



National Department of Health
PAPUA NEW GUINEA
NATIONAL GUIDELINES
FOR HIV CARE AND
TREATMENT

2019

Foreword

The first case of HIV was detected in Papua New Guinea (PNG) three decades ago and the epidemic has been labeled both concentrated and generalized. During this period, the country has responded in several ways, including formulating and implementing a series of strategic plans. Many of the initial interventions were geared towards preventing further spread of HIV.

With improved surveillance and monitoring system the epidemic has now been found to be severe in key populations and certain vulnerable groups including women, children, youth and migrant populations. This calls for a broadening of our approach to the epidemic through the strengthening and expansion of the care and treatment component of our response.

The National HIV Program scale-up plan, which includes prevention, care and treatment, is a culmination of multiple initiatives. Now we are moving forward to achieve UNAIDS 90-90-90 targets of 90% of people living with HIV (PLHIV) knowing their HIV status, 90% of people who know their HIV-positive status accessing treatment and 90% of people on treatment having suppressed viral load, by 2020.

HIV testing and Treatment have been expanded to all 22 provinces of the country. Over 40,000 people have been estimated as PLHIV in PNG since 1987 when the first case of HIV was detected. More than twenty thousand (20,000) people including children are taking HIV antiretroviral treatment (ART).

The National Guidelines for HIV Care and Treatment in PNG are one of the many tools that have been developed to provide healthcare workers with guidance on various aspects of care and treatment. In this, the fifth edition of the Guidelines, there is much wider coverage of such areas as; Adult and Pediatric HIV management including adherence issues; Prevention of Parent-to-Child Transmission (PPTCT); Prophylaxis and Treatment of opportunistic infections (OIs); and management of co-morbidities.

Since 2017 PNG has been implementing "Test and Treat" policy. These guidelines have been aligned with the WHO HIV standard guidelines and will introduce new treatment regimen based on the result of the PNG National HIV Pre-treatment Drug Resistant Survey. With the maturing ART program, the new treatment regimen and routine HIV viral load testing needs to be scaled-up to all 22 provinces successfully.

HIV is a rapidly changing and growing field and therefore frequent revision of the material contained within these guidelines will be required. I look forward to receiving feedback from the users of the document to assist in this continual process.



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Mr. Pascoe Kase
Secretary for Health

Acknowledgements

These guidelines were prepared by the Papua New Guinea (PNG) National Department of Health (NDoH). The guidelines are based on the best international evidence in practice in resource limited settings and are designed to ensure that HIV Care and Treatment in PNG is implemented in a way that will benefit both individuals and the country overall. In particular, the use of antiretroviral medications needs to be regulated to ensure that the public benefit is not eroded by the development of viral resistance.

This document would not have been possible without the contribution and commitment of the many national healthcare workers who have been at the forefront of this epidemic. In particular, acknowledgement is given to all HIV Medical Doctors, all Physicians, Pediatricians and Obstetrics and Gynecology, Sexual Health societies and NDoH HIV Care and Treatment team. The NDoH also appreciates and acknowledges the valuable support for developing the new guidelines by various partners including the World Health Organization (WHO), the U.S. Agency for International Development (USAID), the Centers for Disease Control and Prevention (CDC), Family and Health International (FHI360), and World Vision International.

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ABBREVIATIONS

3TC	Lamivudine
ABC	Abacavir
AFB	Acid Fast Bacilli
AIDS	Acquired Immunodeficiency Syndrome
ALT	Alanine Aminotransferase
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
AZT	Zidovudine
AST	Aspartate Aminotransferase
BSL	Baseline Sugar Level
CD4	Cluster Differentiation 4 Cells
CDC	Centers for Disease Control and Prevention
CHW	Community Health Worker
CMV	Cytomegalovirus
CNS	Central Nervous System
COPD	Chronic Obstructive Pulmonary Disease
CPT	Cotrimoxazole Preventive Therapy
CPHL	Central Public Health Laboratory
CSF	Cerebral Spinal Fluid
CT	Computerized Tomography
CVD	Cardiovascular Disease
CXR	Chest X-Ray
DBS	Dried Blood Spot
DTG	Dolutegravir
EAC	Enhanced Adherence Counselling
EBV	Epstein-Barr virus
EC	Emergency Contraception
ECG	Electrocardiogram
EFV	Efavirenz
EID	Early Infant Diagnosis
ESR	Erythrocyte Sedimentation Rate
FBC	Full Blood Count
FSC	Family Support Centre
GBV	Gender-based Violence
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HEO	Health Extension Officer
HIV	Human Immunodeficiency Virus
HIV-DR	Human Immunodeficiency Virus Drug Resistance
HPV	Human Papilloma Virus
HSV	Herpes Simplex Virus
HTC	HIV Testing and Counselling
IMAI	Integrated Management of Adult and Adolescent Illness
INSTI	Integrase Strand Transfer Inhibitor
INH	Isoniazid
IPT	Isoniazid Prophylaxis Treatment
IPV	Intimate Partner Violence

LFT	Liver Function Test
LTFU	Lost-to-Follow-Up
LPV	Lopinavir
MAC	Mycobacterium Avium Complex
MNCH	Maternal, Neonatal, and Child Health
MTCT	Mother-to-Child Transmission of HIV
MTB	Mycobacterium Tuberculosis
NAC	National AIDS Council
NAT	Nucleic Acid Test
NCD	Non-Communicable Disease
NDoH	National Department of Health
NGO	Non-Government Organization
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Analogue Reverse Transcriptase Inhibitor
NVP	Nevirapine
OCP	Oral Contraceptive
OHL	Oral Hairy Leukoplakia
OI	Opportunistic Infection
ORT	Oral Rehydration Therapy
PBFW	Pregnant Breast Feeding Women
PCP	Pneumocystis Jirovecii Pneumonia
PCR	Polymerase Chain Reaction
PEP	Post Exposure Prophylaxis
PGL	Persistent Generalized Lymphadenopathy
PI	Protease Inhibitor
PITC	Provider Initiated Testing and Counselling
PLHIV	People Living with HIV
PMTCT	Prevention of Mother-to-Child Transmission
PNG	Papua New Guinea
PPE	Pruritic Purpura Eruption
PPTCT	Prevention of Parent-to-Child Transmission
r	Ritonavir Boosted
RDT	Rapid Diagnostic Test
RTV	Ritonavir
RFP	Rifampicin
RFT	Renal Function Test
RMO	Regimental Medical Officer
SGBV	Sexual and Gender-Based Violence
SOP	Standard Operating Procedure
SRH	Sexual Reproductive Health
STI	Sexual Transmitted Infections
TB	Tuberculosis
TDF	Tenofovir
TLC	Total Lymphocyte Count
TLD	Tenofovir/Lamivudine/Dolutegravir
TLE	Tenofovir/Lamivudine/Efavirenz
UEC	Urea Electrolytes Creatinine
USAID	U.S. Agency for International Development
WHO	World Health Organization
VCT	Voluntary Counselling and Testing

VZV
VL

Varicella Zoster Virus
Viral Load

QUICK GUIDE FOR THE NATIONAL HIV CARE AND TREATMENT GUIDELINES 2019

1. Criteria for ART initiation

“Test and treat all”

ART should be initiated in all PLHIV, regardless of WHO clinical stage and at any CD4 cell count.

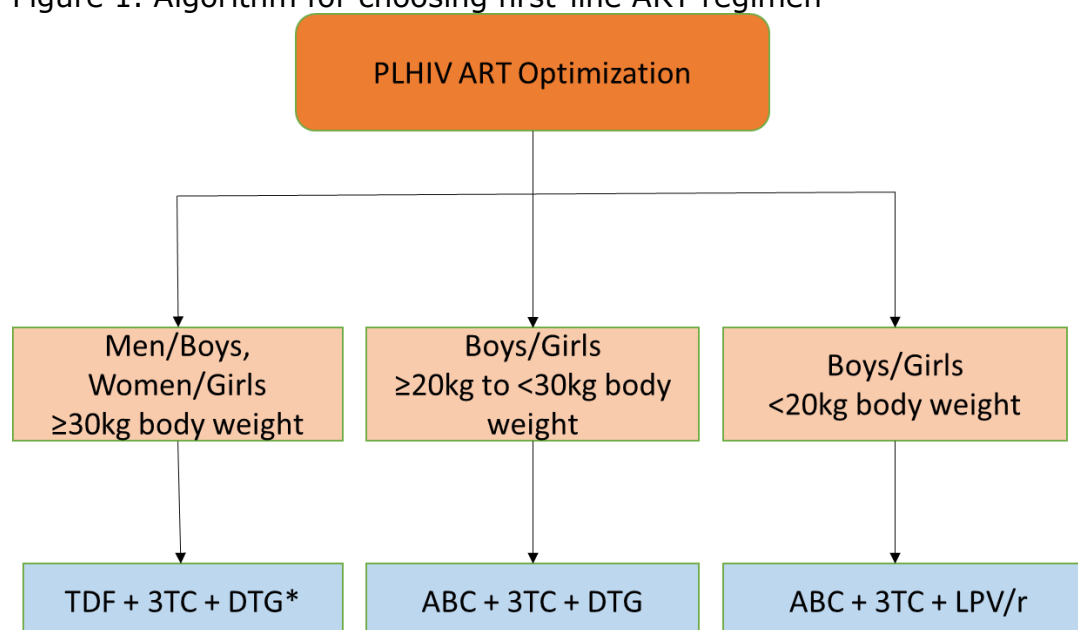
2. First-line ART regimen (Initial ART regimen for PLHIV)

- Dolutegravir (DTG)-containing regimens are recommended as the first-line regimen for PLHIV due to superior efficacy, tolerability, higher threshold for resistance compared to NNRTI-containing regimens (Efavirenz and Nevirapine), and also due to the presence of high drug resistance to Efavirenz (EFV) and Nevirapine (NVP) in PNG. PLHIV eligible for DTG-containing regimens are those who weigh equal to or more than 20kg, including women and adolescent girls of childbearing potential; these women and girls should be fully informed of the potential increase in risk of neural tube defects of DTG use at conception and be provided with contraceptives as desired, however use of contraception should not be requirement for women to have access to DTG-based regimens.
- Notes of caution on using DTG
 - ✓ Exposure to DTG at the time of conception might be associated with neural tube defects (NTDs) among infants. Currently the WHO states that risk-benefit models suggest that the benefits of DTG for women of childbearing potential newly initiating ART are likely to outweigh the risks. As further data on this topic become available, these guidelines will be updated.
 - ✓ WHO has affirmed the importance of a **woman-centered approach** to DTG. Adolescent girls and women of childbearing potential will need support to weigh the risks and benefits in the context of their lives, including their own risks of pregnancy and side effects experienced on other regimens. Even if some increase in risk of NTDs is confirmed, it may be reasonable for individual women to choose DTG, including women who are unable to access, or choose not to use hormonal or long-acting contraception.
 - ✓ Adolescent girls and women of childbearing potential who are offered and using consistent and reliable contraception (do not currently want to become pregnant) can receive DTG.
 - ✓ Adolescent girls and women of childbearing potential who:
 - intend to get pregnant or
 - are offered but not using consistent and reliable contraception or
 - are without access to consistent and reliable contraceptionshould be given the option to choose a DTG-based or non-DTG-based regimen after appropriate risk/benefit counseling known as **informed choice** as there as risks associated with both regimens.
 - Starting ART: For those initiating ART, a DTG-based can be started with informed choice (e.g., TDF + 3TC + DTG).

- Continuing ART: Those already taking an EFV-based regimen can be switched to a DTG-based regimen with informed choice.
- For those considering to continue on an EFV-based regimen, risk of NNRTI drug resistance with an EFV-based regimen must be taken into consideration. Also, confirmation of viral load suppression must be taken into account.
 - If viral suppression cannot be confirmed, efforts should be made to switch to a DTG-based regimen with informed choice.
 - Even if viral load suppression is confirmed, a DTG-based regimen should still be offered with informed choice.
- ✓ Pregnant adolescent girls and women:
 - Starting ART: Those who present during the 1st trimester of pregnancy can start on a DTG-based regimen with informed choice during the first trimester.
 - Continuing ART: Those already taking an EFV-based regimen who present during the 1st trimester on an EFV-based regimen should switch to a DTG-based regimen with informed choice during the first trimester.
 - For those considering to continue on an EFV-based regimen, risk of NNRTI drug resistance with an EFV-based regimen confirmation of viral load suppression must be taken into account.
 - If viral suppression cannot be confirmed, efforts should be made to switch to a DTG-based regimen with informed choice.
 - Even if viral load suppression is confirmed, a DTG-based regimen should still be offered with informed choice.
 - All pregnant women should be prioritized for viral load testing.

An LPV/r-based regimen should only be used as a first-line regimen for adults in special cases when a DTG-based or EFV-based regimen is not an option; please consult with ARV physician or RMO before using this regimen. Phasing out NVP and EFV-based regimens is a priority. See the algorithm for choosing first-line regimen as shown in figure 1:

Figure 1. Algorithm for choosing first-line ART regimen



*Effective contraception should be offered to adult women and adolescent girls of childbearing age or potential. DTG can be prescribed for adult women and adolescent girls of childbearing age or potential who wish to become pregnant or who are not otherwise using or accessing contraception if they have been fully informed of the potential increase in the risk of neural tube defects (at conception and until the end of first trimester). If women identify after the first trimester, DTG should be initiated or continued for the duration of the pregnancy.

Table 1. Preferred and alternative first line

	Preferred first-line regimens	Alternative first-line regimens
MEN/BOYS, WOMEN/GIRLS ≥30kg body weight		
<ul style="list-style-type: none"> Adults Adolescents Children body weight ≥30kg	TDF + 3TC + DTG	ABC + 3TC + DTG ^a
	Note: Risks and benefits of starting a first-line DTG-based regimen will be discussed with women and girls of childbearing age. Effective contraception should be offered. DTG can be prescribed if they wish to become pregnant or also if they are not otherwise using or accessing consistent and effective contraception if they have been fully informed of the potential increase in the risk of neural tube defects (at conception and until the end of the first trimester). If women identify pregnancy after the	

	<p>first trimester, DTG should be initiated or continued for the duration of the pregnancy.</p> <p>Similarly for those women and girls of child-bearing age already on first-line ART, risks and benefits of switching to a first-line DTG-based regimen will be discussed with client. Documentation of being fully informed and client choice must be documented in client record.</p> <p>For all others groups' $\geq 30\text{kg}$ already on a first-line EFZ-based regimen or NPV-based regimen can be switched to the appropriate DTG-based regimen.</p>
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BOYS and GIRLS $\geq 20\text{kg}$ to $<30\text{kg}$ body weight

<ul style="list-style-type: none"> Children body weight $\geq 20\text{kg}$ to $<30\text{kg}$ 	ABC + 3TC + DTG	ABC + 3TC + LPV ^{r^b} ABC + 3TC + RAL ^{b,c}
	Note: Those already on a first-line EFV-based regimen or NPV-based regimen $\geq 20\text{kg}$ to $<30\text{kg}$ can be switched to the appropriate DTG-based regimen.	

BOYS and GIRLS $<20\text{kg}$ body weight

<ul style="list-style-type: none"> Children body weight $<20\text{kg}$ 	ABC + 3TC + LPV/r^{d,e}	ABC + 3TC + RAL ^{b,c}
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^a ABC can be used in special circumstances where TDF is contraindicated.

^b The following regimen can be used in special circumstances where no other alternative is available:

- AZT + 3TC + LPV/r
- AZT + 3TC + RAL

^c RAL should be used as an alternative regimen only if LPV/r solid formulations are not available.

^d LPV/r should not be used for premature babies and babies less than 2 weeks of age; AZT + 3TC + RAL can be used as the preferred first-line for neonates but for the shortest time possible, until a solid formulation of LPV/r or DTG can be used; AZT + 3TC + NVP can be used as alternative regimen for neonates.

^e DTG can be used $<20\text{kg}$ once pediatric formulations are available.

Second-line ART regimen

Assess the patient carefully for clinical, immunological or virological treatment failure before switching to second ARVs shown in table2. Consult ARV physician or RMO before switching to second line ARVs.

Table 2. Preferred and alternate second-line ART regimens

	If patient is failing first-line ART regimen below	Switch to second-line ART regimen below ^a
MEN/BOYS, WOMEN/GIRLS ≥30kg body weight		
<ul style="list-style-type: none"> Adults Adolescents ≥30kg Children body weight ≥30kg 	TDF + 3TC + DTG	AZT + 3TC + LPV/r
	TDF + 3TC + EFV or NPV	AZT + 3TC + DTG
	AZT + 3TC + EFV or NVP	TDF + 3TC + DTG
<p>Note: Risks and benefits of switching to a DTG-based regimen will be discussed with women and girls of child-bearing age. Effective contraception should be offered. DTG can be prescribed if they wish to become pregnant or also if they are not otherwise using or accessing consistent and effective contraception if they have been fully informed of the potential increase in the risk of neural tube defects (at conception and until the end of the first trimester). If women identify pregnancy after the first trimester, DTG should be initiated or continued for the duration of the pregnancy.</p> <p>Documentation of being fully informed and client choice must be documented in client record.</p>		
BOYS and GIRLS ≥20kg to <30kg body weight		
<ul style="list-style-type: none"> Children body weight ≥20kg to <30kg 	ABC + 3TC + DTG	AZT + 3TC + LPV/r
	ABC + 3TC + EFV or NVP	AZT + 3TC + DTG
	AZT + 3TC + NPV or EFV	ABC + 3TC + DTG
BOYS and GIRLS <20kg body weight		
Children body weight	AZT + 3TC + LPV/r ABC + 3TC + LPV/r	ABC + 3TC + RAL ^b AZT + 3TC + RAL ^b

<20kg		
	ABC + 3TC + EFV or NVP	AZT + 3TC + LPV/r ^b
	AZT + 3TC + NVP	AZT + 3TC +LPV/r ^b

^a If ABC + 3TC or TDF + 3TC was used in the first-line failing regimen, AZT + 3TC should be used in second-line and vice versa

^b DTG can be used <20kg once pediatric formulations are available

3. HIV/ TB co-infection

Adults and adolescents

Due to drug-drug interactions with Rifampicin

- If ≥ 30 kgs and on TLD or DTG (50mg)-based regimen has been used, DTG needs to be increased to 100 mg per day (i.e. 50mg needs to be taken 12 hours after the first 50mg dose) e.g., TLD every morning + 50mg DTG every evening.
- If LPV/r (400/100mg)-based regimen has been used, LPV/r needs to be increased to 800/200mg twice daily.
- If NNRTI-based regimen has been used, EFV is preferred over NVP.

Children and infants

A) Children initiating ART while on TB treatment

Note: LPV/r must be “super-boosted” during TB treatment by increasing the amount of ritonavir (RTV) as shown in table 3.

- Children 6 years or less (weight < 20 kgs)
Transition to LPV/r and recommend super-boosting with Ritonavir 25mg tab or solution based on recommended weight-band dosing (refer to annex on RTV super-boosting by age band). After completion TB treatment, stop RTV super-boosting and continue with LPV/r based regimen.
 - If super-boosting with extra RTV is not available, children should be switched to Triple NRTIs (AZT + 3TC + ABC), alternatively.
 - The triple NRTIs is only recommended for the duration of TB treatment. After TB treatment is completed, it should be changed back to the original age-appropriate regimen.
- Children older than 6 years (weight 20kg to ≤ 30 kgs)
2NRTIs + RAL, if there is access to RAL, a double dose of RAL should be used (12mg/kg given twice daily). After TB treatment is completed, treatment should be changed back to the original age-appropriate regimen (i.e. discontinue RAL)
 - If no access to RAL then use Triple NRTIs (AZT + 3TC + ABC), which is only recommended for the duration of TB treatment. After TB treatment is completed, it should be changed back to an age-appropriate regimen.
 - If patient is on DTG based regimen (ABC + 3TC + DTG), use triple NRTIs (AZT + 3TC + ABC) for the duration of TB treatment. After TB treatment is completed, it should be changed back to DTG-based regimen.

B) Children initiating TB treatment while receiving ART

- Children 6 years or less (weight < 20 kgs)
 - If LPV/r -based regimen has been used, ritonavir needs to be added until it reaches the same dose as LPV in mg, in a ratio of 1:1.
 - If NNRTI-based regimen has been used, EFV is more preferred than NVP.

- Another option is Triple NRTIs (AZT + 3TC + ABC), which is only recommended for the duration of TB treatment. After TB treatment is completed, it should be changed to an age-appropriate regimen.
- Children older than 6 years (weight 20kg to ≤30kgs)
2NRTIs + RAL, if there is access to RAL, a double dose of RAL should be used (12mg/kg given twice daily). After TB treatment is completed, treatment should be changed back to the original age-appropriate regimen (i.e. discontinue RAL)
 - If no access to RAL then use Triple NRTIs (AZT + 3TC + ABC), which is only recommended for the duration of TB treatment. After TB treatment is completed, it should be changed back to an age-appropriate regimen.
 - If patient is on DTG based regimen (ABC + 3TC + DTG), use triple NRTIs (AZT + 3TC + ABC) for the duration of TB treatment. After TB treatment is completed, it should be changed back to DTG-based regimen.
 - If LPV/r-based regimen has been used, ritonavir needs to be added until it reaches the same dose as LPV in mg, in a ratio of 1:1. After TB treatment is completed, it should be changed to the original dose.
 - If NNRTI-based regimen has been used, EFV is more preferred than NVP.

Table 3. Dosing for RTV super-boosting of LPV/r for children receiving rifampicin containing TB treatment

Drug	Strength of paediatric tablets or oral liquid	Number of tablets or MLS by weight-band morning (AM) and evening (PM)										Strength of adult tablet	Number of tablets by weight band	
		3–5.9 kg		6–9.9 kg		10–13.9 kg		14–19.9 kg		20–24.9 kg			25–34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
For children able to swallow tablets														
LPV/r ^a	Tablet 100/25 mg	–	–	–	–	2	1	2	2	2	2	–	3	3
RTV	Tablet 100 mg	–	–	–	–	1	1	1	2	1	2	100 mg	2	2
	Tablet 50 mg	–	–	–	–	2	2	3	3	3	3			
	Tablet 25 mg	–	–	–	–	4	4	6	6	6	6			
For children unable to swallow tablets														
LPV/r	Oral solution ^c 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	-	-	-
	Pellets ^d 40 mg/10 mg	2	2	3	3	4	4	5	5	6	6	-	-	-
RTV ^e	Oral solution 80 mg/ml	0.8 ml	0.8 ml	1.2 ml	1.2 ml	1.5 ml	1.5 ml	2 ml	2 ml	2.3 ml	2.3 ml	-	-	-
RTV	Powder 100 mg/packet	-	-	1	1	1	1	1	2	1	2	-	-	-

^a Suggested RTV dose for super-boosting to achieve the same dose as LPV in mg, in a ratio equal or approaching to 1:1. This dosing approach is supported by a study which explored this approach in young children receiving LPVr^a.

^b The LPV/r heat-stable tablet formulation must be swallowed whole and should not be split, chewed, dissolved or crushed. Adult 200/50 tablet could be used for patients 14-24.9kg (1 tab qam and 1 tab qpm) and for patients 25-34.9kg (2 tab qam and 1 tab qpm).

^c RTV liquid requires a cold chain during transport and storage.

^d LPVr pellets formulation should not be used in infants younger than 3 months. More details on the administration of LPVr pellets can be found at <http://www.emtct-iatt.org/wp-content/uploads/2015/09/IATT-LPVr-Factsheet-Final-30-September-2015.pdf>. The dosing schedule provided applies to equivalent solid dosage forms that may become available such as LPVr granules.

^e RTV oral solution dosing is based on the dosing tested in the trial that supports the use of super boosting.

4. HIV/HBV co-infection

The dual NRTI drugs (TDF + 3TC)-containing regimen is recommended for ART, and active against Hepatitis B virus (HBV) as well.

If ARV regimen needs to be changed because of HIV drug resistance or toxicity, TDF with 3TC should be always continued together with the new ARV drugs as discontinuation of TDF and/or 3TC is associated with flares and reactivation of HBV (e.g., AZT + TDF + 3TC + LPV/r).

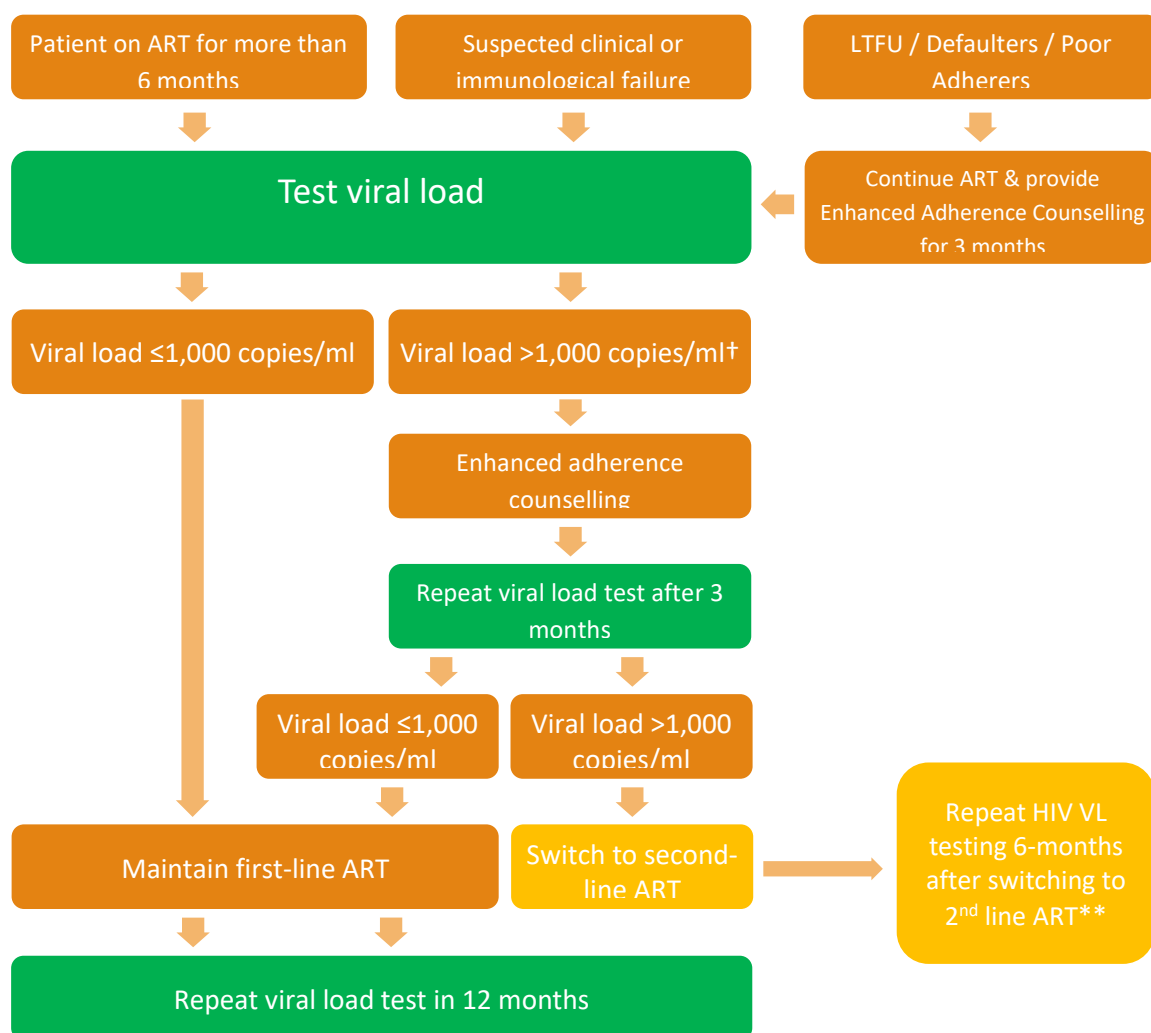
5. Monitoring treatment failure with HIV viral load testing

At the sites where HIV viral load (VL) testing is available, HIV VL testing should be used for routine monitoring/diagnosing treatment failure. HIV VL testing should be done by following the national HIV VL algorithm shown below.

