MINISTRY OF HEALTH

Job Aids

for ART Providers in Kenya

February 2015

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FOREWORD

Kenya has witnessed phenomenal expansion of HIV prevention, care and treatment interventions, as a result of the Government's and stakeholder's commitment to achieving universal access to these interventions. There is expanded access to antiretroviral agents both for long-term therapy and for prevention of HIV transmission for those who need them throughout the country.

Most HIV care and prevention services are offered at primary care levels. These Job Aids for ART providers have been developed in line with latest version of the Guidelines for Antiretroviral Therapy in Kenya. The collection of Job Aids covers diagnosis of HIV infection, pre-ART care for HIV infected persons, preparation for and initiation of ART, treatment monitoring, antiretroviral treatment failure management, post-exposure prophylaxis and management of priority opportunistic infections and comorbidities among other guidance.

The collection of Job Aids comprises of tables, algorithms and flow charts to be utilized as decision support tools during healthcare worker-patient interaction. It's hoped that healthcare workers will find the aids helpful tools in their day-to-day encounters with patients.

Finally, appreciation goes to the ART taskforce, PMTCT TWG and all the members who participated in the development of the Rapid advice on ART June 2014 who contributed their time and expertise to put together these job aids. Special thanks go to the Centers for Disease Control and Prevention, Kenya Office for providing financial assistance towards the compilation and publication of these job aids.

Dr. Martin Sirengo
Head, National Aids & STI Control Program
Ministry of Health

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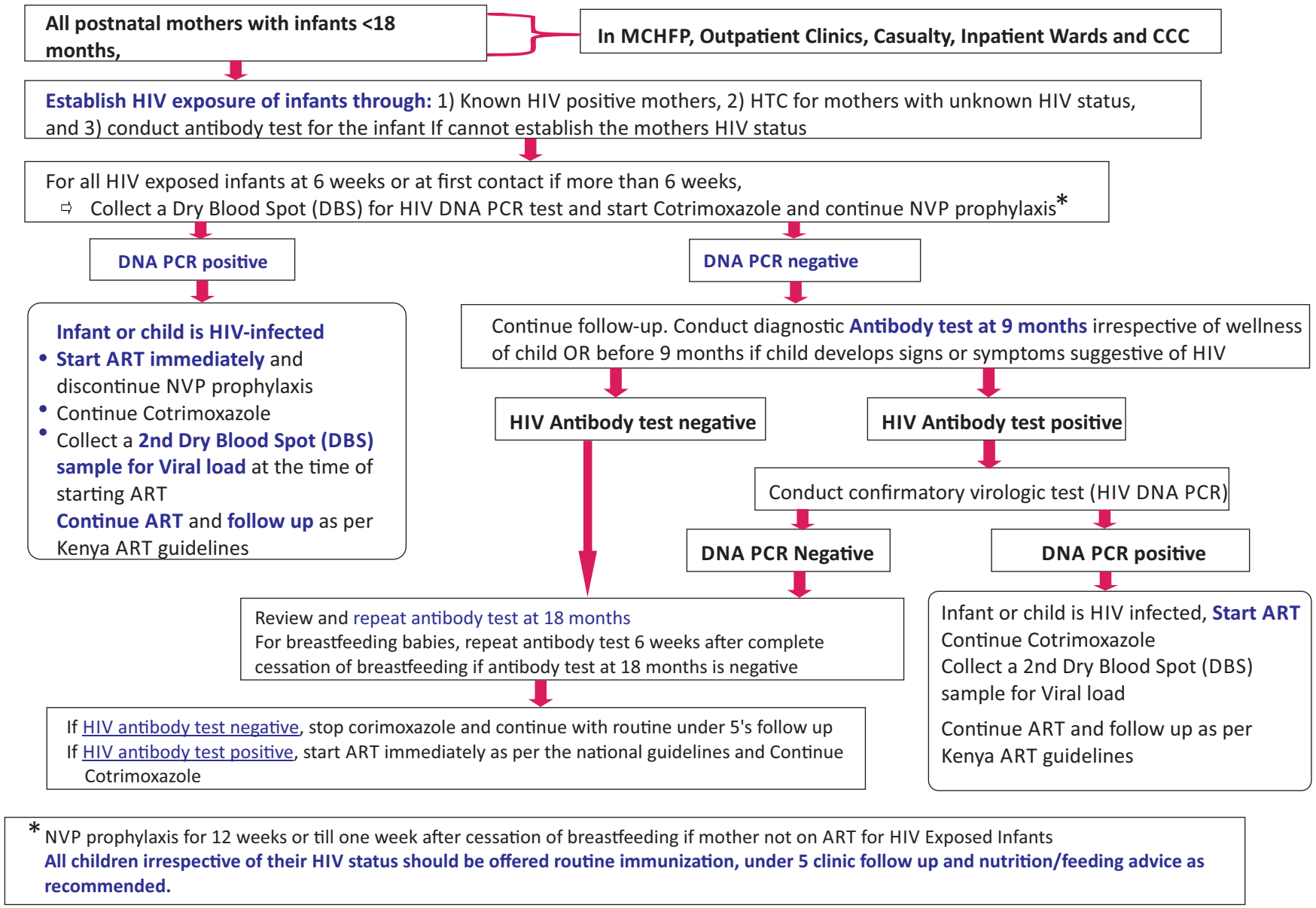


* NVP prophylaxis for 12 weeks or till one week after cessation of breastfeeding if mother not on ART for HIV Exposed Infants

All children irrespective of their HIV status should be offered routine immunization, under 5 clinic follow up and nutrition/feeding advice as recommended.

Diagnosis of Severe HIV Disease in Children under 18 months

Occasionally, children less than 18 months of age will present to healthcare facilities with severe disease suggestive of HIV infection. In some cases lack of immediate availability virologic test for confirmation of HIV infection could result in undue delay in instituting life-saving ART.

In such cases, **a presumptive diagnosis of severe HIV disease** should be made based on the criteria in Table 1.1 below, and prompt ART initiated.

Table 1.1 Presumptive Diagnosis of Severe HIV Disease in Children under 18 months

Presumptive Diagnosis of Severe HIV Disease in children less than eighteen months old where virologic confirmation of HIV infection is not readily available
Child < 18 months of age; HIV antibody test positive and **symptomatic** with: 2 or more of the following: · Oral candidiasis/thrush · Severe pneumonia · Severe sepsis OR An AIDS Defining Condition * Other factors that support the diagnosis of clinical stage 4 HIV infection in this infant are recent maternal death or advanced HIV disease in mother; and/or Child's CD4% <20% * AIDS defining conditions include any of the diseases listed in the WHO Clinical Stage 4
HIV Diagnosis for children < 18 months with presumptive diagnosis of severe HIV disease should be confirmed using HIV DNA PCR (or serological tests for children >18 months of age) as soon as is feasible.

Figure 1.2 HIV testing algorithm

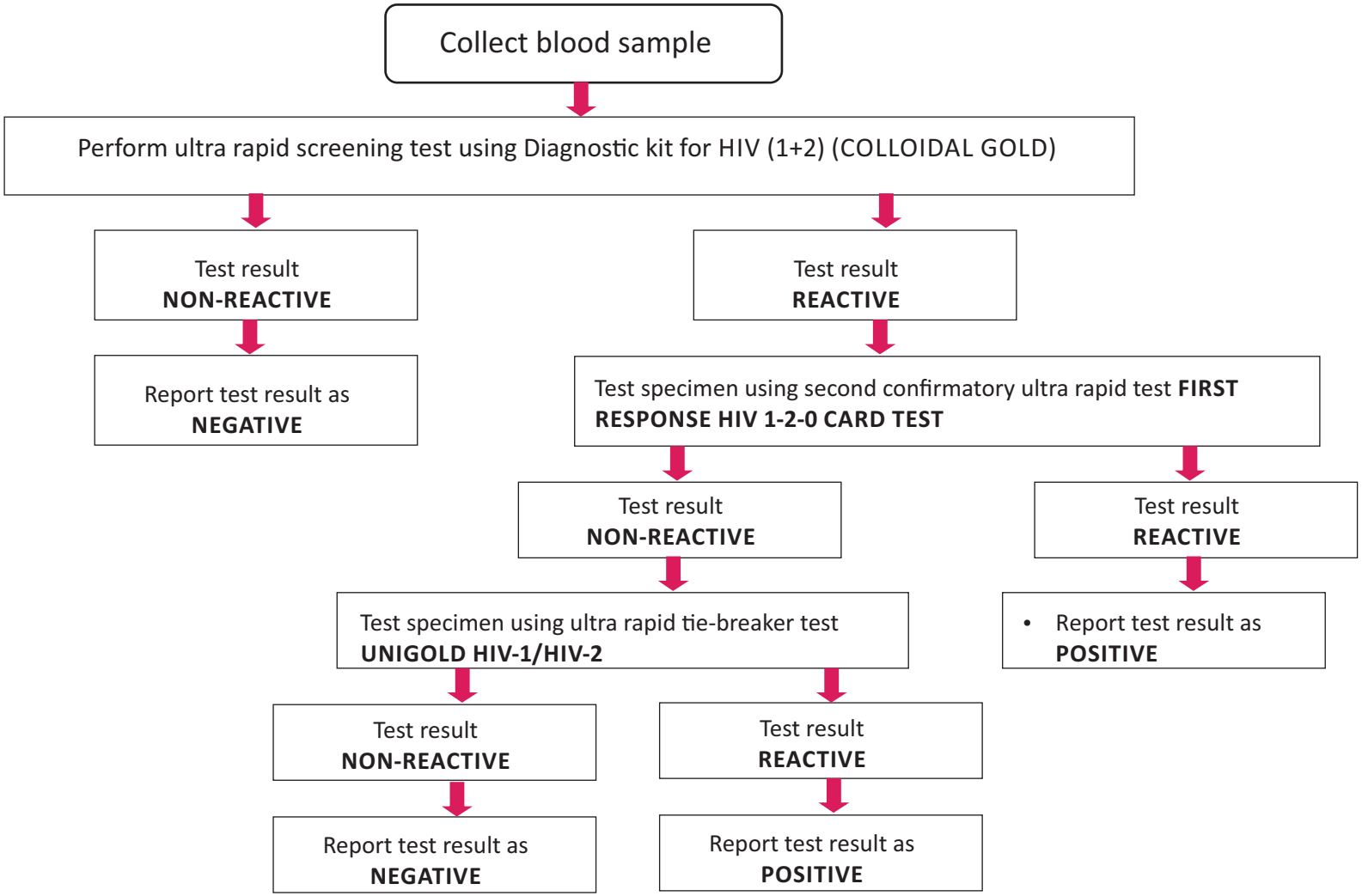


Table 1.2 WHO clinical staging of HIV infection

Children	Adolescents and adults
Clinical stage 1	
Asymptomatic Persistent generalized lymphadenopathy (PGL)	Asymptomatic Persistent generalized lymphadenopathy (PGL)
Clinical stage 2	
Unexplained persistent hepatosplenomegaly Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis) Herpes zoster Lineal gingival erythema Recurrent oral ulcerations Papular pruritic eruptions Fungal nail infections Extensive wart virus infection Extensive molluscum contagiosum Unexplained persistent parotid enlargement	Moderate unexplained weight loss (< 10% of presumed or measured body weight) Minor mucocutaneous manifestations (seborrheic dermatitis, popular pruritic eruptions, fungal nail infections, recurrent oral ulcerations, angular cheilitis) Herpes zoster Recurrent upper respiratory tract infections (sinusitis, tonsillitis, bronchitis, otitis media, pharyngitis)

Children	Adolescents and adults
Clinical stage 3	
Unexplained moderate malnutrition not adequately responding to standard therapy	Unexplained severe weight loss (over 10% of presumed or measured body weight)
Unexplained persistent diarrhoea (14 days or more)	Unexplained chronic diarrhoea for longer than one month
Unexplained persistent fever (above 37.5 oC, intermittent or constant, for longer than one month)	Unexplained persistent fever (intermittent or constant for longer than one month)
Persistent oral Candidiasis (after first 6 weeks of life)	Persistent oral candidiasis
Oral hairy leukoplakia	Lymph node TB
Lymph node TB	Oral hairy leukoplakia
Pulmonary TB	Pulmonary tuberculosis
Acute necrotizing ulcerative gingivitis/periodontitis	Severe bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)
Unexplained anaemia (<8.0 g/dl), neutropenia (<0.5x109/L) or chronic thrombocytopenia (<50 x 109/L)	Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
Severe recurrent bacterial pneumonia	Unexplained anaemia (below 8 g/dl), neutropenia (below 0.5 x 109/l) and/or chronic thrombocytopenia (below 50 x 109 /l)
Symptomatic lymphoid interstitial pneumonitis	
Chronic HIV-associated lung disease including bronchiectasis	

Children	Adolescents and adults
Clinical stage 4	
Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy	*Conditions where a presumptive diagnosis can be made using clinical signs or simple investigations:*
Pneumocystis pneumonia	HIV wasting syndrome
Recurrent severe bacterial infections (e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)	Pneumocystis jirovecipneumonia (PCP)
Chronic herpes simplex infection; (orolabial or cutaneous of more than one month's duration, or visceral at any site)	Recurrent severe bacterial pneumonia (≥ 2 episodes within 1 year)
Oesophageal candidiasis (or candiadisis of trachea, bronchi or lungs)	Cryptococcal meningitis
Extrapulmonary TB	Toxoplasmosis of the brain
Kaposi sarcoma	Chronic orolabial, genital or ano-rectal herpes simplex infection for > 1 month
Cytomegalovirus (CMV) infection; retinitis or CMV infection affecting another organ, with onset at age more than 1 month	Kaposi's sarcoma (KS)
Central nervous system toxoplasmosis (after the neonatal period)	HIV encephalopathy
HIV encephalopathy	Extra pulmonary tuberculosis (EPTB)
Extrapulmonary cryptococcosis including meningitis	***Conditions where confirmatory diagnostic testing is necessary:***
	Cryptosporidiosis, with diarrhoea > 1 month
	Isosporiasis
	Cryptococcosis (extra pulmonary)
	Disseminated non-tuberculous mycobacterial infection

Children	Adolescents and adults
Clinical stage 4 - continued	
Disseminated non-tuberculous mycobacterial infection	Cytomegalovirus (CMV) retinitis or infection of the organs (other than liver, spleen, or lymph nodes)
Progressive multifocal leukoencephalopathy	Progressive multifocal leucoencephalopathy (PML)
Chronic cryptosporidiosis (with diarrhoea)	Any disseminated mycosis (e.g. histoplasmosis, coccidiomycosis)
Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidioidomycosis, penicilliosis)	Candidiasis of the oesophagus or airways
Chronic isosporiasis	Non-typhoid salmonella (NTS) septicaemia
Lymphoma (Cerebral or B cell non-Hodgkin)	Lymphoma cerebral or B cell Non-Hodgkin's
HIV-associated cardiomyopathy or nephropathy	Lymphoma
	Invasive cervical cancer
	Visceral leishmaniasis
	Symptomatic HIV-associated nephropathy or HIV associated cardiomyopathy

For children younger than 5 years, moderate malnutrition is defined as weight for height <-2z score; or upper arm circumference ≥ 115mm to < 125mm: severe wasting is defined as weight for height-for age <3 z-score, stunting is defined as length for age/height for age <-2z score and severe acute malnutrition is defined as either weight for height <-3 z-score or mid-upper are circumference <115 mm or the presence of oedema.

SECTION 2

Essential Package of care for HIV exposed Infants, HIV Infected Children, Adolescents and Adults

All HIV - infected children, adolescents, and adults in HIV care should be offered a comprehensive package of services irrespective of ART status.

Table 2.1 Essential Package of Care for HIV-exposed and the HIV-infected child

There are two groups of children with respect to HIV infection: **(a) HIV-exposed children - children born to HIV-infected mothers but whose HIV status is not yet known** **(b) HIV-infected children - children whose HIV infection is confirmed**
Eight steps of care for all children irrespective of HIV status
1. Early infant diagnosis (early testing for HIV infection) by HIV DNA PCR and HIV antibody tests 2. Health education and counseling of the child's caregiver on: • Infant feeding • Immunization • Childhood and HIV-related disease symptoms • Adherence counselling including need for regular follow-up 3. Preventing opportunistic infections through the use of immunization, co-trimoxazole and isoniazid prophylaxis 4. Monitoring of growth and development 5. Immunization 6. Nutritional care; assessment, counselling, supplementation and support 7. Regular presumptive de-worming every 6 months 8. Regular follow-up, with a clearly communicated follow up schedule starting at birth; then weeks 2, 6, 10, 14 and weeks of age, then monthly in the first year, every 3 months in second year, 6 monthly thereafter or at least annually till age 5 years and on regular basis for all HIV-positive children. **Additional services for HIV-infected children** • Staging of HIV disease (clinical and immunological) • Psychosocial assessment and counselling and to emphasize on disclosure • Screening and prompt treatment of infections including opportunistic infections • Counselling for and providing antiretroviral therapy

Immunisation

All HIV-exposed infants and children should receive immunizations according to the recommended DVI schedule.

The following modifications in immunization are required in HIV exposed infants and those confirmed with HIV infection

i. Measles - HEI and HIV infected infants should receive their first measles vaccination at 6 months of age; and a second dose given at 9 months or as soon as possible thereafter; unless they are severely immuno - compromised i.e. CD4% < 25%.
ii. BCG should be given to all HIV-exposed infant at birth. However, for those who are severely immunocompromised, BCG should not be given.

Vaccination schedule for HIV exposed and infected children

Age	Vaccine
Birth	OPV, BCG
6 weeks	Pentavalent, OPV, PCV10, Rota 1
10 weeks	Pentavalent, OPV, PCV10, Rota 2
14 weeks	Pentavalent, OPV, PCV10
6 months	Measles
9 months	Measles

Nutrition

Essential Nutrition Actions (for all infants and children)

- Infants should be exclusively breastfed from immediately after birth through six months of age. Breastfeeding should be frequent and on-demand, day and night.
- Complementary solid food (to breast milk) should be introduced from six months of age but breastfeeding should continue on demand.
- For sick infants and children additional feeding is necessary to recover nutritional status during and after illness. Infants and children require adequate micronutrient intake, particularly in the case of vitamin A, iron, iodine and zinc

Table 2.2 Essential Package of Care for the HIV-infected adolescents

1	Confirmation and documentation of HIV Infection
2	Take a complete medical and social history including prenatal, birth and family history.
3	Educate on Basic facts of HIV & AIDS, Sexuality, developmental changes, Primary and secondary abstinence and safer sex practices
4	Enquire on disclosure of HIV to the adolescent (for perinatal infected) or disclosure to others for behaviorally infected and also inquire HIV status for father, mother and siblings
5	Identify concomitant medical conditions (for example, hepatitis B or C infection, other co-infections or OIs, pregnancy)
6	Enquire about medication use , including contraceptive use, traditional therapies; Cotrimoxazole and ARVs
7	Assess development as appropriate for age & sex using Tanner's staging. Do physical examination including STI screening if sexually active
8	Review immunization status of adolescent and ensure that it is up to date. Educate on HPV and HBV vaccination (where available)
9	Prevent, diagnose, and treat concomitant conditions and opportunistic infections, e.g TB, diarrhea, malaria, and pregnancy etc
10	Assess WHO clinical stage and determine ART eligibility. If eligible prepare and start ART.
11	Schedule indicated laboratory tests e.g. CD4, tests for monitoring toxicities, viral load as appropriate
12	Carry out mental health screening and refer for additional mental health care if necessary
13	Assess growth and nutrition (weight, height) as appropriate for age and sex
14	Provide Sexual and Reproductive Health Services including information, screening, diagnosis, treatment, counseling.
15	Where applicable, carry out a Gender Based Violence (GBV) screening and offer/refer for counseling and care if necessary
16	Conduct psychosocial assessment and plan for long term care. Discuss Positive Living i.e. Positive Health, Dignity & Prevention (PHDP).
17	Reinforce and support adherence to ART. Advice on nutrition, when to seek medical care and medication side effects.
18	Provide education & support for family members and/or partner. Schedule next visits (be flexible to accommodate schooling)

Figure 2.1 Adolescent transition to adult care algorithm

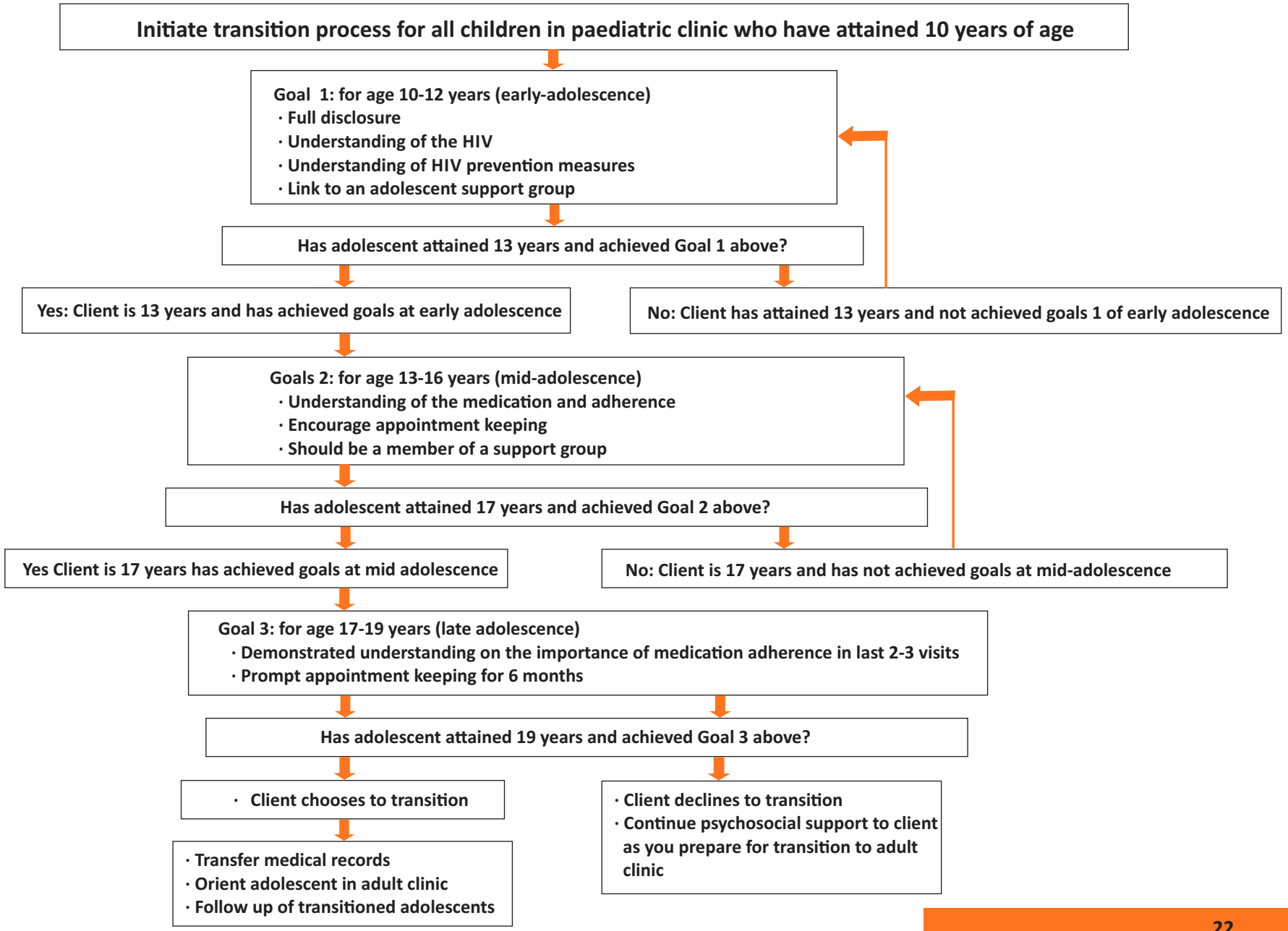


Table 2.3 Adolescent transition template

1	**Steps to facilitate transition process**	**Suggested activities to facilitate the transition process**	**Comments**
		Discuss transition during adolescent support group meetings and group health education sessions	
		Discuss transition during clinical check ups and individual counseling sessions with adolescent clients	
		Discuss transition with caregivers, during group or individual sessions	
2	**Encourage increasing responsibility for his or her own health care management**	Ensure the adolescent understands his or her own health condition, care plan, and medications	
		Talk about transition and transfer to the adult clinic, discuss expectations, and answer any questions	
		Talk to adolescents about general coping, positive living, and building supportive relationships	
		Give caregivers an opportunity to discuss their feelings about transition and any concerns about having a less active role in the adolescent's care	
3	**Assess client's ability to make independent health care decisions, assess readiness for the transition and determine additional support needs**	Assess client's understanding of own care and transition process	
		Assess caregiver's understanding of clients care and transition process	
		Encourage the adolescent to make their next appointment and to refill their medications on their own	
		Initiate any needed referrals, including to support groups	

Adolescent transition template

		Suggested activities to facilitate the transition process	Comments
4	**Provide continuing guidance during the transition process**	Review plans for continued adherence to care	
		Review adherence to medicines and ensure the client has, and knows how to use, and keep track of doses	
		Ensure client knows where to access help/assistance, if he or she has questions about the adult clinic	
5	**Implement the transfer to an adult clinic**	Transfer medical records to adult clinic	
		Transfer the adolescent to the adult clinic (where applicable)	
		Discuss the adolescent's care with healthcare workers at the adult clinic, (where applicable)	
		Provide orientation to the adolescent in the adult clinic	
		Follow up after the transfer •Schedule a follow-up visit with the adolescent, •Encourage Peer Educators to visit the adult clinic and talk with newly transitioned adolescents	

