The Guideline Use of Antiretroviral Drugs for Treating and Prevention of HIV Infection

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National STD AIDS Control Programme
Ministry of Health
Sri Lanka

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Contributors:

Dr.K.Buddhakorale- HIV Care Coordinator, Consultant Venereologist, NSACP
Dr.N.Abeygunasekare- Consultant Venereologist, CSTH
Dr.K.A.M.Ariyaratne-Consultant Venereologist, NSACP
Dr.J Elvitigala - Consultant Microbiologist, NSACP
Dr. Himali Perera - Consultant Venereologist, STD clinic, GH Kalutara
Dr.L.I.Rajapaksa-Consultant Venereologist, NSACP
Dr.J.Ranatunga- Consultant Venereologist, CNTH
Dr.C.D.Wickramasuriya-Consultant Venereologist, NSACP

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Dr. Sisira Liyange – Director, NSACP
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Dr. Gayani Premawansa – Consultant Physician, CNTH
Dr. Pushpa Punchihewa – Consultant Paediatrician, LRH
Dr. Pathmakanthi Wijesuriya – Consultant Paediatrician, LRH
Dr. U. Rathnasiri – Consultant Obstetrician, DMH
Dr.S.Beneragma – Consultant Epidemiologist, NSACP
Dr. M. Bandara – Senior Registrar, NSACP
Dr. N. Jayasuriya – Senior Registrar, NSACP
Dr. U. Jayasinghe - Senior Registrar, NSACP
Dr. D. Mendis - Senior Registrar, NSACP
Dr. S. Somawardhana – Senior Registrar, NSACP
Dr.P.Weerasinghe – Senior Registrar, NSACP
Dr. D.I. Rajapaksha – Registrar, NSACP

Coordinated by;

Dr.L.I.Rajapaksa, Coordinator- Training and capacity building
National STD/AIDS control Programme,
Sri Lanka.

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Message of the Director, National STD AIDS Control Programme

Sri Lanka remains one of the few countries in the region which maintains low prevalence of HIV. The estimated number of people living with HIV at the end of 2013 was 3000-4000 and the estimated prevalence among adults is less than 0.1%. By the end of 2012, 1649 cases were reported to NSACP with HIV infection. Male to female ratio remain as 1.5:1.

Twenty nine STD clinics throughout the country provide HIV care services. ART services are initiated at the STD clinics having specialist services. In addition, tertiary care hospitals and Infectious Diseases Hospital provide inward facilities for PLHIV. All eligible patients who are registered for services are offered ART according to the guidelines. All pregnant women are managed according to the locally adapted guidelines on PMTCT, offering ART for mother and baby.

Provision of free ARV in 2004 has improved living conditions of the PLHIV in Sri Lanka. Development of "National guidelines on HIV care" in 1998 and "National ART guidelines" in 2005 and regular training of STD clinic staff have further improved the quality of services.

Tremendous progress has been made over the past few years in managing adults and children with HIV. Effective implementation of antiretroviral treatment programmes require more than the provision of drugs. Training and capacity building of health care workers is essential if these complex medicines are to be used effectively and sustainably.

HIV has become a chronic disease with wide use of ART. ART is a changing subject. With new developments in the field of ART, there is a strong need to update the current guidelines. This has been facilitated by the recent release of the consolidated guidelines on ART by WHO.

This guideline "The Guide Line for use of Antiretroviral Drugs for treating and Prevention of HIV infection" is the result of team work involving consultant venereologists, microbiologist and epidemiologist and senior registrars of NSACP and consultant physicians, paediatricians and obstetricians of main tertiary care units of the country. I am confident that this guideline will prove to be a valuable tool in improving services offered to PLHIV, thus helping to maintain the low prevalence of HIV in the country.

Dr. Sisira Liyanage
Director
National STD AIDS Control Programme

Abbreviations and Acronyms

3TC - lamivudine
ABC - abacavir
ART- antiretroviral treatment
ARV – antiretroviral drugs
ATV - atazanavir
AZT - Zidovudine
BB – beach boys
BMI – body mass index
CMV – Cytomegalo virus
CXR – chest X ray
DRV - darunavir
DU – Drug users
EFV - efavirenz
FBC – full blood count
FSW – female sex worker
FTC - emticitabine
Hb - haemoglobin
HBV – Hepatitis B virus
HCV – hepatits C virus
HEP B – Hepatitis B
HEP C – Hepatitis C
HIV – Human Immuno deficiency Virus
IDU – injection drug user
IDV - indinavir
LFT – liver function tests
LPV - lopinavir
MSM – men having sex with men
NGO – Non governmental organization
NNRTI – Non nucleoside reverse transcriptase inhibitor
NRTI – nucleoside reverse transcriptase inhibitor
NSACP – National STD AIDS Control Programme
NVF - Nelfinavir
NVP - nevirapine
OI – Opportunisitc infections
PCR – polymerase chain reaction
PI – protease inhibitor
RAL - raltegravir
RT - ritonovir
SQV - saquinavir
STI – Sexually Transmitted Infections
TB - Tuberculosis
TDF - tenofovir
TOXO - Toxoplasmosis
UFR – urine full report
WHO – world health organization

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1. Antiretroviral treatment

It is critical for people living with HIV to enroll in care as early as possible. This enables both early assessment of their eligibility for ART and timely initiation of ART as well as access to interventions to prevent further transmission of HIV, prevent other infections and comorbidities and thereby to minimize loss to follow-up.

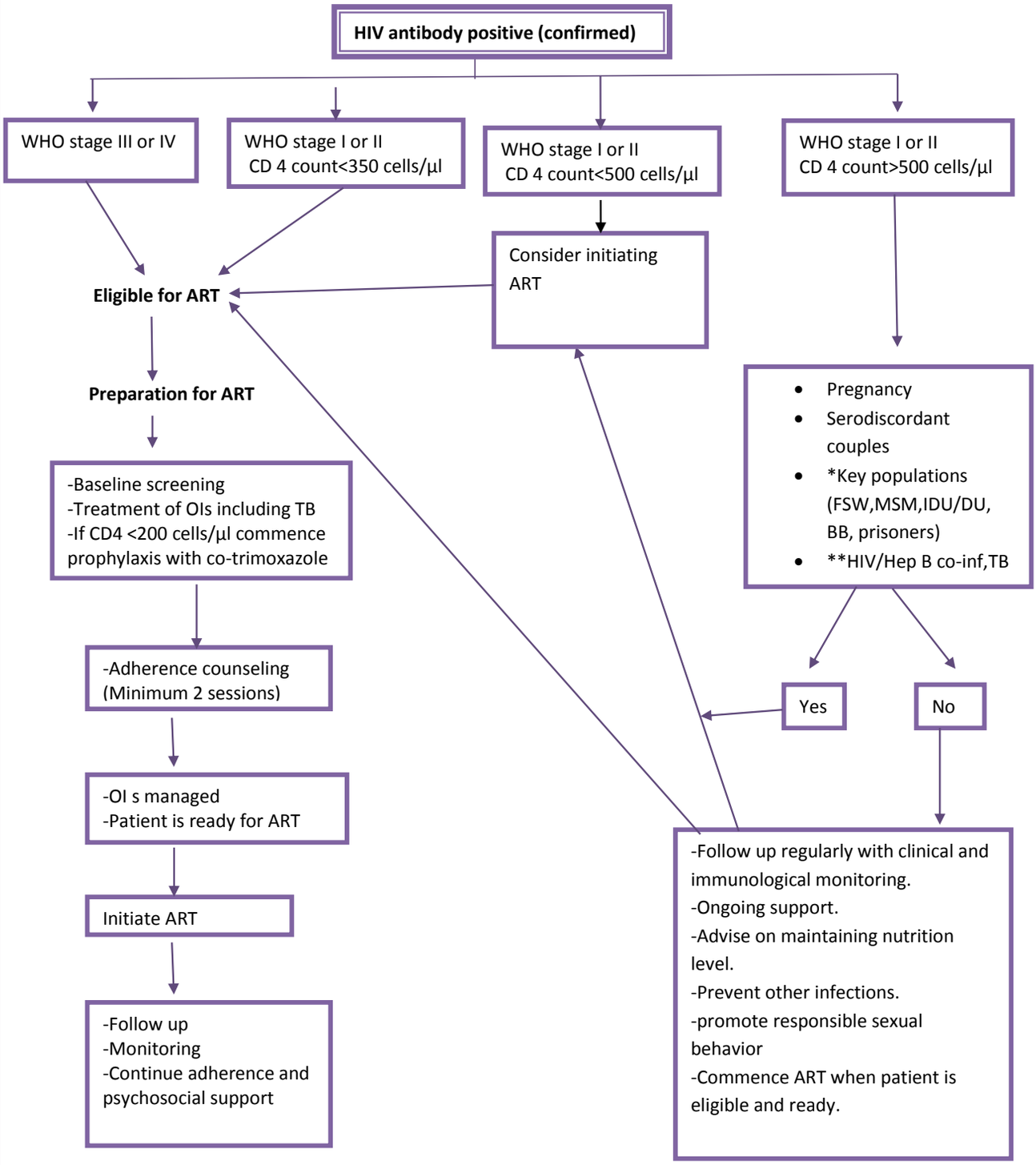
Enrolment in care provides an opportunity for close clinical and laboratory monitoring and timely initiation of ART.

General HIV care includes the following:

- Counselling – psychological management
- Manage acute infections
- Screen for infections – STI, TB, Toxo, CMV, Hep B, Hep C
- Prophylaxis to prevent infections if CD4 < 200 cells – Cotrimoxazole 2 tab daily
- Monitor - CD4 count & viral load
- When eligible - Antiretroviral therapy
- Provide social, psychological and financial support through NGO
- Family planning services and pap smear screening among females
- Prevention services for mother to child transmission of HIV

Early treatment initiation is associated with clinical benefits to the individual with improved survival and HIV prevention benefits to the community by reducing onward transmission of HIV infection.

2. Flow chart 1. ART Eligibility for adults and adolescents



3. When to start ART

Table 1. When to start ART in Adults and adolescents

Recommendations
Consider initiating ART in individuals with CD4 count ≤500 cells/mm3 **Priority when CD4 count is < 350 cells/mm3**
Consider early initiation of ART among key populations if they are continuing risk practices.; MSM, FSW, DU, Beach Boys, prisoners **Pregnant and breastfeeding women with HIV-ART Should be started.**
Recommendations for co-infections **Recommendations for tuberculosis/HIV co infection** **ART should be considered in all TB patients, including those with drug-resistant TB, irrespective of the CD4 count. Antituberculosis treatment should be initiated first, followed by ART as soon as possible within the first 8 weeks of treatment. The HIV-positive TB patients with profound immunosuppression (such as CD4 counts less than 50 cells/ul) should receive ART immediately within the first two weeks of initiating TB treatment. Efavirenz should be used as the preferred NNRTI in patients starting ART while on antituberculosis treatment.** **Recommendations for Hepatitis B/HIV co infection** **Hepatitis B co infection with an HBV DNA ≥2000 IU/mL or liver fibrosis should be treated regardless of CD4 count. When HBV DNA level is less than 2000 IU/mL with no evidence of fibrosis and a normal ALT, the patient can be monitored 6-monthly if the CD4 count is more than 500 cells/ul. Once HBV or HIV treatment is needed, ART should be initiated with the combination of TDF + FTC or TDF + 3TC as the NRTI backbone of a fully suppressive ARV regimen.** **Recommendations for Hepatitis C/HIV co infection** **ART may slow the progression of liver disease by preserving or restoring immune function and reducing HIV-related immune activation and inflammation. Therefore, ART should be considered for HIV/HCV co infected patients, regardless of CD4 count. However, when treatment for both HIV and HCV is indicated, consideration of potential drug-drug interactions and overlapping toxicities should guide ART regimen selection or modification. When CD4 count is >500 cells/ul and anti HCV therapy is required, ART can be deferred until completion of HCV treatment. Early commencement of ART is necessary before anti-HCV therapy when the CD4 count is low (particularly <350 cells/ul) to allow immune recovery.** **Recommendations for HIV-2 infection** **Since HIV-2 is naturally resistant to NNRTIs, treatment-naive people infected with HIV-2 should be treated with a regimen containing three NRTIs (TDF + 3TC (or FTC) + AZT or AZT + 3TC + ABC) or a ritonavir-boosted PI plus two NRTIs. If a PI-based regimen is used, the preferred option for first-line therapy should be LPV/r.** **HIV-positive individual in a serodiscordant partnership - to reduce HIV transmission risk to stable partners of both heterosexual and MSM relationships are considered.**

**On case by case basis providers may elect to defer therapy based on clinical and psychosocial factors.

4. Baseline assessment prior to ART initiation

Before any person is started on ART, he/she should undergo a baseline assessment that addresses the following questions:

- What is the clinical status?
- What is the immunological, virological, hematological, biochemical and microbiological status etc.?
- What is the family/social support available to continue treatment?
- Should OI treatment and/or prophylaxis be provided?
- Should ART be considered? (Determine other medical conditions e.g. TB, pregnancy, major psychiatric illness and other medications being taken including traditional therapies.)
- Is the person interested in and motivated to take ART?
- Should other support services be provided? (eg. self help groups)

5. Laboratory monitoring before initiating ART

Clinical assessment and laboratory tests play a key role in assessing individuals before ART is initiated.

Table 2. Laboratory monitoring before initiating ART

Phase of HIV management	Recommended	Desirable (if feasible)
HIV diagnosis	• Screening for sexually transmitted infections • Pap smear • CD4 cell count • Viral load test • Full blood count • Liver function tests • Serum creatinine, blood urea and serum electrolytes • Fasting Blood sugar • Lipid profile • Hep B surface antigen • HCV antibody • TB screening • *Cryptococcus* antigen if CD4 count <100 cells/mm3 • Toxoplasma antibodies • Cytomegalo Virus antibodies • Pregnancy test • Assessment for major non communicable chronic diseases and comorbidities	
Follow up before ART	CD4 cell count (every 6 months)	
ART Initiation	• CD4 cell count • Viral load test • Full blood count • UFR • Liver function tests • Renal function tests • Fasting Blood sugar • Lipid profile • Pregnancy test • TB screening	❖ HLA- B * 5701 testing for ABC

6. Assessment of patient's readiness for therapy

-Build up confidence and assess patient's knowledge.

-Mention the clinic protocol on ARV treatment including the importance of adherence and explain the objectives of the treatment to patient.

-The objectives of the treatment are:

- to build up immunity
- to avoid occurrence of OI
- to increase survival and quality of life

-Repeat discussions may be necessary to prepare patient for therapy.

-Ensure the patient has understood that:

- the treatment is a suppressive treatment which prevents viral replication.
- the treatment does not kill the virus.
- the treatment has to be taken regularly to avoid resistance and if resistance develops, treatment may fail.
- it is a life long treatment.

-Advice and encourage the patient to disclose the diagnosis to the partner or a family member and encourage testing of the sexual partner if status is unknown.

-Ensure the partner or family has understood their role in supporting therapy.

-**Remember ARV therapy for the individual patient is not an emergency.**

-The public health emergency is to get large numbers of right patients on treatment with good adherence and good overall HIV care.

-For the individual patient management of life threatening OI can be an emergency.

7. Adherence

Adherence is patients ability to follow a treatment plan, take medications at prescribed times and follow restrictions regarding food and other medications. It is important to make sure that the patient has satisfactory blood level of ARV as HIV can multiply in a low concentration of drugs.

HIV is constantly making copies of it and in this process mistakes can occur leading to appearance of new variants. These new variants are called mutants and some of these mutants may be drug resistant. These drug resistant mutants can proliferate even in the presence of normal ARV concentration in the blood. This will lead to treatment failure.It is mandatory to maintain sufficient ARV concentration in blood through good adherence. This will prevent the emergence of drug resistant mutations.

The goal of the ART is maximal and durable viral suppression. To achieve this goal, there should be successful anti retroviral therapy which requires adherence of >95%. Failure rates increase sharply as adherence decreases.

Adherence counselling

- Essential to prepare a patient adequately before initiating ART
- Requires 2-3 sessions with the patient prior to starting ART
- Sets the ground for better adherence long term
- Ongoing process with a two way exchange between patient and provider

Session 1 – Explain HIV natural history, viral replication and role of ART
Session 2 – Continue the efficacy of treatment and importance of adherence, resistance development, assess support available and readiness for treatment.
Session 3 – Assessment of patient readiness and initiation of ART, measures identified to improve adherence

Forms of non adherence

- Missing one dose of a given drug
- Missing multiple doses of one or more prescribed medications
- Missing whole days of treatment
- Not observing the intervals between doses
- Not observing dietary restrictions

It is important to discuss the adherence strategy including family involvement, treatment buddy and use of other tools such as pill diary, treatment reminder cues etc.

8. Counseling for treatment adherence

When counseling a patient for adherence, the following should be stressed:

- Treatment compliance should be strict and adherence to recommended regimens should be greater than 95% to avoid development of resistance.
- Treatment has to be continued for life.
- Timing of drug intake is critical (eg. Drugs taken twice daily must be taken every 12 hours +/_ one hour)
- Some drugs are taken with food, some drugs are taken on an empty stomach, some require increase intake of water. Those instructions should be given clearly to the patient.
- Drug side effects have to be understood.
- Financial and social support structures including family members should be assessed.
- Family planning and child bearing issues such as methods of contraception should be addressed.
- Patient should understand the need to attend STD clinic regularly for monitoring of efficacy and adherence.

Adherence levels need to be assessed in every visit.

Patient should be asked about

- Change in medications
- Dietary instructions
- Storage
- Taken all doses
- Taken on time
- Reasons for missing doses
- Complete pill count and self report
- Difficulties or side effects experienced

Patient should be questioned on missing doses (preferably during the last week) in a non judgemental way. The patient should understand the purpose is not to find fault but to understand reasons for non adherence and to help him/her to improve the outcome.

