Republic of Namibia
Ministry of Health and Social Services

NATIONAL GUIDELINES FOR ANTIRETROVIRAL THERAPY

POCKET GUIDE 2021

Directorate of Special Programmes

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POCKET GUIDE EDITION 2021

This is a Pocket Guide Edition for clinicians and pharmacists of the main National ART Guidelines.

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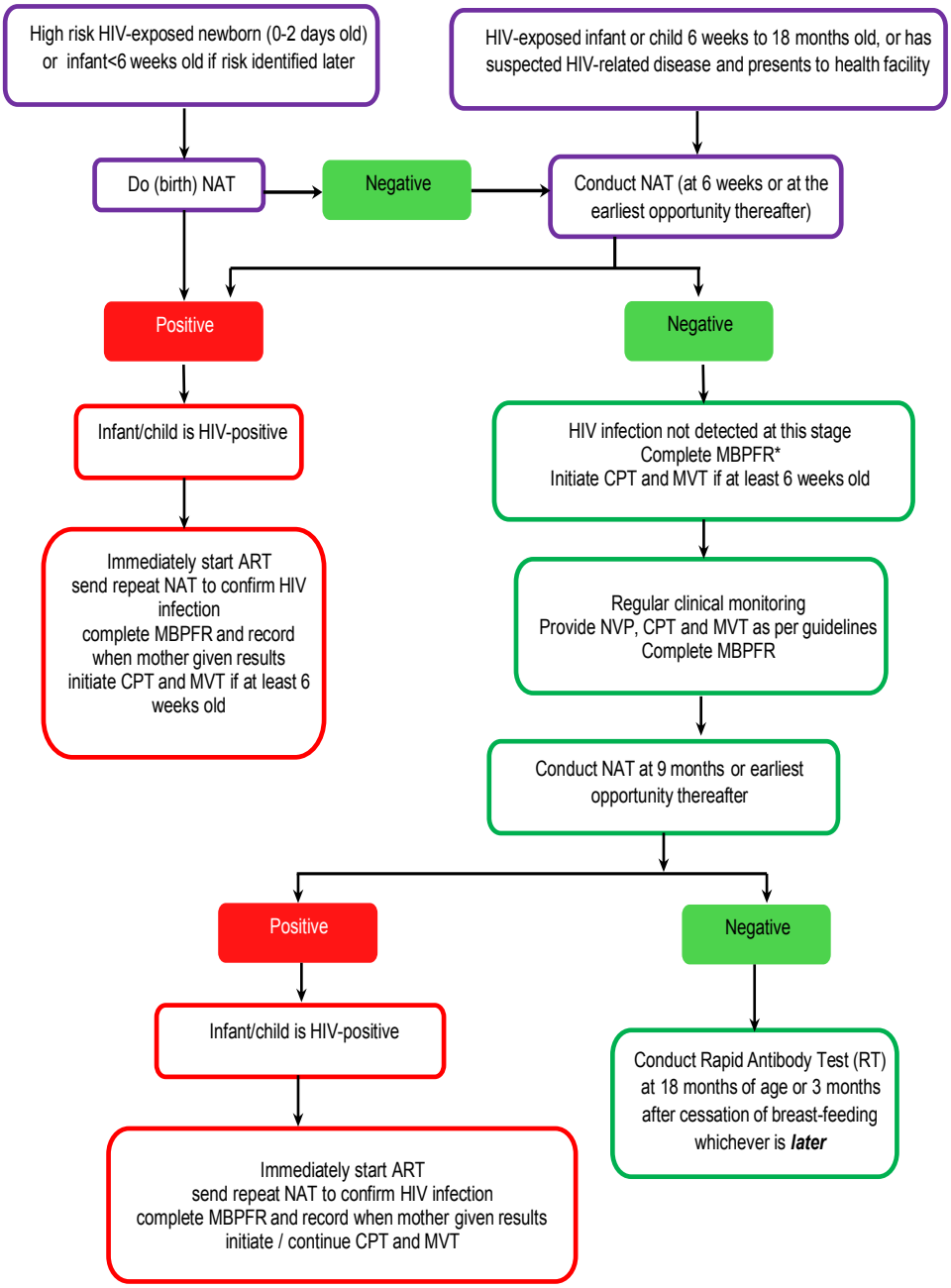
1.1 HIV testing in Neonates, Infants, and Children under 24 months

Figure 1-1:Algorithm for early infant diagnosis of HIV using diagnostic Nucleic Acid Test (NAT) and Rapid Antibody tests for HIV-exposed infants



Note: Near Point-of-care nucleic acid testing should be used to diagnose HIV among infants and children younger than 18 months of age for facilities where it is available.
*MBPFR: Mother-Baby Pair Follow-up Register

1.2 HIV testing in Adolescents, Adults, and Pregnant/Breast Feeding Women

- Adolescents from the age of 14 years and above may consent to HIV testing without parental or guardian's permission
- 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 be responsive to the needs of their clients and not administer HIV testing indiscriminately.
- Maternal retesting at 36 weeks gestation, at labour & delivery, and every 3 months throughout the breastfeeding period is imperative to identify HIV infection and eliminate seroconversion among this priority population.

2 ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION OF HIV

See Chapter 3 for antiretroviral therapy for pregnant and breastfeeding women (Table 3-3) who are treated the same as adults. There is now extensive evidence post the original findings out of Botswana of the superiority of DTG for pregnant/BF women and women of childbearing potential. In addition, recent analysed results from a study conducted in Namibia examining HIV-drug resistance among treatment naïve infants showed levels of drug resistance that threatens the ability to obtain viral load suppression among children even if children are on optimized antiretroviral therapy. This underscores the urgent need for frequent viral load monitoring in the pregnant and breastfeeding population as well as optimized antiretroviral therapy. Pregnant/BF women and women of childbearing potential should be treated the same as the adult population covered in Chapter 3.

2.1 Treatment monitoring of HIV-positive pregnant and breastfeeding women

- For all HIV-positive pregnant women, regardless of ART initiation timing: conduct viral load testing at 34–36 weeks of gestation (or at the latest at delivery) to identify women who may be at risk of treatment failure and/or may deliver infants at higher risk of perinatal transmission. If viral load testing is expected to be undertaken near the planned viral load at 34–36 weeks of gestation, the first viral load test can be delayed until weeks 34–36 of gestation.

  In addition:

  a) For HIV-positive pregnant women receiving ART before conception: conduct a viral load test at the first antenatal care visit (or when first presenting) to identify women at increased risk of in utero HIV transmission to the unborn infant.

  b) For HIV positive pregnant women starting ART during pregnancy: conduct a viral load by three months after ART initiation to ensure that there has been rapid viral suppression.

- For all HIV positive breastfeeding women, regardless of when ART was initiated: conduct a viral load test 6 weeks after delivery, then 3 monthly until end of breastfeeding period to detect viraemic episodes during the postnatal period.

Adherence counselling should be provided at all antenatal care and postnatal visits to ensure that viral suppression is maintained throughout pregnancy and breastfeeding. Please refer to chapter 3 for management of clients who interrupt ART and chapter 5 for Enhanced Adherence counselling (EAC).

Table 2-1: 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 viral load testing is expected to be undertaken in close proximity to the planned viral load at 34–36 weeks of gestation, the first viral load test can be delayed until weeks 34–36 of gestation. • If the VL was <40 copies/ml, repeat every 3 months until delivery, then at 6 weeks postpartum 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 postpartum, and thereafter every 3 months until end of the

	breastfeeding period. If any repeat VL is >1000 copies/ml, 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 breastfeeding period:	• Do VL 3 months after initiation, then 3-monthly until delivery, then 6 weeks postpartum, and thereafter every 3 months until the end of the breastfeeding period. If viral load testing is expected to be undertaken in close proximity to the planned viral load at 34–36 weeks of gestation, the first viral load test can be delayed until weeks 34–36 of gestation. As with patients already on ART, if any VL result is >1000 copies/ml, appropriate action as discussed above should be taken.

NOTE: Viral load specimens and results for pregnant and breastfeeding women should be given priority across the laboratory referral process (including specimen collection, testing and return of results)

Table 2-2: 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 copies/ml or unknown, continue with NVP daily until 1 month after cessation of breastfeeding If NOT breastfeeding since birth or in last 4 weeks, OR mother's VL<40 copies/ml, discontinue infant prophylaxis and continue to monitor mother's VL as prescribed Start CTX prophylaxis until discharge from eMTCT
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. Those who are high risk and present more than 72 hours should have an HIV NAT test immediately.

Table 2-3: Simplified infant NVP and AZT dosing recommendations (eMTCT only)

Infant age	Dosing of NVP		Dosing of AZT (10mg/ml)
	NVP 50mg Tablet	Alternative dose if there is NVP 200mg syrup	
Birth weight < 2000g and older than 35weeks gestation		4mg/kg o.d	4mg/kg b.d
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

Contact an HIV clinical mentor or specialist paediatrician for dosing of premature infants younger than 35 weeks of gestational age.

The 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 the amount to be taken using a syringe is not necessary.

3 ANTIRETROVIRAL THERAPY FOR ADULTS, ADOLESCENTS, INFANTS AND CHILDREN

All HIV positive clients 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. Children < 18 months should be initiated on ART **as soon as the first NAT test is positive**. Refer to 1.1 HIV testing in Neonates, Infants, and Children under 24 months, for initiation of children < 18 months.