At the site where HIV VL is NOT available, CD4 cell count (every 6 months) can assist with treatment failure decisions.

Pregnant and breastfeeding women already on ART should have viral load testing at first ANC Antenatal Care (ANC) visit; those initiating ART should have viral load testing after 3 months on ART. Pregnant and breastfeeding women with unsuppressed viral load test results should repeat viral load test after one to three months of enhanced adherence counselling. An earlier switch to second-line ART (e.g. before enhanced adherence counseling) may be considered to prevent transmission of HIV to the child. Repeat viral load testing for all pregnant and breastfeeding women every 6 months or more frequently through the end of breastfeeding.

Figure 2. Viral Load Testing algorithm



*Evaluate patient for differentiated model of care (i.e. multi-month scripting)

**If patient is not responding after switch to second-line ART, refer the patient to medical officer for review.

6. Prevention of Parent -To-Child Transmission of HIV (PPTCT)

Pregnant and breastfeeding mothers

Effective PPTCT is dependent on early identification and retention on ART of HIV-positive pregnant and breastfeeding women (PBFW) with viral suppression during the critical time-limited period of pregnancy and breastfeeding. ART should be initiated urgently in all PBFW, even if they are identified late in pregnancy or in the postpartum. Pregnant and breastfeeding women should be prioritized for access to treatment monitoring through viral load testing, to assist with clinical decision making to prevent HIV transmission to the child.

Exposed infants

Infant prophylaxis regimen should be chosen based on the assessment of mother-to-child transmission (MTCT) risk as below in table 4.

Table 4. Infant prophylaxis regimens

Infants at High Risk of MTCT are born to women who	Infants at Low Risk of MTCT are born to women who
<p>Are identified as HIV positive in the postpartum period and breastfeeding</p> <p>Acquire HIV infection during pregnancy or breastfeeding</p> <p>Where VL is available, have VL >1,000 copies/ml at delivery or in the last 4 weeks of pregnancy</p> <p>Or</p> <p>Where VL is not available, have been on ART for less than 4 weeks at delivery</p>	<p>Have received at least 4 weeks of ART before delivery</p> <p>Or</p> <p>Have VL <1,000 copies/ml within 4 weeks prior to delivery</p>
ARV prophylaxis for Infants with a High Risk of MTCT	ARV prophylaxis for Infants with low risk of MTCT
<p>AZT and NVP for the first 6 weeks of life</p> <p>+</p> <p>NVP only for an additional 6 weeks</p> <p>Total 12 weeks</p>	<p>NVP only for the first 6 weeks of life</p> <p>Total 6 weeks</p>

7. Prophylaxis for common coinfections

1) Cotrimoxazole preventive therapy (CPT)

Initiation of CPT

All patients are eligible for CPT initiation as soon as they have a diagnosis of HIV.

Duration of CPT

CPT should not be discontinued; it should be continued throughout the person's lifetime.

2) Tuberculosis Preventive Treatment

Isoniazid prophylaxis treatment (IPT)

Eligibility for IPT

- All PLHIV, including PBFW, who have **no** signs or symptoms suggestive of active TB are eligible for IPT.
- Children living with HIV who are 12 months and older should also receive IPT, and HIV-positive infants younger than 12 months should receive IPT only if they have a known TB contact.

Duration of IPT

- Is for 6 months.
- Isoniazid (INH) (10mg/kg/day, maximum 300mg/day) plus Vitamin B6 or Pyridoxine (25mg daily) should be co-administered. Lack of Vitamin B6 should not be a barrier to starting IPT.

8. Post-exposure prophylaxis (PEP)*

Recommended regimens for PEP to be administered for 28 days for those requiring PEP are listed by weight categories in table 5 below.

Table 5. Regimens for PEP

Adults, adolescents and children ≥30kg body weight
First Choice: TDF + 3TC + DTG
Alternative Choice: TDF + 3TC + LPV/r
Children ≥20kg to <30kg body weight
First Choice: AZT + 3TC + DTG
Alternative Choice: ABC + 3TC + DTG
Children <20kg body weight
First Choice: AZT + 3TC + LPV/r
Alternative Choice: ABC + 3TC + LPV/r

* PEP should be started as soon as possible after the incident (within 24 hours is ideal) but it can be given up to 72 hours.

As part of comprehensive post-exposure prophylaxis services, all adolescent girls and women should be offered pregnancy testing at baseline and during follow-up. Emergency contraception should be offered to girls and women as soon as possible within five days of the sexual exposure and information provided on the risks (including the potential risks of neural tube defects) and benefits of DTG. For women and adolescent girls who do not want to take emergency contraception or DTG, an alternative ARV drug (LPV/r) should be provided.

Note: For non-occupational PEP, in addition to ARVs, PEP should include presumptive treatment for Gonococci and Chlamydia, emergency contraceptives and trauma counseling if available.

CHAPTER 1

ANTIRETROVIRAL

DRUGS FOR HIV

PREVENTION

1.1 Antiretroviral drugs for HIV prevention and treatment in PNG

The following guidelines have been prepared to guide healthcare workers in their choice of antiretroviral treatment for HIV-infected individuals. The guidelines should be read in conjunction with the WHO document "Consolidated Guidelines on the use of Antiretroviral Drugs for treating and preventing HIV infection. Recommendations for a public health approach (June 2016)" and "Update on Antiretroviral Regimens for treating and preventing HIV infection and update on Early Infant Diagnosis of HIV (July 2018)" and "Updated Recommendations on First-line and Second-line Antiretroviral Regimens and Post-Exposure Prophylaxis and Recommendations on Early Infant Diagnosis of HIV (December 2018)" and "Update of Recommendations on Second-line and Antiretroviral Regimens" (July 2019).

This document also provides guidance on using antiretroviral drugs for treating adults, adolescent, and children, and preventing HIV infections in infants exposed to HIV-positive mothers. It is envisaged that public, private, and NGO sectors will use these guidelines to assist them in their planning for the use of ART within the country.

Knowledge about efficacy of various antiretroviral combinations and their adverse effects is rapidly evolving, as is the price structure for individual drugs and drug combinations. These guidelines will therefore be subject to regular review by a panel of experts nominated by the National Department of Health. The guidelines will be disseminated to healthcare workers and other partners involved in the HIV/AIDS National Response.

WHO CAN PRESCRIBE ART DRUGS

Initiation of antiretroviral therapy (ART) requires a complete understanding of the rationale, pharmacology and adverse effects of medication. In addition, the healthcare worker needs to be knowledgeable about the treatment of coexisting conditions and the treatment of HIV in special patient groups. The prescribers will be required to be:

- 1) Certified by NDoH and recognized to prescribe ART in PNG
- 2) Trained in HIV/AIDS care and treatment
- 3) Have access to sustainable drug supply and to health facilities to monitor therapy
- 4) Participate in the continuous medical education in the use of ARVs and monitoring of patients on HIV treatment

For this reason, prescribing antiretroviral medication will be restricted to registered medical practitioners (i.e. Medical Doctors, Nurses, Health Extension Officers (HEOs), and community health workers trained in Integrated Management of Adult and Adolescent Illness (IMAI) and demonstrated clinical competence through a training program approved by the NDoH. A list of accredited medical practitioners will be distributed from

time to time by the NDoH to pharmacies dispensing Antiretroviral (ARV) drugs. Delegation by these practitioners to appropriately trained Nurses, HEOs, and Community Health Workers (CHWs) who have support and mentoring will occur to enable timely access to treatment throughout PNG. Recognition of courses attended elsewhere will be at the discretion of the Secretary (or delegate) of the NDoH. Applications for recognition must be made in writing to the Secretary of Health.

WHO CAN INITIATE, MONITOR AND SUPPLY TREATMENT

Uncomplicated patients (i.e. those without OIs or those without advanced diseases) can have ART initiated by HEOs and Nursing Officers who have completed training and demonstrated clinical competence through a training program approved by the NDoH. This initiation of ART treatment can ONLY occur after consultation with, and authorization (verbal or written) by an accredited medical practitioner. These healthcare workers may also monitor patients on ART and re-supply ART to patients they are monitoring.

1.2 Prevention of Parent-to-Child Transmission (PPTCT)

1.2.1 Four Prongs for PPTCT

Provision of antiretroviral drugs to pregnant and breast feeding mothers is effective in Preventing Parent-to-Child transmission of HIV (PPTCT). Elimination of parent-to-child transmission of HIV involves a spectrum of activities popularly summarized as the four prongs:

Prong 1: Primary prevention of HIV infection among women and men of reproductive age

This involves providing HIV prevention interventions with a focus on people in the reproductive age group. .

Prong 2: Prevention of unintended pregnancies among women living with HIV

Increasing access to family planning and integration of family planning in ART programs to prevent unintended pregnancies among PLHIV.

Prong 3: Prevention of HIV transmission from mothers living with HIV to their infants

This involves provision of HIV testing early in pregnancy or breast feeding period for women who miss out on HIV testing during ANC, to identify PLHIV: Lifelong antiretroviral therapy and support should be provided to pregnant women to support adherence to treatment and retention in care during pregnancy, breastfeeding period and for life. Furthermore, mothers should receive the recommended antenatal care and the full package of safe

motherhood. During labor and delivery precautions should be taken to avoid prolonged labor and limit contact of the baby with maternal blood. Infection control procedures should be observed for all mothers in labor regardless of HIV sero-status.

Prong 4: Care, treatment and support for mothers living with HIV, their children and their families

Pregnant and breast feeding mothers living with HIV should receive the full package of HIV care and treatment as required including screening for TB, prevention and treatment of OIs, laboratory monitoring, follow up and support on adherence and retention on treatment.

Couples counselling should be provided to pregnant women and their partners. HIV-positive partners should be started on ART.

Sero-discordant couples should be provided special attention to start the HIV positive individual on treatment as soon as possible to reduce the risk of transmission to the HIV negative partner.

HIV-infected infants, especially those infected *in utero*, have high mortality rates. It is important to provide HIV testing to children born to HIV-positive mothers and provide them care and treatment appropriately and as early as possible. See Figure 3 for the infant HIV testing algorithm.

1.2.2 ARVs for Pregnant and breastfeeding women (PBFW)

When to start ART

Start lifelong ART in all HIV-positive PBFW as soon as possible regardless of CD4 count, WHO clinical stage or gestational age. Whenever possible, ART should be started on the same day as HIV diagnosis to optimize maternal health and provide rapid protection against MTCT.

Efforts should be made to reduce the time between HIV diagnosis and ART initiation, because the most effective way to prevent vertical transmission of HIV is to reduce maternal VL.

What ARV to start

Start one of the ART regimens recommended for pregnant women (see detail in Chapter Two).

The preferred first-line regimen is;

- TDF + 3TC + DTG with informed choice

1.2.3 ARV prophylaxis for infants born to HIV-positive mothers

What ARV prophylaxis should be given to HIV-exposed infants

All infants born to HIV-positive mothers should receive daily antiretroviral prophylaxis. However, the regimen and duration of prophylaxis depends on the infant's risk of vertical HIV transmission.

Table 6. Criteria for determining MTCT risk and prophylaxis regimens for exposed infants

Infants at High Risk of MTCT are born to women who	Infants at Low Risk of MTCT are born to women who
<p>Are identified as HIV positive in the postpartum period and breastfeeding</p> <p>Or</p> <p>Acquire HIV infection during pregnancy or breastfeeding</p> <p>Or</p> <p>Where VL is available, have VL >1,000 copies/ml at delivery or in the last 4 weeks of pregnancy</p> <p>Or</p> <p>Where VL is not available, have been on ART for less than 4 weeks at delivery</p>	<p>Have received at least 4 weeks of ART before delivery</p> <p>Or</p> <p>Have VL <1,000 copies/ml within 4 weeks prior to delivery</p>
ARV prophylaxis for Infants at High Risk of MTCT	ARV prophylaxis for Infants at Low Risk of MTCT
<p>AZT and NVP for the first 6 weeks of life</p> <p>+</p> <p>NVP only for an additional 6 weeks</p> <p>Total 12 weeks</p>	<p>NVP only for the first 6 weeks of life</p> <p>Total 6 weeks</p>

Table 7. Simplified infant prophylaxis dosing

Infant age	NVP	AZT
Birth to 6 weeks		
Birth weight 2000 – 2499g*	10mg once daily	10mg twice daily
	or	or
	1ml of syrup once daily	1ml of syrup twice daily
Birth weight \geq 2500g	15mg once daily	15mg twice daily
	or	or
	1.5ml of syrup (10mg/mL) once daily	1.5ml (10mg/mL) of syrup twice daily
>6 weeks to 12 weeks (for high-risk MTCT)	20mg once daily	
	or	
	2mls of syrup (10mg/mL) once daily	
	or	
	25mg (Half 50mg tablet) once daily	

*For infants weighting less than 2000g and older than 35 weeks of gestational age, the suggested dosage are: NVP 2mg/kg per dose once daily and AZT 4mg/kg per dose twice daily. Consults a pediatrician or medical officer to review and prescribe ARV prophylaxis for premature infants.

Care of HIV-exposed infants

All HIV-exposed infants require the same care that any infant receives, in addition to their HIV-specific care. Risk factors that can affect the early development and wellbeing of all infants and young children, such as adverse birth outcomes, infectious pathogens, suboptimal infant feeding, poor maternal health and wellbeing, and socioeconomic challenges tend to occur more often among infants born to HIV positive mothers. While it is clear that infants and young children infected with HIV face substantial risk of morbidity and mortality, data indicate that HIV-exposed but uninfected infants and young children have higher rates of morbidity and mortality than infants born to HIV-negative mothers. This means that ensuring that all HIV-exposed infants receive a comprehensive package of care to address all their HIV and non-HIV health needs is key to ensuring a healthy, HIV-free infant at the end of breastfeeding. The care of the breastfeeding infant should be linked to the care of the mother. The mother-infant pair should receive their care together whenever possible

because optimal outcomes for the baby are dependent on the health and viral suppression of the mother.

Comprehensive care to be received by all HIV-exposed infants' includes:

- ARV prophylaxis
- HIV testing
- Cotrimoxazole prophylaxis **is recommended for HIV-exposed infants from 4 to 6 weeks of age and should be continued until HIV infection has been excluded by an age-appropriate HIV test to establish final diagnosis after complete cessation of breastfeeding** (at least 3 months after stopping breastfeeding). This is particularly important to prevent opportunistic infections in HIV-infected but not yet diagnosed infants. Initiation of cotrimoxazole can occur at the same appointment when the infant undergoes the first HIV virology test.
- Routine infant care including
 - Breastfeeding support. In PNG, breastfeeding is essential for infant survival, including infants born to HIV-infected mothers. Therefore, NDoH decided that in principle all health facilities will promote and support breastfeeding among all women irrespective of HIV sero-status. Furthermore, HIV-infected breastfeeding mothers should receive ART and support to adhere to treatment especially during the breastfeeding period.
Growth monitoring. Regular, monthly monitoring of growth and development of HIV-exposed infants is critical. Identification of a change in the growth curve or a missed milestone may be the first indication of a failure to thrive or developmental delays and provide an early opportunity for intervention.
 - Immunizations. It is particularly important for HIV-exposed infants and young children to be immunized completely and on time because of their vulnerability to infection. **HIV-exposed and HIV-infected infants and young children should receive all routine immunizations except:**
 - **Infants who are known HIV-infected or have signs/symptoms consistent with HIV should not receive bacillus Calmette–Guérin (BCG) vaccine.** This recommendation is based on 1) the risk of disseminated BCG disease in children infected with HIV vaccinated at birth and 2) the vaccine may provide little, if any, protection against tuberculosis in HIV-infected infants because HIV infection appears to impair the BCG-specific T-cell responses (WHO. Global Vaccine Safety. Use of BCG vaccine in HIV-infected infants, 2010). Note: HIV-exposed infants who are not known HIV positive at birth and are not born with signs of HIV should receive BCG vaccine.
 - Preventive medication against TB as needed: An HIV-exposed infant should receive Isoniazid preventive therapy (IPT) if the infant does not have active TB disease but has known contact with a person with TB disease
- HIV care for the mother and family support
 - The wellbeing of an HIV-exposed infant is strongly associated

with the wellbeing of the mother and the family. A holistic approach to the family unit is recommended to ensure optimal outcomes for HIV-exposed infants. Support to mothers on treatment adherence, HIV disclosure, linking mothers to peer supporters, psychosocial support, linkage to income-generating activities, encouragement of partner testing as well as testing of other biological children will all contribute to a healthy family unit within which the HIV-exposed infant can thrive.

Recommendation for breast feeding among HIV-infected mothers

Mothers known to be HIV-infected should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for at least 12 months of life. Breastfeeding should then stop only once a nutritionally adequate and safe diet without breast milk can be provided.

Women living with HIV may continue breastfeeding for up to 24 months or longer while being fully supported to ensure ART adherence and viral suppression. In settings where health services provide and support lifelong ART, including adherence counselling, the duration of breastfeeding should not be restricted.

When a mother known to be HIV-infected decides to stop breastfeeding at any time, she should stop gradually within one month. Stopping breastfeeding abruptly is not advisable. The infants should continue receiving ARV prophylaxis based on their risk of MTCT.

If infants and young children are known to be living with HIV, mothers are strongly encouraged to exclusively breastfeed for the first six months of life and continue breastfeeding in accordance with the recommendations for the general population: that is, up to two years or beyond.

Advising mothers who are HIV uninfected or whose HIV status is unknown

Mothers who are known to be HIV uninfected or whose HIV status is unknown should be counselled to exclusively breastfeed their infants for the first six months of life and then to introduce complementary foods while continuing breastfeeding for 24 months or beyond.

Mothers whose status is unknown should be offered HIV testing per national testing guidelines.

Mothers who are HIV uninfected should be counselled about ways to prevent HIV infection and about the services that are available, such as family planning, to help them to remain uninfected.

1.2.4 HIV testing of infants and young children

Diagnosing HIV in Infants and young children < 18 months of age

Infant virological testing using nucleic acid testing or "NAT" (formerly known as PCR testing) on dried blood spots (DBS) should be used to diagnose HIV infection in infants and young children less than 18 months of age. The country will use the routine HIV NAT testing laboratory method on dried blood spot (DBS) specimens prepared with whole blood collected from the infants.

Establishing infant exposure status

Maternal HIV status is the best way to establish the HIV exposure status of the infant. All infants with unknown or uncertain HIV exposure being seen in health-care facilities at the first postnatal visit (usually 6 weeks), or other child health visit, should have their HIV exposure status ascertained by rapid HIV testing of the mother if she is accompanying the infant. If maternal status cannot be ascertained and there is concern for HIV exposure to infant, **serologic testing or rapid diagnostic tests (RDTs) for HIV can only be reliably used to assess HIV exposure in infants less than 4 months of age.** HIV-exposure status in infants and children 4-17 months of age should be ascertained by serological testing of the mother. A positive RDT in any child <18 months only confirms HIV exposure and must be followed by an NAT test to ascertain if the child is infected.

When to test infants and young children

It is strongly recommended that all HIV-exposed infants receive early infant diagnosis (EID) using virological testing at six weeks of age or at the earliest opportunity thereafter. Infants with a negative NAT result at 6 weeks should be retained in care until 3 months after breastfeeding to ensure they receive the indicated tests at 9 months and either 18 months or 3 months after cessation of breastfeeding, whichever comes sooner (see figure 3. HIV Testing Strategy for HIV-exposed Infants).

Infants with a positive NAT result at any age

In infants with an initial positive NAT result, ART should be started without delay and, at the same time, a second DBS should be collected for NAT to confirm the initial positive NAT result. **Do not delay ART to wait for the result of the second DBS NAT. In HIV-infected infants, immediate initiation of ART saves lives and commencement of ART should not be delayed while waiting for the results of the confirmatory test.**

Symptomatic or clinically suspicious infants with unknown HIV exposure

If an infant with unknown exposure to HIV has symptoms suspicious of HIV, testing of the mother is the best way to ascertain HIV exposure status of the infant and should be prioritized whenever possible. When testing the mother is not possible, a RDT can only be used reliably to ascertain HIV exposure in infants younger than 4 months of age. A negative HIV rapid test result in infants aged 4-17 months of age does not reliably rule out HIV exposure and can be difficult to explain to the caregivers.

If clinical suspicion for HIV infection is high despite a negative RDT result at any age, a NAT should be performed.

If an RDT is positive (reactive), this confirms that the infant is HIV-

exposed and a NAT must be done to determine if the infant is infected.

In a sick infant with presumed HIV infection, prompt initiation of ART should be advised, even while the PCR test result is pending – **do not wait for the result.**

In breastfeeding infants or children, breastfeeding should not be discontinued in order to perform any kind of diagnostic HIV test. A final outcome of an HIV-exposed infant should be determined using an RDT at 18 months or 3 months after cessation of breastfeeding, whichever occurs later.

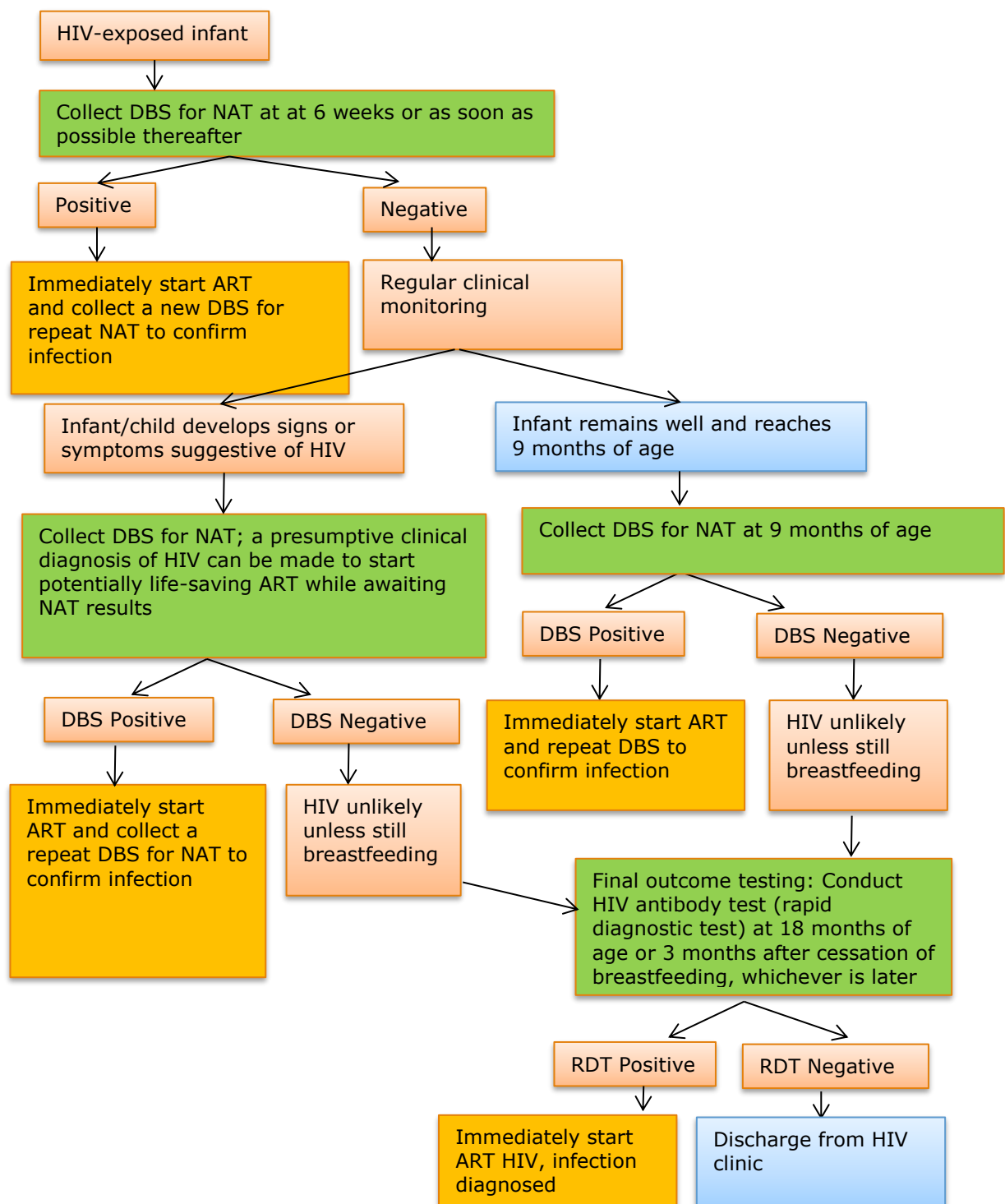
Sample transport and return of results

Testing laboratories should return the infant NAT test results to the clinic and mother/caregiver as soon as possible, but at the very latest within four weeks of specimen collection. Laboratory staff should expedite return to positive NAT results to the clinic and not rely on standard results return systems. Clinic staff should follow up with the laboratory on all NAT results that have not been returned to the clinic after 4 weeks, to establish whether the sample has been lost and another sample should be collected. Every positive NAT result returning to the facility should be treated as an emergency by the clinic staff who should contact the mother as soon as possible to enable prompt initiation of ART.

Diagnosing HIV in Children aged 18 months or older

Children aged 18 months or older, with suspected HIV infection or HIV exposure, should have HIV serological testing performed according to the standard diagnostic HIV serological testing algorithm used in adults.

Figure 3. Testing strategy for HIV-exposed infants



1.3 Post-exposure prophylaxis (PEP)

The most common mode of exposure to occupationally acquired HIV is in health care and first aid settings where health care providers are at increased risk of HIV infection through exposure to infectious body fluids through accidents or when safety precautions are not followed. However, the other most common method of exposure is through sexual assault.

1.3.1 Management of occupational exposure to HIV

Health care settings are the most common source of exposure to occupationally acquired HIV. Exposure prevention remains the primary strategy for reducing occupational HIV transmission. In the event that an occupational exposure occurs, the following should be done.

Treatment of an Exposure Site

Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with tap water. Little evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of blood borne pathogen transmission; however, the use of antiseptics is not contraindicated. The application of disinfectant agents (e.g. bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.

Exposure Report

If an occupational exposure occurs, the circumstances and post exposure management recorded in the exposed person's confidential form for easy follow up and care. The exposure is to be documented in accordance with any institutional requirements and the appropriate authorities notified.

Evaluation of the Exposed Health Care Worker

Healthcare workers exposed to HIV should ideally be evaluated as soon as possible after their exposure in order to allow early initiation of PEP. **At the latest, this must occur within 72 hours of the exposure.** The exposed healthcare worker should be counseled and tested for HIV before PEP is given. In case of refusal to HIV test, every effort should be made to understand why the healthcare worker is declining a test for HIV and educated about the risks and benefits of PEP if they are HIV-negative and ART if they are HIV-positive. If the exposed health care worker were already infected at the time of exposure, he/she should commence ART (not PEP).