If a person missed a dose it should be taken as soon as remembered and continue the next dose as usual. However, this should not be a routine practice. It is not advisable to take double dose.

The health care provider should provide ongoing support after initiation of treatment to avoid adherence issues. If there are missed appointments patient should be reminded of the importance of continuing ARV treatment to maintain low viral load. The patient needs to be given contact details to contact in an emergency and should be clearly informed regarding the plan of treatment, follow up etc.

9. What ART regimen to start with (first-line ART)

Using simplified, less toxic and more convenient regimens as fixed dose combinations is recommended for first line ART. First-line ART should consist of two nucleoside reverse-transcriptase inhibitors (NRTIs) plus a non-nucleoside reverse-transcriptase inhibitor (NNRTI).

Table 3. First-line ART regimens for adults and adolescents

First –line ART	Preferred first –line regimens	Alternative first –line regimens
Adults and Adolescents (10 to 19 years) **≥ 35 kg**	TDF + 3TC (or FTC) + EFV AZT + 3TC + EFV	AZT + 3TC + NVP* TDF + 3TC (or FTC) + NVP ABC+3TC+EFV(or NVP)**

* NVP – Women with CD4 count > 250 cells /mm3 and men with CD4 count > 400 cells /mm3 are at risk for NVP hypersensitivity with fatal hepatic toxicity.

**ABC - Presence of HLA-B 5701 gene indicate higher risk for hypersensitivity.
ABC or boosted PIs (ATV/r, DRV/r, LPV/r) can be used in special circumstances.

10. Expected drug toxicities and side effects after commencing ARV treatment.

Patient on ART can experience various drug toxicities. Toxicities can affect gastrointestinal system, central nervous system, liver, kidney and bone marrow leading to clinical, biochemical, haematalogical, metabolic and other changes. Though any patient on a given ART regimen can experience toxicities, in some patients there are other pre existing factors that can make them more vulnerable to toxicities. Therefore patients with following high risk situations need careful monitoring.

Table 4. Anti Retroviral Drugs and high risk situations

ARV drug	High risk situations for experiencing toxicities
AZT related haematological toxicity	• CD4 count of <200 cells/mm3 • Anaemia at baseline
AZT related lactic acidosis	• BMI > 25 (or body weight > 75kg) • Prolong exposure to nucleoside analogus
TDF related renal toxicity	• Underlying renal disease • Age >40 years • BMI <18.5 (or body weight <50 kg) • Untreated diabetes mellitus • Untreated hypertension • Concomitant use of a boosted PI or nephrotoxic drugs
TDF related decrease in bone mineral density	• History of osteomalacia and pathological fracture • Risk factors for osteoporosis or bone loss
EFV related CNS toxicity	• Depression or psychiatric disease (previous or at baseline)
EFV related hepatotoxicity	• HCV and HBV coinfection • Concomitant use of hepatotoxic drugs
NVP related toxicity	• HCV and HBV coinfection • CD 4 count > 250 cells in a female • CD 4 count > 400 cells in a male
ABC related toxicities	• Presence of HLA-B*5701 gene
ATV/r related ECG changes	• Pre-existing conduction disease • Concomitant use of other drugs that may prolong the PR interval
ATV/r related hyperbilirubenimia	• Underline hepatic disease • Hepatitis B and C co infection
DRV/r	• Underline hepatic disease • Hepatitis B and C co infection • Sulphur allergy
RAL	• Concomitant use of other drugs that increase the risk of myopathy and rhabdomyolysis.

Clinical and biochemical effects due to toxicities can become apparent within first few weeks, first few months and within 6-18 months after initiating treatment.

Therefore patients on ART have to be evaluated during each clinic visits for early detection of short term, medium term and long term toxicities so that the adverse outcomes due to toxicities can be minimized.

Table 5. Laboratory indications to change ARVs due to toxicity

Laboratory indications to change ARVs due to toxicity		
Haemotology	Haemoglobin	Less than 7.0 g/dl
	Neutrophil count	Less than 750/mm^3
	Platelets	Less than 50,000mm^3
Chemistries	Creatinine	More than 3 x upper limit of normal
	Glucose (fasting non diabetics)	Less than 39 mg/dl or more than 251mg/l
Liver function tests	AST (SGOT)	More than 5 x upper limit of normal
	ALT (SGPT)	More than 5 x upper limit of normal
	Alkaline phosphatase	More than 5 x upper limit of normal
	Bilirubin	More than 2.5 x upper limit of normal
	Amylase, lipase	More than 2 x upper limit of normal

Refer Annexures 4,5

Table 6. ART toxicities according to duration of presentation.

Time	Toxicities & side effects	Common causes
Short term (first few weeks)	GI toxicities including nausea and vomiting, diarrhea	AZT, TDF, PIs
	Rash Most rashes occur within the first 2–3 weeks	NVP, EFV, ABC, PIs (rarely)
	Hepatoxicity More common if there is coinfection with hepatitis B or C	NVP, EFV, PIs
	Drowsiness, dizziness, confusion and vivid dreams are associated with the use of EFV.Normally self-resolving but can take weeks to months	EFV
Medium term (first few months)	Anaemia and neutropenia Sudden and acute bone marrow suppression due to AZT can occur within the first weeks of therapy or present as slowly progressive anaemia over months	AZT
	Hyperpigmentation of skin, nails and mucous membranes	AZT
	Lactic acidosis can occur at any time More common after the first few months.	AZT
Long term (after 6–18 months)	Lipodystrophy and lipoatrophy	AZT, PIs
	Dyslipidaemia	EFV, PIs

Sometimes People on ART become symptomatic due to drug toxicities. In such situations it is important to identify the possible drug/s that have led to toxicity and manage accordingly.

Table 7. Symptom- directed toxicity management

Symptom of toxicity	Causative ARV drug	Recommendation
Diarrhoea	NVF, lopinavir/ritonavir (LPV/r), saquinavir/ ritonavir (SQV/r)	Usually self-limited, no need to discontinue ART. Symptomatic treatment should be offered.
Drug eruptions (mild to severe, including Stevens–Johnson syndrome or toxic epidermal necrolysis)	NVP, EFV (rarely)	In mild cases, give antihistamines. Moderate rash, non-progressive and without mucosal involvement or systemic signs, consider a single NNRTI substitution (i.e. NVP with EFV). In moderate and severe cases, discontinue ART and give supportive treatment. After resolution, resume ART with 2 NRTI + PI regimens.
Dyslipidaemia, insulin resistance and hyperglycaemia	PIs EFV	Consider replacing the suspected PI by drugs with a lower risk of metabolic toxicity.
GI intolerance	All ARVs	Usually self-limited, no need to discontinue ART. Symptomatic treatment should be offered.
Haematological toxicities (particularly anaemia and leucopenia)	AZT	If severe (Hb <6.5 g% and/or absolute neutrophil count <500 cells/mm3) replace by an ARV with minimal or no bone marrow toxicity (eg. d4T, ABC or TDF) and consider blood transfusion in severely distressed persons.
Hepatitis	All ARVs (particularly NVP and PI/r)	If ALT >5-fold the basal level, discontinue ART and monitor. After resolution, replace the drug most likely to be associated with another one.
Hyperbilirubinaemia (indirect)	Atazanavir (ATV)	Generally asymptomatic, but can cause scleral icterus (without ALT elevation). Replace ATV with another PI.
Hypersensitivity reaction	ABC	Discontinue ABC and **do not restart**. Give symptomatic treatment. Re-exposure may lead to a severe and potentially life threatening reaction.
Lactic acidosis	All NRTIs	Discontinue ART and give supportive treatment. After clinical resolution, resume ART, replacing the offending NRTI. ABC, TDF and 3TC are less likely to cause this type of toxicity.

During evaluation of patients with ART toxicities it is important to assess the degree of toxicities (Grade toxicities) based on the clinical and laboratory parameters as shown in Annexure viii.

11. Specific Instructions (for First Line Regimen)

11.1. How to give TDF + FTC+ EFV regimen

Tenofovir (TDF) 300 mg daily at night

Emtricitabine (FTC) 200mg daily at night

Efavirenz 600 mg daily at night

Tenofovir (TDF) 300 mg + Emtricitabine (FTC) 200mg + Efavirenz 600 mg is available as a fixed drug combination. One tablet in the night, preferably to be taken on an empty stomach.

11.2. How to give AZT+3TC+EFV regimen

Zidovudine (AZT) 300 mg twice a day

Lamivudine (3TC) 150mg twice a day

Efavirenz (EFV) 600mg daily at night

In the morning - 1 tablet of AZT + 3TC Fixed drug dose tablet can be taken with or without food
In the night - 1 tablet of AZT + 3TC Fixed drug dose tablet
- Efavirenz (EFV) 600mg daily at night (better to take on an empty stomach)

11.3. How to give AZT + 3TC + NVP regimen

Zidovudine (AZT) 300 mg twice a day

Lamivudine (3TC) 150mg twice a day

Nevirapine (NVP) 200mg once daily for first 2 weeks followed by 200 mg twice a day

FIRST 2 WEEKS

In the morning - 1 tablet of AZT + 3TC + NVP Fixed dose can be taken with or without food

In the night - 1 tablet of AZT + 3TC Fixed dose can be taken with or without food

After 2 weeks AST / ALT need to be repeated and if there is no rash and no signs of hepatic toxicity, increase the dose of NVP to 200 mg twice daily. The lead-in dose decreases the risk of rash and early NVP induced hepatitis.

AFTER 2 WEEKS

In the morning - 1 tablet of AZT + 3TC + NVP Fixed dose can be taken with or without food

In the night - 1 tablet of AZT + 3TC + NVP Fixed dose can be taken with or without food

11.4. How to give TDF + FTC + NVP regimen

Tenofovir (TDF) 300 mg once daily.

Emtricitabine (FTC) 200mg once daily.

Nevirapine (NVP) 200mg daily once daily for first 2 weeks followed by 200 mg twice a day

FIRST 2 WEEKS
In the morning - 1 tablet of NVP 200 mg 1 tablet can be taken with or without food
In the night - 1 tablet of TDF + FTC Fixed drug dose tablet can be taken with or without food
After 2 weeks AST / ALT need to be repeated and if there is no rash and no signs of hepatic toxicity, increase the dose of NVP to 200 mg twice daily. The lead-in dose decreases the risk of rash and early NVP induced hepatitis.

AFTER 2 WEEKS
In the morning -1 tablet of NVP 200 mg 1 tablet can be taken with or without food
In the night - 1 tablet of TDF + FTC + Fixed drug dose tablet can be taken with or without food
1 tablet of NVP 200 mg 1 tablet can be taken with or without food

No diet restrictions.

Table 8 . Monitoring patients receiving ART

	Investigation	Remarks
Receiving ART	• CD4 cell count (every 6 months) • HIV viral load (at 6th month, if suppressed annually) • Full blood count • Liver function tests • Renal function tests • Fasting Blood sugar • Lipid profile	**AZT –**FBC 2weekly in the first month Then 3-6 monthly or when indicated **NVP** –AST/ALT/Bilirubin 2 weekly in the first month. Then 3-6 monthly or when indicated **TDF** – UFR/S.creatinine/E-GFR every 6 monthly. if co existing renal problems , DM and hypertension, more frequent monitoring indicated.
Treatment failure	CD4 cell count HIV viral load Resistance testing (preferable)	

12. Treatment adherence and drug resistance

- Poor adherence is associated with viral mutations due to persistence of viral divisions.
- Viral mutations are associated with drug resistance.
- Drug resistance is associated with treatment failure.
- Drug resistance does not occur with an optimal treatment that inhibits viral replication.
- Drug resistance does not occur without any treatment.
- Drug resistant virus may be transmitted to partners if safe sex is not practiced.

Drug resistance occurs when a suboptimal treatment does not fully prevent virus from replicating (detectable viral load).

Studies of drug adherence in the developed world have suggested that adherence rates >95% are desirable to maximize the benefits of ARV treatment and avoid treatment failure.

The increase in ARV resistance may lead to increase transmission of resistant viral strains. Currently approximately 10% of new HIV 1 infection in the United States and Europe are with viral strains exhibiting resistance to at least one drug.

Genotyping is not routinely performed in resource limited settings for patient management.

At the national level, a drug resistance sentinel surveillance system should be implemented to regularly modify recommended treatment regimens, according to the prevalence rate of drug resistance in the infected population.

Monitoring the response to ART and the diagnosis of treatment failure

Monitoring individuals receiving ART is important to ensure successful treatment, identify adherence problems and determine whether and which ART regimens should be switched in case of treatment failure. The value of viral load testing as a more sensitive and early indicator of treatment failure is increasingly recognized and is the gold standard for monitoring the response to ARV drugs.

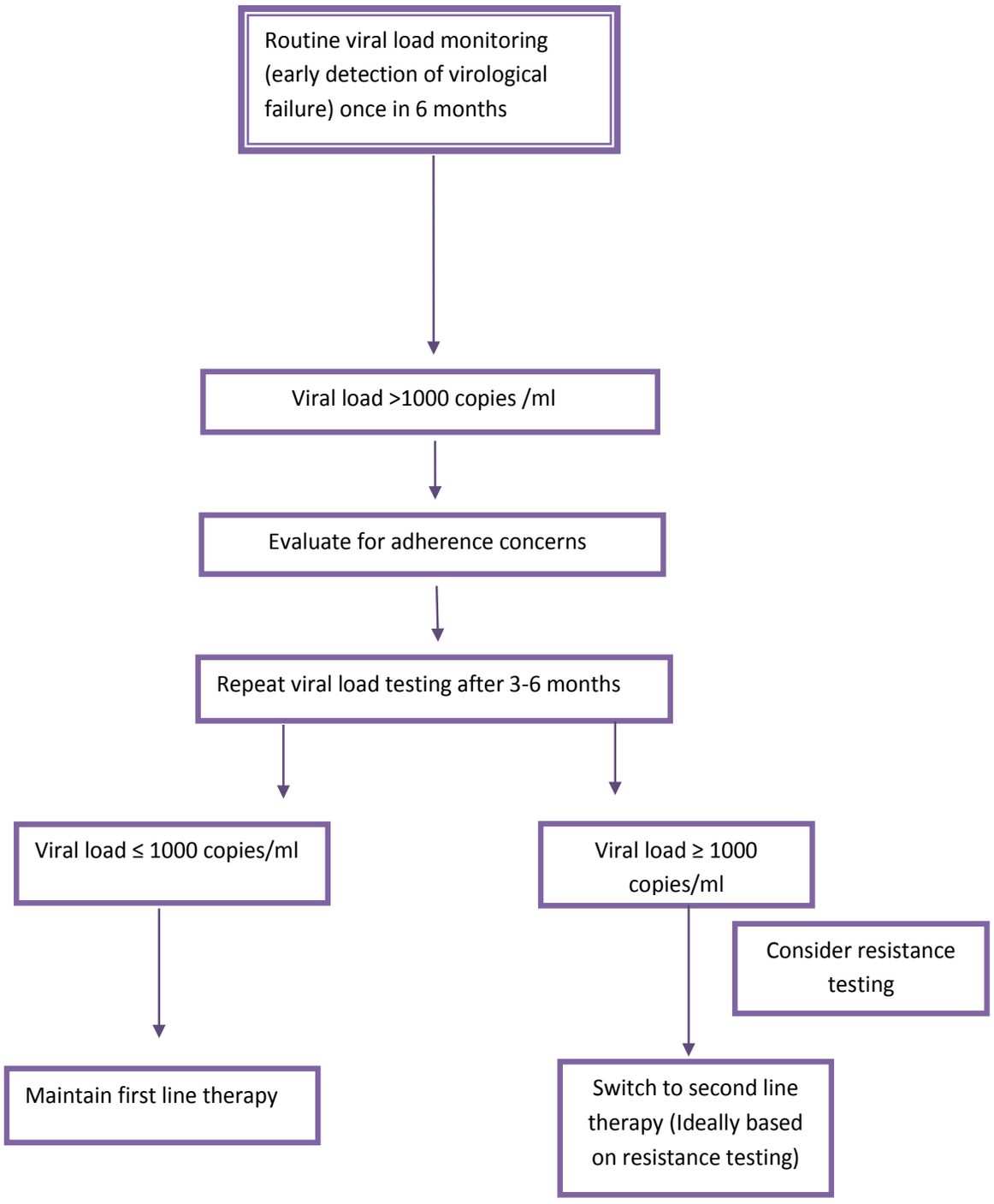
13. Reasons for changing ARV treatment

Table 9. WHO definitions of clinical, immunological and virological failure for the decision to switch ART regimens

Failure	Definition	Comments
Clinical failure	**Adults and adolescents** New or recurrent clinical event indicating severe immune deficiency (WHO clinical stage 4 condition) after 6 months of effective treatment **Children** New or recurrent clinical event indicating advanced or severe immune defiency (WHO clinical stage 3 and 4 clinical condition with exception of TB) after 6 months of effective treatment	The condition must be differentiated from immune reconstitution inflammatory syndrome occurring after initiating ART. For adults, certain WHO clinical stage 3 conditions (pulmonary TB and severe bacterial infections) may also indicate treatment failure.
Immunological failure	**Adults and adolescents** • CD4 count falls to the baseline or below • Persistent CD4 levels below 100 cells/mm3 • CD4 count drop by 50% or more from the peak value **Children Younger than 5 years** Persistent CD4 levels below 200 cells/mm3 or <10% **Older than 5 years** Persistent CD4 levels below 100 cells/mm3	Without concomitant or recent infection to cause a transient decline in the CD4 cell count. Current WHO clinical and immunological criteria have low sensitivity and positive predictive value for identifying individuals with virological failure.
Virological failure	**Plasma viral load above 1000 copies/ml based on two consecutive viral load measurements after 3 months, with adherence support**	**An individual must be taking ART for at least 6 months before it can be determined that a regimen has failed.Viral blips or intermittent low-level viraemia (50–1000 copies/ml) can occur during effect treatment but have not been associated with anincreased risk o treatment failure unless low-level viraemia is sustained.**

Flow Chart 2 – How to detect treatment failure

Viral load testing strategies to detect or confirm treatment failure and switch ART regimen in adults, adolescents and children



14. Second line regimens

What ART regimen to switch to (second-line ART)

Using a boosted PI + two NRTI combinations is recommended as the preferred strategy for second-line ART for adults, adolescents and also for children when NNRTI-containing regimens were used in first-line ART. In children using a PI-based regimen for first-line ART, switching to NNRTI or maintaining the PI regimen is recommended according to age.