Table 2.4 Essential Package of Care for the HIV-infected adults

1	Confirmation and documentation of HIV Infection
2	Take a complete medical, social and family history.
3	Enquire about disclosure of HIV to the sexual partner/s
4	Identify concomitant medical conditions (for example, hepatitis B or C infection, other co-infections or OIs, pregnancy)
5	Enquire about medication use , including contraceptive use, traditional therapies;
6	Cotrimoxazole and ARVs
7	Conduct physical examination, including STI screening
8	Review immunization status. Ensure that immunization is up to date and educate on HPV (where available) and HBV vaccination.
9	Prevent, diagnose, and treat concomitant conditions and opportunistic infections, including TB, diarrhea, malaria etc
10	Assess WHO clinical stage. If not on ART, determine whether the adult meets criteria for ART initiation. If already on ART, determine if any new Stage 3 or 4 events have occurred since ART was initiated.
11	For those eligible for ART, prepare for ART initiation
12	Schedule indicated laboratory tests e.g. CD4, tests for monitoring toxicities, viral load as appropriate
13	Carry out mental health screening and refer for additional mental health care if necessary
14	Assess nutrition status (weight, height, BMI for all and MUAC for pregnant women)
15	Provide Sexual and Reproductive Health (SRH) services e.g family planning, STIs and pregnancy
16	Where applicable, carry out a Gender Based Violence (GBV) screening and refer for counseling and care if necessary
17	Conduct psychosocial assessment , plan for/provide long-term HIV care and follow up including community support
18	Discuss Positive Living i.e. Positive Health Dignity and Prevention (PHDP)
19	Advise and guide (reinforce and support adherence to ART and/or cotrimoxazole, IPT, nutrition, when to seek medical care, medication side effects, as appropriate.
20	Provide education, care, and support for family members and/or partner
21	Continuum of care-schedule next visit, provide flexible follow up dates

Table 2.5 Immunization and nutrition for adolescents and adults

Immunization:
i. All HBsAg negative PLHIV should receive three doses of anti-HBV vaccination ii. Where resources permit, response to the vaccine should be assessed with hepatitis B surface antibody (anti- Hbs) testing after three doses of HBV vaccine. If the vaccine response is suboptimal, revaccination with three doses of standard or double-strength HBV vaccine should be considered when the person shows an adequate immune response (e.g., CD4 count >200 cells/mm3 iii. Pneumococcal polysaccharide vaccine may be considered for people with HIV in WHO Clinical Stage 1 or, if CD4 testing is available, with a CD4 count > 500 cells/mm3 iv. PLHIV should be encouraged to receive annual influenza vaccination with the inactivated subunit influenza vaccine v. The yellow fever vaccine should not be given to PLHIV in WHO Stage 3 or 4 disease or with a CD4 cell count below 200/mm3. The vaccine can be given to PLHIV in WHO Stage 1 or 2 disease if the benefits of vaccination outweigh the risks (i.e necessary travel to an area with a yellow fever epidemic or where the disease is endemic).
Nutrition
• At the initial assessment and at regular intervals thereafter, all PLHIV should receive a full nutritional assessment (weight, height, BMI, mid-upper arm circumference, symptoms related to appetite, nausea, difficult in swallowing, diarrhoea, food drug interactions and adequacy of food intake). • Clinically malnourished individuals (BMI < 18.5) should receive therapeutic and supplementary feeding support until their BMI is above 18.5. • Care and treatment programs should link patients to community organizations and programmes that will help them achieve household food security. • PLHIV should be provided with daily micronutrient supplement (appropriate multivitamin preparation); unless their diets are determined to be adequate and diversified. The standard recommendations for nutrient intake and nutritional support for pregnant and lactating women should be followed.

Cotrimoxazole Preventive Therapy

Cotrimoxazole is an effective prophylactic agent against a broad range of conditions and organisms including toxoplasmosis, PCP, common bacterial infections, sepsis, diarrhoea and malaria.

- All HIV exposed children (born to HIV positive mothers) should be started on CPT from age of 4-6 weeks, or at first visit to a health facility thereafter unless contraindicated.
- CPT should be continued until HIV infection has been excluded and the child is no longer at risk of acquiring HIV infection through breast milk.
- All HIV infected adults, adolescents and children should be started on cotrimoxazole soon after the diagnosis of HIV infection and continued for life.
- Dapsone is recommended for patients who cannot tolerate cotrimoxazole; it is effective against only PCP when used alone It should be discontinued once the Cd4 has been > 200 cells for adults and children greater than 5 years of age or age specific threshold for severe immuno-defeciency for children under 5 years

Table 2.6 Dose for Prophylactic Cotrimoxazole

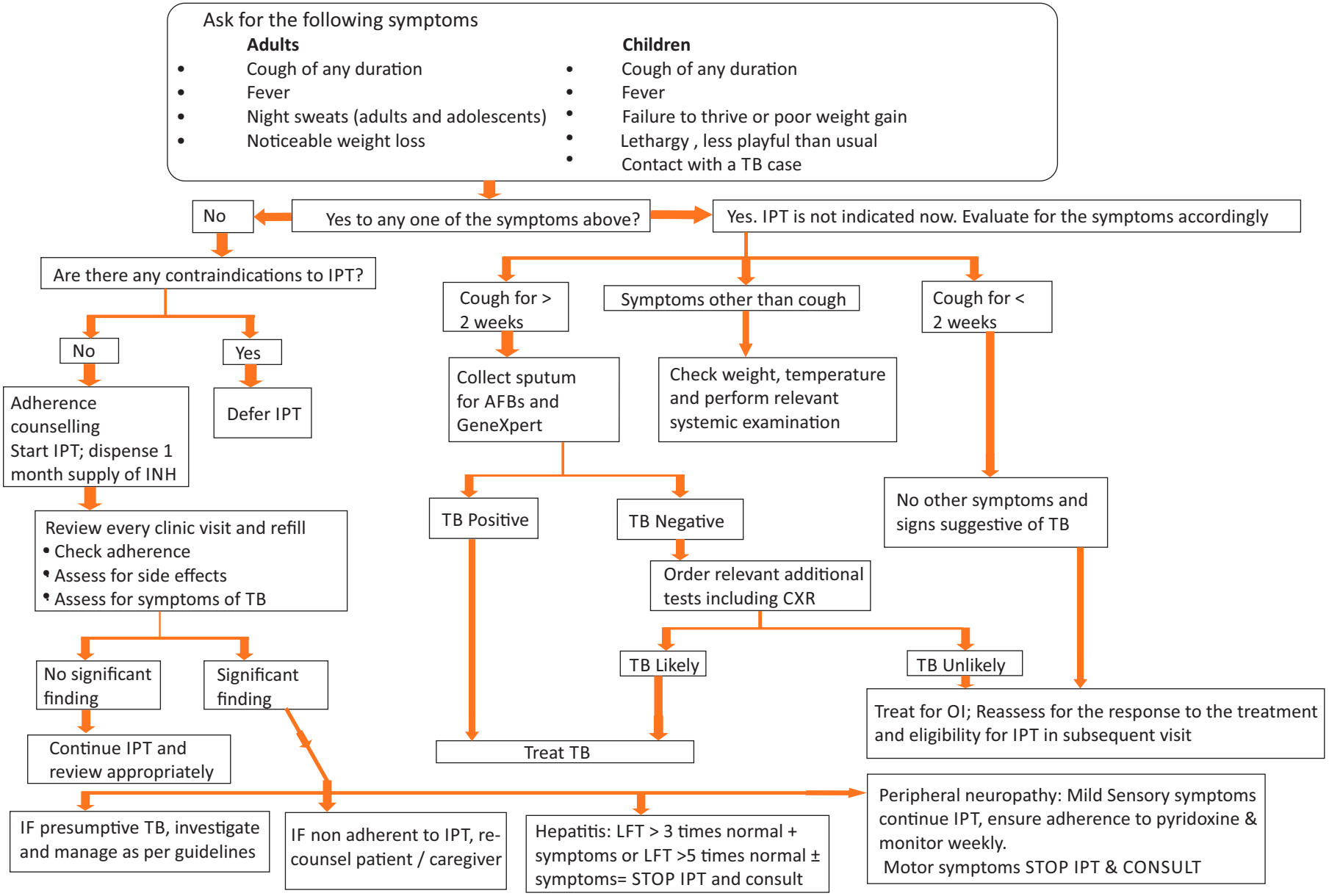
Weight (kg)*	Suspension 240 mg per 5ml	Single strength tablet 480mg (SS)	Double strength tablet 960mg (DS)
1 – 4	2.5 ml	¼ SS tab	--
5 – 15	5 ml	½ SS tab	¼ DS tab
17 – 30	10 ml	1 SS tab	½ DS tab
> 30 (Adults and adolescents)	-	2 SS tabs	1 DS tab

Give appropriate formulation based on weight

Dose of dapsone

- Available as 25 mg and 100 mg tabs
- Children: 4mg /kg per week OR 2 mg/kg once daily; maximum dose is 100 mg.

Figure 2.2 Screening for TB and INH preventive therapy in Children, Adults and adolescents algorithm



Contraindications to IPT

- Active tuberculosis disease
- Signs and symptoms of peripheral neuropathy (persistent tingling, numbness burning sensations in limbs
- Active hepatitis
- Poor adherence to Cotrimoxazole Preventive Therapy or poor understanding of IPT by guardian

Use of GeneXpert

GeneXpert is a molecular diagnostic test for TB disease that can detect *Mycobactrium tuberculosis* DNA and Rifampicin resistance from sputum specimen in less than 2 hours. GeneXpert is increasingly available in Kenya in the public health sector and is now recommended for TB diagnosis.

This technology is more sensitive than sputum microscopy in detecting TB.

Indications for GeneXpert

1. TB Diagnosis

- HIV positive with TB symptoms
- Children under 15 years with TB symptoms
- All smear negative TB cases

2. MDR TB surveillance

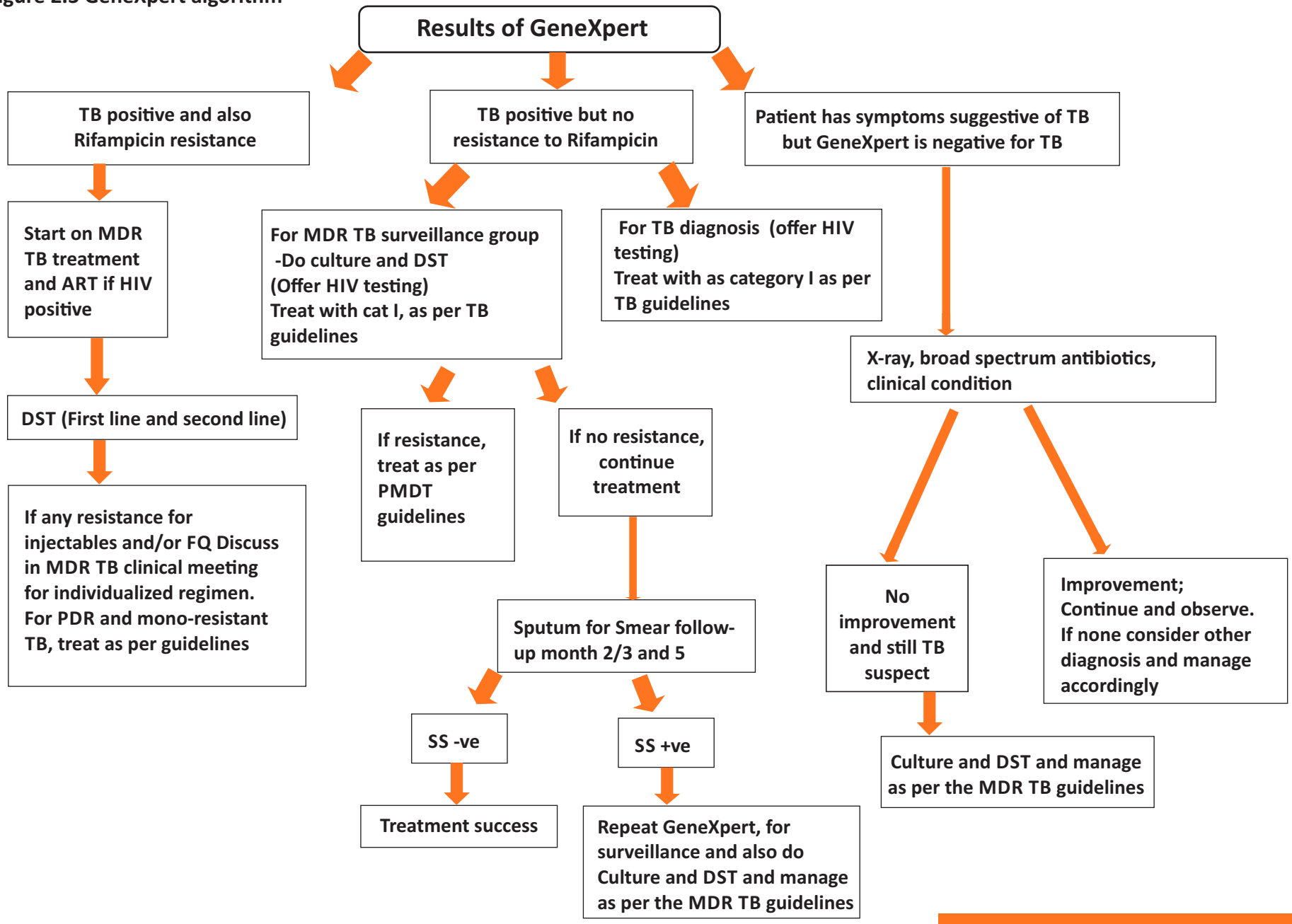
All previously treated patients: a. failures; b. relapses; c. treatment after loss to follow up

- DR TB contacts
- Healthcare workers with TB symptoms
- Patients who develop TB on IPT
- Refugees with symptoms of TB
- Smear positive at 2 months
- Prisoners with TB symptoms

In areas where GeneXpert is available: this should be the first test

Patients diagnosed with GeneXpert should be followed up with microscopy

Figure 2.3 GeneXpert algorithm



Isoniazid Preventive Therapy

It is critical to ensure that active TB is confidently ruled out to avoid inadvertent mono-therapy with Isoniazid in patients with undiagnosed TB, potentially leading to drug resistance.

Indications for IPT

1. HIV-infected children less than 12 months of age who have had recent contact with sputum positive TB disease with no evidence of TB
2. All PLHIV above 12 months of age who screen negative for TB using the ICF tool
3. All children under 5 years irrespective of HIV status who had recent close contact (past 12 months) of sputum positive TB case

Note:

- Past history of TB and current pregnancy are not contraindications for starting isoniazid preventive therapy.
- IPT can be started at any time after successful completion of TB treatment.
- IPT has not been shown to increase the risk of developing isoniazid-resistant TB.

Dose and duration of INH for IPT

IPT should be given at dose of 10 mg/kg/day (maximum 300 mg/day) for 6 months. Those who are on IPT should also be given pyridoxine.

Table 2.7 Dose of Isoniazid for IPT

Weight (kg)	Dose in mg	Number of 100mg INH tablets	Number of 300mg (Adult) tablet
<5	50	½ tablet	-
5.1-9.9	100	1 tablet	-
10-13.9	150	1 ½ tablet or ½ adult tablet	½
14-19.9	200	2 tablets	-
20-24.9	250	2 ½ tablets	-
>25	300	3 tablets 0r 1 adult tablet	1
Adults	300	3 tablets 0r 1 adult tablet	1

Table 2.8 Dosing chart for Pyridoxine

Weight (kg)	Number of tablets of pyridoxine (50mg)
5-7	(1/4) Quarter tablet daily
8-14	(1/2) Half tablet daily
15 and above	(1) One full tablet daily

2.7.1 Follow-up of patients on IPT

All patients on Isoniazid preventive therapy should be:

- Reviewed regularly and messages of adherence continuously reinforced
- Screen for TB disease during each clinic visit using intensive case finding (ICF/IPT) form
- Administer INH together with pyridoxine
- Monitor for INH adverse effects

The facility should maintain a TB contact invitation register.

Table 2.9 Physical examination checklist

All patients should be comprehensively evaluated using clinical assessment and physical examination at all clinical visits.

Important components in the Physical Examination include the following but are not limited to;

Vital signs	• Measure and record vital signs, body weight, height, BMI, pulse oximetry
General appearance	• Look out for weight loss, wasting, mood (depression, anxiety, anger), discomfort, pain
Skin	• Look for skin lesions including PPE, seborrheic dermatitis, herpes simplex and herpes zoster, nodules of Kaposi's sarcoma
Lymph nodes	• Lymph node enlargement particularly asymmetrical or rapidly enlarging lymph nodes which require tests such as FNA or biopsy
Mouth	• Oral exam to look for opportunistic infections (OIs) such as oral candidiasis, oral hairy leukoplakia, purple nodes indicative of Kaposi's sarcoma, cracking at the corners of the mouth (angular cheilitis), gum disease, dental caries
Systemic examination	• Look for signs of respiratory, cardiac, neurologic disease and in abdomen for organ enlargement and ascites
Ano-genital system	• Examine the genitalia and anus for ulcers, sores, urethral discharge, condylomata (genital warts) or Kaposi's lesions • Female patients require cervical cancer using VIA/VILLI method as per reproductive health guidelines

All patients should be comprehensively evaluated using clinical assessment and physical examination at all clinical visits.

Table 2.10 Laboratory assessment

Test	Remarks
HIV test	A historically documented HIV antibody test is sufficient to register a client into care and treatment. In the absence of a documented, confirmed HIV antibody test, testing prior to commencing entry into care or ART is recommended.
Hb	For patients receiving AZT, estimation of haemoglobin level is recommended prior to commencing AZT and at weeks 4, 8 and 12, and as required thereafter.
ALT	Baseline ALT is required in patients at risk of liver disease or hepatotoxicity such as those with hepatitis B or TB co-infection, when NVP is part of first-line regimen and in women starting a NVP-containing regimen with a baseline CD4 cell count > 250 cells/mm3.
Creatinine	Baseline creatinine should be done if available. NRTIs require dose adjustment in case of impaired renal function.
Pregnancy Test (PT)	Should be done in all women of reproductive age (15-49 years).
Urinalysis	Should be available to all PLHIV on entry into care and on follow-up as clinically indicated
Fasting Lipid Profile & Glucose	Fasting lipid profile and glucose are recommended at baseline and annually thereafter when PIs are to be used
CD4 count	Baseline CD4 is indicated for all HIV - infected people on entry into care. In asymptomatic or mildly symptomatic to determine ART eligibility (WHO Stages 1 & 2) patients, it should be done every six months.
Viral Load	Not recommended for ART initiation but should be done for ART monitoring

Table 2.11 Plan after initial evaluation

1. Diagnosis and treatment of OIs take priority
2. Assign WHO Clinical Stage (1, 2, 3 or 4)
3. Ensure that cotrimoxazole prophylaxis is continued.
4. Provide Isoniazid Preventive Therapy (IPT) as per the guidelines.
5. Provide routine immunization unless contraindicated
6. Provide nutritional counselling and support
7. Offer ongoing adherence counselling
8. Agree on follow-up plan and preparation for ART

2.9.1 Psychosocial assessment

The goal of psychosocial assessment and preparation of PLHIV for ART is to:

- Begin the process of empowering the patient/care giver through education and support.
- Address the patient's/care giver concerns as a result of a diagnosis of HIV infection.
- Educate the patient/care giver on HIV infection, disease progression and its management.
- Discuss with the patient/care giver about disclosure and its benefits.
- Discuss and offer the patient/care giver opportunity to join local support organizations.
- Identify (and support the patient in addressing) any factors in the patient's family and social. circumstances that may impact negatively on patient's health and ART outcome.
- Provide adherence education and counselling, and develop mechanisms to ensure high-level adherence.

- Ensure patient is ready, willing and able to start and continue with ART if clinically indicated.
- The initial psychosocial assessment and preparation often takes 2-3 sessions and should be started at the earliest opportunity possible.
- ALL members of the comprehensive care team should carry out psychosocial assessment and offer appropriate support.
- Psychosocial assessment can be offered at triage, consultation, pharmacy or any other clinic station as long as the conditions for privacy and confidentiality are met and providers are appropriately trained.
- Always assess patients/care givers (CG) understanding and knowledge before giving further information.

Guide on patient counseling and education for care and treatment

HIV infection

HIV disease:

- HIV attacks the immune system & weakens the body's defences against infection.Opportunistic infections: OIs occur when body's defences are weak – most are treatable; treatment is best started early, so "you should go/child should be taken to a health care facility early".

Cd4 counts or percent:

- This is a measure of the strength of the immune system or body's defences; inform patients/care giver of CD4 results to encourage self-management

Disclosure:

- Discuss importance of disclosure to a family member/friend to provide ART &psychosocial support as well as enable testing of contacts.
- Disclosure to responsible school staff may be essential for children reliant on them for continued care

Management plan:

- Discuss treatment & follow up plan; ensure patient/care giver understands, consents to & is ready to support its implementation
- Respond to any questions patient may have

ART

Goals & effects of ART

- ART allows immune system to recover, reducing incidence of OIs thus reducing illness and likelihood of death.
- ART improves quality of life & longevity.

Duration of Treatment

- ART is lifelong and should adhere to it
- Children should be supported to take lifelong medication to improve quality of life.

ARV Drugs

- ARVs are lifesaving drugs & the patient's health depends on their taking them or in the case of the child, being given them every day at the right time as prescribed & agreed to by patient/CG.
- They do NOT cure HIV
- ARVs do NOT prevent HIV transmission; sexually active patients must use condoms correctly & consistently
- Avoid alcohol, herbal drugs, and self-treatment as they may interact with other drugs which may result in their not working:

ARV drug regimen

- Discuss regimen chosen for the patient.
- Explain about fixed dose combination (FDC) & the constituent drugs.
- Demonstrate with actual ARVs how patient should take them. For child living with HIV, it is essential that care giver understands & demonstrates how to measure out & dispense the drugs.
- Ensure patient/care giver knows about food requirements of ARVs where necessary & how to disguise unpleasant taste of some of the ARVs, especially for children

Side effects (Adverse Drug Reactions, ADRs) and what to do

- Reassure CG/parent or older child that children tolerate treatment very well
- For all patients, discuss predictable ADRs with reference to regimen chosen without alarming them
- Advise patient/care giver to come/bring patient to CCC for ADRs that warrant attention, e.g. rash, vomiting, abdominal pain, jaundice and painful feet

Adherence preparation

Importance of Adherence

- Link adherence to successful ART outcomes.
- Explain that high level adherence is essential to maintain adequate drug levels in the blood to keep killing new viruses and for ART to work well.
- Explain that missing doses even occasionally reduces the efficacy of ART and results in treatment failure with deterioration of health. (Ask – what are you going to do to ensure not missing your drugs? Discuss the importance of adherence to non-ART medication such as CTX or INH, anti-TB medication etc)

Review patient's willingness to start ART and/or CG's willingness to commit to supporting a CLHA to start ART

- Has the patient/care giver demonstrated ability to keep appointments, to adhere to other medications (e.g. CTX)?
- Has adult patient disclosed his/her HIV status? If not, encourage him/her to do so. Disclosure to at least 1 person who can be the treatment supporter is important; lack of disclosure should not be used to delay ART initiation.
- Does the patient want treatment & understand what this treatment is for?
- Is the patient/care giver willing and able to come for the required clinic follow-up?

If patient is not ready or willing to start (even if ART is indicated medically) defer & continue preparation; review in 1 month.
If a CG is not able to commit to the requirements of ART for a CLHA defer & review social situation.

Discuss arrangements of how patient/CG will come for appointments

do you live nearby? If not, how will you commute? Is this sustainable? Can you pay for transport?
Consider and discuss the option of a HCF nearer the patient's home if it offers ART.

Adherence preparation (continued)

Review proposed adherence promotion strategies

- Family, friend or CHW to remind them (treatment supporter or care giver should be identified and be educated on ART);
- Pill cues (e.g. put tablets next to toothbrush if you brush your teeth twice a day);
- Pill diary; alarm clock/ watch/phone.
- Review home, work or school situation to ensure permits adherence.
- Address any barriers to adherence, including pill storage, safety from violence

Community Links & Patient Support Groups.

Advise patient on community and facility based support groups and facilitate contact

Disclosure (adults and caregivers; involve caregiver when discussing disclosure with older child).