In emergency situations where HIV testing and counselling is not readily

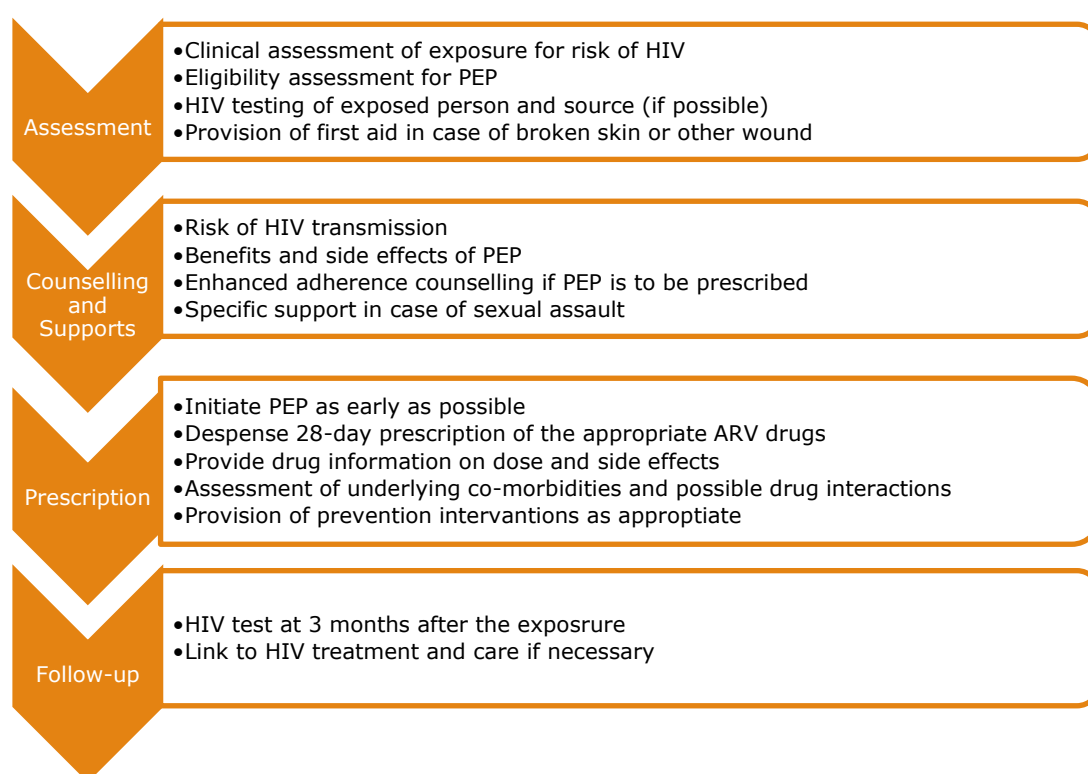
available but the potential HIV risk is high or if the exposed person refuses initial testing, PEP should be initiated and HIV testing and counselling (HTC) undertaken as soon as possible. The provider should clearly document the reason why HTC was not done.

For purposes of considering HIV PEP, the evaluation also should include the following information that might influence drug selection:

- Medications that the exposed person might be taking
- Any current or underlying medical conditions or circumstances (e.g. pregnancy, breast feeding, renal or hepatic disease)

For the healthcare setting, the risk of transmitting Hepatitis B virus (HBV) and Hepatitis C virus (HCV) is higher than the risk of transmitting HIV. Hepatitis B vaccination should also be considered to exposed healthcare workers not previously immunized.

Figure 4. Care Pathway for people exposed to HIV



1.3.2 HIV and GBV Integration

Women and girls in PNG experience high levels of gender-based violence (GBV). The most common forms of GBV are physical, sexual and emotional/psychological violence. These forms of violence contribute to HIV in different ways including:

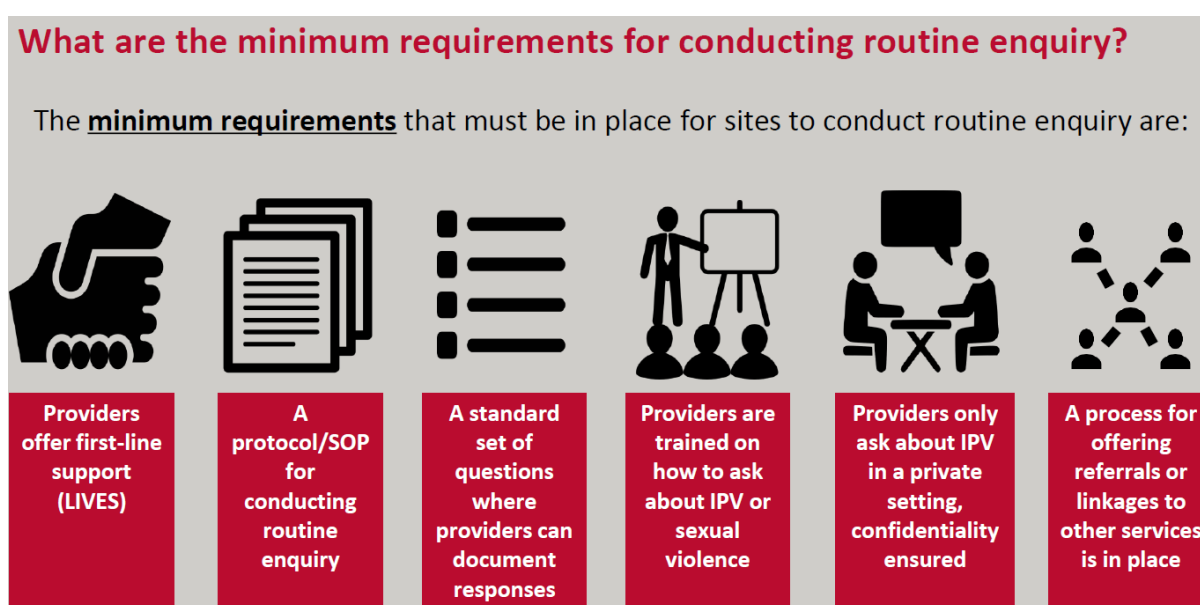
- Direct transmission of HIV via forced sex

- Reduced ability to negotiate for safer sex due to GBV in intimate relationships
- Sexual relationships at earlier ages and increased sexual risk-taking and vulnerability to sex work among victims of child sexual abuse
- Women, MSM, TG people and women engaging in transactional sex are afraid to an HIV test, disclose test results, access services or adhere to treatment
- GBV also contributes to delays in ART initiation, affect patient adherence on ART and ultimately result in patient opting out of treatment or loss to follow up.

Identification of survivors

When survivors access health facilities due to sexual and gender-based violence (SGBV), it is easier to provide post-GBV services. However, survivors might not present to health facilities as a result of SGBV, but due to other health problems. Under such circumstances the trained health care worker might ask about exposure to SGBV but only in the context of assessing conditions that may be caused or complicated by SGBV such as HIV. However, SGBV screening should only be conducted when the following minimum requirements are met:

Table 8. Minimum Requirements for SGBV Screening



Routine GBV screening for HCT clients and registered PLHIV

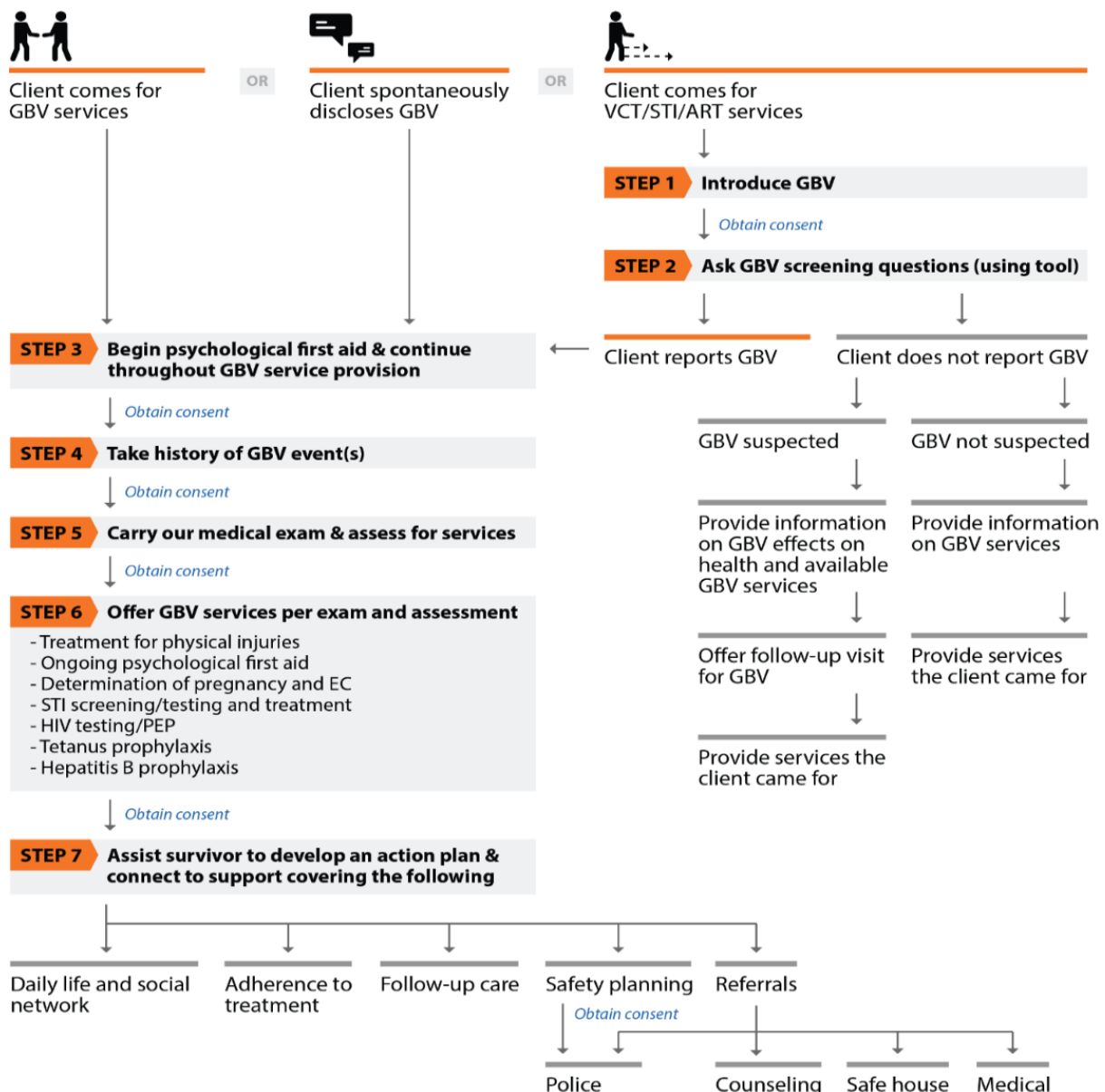
The NDoH recommends that clients who are accessing HTC, STI and ART services should be routinely offered GBV screening services ***if all minimum requirements for SGBV screening noted in the table above have been met***. Consenting clients should be screened in accordance with a protocol such as found in Annex 5, which includes standard screening questions highlighted below. ***Providers should only screen if they have been trained to offer the full complement of GBV clinical services or if the client can access all required GBV clinical services on-site.***

Sample SGBV screening questions:

1. In the past 3 months or since your last visit, has anyone tried to force, forced or coerced you to have sex against your will? Anyone includes: your partner, a client, someone in your family, a friend, neighbour, police, or other persons you know or don't know.
YES () NO () NO RESPONSE ()
2. In the past 3 months or since your last visit, has anyone slapped you, punched you, hit you, or caused you any other type of physical harm? Anyone includes: your partner, a client, someone in your family, a friend, neighbor, police, or other persons you know or don't know.
YES () NO () NO RESPONSE ()
3. In the past 3 months or since your last visit, has anyone insulted you, threatened you, made you feel inadequate or yelled at you? Anyone includes: your partner, a client, someone in your family, a friend, neighbor, police, or other persons you know or don't know.
YES () NO () NO RESPONSE ()
4. Do you currently feel threatened, fearful, or in danger from anyone? Anyone includes: your partner, a client, someone in your family, a friend, neighbor, police, or other persons you know or don't know.
YES () NO () NO RESPONSE ()

The following algorithm shows possible entry point for GBV survivors and subsequent actions

Figure 5. Algorithm for GBV Screening and SGBV Services



Healthcare workers who screen should be able to offer or refer to all of the GBV clinical services on-site according to the following National Clinical Practice Guidelines (NCPG) chart and the NDoH National Clinical Practice Guidelines for Medical and Psychosocial Care for Survivors of Sexual and Gender Based Violence (See Annex 5)

1.3.3 PEP for survivors of sexual assault

Counseling

All persons presenting to a health facility after allegedly being raped should be counseled by the attending healthcare worker about the potential risks of HIV transmission following rape. Children below 12 years of age need to be referred to the hospitals if possible.

The survivor should be offered HIV testing and counselling, but declining HTC should not cause delay in initiating PEP. If the survivor presents shortly after the incident and is too traumatized for HTC, the survivor may decline the test. However, even though the survivor declines HTC, they are still eligible for PEP within 72 hours (3 days) of the sexual assault. The provider should clearly document the reason why HTC was not done. If they initially declined, HIV testing should be offered again at one week during follow-up visit.

Otherwise, survivors who are previously known or found to be HIV positive should be referred to an appropriate health care clinic for long-term management of HIV infection.

Since individuals with HIV are often co-infected with other pathogens, such as syphilis, gonorrhea and hepatitis B, baseline evaluation and treatment should include these testing for these pathogens. A pregnancy test, as well as prevention of unwanted pregnancy should be offered not only to adults but also adolescents.

Additional Treatment and Care to PEP

In addition to PEP, women should be offered:

Presumptive treatment for Syphilis, Gonorrhea and Chlamydia:

- Ceftriaxone 250mg intramuscular as a single dose PLUS Azithromycin 1g orally as a single dose
OR
- Cefixime 400mg orally as a single dose PLUS Azithromycin 1g orally as a single dose

Emergency oral contraception:

If there is a possibility that the assault may cause pregnancy and the assault occurred in the past 72 hours/3 days (as late as 5 days after sexual exposure), then after counseling and consent:

Give Levonorgestrel tablets 3mg stat (if the person is on PEP-ARV) or 1.5mg

stat (not on PEP-ARV) together with an anti-emetic as the high dose causes nausea.

The following alternatives can be used in the absence of emergency contraceptive pills:

- Combined oral contraceptives:
It may be used in the absence of emergency contraception. Give 3 hormone containing tablets stat and repeat 3 tablets after 12 hours. However, make sure that the survivor takes the actual hormone tablets, not the 7 Iron/Fefol tablets that are on the blister pack.

OR

- Oestrogen only pills: 20 Microlut tabs stat and another 20 tabs after 12 hours. (This dose of Microlut does not cause nausea). (This regimen is obviously more cumbersome with the larger number of pills but is mentioned in case there is only Microlut in stock at a health center or for any reason the woman cannot take the combined pill).

Table 9. Antibiotic Drug Regimen for Sexual Assault by Weight

	Azithromycin	Amoxicillin	Augmentin	Probenecid
<10kg	250mg (1/2 tab)	1G (4x250mg)	½ tablet	½ tablet
>10kg	500mg (1 tablet)	1 ½ G (6x250mg)	1 tablet	1 tablet

For further details on managing sexual assault, refer to the NDoH SGBV Guidelines and NDoH STIs Treatment Guidelines.

1.3.4 PEP Drug regimens

Table 10. PEP for adults, adolescents and children ≥30kg

Adults, adolescents and children ≥30kg body weight
First Choice: TDF + 3TC + DTG
Alternative Choice: TDF + 3TC + LPV/r

- Generally, the first choice (TDF + 3TC + DTG) regimen should be selected.
- As part of comprehensive PEP services, all adolescent girls and women should be offered pregnancy testing at baseline and during follow-up. Emergency contraception should be offered to girls and women as soon as possible within five days of the sexual exposure and information provided on the risks (including the potential risks of neural tube defects) and benefits of DTG.
- For women and adolescent girls who do not want to take emergency contraception or DTG, an alternative ARV drug (LPV/r) should be

provided.

- If a TDF-containing regimen (TDF + 3TC) is not possible for clinical reasons (e.g., renal failure, GFR <50 ml/min), an AZT-containing NRTI backbone (AZT+3TC) can be considered. Assess for anemia with hemocue if available. If hemocue not available, please use clinical assessment for anemia and avoid AZT only if anemia strongly suspected. If base line anaemia, repeat the haemoglobin at 2 weeks for those patients on AZT as AZT can cause life-threatening anaemia if given for 4 weeks.
- TDF is not recommended in children weighing less than 30kg. NVP should not be used for PEP among children older than 2 years, adolescent and adults.

Table 11. PEP for children ≥20kg to <30kg or less

Children ≥20kg to <30kg body weight
First Choice: AZT + 3TC + DTG
Alternative Choice: ABC + 3TC + DTG

Table 12. PEP for children 20kg or less

Children <20kg body weight
First Choice: AZT + 3TC + LPV/r
Alternative Choice: ABC + 3TC + LPV/r

*LPV/r should not be used for premature babies and babies less than 2 weeks old

See Annex 4 (Pediatric dosing for PEP)

1.3.5 When to start PEP

PEP should be started as soon as possible after the incident (within 24 hours is ideal) but it can be at any time if the survivor presents within 72 hours of the incident.

PEP should not be given if the survivor presents after 72 hours post-exposure, as there is no evidence of its effectiveness after this time.

However, for individuals who may not be able to access services within 72 hours, providers should consider the range of essential interventions and referrals that should be offered to clients presenting after 72 hours.

1.3.6 Duration of PEP

A 28-day prescription of ARVs should be provided for HIV PEP following initial risk assessment.

Enhanced adherence counselling should be provided to individuals initiating HIV PEP.

If possible the source case should be tested and if HIV negative, PEP can be stopped.

1.3.7 Follow-up of post exposure to HIV

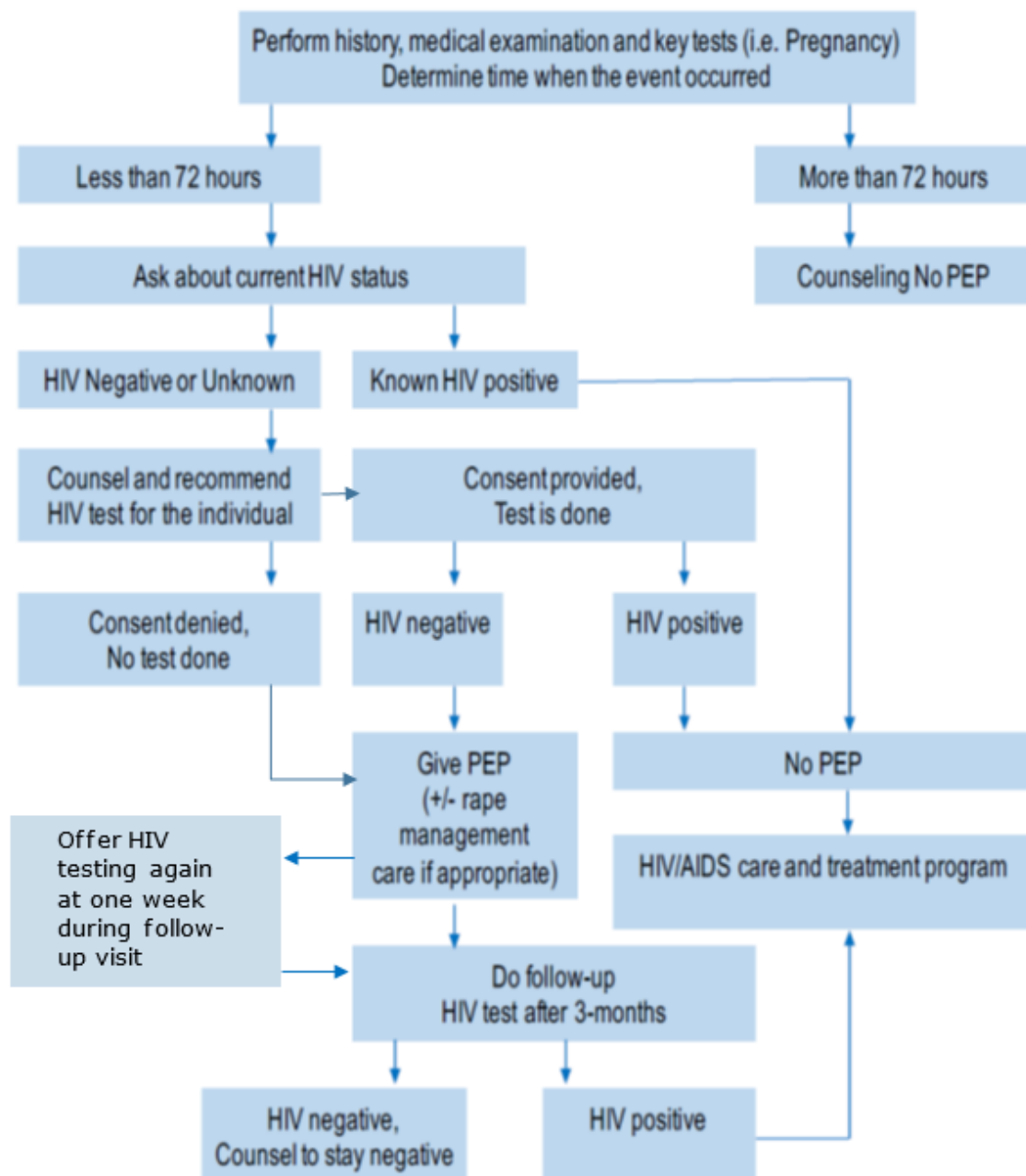
HIV testing should be provided 3 months after the exposure. Repeated testing of negative individuals is not necessary except if the individual has ongoing high risk HIV behavior or can identify a specific incident of HIV exposure in the past 3 months.

Individuals diagnosed with HIV following a PEP should be started on ART.

Any source person confirmed to be HIV positive should also be started on treatment.

Counsel the client to reduce further exposure to HIV.

Figure 6. Algorithm for assessment before PEP initiation



1.3.8 Hepatitis B prophylaxis

The transmission of Hepatitis B (Hep B) is significantly higher than that of HIV. Transmission usually takes place via blood or through sexual intercourse. Every rape survivor should be offered prophylaxis for Hepatitis B as soon as possible after the incident (same as HIV risk assessment). As Hepatitis B has an incubation period of 2-3 months, vaccination is also recommended for survivors who present late. Vaccinate the survivor if the person has not been previously vaccinated.

Table 13. Calendar of vaccination

Dose	Calendar
Hep B1	Day 0
Hep B2	7 days after Hep B1
Hep B3	21-28 days after Hep B2
Hep B4	12 months after Hep B3

Dosage: Hepatitis B Vaccine

Pediatrics: 0.5mls IM is recommended for neonates, infants, children and adolescents up to 14 years of age.

Adults: 1ml IM is recommended for adult age 15 years and above.

N.B. This vaccination calendar is specifically designed for survivors of sexual violence to allow for improved completion rates. The accelerated schedule can confer early protective immunity, lasting up to 1 year. For life-long protection, the booster at 1 year would need to be provided.

Method of administration

Must be administered by intra-muscular (IM) injection into the deltoid muscle in adults and the upper-exterior part of the thigh in children. Do not administer in the buttock muscle, as the immune reaction is insufficient. Possible side effects: minor local or systematic reactions - pain or redness at injection site, fever, headache, myalgia, etc. Very rarely, anaphylactic reaction, serum-disease-like reaction, lymphadenopathy, peripheral neuropathy.

Contra-indications

- History of hypersensitivity reaction to any component of the vaccine
- Assess risk/benefit if known multiple sclerosis
- Pregnancy and breastfeeding: no contra-indication
- No contra-indication in cases of symptomatic or asymptomatic HIV infection.

Associations

May be administered at the same time as the anti-tetanus vaccine, but do not combine the vaccines in the same syringe.

Storage

- Between 2 and 8°C.
- Never freeze.
- After opening, the bottle of 10 doses of vaccine may be kept for 1 month.

1.3.9 Tetanus Prophylaxis

Any person, who presents with breaks in skin or mucosa, especially dirty wounds or injuries caused by implements, should be considered at risk for tetanus unless fully immunized.

Depending on pre-exposure vaccination status: Tetanus Toxoid (TT) and immunoglobulin: see schedule in table 14 below.

Table 14. Schedule for Tetanus Toxoid (TT) and Tetanus Immunoglobulin (TIG)

Risk	<i>Complete vaccination</i> (4 or more doses) < 5 years since administration of latest dose:	<i>Complete vaccination</i> (4 or more doses) 5 – 10 years since administration of latest dose:	<i>Complete vaccination</i> (4 or more doses) >10 years since administration of latest dose:	<i>Incomplete vaccination</i> (Less than 4 doses) No vaccination or unknown status
Minor wound	None	None	TT: one booster dose	Initiate or complete TT
Major wounds (deep wounds, substantial tissue loss, foreign bodies, necrosis)	None	TT: one booster dose	TT: one booster dose	Initiate or complete TT plus TIG

Tetanus incubation usually takes between 3 and 21 days, but can be much longer. Every rape survivor should be immunized for tetanus unless he or she can show that they are fully immunized, as this will have a beneficial effect on their future health (and in women will prevent transmission of tetanus to children).

If there are indications for TIG (see schedule above) administer TIG. If there are clinical signs of a tetanus infection, the survivor should be admitted and managed in hospital.

Table 15. Tetanus Toxoid Vaccination

Dose	Calendar	Effectiveness of protection	Duration of protection
TT1	Day 0	0 %	None
TT2	4 weeks after TT1	80 %	1-3 years
TT3	6 months after TT2	95 %	5 years
TT4	1 year after TT3	99 %	10 years
TT5	1 year after TT4	99%	>10 years

Dosage: TT1: 0.5 mL/injection IM (children and adults).

If the survivor is a child under 5 years who is not vaccinated, the primary series of three injections at a minimum of 4-week intervals is recommended, following the schedule of the regular expanded program of immunization (EPI) with DPT.

Possible side effects

Rare and mild local reaction: redness and pain at the injection site, allergic reactions

Contra-indications

- Known allergy to tetanus toxoid vaccine.
- No contra-indications for pregnant and breastfeeding women.
- No contra-indication in cases of symptomatic or asymptomatic HIV infection.

Storage

- Between 2 and 8°C.
- Never freeze.
- After opening, the bottle of 10 doses of vaccine may be kept for 1 month.

Tetanus Immunoglobulin (TIG)**Indications**

- Tetanus prophylaxis in wound management according to the table in this section.
- Treatment of tetanus (see NDOH clinical guideline).

Dosage and method of administration for prophylaxis

Child and adult: 250 international units (IU) in 1mL by IM injection into the deltoid or gluteal region.

In case more than 24 hours elapsed between wounding and seeking medical care the dosage should be doubled (500 IU).

Possible side effects

Rare and mild local reaction: redness and pain at the injection site, allergic reactions.

Contra-indications

- Known allergy to TIG.
- No contra-indications for pregnant and breastfeeding women.

Storage

- Between 2 and 8°C.
- Never freeze.