Table 9. preferred second-line ART regimens for adults and adolescents.

First line failed regimen	Second line regimen suggested Two NRTI+boosted PI	Alternative Rx
TDF+3TC(FTC)+ EFV/NVP	AZT+3TC+ ATV/r or LPV/r	ABC based
AZT+3TC(FTC)+ EFV /NVP	TDF+3TC/FTC+ ATV/r or LPV/r	ABC based

Second-line ART for adults and adolescents

Second-line ART for adults should consist of two nucleoside reverse-transcriptase inhibitors (NRTIs) + a ritonavir-boosted protease inhibitor (PI).

- Heat-stable fixed-dose combinations of ATV/r and LPV/r are the preferred boosted PI options for second-line ART

Specific Instructions (for Second Line Regimens)

How to give AZT + 3TC + LPV/r regimen

Zidovudine (AZT) 300 mg twice a day

Lamivudine (3TC) 150mg twice a day

Lopinavir/ritonavir (LPV/r) 400mg /100mg twice a day

In the morning - 1 tablet of AZT + 3TC Fixed dose can be taken with or without food
- 2 tablets of LPV/r can be taken with or without food.

In the night - 1 tablet of AZT + 3TC Fixed dose can be taken with or without food
- 2 tablets of LPV/r can be taken with or without food.

How to give TDF+FTC + LPV/r regimen

Tenofovir (TDF) 300 mg once daily.

Emtricitabine (FTC) 200mg once daily.

Lopinavir/ritonavir (LPV/r) 400mg /100mg twice a day.

In the morning - 2 tablets of LPV/r can be taken with or without food

In the night - 1 tablet of TDF + FTC Fixed drug dose tablet can be taken with or without food.

- 2 tablets of LPV/r can be taken with or without food.

Options for third line

- Darunavir
- Raltegravir
- Maraviroc

Can be considered.

15. Management of opportunistic infections (OIs)

Opportunistic infections frequently causing respiratory symptoms

15.1. Pneumocystis pneumonia

Common etiological agent: Pneumocystis jirovecii (Earlier known as Pneumocysitis carinii.)

Clinical presentation

Typically symptoms are sub-acute, may be present for 2-6 weeks. Patient might present with or without fever, exertional dysponea which may progress over weeks, persistent non-productive cough, malaise and chest tightness.

Examination may reveal tachypnoea and bilateral crepitations. In some instances, patient may not have any positive lung signs.

The patient becomes increasingly ill as disease progresses, with worsening of dyspnoea, tachypnoea, hypoxia and may even have confusion and delirum.

PCP is commonly seen with CD4 count less than 200 cells/µl.

Diagnosis

Diagnosis is based on high degree of clinical suspicion. The history, clinical findings and CD4 count may help in making the diagnosis.

- Chest X ray

The initial recommended investigations is a chest x ray.

In some (39%) chest radiograph may be normal.

Classically the radiograph is abnormal with symmetrical, bi- lateral perihilar infiltrates which spreads to the periphery and may progress to diffuse confluent alveolar shadowing. In about 20%, atypical presentations are seen; eg. lobar consolidation, pneumothorax etc. Pleural effusion is rare. If present consider an alternative diagnosis.

- CT scan

High Resolution Computed Tomography (CT) of the chest may reveal typical " Ground Glass" changes.

- Arterial Blood Gases

Blood gas analysis should be done to assess the disease severity.

Arterial blood gases may demonstrate hypoxaemia (while breathing room air)

- with a Pa O2 < 70 mmHg,
- increased A-a oxygen gradient of >30 mmHg
- Oxygen saturation of < 94% which indicates moderately severe or severe disease.

Arterial oxygen tension or saturation falls commensurately with pulmonary involvement.

Definitive diagnosis

Definitive diagnosis is by demonstrating the organisms in broncho- alveolar lavage fluid or induced sputum. Broncoscopy with broncho- alveolar lavage (BAL) has sensitivity >90%, demonstrating the organisms with silver stain or immunofluorescence.

Induced sputum may be helpful in the diagnosis with sensitivity 50-90%.

Management and treatment

Treatment

1.TMP 15-20 mg/kg/day + sulfamethoxazole (cotrimoxazole) 75-100 mg/kg/day PO

Cotrimoxazole 3 single strength tablets (480 mgx 3) every 8 hours for 21 days

Or IV in 4 divided doses if the patient can not take or tolerate oral cotrimoxazole.

Patients with moderately severe or severe disease (PO2< 70 mmHg or A –a gradient >35 mmHg) should receive corticosteroids within 72 hours of starting cotrimoxazole treatment.

Oral Prednisolone 40 mg BD for 5 days
40 mg mane for 5 days
20 mg mane for 11 days
If unable to take oral prednisolone give
IV methylprednisolone -
30mg BD for 5 days .
30 mg daily for 5 days.
15 mg daily 11 days

Alternative treatment

1.TMP 15mg/kg/day PO + Dapsone 100 mg/day for 21 days
2.Clindamycine 600mg IV 8 hourly or 300-450 mg PO 6h + primaquine 15-30 mg base po/day for 21 days.
3.Pentamidine also can be considered.

Preventive therapy (Primary Prophylaxis)

WHO stage III and IV condition regardless of CD 4 count and stage I, II with CD4<200.
Preferred regimen
Trimethoprim – sulfamethoxazole (TMP- SMX) two single strength tablets (SS) per day or one Double Strength(DS)tablet per day. If the patient cannot tolerate 960 mg, one single strength (480 mg) tablet per day may be given.

Alternative regimens

1.TMP-SMX 1DS tablet 3 times a week
If intolerant to TMP-SMX
2.Dapsone 100mg once a day or 50 mg bd
In patients with CD4 < 100 and positive Toxoplasma antibodies add Pyrimethamine 50 mg weekly + folinic acid 25 mg weekly to this regimen.

Secondary Prophylaxis

Everyone who has had PCP must continue with maintenance therapy with two tablets SS or 1 DS tablet of cotrimoxazole per day.

Discontinuation of Prophylaxis

Patients who have increased CD4 > 200 for 3 months may safely discontinue primary and secondary prophylaxis.

15.2 Bacterial pneumonia

Pyogenic bacteria are the most probable cause of bacterial pneumonia.eg: Streptococcus pneumonia, Haemophilus influenza, pseudomonas, klebsiella etc.

Clinical presentation

Acute onset of productive cough, purulent sputum and fever for 1-2 weeks. It can be differentiated from PCP which has slow, progressive symptoms and dry cough.

Diagnosis

- FBC- neutrophil leucocytosis
- Positive Blood culture
- CXR finding - lobar consolidation.

Sputum examination including

- Gram stain
- Sputum culture and sensitivity
- Acid fast stain/ Auramine stain and
- culture for Tuberculosis; Liquid culture is preferred when available
- Xpert MTB/RIF (Real time automated PCR)can be used as the initial diagnostic test in individuals suspected of having HIV-associated TB or multidrug-resistant TB.
- Appropriate staining for Histoplasma, Cryptococcus etc.

Treatment

Empirical therapy is based on the severity of the condition till the antibiotic sensitivity pattern is available.

Primary Prophylaxis

Co trimoxazole prophylaxis reduces the incidence of bacterial pneumonia.

15.3. Tuberculosis

Among people living with HIV, TB is the most frequent life-threatening opportunistic infection and a leading cause of death.

Therefore every person diagnosed with HIV should be referred to district chest clinic to exclude active TB.

(Refer guidelines on management of HIV and TB)

Opportunistic infections frequently causing headache/neurological symptoms.

15.4. Cryptococcal infection

Common etiological agent : Cryptococcus neoformans (A fungus)

Clinical presentation

The usual presentation is subacute meningitis with fever, headache, vomiting and neck rigidity in a patient with a CD4 <100/mm3.

Laboratory diagnosis is by

- serum for Cryptococcal antigen
- India Ink stain of CSF
- Fungal Culture and sensitivity testing of CSF
- CSF Cryptococcal antigen (CRAG) - positive in over 90% of cases.
- Lumbar puncture after CT/MRI

Management and treatment

Treatment

Preferred: Amphotericin B 0.7mg/kg IV daily + 5 Flucytosine 100mg/kg/day PO in four divided doses for 14 days (induction phase) followed by fluconazole 400 mg daily for 8-10 weeks or until CSF is sterile (consolidation phase).

Maintenance therapy with flucanozole 200mg daily for life or until immune recovery (suppressive phase).

Alternative regimens

- Amphotericin B 0.7mg/kg IV daily +5 Flucytosine 100mg/kg/day PO for 14 days followed by Itraconazole 200mg BD for 8 weeeks.
- Amphotericin B 0.7mg/kg IV daily for 2 weeks followed by fluconazole 400mg/day PO for 8-10 weeks.
- Fluconazole 400-800 mg/day PO + 5 Flucytosine 100mg/kg/day PO for 6-10 weeks followed by Fluconazole 200mg once daily.

Notes on the use of Amphotericin B

Amphotericin B is given by slow IV infusion over 45 minutes, 4 times a day (with 5% dextrose co-infusion in a separate IV line). Patient needs careful observation, especially with initial doses as fever and chills can occur. The other main side effects of Amphotericin B are electrolyte disturbances (especially hypokalaemia) and hypoglycaemia. Frequent monitoring of electrolytes and blood sugar are required. Potassium supplements need to be considered when necessary.

The infusion set should be covered to prevent exposure to light.

Flucytosine is associated with haematological toxicity. Therefore, daily blood counts are required.

Secondary prophylaxis

Preferred: Fluconazole 200mg daily. (Contraindicated in pregnancy)

Discontinue secondary prophylaxis when CD4 count is > 200 mg cells/ µl.

Primary prophylaxis

Not indicated.

ART should be started approximately 2 weeks after commencement of cryptococcal treatment.

Opportunistic infections frequently causing skin and mucosal symptoms

15.5. Oral Candidiasis

Aetiological agent : Candida albicans is the predominant species. But C.tropicalis, C. glabrata and C.krusei may also be responsible.

Clinical presentation

Patients complain of changes in taste and burning sensation in the mouth. This may be associated with dysphagia. The presence of odynophagia is indicative of oesophageal involvement.

There are four clinical presentations.

- Pseudomembranous candidiasis is characterized by removable white or creamy plaques consisting of a mixture of fungal hyphae, desquamated epithelium and inflammatory cells. These plaques can appear anywhere on the oral and pharyngeal mucosa.
- Erythematous candidiasis is less obvious, manifesting as red patches on the palate and dorsal surface of the tongue and buccal mucosa.
- Angular cheilitis is another form which manifests as cracking, fissuring and redness at the commissures: these may be unilateral or bilateral and may be found in the absence of intraoral candidiasis.
- Hyperplastic candidiasis ,which presents as non- removable white patches is rare.

Diagnosis

- Mainly clinical

-KOH preparation of a smear from lesion.

- Culture and sensitivity provides information about the antifungal susceptibility Treatment

Treatment -

Fluconazole 100mg once daily for 7-14 days.

Itraconazole200mg bd for 7-14 days

15.6. Candida oesophagitis

Empirical diagnosis is based on the presence of oral candidiasis (80%) with odynophagia (painful swallowing)

Endoscopy recommended with atypical presentations or failure to respond to empirical treatment.

Preferred regimen

Fluconazole 200mg/day oral up to 800mg/day for 14-21 days.

(Fluconazole is clinically superior to ketoconazole and Itraconazole due to more predictable absorption.)

Alternative regimen

Ampotericin B 0.3- 0.7 mg/kg/day IV for 14-21 days

Itraconazole 200mg/day oral for 14-21 days

Secondary prophylaxis

Only with relapsing disease.

Fluconazole100-200mg /day

15.7. Vaginal candididsis

Clotrimazole 200mg pessary at night for 3 days
Clotrimazole 100mg pessary at night for 7 days
Micanazole 200mg vaginal tablet at night for 3 days

May use local application with Clotrimozole 1% cream / Micanazole 2% cream for vulvitis.

If persistent or refractory
Fluconazole 100mg-200mg oral for 1-7 days
Itraconazole 200mg twice a day for 1 day

15.8. Herpes simplex virus infection (HSV)

Clinical presentation

Typical blisters usually in oral, genital or perirectal area when CD4<100 cells/ µl.
Diagnosis

- Clinical presentation
- Tzank smear
- HSV culture
- HSV PCR

Treatment of genital and oro labial herpes

-Normal saline washes , analgesics for pain.
-Aciclovir 200 - 400mg 5 times daily for 7-10days
-For severe cases, Aciclovir IV 5mg/kg /8 hourly until lesions regress.
-In HSV encephalitis, Aciclovir 10mg/kg /IV 8 hourly for 14-21 days.

Secondary prophylaxis

In case of frequent recurrences (>6 recurrences/year) long term suppressive therapy with Acyclovir 400mg twice daily may be necessary.

Primary prophylaxis

Not recommended.

OTHER OPPORTUNISTIC INFECTIONS AND HIV RELATED ILLNESS

15.9. Herpes Zoster

Clinical presentations

Typical painful blisters in clusters along dermatomes. May involve multiple dermatomes and eye as well. Diagnosis is based on history and examination findings. No laboratory tests are required.

Treatment

Acyclovir 800 mg 5 times a day for 7 days
May need potent analgesics
Severe cutaneous or visceral disease– Acyclovir IV 30 mg /kg/day
Antibiotics for secondary infection
Postherpetic neuralgia should be treated with pain modifying agents eg. Carbamazepine, gabapentin

Primary or secondary prophylaxis

Not recommended

15.10. CYTOMEGALOVIRUS (CMV)

Clinical presentations

Retinitis: blurred vision or loss of central vision that can lead to blindness.
Colitis: fever, diarrhoea and abdominal pain.
Oesophagitis: ulcerations, pain and difficulty in swallowing.
Pneumonitis : pneumonia like symptoms.
Encephalitis : confusion, fever and malaise.

Diagnosis

Retinitis: refer to Ophthalmologist
Esophagitis and colitis: endoscopy and/or biopsy.
Pneumonitis: Check for PCP and tuberculosis first (EPSA).
Encephalitis: CT scan, MRI and CSF CMV-PCR
CMV antigen

Treatment

Ganciclovir with or without foscarnet
Commence ART when appropriate.

15.11. CERVICAL CANCER

Clinical presentations

Often asymptomatic. Can cause vaginal discharge, vaginal bleeding and pelvic pain

Diagnosis

Annual PAP smear is recommended for all HIV positive women as they are at increased risk of developing cervical dysplasia and cancer.

Treatment

Patients with Pap smear reports of dysplasia or intraepithelial neoplasia require colposcopy and may require cone biopsy or surgery. Adjuvant therapy (chemotherapy/radiotherapy) may be required. Therefore refer to a gynecologist.

15.12. CNS TOXOPLASMOSIS

Clinical presentations

Altered mental state (confusion, delusional behavior), severe headache, focal signs such as hemi-paresis, fever, seizures and coma. May develop headache and vomiting due to increased intracranial pressure Can also affect the eye causing eye pain and reduced vision. Usually the CD4 count less than 100.

Diagnosis

- Toxoplasma antibodies
- MRI scan
- Clinical diagnosis is based on the symptoms.
- Cerebral CT scan will show multiple ring enhancing lesions at grey-white interface ,deep gray matter of basal ganglia /thalamus
- MRI scan

Preferred Treatment

Pyrimethamine 200mg oral loading dose then 50-75mg once a day + sulfadiazine 1 g every 6 hours for 6 weeks depending on response to treatment followed by long term secondary prophylaxis.
Sulphadiazine may cause anaemia, thrombocytopenia and leucopenia. Careful hematological monitoring with complete blood counts is recommended. Drugs can cause haemolysis in patients with G6PD deficiency.
Rash can be associated with the use of pyramethamine and sulphadiazine. Other possibilities such as CNS lymphoma or Tuberculoma need to be considered among patients who do not show response to therapy within 1-2 weeks.

Alternative Treatment

Pyrimethamine 50-75 mg/day + Leucovorin 10-20 mg/day for 6 weeks followed by maintenance dose.
Clindamycin 600mg every 6 hours

Primary prophylaxis

Cotrimoxazole 2 ss tablets daily

Secondary Prophylaxis

Pyrimethamine 50mg once a day + Sulfadiazine 500mg four times per day.

15.13. Papular Pruritic eruption(PPE)

Clinical presentations

Papular pruritic eruption (PPE) is a common skin manifestation of HIV, particularly in the Asian region. The underlying etiology is considered to be an abnormal response to arthropod bites in susceptible individuals. The severity of symptoms is inversely proportional to absolute CD4 counts. The rash is mainly on the extremities and is extremely itchy at the beginning.

Diagnosis

Mainly clinical based on the symptoms.

