HIV/AIDS CARE AND TREATMENT

GUIDE FOR IMPLEMENTATION

World Health Organization
Western Pacific Region

HIV/AIDS CARE AND TREATMENT:

GUIDE FOR IMPLEMENTATION

WORLD HEALTH ORGANIZATION

Regional Office for the Western Pacific

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This is an interim guide released for country adaptation and use
to help with the emergency scale-up of antiretroviral treatment (ART) and
accelerated HIV prevention in resource-limited settings in the Western Pacific Region.
This interim guide will be revised soon based on early implementation experience.

Please send comments and suggestions to
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Glossary of Terms

ABC	abacavir
APSA	advanced package of services and activities
3TC	lamivudine
AIDS	acquired immunodeficiency syndrome
AFB	acid-fast bacilli
ALT	alanine aminotransferase
AZT	azidothymidine (zidovudine)
ART	antiretroviral therapy
ARV	antiretroviral
BAL	broncho-alveolar lavage
bid	two times per day
CBC	complete blood count
CBO	community-based organization
CMV	cytomegalovirus
CNS	central nervous system
CSF	cerebrospinal fluid
CT	computerized tomography
d4T	stavudine
ddC	zalcitabine
ddI	didanosine
DOTS	directly observed treatment, short-course
EBV	Epstein-Barr virus
EIA	enzyme immune assay
ELISA	enzyme linked immunosorbent assay
EFV	efavirenz
EPSA	essential package of services and activities
FBO	faith-based organization
Hbs Ag	hepatitis B surface antigen
HCV	hepatitis C virus
Hgb	hemoglobin
HIV	human immunodeficiency virus
HPV	human papilloma virus
HSV	herpes simplex virus
IGA	income-generating activities
IM	intramuscular
INH	isoniazid
IPT	isoniazid preventive therapy
IV	intravenous
MAC	mycobacterium avium complex
LPV	lopinavir
LPV/r	lopinavir/ritonavir
NGO	nongovernmental organization
NRTI	nucleoside reverse transcriptase inhibitor
NNRTI	non-nucleoside reverse transcriptase inhibitor
NFV	nelfinavir
NVP	nevirapine
od	once daily
PCP	pneumocystis carinii pneumonia
PCR	polymerase chain reaction
PI	protease inhibitor
PPE	papular pruritic eruption
qid	four times a day
RTV	ritonavir
SPSA	supportive package of services and activities
SQV	saquinavir
TB	tuberculosis
tid	three times a day
TLC	total lymphocyte count
TMP/SMZ	trimethoprim-Sulfamethoxazole
UNAIDS	Joint United Nations Joint Programme on AIDS/AIDS
VL	viral load
WB	Western blot
WBC	white blood cell
WHO	World Health Organization
ZDV	zidovudine (azidothymidine)

Introduction

Responding to the global AIDS treatment gap and accelerating HIV prevention

Today, an estimated 34-46 million people are living with HIV/AIDS. Almost 6 million people in developing countries will die in the next two years if they do not receive treatment, and only 400 000 people were treated for HIV/AIDS in 2003.[1] In September 2003, the World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) declared lack of access to antiretroviral treatment (ART) a global health emergency. In response, these organizations and their partners launched an effort to provide 3 million people in developing countries with ART by the end of 2005 (the 3 by 5 Initiative).

Evidence from many parts of the world indicates that introducing treatment in affected communities can reduce the fear, stigma, and discrimination that surround HIV/AIDS, increase uptake of HIV testing and counselling, and reinforce prevention efforts.

In line with this global initiative, countries in the Western Pacific Region are developing HIV/AIDS care and treatment programmes with wider use of ART at their core. These countries include Cambodia, China, Papua New Guinea, and Viet Nam. The wider use of ART is supported by funds from the GFATM, bilateral donor agencies, nongovernmental organizations (NGOs), and United Nations (UN) agencies.

Region-specific response needed

The countries in the Region have a number of specific characteristics:

(a) Relatively low HIV prevalence: The context of HIV/AIDS care and treatment in the Western Pacific Region varies considerably from sub-Saharan Africa, the disease's epicentre. Western Pacific Region has an estimated total of 1.4 million adults aged 15-49 and 19 000 children living with HIV/AIDS. The Region has an adult HIV/AIDS prevalence rate of 0.1%, while nearly 8% of adults in sub-Saharan Africa are infected. Prevalence rates are even higher (20%–40%) in southern sub-Saharan Africa.[2]

(b) Need for simultaneous comprehensive care development and wider use of ART: As HIV/AIDS care and treatment activities are small in scale or nonexistent, a major challenge for the Region is to establish mechanisms for comprehensive care including clinical services, psychosocial support, mobilization of HIV prevention, and coordination between various players, while promoting wider use of ART. Countries with extensive ART programmes, such as Brazil and Thailand, used their existing structure of comprehensive care to promote ART.

(c) Focus on vulnerable populations: The HIV epidemic in China occurred primarily through injecting drug use, sex work, and plasma donation. In Viet Nam the epidemic is primarily associated with injecting drug use and sex work, while Cambodia has a generalized epidemic with sex workers particularly vulnerable. HIV prevalence in Papua New Guinea is more difficult to estimate, but the epidemic is thought to be generalized with sex workers being particularly vulnerable. Injecting drug users and sex workers require specialized approaches to

[1] *The World Health Report 2004*. Geneva, World Health Organization, 2004.
[2] *HIV/AIDS in Asia and the Pacific Region 2003*. World Health Organization Western Pacific – South-East Asia, 2004.

HIV/AIDS treatment and care integrated with prevention strategies. China and Viet Nam place injecting drug users and sex workers in rehabilitation centres, sometimes for years. This creates a special challenge for accessing HIV/AIDS treatment and care.

(d) User-fee-oriented health services: In recent years many countries in the Region have changed from publicly funded health systems to systems based on a market economy. This has resulted in higher user fees for access to medical care. HIV/AIDS is known to disproportionately affect the poor. As a result, people living with HIV/AIDS and their families often become destitute in order to access care and treatment. Once destitute, it becomes increasingly difficult to access medical care.

(e) Lack trust in health services: The stigma associated with HIV/AIDS and discrimination among health workers is reported to be high in the Region, particularly because of associations with injecting drug use and sex work. People living with HIV/AIDS report difficulty in accessing health facilities, inappropriate treatment and care at high costs, and a lack of HIV/AIDS resources. These experiences lead people living with HIV/AIDS to have little trust in health services.

(f) Ongoing national responses to HIV/AIDS care and treatment: In response to these Region-specific issues, Cambodia, China, Papua New Guinea, and Viet Nam have established central management units for HIV/AIDS care and treatment through their national AIDS programmes or national AIDS coordinating committees. These units provide guidance for a standardized, unified, and coherent approach such as technical guidelines and frameworks that emphasize the local partnership and coordination mechanisms such as day care centres. Field projects have been implemented according to the frameworks, and lessons learnt from them will form the basis for rapid expansion.

A Region-specific approach is needed to address these issues, as well as to customize HIV/AIDS care and treatment for developing countries' diverse requirements.[3]

Purpose of the guide for implementation

This guide is prepared in response to the 3 by 5 Initiative and to the call for countries to act on the "three ones":

- one agreed AIDS action framework that provides the basis for coordinating the work of all partners;
- one national AIDS coordinating authority with a broad-based, multisectoral mandate; and
- one agreed country-level monitoring and evaluation system.

This document is intended as a guide for country adaptation by national and local coordinating bodies/working groups, including people living with HIV/AIDS to develop, structure, and implement a service package and operational procedures for HIV/AIDS care and treatment in the Region. Countries with relatively high HIV/AIDS prevalence rates in the Region are Cambodia, China, Papua New Guinea, and Viet Nam, but countries with lower HIV prevalence rates will also benefit from this guide.

[3] Kitahata MM, Tegger MK, Wagner EH and Holmes KK. Comprehensive health care for people infected with HIV in developing countries. *BMJ*, 2002, 325:954-957.

Primary attention is given to the establishment of HIV/AIDS care and treatment for adults and adolescents at the district or intermediate level as part of a framework for country action. An example of a framework for action is provided in Annex A.

Assumptions

This guide assumes the following to be either in place or in development in each country in the Region with the initiation of ART:

- top-level political commitment to ART;
- adequate financial resources for ART implementation;
- an uninterrupted supply of commodities, including ARV dugs;
- an enabling regulatory framework for training and certifying new and existing health workers;
- national guidelines for HIV/AIDS treatment and care; and
- accelerated HIV/AIDS prevention programmes.

This document focuses on HIV/AIDS care and treatment for adults and adolescents. Care and treatment for children, especially clinical care, will be developed in the next edition of this document or as a separate document.

Levels of service delivery

For clarity, this document identifies four levels of service delivery:

(a) The home or community level: The home or community level includes people living with HIV/AIDS, including their groups and networks; community-based organizations (CBO); nongovernmental organizations (NGOs); and home- and community-based care. Also included at this level are health posts usually staffed by community health workers or auxiliary nurses.

Each country in the Region has a different mix of players at this level. For example, China and Viet Nam has commune committees and various local unions and leagues. Papua New Guinea relies almost exclusively on international organizations, NGOs, and faith-based organizations (FBOs) at the community level, whereas Cambodia has a mix of commune and community organizations, NGOs, FBOs, and international organizations.

(b) The health-centre level: The health centre is the first level of the formal health care system. In this document, “health centre” refers to larger facilities that may have trained staff such as nurses, midwives, clinical officers, or medical assistants. In some countries, such as China and Viet Nam, there are doctors at the health-centre level. Maternity and minimal laboratory services are often available. Cambodia and Viet Nam have commune health centres, while the health-centre level in China refers to village clinics or township hospitals. Papua New Guinea has care centres at this level that are almost exclusively staffed by NGOs and FBOs.

(c) The district or intermediate level: At the district level, there is typically a hospital with general medical, paediatric, maternity, limited surgical care, in- and outpatient care, and intermittent specialty care. Referrals to the district hospital come from the health-centre level and from private practitioners in the district.

In Cambodia, the intermediate level means the operational district; in Viet Nam, it means the district health centre or hospital; and in China, the intermediate level corresponds to the township or county hospitals. In Papua New Guinea, the district or intermediate level for rural communities means the district hospital, and in urban areas it means urban health centres or private hospitals.

Staff at the district/intermediate level typically includes generalist physicians, nurses, midwives, a pharmacy technician or pharmacists, medical assistants, and laboratory technicians or technology assistants. Laboratory services normally include complete blood counts; malaria smears; tuberculosis (TB) smears; Gram and Wright stains; HIV testing; glucose, urine and pregnancy tests; and chest X-rays. Spinal taps (examination of cerebrospinal fluid), India ink stains, fundoscopy, and liver enzyme tests (alanine aminotransferase [ALT]) should also be made available. CD4 counts are becoming available at this level in countries such as Cambodia. Private hospitals are often present at this level and may be associated with health centres and other levels of care.

District management is responsible for service delivery by different public and private health service organizations, including NGOs, that operate in the district, as well as for the coordination, monitoring, and supervision of disease- and area-specific programmes such as those for TB, immunization, maternal and child health, antenatal care, sexually transmitted infections, family planning, and HIV.

(d) The provincial or tertiary level: At the provincial or tertiary level, there are hospitals with general and specialized care for surgery, complex illnesses, and many kinds of in- and outpatient services. All levels of health care providers are offered, as well as general medical, acute, and chronic care clinics that treat conditions such as HIV/AIDS. More complete laboratory services and reference laboratories where chemistry, CD4 counts, and viral loads can be determined are sometimes available at this level.

Document organization

This document is divided into three parts:

- Part 1: Key elements of HIV/AIDS care and treatment and their implementation in the Region
- Part 2: Packages of services and activities at different levels of the health system
- Part 3: Standard operating procedures and practices

Part 1

Key elements of HIV/AIDS care and treatment and their implementation in the Region

Those infected with and affected by HIV – including families and children – face physical, psychological, and socioeconomic constraints including stigma and discrimination. Support needs are even greater when people living with HIV/AIDS are marginalized and their living situations are unstable, as is often the case with injecting drug users and sex workers. Most importantly, many people living with HIV/AIDS suffer from worsening health and increasing physical disabilities.

HIV/AIDS treatment has the following crucial features:

- ART is lifelong and requires a chronic care approach.
- Adherence to ART of 95% is necessary to prevent viral resistance and treatment failure.
- ART will increase the frequency with which people use testing and counselling services, leading to accelerated HIV prevention activities with an increased role for people living with HIV/AIDS.

In order to optimize adherence to ART and to improve quality of life for people living with HIV/AIDS, it is essential to develop comprehensive care and treatment across the continuum as described below.

1. Key elements of comprehensive HIV/AIDS care and treatment

This document focuses on HIV/AIDS care and treatment for adults and adolescents. Care and treatment for children, especially clinical care, will be developed in the next edition of this document or as a separate document.

1) Mobilization and coordination of key players, including people living with HIV/AIDS

- Public health and clinical services (including tuberculosis [TB], antenatal care, maternal and child health, sexually transmitted infections, family planning, HIV prevention), people living with HIV/AIDS, local authorities, community-based organizations (CBOs), faith-based organizations (FBOs), and nongovernmental organizations (NGOs) need to be mobilized and coordinated.
- Referrals need to be developed across and within levels of service delivery to help persons living with HIV/AIDS access care and treatment, including chronic care management.
- Peer support groups for people living with HIV/AIDS need to be promoted and developed.
- People living with HIV/AIDS need to participate in planning, implementation, delivery, monitoring, and evaluation of care and treatment.

2) Testing and counselling

- HIV testing and counselling should be voluntary and the gateway to treatment, care, and prevention.
- Pretest education/counselling and post-test counselling are essential.
- Confidentiality must be protected.

3) Clinical care

- Chronic care management involves an approach that is centred on the people living with HIV/AIDS and their families, with planned medical visits and regular follow-up.
- Clinical care includes (a) prophylaxis, diagnosis, and treatment of opportunistic infections, including TB; (b) management of ART; (c) support for adherence to treatment; and (d) symptom and pain management in palliative care.

4) Psychological and socioeconomic support

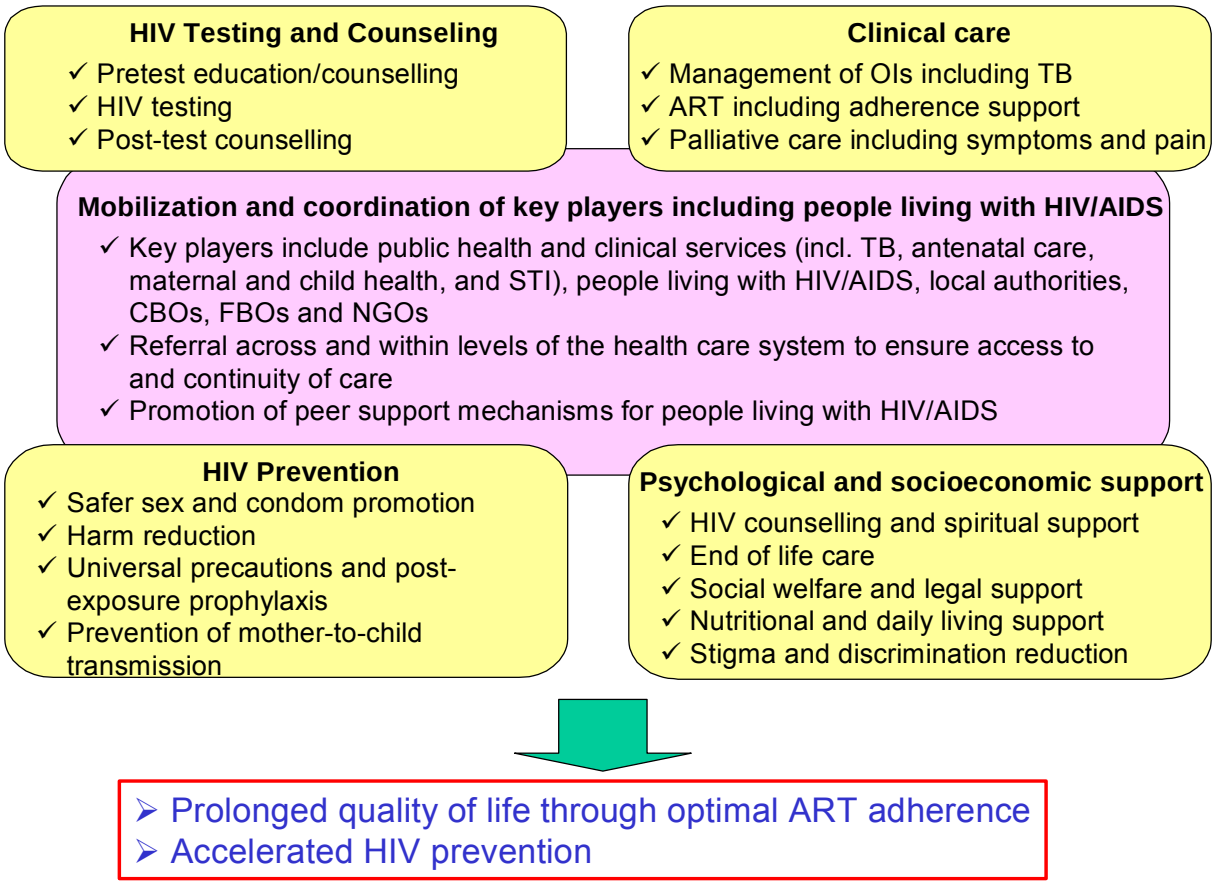
- Psychological, spiritual, and educational support (individual, group, couple, family, and community counselling and education) should be offered, particularly through peer support and group activities for people living with HIV/AIDS.
- End-of-life support should be extended to people living with HIV/AIDS.
- Social welfare and legal support should be developed for the poor and destitute, including income-generating activities and other forms of support such as food security, housing, clothing, and legal support for people living with HIV/AIDS and their family members, including orphans and vulnerable children.
- Nutritional and daily living support should be offered.
- Discrimination and the stigma and against people living with HIV/AIDS should be addressed.

5) HIV prevention

- HIV prevention should be linked to care, including: (a) promotion of safer sex and condom use; (b) harm reduction for injecting drug users, such as needle exchanges and substitution treatments including methadone; (c) universal precautions; (d) post-exposure prophylaxis; and (e) prevention of mother-to-child transmission.

Figure 1 provides an overview of the key elements in comprehensive HIV/AIDS care and treatment for adults and adolescents. The centre of the figure emphasizes the importance of mobilizing and coordinating key players, including people living with HIV/AIDS, in care and treatment. Surrounding it are the key elements of comprehensive care, including testing and counselling, clinical care, psychological and socioeconomic support, and HIV prevention.