CHAPTER 2

ANTIRETROVIRAL

DRUGS FOR HIV

TREATMENT

2.1 ART in adults and adolescents

2.1.1 WHEN TO START TREATMENT

ART should be initiated in all adults living with HIV, regardless of WHO clinical stage (Annex 1) and at any CD4 cell count.

In addition, when the patient initiates ART, those conditions below need to be assessed. However, the assessment should not delay the commencement of ART. Same day initiation of ART is recommended.

- The patient has verbal or written confirmation of HIV-positive status
- Baselines tests must be done (refer 2.1.2)
- Any opportunistic infection has been or is being treated/stabilized
- The patient has been prepared and is ready for ART therapy by undergoing adequate counselling
- The patient has a treatment supporter
- There is a reliable drug supply
- Favorable social criteria should be considered
- Determine HIV status of contact(s) and conduct Index Partner Testing. See figure 7 for steps for offering index testing.

2.1.2 BASELINE TESTS (BEFORE ART INITIATION)

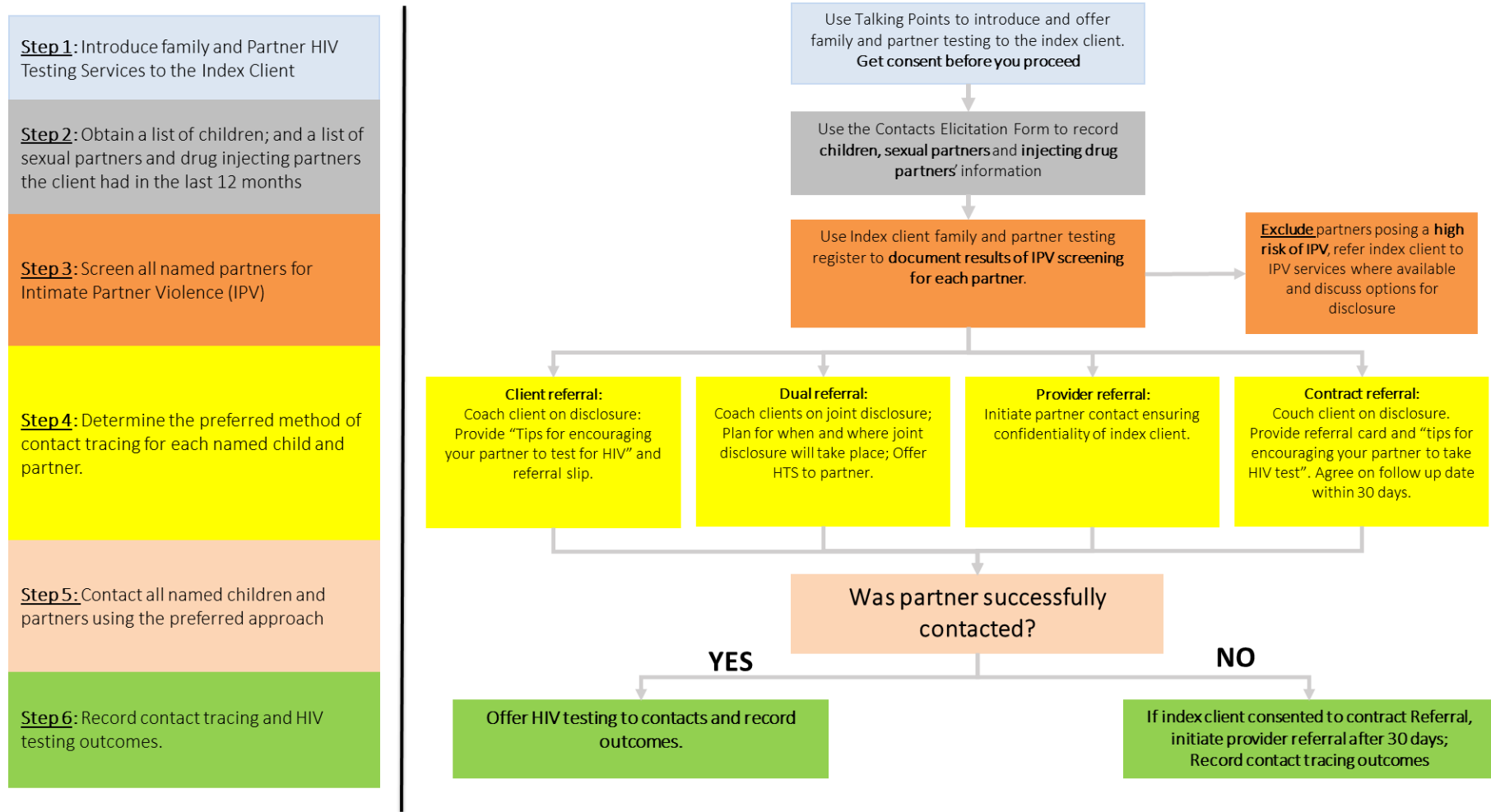
The minimum clinical and laboratory tests need to be done as a baseline data at the initiation of antiretroviral therapy.

However, lab test results should not be a pre-requisite to the initiation of ART.

- A confirmed HIV antibody positive test** (over 18 months of age)
*** A confirmed HIV antibody using the national HIV testing algorithms*
- Baseline CD4 cell count
- Haemoglobin test for starting AZT
- Renal Function tests - creatinine clearance and electrolytes tests for TDF
- Liver functions test - serum alanine (ALT) or aspartase aminotransferase (AST) for NVP
- Screening for TB
 - Symptom screening for all PLHIV at diagnosis and at each clinical encounter using the 4-symptom screen (cough of any duration, fever, weight loss, or night sweats). Presence of any one of these symptoms should prompt further evaluation for TB.
 - GeneXpert MTB/RIF® examination should be the first-line test for all PLHIV with a positive symptom screen, given the higher sensitivity and concomitant ability to diagnose rifampin resistance.
 - CXR can be used to aid in TB diagnosis, particularly in PLHIV who have a negative GeneXpert result, but who have clinical

- symptoms consistent with TB.
 - Lateral flow urine LAM can aid in diagnosis of TB in PLHIV with CD4 <100 cells/mm³ or who are seriously ill, regardless of CD4 cell count.
 - Sputum smear for AFB should be used as a last resort if GeneXpert is not available due to the sub-optimal sensitivity of this test in PLHIV.
- Screening for STIs
 - Syphilis serology (Rapid test, TPHA)
 - Syndrome-based diagnosis
- Pregnancy test for women
 - Investigate which trimester she is in if she is pregnant
 - Check whether she is using contraceptive or not
- Hepatitis B surface antigen (HBsAg)
 - Rapid test for HBsAg
- Screening for non-communicable diseases
 - Blood pressure measurement
 - Serum glucose
- Pap Smear (if available)

Figure 7. Steps for Offering Index Client Family and Partner HIV Testing Services



2.1.3 WHAT DRUGS TO USE (FIRST LINE THERAPY)

Tenofovir (TDF) + Lamivudine (3TC) + Dolutegravir (DTG) as a fixed-dose combination is recommended as the preferred option for naïve adults and adolescent patients $\geq 30\text{kg}$ to initiate ART. For adolescent $< 30\text{kg}$ and $\geq 20\text{kg}$, should be initiated on ABC + 3TC + DTG.

If TDF + 3TC + DTG is contraindicated or not available, alternative options, AZT + 3TC + DTG, is recommended.

Due to high levels of drug resistance to Efavirenz (EFV) and Nevirapine (NVP) in PNG, a Dolutegravir (DTG) containing-regimen is recommended as first-line regimen for PLHIV weighing more than $\geq 20\text{kg}$, including women and adolescent girls of childbearing potential or who are pregnant but opt to take a DTG-based regimen after being fully informed of the potential increase in the risk of neural tube defects (at conception and until the end of first trimester).

- Notes of caution on using DTG
 - ✓ Exposure to DTG at the time of conception might be associated with neural tube defects (NTDs) among infants. Currently WHO states that risk-benefit models suggest that the benefits of DTG for women of childbearing potential newly initiating ART are likely to outweigh the risks. As further data on this topic become available, these guidelines will be updated.
 - ✓ WHO has affirmed the importance of a **woman-centered approach** to DTG. Adolescent girls and women of childbearing potential will need support to weigh the risks and benefits in the context of their lives, including their own risks of pregnancy and side effects experienced on other regimens. Even if some increase in risk of NTDs is confirmed, it may be reasonable for individual women to choose DTG, including women who are unable to access, or choose not to use hormonal or long-acting contraception.
 - ✓ Adolescent girls and women of childbearing potential who are offered and using consistent and reliable contraception (do not currently want to become pregnant) can receive DTG.
 - ✓ Adolescent girls and women of childbearing potential who:
 - intend to get pregnant or
 - are offered but not using consistent and reliable contraception or
 - are without access to consistent and reliable contraceptionshould be given the option to choose a DTG-based or non-DTG-based regimen after appropriate risk/benefit counseling known as **informed choice** as there are risks associated with both regimens.
 - Starting ART: For those initiating ART, a DTG-based can be started with informed choice (e.g., TDF + 3TC + DTG).
 - Continuing ART: Those already taking an EFV-based regimen can be switched to a DTG-based regimen with informed choice.
 - For those considering to continue on an EFV-based regimen, risk of NNRTI drug resistance with an EFV-based regimen must be taken into

consideration. Also, confirmation of viral load suppression must be taken into account.

- If viral suppression cannot be confirmed, efforts should be made to switch to a DTG-based regimen with informed choice.
- Even if viral load suppression is confirmed, a DTG-based regimen should still be offered with informed choice.

✓ Pregnant adolescent girls and women:

- Starting ART: Those who present during the 1st trimester of pregnancy can start on a DTG-based regimen with informed choice during the first trimester.
- Continuing ART: Those already taking an EFV-based regimen who present during the 1st trimester on an EFV-based regimen should switch to a DTG-based regimen with informed choice during the first trimester.
- For those considering to continue on an EFV-based regimen, risk of NNRTI drug resistance with an EFV-based regimen confirmation of viral load suppression must be taken into account.
 - If viral suppression cannot be confirmed, efforts should be made to switch to a DTG-based regimen with informed choice.
 - Even if viral load suppression is confirmed, a DTG-based regimen should still be offered with informed choice.
- All pregnant women should be prioritized for viral load testing.

An LPV/r-based regimen should only be used as a first-line regimen for adults in special cases when a DTG-based or EFV-based regimen is not an option; please consult with ARV physician or RMO before using this regimen

See Annex 3 (Drugs formulations and doses for adults and adolescents).

Table 16. First Line ART Regimen

	Preferred first-line regimens	Alternative first-line regimens
MEN/BOYS, WOMEN/GIRLS ≥30kg body weight		
<ul style="list-style-type: none"> • Adults • Adolescents • Children body weight ≥30kg	TDF + 3TC + DTG	ABC+ 3TC + DTG ^a
	<p>Note: Risks and benefits of starting a first-line DTG-based regimen will be discussed with women and girls of child-bearing age. Effective contraception should be offered. DTG can be prescribed if they wish to become pregnant or also if they are not otherwise using or accessing consistent and effective contraception if they have been fully informed of the potential increase in the risk of neural tube defects (at conception and until the end of the first trimester). If women identify pregnancy after the first trimester, DTG should be initiated or continued for the duration of the pregnancy.</p> <p>Similarly for those women and girls of child-bearing age already on first-line ART, risks and benefits of switching</p>	

	<p>to a first-line DTG-based regimen will be discussed with client. Documentation of being fully informed and client choice must be documented in client record.</p> <p>For all others groups' $\geq 30\text{kg}$ already on a first-line EFZ-based regimen or NPV-based regimen can be switched to the appropriate DTG-based regimen.</p>
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BOYS and GIRLS $\geq 20\text{kg}$ to $<30\text{kg}$ body weight

<ul style="list-style-type: none"> Children body weight $\geq 20\text{kg}$ to $<30\text{kg}$ 	ABC + 3TC + DTG	ABC + 3TC + LPV ^{r,b} ABC + 3TC + RAL ^{b,c}
	Note: Those already on a first-line EFV-based regimen or NPV-based regimen $\geq 20\text{kg}$ to $<30\text{kg}$ can be switched to the appropriate DTG-based regimen.	

BOYS and GIRLS $<20\text{kg}$ body weight

<ul style="list-style-type: none"> Children body weight $<20\text{kg}$ 	ABC + 3TC + LPV/r^{d,e}	ABC + 3TC + RAL ^{b,c}
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^a ABC can be used in special circumstances where TDF is contraindicated.

^b The following regimen can be used in special circumstances where no other alternative is available:

- AZT + 3TC + LPV/r
- AZT + 3TC + RAL

^c RAL should be used as an alternative regimen only if LPV/r solid formulations are not available.

^d LPV/r should not be used for premature babies and babies less than 2 weeks of age; AZT + 3TC + RAL can be used as the preferred first-line for neonates but for the shortest time possible, until a solid formulation of LPV/r or DTG can be used; AZT + 3TC + NVP can be used as alternative regimen for neonates.

^e DTG can be used $<20\text{kg}$ once pediatric formulations are available.

ART for HIV/TB co-infection

- Use TDF + 3TC + DTG (preferred) or ABC + 3TC + DTG (alternative)
- Due to drug-drug interactions with Rifampicin
- If $\geq 30\text{kgs}$ and on TLD or DTG (50mg)-based regimen has been used, DTG needs to be increased to 100 mg per day (i.e. 50mg needs to be taken 12 hours after the first 50mg dose) e.g., TLD every morning + 50mg DTG every evening.
 - If LPV/r (400/100mg)-based regimen has been used, LPV/r needs to be increased to 800/200mg twice daily.

If NNRTI-based regimen has been used, EFV is preferred over NVP.

- Start TB treatment first, followed by ART as soon as possible afterwards (and within the first 8 weeks). Those with profound immunosuppression (i.e. CD4 counts less than 50 cells/mm³) should receive ART immediately within the first 2 weeks of initiating TB treatment.

ART for HIV and HBV or HCV co-infection

TDF + 3TC + DTG can be used with monitoring of liver function. DTG may cause serious adverse effects including abnormal liver function, particularly in patients with HBV or HCV.

- Evidence of severe chronic liver disease should be closely monitored, because these individuals are at greater risk of mortality from liver disease.

2.2 ART IN CHILDREN

2.2.1 BACKGROUND ON ART IN CHILDREN

Children have specific physiological, clinical, practical and social issues to consider when treating HIV-infected children with ART. All children and infants diagnosed with HIV are eligible for ART, regardless of CD4 count or clinical staging (Annex 2).

The following are some of these specific issues.

- a. Children metabolize drugs differently from adults.
- b. For children under 18 months of age, detection of HIV DNA by PCR (EID testing) at 6 weeks of age is the gold standard diagnostic test for diagnosing HIV.
- c. The natural history of the infection is different from adults. The disease progression in infants is more rapid and aggressive. Children are also more susceptible to neurologic complications and some WHO staging conditions are different.
- d. This may also lead to adherence issues hence adherence counselors working with children should receive training specific for this population.
- e. The absolute lymphocyte count is also higher and more variable in children than in adults. Age related thresholds have been developed to be used where CD4 counts are not available. These are less accurate and are not useful markers for longitudinal follow up.

As a general principle, the ART regimen that the parents or guardians are, or will be taking, should also be taken into consideration when deciding on the most appropriate regimen for the child. In determining the initial choice of

ART the availability of a suitable formulation and the simplicity of the dosage schedule are also important and should be taken into consideration.

2.2.2 WHEN TO START ART IN CHILDREN

Initiating ART in itself is a complex undertaking. To prescribe ART to the children of PNG whose compliance with routine drug regimens is in general, already a challenge will be a major task. Therefore, in order to gain the benefits of being on ART and to minimize the risk of poor adherence and subsequent viral drug resistance, the use of both clinical and "social" selection criteria is recommended.

Initiation of ART in infants and children

ART should be initiated in all infants and children living with HIV, regardless of WHO clinical stage or at any CD4 count. Encourage early ART initiation including same day where possible

Initiation of ART in infants under 18 months of age

For infants and children aged under 18 months definitive diagnosis can be made at 6 weeks of age or at the earliest opportunity thereafter using HIV DNA PCR laboratory testing. However, if there are symptoms suggestive of HIV infection a presumptive clinical diagnosis of severe HIV infection may be necessary in order to permit decision-making on the need for the initiation of potentially life-saving ART whilst arranging for a definitive diagnosis.

A presumptive diagnosis of HIV disease should be made if:

- a) The infant is confirmed as being HIV antibody positive, and;
- b) Diagnosis of any AIDS indicator condition can be made

The infant is symptomatic with 2 or more of the following:

- oral thrush
- severe pneumonia
- severe sepsis/bacterial infection
- failure to thrive or wasting or AIDS indicator condition (See Annex 2 for AIDS indicator condition)

Confirmation of the diagnosis of HIV infection should be sought, either by DNA PCR laboratory testing as soon as possible or HIV antibody testing at 18 months of age.

2.2.3 WHAT ARV REGIMEN TO START IN CHILDREN

The following regimens should be given based on the weight of the child. Children weighing $\geq 30\text{kg}$ can be started on TDF + 3TC + DTG.

Table 17. Summary of ART regimens for first-line ART in neonates, infants and children

ART Regimens	Neonates	Children <20 kg body weight	Children ≥ 20 kg to <30 kg body weight
Preferred	AZT + 3TC + RAL	ABC + 3TC + LPV/r	ABC+3TC+DTG ^a
Alternative	AZT + 3TC + NVP	ABC + 3TC + RAL ^b	ABC + 3TC + RAL ^b ABC + 3TC + LPV/r
Special circumstances (In cases where no other alternatives are available)	AZT + 3TC + LPV/r ^c	ABC + 3TC + EFV ^(from 3 years of age) AZT + 3TC + EFV ^(from 3 years of age) AZT + 3TC + LPV/r AZT + 3TC + NVP AZT + 3TC + RAL	ABC + 3TC + EFV ^(from 3 years of age) AZT + 3TC + EFV ^(from 3 years of age) AZT + 3TC + LPV/r AZT + 3TC + NVP AZT + 3TC + RAL

^a DTG can be used <20kg only once pediatric formulations are available for <20kg

^b RAL should be used as an alternative regimen only if LPV/r solid formulations are not available

^c LPV/r should not be used for premature babies and babies less than 2 weeks of age; AZT + 3TC + RAL can be used as the preferred first-line for neonates but for the shortest time possible, until a solid formulation of LPV/r or DTG can be used; AZT + 3TC + NVP can be used as alternative regimen for neonates.

In general children metabolize NNRTI and PI drugs faster than adults and require weight for kilogram higher doses than adults to achieve appropriate drug levels. ABC causes a potentially fatal hypersensitivity reaction in 5% of patients. This usually occurs in the first six weeks of treatment. Treatment should not be restarted if hypersensitivity has occurred.

Due to high rates of drug resistance to NNRTIs in children, NVP and EFV should be avoided unless preferred and alternative regimens are unavailable. If NNRTIs have to be used, NVP can be used for children of all ages while EFV should only be used in children over 3 years because of the lack of pharmacokinetic data for children under 3 years. NVP should be given as once per day for the first 14 days to reduce toxicity and then twice daily after 14 days.

Note: there is no need for 2-week NVP lead for those children less than 3 years old already on TB treatment containing Rifampicin as Rifampicin induces CYP450.

AZT is associated with anemia due to bone marrow toxicity in 5-10% of patients. If hemoglobin prior to initiation is less than 8g/dl (without a correctable cause) combination with ABC or TDF should be used.

Pediatric formulations of LPV/r need to be administered appropriately, as bioavailability and side effects can be affected:

- LPV/r pellets or granules should not be dissolved. These formulations

can develop a bitter taste when not given immediately, which can result in spitting/vomiting of the medication.

- LPV/r tablets should be swallowed whole and should not be crushed or split. If they are split/crushed, the bioavailability is lowered and this lower drug level can allow for viral replication and potentially development of drug resistance.

2.2.3 HIV/ TB co-infection in Children

Children and infants initiating ART while on TB treatment

Note: LPV/r must be “super-boosted” during TB treatment by increasing the amount of ritonavir (RTV)

- Children 6 years or less (weight <20kgs)
Transition to LPV/r and recommend super-boosting with Ritonavir 25mg tab or solution based on recommended weight-band dosing (refer to annex on RTV super-boosting by age band). After completion TB treatment, stop RTV super-boosting and continue with LPV/r based regimen.
 - If super-boosting with extra RTV is not available, children should be switched to Triple NRTIs (AZT + 3TC + ABC), alternatively.
 - The triple NRTIs is only recommended for the duration of TB treatment. After TB treatment is completed, it should be changed back to the original age-appropriate regimen.
- Children older than 6 years (weight >20kg to ≤30kgs)
2NRTIs + RAL, if there is access to RAL, a double dose of RAL should be used (12mg/kg given twice daily). After TB treatment is completed, treatment should be changed back to the original age-appropriate regimen (i.e. discontinue RAL)
 - If no access to RAL then use Triple NRTIs (AZT + 3TC + ABC), which is only recommended for the duration of TB treatment. After TB treatment is completed, it should be changed back to an age-appropriate regimen.
 - If patient is on DTG based regimen (ABC + 3TC + DTG), use triple NRTIs (AZT + 3TC + ABC) for the duration of TB treatment. After TB treatment is completed, it should be changed back to DTG-based regimen.

Children initiating TB treatment while receiving ART

- Children 6 years or less (weight <20kgs)
 - If LPV/r -based regimen has been used, ritonavir needs to be added until it reaches the same dose as LPV in mg, in a ratio of 1:1.
 - If NNRTI-based regimen has been used, EFV is more preferred than NVP.
 - Another option is Triple NRTIs (AZT + 3TC + ABC), which is only recommended for the duration of TB treatment. After TB treatment is completed, it should be changed to an age-appropriate regimen.
- Children older than 6 years (weight 20kg to ≤30kgs)
2NRTIs + RAL, if there is access to RAL, a double dose of RAL should be

used (12mg/kg given twice daily). After TB treatment is completed, treatment should be changed back to the original age-appropriate regimen (i.e. discontinue RAL)

- If no access to RAL then use Triple NRTIs (AZT + 3TC + ABC), which is only recommended for the duration of TB treatment. After TB treatment is completed, it should be changed back to an age-appropriate regimen.
- If patient is on DTG based regimen (ABC + 3TC + DTG), use triple NRTIs (AZT + 3TC + ABC) for the duration of TB treatment. After TB treatment is completed, it should be changed back to DTG-based regimen.
- If LPV/r-based regimen has been used, ritonavir needs to be added until it reaches the same dose as LPV in mg, in a ratio of 1:1. After TB treatment is completed, it should be changed to the original dose.
- If NNRTI-based regimen has been used, EFV is more preferred than NVP.

Table 18. Dosing for RTV super-boosting of LPV/r for children receiving rifampicin containing TB treatment

Drug	Strength of paediatric tablets or oral liquid	Number of tablets or MLS by weight-band morning (AM) and evening (PM)										Strength of adult tablet	Number of tablets by weight band	
		3–5.9 kg		6–9.9 kg		10–13.9 kg		14–19.9 kg		20–24.9 kg			25–34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
For children able to swallow tablets														
LPV/r ^b	Tablet 100/25 mg	–	–	–	–	2	1	2	2	2	2	–	3	3
RTV	Tablet 100 mg	–	–	–	–	1	1	1	2	1	2	100 mg	2	2
	Tablet 50 mg	–	–	–	–	2	2	3	3	3	3			
	Tablet 25 mg	–	–	–	–	4	4	6	6	6	6			
For children unable to swallow tablets														
LPV/r	Oral solution ^c 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	–	–	–
	Pellets ^d 40 mg/10 mg	2	2	3	3	4	4	5	5	6	6	–	–	–
RTV ^a	Oral solution 80 mg/ml	0.8 ml	0.8 ml	1.2 ml	1.2 ml	1.5 ml	1.5 ml	2 ml	2 ml	2.3 ml	2.3 ml	–	–	–
RTV	Powder 100 mg/packet	–	–	1	1	1	1	1	2	1	2	–	–	–

^a Suggested RTV dose for super-boosting to achieve the same dose as LPV in mg, in a ratio equal or approaching to 1:1. This dosing approach is supported by a study which explored this approach in young children receiving LPV/r.

^b The LPV/r heat-stable tablet formulation must be swallowed whole and should not be split, chewed, dissolved or crushed. Adult 200/50 tablet could be used for patients 14–24.9 kg (1 tab qam and 1 tab qpm) and for patients 25–34.9 kg (2 tab qam and 1 tab qpm).

^c RTV liquid requires a cold chain during transport and storage.

^d LPV/r pellets formulation should not be used in infants younger than 3 months. More details on the administration of LPV/r pellets can be found at <http://www.emctt-iatt.org/wp-content/uploads/2015/09/IATT-LPVr-Factsheet-Final-30-September-2015.pdf>. The dosing schedule provided applies to equivalent solid dosage forms that may become available such as LPV/r granules.

^e RTV oral solution dosing is based on the dosing tested in the trial that supports the use of super boosting.

Children initiating ART while on TB treatment

2.2.4 Assessment points for initiation of ART in children

- Children considered for treatment should have easy access to or in walking distance from the ART distributing health facility.
- In the situation in which the child's parents were diagnosed with HIV in the antenatal period, they should have had adequate (ideally

2-3 visits) counseling in the antenatal period followed by 2-3 sessions of follow-up counseling after birth. Information given should include details of ART, however do not delay commencing ART. Encourage early ART initiation including same day where possible.

- iii. Children born to parents detected to be HIV-positive in the antenatal period must have had regular monthly follow-up after birth.
- iv. Parents (not on ART) of children whose diagnosis is made during an illness should have ongoing counseling sessions however ART must be commenced after HIV diagnosis is made.
- v. Parents are required to nominate a treatment support person who should also attend their counseling sessions. This is to ensure continuation of treatment in the event that the parents become ill.
- vi. The family should be referred to a community-based organization within the area in which they live. The organization must be credible and acceptable to the family and be able to provide continued support outside of the hospital.

These assessment points are guides to consider for better treatment outcome. Each case should be assessed on individual bases. It should not be used to stop initiation of treatment

2.2.5 BASELINE LABORATORY TESTS IN CHILDREN (BEFORE STARTING ART)

- Full blood count (HB, TLC, WBC and Differential)
- CD4 if available
- Electrolytes, Urea, Creatinine, LFT) and Blood Glucose
- Sputum for AFB and/or CXR and /or GeneXpert (if available)

2.3 Drug interactions

All ARV medications have the potential to interfere with other medications. Particular drug interactions that more commonly will be encountered in PNG are listed in the following table.