Preferred Treatment

Topical steroids
Anti –pruritic agents

16. **Management of HIV in children**

17. Diagnosis of paediatric HIV infection

- Virologic assays that directly detect HIV must be used to diagnose HIV infection in infants younger than 18 months.
- HIV DNA polymerase chain reaction and HIV RNA assays are recommended as preferred virologic assays.
- A positive virologic test should be confirmed by a repeat virologic test on a second specimen.
- Definitive exclusion of HIV infection in non breastfed infants is based on two or more negative virologic tests, with one obtained at 4-6 weeks of age and one at 4 months of age, or two negative HIV antibody tests from separate specimens obtained at >6 months of age.
- Some experts confirm the absence of HIV infection at 12 to 18 months of age in infants with prior negative virologic tests by performing an antibody test to document loss of maternal HIV antibodies.
- HIV antibody assays alone can be used for diagnosis of HIV infection in children with perinatal exposure who are >18 months of age and in children with non-perinatal exposure.

18. When to start ART in children

Recent analysis show that CD4 cell counts provide greater prognostic value than CD4 percentage for short term disease progression in children.

ART should be started in all HIV infected infants aged < 12 months.

All children with AIDS or significant symptoms should be started on ART.

*On case by case basis providers may elect to defer therapy based on clinical and psychosocial factors.

ART should be started in children > 1 year with the following:

Table 10. Eligibility criteria to start ART in children

Aged 1-3 years	**CD4 < 1000 cells/mm^3 or CD4 percentage <25%**
3-5 years	CD4 < 750 cells/mm^3 or CD4 percentage <25%
>5 years	CD4 <350 - 500 cells/mm^3

19. First-line ART regimens for children

Table 11. first-line ART regimens for children

	Preferred	alternative
Children <3 years	**AZT + 3TC + LPV/r** **ABC+3TC+LPV/r (> 3 months)**	**ABC + 3TC + NVP** **AZT + 3TC + NVP**
Children 3 -10 years and adolescents < 35 kg	AZT/ABC + 3TC + EFV/ LPV/rt	AZT + 3TC + NVP ABC + 3TC + NVP *TDF + 3TC (or FTC) + EFV *TDF + 3TC (or FTC) + NVP

- For children of all ages NRTI backbone can be AZT+ 3TC or FTC.
- ABC can be used for children > 3 months. HLAB 5701 need to be done. ABC + 3TC or FTC can be considered.
- For children younger than 3 years a PI based regimen is the preferred approach, if not feasible consider NVP based regimen. Consideration can be given to substituting LPV/r with an NNRTI after virological suppression is sustained.
- For children more than 3 years EFV can be used.
- For children <3 years who develop TB while on ART regimen containing NVP or LPV/r, ABC+3TC+AZT is an option.
- *TDF – not suitable for children as there is limited experience among children. TDF has numerous drug interactions.
- Atazanvir / ritonavir can be considered for children more than 6 years.

Ref: WHO guideline and NIH guideline on ART in children

20. Second-line ART for children (including adolescents)

New recommendations

- After failure of a first-line NNRTI-based regimen, a boosted PI plus two NRTIs are recommended for second-line ART; LPV/r is the preferred boosted PI
- After failure of a first-line LPV/r-based regimen, children younger than 3 years should remain on their first-line regimen, and measures to improve adherence should be undertaken.
- After failure of a first-line LPV/r-based regimen, children 3 years or older should switch to a second-line regimen containing an NNRTI plus two NRTIs; EFV is the preferred NNRTI.
- After failure of a first-line regimen of ABC or TDF + 3TC (or FTC), the preferred NRTI backbone option for second-line ART is AZT + 3TC
- After failure of a first-line regimen containing AZT + 3TC (or FTC), the preferred NRTI backbone option for second-line ART is ABC or TDF + 3TC (or FTC)

Table 12. recommended first- and second-line ART regimens for children

	Children	First-line ART regimen	Second-line ART regimen
LPV/r-based first-line regimen	Younger than 3 years	ABC + 3TC + LPV/r*	AZT + 3TC + LPV/rt
		AZT + 3TC + LPV/r*	ABC + 3TC + LPV/r *
	3 years and older	ABC + 3TC + LPV/r	AZT + 3TC + EFV
		AZT + 3TC + LPV/r	ABC or TDF[b] + 3TC + EFV
NNRTI-based first-line regimen	All ages	AZT + 3TC + NVP ABC + 3TC + EFV (or NVP)	AZT + 3TC + LPV/r[c]
		TDF + 3TC (or FTC) + EFV (or NVP)	
		AZT + 3TC + EFV (or NVP)	ABC or TDF + 3TC[c] (or FTC) + LPV/r[c]

NVP may be considered under 3 years if there is no other option.

[*] this case, switching to a second-line NVP-based regimen should be considered.

[c] ATV/r can be used as an alternative to LPV/r in children older than 6 years.

21. Prevention of mother to child transmission of HIV

Table 13. When to start ART in pregnant and breastfeeding women

National PMTCT programme option	Pregnant women with HIV
Consider using lifelong ART for all pregnant women (" Option B+") *	Regardless of WHO clinical stage or CD4 count
	Initiate ART and maintain after delivery

All pregnant women with HIV should initiate ART, which should be maintained at least for the duration of mother to child transmission risk. Women meeting eligibility criteria should continue life long ART.

ART options -

AZT+3TC+LPV/r
AZT+3TC+EFV
TDF+3TC(FTC)+EFV

PMTCT prophylaxis – When ART is stopped after delivery
AZT+3TC+LPV/r – no need of a tail
AZT+3TC+EFV – tail of AZT+3TC for 2/52
TDF+ 3TC(FTC)+ EFV – no need of a tail

Infants should receive six weeks of ART starting from birth with twice daily AZT or daily NVP.

*For further details refer "Guideline on management of pregnant women with HIV".

Table 14. Suggested clinical evaluation and monitoring of patients on ART

Investigations	At baseline	Time interval from start of ART							
		2 weeks	4 weeks	8 weeks	12 weeks	Monthly	3-4 monthly	6 monthly	Annually
Clinical review	√	Monitor tolerability and adherence				Until stable	Once stable		
STI screen,PAP	√							Higher risk	Lower risk
Mantoux test (PPD)	√								Previous negative
CXR	√	When required							
CD4 (or TLC)	√				√		√		
Viral load	√							√	If UD Annualy
FBC (Hb&WBC/DC)	√		√		√		√		
Lipid profile	√		When required					On PI/NNRTI +risk	On PI/NNRTI
FBS	√								
LFT (ALT&AST)	√	On NVP	On NVP		√		√		
Serum creatinine	√	√	When required /on TDF					√	
Blood urea	√								
Serum electrolytes	√		When required						
Hepatitis B s Ag	√								
HCV antibody	√								
Pregnancy test	When required								
Toxoplasma Ab	√								
CMV Ab	√								

22. Monitoring and Evaluation of HIV Epidemiology, Treatment and Care programmes

Implementation of a comprehensive Monitoring and evaluation (M&E) is necessary for Health care workers and HIV programme managers to assess the effectiveness of treatments and linkages between services along the cascade of treatment and care for HIV and associated conditions (Fig 1). This chapter describes the system available for M&E across the HIV treatment and care cascade in Sri Lanka.

Figure 1. The HIV treatment and care cascade

Table 15. Method used to collect data according to the step in the HIV treatment and care cascade

Step in the cascade	Indicator/s	Methods used to collect data
1. People living with HIV	Estimated number of people living with HIV	Using the "Spectrum" software based on the M&E data, surveillance data and various assumptions
2. HIV diagnosis	Percentage of the general population with known HIV test status and within specific populations	Behavioural surveillance or Integrated biological and behavioual surveillance
	Number of people newly diagnosed with HIV infection within a specific time period	Using the "Spectrum" software based on the M&E data, surveillance data and various assumptions Note: Newly reported cases during a specific period includes both new infections and old infections and this data are collected using H1214 form by the epidemiology unit of NSACP
3. Linkage and enrolment in HIV care	Percentage of people newly diagnosed with HIV infection enrolled in HIV care	A substitution for this indicator "Percentage of people newly reported with HIV infection enrolled in HIV care within 6 months of diagnosis" by the epidemiology unit of NSACP
	Profile of people living with HIV initiating HIV care	By managing data submitted in the form "Strategic Information on Laboratory Confirmed HIV Infections" by SIM unit of NSACP
4.1 Antiretroviral	Number of people receiving ART (and coverage)	Numerator of this indicator is calculated by the Quarterly ART return by the SIM unit.

drugs: coverage		For the coverage, the denominator is calculated by the “Spectrum” software based on the M&E data, surveillance data and various assumptions
	Number of people receiving ARV drugs for PMTCT (and coverage)	Numerator of this indicator is calculated by the Quarterly ART return by the SIM unit. For the coverage, the denominator is calculated by the “Spectrum” software based on the M&E data, surveillance data and various assumptions
4.2 Antiretroviral drugs: Supply	Percentage of ART facilities with ARV drug stock-outs in a given period	This is calculate annually using ART stock register maintained by the NSACP pharmacy.
4.3 Antiretroviral drugs: Retention	Adherence	Currently this is not captured by routine M&E system.
	Percentage retained on ART and PMTCT	12 month, 24 month and 60 month retention rates on ART are calculated using cohort analysis method. Patient records, ART registers are used to calculate survival rates using the table given in the annex .
5. Viral suppression	Percentage of viral suppression	Currently this is not captured by routine M&E system as viral load testing is not regularly and universally available in all ART centers.
6. Impact	Mortality rate	- Estimated mortality is calculated using the “Spectrum” software based on the M&E data, surveillance data and various assumptions. - Reported death are counted using the HIV cases notification system
	Incidence and the number of adults and children acquiring HIV infection	- Estimated new cases per year (incidence) is calculated using the “Spectrum” software based on the M&E data, surveillance data and various assumptions.
	Mother-to-child transmission rate	Estimated MTCT rate is calculated using the “Spectrum” software based on the M&E data, surveillance data and various assumptions.
	Survival Rate	12 month, 24 month and 60 month survival rates on ART are calculated using cohort analysis method. Patient records, ART registers are used to calculate survival rates using the table given in the annex .

23. Recording and Reporting Formats and brief instructions

1. **Request for HIV antibody test/notification** (H1214, refer annex for the format)

This format is meant to collect basic epidemiological information of all people who undergo HIV antibody screening. In practice, this is used to collect basic epidemiological data when a person is HIV antibody screening test positive and requesting a HIV antibody confirmatory test (Western or Line Blot tests).

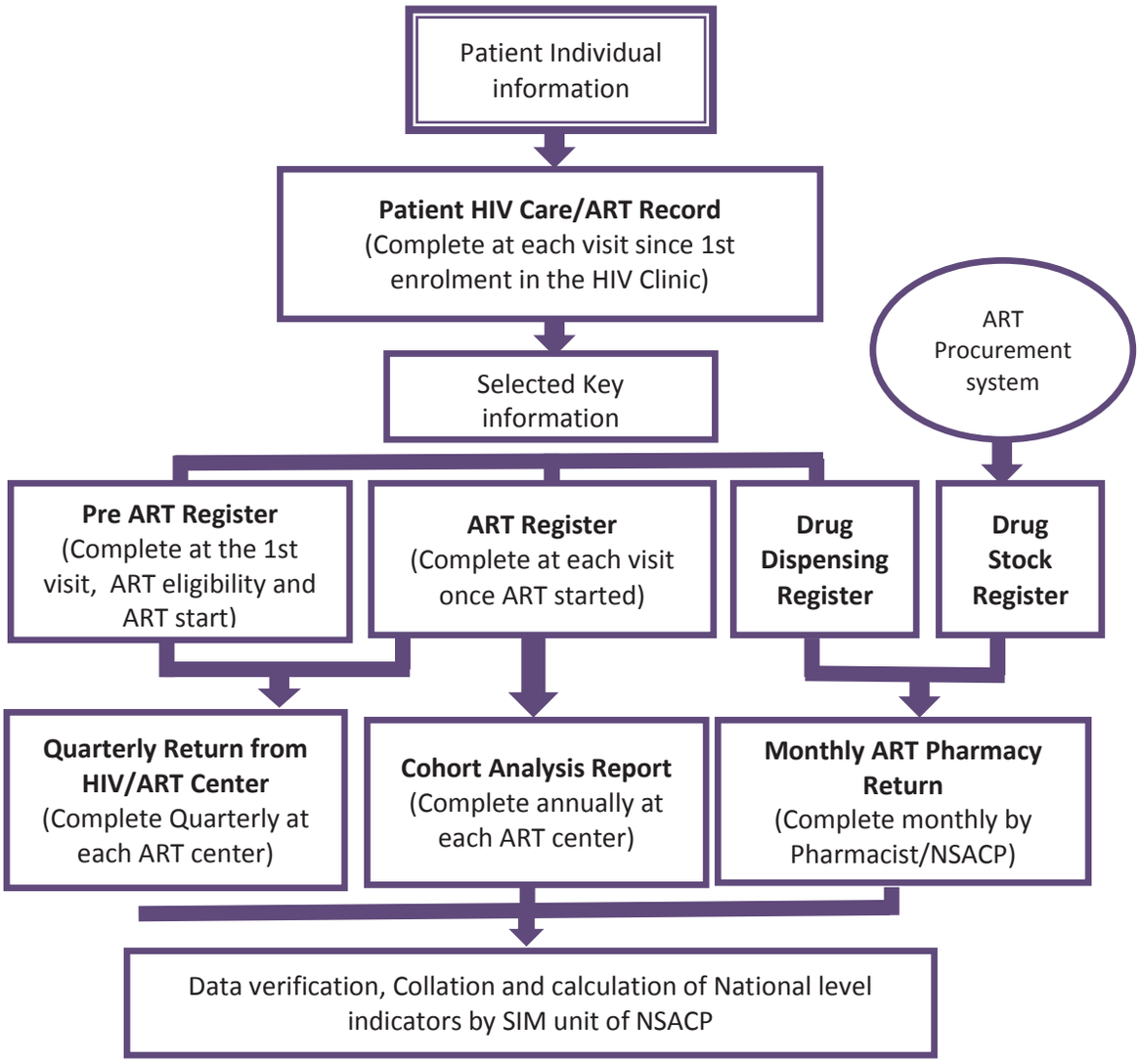
This format is collected by the National Reference Laboratory of NSACP and sent to the epidemiology unit for data verification and data management. A summary of the findings from this data source is compiled at the end of every quarter.

2. Strategic Information on Laboratory Confirmed HIV Infection (Refer annex for the format)

This format is used to collect more detailed data from the HIV positive persons who get registered in ART centers for follow up of care. Those who get enrolled in ART centers are more likely to report personal details after developing a better rapport with the care provides.

Completed form needs to be sent to SIM unit of NSACP for data management. A summary of the findings from this data source is compiled at the end of every year.

Fig. 2. Recording and reporting system in the current paper based HIV/ART facility monitoring



3. The Patient HIV Care/ART Record (Refer annex for the format)

To provide effective lifelong care, it requires keeping track of the patient's baseline and follow-up care and treatment history. All relevant health care providers in the medical team (such as doctor, nurse etc) needs to know key clinical details and what was done on previous visits.

The Patient HIV Care/ART Record is maintained for each patient under HIV care whether or not they started on ART. It is important to complete this form for each patient visit. In this record standard information is noted under four categories.

i. Demographic information, collected at first visit or on enrollment which is updated if the information has changed.
ii. HIV care history, collected for all patients enrolled in HIV care whether or not they have started ART.
iii. ART summary, collected at start and change in treatment as well as at 6 months and yearly follow-up.
iv. Patient follow-up information, collected every time the patient visits the facility.

4. Pre-ART Register and ART Register (Refer annex for the formats)

Registers are convenient tools to facilitate the aggregation of individual information from the Patient HIV Care/ART Records for completing quarterly ART return and for obtaining programme indicators. Without registers, each patient record would need to be checked one by one to calculate the required indicators.

In the registers, patients are recorded:

- by date of first visit in the clinic (enrollment) in the Pre-ART Register; and
- by date of start of ART in the ART Register.

The pre-ART Register has to be completed:

- at the first visit for most of the information
- at the start of cotrimoxazole preventive therapy
- at the start of TB treatment
- at medical eligibility for ART
- at start of ART; and
- whenever follow-up was ended before ART was started.

The ART Register has to be completed for all patients starting ART, during all monthly follow-up visits since the date of starting treatment to the end of follow-up on ART.

5. ARV Drug Dispensing Register (Refer annex for the format)

The ARV Drug Dispensing Register is maintained by the pharmacist in the NSACP. The purpose of this Register is two-fold:

- to document and account for every tablet of each drug by obtaining the patient's signature against the number of tablets given; and
- to calculate the daily consumption of each drug.

6. ARV Drug Stock Register (Refer annex for the format)

This Register is maintained by the pharmacist in the NSACP. At the end of each month, ART Monthly Return from the Pharmacy is completed using this register.

7. ART Monthly Return from the Pharmacy (Refer annex for the format)

This return is prepared by the pharmacist of the NSACP based on the ARV Drug Dispensing Register and ARV Drug Stock Register. This return is used to describe ARV prescription patterns and drug stock positions.

8. Quarterly Return From HIV /ART Clinic (Refer annex for the format)

The Quarterly Return from the HIV/ART centers gives a cross-sectional information on the programme performance. Cross-sectional means that the indicators are compiled at one time point (at the end of each quarter) without taking into account the duration of follow-up of the patients i.e. the indicator "cumulative number on ART", indicates how many patients are continuing ART at the end of the quarter, but does not convey for how long these patients have been under ART.

The Patient HIV Care/ART Record and pre-ART and ART registers have to be updated from “unstructured” patient notes before completing this return.

9. Cohort analysis report (Refer annex for the format)

As ART follow-up is a lifelong process, it is necessary to have "longitudinal" indicators (i.e. information for a period of time), which takes into account the duration of follow-up, such as how many patients have been on treatment for 12 months, 24 months and 60 months. This is the purpose of the Cohort Analysis Report.