Table 3-1: Clinical Indications of Deferring Same Day 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	Patients with confirmed TB disease, defer same day ART initiation but start within 2 weeks after the start of TB treatment.

Table 3-2: Baseline clinical assessment for infants, children and adolescents 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 in full ART GL 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.
☐	**Comorbidities**	Screen for active TB, other OIs
☐	**TPT eligibility**	Ask TPT screening questions and prescribe TPT if eligible, see Chapter 7, Management of Comorbidities and Other Services (See Figure 6-2)
☐	**Immunisation status**	Review the vaccinations given as recorded in the health passport and plan catch-up vaccinations if due.
☐	**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 ≥5 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.

3.1 Recommended First Line ART Regimens

Table 3-3: Recommended First Line ART Regimens for Adults, Adolescents, Infants and Children

Populations	Preferred first-line regimen	Alternative first-line regimen
Adults and Adolescents weighing at least 30 kg	TDF + 3TC (or FTC) + DTG[a,b] (TLD_1)*	TDF + 3TC + EFV 400mg TAF + 3TC + DTG**
Adolescents 25kg to < 30kg	TAF + 3TC + DTG	ABC + 3TC + DTG ABC + 3TC + ATV/r[c]
Adolescents 20kg to < 25kg	ABC + 3TC + DTG	ABC + 3TC + ATV/r[c]
Children from 4 weeks weighing at least 3kg	ABC + 3TC + $_p$DTG	ABC + 3TC + ATV/r[c] ABC + 3TC + LPV/r[d]
Neonates	AZT (or ABC) + 3TC + RAL[e]	AZT + 3TC + NVP[e]

[a]TB patients on Rifampicin to receive an additional dose of DTG 50mg
[b]There is now extensive evidence post the original findings out of Botswana of the superiority of DTG for pregnant/BF women and women of childbearing potential.
[c]ATV/r (200mg) capsule with RTV boost can be used for children from 10kg if they can swallow the capsule whole
[d]LPV/r granules starting at 2 weeks or LPV+r 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 LPV+r 100/25mg
[e]Immediately switch to ABC/3TC/DTG once child reaches 3kg and 4 weeks old.
*TLD_1 means patient is on TLD as first line
TAF may be considered for people with **established osteoporosis and/or impaired kidney function

Paediatric Dolutegravir 10mg (pDTG)

Paediatric dolutegravir 10 mg dispersible, scored tablets (pDTG) is a new generic formulation of DTG suitable for infants and CLHIV who are:

≥ 4 weeks of age and,
Weigh at least 3 kg up to less than 20 kg

Children receiving TB treatment containing RIF should be given double their daily standard dose of DTG 10 mg ($_p$DTG) for the duration of TB treatment. Alternatively, RAL 100mg scored chewable tablets can be given if they weigh at least 6 kg BUT AT AN INCREASED DOSE OF 12mg/kg/dose b.d

3.1.1 Criteria of Use of TAF/FTC/DTG

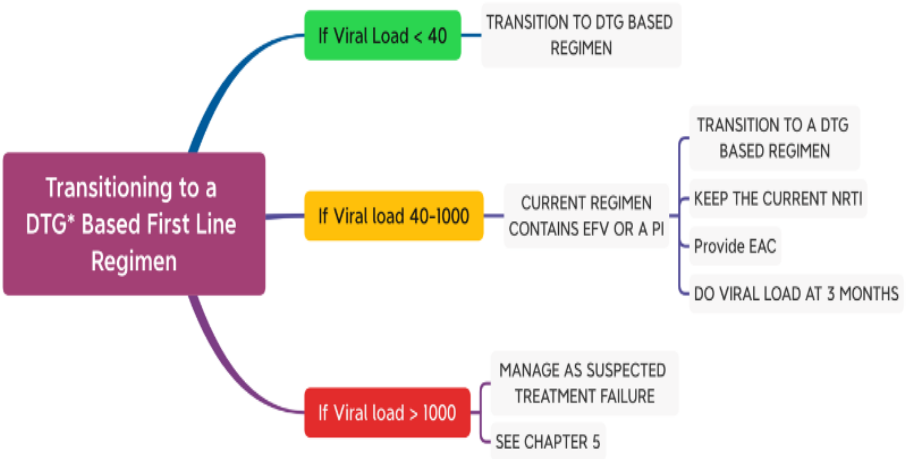
1. All newly HIV diagnosed individuals who:
    a. Have a weight of 25 kg up to 30kg.
    b. Have **established** osteoporosis and/or impaired kidney function.
2. All clients who have Creatinine Clearance between 30 to 59 mL/min on or eligible for TLD_1 or TLD_2.

All clients who are transitioned to $T_{AF}ED$ due to renal insufficiency should remain on $T_{AF}ED$ despite improvement of the creatinine clearance (more than 60 mL/min).

3.1.2 Transitioning patients to the preferred first line Regimen.

When transitioning a client from their current first line regimen to the preferred regimen; Its best that the VL is < 40 copies/ml and not older than 6 months, if not please consult. HCWs should carefully assess whether the patient is eligible for a direct substitution or if a regimen switch is required. Before transitioning, please counsel the patients appropriately on the potential for new side effects as well as the benefits of DTG.

Figure 3-1: Transitioning patients on first line to DTG based first line regimens



* Please counsel the patients appropriately on the potential for new side effects as well as the benefits of DTG

3.2 Second Line ART Regimens

Table 3-4: Recommended Second Line ART Regimens for Adults, Adolescents, Infants and Children

Populations	Failing first-line regimen	Preferred Second-line regimen
Adults and Adolescents from 25kg	TDF + 3TC (or FTC) + DTG (TLD_1)* TAF + 3TC + DTG ABC + 3TC + DTG	AZT/3TC/(ATV/r or LPV/r)
	TDF + 3TC + EFV 400mg TDF + 3TC + ATV/r ABC + 3TC + LPV/r	AZT/3TC/DTG
Children from 4 weeks weighing at least 3kg up to 25kg	ABC + 3TC + LPV/r ABC + 3TC + ATV/r	AZT/3TC/$_p$DTG
	ABC + 3TC + $_p$DTG	AZT/3TC/(LPV/r or ATV/r)

3.2.1 Simplifying Second line ART Regimens

There are some patients who are currently on the old four drug second line combination. Evidence shows that three drug regimen is non-inferior and has an added advantage of reduced pill count hence improves adherence.

Table 3-5: Simplifying Second Line ART Regimens

Current Second Line ART Regimen	VL Result within 6 months		
	VL < 40	VL 40 - 1000	VL > 1000
TDF/3TC/AZT/PIs (If AZT was part of first line) *	TDF/3TC/DTG (TLD_2)a	TDF/3TC+ DTG(TLD_2) Repeat VL in 3 months with good adherence. Consult HIV clinical mentor or specialist if LLV persists.	TDF/3TC+PIs. Manage as possible treatment failure. Consult HIV Clinical mentor or specialist for possible genotype.
TDF/3TC/AZT/PIs (If TDF was part of first line) *	AZT/3TC/DTG_2	AZT/3TC/DTG Repeat VL in 3 months with good adherence. Consult HIV clinical mentor or specialist if LLV persists.	AZT/3TC+PIs Manage as possible treatment failure. Consult HIV Clinical mentor or specialist for possible genotype.
ABC/3TC/AZT/PI (If ABC was part of first line) *			
ABC/3TC/AZT+NNRTIs (If ABC was part of first line) *			Immediately Consult HIV Clinical mentor or specialist
ABC/3TC/AZT/PI (if AZT was part of first line) *	TDF/3TC/DTG (TLD_2)a or ABC/3TC/DTG_2 (Depending on weight)	TLD_2 or ABC/3TC+ DTG Repeat VL in 3 months with good adherence. Consult HIV clinical mentor or specialist if LLV persists.	ABC/3TC+PIs. Manage as possible treatment failure. Consult HIV Clinical mentor or specialist for possible genotype.
ABC/3TC/AZT+NNRTIs (If AZT was part of first line) *			Immediately Consult HIV Clinical mentor or specialist

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

3.3 Third line ART for Adults and Adolescents

Third line regimens are based on HIV drug resistance results. A decision to perform an HIV Resistance Test should be made in consultation with HIV clinical mentors or specialist physicians after ruling out poor adherence and other factors. The resistance test should be done whilst the patient is taking treatment.

3.4 Management of clients who interrupt ART

Any patient who misses their clinic visit or pill pickup for 28 consecutive days or more is defined as "interrupted treatment" (IIT). All treatment interrupters should be traced, linked back to care, and interviewed to assess for underlying reasons for treatment interruption. Patients who return after treatment interruption for at least 6 months should have a CD4 test assessed, managed for any co-infections, and provided appropriate prophylaxis. In addition, linking all returning patients to post-tracing services ensure that patients who are successfully traced are warmly received back into care and immediately linked to services to prevent future IIT (*Refer to the Tracing and Post-Tracing Services SOP*).

3.4.1 Missed doses

Once daily dosing: If a 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 a patient normally takes medication in the evening and misses the dose but then remembers in the morning of the next day, take the missed dose immediately. If remembered in the afternoon, take the missed dose immediately and skip the evening dose.

Twice daily dosing: 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 dose as per normal schedule.