Figure 1. An overview of the key elements in HIV/AIDS care and treatment



2. Implementation of key elements in the Region: the district/intermediate level as the focus for HIV/AIDS care and treatment

2.1 The need to develop a focus for HIV/AIDS care and treatment

HIV/AIDS care and treatment is relatively new for countries in the Region, and there is an urgent need to introduce and spread the use of ART even though resources and capacity are limited.

Experiences in the Region show that HIV/AIDS care and treatment activities can easily be uncoordinated and fragmented when they are provided by different players. Administrative divisions between clinical and public health services sometimes form serious barriers to effective care and treatment, while CBOs and NGOs only provide certain services with limited coverage.

The countries in the Region need to develop a focus for HIV/AIDS care and treatment and establish a mechanism for local team-building and coordination. This can be achieved through intensive interaction between health workers, people living with HIV/AIDS, and others involved in HIV/AIDS care. Team building and interaction will promote efficiency and the emergence of committed, compassionate, and capable players working together to provide effective HIV/AIDS care and treatment.

2.2 The district or intermediate level as the focus

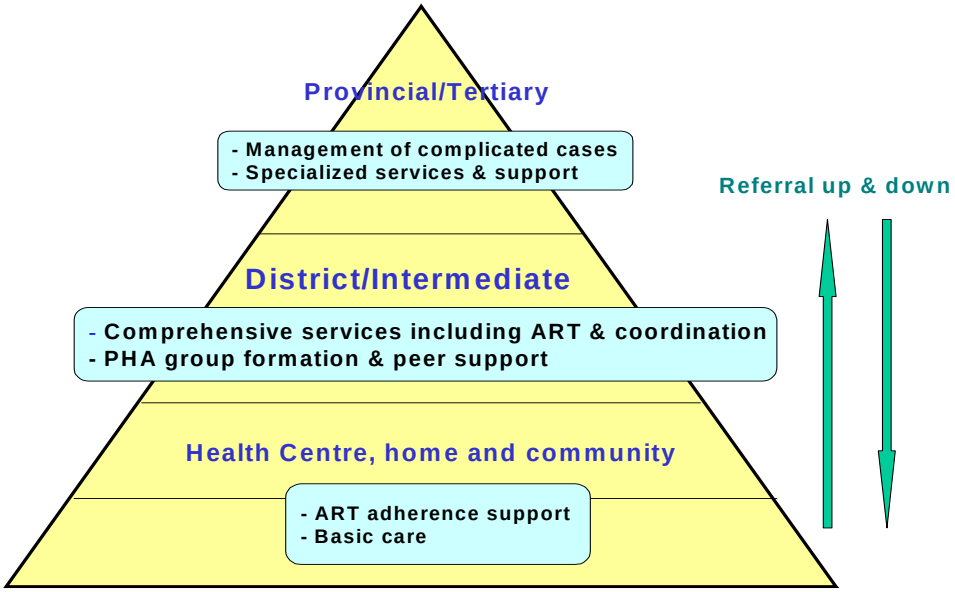
While HIV/AIDS care and treatment should be made available as close to patients' homes as possible, the focus for service delivery may vary depending on HIV prevalence.

For countries such as Cambodia, China, Papua New Guinea, and Viet Nam, where HIV prevalence is relatively high, the district or intermediate level of service delivery should be the focus of HIV/AIDS care development. This is because the district/intermediate level:

- has the capacity to provide HIV/AIDS clinical management for opportunistic infections and ART;
- has sufficient numbers of people living with HIV/AIDS to form viable groups;
- is not too far for people living with HIV/AIDS to travel for care; and
- is not too close to homes or communities where stigma and discrimination are often still barriers to accessing care and treatment.

Figure 2 provides an overview of the continuity and referral of HIV/AIDS care and treatment at the different levels of service delivery, with a focus on the district/intermediate level.

Figure 2. Different levels of health service delivery for HIV/AIDS care and treatment

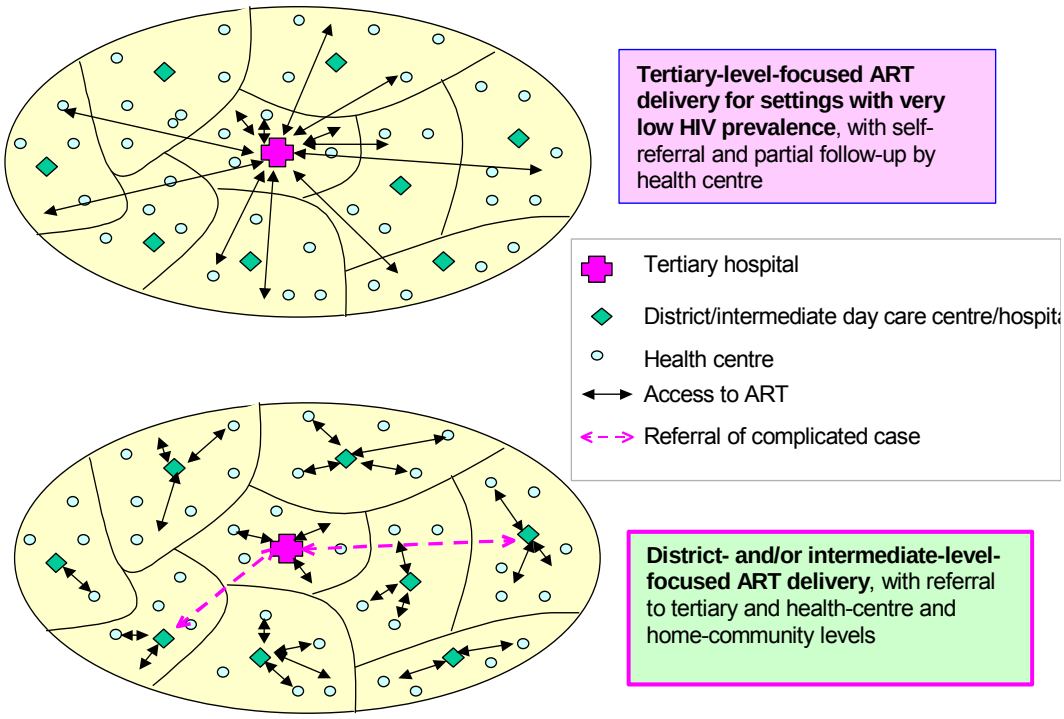


ART is often introduced at provincial or tertiary hospitals with better-qualified health workers and better-quality equipment. In some instances, community health centres and home-based care teams follow up. Although the provincial or tertiary level might seem like a logical place to start, people living with HIV/AIDS have limited access to tertiary facilities because of the stigma attached to their condition, as well as factors including the distance and cost of travel. Such a system is not sustainable for the vast majority of patients over the long term.

It is therefore crucial to decentralize basic HIV/AIDS care and treatment to day care centres or hospitals at the district or intermediate level as illustrated in Figure 3. Prophylaxis and treatment of common opportunistic infections and basic ART management should be provided, including prescription and follow-up of the first-line regimen. Tertiary hospitals should play a major role in providing specialized services for complicated cases and for those living in areas where tertiary hospitals are located (e.g. provincial or national capitals).

As the day care centres and hospitals at the district and intermediate levels gain experience, it might be necessary to expand outreach services to people living with HIV/AIDS who are homeless, injecting drug users, sex workers, or housed in closed settings such as rehabilitation centres and prisons. An essential factor for effective outreach will be the close functional links between HIV/AIDS care and treatment services at the district or intermediate level and referral and support at the community and tertiary levels.

Figure 3. ART delivery and geographical location



2.3 **Developing formal partnership: Local coordinating committee**

Developing comprehensive HIV/AIDS care and treatment across the continuum requires formal coordination. This coordination should be the responsibility of a local HIV/AIDS coordinating committee that should have people living with HIV/AIDS, CBOs, and NGOs as members. The committee should meet regularly (e.g. once a month) to oversee district or intermediate level coordination.

Partnerships within the district or intermediate level include:

- public health services such as communicable disease control and preventive medical services;
- clinical services through hospitals such as in- and out-patient departments, voluntary counselling and testing, antenatal care, sexually transmitted infections, family planning, maternal and child health, maternity, TB care and prevention, and laboratory and diagnostic services;
- groups for people living with HIV/AIDS and peer support networks;
- CBOs, NGOs, and FBOs; and
- local authorities such as district government and district people's committees.

Partnerships with other levels of service delivery include:

- public health services and hospitals at the tertiary level;
- health centres (at the township, community, village, and commune levels);
- CBOs, mass organizations, NGOs, and FBOs in the community level;
- home-based care services; and
- closed settings such as rehabilitation centres for injecting drug users and sex workers.

In order to organize access to HIV/AIDS care and treatment, effective links need to be established with activities for injecting drug users, sex workers, and other vulnerable populations; TB prevention programmes, services for sexually transmitted infections and prevention of mother-to-child transmission, home-based care, acute care clinics, hospital wards, and so forth.

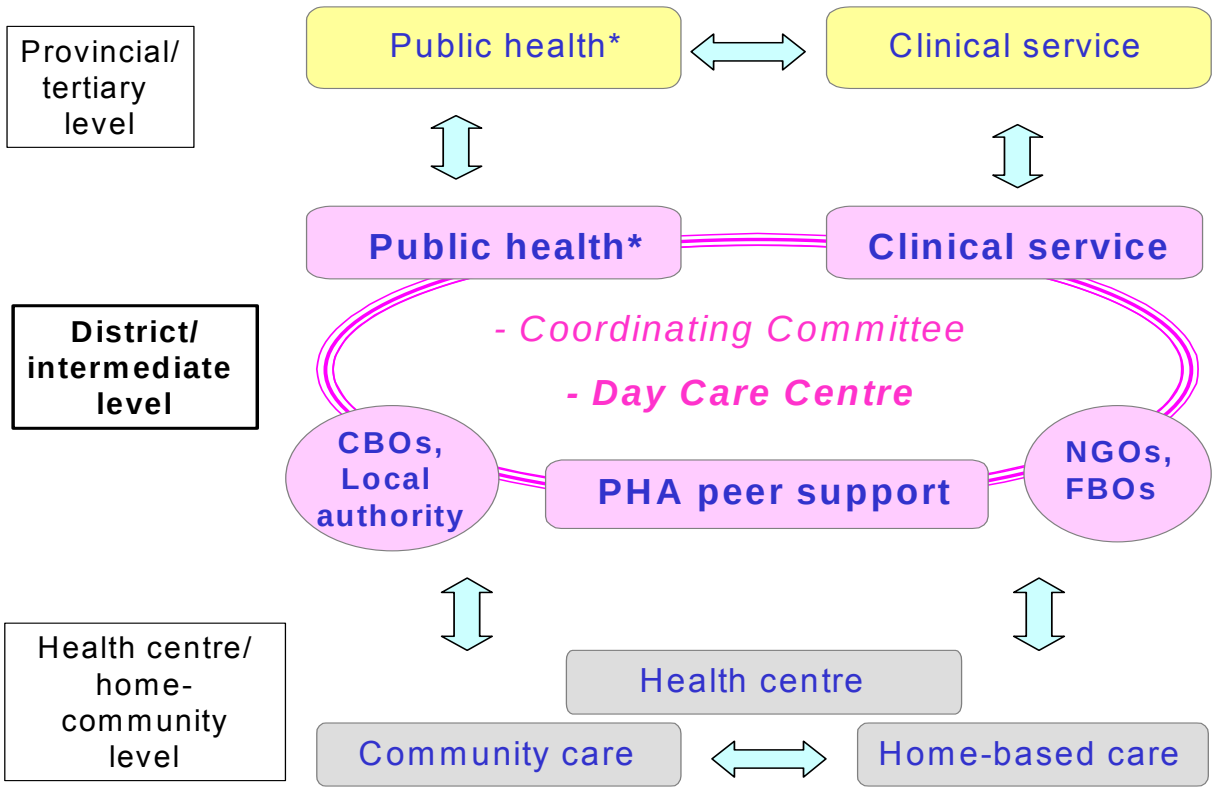
2.4 **Developing "hubs" and "hearts" for day-to-day management: day care centres**

A day care centre is a place where HIV care and treatment is provided through partnerships of key players (see 2.3) with a central role for people living with HIV/AIDS and their peer support.

Day care centres act as a "hubs" or centres for HIV/AIDS care and treatment at the intermediate or district level, developing links and referrals with various services at that level as well as the tertiary, health centre, and home-community levels. It also creates opportunities for mutual learning and facilitates the emergence of committed, compassionate, and capable players working in coordination ("heart").

The following figure shows partnership development (marked with arrows), as well as the locations and levels of service delivery with the day care centre as the "hubs" of HIV/AIDS treatment and care. Peer support for people living with HIV/AIDS is an integral component of the day care centres.

Figure 4. Partnerships across the different levels with the DCC as hub



** Public health facilities include the offices of public health, preventive medicine and disease control, while clinical services are typically provided through hospitals.*

There are a number of ways to promote day care centres as “hubs” and “hearts”:

- HIV clinics/services could be set up at outpatient departments, with space provided for meetings and other key day care centre activities within the district hospital or health centre. Clinical services can also be provided in the space to day care centre members.
- Freestanding HIV clinics could be set up, with space for meetings and other key activities, maintaining close links to the district hospital/health centre.
- Existing space for group activities for people living with HIV/AIDS outside the district hospitals/health centres could be converted into day care centres. Meetings and other key activities such as clinical services could be provided there. Close functional links with the district hospitals or health centres will be essential.

Regardless of how the day care centres are initiated, dedicated staff should be assigned to them, and peer support and involvement by people living with HIV/AIDS should be an integral part of their day-to-day administration.

In some locations, the day care centre would be the main provider of all components of HIV/AIDS care and treatment. In other locations, selected activities might be performed by other district or intermediate level services that are complemented by day care centre activities.

The development of the day care centre is important for the following reasons:

- It ensures practical coordination between and collaboration of all stakeholders, including clinical and public health services, people living with HIV/AIDS, NGOs, and CBOs at different levels.
- It provides a one stop/user-friendly services for people living with HIV/AIDS, giving functional referrals and links to a variety of services and activities.
- It provides a place for peer support and systematic formation of groups for people living with HIV/AIDS as the foundation for comprehensive care and treatment.
- It integrates care and treatment with prevention.
- It facilitates the mutual learning and the emergence of a core group of committed, compassionate, and capable players for responding to diverse and changing needs.
- It optimizes adherence to ART through all the advantages described above.

2.5 **Examples of selected day care centres in the Region**

The term “day care centre” is generic and countries within the Region have renamed them to reflect their cultural and traditional values. In Cambodia they are called “Mondule Mith Chouy Mith” (MMM) (“Friends Support Friends”). In China, some day care centre names include “Warm House” and “House of Red Ribbon.” In Papua New Guinea, day care centres are called “Heduru” (“Helping”) and in Viet Nam they are called “Supporting and Counselling Centres for the Community.”

Examples from Cambodia, China, Papua New Guinea, and Viet Nam follow. A brief overview is presented and the strengths and challenges for each day care centre programme provided.

Box 1. Cambodia: Mondule Mith Chouy Mith (MMM)
Moung Roussei Operational District, Battambang Province*

The Mondule Mith Chouy Mith (MMM) at Moung Roussei was part of the first wave of day care centres established as part of a national Continuum of Care (CoC) initiative.** The National CoC framework was developed through strong government leadership and with the support and collaboration of key players involved in HIV/AIDS care and treatment in Cambodia.

The MMM is situated within the Moung Roussei operational district hospital compound. Also included in this compound are in- and outpatient departments, as well as laboratory, X-ray, pharmacy, and administrative services. The MMM is located in an existing meeting room that is surrounded by trees and grass. People living with HIV/AIDS meet at the MMM once a month for peer and spiritual support, health education, recreation, and to meet with the hospital director and other operational district administrators involved in HIV/AIDS care and treatment.

An outpatient department within the hospital compound serves as the HIV/AIDS chronic care clinic and is open three days a week. Voluntary counselling and treatment, physical check-ups, opportunistic infection treatment and prophylaxis (including free drugs), HIV counselling, and drug adherence education and counselling are provided. ART started in June 2004.

Although the MMM is in the district compound, there is a physical separation between the MMM and HIV/AIDS chronic care outpatient clinic. However, the team at Moung Roussei are exploring ways to connect the MMM and the outpatient department, if not physically then through shared activities. For example, people living with HIV/AIDS who travel long distances are scheduled to attend the HIV/AIDS chronic care outpatient clinic on the same day as they attend MMM meetings. In addition, two people living with HIV/AIDS work as staff members in the HIV/AIDS outpatient clinic. Other initiatives such as joint team meetings and shared recreational activities promote connection between the MMM and the HIV/AIDS outpatient clinic.

* National Centre for HIV/AIDS Dermatology and STD (NCHADS) and Family Health International. Cambodia cares: Implementing a Continuum of Care for PLHA, including ART in Moung Roussey, Cambodia. July 2004.

Box 2. China: Warm House
Junchuan Township in Suizhou City, Hubei Province

The Warm House in Junchuan Township was established building on existing activities in China such as the House of the Red Ribbon and the House of Loving Care. The Warm House acts as a focal point for implementing the national HIV/AIDS comprehensive care framework* through the China CARES Project.

The main mode of HIV transmission in Suizhou City and Junchuan Township was through contaminated plasma donation in the 1990s, with further transmission to sexual partners and children. The Warm House provides voluntary counselling and testing; clinical management, including treatment of opportunistic infections and ART; and HIV prevention. Social and financial support – such as food for the destitute, waiving of school fees, and tax exemptions to help with transportation and other necessities – are also provided. Local doctors conduct home visits when necessary.

The China CARES project falls within two jurisdictions: communicable disease control and hospital administration. Until recently, these two jurisdictions had limited coordination in HIV/AIDS care and treatment. However, the Government of China has recently developed guidelines and protocols for the coordination of communicable disease control and hospital administration, which should provide people living with HIV/AIDS with greater access to affordable clinical care.

The HIV/AIDS team in Junchuan Township and Suizhou County is also exploring ways to promote greater involvement of people living with HIV/AIDS, HIV counselling, and prophylaxis for opportunistic infections.

* National Centre for AIDS/Sexually Transmitted Disease Prevention and Control, Chinese Centre for Disease Control and Prevention. Operational Framework for Comprehensive HIV/AIDS Care at Grassroots Level 2003.

Box 3. Papua New Guinea: Heduru HIV/AIDS Clinic, Port Moresby

The Heduru clinic is part of Port Moresby General Hospital, the main referral hospital in Papua New Guinea. The main mode of HIV/AIDS transmission in the country is heterosexual intercourse.