Cohorts is formed according to the year the patients started ART, not according to the year of entering into HIV care. To compile the Cohort Analysis Report you need the ART Register only. Currently cohort analysis it is analyzed on a yearly basis. It is important to update the ART Register from the “unstructured” patients notes before doing cohort analysis.

ART cohort analysis is done at ART center level and send to SIM unit of NSACP, where data are collated to calculate a national level indicators.

References:

1. Consolidated guidelines on the use Of Antiretroviral drugs for treating and preventing HIV Infection, WHO, 2013
2. Training tool kit, Participant Manual, HIV Care and ART Recording and Reporting System, WHO, 2006

24. Post Exposure Prophylaxis

The risk of occupational exposure to HIV among health care workers is likely to be increasing as more people living with HIV are coming into contact with health systems for treatment. Although preventing exposures to blood and body fluids is the primary means of preventing occupationally acquired HIV infection, appropriate post exposure management is an important element of workplace safety.

In the context of HIV, post-exposure prophylaxis refers to the set of services that are provided to prevent HIV infection in an exposed person.

Health care personnel, police, prison guards **are** also **at** risk **of** exposure to HIV while performing their duties.

Health care personnel

The term HCP refers to all paid and unpaid persons working in health-care settings who have the potential for exposure to infectious materials (e.g., blood, tissue, and specific body fluids and medical supplies, equipment, or environmental surfaces contaminated with these substances.

Risky Exposures
Exposure that may place an HCP at risk for a blood borne infection is defined as:

- A percutaneous injury (e.g. needle-stick or cut with a sharp instrument)
- Contact with the mucous membranes of the eye or mouth
- Contact with non-intact skin when the exposed skin is chapped, abraded or afflicted with dermatitis)
  with blood or other potentially infectious body fluids.

Infectious body fluids
Body fluids with high HIV concentration are

- Blood
- Semen
- Vaginal secretions
- Cerebro-spinal fluid
- Synovial, pleural, peritoneal, pericardial fluid
- Amniotic fluid

Body fluids with very low or no HIV are tears, sweat, urine, feces, saliva and breast milk.
Exposure to these carries no risk unless contaminated with blood.

Transmission risk
Risk of acquiring HIV following occupational exposure is much less than Hep B or Hep C. Risk of HIV transmission following needle stick exposure and mucous membrane exposure are 0.3% and 0.09% respectively. Risk of transmission following needle- stick exposure in Hep B is 9-30% and in Hep C, 1-10%.

Risk assessment following occupational exposure
Risk assessment includes the assessing the source as well as the exposure.

Assessing the source

Source may be a known HIV positive or HIV status unknown person/source. In case of an unknown person, HIV testing of the source (rapid test) can be done after obtaining consent. Positive rapid test should be followed by other tests (ELISA).
If source cannot be traced, risk of infection should be decided on case by case after considering clinical and/or epidemiological likelihood of HIV infection of the source.
If the source is a known HIV positive; stage of HIV infection, viral load and history of ART should be noted.

Assessing the exposure

- Time of exposure
- Type of object involved
- Type and volume of body fluid the person was exposed
- The severity of the injury

should be noted

Steps in the management of occupational exposure

1. Managing the exposure site
2. Establish the eligibility for PEP
3. Counselling
4. Prescribing ARV
5. Laboratory evaluation and monitoring for adherence
6. Reporting

Management of the exposure site

- Needle stick or sharp injury - Immediately wash the wound and surrounding skin with running water and soap. Do not scrub or use antiseptics.
- Eye - Irrigate the exposed eye immediately with water or normal saline. Sit on a chair, tilt the head back and ask a colleague to gently pour water or normal saline over the eye.
- Mouth - Spit out fluid immediately. Rinse the mouth thoroughly, using water or saline and spit again. Repeat this process several times.

Eligibility for PEP
Preferrably within 2-8 hours.

- Exposure within 72 hrs.
- HIV positive source
- Unknown source (consider clinical and/or epidemiological likelihood)

Counselling

Exposed person should be provided with all the information about PEP including risks and benefits in order to make an informed decision. Educate about adherence, side effects of ARV, consistence condom use, avoidance of breast feeding and blood donation.

Prescribing ARV

- Regimen – TDF + FTC + LPV/RTV or TDF + FTC + EFV
- Duration of therapy is 28 days.

- Inform about side effects and drug interactions.
- If source patient's HIV status is unknown, HCP can take ARV till test results are available.

Laboratory evaluation and monitoring for adherence

- Baseline HIV testing of HCP. Rpt after 3and 6 months.
- Baseline FBC, LFT tests. Rpt in 2 weeks. Pregnancy test if indicated.
- Monitor for drug adherence.

Reporting

Report the incident to the relevant authorities depending on the place of work. Fill in the accident reporting register with the necessary details. Following information should be included in the register.

- Identification of the HCP- Name, age, sex, designation, place of work
- Identification of the source – Name, age ,sex, identification number, brief clinical history, HBV HCV HIV status if available
- Incident – Time, place, details of the exposure
- Action taken

25. Contraception for women with HIV infection

General contraception management

- Most available methods of contraception may be considered in HIV-positive women and are safe and effective; however, special considerations need to be made in women currently taking or about to commence ART.
- Consistent condom use should be encouraged in conjunction with the additional contraceptive methods (II).
- A full choice of options for contraception should be discussed, with appropriate counselling about potential drug interactions and reduced contraceptive efficacy (III).

Key points and recommendations

- For HIV-positive women not on ART, all available contraceptive methods are suitable, although N-9 spermicide should be avoided.
- Because of induction of liver enzymes, COC, POP and etonogestrel, implant may be less effective in those on HAART. Nonetheless, there is a role for these methods inconjunction with an additional method. The efficacy of DMPA, LNG-IUS and Cu-IUD are not known to be affected by liver enzyme inducers, and offer very effective contraception for those on HAART.
- A Cu-IUD is the recommended method of emergency contraception for women on HAART. If POEC is used, a doubling of the standard dose to 3mg stat (immediately) is recommended.

ANNEXES

12. ANNEXES

Annex 1. WHO clinical staging of HIV disease in adults, adolescents and children

Source: Adapted from *WHO case definitions of HIV for surveillance and revised clinical staging and immunological classification of HIV-related disease in adults and children*. Geneva, World Health Organization, 2007 (www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf).

Adults and adolescents[a]	Children
Clinical stage 1	
Asymptomatic	Asymptomatic
Persistent generalized lymphadenopathy	Persistent generalized lymphadenopathy
Clinical stage 2	
Moderate unexplained weight loss (<10% of presumed or measured body weight)	Unexplained persistent hepatosplenomegaly
Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis)	Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis)
Herpes zoster	Herpes zoster
Angular cheilitis	Lineal gingival erythema
Recurrent oral ulceration	Recurrent oral ulceration
Papular pruritic eruption	Papular pruritic eruption
Fungal nail infections	Fungal nail infections
Seborrhoeic dermatitis	Extensive wart virus infection
	Extensive molluscum contagiosum
	Unexplained persistent parotid enlargement
Clinical stage 3	
Unexplained severe weight loss (>10% of presumed or measured body weight)	Unexplained moderate malnutrition[b] not adequately responding to standard therapy
Unexplained chronic diarrhoea for longer than 1 month	Unexplained persistent diarrhoea (14 days or more)
Unexplained persistent fever (intermittent or constant for longer than 1 month)	Unexplained persistent fever (above 37.5°C, intermittent or constant, for longer than one 1 month)
Persistent oral candidiasis	Persistent oral candidiasis (after first 6 weeks of life)
Oral hairy leukoplakia	Oral hairy leukoplakia
Pulmonary tuberculosis	Lymph node tuberculosis
Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)	Pulmonary tuberculosis
Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis	Severe recurrent bacterial pneumonia
Unexplained anaemia (<8 g/dl), neutropaenia (<0.5 x 10^9/l) and/or chronic thrombocytopaenia (<50 x 10^9/l)	Acute necrotizing ulcerative gingivitis or periodontitis
	Unexplained anaemia (<8 g/dl), neutropaenia (<0.5 x 10^9/l) or chronic thrombocytopaenia (<50 x 10^9/l)

Adults and adolescents[a]	Children
Clinical stage 3	
	Symptomatic lymphoid interstitial pneumonitis Chronic HIV-associated lung disease, including bronchiectasis
Clinical stage 4[c]	
HIV wasting syndrome *Pneumocystis (jirovecii) pneumonia* Recurrent severe bacterial pneumonia Chronic herpes simplex infection (orolabial, genital or anorectal of more than 1 month's duration or visceral at any site) Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) Extrapulmonary tuberculosis Kaposi sarcoma Cytomegalovirus infection (retinitis or infection of other organs) Central nervous system toxoplasmosis HIV encephalopathy Extrapulmonary cryptococcosis, including meningitis Disseminated nontuberculous mycobacterial infection Progressive multifocal leukoencephalopathy Chronic cryptosporidiosis Chronic isosporiasis Disseminated mycosis (extrapulmonary histoplasmosis, coccidioidomycosis) Lymphoma (cerebral or B-cell non-Hodgkin) Symptomatic HIV-associated nephropathy or cardiomyopathy Recurrent septicaemia (including nontyphoidal *Salmonella*) Invasive cervical carcinoma Atypical disseminated leishmaniasis	Unexplained severe wasting, stunting or severe malnutrition[d] not responding to standard therapy *Pneumocystis (jirovecil) pneumonia* Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia) Chronic herpes simplex infection (orolabial or cutaneous of more than 1 month's duration or visceral at any site) Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) Extrapulmonary tuberculosis Kaposi sarcoma Cytomegalovirus infection (retinitis or infection of other organs with onset at age more than 1 month) Central nervous system toxoplasmosis (after the neonatal period) HIV encephalopathy Extrapulmonary cryptococcosis, including meningitis Disseminated nontuberculous mycobacterial infection Progressive multifocal leukoencephalopathy Chronic cryptosporidiosis (with diarrhoea) Chronic isosporiasis Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidioidomycosis, penicilliosis) Cerebral or B-cell non-Hodgkin lymphoma HIV-associated nephropathy or cardiomyopathy

[a] In the development of this table, adolescents were defined as 15 years or older. For those aged less than 15 years, the clinical staging for children should be used.

[b] For children younger than 5 years, moderate malnutrition is defined as weight-for-height <–2 z-score or mid-upper arm circumference ≥115 mm to <125 mm.

[c] Some additional specific conditions can be included in regional classifications, such as penicilliosis in Asia, HIV-associated rectovaginal fistula in southern Africa and reactivation of trypanosomiasis in Latin America.

[d] For children younger than 5 years of age, severe wasting is defined as weight-for-height <–3 z-score; stunting is defined as length-for-age/height-for-age <–2 z-score; and severe acute malnutrition is either weight for height <–3 z-score or mid-upper arm circumference <115 mm or the presence of oedema.

Annex 7. Dosages of recommended antiretroviral drugs[a]

Dosages of antiretroviral drugs for adults and adolescents

Generic name	Dose
Nucleoside reverse-transcriptase inhibitors (NRTIs)	
Abacavir (ABC)	300 mg twice daily or 600 mg once daily
Didanosine (ddI)	400 mg once daily (>60 kg) 250 mg once daily (≤60 kg)
Emtricitabine (FTC)	200 mg once daily
Lamivudine (3TC)	150 mg twice daily or 300 mg once daily
Stavudine (d4T)	30 mg twice daily
Zidovudine (AZT)	250–300 mg twice daily
Nucleotide reverse-transcriptase inhibitors (NtRTIs)	
Tenofovir (TDF)	300 mg once daily
Non-nucleoside reverse-transcriptase inhibitors (NNRTIs)	
Efavirenz (EFV)	600 mg once daily
Etravirine (ETV)	200 mg twice daily
Nevirapine (NVP)	200 mg once daily for 14 days, followed by 200 mg twice daily
Proteases inhibitors (PIs)	
Atazanavir + ritonavir (ATV/r)	300 mg + 100 mg once daily
Darunavir + ritonavir (DRV/r)	800 mg + 100 mg once daily or 600mg + 100 mg twice daily
Lopinavir/ritonavir (LPV/r)	400 mg/100 mg twice daily
	Considerations for individuals receiving TB therapy In the presence of rifabutin, no dose adjustment required. In the presence of rifampicin, adjusted dose of LPV/r (LPV 800 mg + RTV 200 mg twice daily or LPV 400 mg + RTV 400 mg twice daily) or SQV/r (SQV 400 mg + RTV 400 mg twice daily), with close monitoring.
Integrase strand transfer inhibitors (INSTIs)	
Raltegravir (RAL)	400 mg twice daily

[a] For adolescents weighing less than 35 kg, see the next page for weight-based dosing for ARV formulations for children.

Table 6. Simplified dosing for urgently needed ARV drugs for children recommended by the Paediatric Antiretroviral Working Group

Drug	Strength of tablet or sprinkle sachet or capsule (mg)	No. of tablets or sprinkle capsules/sachets by weight band											
		3–5.9kg		6–9.9kg		10–13.9 kg		14–19.9kg		20–24.9kg		25–34.9kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
ABC/3TC/NVP	60mg/30mg/50mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	4	4
LPV/r sprinkles	40mg/10 mg	2	2	3	3	4	4	5	5	6	6	–	
ABC/3TC/ LPV/r	30mg/15mg/ 40mg/10mg	2	2	3	3	4	4	5	5	6	6	–	
AZT/3 TC/ LPV/r	30mg/15mg/ 40mg/10mg	2	2	3	3	4	4	5	5	6	6	–	
DRV/r	240/40mg	–	–	–	–	1	1	1	1	2	1	–	
ATV/r	100/33mg	–		–		1		1		2		–	
ABC/3TC	120/60mg	1		1.5		2		2.5		3		–	
TDF/3TC	75mg/75mg	–		–		1.5		2		2.5		3–3.5[a]	
TDF/3TC/ EFV	75mg/75mg/ 150mg	–		–		1.5		2		2.5		3–3.5[a]	
TDF/3TC adult double scored[b]	300mg/ 300mg	–		–		one third		one half		two thirds		1	
TDF/3TC/EFV adult double scored[b]	300mg/300mg/ 600mg	–		–		one third		one half		two thirds		1	

[a] 3 tablets for 25–29.9 kg and 3.5 tablets for 30–34.9 kg.

[b] A double-scored tablet has two score lines on one side of the tablet and one score line on the other side, enabling it to be divided into thirds or halves as needed

Annex iv Grading of toxicities according to the clinical parameters:

Toxicity	Grade 1	Grade 2	Grade 3	Grade 4
Nausea	Mild OR transient; reasonable intake maintained	Moderate discomfort OR intake decreased for <3 days	Severe discomfort OR minimal intake for ≥3 days	Hospitalization required
Vomiting	Mild OR transient; 2–3 episodes per day OR mild vomiting lasting <1 week	Moderate OR persistent; 4–5 episodes per day OR vomiting lasting ≥ 1 week	Severe vomiting of all food/fluids in 24 hours OR orthostatic hypotension OR IV treatment required	Hypotensive shock OR hospitalization for IV treatment required
Diarrhoea	Mild OR transient; 3–4 loose stools per day OR mild diarrhoea lasting <1 week	Moderate OR persistent; 5–7 loose stools per day OR diarrhoea lasting ≥1 week	Bloody diarrhoea OR orthostatic hypotension OR >7 loose stools/day OR IV treatment required	Hypotensive shock OR hospitalization required
Dyspnoea	Dyspnoea on exertion	Dyspnoea with normal activity	Dyspnoea at rest	Dyspnoea requiring O2 therapy
Fever	37.7–38.5°C	38.6–39.5°C	39.6–40.5°C	>40.5°C for ≥12 continuous hours
Headache	Mild, or does not require treatment	Moderate, which responds to non-narcotic analgesics	Severe, which responds to initial narcotic analgesic	Intractable
Allergic reaction	Pruritus without rash	Localized urticaria	Generalized urticaria,angioedema	Anaphylaxis
Rash Hypersensitivity	Erythema, pruritus	Diffuse, maculopapular rash OR dry desquamation	Vesiculation OR moist desquamation OR ulceration	Stevens Johnson syndrome, toxic epidermal necrolysis, erythema multiforme,exfoliative dermatitis
Fatigue	Normal activity reduced <25%	Normal activity reduced 25–50%	Normal activity reduced >50%; cannot work	Unable to care for self

Annexure v severity grading of toxicities according to the laboratory parameters:

