosis with hepatic steatosis (rare)
Tenofovir alafenamide fumarate (TAF)	Tablet: 25 mg FDC: TAF/FTC/DTG 25/200/50mg	25 mg od	Take with food	Improved safety profile of TAF vs. TDF for osteoporosis and osteopenia, decreased renal toxicity
Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)				
Efavirenz (EFV)	Tablet: 200mg FDC: TDF/3TC/EFV 300/300/400mg;	600 mg od	With or without food; Bed time administration to avoid CNS symptoms	CNS Symptoms: dizziness, somnolence, insomnia, confusion, hallucinations, agitation Elevated transaminase levels Skin rash
Nevirapine (NVP)	Tablet 200 mg FDC: AZT/3TC/NVP 300/150/200 mg	200 mg od x 14 days, then 200 mg bd	With or without food	Skin rash, Stevens-Johnson Syndrome Elevated serum aminotransferase levels Hepatitis, life-threatening hepatic toxicity
Etravirine (ETV)	Tablet: 200mg, 100mg	200 mg bd	Take with food	Skin rash, nausea, and diarrhoea, elevation in serum cholesterol, triglyceride, glucose, and hepatic transaminase levels.
Protease Inhibitors (PIs)				

ARV	Formulation /Strength	Dose for adults*	Special Considerations	Side effects and adverse effects
Lopinavir + ritonavir (LPV/r)	FDC (heat-stable): 200mg/50 mg	400 mg/100 mg bd	With food	GI intolerance, nausea, vomiting, elevated transaminase enzymes, hyperglycaemia, fat redistribution and lipid abnormalities
Ritonavir (RTV)	Capsule/Tablet: 100 mg	Use only as booster PI	Take with food. High-fat snacks may reduce side effect	Gastrointestinal intolerance, nausea, vomiting, paraesthesia, hepatitis and pancreatitis, hyperglycaemia, fat redistribution and lipid abnormalities
Atazanavir (ATV)	Capsule: 200mg, 100mg FDC: ATV/r 300mg/100 mg	300mg od (must be used in combination with ritonavir 100mg)	Take with a light meal	Benign increase in bilirubin, prolonged QT (caution with conduction defects or drugs that do this), increased glucose, lipodystrophy, and increased haemorrhage in patients with haemophilia.
Darunavir (DRV)	Tablet: 600mg, 300mg,	600mg bd (must be used in combination with ritonavir 100mg)	Take with food	Nausea, diarrhoea, GI discomfort, headache, hypercholesterolemia, hypertriglyceridemia, lipodystrophy, increased glucose, transaminitis, inflammation of the nose and throat, and increased haemorrhage in patients with haemophilia. Rash, SJS, Erythema multiforme, Hepatotoxicity, crystalluria
Integrase strand transfer inhibitors (INSTIs)				
Raltegravir (RAL)	Tablet: 400mg	400 mg bd	Take with or without food	Diarrhoea, nausea, and headache. Use with caution in patients who are at increased risk for myopathy and rhabdomyolysis, which includes patients using other medications known to cause these conditions. Rash,

ARV	Formulation /Strength	Dose for adults*	Special Considerations	Side effects and adverse effects
				SJS, TEN, hypersensitivity reaction, depression, suicidal ideation
Dolutegravir (DTG)	Tablet: 50mg FDC: TDF/3TC/DTG 300/300/50mg; TAF/FTC/DTG 25/200/50mg	50mg od	Take with or without food	GI symptoms, skin reactions, insomnia; Not recommended for patient with severe hepatic impairment **New Medicine: subject for additional monitoring **

**For appropriate paediatric formulations and dosage, please see appendix 12*

12.5 Appendix 5: Antiretroviral medication dosage adjustment for renal and hepatic failure

Medicine Name	Form	Usual adult dose	Renal failure dosing				Liver failure dosing
			CrCl 30-50 ml/ min	CrCl 10-29 ml/ min	CrCl <10 ml//min	Dialysis	
Abacavir (ABC)	300mg tablets	300mg BD	Dosing adjustment not necessary				Usual dose Avoid in severe cases
Didonasine (ddI)	125, 250, 400mg tablets	<60kg: 250mg od	125mg od	125mg od	125mg od	125mg od	Usual dose Monitor for toxicity
	250mg, 400mg tablets	>60kg: 400mg od	200mg od	125mg od	125mg od	125mg od	
Lamivudine (3TC)	150mg tablet	150 mg BD	150mg od	150mg 1st dose, then 100mg od	150mg 1st dose, then 50mg od	150mg 1st dose, then 50mg od	Usual dose
Stavudine (d4T)	15, 20, 30mg tablets	30mg BD	15mg BD	15mg od	15mg od	15mg od	Usual dose
Zidovudine (AZT)	100mg capsule, 300mg tablets	300mg BD	Usual dose	Usual dose	(<15 ml/min) 100mg tds	100mg tds	Reduction in daily dose or extension of dosing interval may be needed; 50% decrease in dose or doubling of the dosage interval has been recommended (limited data)
Tenofovir (TDF)	300mg tablets	300mg od	300mg q48h	300 mg twice per week	300mg weekly	300mg weekly	Usual dose

12.6 Appendix 6: Dietary Management of common HIV-Related Symptoms

Illness	Diet	Care and nutrition practices
Anorexia **(appetite loss)**	• Stimulate appetite by eating favourite foods. • Eat small amounts of food more often. • Eat more energy-dense foods. • Avoid strong-smelling foods.	If appetite loss is a result of illness, seek medical treatment.
Diarrhoea	• Drink a lot of fluids (soups, diluted fruit juices, boiled water and light herbal teas) to avoid dehydration. • Avoid strong citrus fruits (orange, lemon) because they irritate the stomach. • Eat foods rich in soluble fibre (millet, banana, peas, and lentils) to help retain fluids. • Eat fermented foods such as porridges and yoghurt. • Eat easily digestible foods such as rice, bread, millet, maize porridge, potato, sweet potato, and crackers. • Eat small amounts of food frequently. • Continue to eat after illness to recover weight and nutrient loss. • Eat soft fruits and vegetables such as bananas,	**Prevention** • Drink clean boiled water. • Wash hands with water and soap before handling, preparing, serving, or storing food. • Wash hands with water and soap after using a toilet or latrine or cleaning a child after defecation. **Treatment** • Drink more fluids to prevent dehydration. Prepare rehydration solutions using oral rehydration sachets or a homemade solution f cereals. • Go to a health facility if symptoms