- Discuss the importance of disclosure especially to partners who may be at risk of continued exposure to HIV
- Disclosure to a treatment supporter (TS) may be crucial in ensuring adherence and in providing emotional support. For CLHA in (boarding) schools, disclosure to responsible school staff is often necessary to ensure child continues clinical care & ART
- Discuss, encourage, facilitate & record testing of exposed individuals in the family &/or among sexual contacts
  Fill family status card, update it & follow through with info on status of family members until all are tested & in care if needed

Clinic Adherence Support Tools

Fill ART DIARY & REGISTERS; fill and update "Patient Locator Card" – practical contact details for patient & identified TS, as well as community support organization they are attached to that can facilitate default tracing. Fill appointment card. Give appointment for commencing ART

Adherence preparation (continued)

Continuing Counseling and Support

- Always leave time for patients to raise issues of concern to themselves that may require counselling and support.
- Remember that it may take time for patients to be able to open up and freely discuss their problems.
- Patient education is a continuous process.
- Children should be educated from as early as possible, in an age appropriate way, according to their desire for & capacity to absorb the information.
- CG should be actively involved in the child's evolving education

Checklist to maximize Adherence

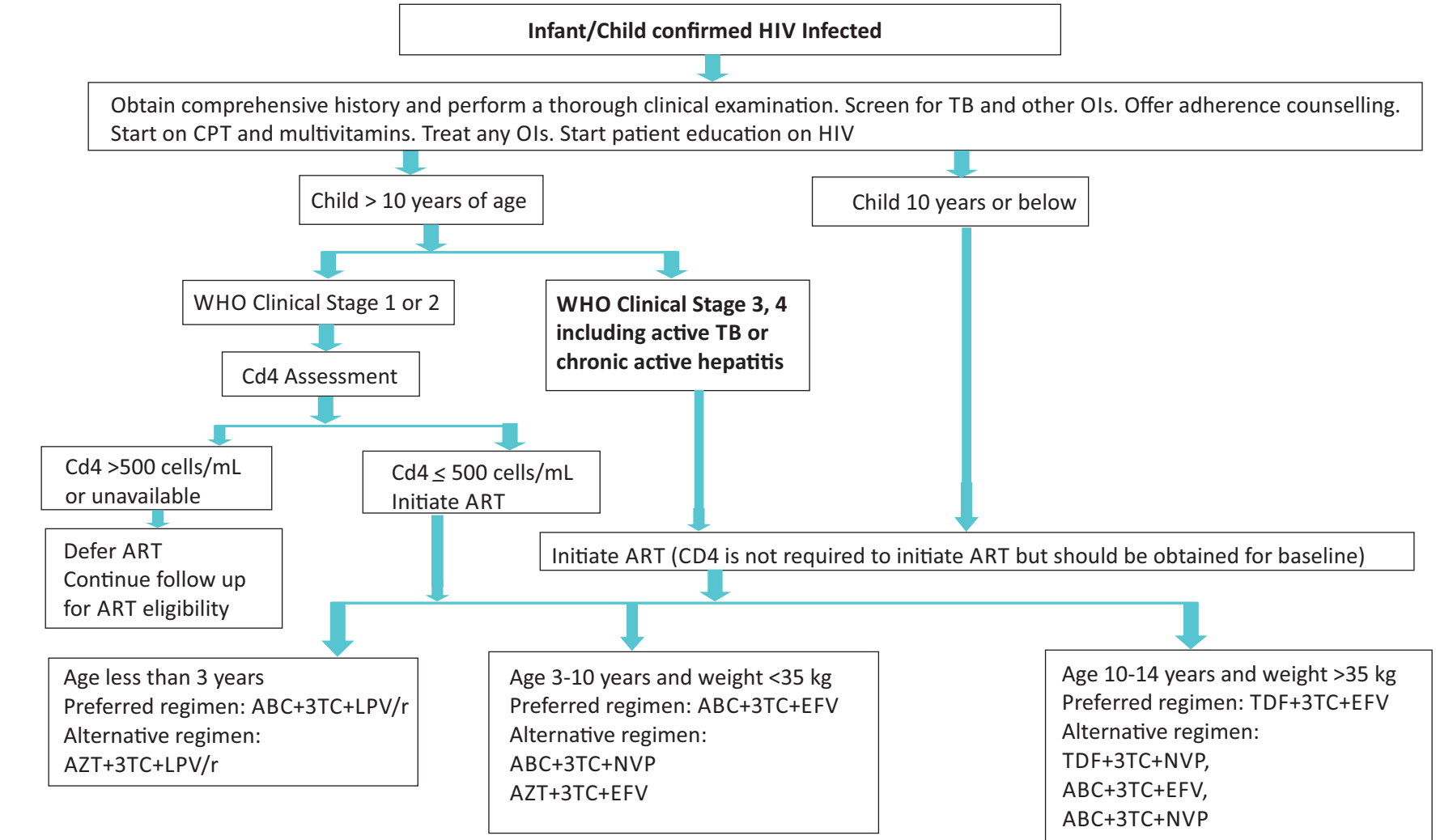
1. Patient/caregiver attended all scheduled preparation visits?
2. Patient/care giver prepared well before ART begins? Written information provided where useful?
3. Patient/care giver given information on and understands the benefits of ART?
4. Patient/care giver able to demonstrate how they will take/give child their ARVs?
5. Information about predictable and common side effects of intended regimen.
6. Patient/care giver knows what to do should common mild or serious side effects occur?
7. Has patient disclosed diagnosis? (Family members at risk, sexual contacts? Status of family/contacts at risk?)
8. Patient advised and encouraged to identify a treatment supporter, ideally a family member?
9. Patient informed of group sessions for education and counseling?
10. Patient locator information and contact details up to date?

Note: A thorough adherence review is mandatory and should include non-judgemental assessment of social and, where necessary, financial circumstances; to ensure future treatment success. However, it should be noted that even with good adherence levels, HIV drug resistance can occur due to selective pressure from ART and the immune system.

SECTION 3

Antiretrovial Therapy

Figure 3.1 When and what ART to start in children



An adolescent is a person aged 10 to 19 years

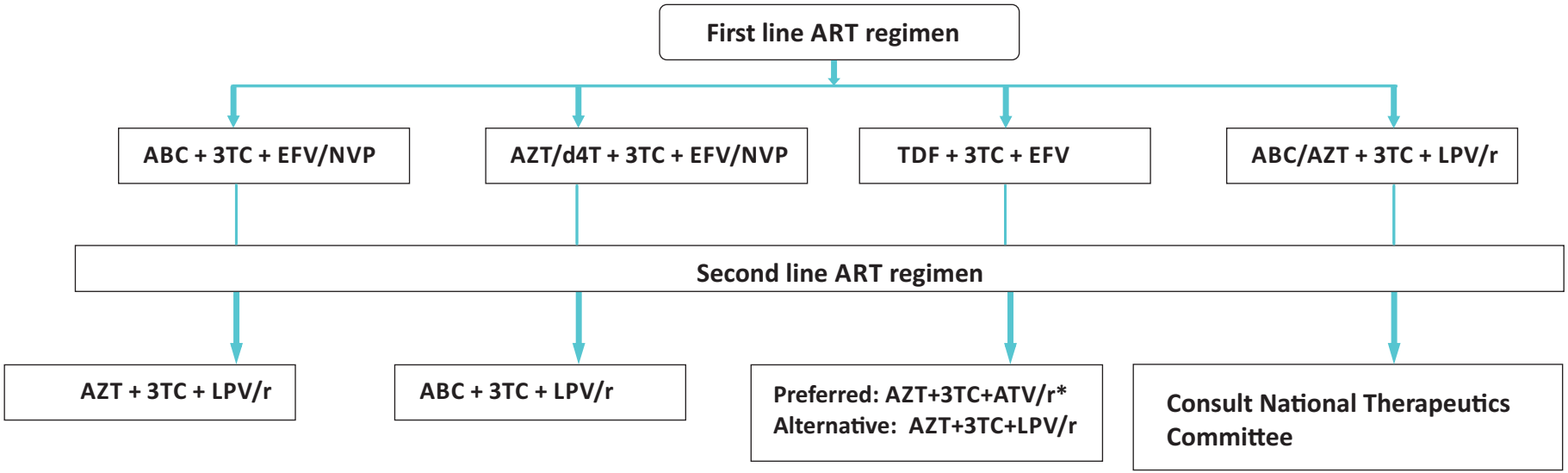
* Children less than 3 years who are not NVP exposed and are unable to tolerate Lopinavir/ritonavir can be substituted to an NNRTI based regimen

** Consider transitioning from ABC based regimen to a simplified once daily TDF/3TC/EFV based regimen in children if their weight remains consistently above 35kg (at least 2 readings, 1 month apart) for better adherence**. A viral load test should be conducted before any single drug substitution to rule out treatment**

Table 3.1 Definition of Treatment Failure in children

Clinical Failure • Disease progression: New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO stage 3 and 4 clinical condition with exception of TB) • Growth failure despite adequate nutritional support. • Progressive neuro-developmental deterioration.
Immunological Failure **Younger than 5 years age:** • Persistent CD4 levels < 200 cells/mm3 or < 10 % **Older than 5 years age:** • Persistent CD4 levels < 100 cells/mm3
Virological Failure • Virological failure is defined as persistent viral load above 1,000 copies/ml based on consecutive viral load measurements after 3 months with adherence support after 6 months of effective antiretroviral therapy (Refer to VL algorithm)

Figure 3.2 Second line ART in children algorithm



* Note
- Do not use ATV/r in children under 6 years of age.
- Children above 6 years of age can be given ATV/r but currently appropriate formulations are not available.
- Adult formulation of ATV/r 300 mg/100 mg can only be used in children weighing >40 kg.

3.3 Dosages of antiretroviral agents in children and use of Efivarenz in younger children

The US FDA has approved use of EFV in children 3 months and above and weighing more than 3.5 kg.
Currently in Kenya, use of EFV in children aged <3 years and weighing <10 kg is recommended ONLY in TB/ HIV co-infection management without prior exposure to NVP for PMTCT

Table 3.2 Efavirenz Dosing in Children

Weight (kg)	EFV dose (mg)* Tablets	Quantities
3.5 to 4.9	100	½ of the 200mg double scored tablet
5 to 7.4	150	¾ of 200mg double scored tablet
7.5 to 13.9	200	1 of the 200mg tablet
14 to 19.9	300	1 ½ of the 200mg double scored tablet
20 to 24.9	300	1 ½ tablet of the 200mg double scored tablet
25 to 34.9	400	2 of the 200mg tablets
35 and above	600	1 of the 600mg tablet

Table 3.3 Dosages of antiretroviral agents in children

Weight Range (kg)	Fixed dose combination			Single formulations where FDCs are not available					
	Abacavir (ABC) + Lamivudine (3TC)	Abacavir (ABC) + Lamivudine (3TC)	Abacavir (ABC) + Lamivudine (3TC)	Efivarenz (EFV)	Nevirapine (NVP) (use weight appropriate formulation)		Lopinavir/ Ritonavir (LPV/r)	Additional dosing for ritonavir for TB/HIV co-infection	
	TWICE Daily	TWICE Daily	TWICE Daily	ONCE Daily	ONCE daily for first 2 weeks then twice daily		TWICE Daily		
	60mg ABC + 30mg 3TC tablets	60mg ZDV + 30mg 3TC tabs	60mg ZDV + 30mg 3TC + 50mg NVP tabs	200mg EFV tabs	10 mg/ml suspension	200 mg tabs	LPV/r 80/20mg per ml solution	LPV/r 200/ 50 mg tabs	RTV liquid (80mg/ml as 90ml bottle)
3 - 5.9	1 tab	1 tab	1 tab	See notes	5 ml	-	1.5 ml	-	1 ml
6 - 9.9	1.5 tab	1.5 tab	1.5 tab	See notes	8 ml	-	1.5 ml	-	1 ml
10- 13.9	2 tab	2 tab	2 tab	1 tab	10 ml	0.5 tab	2 ml	-	1.5 ml
14- 19.9	2.5 tab	2.5 tab	2.5 tab	1.5 tab	15 ml	1 tab in am 0.5 tab in pm	2.5 ml	1 tab twice daily	2 ml
20- 24.9	3 tab	3 tab	3 tab	1.5 tab	15 ml	1 tab in am 0.5 tab in pm	3 ml	1 tab twice daily	2.5 ml
25- 34.9	300 + 150 mg	300 + 150 mg	300/150/ 200 mg	2 tab	-	1 tab	4 ml-	2 tab in am 1 tab in pm	4 ml in am & 2 ml in pm

Notes: Paediatric ARV drug dosing chart

Paediatric fixed dose combinations (FDCs) are available as ABC/3TC, AZT/3TC and AZT/3TC/NVP. All children requiring ART should be put on appropriate FDCs based on their weight.
ABC/3TC tablets - can be chewed or crushed or dispersed in water (5-15 ml) or onto a small amount of food and immediately ingested. Children above 25 kg should be treated as per the adult dose of ABC 300mg+ 3TC 150 mg twice daily.

AZT/3TC and AZT/3TC/NVP tablets are water dispersible and should be given in 5-15 ml of water.
For adolescents on ABC based regimen consider transitioning to TDF/3TC/EFV if their weight remains consistently > 35kgs (at least 2 readings one month apart) for better adherence. Available Tenofovir/Lamivudine and Tenofovir/Lamivudine/Efavirenz FDCs - can be used in children older than 10 years and above 35 kgs.
Reference should be made to the national guidelines for dosing.

Single formulations

These formulations should only be used where appropriate Paediatric or adult FDCs cannot be used.

Abacavir (ABC) - tablets may be swallowed whole or crushed.

Lamivudine (3TC) - tablets may be swallowed whole or crushed.

Efavirenz 200mg - tablet is double scored and may be divided into four or two equal parts. Tablet may be crushed and dispersed in water (5-15 ml) or onto a small amount of food and immediately ingested.

Lopinavir/ritonavir - dose is calculated based on Lopinavir component. Oral solution should be taken with food. Oral solution must be refrigerated until dispensed. After removing from refrigeration oral solution is only stable for 60 days (2 months) at room temperature (up to 25° C). Where temperatures are expected to exceed 25°C, the feasibility of dispensing smaller amounts and giving more frequent refills should be considered (for instance, no more than monthly supplies dispensed at one time). The amount of solution has been rounded up to nearest ½ ml for easier measurement as per the manufacturer's recommendation.

Ritonavir Liquid - Children with TB/HIV co-infection who are on LPV/r based ART, will need additional dosing with Ritonavir to make LPV: RTV as 1:1 (due to reduced concentration of LPV/r when used with Rifampicin) and should be given as indicated. The dosing is rounded off to nearest ml for ease of administration of RTV.

Figure 3.3 When and what ART to start in adults and adolescents including pregnant women

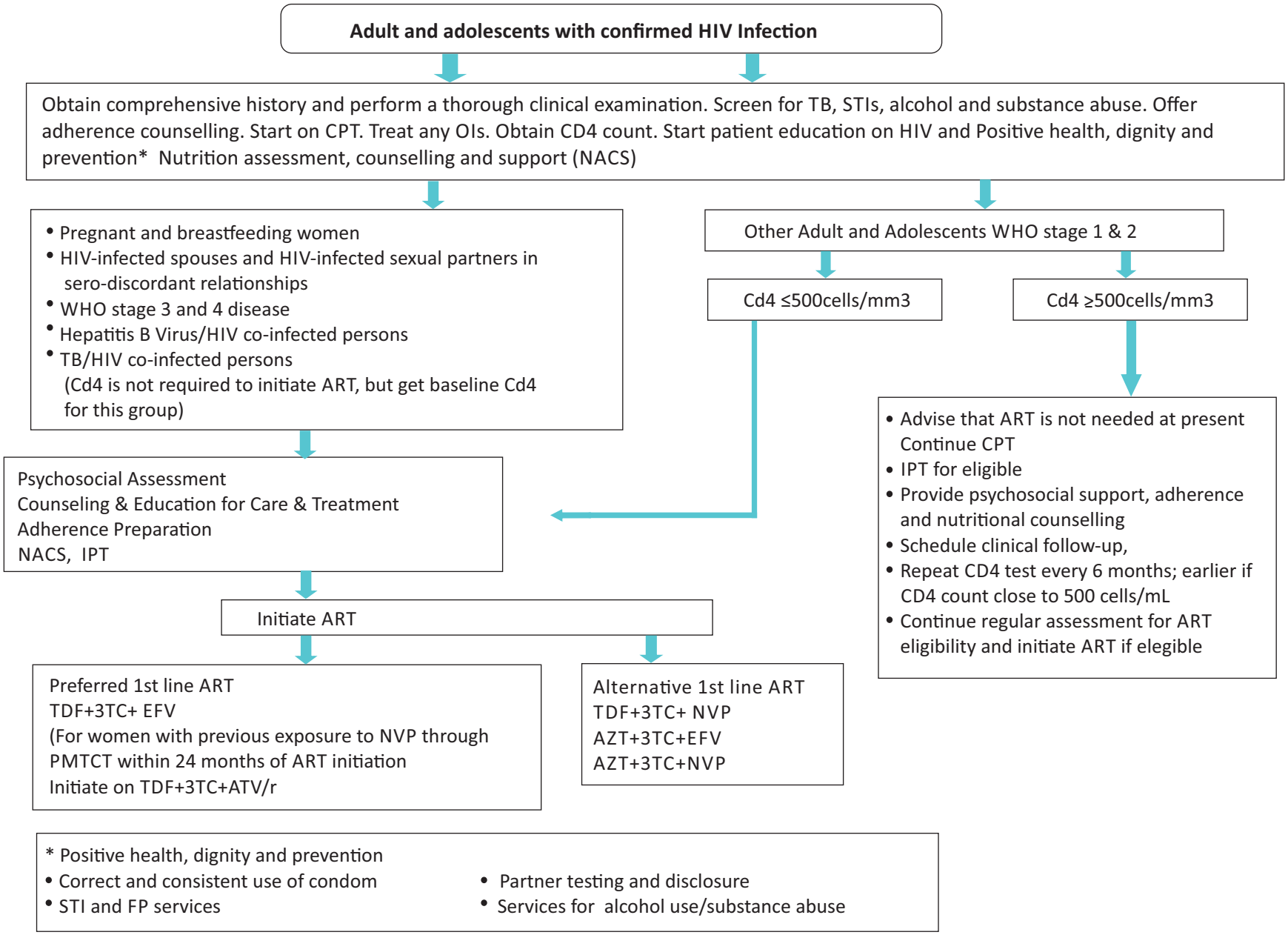
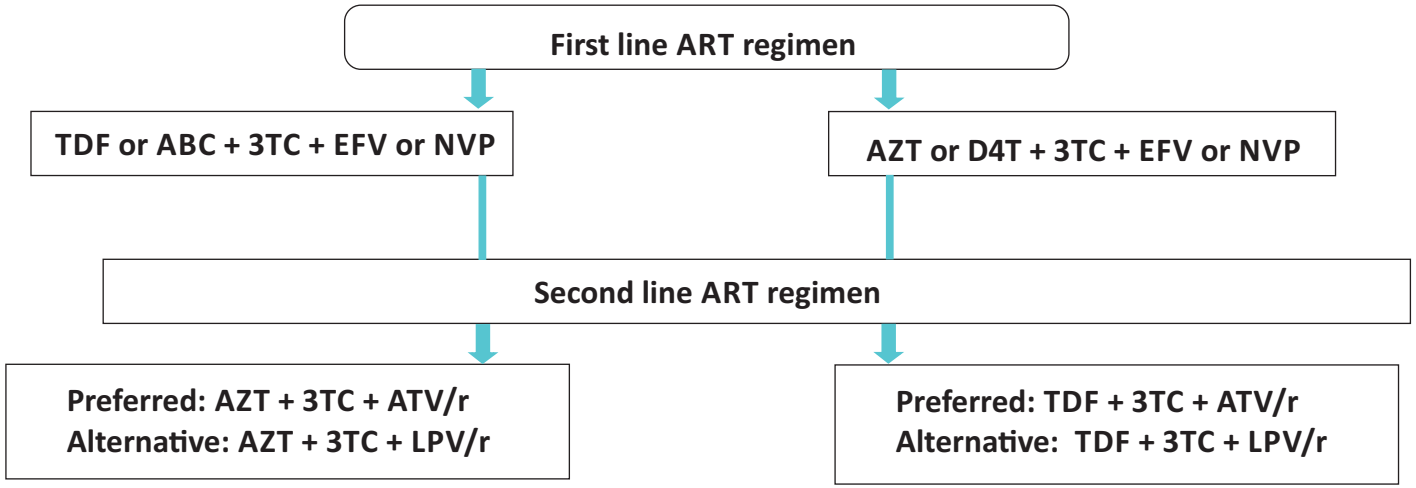


Table 3.4 Definition of treatment failure in adults and adolescents

Definition of Treatment Failure in Adults and Adolescents
Clinical Failure • New onset of significant OIs or malignancy, usually WHO Stage 3 or 4 conditions. • Recurrence of previously treated OIs after at least six months of ART. A diagnosis of treatment failure therefore should not be considered in adherent patients who develop OIs and have been on treatment for < 6months. • Unintentional weight loss in a patient who was doing well on ARVs without any overt signs and/or symptoms should trigger suspicion of regimen failure
Immunological Failure • CD4 count falls to or below pre-ART level OR • CD4 count falls by 30% or more from on treatment peak value OR • CD4 count remains persistently below 100 cell/mm3 after at least 12 months of effective ART
Virological Failure • Virological failure is defined as viral load > 1,000 copies/ml after at least 6 months of effective antiretroviral therapy (Refer to VL algorithm)

Figure 3.4 Recommended Second-line Regimen in Adults and Adolescents algorithm



Guidance on use of Atazanavir

Atazanavir (ATV) is a protease inhibitor in the same class as Lopinavir (LPV) and requires pharmacologic boosting with ritonavir as does Lopinavir. The available ATV/r tablet is a co-formulation of ATV and ritonavir. It is taken once daily.

Recommended Dosage

Adults and children > 40 kg

·1 Tablet of ATV 300mg/ RTV 100mg (fixed dose combination) given once daily

Children

·ATV/r is not recommended for children aged less than 6 years

Dosing for children aged 6 - 18 years

Table 3.5 Atazanavir dosing

Weight (kg)	Once-Daily Dose
15 to <20 kg	ATV 150 mg plus RTV 100 mg, once daily with food
20 to <40 kg	ATV 200 mg plus RTV 100 mg, once daily with food
≥40 kg	ATV 300 mg plus RTV 100 mg, once daily with food

NB: Formulations for children weighing below 40kgs are currently NOT available in the national program. The ATV 300/ RTV 100mg tablet should NOT be crushed or split.

Dosing information

- Atazanavir/ritonavir must be taken with food to enhance absorption.
- Tablets should be taken whole and should **NOT** be crushed or split

Co-administration with other medicines

- ATV absorption is dependent on low gastric pH; therefore ATV/r co-administered with proton-pump inhibitors (PPI) eg Omeprazol, or H2-receptor antagonists (eg cimetidine, ranitidine) should be avoided. If given it should be administered with food about 12 hours after the proton-pump inhibitor or H2-receptor antagonists.
- ATV/r should be used with caution in patients taking antacids, ATV/r should be taken 2 hours before or 1 hour after the use of antacids
- Patient with peptic ulcer disease who are likely to continuously use antacids, PPI or H2-recepteor antagonist should preferably be started on LPV/r

General information:

- ATV/r is safe to use in pregnancy
- ATV/r co-administered with rifampicin results in reduced blood levels of ATV/r. In TB/HIV co-infected patient on ATV/r, Rifampicin should be replaced with **Rifabutin 150mg once daily.**

Contra-indications / pre-cautions

- Not recommended in use in children aged less than 6 years

Common Toxicities

Atazanavir/ritonavir is generally well tolerated, it has fewer GI intolerance and less effects on lipid profile compared to LPV/r partly as a result of reduced ritonavir used.

Common toxicities include headache, fever, arthralgia, depression, insomnia, dizziness, nausea, vomiting, and diarrhea. These effects tend to go away with time in the course of treatment.

Patients taking ATV/r may experience asymptomatic elevation of indirect bilirubin (unconjugated bilirubin) which may result in jaundice or icterus. Jaundice from unconjugated hyperbilirubinemia is largely a cosmetic issue and not related to hepatitis or liver damage. Service providers should exclude other causes of jaundice and advice clients appropriately. Adverse events even when cosmetic may be disturbing to the patients; service providers should substitute to LPV/r for patients who experience significant jaundice.

Kidney stones (nephrolithiasis) has been reported in patient taking ATV/r, although this is a rare occurrence, health service providers should monitor patients closely

Possible third-line ART

All patients on ART should be monitored for treatment failure using viral load testing. (Refer to Viral load monitoring algorithm).

Third line regimen must be based on HIV drug resistance patterns.
ARV drugs for constituting a third line regimen will include new drugs with minimal risk of cross-resistance to previously used regimens. These include integrase inhibitors, new-generation NNRTIs and PIs.

Table 3.6 Possible third-line ART

Class	Drug	Remarks
Recycling drugs that confer benefit	Lamivudine, Tenofovir (3TC, TDF)	Standard drugs used in 1st or 2nd line ART
Non-nucleoside reverse transcriptase inhibitor	**Etravirine**	Second generation NNRTI. The use of etravirine in our setting should be guided by NNRTI resistance. Recommended dosing is 200 mg twice daily
Protease inhibitor	**Darunavir (DRV)**	Recommended dose for adults and adolescents with no DRV resistance mutations is 800 mg together with 100 mg of ritonavir once daily with food. In the presence of one of the DRV resistance mutations, DRV is given as 600 mg with 100 mg of RTV twice daily with food.
Integrase inhibitor	Raltegravir (RAL)	Recommended dose in adults is 400 mg twice daily. In patients on rifampicin, the dose is increased to 800 mg twice daily.