4 BIO-CLINICAL MONITORING FOR PATIENTS ON ART

Table 4-1: Laboratory assessment for children, adolescents, adults pregnant and breastfeeding 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
	TB LAM	If CD4<100 (or <200 if inpatient) OR has TB symptoms OR seriously ill OR child<5 years
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)
Low level viraemia 40-1000	VL	Repeat viral load testing after 3 months of good adherence
Suspected treatment failure	VL	Repeat VL after 3 months of good adherence to treatment and once OIs are excluded
Virological failure	CD4[3]	After the first encounter of suspected virologic failure
	HIV Drug Resistance	Before Switching to a 3rd line regimen all ages
	HBsAg if Hepatitis B status is not known	After consultation with an HIV specialist or a clinical mentor
Secondary fluconazole prophylaxis following cryptococcal meningitis	CD4[4]	6-monthly while on fluconazole prophylaxis until 2 consecutive values >200 cells/mm^3 creatinine clearance in adults and adolescents ≥18 years old

[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

Table 4-2: Calculation of Creatinine Clearance

Creatinine Clearance Calculation	
Adults and adolescents ≥18 years old	**< 19 years old**
$\frac{(140\text{-age in years}) \times \text{weight in kg} \times 1.22}{\text{Serum creatinine in micromoles/L}}$ Multiply the answer above by 0.85 for creatinine clearance in women	SCHWARTZ equation CrCl (ml/min/1.73m^2) ≈ [length (cm) x k x 88.4]/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

Table 4-3: Normal GFR in Children and Young Adults

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

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

Creatinine Clearance (ml/min)	Recommended Dosing of TDF 300 mg	Dosing of TAF/FTC/DTG
≥50	Every 24 hours	Normal dosing
30-49	Every 48 hours	Normal dosing
10-29	Twice a week	Not recommended
≤ 10	300mg weekly Consult HIV Specialist / Clinical Mentor for Guidance.	
Haemodialysis patients	Every 7 days or after a total of 12 hours of dialysis (administer following completion of dialysis) Consult for guidance	

4.1 CD4 Lymphocyte counts

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

4.2 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. Adult 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:

- Infants, children, and adolescents <19 years: VL every 6 months.
- Pregnant women: every 3 months until delivery and always at 34-36wks gestation. If viral load testing is expected to be undertaken near the planned viral load at 34–36 weeks of gestation (see Chapter 2), the first viral load test can be delayed until weeks 34–36 of gestation.
- Breast-feeding women: 6 weeks after delivery, then 3-monthly until end of breastfeeding period; then reverting to an annual VL test.
- Known Positive patients and on ART > 3 months, should have a latest documented HIV viral load during labour and delivery.

4.3 Viral Load Results Interpretation

In the Namibian context, the following operational definitions are used to interpret viral load results.

- Virological suppression is VL results < 40 copies/ml or target not detected (TND).
- Low level viremia is VL results between 40-1000 copies/ml.
- Virological failure is VL results ≥ 1000 copies/ml taken 3 months apart with adherence support following the first viral load test.

4.4 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.

4.5 Eligibility For HIV Resistance Testing

- A patient who has failed a second line regimen and needs a third line regimen.
- Patients with unclear ART history and those failing on AZT based regimens for more than 5 years (in consultation with an HIV clinical mentor).
- Patients switched to multiple first line regimens in the presence of high viral load.

4.6 Ordering of HIV Resistance Tests

Ordering an HIV genotype resistance test should be done using the specific form for that purpose. On this form, the 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.

4.7 Interpreting HIV Resistance Results

The MHSS has established the 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 MANAGEMENT OF PATIENTS WITH UNSUPPRESSED VIRAL LOAD

5.1 Definitions

In the Namibian context, the following operational definitions are used to interpret viral load results.

- Virological suppression is VL results < 40 copies/ml or target not detected (TND).
- Low level viremia is VL results between 40-1000 copies/ml.
- Virological failure is VL results ≥ 1000 copies/ml taken 3 months apart with adherence support following the first viral load test.

5.2 Factors associated with virologic failure

Patient/Adherence-Related Factors	HIV-Related Factors	Antiretroviral Regimen-Related Factors
Missed clinic appointments with interruption of, or intermittent access to ART.	Presence of transmitted or acquired drug-resistant virus	Adverse drug-drug interactions High pill burden and/or dosing frequency
Mental health illness	Higher pre-treatment (Baseline) HIV VL	Low genetic barrier to resistance Adverse drug effects
Alcohol and active substance abuse	Prior treatment failure	Medicine stock-outs
Psychosocial Factors: Stigma, discrimination leading to non-disclosure and reduced access to care Unstable housing leading to reduced access to care Hesitancy to take ARV's due to lack of food	Innate resistance to ARV drugs	Prescription errors e.g. (underdosing in children, wrong medicine, wrong dosage frequency)
Cost and affordability of ARV drugs		Suboptimal pharmacokinetics e.g., variable absorption, metabolism
		Prior exposure to suboptimal regimens (e.g., mono or dual therapy)
		Suboptimal virological potency

5.3 Approach To A Patient With Unsuppressed Viral Load

- Make sure that patient has good adherence to ART before repeat of VL
- For HIV positive PBFW with high viral load and on NNRTI's and good adherence, all effort should be done to make sure that they will be switched to potent regimen as soon as possible even if there is only one VL taken at least at 6 months of ART
- Due to their high genetic barrier, resistance to DTG develops very slowly. An elevated VL on DTG is therefore more likely to be related to suboptimal adherence than due to HIV drug resistance. For this reason, a client should be on DTG for at least 1 year from the date of the first high viral load before a switch is considered.

5.4 Definition of Enhanced Adherence counselling

Enhanced Adherence Counselling (EAC), also known as Intensified Adherence Counselling, is an ongoing counselling process provided to a patient with unsuppressed viral load or non-adherent patient returning to care, aimed at maximising medication adherence by identifying barriers to adherence, working together with the patient to explore targeted interventions to address these barriers.

5.5 Barriers to Adherence and Possible Interventions

Barriers	Questions to assess barriers	Possible Interventions
Stigma and Discrimination	-Are you afraid that people will find out about your HIV status? -Does that prevent you from coming to the clinic or taking your medicines?	-Peer to peer counselling -Linkage to support groups -Encourage and if needed assist status disclosure to partner
Depression	-Do you feel hopeless, depressed, lack motivation to live, sleepless or sleep too much, have trouble to concentrate? -Do you lack pleasure in doing activities you used to enjoy, poor appetite or eating too much, feel tired all the time?	-Refer to PHQ9 for assessment of depression -Involve the treatment supporter. -CETA* assessment -Refer to social workers/Psychologist/Psychiatrists
Substance Abuse	-How often do you take a drink containing alcohol? -Do you use drugs? -Do you feel this affects your ability to take your medicines?	-Refer to CAGE alcohol screening tool -Refer to social workers/psychologist/Psychiatrists.
Scheduling difficulty	-Have you ever been too busy (work, school, sports, entertainment, or other social activities) or experienced a schedule change that has made it difficult for you to collect or take your medicines? -Who is responsible of making and tracking your schedule?	-Use the treatment supporter -Use of reminders such clocks, phones, radios -Linkage to trios -Attach NATS for peer support -Enrolment into teen clubs if fully disclosed to.
Transport problems	-Do you have challenges getting to the clinic to collect your medicines? -If yes, what are the issues? (e.g. long distance, expense)	-Link to appropriate DSD models such as MMD, ART home delivery, CAGs etc
Forgetfulness	-How often did you forget to take your medications in the last 3 days? -Do you take them at the set time of the day?	-Use the treatment supporter -Use of reminders such clocks, phones, SMS reminders, radios -Linkage to trios -Consider use of DOT -Pill box, medication calendar
Medications issues	-Have you at any time considered or stopped taking your medicines due to feeling bad after taking them? -Have the medicines ever made you quite sick that you had to be admitted in hospital. -Would reducing how often you take your medicines or reducing the number of tablets you take per day influence how you take your medicines? -Have you ever shared your medicines with others?	-Encourage clients to report any AEs during health education sessions -Substitution/Switching to less toxic regimens -Consider use of FDC regimens where appropriate
Disclosure issues	-Are you afraid of taking your medications in the presence of anyone? -Have you disclosed your HIV status to anybody? -Does the child know why s/he is taking medications?	-Initiate and facilitate HIV status disclosure (use of tools e.g why I take my medications) -Linkage to NATS and teen clubs

Long Clinic waiting time and any other challenges	-Have you ever left the clinic before receiving your medicines because of long queues? -What other challenges are you facing with your medicines?	-Encourage stable clients to enrol into appropriate DSD models -Prioritise case management of high VL clients. -Assist orphans and vulnerable children (OVC) with social support and processing of social grants through the MoGE&CW. -Link child with community-based organizations (CBOs).

5.6 Structure of EAC sessions

EAC SESSION 1

1. Welcome and introduction.
2. Explain the viral load result.
3. Explain the EAC procedure.
4. Assess previous and current adherence.
5. Explore barriers to adherence and identify ways forward.
6. Agree with the client what adherence intervention(s) they are going to implement.
7. Supply one-month ART refill.
8. Conclude the session.