Illness	Diet	Care and nutrition practices
Nausea and vomiting	• Eat small frequent meals. • Eat soups, unsweetened porridge, and fruits such as bananas. • Eat lightly salty and dry foods such as crackers to calm the stomach. • Drink herbal teas and lemon juice in hot water. • Avoid spicy and fatty foods. • Avoid caffeine (coffee and tea) and alcohol. • Drink liquids such as clean boiled water.	• Avoid an empty stomach; nausea is worse if nothing is in the stomach. • Avoid lying down immediately after eating—wait at least 20 minutes. • Avoid vomiting. • Rest between meals.
Thrush	• Eat soft, mashed foods such as carrots, scrambled eggs, mashed potatoes, bananas, soups, and porridge. • Eat cold or room-temperature foods. • Avoid spicy, salty, or sticky foods that may irritate mouth sores. • Avoid sugary foods that cause yeast to grow. • Avoid strong citrus fruits and juices that may irritate mouth sores. • Avoid alcohol and drink plenty of fluids.	• Seek medical treatment. • Use a spoon or cup to eat small amounts of foods. • Tilt your head back when eating to help with swallowing. • Rinse your mouth with boiled warm, salty water after eating to reduce irritation and keep infected areas clean so yeast cannot grow.
Constipation	• Eat more high-fibre foods such as maize, whole wheat bread, green vegetables, and washed fruits with the peel. • Drink plenty of liquids. • Avoid processed or refined foods.	• Avoid cleansing practices such as enemas and medications. • Drink plenty of fluids, including boiled water.
Loss of taste or abnormal taste	• Use flavour enhancers such as salt, spices, herbs, and lemon.	• Eat small frequent meals • Chew food well and move it around the mouth to stimulate receptors

12.7 Appendix 7: Algorithm for classification of Malnutrition in Adults

ASSESS		CRITERIA	CLASSIFICATION	TREATMENT/ CARE
HISTORY	**LOOK FEEL AND MEASURE**			
Ask the client or refer to records: 1. Has the client lost weight in the past month/since the last visit? 2. Has the client had: ▪ Active TB (on treatment)? ▪ Another chronic opportunistic infection (OI) or malignancy (e.g., oesophageal infections)? ▪ Mouth sores/oral thrush? 3. Has the client's body composition/fat distribution changed noticeably? ▪ Thinning of limbs and face? ▪ Fat distribution on limbs, breasts, stomach, back? 4. Has the client had: ▪ Nausea and vomiting? ▪ Persistent fatigue? ▪ Poor appetite?	**Prevention** ▪ Drink clean boiled water. ▪ Wash hands with water and soap before handling, preparing, serving, or storing food. ▪ Wash hands with water and soap after using a toilet or latrine or cleaning a child after defecation. **Treatment** ▪ Drink more fluids to prevent dehydration. Prepare rehydration solutions using oral rehydration salt sachets or a homemade solution from cereals. 1. Go to a health facility if symptoms such as severe dehydration, fainting, dizziness, shortness of breath, bloody stools, high fever, vomiting, severe If the client has oedema on both legs or base of the spine: ▪ Rule out pre-eclampsia, kidney problems, elephantiasis, heart failure, and wet beriberi (vitamin B1 deficiency with oedema). 2. Measure the client's weight (kg) and height (cm).	**Adults (non-pregnant and non-post-partum)** BMI < 16 kg/m² (If can't measure BMI, MUAC < 19 cm) **OR** Bilateral pitting oedema (both feet or legs are swollen, and the skin remains indented when pressed with a finger)	**Severe acute malnutrition (SAM) with complication** (fever, hypothermia, severe anaemia or dehydration, vomiting, bilateral oedema +++) **or no appetite**	**<u>Inpatient treatment</u>** **Refer to therapeutic feeding programmes**
		Pregnant women and women up to 6 months post-partum MUAC < 19 cm	**SAM with appetite and no complication**	**<u>Outpatient treatment</u>** **Refer to therapeutic feeding programmes**
		Adults (non-pregnant and non-post-partum)	**Moderate/mild malnutrition**	**Refer to supplementary**

	3. Compute body mass index (BMI). 4. Measure mid-upper arm circumference (MUAC) for all pregnant women, all women up to 6 months post-partum, and adults who cannot stand straight. 5. Examine the client for conditions that cause secondary malnutrition (e.g., injuries, burns, surgical procedures, pregnancy, diarrhoea, or disease of the gastrointestinal tract, thyroid, kidney, liver, or pancreas). 6. Look for medical complications and danger signs (e.g., anaemia, severe dehydration, active TB, severe bilateral oedema). 7. If the client has no medical complications, give an appetite test using ready-to-use therapeutic food (RUTF).	BMI ≥ 16.0–< 18.5 kg/m^2 (If can't measure BMI, MUAC ≥ 19–< 22 cm) **Pregnant women and women up to 6 months post-partum** Weight loss or no weight gain MUAC ≥ 19–< 22 cm	**Significant weight loss**	**feeding programmes**
		Severe lung disease Active TB (first 3 months of treatment) Chronic diarrhoea Difficulty swallowing	**Signs of symptomatic disease**	
		Adults (non-pregnant and non-post-partum) BMI ≥ 18.5 kg/m^2 (If can't measure BMI, MUAC ≥ 22 cm) **Pregnant and post-partum women** MUAC ≥ 23 cm	**Normal**	**Nutrition counselling**