The clinic provides voluntary counselling and testing, HIV counselling and management of sexually transmitted infections. ART and treatment and prophylaxis of opportunistic infections started in early 2004. Involvement at the clinic of people living with HIV/AIDS is beginning with the development of Papua New Guinea's first peer support network.

Port Moresby is the capital of Papua New Guinea and access to HIV/AIDS treatment and care is limited to the national referral hospital. However, Papua New Guinea has many NGOs, CBOs, and FBOs that could provide many HIV/AIDS treatment and care services at the district level.

Considerable efforts are now underway to provide HIV/AIDS care and treatment at a level of service delivery that is closer to the people, as well as to create functional links between the Heduru clinic and NGOs, CBOs, and FBOs. The Government of Papua New Guinea hopes to spread HIV/AIDS care and treatment to other provinces.

Box 4. Viet Nam: District 8 Day Care Centre, Ho Chi Minh City

The day care centre in District 8 began as a pilot project in 2003 as part of a national HIV/AIDS initiative. The main modes of HIV transmission in Viet Nam are injecting drug use and sex work. Day care centre services in District 8 include voluntary counselling and testing; clinical management of HIV/AIDS, including treatment and prophylaxis of opportunistic infections; psychosocial support and counselling; health promotion; and HIV/AIDS information and education. Implementation of ART is planned for the end of 2004. Peer support development for people living with HIV/AIDS has been increasing since the day care centre opened, but more involvement of people living with HIV/AIDS is needed. People living with HIV/AIDS are currently paid members of the day care centre team.

The District 8 Day Care Centre team is exploring ways to provide greater access to HIV/AIDS care and treatment for injecting drug users and sex workers. In Viet Nam, injecting drug use and sex work are regarded as social evils, and offenders are often sent to rehabilitation centres. This means that many people living with HIV/AIDS are afraid to access care in case they are apprehended. However, links and referrals are now being created between the rehabilitation centres and the day care centre with a goal to eventually provide HIV/AIDS care and treatment in the rehabilitation centres and referral back to the day care centre upon discharge.

The day care centre is physically separated from the District 8 health centre. The advantage of this separation is that people living with HIV/AIDS feel comfortable accessing services. However, if this separation remains, stigma and discrimination within hospitals might also remain high. Although a referral mechanism is in place, this physical separation could be a challenge for links to services for sexually transmitted infections, family planning, and antenatal care, as well as to diagnostic and laboratory facilities. The day care centre team is aware of these issues and is exploring ways to promote wider access to HIV/AIDS care and treatment. The day care centre is situated next to the TB clinic, however, and this proximity makes coordination and referral between HIV and TB more manageable.

2.6 Collaboration between TB and HIV/AIDS programmes[4]

As many as 50% of people living with HIV/AIDS develop TB during their lifetime, compared to 5%–10% of people who are HIV negative. HIV also increases the rate of recurrent TB. Increasing incidence of TB among people living with HIV/AIDS poses an increased risk of TB transmission to the general community. The impact of TB on HIV/AIDS programmes includes:

- TB is the most common, treatable infectious HIV-related disease and the most common cause of death among people with HIV/AIDS in countries that have a high burden of TB.
- Late TB diagnosis contributes to increased death rates in people living with HIV/AIDS.
- TB may accelerate the progression of HIV-related immunosuppression.

Tackling HIV should include tackling TB as a major killer of people living with HIV/AIDS. Likewise, preventing TB should include treating HIV as the most potent force driving the TB epidemic. This will require systematic collaboration between the national AIDS programmes and the national TB programmes at every level of health service.

In its implementation, the HIV/AIDS day care centre and hospitals at district/intermediate level are ideally suited to coordinating the two programmes, particularly in case finding and collaborative management of both HIV/AIDS and TB. Health centres, home-based care, and community organizations can also play a supportive role in TB/HIV case-finding, referral, and treatment support.

1) TB/HIV diagnosis and referral

The national HIV/AIDS programmes will refer persons infected with HIV and/or are suspected of TB to facilities with diagnostic capacity for TB. Early referral, prior to HIV testing and counselling, is possible. The national TB programmes will also refer patients for testing and counselling based on agreed criteria.

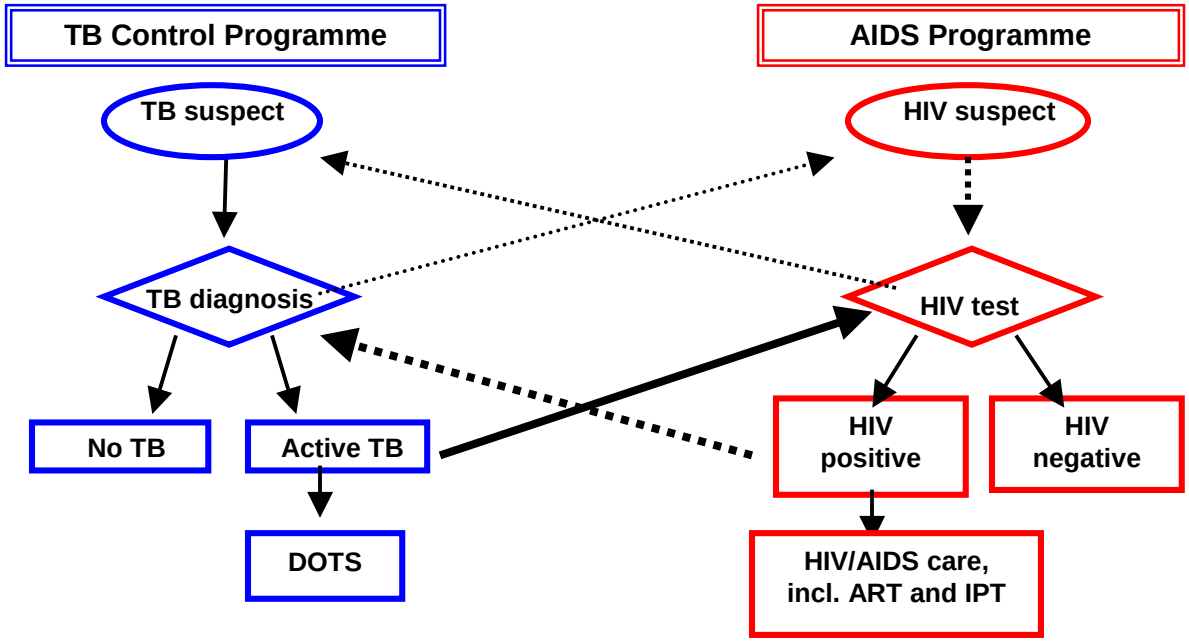
The principles of diagnosis and referral for national HIV/AIDS programmes and national TB programmes include:

- The national HIV/AIDS programme is responsible and accountable for testing and counselling in terms of qualifying the institution, supervising, training, recording and reporting.
- The national TB programme is responsible and accountable for TB diagnosis in terms of qualifying the institution, supervising, training, recording and reporting.
- Effective referral mechanisms between the national HIV/AIDS programme and the national TB programme must be established and agreed upon by both programmes.

Figure 5 provides an overview of the referral mechanisms for the diagnosis of TB and HIV.

[4] *Tuberculosis and HIV: A framework to address TB/HIV co-infection in the Western Pacific Region*. Manila, WHO Regional Office for the Western Pacific. 2004.

Figure 5. Referral mechanisms for the diagnosis of TB and HIV



With regard to the referral of people living with HIV/AIDS to NTP for TB diagnosis, HIV-positive persons tend to be concentrated in specific settings according to the situation in the country. Examples include testing and counselling sites, day care centres, HIV clinics at hospital outpatient departments, clinics for sexually transmitted infections, groups for people living with HIV/AIDS, home-based care for people living with HIV/AIDS, prisons and rehabilitation camps for injecting drug users and sex workers, and household contacts with HIV-positive TB patients.

2) TB/HIV interventions

The principles of TB/HIV interventions include:

- The national HIV/AIDS programme is responsible and accountable for any intervention directly related to HIV/AIDS.
- The national TB programme is responsible and accountable for any intervention directly related to TB.
- The national HIV/AIDS and TB programmes can complement each other in providing prevention, treatment, care, and support, and should agree on a clear division of responsibilities.

In practice, isoniazid (INH) preventive therapy (IPT), if used, could be provided at day care centres by the HIV/AIDS programme under the supervision of the TB programme (depending on local arrangements). Similarly, cotrimoxazole prophylaxis for TB patients infected with HIV could be provided by the TB programme under the supervision of the HIV/AIDS programme.

Countries may not need to implement all collaborative TB and HIV interventions, but should consider the variation of HIV prevalence rates within the country to determine the types of collaborative TB/HIV activities to implement (see Table 1).

Table 1. Thresholds for commencing collaborative TB/HIV activities

Category	Criteria	Recommended collaborative TB/HIV activities
I	Countries with national adult HIV prevalence rate ≧ 1% OR Countries in which national HIV prevalence among TB patients is ≧ 5%	A. To establish the mechanisms for collaboration: - coordinating body for TB and HIV activities - surveillance of HIV prevalence among TB patients - joint TB-HIV planning - monitoring and evaluation B. To decrease the burden of TB in people living with HIV/AIDS - intensified TB case finding - INH preventive therapy (IPT) - TB infection control in care and congregate settings C. To decrease the burden of HIV in TB patients - HIV testing and counselling - HIV prevention methods - HIV/AIDS treatment and care including ART
II	Countries with national adult HIV prevalence rate below 1% OR Administrative areas that have adult HIV prevalence rate ≧ 1%	A. In administrative areas with ≧ adult HIV prevalence - implementation of activities designed for Category I countries in the administrative areas identified B. In other parts of the country - implementation of activities designed for Category III countries
III	Countries with national adult HIV prevalence rate below 1% AND No administrative areas with adult HIV prevalence rate ≧ 1%	A. Joint national TB-HIV planning: - Surveillance of HIV prevalence among TB patients B. To decrease the burden of TB in people living with HIV/AIDS (with focus on high HIV and TB risk groups, e.g. injecting drug users, sex workers, and congregate settings (such as jails and rehabilitation camps) - intensified TB case finding - INH preventive therapy (IPT) - TB infection control in care and congregate settings

2.8 Care and treatment for injecting drug users and sex workers

Vulnerable populations such as injecting drug users and sex workers often come in conflict with the law and may be sent to rehabilitation centres or prisons. With national government approval and support, these closed settings can provide effective HIV/AIDS care and treatment. This includes prophylaxis and treatment of opportunistic infections, as well as ART. However, to ensure a continuum of HIV/AIDS care and treatment the following issues must be addressed:

- Close collaboration and coordination are needed between the closed setting and the HIV/AIDS care and treatment centre at the district/intermediate level (e.g. day care centres).
- Upon discharge, effective referral with close follow-up is needed between the closed setting and the HIV/AIDS care and treatment centre.
- Peer support is needed for discharged people living with HIV/AIDS.
- Knowledgeable and sensitive health workers and others are needed to support vulnerable people living with HIV/AIDS and to maintain harm-reduction activities.

Box 5 in Part 3 provides important elements to providing HIV/AIDS care and treatment for injecting drug users.

3. Setting up HIV/AIDS treatment and care at the district or intermediate level

To start HIV/AIDS treatment and care at the district or intermediate level of service delivery, the following steps should be taken:

1) Set up coordination committee on HIV/AIDS care and treatment at the district or intermediate level

Members should include district- or intermediate-level HIV/AIDS managers, members of district HIV/AIDS programmes, district hospital administrators, representatives from HIV/AIDS health worker staff (e.g. doctors, nurses, and other allied health workers), representatives from HIV-linked programmes (e.g. voluntary counselling and testing, TB care and treatment, antenatal care, care and treatment for sexually transmitted infections, and HIV prevention), people living with HIV/AIDS, NGO partners and/or members of community, and commune or mass organizations.

Depending on the country, other representatives might include home-based care team members and religious leaders. Each country will have a different mix on the coordination committee.

The aim is to include influential leaders, people living with HIV/AIDS, and those involved in HIV/AIDS treatment, prevention, and care at the district level as well as members from health centres, community/commune organizations, and home-based care teams.

The committee should meet regularly (e.g. once a month) to oversee district or intermediate level coordination for HIV/AIDS care and treatment.

2) Create an HIV/AIDS care team:

This team should include personnel involved in HIV/AIDS care and treatment at the district/intermediate level, including people living with HIV/AIDS.

The main purpose of clinical team development is to promote quality HIV/AIDS care and treatment. This can be done through regular team meetings (e.g. once a week) to discuss case studies and case management issues.

It is very important to appoint a HIV care coordinator who should serve as a focal point for planning, implementing, monitoring and evaluating HIV/AIDS care and treatment in the area.

Scope of work of the HIV care coordinator might include; i) secretariat of the coordination committee, ii) mobilization and coordination of key players, iii) management of the HIV care team, iv) training and continuous support of personnel, v) supply of drugs, diagnostics and other commodities, vi) financial management, vii) referral of cases, viii) patient monitoring, recording and reporting, ix) programme monitoring and evaluation.

The following table is a guide to conducting a situation analysis and to plan, implement, monitor, and evaluate HIV/AIDS care and treatment programmes.

Table 2. Steps to set up HIV/AIDS care and treatment at the district or intermediate level

Steps	Activities
Assessment	▪ Assess extent of the HIV/AIDS epidemic, population most affected, main modes of transmission, and attitudes of health workers. ▪ Identify key stakeholders (those that can facilitate or hinder the HIV/AIDS programme). ▪ Conduct resource mapping (HIV/AIDS related resources). ▪ Assess the needs of people living with HIV/AIDS, health workers, and other key stakeholders. Determine education needs. ▪ Assess necessary supplies, drugs, and equipment; essential package of services and activities; and referral system (see Part 2).
Planning	▪ Identify strategies to work with supportive and unsupportive stakeholders. ▪ Conduct a workshop with key players at the district level. ▪ Develop a day care centre or hub for HIV/AIDS care and treatment. ▪ Set realistic goals, objectives, and priorities. ▪ Develop timelines (short-, medium-, and long-term). ▪ Plan training, including ongoing training. ▪ Develop a financial plan. ▪ Develop a case management system. ▪ Develop a resource list and referral mechanisms. ▪ Adopt treatment protocols and a record-keeping system (see Part 3). ▪ Adopt recording and reporting system for monitoring and evaluation (see Section 4, Part 1).
Implementation	▪ Implement plans developed in the previous steps. ▪ Collaborate, refer, and coordinate with other HIV/AIDS projects and resources within and outside the district/intermediate level.
Monitoring and evaluation	Develop and implement: ▪ quality assurance mechanisms; ▪ staff supervision and monitoring; ▪ informal evaluation mechanisms (internal review); and ▪ formal (outcome) evaluation mechanisms. Remain reflexive: responding to the results of informal and formal evaluations and making necessary changes.

4. Monitoring and evaluation

Standardized and harmonized monitoring and evaluation indicators have been developed to support countries in their efforts to promote the wider use of ART. This section provides three sets of sample indicators on ART for national HIV/AIDS programmes.

The first one is extracted from the working document, "Monitoring and evaluating of national ART programmes in the rapid scale-up to 3 by 5," developed by WHO.[5] This is followed by another set of sample indicators for patient monitoring and evaluation on ART, which are being discussed at global level following "HIV Patient ART Monitoring Meeting" organized by WHO in March 2004. Finally a set of sample indicators on programme development is presented as a reference. Further work is needed to standardize these indicators, and other sets of indicators are now available that need to be taken into account when appropriate.[6]

Table 3. Sample indicators for overall measurement of progress toward three by five

Level	Area	Indicator
Input	National policy and guidelines	1: Existence of national policy and guidelines for ART programmes
Process	Human resources	2: Number of health personnel trained to deliver ART services according to national/international standards per 1,000 in need of treatment
	Drug supply	3: Percentage of ARV distribution nodes that report on inventory consumption, quality, losses, and adjustments on a monthly basis (under development)
Output	Coverage of programme and access	4: Percentage of districts with at least one centre that provides ART services in line with national standards*
		5: Percentage of designated facilities providing ART in line with national standards
Outcome	People on treatment	6: Percentage of people with advanced HIV infection receiving ARV combination therapy
		7: Number of drug regimens distributed to patients per month
		8: 12-month programme retention rate
Impact	Health status/survival	9: Percentage of adults on treatment who have gained weight by at least 10% six months after the initiation of treatment
		10: Percentage of people still alive at 6, 12, and 24 months after initiation of treatment

* Only in generalized epidemics and in the development phase of programmes

[5] The document can be downloaded from the WHO web site (http://www.who.int/3by5/publications/documents/artindicators/en/)

[6] *A guide to monitoring and evaluation for collaborative TB/HIV activities* [field test version]. Geneva, WHO, 2004 (WHO/HTM/TB/2004.342, WHO/HIV/2004.09); *National AIDS programmes: a guide to monitoring and evaluating HIV/AIDS care and support*. Geneva, WHO, 2004.

Table 4. Indicators to monitor HIV care and ART for clinic or district coordinator use[7]

To Monitor:	Measure these indicators:	How to calculate number or numerator/denominator:	
HIV care and access to ART	Number enrolled in HIV care	New in last month and cumulative number of persons enrolled in HIV care	
	Number of persons who are enrolled and eligible for ART but have not been started on ART		
	Number started on ART	New last month and cumulative number of persons ever started on ART	
	Proportion of those eligible for ART in clinic who have been started on ART	Started on ART in this clinic / Enrolled in HIV care and eligible	
	Proportion of people with advanced HIV infection receiving ARV combination therapy (UNGASS core indicator)	At district level, numerator is derived by adding all on ART. Denominator is an estimate based on HIV prevalence and expected proportion with AIDS (not from register data).	
Success of ART	Proportion of people alive and known to be on treatment at six, 12, and 24 months after initiation of treatment	(H + I + J) / Total ever started on ART	H: Start or continue on original first-line regimen I: Substituted to alternative first-line regimen J: Switched to second-line (or higher) regimen
	Proportion of people still prescribed a first-line regimen 12 months after initiating ART	(H + I) / (H + I + J)	
	Proportion still on original first-line regimen	H / (H + I + J)	
	Proportion who have substituted to an alternative first-line regimen	I / (H + I + J)	
	Proportion switched to a second-line (or higher) regimen	J / (H + I + J)	
	Proportion with good adherence		
	Proportion of people on ART at six, 12, 24 months whose functional status is working		
	Median CD4 count increase after six and after 12 months of ART compared to baseline		
HIV drug resistance: early warning indicators	Proportion of adults on standard 1st line ARV regimen	Number of adults on first-line ART during the time period who are prescribed a standard first-line ARV regimen / Total number of adults prescribed a first-line ART regimen during the time period	
	Proportion of patients who started ART six (or 12) months ago who picked up ARV medications six out of six months or 12 out of 12 months	Persons who started ART six (or 12) months ago who picked up ARV medications six out of six (or 12 out of 12) months / Persons who started ART six (or 12) months ago who are still picking up medication at six (or 12) months	
	Proportion of patients who started a first-line ARV regimen who are still prescribed and still picking up their first-line ARV regimen at 12 and 24 months	Persons still prescribed and still picking up their standard first-line ARV regimen 12 and 24 months after starting ART for first time / Persons who started first-line ART for the first time during the time period under consideration	
	See above: proportion of people still prescribed a first-line ARV regimen 12 months after initiating ART		

[7] WHO, UNAIDS, United States Agency for International Development (USAID), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA) and GFATM. *Interim Patient Monitoring Guidelines for HIV Care and ART: Based on the WHO Patient ART Monitoring Meeting*. Geneva, 29-31 March 2004.