Toxicity	Grade 1	Grade 2	Grade 3	Grade 4
Haemoglobin	8.0–9.4 g/dl OR 80–94 g/L OR 4.93–5.83 mmol/L	7.0–7.9 g/dl OR 70–79 g/L OR 4.3–4.92 mmol/L	6.5–6.9 g/dl OR 65–69 g/L OR 4.03–4.30 mmol/L	<6.5 g/dl OR <65 g/L OR <4.03 mmol/L
Absolute neutrophil Count	1000–1500/ mm3 OR 1.0–1.5 g/L*	750–999/mm3 OR 0.75–0.99 g/L*	500–749/mm3 OR 0.5–0.749 g/L*	<500/mm3 OR <0.5 g/L*
Platelets	75 000–99 000/mm3 OR 75–99 g/L*	50 000–74 999/mm3 OR 50–74.9 g/L*	20 000–49 999/ mm3 OR 20–49.9 g/L*	<20 000/ mm3 OR <20 g/L*
Hyponatraemia	130–135 mEq/ L OR 130–135 mmol/L	123–129 mEq/L OR 123–129 mmol/L	116–122 mEq/L OR 116–122 mmol/L	<116 mEq/L OR <116 mmol/L
Hypernatraemia	146–150 mEq/L OR 146–150 mmol/L	151–157 mEq/L OR 151–157 mmol/L	158–165 mEq/L OR158–165 mmol/L	>165 mEq/L OR >165 mmol/L
Hyperkalaemia	5.6–6.0 mEq/L OR 5.6–6.0 mmol/L	6.1–6.5 mEq/L OR 6.1–6.5 mmol/L	6.6–7.0 mEq/L OR 6.6–7.0 mmol/L	>7.0 mEq/L OR >7.0 mmol/L
Hypokalaemia	3.0–3.4 mEq/L OR 3.0–3.4 mmol/L	2.5–2.9 mEq/L OR 2.5–2.9 mmol/L	2.0–2.4 mEq/L OR 2.0–2.4 mmol/L	<2.0 mEq/L OR <2.0 mmol/L
Hyperbilirubinaemia	>1.0–1.5 X ULN	1.6–2.5 X ULN	2.6–5 X ULN	>5 X ULN
Hypoglycaemia	55–64 mg/dL OR 3.01–3.55 mmol/L	40–54 mg/dl OR 2.19–3.00 mmol/L	30–39 mg/dl OR 1.67–2.18 mmol/L	<30 mg/dl OR <1.67 mmol/L
Hyperglycaemia (non fasting and no prior diabetes)	116–160 mg/dl OR 6.44–8.90 mmol/L	161–250 mg/dl OR 8.91–13.88 mmol/L	251–500 mg/dl OR 13.89–27.76 mmol/L	>500 mg/dl OR >27.76 mmol/L
Triglycerides	-	400–750 mg/dl OR 4.52–8.47 mmol/L	751–1200 mg/dl OR 8.48–13.55 mmol/L	>1200 mg/dl OR >13.55 mmol/L
Creatinine	>1.0–1.5 X ULN	1.6–3.0 X ULN	3.1–6.0 X ULN	>6.0 X ULN
AST (SGOT)	1.25–2.5 X ULN	2.6–5.0 X ULN	5.1–10.0 X ULN	>10.0 X ULN
ALT (SGPT)	1.25–2.5 X ULN	2.6–5.0 X ULN	5.1–10.0 X ULN	>10.0 X ULN
Gamma glutamyl Transpeptidase(GGT)	1.25–2.5 X ULN	2.6–5.0 X ULN	5.1–10.0 X ULN	>10.0 X ULN
Alkaline phosphatase	1.25–2.5 X ULN	2.6–5.0 X ULN	5.1–10.0 X ULN	>10.0 X ULN
Amylase	1.0–1.5 X ULN	1.6–2.0 X ULN	2.1–5.0 X ULN	>5.0 X ULN
Lipase	>1.0–1.5 X ULN	1.6–3.0 X ULN	3.1–5.0 X ULN	>5.0 X ULN
Lactate	<2.0 X ULN without acidosis	>2.0 X ULN without acidosis	Increased lactate with pH <7.3 without life-threatening consequences	Increased lactate with pH <7.3 with life-threatening consequences
Proteinuria	1+	2–3+	4+	Nephrotic syn
Proteinuria (24-hour urine)	200 mg–1 g loss/day OR	1–2 g loss/day OR 0.3–1.0%	2–3.5 g loss/day OR >1.0% OR	Nephrotic syndrome

	<0.3% OR <3 g/L	OR 3–10 g/L	>10 g/L	OR >3.5 g loss/day
Haematuria	Microscopic only	Gross, no clots	Gross plus clots	Obstructive

Annexure v Management of ART drug toxicities depends on the severity grade

Severity Grade	Intervention
Grade 1	No change in therapy required
Grade 2	Consider continuation of ART as long as feasible. If there is no improvement with symptomatic therapy, consider single drug substitution.
Grade 3	Substitute another drug for the offending one without stopping ART.
Grade 4	Immediately discontinue ART and manage the medical event (symptomatic and supportive therapy) and reintroduce ART using a modified regimen by substituting the offending drug with another one when the patient is stabilized.

Following severity assessment when substitution of offending drug/s is indicated, new drug/s to be included in the triple ART regimen need to be selected carefully considering the prevailing clinical and biochemical parameters of the patient. Table below gives the possible options for substitution.

Annexure vi Toxicities of individual ARV drugs and recommended substitutions:

Drug	Frequently associated toxicity	Suggested substitution
AZT	Severe anemia, neutropenia, low platelet myopathy, lipoatropy, lypodystrophy, lacticacidosis or severe heapatomegaly with steatosis	Replace with TDF or ABC Boosted PI + NNRTI if ABC and TDF are not available (e.g. IDV/r + EFV)
ABC	Hypersensitivity reaction	AZT or TDF
TDF	Renal toxicity (renal tubular dysfunction) Decrease bone mineral density Lactic acidosis or severe hepatomegaly with steatosis	Replace with AZT or ABC
EFV	Hypersensitivity reaction Stevens-Johnson syndrome Hepatic toxicity Persistent and severe CNS toxicity (depression, confusion) Hyperlipidaemia Male gynaecomastia	CNS toxicity , hyperlipidaemia and male gynaecomastia can be substitute with NVP Hypersensitivity and hepatotoxicity Substitute with a PI Use triple NRTI if no other choice
NVP	Hypersensitivity reaction Stevens-Johnson syndrome Hepatic toxicity	EFV. If patient cannot tolerant replace with a PI. Use triple NRTI if no other choice
LPV/r	Hyperlipidaemia (especially triglycerids) Elevated serum transaminases Hyperglycaemia Fat maldistribution Increased bleeding episodes in patients with Haemophilia PR interval prolongation QT interval prolongation and torsade de pointes	ATV/r or DRV/r
IDV	Renal toxicity (nephrolithiasis)	Replace with another PI.
ATV/r	Indirect hyperbilirubinaemia (Clinical jaundice) Prolonged PR interval — first degree symptomatic AV block in some patients Nephrolithiasis	Replace with LPV/r or DRV/r
DRV/ r	Hepatotoxicity Severe skin and hypersensitivity reaction	Replace with LPV/r or ATV/r

Table 3. Simplified dosing of child-friendly solid and oral liquid formulations for twice-daily dosing

Drug	Strength of tablets (mg) or oral liquid (mg/ml)	Number of tablets by weight band morning and evening										Strength of adult tablet (mg)	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
Solid formulations														
3TC	Tablet (dispersible) 30 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	150	1	1
AZT	Tablet (dispersible) 60 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300	1	1
ABC	Tablet (dispersible) 60 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300	1	1
NVP[a]	Tablet (dispersible) 50 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	200	1	1
LPV/r[b]	Tablet (heat stable) 100 mg/25 mg	–	–	–	–	2	1	2	2	2	2	100/25	3	3
Liquid formulations														
AZT	10 mg/ml	6 ml	6 ml	9 ml	9 ml	12 ml	12 ml	–	–	–	–	–	–	–
ABC	20 mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	–	–	–	–	–	–	–
3TC	10 mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	–	–	–	–	–		
NVP[a]	10 mg/ml	5 ml	5 ml	8 ml	8 ml	10 ml	10 ml	–	–	–	–	–	–	–
LPV/r[b]	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	–	–	–

[a] NVP dose escalation with half dose for 2 weeks when initiating ART is still recommended to avoid toxicity from high initial NVP levels. However, secondary analysis from the (CHAPAS)-1 trial recently suggested that younger children have a lower risk of toxicity, and consideration can be given to starting with a full dose (Fillekes Q et al. Is nevirapine dose escalation appropriate in young African HIV+ children? 20th Annual Conference on Retroviruses and Opportunistic Infections, Atlanta, GA, USA, 3–6 March 2013 (http://retroconference.org/2013b/Abstracts/46904.htm, accessed 15 May 2013). More definitive evidence is expected from an ongoing trial.

[b] 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 or crushed.

Annexure viii Key ARV drug interactions and suggested management[a]

ARV drug	Key interactons	Suggested management
AZT	Ribavirin and peg-interferon alfa-2a	First-line: substitute AZT with TDF Second-line: substitute AZT with d4T
Boosted PI(ATV/r, LPV/r)	Rifampicin	Substitute rifampicin with rifabutin Adjust the PI dose or substitute with three NRTIs (for children)
	Lovastatin and simvastatin	Use an alternative dyslipidaemia agent (for example pravastatin)
	Estrogen-based hormonal contraception	Use alternative or additional contraceptive methods
	Methadone and buprenorphine	Adjust methadone and buprenorphine doses as appropriate
	Astemizole and terfenadine	Use alternative antihistamine agent
	TDF	Monitor renal function
EFV	Amodiaquine	Use an alternative antimalarial agent
	Methadone	Adjust the methadone dose as appropriate
	Estrogen-based hormonal contraception	Use alternative or additional contraceptive methods
	Astemizole and terfenadine	Use an alternative anti-histamine agent
	Rifampicin	Substitute NVP with EFV
NVP	Itraconazole and ketoconazole	Use an alternative antifungal agent (for example fluconazole)

Annexure ix Antiretroviral drugs, side effects and food restrictions

Generic name	Standard adult dose	Adverse effects	Specific instructions for Drug administration
Nucleoside reverse transcriptase inhibitors (NRTIs)			
3TC, lamivudine	150mg twice a day	**Common:** Nausea, vomiting, diarrhoea, headache, abdominal pain, hair loss, fever, insomnia (difficulty sleeping), rash, tiredness, joint pain **Rare:** Lactic acidosis, liver damage	Take with or without food
AZT, zidovudine	300 mg twice a day	**Common:** Nausea, vomiting, fatigue, headache, dizziness, weakness, muscle pain, loss of appetite, fever **Rare:** Blood disorders, (anemia and other myelosuppression)lipoatrophy, lactic acidosis	Take with or without food
FTC, emtricitabine	200mg once a day	**Common:** Nausea, diarrhoea, headache, raised creatine kinase levels, skin darkening **Rare:** Lactic acidosis, liver damage	Take with or without food
Abacavir	300mg twice a day	**Common:** Nausea, vomiting, diarrhoea, fever, headache, abdominal pain, tiredness, loss of appetite **Rare:** Hypersensitivity reaction, lactic acidosis	Take with or without food
Nucleotide reverse transcriptase inhibitor (NtRTI)			
Tenofovir	300 mg once a day	**Common:** Nausea, vomiting, diarrhoea, flatulence, dizziness, low blood phosphate levels, weakness, rash,	Take with food

		headache, stomach pains, fatigue, bloating **Rare:** Renal problems, bone thinning	
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)			
Efavirenz	600mg once a day	**Common:** Rash, dizziness, sleep disturbance, abnormal dreams, impaired concentration, nausea, vomiting, headache, tiredness, diarrhoea, anxiety, depression **Rare:** Psychosis, severe rash, liver problems	Take on an empty stomach, preferably at bedtime
Nevirapine	200mg once a day for two weeks **then** 200mg twice a day	**Common:** Liver toxicity, allergic reaction, rash, nausea, headache, fatigue, stomach pain, diarrhoea **Rare:** Severe rash (Stevens Johnson syndrome)	Take with or without food
Protease inhibitors			
Lopinavir / ritonavir	400 mg /100 mg (two tablets) twice a day	**Common:** Lipodystrophy, raised liver enzymes, nausea, vomiting, diarrhoea, abdominal pain, weakness, heartburn, headache, raised lipids, liver toxicity, diabetes **Rare:** Changes in heart rhythm	Swallow whole. Take with or without food
Atazanavir	300mg with 100mg ritonavir once a day	**Common:** Nausea, diarrhoea, rash, stomach ache, headache, insomnia (difficulty sleeping), vomiting, hyperbilirubinaemia, lipodystrophy, liver toxicity, diabetes **Rare:** Kidney stones, abnormal liver function, changes in heart rhythm	Take with food
Darunavir	600mg with 100mg ritonavir twice a day **or** 800mg with 100mg ritonavir once a day	**Common:** Diarrhoea, nausea, rash, stomach pain, vomiting, headache, lipodystrophy, liver toxicity, diabetes, fever	Take with food

		Rare: Abnormal liver function, changes in heart rhythm	
Integrase inhibitor			
Raltegravir	400mg twice a day	**Common:** Headache, insomnia (difficulty sleeping) **Rare:** Severe rash, hypersensitivity reaction, extreme hirst	Take with or without food

Spectrum of dermatological manifestation in HIV infection

Rash morphology	Differential diagnosis
Follicular	Bacterial, eosinophilic folliculitis, pityrosporum folliculitis, follicular eczema
Eczematous	dermatitis, drug eruptions, Seborrhoeic dermatitis
Papular	Molluscum contagiosum, HPV, Scabies, Cryptococcosis, Histoplasmosis, Kaposis sarcoma
Macular/Maculopapular	Secondary syphilis, Parvo virus B19, HBV, Dissaminated candidiasis, widespread scabies and drug reactions. considerOI with skin manifestations such as cryptococcosis, histoplasmosis, penicilliosis and coccidiomycosis
Vesicular	Herpes zoster , Varicellar infection, herpes simplex and drug reactions
Petechial and pustular	Bacterial causes such as disseminated gonococcal infection, pseudomonal , staphylococcal sepsis, infective endocarditis, listeriosis Viral causes such as Parvo virus B19, cutaneous vasculitis and drug reactions
Nodular	Prurigo nodules from persistent scratching, basal and squamous cell carcinoma, Kaposis sarcoma ,mycobacteria, bartonella, histoplasmosis, coccidiomycosis
Psoriasiform lesions	Psoriasis, Reiter's syndrome

Clinical Diagnosis and Management of Skin Conditions

1.Non infectious diseases			
Condition	**Clinical features**	**Diagnosis**	**Treatment**
Eosinophilic folliculitis	Erythematous, pruritic, follicular papules(centred around follicles)/ pustules on face , upper trunk, upper arms, Intense itching; This can lead to excoriation with secondary bacterial infections, prurigo nodularis, lichen simplex chronicus and post-inflammatory hyperpigmentation.	Clinical	Treat mild disease with topical steroids and oral antihistamines Treat moderate to severe disease with oral Itraconazole, isotretinoin, or phototherapy
Pruritic popular eruptions (PPE)	Hyperpigmented, hyperkeratotic pustules and nodules which are usually symmetrically distributed on the arms, legs, lower back, buttocks	Clinical	Treatment- Topical steroids, systemic antihistamines to relieve the itching that often accompanies this condition. If secondary impetigo occurs topical or systemic antibiotics may be needed. Phototherapy is also recommended. The condition improves with immune recovery on ART but scarring from old lesions may be permanent
Xerosis	Dry and rough skin , sometimes with fine cracks	Clinical	A moisturising skin lotion can be used to relieve dryness and antihistamine for itching (chlorpheniramine). Emmollients including urea, lactic acid or salicylic acid. The condition impoves with immune restoration on ART
Seborrhoeic dermatitis	Erythematous plaques with greasy scaling on the scalp, face, postauricular, area and chest	Clinical	In mild cases 1% hydrocortisone cream or 0.1% triamcinalone or similar topical steroid cream. This condition also responds to topical antifungals. Use of ketoconazole shampoo to wash the head and later spread shampoo over the face, eye brows. Leave for 5 minutes and wash off. Repeat daily until lesions have cleared and use once weekly to prevent recurrence. Ketoconazole cream also can be used on the face. Refractory cases oral ketoconazole 200mg/day for 7-14 days can be used
Drug reaction	HIV infected people have a higher incidence of drug reactions. Generalized erythematous, pruritic rash with or without fever and signs of hepatotoxicity. Severe drug reactions (Stevens-Johnson syndrome and TEN-toxic epidermal necrolysis) result in blistering of skin and or mucous membranes, typically in the first days to weeks of commencing the new drug	Clinical	Stop the causative drug. Give antihistamines and topical moisturising creams. Hospitalization with cardiorespiratory support may be needed for patients with SJS and TEN. Most experts recommend the use of short course of systemic steroids in case of sever drug reactions. Start with prednisone. 0.5mg/kg per day, and reduce the dose over 5-10d Once suspected dermatological referral is needed

	*Use of ART can cause lichenoid eruptions, mobiliform eruptions, genital and oral ulcerertion		
Infection	**Clinical features**	**Diagnosis**	**Treatment**
Primary HIV infection	Generalized maculopapular rash usually with fever and systemic symptoms	Serology for HIV RNA or DNA may be negative in early primary infection	No specific treatment is indicated for the rash or for primary infection. Patient counselling, education and behaviour modification are necessary
Psoriasis	This can present for the first time at the progression to AIDS. Well defined salmon pink plaques bearing large, centrally adherent silvery white polygonal scales. There are different types- Plaque psoriasis, scalp, guttate, flexural, palmar, plantar and pustular. There can be nail changes such as thimble pitting, onycholysis and sub-ungual hyperkeratosis. In addition can be complicated with psoriatic arthropathy.	Clinical	Topical applications- coal tar, dithranol, cacineurin inhibitors Flexural psoriasis steroids can be used When extensive methotrexate can be given, but ciclosporine is better avoided in immunosuppression UV radiation, PUVA, retinoids, biological agents
2. Viral infections			
Primary varicella or chickenpox	Crops of pruritic vesicles that becomes generalised. Malaise, headache, fever, myalgia. Greater incidence of complications as encephalitis, pneumonitis and hepatitis	Clinical Culture DFA/PCR Tzanck smear	Acyclovir 800mg 5 times daily 5-7 days Valacycovir tds/ Famcyclovir 500mg tds- 5-7 days Prevention with vaccination
Herpes zoster	Typically painful blisters in clusters along dermatomes. Can involve the eye. HIV infection should be suspected if lesions are multidermatomal or episodes are r22ecurrent. Prodromal symptoms include paraesthesia and or pain in the dermatomes a few days before the rash appear. Fever, malaise and headache may precede the outbreak of blisters	Clinical Tzanck smear	Acyclovir 800mg 5 times daily for 7 days should be started within 72 hours of onset of the blisters. Famiciclovir and Valacyclovir are alternatives. For ophthalmic zoster, acyclovir ointment can be applied in the eye every 4 hours Pain is managed with paracetamol 1g 6 hourly; stronger analgesics can be used if necessary. Amitriptyline 25-50mg before bedtime is useful for the control of the neuropathic pain and for post herpetic neuralgia, which may persist for months after the episode.