EAC SESSION 2

1. Welcome and introduction.
2. Assess patient's adherence since last visit.
3. Assess patient's knowledge regarding treatment failure.
4. Review adherence barriers and whether the client implemented intervention(s) agreed upon the previous visit.
5. Agree with the client on adherence intervention(s).
6. Supply one-month ART refill.
7. Conclude session.

EAC SESSION 3

1. Welcome and introduction.
2. Assess patient's adherence since last visit.
3. Review adherence barriers and implementation of solutions.
4. Review adherence barriers and whether the client implemented intervention(s) agreed upon the previous visit.
5. Explain that the next VL will be taken after 3 months of confirmed good adherence.
6. Supply one-month ART refill.
7. Conclude session.

EAC SESSION 4

1. Welcome and introduction.
2. Assess if the adherence interventions were successfully implemented.
3. If well implemented, do the 2nd viral load.
4. If not, review the interventions and repeat the enhanced adherence sessions.
5. Supply one-month ART refill.
6. Conclude session.

5.7 Guidance On Patient Encounters

HISTORY

- Assess adherence through pill counts (be non-judgemental), compliance of the follow up dates (PCBs, EDT and EPMS)
- Determine the disclosure status for all the children from the age of 5-19 years and enrol in disclosure program if not already carried out
  - Assess the need to go through the disclosure chapters ("Why I Take my Medicines" book) even with those patients for whom disclosure is said to have been done
  - For adults you may need to go through the "ARVs and Healthy Me" book
- Explore availability of psychosocial and treatment support system
  - Parents or Caregiver
  - Age of the caregiver
  - Assess parents/caregiver's latest VL if on ART
  - Financial support
  - Accessibility to ARVs

- Namibia Adolescent Treatment Supporter (NATS) team if available
- Teen club enrolment
- Partner's HIV and disclosure status, latest viral load result for positive partner.
- Orphan and Vulnerable Children's programs.
- DREAMS program support
- CETA (Common Elements Treatment Approach) program
- Source of income

- Review the academic performance for school going children for cognitive development
- Screening of Mental health conditions such as depression screening using validated PHQ-9, GAD-7 questionnaires for children above 10 years
- Explore history of substance abuse e.g. Using the CAGE Screening Tool
- Conduct sexual and reproductive health history
- Previous ARVs history
  - MTCT prophylaxis
  - Drug tolerability (palatability, nausea, vomiting and diarrhoea)
  - Previous transitioning or switching
  - Prior resistance test results
  - Explore unclear previous ART exposure (patients with no transfer letters)
  - Assess possible pharmacokinetic issues
  - Check for drug-drug and drug–food interactions; use recommended tools such as the Liverpool HIV interaction checker or the Medscape drug interaction checker
- **Discuss the implication of the viral load result with the patient/caregiver/treatment supporter**
- Assess the possibility of getting treatment supporters and invite them on the next follow up

EXAMINATION

- Conduct Anthropometric measurements such as BMI, MUAC, etc
- Rule out common Opportunistic infections, such as TB, Pneumonia (eg PCP), Persistent diarrheal, Oesophageal Candidiasis, Cryptococcosis
- Conduct comprehensive physical examinations and WHO Staging
- Consider TB LAM if eligible (Bedside test)

INVESTIGATIONS

- Serum creatinine and CD4
- Consider HBsAg if Hepatitis B status is not known
- If CD4 is less than 200cells/ml proceed to order CrAg test
- ***NB: In pregnant and breastfeeding women presenting with VL greater than 1000c/ml enhanced adherence counselling should be conducted and immediately and VL repeated after 6 weeks then action to be taken appropriately***
- Add any other relevant tests as required

FOLLOW UP VISITS

- Assess for adherence and check if patient recalls the previous discussions.
- Assess for adherence and check if patient recalls the discussion on the first and second visit
- Do VL at month three after good adherence
- Review the VL result
- Make clinical decision based on Figure 5.2.
- **Consult HIV experienced Physician or Clinical Mentor for possible HIV drug resistance testing**
  - Perform HIV drug resistance testing while patient is still on the failing regimen

5.8 Key Principles of Switching ART Regimens

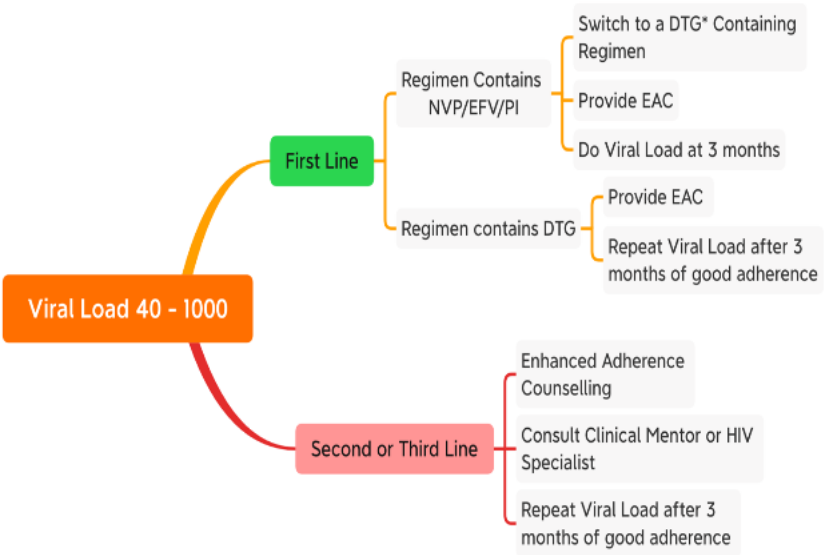
i. Review the client's ART history and all regimens or ART drugs that they have been exposed to.

ii. Due to the high genetic barrier to resistance for DTG. An elevated VL on DTG therefore more likely to be related to suboptimal adherence than due to HIV drug resistance. **For this reason, a client should be on DTG for at least 1 year from the date of the first high viral load before a switch is considered.**

iii. In patients with comorbidities, always check for possible drug-drug interactions of the new proposed ART regimen.

5.9 Management of Patients with Viral Load 40 to 1000

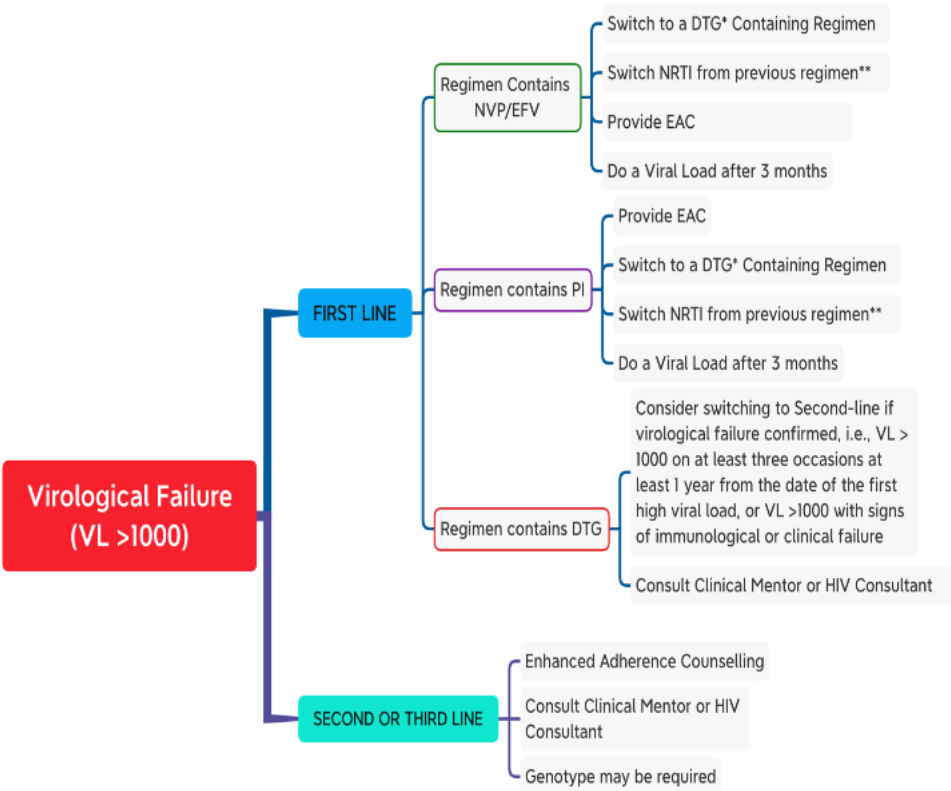
Figure 5-1: Management of Patients with Viral Load 40 - 1000



* Please counsel the patients appropriately on the potential for new side effects as well as the benefits of DTG

5.10 Management of Patients with Viral Load > 1000

Figure 5-2: Management of Patients with VL > 1000



* Please counsel the patients appropriately on the potential for new side effects as well as the benefits of DTG
**Use a different NRTI eg if failed on AZT use TDF or ABC and if failed on ABC or TDF use AZT.

5.11 Switching from 2nd line to 3rd line

- Patients confirmed to be failing on second line should have a Resistance test done in consultation with the CM/HIV specialist.
- Resistance test results should be discussed by the HIVDR committee to select an individualized regimen.
- Clinical cases can be submitted using this link: http://bit.ly/hivdrcase
- Pre-emptive 3rd line can be considered in consultation for severely immunocompromised patients (CD4 <200 cells/mm^3), eMTCT cases and clients with delayed genotypic resistance test results. Treatment optimization to be done after genotypic resistance test results.