Table 5. Sample indicators for monitoring and evaluation of programme development

1) Mobilization and coordination ▪ Number of districts with coordination committee on HIV/AIDS care and treatment involving people living with HIV/AIDS, NGOs, CBOs, and TB programme officer ▪ Number of districts with day care centre ▪ Number of districts with groups for people living with HIV/AIDS ▪ Number of districts with a designated team for HIV/AIDS care and treatment ▪ Number of districts with a designated team for HIV/AIDS care and treatment involving people living with HIV/AIDS ▪ Number of districts with referral system ▪ Number of districts with training programme on HIV/AIDS care and treatment involving stakeholders
2) Types of services provided ▪ Number of districts providing HIV testing and counselling ▪ Number of districts providing prophylaxis and treatment of selected opportunistic infections ▪ Number of districts providing ART ▪ Number of districts providing palliative care ▪ Number of districts providing psychological support ▪ Number of districts providing social and economic support ▪ Number of districts providing HIV prevention services
3) Attendance ▪ Numbers of people living with HIV/AIDS attending day care centres ▪ Numbers of people living with HIV/AIDS attending outpatient HIV/AIDS clinic (these numbers should be compared with the estimated number of people living with HIV/AIDS in a given district)
4) Quality of care ▪ Peer support activities for people living with HIV/AIDS ▪ Participation by people living with HIV/AIDS in treatment and care in decision-making and service delivery ▪ Levels of HIV stigma ▪ Levels of satisfaction of people living with HIV/AIDS ▪ Levels of health worker satisfaction
5) Training ▪ Number of health workers with training on HIV/AIDS care and treatment ▪ Number of people living with HIV/AIDS with training on care and treatment ▪ Number of members of CBOs and NGOs with training on HIV/AIDS care and treatment ▪ % of central, regional, and district drug storage locations whose stock cards for ART drugs are up to date and accurate at each six-monthly review.

ARV resistance surveillance system is being developed. This system can be used for ARV resistance monitoring at the national level.

This overview provides guidance only for developing monitoring and evaluation tools. General monitoring and evaluation indicators should be developed at the national level, with district/intermediate level indicators developed for specific programme monitoring and evaluation.

PART 2

Packages of services and activities at different levels of the health system

Part 2 provides details on the package of services and activities to be provided at different service delivery levels. First, a simple overview of programme activities at different service delivery levels will be provided. This will be followed by details of activities, staff requirements, equipment and drugs that should be available at each level of service delivery.

The purposes of defining packages of services and activities to be available at each level of service delivery (tertiary, intermediate/district, and community) are to:

- clearly outline the services and activities to be provided at each level of service delivery;
- promote efficiency in service delivery while avoiding overlap and unnecessary costs;
- enable effective referral mechanisms to be developed between each level of service delivery; and
- provide guidance for planning of HIV/AIDS care and treatment, including costing and allocation of resources such as personnel, drugs, diagnostics, and supplies to be provided at each level.

As described in Part 1, the focus for developing HIV/AIDS care and treatment is placed on the district or intermediate level of the health system. Therefore, the services and activities to be provided at this level are defined as the essential package of services and activities (EPSA).

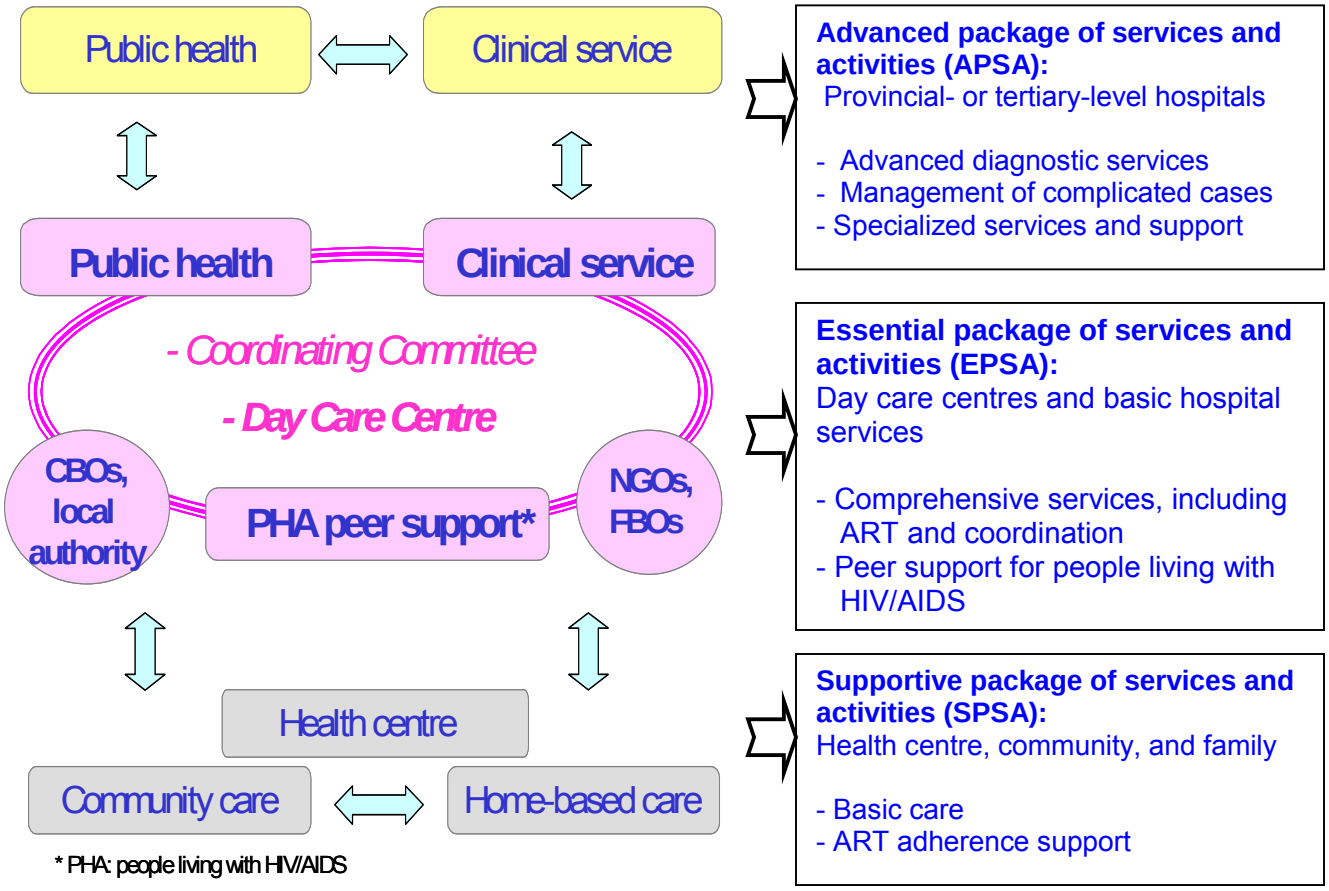
Although there are some variations in the roles played by the day care centres and the district- or intermediate-level hospitals (Part 1) the two levels of the system should complement each other. They also provide technical and administrative supervision and support to health centres and to home- and/or community-level care.

Tertiary- or provincial-level hospitals should be able to manage complicated cases that are beyond capacity of district- or intermediate-level health facilities. EPSA should also be made available for those who reside in the district or administrative area where the tertiary level hospital is located.

The tertiary- or provincial-level facilities are responsible for providing technical and administrative supervision and support to health facilities at lower levels. These services and activities are defined as the advanced package of services and activities (APSA).

Health centres, home-based care teams (if available), community, and family should play crucial roles in psychological support, education, and socioeconomic support, with special emphasis on ART adherence. Referral of cases, provision of basic clinical care and palliative care, as well as promotion of access to testing and counselling, prevention, and health promotion are also important for this level. These are defined as the supportive package of services and activities (SPSA).

Figure 6. Overview of package of services and activities



The following tables show detailed services and activities, staff requirements, equipment, and drugs that should be available at the tertiary level (APSA); the district or intermediate level (EPSA); and the health-centre, home-based, and community-care level (SPSA).

Table 6. Advanced package of services and activities (APSA): provincial- and/or tertiary-level hospitals

Structure and staff	Services and activities	Drugs, laboratory equipment and other resources	Remarks
Structure: Tertiary referral hospital at the national, regional, and/or provincial level. **Staff:** HIV care coordinator if appropriate (see Table 7) HIV/AIDS expert medical staff (doctors, nurses) Counsellors Social workers Laboratory technicians with specialized training for CD4, complex blood chemistry (possibly viral load) Pharmacists with expertise in opportunistic infections and ART drug management Other diagnostic technicians	▪ Diagnosis and management of complex opportunistic infections ▪ Diagnosis and management of complex drug side-effects (opportunistic infections and ART) ▪ Assessment of ART failure and provision of second-line ART ▪ Adherence support ▪ Refer back to district level for chronic care management ▪ Support/advise district level HIV/AIDS care and treatment team Plus All services and activities outlined in tables of district/intermediate level hospital and of day care centres (EPSA) should be made available for those who reside in the district or relevant administrative area where the tertiary level hospital is located	▪ Laboratory equipment to perform CD4 counts (possibly viral load), serology (HBV, HCV, syphilis), chemistry (e.g. liver and renal function and metabolic assessment), basic microbiology and culture ▪ Second-line ART regimen (ABC or TDF) + ddI + (SQV/r or LPV/r) ▪ Drugs for treatment of complex opportunistic infections (MAC, CMV, etc.) ▪ Referral forms for continuity of care **Top referral hospitals should also have the following services:** - Histology - Complex microbiology (Mycobacteria other than TB, resistance testing) - Complex imaging (CT scans, endoscopy, bronchoscopy)	Tertiary level hospitals will be referral hospitals at different levels of the health system (national, regional, provincial). These hospitals should have expert HIV/AIDS practitioners and perform complex diagnosis and treatment. These practitioners should also provide advice, training, and support to district-level hospital and day care centre staff.

Table 7. Essential package of services and activities (EPSA): district- or intermediate-level day care centres

Structure and staff	Services and activities	Drugs, laboratory equipment, and other resources	Remarks
Structure The day care centre may be part of the district hospital or it might be a stand-alone facility. If stand-alone, close links to district hospital are essential **Staff** *HIV care coordinator:* Focal point for planning, implementing, monitoring and evaluating HIV/AIDS care and treatment in the area (see section 3-2) Create an HIV care team) *Participation by people living with HIV/AIDS:* Selected people living with HIV/AIDS and health workers to facilitate day care centre meetings and activities *Clinical management*: Doctor, nurses, counsellors, people living with HIV/AIDS, pharmacists, and laboratory technicians (working part or full time) as integral part of the HIV clinical care team at district- and/or intermediate-level hospital *Others:* Possibly: social workers, midwives	**Mobilization and coordination of key players, including people living with HIV/AIDS** ▪ Regular meetings and case conference with stakeholders ▪ Develop referral criteria and procedures ▪ Support/advise health centre and home-community level ▪ Regular meetings and capacity building activities among people living with HIV/AIDS ▪ Involve people living with HIV/AIDS in service planning, provision and evaluation **HIV testing and counselling** ▪ Provide or refer to testing and counselling***** **Clinical** ▪ Initiate and follow up cotrimoxazole prophylaxis and refer to health centre for follow-up if adequate****** ▪ Provide or refer to district hospital for screening, diagnosis, and treatment of selected opportunistic infections ▪ Initiation and follow-up of first-line ART regimen and refer to health centre for follow-up if adequate ▪ Refer complicated cases to tertiary level ▪ Provide management of symptoms and pain **Psychological and socioeconomic support** ▪ Individual, couple, family and group counselling and education ▪ Recreational activities ▪ Nutritional and daily life support ▪ Refer complicated cases to tertiary level ▪ Education for the hospital staff and the community ▪ Advocate for or use local scheme for free of charge or at subsidized rates of clinical services (equity fund, etc.) ▪ Advocate for and refer to social welfare services ▪ Develop or refer to income-generating activities ▪ Provide or refer to support for families and affected children ▪ Provide or refer to end-of-life care **HIV prevention** ▪ Promote safer sex and condom use, refer to services for sexually transmitted infections ▪ Provide or refer to harm reduction and substitution treatment for injecting drug users******* ▪ Universal precautions, post-exposure prophylaxis, and prevention of mother-to-child transmission	**HIV testing** ▪ HIV rapid test kits (WHO approved) **Clinical examinations** ▪ Basic physical examination equipment ▪ Laboratory equipment to collect specimens **Drugs** ▪ Drugs for treatment and prophylaxis of opportunistic infections (Table 11) ▪ Five selected ARV first-line-regimen drugs (AZT, d4T, 3TC, NVP, and EFV) ▪ Drugs for symptom relief and pain management (Table 20, Figure 9) ▪ Drugs for substitution treatment (methadone) **Prevention** ▪ Condoms ▪ Needle and syringes ▪ Drugs/supplies for Universal precautions, post-exposure prophylaxis, and prevention of mother-to-child transmission **Monitoring and evaluation** ▪ Patient/monitoring and evaluation records and reports ▪ Referral cards	* HIV testing and counselling should be available in voluntary testing and counselling centres, district hospitals, and/or day care centres. ** INH prophylaxis and fluconazole prophylaxis should also be available if indicated in national guidelines (Table 11, Part 3). *** Harm reduction for populations of injecting drug users is essential in countries with a high prevalence of injecting drug use (see prevention Part 3). Harm reduction activities are usually provided in outreach centres or in the day care centre. Linkages and referral to provide harm reduction services on an outreach basis might be necessary.

Table 8. Essential package of services and activities (EPSA): district- or intermediate-level hospitals

Structure and staff	Services and activities	Drugs, laboratory equipment and other resources	Remarks
Structure Outpatient departments, inpatient department, laboratory services, pharmacy, and radiology Referral pathways to other programmes for testing and counselling, TB, antenatal care, sexually transmitted infections, and family planning **Staff** HIV clinical care team including physicians, nurses, pharmacists, and laboratory technicians. Other allied health professionals might include midwives, counsellors, and TB programme personnel. People living with HIV/AIDS (acting as treatment educators, adherence supporters, HIV prevention educators, and supporters)	**HIV testing and counselling** ▪ Provide or refer to testing and counselling***** **Outpatient departments** ▪ Initiate and follow up cotrimoxazole prophylaxis and refer to health centre for follow-up if adequate****** ▪ Screen, diagnose, and treat selected opportunistic infections, including TB (Table 11) ▪ Initiate and follow up first-line ART regimen and refer to health centre for follow-up if adequate ▪ Symptom management including pain management ▪ Support ART adherence through education and counselling for people living with HIV/AIDS and their family members ▪ Psychological support and education ▪ Universal precautions ▪ Post-exposure prophylaxis ▪ Refer to day care centres, inpatient departments, TB services, stand-alone voluntary counselling and testing centres, clinics for sexually transmitted infections, family planning, antenatal care, and services for the prevention of mother-to-child transmission, as necessary ▪ Involve people living with HIV/AIDS in the provision of services **TB services** ▪ Diagnosis and treatment of TB, including smear-negative and extrapulmonary TB ▪ Refer TB patients to HIV testing and counselling ▪ Management of basic treatment and prophylaxis of opportunistic infections, in collaboration with medical wards, day care centres or HIV outpatient clinic **Inpatient care/medical ward** ▪ Diagnosis and treatment of opportunistic infections and provision of ART ▪ Palliative care ▪ Counselling, universal precautions, and post-exposure prophylaxis **Maternity** ▪ HIV testing and counselling linked with maternal and child health, antenatal care, labour, and delivery ▪ Prevention of mother-to-child transmission **Linkages with prevention activities** ▪ Promote safer sex and condom use ▪ Provide or refer to services for sexually transmitted infections ▪ Provide or refer to harm reduction and substitution treatment for injecting drug users **Referral system development** ▪ Develop criteria and procedures of referral within hospital and to tertiary hospitals, day care centres, and health centres ▪ Support/advise health centre and home-community level	**Laboratory** (Table 10) **Radiology** (Table 10) Chest X-ray **Drugs** ▪ Drugs for OI prophylaxis (Table 11) ▪ Drugs for treatment of selected OI (Table 11) ▪ ARV first line regimen drugs (AZT, d4T, 3TC, NVP and EFV) ▪ Drugs for symptom relief and pain management (Table 20, Figure 9) ▪ Drugs for substitution treatment (methadone) **Prevention** ▪ Condoms ▪ Needle and syringes ▪ Drugs/supplies for universal precautions, post-exposure prophylaxis, and prevention of mother-to-child transmission **Monitoring and evaluation** ▪ Patient/monitoring and evaluation records and reports ▪ Referral cards	* HIV testing and counselling should be available in voluntary counselling and testing centres, district hospitals, and/or day care centres. ** INH prophylaxis and fluconazole prophylaxis should also be available if indicated in national guidelines (Table 11, Part 3)

Table 9. Supportive package of services and activities (SPSA): health centre, home- and/or community-based care

Structure and staff*	Services and activities	Drugs, laboratory equipment and other resources	Remarks
Health centre **Structure:** Health centres are at the primary health care level and based within communities **Staff:** might include doctor, nurses, midwives, community volunteers, and people living with HIV/AIDS** **Home-based care team** **Structure:** Home-based care team office as part of health centre, or with close links to health centre **Staff:** *Home-based care team members*: Health workers from health centre People living with HIV/AIDS NGO/FBO staff*** Community health volunteers Respected traditional healers (identified by the community) *Health worker from health centre mainly for coordination, supervision, and technical support* **Community** All HIV/AIDS-related organizations that operate within the community, such as CBOs (including mass organizations*), NGOs, FBOs, and local authorities **Family support** Member of the same household, person living with HIV/AIDS, or member of extended family	**Mobilization and coordination of key players, including people living with HIV/AIDS** ▪ Coordinate home-based care, NGOs, CBOs, FBOs, and community ▪ Promote/encourage peer support and development of groups for people living with HIV/AIDS **HIV testing and counselling** ▪ Provide or refer to HIV testing and counselling **Clinical** ▪ Refer to day care centre/district hospital and follow up prophylaxis of opportunistic infections ▪ Provide symptomatic care ▪ Refer to TB services systematically ▪ ART: Adherence support, manage minor side-effects and refer to district or tertiary level if necessary ▪ Provide symptom and pain management **Psychological and socioeconomic support** ▪ Individual, couple, family, and group counselling and education ▪ Education for hospital staff and the community ▪ Refer complicated cases to district and tertiary level ▪ Provide or refer to social welfare services ▪ Provide or refer to income-generating activities ▪ Provide or refer to support for families and affected children ▪ Provide or refer to end-of-life care **HIV prevention** ▪ Promote safer sex and condom use, refer to services for sexually transmitted infections ▪ Provide or refer to harm reduction and substitution treatment for injecting drug users ▪ Universal precautions post-exposure prophylaxis, refer to programmes for prevention of mother-to-child transmission ▪ Promote healthy lifestyle, including nutrition	**Health centre** ▪ Simple physical examination equipment ▪ Drugs for simple symptom relief and pain management (Table 20, Figure 9) ▪ Drugs for prophylaxis of opportunistic infections (Table 11) ▪ Equipment to collect laboratory specimens for transportation ▪ Information, education, and communication materials ▪ Condoms, needles, and syringes **Home-based care/outreach team** ▪ Home-based care/outreach kits: e.g. soap, disinfectant, calamine lotion, local herbal remedies, gentian violet, vitamins, iodine solution, condoms, and simple medications**** ▪ Information, education; and communication materials; condoms, needles, and syringes **Community** ▪ Information, education, and communication materials; condoms ▪ Social welfare (subsistence allowance, food, shelter, clothing, etc.) ▪ Income-generating activities (materials, seed funding, marketing information, etc.) ▪ Support for affected children (schooling, legal help, staying with extended families, etc.) **Family support** ▪ Basic nursing care supplies (if necessary) ▪ Information, education, and communication materials; condoms	* Health centres, home-based care teams, communities, and family should complement each other to make SPSA available. ** The number and composition of health centre staff will vary in each country. It is essential to have people living with HIV/AIDS involved in the health centre. *** Apart from health centre staff and people living with HIV/AIDS, members of the home-based care teams will vary depending on the local conditions and the country. **** Simple medications such as paracetamol, nystatin, aluminium or magnesium tablets, and oral rehydration salts may be included in home-based care kits. (Table 8, Table 20, Figure 9).