Table 19. Drug Interactions

Drug	ART Agent	Interaction	Suggested Action
Alpha blockers, beta blockers and calcium channel blockers	All PIs and Efavirenz	Hypotension and syncope due to decreased drug clearance, at times potentially life threatening	Monitor closely and adjust dose if signs of toxicity
Amitriptyline	RTV	Over sedation	Reduce dose
Anti-psychotic drugs	RTV	Increased potential for side effects due to decreased drug clearance	Monitor closely and adjust dose if indicated, particularly with Haloperidol
Antacids (Maalox, Mylanta, Riopan, Milk of Magnesia, others)	DTG	Potentially decreased DTG effectiveness	Administer dolutegravir 2 hours before or 6 hours after antacids
Benzodiazepines especially Midazolam	All PIs	Over sedation and risk of respiratory depression	Avoid the use of these drugs unless clinically indicated i.e. Status epilepticus
Carbamazepine	DTG	Decreased DTG levels due to induction of CYP3A	Increase DTG dose to 50mg twice daily
Cimetidine	RTV	Increased potential for side effects due to decreased drug clearance	Monitor closely and adjust dose if indicated
Dofetilide	DTG	Potential increased dofetilide toxicity	Contraindicated: do not co-administer
Ergometrine	All PIs and EFV	Ergotism due to decreased clearance of ergot alkaloids	Use syntocin, and/or Misoprostol as clinically indicated

Ferrous fumarate	DTG	Potentially decrease DTG effectiveness	Administer dolutegravir 2 hours before or 6 hours after medicines with divalent cations
Ketoconazole	NVP, SQV, RTV and EFV	Potential for toxicity due to decreased drug clearance	Ketoconazole should not be used with NVP due to risk of hepatotoxicity Max. dose of 200mg/day if used with PI's. Fluconazole is recommended with PI's
Metformin	DTG	Potentially increase adverse effects of Metformin	Start from low-dose Metformin and titrate up carefully
Multi-vitamin	DTG	Potentially decrease DTG effectiveness	Administer DTG 2 hours before or 6 hours after multivitamins
Nonsteroidal anti-inflammatory drugs	RTV	Increased potential for side effects due to decreased drug clearance	Avoid the use of these drugs unless clinically indicated and no alternative available
Oral Contraceptives (OCP)	EFV, NVP, LPV, and RTV	Failure of OCP due to increased clearance	Alternate or additional form of contraception
Oral hypoglycaemics	All PIs	Risk of hypoglycaemia due to decreased drug clearance	Close monitoring of BSL

Pethidine	RTV	Increased potential for side effects due to decreased drug clearance especially seizures	Avoid the use of this drug unless clinically indicated and no alternative available
Phenytoin and Carbamazepine	LPV, RTV, EFV and possibly other ART agents	Two-way interaction- LPV, EFV and Phenytoin have increased Clearance RTV may reduce Carbamazepine clearance	Monitor clinically for toxicity or reduced levels Monitor serum anticonvulsant drug levels if able
Phenobarbital Phenytoin	DTG RAL	Potentially decreased DTG effectiveness	Contraindicated: Co-administration is not recommended
Prednisone and Dexamethasone	RTV and SQV	Increased potential for side effects due to decreased drug clearance	Monitor closely and adjust dose if indicated
Rifampicin	PIs DTG	Decreased PI/DTG levels due to induction of CYP3A	Children older than 6 years (weight 20kg to ≤30kg): Add Ritonavir on LPV/r until it reached the same dose as LPV in mg, in a ratio of 1:1. Increase DTG dose
Rifampicin	PIs DTG	Decreased PI/DTG levels due to induction of CYP3A	Adults and adolescents ≥30kg: TLD (standard fixed-dose combination tablet) + 50mg DTG dosed 12 hours later

Thyroid Replacement Therapy	PIs	Increased potential for side effects due to decreased drug clearance	Monitor closely and adjust dose if indicated
Warfarin	RTV	Unpredictable levels	Monitor closely

2.4 Adherence

For patients on ART, medication adherence is critically important to treatment success and for achieving sustained viral suppression. Viral replication in the presence of sub-optimal doses of ART may lead to emergence of drug resistance and loss of future treatment options. Patients for whom there is serious concern about adherence should not be commenced on ART, rather every effort should be made to identify the support they need to be adherent (e.g., peer support, assistance with disclosure). Near-perfect pill taking is required to achieve viral suppression and to avoid the emergence of drug resistance. When patients skip doses and do not take their ART medications as prescribed, ART drug resistance may develop, and the patient may not improve or may result in potential case of treatment failure.. Missing doses is a common problem, and many patients need help to take 100 percent of their medicines as prescribed, including through routine adherence assessment and support. Antiretroviral therapy should not be prescribed in the absence of adherence support, including a treatment supporter; every effort should be made to find the client adequate treatment support. Ongoing counseling about the importance of adherence, the role of a treatment supporter in assisting with adherence, and the measurement of adherence are an essential component of HIV Care and Treatment.

Adherence can be especially challenging for children, as they are reliant on their caregivers and undergo developmental and psychosocial changes as they age into adolescence. Caregivers should be encouraged to supervise the child or adolescent. At each visit, providers should ensure that caregivers understand the correct dosage for the child's weight, as well as proper administration of pediatric formulations (especially lopinavir/ritonavir). Providers should support caregivers on age-appropriate disclosure to children on ART, which can help with adherence and allow linkage to peer support during adolescence.

2.5 Data collection

It is very important that ART use is monitored within PNG to define how improvements can be made in the clinical and program management. It will be a requirement for healthcare workers to maintain a database of patients on treatment and forward specified data to NACS/NDOH when and as required. For more detailed guidelines and procedures on ART (or HIV treatment) data collection, please refer to the Standard Operating Procedures (SOPs) for HIV Routine Data Reporting

(NDoH, 2013). The SOPs includes the following components:

- How to fill out ART Monthly Data Collection Sheet (Form SURV1,2 and 4)
- How, where, and when to report Form SURV1,2 and 4
- How to store, manage and secure the SURV1, 2 and 4 data and forms
- How to request Form SURV1, 2 and 4, and ARVs and other supplies

Training of healthcare workers (HCW) at clinics and data management staff will be important to be able to collect and enter quality data in ART site data bases. Tracking and tracing activities should occur daily to know who didn't complete an expected appointment or drug pick-up in order to start activities to return them to care as soon as possible. Also, the staff at clinic should be able to conduct clinic monthly analysis of ART data in their specific clinics, and use findings to improve the quality of services delivered. They should be able to conduct patients' retention rates analysis in their clinics to inform quality of their programs.

CHAPTER 3

MONITORING DRUG TOXICITY AND TREATMENT FAILURE

3.1 Monitoring ART (After ART initiation)

Symptom directed lab monitoring for safety and toxicity is recommended for those on ART. Other testing may be added according to the patient's clinical condition.

Monitoring Drug Toxicity

- Haemoglobin test for starting AZT
- Renal Function tests - creatinine clearance and electrolytes tests for TDF
- Liver functions test - serum alanine (ALT) or aspartase aminotransferase (AST) for DTG and NVP

Monitoring Treatment Failure

- VL testing is the best lab test to monitor for treatment failure and should be used. However, if VL testing has limited availability, CD4 cell count testing should be as an alternation option.
- The site where HIV VL testing is available
 - HIV VL testing is used for monitoring treatment failure
 - CD4 cell count monitoring can be stopped where routine HIV VL testing is available; consider use of CD4 at baseline or reengaging in care to help triage patients that might have advanced disease
 - HIV VL testing should be done by following the national HIV VL algorithm (see Figure 4)
 - HIV VL testing is not recommended as a baseline
 - In the case of suspected treatment failure and at routine intervals (per the table), VL testing is done to assess for treatment failure. If the VL is greater than 1,000 copies/ml, enhanced adherence counselling (EAC) must be done for adherence and VL testing is done after 3 months
 - If the VL is still greater than 1,000 copies/ml at this second test, this confirms treatment failure and patient should be switched to second line (see Figure 8)
- The site where HIV VL is NOT routinely available
 - CD4 cell count (every 6 months) can assist with treatment failure decisions
 - Targeted VL, however, can be requested any time there is suspected treatment failure and clinicians should make effort to request VL before switching regiments.

HIV- positive patients who are on ART should be monitored in accordance with the schedule in table 20. As an example, some routine tests to be performed during the course of the treatment are shown in Table 20.

Table 20. Schedule of Routine Laboratory Monitoring of ART

Laboratory test	Baseline	Three months	Six months	Nine months	Twelve months	Every 6 months thereafter if stable	Every 12 months thereafter if stable
CD4*	✓		✓		✓	✓	
Viral Load†			✓				✓
Hb	✓	✓	✓	✓	✓	✓	
Liver Function	✓	✓	✓	✓	✓	✓	
Renal Function	✓	✓	✓	✓	✓	✓	

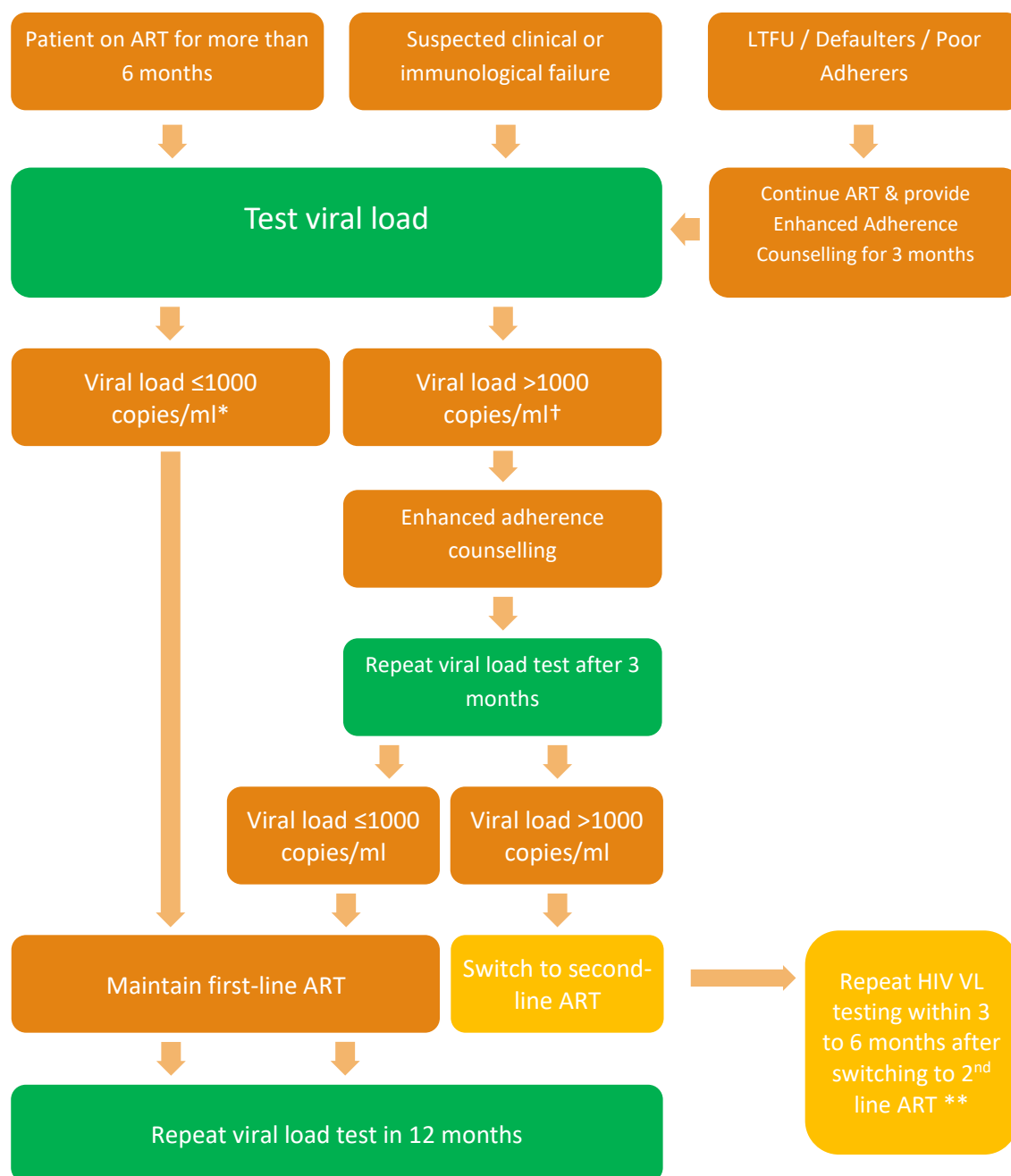
*Note: *Where HIV viral load (VL) is NOT available, CD4 cell count (baseline and every 6 months) can assist with treatment failure decisions; †where routine HIV VL testing is available, follow-up CD4 cell count monitoring can be stopped (baseline CD4 cell count should be done).*

At the sites where HIV viral load (VL) testing is available, HIV VL testing should be used for monitoring/diagnosing treatment failure. HIV VL testing should be done by following the national HIV VL algorithm shown below.

At the site where HIV VL is NOT available, CD4 cell count (every 6 months) can assist with treatment failure decisions.

Pregnant and breastfeeding women already on ART should have viral load testing at first ANC visit; those initiating ART should have viral load testing after 3 months on ART. Pregnant and breastfeeding women with unsuppressed viral load test results should repeat viral load test after one to three months of enhanced adherence counselling. An earlier switch to second-line ART (e.g. before enhanced adherence counseling) may be considered to prevent transmission of HIV to the child. Repeat viral load testing for all pregnant and breastfeeding women every 6 months or more frequently through the end of breastfeeding.

Figure 8. HIV Viral Load Testing Algorithm



*Evaluate patient for differentiated model of care (i.e. multi-month scripting)

**If patient is not responding after switch, refer the patient to medical officer for review

3.2 Drug substitution

3.2.1 Drug Toxicity

Substitution of single agents can be made if drug toxicity occurs and can be ascribed to a component of the triple therapy given as first line.

Table 21. Drug toxicity and substitution for adults and adolescent and children

If toxicity...	Due to ...	Then switch to ...
TDF/3TC/DTG	TDF – Renal failure	ABC or AZT Do not initiate TDF at Creatinine clearance (CrCl) <50ml/50ml/min, uncontrolled hypertension, untreated diabetes, proteinuria, or presence of renal failure
	DTG – Hepatotoxicity, Hypersensitivity reaction	LPV/r For severe hepatotoxicity and hypersensitivity, substitute with LPV/r
TDF/3TC/NVP	TDF –see above	ABC or AZT
	NVP – hepatotoxicity NVP – Steven Johnson Syndrome	DTG ^a LPV/r
AZT/3TC/NVP	AZT – Bone Marrow Suppression	TDF or ABC
	NVP – see above	DTG ^a LPV/r
TDF/3TC/EFV	EFV – Unremitting CNS toxicity	DTG ^a LPV/r
	TDF – see above	ABC or AZT
LPV/r in children	LPV/r – GI side effects	RAL ^b

^aDTG for >20kg

^bIf RAL unavailable use EFV for children ≥ 3 years or NVP for children <3

3.2.2 Treatment Failure

Definition of treatment failure

Failure of a drug regimen is usually on the basis of viral drug resistance, and can only be confirmed by documentation of a rising VL. In PNG treatment failure will be recognized by using VL tests, which will be at the regional laboratories in conjunction with the Central Public Health Laboratory (CPHL) in Port Moresby. In the absence of this measurement, a lack of clinical response (such as persistent diarrhea, weight loss, appearance of a previous or new OI) after 6 months of treatment in a patient adherent to medication is likely to be due to viral drug resistance. If non-adherence is considered the cause for treatment failure, consideration should be given to interventions that improve adherence. Treatment failure using clinical and immunological criteria should not be used before six months as immunological reconstruction syndrome (IRIS) may be a confounding factor and responsible for the apparent treatment failure.

Table 21. Virological, Immunological and Clinical Failure

Failure	Definition	Remarks
Clinical Failure	Adults and adolescents New or recurrent clinical event indicating severe immunodeficiency (WHO stage 3 and 4 condition) after 6 months of effective treatment	The new or recurrent condition must be distinguished from immune reconstitution syndrome For adults, certain WHO clinical stage 3 conditions (pulmonary TB and severe bacterial infections) may also indicate treatment failure*
	Children New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4 clinical condition with the exception of TB) after 6 months of effective treatment	

Immunological Failure	Adults and adolescents CD4 cell count at or below 250 cells/mm ³ following clinical failure; or persistent CD4 levels ₃ below 100 cells/mm ³	Where available, use VL to confirm treatment failure. Where viral load testing is not available, CD4 monitoring and clinical monitoring are recommended Without other concomitant or recent infection to explain transient CD4 cell decrease; previous guidelines defined immunological failure based on a fall from baseline, which is no longer applicable in the context of CD4-independent treatment initiation
	Children Younger than 5 years Persistent CD4 levels below 200 cells/mm ³ Older than 5 years Persistent CD4 levels below 100 cells/mm ³	Current WHO clinical and immunological criteria have low sensitivity and positive predictive value for identifying individuals with virological failure. There is currently no proposed alternative definition of treatment failure and no validated alternative definition of immunological failure
Virological Failure	VL above 1,000 copies/ml based on two consecutive VL measurements in 3 months, with adherence support following the first VL test	Where available, use VL to confirm treatment failure An individual must be taking ART for at least 6 months before it can be determined that a regimen has failed

* See the list of clinical conditions associated with advanced or severe HIV disease associated with immunodeficiency in Annex 1.

3.3 Second-line regimen for adults and adolescents

WHO recommends that the regimen be changed **if treatment failure occurs**. The new second-line regimen in adults and adolescents should consist of new 2 nucleoside reverse-transcriptase inhibitors (NRTIs) plus LPV/r or DTG.

3.3.1 Choice of new 2 NRTIs

The following sequence of second-line NRTIs option is recommended:

- After failure on a TDF + 3TC –based first-line regimen, switch TDF +3TC to AZT + 3TC

- After failure on an AZT + 3TC –based first-line regimen, switch AZT + 3TC to TDF + 3TC

3.3.2 Choice of LPV/r or DTG

- After failure on an NNRTIs (NVP or EFV)-based first-line regimen, switch NNRTIs to DTG.
- If DTG-based regimen has been used, switch DTG to LPV/r.

3.3.3 Second-line for co-infected patients

Second-line for HIV/TB Co-infection

- Choice of new 2 NRTIs is the same as mentioned above
- If rifampicin is used for TB treatment,
 - the dose of DTG needs to be **doubled, 50mg DTG given 12 hours after TLD, so total becomes 100mg daily.**
 - the dose of LPV/r needs to be **doubled (LPV/r 800mg/200mg twice daily)**
- If rifabutin is available for TB treatment, standard second-line regimen is recommended

Second-line for HIV/HBV or HCV Co-infection

- AZT + TDF + 3TC + DTG could be used as an option. However, please be aware that DTG may cause serious adverse effects including abnormal liver function, particularly in patients with HBV/HCV co-infection. Close monitoring the patient is the must.
- AZT + TDF + 3TC + LPV/r is an alternate second-line regimen for HIV and HBV or HCV co-infection.
- TDF with 3TC are active against HBV. Treatment of HIV/HBV coinfection without the use of TDF in the regimen may lead to flares of hepatitis B due to ART-associated immune reconstitution. Similarly, treatment discontinuation, especially of 3TC, has been associated with HBV reactivation, ALT flares and, in rare cases, hepatic decompensation.
- If ARV drugs need to be changed because of treatment failure or toxicity, then TDF with 3TC should be continued together with the new ARV drugs.

3.4 Second-line regimen for children

WHO recommends that the entire regimen be changed if treatment failure occurs. The new second-line regimen has to involve drugs that retain activity against the patient's virus strain and should ideally include a minimum of three active drugs, one of them drawn from a new class, in order to increase the likelihood of treatment success and minimize the risk of cross-resistance.

For children on a DTG-based first line, the Protease Inhibitor (PI) class is for the recommended second-line treatments, preferably supported by two new NRTIs. For children on a LPV/r-based first line, an integrase inhibitor is recommended for second line (RAL if <20 kg, DTG if ≥20kg). For children on an NNRTI-based first line with NVP or EFV, integrase inhibitors (DTG) are recommended second line for children >20 kg, while PIs (LPV/r) are recommended for <20 kg. Definitive diagnosis of failure of a drug regimen is the same as in adults.

The important clinical signs of response to therapy include improvement in growth for those failing to thrive, improvement in neurological symptoms, development in those with delayed developmental milestones and decrease in the frequency of OIs.

Clinical monitoring should include weight and height growth, developmental milestones and neurological symptoms. Children with evidence of developmental delay should be referred to a pediatrician for more detailed evaluation. In the absence of CD4 cell assays charted height and weight growth may be the most important indicator of response to therapy. Monitoring height and weight for height can also provide additional information. It is recommended that all children on ART have their WEIGHT and (if possible) HEIGHT measured on each visit to the clinic.

Table 22. Preferred second-line regimens

	If patient is failing first-line ART regimen below	Switch to second-line ART regimen below ^a
MEN/BOYS, WOMEN/GIRLS ≥30kg body weight		
<ul style="list-style-type: none"> • Adults • Adolescents ≥30kg • Children body weight ≥30kg 	TDF + 3TC + DTG	AZT + 3TC + LPV/r
	TDF + 3TC + EFV or NPV	AZT + 3TC + DTG
	AZT + 3TC + EFV or NVP	TDF + 3TC + DTG
	Note: Risks and benefits of switching to a DTG-based regimen will be discussed with women and girls of child-bearing age. Effective contraception should be offered. DTG can be prescribed if they wish to become	

	<p>pregnant or also if they are not otherwise using or accessing consistent and effective contraception if they have been fully informed of the potential increase in the risk of neural tube defects (at conception and until the end of the first trimester). If women identify pregnancy after the first trimester, DTG should be initiated or continued for the duration of the pregnancy.</p> <p>Documentation of being fully informed and client choice must be documented in client record.</p>
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BOYS and GIRLS ≥20kg to <30kg body weight

<ul style="list-style-type: none"> Children body weight ≥20kg to <30kg 	ABC + 3TC + DTG	AZT + 3TC + LPV/r
	ABC + 3TC + EFV or NVP	AZT + 3TC + DTG
	AZT + 3TC + NPV or EFV	ABC + 3TC + DTG

BOYS and GIRLS <20kg body weight

Children body weight <20kg	AZT + 3TC + LPV/r	ABC + 3TC + RAL ^b
	ABC + 3TC + LPV/r	AZT + 3TC + RAL ^b
	ABC + 3TC + EFV or NVP	AZT + 3TC + LPV/r ^b
	AZT + 3TC + NVP	AZT + 3TC + LPV/r ^b

^a If ABC + 3TC or TDF + 3TC was used in the first-line failing regimen, AZT + 3TC should be used in second-line and vice versa

^b DTG can be used <20kg once pediatric formulations are available

3.5 Third-line regimens

The Government has not provided recommendations for third-line ARV regimen given the costs and capacity to monitor patients. However, the National HIV programme should consider developing policies for third-line ART. If available, third-line regimens should include new drugs with minimal risk of cross-resistance to previously used regimens.

Patients failing a second-line regimen with no new ARV options should continue with a tolerated regimen.

Please consult ARV physicians or RMOs to seek the best option.

CHAPTER 4

PROPHYLAXIS FOR COMMON COINFECTIONS

4.1 Cotrimoxazole Preventive Therapy (CPT)

Many OIs in HIV-infected individuals can be prevented by the use of Cotrimoxazole prophylaxis. The diseases include; Bacterial pneumonias, Pneumocystis Jirovecii Pneumonia, Toxoplasmosis, Severe bacterial infections and Malaria.

4.1.1 CPT for Adults and adolescent

Initiation of CPT

All patients are eligible for CPT initiation as soon as they have a diagnosis of HIV.

The only exclusions are those who have allergy to Cotrimoxazole.

Baseline Liver Function Tests (LFT) and Renal Function Tests (RFT) are recommended before long-term administration of Cotrimoxazole.

Dose of CPT

One double strength tablet (800/160mg) or two single strength tablets once a day on a daily basis.

4.1.2 CPT for Children

Cotrimoxazole prophylaxis should be given to all babies with the following conditions: (See Table 23 for dosage)

- All HIV-exposed infants from 6 weeks to 2 months of stopping breast feeding (until confirmed negative using DNA PCR laboratory testing results) to prevent PCP and other bacterial infections when born to an HIV- infected mother (irrespective of whether the woman received ART prophylaxis during pregnancy).
- All HIV-infected infants and children

4.1.3 Duration of CPT

CPT is recommended not be discontinued; it should be continued throughout the person's lifetime.

However, regular follow up initially every month for the first three months, then every three months if the medication is well tolerated. It is mandatory to monitor for side effects and adherence. It is recommended that monitoring includes assessment of skin reactions, measurements of haemoglobin, and white blood counts every six months and when clinically indicated.

Exceptions (Criteria for stopping) are:

- Occurrence of severe side effects such as cutaneous reactions, or fixed drug reactions.
- Renal and/or hepatic insufficiency or severe hematological toxicity.

4.2 Tuberculosis Preventive Treatment (TPT)

Isoniazid Preventive Therapy (IPT)

4.2.1 Background

TB is the most common cause of death in hospitalized adults and children living with HIV, accounting for about a third of all mortality. Six months of Isoniazid reduces mortality by ~39%, independent of ART.

TPT is an intervention that should be part of the package of care for all people living with HIV, regardless of CD4 cell count. It should be offered after symptom screening has been done; anyone with negative symptom screening can commence IPT as long as there are no additional contraindications. PLHIV who have one or more symptoms should complete TB diagnostic evaluation using GeneXpert; persons who do not have TB disease can be referred for IPT.

Isoniazid (INH) will be provided to eligible clients through collaboration between HIV/AIDS and TB Control Programs. This information must be captured in the appropriate surveillance forms for reporting purposes. It is also essential that HIV inpatients and outpatients in health care facilities are isolated from those patients with active TB.

As additional TPT regimens become available, these guidelines will be updated.

4.2.2 Eligibility for IPT in Adults and adolescent

All HIV positive people who have no signs and symptoms suggestive of active TB (cough, fever, body weight loss, or night sweat) are eligible for TB preventive therapy (Figure 5). Of note, pregnant and breastfeeding women

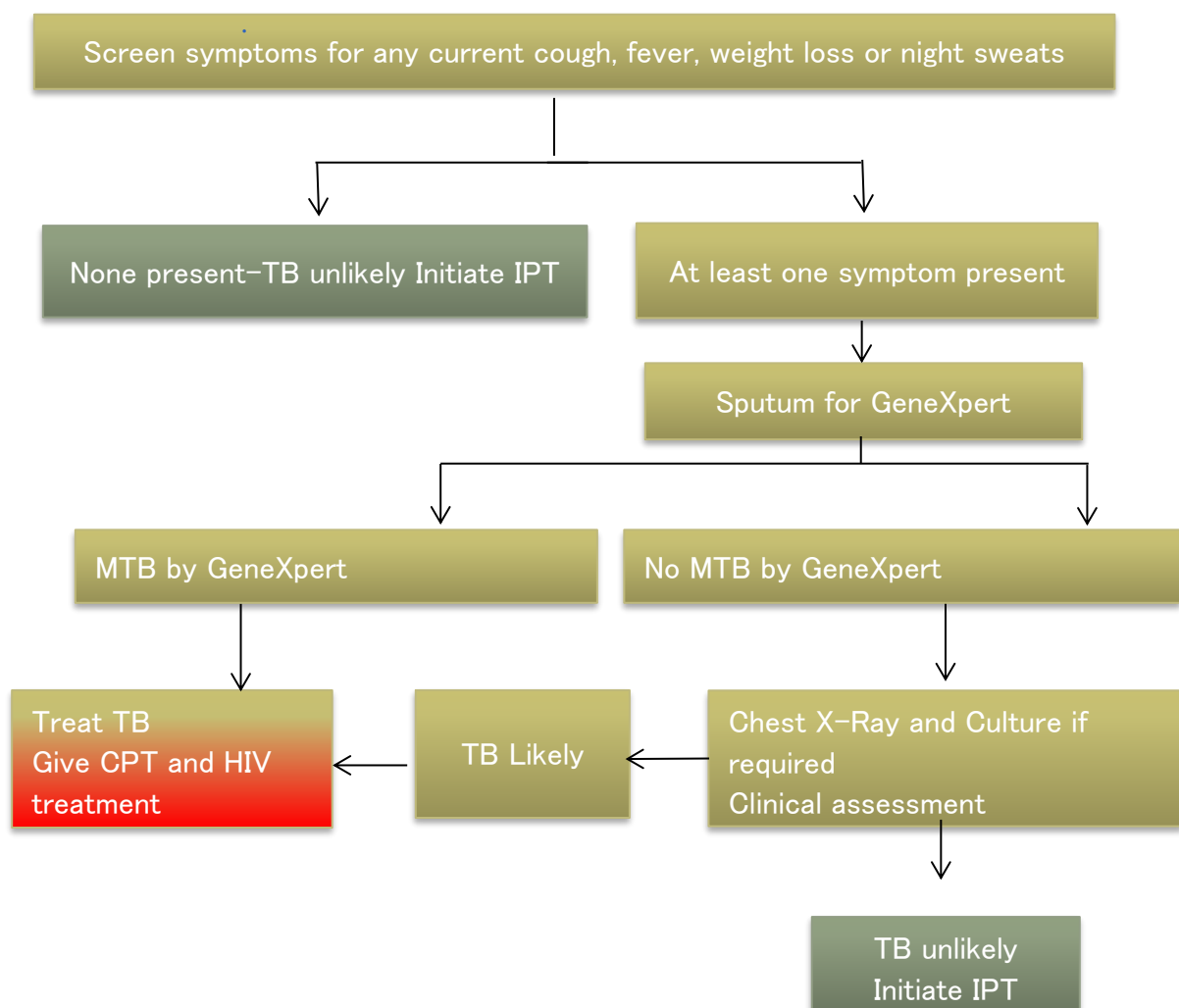
with HIV can receive IPT.