Table 5-1: Viral load monitoring after regimen switch

Viral Load Monitoring	Adults*	Children*
Schedule after switch from 1st line to 2nd line	• 3M, 6M**, 12M, and then every 12 months if fully suppressed	• 3M, 6M**, and then every 6 months if fully suppressed
Schedule after switch from 2nd line to 3rd line	• 3M, 6M**, and then every 6 months if fully suppressed	• 3M, 6M**, and then every 6 months if fully suppressed

* Refer to appropriate guidelines for pregnant and breastfeeding women, and those who are unsuppressed (VL>40).
**If at 6M the VL is still unsuppressed, explore barriers to adherence.

6 MANAGEMENT OF CO-MORBIDITIES AND OTHER SERVICES

6.1 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.

Table 6-1: 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 children with 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

Table 6-2: 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 6-1: 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.

6.2 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 cotrimoxazole and do not give Dapsone.

NOTE: Dapsone is useful in the prevention of Pneumocystis Jirovecii Pneumonia (PCP). PCP is more common at 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.

6.3 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.

All PLHIV including children above 1 year of age should be given TPT once TB disease is excluded.

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.

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 TPT should be given once active TB disease has been excluded.

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

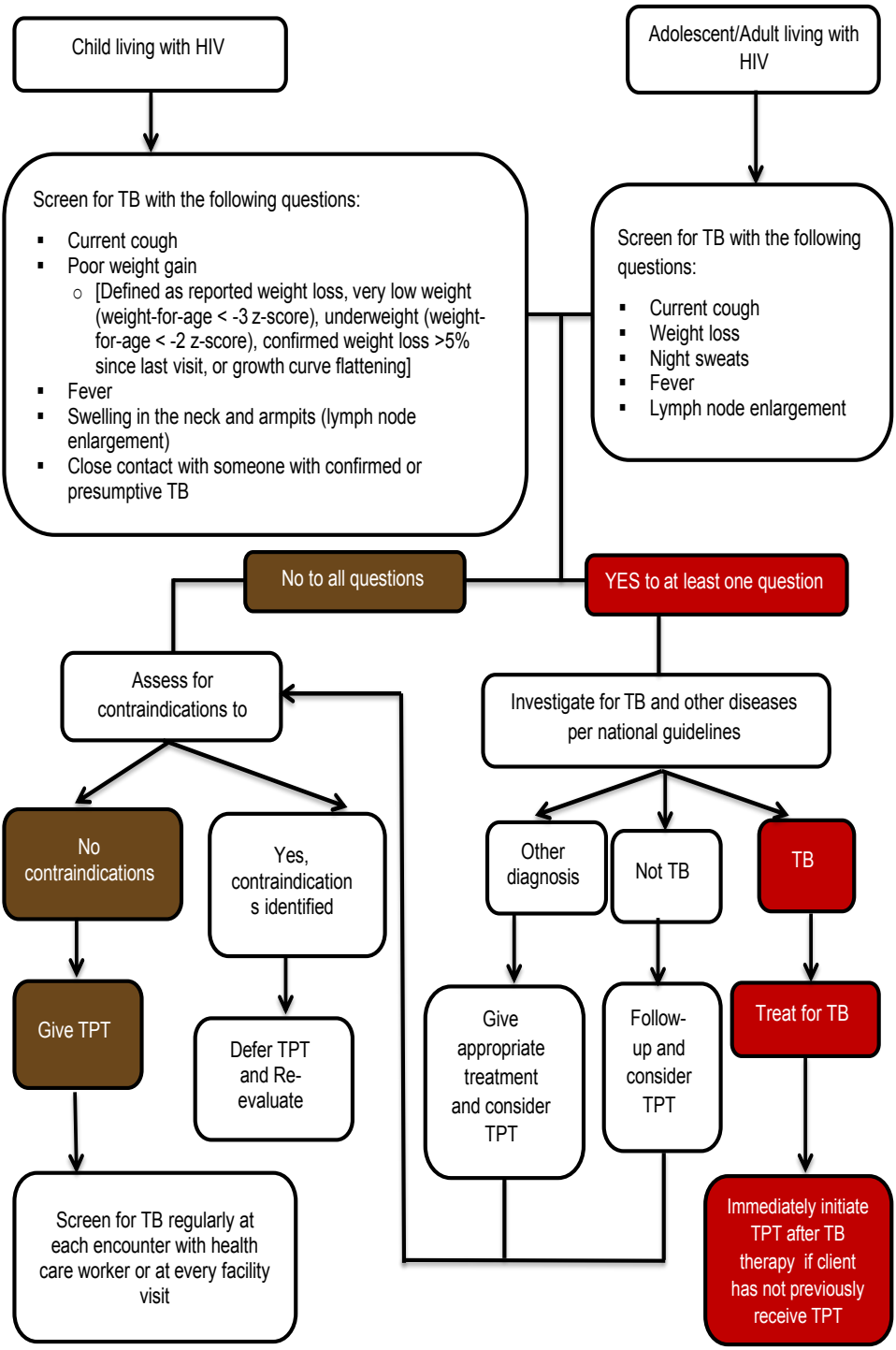
PLHIV who has already completed a course of TPT and is subsequently exposed to a patient with bacteriologically confirmed pulmonary TB, consider giving another course of TPT after every episode of exposure. TB patients who have completed a course of anti-TB treatment and have not previously received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

See Figure 6-2, below for the algorithm on TB screening and TPT among children, adults and adolescents living with HIV.

6.3.1 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 6-2: Algorithm for TB screening and TPT among children, adults and adolescents living with HIV



- **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.**

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

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

6.3.2 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)

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

6.3.3 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.
- Rifamycins may cause harmless orange/red discolouration of body fluids. This colour, which is due to the colour of the tablets, 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.

6.3.4 TPT regimens

The recommended TPT regimens are:

- Isoniazid and Rifapentine given in combination weekly for a total of 12 doses (3HP)
- Isoniazid given once daily for a period of 6 months (6H).
- For children, Isoniazid and Rifampicin can be given daily for a three-month period.

After establishing TPT eligibility, the following regimens can be administered (Table 6-3), depending on availability, patients' current ART regimen and age.

Table 6-4: TPT Regimens

ART regimen	Preferred Regimen	Alternative
On Efavirenz, Raltegravir and DTG based Regimens regardless of Viral Load	3HP*(for adults and children >2 years) 3HR (in children only)	6H
Pregnant women	6H	
Children <2 years	3HR	6H
PI based regimen	6H	

*3HP should not be used in; pregnant women, children <2 years and patients who are on PI containing regimen

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

- 3HP – Completes 12 doses within 16 weeks
- 6H – Completes 180 doses within 9 months
- 3HR – Completes 90 doses within 16 weeks

In non-adherent patients, prophylaxis should be discontinued. Pyridoxine should be given along with isoniazid to prevent isoniazid associated neuropathy. Health care workers should ensure that the outcome is updated in the ePMS Quantum System as "TPT Completed."

6.3.5 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.

6.4 TB diagnosis for PLHIV

Any PLHIV found to have symptoms of TB following routine screening and at any time should be evaluated using Xpert MTB/RIF and the urine TB-LAM test according to the national algorithm for the laboratory diagnosis of TB. In PLHIV without specific TB symptoms but are severely ill* regardless of CD4, or those with low CD4 (≤100 for outpatients and <200 for inpatients) or bedridden the Xpert MTB/RIF test and a urine TB-LAM test should be done. Although a positive TB–LAM confirms TB, a negative LAM result doesn't rule out TB. In PLHIV who have tested Xpert MTB/RIF negative and TB-LAM a specimen may be sent for mycobacteria culture and drug susceptibility testing.

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

6.5 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. The old practice of delaying ART initiation in individuals with TB symptoms may result in harm because of delays in ART initiation and increase the risk of pre-treatment loss to follow-up. ART initiation may proceed while rapidly investigating for TB (except for TB meningitis), with close follow-up within seven days to initiate TB treatment if a diagnosis of TB is made.

However, if TB has already been diagnosed; ART should be started as soon as possible within two weeks of initiating TB treatment, regardless of CD4 count.

Table 6-5: 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**)
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.

6.6 Children with TB and HIV co-infection

6.6.1 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.

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 outweighs the risk from IRIS (see 3.9 section for the management of IRIS).

Table 6-6: 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 (Preferred) If DTG not available: ABC + 3TC + RAL (use RAL from 6kg, chewable, higher dosage: 12mg/kg/dose bd) ABC + 3TC + super-boosted lopinavir/ritonavir (LPV/r + R) * If none of the options above are applicable/available, seek specialist advice 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 (use chewable RAL, higher dosage: 12mg/kg/dose bd) 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 + EFV or if child has had previous eMTCT/PMTCT NVP exposure: 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.

6.6.2 Initiating TB treatment on infants and children currently on ART

Start TB treatment and adjust ART as in Table 6-4; 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.

6.7 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 *PJP* prophylaxis, PJP occurred in up to 80% of patients.

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).

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.