12.8 Appendix 8: Algorithm for classification of Malnutrition in Children 6 months–14 years old

ASK	LOOK,FEEL and MEASURE	CRITERIA	CLASSIFICATION	TREATMENT/CARE
Ask mother or caregiver or refer to records: 1. Has the child lost weight in the past month/since the last visit? 2. Has the child had: ○ A cough for more than 21 days? (This may be a result of HIV-related chronic lung disease such as lymphocytic interstitial pneumonia [LIP] or bronchiectasis.) ○ Active tuberculosis (TB) (on treatment)? ○ Diarrhoea for more than 14 days? ○ Another chronic opportunistic	**1. Look for severe visible wasting:** ○ Loss of muscle bulk on arms, shoulders, buttocks, and thighs, with visible rib outlines ○ Sagging skin on buttocks 2. **Check for oedema** (swelling) in both feet or base of spine. **3. Measure child's weight (kg) and height (cm)** and find weight for height (WFH) using 2006 WHO child growth standards. **4. Measure mid-upper arm circumference (MUAC).** **5. Look at the shape of the curve on the growth chart.**	**Bilateral pitting oedema** +++ (both feet and/or legs are swollen, and the skin remains indented when pressed with the thumb) **OR** WFH < –3 z-scores (WHO 2006) **OR** BMI for age 10–14 years: ≤ –3 z-score **OR** MUAC 6–59 months: < 11.5 cm 5–9 years: < 13.5 cm 10–14 years: < 16.0 cm **AND** Does not pass an appetite test	**Severe acute malnutrition (SAM)**	
			With medical complication (WFH <–4 z-scores, shock, anorexia, intractable vomiting, convulsions, lethargy, lower respiratory tract infection, high fever, severe anaemia or dehydration, hypoglycaemia, hypothermia, pneumonia, TB)or **no appetite**	**Inpatient treatment** **Refer to therapeutic feeding programmes**
			Without medical complication and with appetite Clinical wellness Alertness Caregiver able/willing to manage SAM at home and return to clinic every 14 days	**Outpatient treatment** **Refer to therapeutic feeding programmes**

infection (OI) or malignancy?	• Has the child lost weight since the last visit? (Measure again to confirm current weight.) • Is the growth curve flattening? • Is the child gaining weight? Weight loss  Growth curve flattening  Weight gain 	6–59 months: WFH or BMI for age between –3 and –2 z-scores **OR** MUAC 6–59 months: ≥ 11.5–< 12.5 cm 5–9 years: ≥ 13.5–< 14.5 cm 10–14 years: ≥ 16.0–< 18.5 cm	**Moderate/mild malnutrition (MAM)** **Poor weight gain**	**Refer to supplementary feeding programmes**
		Weight gain parallel to or higher than median growth curve WFH ≥ –2 z-score **OR** MUAC ≥ 12.5 cm	**Normal** **Growing appropriately**	**Nutrition counselling**
		Chronic lung disease, TB, persistent diarrhoea, or other chronic opportunistic infection or malignancy	**Condition with increased nutritional needs**	**Refer to supplementary feeding programmes**

12.9 Appendix 9: Safety Yellow Form

Ministry of Health and Social Services

ADVERSE MEDICINE REACTION REPORTING FORM
(For Healthcare Professionals)

Safety Yellow Form Confidential

A) PATIENT INFORMATION

Patient Initials or Hospital Reg. No.	DOB...../...../..... or Age.....	Gender ☐M ☐F ☐Unk.	Weight (Kg):
Pregnant ☐Y ☐N	If YES, Estimated Gestational Period:	Known Allergies:	

B) TYPE OF REPORT Initial ☐ Follow up ☐ If Follow up, AMR ID No. :

DESCRIPTION OF ADVERSE EVENTS Indicate provisional/ final diagnosis of the adverse events	Date event started	Date event stopped	Action Taken: (e.g. Medicine withdrawn/substituted/dose reduced/medical treatment etc...)

SERIOUSNESS	☐ Hospitalization ☐ Life-Threatening	☐ Disability or permanent damage ☐ Non Serious adverse event	☐ Congenital anomaly/birth defect ☐ Other; Specify: .....
PATIENT OUTCOME	☐ Recovered ☐ Recovering ☐ Not recovered ☐ Unknown	Died ☐ Due to Reaction ☐ Unrelated to reaction	☐ Reaction maybe contributory Date of death: ...../...../.....

C) RELEVANT LABORATORY TEST (May be attached if necessary)

Were there any relevant laboratory test(s) done? ☐Y ☐N

Laboratory Test	Test Date	Test Results

D) RELEVANT MEDICAL HISTORY: including pre-existing medical conditions (e.g. diabetes, liver problem, alcohol use etc.)

E) INFORMATION ON MEDICINE: *For vaccines please complete the AEFI reporting form*

Trade Name [Generic Name if Trade Name is unknown] -List medicines used in the last 3 months -Enter Fixed Dose Combination as one medicine -Tick suspected medicine (s)		Dose and Frequency	Route of admin	Start date	Stop date or ongoing	Reason for use
	☐					
	☐					
	☐					
	☐					
	☐					
	☐					

F) REPORTER INFORMATION

Name		Email		Tel:	
Profession	☐ Doctor	☐ Pharmacist	☐ Nurse	☐ Pharm Ass	☐ Others:
Health Facility/ Practice Name		Region		Date:	