Follow-up of Patients after Initiation of ART (1st, 2nd and 3rd line ART)
All patients on ART should be followed up and assessed at every visit as per the essential package of care (Section 2)

General principles of HIV TB co-infection management

- Start TB treatment immediately as per the national TB guidelines
- If ART-naïve, start ART after TB treatment is tolerated preferably within 2 weeks but not later than 8 weeks.
- Change appropriate ARVs with TB drugs if on ART
- If patient has been on ART for a period of more than 6 months, assess for the treatment failure as per the national guidelines and manage accordingly.

3.8.1 Management of TB/HIV co-infection in children

Table 3.7 Management of TB/HIV co-infection in children

Children newly diagnosed with TB and HIV (ART naïve)
· Start TB treatment immediately as per the national TB guidelines
· Start appropriate ART after TB treatment is tolerated, preferably within 2-8 weeks

Age	Preferred regimen	Alternative regimen	Comments
0-3 years	ABC + 3TC + LPV/r + RTV (add extra dose of RTV to make the LPV/RTV ratio 1:1 (super boosted LPV)	AZT + 3TC+LPV/r ABC + 3TC + EFV* AZT + 3TC + EFV* ABC + 3TC + AZT**	* Note: US FDA has approved use of EFV in children 3 months old and above and weighing more than 3.5 kg. Currently in Kenya, use of EFV in children aged < 3 years and weighing < 10 kg is recommended ONLY in TB/ HIV co-infection management without prior exposure to NVP for PMTCT ** ABC + 3TC + AZT (triple nucleoside) is an inferior regimen and should only be used if other regimens are not tolerated. After completion of TB treatment, change the triple nucleoside based ART regimen to ABC + 3TC + LPV/r
≥3-10 years	ABC + 3TC + EFV	AZT + 3TC + EFV	
>10-14 years	(<35 kgs) ABC + 3TC + EFV (>35 kgs) TDF + 3TC + EFV	AZT + 3TC + EFV	

Child develops TB while on ART

Assess for treatment failure using viral load, if patient has been on ART for a period of **more than 6 months.**

Change the first line regimen to an appropriate 2nd line regimen if treatment failure is confirmed

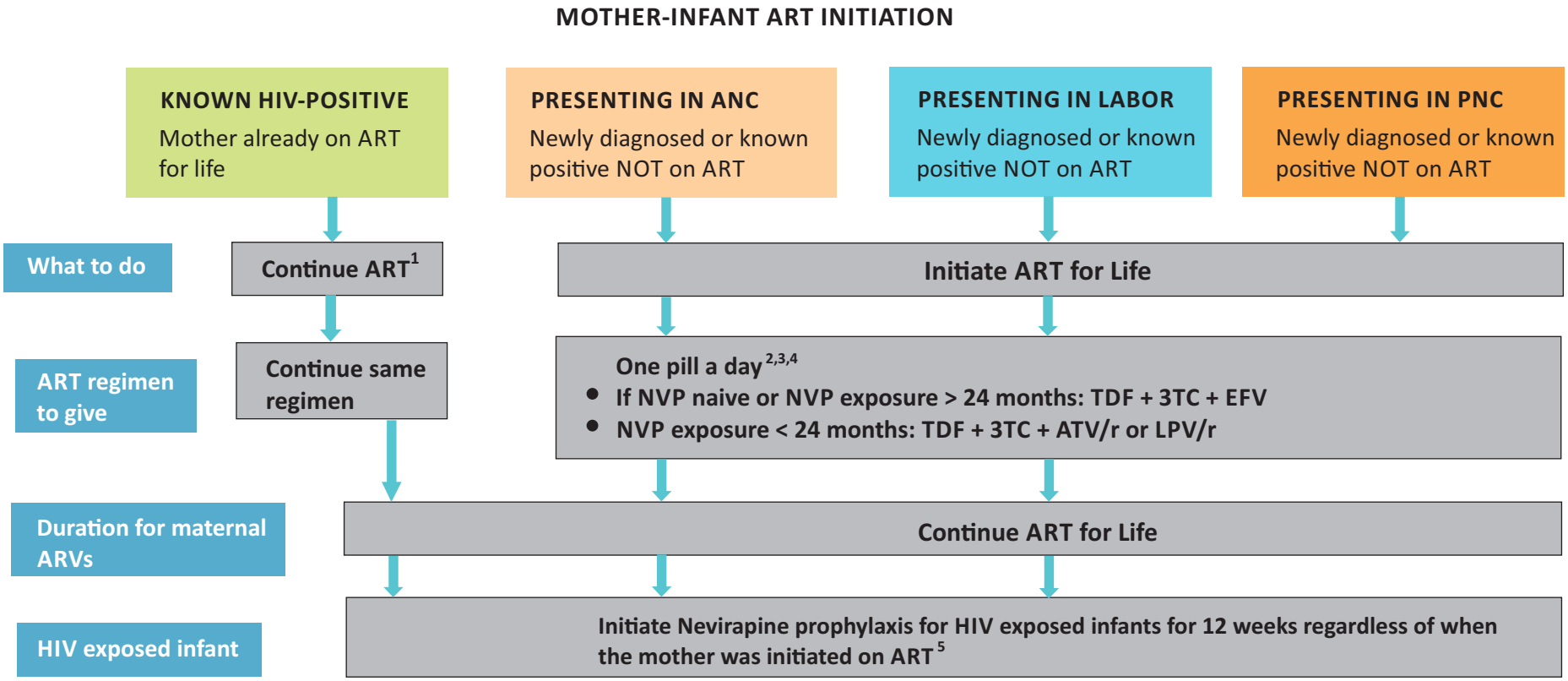
Age	Current regimen	Recommended ARV substitution while on TB treatment	Comments
0-10 years	If EFV-based ART	Continue EFV	
	If NVP-based ART	Change NVP to EFV	
	If LPV/r-based ART	Super boost LPV/r (LPV:Ritonavir = 1:1)	Switch back to normal dose of LPV/r after completion of TB treatment
		Alternative: Triple nucleoside of ABC+3TC+AZT	*Please note that triple nucleoside is an inferior regimen and should only be used in children not able to tolerate super boosted LPV/r* *Triple nucleoside should not be used in children who have failed 1st line ART; in such cases clinician should consult/refer to a specialist for management*
> 10 yrs	EFV-based ART	Continue EFV	
	NVP-based ART	Change NVP to EFV	
	If LPV/r-based ART	If < 35 kg weight: Super boost LPV/r (LPV:Ritonavir = 1:1) with rifampicin-based TB treatment	Switch back to normal dose of LPV/r after completion of TB treatment
		If weight is > 35 kg: Continue current regimen **and** use **Rifabutin (150mg once daily)** instead of rifampicin	

Note: Rifabutin dosing for TB treatment in TB/HIV patients on PI based ART has been reviewed. Rifabutin should be administered as ONCE DAILY dosing of 150 mg alongside other anti-TB drugs.

Table 3.8 Management of TB/HIV co-infection in adults and adolescents including pregnant women

TB patient newly diagnosed with HIV (ART-naïve) • Start TB treatment immediately as per the national TB guidelines • If ART-naïve, start ART after TB treatment is tolerated, within 2-8 weeks		
Scenario	**ART regimen**	**Comments**
Newly diagnosed HIV in a TB patient (ART naive)	Preferred: TDF + 3TC + EFV Alternative: AZT + 3TC + EFV	Continue same ART regimen after completing TB treatment. ART is not considered to be failing within 6 months of initiation
Patient develops TB while on ART • Carry out a viral load(VL) test if patient has been on ART for a period of **more than 6 months and does not have a recent undetectable viral load; change the first line regimen to an appropriate 2nd line regimen if treatment failure is confirmed**		
If on NVP-based first line ART regimen	Change NVP to EFV	• Assess for treatment failure • Continue additional adherence counseling and support
If on LPV/r or ATV/r-based regimen	Continue current regimen and use **Rifabutin (150mg given once daily)** instead of rifampicin* for TB treatment	• Assess for treatment failure • Continue additional adherence counseling and support

Figure 3.5 Mother-Infant ART initiation guide



1. Conduct Viral load testing for all known HIV-positive pregnant women who have been on ART for >6 months and thereafter as per viral load monitoring protocol
2. For mothers already on **OPTION B CONTINUE** regimen as treatment for life, those on **OPTION A, CONVERT** to appropriate 1st line ART regimen; monitor with viral load and manage treatment response as per National Guidelines
3. Conduct a full clinical evaluation, WHO staging, baseline CD 4 testing, ANC profile and adherence counselling
4. Immediate ART on HIV positive status confirmation; **EFAVIRENZ** is now recommended for use at any gestation
5. Infants nevirapine prophylaxis:
   a. Should be offered till 1 week after cessation of breastfeeding if maternal ART is interrupted or mother declines ART
   b. Should be stopped if child turns HIV positive and infant ART initiated immediately.

Table 3.9 HIV exposed Infant ARV Prophylaxis

HIV EXPOSED INFANT ARV PROPHYLAXIS	
HIV EXPOSED INFANT ARV PROPHYLAXIS Start at birth Give Nevirapine (NVP) syrup for 12 weeks if mother on ART Give Nevirapine (NVP) until one week after cessation of breastfeeding if maternal ART is interrupted or mother declines ART	
AGE	**NVP DOSE**
0 to 6 weeks	Birth weight < 2,500g : 10mg (1ml) once daily Birth weight > 2,500g : 15mg (1.5ml) once daily
6 weeks to 14 weeks	20mg (2mls) once a day
14 weeks to 6 months	25mg (2.5mls) once a day
6 months to 9 months	30mg (3mls) once a day
9 months to 12 months	40mg (4mls) once a day
> 12 months	50mg (5mls) once a day

3.10.1 Use of CD4 test in HIV patient monitoring

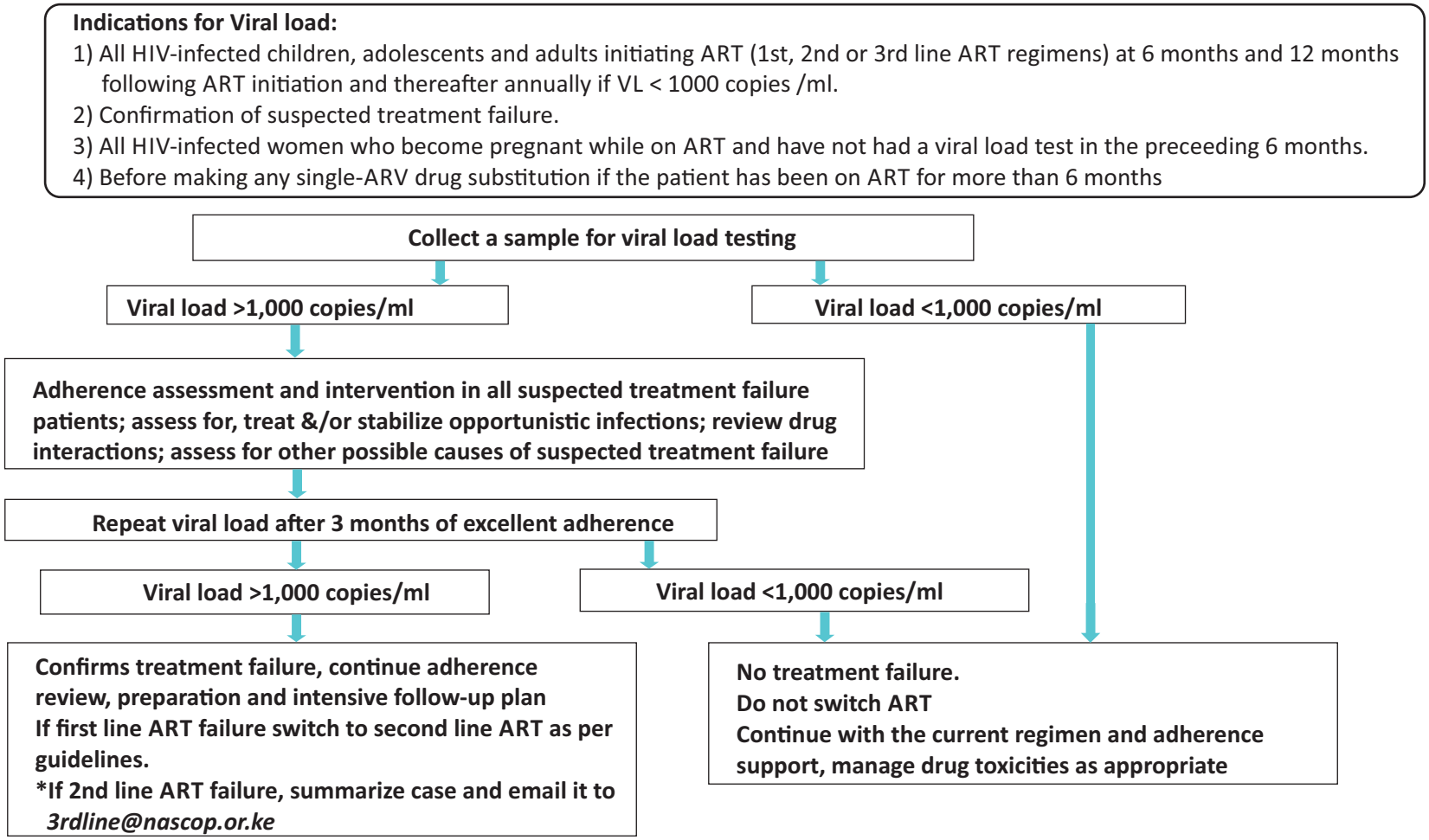
Table 3.10 Use of CD4 test in HIV patient monitoring

Indications for CD4 Count

- A CD4 count should be performed for all PLHIV at time of enrolment into care to support eligibility criteria for ART. This will also serve as a baseline for monitoring clinical progress of those no qualifying for ART immediately.
- All PLHIV who are not on ART should be receive CD4 count testing every 6 months to determine their eligibility for ART
- All patients on ART who are on secondary fluconazole prophylaxis should receive CD4 count testing every 6 months to determine when to discontinue their prophylaxis
- CD4 count may be performed to aid in the differential diagnosis for PLHIV who present with new signs/symptoms of an OI, regardless of ART status. For example in a patient presenting with focal neurological signs with CD4 cell count of less than 100 cells/mm3 toxoplasmosis is likely, while if CD4 cell count is 400 cells/mm3 Toxoplasmosis is unlikely, just as a patient presenting with worsening dyspnea and with a CD4 of 500cells/mm3 is unlikely to have PCP

Note:
Baseline CD4 cell count is recommended for all PLHIV at enrolment.
Where viral load monitoring in ART patients is not readily available, 6 monthly CD4 count testing is still recommended for monitoring ART response.

Figure 3.6 Use of viral load test in HIV patient monitoring algorithm



NB: Plasma remains the preferred specimen type for viral load testing. Facilities in close proximity and easy access to a testing laboratory should use plasma samples. Facilities with poor access or in remote areas should use DBS.

***Guidance for second line ART failure**

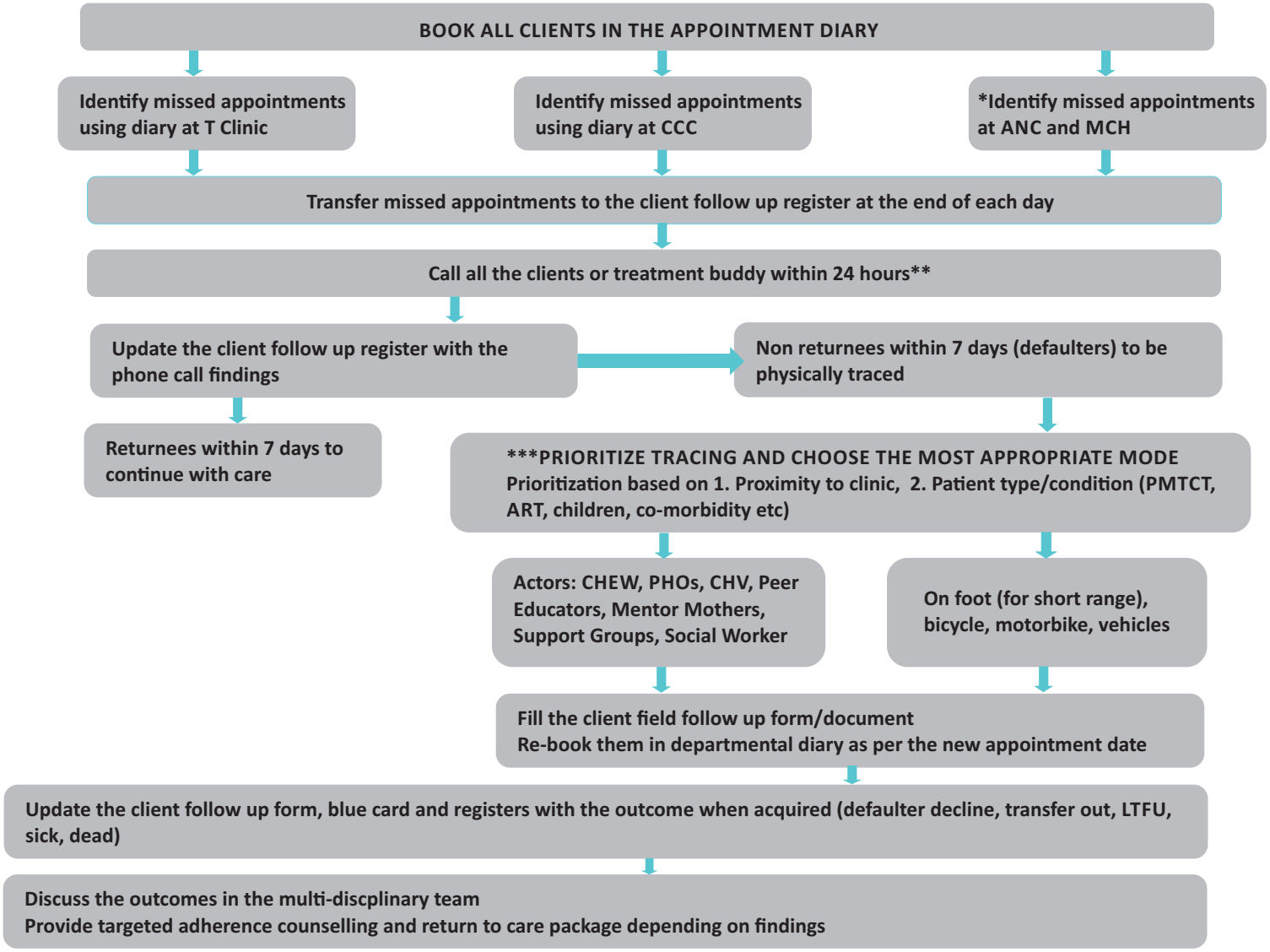
- Patients confirmed to have failed 2nd line ART: Summarize case in the clinical summary form provided by NASCOP and submit to 3rdline@nascop.or.ke for approval of Drug Resistance Testing
- NASCOP ART Therapeutics TWG will determine need for DR testing and advise the facility. Results of HIV DR testing should be submitted to this TWG to determine ART regimen
- Meanwhile continue with current regimen

Table 3.11 Clinical and laboratory follow up of PLHIV

	Pre-ART		ART week		ART - Month								
Appointment	Entry into care	Follow-up before ART	0	2	1	2	3	4	5	6	8	12	STABLE
Clinical Evaluation, Wt, Ht, ADRs	+	+	+		+	+	+	+	+	+	+	+	Every visit
TB Screening	+		+		+	+	+	+	+	+	+	+	Every visit
Adherence check	+		+		+	+	+	+	+	+	+	+	Every visit
Hb	+				+[2]		+[2]	Symptom directed					
ALT	+				+[3,4]		+[3,4]	Symptom directed					
Creatinine[5]	+			Symptom directed									
Pregnancy Test (PT)	+	If indicated											
Urinalysis	+	Symptom directed											
Fasting Lipid profile & Glucose[6]	+		Annually for patients on PIs										
CD4 count[7]	+	Every 6 months											
Routine Viral Load[8]										+		+	Annually
Laboratory tests, while desirable, are not a prerequisite for initiation or for routine follow up of patients on ART													

[1] Weight and Height should be measured in children regularly and in adults for BMI calculation at initial assessment
[2] Schedule when AZT is used
[3] Schedule when NVP is used
[4] Schedule in pregnant women: ALT should be done at baseline, 2, 4 weeks then monthly until the woman delivers; especially important in women with CD4 >250 cells/mm3 at ART initiation on NVP-based regimen
[5] All patients should have creatinine measured if available. NRTI doses may need to be adjusted if renal function (RF) abnormal. TDF should be avoided if renal function is abnormal
[6] Schedule if PIs used
[7] CD4 tests should be done in all PLHIV at enrolment and 6 monthly thereafter to determine immunological ART eligibility
[8] Routine viral load testing should be done at 6 and 12 months after ART initiation, then annually thereafter for treatment monitoring and for confirmation of Art failure as recommended in viral load algorithm

Figure 3.7 Defaulter management algorithm



* Weekly calls to support adherence in the first month of treatment reduces risk of missing appointment; collect good contact information at enrolment.

** Several phone contact attempts should be made to reach the client/ treatment buddy if initial attempt fails

*** PMTCT clients who initiate ART on the same day of diagnosis and in labor, children < 2 years, and active OI/TB

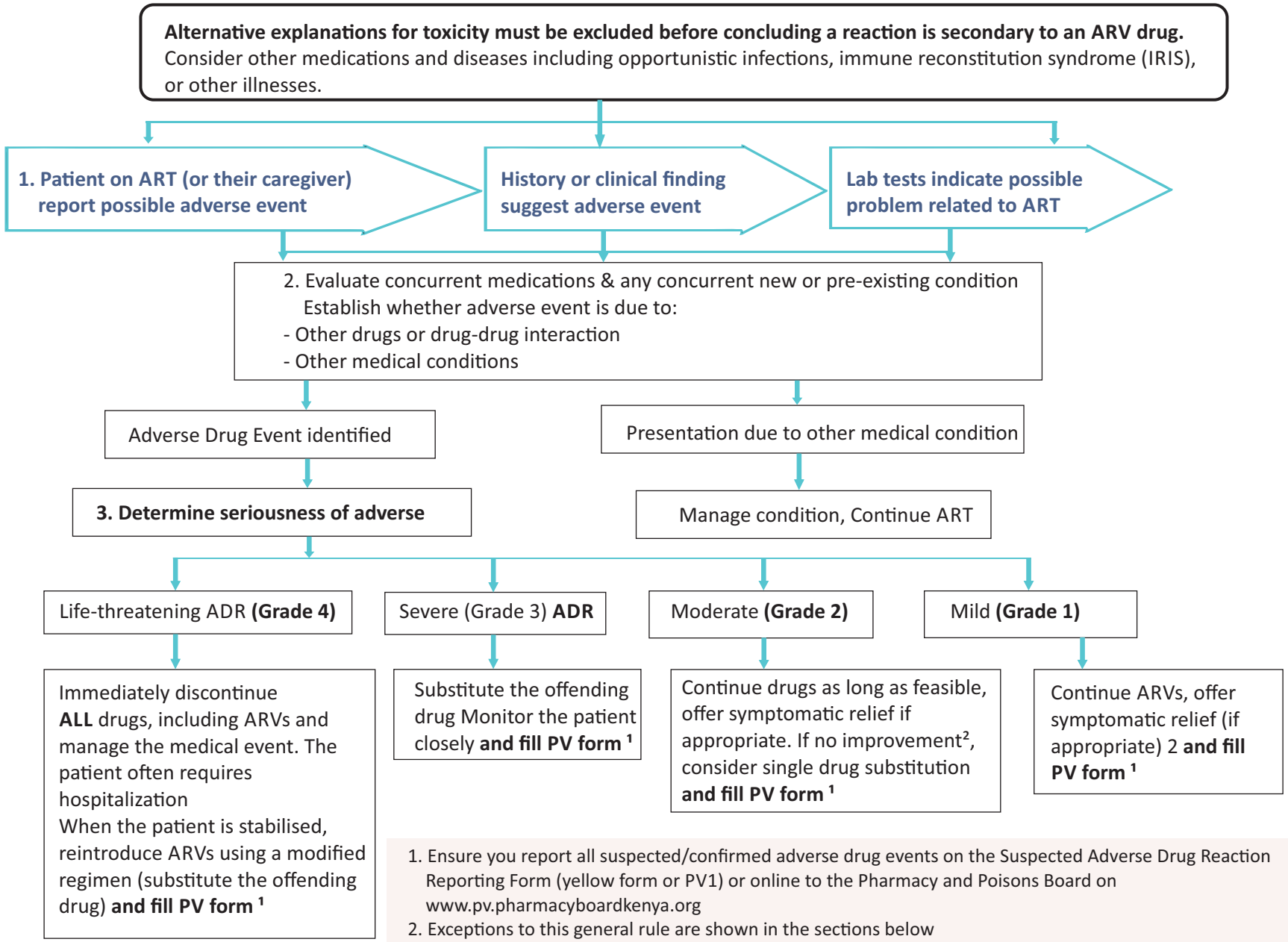
Managing Adverse Drug Reactions and ARV Drug Interactions

At every clinic visit the patient on ART should be monitored clinically for toxicities using appropriate history (history of symptoms that suggest toxicity) and physical examination (relevant signs). Laboratory monitoring at intervals may also be used to identify specific toxicities.

Evaluate concurrent medications and establish whether the toxicity is attributable to an ARV drug (or drugs), or to a non-ARV medication taken at the same time. Consider other disease processes (e.g. concurrent infectious process / common childhood illnesses). Not all problems during treatment are caused by ARV drugs.
All toxicities should be graded. Manage the adverse event according to the severity.