Herpes simplex	Typicalal blisters, with pain and tingling, usually genital area or face. Chronic HSV infection presents as progressive, shallow, clean based ulcers on genitalia, perianal, perioral areas	Clinical/Isolation in cell culture Presumptive presence of multinucleated giant cells in scrapings stained with Giemsa stain/Tzanck smear ®Serology may be helpful	Saline wash-2-4 times a day Analgesics Keep the area clean and dry Acyclovir 400mg 3 times daily -7days Valacyclovir 500mg bd- 7d Famcyclovir 250 tds-7d Secondary bacterial infections- Cotrimoxazole or ciprofloxacin Fungal infections- fluconazole (avoid topical) In immunosuppressed HSV can be chronic and invasive (esophagitis and encephalitis) Recurrence- suppressive therapy- refer STI management guidelines
Infection	**Clinical features**	**Diagnosis**	**Treatment**
Molluscum contagiosum	Raised dome shaped, flesh coloured papules with central umbilication containing caseous material lesions usually on face, neck, genital area, axilla and groins	Clinical Biopsy of lesions- molluscum bodies on Giemsa staining	Cryotherapy, curettage, TCA, Imiquimod under occlusion, topical cidofovir in recalcitrant disease, often improves with ART
3. Fungal infections-superficial			
Dermatophyte infections	Tinea cruris, corporis, onychomycosis Proximal nail white onychomycosis is also a marker of HIV infection Can present as deep dermal morphologies as multiple fluctuant erythematous nodules on extrimities	Clinical Microscopy of scrapings with (KOH) preparations Culture	Superficial disease with topical applications Wide spread disease with systemic antifungals Fluconazole and Itraconazole Onychomycosis with terbinafine
Malassezia furfur (Pityriasis versicolor)	Pruritic pustules, papules and macules on the face ,chest, back and shoulders	Microscopy of scrapings with KOH	Topical Clotrimazole , if fails systemic Fluconazole, itraconazole
4. Parasitic infestations and infections			
Scabies	Rash and excoriations on torso; burrows in web spaces, and wrist; face spared	Microscopy of skin scrapings, KOH or	Permethrin cream 5%: Apply from chin to toes and take a shower 10-12 hours later; repeat after 1 week Or

Norwegian scabies	Extensive crusting(psoriasis like lesions) with thick hyperkeratotic scales on elbows, knees, palms and soles	mineral oil preparation	25% benzyl benzoate solution: Apply below head. The application is left to dry on the skin and then repeated for 3 consecutive days. Itching can be relieved by taking chlorpheniramine tablets And Clothes and bedding should be washed/boiled and kept separately for 3 days to prevent re-infestation. Household contacts should be treated. After treatment, all the clothes and bed linen should be washed/boiled and dried. Clothes which cannot be washed has to be tied up in bags for 2-3 weeks Household and other close contacts require the same treatment. In severe cases ivermectin administered in a single oral dose of 200µd/kg may be considered
Infection	**Clinical features**	**Diagnosis**	**Treatment**
Leishmaniasis	Cutaneous disease is usually accompanied by visceral disease. Cutaneous manifeststions are common. Skin lesions present as papules modules or plaques mainly on the exposed areas and. Mucocutaneoius disease affect the nasal, buccal and pharyngeal areas with disfiguring. Bone marrow , liver, spleen, lymph nodes, GI and respiratory involvement occur in visceral disease. Visceral disease has been reported but rare in Sri Lanka	Demostration of parasite in blood, tissue, scrapings, skin biopsy Culture PCR	Pentavalent antimonial salts/ Sterbogluconate
5. Other opportunistic infections			
Cryptococosis*	Generalized papulonecrotic skin lesions and umbilicatted nodules resembling molluscum contagiosum, associated with fever and other symptoms of disseminated cryptococcosis such as meningitis and lung infection	Microscopy of skin biopsy, lymph node aspirate or CSF. India ink, Wright or cotton blue stain	Preferred: IV amphotericin B(0.7mg/kg daily) + Flucytocine(25mg/kg 4 times a day) for 2 weeks, then fluconazole(400mg daily) for 8 weeks

Penicilliosis *	Papulonecrotic and umbilicated skin lesions associated with systemic symptoms of fever, lung involvement, cough,weight loss, anaemia, hepatosplenomegally and lymphadenopathy. 70% of the patients with disseminated penicillium marneffei infection will have skin lesions. Endemic in northern Thailand, Southern China, Vietnam, Indonesia and Hongkong	Microscopy of clinical specimens and culture	IV amphotericin B(0.7mg/kg daily) for 2 weeks, then Itraconazole 400mg orally daily for 8 weeks Secondary prophylaxis is given with Itraconazole 200mg daily for life time or until immune recovery
Histoplasmosis *	Pustules , nodules, ulcers and papules in a patient with systemic symptoms including those due to lung , CNS, GI, and occular involvement	Tissue biopsy. H&E staining Blood or tissue culture	IV amphotericin B (0.7mg/kg daily) or liposomal amphotericin b 3mg/kg/day. Secondary prophylaxis is given with Itraconazole 200mg daily for life time or until immune recovery
Coccidiomycosis	Erythema nodosum,ulcers and deep abscesses rarely. Common syndromes are due to pneumonia. Meningitis, liver and lymph node involvement can occur	Culture Serology	Fluconazole 400mg daily/ Itraconazole200mg twice daily. Treatment differs according to the organ involvement
Infection	**Clinical features**	**Diagnosis**	**Treatment**
Mycobacterium avium complex (MAC)*	Papulopustular eruptions on trunk and extremities. Systemic symptoms include fever and pulmonary symptoms, lymphadenopathy, diarrhoea and weight loss, night sweats	AFB on skin biopsy Blood culture	**Preferred**- Azithromycin 500-600mg once daily or clarithromycin 500mg bd + ethambutol 15mg/kg/day +Rifabutin 300mgonce a day **Maintenance**- clarithromycin 500mg bd or Azithromycin 500mg a day +ethambutol 15mg/kg once a day
Cutaneous TB	TB verrucosa cutis: Asymptomatic warty papules on hand or extrimities often mistaken for verruca vulgaris. Lesions may evolve and persist for years Dissaminated TB- Presence of papulonecrotic Lesions(indistinguishable from penicilliosis, histplasmosis and cryptococcosis	Tissue/skin scraping Ziel-Neelsen stain	As TB treatment

Health 1214

CONFIDENTIAL

REQUEST FOR HIV ANTIBODY TEST/NOTIFICATION

(To be retained by the Physician Requesting Test)

PATIENT No. : ☐☐☐☐☐☐

NAME OF PATIENT : ....

ADDRESS : ....

....

DATE OF REQUEST ☐☐☐☐☐☐ D M Y

ETHNICITY : ....

Tear Off : —

DATE OF REQUEST ☐☐☐☐☐☐ D M Y

PATIENT No. : ☐☐☐☐☐☐

INFORMED CONSENT FOR HIV TESTING OBTAINED FROM PATIENT 1. YES 2. NO ☐

NAME OF PATIENT (FIRST TWO LETTERS : .... OF GIVEN NAME AND SURNAME ONLY)

DISTRICT OF RESIDENCE : .... ☐

DATE OF BIRTH : ☐☐☐☐☐☐ D M Y AGE ☐☐

SEX : 1. MALE 2. FEMALE ☐

MARITAL STATUS : 1. NEVER MARRIED ☐

2. CURRENTLY MARRIED/LIVING TOGETHER

3. SEPARATED/DIVORCED/WIDOWED

OCCUPATION : .... ☐☐

(Please Specify)

REASON FOR TESTING : 1. PATIENT WITH SYMPTOMS (Confirmatory test) ☐

2. ASYMPTOMATIC 3. VISA SCREENING 4. ORGAN DONOR

5. SURVEY 6. STD CLINIC ATTENDEE 7. OTHER (Specify) ....

RISK FACTORS : .... ☐

(Please Specify) ....

SPECIMEN : 1. BLOOD 2. OTHER (Specify) ☐

REFERRING DOCTORS NAME : ....

(In Capitals)

DESIGNATION : ....

SIGNATURE : ....

ADDRESS (Clinic, Hospital, GP etc.) : ....

....

FOR LABORATORY USE ONLY

			P	N	I
SCREENING TEST :	A. ELISA TEST	A	☐	☐	☐
	B. PARTICLE AGGULUTANATION TEST	B	☐	☐	☐
	C. SIMPLE, RAPID DIAGNOSTIC TEST	C	☐	☐	☐

			P	N	I
CONFIRMATORY TEST :	A. WESTERN BLOT	A	☐	☐	☐
	B. OTHER (Specify)	B	☐	☐	☐

DATE OF SCREENING TEST : ☐☐☐☐☐☐ D M Yr

DATE OF CONFIRMATORY TEST : ☐☐☐☐☐☐ D M Yr

SIGNATURE OF MICROBIOLOGIST/MO/LABORATORY ....

Confidential

National STD/AIDS Control Programme, Ministry of Health, Sri Lanka

STRATEGIC INFORMATION ON LABORATORY CONFIRMED HIV INFECTIONS

(VERSION 06/07/2011/SIM)

Office use only

Serial No. ☐☐☐☐☐

SL No. ☐☐☐☐☐

Comments:----------

Instructions: 1. Complete for all new and old HIV infected persons
2. Circle correct answers
3. Send completed forms in a confidential cover to:
Coordinator, SIM Unit, through Director, *National STD/AIDS Control Programme, 29, De Saram Place, Colombo 10*

1. Identification information

1.2 FIRST NAME (last two letters only) ☐☐

1.2 LAST NAME (last two letters only) ☐☐

1.3 DATE OF BIRTH (dd/mm/yyyy) ----/------/------

1.4 HIV CLINIC NUMBER ☐☐☐☐☐☐

2. Socio-demographic information

2.1 SEX
I. Male
II. Female
III. Others (transgender/transvestite etc)

2.2 AGE AT DIAGNOSIS(years/months, if <1 year) ☐☐

2.3 DISTRICT OF RESIDENCE _____

2.4 COUNTRY OF BIRTH
I. Sri Lanka II. Other (specify)_____

2.5 MARITAL STATUS
I. Never married
II. Currently married/Living together
III. Separated/Divorced/Widowed

2.6 ETHNICITY
I. Sinhalese II. Tamil
III. Moore IV. Other

2.7 OCCUPATIONAL STATUS
I. Unemployed II. Student III. Retired
IV. Employed as_____

3. HIV Testing details

3.1 SAMPLE NUMBER _____

3.2 DATE OF LAB CONFIRMATION(dd/mm/yyyy) ------/-----/-----

3.3 EVER TESTED FOR HIV BEFORE?
I. Yes (date of last negative report)_____
II. Never
III. Not known

4. Reason for HIV testing *(More than one option possible)*
I. Voluntary testing
II. Provider initiated testing
III. Investigation of clinical symptoms suggestive of HIV
IV. Partner/spouse/parent/child, diagnosed with HIV infection
V. STD screening
VI. Blood donor screening
VII. Screening before medical/surgical procedure
VIII. Screening for Visa/Insurance/Legal / Foreign jobs
IX. ANC screening
X. Others (specify).....

5. Clinical status of the HIV infected person at the time of diagnosis
I. Asymptomatic II. Symptomatic HIV III.AIDS

6. Information on exposure to HIV

6.1 SEXUAL EXPOSURE(mark only one response)
I. Sexual contact with person of opposite sex
II. Sexual contact with both sexes
III. Sexual contact with person of same sex
IV. No sexual contact
V. No response

6.2 HISTORY OF BLOOD EXPOSURE
I. No
II. Injecting drug use
III. Receipt of blood/tissue, specify year ----------
IV. Needle stick injury/Mucosal splash, specify year ----------

6.3 ACQUIRED FROM MOTHER TO CHILD TRANSMISSION
I. Yes II. No III. Not known

6.4 Ever engaged in commercial sex work/Client of sex worker?
I. Yes II. No III. No response

6.5 Ever gone abroad?
I. Yes II. No III. No response
If yes, give details (countries, purpose and duration)
_____

6.6 Ever had sex with a foreigner?
I. Yes II. No III. Not known/No response

7. Information of spouse (or living-together partner)

7.1. HIV STATUS OF THE SPOUSE
I. Positive II. Negative
III. Not known IV. Not applicable

7.2 Has the spouse ever gone abroad?
I. Never II. Yes III. Not applicable
If yes, give details (countries and purpose)
_____

7.3 RISK FACTORS FOR HIV IN SPOUSE
I. None II. MSM III. Sex worker IV. Drug user
V. Other (specify)----------
VI. Not known VII. Not relevant

7.4 LIKELIHOOD OF GETTING INFECTED FROM THE SPOUSE?
(Doctor's opinion based on history and clinical picture)
I. Likely II. Unlikely
III. Not sure IV. Not applicable

8. Information of reporting doctor

8.1 NAME OF DOCTOR----------
8.2 DESIGNATION ----------
8.3 ADDRESS/PLACE OF WORK ----------
8.4 DATE OF REPORTING ----------

HIV CARE & ANTIRETROVIRAL TREATMENT (ART) PATIENT RECORD

(To be stored in a locked cabinet at the health centre and arranged serially by registration number)

1. Patient Identification Data (Write complete information)

Patient Registration Number : ☐☐ ☐ ☐☐☐☐ (Clinic code, M/F, XXXX)

Name of the Clinic:_____ District: _____

Name of patient: _____

Age: __ __ (date of birth) __/__/____ dd / mm / yy Sex: ☐ Male ☐ Female

Patient's phone number: _____

Address: _____

_____

Distance from residence to clinic/hospital (km) :_____

Treatment supporter's name :_____

Treatment supporter's address :_____

Treatment supporter's phone number :_____

Date confirmed HIV+ test: ____/____/____ dd / mm / yy **Place:** _____

Entry point (Mode of referring the patient for HIV care):

☐ 1-STD ☐ 2-TB ☐ 3-Outpatient ☐ 4-Inpatient ☐ 5-Paediatric ☐ 6-PMTCT ☐ 7-VCT ☐ 8-Private
☐ 9-NGO ☐ 10-Self referred ☐ 11-IDU outreach ☐ 12- CSW outreach ☐ 13-Visa screening-local
☐ 14- HIV screening- foreign ☐ 15-Contact/Family Screening ☐ 16. Blood donor ☐17-Other_____

☐ Patient transferred-in, **on ART** from another clinic /hospital

Name previous clinic: _____ Date transferred in : _____

2. Personal History

Probable mode of HIV transmission

☐ 1. FSW ☐ 2.Client of FSW ☐ 3. Spouse
☐ 4 Other heterosexual ☐ 5. MSM
☐ 6. IDU ☐ 7. Blood transfusion
☐ 8. Mother to child transmission
☐ 9 Unknown

Probable place of HIV transmission

☐ 1. Local ☐ 2.Foreign

For **IDUs** Substitution therapy ☐ Y ☐ N
Drug abuse: ☐ Y ☐ N

Literate ☐ Yes ☐ No

Employed ☐ Yes ☐ No

Alcoholism ☐ Habitual ☐ Social ☐ No use

3. Family History (Tick one choice)

Marital status: ☐ Single ☐ Married ☐ Divorce/separate ☐ Widowed

Estimated monthly household income: Rs.