Figure 6-3: 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 $Pa0_2$ 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)

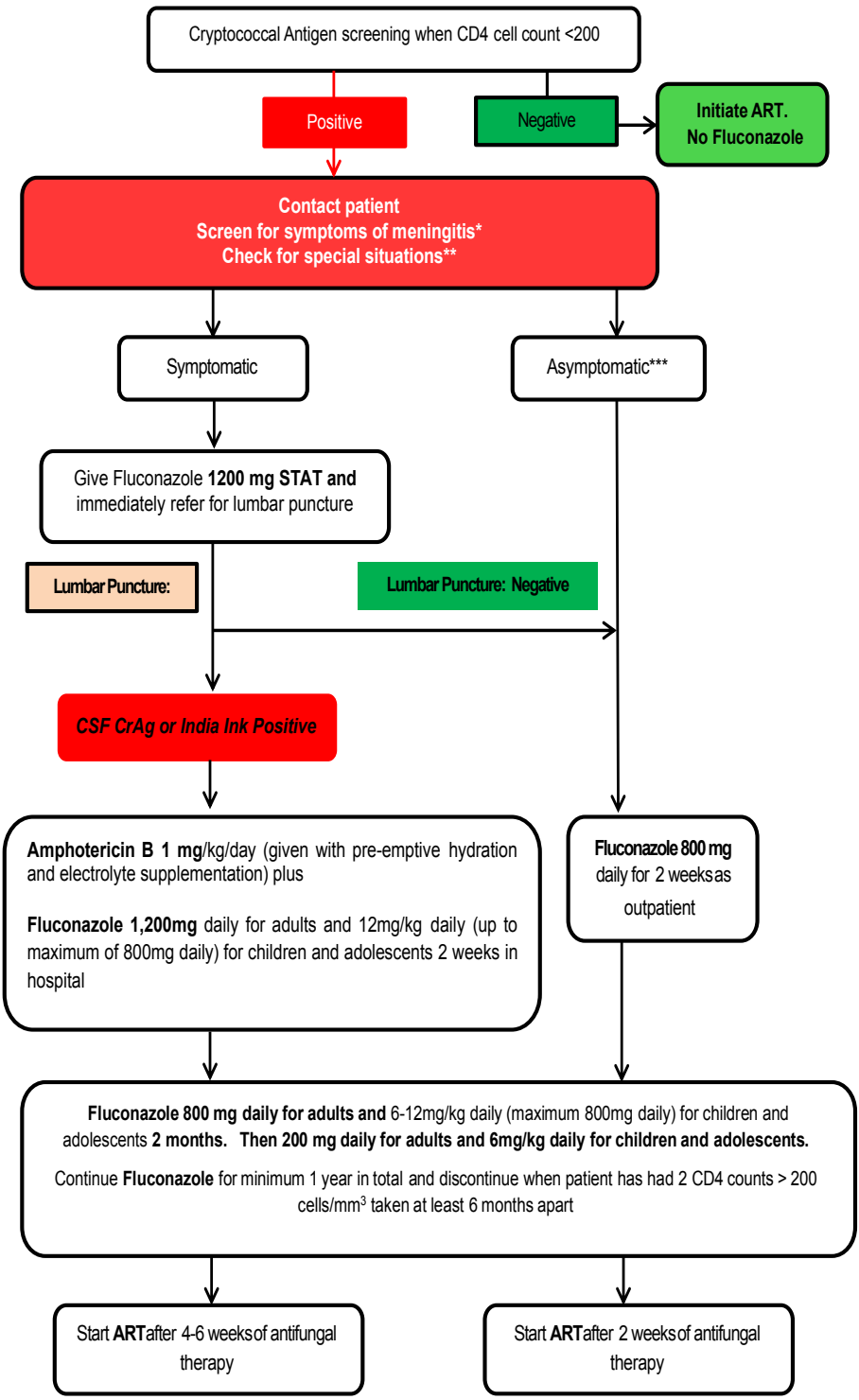
Alternatives for patients with severe CTX allergy include TMP + dapsone or clindamycin + primaquine.

PJP prophylaxis: CTX 2 tablets (960 mg)/day lifelong for all HIV positive patients (See Table 6-1).

6.8 Management of Cryptococcal Disease

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.

Figure 6-4: 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

6.9 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 if low dose TDF is available. Such children should be routinely screened for renal function. When TAF is available for children, substitute TAF for TDF

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 or preferably TAF/XTC when eligible by age and weight.

6.10 Primary Care Management among PLHIV

With the availability of potent antiretroviral therapies, the life expectancy of people living with HIV has improved and transitioned to a chronic disease model. Health care providers should have comprehensive knowledge and skills to screen, identify and manage common primary conditions. In addition, refer to the guidance in the Standard Treatment Guidelines or other programme guidance in managing these conditions.

- Cardiovascular risk: Numerous evidence indicate a 1.5- to 2-fold greater risk of cardiovascular disease in persons with HIV when compared with those without HIV. The following strategies can be implemented to avoid cardiovascular risk.
    - Start antiretroviral therapy as soon as possible after diagnosis
    - Achieve and sustain suppressed HIV RNA levels
    - Encourage smoking cessation
    - Promote physical activity
    - Manage lipid, blood pressure, and glycaemic abnormalities
    - Avoid substance abuse
- Hypertension
- Hyperlipidaemia
- Diabetes Mellitus
- Chronic Kidney disease
- Osteoporosis
- Cancer surveillance
    - Cervical cancer screening
    - Anal Cancer screening

7 Pre-Exposure Prophylaxis (PrEP)

7.1 Indications for PrEP

- 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 or whose VL status is unknown)
- 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 recent/recurrent STIs
- Those with multiple and/or concurrent sexual partners
- 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.

7.2 Contraindications to PrEP Use

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

- HIV positive
- Unknown HIV status or unwilling to get tested
- Flu-like signs and symptoms suggestive of acute HIV infection (AHI)
- Adolescents weighing <30kg
- Adolescents aged <15 years who are not tanner stage 3 or greater
- 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 (see Figure 7.1).

7.3 PrEP Regimens

The recommended regimens for oral PrEP 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 WHO has recently approved and recommended use of the **dapivirine** vaginal ring (DVR) as an alternative to oral PrEP. The ring is a female-controlled HIV prevention method that could provide an acceptable option for women who are unable or do not want to take oral PrEP. The ring is made of silicone and contains dapivirine (an NNRTI), which is slowly released from the ring into the vagina over a month. The ring must be continuously worn in the vagina for **28 days** and then should be replaced by a new ring. Healthcare providers will be notified and more guidance on implementation will be provided when the ring becomes available in Namibia.

Preliminary data shows the integrase inhibitor **cabotegravir** given as an injection every 8 weeks has the highest efficacy compared to other PrEP formulations, for all populations. This injectable ARV will be added to the list of PrEP options in Namibia once it is approved and available locally.

7.4 PrEP Initiation and Follow Up

Figure 7-1: PrEP initiation algorithm for clients with recent HIV exposure

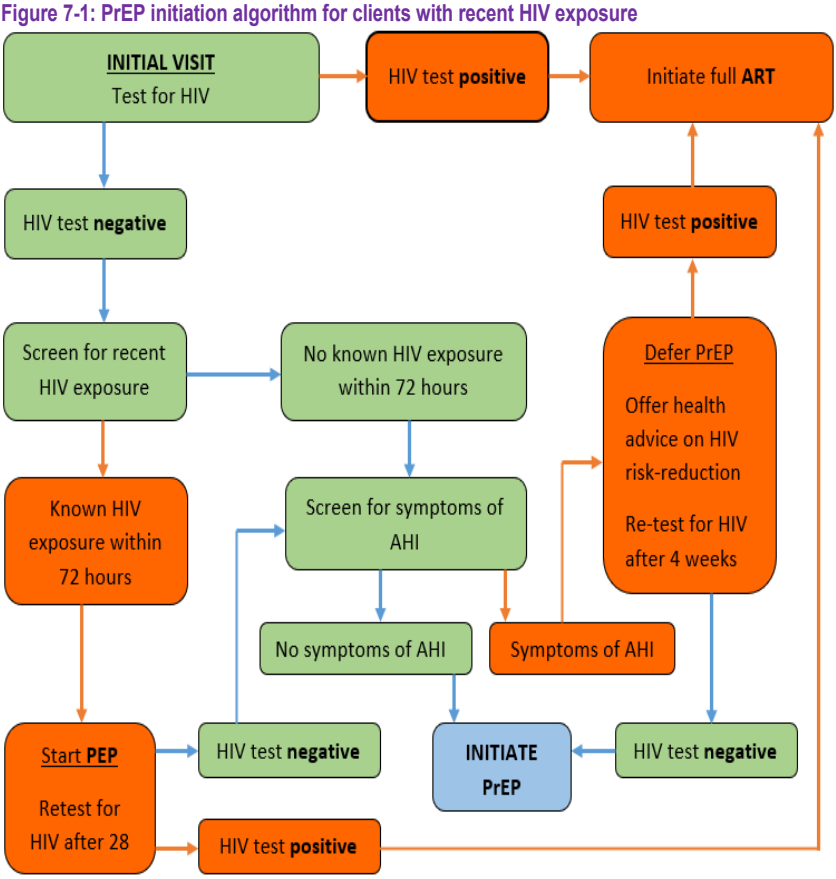


Table 7-1: Summary of PrEP visits and procedures

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 • Provide PrEP counselling (see counselling and key messages for PrEP users below) • Contraceptive counselling and offer services • Provide condoms and lubricants • Refer HIV-negative males 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**: • Review lab results • 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/reactive at baseline)

7.5 Counselling and key messages for PrEP users

- Oral PrEP is highly effective in preventing HIV infection only when taken daily as prescribed.
- It takes about **7 days** for PrEP to reach protective levels in anal tissue and **21 days** in vaginal tissue. Advise on dual protection (PrEP **and** condom use) during this lead-in period.
- If the client misses a PrEP dose on a given day and realizes 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.
- 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.
- Educate client about PrEP side-effects and management.
- 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 meant to be used during periods of perceived high HIV acquisition risk, rather than continually and lifelong, as is the case with ART. In consultation with the HCW, PrEP can be stopped when users consider themselves to be no longer at substantial risk of HIV infection.
- PrEP must be continued for **28 days** after last potential exposure to HIV.
- After discontinuation of PrEP clients should be re-tested for HIV at least annually.
- PrEP can be restarted if the client becomes at substantial risk again and meets clinical eligibility criteria.
- PrEP does not protect against STIs or pregnancy. Provide contraceptive counselling and offer services.
- Advise the client on healthy lifestyles such as avoiding alcohol, tobacco, and recreational drugs.