Table 10. Laboratory services for HIV/AIDS care and treatment at the district or intermediate level

- Rapid HIV Ab testing
- Second serologic method capability to resolve indeterminate rapid HIV Ab test
- Complete blood count (CBC) and differential including total lymphocyte count (TLC)
- CD4 count*
- Alanine aminotransferase (ALT)**
- Glucose
- Pregnancy test
- Sputum smear for TB
- Gram and Wright stains
- Spinal tap (lumbar puncture, examination of cerebrospinal fluid) and India ink stain**
- Fundoscopy**
- Malaria smears
- Urinalysis
- Chest X-ray

***** CD4 count is promoted as standard of care but is not absolutely necessary. Total lymphocyte count can be used in patients with HIV-related symptoms (WHO Stage II) for initiating treatment as a substitute where CD4 count is unavailable.

** Currently it may not be available at district or intermediate level, but should be equipped.

Table 11. Opportunistic infections and other illnesses to be managed at the district or intermediate level*

Main symptoms	Disease	Prophylaxis (P: primary, S: secondary)	Diagnosis	Treatment
Respiratory	TB	P: INH	Smear, chest X-ray	National TB programme regimen
	Bacterial pneumonia	P: Cotrimoxazole	Chest X-ray, smear	Antibiotics
	Pneumocystis carinii pneumonia (PCP)	P and S: Cotrimoxazole	Clinical, chest X-ray	Cotrimoxazole
Neurological	Toxoplasmosis	P: Cotrimoxazole S: Pyrimethamine + sulfadiazine	Clinical	Pyrimethamin + sulfadiazone, or referral*
	Cryptococcosis	S: Fluconazole	Clinical, spinal tap, India ink stains	Amphotericin B, flucytosine, fluconazole, or referral *
	TB meningitis	P: isoniazid (INH)	Clinical, spinal tap	National TB programme regimen
	Bacterial meningitis		Clinical, spinal tap	Antibiotics
Skin and mucosal	Candidiasis		Clinical	Topical (gentian violet, nystatin or clotrimazole lozenges), fluconazole or ketoconazole
	Penicilliosis	S: Itraconazole	Clinical, smear	Amphotericin B, itraconazole, fluconazole, or referral*
	Herpes simplex		Clinical	Topical, acyclovir if available
	Herpes zoster		Clinical	Topical, acyclovir if available
	Pruritic papular eruption (PPE)		Clinical	Steroid (ART effective)
	Seborrheic dermatitis		Clinical	Steroid (ART effective)
Diarrhoea	Diarrhoea		Clinical, empirical treatment	Rehydration fluids, loperamide, antibiotics, metronidazole, cotrimoxazole, mebendazole, (ART)
Fever	Septicaemia		Clinical, empirical treatment	Antibiotics
Lymphadeno-pathy	TB		Clinical, Aspiration	National TB Programme regimen
Others	Cytomegalovirus (CMV)			(ART)
	Cervical cancer		PAP smear, or referral	Referral

*See Part 3 for details of clinical management

**Use of amphotericin B or pyrimethamine + sulfadiazine requires specific clinical capacity

PART 3

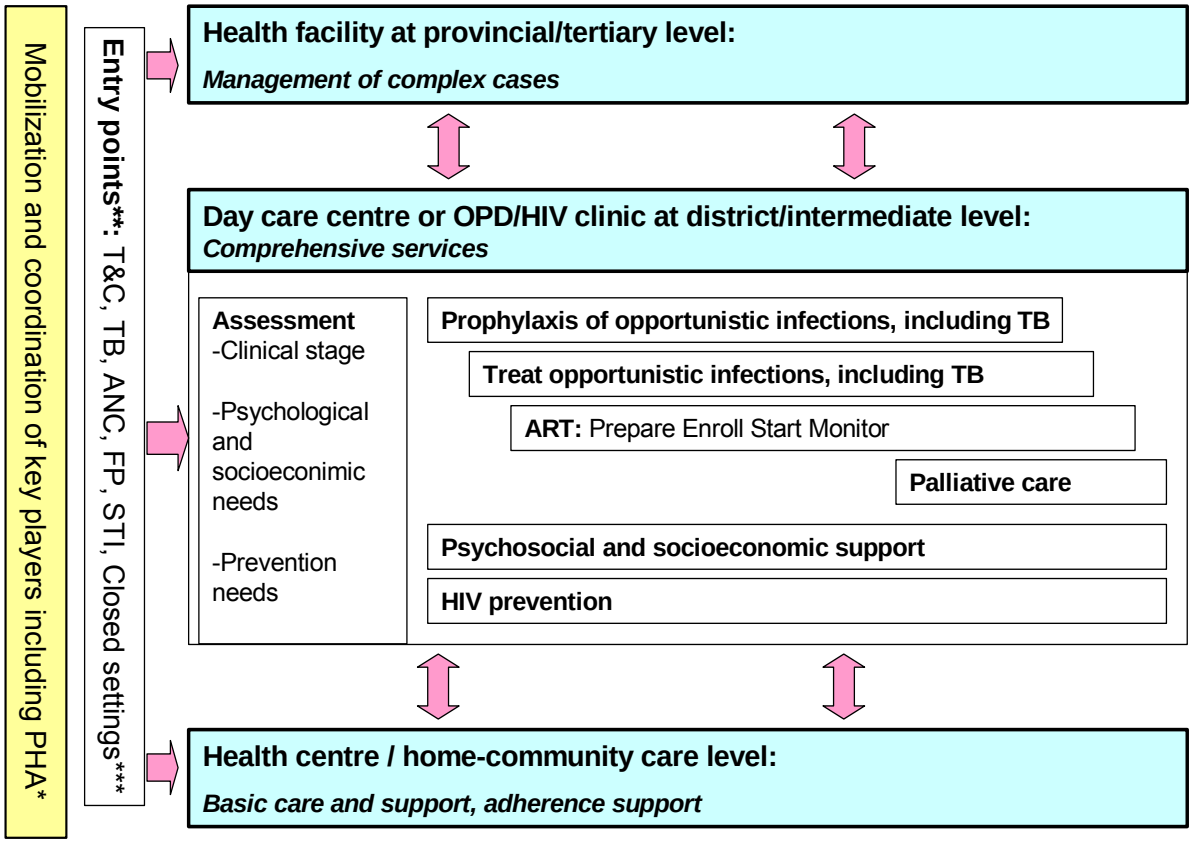
Standard operating procedures and practices

Part 3 contains operating procedures and practices, with emphasis on the essential package of services and activities (EPSA) outlined in Part 2. These services and activities include:

- mobilization and coordination of key players, including people with HIV/AIDS;
- HIV testing and counselling;
- clinical management, including prophylaxis and treatment of opportunistic infections, ART, and palliative care;
- psychological and socioeconomic support; and
- HIV prevention**.**

The following figure illustrates an overview of case management indicating relevant sections in Part 3.

Figure 7. Overview of case management



* PHA: people living with HIV/AIDS

** T&C: testing and counselling; ANC: antenatal care; FP: family planning; STI: sexually transmitted infection

*** *Closed settings (e.g. rehabilitation centre for injecting drug users and sex workers, jail) can also provide comprehensive services, including ART.*

1. Mobilization and coordination of key players, including people living with HIV/AIDS

Key players in HIV/AIDS treatment and care should be mobilized and coordinated within and across the various levels of service delivery. This mobilization and coordination includes:

- identifying key players involved in or associated with HIV/AIDS care and treatment;
- identifying key players who might be supportive in HIV/AIDS care and treatment and encouraging their participation;
- identifying key players who might be less supportive in HIV/AIDS care and treatment and developing strategies to encourage participation;
- mobilizing key players in public health and clinical services (including testing and counselling, TB, antenatal care/maternal and child health, family planning, and sexually transmitted infections) as well as other players such as people living with HIV/AIDS, CBOs, local authorities, FBOs, and NGOs;
- educating and supporting key players on issues related to HIV/AIDS care and treatment with particular attention to mobilization, coordination, and referral;
- developing close links and referral across and within levels of service delivery;
- developing close links, coordination, organization, and referral with entry points (testing and counselling, TB, antenatal care, maternal and child health, family planning, services for sexually transmitted infections, referral/provincial hospitals, health centres, closed settings, etc.) to establish continuity of care;
- promoting and advocating for development of groups for people living with HIV/AIDS and peer support; and
- ensuring participation of people living with HIV/AIDS in planning, implementation, and evaluation.

2. HIV testing and counselling[8]

In many low- and middle-income countries, the primary model for HIV testing and counselling has been client-initiated and voluntary. Increasingly, provider-initiated approaches in clinical settings are being promoted, i.e. health care providers routinely offer HIV testing in a context in which the provision of, or referral to, effective prevention and treatment services is assured.

The conditions of the "3 Cs" advocated since the HIV test became available continue to underpin HIV testing of individuals. Such testing must be:

- **confidential**;
- accompanied by **counselling**; and
- only conducted with informed **consent**, meaning that it is both informed and voluntary.

In provider-initiated HIV testing, explicit mechanisms are necessary to promote referral to post-test counselling services that emphasize prevention for all those being tested. Referral to medical and psychosocial support is also essential for those testing positive.

Patients retain the right to refuse provider-initiated testing, whether for diagnosis, an offer of ARV to prevent mother-to-child transmission, or encouragement to learn HIV status.

HIV testing without consent may be justified in the rare circumstance in which a patient is unconscious, his or her parent or guardian is absent, and knowledge of HIV status is necessary for purposes of optimal treatment.

Rapid HIV tests are recommended. Many of these tests are presented as strips or cartridges incorporating the reagents and do not require additional equipment. They are suitable for the performance of single tests, are easy to use, and can be carried out by any trained health care worker. Most of them can be stored at room temperature. The diagnostic performance of a high-quality rapid test is comparable to that of traditional enzyme linked immunosorbent assay (ELISAs).

Choosing screening tests and the combination of tests for confirmation should follow the nationally developed testing algorithms. The development of the algorithms need to take into account various factors, including prevalence of HIV in the populations tested (e.g. general population, clients accessing HIV testing in voluntary testing and counselling sites, clinics for sexually transmitted infections, TB clinics, antenatal care clinics, and closed settings) and international recommendations provided by UNAIDS and WHO.

1) Pretest education and counselling

Pretest counselling and education is designed to ensure that those tested are adequately informed about the testing process and the potential consequences of the result.

Informed consent is a fundamental part of pretest education and counselling and to ensure that people are not tested in a coercive manner.

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[8] UNAIDS and WHO. *UNAIDS/WHO Policy Statement on HIV Testing*. June 2004.
Adapted from: *Rapid HIV Tests: Guidelines for use in HIV testing and counselling services in resource-constrained settings*. Geneva, WHO, 2004; UNAIDS and WHO. Revised recommendations for the selection and use of HIV antibody tests. *In WHO. Weekly Epidemilogical Record. Number 12, 21 March 1997.*

Health workers that have limited counselling education and experience can provide basic information in pretest group education sessions. However, counsellors may be required to provide individual pretest counselling to clients in need of one-on-one counselling and referral. Health workers and counsellors must therefore work together closely.

Contents of pretest education and counselling include:

- HIV and AIDS overview;
- HIV transmission, sources, and prevention;
- sexually transmitted infections and HIV;
- mother-to-child transmission and its prevention;
- HIV testing processes;
- benefits and risks of HIV testing;
- confidentiality;
- implications of both positive and negative test results;
- identification of supportive HIV services;
- family planning;
- individual counselling and risk assessment; and
- testing and counselling for couples.

Other issues that the individual may raise during pretest counselling should also be addressed.

2) Obtaining informed consent

- Ensure sufficient time to think through the issues.
- Check understanding and correct any misconceptions.
- Specifically ask the client if they agree to be tested or wish to opt out.

3) Administer the test

The HIV testing process should be explained to all individuals who want to have a test. The explanation should cover:

- drawing of blood or finger-prick procedure;
- testing procedure;
- tests used;
- how results are interpreted; and
- assurances of confidentiality.

One of the most important aspects of testing is that people should get their results the same day whenever possible. Evidence suggests that there is a lower return rate for results that are not available on the day of testing. Simple rapid tests (WHO approved) provide same-day results.

If the test is positive or indeterminate, a second confirmatory test should be done using another testing method.

4) Giving POSITIVE results

- Establish client readiness to receive the result.
- Give the result simply and clearly, and give her/him time to consider the result.
- Use open-ended questions to determine his/her understanding of the result.

- Review facts covered in pretest sessions.
- Acknowledge the difficulty of receiving the diagnosis and support his/her feelings.
- Discuss benefits of knowing one's serostatus.
- Determine how he or she will get through the next few hours or days.
- Check to see who might be available to offer immediate support.
- Discuss possible disclosure of the result and when it may happen and with whom. Suggest telling only closest contacts (spouse, significant other) in the short term.
- Discuss any immediate concerns, including personal safety.
- Arrange a specific date and time for follow-up visits with the same counsellor or health worker, if possible.
- Provide the client with a telephone number and contact person's name, if possible.
- Provide an emergency telephone number and contact person's name, if possible.

5) Giving NEGATIVE results

- Establish client readiness to receive the result.
- Give result simply and clearly.
- Explain the meaning of the result and the “window period.”
- Provide information on prevention of HIV infection.
- Describe the risk of mother-to-child transmission to female patients if they become infected during pregnancy or while breastfeeding.
- Educate partner and encourage partner testing.
- Provide linkage to future counselling, if needed .
- Discuss possible disclosure and when it may happen, identify who needs to know and how to tell them.
- Refer to linking services if appropriate (e.g. tuberculosis, sexually transmitted infections, and antenatal care).

6) Assessing and managing adverse events

- Use post-test result-giving and counselling session to assess immediate concerns, including possible suicide, depression, anger, violence, and management of partner/family consequences.
- Identify trusted supports in family and social environment.
- Explain concern about possible adverse events and that further support is needed and will be sought with permission.

7) Referral for follow-up

- All people found positive require medical referral.
- All people found positive require psychosocial referral, e.g. from NGOs and CBOs.
- Post-test follow-up counselling should be organized on site or as appropriate.
- Where specific adverse events arise with giving the result, make referrals to appropriate colleagues/services.

3. Clinical management

3.1 Initial assessment

The following questions should be raised at the first visit of a person diagnosed with HIV/AIDS:

- Should treatment and/or prophylaxis of opportunistic infections be provided?
- Should ART be considered? (eligibility criteria, other medical conditions, previous ART, TB, pregnancy, anaemia, liver functions, concomitant medications)
- Is the person ready for ART?
- Should other support be provided? (e.g. counselling, peer support groups)

Table 12. Key points for clinical review of symptoms and signs[9]

ASK	LOOK

If this is the first visit:
Review history. Check record for TB, other opportunistic infections, and chronic problems.
 	
For all visits:
• How have you been? What problems have you had?
• Have you had any of the following? If yes, ask for how long:
  o Headache? Fever? Night sweats?
  o Cough?
  o Nausea or vomiting? Poor appetite?
  o Mouth sores? Abdominal pain?
  o Diarrhoea?
  o New skin rash?
  o Fatigue?
  o Signs of sexually transmitted infections? (use locally adapted question)
  o Sexual problems? Tingling, numb, or painful feet/legs?
  o Any other pain? If yes, where?
• Have you needed urgent medical care? If yes, ask for record/diagnosis
• Which medications are you taking and how often?
• Assess adherence (if on opportunistic infection prophylaxis and/or ART)
• What problems have you had taking the medicines? How are you taking the medicines?
• Taking any other drugs (traditional remedies, TB, ARV, illicit drugs, etc.)?
• How are things at home?
• Is there any thing else you would like to talk about?
	In all patients:
	• Look for pallor. If patient is pallid, check haemoglobin level.
	• Look at whites of eyes: are they yellow?
	• Look for thrush.
	• Weigh, calculate, and record weight gain or loss. If weight loss, ask about food intake.
	• Count pills to estimate adherence.
	• If patient is sad or has lost interest, assess for depression.
	
	If any new symptoms:
	• Measure temperature.
	• Check for nodes.
	• Look for rash.
	• Look for evidence of violence.
	• Do further assessment of symptoms.
	