3.12.1 General principles of adverse drug reaction management algorithm

Figure 3.8 General principles of adverse drug reaction management algorithm



1. Ensure you report all suspected/confirmed adverse drug events on the Suspected Adverse Drug Reaction Reporting Form (yellow form or PV1) or online to the Pharmacy and Poisons Board on www.pv.pharmacyboardkenya.org
2. Exceptions to this general rule are shown in the sections below (TDF, NVP, ABC, AZT)

Table 3.12 ARV associated toxicity

ARV drug	Common toxicity
TDF	Asthenia, headache, diarrhoea, nausea, vomiting, flatulence Renal insufficiency, Fanconi syndrome Osteomalacia Decrease in bone mineral density Severe acute exacerbation of hepatitis may occur in HBV-co-infected patients who discontinue TDF
AZT	Bone marrow suppression: macrocytic anaemia or neutropaenia Gastrointestinal intolerance, headache, insomnia, asthenia Skin and nail pigmentation Lactic acidosis with hepatic steatosis
ABC	Hypersensitivity reaction
EFV	Hypersensitivity reaction Stevens Johnson Syndrome Rash Hepatic toxicity Persistent and severe central nervous system toxicity (depression, confusion) Hyperlipidaemia
NVP	Hypersensitivity reaction Stevens Johnson Syndrome Rash Hepatic toxicity Hyperlipidaemia

Dietary recommendations for common signs and symptoms associated with HIV

Table 3.12 ARV associated toxicity (continued)

ARV drug	Common toxicity
LPV/r	GI intolerance, nausea, vomiting, diarrhoea Asthenia Hyperlipidemia (especially hypertriglyceridaemia) Elevated serum transaminases Hyperglycaemia Fat maldistribution Possible increased bleeding episodes in patients with haemophilia PR interval prolongation, QT interval prolongation and torsade de pointes
ATV/r	Indirect hyperbilirubinaemia Clinical jaundice Prolonged PR interval—first degree Symptomatic AV block in some patients Hyperglycaemia Fat maldistribution Possible increased bleeding episodes in individuals with haemophilia Nephrolithiasis

3.12.3 Dietary recommendations for common signs and symptoms associated with HIV

Table 3.13 Dietary recommendations for common signs and symptoms associated with HIV

Sign/ Symptom	Dietary Recommendations for the patients
Anorexia	Try to stimulate appetite by eating a variety of foods Eat small frequent meals, food rich in soluble fibres Select foods that are more energy dense Avoid strong-smelling foods, strong citrus fruits Drink plenty of fluids, soups, diluted fruit juices, boiled water, fermented foods such as yoghurt and porridges
Taste changes	Use flavor enhancers such as salt, spices, herbs, and lemon Chew food well and move it around in mouth to stimulate taste receptors and porridges
Diarrhoea	Drink plenty of fluids (boiled/treated water) Reduce or avoid intake of milk and milk products, coffee, tea, alcohol, fatty foods and gas forming foods such as cabbages and carbonated soft drinks Eat small frequent meals such as porridge, yoghurt, vegetables and fermented milk, foods rich in potassium such as bananas and pumpkins and porridges
Fever	Drink plenty of soups Eat foods rich in energy and nutrients such as groundnuts, maize, potatoes and carrots Drink plenty of healthy fluids Eat small frequent meals
Nausea and vomiting	Eat small frequent meals Drink plenty of fluids like soups, unsweetened porridge and fresh fruit juice Eat lightly salted and dried food Avoid spicy and fatty foods, caffeine and alcohol, oily fried foods and foods with strong smells
Mouth sores and oral thrush	Eat cold or room temperature food Eat soft mashed foods such as mashed potatoes Avoid spicy, salty or sticky food, sugary food and acidic foods, alcohol Clean the mouth with warm salty water at least twice daily

Table 3.12.3 Dietary recommendations for common signs and symptoms associated with HIV (continued)

Sign/ Symptom	Dietary Recommendations for the patients
Constipation	Maintain a regular eating schedule and don't skip meals Eat more foods that are high in fibre such as cereals, oats, nuts, and whole meal bread Drink plenty of liquids Avoid processed or refined foods, laxatives as they cause loss of fluids Exercise as much as possible
Anaemia	Increase intake of iron-rich foods such as animal products, eggs, green leafy vegetables; fruits rich in vitamin C such as oranges, citrus and mangoes; legumes, nuts; oils seeds and fortified cereals Take iron supplements as per prescriptions Reduce intake of teas and coffees
Muscle wasting	Increase food intake by increasing quantity and frequency of consumption of food Improve quality and quantity of foods by consuming a variety of foods Increase protein in diet, starchy foods such as cereals and other staple foods Eat small, frequent meals
Loss of appetite	Eat small amounts of nutritious food frequently, Use favorite foods and natural spices Eat in the company of friends or relatives Take nutritious snacks between meals Drink plenty of boiled or treated water, and other fluids Avoid smoking and alcohol consumption Conduct simple exercises If related to depression, refer to a counselor

3.13.1 Symptom - directed management of ARV-associated toxicity

Table 3.14 Symptom - directed management of ARV-associated toxicity

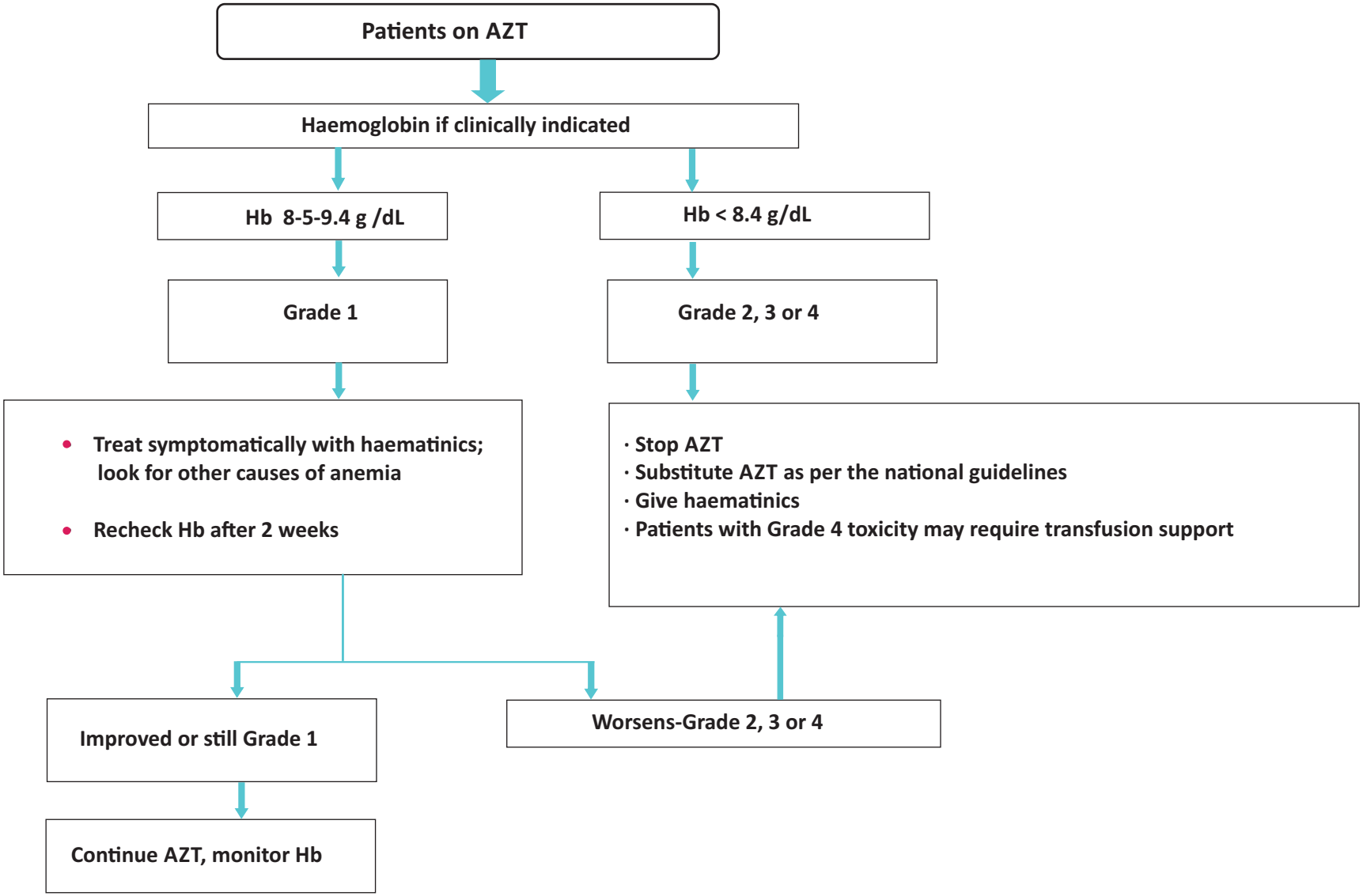
Adverse events	Major first line ARVs	General Recommendations	Dietary recommendations
Hypersensitivity reactions	ABC	Substitute ABC with AZT if it is first line ART If it is in second line ART, Discontinue ART. Give supportive treatment with laboratory monitoring. Resume ART with an NRTI with low pancreatic toxicity risk such as AZT or TDF	Take with food
Drug eruptions (mild to severe, including Stevens-Johnson syndrome or toxic epidermal necrolysis)	NVP and less commonly, EFV	In mild cases, symptomatic care. EFV rash often stops spontaneously after 3-5 days without need to change ART. If moderate rash, non-progressing and without mucosal involvement or systemic signs, consider a single NNRTI substitution (i.e. from NVP to EFV). In moderate and severe cases, discontinue ART and give supportive treatment. After resolution, resume ART with a bPI-based regimen or tripled NRTI	Better to take without food, but if it causes nausea or stomach problems, take with a low-fat meal
Dyslipidaemia	All NRTIs (particularly d4T), EFV	Consider replacing the suspected ARV	Can be taken without regard to food
Anaemia and neutropaenia	AZT	If severe (Hb <9.4 g/dl and/or ANC <750 cells/mm3), replace with an ARV with minimal or no bone marrow toxicity	Can be taken without regard to meals Do not take with a high fat meal
Hepatitis	All ARVs (particularly NVP)	If ALT is at more than five times the basal level, discontinue ART and monitor. After resolution, restart ART replacing the causative drug (e.g. EFV replaces NVP)	Can be taken without regard to food
Lactic acidosis	All NRTIs (particularly d4T)	Discontinue ART and give supportive treatment. After resolution, resume ART, with TDF	Take with food Should be taken with moderate fat meal for better absorption

3.13.1 Symptom - directed management of ARV-associated toxicity

Table 3.14 Symptom - directed Management of ARV-associated toxicity (continued)

Adverse events	Major first line ARVs	General Recommendations	Dietary recommendations
Neuropsychiatric changes	EFV	Usually self-limited, without the need to discontinue ART. If intolerable to the patient, replace NVP with EFV or bPI. Single substitution recommended without cessation of ART	
Renal toxicity (renal tubular dysfunction)	TDF	Dosage adjustment for individuals with altered creatinine clearance Consider substitution with AZT	
Peripheral neuropathy		Replace d4T with AZT, TDF Symptomatic treatment (amitriptyline, vitamin B6)	

Figure 3.9 Management of AZT-Associated Bone Marrow Suppression



3.13.2 Management of AZT-Associated Bone Marrow Suppression

Table 3.15 Clinical Grading of AZT-associated bone marrow suppression

Indices	Grade 1	Grade 2	Grade 3	Grade 4
Hb (g/dL)	8.5 - 9.4	7.5 – 8.4	6.5 – 7.4	< 6.4
Neutrophil count (cells/mL)	1000 - 1300	750 - 999	500 - 749	< 500

Patients with moderate or severe anaemia starting a first line regimen should ideally be started on a TDF or ABC -based regimen.

3.13.3 Nevirapine hepatotoxicity

Figure 3.10 Management of a Nevirapine associated hepatoxicity

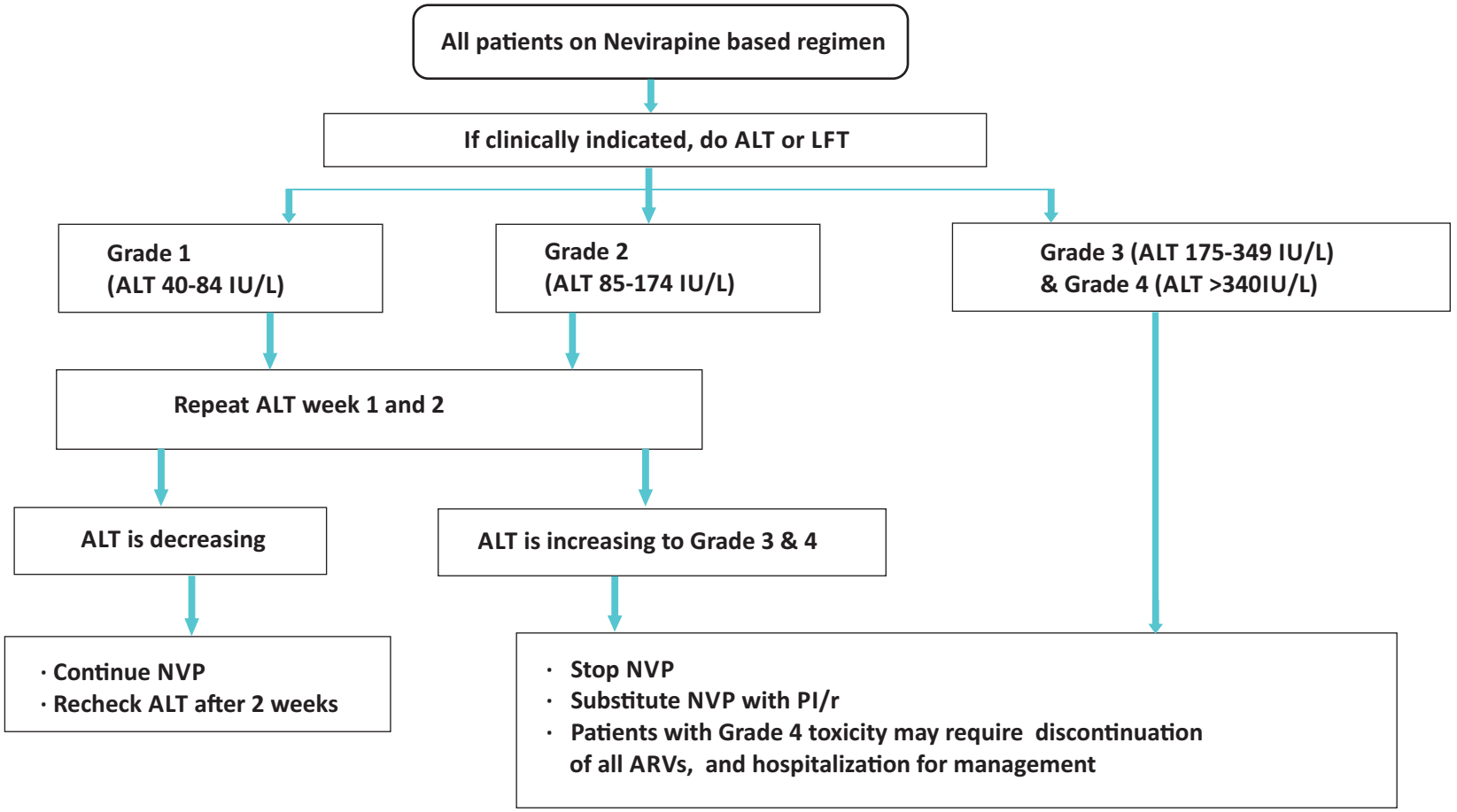


Table 3.16 Nevirapine associated Hepatoxicity grading

Normal ALT	Grade 1	Grade 2	Grade 3	Grade 4
<35 IU/L (1 X upper normal limits ULN)	40-84 IU/L (1.25-2.5 XULN)	84-174 IU/L (2.5-5XULN)	175-349 IU/L (5.1-10X ULN)	>350 IU/L (>10 X ULN)

3.13.4 Nevirapine associated rash

Figure 3.11 Management of a Nevirapine associated rash

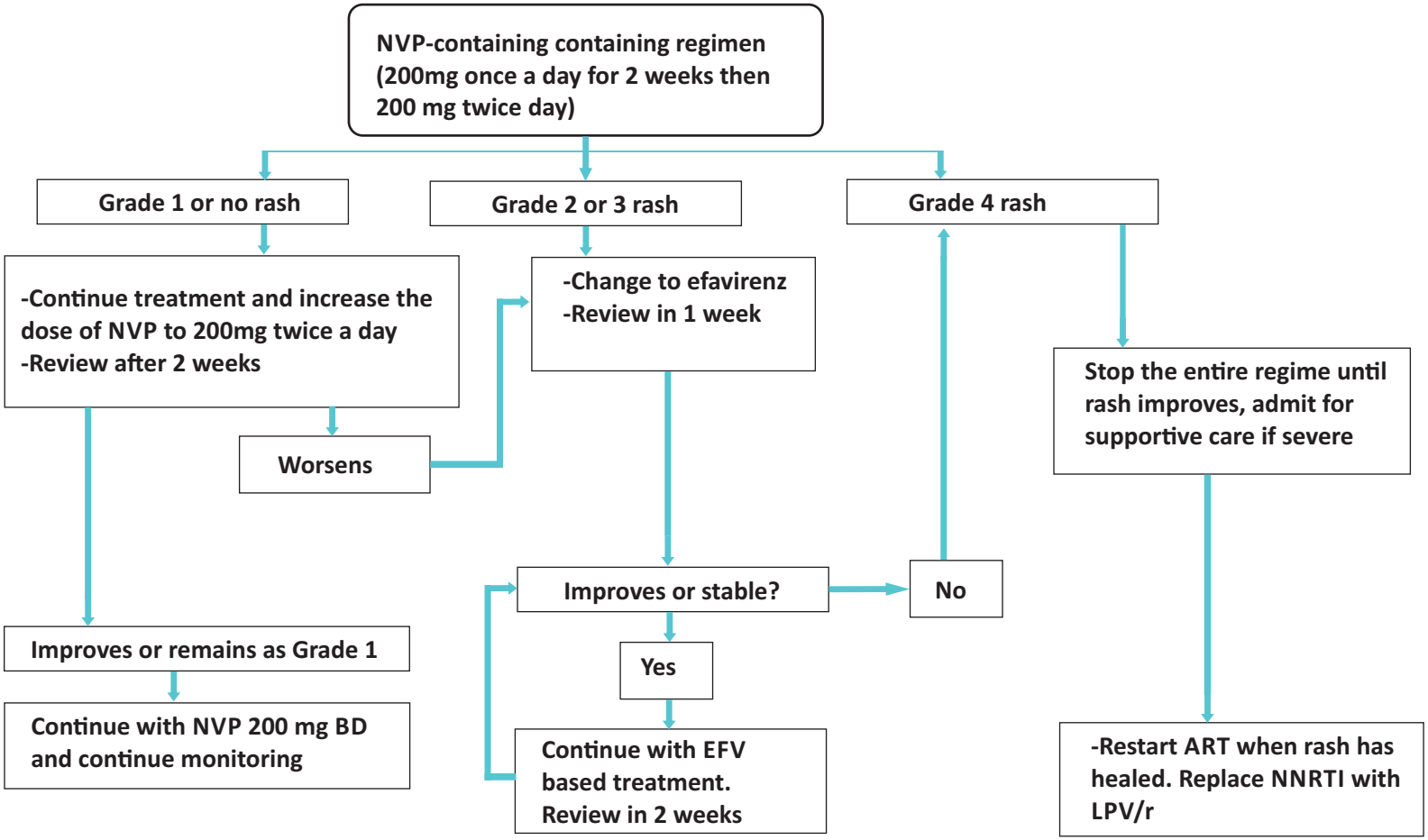


Table 3.17 Clinical Grading of NVP Associated Rash

	Grade 1	Grade 2	Grade 3	Grade 4
Rash	Erythema, pruritus affecting < 50% body surface area	Diffuse maculo-papular rash OR dry desquamation affecting > 50% of body surface area	Vesiculation OR moist desquamation OR ulceration	Mucous membrane involvement, Stevens Johnson, Erythema multiforme

In managing nevirapine toxicity, care should be taken to avoid periods of suboptimal therapy with NNRTI class of drugs.

Figure 3.12 Management of Abacavir toxicity

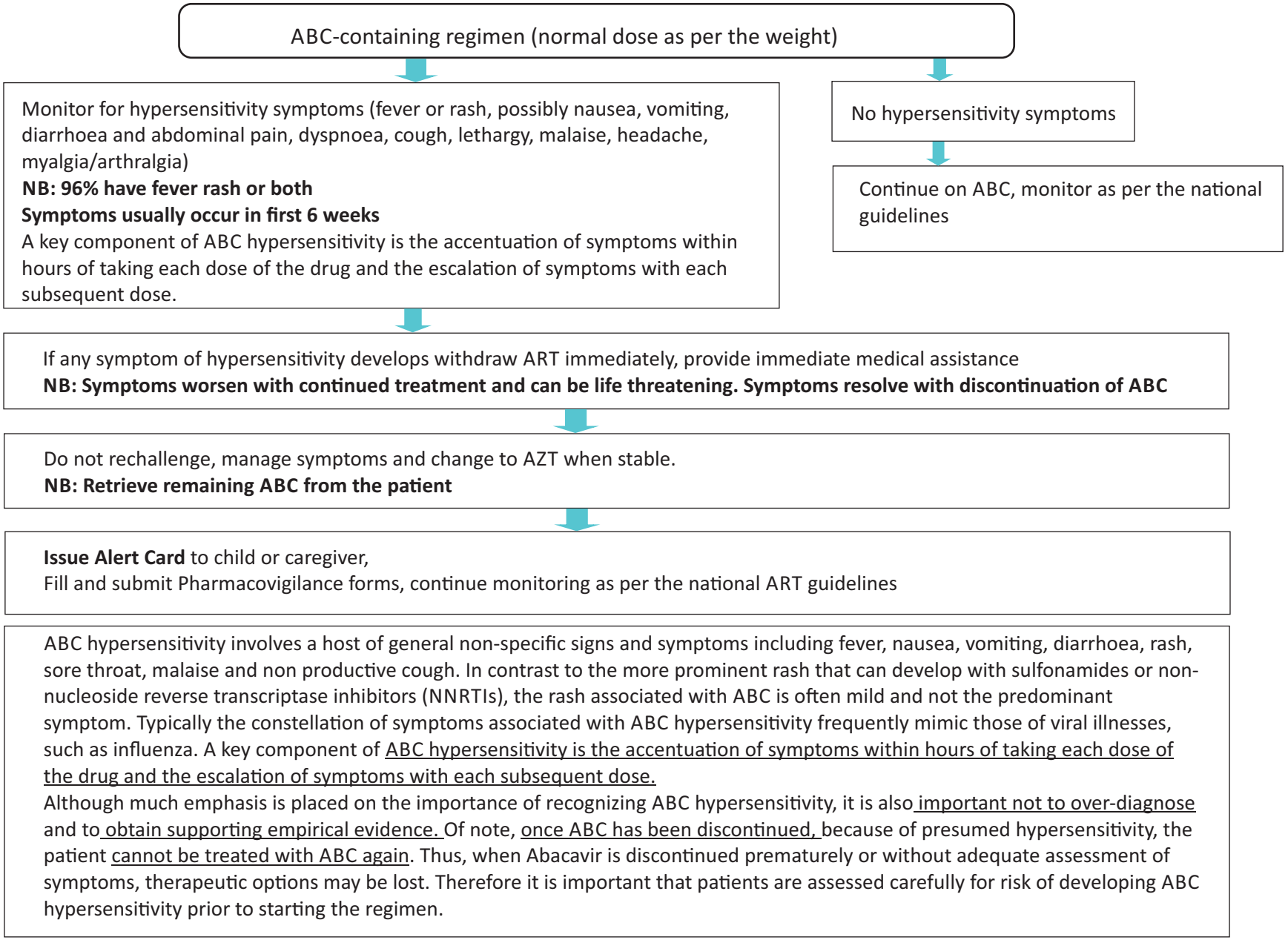
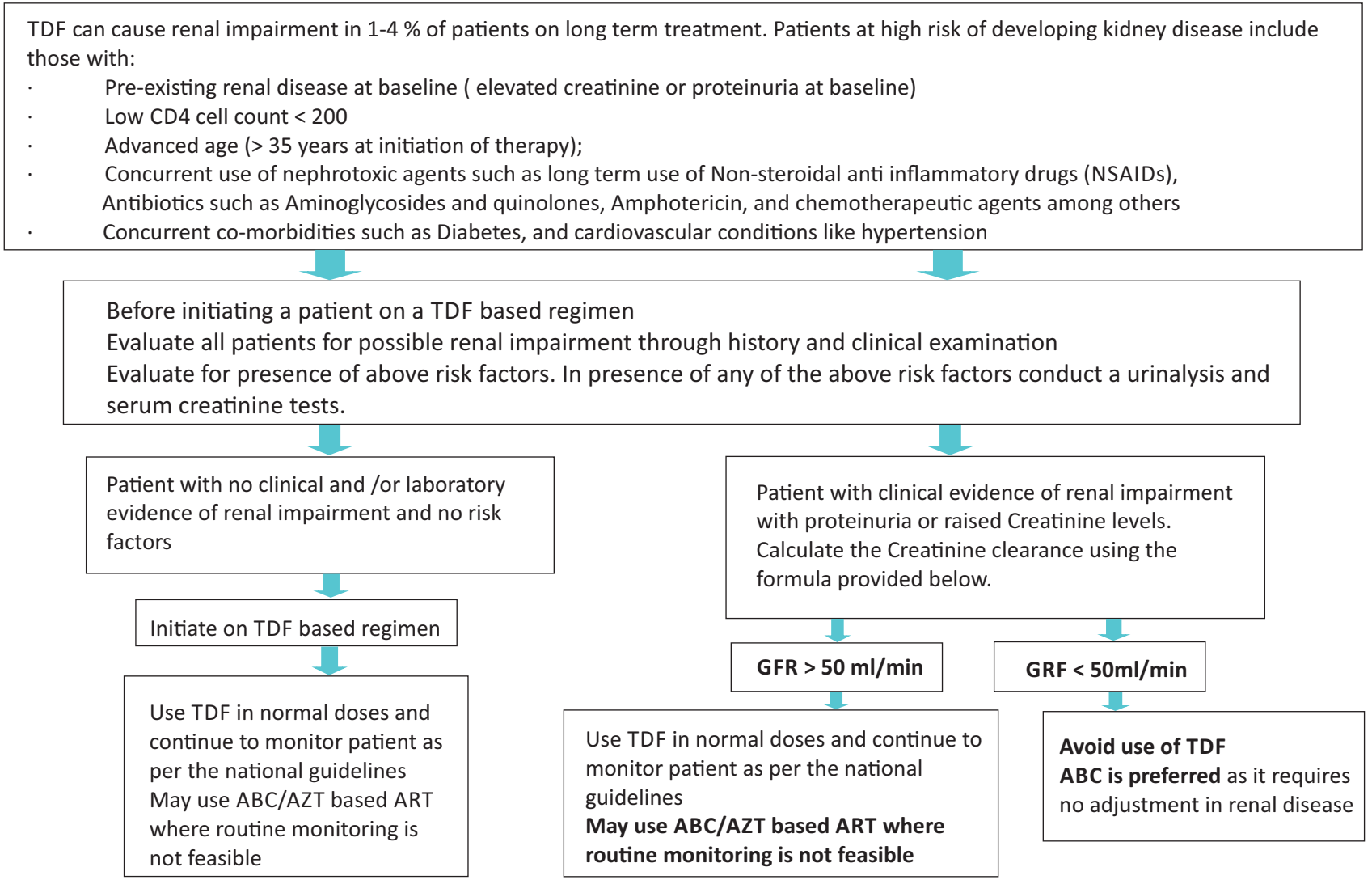


Figure 3.13 Management of Tenofovir toxicity



Where feasible, all patients should have a baseline urinalysis and serum Creatinine (and an estimated Creatinine clearance calculated) prior to initiation of TDF. Follow up tests should be symptom directed. Patients who develop significant renal impairment should have a Creatinine clearance estimated and the decision on the NRTI component of the treatment in line with the national treatment guidelines should be made.