7.6 Stopping PrEP

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

7.7 PrEP Use in Individuals with Hepatitis B Infection

- Provide PrEP regardless of baseline HBsAg result.
- If baseline HBsAg is positive (reactive), do ALT. If elevated, refer for full clinical assessment.
- Re-check HBsAg at **6 months** after initiation of PrEP, if "reactive" at baseline, to rule out chronic/persistent HBV infection.
- Check HBsAg before stopping PrEP in all users with chronic HBV infection. If still "reactive" consult Clinical Mentor/Specialist Physician or refer to next level of care.
- Consider a full hepatitis B vaccination schedule for individuals who are negative for both Hepatitis B surface antigen (HBsAg) and Hepatitis B antibody (HBsAb) and are at increased risk of becoming infected with HBV.

8 Post-Exposure Prophylaxis (PEP)

8.1 PEP Recommendations for Occupational Exposure

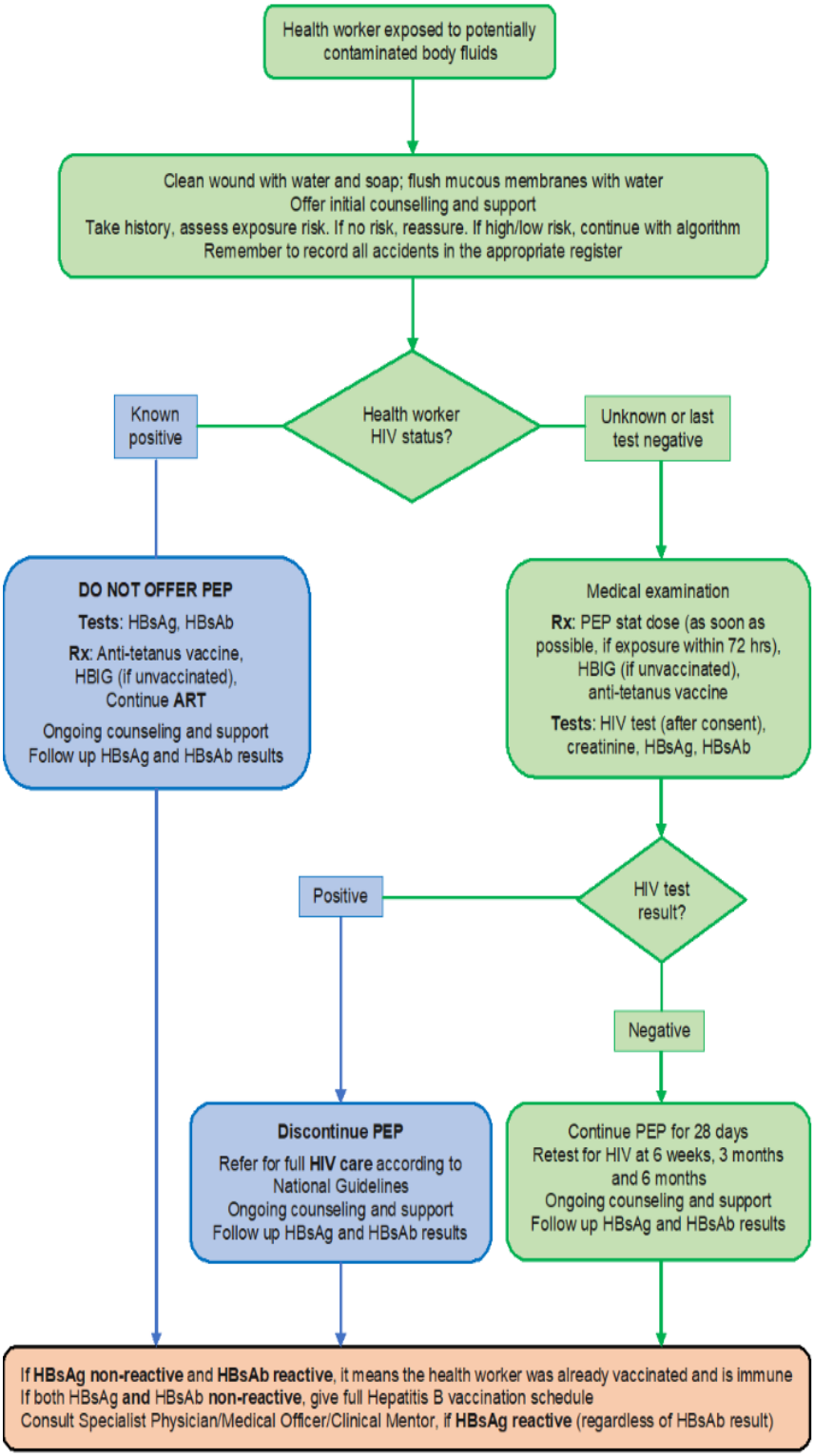
a. PEP is more effective when initiated promptly, preferably within 1-2 hours post-exposure.
b. PEP is not effective if taken more than 72 hours after exposure.
c. **It is recommended to initiate PEP immediately if the source patient is HIV-positive or if the HIV status is unknown**. If the HIV results later become available, decisions about discontinuation of PEP can be made on a case-by-case basis.
d. Baseline tests for PEP:
   - HIV rapid test
   - HBsAg
   - HBsAb
   - Creatinine clearance
e. The schedule for repeating HIV test in exposed HCWs who are HIV-negative at baseline is as follows:
   - at 6 weeks
   - at 12 weeks
   - at 6 months
f. Relative contraindications to PEP use include significant renal or liver impairment and severe illness.
g. When in doubt about the use of PEP, initiate PEP while seeking urgent consultation with an HIV Clinical Mentor a Specialist Physician.
h. The risk of transmission of hepatitis B from a percutaneous exposure is 20-40%, which is significantly greater than the risk of transmission of HIV. Ensure to get the hepatitis B antibody titre of the exposed HCW. Hepatitis B immune globulin (HBIG) followed by full hepatitis B vaccination must be provided for all unvaccinated, non-immune HCWs following sharps injuries or exposure to infected materials.

Table 8-1: Exposure risk and recommended regimens

	Low risk exposure	High risk exposure
Risk classification	Exposure to a small volume of blood or less infectious body fluids such as breastmilk An injury with a solid needle Any superficial injury or mucocutaneous exposure	Exposure to large volume of blood or potentially infectious fluids, e.g., contaminated blood transfusion, sexual assault (rape) Injury with a hollow bore needle Deep and intensive injury Source patient has advanced HIV disease, high VL, or VL is unknown[1]
PEP regimens	Preferred: • TDF/FTC (3TC) Alternative: • AZT/3TC • ABC/3TC	Preferred[1]: • TDF/3TC/DTG[2] Alternative: • TDF/FTC (3TC) + 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]

[1] Refer to **Table 8-3** for regimen selection if source patient is suspected to be failing on ART
[2] Consider double dosing DTG (50 mg bd) in clients taking CYP450 inducers, e.g., Rifampicin
[3] The preferred PI is ATV/r, with LPV/r and DRV/r as alternatives

Figure 8-1: Algorithm for PEP after occupational exposure



8.2 Prophylaxis after Sexual Assault (Rape)

All survivors of sexual assault should be counselled by the examining HCW about the potential risk of HIV transmission. If the survivor presents within 72 hours, PEP must be offered if indicated.

Baseline lab tests	○ HIV test ○ CrCl (if using TDF-based regimen for PEP) ○ RPR ○ Pregnancy test ○ HBsAb

Note: A 3-day PEP starter pack must be considered in situations where it is not possible to do an HIV test immediately (e.g., no HIV tester or survivor not ready to consent). In the case of the survivor not being ready to consent, explain the importance of an HIV test and give a return appointment 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 can be given after HIV testing at the 3-day follow up visit.

In situations where the survivor is unlikely to return for HIV testing and for re-supply of drugs, the HCW may use his/her own discretion on a case-by-case basis to issue a full one-month supply of PEP at once.

- 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 of PEP include significant renal or liver impairment and severe illness.
- When in doubt about the use of PEP, initiate PEP while seeking urgent consultation with an HIV Clinical Mentor or a Specialist Physician.
- Monitor for toxicities due to PEP. If subjective or objective toxicity is noted, ARV substitution should be considered with expert consultation, and further diagnostic tests may be indicated.
- Re-test for HIV at 6 weeks, 12 weeks, and 6 months. Rape survivors who become infected with HIV should be linked to full ART care.