Family members: spouse/children relationship	Age/ sex	HIV +/-/unknown	ART Y/N	Regist. No if on care

4. Antiretroviral treatment history

Was ART received before? ☐ Yes ☐ No

If yes ☐ PMTCT ☐ Earlier ART ☐ PEP Place: ☐ Private ☐ Govt

Drugs and duration:

5. Clinical and Laboratory Investigations

	Date (dd/mm /yy)	WHO stage	Weight (kg)	Height (cm)	Performance A/B/C*	CD4 count (or % in children)	Viral load
At 1st visit in clinic							
At ART medical eligibility				child			
At start of ART				child			
At 6 months ART				child			
At 12 months ART				child			
At 24 months ART				child			

6. Antiretroviral Treatment

Treatment Started
Date:__/___/___
dd/mm/yy

☐ ZDV+3TC+EFV
☐ ZDV+3TC+NVP
☐ D4T30+3TC+EFV
☐ D4T30+3TC+NVP
☐ FTC/TDF/EFV
☐

SUBSTITUTION within 1st line, SWITCH to 2nd line, STOP, RESTART

Date	Substitution, switch or stop	Reason (code)	Date restart	New regimen

Reasons SUBSTITUTE: 1 toxicity side effects, 2 pregnancy, 3 risk of pregnancy, 4 newly diagnosed TB, 5 new drug available, 6 drug out of stock, 7 other reason (specify)

Reasons for SWITCH: 1 clinical treatment failure, 2 immunological failure, 3 virologic failure

Reasons STOP: 1 toxicity side effects, 2 pregnancy, 3 treatment failure, 4 poor adherence, 5 illness hospitalization, 6 drug out of stock, 7 patient lack of finance, 8 patient decision, 9 planned treatment interruption, 10 others

7. Tuberculosis treatment during HIV care

Disease class (tick)
☐ Pulmonary TB
☐ Smear-positive
☐ Smear-negative
☐ Extrapulmonary site: _____
☐ Recurrent

TB Regimen (tick)
☐ Category I
☐ Category II
☐ Other specify:

Date start TB Rx: ☐☐/☐☐/☐☐ dd / mm / yy

TB registration
District: _____
Health Centre: _____
TB number:

TB Treatment outcome: ☐ Cure ☐ Rx completed ☐ Rx failure ☐ Died ☐ Default ☐ Transfer out
Date: ☐☐/☐☐/☐☐ dd / mm / yy

8. End of Follow-up

☐ Death Date of death: ☐☐/☐☐/☐☐

☐ Lost to follow-up (>3 months) Date last visit: ☐☐/☐☐/☐☐

☐ Transferred out Date: ☐☐/☐☐/☐☐ dd / mm / yy New clinic:_____

* Performance scale: **A**- Normal activity; **B**- bedridden <50% of the day during last month; **C**- bedridden > 50% of the day during last month

9. Medical history at the commencement of HIV care

1. Coexisting conditions :

☐ 1. HBV ☐ 2.HCV ☐ 3.Diabetes ☐ 4. Hypertention ☐ 5. IHD ☐ 6. Asthma

2. STI s: Current ☐ 1.Yes ☐ 2. No _____

Past history ☐ 1.Yes ☐ 2. No _____

3. Other medical / Surgical conditions :

4. Current Medication : **5. Drug allergy:**

6. Contraception :

☐1. Condoms ☐2. Oral contraceptives ☐ 3. IUD ☐ 4.Tubal ligation

☐5. Vasectomy ☐6. DMPA ☐7. Other_____ ☐ 8. None

7. Gynecological/ Obsteric history

P_____ C_____ Last Menstrual Period : _____

Last Pap smear : **Pregnant now:** ☐ 1. Yes ☐ 2.No

Refer for PMTCT ☐ 1.Yes ☐ 2.No

8.Other Remarks :

9.Linkage to NGOs/ Care Institutions

Date	Name of organizations/type*	Purpose**

* 1. NGO 2. Community care and support 3. PLHA network 4. Other

** 1. Adherence 2. Retention 3. Psychosocial support 4. Other

10. For pediatric patients only (under 15 years of age)

1. Staying with:

☐ 1. Own family ☐2. In a centre and contact with family ☐3. In a centre but no contact with family

☐4. Other_____

2. Details of primary caregiver

- Type ☐1. Both parent ☐2. Single parent ☐ 3. Relatives ☐ 4. Others: ___
- Sex: ☐1. Male ☐ 2. Female
- Age: _____ years
- Education ☐1. Non literate ☐2. Primary ☐ 3. Secondary ☐4. Tertiary and above

3. Details of Child

- Birth History: ☐1. Normal vaginal delivery ☐2. Caesarean ☐ 3. Vacuum ☐ 4. Forceps
- Place of Birth (Institution):_____Birth weight: _____kg
- Neonatal complications:_____
- Infant feeding: ☐1. Exclusive Breast feeding ☐ 2. Replacement ☐ 3. Mixed
- DNA PCR results: 1st _____ 2nd _____ Others_____
- Developmental milestones: ☐ 1. Normal ☐ 2. Delayed ☐ 3. Other

4. Immunization details

Age	Vaccine	Due on	Given on	Age	Vaccine	Due on	Given on
Birth	BCG			3 years	MR		
	Polio 1				Vit A		
2 months	DPT 1			5 years	Polio5		
	Hep B 1				DT		
	Polio 2			10-14 years	Rubella		
4 months	DPT 2				ADT		
	Hep B 2			**Other Vaccines**			
	Polio 3						
6 months	DPT 3						
	HepB 3						
9 months	Measles						
	Vit A						
	Polio4						
18 months	DPT4						
	Vit A						

11. HIV CARE/ ART FOLLOW-UP

S. No	1. Date of visit*	2. Date next visit	3. Weight (kg)	4. Height (CM) for Child	5. WHO Clinical Stage	6. Performance scale*	7. Opportunistic infections code*	8. Drugs prescribed for OIs / Prophylaxis for OIs	9. Antiretroviral drugs and dose prescribed	10. ART Side effects - code*	11. Adherence to ART* - >95%, 80-95%, <80%	12. Any other medicine	13. Pregnancy Y/N or FP method*	14. Condoms Given Y/N	15. Remarks/ Referrals	16. Staff Signature
1.																
2.																
3.																
4.																
5.																
6.																
7.																
8.																
9.																
10.																
11.																
12.																

*Instructions and codes:

Date: Write the date of actual visit starting from the 1st visit for HIV care – ALL DATES: **DD/MM/YY**

Performance scale: A- Normal activity; B- bedridden <50% of the day during last month; C- bedridden > 50% of the day during last month

FP: family planning; 1 condoms, 2 oral contraceptive pills, 3 injectable/implantable hormones, 4 diaphragm/cervical cap, 5 intrauterine device, 6 vasectomy/tubal ligation/hysterectomy

Opportunistic infections: Enter one or more codes − Tuberculosis (TB); Candidiasis (C); Diarrhea (D); Cryptococcal meningitis (M); Pneumocystis Carinii Pneumonia (PCP); Cytomegalovirus disease (CMV); Penicilliosis (P); Herpes zoster (Z); Genital herpes (H); Toxoplasmosis (T); Other-specify

Adherence: Check adherence by asking the patient if he/she has missed any doses. Also check the bottle/blister packet. Write the estimated level of adherence (e.g. >95% = < 3 doses missed in a period of 30 days; 80-95% = 3 to 12 doses missed in a period of 30 days; < 80% = >12 doses missed in a period of 30 days

Side effects: Enter one or more codes − S=Skin rash; Nau-nausea; V=Vomiting; D=Diarrhoea; N=Neuropathy;J=Jaundice; A=Anemia; F=Fatigue; H=Headache; Fev=Fever; Hyp=Hypersensitivity; Dep=Depression; P=Pancreatitis; L=Lipodystrophy; Drows=Drowsiness; O=Other− Specify

12. HIV CARE & ART FOLLOW-UP- INVESTIGATIONS

Outcomes of Investigations (*To be recorded if available., If space is not adequate, write details of results in the note section of the patient record)*

	Test / Date	1. / /	2. / /	3. / /	4. / /	5. / /	6. / /	7. / /	8. / /	9. / /	10. / /	11. / /	12. / /
1	Hb % / PCV												
2	WBC/DC												
3	Platelet count												
4	Fasting Blood sugar												
5	UFR												
6	Blood urea												
7	S. creatinine												
8	S. electrolytes												
9	S. bilirubin												
10	SGOT												
11	SGPT												
12	Alkaline phosphatase												
13	Serum protein												
14	Serum cholesterol												
15	Triglycerides												
16	CD4 count / CD4 %												
17	CD8 count												
18	CD4/CD8												
19	Viral Load												
20	CXR (PA) view												
21	Mantoux (PPD)												
22	ESR												
23	CMV Ab												
24	Toxoplasmosis Ab												
25	HB s Ag												
26	Anti-HCV Ab												
27	Pap smear												
28	VDRL / TPPA												
29	GC culture												
30													
31													
32													
33													

PRE ART REGISTER

Month: _____ Year: _____ Name of Clinic / Hospital: _____

	1	2	3	4	5	6		7	8	9	10	11	12	13	14	15	16		
	Date 1st entered into HIV care at this clinic	Registration number	Patient's name, Address and Contact number	Age	Sex M/ F	HIV Confirmation test		Entry point code 1 to 13*	risk factor code 1to7**	Literate Y/N	Employed Y/N	CPT*** Date Start	Date of **TB** Screening & Result#, Category Regimen Date Rx start	Date medically eligible for ART	Why medically eligible?	Date ART started	End of follow-up before ART		
						Date	Place										Date of death	Date lost to FU (last visit)	Date transferred
1															WHO stage CD4 #/% TLC#				
2															WHO stage CD4 #/% TLC#				
3															WHO stage CD4 #/% TLC#				
4															WHO stage CD4 #/% TLC#				
5															WHO stage CD4 #/% TLC#				
6															WHO stage CD4 #/% TLC#				
7															WHO stage CD4 #/% TLC#				
8															WHO stage CD4 #/% TLC#				
9															WHO stage CD4 #/% TLC#				
10															WHO stage CD4 #/% WHO stage				

Pre ART register: At first visit fill column 1 to 10. Columns 11 to 16 to be filled when applicable.

***Entry point:** 1-STD 2-TB 3-Outpatient 4-Inpatient 5-Paediatric 6-PMTCT 7-VCT 8-Private 9-NGO 10-Self referred 11-IDU outreach 12- CSW outreach 13-Visa screening-local 14- HIV screening- foreign 15-Contac/Family Screening 16. Blood donor 17-Other_____ (Write code TR if the patient was transferred in on ART)

****Mode of HIV transmission:** 1-Commercial sex worker (CSW), 2-Other heterosexual route, 3-Men having sex with men (MSM), 4-Injecting drug use (IDU), 5-Blood transfusion, 6-Mother to child, 7-Unknown

*****CPT:** Cotrimoxazole preventive therapy **#TB Screening result: Neg**-Negative; **LTB**-Latent TB; **PTB(SS+)** Pulmonary TB(Smear+ve); **PTB(SS-)** Pulmonary TB (Smear-ve); **EPTB** Extra-Pulmonary TB (Mention the site)

PREART/SIM/2010

ART REGISTER Month:_____Year:_____Name the Clinic / Hospital_____

	Date of starting ART	Registration number	Patient's name	Age	Sex M/ F	Patient's address and contact number	Treatment supporter's name and contact number	Prior ARV history	WHO stage at start of Rx	Performance scale^ A-normal activity B-bedridden<50% C-bedridden>50%	Weight^ (kg) (and height)	CD4 count^ (absolute number for adults and % for children)	TB Screening & treatment during ART Date of TB Screening & Result***, Category Regimen Date Rx start	ART regimen started
1								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		
2								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		
3								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		
4								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		
5								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		
6								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		
7								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		
8								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		
9								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		
10								□ Y □ N		At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.	At start At 6 mo. At 12 mo. At 24 mo.		

^Peformance scale-weight-CD4 at start, 6, 12, 24 months of treatment - Height: at start for adults, at start, 6, 12, 24 months for children

* **Reasons for subsitution within first line treatment:** 1-toxicity or side effects; 2-pregnancy;3-risk of pregnancy; 4-newly diagnosed TB; 5-new drug available; 6-drug out of stock; 7-other reason.

****Reasons for switching to second line treatment:** 1-toxicity or side effects; 2-pregnancy; 3-risk of pregnancy; 4-newly diagnosed TB; 5-new drug available; 6-drug out of stock; 7-other reason; 8-clinical treatme

Reasons for stopping ART: 1- toxicity side effects; 2-pregnancy; 3-treatment failure; 4-poor adherence; 5-illness hospitalisation; 6-drug out of stock; 7-lack of finance; 8-patient's decision to stop; 9 other.

TB Screening result: Neg-Negative; **LTB**-Latent TB; **PTB(SS+)** Pulmoray TB(Smear+ve); **PTB(SS-)** Pulmonary TB (Smear-ve); **EPTB** ExtraPulmoray TB (Mention the site)

ART/SIM/2010

Treatment substituted within 1st line drugs			Treatment switched to 2nd line			End of follow-up on ART			Monthly visits: • 1st row, write patient outcome: on treatment **(OT)** if patient picked up ART drugs; stopped **(ST)** if ART was stopped by the doctor; missing **(MIS)** if the patient missed the scheduled visit; lost to follow-up**(LFU)** if the patient is missing for ≥3 months; restart **(RS)** if ART was restarted after an interruption; transferred out**(TR)**; dead **(D)**; **(NA)** if the patient was not scheduled to visit this month• 2nd row: write adherence for the patients on treatment (A=>95%, B=80-95%, C=<80%)																							
Date	Reason *	New Regimen	Date	Reason **	New Regimen	Date of death	Date Lost to FU (last visit)	Date Transfered out on ART	week 2	month 1	mo. 2	mo. 3	mo. 4	mo. 5	mo. 6	mo. 7	mo. 8	mo. 9	mo. 10	mo. 11	mo. 12	mo. 13	mo. 14	mo. 15	mo. 16	mo. 17	mo. 18	mo. 19	mo. 20	mo. 21	mo. 22	mo. 23	mo. 24

ent failure; 9-immunological failure; 10 -virological failur

ART DR/SIM/2010

Antiretroviral Drug Dispensing Register

National STD/AIDS Control Programme, Sri Lanka

Date	Patient's number	Number of tablets dispensed														
		AZT+3TC	EFV 600mg	D4T(30)+3TC	AZT+3TC+NVP	D4T(30)+3TC+ NVP	TDF+FTC	Lop200+ Rit50	Syrup AZT	Syrup 3TC	Syrup NVP					

Signature of the pharmacist: _____

Antiretroviral Drug Stock Register
National STD/AIDS Control Programme, Sri Lanka

Name of the drug _____

Date	Opening stock	Stock received	Stock dispensed	Stock expired/ discarded	Balance stock

Monthly summary for _____

Stock at the start of the month	:	Stock dispensed during the month	:
Stock received during the month	:	Stock expired/discarded during the month	:
Stock at the end of the month	:		

ART D S R/SIM/2010

QUARTERLY RETURN FROM HIV CLINIC/ART CENTER

Name of the HIV Clinic/ ART Centre: _____

Period of the return : __ /__ / 201 _ to __ /__ / 201 _ (___ Quarter of 201 _)

(Revision-08.08.2012)

Instruction: Completed returns to be sent to Director/NSACP, c/o SIM unit, 29, De Saram Place, Colombo 10 by post or by fax to 011 2682859 before 20th of the month following each quarter.

1. Enrollment in HIV care (Pre-ART and ART)	Adults (15+)		Children (<15)		Total
	Male	Female	Male	Female	
1.1 Cumulative number of patients ever enrolled in HIV care (Pre-ART and ART) at beginning of this quarter *(1.3 of last quarter)*					
1.2 Number of new patients enrolled in HIV care during this quarter *(From Pre ART register)**					
1.3 Cumulative number of patients ever enrolled in HIV care at the end of this quarter *(1.1 + 1.2)*					
1.4 Total number of patients at **pre-ART** stage at the end of this quarter *(Include only currently active pre-ART patients after deducting loss to follow-ups(LFU), those who on ART, Transfer-outs and Deaths from 1.3)*					

*(*All new patients should be registered in the Pre-ART register irrespective of whether they are on ART at the time of registration)*

2. Enrollment on ART	Adults (15+)		Children (<15)		Total
	Male	Female	Male	Female	
2.1 Cumulative number of patients ever started on ART at the beginning of this quarter *(2.4 of last quarter)*					
2.2 New patients started on ART during this quarter *(From ART register)*					
2.3 Number of patients on ART transferred-in during this quarter *(ART register)*					
2.4 Cumulative number of patients ever started on ART at the end of this quarter *(2.1+2.2+2.3)*					
2.5 Total number of patients currently on ART at the end of this quarter *(Include only currently active ART patients after deducting loss to follow-ups(LFU), Transfer-outs and Deaths from 2.4)*					

3. Outcomes on ART	Adults (15+)		Children (<15)		Total
	Male	Female	Male	Female	
3.1 Cumulative number of death reported at the end of this quarter *(Include only those on ART)*					
3.2 Cumulative number of patients transferred-out under ARV at the end of this quarter *(ART register)*					
3.3 Number of patients lost to follow-up during this quarter *(ART register)*					
3.4 Number of patients stopping ART during this quarter *(ART register)*					
3.5 Total number of patients currently on ART at the end of this quarter *(=2.5)*					
• 3.5.1 Among them, number on original 1st line regimen *(ART register)*					
• 3.5.2 Number on substituted 1st line regimen among those on treatment *(ART register)*					
• 3.5.3 Number switched on 2nd line regimen among those on treatment *(ART register)*					
3.6 Cumulative Number of patients who re-entered into ART (after LFU) during this quarter					

4. Details of opportunistic infections in the quarter *(Include both Pre-ART and ART patients, source: patient record section 11, 7th column on OI, Include both presumptive and confirmed cases)*			
Opportunistic infection	**Number of patients**	**Opportunistic infection**	**Number of patients**
4.1. Tuberculosis		4.7. Cryptococcal Meningitis	
4.2. Candidiasis (Oral, Oesophageal)		4.8. Toxoplasmosis	
4.3. Chronic Diarrhea		4.9. CMV Retinitis	
4.4. PCP		4.10. MAC	
4.5. Herpes Zoster		4.11 Other_____	
4.6. Pneumonia		4.12 Other_____	

5. PMTCT *(source: From a separate register for PMTCT)*	Age in years		Total
	< 25	25+	
5.1 Number of HIV-positive pregnant women attended the clinic during this quarter			
5.2 Number of pregnant women on ARV at the end of this quarter			
• 5.2.1 Among them, number on single drug prophylactic regimen			
• 5.2.2 Number on combination prophylactic regimen			
• 5.2.3 Number on Highly active prophylactic regimen for PMTCT			
• 5.2.4 Number of HIV-positive pregnant women on ART for their own health			

6. TB/ HIV Co-infection *(Sources: Patient record, Pre-ART and ART registers)*		Newly enrolled PLHIV during the quarter						Previously enrolled PLHIV					
		Adults (15+)y		Children (<15) 0-4y		Children (<15) 5-14y		Adults (15+)y		Children (<15) 0-4y		Children (<15) 5-14y	
		M	F	M	F	M	F	M	F	M	F	M	F
6.1 Number of patients on anti-TB treatment at the time of diagnosis of HIV													
6.2 Number of HIV positive patients having past history of TB													
6.3 Number of HIV positive patients screened for TB													
6.4 Of them, (6.3) number of ;	6.4.1 Latent TB infection												
	6.4.2 Pulmonary TB (Sputum Smear +ve)												
	6.4.3 Pulmonary TB (Sputum Smear -ve)												
	6.4.4 Extra Pulmonary TB												
6.5 Number of patients on DOTS treatment for TB during this quarter													
6.6 Number of patients on INAH prophylaxis therapy (IPT) during this quarter													
6.7 Number of patients on co-trimoxazole preventive therapy (CPT) during this quarter													

Return completed by (Name and designation):_____ **Checked by** (Name and designation) :_____

Date of completion: __ / __ / 201 _