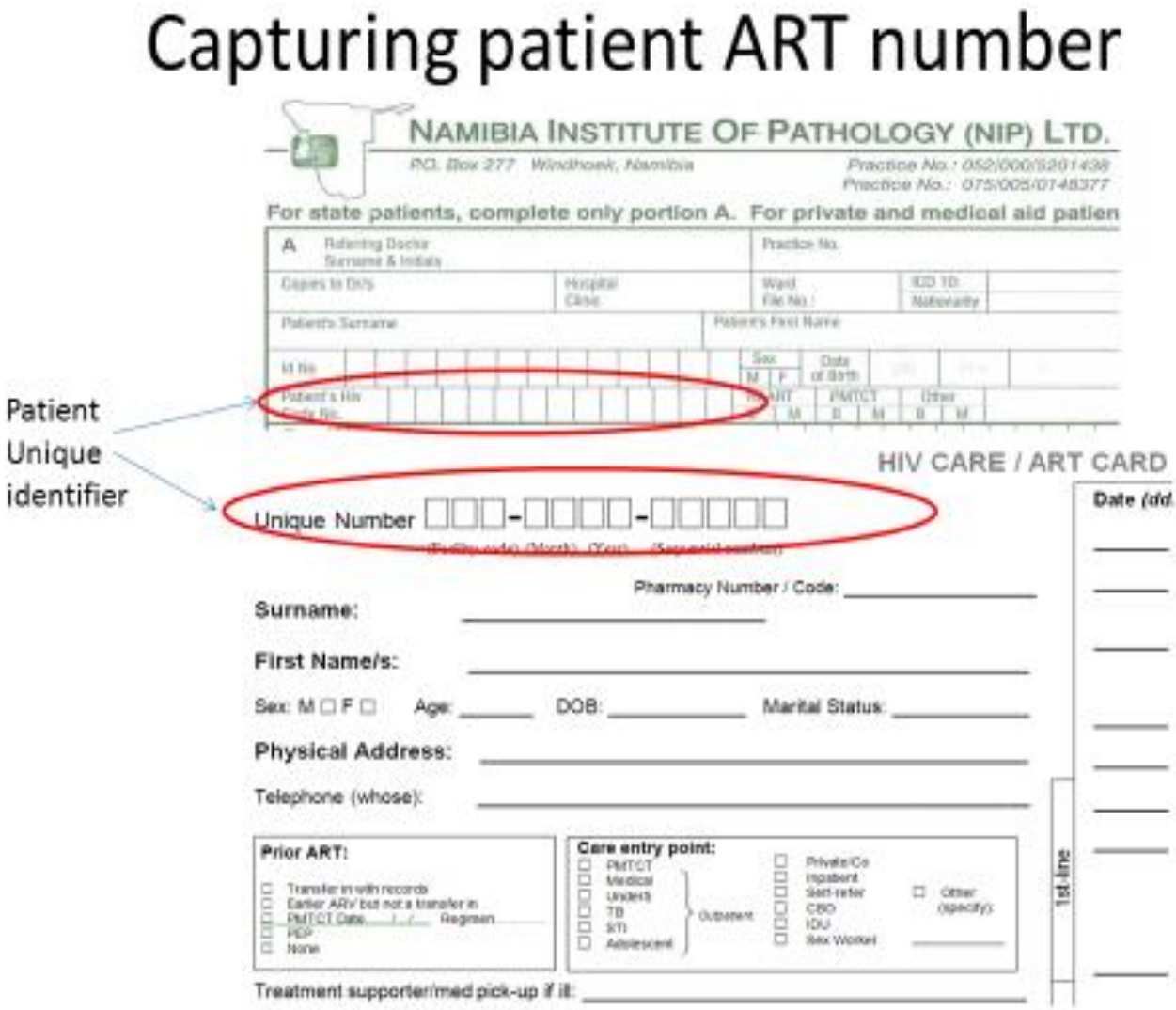
Please note that submission of a report does not constitute an admission that medical personnel or the medicine caused or contributed to the event

Please tick IF YOU need: ☐*More AMR forms* ☐*Additional information*

Send/Fax/Fax2Mail/Email to:
Therapeutics Information and Pharmacovigilance Centre (TIPC)
15 Ruhr Street Northern Industry, Windhoek
Tel: (061) 203 2406/ 203 2312
Fax: (061) 226631
Fax2Mail: 0886606781
Email: info.TIPC@mhss.gov.na

Version 3_ Oct/2018

12.10 Appendix 10: Laboratory Request Form



12.11 Appendix 11: Interactions between ARVs and some commonly used medicines

ARV drug	Key interactions	Suggested management
AZT	Ribavirin and pegylated interferon alpha-2a	Substitute AZT with TDF
Boosted PIs (ATV/r, DRV/r and LPV/r)	Rifampicin	Substitute rifampicin with rifabutin; Adjust the dose of LPV/r or substitute with three NRTIs (for children)
	Halofantrine	Use an alternative antimalarial agent
	Lovastatin and simvastatin	Use an alternative statin (such as pravastatin)
	Hormonal contraceptives	Use alternative or additional contraceptive methods
	Metformin	Adjust methadone and buprenorphine doses as appropriate
	Astemizole and terfenadine	Use an alternative antihistamine agent
	TDF	Monitor renal function
	Simeprevir	Use an alternative direct-acting antiviral agent
	Ombitasvir + paritaprevir/ritonavir + dasabuvir	Use an alternative direct-acting antiviral agent
DTG	Dofetilide	Use an alternative antiarrhythmic agent
	Rifampicin	Adjust the dose of DTG or substitute rifampicin
	Carbamazepine, phenobarbital and phenytoin	Use an alternative anticonvulsant agent (such as valproic acid or gabapentin)
	Polyvalent cation products containing Mg, Al, Fe, Ca and Zn	DTG may be given with calcium (Ca) and/or Iron (Fe) if it is also taken with food. Otherwise, use DTG at least two hours before or at least six hours after supplements containing polyvalent cations, including but not limited to the following products: multivitamin supplements containing Fe, Ca, Mg or Zn; mineral supplements, cation-containing laxatives and antacids containing Al, Ca or Mg. Monitor for efficacy in suppressing viral load.
	Metformin	Maximum metformin dose 500 mg 12-hourly
EFV	Amodiaquine	Use an alternative antimalarial agent
	Cisapride	Use an alternative gastrointestinal agent
	Methadone	Adjust the methadone dose as appropriate
	Hormonal contraceptives	Use alternative or additional contraceptive methods
	Astemizole and terfenadine	Use an alternative antihistamine agent
	Ergotamine and dihydroergotamine	Use an alternative antimigraine agent
	Simeprevir	Use an alternative direct-acting antiviral agent
	Midazolam and triazolam	Use an alternative anxiolytic agent