8.2.1 PEP regimens after sexual assault

Rape must be considered **high-risk exposure**. The regimen to be given should contain 3 drugs.

8.2.1.1 Clients above 10 years old

The recommended PEP regimen for All Clients above 10 years is TDF/3TCor FTC/DTG for 28 days

A boosted PI should be used as an alternative to DTG for women of child-bearing potential who prefer not to take emergency contraception or use DTG for PEP.

8.2.1.2 Children < 10 years old

The recommended PEP regimen for children less than 10 years is AZT/3TC/DTG for 28 days

The regimen to be used must comprise an NRTI backbone of AZT/3TC (or ABC/3TC) and a 3rd drug. Alternatives for the 3rd drug depends on the survivor's weight, if less than 10kg – LPV/r and if above 10kg – ATV/r.
Refer to dosing charts for appropriate weight-dependent doses!

Table 8-2: Determining PEP regimen if HIV source is failing on ART

HIV source's ART regimen	Recommended PEP regimen for exposed HCW or sexual assault survivor
TDF (or ABC)-based NRTI backbone	Use AZT-based NRTI backbone
AZT-based NRTI backbone	Use TDF (or ABC)-based NRTI backbone
NNRTI (EFV or NVP)-based regimen	Use DTG or PI as 3rd drug
PI-based regimen	Use DTG as 3rd drug
DTG-based regimen	* Consult HIV Clinical Mentor/Specialist Physician

8.2.2 Comprehensive management after sexual assault

- STI treatment: Cefixime 400mg oral STAT or ceftriaxone 250mg IM STAT **plus** metronidazole 2g oral STAT **plus** azithromycin 1g oral STAT. (Consult Medical Officer for paediatric doses)
- Emergency contraception, as soon as possible, within 120 hours. Options include:
    - **Ovral** (norgestrel 500mcg and ethinyloestradiol 50mcg) given as 2 tablets STAT **and** 2 tablets 12 hours after the first dose.
    - **Levonorgestrel** 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 (HBIG) and hepatitis B vaccination should be started as soon as possible if the 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 3-6 months.
- A tetanus booster must be given.
- Medico-legal assessment of injuries.
- Completion of appropriate registers.
- Counselling, identification of support needs, and necessary referrals must be done.
- On subsequent visits, issues relating to stress management should be discussed as part of the support program. 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.

Special considerations for children:

- Dose adjustment according to age and weight.
- Ongoing, comprehensive support.
- Referral to a paediatrician, where necessary.

8.3 PEP In Accidental sexual exposure

It is recognized that clients sometimes present with a history of accidental sexual exposure, e.g., burst condom. If the client presents within 72 hours, clinicians should offer PEP, but counselling concerning correct condom use and risky behaviour is essential. PEP regimen is the same as for rape. For repeated accidental sexual exposure, offer PrEP for ongoing prevention and discuss with the client that they need to take it for as long as s/he is experiencing repeated HIV exposure (Refer to PrEP initiation algorithm, Table 7-1).

8.4 PEP In Other Situations

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 8-1) can be used in these situations.

9 Medicines Management and Patient Safety

Table 9-1: 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 4). If not HBV co-infected, change TDF to ABC Do not initiate TDF at an estimated glomerular filtration rate of <60 mL/min, uncontrolled hypertension, untreated diabetes, or kidney failure
Haematological toxicity (bone marrow suppression: macrocytic anaemia or neutropenia)	AZT	Dizziness, headache, syncope, palpitations, chest pain, shortness of breath, pale skin, menorrhagia in females, inability to concentrate, cold hands and feet	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 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 Stevens 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, diarrhoea, 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
Hepatotoxicity; Hepatitis	All ARVs (particularly ATV/r)	Jaundice due to unconjugated hyperbilirubinemia, 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 gynecomastia	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 AZT All PIs and EFV INSTI (RAL, DTG)	Significant loss of subcutaneous fat; abnormal fat distribution	Replace suspected ARV with less toxic agent
Dyslipidaemia	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

9.1 How to Report Adverse Events

Medicine safety reporting forms can be obtained from the pharmacy or the NMRC website. Complete all relevant sections of the form, where possible, using a separate form for each patient. Fax or email the completed form to the Therapeutics Information and Pharmacovigilance Centre (TIPC)*.

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

* The TIPC is the MoHSS official Centre for provision of unbiased therapeutic information and pharmacovigilance services to health care workers and the public in Namibia.

Appendix 1: 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)										Strength of adult tablet	Number of tablets	
			3 – <6 kg		6 – <10 kg		10 – <14 kg		14 – <20 kg		20 – <25 kg			25 – <35 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
		300 mg/150 mg	–	–	–	–	–	–	0.5	0.5	1	0.5			
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		600mg/300 mg	1	
		Tablet (dispersible) 120/60 mg	1		1.5		2		2.5		3		600 mg/300 mg	1	
		Tablet (dispersible) 300 mg/150 mg	–		–		–		1		1.5			2	
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		300mg 1						
		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					
		Chewable tablets 100mg	-	-	When using RAL with RIF, calculate dosage: 12mg/kg/dose bd														
Dolutegravir	DTG	Tablet 50 mg	–		–		–		–		1		–	1					

ARV Medicine	Abbreviation /FDC	Strength of Paediatric formulation	Number of tablets or sprinkle capsules or sachets by weight band										Number of tablets			
			3 – <6 kg		6 – <10 kg		10 – <14 kg		14 – <20 kg		20 – <25 kg		25 – <30 kg		30 – <35 kg	
			AM	PM	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					
	TDF/3TC/DTG	300 mg/300 mg/50 mg													1	
	TAF/FTC/DTG	25 mg/200 mg/50 mg											1		1	

Appendix 2: 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 fumarate (TDF)	Tablet: 300 mg FDC: TDF/3TC 300/300mg; TDF/3TC/EFV 300/300/400mg; TDF/3TC/DTG 300/300/50mg	300 mg od	Take with food	Abdominal pain, anorexia, asthenia, diarrhoea, dizziness, dyspnoea, flatulence, headache, hypophosphatemia, lactic acidosis, nausea, 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. Bedtime 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, diarrhoea, elevation in serum cholesterol, triglyceride, glucose, and hepatic transaminase levels.
Protease Inhibitors (PIs)				
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, 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, 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 1

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]***

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

Appendix 4: 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

Appendix 6: 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	☐ Disability or permanent damage	☐ Congenital anomaly/birth defect
	☐ Life-Threatening	☐ Non Serious adverse event	☐ Other; Specify: .....
PATIENT OUTCOME	☐ Recovered ☐ Recovered with sequelae	☐ Due to Reaction	☐ Reaction maybe contributory
	☐ Recovering ☐ Not recovered ☐ Unknown	Died ☐ Unrelated to reaction	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

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Appendix 7: Laboratory Request Form

Appendix 8: 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 with rifabutin
	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

Appendix 9: 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
VIRAL AID	MED AID No.		Collected By

INSTRUCTIONS ON SPECIMEN COLLECTION

PLEASE NOTE:
BLOOD MUST BE COLLECTED IN 2 X EDTA 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:

.....

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Appendix 10: TPT Dosage Chart

3HP CHILDREN AGED 2-14 YEARS PER WEEKLY DOSE (12 DOSES TOTAL)						
Formulation	General dose per kg	10-15kg	16-23kg	24-30kg	31-34kg	>35kg
Isoniazid 100mg*	25mg	3	5	6	7	7
Rifapentine 150mg	-	2	3	4	5	5
Isoniazid + Rifapentine FDC (150mg/150mg)#	*where available*	2	3	4	5	5
** Isoniazid 300mg tablets may be used to reduce pill burden.*						

3HP ADULTS AGED >14 YEARS PER WEEKLY DOSE (12 DOSES TOTAL)						
Formulation	General dose per kg	30-35kg	36-45kg	46-55kg	56-70kg	>70kg
Isoniazid 300mg	15mg	3	3	3	3	3
Rifapentine 150mg	-	6	6	6	6	6
Isoniazid + Rifapentine FDC (300mg/300mg)#	*where available (different from the child FDC above)*	3	3	3	3	3

6H CHILDREN AGED <11 YEARS AND ADULTS >12 YEARS DAILY DOSE (6 MONTHS)							
Formulation	General dose per kg	<5kg	5-9kg	10-14kg	15-19kg	20-24kg	≥25kg
Isoniazid 100mg**	10mg (7-15)	½	1	1 ½	2	2 ½	
Isoniazid 300mg	5mg (4-6)	-	-	-	-	-	1

3HR CHILDREN < 11 YEARS, CHILDREN >25KG OR > 11 YEARS AND ADULTS DAILY DOSE (3 MONTHS)								
Formulation	4-7kg	8-11kg	12-15kg	16-24kg	25-37kg	38-54kg	55-74kg	>75
Rifampicin + Isoniazid child FDC (75mg/50mg)	1	2	3	4	-	-	-	-
Rifampicin + Isoniazid adult FDC (150mg/75mg)	-	-	-	-	2	3	4	5
***One 300mg tablet may be used*								

Appendix 11: PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

ID #: _____ **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 _____

A2663B 10-04-2005

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 clinician, and a definitive diagnosis is made on clinical grounds taking into account how well the patient understood 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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