	If first visit (also check every six months; skip if known problem)
	Tell the patient you want to check his memory:
	• Name three unrelated objects clearly and slowly. Ask patient to repeat them.
	• Can he/she repeat them? (registration problem?)
	If yes: wait five minutes and ask again: "Can you recall the three objects? (recall problem?)

[9] Adapted from: *Chronic HIV care with ARV therapy: Integrated management of adolescent and adult illness interim guide for first-level-facility health workers*. Geneva, WHO, December 2003.

Table 13. WHO HIV CLINICAL STAGING (modified)[10]

	Clinical Stage I Asymptomatic	Clinical Stage II Mild Disease	Clinical Stage III Moderate Disease	Clinical Stage IV Severe Disease (AIDS) *
Weight	No weight loss	Weight loss 5-10%	Weight loss >10%	HIV wasting syndrome
Symptoms: Treat common opportunistic infections and other conditions in Part 3. Follow the treatment plan at district day care centre or outpatient department	No symptoms or only: o Persistent generalized lymphadenopathy (PGL)	o Recurrent upper respiratory infections such as sinusitis or otitis o Minor mucocutaneous manifestations (seborrheic dermatitis, fungal nail infections, recurrent oral ulcers, angular chelitis) o Herpes zoster within the past five years	o Oral candidiasis o Oral hairy leucoplakia o Pulmonary TB with last year o Severe bacterial infections (pneumonia, pyomyositis) o Unexplained diarrhoea for longer than one month o Unexplained fever for longer than one month	o Cryptococcosis, extrapulmonary (meningitis) o Toxoplasmosis of the brain o HIV encephalopathy o Progressive multifocal leucoencephalopathy o Cytomegalovirus disease (except of liver, spleen or lymph node) o Candidiasis (oesophagus, trachea, bronchi) o Pneumocystis carinii pneumonia (PCP) o Extrapulmonary TB o Invasive cervical cancer o Penicilliosis ** o Herpes simplex ulcerations for longer than one month o Kaposi sarcoma o Lymphoma o Non-typhoid salmonella septicaemia o Cryptosporidiosis with diarrhoea for longer than one month o Atypical mycobacteriosis, disseminated or pulmonary (MAC) o Any disseminated endemic mycosis
Prophylaxis (according to national policy)	o isoniazid (INH) prophylaxis if eligible	o isoniazid (INH) prophylaxis if eligible o Cotrimoxazole prophylaxis	o isoniazid (INH) prophylaxis if eligible and able to exclude TB o Cotrimoxazole prophylaxis o Other prophylaxis on treatment plan	o INH prophylaxis if eligible and able to exclude TB o Cotrimoxazole prophylaxis o Other prophylaxis on treatment plan
ART	o Only if CD4<200	Only if CD4<200 or total lymphocyte <1200/mm3	o If CD4 not available, treat all in Stage III o If CD4 available, take into consideration CD4<350 when deciding to treat o Evaluate for ART (see ART Part 3) o Prepare for adherence	o All in Stage IV are medically eligible o Evaluate for ART (see ART Part 3) o Prepare for adherence (this requires several visits and home visit if possible)

* May require information on advanced clinical diagnosis,
** Will probably be added to the list for the next revision of the WHO staging.

[10] Adapted from: *Chronic HIV care with ARV therapy: Integrated management of adolescent and adult illness: Interim guidelines for first level facility health workers.* Geneva, WHO, December 2003.

3.2 Prophylaxis of opportunistic infections

1) Pneumocystis carinii pneumonia (PCP)

Primary prophylaxis should be given to
- WHO Stage II, III, and IV conditions, regardless of CD4 count
- WHO Stage I condition with CD4 cell counts < 200 (if available)

Use cotrimoxazole 80 mg/400 mg two (or one) tablets per day. If cotrimoxazole cannot be tolerated, use dapsone 100 mg per day.

Secondary prophylaxis (following treatment for PCP) is the same regimen as for primary prophylaxis.

Prophylaxis (primary or secondary) is normally lifelong. If patients are treated with antiretroviral therapy, cotrimoxazole can be stopped if CD4 count is >200 for three to six months. If no CD4 testing is not available, it is safer to continue cotrimoxazole.

Cotrimoxazole:
- Significantly reduces the risk of the development and recurrence of PCP.

- Is also highly effective as primary prophylaxis against toxoplasmosis (below).

- May reduce the incidence of some bacterial infections and toxoplasmosis. The drug is active against nocardia, legionella, salmonella, haemophilus influenzae, streptococcus pneumoniae, methicillin-sensitive staphylococcus aureus, and many Gram-negative bacilli.

- Common side-effects include nausea, vomiting, rash (usually 1-2 weeks after initiation), fever, anaemia, neutropenia, and hepatitis. Many patients can continue to take cotrimoxazole despite side-effects. Rechallenging of the drug, possibly using desensitization, could be effective.

2) Toxoplasmosis

Primary prophylaxis is with cotrimoxazole (80 mg/400 mg) two tablets per day

Secondary prophylaxis (or long term maintenance therapy) is with sulfadiazine 500 mg four times per day (2000 mg/day) plus pyrimethamine 25 mg per day. Cotrimoxazole is not recommended for secondary prophylaxis.

3) Tuberculosis (TB)

Primary prophylaxis of TB with isoniazid (INH) – INH preventive therapy (IPT) – reduces the risk of latent TB infection becoming active tuberculosis. IPT should be provided as part of HIV/AIDS care and treatment, with technical supervision of a TB programme.

Secondary prophylaxis is not recommended.

Advantage of IPT	Issues
Reduces the risk of active TB in people living with HIV/AIDS who have latent TB infection	Effectiveness of IPT wanes after one to two years
Well tolerated, with few side-effects	Limited compliance in routine settings
No evidence that IPT induces INH-resistant TB strains, as long as active TB is excluded through the screening process	Should only be introduced in settings with the capacity to exclude active TB
Provides a tangible benefit after, and is popular with, voluntary counselling and testing clients	The requirement for tuberculin skin testing (optional) and chest X-ray (essential) is a barrier to people living with HIV/AIDS before starting IPT
Popular with counsellors providing voluntary counselling and testing services	

When IPT is offered to people living with HIV/AIDS, the following steps should be followed:

(a) Exclude active TB:

- ask about cough, chest pain, fever, enlarged lymph glands, and night sweats;
- screen those with symptoms for TB (sputum smear);
- chest X-ray for all people living with HIV/AIDS being considered for IPT; and
- refer active TB cases to the TB programme for registration and treatment.

(b) Targeting those most likely to benefit

- Recommend PPD testing
- If PPD is not feasible, IPT may be given to people living with HIV/AIDS in the following settings:
  - those living in populations with a TB prevalence estimated to be >30%
  - health care workers
  - voluntary counselling and testing clients
  - household contacts of TB patients
  - closed settings (prisons, rehabilitation centre, mines, etc.)
  - other groups at high risk of TB transmission or infection (e.g. groups for people living with HIV/AIDS, day care centres, HIV-positive mothers participating in programmes to prevent mother-to-child transmission)

(C) Provision of IPT to those without active TB

- INH five mg/kg (maximum 300 mg), pyridoxine 50 mg/day once daily for six months

(D) Monitoring for adherence and toxicity

People living with HIV/AIDS taking IPT should be monitored at once monthly visits for the following:

- adherence to treatment
- side-effects
  - minor: gastrointestinal intolerance (anorexia, nausea, abdominal pain), peripheral neuropathy
  - major: hepatitis, skin rashes

- signs or symptoms of active TB

4) Fungal infections (cryptococcal meningitis, penicilliosis, and histoplasmosis)

Primary prophylaxis

Fluconazole: Only recommended in some countries with high prevalence of cryptococcal meningitis. Use fluconazole 400 mg once per week for those CD4 <100.

Itraconazole: Only recommended in some countries with high prevalence of penicilliosis and/or histoplasmosis. Use itraconazole 200 mg once daily for those CD4 <100.

Secondary prophylaxis

Fluconazole: (Following treatment of cryptococcal meningitis) Use fluconazole 200 mg once daily. Prophylaxis is lifelong or until CD4 count is >100 for three to six months in ART-treated patients. Discuss risks and benefits if pregnant or planning pregnancy.

Itraconazole: (Following treatment of penicilliosis or histoplasmosis) Use itraconazole 200 mg once daily.

3.3 Management of opportunistic infections[11]

The following opportunistic infections and HIV-related conditions are relatively common and could be prevented with prophylaxis, diagnosed, and/or treated at the district or intermediate level (EPSA), with referred services for more complex diagnosis and treatment at provincial/tertiary level hospitals (APSA).

1) Opportunistic infections and other conditions frequently causing respiratory symptoms

Patients with severe dyspnoea and/or respiratory distress should be immediately referred to a provincial/tertiary level facility.

Diagnosis of respiratory symptoms at the district/intermediate level should be based on clinical symptoms, sputum examination (acid-fast bacilli [AFB]), and chest X-rays.

Tuberculosis (TB): Systematic collaboration with TB programme is crucial	
Symptoms	Cough lasting longer than two weeks, night sweats, fever, shortness of breath, and weight loss. TB in patients with HIV is often extrapulmonary and can present with enlarged lymph glands (especially in the neck), diarrhoea, and headaches.
Diagnosis	**EPSA =** Sputum examination for AFBs, chest X-ray, needle aspiration of lymph node for AFB, **EPSA or APSA =** Lumbar puncture for suspected TB meningitis (see section on headache/neurological symptoms), stool examination for AFBs if diarrhoea for AFB stain **APSA =** CT scan and lymph node biopsy.
Preventative therapy (primary prophylaxis)	**EPSA =** Exclude active TB by history (cough, fever, weight loss), examination, and chest X-ray if any lung symptoms are present. Look for large, painful lymph nodes. Isoniazid (300mg once a day) for six months plus pyridoxine 50 mg/day
Treatment	**EPSA =** Follow protocol of national TB programme (NTP). An example for smear-positive pulmonary TB includes: isoniazid (5mg/kg once a day) + rifampicin (10 mg/kg once a day) + pyrazinamide (25 mg/kg once a day) + ethambutol (15 mg/kg once a day) all for two months, followed by isoniazid (5mg/kg once a day) + rifampicin (10 mg/kg once a day) for four months. TB treatment is the same for HIV-positive as for HIV-negative TB patients, with the exception that thiacetazone is contraindicated in those who are HIV positive. In TB meningitis, ethambutol should be replaced by streptomycin.

[11] Duncombe C. *HIV/AIDS Clinical Management Training modules* (draft). HIV-NAT. Thai Red Cross AIDS Research Centre. Bangkok, Thailand (available from WHO Western Pacific Regional Office, Manila, the Philippines); Bartlett J and Gallant J. *Medical Management of HIV Infection: 2004 Edition*. Johns Hopkins Medicine; *Clinical Management of HIV and AIDS at District Level*. WHO South-East Asia Regional Office, 1998; *Treatment of Tuberculosis: Guidelines for National Programmes*. Geneva, WHO, 2003; *TB/HIV: A Clinical Manual. Second Edition*. Geneva, WHO, 2004.

Bacterial pneumonia	
Symptoms	Productive cough, purulent sputum, and fever for one to two weeks. PCP presents more slowly and there is normally no sputum. Typical chest X-ray finding is lobar consolidation. Gram-positive pyogenic bacteria will be the most probable cause of bacterial pneumonia.
Diagnosis	**EPSA =** Chest X-ray (lobar consolidation), sputum examination (Gram stain): streptococcus pneumoniae, haemophilus influenzae, staphylococcus aureus, etc. Acid-fast stain: Tuberculosis **APSA =** Sputum culture and sensitivity
Primary prophylaxis	**EPSA =** Cotrimoxazole 80 mg/400 mg two (or one) tablets per day. Cotrimoxazole (given for pneumocystis carinii pneumonia [PCP] prophylaxis) may reduce the incidence of bacterial pneumonia
Treatment	**EPSA** = Empirical therapy Selection of recommended antibiotics for empirical therapy should be based on assessment of resistance profile of bacteria in each country**.** **APSA =** Selection of antibiotics should be based on sputum examination.
Referral to tertiary hospital	Patient who do not respond to initial therapy require further investigation for pathogens including fungus (histoplasmosis, cryptococcosis, penicilliosis).

Pneumocystis carinii pneumonia (PCP)	
Symptoms	Fever, dry cough (no sputum) difficulty in breathing, weight loss, night sweats, and fatigue.
Diagnosis	**EPSA** = PCP can be diagnosed through clinical symptoms and chest X-ray. **APSA =** Induced sputum examination, bronchoalveolar lavage (BAL)
Preventative therapy (primary prophylaxis)	**100% PCP prophylaxis for all patients with HIV-related symptoms is essential.** WHO Stage II, III, and IV condition regardless of CD4, Stage I with CD4 < 200 (if available) **EPSA =** Cotrimoxazole 80 mg/400 mg two (or one) tablets per day. Dapsone 100mg once a day if intolerant to cotrimoxazole. Cotimoxazole also may reduce the incidence of some bacterial infections and toxoplasmosis. The drug is active against nocardia, legionella, most salmonella, most haemophilus influenzae, most methicillin-sensitive staphylococcus aureus, many Gram-negative bacilli, and streptococcus pneumoniae.
Treatment	**EPSA =** Cotrimoxazole (two double-strength tablets or four single strength tablets every eight hours for two weeks. Cotrimoxazole can be given intravenously if available. Dose is based on trimethoprim (15 mg/kg/day in four divided doses). **APSA =** Prednisone (orally or intravenously) should be considered for people with acute illnesses (40 mg every 12 hours for five days, then 40 mg once a day for five days, then 20 mg once a day for 11 days).
Secondary prophylaxis	**EPSA=** Everyone who has had PCP must continue with maintenance therapy two tablets per day for life (unless ARV is available and then can be discontinued when the CD4 is >200 for three to six months).
Referral to tertiary hospital	Patients who do not respond to cotrimoxazole within three days and patients who develop rash from cotrimoxazole to tertiary level. Refer patients with severe shortness of breath, high fever (>39 deg) and those who are very sick.

2) Opportunistic infections frequently causing headaches/neurological symptoms

Existence of neurological focal signs, with or without fever and severe headache, suggests toxoplasmosis.

If the patient does not have a neurological focal sign (cerebral space-occupying lesion) and if fundoscopy does not show papilloedema (raised intracranial pressure), examination of cerebrospinal fluid (CSF) should be considered for the diagnosis of cryptococcal meningitis, TB meningitis, and bacterial meningitis.

A blood smear for malaria parasites should be carried out in areas where the disease is endemic or where there is a history of recent travel to such an area.

Toxoplasmosis	
Symptoms	Constellation of severe headache, fever, and neurological focal signs (such as hemiparesis) is typical. Can also cause altered mental states (confusion, delusional behaviour), seizures, coma, eye pain, and reduced vision.
Diagnosis	**EPSA =** Clinical diagnosis based on the symptoms **APSA =** Cerebral CT scan
Primary prophylaxis	**EPSA =** Cotrimoxazole 80 mg/400 mg two tablets per day
Treatment	**EPSA or APSA =** Pyrimethamine (200 mg loading dose then 50-75 mg once a day) + sulfadiazine (1 g every six hours) for three to six weeks depending on response to treatment. Clinical improvement expected within one week. Sulphadiazine may cause anaemia, thrombocytopenia, and leucopenia. Careful haematological monitoring with complete blood count is recommended. Rash can be associated with the use of pyramethamine and sulphadiazine. **APSA =** Clindamycin (600 mg every six hours).
Secondary Prophylaxis	**EPSA =** Pyrimethamine (50 mg once a day)+Sulfadiazine (500 four times per day)
Referral to tertiary hospital	In many cases, patients with suspected toxoplasmosis are referred to tertiary hospitals. Patients who do not show response to therapy within one to two weeks, or who develop complications from therapy, should be referred to specialist facility.

Cryptococcal infection	
Symptoms	Cryptococcal meningitis presents with headaches, fever, fatigue, altered mental status, and irritability. Nausea, vomiting, stiff neck, and seizures are less common. Neurological focal signs are rare. Can also cause pneumonia (coughing, sweats, and difficulty in breathing).
Diagnosis	**EPSA or APSA =** Lumbar puncture (following fundoscopy) and India ink stain of CSF with light microscopy Bacterial meningitis: increase of polynuclear cells in CSF TB meningitis: increase of lymphocytes, AFB
Primary prophylaxis	Not recommended (except in some countries with high prevalence)
Treatment	**EPSA or APSA =** **Preferred:** IV amphotericin B (0.7 mg/kg daily) + flucytosine (25 mg/kg four times a day) for two weeks then fluconazole (400 mg daily) for eight weeks. **Alternatives:** IV amphotericin B (0.7mg/kg daily) for two weeks then fluconazole (400 mg daily) for eight weeks **Notes on the use of amphotericin B** Amphotericin B is given by slow IV infusion over 45 minutes four times per day. Patient needs careful observation, especially with initial doses, as fever and chills can occur. The other main side-effects of amphotericin B are electrolyte disturbances (especially hypokalaemia) and hypoglycaemia. Frequent monitoring of electrolytes and blood sugar are required, with 5% dextrose co-infusion and potassium supplements to maintain normal levels
Secondary prophylaxis	**EPSA =** Everyone who has had cryptococcal disease should be on maintenance therapy with fluconazole (200mg daily) for life. Pregnant women should not take fluconazole.
Referral to tertiary hospital	Suspected cases should be referred to provincial/tertiary hospitals for diagnosis and treatment unless the district/intermediate hospital has the required treatment and trained staff.

3) Opportunistic infections and other conditions frequently causing skin and mucosal symptoms

Common skin and mucosal conditions that can be managed mainly at the district/intermediate level are shown below. Additions and deletions should be made according to national profile of skin and mucosal conditions, taking into account prevalence and availability of diagnosis and treatment. Reference of HIV-associated skin diseases is also indicated at the end of the section.