12.12 Appendix 12: Paediatric dosage chart

ARV Medicine	Abbreviation /FDC	Strength of paediatric formulation	Number of tablets /sachets or volume of liquid (mls) by weight band morning and evening (or once daily)											Number of tablets	
			3 – 5.9 kg		6 – 9.9 kg		10 – 13.9 kg		14 – 19.9 kg		20 – 24.9 kg		Strength of adult tablet	25 – 34.9 kg	
			AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
Zidovudine	AZT	10 mg/ml	6 ml	6 ml	9 ml	9 ml	12 ml	12 ml	–	–	–	–		–	–
	AZT/3TC	Tablet (dispersible) 60 mg/30 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 mg/150 mg	1	1
	AZT/3TC/ NVP	Tablet (dispersible) 60 mg/30 mg/50 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 mg/150 mg/200 mg	1	1
Lamivudine	3TC	10 mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	–	–	–	–		–	–
Abacavir	ABC	Tablet (dispersible) 60 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 mg	1	1
	ABC/3TC	Tablet (dispersible) 60/30 mg	2		3		4		5		6		600 mg/300 mg	1	
		Tablet (dispersible) 120/60 mg	1		1.5		2		2.5		3		600 mg/300 mg	1	
Nevirapine	**NVP (eMTCT only)**	Tablet (dispersible) 50 mg	0.5		1		1								
		10 mg/ml	2 ml		3 ml		4 ml								
Efavirenz	EFV	Tablet (scored) 200 mg	–		–		1		1.5		1.5			2	
Lopinavir /ritonavir	LPV/r	80/20 mg/ml	1 ml	1 ml	1.5 ml	1.5 ml	2 ml	2 ml	2.5 ml	2.5 ml	3 ml	3 ml		–	–

		Granules 40 mg/10 mg sachet	2	2	3	3	4	4	5	5	6	6	–	–	–
		Tablet 100 mg/25 mg	–	–	–	–	2	1	2	2	2	2	–	3	3
Atazanavir	ATV	Capsules 100 mg	–		–		2		2		2				
		Capsules 200 mg	–		–		1		1		1				
Darunavir	DRV	Tablet 75 mg	–	–	–	–	–	–	5	5	5	5	600 mg		1
Ritonavir	RTV (std dose)	Tablet 25 mg							2	2	2	2	100 mg	1	1
	RTV (super-boosting LPV)	Tablet 25 mg	–	–	–	–	4	4	6	6	6	6			
		Tablet 100 mg	–	–	–	–	1	1	1	2	1	2	–	2	2
Raltegravir	RAL	Chewable tablets 100 mg	–	–	0.5	0.5	1	0.5	1	1	1.5	1.5	400 mg	1	
Dolutegravir	DTG	Tablet 50 mg	–		–		–		–		1		–	1	

Anticipated simplified dosing for formulations under development*

ARV Medicine	Abbreviation /FDC	Strength of paediatric formulation	Number of tablets or sprinkle capsules or sachets by weight band										Number of tablets	
			3–5.9 kg		6–9.9 kg		10–13.9 kg		14–19.9 kg		20–24.9 kg		25–34.9 kg	
			AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Abacavir	ABC/3TC/LPV/r	30 mg/15 mg/40 mg/10 mg	2	2	3	3	4	4	5	5	6	6		
	ABC/3TC/EFV	150 mg/75 mg/150 mg	–		–		1.5		2		2.5		3	
Darunavir	DRV/r	120 mg/20 mg	–	–	–	–	2	2	3	3	3	3	4	
Dolutegravir	DTG	Scored dispersible 10 mg	1		1.5		2		2.5		3			
	ABC/3TC/DTG	60 mg/30 mg/5 mg	2		3		4		5		6			

**Expected to be available starting in 2020*

12.13 Appendix 13: Form 13A for reporting of a child suspected of being in need of protective services (professionals)

NOTE: A separate form must be completed for

DATE OF REPORT: _

TO: State-employed social worker / member of the police at_(place)

REPORT BY:

Name		
Contact information		
Profession		
❑ school principal ❑ teacher ❑ medical or dental practitioner ❑ pharmacist ❑ school counsellor ❑ dentist ❑ psychologist ❑ psychological counsellor	❑ nurse ❑ physiotherapist ❑ speech therapist ❑ occupational therapist ❑ traditional leader ❑ traditional health practitioner ❑ legal practitioner ❑ religious leader	❑ labour inspector ❑ social worker (in private practice or employed by a child protection organization or a member of staff at a facility registered under the Child Care and Protection Act) ❑ other ___ (capacity)
Institution where I work (if relevant) (name of school, hospital or clinic, law firm, religious institution, child protection organisation, child-related registered facility, etc)		
Location where incident took place (local authority or region)		

I suspect that the child described below may be in need of protective services pursuant to section 132 of Child Care and Protection Act, 2015, for the reasons described below.

PART A: INFORMATION ABOUT CHILD CONCERNED *Provide as much information as possible.*				
Name				
Date of birth OR approximate age	/ /	Sex	❑ Male	❑ Female
ID number *(if applicable and known)*				
Residential address		Contact number ( )		
Email contact				
School attended				
Grade				
Home language				
Person currently caring for child				

PART B: CONTACT PERSON TRUSTED BY CHILD *Provide as much information as possible.*					
Name			Sex	❑ Male	❑ Female
Residential address		Postal address			
Telephone		Cellphone			
Email		Fax			
ID number *(if known)*					
Home language					
Person's relationship to child					

PART C: INFORMATION ABOUT PARENTS OF CHILD *Provide as much information as possible.*	
Mother	
Surname	

First name(s)			
Residential address		Postal address	
Telephone		Cellphone	
Email		Fax	
ID number *(if known)*			
Home language			
Father			
Surname			
First name(s)			
Residential address		Postal address	
Telephone		Cellphone	
Email		Fax	
ID number *(if known)*			
Home language			

PART D: DESCRIPTION OF CIRCUMSTANCES GIVING RISE TO REPORT *Attach additional pages if necessary.*	
Timeframe	q Date (or approximate date) of incident:
	q Ongoing problem from date (or approximate date):
	q Date/timeframe unknown
Place of incident or problem:	