It is essential to exclude active tuberculosis in every patient prior to starting preventive therapy by using TB screening algorithms. This is critical in order to avoid drug resistance when drugs are given to patients with TB disease who require the full regimen. The WHO 4-symptom screen has a high negative predictive value, which means that persons who have no symptoms can be started on IPT with high confidence and do not need additional diagnostic evaluation before starting IPT.

Other potential contraindications to TPT and things to screen for active hepatitis (acute or chronic), regular/heavy alcohol use, symptoms of peripheral neuropathy, and potentially NVP use.

Patients who are eligible for IPT and who are required to start ART can receive IPT concurrently as there is no interaction between isoniazid and the current ART regimen used. It is essential to screen for TB and adverse events on after starting TB and empower patients to recognize issues of potential side effects and seek help if needed.

Figure 9. Algorithm for TB screening for ambulatory people infected with HIV



4.2.3 Eligibility for IPT in children

IPT for children with HIV should be given after ruling out TB. ART in children with HIV improves immune function and reduces the risk of TB infection. However, children should be routinely screened for TB using the pediatric TB screen (poor weight gain, fever, current cough or contact history with a TB case). Always consult a pediatrician on the management of all children with suspected HIV and TB.

Eligibility for IPT in children is:

- a. Any child who is less than 5 years old, who has close contact to an adult with TB, such as a family or household member diagnosed with TB (bacteriologically confirmed or not), as long as the child is *not* symptomatic for TB (in which case they need full assessment and treatment) and if no active TB disease IPT six months should be given.
- b. Children living with HIV who are more than 12 months of age and who are unlikely to have active TB on symptom-based screening and have no contact with a TB case should receive IPT.
- c. Children living with HIV with a positive TB screen but negative diagnostic workup. Children with a positive screen (poor weight gain, fever or current cough or contact history with a TB case) may have TB and should be evaluated for TB and other conditions. If the evaluations show no TB, they should be offered IPT regardless of their age.
- d. Children living with HIV who are less than 12 months of age, only those who have contact with TB case and who are evaluated for TB should receive IPT if the evaluation shows no TB disease.

If children are symptomatic for TB (i.e. have chronic cough, fever, weight loss, malnutrition, enlarged lymph nodes or prolonged pneumonia), a pediatrician should fully evaluate them to exclude active TB disease, even if their lab testing is negative. If the child has TB, then s/he should receive full TB treatment. Never give IPT to children who are symptomatic for TB without a proper evaluation.

4.2.4 Recommended Regimen and Duration

The standard regimen for IPT is:

- Isoniazid (INH) daily 10mg/kg/day (maximum 300mg per day) and
- Vitamin B6 (Pyridoxine) 25mg daily.

INH should be co-administered with Vitamin B6 or Pyridoxine to prevent neurologic side effect, but absence of B6 should not delay IPT initiation

The recommended duration is 6 months.

The doses of Isoniazid for IPT in children, adolescent and adults are listed below:

Table 23a. Simplified, weight- based dosing for Cotrimoxazole, Isoniazid and Vitamin B6 (Pyridoxine)

Drug	Strength of paediatric tablet or oral liquid	Number of tablets or ml by weight band once daily					Strength of adult tablet	Number of tablets by weight band
		3–5.9 kg	6–9.9 kg	10–13.9 kg	14–19.9 kg	20–24.9 kg		
INH	100 mg	0.5	1	1.5	2	2.5	300 mg	1
CTX	Suspension 200/40 per 5 ml	2.5 ml	5 ml	5 ml	10 ml	10 ml	–	–
	Tablets (dispersible) 100/20 mg	1	2	2	4	4	–	–
	Tablets (scored) 400/80 mg	–	0.5	0.5	1	1	400 mg/80 mg	2
	Tablets (scored) 800/160 mg	–	–	–	0.5	0.5	800 mg/160 mg	1
INH/CTX/B6*	Tablets (scored) 300 mg/960 mg/25 mg	–	–	–	0.5	0.5	960 mg/300 mg/25 mg	1

* A scored tablet (480mg/150mg/12.5 mg) is under development.

Table 23b. Simplified weight based dosing for Vitamin B6 (Pyridoxine).

Drug	Strength of tablet or oral liquid (mg or mg/5ml)	Number of tablets or millilitres by weight band once daily*					Strength of adult tablet (mg)	Number of tablets by weight band once daily	
		3.0–5.9 kg	6.0–9.9 kg	10.0–13.9 kg	14.0–19.9 kg	20.0–24.9 kg		25.0–34.9 kg	Adolescent and Adults
Pyridoxine	25 mg	0.25	0.25	0.25	0.5	0.5	25 mg	1	1

4.3 TB Infection Control

Facility-level and administrative infection control measures are important and needed at every site. Robust facility measures lay ground work for other measures and should entail rapidly identifying and isolating individuals with TB, establishing a facility-based Infection Control officer, and annual surveillance of staff for TB infection and/or disease. Administrative Measures are critical to prevent the spread of disease and should be in place to identify, separate, investigate, and treat patients and staff with TB symptom's; to carefully obtain and process any infectious material (e.g., sputum); and to follow appropriate ventilation requirements including outside waiting rooms and/or open window, cross-ventilation policy. Please see table 24 below for other Infection Control measures.

Table 24. Infection Control Measures summary.

Key Component	Indicator	Details
FACILITY LEVEL MEASURES	Facility plan for implementation of TB infection control	Appointment of facility-based Infection Control officer Policies and procedures for rapid identification and isolation of TB cases
	Optimized Space	Waiting area ventilated and uncrowded Air flow assessment performed if available
	Annual surveillance of health care workers is conducted	Symptom screen/ TB skin test/ Interferon-gamma Release Assay (IGRA)/ Chest x-ray
	TB IC Policies Monitored	Policies evaluated Documentation of frequency of training, training materials updated
ADMINISTRATIVE CONTROL MEASURES	Identification and separation of patients with symptoms	Identification and separation of potentially infectious (coughing) patients Separate waiting rooms or outdoor waiting areas
	Separation of sputum collection areas	Separate outside sputum collection area which is well ventilated
	Cough hygiene education	Cough hygiene education signs Surgical masks for coughing patients
	Hand Hygiene Policy	Resources for hand washing/disinfection Written policy or appropriate instructions for hand hygiene
ENVIRONMENTAL CONTROL MEASURES	The ventilation system is optimized	Windows open Air flow assessment performed if available Use of other ventilation or air cleaning methods
PERSONAL PROTECTIVE EQUIPMENT	N95 masks or equivalent, fit testing for masks.	N95 Mask, gloves and respirators available Written fit-testing procedures Records for fit testing

Adapted from: Godfrey, et al. BMC infectious diseases 2016

CHAPTER 5

MANAGING

OPPORTUNISTIC

INFECTIONS

5.1 Introduction

HIV infection destroys the CD4 cells in a person thereby causing immunosuppression.

Immune deterioration in an HIV-positive individual makes way for OIs to occur.

Identifying and managing treatable OI in HIV-positive individuals is an important component of managing HIV-infected individuals.

Note: In this chapter, showing only adult treatment doses. Please refer to PNG National Pediatric Guidelines for Pediatric doses.

5.2 Clinical features

COUGH AND DYSPNOEA

Persistent cough and or dyspnoea can usually be attributed to one of the following:

- Bacterial pneumonia
- Viral pneumonia
- Pulmonary TB
- PCP
- Cardiac failure
- Allergic bronchitis
- Chronic bronchitis
- Bronchial asthma

It may not be possible to determine the underlying cause of cough and dyspnoea on clinical history and physical examination alone and hence laboratory tests may be of critical value.

Investigations:

- Full Blood Count
- Xpert MTB/RIF
- Sputum for AFB x 2 (if GeneXpert® is not available)
- Sputum for pyogenic culture and sensitivity
- Chest x-ray
- Electrocardiogram (ECG--where available)

SKIN RASHES, SORES AND GENERALIZED PRURITIS

Causes include:

- Generalized pruritic papular eruption (PPE)
- External parasites e.g. scabies
- Generalized fungal skin infections
- Herpes zoster virus (HZV)
- Herpes simplex virus (HSV)

- Kaposi sarcoma virus
- Generalized bacterial skin infection e.g., Impetigo
- Drug reactions/drug interactions

Investigations

- Exclude scabies, bacterial, and fungal infections for which treatment are available
- Skin scraping for fungal element
- Pus swab for culture and sensitivity

Management

- Treat the underlying cause
- Refer for specialize management.
- Advise on skin care and refer to skin specialist

ALTERED MENTAL STATUS AND PERSISTENT SEVERE HEADACHE

Amongst the numerous causes of altered mental status and severe headache are:

- Malaria
- Typhoid
- Severe dehydration
- Hypoglycemia
- Bacterial and/or fungal meningitis
- Toxoplasma encephalitis
- HIV-dementia
- Depression
- Psychotic conditions

Note: In altered consciousness, cerebral malaria must always be excluded since this is a common and curable infection.

Investigations

- Blood slide for malarial parasites
- Lumbar puncture for cerebral spinal fluid (CSF) examination including studies for Cryptococcal meningitis (e.g., Indian ink stain, cryptococcal antigen test (CrAg))
- Blood cultures and sensitivity studies
- CT Scan (where available)

WEIGHT LOSS

Weight loss in persons with HIV disease including AIDS may be due to:

- Reduced food intake
- Difficulty/painful swallowing
- Diminished gastrointestinal uptake (malabsorption, diarrhea),

- TB (a frequent cause of rapid weight loss)
- Intestinal worms
- Other debilitating diseases e.g., cancer
- Intractable vomiting

Treatment of weight loss

- Treat underlying cause
- High calorie and protein food intake

5.3 Clinical stage I – Diseases states and treatment

PERSISTENT GENERALIZED LYMPHADENOPATHY (PGL)

Lymphadenopathy may be due to a number of causes including those listed below:

- HIV itself
- Mycobacterium tuberculosis infection.
- Kaposi's Sarcoma or lymphomas
- Other causes e.g., pyogenic bacterial infection

Investigations

- Aspirate the node with a 21G needle and stain the aspirate for acid-fast bacilli (AFB)
- Lymph node biopsy for histological diagnosis
- Chest X-ray
- FBC and ESR

5.4 Clinical stage II – Diseases states and treatment

IMPETIGO

A highly contagious bacterial infection, impetigo often starts when a small cut or scratch becomes infected. This type of bacterial infection is usually more common in children but can affect HIV-positive adults. The nose is most often the source of the infection.

The symptoms of impetigo are honey-colored, crusty sores that often appear on the face between the upper lip and nose. The rash consists of red spots or, blisters that rupture, discharge, and become encrusted. People with impetigo should not scratch the sores because they may inadvertently spread the infection to other parts of their bodies.

This skin infection is caused by one of two bacteria: group A Streptococcus, which is the bacteria also responsible for "Strep throat," or Staphylococcus. If impetigo is caused by streptococcus it will begin with tiny blisters. These blisters can eventually erupt revealing small, wet patches of red skin.

Gradually, a tan or yellowish brown crust will cover the affected area giving the appearance that it is coated with honey. If caused by staphylococcus, people can notice larger blisters that appear to contain a clear fluid. These blisters stay intact for a longer period of time compared to the smaller ones.

Treatment

Local antiseptics to clean lesions:

- Mucopurin 2% TDS topical application
- Fusidic Acid Cream 2% TDS topical application

If infection severe:

- Amoxicillin 500mg TDS PO for 5 days

If no response try:

- Flucloxacillin 250mg QID PO for 10 days OR
- Erythromycin 500mg QID PO for 7 days
- Pediatric Syrup Cephalexin 20mg/kg/Dose BD for 10 days

SEBORRHOEIC DERMATITIS

Seborrheic dermatitis is a disease that causes flaking of the skin. It usually affects the scalp. In adolescents and adults, it is commonly called "dandruff." In babies, it is known as "cradle cap." Seborrheic dermatitis can also affect the skin on other parts of the body, such as the face and chest, and the creases of the arms, legs and groin. Seborrheic dermatitis usually causes the skin to look a little greasy and scaly or flaky.

Treatment

Good general hygiene including washing with soap removes oils from affected areas and improves seborrhea. Pharmacologic treatment options for seborrheic dermatitis include antifungal preparations (selsun shampoo for the head; Clotrimazole 1% with Hydrocortisone 1% topically OR azole drugs (such as Fluconazole) for unresponsive or extensive diseases) to decrease colonization by yeast. If topical Clotrimazole is not used, apply Hydrocortisone 1% cream twice daily to the affected area until inflammation clears.

For severe disease, Keratolytics such as Salicylic acid or coal tar preparations may be used to remove dense scale; then topical steroids may be applied. Other options for removing adherent scale involve applying any of a variety of oils (peanut, olive or mineral) to soften the scale overnight, followed by use of a detergent or coal tar shampoo.

A severe, explosive onset of seborrheic dermatitis may be evident in HIV infection, regardless of age. It may appear as a butterfly rash, similar to the acute facial eruption associated with Systemic Lupus Erythematosus (SLE).

The dermatitis may be treated with topical preparations, but if severe, treatment with Fluconazole 150mg/day PO for 5-10 days, OR Ketoconazole* 200mg/day PO for 5-10 days OR Itraconazole* 200mg/day PO for 5-7 days may be necessary.

TINEA CAPITIS/CORPORIS/CRURIS/PEDIS

Use of topical treatments such as Benzoic Acid Compound Ointment (Whitfield's) or Clotrimazole 1% cream is often adequate. Where there is no response, or there is extensive spread, and/or involvement of two or more body areas, systemic azole therapy may be indicated.

Treatment

Fluconazole 100mg/day PO for 7 days, OR Ketoconazole* 200mg/day PO for 2 - 4 weeks OR Itraconazole* 100mg/day PO for 2 – 4 weeks.

**Due to liver toxicity concerns, Ketoconazole and Itraconazole should not be given to patients taking NVP.*

PAPULAR PRURITIC ERUPTIONS

Hyper pigmented papules and nodules (up to 1cm) with severe itching. Often ulcerations and scars because of scratching. Most frequently on the extensor side of arms and legs.

Treatment

- Antihistamines
(Phenergan 10mg TDS PO if bothersome during the day otherwise just Phenergan 25mg Nocte PO)
- Mild topical steroids
(such as Hydrocortisone 1%) applied BID to QID as necessary
- Calamine lotion for comfort
- Commence ART ASAP

HERPES ZOSTER

Herpes Zoster (or Shingles as it is commonly known) is caused by a reactivation of VZV. Chicken pox is the clinical manifestation of primary infection with VZV. After recovery from primary infection, VZV is not eliminated from the body but rather, the virus lies dormant in the sensory nervous system. When latent infection reactivates, the result is an episode of shingles, which is characterized by localized rash and pain along a dermatomal distribution. This can involve any dermatome, including the lower sacral dermatome. However, as lower sacral dermatomal zoster is much less common than genital herpes, so-called "recurrent zoster" is usually recurrent HSV infection.

The rash of zoster is often intensely pruritic and spreads throughout the dermatome, evolving through papular, vesicular and crusting stages. It usually lasts two to four weeks. The most troubling symptom is usually pain, which ranges from mild to severe, and from burning to lancinating (piercing knifelike pain). Paresthesia, or anesthesia and allodynia (pain induced by touch, often from trivial stimuli), can accompany severe pain. The pain may be self-limited or persist beyond the rash for up to a year ("post herpetic neuralgia").

It is important to note that primary VZV infection in immuno-compromised persons may be associated with the following:

- Numerous lesions
- Disseminated disease associated with pneumonitis, hepatitis and hemorrhagic skin lesions
- CNS manifestations including encephalitis and cerebellar ataxia
- Prolonged healing time
- Bacterial super-infection
- HZV in HIV- infected individuals may be more severe, with more recurrences and may involve more than one dermatome

Treatment

Uncomplicated Zoster does not require indoor admissions. However, admissions should be considered if:

- There are severe symptoms in presence of immunosuppression
- Atypical presentations like Myelitis
- Involvement of more than two dermatomes
- Significant bacterial super-infections
- Disseminated HZV
- Ophthalmic involvement
- Meningo-encephalic involvement

Antiviral therapy is appropriate for all patients presenting with shingles within 72 hours of rash onset. On current evidence, Valaciclovir is probably the most effective agent available, based on the knowledge that it speeds pain resolution faster than Acyclovir and offers more convenient dosing than Acyclovir but either can be used.

- Valciclovir 1g TDS PO for 7-14 days; OR
- Aciclovir 800mg PO 5 times/day for 7 – 14 days
- With disseminated VZV or ophthalmic nerve involvement give IV/Oral Acyclovir 10mg/kg 8 hourly for 7 - 14 days
- Strong analgesics are indicated (Codeine with Paracetamol or Codeine phosphate). The pain may be refractory even to potent analgesics.
- Erythromycin or Cloxacillin 500mg 6 hourly times daily for 7 days for bacterial super-infection if present
- Patients on NVP or LPV/r should not be provided with Cabamazapine or post-herpetic neuralgia however Amitriptyline may be used. The usual dose is 25mg orally nocte. The dose may be increased every 2 to 3 days but care should be taken to avoid excessive drowsiness.

- Most adults require less than 100mg daily
- Evidence has shown that the complications of steroid therapy (prednisolone) tends to outweigh the benefits in herpes zoster and is therefore not recommended

UPPER RESPIRATORY TRACT INFECTIONS (e.g., bacterial sinusitis)

Bacterial sinusitis usually caused by *Streptococcus Pneumoniae* or *H. Influenza*. In health adult's spontaneous resolution will occur in about 70% of people within about 2 weeks. HIV positive patients however should be treated with antibiotic therapy to avoid complications.

Treatment

- Amoxicillin 500mg TDS PO for 5 – 7 days
- If no response use Amoxicillin + Clavulanate 875 + 125 mg (Augmentin) TDS PO for 7 – 14 days.
- If hypersensitive to Penicillin, use Doxycycline 100mg PO daily for 5 – 7 days.

5.5 Clinical stage III – Diseases states and treatment

FEVER

Fever may be due to a variety of causes and clinical features may suggest diagnosis. If no pointing features to a diagnosis are present, as a minimum the following should be done:

- Blood slide for malaria parasites,
- Blood and urine cultures if clinically indicated.
- Chest X-ray
- Blood for culture
- Urinalysis
- Full blood Count and ESR
- Sputum for AFB if indicated. Use Xpert if available

ORAL CANDIDIASIS

Patients with oral candidiasis will have white "curd like" lesions in the oral cavity. These are characteristically painful lesions and may be scrapped off with a spatula.

Treatment

For treatment any of the following may be used:

- Fluconazole 100/200mg/day PO for 5-7 days OR
- Nystatin oral suspension (100,000u/ML) 4-6ml QID for 10-14 days OR
- Miconazole Gel 2% 2.5ml PO QID for 10-14 days OR
- *Itraconazole 100mg/day PO for 10-14 days OR
- *Ketoconazole 200mg/day PO for 10-14 days

Where none of the above is available, 5mls of Gentian Violet 1% can be used BD as a mouth gargle for 5-7 days.

*Due to liver toxicity concerns, Ketoconazole and Itraconazole should not be given to patients taking Nevirapine (NVP)

ORAL HAIRY LEUKOPLAKIA

Oral hairy leukoplakia (OHL) is a white thickening or coating of the lining of the mouth. It looks like white vertical folds or ridges. These ridges are almost always located on the sides of the tongue, although in unusual cases they can sometimes they can be found under the tongue or on the inside of the cheek. Oral hairy leukoplakia may look like oral candidiasis (thrush). Thrush can be scraped off. The white ridges of oral hairy leukoplakia do not scrape off nor is OHL painful. Oral hairy leukoplakia occurs in people who have HIV and who have moderate to severe immune system damage.

It is associated with Epstein-Barr virus (EBV) and occurs almost exclusively in patients who are immuno-compromised. Whether OHL develops after super infection with EBV or activation of a latent infection due to reduced immune surveillance is not known. OHL is more common in immuno-compromised patients who smoke.

Treatment

OHL is rarely treated. Painful super infection with *Candida* can be addressed with Nystatin and other antifungals. Patients with OHL are generally eligible for ART. Immune restoration with ART will eliminate the condition.

VAGINAL CANDIDIASIS

This is one of common illnesses presenting with itchy curd-like discharge. It can be managed with:

- Clotrimoxazole pessaries
- Nystatin Pessaries

If unresponsive or pessaries unavailable; give:

- Fluconazole 150mg PO Stat

DIARRHEA

Diarrhea in persons with HIV disease including AIDS can be due to a number of causes including:

- Common pathogens such as: Amoebiasis, Salmonella or Shigella
- Chronic malabsorption
- Cryptosporidiosis
- Mycobacterium Avium Complex (MAC) infection
- Isosporidiosis
- Clostridium Difficile infection

Investigations

Examine stools for treatable causes

Treatment

- Rehydration, Oral Rehydration Therapy (ORT)
- Treat underlying cause – give antibiotic therapy* and Albendazole 400mg stat
- Nutritional therapy
- In persistent diarrhea among adults with no obvious treatable cause and no response to antibiotic therapy, give anti-diarrheal drugs such as Loperamide to minimize fluid loss and commence on ART. Cease Loperamide ASAP

***Note: Due to resistant of Shigella and Campylobacteria to Cotrimoxazole, Ciprofloxacin is the drug of choice**

PULMONARY TUBERCULOSIS

There is now only one category for treatment for TB patients. All TB patients whether bacteriologically confirmed or clinically diagnosed will receive Category 1. All attempts should be made to diagnose TB in PLHIV using Xpert MTB/RIF. The following table indicates the drugs and different durations of treatment.

- All TB patients whether pulmonary or EPTB, new or previously treated and regardless of the results of their bacteriological investigations (bacteriologically confirmed or not) will receive category 1 treatment.
- Category 1 treatment consists of 2 months of intensive phase with 4 drugs (RHZE) and 4 months continuation phase with 2 drugs (RH). All health workers in PNG must strictly adhere to this.
- There is no separate treatment for previously treated TB patients. Category 2 treatment previously used for retreatment cases is not used anymore as it is no longer recommended for PNG by NTP.

- All patients who are suspected of drug resistant TB including all previously treated TB patients and all patients who do not convert their smears to negative during treatment or do not improve on category 1 treatment during any stage in the treatment must be screened for drug resistant TB by GeneXpert.
- All PLHIV undergoing evaluation for TB should be tested by GeneXpert, per the national SOP for management of drug-resistant TB.
- All TB patients must be treated using Fixed Dose Combination (FDC) drugs and treatment must be given daily under observation.
- All treatment must be directly supervised or observed by a DOT provider.

Sputum must be examined to monitor progress of treatment for all pulmonary TB patients at the end of intensive phase (2 months), at the end of 5th month and at the end of treatment (6 months). Sputum should be collected and sent for testing on a GeneXpert for patients who still remain sputum positive during the different follow-up examinations.

Please see the National Treatment Guidelines for Tuberculosis.

Multidrug-resistant tuberculosis (MDR TB)

All PLHIV diagnosed with Rifampin-resistant or MDR TB are at high risk for mortality, particularly if not on ART, and should be immediately initiated on appropriate TB treatment. Concurrent treatment for MDR TB and HIV has been shown to be safe and effective in high-burden settings. Key considerations include high pill burden, overlapping drug toxicities, drug-drug interactions and IRIS. Depending on results of second-line probe assay (LPA) or drug-susceptibility testing (DST), patients may receive the shorter regimen or one of the longer regimens.

Key principles for management of MDR TB and HIV co-infection:

- **The shorter and longer TB treatment is unchanged in people with HIV although changes to ART may be required.** High pill burden, overlapping drug toxicities, drug-drug interactions, and the risk of immune reconstitution syndrome (IRIS) make patients living with both diseases is complex to manage and monitoring should be *rigorous*.
- **CD4, VL is done at baseline and then at 6 months, and 1 year.** The goal is rapid sustained viral suppression; an unsuppressed VL (>1,000 cp/ml) requires action, including EAC and possible switch in ART to second-line regimen.
- **ART should be started within two weeks of starting RR/MDR-TB treatment** (in CNS disease, ART is started 4-6 weeks post TB treatment due to the risk of intracranial IRIS)¹⁸.
- **Co-trimoxazole prophylaxis reduces mortality and** (unless contraindicated or hypersensitivity) **should be given with TB treatment regardless of CD4 count**¹⁷. Co-trimoxazole can be used with LZD; regular

FBC and neutrophils count monitor for bone marrow suppression.

- **Additional counseling and support** should be provided by the clinical team (TB nurse, doctor and counselors). Key points to address in counseling include increased pill burden and warning signs of opportunistic infections that require presentation to care.
- **Aggressively diagnose and manage co-morbid opportunistic infections.** In adults with CD4 < 100, reflex cryptococcal antigen (CrAg) test is done before ART initiation; a positive test should be treated with pre-emptive fluconazole treatment; evidence of cryptococcol meningitis (CrAg on cerebrospinal fluid or symptoms of meningitis) requires hospitalized anti-fungal treatment followed by fluconazole ≥ 1 year (discontinue when CD4 > 200 taken 6 months apart). ECG monitoring should be vigilant for QT (QTc) interval prolongation with concomitant use of BDQ and fluconazole.

MDR TB and HIV drug-drug interactions

- Efavirenz (EFV) and BDQ are contraindicated together (EFV lowers the BDQ levels). Therefore, EFV should be changed to another antiretroviral agent (see below).
- LZD and AZT both cause bone marrow suppression; AZT should be changed to TDF (or ABC if renal impairment).
- Amikacin and TDF can both cause renal impairment and should not be used together.

Please see the Standard Operating Procedure for the Management of Drug-Resistant Tuberculosis.