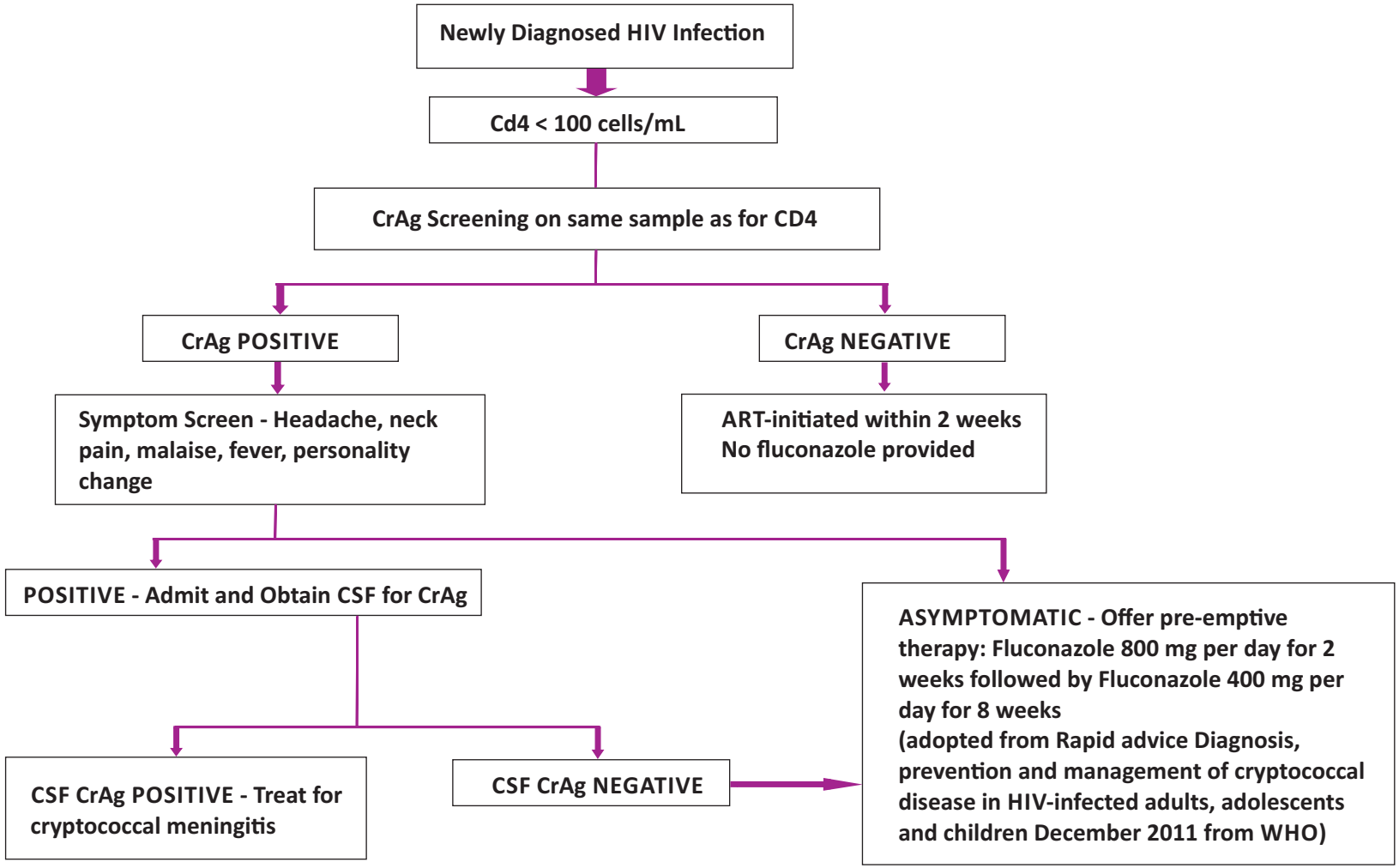
Table 3.18 Calculating Creatinine clearance (Cockroft - Gault Equation)

Calculating Creatinine clearance (Cockroft - Gault Equation)	
In Men	**In Women**
$\text{CrCl (mL/min)} = \frac{(140 - \text{age in years}) \times \text{weight(kg)}}{\textbf{Cr (mg/dL)} \times 72}$	$\text{CrCl (mL/min)} = \frac{(140 - \text{age in years}) \times \text{weight(kg)} \times 0.85}{\textbf{Cr (mg/dL)} \times 72}$
$\text{CrCl (mL/min)} = \frac{1.23 \times (140 - \text{age in years}) \times \text{weight(kg)}}{\textbf{Cr (µmol/L)} \times 72}$	$\text{CrCl (mL/min)} = \frac{1.04 \times (140 - \text{age in years}) \times \text{weight(kg)}}{\textbf{Cr (µmol/L)} \times 72}$

SECTION 4

Management of Communicable and Non-communicable Diseases

Figure 4.1 Screening for Cryptococcal Antigenaemia



Screen all patients ≥ 19 years with CD4 ≤ 100 cells/mm3 (including pregnant women)
Children and adolescents should receive CrAg screening only if cryptococcal meningitis is suspected

Table 4.1 Treatment of Cryptococcal meningitis

Target population	Regimen	Induction (2 weeks)	Consolidation (8 weeks)	Maintenance	When to initiate ART
Adults	Preffered	Amphotericin B 0.7-1 mg/kg/day + Fluconazole 800 mg daily	Fluconazole 400-800 mg daily	Fluconazole 200 mg till CD4 > 200 for at least 6 consecutive months	Initiate ART in 2-4 weeks
	Alternative	Fluconazole 1200 mg daily	Fluconazole 800 mg daily		Initiate ART in 4-6 weeks
Children and Adolescents	Preffered	Amph B 0.7-1 mg/kg/day + fluconazole 12 mg/kg/day up to 800 mg/day	Fluconazole 6-12 mg/kg /day up to 400-800mg /day	Fluconazole 6 mg/kg/day up to 200 mg/day	Initiate ART in 2-4 weeks
	Alternative	Fluconazole 12 mg/kg/day up to 1200 mg/day	fluconazole 12 mg/kg /day up to 800 mg/day	Fluconazole 6 mg/kg/day up to 200 mg/day	Initiate ART in 4-6 weeks

Monitoring for and Managing Amphotericin B Toxicity

Table 4.2 Monitoring for and Managing Amphotericin B Toxicity

Electrolyte	Monitoring	Intervention
Potassium	Baseline and twice weekly	If < 3.3, give KCL 40 mmol or 1-2 KCl tabs 8 hourly. Give magnesium
Creatinine	Baseline and twice weekly	If > 2 fold from baseline, omit a dose of Amph B or increase hydration to 1L 8 hourly If improves, re-start Amph B at 0.7 mg/kg/day on alternate days. If not, stop Amph B and give fluconazole 1200mg/day

Table 4.3 Minimum package for amphotericin B toxicity prevention, monitoring and management

For patients receiving amphotericin B, the following minimum toxicity prevention, monitoring and management regimen is recommended.

Pre-emptive hydration and electrolyte supplementation

Adults:
One litre of normal saline solution with one ampoule (20 mmol) of KCL over 2-4 hours before each controlled infusion of amphotericin B (with one litre of 5% dextrose) and one to two 8mEq KCL tablets orally twice daily. An additional one 8mEq KCL tablet twice daily may be added during the second week. If available, magnesium supplementation should also be provided (two 250mg tablets of magnesium trisilicate twice daily).

Adolescents and Children:
- Up to one litre of normal saline solution with one ampoule (20 mmol) of KCL at 10-15 ml/kg over 2-4 hours before each controlled infusion of amphotericin B. If saline is unavailable, then other intravenous rehydration solutions that contain potassium can be used eg. Darrow's or Ringer's Lactate solutions.
- Potassium replacement should not be given patients with pre-existing renal impairment or hyperkalaemia.
- A test dose for amphotericin B is not recommended

Monitoring
- Serum potassium and creatinine (baseline and twice weekly), especially in the second week of amphotericin B administration.
- Haemoglobin (baseline and weekly)
- Careful attention to fluid monitoring of intake and output, and daily weight

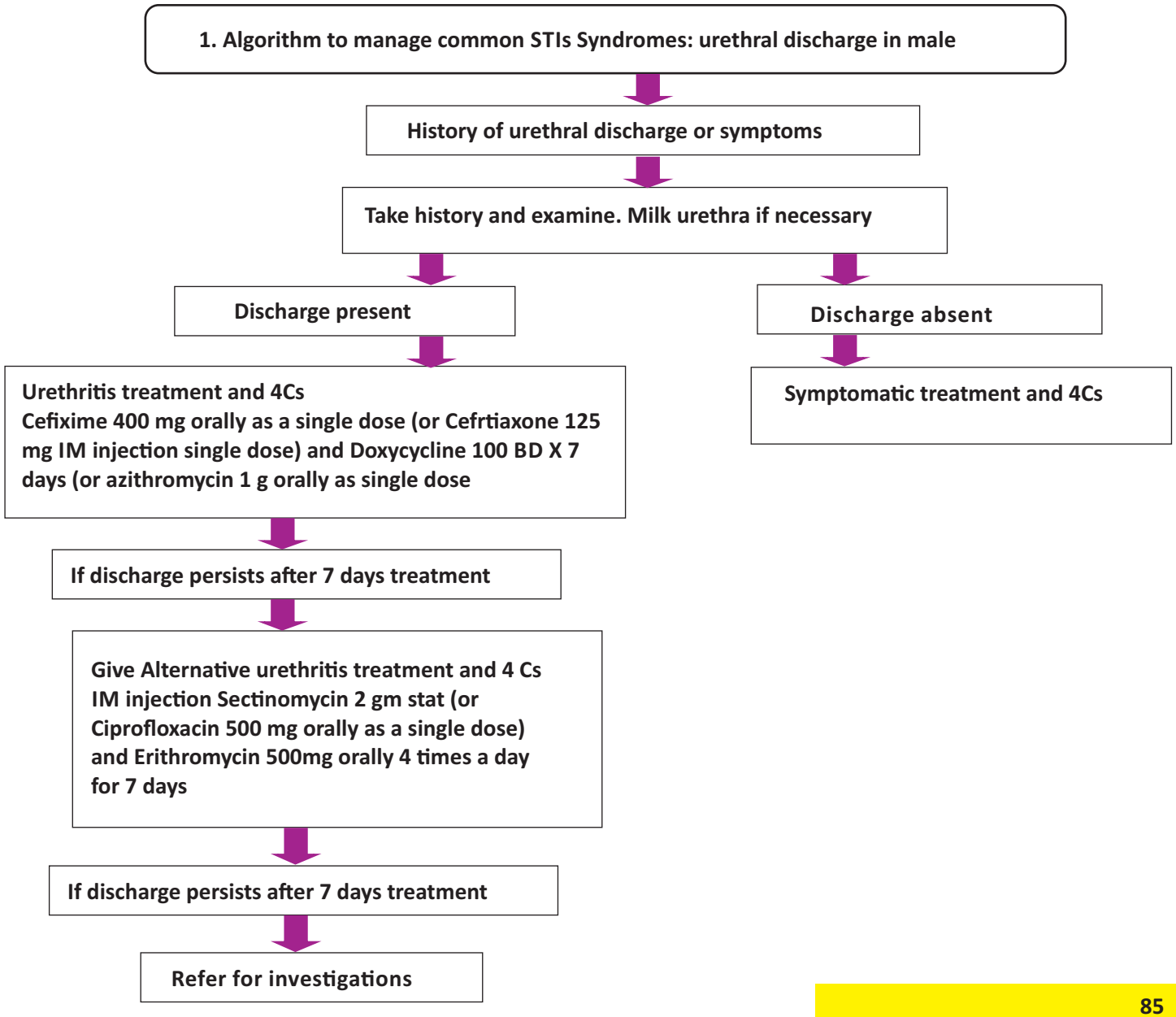
Management
- If significant hypokalaemia (K <3.3mmol/l), increase potassium supplementation to two KCL ampoules (40 mol), or one or two 8mEq KCL tablets three times daily. Monitor potassium daily.
- If hypokalaemia remains uncorrected, double magnesium oral supplementation
- If creatinine increases by >2 fold from baseline value, either temporary omission of an amphotericin B dose, or increase pre-hydration to one litre 8 hourly. Once improved, restart at 0.7 mg/kg/day and consider alternate day amphotericin B. If creatinine remains elevated, discontinue amphotericin and continue with fluconazole at 1200mg/day. Monitor creatinine daily.

Table 4.4 Four Cs (4 Cs) for all STI patients

Counseling	Compliance	Condoms	Contact treatment
• Counseling on the risks of STIs including HIV • Discuss other 3 Cs • Offer HIV testing and counseling services	Your patient should: • Avoid self medication • Take the full course of medication and not to share or keep it • Follow your other instructions	· Proper use of condom is the only other alternative to abstinence to protect from STIs • Give condoms to your patients • Explain and demonstrate the correct use of condoms	Your patient should • Tell all his/her sexual partners to seek medication

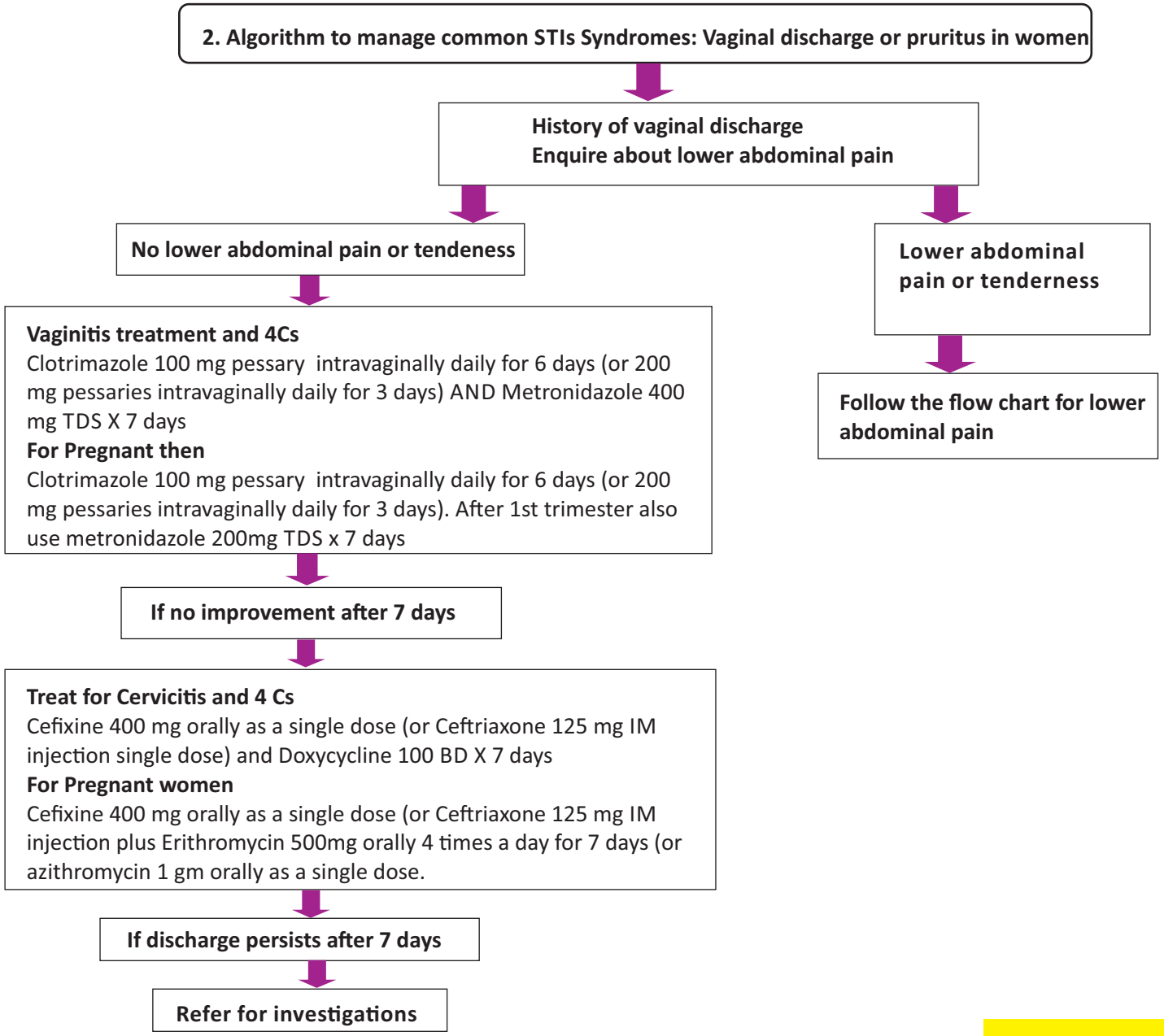
4.2.1 Algorithm to manage common STIs Syndromes: urethral discharge in male

Figure 4.2 Managing common STIs Syndromes: urethral discharge in male



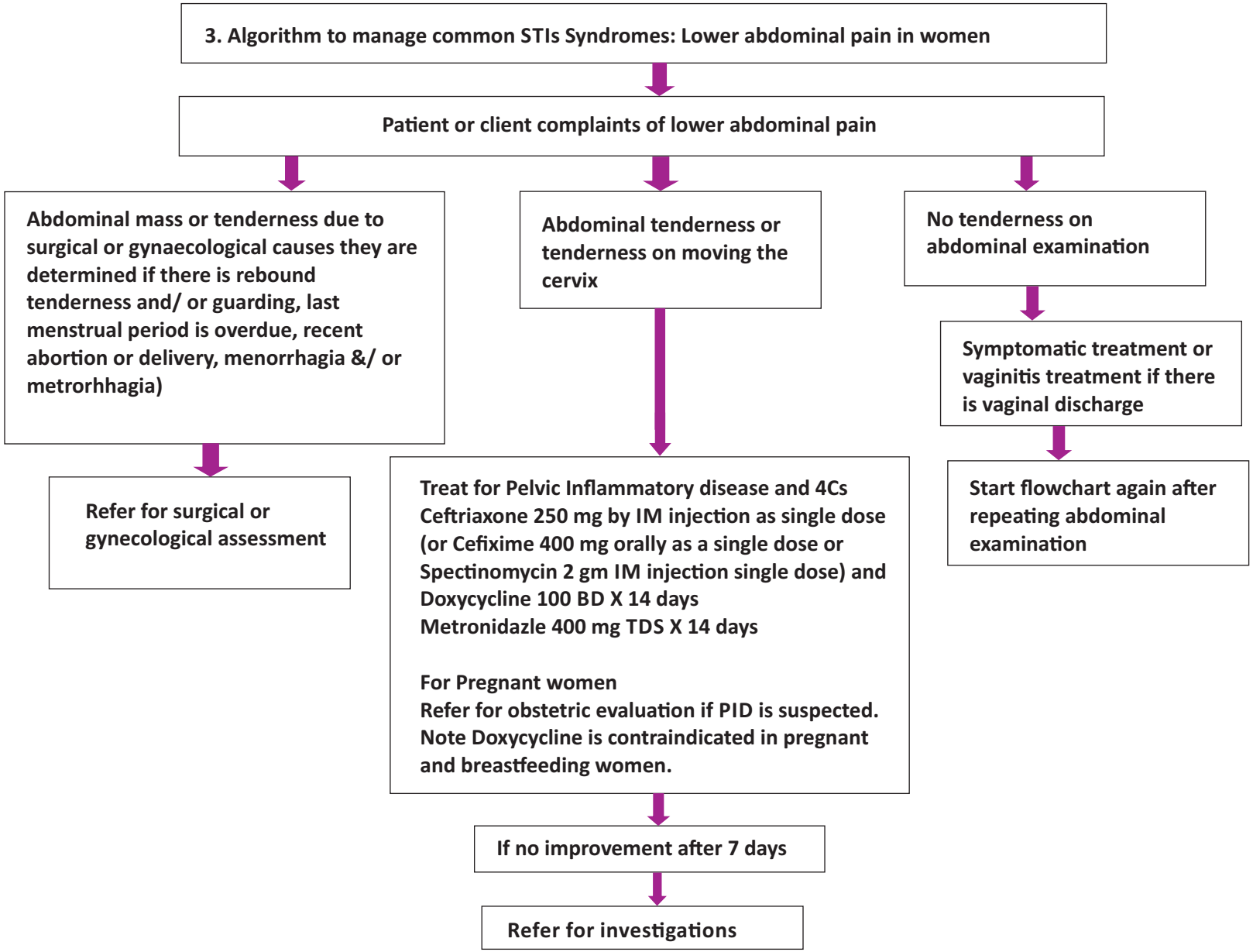
4.2.2 Algorithm to manage common STIs Syndromes: Vaginal discharge or pruritus in women

Figure 4.3 Managing common STIs Syndromes: Vaginal discharge or pruritus in women