Oral, oesophageal, and cutaneous candidiasis	
Symptoms	Oral: White patches on gums, tongue, or lining of mouth; pain Oesophageal: Difficulty in swallowing and loss of appetite Cutaneous: Wet and itchy lesions with scaling and satellite papules Also causes vaginitis: vaginal irritation, itching, burning, and thick white discharge.
Diagnosis	**EPSA =** Oral: Visual examination. White plaques which can be easily removed with swab or gloved finger. Swab and microscopic examination if available. (Oral hairy leucoplakia: Unilateral or bilateral adherent white or grey patches on lingual lateral margins. Patches are irregular folds and cannot be scraped off, unlike candidiasis. Rarely symptomatic and treatment may not be necessary.) Oesophageal: Presence of pain on swallowing and typical oral lesions. Endoscopy is not normally required unless unresponsive to fluconazole treatment. Cutaneous: Usually clinical
Treatment	**EPSA =** Mild: topical therapy such as gentian violet applied three times per day or nystatin or clotrimazole lozenges dissolved in mouth three times per day. For vaginal candidiasis, clotrimazole or nystatin pessaries (which can also be used in the mouth) inserted three times per day for seven days. Moderate: Systemic therapy with fluconazole 200 mg per day or ketoconazole 200 mg per day for 14-21 days Start ART as soon as patient can swallow pills comfortably.
Refer to tertiary hospital	Severe mouth, vaginal infection, severe pain on swallowing, or if patient cannot swallow fluconazole. Refer for endoscopy if no response to fluconazole within three days.

Herpes simplex	
Symptoms	Typical blisters, usually in genital area or face
Diagnosis	**EPSA =** Clinical diagnosis based on history and examination No laboratory tests required
Primary prophylaxis	Not recommended
Treatment	**EPSA or APSA** (depending on availability of acyclovir) **=** Usually self-limiting and may not require treatment. Local lesion care, such as with gentian violet and chlorhexidine. If indicated, acyclovir 200-400 mg five times daily for seven days. In immunosuppressed patients, herpes simplex can be chronic and invasive (e.g. oesophagitis, encephalitis).
Secondary prophylaxis	**APSA =** In cases of frequent recurrences, long-term suppressive therapy with acyclovir 400 mg twice daily may be necessary**.**
Refer to tertiary hospital	Patient with suspected systemic infection, such as herpes simplex encephalitis or oesophagitis.

Herpes zoster	
Symptoms	Typical painful blisters in clusters along dermatomes. Can involve the eye.
Diagnosis	**EPSA =** Clinical diagnosis based on history and examination. No laboratory tests required.
Primary prophylaxis	Not recommended
Treatment	**EPSA or APSA =** (depending on availability of acyclovir) Local lesion care, such as with gentian violet and chlorhexidine. Acyclovir 800 mg five times daily orally for seven days, commenced within 72 hours of onset of blisters. Famciclovir and valaciclovir are alternatives. Acyclovir ointment applied into eye every four hours for ophthalmic herpes zoster.
Secondary prophylaxis	Not recommended
Refer to tertiary hospital	Patients who do not respond to initial oral acyclovir therapy and patients with severe, extensive, or necrotizing lesions.

Pruritic papular eruption (PPE)	
Symptoms	Hyperpigmented, hyperkeratotic papules and nodules which often appear symmetrically on arms, legs, lower back, buttocks, etc.
Diagnosis	**EPSA =** Clinical diagnosis
Treatment	**EPSA or APSA =** High potency topical steroid (limited response). May benefit from oral antihistamine. ART effective.

Seborrheic dermatitis	
Symptoms	Erythematous plaques with greasy scaling on the scalp, face, postauricular area, and chest.
Diagnosis	**EPSA =** Clinical diagnosis
Treatment	**EPSA or APSA:** Low or middle potency topical steroid (responds well). Topical antifungal cream may also be needed. ART effective.

Penicilliosis	
Symptoms	Caused by the fungus penicillium marnefei, this disease presents as typical papulo-necrotic skin lesions and often as systemic disease with fever, lung involvement, cough, weight loss, anaemia, and lymphadenopathy. It is endemic in Northern Thailand, Southern China, Vietnam, Indonesia, and Hong Kong.
Diagnosis	**EPSA =** presumptive: smear, skin scraping for Wright stain and microscopy **APSA =** definitive: culture
Treatment	**EPSA or APSA =** IV amphotericin B (0.7 mg/kg daily) for two weeks then itraconazole 400 mg orally daily for 10 weeks. In mild cases: Itraconazole 400 mg orally daily for eight weeks. **EPSA =** maintenance therapy (fluconazole)
Secondary Prophylaxis	**EPSA =** Itraconazole 200 mg per day for life
Referral to tertiary hospital	For many cases, refer to tertiary hospitals for complex treatment.

HIV-associated skin diseases	
Viral infections	Herpes simplex, herpes zoster, molluscum contagiosum, human papilloma virus, oral hairy leucoplakia (EB virus)
Fungal infections	Superficial mycosis: candidiasis, cermatophytosis (cutaneous ringworm, onychomycosis)
Bacterial infections	Folliculitis and frunculosis, pyoderma
Mycobacterial infections	Tuberculosis, atypical mycobacteria
Parasite infections	Scabies
Drug reactions	ARV (e.g. non-nucleoside reverse transcriptase inhibitor [NNRTIs]), antibiotics (e.g. cotrimoxazole)
Neoplasm	Kaposi sarcoma, lymphoma
Other dermatitis	Pruritic popular eruption (PPE), seborrheic dermatitis, psoriasis, xerosis

4) Opportunistic infections and other conditions frequently causing chronic diarrhoea

Diarrhoea: Diarrhoea may be caused by organisms which effect any person, or by organisms specific to HIV-related immunosuppression	
Common causes	Salmonellosis and shigellosis, campylobacter spp, giardiasis, entamoeba histolytica, isospora belli, strongyloidiasis, cryptosporidiosis, mycobacterium tuberculosis, mycobacterium avium complex (MAC) infection, cytomegalovirus (CMV), and HIV (no other pathogens)
Diagnosis	**APSA =** Identification of the organism by multiple stool examinations Stain for AFBs (TB and MAC) and modified AFB stain (cryptosporidium, isospora) Culture for bacterial pathogens (salmonella, shigella, and campylobacter)
Primary prophylaxis	Cotrimoxazole may reduce the incidence of some bacterial diarrhoeas.
Treatment	**EPSA =** Initial treatment should be with rehydration fluids (oral and/or IV fluids and electrolytes). Antimotility agents like loperamide 10-20 mg three times per day, unless there is blood in stool or fever **Empirical therapy** Cotrimoxazole two tablets bid P0 five days plus metronidazole: 400 mg tid P0 seven days. If no response and/or fever and bloody stools: ciprofloxacin: 500 mg bid P0 five days. If no response, mebendazole 100 mg tid P0 three days. **APSA =** **Specific therapy** Salmonellosis and shigellosis: ciprofloxacin 500 mg, one tablet bid for seven days or oflxacine or ceftriaxone 1 g, IM or IV, one injection each day for five days. Campylobacter spp: erythromycin (tablet 500 mg) three tablets daily for five days. Giardiasis: metronidazole tablet 250 mg, two tablets tid for five days. Entamoeba histolytica**:** metronidazole tablet 250 mg, two tablets tid for seven to 10 days. Isospora belli**:** cotimoxazole 480 mg, two tablets four times daily for seven days. Helminth infection**:** mebendazole 100 mg tid P0 three days. Strongyloidiasis: thiabendazole 25 mg/kg, three times daily for three days. Cryptosporidiosis**:** no proven effective treatment. Maintenance of fluid and electrolyte balance is of greatest importance, and constipating agents may also be useful. Cryptosporidiosis may resolve with immune reconstitution on ART. Commence ART if available. Mycobacterium tuberculosis (TB**):** treat as extrapulmonary TB, according to national TB guidelines Mycobacterium avium complex (MAC) infection**:** drugs to be given are ethambutol, clarithromycin, rifampicin, and/or azithromycin. Salmonellosis, shigellosis, campylobacteriosis, and isosporiasis in HIV-infected patients often relapse. If relapse occurs after an initial course of antimicrobial therapy, a six- to 12-week course of therapy should be administered. These conditions (especially if recurrent) may respond to immune reconstitution on ART. Commence ART if available.
Refer to tertiary hospital	Patients not responding to symptomatic and initial antibiotic therapy and those who are severely dehydrated.

5) Opportunistic infections and conditions frequently causing fever

Presence of persistent or recurrent fever requires a series of investigations (e.g. history taking, physical examination, CBC, urinalysis, malaria smear, sputum examination, chest X-ray, CSF examination, skin scraping) to look for the cause (e.g. TB, bacterial infection, fungal infection in respiratory tract, urinal tract, skin, central nervous system [CNS], etc.).

Persistent or recurrent fever with no or limited localizing findings	
Common causes	Bacteremia: salmonella, streptococcus pneumoniae, haemophilus influenzae, etc. Mycobacteremia: TB, mycobacterium avium complex (MAC) Systemic fungal infection: cryptococcosis, penicilliosis, histoplasmosis Others: malaria, HIV (with no other pathogens), drug reaction
Diagnosis	**EPSA =** Look for the cause of fever through history taking, physical examination, CBC, urinalysis, malaria smear, sputum AFB, chest X-ray, CSF examination, skin scraping. Persistent fever and anaemia after ruling out malaria and common opportunistic infections including TB may suggest MAC. If the cause is not found, empirical treatment with broad-spectrum antibiotics should be considered. **APSA =** Identification of organism in blood culture.
Preventative therapy	Cotimoxazole also may reduce the incidence of some bacterial infections and toxoplasmosis. The drug may reduce the incidence of some bacterial infections and toxoplasmosis. The drug is active against nocardia, legionella, most salmonella, most haemophilus influenzae, most methicillin-sensitive staphylococcus aureus, many Gram-negative bacilli, and streptococcus pneumoniae.
Treatment	**EPSA =** **Empirical therapy** Selection of recommended antibiotics for empirical therapy should be based on assessment of resistance profile on bacteria in each country. For example, ciprofloxacin 500 mg, one tablet bid for seven days or cotrimoxazole one double-strength or two single-strength tablets bid of 7-14 days **APSA =** Specific therapy according to blood culture result. Malaria should be treated according to national guidelines. MAC may resolve with ART.
Refer to tertiary hospital	Refer patients for whom definitive diagnosis is required and patients not responding to empirical treatment.

6) Opportunistic infections and conditions frequently causing lymphadenopathy

Lymphadenopathy	
Common causes	Bacterial infections: nocardia, syphilis, Mycobacterial infections: TB, mycobacterium avium complex (MAC) Fungal infections: cryptococcosis, penicilliosis, histoplasmosis Viral infections: cytomegalo virus Neoplasm: lymphoma, kaposi sarcoma HIV: progressive generalized lymphadenopathy (PGL) (usually no prognostic significance)
Diagnosis	**EPSA =** Rule out local or contiguous infection which might explain lymphadenopathy Chest X-ray, lymph-node aspiration for AFB in case of any of the following is present: fever, weight loss, asymmetrical nodes, tenderness, extranodal foci such as skin lesions. (PGL: no tenderness, symmetrical, 1 cm in diameter, in two or more extra inguinal sites, for three or more months) **APSA =** Biopsy of lymph nodes
Treatment	**EPSA =** TB: according to national guidelines **APSA =** according to pathogens identified
Refer to tertiary hospital	Refer patients who were not found to be TB

7) Other conditions

Cytomegalovirus (CMV): Cytomegalovirus is a virus that infects the entire body.	
Symptoms (CMV related)	**Retinitis (in eye, retina):** blurry vision or loss of central vision that can lead to blindness. **Colitis (colon):** fevers, diarrhoea, and stomach pain. **Oesophagitis (throat):** ulcerations, pain, and difficulty in swallowing. **Pneumonitis (lungs):** pneumonia-like symptoms. **Encephalitis (brain):** confusion, fever, and tiredness.
Diagnosis	**EPSA =** Retinitis: Fundoscopic examination shows perivascular yellow-white retinal infiltrates without intraretinal haemorrhage (“cottage cheese and ketchup”) **APSA =** Retinitis: Ophthalmology exam Oesophagitis and colitis: Endoscopy and/or biopsy Pneumonitis: Check for PCP and tuberculosis first (EPSA). Diagnosis of CMV needs referral to specialized hospital Encephalitis: CT scan, etc.
Treatment	**APSA =** Refer all patients with suspected CMV to specialized hospital If specific therapy is unavailable, commence ART

Cervical cancer	
Symptoms	Often asymptomatic. Can cause vaginal discharge, vaginal bleeding and pelvic pain. HIV-positive women are at increased risk of cervical dysplasia and cancer compared to HIV-negative women.
Diagnosis	**EPSA =** Annual Pap smear is recommended for all HIV-positive women. Pap smear will detect human papilloma virus (HPV), the cause of most cervical cancers, as well as cervical dysplasia and cancer. **APSA =** Colposcopy and cone biopsy.
Treatment	**APSA =** Patients with Pap smear reports of dysplasia or intraepithelial neoplasia require colposcopy and may require cone biopsy or surgery. Adjuvant therapy (chemotherapy/radiotherapy) may be required.
Refer to tertiary hospital	**APSA =** If colposcopy and surgical facilities not available or if further investigations are indicated such as ultrasound (hepatic metastases) or CT scan (lymph node or bone metastases).

3.4 Management of antiretroviral treatment (ART)

1) Clinical eligibility

(a) Recommendations for initiating ART in adults and adolescents with documented HIV infection[12] (see Annex A: WHO staging for adults and adolescents)

IF CD4 AVAILABLE:

- **WHO Stage IV, irrespective of CD4 cell count**
- **WHO Stage III** (including but not restricted to HIV wasting, chronic diarrhoea of unknown etiology, prolonged fever of unknown etiology, pulmonary TB, recurrent invasive bacterial infections, or recurrent/persistent mucosal candidiasis) **with consideration of using CD4 counts <350/mm^3 to assist decision-making**[13]
- **WHO Stage I or II disease with CD4 counts ≤ 200/mm^3** [14]

IF CD4 TEST UNAVAILABLE:

- **WHO Stage IV, regardless of total lymphocyte count**
- **WHO Stage III** (including but not restricted to HIV wasting, chronic diarrhoea of unknown etiology, prolonged fever of unknown etiology, pulmonary TB, recurrent bacterial infections, or recurrent/persistent mucosal candidiasis) **irrespective of total lymphocyte count**
- **WHO Stage II with total lymphocyte count ≤ 1200/mm^3** [15]

[12] *Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach*. Geneva, WHO, December 2003.

[13] CD4 count is advisable to assist with determining need for immediate therapy. For example, pulmonary TB may occur at any CD4 level and other conditions may be mimicked by non-HIV etiologies (e.g. chronic diarrhoea, prolonged fever).

[14] The precise CD4 level above 200/mm^3 at which ARV treatment to start has not been established.

[15] Total lymphocyte count of = 1200/mm^3 can be substituted for the CD4 count when the latter is unavailable and HIV-related symptoms (Stage II or III) exist. It is not useful in the asymptomatic patient. In the absence of CD4 cell testing, asymptomatic HIV-infected patients (WHO Stage I) should not be treated because there is currently no other reliable marker available in resource-limited settings.

(b) Management of opportunistic infections and other conditions before commencing ART

If patent has this condition	Do this
Tuberculosis (TB)	Treat TB first Start ART according to the next table
Pneumocystis carinii pneumonia (PCP) Bacterial pneumonia Cryptococcal meningitis, toxoplasmosis, penicilliosis, Invasive fungal diseases, Significant diarrhoea which may reduce absorption of ART (e.g. more than five loose stools per day) Malaria	Treat these illnesses first Start ART when treatment is completed
Oesophageal candida,	Treat oesophageal candida first. Start ART as soon as the patient can swallow comfortably
Any undiagnosed active infection with fever and patient is unwell	Manage the condition first Start ART when stable
Drug reaction	Do not start ART during an acute reaction
Clinical hepatitis (jaundice) (elevated ALT, five times higher than normal limit if ALT available)	Look for cause and treat if possible (hepatitis B and C)
Anaemia: haemoglobin < 8 g/dl	Look for treatable cause (blood loss, MAC, TB, etc.). If no treatable cause, commence ART with a regimen that contains no AZT (HIV is often the cause of the anaemia)
Pregnancy	Initiate ART after the first trimester. If severely ill and early therapy clearly outweighs any potential foetal risk, commence ART. EFV should be avoided for pregnant women or women with the potential

Chronic conditions which may be improved or resolved with ART
Mycobacterium avium complex (MAC) Cytomegalovirus (CMV) Chronic diarrhoea Skin conditions such as pruritic papular eruption (PPE), seborrheic dermatitis

(c) ART for HIV-infected individuals with active TB [a, b, c, d]

<table>
<tr><th>Patient clinical status</th><th>No CD4 available</th><th>CD4 available</th></tr>
<tr><td>Pulmonary TB only (no other sings of WHO Clinical Stage III or IV)</td><td>Start and complete TB treatment then start ART</td><td rowspan="2">If CD4 > 350:
Start and complete TB treatment, then start ART unless non-TB Stage IV conditions are present (start earlier if present, based on clinical judgement)

If CD4 between 200-350:
Start TB treatment. Start ART after initiation phase of TB treatment (start earlier if severely compromised)

If CD4 < 200:
Start TB treatment.
Start ART as soon as TB treatment is tolerated (between two weeks and two months)</td></tr>
<tr><td>Pulmonary TB and patient has or develops other signs of Stage III or IV</td><td>Start TB treatment.
Timing of ART initiation should be based on clinical judgement in relation to other signs of immunodeficiency</td></tr>
<tr><td>Extrapulmonary TB</td><td colspan="2">Start TB treatment.
Start ART as soon as TB treatment is tolerated (between two weeks and two months), irrespective of CD4</td></tr>
</table>

a. There is currently insufficient evidence – these guidelines support a format for decision-making but need a national decision and more data.
b. EFV-containing regimens (d4T/3TC/EFV and ZDV/3TC/EFV) to be used when patients is taking rifampicin. But EFV is contraindicated in pregnant women or women of childbearing potential without effective contraception.
c. Alternative to the EFV portion of the regimen include: SQV/RTV (400/400 mg bid), SQV/r (1600/200 mg qd in sgc), LVP/RTV (400/400 mg bid) and ABC.
d. NVP (200 mg qd for two weeks followed by 200 mg bid) may be used in place of EFV in absence of other options.

2) Selection procedures for people living with HIV/AIDS

In addition to clinical eligibility criteria, various aspects including readiness and psychosocial status of people living with HIV/AIDS need to be assessed before initiating ART. This is especially the case in the areas where needs for ART far exceed its availability.