Description of incident or basis for concern:

Description of any physical injuries or psychological harm observed which indicate abuse or neglect:			
Degree of risk to child, in your professional opinion:			
❑ Mild	❑ Moderate	❑ Severe	❑ Unknown
Describe Interventions by you, or any other interventions you are aware of:			
Details of medical interventions you are aware of:			
Treated at hospital or clinic? ❑ Yes ❑ No	❑ Doctor:__(name) ❑ Nurse:__(name)		Hospitalised: ❑ for assessment ❑ for treatment ❑ as place of safety
Where? (name of hospital or clinic)	Contact person		Telephone number

PART E: ALLEGED ABUSER *Provide as much information as possible, if relevant.*				
Surname				
First name(s)				
Nicknames or aliases				
ID number *(if known)*				
Date of birth or approximate age	/ /	Sex	❑ Male	❑ Female

Residential address		Postal address	
Telephone		Cellphone	
Email		Fax	
Home language			
Relationship to child			

Declaration
I, the undersigned, hereby declare that the information provided in this statement is to the best of my knowledge true and correct. Signature of applicant: _____ Date:___Place: _____

FOR OFFICIAL USE ONLY – to be completed by social worker or police officer who receives report	
Name and particulars of social worker who received report	Name: Registration number: Ministry *(if applicable)*:
Name of investigating social worker to whom case was referred *(if applicable)*	
Date of referral	
OR	
Name and rank of police official who received report, and relevant police station	Name: Rank: Police station:
Name of investigating social worker to whom case was referred	

Date of referral		
MEDICAL INTERVENTION		
Treated at hospital or clinic? ❑ Yes ❑ No	Examined by: ❑ Doctor:__(name) ❑ Nurse:__(name)	Hospitalised: ❑ for assessment ❑ for treatment ❑ as place of safety
Where? (name of hospital or clinic)	Contact person	Telephone number
ACTION TO PROTECT CHILD		
Removal of child to place of safety: No Yes If yes, date: ___ Place of safety:	Other (describe):	
ACTION AGAINST ALLEGED ABUSER		
Police docket opened ❑ No ❑ Yes If yes, date: ___ CR number: ___	Removed from home ❑ No ❑ Yes If yes, date: ___ Attach Form 14.	

RECOMMENDED ACTIONS
PENDING ACTIONS

12.14 Appendix 14: Standard Operating Procedures: Community ART Groups (CARGs)

Description	• Self-formed groups of clients on ART comprised of 6-12 members. They are usually from the same geographic area and usually in hard-to reach communities with limited access to a health facility. Members should be willing to disclose their status to each other. They rely on pre-existing social networks, such as support groups, workmates and family relations. Each member should attend the clinic and seen by doctor or nurse for their clinical visits and monitoring blood visits every 6 months. However, group members take turns to collect each other's medicines. • Group members must meet at least 24 hours prior to the members' scheduled refill date. During this initial meeting, the booklets for group members are handed over to the group representative. The representative, with the support of the group leader, will also ask general screening questions as elaborated in the standard operating procedures. Unwell group members should accompany the representative to the clinic so that their conditions are reviewed. The ARV refills will be for a period of 1-3 months depending on the available stock of ARV medicines. • After the visit to the facility, the group representative should meet with the group members within 24 hours preferably on the same day of collection, to distribute and return the members' medicines and booklets
Eligibility Criteria	• Virally suppressed (two previous consecutive tests should be < 50) • In the absence of VL, rising CD4 cell counts or CD4 counts above 350 cells/mm3 • No OIs (eg TB) • Patients who stayed > 12 months on ART • Patients with challenges related to access to health facilities • Non-pregnant, non-breast-feeding women • Adults >18 years of age
Setting up CARGs	**At facility level**: • A multidisciplinary team (MDT) should meet to discuss client flow, roles and responsibilities and identify focal persons. Facilities should also work together with community partners and community support groups to facilitate demand creation in the community. • Each group's files should be stored at the same place, facilitating recording of information, finding test results and identifying which member has come to represent the group. Group folders containing all members' files can be used to improve filing efficiency.
	Recruitment of clients: • The health care worker should screen clients to assess them based on eligibility criteria for the groups during a clinical visit. • Once assessed as stable by the HCW, the client can choose to join a CARG and be referred to the HCW focal point coordinating CARG formation. • If the clients wish to form a group; they should visit a clinic as a group for screening • All clients joining a CARG group should undergo an orientation session

	• Each group should identify a group leader who will ensure that group ethics are adhered to • The newly formed group is trained on: (a) the approaches, roles and responsibilities of members; (b) how to monitor the adherence of members and (c) how to provide group counselling and education sessions.
Group meeting in the community prior to clinic visit	• CARG members meet in the community at a convenient venue and time • Each member of the group reports on his/her adherence. The representative or focal person (if other group members are illiterate) will collect the information of each member's adherence assessment result. • Clients must be empowered to self-screen for TB and report symptoms of TB or any other condition. Group members who are unwell or have TB symptoms must join the group representative to attend a consultation at the health facility. • Unwell group members will be identified and must join the group representative to attend a consultation at the health facility. • The group representative attending the facility for consultation and on behalf of the other members must collect all ART booklets and other group monitoring tools for the group members and bring them to the clinic for refill. • Members of the group may opt to all contribute financially for transport fare. • Members discuss the venue for meeting when the representative is back from the facility to distribute the drugs.
Procedures during visit at health facility	• During consultation, the group representative will report back on the adherence and general health of other group members. • ART booklets are updated (visit date, comment on refill, i.e., group representative refilled, and next visit date to be written). • Chronic care files must also be updated with this information for each group member file. • The visiting group representative has the opportunity to have a clinical review, as well as adherence counselling. • All routine and other required laboratory investigations must be done on this visit day. • Pending results for any member who might have been consulted prior to this must only be communicated as "normal" if there are no abnormalities. Otherwise, individual clients with abnormal results are supposed to be called at the time of receipt of their results by healthcare workers. • Any member requiring additional clinical follow up should be identified and asked to attend the clinic. • Prescription sheets should be written for all group members. • The community ART group tools including registers should be updated by the nurse whenever there are any changes in CARG composition or an outcome occurs.
CARG group meeting after clinic visit	• The group must meet within 24 hours at a convenient place for drug distribution. • When necessary and as advised by the staff at the health facility, the group representative may request a group member to go to the clinic for a special consultation.