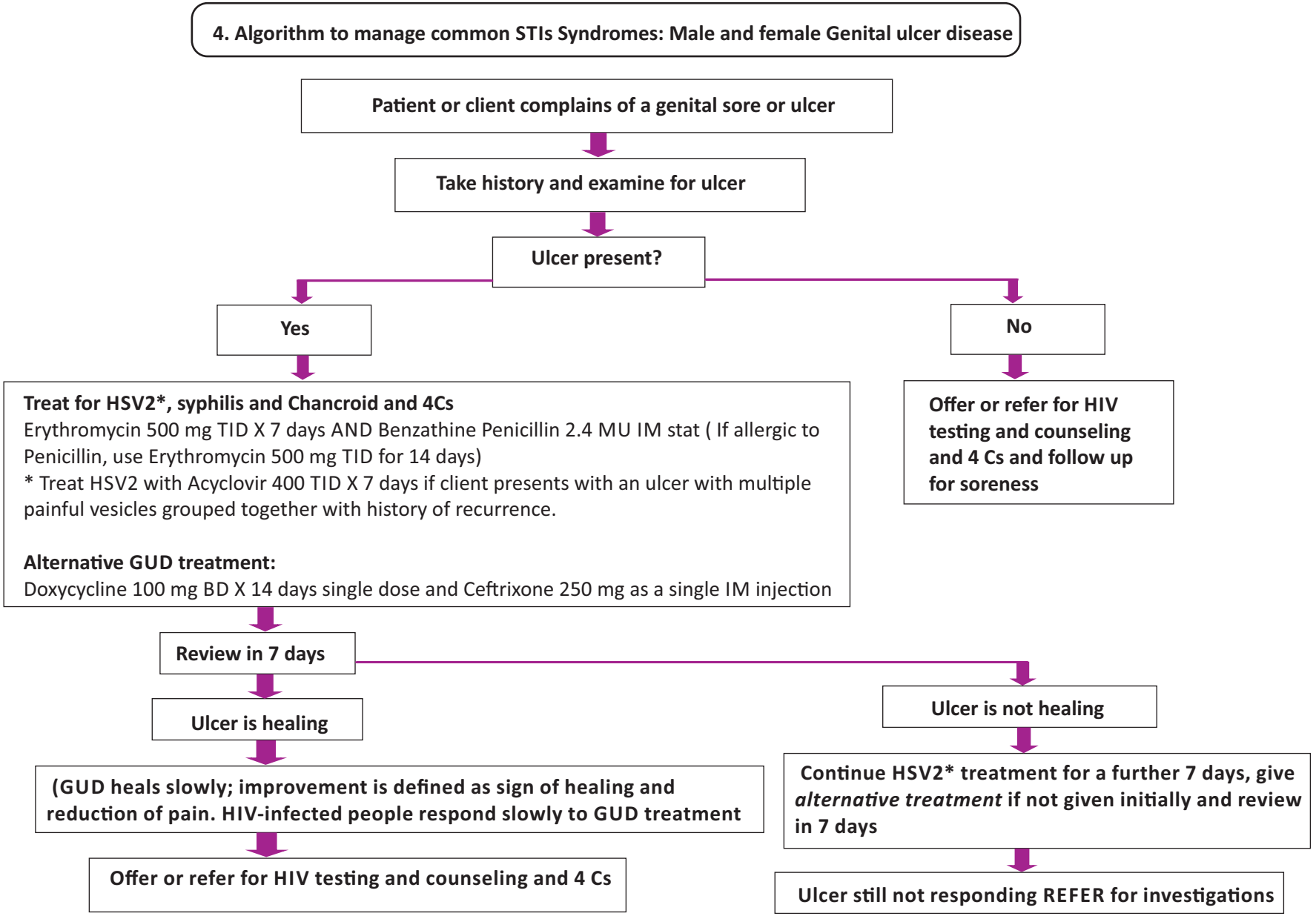
4.2.3 Algorithm to manage common STIs Syndromes: Lower abdominal pain in women

Figure 4.4 Managing common STIs Syndromes: Lower abdominal pain in women



4.2.4 Algorithm to manage common STIs Syndromes: Male and female genital ulcer disease

Figure 4.5 Managing common STIs Syndromes: Male and female Genital ulcer disease



4.2.5 Algorithm to manage common STIs Syndromes: Opthalmia Neonatorum

Figure 4.6 Managing common STIs Syndromes: Opthalmia Neonatorum

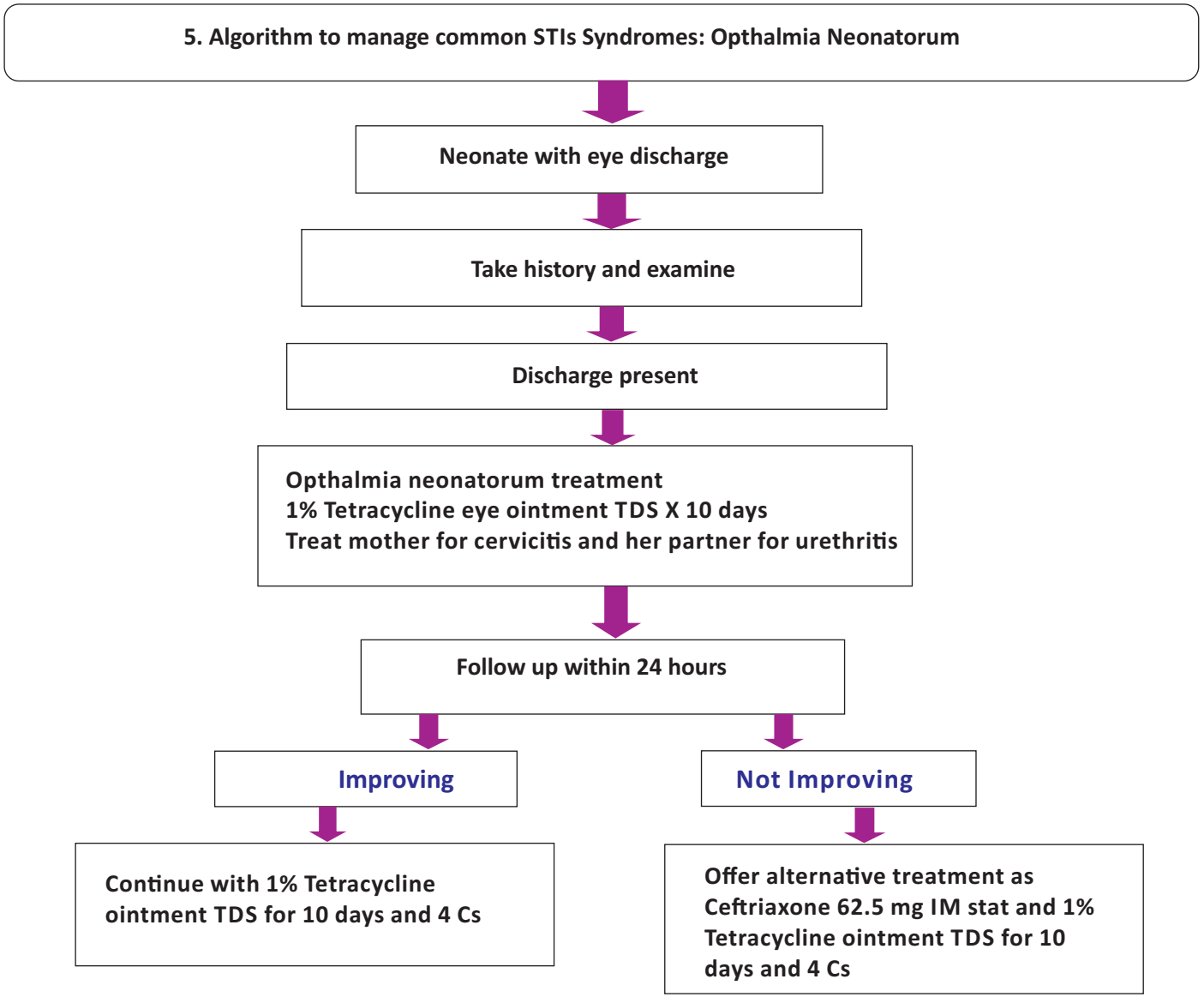


Table 4.5 Staging classification for KS from AIDS Clinical Trial Group (ACTG)

	Good Risk (0)[1] (all of the following)	**Poor Risk (1)[2]** (any of the following)
Tumour	Confined to skin and/or lymph nodes and/or minimal oral disease 3	Tumor associated edema or ulceration Extension oral KS in other non-nodal viscera Mucous lesion located on the conjunctiva
Immune system (I)	CD4 cells >200/mm3	Cd4 cells < 200/mm3
Systemic illness (S)	No history of OI or thrush No 'B' symptoms4 Kanorfsky performance status >70	History of OI and/or thrush 'B' symptoms present Performance status <70 Other HIV-related illness (e.g. neurological disease, lymphoma)

[1]Combination of T (0) I (0) S (0) is good risk disease

[2]T (1), I (1) or S (1) or combination of any is poor risk disease

[3]Minimal oral disease is non-nodular KS confined to the palate
[4] 'B' symptoms are unexplained fever, night sweats, > 10% unintentional weight loss, or diarrhea persisting for more than 2 weeks

Figure 4.7 Staging classification for KS from AIDS Clinical Trial Group

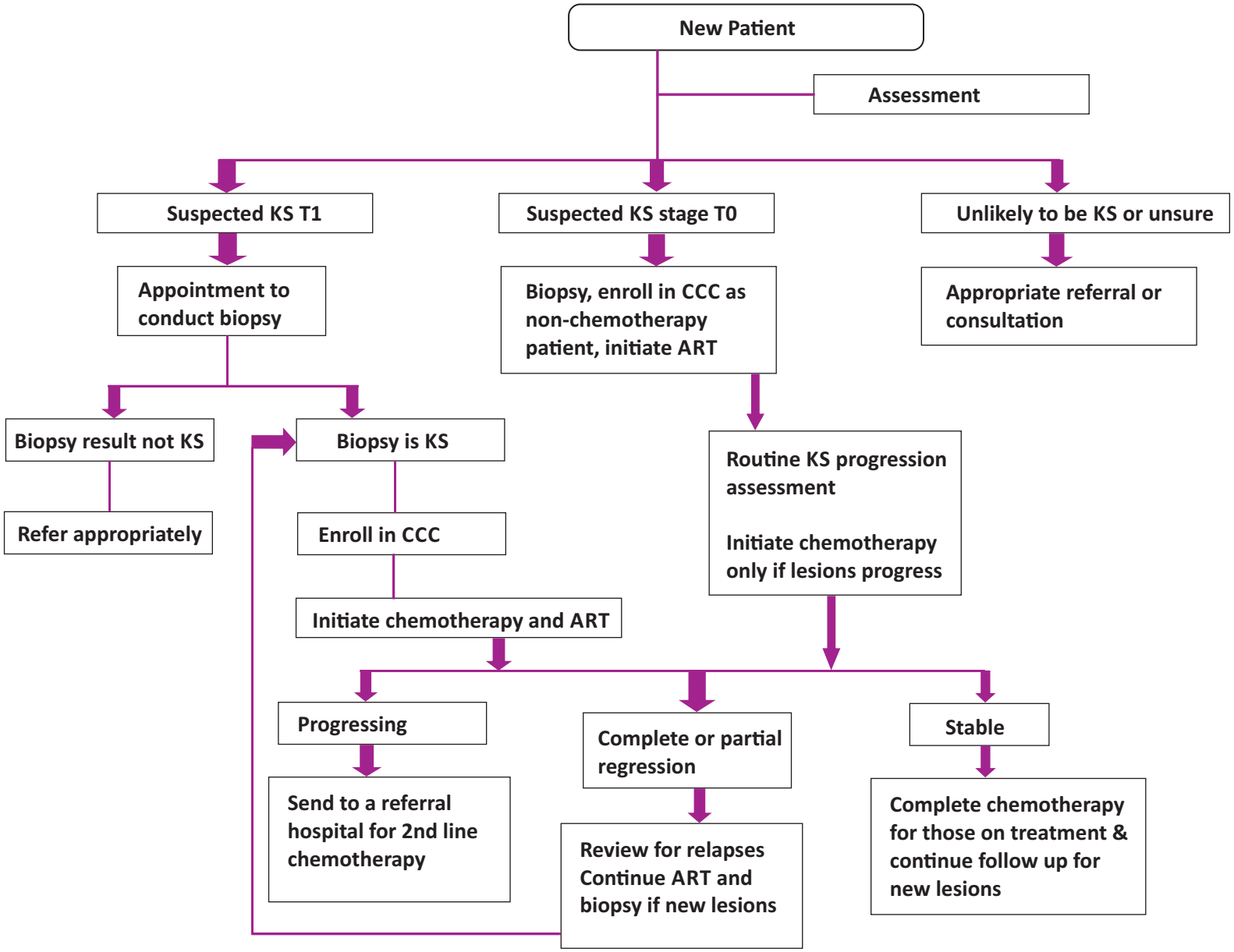


Table 4.6 Chemotherapeutic agents for Kaposi's sarcoma

Goals of treatment

- Symptom palliation
- Prevent disease progression
- Shrinkage of tumor
- Alleviate edema, organ compromise and psychological stress

Treatment options	Dosing and cycle	Comments
ART (mandatory for all KS patients	Give as indicated in ART guidelines PI and NNRTI equally effective	Maybe sufficient for good risk disease IRIS may occur
Triple chemotherapy (ABV, preferred)	Vincristine (2 mg) + Bleomycin (15U/m2) + Doxorubicin(Adriamycin)(40 mg/m2) **Give every 3 weeks for 6 cycles**	Achieves higher remission rates with a response rate of 25-88%
Dual chemotherapy (BV, alternative)	Bleomycin 15 U IM + vincristine 2 mg IV **Give every 2 weeks for 6 cycles**	Similar efficacy to ABV but has no myelotoxicity
Monotherapy (alternative)	Vincristine or Vinblastine 2 mg I.V Give weekly for 6 - 9 cycles	Lesion regression rate is 33%
	Bleomycin 15 IU I.M **Give every 2 weeks for 6-9 cycles**	Lesion regression rate is 33%

Table 4.7 Chemotherapy guidance for Kaposis Sarcoma

FORMULATION & DOSAGE	DRUG RECONSTITITION & ADMINISTRATION	SIDE EFFECTS
VINCRISTINE SULPHATE		
Vial contains 1mg/ml of reconstituted solution Adults; 1.4mg/m2 Children; 2mg/m2 Child ≤10 kg, start at 0.05mg/kg	Keep the solution away from direct sunlight **For intravenous (IV) injection only** **Intrathecal use leads to ascending paralysis and death** Given directly into a vein as a bolus over one minute or into the tubing of a rapidly running IV fluid (Normal Saline or 5% Dextrose)	GIT; Constipation, cramps, weight loss, nausea, vomiting, oral ulcers, diarrhea, paralytic ileus, intestinal necrosis/perforation, anorexia GUT—Polyuria, dysuria, urine retention due to bladder atony
Reduce dose by 50% if bilirubin > 3mg/100ml	Discontinue in case of extravasations and insert branula into a different large bore vein. May use local heat or local injection of hyaluronidase in extravasation	GIT; Constipation, cramps, weight loss, nausea, vomiting, oral ulcers, diarrhea, paralytic ileus, intestinal necrosis/perforation, anorexia GUT - Polyuria, dysuria, urine retention due to bladder atony CVS -Hypertension, hypotension, coronary artery disease, Myocardial Infarction in prior mediastinal radiation Neurologic; Sensorimotor neuropathy, convulsions, coma, transient cortical blindness, optic atrophy Endocrine—SIADH Hematologic; anemia, leukopenia, thrombocytopenia Other - Fever, headache, alopecia, skin hypersensitivity Pregnancy category D

BLEOMYCIN SULPHATE		
Vial of 15 U and 30U of Bleomycin powder, stable at 2-8 degrees Adults & Children 10-15 U/m2 Adjust dosage for patients with renal dysfunction	Can be administered I.M, IV, SC or intra-pleurally. **IV administration recommended** Reconstitute the 15U vial with 5ml (1-5 ml for IM, SC) of sterile water for injection, NS or bacteriostatic water for injection. Reconstitute the 30U vial with 10 ml (2-10 ml for IM, SC)of the above diluents Reconstitution with dextrose leads to loss of potency Reconstituted solution stable for 24 hr at room temperature; give slowly over 10 min	Pulmonary dysfunction either pneumonitis or fibrosis leading to dyspnoea at cumulative doses > 400 U in elderly or lower in the young. Mortality 1% Do CXRs every 2 weeks in suspected cases Stop treatment if patchy opacities in lower lung fields seen on X-ray Pulmonary Function Tests show reduced total lung volume and vital capacity Pregnancy category D
ADRIAMYCIN (DOXORUBICIN HYDROCHLORIDE)		
ADRIAMYCIN RDF (Doxorubicin Hydrochloride USP) Available as 10, 20 and 50 mg single dose vials and a 150 mg multi-dose vial Adults & children; 40-60 mg/m2 Reduce dose by 50% if bilirubin is 1.2 -3 and by 75% if bilirubin is 3.1-5 mg/dl	Reconstitute with NS as follows to give a concentration of 2 mg/ml 10 mg → 5 ml 20 mg → 10 ml 50 mg → 25 ml 150 mg → 75 ml Withdraw air from the vial during reconstitution to avoid excessive pressure build-up Shake to allow contents to dissolve and keep from direct sunlight The reconstituted solution is stable for 7 days at room temperature and 15 days at 2 to 8 o C	Hematological; Myelosuppression therefore avoid when FBC is abnormal, AML Myocardial toxicity with congestive heart failure may occur during therapy or months to years later Baseline ECG and ECHO recommended in pre-existing heart disease, prior mediastinal irradiation, concurrent cyclophosphamide use and at cumulative doses of ≥ 400 mg/m² Risk of delayed cardiotoxicity high in kids Refer if ejection fraction (EF) declines by 10% below the lower limit of normal, by 20% at any level or the absolute EF is < 45% Arrhythmias may occur during or after administration therefore monitor pulse

CONTINUED...ADRIAMYCIN (DOXORUBICIN HYDROCHLORIDE)		
	Administer I.V into a large vein as a slow infusion in NS or 5%D. Discard unused solution from the single use vials immediately and from multiple use vial once exceeds storage recommendations Irrigate skin/eyes with copious amounts of water if exposed	Skin; alopecia, hyperpigmentation of nail beds and dermal creases, onycholysis, rash GIT; nausea, vomiting, mucositis, ulcers, necrosis, diarrhoea, anorexia Local; cellulitis, vesication, tissue necrosis, extravasation (erythematous streaking proximal to site of injection, phlebosclerosis) facial flushing (if given rapidly) Hypersensitivity; fevers, chills, anaphylaxis Other; conjunctivitis, lacrimation

Table 4.7 Chemotherapy guidance for Kaposis Sarcoma (continued)

Other drugs		
1. Pegylated liposomal doxo & daunorubicin Dose 20mg/m2 doxo every 3 wk, 40mg/m2 dauno every 2 wk	**Are FDA approved first line. May be used as second line in patients failing ABV** Is expensive Gives higher drug tumor conc, less cardiotoxic & myelosuppressive, response rate 45%	
2. Local treatment (<25 skin lesions);	Surgical excision, intra-lesional chemotherapy, radiation, cryotherapy, topical altretinoin gel	
3. Etoposide	Dose; 50 mg/day for 7 consecutive days of every two week cycle. May accelerate to 100mg	
4. Paclitaxel	Dose; 100 mg/m2 I.V every 2 weeks, overall response rate comparable to PLD (56%-71%)	Alopecia, myalgia, arthralgia, aggravation of preexisting neuropathy, neutropenia, fevers and rash

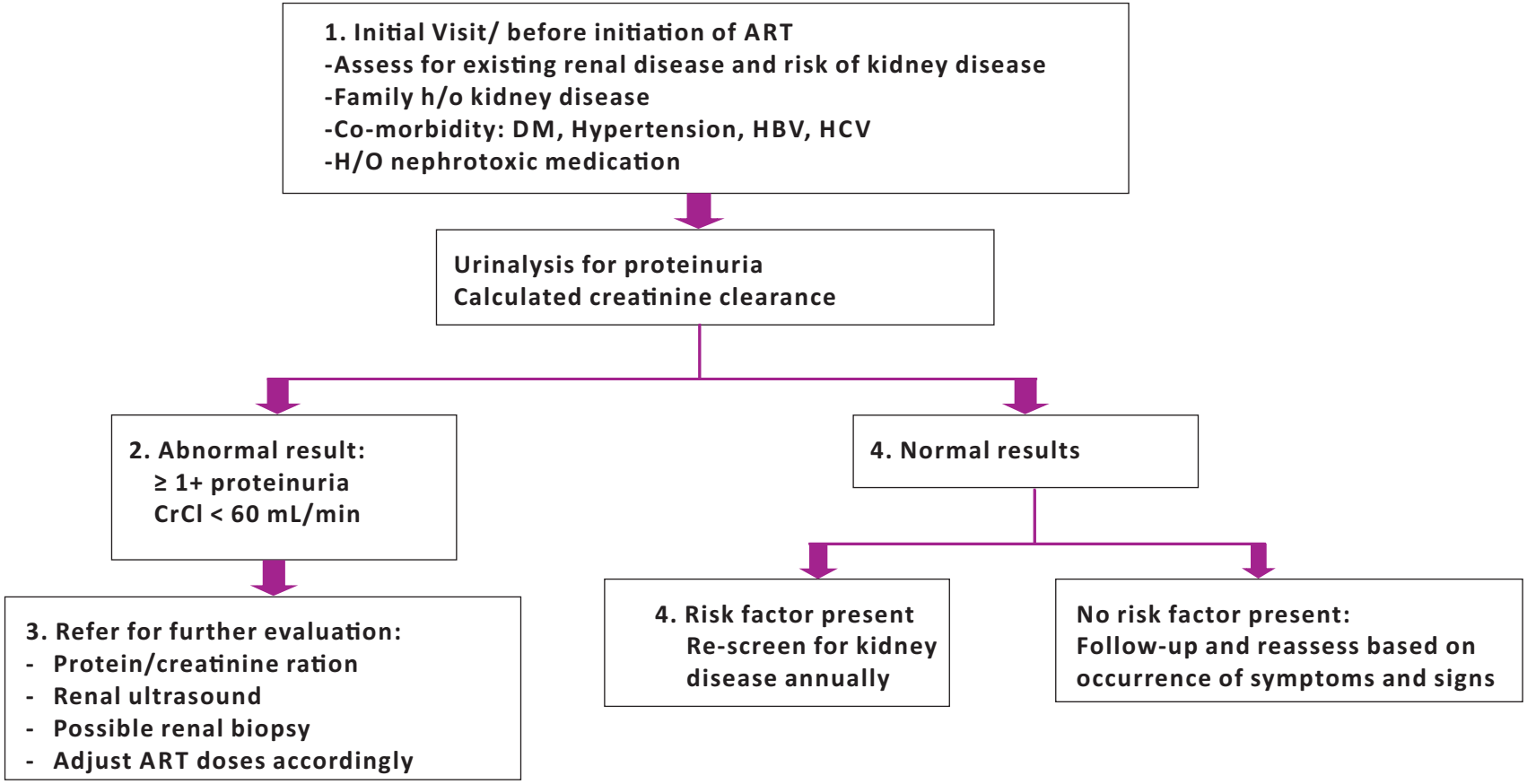
Table 4.8 Schedule of clinic visits and actions in KS management

Schedule of clinic visits and actions in KS management	
First visit / contact	• Take history, and conduct a physical examination and document in the clinical oncology forms • Establish the performance status of the patient using the kanorfsky scale • Stage the patient using the revised ACTG classification • Take baseline samples for the laboratory o ALT, Creatinine o Complete Blood Count o CD4 (or review results) • Do biopsy if KS is suspected • Treat inter-current infections • Prescribe Co-trimoxazole and ART (after adherence counselling) • Give patient an appointment in one week's time
Second visit (Week 2)	• Review patient's clinical condition and biopsy results; if KS confirmed; o Review lab results to determine eligibility for chemotherapy i.e. o Hb >10 g/dL o WBC count > 4 × 10 9/L o Creatinine Clearance > 50 ml/min o LFT normal o Discuss the treatment plan with the patient and get informed consent o Counsel patient on Kaposi's Sarcoma management • Give a specific appointment and prepare patient (counselling on chemotherapy administration, side effects, monitoring, compliance and outcomes; anti-emetics, hydration) • Administer pre- treatment drugs • Select a regimen either triple (ABV) or dual (BV) chemotherapy depending on clinical/lab status and administer • Closely monitor patient during and for one hour after the chemotherapy for extravasation, or change in vital signs Advise patient to visit the lab for the tests above before the next appointment
Follow up	• During each of the 3 weekly follow-up visits; o Review lab results o Conduct a thorough clinical assessment and document treatment response o Educate patient at each visit on treatment compliance and toxicity o Administer pre-treatment drugs o Administer chemotherapy only if there are no contra-indications Conduct clinical and laboratory monitoring for toxicity

Table 4.9 Evaluation of the treatment response (AIDS Clinical Trial Group, ACTG)

Complete Response (CR)	**Absence of detectable lesion, including tumour associated oedema, for more than 4 consecutive weeks**
Partial Response (PR)	**· Diminution of 50% of the total number and/or the size of previously existing lesions (skin, oral, measurable visceral disease) for more than 4 consecutive weeks and/or flattening of 50% of the nodular lesions without occurrence of new lesions** **Complete Response but with persistence of residual oedema**
Progression	**· Any response not meeting the criteria for progression or Partial Response** **· Increase in 25% or more in the number and/or size of previously existing lesions** **· Appearance of new cutaneo-mucous lesions (nodules, plaque, macula, edema, ulceration or infiltration) or new localizations**

Figure 4.11 Screening for Kidney Disease in HIV infection



Notes:

1. All HIV infected patients should be assessed for existing kidney disease or risk of kidney disease through history and examination. Where available, all patients should undergo dipstick urinalysis for proteinuria, and a calculated creatinine clearance (particularly for patients initiating TDF containing ART and those with an abnormal urinalysis). Where these tests are not routinely available preference should be given to those considered at risk or with pre-existing kidney disease
2. Proteinuria is defined as persistent if confirmed on >2 occasions two weeks apart.
3. Referral for further evaluation is indicated for patients with persistent proteinuria and/or creatinine clearance < 60 ml/min. For further details, see **Table 5.1 .**
4. If there is no evidence of renal disease, in patients at risk for proteinuric renal disease, re-assess renal function biannually.