Table 25. Categories of Treatment and their Anti-TB Drug Regimens

Treatment category	Type of patient	Drug Regimen and duration			
		Intensive Phase		Continuation Phase	
		Drugs	Duration	Drugs	Duration
Category I	All TB patients and EPTB except for severe forms of EPTB (TBM, Osteoarticular, etc.)	Rifampicin (R) Isoniazid (H) Pyrazinamide (Z) Ethambutol (E)	} 2 months	Rifampicin (R) Isoniazid(H)	} 4 months
	For severe forms of EPTB (e.g.: TBM, Osteoarticular, etc.)	Rifampicin (R) Isoniazid (H) Pyrazinamide (Z) Ethambutol (E)	} 2 months	Rifampicin (R) Isoniazid(H)	} 7 months
		<i>Drug Regimen code: 2 (RHZE)/4 & 7 (RH) - in FDC given daily</i>			
Category IV	DR/MDR TB	Second line drugs as per PMDT TB SOP			

SEVERE BACTERIAL INFECTION

Bacterial pneumonia is a common cause of HIV-1-related morbidity and mortality. Incidence of approximately 100 cases per 1,000 HIV-1-infected persons per year have been reported, a rate much higher than that in the non-infected population. In a study comparing rates among cohorts with similar other risk factors for bacterial pneumonia, those with HIV-1 infection were 7.8 times more likely than HIV-sero-negative persons to develop bacterial pneumonia. For certain persons, bacterial pneumonia is a symptom of HIV-1 disease. Patients can develop serious pneumococcal infections with relatively preserved CD4+ T lymphocyte counts. The high rates of bacterial pneumonia and other pyogenic respiratory tract infections probably result from multiple factors including qualitative B-cell defects that impair the ability to produce pathogen-specific antibody, impaired neutrophil function or numbers or both.

The etiology of bacterial pneumonia among patients with HIV-1 infection shows a relative prominence of *Streptococcus Pneumoniae*, followed by *Haemophilus Influenzae*, *Pseudomonas aeruginosa*, and *Staphylococcus Aureus*. In the majority of studies, the pathogens of atypical pneumonia (*Legionella Pneumophila*, *Mycoplasma Pneumoniae*, and *Chlamydia Pneumoniae*) are rarely encountered.

On the basis of data derived from studies of pneumococcal bacteremia, infection with *S Pneumoniae* is 150–300 times more common in patients with HIV-1 infection than in age-matched HIV-uninfected populations. Recurrent pneumococcal pneumonia, either with the same or unrelated serotype, is also more common among HIV-infected patients, with a rate of 8%–25% within 6 months. Reinfection with a different strain is more common than relapse.

The presentation of bacterial pneumonia in HIV- positive patients will be similar to that in HIV negative patients. Remember that in immuno-compromised patients pneumonia can be caused by fungal infection such as *Aspergillus* and *Cryptococcus*.

Treatment

Same as for HIV-negative patients:

- Amoxicillin 500mg TDS PO for 5 – 7 days if mild; OR
- Benzyl Penicillin 1,000,000 units QID parentally then change to oral Amoxicillin when improved; OR
- If no response or deteriorating, Chloramphenicol 1gram QID parentally then when improved and no fever, change Chloramphenicol 750mg TDS PO for a total period of at least 10 days.
- Adjunct treatment such as oxygen, pain relief etc. as required – see Standard Treatment Manual

If suspected, treat patient with Amphotericin B parentally (0.7mg/kg for Cryptococcosis and 1.0/mg/kg for Aspergillosis). Alternatively, Fluconazole can be used (20mg/kg daily for the first dose (PO or IV) then 10mg/kg daily

for subsequent doses for at least 4 weeks).

5.6 Clinical stage IV – Diseases states and treatment

NORWEGIAN SCABIES

Clinical diagnosis is made by observing typical lesions on wrists, finger web spaces, axillae, penis or thighs or on eliciting the classic pattern of pruritus (at night, after a hot shower/bath). If associated with exposure to an infected person, the index of suspicion should be high even in the context of non-specific symptoms. Immunosuppressed patients may present with Norwegian scabies. Large numbers of mites are present and the condition may not be pruritic. Extensive crusting may be seen.

Treatment

Immunosuppressed/HIV patients are generally resistant to the topical therapy of Permethrin 5% applied topically. If used, Permethrin should be applied from the neck down. Pay particular attention to the areas between the fingers and toes, under fingernails and toenails, wrists, armpits, genitals, buttocks and perianal area. It is usually helpful for a second person to assist with the application of cream to areas that are not easily accessible. Permethrin should be kept on for at least 8 hours but no more than 24 hours. Reapply to hands if washed before 8 hours. This treatment needs to be given weekly for 6 weeks. Oral antihistamines can be given for pruritus.

If there is no response to Permethrin, if no Permethrin is available or if clinically indicated, Ivermectin is given at a dose of 200mcg/kg stat with a further 200mcg/kg dose repeated one week later. If clinically indicated, a third dose can be given after a further week but this is generally not needed. Washing in warm water, drying clothes/linens in the sun and observing personal hygiene is part of treatment.

HERPES SIMPLEX VIRUS (HSV) INFECTION

Clinical features:

Classical presentation of primary HSV infection includes:

- Lymph node enlargement
- Small painful vesicles
- Painful ulcers on the mucosa and skin
 - Pain along gluteal and upper thigh muscles (Sacral radiculomyelitis) may occur with genital/rectal HSV
- Lymph node enlargement
- Headache

Lesions usually resolve within 10-21 days after primary infection. The HSV

then becomes latent in trigeminal and sacral nuclei and may reactivate. Clinical features common in those with HIV and AIDS include persistent/erosive genital/peri-rectal ulcerations. These are mainly associated with HSV-2 and more recurrent herpetic lesions.

Diagnosis

The diagnosis is usually based on clinical history and physical findings. Laboratory tests include serology, culture, immunofluorescence or immunoassay. Neither immunofluorescence nor immunoassay is available in the public health system in PNG.

Treatment

- Acyclovir 400mg PO TDS for 7–10 days; OR
- Valaciclovir 500mg PO TDS for 7–10 days.
- With severe HSV infections, give IV/Oral Acyclovir 10 mg/kg/day TDS, for 7-14days

CYTOMEGALOVIRUS (CMV) INFECTION

Clinical features

Human cytomegalovirus (HCMV) is a common human pathogen, infecting approximately 50% of adult populations in developed countries. CMV infections are typically sub-clinical but can become life threatening in immuno-compromised individuals. HCMV infection itself causes immunosuppression and has been linked with the progressive immunosuppression in persons infected with HIV. The most common manifestation is retinitis but colitis and pneumonitis are also frequently seen. HCMV may also present as encephalitis, hepatitis, adrenalitis, pancreatitis and/or epididymitis.

Diagnosis

The definitive diagnosis relies on clinical and laboratory findings:

- End organ disease such as retinitis with cotton wool and haemorrhage changes seen in retina, severe diarrhea and
- Microscopic finding of cytomegalic cell containing large central basophilic intranuclear inclusion (Papanicolaou or hematoxylin eosin stain)
- HCMV Antigen detection (monoclonal antibodies) of tissue, blood or bronchoalveolar lavage specimens
- Serology – seroconversion is a good marker for primary CMV infection but many individuals have past infection and are antibody positive at baseline

Treatment

- Ganciclovir – IV infusion over 1 hour at 5mg/kg given twice a day during initial induction (2 – 3 weeks) and then 5mg/kg IV once daily for 7 days. (Decrease dose in renal impairment). Maintenance dose of 3 grams orally daily for 20 weeks.
- **It should be noted that oral Ganciclovir is not recommended for induction therapy of acute CMV disease. In acute CMV disease, IV Ganciclovir must be used for induction therapy.**

Valganciclovir is more effective and produces higher blood levels than ganciclovir but is not available in PNG.

CRYPTOCOCCUS NEOFORMANS INFECTION

A major cause of meningitis in HIV-infected persons and disseminated disease. Contrary to bacterial meningitis, fever may be absent in these cases. Diagnosis depends on demonstration of positive CSF Indian Ink preparation. Prompt lumbar puncture with measurement of CSF opening pressure and rapid CSF cryptococcal antigen (CrAg) assay or rapid serum CrAg is the preferred diagnostic approach in case available.

Treatment

The routine use of antifungal primary prophylaxis for Cryptococcal disease is HIV-infected adults, adolescents and children with a CD4 count of less than 100 cells/mm³ and who are CrAg negative or where the CrAg is unknown is not recommended prior to ART initiation unless a prolonged delay in ART initiation is likely.

Induction, consolidation and maintenance antifungal treatment regimens:

- **For the induction phase** of treatment in HIV-infected adults, adolescents and children with cryptococcal disease (meningeal and disseminated non-meningeal) the following antifungal regimens are recommended:

Preferred:

Amphotericin B (1.0mg/kg/day) and Flucytosine (100mg/kg/day, divided into four doses per day) for short-course (one week) induction period.

Alternate regimens depending on drug availability:

Amphotericin B (1mg/kg/day) + fluconazole (1200mg daily for adults, 12mg/kg/day for children and adolescents up to maximum of 800mg daily) (to complete two weeks of induction) when a minimum package of pre-emptive hydration and electrolyte replacement and toxicity monitoring and management cannot be provided for a full two-week induction period.

Fluconazole (800mg daily for adults, 12mg /kg/day for children and

adolescents) + flucytosine (100mg/kg/day, divided into four doses per day) for a full two week induction period when Amphotericin is not available.

- **For the consolidation phase** the following 8 weeks of antifungal treatment is recommended:

Fluconazole (800mg/day for adults, 6-12mg/kg/day for children and adolescents up to a maximum of 800 mg daily).

- **For maintenance treatment** of cryptococcal disease in HIV-infected adults, adolescents and children, oral fluconazole 200mg daily (6mg/kg/day).

Prevention, monitoring and management of amphotericin B toxicity

In HIV-infected adults receiving amphotericin B – containing regimens for treatment of Cryptococcal disease, a minimum package of toxicity prevention, monitoring and management is recommended related to toxicities of hypokalemia and nephrotoxicity.

Timing of ART initiation:

Immediate ART initiation is not recommended in HIV patients with cryptococcal meningitis due to high risk of IRIS that may be life threatening.

In HIV-infected adults, adolescents and children with a recent diagnosis of cryptococcal meningitis, ART initiation should be deferred until there is evidence of sustained clinical response to anti-fungal therapy, and after 4 weeks of induction and consolidation with Amphotericin B – containing regimens combined with flucytosine or fluconazole, or after 4-6 weeks of treatment with high doses of oral fluconazole induction and consolidation phase.

Discontinuation of azole maintenance treatment (secondary prophylaxis)

In HIV-infected adults and adolescents with successfully treated cryptococcal disease (meningeal and non-meningeal), discontinuation of antifungal maintenance treatment is recommended based on the following criteria:

- If HIV VL monitoring is not available when patients are stable and adherence to ART and antifungal maintenance therapy for at least one year and have a CD4 count of greater than or equal to 200 cells/mm³.
- If HIV VL is available, the patient is stable and adherence to ART and antifungal maintenance treatment for at least one year and with CD4 count greater than or equal to 100 cells/mm³ and have a suppressed viral load.

In HIV-infected children aged between 2 and 5 years with successfully treated cryptococcal disease (meningeal and non-meningeal), discontinuation of antifungal treatment maintenance is recommended if child is stable and adherent to ART and antifungal maintenance treatment for at least one year and with a CD4 count percentage greater than 25% or absolute count greater than 750 cells/mm³ (two measurements done six months apart).

Maintenance therapy for cryptococcal disease should NOT be discontinued in children less than two years.

Maintenance treatment for cryptococcal disease should be restarted if CD4 count drops to 100 cells/mm³ or below in HIV infected adults and adolescents (or CD4 count less than or equal to 25% or 750 cells/mm³ in children between two and five years, or if WHO clinical stage 4 event occurs, irrespective of patients age).

OESOPHAGEAL CANDIDIASIS

Candidiasis is the most common fungal infection in HIV and AIDS. Clinical manifestations depend on the site of disease, which can include mouth, pharynx, esophagus, and vagina.

Note: Candidiasis in the esophagus, trachea, bronchi or lungs is diagnostic of WHO Clinical Stage IV.

Diagnosis

The diagnosis is mainly based on clinical findings.

Treatment

For oesophageal candidiasis patients will usually complain of painful swallowing. If the patient has oral candidiasis or has a recent history of this, a presumptive diagnosis should be made of esophageal candidiasis. The following treatment options are available:

- Fluconazole 200mg PO Stat then 100mg daily for 14 days; OR
- Itraconazole 200mg PO daily for 14 days.

If unresponsive or unable to swallow:

- Amphotericin B 0.5mg/kg IV daily for 14 days.

Once oesophageal candidiasis is treated with Fluconazole, the dose should be reduced to 100mg daily and then continued indefinitely or until immune recovery occurs on HAART.

PNEUMOCYSTIS JIROVECI PNEUMONIA (PCP)

Quite common in HIV-infected individuals.

Clinical presentation:

- Non-productive cough, fever, chest tightness and shortness of breath that has evolved over 2-4 weeks.
- Chest signs may be minimal despite severe shortness of breath.
- CXR may show diffuse and symmetrical increased interstitial markings to diffuse alveolar pattern with infiltrations characterized by asymmetry, nodularity or cavitations. Chest radiograph may appear normal in 10% of patients. Pneumothorax is sometimes seen.

Diagnosis

In our circumstances diagnosis is based on clinical presentation and exclusion of other common causes of severe dyspnoea.

Treatment of PCP

The management of PCP depends on the severity of the disease.

Severe Disease (Dyspnoea without exertion and severe hypoxia)

- Cotrimoxazole (Trimethoprim 15-20mg/kg/day + Sulphamethoxazole 75-80mg/kg/day) IV or oral for 21 days in 3 divided daily doses plus corticosteroids (see below).

Mild and Moderate Disease PCP is normally considered moderate if there is dyspnoea on minimal exertion)

- Cotrimoxazole 1920mg 3 times /day for 21 days (4 single strength tabs 8 hourly for 7 days, Then 4 single strength tablets 12 hourly for 7 days, then 4 single strength tablets daily for 7 days). With patients with moderate disease, consideration should be given to commencing initial therapy IV, particularly where treatment compliance may be an issue.
- Trimethoprim 12-15mg/kg/day + Dapsone 100mg/day for 21 days

For those allergic to Sulphur

Trimethoprim 12-15mg/kg/day + Dapsone 100mg/day for 21 days

Use of Corticosteroids in PCP

Research has demonstrated that there is reduced morbidity and mortality with PCP if corticosteroids are administered concomitantly with antimicrobial therapy. In moderate and severe disease, Prednisone 40mg PO BD for five days, then 40mg PO Daily for five days, then 20mg PO Daily until completion of therapy. If oral corticosteroid therapy is not possible, then hydrocortisone

(100mg IV q6h) may be used until oral therapy can be commenced (Methylprednisolone at 75% of the prednisone dose can be used if parental therapy is indicated and there is no parenteral prednisone). The 21-day course can then be completed orally in accordance with the above schedule. Corticosteroid therapy can be complicated by CNS toxicity and other OIs.

Prophylaxis (Primary and Secondary) therapy for PCP

Adults – One double strength CTX tablet (160/800mg) or two single strength tablets once a day on a daily basis.

Children – See table 23a for CTX dosing.

CEREBRAL TOXOPLASMOSIS

Clinical features

- Focal paralysis or motor weakness depending on area affected.
- Neuro-psychiatric manifestation corresponding to the affected area in the brain.
- Altered mental status (forgetfulness, etc.).

Treatment Acute infection

TabS Sulphadiazine 1g (<60kg) or 1.5g (>60kg) 6 hourly + tablets Pyrimethamine 200mg loading dose then 50mg/day (<60kg) or 75mg (>60kg)+ tablets Folinic acid 10-20mg/day for 6 weeks. After six weeks of treatment move to prophylaxis regimen.

Alternative Treatment Regimen (less effective)

Cotrimoxazole (TMP 10mg/kg and SMX 50mg/kg daily) given 12 hourly either IV or PO. Continue for 4–6 weeks after the resolution of signs/symptoms then on to secondary prophylaxis

Secondary Prophylaxis Regimen

- Tablets Sulphadiazine 500mg 6 hourly + Tabs Pyrimethamine 25-50mg/day + Tabs Folinic acid 25mg/day
- For those allergic to sulphur:
Replace Tablet Sulphadiazine with capsule Clindamycin 450mg 6 hourly.
- Discontinue maintenance therapy when CD4 count>200 cells/mm³ for 6 months.

Alternative Secondary Prophylaxis

Use Cotrimoxazole 2 SS (SMX 400/TMP 80mg X 2tabs) or 1 DS (SMX 800/TMP 160mg) twice daily.

5.7 Other diseases

HUMAN PAPILLOMA VIRUS (HPV) INFECTION

Clinical features

The virus may be present for years before symptoms develop. Genital warts develop following infection with some sub-types of HPV and usually progress rapidly whenever there is a decline in immune status (such as in pregnancy or in HIV infection). The warts are soft and fleshy and are easily traumatized during sexual activity. In pregnancy or in immuno-compromised individuals the warts may develop so greatly as to completely cover the vulva and occlude the introitus and urethral meatus.

Women who have ano-genital HPV infection (ano-genital warts) have an increased risk of developing cancer of the cervix and both men and women who have anal warts have an increased risk of later developing anal cancer.

Diagnosis

The diagnosis in PNG is based on clinical history and physical findings.

Treatment

The options in PNG are limited:

- Trichloroacetic acid in 80% to 90% solution may be used to treat small moist warts. It should be applied by the clinician to each wart (being careful not to burn surrounding tissue) weekly for up to 6 weeks. This is only appropriate for small numbers of discrete warts.
- Imiquimod 5% cream is applied to warts (with the fingers) 3 times a week (alternate nights) for up to 16 weeks. This medication stimulates the production of interferon and other cytokines. It is not available in the public health system but can be obtained by prescription from some private pharmacies. Safety in pregnancy has not yet been established.
- Electrocautery is probably the only real option available in PNG to treat the large mass genital warts that are becoming increasingly seen. Female patients are usually referred to the Gynecology Clinic and males to the Surgical Clinic for booking. Cautery will usually need to be done under general (ketamine) anesthesia.

INTESTINAL PROTOZOA INFECTION

For intestinal protozoa, which is a common cause of diarrhea and difficult to diagnose, the recommended treatment:

Tab's Albendazole 400mg BD for one week.

Other alternatives are Metronidazole Tabs or Thiabendazole.

5.8 Non-communicable diseases and HIV

People living with HIV are at risk of developing a range of chronic non-communicable disease (NCDs), including

- cardiovascular disease (CVD)
- hypertension
- diabetes
- chronic obstructive pulmonary disease (COPD)
- kidney disease
- cancers
- mental illness (e.g., depression)

It is recommended that all PLHIV should be assessed and have a cardiovascular risk assessment routinely and managed according to protocols recommended for the general population. All PLHIV must be offered advice on prevention and risk reduction of cardiovascular diseases by addressing modifiable factors such as high blood pressure, smoking, obesity, unhealthy diet and lack of physical activity.

Depression in People Living with HIV is also common. All PLHIV should be assessed for depression and linked to mental health services accordingly. People living with HIV are at risk of mental, neurological and substance –use disorders.

CHAPTER 6

SERVICE DELIVERY

6.1 Service Delivery Approaches

Implementing “Test and Treat for all PLHIV” poses a higher demand to the health system particularly in the following areas.

- Exponential increase in demand for antiretroviral treatment puts a burden on the health system to provide chronic care/lifelong care to a high number of clients with diverse needs.
- Most clients will be starting HIV treatment earlier, in the asymptomatic stage. These people require support to commit to lifelong ART.
- Decline in levels of retention on treatment in the health care system. Adopting “Test and Treat for all” requires more effort to retain the increased number of PLHIV on treatment considering the fact that many of them will be asymptomatic with varied commitment to lifelong therapy.
- Although most people will present earlier programs must maintain or improve the capacity to respond to clients who present with advanced disease and are at high risk of mortality and morbidity.

Health facilities need to adapt service delivery models to address the above challenges by

- Differentiating HIV care to target the individual needs
- Strengthening continuum of HIV care from testing to initiation of treatment and retention in treatment

Differentiated HIV care

The differentiated HIV care framework, proposes that service delivery packages and models of care should be targeted to meet the specific needs of the respective category of clients.

The differentiated care framework (Table 16) is characterized by four delivery components:

- Types of services delivered
- Location of service delivery
- Provider of services
- Frequency of services

Table 26. Recommended Differentiated HIV care Model for PNG

Category of Client	Definition	Service package	Service Frequency	Service Location	Health Care carder
New Clients presenting with early HIV infection	Clients starting ART or are within six months of commencing ART with WHO stage 1 or 2	Early initiation of ART Baseline lab tests Adherence counselling Pharmaco-vigilance reviews OI prophylaxis Follow up services and tracking	2 weeks after initiation, 4 weeks after initiation, thereafter 4weekly for 6 months.	Health Facility initiating ART. After 6 months the client can start attending a satellite ART site for drug refills	ART prescriber trained on IMAI Link client to adherence or peer support groups.
People with Advanced Disease	Presenting with CD4 count below 200cells/mm ³ or WHO disease stage 3 or 4	Rapid initiation of ART (once the risk of immune reconstitution inflammatory syndrome is ruled out); Screening and treatment for	Client may require more frequent visits. Service frequency is guided by the mode of care for the predominant or life threatening medical	Main ART site. i.e. Hospital or health center with human resource and laboratory capacity to provide the service package	Doctor Or HEO

		tuberculosis (TB) or isoniazid preventive treatment (IPT) as indicated; Co-trimoxazole (CTX) prophylaxis; Systematic screening for cryptococcus antigen; Screening for toxoplasmosis; Intensive follow-up.	condition.	required	
PLHIV stable on ART	Clients who have received ART for at least 12 months. Client has no adverse drug reactions that require regular monitoring, No current illnesses	Drug refills Medication pick-ups. Laboratory monitoring 6 monthly Cessation of CD4 count monitoring if viral load testing is available.	Less frequent (every 3-6 months) clinic visits Children adolescents need to be monitored more frequently for treatment dosing /weight changes, disclosure, and adherence	Health facility based care will continue Clients may use satellite ART site or other approach for drug refills but should visit the ART site at least once in 6 months for	Appointments for drug refills or adherence counselling can be attended by CHW or pharmacist/dispenser Client may see the clinician only when medical review is required or 6 monthly for laboratory monitoring

	<p>Not pregnant or currently breastfeeding</p> <p>Has good understanding of lifelong adherence</p> <p>There is evidence of treatment success (i.e. two consecutive viral load measurements below 1000 copies /mL or rising CD4 cell counts, in the absence of viral load testing.</p>		<p>support.</p> <p>less frequent (3 - 6 monthly) medication pick up</p>	<p>laboratory monitoring.</p> <p>Community ARV delivery may be used for stable patients provided that sufficient support and resources can be provided. Clinic records should be updated regularly so that client is not misclassified as LTFU.</p>	<p>Peer-led ART refills for programs with established trained peer educators provided regular mentoring and support can be provided to the peer educators.</p>
PLHIV unstable on ART	<p>PLHIV with treatment failure or Poor adherence</p> <p>Has OIs and adverse drug events</p>	<p>Regular clinical and laboratory review depending on the condition until the client is no-longer at risk.</p> <p>Adherence support</p>	<p>Monthly until the client is no longer at risk</p>	<p>Facility based care reinforced with bi-weekly community level support where available</p>	<p>Doctor or HEO</p> <p>Specialized clinics for PPTCT and pediatric HIV care to cater for needs for respective clients.</p>

	<p>High risk of LTFU or reconnected to care after LTFU</p> <p>Pregnant/breast feeding women, children and adolescents are included in this category because they require close monitoring.</p>	<p>monthly for 3 months.</p> <p>Management of OIs.</p> <p>Re-assess viral load after 3months.</p> <p>Viral load literacy for client</p> <p>ARV regimen switch committee to assess if the client should be started on second line regimen.</p>		<p>through home visits, phone calls etc.</p> <p>The client should be managed in the hospital or major health center with capacity to manage the medical condition</p>	
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6.2 Strengthening the continuum of HIV care

6.2.1 Early Initiation of HIV treatment

NDoH recommends that all newly diagnosed HIV-positive clients should be provided a package of services to ensure timely linkage to care and treatment.

Health workers should not unduly delay treatment especially for pregnant women, children or clients presenting with advanced disease.

Some of the approaches that can be used to improve linkage from HIV testing to treatment and accelerating ART initiation include;

- Providing integrated services, where HIV testing, HIV prevention, treatment and care, TB and sexually transmitted infection (STI) screening and other relevant services are provided together at a single facility or site
- Decentralized ART provision by using satellite ART sites to take the services nearer to the people. This reduces transport related barriers to initiation of treatment
- Promoting couple testing and male partner involvement in PPTCT may increase rates of HIV testing and linkage to care
- Support and involvement of trained peer educators and other lay providers to act as peer navigators, expert patients/clients and community outreach workers to provide support, and actively track, identify and reach people lost to follow-up
- Ensure any baseline required tests are done as soon as possible.
- Using communication technologies, such as mobile phones and text messaging, which may help with early initiation of ART among children receiving EID testing; disclosure, adherence and retention, particularly for adolescents and young people

6.2.2 Retention of PLHIV in HIV care and treatment

Health care workers and program managers should put concerted effort to maintain PLHIV on lifelong care. Some approaches that may be used to improve retention on treatment include;

- Using expert clients to provide education and counselling in the ART clinics
- Paying particular concern to pregnant and postpartum mothers to reduce LTFU which commonly occurs in the transition from MCH clinics

to the ART clinic after the post-partum period

- Providing age-appropriate counselling on disclosure to children living with HIV
- Training care givers on the importance of disclosure and regular follow up for children on HIV treatment
- Peer psychosocial support through the use adherence clubs or mentor-mothers to provide counseling at the health facility
- Providing adolescent friendly services that take into consideration their special needs, including adolescent peer support
- Providing friendly services to key populations taking into consideration that they are often mobile. Eliminating stigma and discrimination in service delivery
- Patients with a VL suppression (<copies/ml), 3-6 months ART supply dispensing is recommended to reduce clinic visits.

6.2.3 Adherence Support

Adherence to ART is the primary determinant of viral suppression, risk of transmission, disease progression and death. Individual factors may include forgetting doses, being away from home, changes in daily routine, depression or other illness and substance or alcohol use.

Adherence to ART may be challenging in the absence of supportive environments for people living with HIV and in the presence of HIV-related stigma and discrimination.

Medication-related factors may include adverse events and the complexity of dosing regimens, such as those for children. Health system factors include distance to health services, long waiting times to receive care and obtain prescription refills, receiving only one month's supply of drugs, pharmacy stock-outs and the burden of direct and indirect costs of care.

The following specific population groups face challenges with adherence and need extra attention.