12.15 Appendix 15: Standard Operating Procedures for Fast-Track ART Refill Model

Description	• This model is offered to stable ART clients who wish to refill at the facility **individually**. The minimum standard is that **clinical reviews must be conducted every six months coupled with laboratory tests as appropriate. In between the clinical visits (i.e., at every three months), refills should be fast-tracked.** Stable ART clients eligible for fast-track should be educated on basic self-care management and empowered to conduct self-assessments to decide whether they can directly pick up their ARVs from the pharmacy or return to mainstream care for unscheduled visits if unwell. Adequate client empowerment is critical to limit loss to follow up, non-adherence to their ARVs, disease progression and treatment failure.
Eligibility Criteria	• Virally suppressed (two previous consecutive tests should be < 50) • In the absence of VL, rising CD4 cell counts or CD4 counts above 350 cells/mm3 • No OIs (eg TB) • Patients who stayed > 12 months on ART • Patients with challenges related to access to health facilities • Non-pregnant, non-breast-feeding women • Adults >18 years of age
Recruitments of clients into Fast Track model	• Facility nurse should identify clients that meet the eligibility criteria and wish to be fast-tracked for their ARV refill • Patient should be booked for the next refill and clinical visits
During the clinic visit	• The client should go straight to the pharmacy to collect their medication • If unwell, the client can visit nurse/doctor for a clinical consultation • The pharmacist will update the client's care booklet
After the visit	• The patient monitoring books are taken for data entry into ART register or the ePMS

12.16 Appendix 16: ARV Resistance Test Request Form

NAMIBIA INSTITUTE OF PATHOLOGY LIMITED

P.O. Box 277 Windhoek, Namibia

Practice No.: 052/000/5201438
Practice No.: 075/005/0148377

Tel: +264-61-2954200
Fax: +264-61-233285

ARV RESISTANCE TEST REQUEST FORM

REFERRING DOCTOR	PRACTICE No.		
COPIES TO DR/s	HOSPITAL	WARD	
PATIENT'S SURNAME	PATIENT'S FIRST NAME		URGENT
ID No.	SEX M F	DATE OF BIRTH DD MM YY	Contact Person
ACCOUNT TO (Mr. / Ms)	Tick for **STATE**		Tel No. _____
ADDRESS			Fax No. _____
TEL No. (Home)	TEL (Work)	EMPLOYER	Collection Date / Time
MEDICAL AID	MEDICAL AID No.		Collected By

INSTRUCTIONS ON SPECIMEN COLLECTION

PLEASE NOTE:
BLOOD MUST BE COLLECTED IN 2 X PPT TUBES AND MUST REACH THE NIP WINDHOEK CENTRAL REFERENCE LABORATORY WITHIN 48 HOURS AFTER COLLECTION. NO SPECIMENS WILL BE REFERRED TO THE REFERENCE LABORATORY IN SOUTH AFRICA WITHOUT HIV SPECIALIST/CONSULTANT AUTHORIZATION.

PATIENT CLINICAL INFORMATION

REASON FOR RESISTANCE TESTING:

.....

.....

.....

.....

.....

MOST RECENT VIRAL LOAD & LAB NO IF AVAILABLE:

.....

CURRENT ARV REGIMEN OF THIS PATIENT:

.....

.....

INITIATION DATE OF FIRST ARV TREATMENT:

.....

PREVIOUS ARV REGIMEN OF THIS PATIENT:

.....

.....

.....

.....

.....

AUTHORIZATION REQUIRED FOR STATE PATIENTS

NAME OF SPECIALIST/CONSULTANT WITH WHOM CASE WAS DISCUSSED AND AUTHORIZED ARV RESISTANCE TESTING:

.....

.....

PHONE NUMBER OF REQUESTING DOCTOR:

.....

PHONE NUMBER OF AUTHORISING SPECIALIST/CONSULTANT:

.....

Rec 001/03 Version 1

12.17 Appendix 17: Vaccination Schedule

At birth	Monovalent HepB vaccine to all newborn babies within 24 hours -14 days after birth If mother is hepatitis B surface antigen (HBsAg)-positive, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours after birth. BCG vaccine Oral Polio Vaccine (OPV) 0
At Six weeks	Pentavalent 1 Pneumococcal (PCV)1 Rotavirus1 Oral Polio Vaccine (OPV)1
At Ten Weeks	Pentavalent 2 Pneumococcal (PCV)2 Rotavirus2 Oral Polio Vaccine (OPV)2
At Fourteen Weeks	Pentavalent 3 Pneumococcal (PCV)3 Oral Polio Vaccine (OPV)3 Inactivated Polio Vaccine (IPV)
At Nine Months	Measles Rubella (MR)1
At Fifteen months	Measles Rubella (MR)2
Five years old	Dipththeria Pertussis (DT) Oral Polio Vaccine (OPV)
Ten years old	Dipththeria Pertussis (DT) Oral Polio Vaccine (OPV)
Fifteen years old	Tetanus Toxoid (TT) (for further doses needed, refer to the Expanded Programme of Immunisation Guidelines

12.18 Appendix 18: Patient Health Questionnaire (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME:_____ DATE:_____

Over the last *2 weeks*, how often have you been bothered by any of the following problems? *(use "✓" to indicate your answer)*	Not at all	Several days	More than half the 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 figety 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	0	1	2	3
add columns		+	+	

(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card). TOTAL:

10. If you checked off *any problems*, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?	
	Not difficult at all _____
	Somewhat difficult _____
	Very difficult _____
	Extremely difficult _____

PHQ-9 Patient Depression Questionnaire

For initial diagnosis:

1. Patient completes PHQ-9 Quick Depression Assessment.
2. If there are at least 4 ✓s in the shaded section (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.