Management of kidney disease in HIV infection

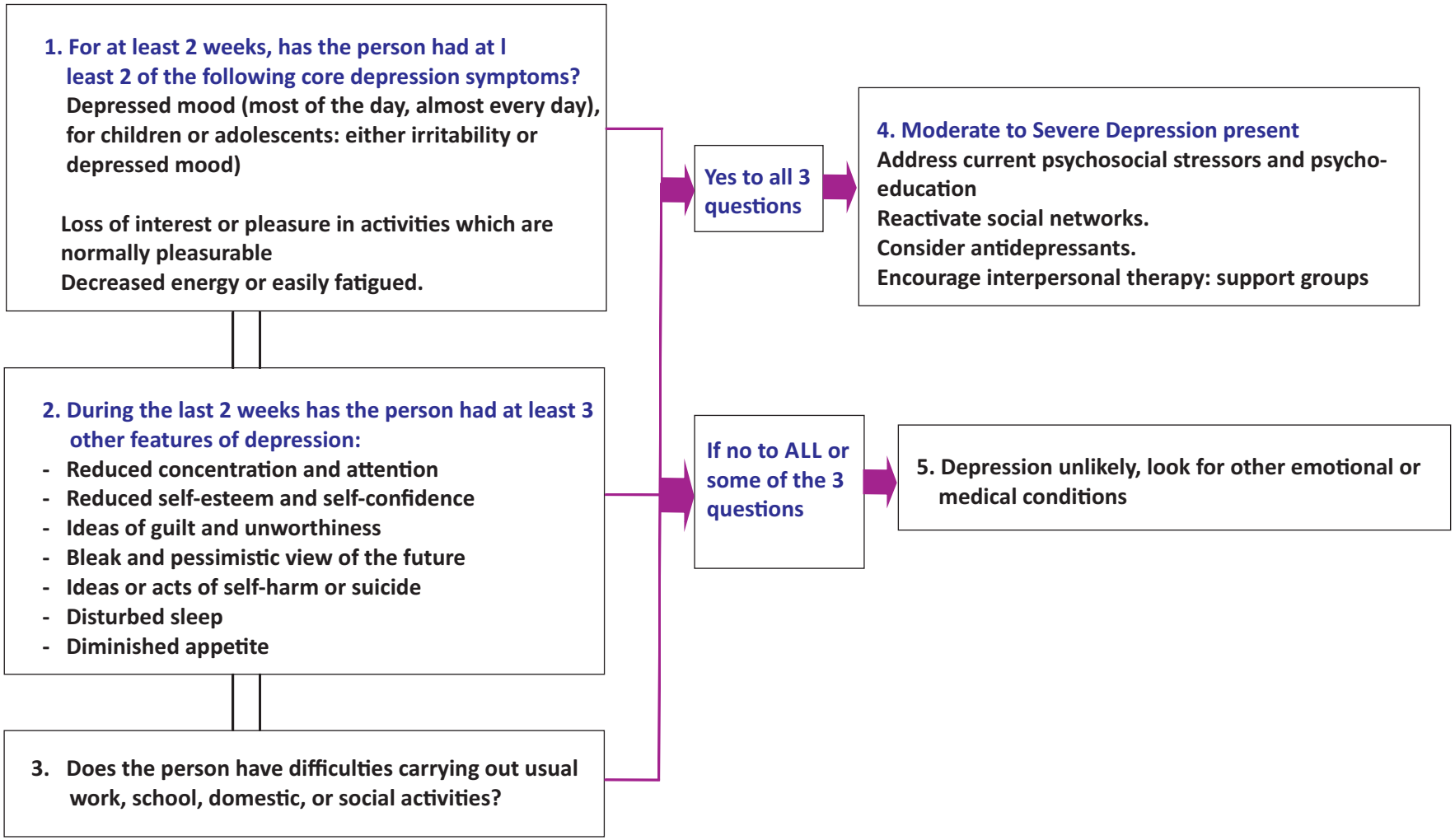
Table 4.10 Management of kidney disease in HIV infection

Intervention	Comments
General Measures - Treat dehydration promptly and aggressively - Avoid nephrotoxic drugs - Life style measures (smoking, weight, diet) - Treat dyslipidaemia and diabetes, hypertension - Adjust drug dosages where necessary	Refer for further evaluation patients with · Persistent proteinuria, · CrCl < 60, HBC/HCV co-infection
Start ACE inhibitors if: a) Hypertension, and/or b) Proteinuria	Target BP SBP < 130, DBP < 80 mmHg
ART	Start ART in ALL patients with persistent proteinuria and oedema irrespective of CD4 count

Table 4.11 Dosing of ARVs in renal and hepatic impairment

Agent	Dose for normal renal function	Estimated Creatinine Clearance (CrCL) in ml/min		
		> 50	10 – 50	10 – 50
Abacavir/ABC	300mg po bid	**No adjustment recommended**		
Lamivudine/3TC	150mg bid	100%	150mg qd	150mg qd
Zidovudine/AZT	300mg bid	300mg bid	300mg bid	300mg qd
Efavirenz/EFV	600mg po qd	No adjustment recommended		
Nevirapine/NVP	200mg qd x 14 days, then 200mg po bid	No adjustment recommended		
Loprinavir/ ritonavir LPV/r	400/100mg bid	No adjustment recommended		
Azatanavir/ritonvir	300/100 mg OD			
Darunavir				
Zidovudine/Lamivudine AZT/3TC	300/150mg bid	300/150mg bid		Use individual drugs at doses listed above

Figure 4.9 Depression assessment



Adopted from WHO

Non-pharmacological management of depression

1. Psycho-education (targeting the patient and trusted caregiver/family)
2. Address psychosocial stressors
3. Pharmacological Management

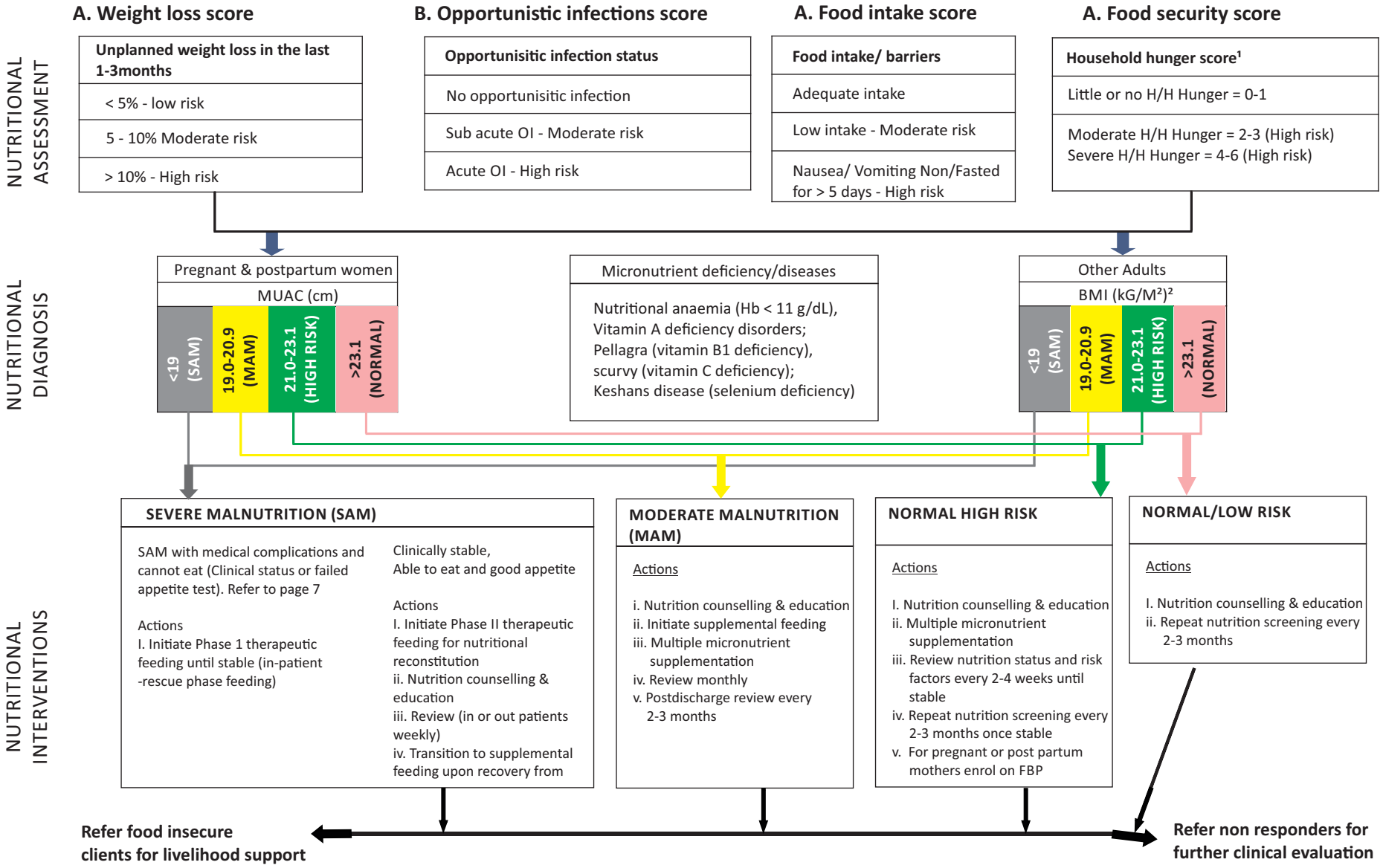
- Minor depression often responds to supportive counselling (as above).
- Patients with moderate to severe depression may benefit from antidepressant medication. It takes least 6 to 8 weeks of antidepressant medication to see benefit in most patients; and it should be continued for at least 6 months.
- In selecting the appropriate antidepressant to use, consider the drug's side effect profile and the potential for drug interactions especially with antiretroviral agents and other OI medication.

Fluoxetine is a selective serotonin re-uptake inhibitor (SSRI), which is better tolerated (but can also cause anorexia, weight loss, nausea, anxiety, agitation, insomnia, drowsiness, dry mouth, diarrhoea, acute dystonia and motor restlessness). It is given in doses of 10 to 40 mg once daily; in the morning. Ritonavir minimally increases blood levels of fluoxetine. No dose adjustment is required.

4. Indications for Specialist Referral

- Suicidal intent
- Risk of harm to others
- Disabling disease
- Severe physical deterioration attributable to depression
- Manic symptoms

Figure 4.10 Diagnosis and management of malnutrition in HIV infected adult patients



[1] Refer to household food security assessment tool
[2] For overweight and obese, refer for counselling
[3] Implement local clinical policy and protocal

SECTION 5

Post Exposure Prophylaxis

Table 5.1 Risk assessment following exposure based on type of exposure

Exposure	Low Risk	High Risk
Type	Intact skin	Mucus membrane/ non-intact skin Percutaneous injury
Source	HIV negative	HIV status unknown; clinically well/unwell
Material	Saliva, tears, sweat, faeces, urine, sputum, vomit	Semen, vaginal secretions, synovial, pleural, pericardial, peritoneal, amniotic fluids Blood and bloody bodily fluids; CSF; viral cultures in laboratories

Risk assessment should be carried our based on the type of exposure. E.g. if exposure to blood is on intact skin, it is low risk but exposure to saliva or vomit on a non - intact skin may be considered low- risk but it can be high risk if vomit or saliva contains blood.

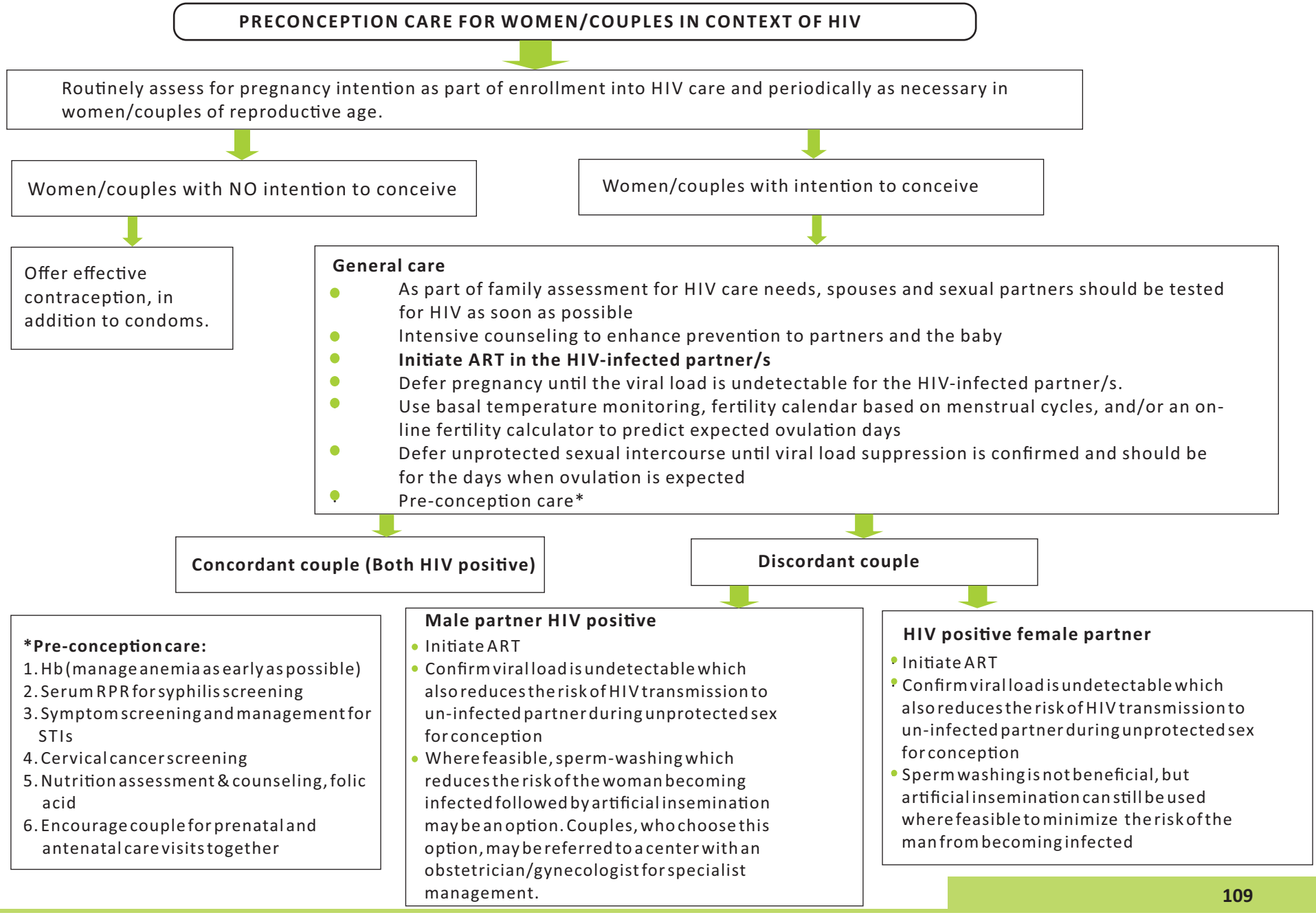
Table 5.2 Summary of medical management of HIV post-exposure prophylaxis

	Recommended Action
Eligibility	Exposure within 72 hours (The early the better outcome) Exposed individual not HIV infected(R/o by doing rapid test) High risk exposure Source individual HIV positive or of unknown HIV status
Counseling and Testing the exposed individual	Verbal consent adequate for HIV testing Base-line HIV test in HIV exposed person Voluntary testing for both exposed and source individuals
ARV agents for PEP	Occupational exposure if high risk: TDF or AZT + 3TC + ATV/r or LPV/r
	Sexual assault (Adult): TDF or AZT + 3TC + ATV/r or LPV/r
	Sexual assault (children): AZT or ABC + 3TC + LPV/r (Adult formulation of ATV/r can be used in children weighing >40Kg)
Time of Initiation	As soon as possible after exposure, but no later than after 72 hours
Duration of therapy	28 days
Dose of PEP	Same as indicated for ART, use dosing wheel for children for age appropriate dosing.
Follow-up	Follow-up HIV testing at 3 and 6 months after exposure Pregnancy testing Hepatitis B and C screening (if available) Management of side effects
Counselling	Adherence counseling, risk reduction, trauma and mental health problems, social support and safety, safe sex practices
Additional services for sexual assault	Emergency Contraceptive for non-pregnant women, Document clinical evidence of an assault and collection of forensic services. Alert authorizes and refer for appropriate legal services STI prophylaxis: • Adult non-pregnant : PO Doxycycline 100mg BD X 7 days + PO Norfloxacin 800 mg stat • Adult pregnant: IM inj. Spectinomycin 2gm stat + PO Erythromycin 500 mg QID X 7 days • Children: PO Amoxycillin 15 mg/kg/dose TDS X 7 days+ PO Erythromycin 10 mg QID X 7 days

SECTION 6

Pre-conception Care and Contraceptive Options in People Living with HIV

Figure 6.1 Preconception care for women/couples in context of HIV



6.2 Contraceptive options

- HIV-infected women and couples living with HIV infection should be encouraged to discuss their reproductive intentions. Where pregnancy is not desired, effective contraception should be offered; if hormonal methods are chosen, dual method should always be encouraged.
- Effective use of contraception in HIV+ women plays an important role in the prevention of unintended pregnancies and thus the prevention of mother to child transmission (PMTCT) of HIV infection.
- Hormonal contraception may be used in HIV-infected women; however the choice of hormonal contraception should take into account ARV drug use.
  Where pregnancy is desired, a couple's status should be considered; if discordance exists, appropriate advice and support should be given. If pregnancy has occurred in a HIV-infected woman, in addition to PMTCT services, the mother's own health should be optimized.

Table 6.1 Contraceptive methods for use in PLHIV

Method	Comments	Use in PLHIV
Condoms	• Male & female condoms available • Provide dual protection against STIs/HIV & pregnancy. • Require attention & care for correct use each time. • May require co-operation of partner	• **Can and should be used at all stages of HIV infection** • **Can and should be used by patients on ART** • Correct and consistent use by HIV infected patients is recommended regardless of the use of other methods of contraception (dual contraception).
Hormonal Methods	• Very effective and easy to use • Suitable for short- or long-term use • Reversible • Associated with non-contraceptive health benefits • Serious complications are rare	• Can be used without restriction in HIV+ women not on ART • Can be used without restriction in all HIV+ women for emergency contraception • Some ARV drugs may reduce method effectiveness • DMPA*/Implants can however be used with ART; re-injection of DMPA should be done at 10-12 weeks • If a hormonal method is chosen, condoms should still be used correctly and consistently
Intrauterine Contraceptive Device	• Highly effective, long-term, reversible method • Remains in place up to 12 years Almost 100 percent effective • Has no effect on fertility when used by nulliparous women • Should not be provided to women with high risk sexual lifestyle • Bacterial STIs should be screened for and /or treated as a precautions prior to insertion • of IUCD	• Attractive method for women with HIV who desire very reliable pregnancy protection • Can be inserted in HIV+ women who do not have WHO Stage 4 disease/AIDS defining illness • For women with stage 4 disease IUD can be inserted once they are on ART and have controlled symptoms of severe illness
Sterilization	• Good, very effective for couples or individuals who want no more children • Safe, simple surgical procedure Considered permanent	• No medical reasons to deny sterilization to clients with HIV • Procedure may be delayed in event of acute HIV-related infection or stage 4 disease pending immune reconstitution • Encourage condom use as well

Table 6.2 Family planning and contraceptives for people living with HIV

Summary chart		Condition				
Contraceptive method		HIV-	AIDs	ARV therapy NRTIs	NRTIs	PI
DMPA		1	1	1	1	1
NET-EN		1	1	1	2	2
Implants		1	1	1	2	2
Oral contraceptives		1	1	1	2	3
IUCD	Initiation	2	3*	2/3*	2/3*	2/3*
	Continuation	2	2	2	2	2
Condoms		No restrictions; use is encouraged to prevent STI/HIV transmission				
ECPs		No restrictions				
Sterilization		No reasons to deny. Delay in case of acute HIV-related infection				
FAB methods		Can use if menstrual cycle is regular. Encourage to continue using condoms outside the fertile window to prevent STI/HIV transmission.				
LAM		Advice on the risk of transmission; exclusive breastfeeding reduce risk compared to mixed feeding.				
Spermicides and diaphragm		Use is not recommended, may increase risk of HIV transmission/superinfection				

Category 2 if client with AIDs is clinically well on ARV therapy; otherwise category 3.
1. Use method in any circumstances, 2 - Generally use the method,
3. Use of method not usually recommended unless other more appropriate methods are not available or not acceptable

PREGNANCY ASSESSMENT, PREGNANCY INTENTION AND CONTRACEPTIVE USE TOOL

NAME: _____ **DOB**_____ **CCC No.** _____

Marital Status: ☐ Single ☐ Married ☐ Separated/Divorced ☐ Widowed
Partner Status: ☐ +Ve- ☐ -Ve ☐ Not Known On ART: ☐ Yes ☐ No

DATE			**Initial Date**	**At 3 months**	**At 6 months**	**At 9 months**	**At 9 months**	**At 12 months**	**At 15 months**	**At 18 months**	**At 18 months**	**At 24 months**
1. CONTRACPETIVE	**Do you use condoms?**	Male condom?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		Female condom?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
	Are you on any contraceptive? (excluding condom)		Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
	3) If yes, which method(s) of contraception do you use? **(tick all that apply)**	I. Oral Contraceptive	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		ii. Injectable Contraceptive	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		iii. Intrauterine Device	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		iv. Implants	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

Pregnancy Intention and Contraceptive Use Checklist

DATE			Initial Date	At 3 months	At 6 months	At 9 months	At 9 months	At 12 months	At 15 months	At 18 months	At 18 months	At 24 months
1. CONTRACPETIVE	**Do you use condoms?**	Male condom?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		Female condom?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
	Are you on any contraceptive? (excluding condom)		Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
	3) If yes, which method(s) of contraception do you use? **(tick all that apply)**	v. Tubal ligation	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		vi. Vasectomy (Partners)	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		vii. Abstinence	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		viii. Lactational Amenorrhoea	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		ix. Natural Method	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		x. Emergency contraceptive pills	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

Pregnancy Intention and Contraceptive Use Checklist

DATE			Initial Date	At 3 months	At 6 months	At 9 months	At 9 months	At 12 months	At 15 months	At 18 months	At 18 months	At 24 months
1. CONTRACPETIVE	**Do you use condoms?**	Male condom?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		Female condom?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
	Are you on any contraceptive? (excluding condom)		Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
	3) If yes, which method(s) of contraception do you use? **(tick all that apply)**	v. Tubal ligation	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		vi. Vasectomy (Partners)	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		vii. Abstinence	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		viii. Lactational Amenorrhoea	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		ix. Natural Method	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
		x. Emergency contraceptive pills	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

Pregnancy Intention and Contraceptive Use Checklist

		Initial Date	At 3 months	At 6 months	At 9 months	At 9 months	At 12 months	At 15 months	At 18 months	At 18 months	At 24 months
	4) If the client is not on a method counsel and indicate contraceptive method of choice.										
II. PREGNANCY ASSESSMENT	5) Have you been experiencing regular menses?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
	6) When was your last normal menstrual period? **(Indicate date. If > than 6 weeks complete sections 7 and 8)**										
	7) Have you experienced any of the following symptoms: Nausea, breast tenderness, unusual tiredness, spotting? (If yes go to question 8)	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
	8) Do a pregnancy test for those who have missed their menstrual period for >6 weeks, or have signs and symptoms of pregnancy and are not on a contraceptive method.	Pos / Yes / No	Pos / Yes / No	Pos / Yes / No	Pos / Yes / No	Pos / Yes / No	Pos / Yes / No	Pos / Yes / No	Pos / Yes / No	Pos / Yes / No	Pos / Yes / No
III. PREGNANCY INTENTION	9) Are you planning to conceive in the next 3 months? (If No, and the client is not on a contraceptive method, go to question 4)	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No
IV. PMTCT SAFE PREGNANCY	10) Is the CD4 count >350 cells/mm^3? (If yes assess for any illness and treat and plan for pregnancy, If no assess and treat for illness and advice on FP method) NB: For those on ART more than 6 months, do VL if feasible.										

EDITORIAL TEAM : LIST OF CONTRIBUTORS

Contributors

Dr. Irene Mukui NASCOP
Dr. Shobha Vakil NASCOP/HRH CBP
Dr. Jared Mecha UON
Dr. Maureen Kimani MOH
Dr. Linda Misiko NASCOP
Dr. Reson Marima UMB
Dr. Jeremy Penner Health Strat
Dr. Angela Mcligeyo CHS
Dr. Maureen Syowai ICAP
Dr. Neveen Elantouny Coptic Hospital
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Dr. Enos Masini NLTLD-U
Betty Chepkwony NASCOP
Dr. Fridah Njogu - Ndogwe CHS
Dr. Eric Mugambi CRISSP

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Editorial team

Dr. Irene Mukui NASCOP
Dr. Shobha Vakil NASCOP/ HRH CBP
Dr. Jared Mecha UON/CRISSP
Dr. Maureen Kimani MOH
Dr. Linda Misiko NASCOP
Dr. Reson Marima UMB
Dr. Joseph Nkuranga UMB

Design, editing and layout

Steve Adala

Copyright statement

For clarifications contact
National AIDS and STI Control Program (NASCOP)
P.O. Box 19361 00202,
Nairobi Kenya,
Tel: 254 020 2630867,
Email: info@nascop.or.ke,
Website: www.nascop.or.ke

National AIDs & STI Control Program

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