- Pregnant and postpartum women: Due to pregnancy-related conditions such as nausea and vomiting which negatively affect treatment adherence. Other individual factors e.g. lack of partner disclosure and support, and fear of stigma and discrimination
- Adolescents face specific challenges in adherence to treatment due to

psychosocial issues such as peer pressure and the perceived need to conform, inconsistent daily schedules, transitioning from childhood to adult care and the assumption that the older adolescent has increased responsibility over their health

- Infants and young children require the commitment and involvement of a responsible caregivers to adhere to treatment. HIV care and treatment should be provided to parents and other family members of children living with HIV to support optimal care for the child living with HIV. Clinicians need to pay attention to other pediatric conditions like malnutrition. Choose appropriate ARV regimen and formulation to reduce pill or volume burden and monitor dosing and administration at each visit.
- People with mental health conditions and substance use: Assessment and management of depression should be included in care services for all PLHIV
- Use of alcohol and other substances (i.e. drug/substance abuse): Treatment of depression and substance use disorders should be provided regardless of HIV status
- Key populations face particular challenges. They are often mobile and have high risk of substance abuse and depression. Health workers should provide counselling, behavioral skills training and medication adherence training, treatment of depression and management of substance use where necessary. Provide supportive interventions and link key populations to peer psychosocial support groups, where available

6.2.4 Task shifting and task sharing

Task shifting and task sharing involves the redistribution of tasks within the health workforce teams so that specific tasks are reassigned to health workers with shorter training and fewer qualifications to make efficient use of the available human resources.

The following models of task shifting/task sharing have been used in PNG to support scale-up of ART services and are therefore encouraged;

- Using IMAI Trained non-physician clinicians, midwives and nurses to initiate first-line ART
- Using trained non-physician clinicians, midwives and nurses to maintain clients on ART by providing refills at the satellite sites
- Trained and supervised community health workers to dispense ART

6.2.5 Decentralization of ART services

Decentralizing HIV treatment and care services reduces waiting times for people receiving care in facilities and brings HIV services closer to people's homes

NDoH recommends the following models of decentralized HIV care;

- Initiation of ART in hospitals with maintenance of ART in peripheral health facilities
- Initiation and maintenance of ART in peripheral health facilities
- Prescribing and dispensing AZT and NVP suspension for HIV exposed babies in MCH clinics with trained health workers

Community level approaches for example initiation of ART at peripheral health facilities with maintenance at the community level has not been used in PNG.

However, this approach could be tested to improve access to ART particularly for very remote areas where clients face high economic burden accessing ART sites.

6.2.6 Integrating and linking services

Providing integrated and linked services reduces missed opportunities for initiating ART, enhancing adherence support and retention of clients in care.

Maternal and Child health services

- NDoH recommends offering HIV testing and syphilis testing to pregnant women through provider-initiated approaches as an essential component of MNCH services
- ART should be provided in maternal and child health clinics, and clients linked to the ART site after the postpartum period.
- In the absence of a trained service provide clients should be linked to the most accessible ART site but continue to attend maternal and child health services.

Delivering ART in TB treatment settings and TB treatment in HIV care settings

- ART should be initiated for people living with HIV in TB treatment settings, with linkage to ongoing HIV care and ART
- Where possible, TB treatment may be provided for PLHIV in HIV care settings where a TB diagnosis has also been made

ANNEX

Annex 1: WHO CLINICAL STAGING FOR ADULTS AND ADOLESCENTS

<p>Clinical stage I</p> <ul style="list-style-type: none"> ○ Asymptomatic ○ Persistent generalized lymphadenopathy <p>Performance scale 1: asymptomatic, normal activity</p>
<p>Clinical stage II</p> <ul style="list-style-type: none"> ○ Weight loss, <10% of body weight ○ Minor mucocutaneous manifestations (seborrheic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular cheilitis) ○ Herpes zoster within the last five years ○ Recurrent upper respiratory tract infections (i.e. bacterial sinusitis) <p>And/or performance scale 2: symptomatic, normal activity</p>
<p>Clinical stage III</p> <ul style="list-style-type: none"> ○ Weight loss, >10% of body weight ○ Unexplained chronic diarrhea, >1 month ○ Unexplained prolonged fever (intermittent or constant, >1 month) ○ Oral hairy leukoplakia ○ Severe bacterial infections (i.e. pneumonia, pyomyositis) • Oral candidiasis (thrush) • Pulmonary tuberculosis within the past year <p>And/or performance scale 3: bedridden <50% of the day during the last month</p>
<p>Clinical stage IV</p> <ul style="list-style-type: none"> ○ Norwegian Scabies > 1 month ○ Non-typhoid Salmonella septicemia • HIV wasting syndrome^a • Pneumocystis carinii pneumonia • Toxoplasmosis of the brain • Cryptosporidiosis with diarrhea >1 month • Cryptococcosis, extrapulmonary • Cytomegalovirus disease of an organ other than liver, spleen or lymph nodes • Herpes simplex virus infection, mucocutaneous >1 month, or visceral any duration • Progressive multifocal leukoencephalopathy • Any disseminated endemic mycosis (i.e. histoplasmosis, coccidioidomycosis) • Candidiasis of the oesophagus, trachea, bronchi or lungs • Atypical mycobacteriosis, disseminated • Extrapulmonary tuberculosis • Lymphoma • Kaposi's sarcoma • HIV encephalopathy, as defined by the Centers for Disease Control and Prevention^b <p>And/or performance scale 4: bedridden >50% of the day during the last month</p>

Notes

Both definitive and presumptive diagnoses are acceptable

^a HIV wasting syndrome: weight loss of >10% of body weight, plus either unexplained chronic diarrhea (>1 month) or chronic weakness and unexplained prolonged fever (>1 month).

^b HIV encephalopathy: clinical findings of disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection which could explain the findings.

- AIDS Indicator conditions

Annex 2: WHO CLINICAL STAGING FOR CHILDREN

Clinical stage I <ul style="list-style-type: none">○ Asymptomatic○ Persistent generalized lymphadenopathy
Clinical stage II ⁽¹⁾ <ul style="list-style-type: none">○ Unexplained persistent hepatosplenomegaly○ Papular pruritic eruptions○ Extensive wart virus infection○ Extensive molluscum contagiosum○ Recurrent oral ulcerations○ Unexplained persistent parotid enlargement○ Lineal gingival erythema○ Herpes Zoster○ Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)○ Fungal nail infections
Clinical stage III ⁽¹⁾ <ul style="list-style-type: none">○ Unexplained moderate malnutrition not adequately responding to standard therapy○ Unexplained persistent diarrhea (14 days or more)○ Unexplained persistent fever (above 37.5 C, intermittent or constant, for longer than one month)○ Acute necrotizing ulcerative gingivitis/periodontitis○ Chronic HIV associated lung disease including bronchiectasis○ Unexplained anemia (<8), neutropenia (<0.5 x 10⁹), or chronic thrombocytopenia (<50 x 10⁹)<ul style="list-style-type: none">● Persistent oral candidiasis (after first 6 weeks of life)● Oral hairy leukoplakia● Lymph node TB● Pulmonary TB● Severe recurrent bacterial pneumonia● Symptomatic lymphoid interstitial pneumonitis

Clinical stage IV ⁽¹⁾

- Norwegian Scabies > 1 month
- HIV associated cardiomyopathy or nephropathy
- Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy
- Pneumocystis pneumonia
- Recurrent bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)
- Chronic herpes simplex infection (orolabial or cutaneous of more than one month's duration or visceral at any site)
- Extra-pulmonary TB
- Kaposi sarcoma
- Oesophageal candidiasis (or Candida of trachea, bronchi or lungs)
- CNS Toxoplasmosis (after the neonatal period)
- HIV encephalopathy
- Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, with onset at age over 1 month
- Extrapulmonary cryptococcosis (including meningitis)
- Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiomycosis)
- Chronic cryptosporidiosis (with diarrhea) or chronic isosporiasis
- Disseminated non-tuberculous mycobacteria infection
- Cerebral or B cell non-Hodgkin lymphoma
- Progressive multifocal leukoencephalopathy

Note

Both definitive and presumptive diagnoses are acceptable

¹ Unexplained refers to where the condition is not explained by other causes

- AIDS indicator conditions

Annex 3: DRUGS FORMULATIONS AND DOSES FOR ADULTS AND ADOLESCENTS (available in PNG)

Generic name	Dose
Nucleoside reverse-transcriptase inhibitors (NRTIs)	
Abacavir (ABC)	300mg twice daily or 600mg once daily
Lamivudine (3TC)	150mg twice daily or 300mg once daily
Zidovudine (AZT)	300mg twice daily
Tenofovir (TDF)	300mg once daily
Non-nucleoside reverse-transcriptase inhibitors (NNRTIs)	
Efavirenz (EFV)	400–600mg once daily
Nevirapine (NVP)	200mg once daily for 14 days, followed by 200mg twice daily
Proteases inhibitors (PIs)	
Lopinavir/ritonavir (LPV/r)	400mg/100mg twice daily
	Considerations for individuals receiving TB therapy In the presence of rifampicin, adjusted dose of LPV/r (LPV 800mg + RTV 200mg twice daily or LPV 400mg + RTV 400mg twice daily) with close monitoring.

Generic name		Dose
Integrase strand transfer inhibitor (INSTIs)		
Dolutegravir (DTG)	50mg once daily	
	Considerations for individuals receiving TB therapy In the presence of rifampicin, adjusted dose of DTG (DTG 50mg twice daily) with close monitoring.	
Fix-dose combination tablets		
TDF/3TC/DTG	300mg/300mg/50mg once daily	
TDF/3TC/EFV	300mg/300mg/600mg once daily	
AZT/3TC/NVP	300mg/150mg/200mg twice daily	
TDF/3TC	300mg/300mg once daily	
AZT/3TC	300mg/150mg twice daily	
ABC/3TC	600mg/300mg once daily	

Annex 4: DRUGS FORMULATIONS, DOSES AND SCHEDULE FOR PAEDIATRIC CASES (available in PNG)

Fixed-dose solid formulations for twice-daily dosing for infants and children 4 weeks of age and older

Drug	Strength of tablets (mg)	Number of tablets by weight band morning and evening										Strength of adult tablet (mg)	Number of tablets by weight band	
		3.0–5.9 kg		6.0–9.9 kg		10.0–13.9 kg		14.0–19.9 Kg		20.0–24.9 kg			25.0–34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
AZT/3TC	Tablet (dispersible) 60 mg/30mg30mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300mg/150mg150mg	1	1
AZT/3TC/ NVP	Tablet (dispersible) 60 mg/30mg/50mg50mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300mg/150mg/200mg	1	1
ABC/3TC	Tablet (dispersible) 60 mg/30mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	600mg/300mg	0.5	0.5

Solid and oral liquid formulations for once- daily dosing for infants and children 4 weeks of age and older

Drug	Strength of tablet (mg)	Number of tablets or capsules by weight band once daily					Strength of adult tablet (mg)	Number of tablets or capsules by weight band once daily
		3.0–5.9 kg	6.0–9.9 kg	10.0–13.9 kg	14.0–19.9 kg	20.0–24.9 kg		
								25.0–34.9kg
EFV ^a	Tablet (scored) 200mg	–	–	1	1.5	1.5	200mg	2
ABC/3TC	Tablet (dispersible) 60/30mg	2	3	4	5	6	600mg/300mg	1
ABC/3TC	Tablet (dispersible) 120/60mg	1	1.5	2	2.5	3	600mg/300mg	1
DTG	Tablet 50 mg	–	–	–	–	1	50 mg	1

^a EFV is not recommended for children younger than 3 years and weighing less than 10kg.

Solid and oral liquid formulations for twice- daily dosing for infants and children 4 weeks of age and older

Drug	Strength of tablets (mg) or oral liquid (mg/ml)	Number of tablets or ml by weight-band morning (AM) and evening (PM)	Strength of adult tablet (mg)	Number of tablets by weight band
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		3.0–5.9 kg		6.0–9.9 kg		10.0–13.9 kg		14.0–19.9 kg		20.0–24.9 kg			25.0–34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
Solid formulations														
ABC	Tablet (dispersible) 60mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300mg	1	1
NVP	Tablet (dispersible) 50mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	200mg	1	1
LPV/r ^a	Tablet ^b 100mg/25mg	–	–	–	–	2	1	2	2	2	2	100mg/25mg	3	3
	Pellets ^c 40mg/10mg	2	2	3	3	4	4	5	5	6	6	100mg/25mg	3	3
RAL	Chewable tablets 25 mg	1	1	2	2	3	3	4	4	6	6	400mg	1	1
	Chewable tablets 100mg	–	–	–	–	–	–	1	1	1.5	1.5	400mg	1	1
	10 mg/mL (Oral granules for suspension:100mg/sachet)	3 mL	3 mL	5 mL	5 mL	8 mL	8 mL	10 mL	10 mL	–	–	–	–	–
Liquid formulations														
AZT	10mg/m1	6ml	6ml	9ml	9ml	12ml	12ml	–	–	–	–	–	–	–
ABC	20mg/ml	3ml	3ml	4ml	4ml	6ml	6ml	–	–	–	–	–	–	–
3TC	10mg/ml	3ml	3ml	4ml	4ml	6ml	6ml	–	–	–	–	–	–	–
NVP	10mg/ml	5ml	5ml	8ml	8ml	10ml	10ml	–	–	–	–	–	–	–
LPV/r ^a	80/22 mg/ml	1ml	1ml	1.5ml	1.5ml	2ml	2ml	2.5 ml	2.5 ml	3ml	3ml	–	–	–

- ^a LPV/r liquid requires a cold chain during transport and storage. The LPV/r heat-stable tablet formulation must be swallowed whole and should not be split, chewed, dissolved or crushed.
- ^b The adult 200/50mg tablet could be used for children 14.0–24.9kg (1 tablet in the morning and 1 tablet in the evening) and for children 25.0–34.9kg (2 tablets in the morning and 1 tablet in the evening)
- ^c The LPV/r pellets formulation should not be used for infants younger than 3 months. More details on the administration of LPV/r pellets is available at <http://www.emtct-iatt.org/wp-content/uploads/2015/09/IATT-LPVr-Factsheet-Final-30-September-2015.pdf>.

Annex 5: SGBV Screening Protocol

“From the very first moment, throughout the entire interaction with survivors of GBV, and at every encounter, health workers must ensure to apply a survivor centred approach, which means prioritizing the rights, wishes and needs of the survivor.”

NDOH, Medical and Psychosocial Care for Survivors of Sexual and Gender Based Violence,
National Clinical Practice Guidelines

Per the NDOH¹ above, GBV services will be provided in accordance with human rights as set forth in international human rights agreements which PNG has signed.

These rights include the right to:

- **Life** – a life free from fear and violence;
- **Self-determination** – being entitled to make their own decisions including sexual and reproductive decisions; entitled to refuse medical procedures and/or take legal action;
- **The highest attainable standard of health** – health services of good quality, available, accessible and acceptable to the client;
- **Non-discrimination** – health care services offered without discrimination, and treatment is not refused based on race, ethnicity, caste, sexual orientation, religion, disability, marital status, occupation, or political beliefs;
- **Privacy and confidentiality** – provision of care, treatment, and counselling that is private and confidential; information disclosed only with the consent of the client;

¹ Throughout this protocol, “NCPG” followed by a page number indicates a page in the National Clinical Practice Guidelines which should be referenced for additional support.

- **Information** –the right to know what information has been collected about their health and have access to this information, including their medical records.

How GBV survivors are identified

If our facility we may identify GBV survivors in any one of three ways:

- The Survivor comes to the clinic because she/he has experienced violence and needs help.
- A client discloses GBV within the context of seeking other services. For example, a client may answer “no” to all of the screening questions and then, later, after testing positive for HIV may share that she is afraid to tell her partner that she is positive because he beats her.
- Survivors are identified through screening.

Clients Present with GBV

Some clients will come to our clinic because they have experienced GBV. From the moment they arrive, they need to be treated with compassion and have their confidentiality respected.

- At registration, the client should be able to state the reason for her/his visit privately to the receptionist.
- This client should be prioritized ahead of other clients for immediate service with a nurse.
- **Proceed to step 3.**

Clients Spontaneously Disclose GBV

It is not unusual that a client may refuse GBV screening or deny GBV during screening only to disclose it later. She/ he may not recognize their experience as GBV but just views it as normal life. She/ he may be used to denying their GBV experiences as a protective measure. She/he may need time to become comfortable with the provider before being willing to share her/his experience. When this happens:

- If the client discloses GBV in the presence of others such as a partner, friends, family members, or anyone else, take the client aside to see whether she/he feels safe discussing GBV or receiving GBV services with others in the room.
- **Proceed to Step 3.**

Clients Identified Through GBV Screening

Who, when, where, by whom and how to Screen

WHO: every person who comes for VCT, STI or ART, will be screened unless they are below the age of 18. *Do not screen those under the age of 18 or who come for couples counseling whether for VCT, ART or STI.*

WHEN: At every clinic visit at the client's first point of service contact – whether VCT, STI or ART – where prompted by the VCT, ART STI intake/initial visit or follow-up/recall visit form. Clients should only be screened once per visit.

WHERE: Screening questions may only be asked in a VCT, STI or ART consultation room with the door closed to ensure confidentiality. No one else should be able to hear or see the screening take place.

BY WHOM: screening may be done only by VCT counselors, STI nurses or ART nurses who have been trained to screen. Male counselors/nurses should screen male clients and female counselors/nurses should screen female clients. TG clients should be screened by whichever sex provider they have chosen to see.

HOW: All screening must ensure confidentiality, privacy and respect for the client's rights and follow the GBV screening protocol.

Step 1: Say this to all clients: *Mistreatment and violence are common in our community and can have an effect on people's health. Because of that, I like to ask clients about their experiences with violence to help them receive the most appropriate healthcare and support. I want you to feel comfortable and to trust that you can talk to me about any violence or other types of abuse you may be experiencing. What you share is confidential and won't be shared with anyone outside of the healthcare team. There is support available here at the center if you want or need it. Is it okay if I ask you a few questions? Let me know if you prefer not to answer any of these questions; that is perfectly fine.*

(If client indicates it is ok, proceed to Step 2, asking GBV screening questions.)

Step 2: Ask all clients these Questions:

5. In the past 6 months or since your last visit, has anyone tried to force, forced or coerced you to have sex against your will? Anyone includes: your partner, a client, someone in your family, a friend, neighbor, police, or other persons you know or don't know.
YES () NO () NO RESPONSE ()
6. In the past 6 months or since your last visit, has anyone slapped you, punched you, hit you, or caused you any other type of physical harm? Anyone includes: your partner, a client, someone in your family, a friend, neighbor, police, or other persons you know or don't know.
YES () NO () NO RESPONSE ()

7. In the past 6 months or since your last visit, has anyone insulted you, threatened you, made you feel inadequate or yelled at you?
Anyone includes: your partner, a client, someone in your family, a friend, neighbor, police, or other persons you know or don't know.
YES () NO () NO RESPONSE ()
8. Do you currently feel threatened, fearful, or in danger from anyone? Anyone includes: your partner, a client, someone in your family, a friend, neighbor, police, or other persons you know or don't know.
YES () NO () NO RESPONSE () If client replied "no" to all other screening questions above, but is currently in danger, **proceed to Step 7.**

If the clients answers "NO" to all questions, and you have no reason to suspect GBV then continue with the services which the person came for.

If the client answers "NO" to all questions but you suspect GBV then:

- Do not pressure her/him, and give her/him time to decide what she/he wants to tell you.
- Tell her/him about services that are available if she/he chooses to use them.
- Offer information on the effects of violence on health.
- Offer her/him a follow-up visit.
- Continue with the services which she/he came for.

Step 3: Begin Psychological First Aid

If the client answers "YES" to any GBV Screening question, then:

- a. Immediately commence Psychological First Aid. See NCPG:
- **Providing Psychological First Aid**, pages 18-20
 - **Reception of the survivor**, Page 12
 - **Establishing initial interaction with the Survivor of SGBV**, pages 12-13
 - **Annex 5: Psychological Support**, NCPG pages 54-57.
 - **If you are a VCT Counsellor, refer the survivor immediately to the trained STI or ART nurse in your clinic to provide the full GBV services. Inform the survivor what you are doing, ask for her/his permission to be referred, escort her/him to the nurse and stay for the history taking if she/he wishes.**

- b. Start by saying:

“I am so sorry to hear about your experience. Please know that you are not alone. Mistreatment and abuse are quite common. No one deserves to be abused and you have the right to live a life free of violence. I would like to ask you more about your experience so that we can evaluate any effects on your health so that we can determine what services you need and you have the information to decide what you want to do. Do I have your permission to ask questions?”

Step 4: Take History

- a. Obtain consent for History taking. Use NCPG **Consent/ Assent form**
- b. Take history if consent is given. Use NCPG **Medical Examination Record** for history and medical examination. See NCPG, **Medical Interview**, page 12.

Step 5: Carry Out Medical Exam

- a. For physical and sexual violence cases, proceed to physical exam. Seek consent first using NCPG **Consent/ Assent form** and document findings in the NCPG **Medical Examination Record** for history and medical examination. See NCPG, **Physical examination**, pages 14-16 as applicable.
- b. **Carry out a pelvic exam last and collect evidence as appropriate and only after seeking consent.** Seek consent first using NCPG **Consent/ Assent form** and document findings in the NCPG **Medical Examination Record** for history and medical examination. See NCPG, **Physical examination**, pages 15.

Step 6: Offer health Services according to Exam Findings

Services should be offered according to the following NCPG chart:

	Survivors presenting within 72 Hours		Survivors presenting 72 – 120 Hours		Survivors presenting after 120 Hours	
Intervention	Women/girls	Men/boys	Women/girls	Men/boys	Women/girls	Men/boys
Physical injuries	Clean/repair wounds. For traumatic fistulas refer to specialist care	Clean/repair wounds	Clean/repair wounds. For traumatic fistulas refer to specialist care	Clean/repair wounds	Clean/repair wounds. For traumatic fistulas refer to specialist care	Clean/repair wounds
Psychological First Aid	Yes	Yes	Yes	Yes	Offer basic counselling	Offer basic counselling
Determination of pregnancy	Determine if survivor was pregnant already before rape (not a pre-requisite for treatment)	N/A	Determine if survivor was pregnant already before rape (not a pre-requisite for treatment)	N/A	Determine if survivor was pregnant already before rape (not a pre-requisite for treatment)	N/A
Emergency contraceptives	Give within 120 hours after rape – if reproductive age (menstruating)	N/A	Give within 120 hours after rape – if reproductive age (menstruating)	N/A	No	N/A
Termination of unwanted Pregnancy	N/A	N/A	Offer option of TOP	N/A	Offer option of TOP	N/A
Prophylaxis of STI	Yes	Yes	Yes	Yes	Yes	Yes
Prevention of HIV	Yes	Yes	No	No	No	No
HIV testing	Recommended but not pre-requisite	Recommended but not pre-requisite	Recommended but not pre-requisite	Recommended but not pre-requisite	Recommended but not pre-requisite	Recommended but not pre-requisite
Tetanus Prophylaxis	According to risk and pre-exposure vaccination status	According to risk and pre-exposure vaccination status	According to risk and pre-exposure vaccination status	According to risk and pre-exposure vaccination status	According to risk and pre-exposure vaccination status	According to risk and pre-exposure vaccination status
Hepatitis B Prophylaxis	Vaccinate according to protocol	Vaccinate according to protocol	Vaccinate according to protocol	Vaccinate according to protocol	Vaccinate according to protocol	Vaccinate according to protocol

Refer to the Medical and Psychosocial Care for Survivors of Sexual and Gender Based Violence, National Clinical Practice Guidelines (NCPG) for the following:

Medical Issue	Treatment Page in NCPG	Algorithm Page in NCPG
Wounds and other injuries	17	62
Prevention of pregnancy and unwanted pregnancy	21-22	61
Prevention/treatment of STIs	23	
Post Exposure Prophylaxis (PEP)	24-27	59, 60
Prevention of Hepatitis B.	28	63
Prevention of Tetanus	28-29	64
Psychological First Aid	18-20	65

Step 7: Assist the Survivor to Develop an Action Plan and Connect to Support

Before the survivor leaves, assist him or her to make a plan which covers the following:

- ***Return to daily life and connecting to social supports:*** Help the survivor to think about how she/he will re-start normal daily activities, encourage structure and how engaging family, friends, and others in their social network might be helpful in the healing process. See **Link** section of Psychological First Aid, NCPG page 19.
- ***Adherence to treatment:*** If the survivor is taking medicine then review the schedule and help them to plan for adhering to their treatment.
- ***Follow-up care.*** Help the survivor to understand and plan for all follow-up visits. See **Follow up care**, NCPG page 32.
- ***Referrals:*** Many survivors will need support in dealing with the effects of the violence. In addition to referrals and follow-up for medical care, be prepared to refer for:
 - *Police:*

- If the survivor is in immediate danger (see safety below) then refer her to the police and arrange for facilitated referral/transportation.
- If the survivor wishes to report the violence to the police, then seek consent to provide the medical report to the police. Consent is needed in two places. First, check the box for “Provide a medical report to the police” on the **Consent/Assent** Form. Then fill out the **Medical Report - Family Support Centre form** – see **Medico- Legal interaction**, NCPG page 31. Second, seek the survivor’s consent using the “**Notification for release of survivor Medical Report**” form. Then arrange for transportation to the police.
 - *Safe House*: if the survivor cannot safely return home then call the safe house and arrange transport.
 - *Counselling*: Refer the survivor to the designated counselling.
- **Safety**. If the survivor answered “yes” to question 4, “Do you currently feel threatened, fearful, or in danger from anyone?” or if at any time they expressed concern for their safety, then discuss with the survivor what can be done to help ensure their safety. If the survivor is in immediate danger, then encourage her/him to go to the police. Every safety plan is different depending on who the survivor is in danger from and their own strengths and resources. Help the survivor to assess:
 - Whether the survivor has a safe place to return to after the visit.
 - If not, organize as best as possible an alternative that can provide some measure of safety or provide a referral to a safe house.
 - If the individual has children to care for, ask about their safety and plan for their short-term care and protection.

Step 8: Record Data

Per PEPFAR guidance, to be counted, each case of GBV must receive the following services **at the same facility**:

- a. **Sexual violence**. A case is classified as sexual violence only if there was penetration. All other kinds of sexual assault should be classified as **Non-penetrative Sexual, Physical and/or Emotional violence**.
To count as a sexual violence case, the survivor must be assessed and offered all of the following as applicable:
 - Rapid HIV testing with referral to care and treatment as appropriate
 - PEP for HIV – if the person reached within 72 hours
 - STI screening and treatment
 - Emergency contraception – if the person reached within 72 hours

- Counseling (other than counseling for testing, PEP, STI and EC)
 - Referrals – legal, police, psychosocial support, safe house, child protection
 - Tetanus and Hepatitis B are not required under PEPFAR but are part of the package of services under the NCPG.
- b. **Non-penetrative Sexual, Physical and/or Emotional violence:** A case is classified under this category if it is not rape with penetration. To count as a case, the survivor must be assessed and offered all of the following as appropriate:
- Rapid HIV testing with referral to care and treatment as appropriate
 - STI screening, testing and treatment
 - Counseling (other than counseling for testing, PEP, STI and EC)
 - Referrals – legal, police, psychosocial support, safe house, child protection, economic empowerment
 - Tetanus and Hepatitis B are not required under PEPFAR but are part of the package of services under the NCPG. B
- c. **Post Exposure Prophylaxis (PEP)** – A case can only be counted *if the person completes the full course of treatment*

References:

National Department of Health (2014). Medical and Psychosocial Care for Survivors of Sexual and Gender Based Violence, National Clinical Practice Guidelines, Papua New Guinea.

World Health Organization (2014). Health care for women subjected to intimate partner violence or sexual violence. A clinical handbook. Available at: <http://www.who.int/reproductivehealth/publications/violence/vaw-clinical-handbook/en/>