Consider Major Depressive Disorder

- if there are at least 5 ✓s in the shaded section (one of which corresponds to Question #1 or #2)

Consider Other Depressive Disorder

- if there are 2-4 ✓s in the shaded section (one of which corresponds to Question #1 or #2)

Note: Since the questionnaire relies on patient self-report, all responses should be verified by the clinici and a definitive diagnosis is made on clinical grounds taking into account how well the patient understoc the questionnaire, as well as other relevant information from the patient.
Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational, or other important areas of functioning (Question #10) and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication, or other drug as the biological cause of the depressive symptoms.

To monitor severity over time for newly diagnosed patients or patients in current treatment for depression:

1. Patients may complete questionnaires at baseline and at regular intervals (eg, every 2 weeks) at home and bring them in at their next appointment for scoring or they may complete the questionnaire during each scheduled appointment.
2. Add up ✓s by column. For every ✓: Several days = 1 More than half the days = 2 Nearly every day = 3
3. Add together column scores to get a TOTAL score.
4. Refer to the accompanying **PHQ-9 Scoring Box** to interpret the TOTAL score.
5. Results may be included in patient files to assist you in setting up a treatment goal, determining degree of response, as well as guiding treatment intervention.

Scoring: add up all checked boxes on PHQ-9

For every ✓ Not at all = 0; Several days = 1;
More than half the days = 2; Nearly every day = 3

Interpretation of Total Score

Total Score	Depression Severity
1-4	Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

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12.19 Appendix 19: Essential Data Elements on HIV Care / ART Card

Demographic information	HIV care and family status	ART summary	Patient follow up information
- Unique number/identifier - Name, health passport number, sex, age at registration, date of birth, marital status - Physical address, telephone details - Prior ART - Entry point into HIV care	- Treatment supporter name, physical address and contact information - Home-based care provider details - If family members/partners in same household: name, age, HIV status, HIV care enrolled, unique number - ART treatment interruptions; date stopped or lost, reason and date restarted - Medicine allergies	- Date confirmed HIV positive - Date enrolled in HIV care - ART START date/ initial regimen / functional status and weight at ART start - ART substitutions within 1st line regimens - Switches to 2nd line and substitutions within second-line regimen - Transferred In: date, facility transferred in from - Transfer Out: date, facility transferred out to - Date, if previously on TB treatment	- Follow-up date, tick if scheduled - Next follow-up date - Duration in months since starting ART - Duration in months on current regimen - Weight/Height - BMI/MUAC - Pregnancy status, FP method/s - STI Screen - Nutritional Status - Functional status - WHO Clinical Stage - TB Screening including TPT - TB Diagnosis, Treatment and Outcome - Side effects - New OIs or other problems - Cotrimoxazole adherence, dose, no. days prescribed - Other medications prescribed - ARV medicine: adherence, dose, no. of days prescribed - Referrals, consultations, hospitalisations - Alcohol Screening - Laboratory test dates and results: CD4, HB, ALT, viral load - Dr/Nurse signature

12.20 Appendix 20: Standard Reporting Tools for HIV Program

	Community/Out of facility	Facility	Sub-national and national
Paper based tools and Registers	- Patient health passport - HTS register - Patient Care Booklet - Viral load monitoring register - CAG register - Bi-directional referral form - Case management register	- Patient health passport - HTS register - Patient Care Booklet - Active medicine safety monitoring form - ART register - Viral load monitoring register - TPT register - PrEP register - Booking register/Appointment book - Bi-directional referral form - Adverse events reporting form (TIPC) – yellow form	Monthly /quarterly summary reports
Electronic capturing and reporting Systems		- EPMS - EDT - PMIS dashboard - MEDITECH - HTS - P-tracker - eTB manager - HIV qual - DHIS2 - Other	Monthly /quarterly summary reports
Reports	- Monthly summary report form for HIV testing - CAG quarterly report - Customized reporting tools	- Monthly & Quarterly summary report form for HIV testing - Monthly & Quarterly facility report - Customized reporting tools	Quarterly & Annual report.

12.21 Appendix 21: Core list of monitoring Indicators for the Namibia HIV program

Areas	Indicators
Testing	**Number of individuals who received HIV Testing Services (HTS) and received their test results**
	Number of partners of index client tested
	Number of individuals HIV self-test kits distributed to
Treatment /Retention/ Suppression	**Number of adults and children currently receiving antiretroviral therapy (ART)**
	Number of people living with HIV who initiate ART
	Percentage of adults and children known to be on treatment 12 months after initiation of antiretroviral therapy
	Percentage of patients with specific outcomes at 12 months(on first-line ART, DEAD, LTF, STOP)
	Percentage of people living with HIV who are receiving ART
	Percentage of ART patients with a viral load result documented in the medical record and/or laboratory information systems (LIS) within the past 12 months with a suppressed viral load (<1000 copies/ml)
TB/HIV	**The proportion of ART patients screened for TB in the semi-annual reporting period who are receiving TB treatment**
	Proportion of people living with HIV started on ART with active TB disease
	The number of ART patients who completed a standard course of TB preventive therapy within the semi-annual reporting period
	The number of HIV-positive new and relapsed TB cases on ART during TB treatment
	Percentage of new and relapse TB cases with documented HIV status
eMTCT	**Percentage of final outcomes among HIV exposed infants registered in a birth cohort**
	Percentage of infants born to HIV-positive women who received a first virologic HIV test (sample collected) by 2 months of age.
	Percentage of pregnant women with known HIV status at antenatal care (includes those who already knew their HIV status prior to ANC)
	Number and percentage of HIV-positive pregnant women who received antiretroviral medicine (ARV) during pregnancy to reduce the risk of mother-to-child transmission
	Percentage of pregnant women with known HIV status
ART for Prevention	**Number of people receiving PrEP for the first time during the reporting period**
Medicine managment	**Stockout rate at service delivery point**
	Service delivery points reporting rate to logistic Management Information System LMIS

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