A committee may need to be established that should consist of those who are directly involved in care and treatment, including health workers (physicians, nurses, and social workers if available) and people living with HIV/AIDS. Respected community leaders and others deemed suitable could be involved while confidentiality of the patient information should be fully respected. For example, the committee should assess and take into account the following issues:

- **Demonstrated understanding of HIV/AIDS and ARV treatment**
- **Demonstrated understanding of adherence (at least 95%)**
- **Demonstrated understanding of ART side-effects**
- **Demonstrated understanding of the need for follow-up** (regular attendance at day care centre or outpatient HIV clinic)
- **Availability of treatment support person**
- **Family selection** (priority often given to families i.e. HIV-infected parents and children, pregnant women, and head of households)
- **Economic need** (cannot pay for treatment)
- **Lifestyle stability**
- **Prior history of treatment adherence** (opportunistic infections and/or TB treatment)

The following indicators should be monitored to ensure equity in selection of people living with HIV/AIDS:

- Sex:
- Age:
- Family dependents:
- Income/economic status:
- Occupation:
- Mode of HIV transmission:
- Geographical distribution: address

These indicators should be checked at regular intervals and compared with the epidemiological profile of the district or epidemiological data that represents the district or intermediate level (i.e. data may only be available at the provincial level).

If the profile collected in the equity monitoring system does not correspond with the epidemiological profile of the area, questions should be asked about the selection of people living with HIV/AIDS, and selection bias addressed.

3) Adherence to ART

Adherence to ART is an essential component of treatment success. ART requires 95% adherence to avoid reduced viral resistance and treatment failure. This means a patient should not miss taking pills more than three times a month in the case of a twice-daily regimen. The following measures should be taken to optimize the adherence.

Table 14. Measures to optimize adherence to ART

(1) Ensure affordable and simplified treatment with uninterrupted supply of ARV ❑ Providing service package including ARV for free or at minimal charge for people who can least afford care and treatment ❑ Ensuring no stock-out of ARV through improved drug supply management ❑ Simplifying treatment minimizing pill burden with fixed-dose combination (FDC), pill boxes, and/or blister packs
(2) Prepare health facilities, groups for people living with HIV/AIDS, CBOs, and NGOs for adherence support ❑ Making health facility user-friendly and trustworthy: respecting confidentiality, overcoming stigma and discrimination, and remaining flexible with opening times ❑ Promoting and facilitating peer support and formation of groups for people living with HIV/AIDS through day care centres and other mechanisms ❑ Mobilizing and coordinating CBOs, NGOs, and community volunteers ❑ Considering directly observed treatment (DOT) in closed settings with effective referrals with health facilities at the district/intermediate level ❑ Training health workers, members of groups for people living with HIV/AIDS, CBOs, and NGOs for adherence support including management of drug toxicity and drug interaction
(3) Prepare patients before initiating ART ❑ Establishing a trusting relationship with health workers and providing necessary information and advice (Table 15) ❑ Encouraging participation in day care centre activities and helping identify treatment support persons/organizations ❑ Developing individual treatment plans fitting ART into patients' lifestyles/daily events and identifying treatment reminders ❑ Promoting lifestyle stability and offering drug substitution therapy (e.g. methadone) to injecting drug users, if appropriate ❑ Assessing readiness and commitment of patients for ART (regular attendance, adherence history of prophylaxis for opportunistic infections and TB treatment, adequate knowledge)
(4) Monitor adherence and provide continuous support and education ❑ Developing an appointment schedule with access between visits for advice and care ❑ Assessing adherence to treatment in supportive manner (Table 16) ❑ Identifying the reasons of low adherence and intensify support and education in coordination with treatment support persons/organizations

Table 15. Key advice points to prepare patient for ART[16]

1) HIV/AIDS and progression of its related illnesses
1) ART: - **Life-saving, but requires a lifelong commitment on the part of the patient** - **The drugs do not cure HIV** - **The drugs do not prevent HIV transmission to others: patients need to practice prevention**
1) Need for complete adherence: - **Must be taken twice daily, without interruption, in the case of a twice-daily regimen** - **If patient forgets more than three times a month, the treatment may fail in the long run** - **Must be taken at the right time: every 12 hours (needs adjustment according to regimen)** - **If a patient forgets a dose, do not take a double dose** - **Drugs must not be shared with family members or friends – patients must take full doses**
2) Side-effects and drug interaction (See Annex C)
3) Importance of disclosure of HIV status for support from others - **Support from family or friends** - **Support from other people living with HIV/AIDS, or peer support (join group for people living with HIV/AIDS or day care centre activities)**
4) Importance of testing partners and children

Table 16. Assessment of adherence to treatment

Review the medications with the patient and their treatment supporter	**If poor adherence, determine the problem**
1) Ask questions in a respectful and non-judgemental way - "Many patients have trouble taking their medications. What trouble are you having?" - "Can you tell me when/how you take each pill?" - "When is it most difficult for you to take the pills?" - "It is sometimes difficult to take the pills everyday and on time. How many have you missed in the last seven days, last month (insert agreed time period)?" **2) Ask about the common and locally important factors that may interfere with adherence** **3) Ask about stigma related to taking the pills. Count pills.**	▪ Side-effects? ▪ Simply forgot? ▪ Ran out of pills? ▪ Which dose missed: morning or evening? ▪ Cost? ▪ Reminds you of HIV? ▪ Misunderstood? ▪ Changed work situation? ▪ Not comfortable taking pills around others? ▪ Stigma? ▪ Different timing when away from home or holiday, travel, weekend? ▪ Seldom at home and disorganized? ▪ Problem with diet (food availability)? ▪ Another medical problem? ▪ Screen for excess alcohol use and depression and treat, if present

[16] Adapted from: *Chronic HIV care with ARV therapy: Integrated management of adolescent and adult illness: Interim guidelines for first level facility health workers.* Geneva, WHO, December 2003

4) Instructions for commencing first line ART regimen[17] ("start")

In the management of ART, it is useful to keep in mind the " four Ss": "start", "substitute," (replacing ARV due to drug toxicity), "switch," (changing regimen due to treatment failure) and "stop".

WHO recommends the following ARV medications as first-line regimens, with alternate choices depending on side-effects and other co-existing conditions:

(d4T or AZT) - 3TC - (NVP or EFV)

(a) d4T-3TC-NVP

Give every 12 hours

Note that NVP requires an escalating dose of 200 mg once daily for two weeks, then 200 mg twice daily

Usual adult and adolescent dose:

- NVP 200 mg once daily for two weeks then 200 mg twice daily (first two weeks it is necessary to use separate tablets)
- d4T 40 mg twice daily (30 mg twice daily if less than 60 kg)
- 3TC 150 mg twice daily

These are available in fixed-dose combinations for d4T (40 mg and 30 mg)

No dietary restrictions
No laboratory requirements before starting ART

Minor side-effects	Major toxic effects
NVP-related ▪ Mild rash	NVP-related ▪ Severe rash: first eight weeks. Could be life-threatening with systemic symptoms such as fever, mucosal lesions, urticaria, Stevens-Johnson syndrome, or toxic epidermal necrolysis ▪ Liver toxicity: first eight weeks. Jaundice or liver tenderness
d4T-related ▪ Nausea ▪ Diarrhoea ▪ Headache ▪ Fatigue	d4T-related ▪ Neuropathy: After two to six months ▪ Lactic acidosis: After six months. Progressive fatigue, shortness of breath, weight loss, and elevated liver enzymes. ▪ Pancreatitis: ▪ Fat changes: After nine to 12 months. Arms, legs, buttocks, and cheeks become thin; breasts, belly, and back of neck gain fat.

[17] Adapted from: *Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach*, Geneva, WHO, December 2003; and *Chronic HIV care with ARV therapy: Integrated management of adolescent and adult illness: Interim guidelines for first level facility health workers.* Geneva, WHO, December 2003.

(b) d4T-3TC-EFV

Give d4T-3TC every 12 hours

- Give d4T-3TC in morning
- Give d4T-3TC plus EFV 600 mg at night

Usual adult and adolescent dose:

- EFV 600 mg once daily (at night)
- d4T 40 mg twice daily (30mg twice daily if less than 60 kg)
- 3TC 150 mg twice daily

Lab: Must exclude pregnancy in women of childbearing age (pregnancy test is mandatory), ask about menstrual periods and possibility of pregnancy each visit, and assure reliable contraception (not oral contraceptives).

Avoid if serious psychiatric problem (current or past)

Do not take EFV with fatty meals

Minor side-effects	Major toxic effects
EFV-related ▪ Somnolence, insomnia, confusion, bizarre dreams, confusion, dizziness ▪ Mild rash d4T-related ▪ nausea ▪ diarrhoea ▪ headache ▪ fatigue	EFV-related ▪ Severe confusion, psychosis, depression: First several weeks. ▪ Severe rash: First several weeks. Could be life-threatening with systemic symptoms with mucosal lesions or urticaria, or Stevens-Johnson syndrome or toxic epidermal necrolysis. Less frequent than NVP. ▪ Liver toxicity: Jaundice or liver tenderness d4T-related ▪ Neuropathy: After two to six months ▪ Lactic acidosis: After six months. Progressive fatigue, shortness of breath, weight loss, and elevated liver enzymes. ▪ Pancreatitis: ▪ Fat changes: After nine to 12 months. Arms, legs, buttocks, and cheeks become thin; breasts, belly, and back of neck gain fat.

(c) AZT-3TC-NVP

Give every 12 hours

Note that NVP requires an escalating dose of 200 mg once daily for two weeks, then 200 mg twice daily

Usual adult and adolescent dose:

- NVP 200 mg one daily for two weeks then 200 mg twice daily
- 3TC 150 mg twice daily
- AZT 300 mg twice daily

No food restrictions

Lab: Measure haemoglobin before starting AZT, then once every one to three months depending on clinical assessment.

Minor side-effects	Major toxic effects
NVP-related ▪ Mild rash AZT-related ▪ Nausea ▪ Diarrhoea ▪ Headache ▪ Fatigue ▪ Fingernail discoloration (dark blue)	NVP-related ▪ Severe rash: first eight weeks. Could be life-threatening with systemic symptoms such as fever, mucosal lesions, urticaria, Stevens-Johnson syndrome, or toxic epidermal necrolysis ▪ Liver toxicity: first eight weeks. Jaundice or liver tenderness AZT-related ▪ Severe anaemia: Acute onset within several weeks or slow onset over months ▪ Neutropenia: After three to six months ▪ Severe gastrointestinal intolerance ▪ Liver toxicity: First several weeks. Less frequent than NVP ▪ Lactic acidosis: After six months. Progressive fatigue, shortness of breath, weight loss, and elevated liver enzymes. Less frequent than d4T ▪ Muscle tenderness or inflammation ▪ Fat changes: After nine to 12 months. Less frequent than d4T. Arms, legs, buttocks, and cheeks become thin; breasts, belly, and back of neck gain fat.

(d) AZT-3TC-EFV

Give AZT-3TC every 12 hours plus EFV at night

Usual adult and adolescent doses:
- 3TC 150 mg twice daily
- AZT 300 mg twice daily
- EFV 600 mg at night

Lab: Measure haemoglobin before starting AZT, then once every one to three months depending on clinical assessment.

Must exclude pregnancy in women of childbearing age (pregnancy test mandatory), ask about menstrual periods and possibility of pregnancy at each visit, assure reliable contraception (not BCP). Consider injectable contraceptive plus condoms.

Avoid if serious psychiatric problem (current or past)

Do not take EFV with fatty meals

Minor side-effects	Major toxic effects
EFV-related ▪ Somnolence, insomnia, confusion, bizarre dreams, dizziness ▪ Mild rash AZT-related ▪ Nausea ▪ Diarrhoea ▪ Headache ▪ Fatigue ▪ Fingernail discoloration (dark blue)	EFV-related ▪ Severe confusion, psychosis, depression: First several weeks. ▪ Severe rash: First several weeks. Could be life-threatening with systemic symptoms with mucosal lesions or urticaria, or Stevens-Johnson syndrome or toxic epidermal necrolysis. Less frequent than NVP. ▪ Liver toxicity: Jaundice or liver tenderness AZT-related ▪ Severe anaemia: Acute onset within several weeks or slow onset over months ▪ Neutropenia: After three to six months ▪ Severe gastrointestinal intolerance ▪ Liver toxicity: First several weeks. Less frequent than NVP ▪ Lactic acidosis: After six months. Progressive fatigue, shortness of breath, weight loss, and elevated liver enzymes. Less frequent than d4T ▪ Muscle tenderness or inflammation ▪ Fat changes: After nine to 12 months. Less frequent than d4T. Arms, legs, buttocks and cheeks become thin; Breasts, belly, back of neck gain fat

5) Clinical/laboratory monitoring

Once ART has begun, patient monitoring should cover

- adherence (Table 16);
- drug toxicity;
- efficacy of treatment (weight, CD4 count); and
- detection of opportunistic infections and other conditions (occurrence/recurrence of opportunistic infections due to treatment failure and immune reconstitution syndrome).

(a) Laboratory monitoring (Table 17)

- routine testing for detection of drug toxicity (e.g. ALT for d4T, Hgb and WBC for AZT)
- monitoring of treatment efficacy (e.g. CD4 if available)
- symptom-directed testing for detection of opportunistic infections and other conditions (e.g. sputum smears for AFB, chest X-rays) for drug toxicity (e.g. amylase for pancreatitis if available)

Table 17. Laboratory monitoring for district/intermediate level for recommended first-line regimens[18]

Regimen	At baseline (pretherapy)	On therapy
d4T/ 3TC/ NVP	Desirable but not required: CD4	For routine testing: ALT for toxicity For efficacy: CD4 every six to 12 months, if available
AZT/ 3TC/ NVP	Hgb (mandatory) Desirable but not required: CBC, CD4	For routine testing: Hgb, WBC, ALT for toxicity For efficacy: CD4 every 6-12 months, if available
d4T/ 3TC/ EFV	Pregnancy test (mandatory) Desirable but not required: CD4	For routine testing: None routinely required for toxicity For efficacy: CD4 every six to 12 months, if available.
AZT/ 3TC/ EFV	Pregnancy test, Hgb (mandatory) Desirable but not required: CBC, CD4	For routine testing: Hgb, WBC for toxicity For efficacy: CD4 every six to 12 months, if available.

Symptom-directed testing for district/intermediate level includes; Sputum examination for AFB, chest X-ray, Gram and Wright stains, spinal tap (examination of cerebrospinal fluid) and India ink stain, fundoscopy, urinalysis, and malaria smears. More advanced testing (e.g. amylase for pancreatitis) should be available at the provincial/tertiary level.

[18] Adapted from: *Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach*. Geneva, WHO, December 2003.

(b) Major toxic effects of first-line ARV drugs and management ("substitute")

Major toxic effects of first-line ARV drugs and their management including drug substitution are summarized in Table 18 below.

Table 18. Major potential toxic effects of first-line ARV regimens and recommended drug substitutions

Major toxic effect[s]	Management	Drug substitution
NVP-related severe rash	Discontinue all drugs and wait until the symptoms resolve.	
	- Not life-threatening	NVP → EFV
	- Life-threatening (Stevens Johnson syndrome)	NVP → PI
NVP/EFV-related severe hepatotoxicity	Monitor clinical symptoms and/or preferably ALT. NVP/EFV should be replaced if clinical hepatitis or elevation of ALT five times the upper normal limit.	NVP → EFV EFV → PI
EFV-related persistent CNS toxicity	The symptoms usually improve in two to four weeks. If persist and are unacceptable or harmful, EFV should be replaced.	EFV → NVP
d4T-related neuropathy	The symptoms usually resolve in two to three weeks. Treat with amitriptyline 25-100 mg once a day (it takes three weeks to be effective). If severe, replace d4T.	d4T → AZT
d4T-related lipoatrophy (fat change)	Counsel patient. Replacement of d4T typically does not reverse lipoatrophy but may slow its progression.	d4T → TDF or ABC
d4T-related pancreatitis	Amylase is useful for diagnosis but its role is limited. Discontinue all drugs and wait until the symptoms resolve.	d4T → AZT
d4T/AZT-related lactic acidosis	Discontinue all drugs and wait until the symptoms resolve.	(→ NNRTI/PI regimen)
AZT-related persistent GI intolerance	Take with food. Anti-emetics (metoclapramide) and anti-diarrhoeals (loperamide). If persists, replace AZT.	AZT → d4T
AZT-related severe anaemia and neutropenia	Monitor clinical symptoms and/or preferably Hgb, WBC. Anaemia: Vitamin B12 and iron do not help. If severe anaemia, replace AZT. May require blood transfusion. Neutropenia: Replace AZT if severe.	AZT → d4T

(c) Treatment failure and regimen change ("switch")

In the case of treatment failure, the entire regimen should be changed to a second-line regimen. **A single drug should not be added or changed to a failing regimen.**

Table 19. Clinical and CD4 cell count definitions of treatment failure in adults and adolescents[19]

Clinical signs of treatment failure	CD4 cell criteria for treatment failure
▪ **Occurrence of new opportunistic infection or malignancy signifying clinical disease progression.** This must be differentiated from immune reconstitution syndrome (IRS) which can occur in the first three months following ART initiation. The latter does not signify treatment failure and the opportunistic infections should be treated as usual, without changes in the ART regimen ▪ **Recurrence of prior opportunistic infections** (Recurrence of TB may not represent disease progression as re-infection may occur. Clinical evaluation is necessary.) ▪ **Onset or recurrence of WHO Stage III conditions**	▪ **Return of CD4 cell to pre-therapy baseline or below without other concomitant infection to explain transient CD4 cell decrease** (if patient is asymptomatic and treatment failure is being determined by CD4 cell criteria alone, consideration should be given to performing a confirmatory CD4 cell count if resources permit) ▪ **>50% fall from on therapy CD4 peak level without concomitant infection to explain transient CD4 decrease.** (As with the first criteria for treatment failure, do confirmatory CD4 cell count if resources permit)

In cases of high-grade resistance to AZT, d4T, or 3TC, other nucleoside reverse transcriptase inhibitors (NRTIs) may have diminished efficacy. However, ABC, ddI, and TDF are more likely to have residual efficacy against such resistant strains. As EFV and NVP are cross-resistant, a ritonavir (r) enhanced protease inhibitor (PI) component is recommended. The WHO-recommended second-line regimen is as follows.

Failure on	Switch to
d4T or AZT 3TC NVP or EFV	**tenofovir (TDF) or abacavir (ABC)** **ddI[a]** **lopinavir (LPV)/r or saquinavir (SQV)/r[b]**

a. Dose of ddI should be reduced from 400 mg to 250 mg when coadministered with TDF.
b. LPV/r and SQV/r require secure cold chain. Nelfinavir (NFV) can be considered as an alternative in settings without cold chain. Indinavir (IDV)/r should also be considered as an alternative due to its renal side-effects.

[19] *Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach*. Geneva, WHO, December 2003.

(d) Immune reconstitution syndrome (IRS)

Within two to 12 weeks after the start of ART, signs and symptoms of a new or recurrent opportunistic infection or other inflammatory condition may occur as the immune system is restored because of an inflammatory response to a previously subclinical opportunistic infection. It is called immune reconstitution syndrome (IRS). IRS is more common in patients with advanced immunosuppression (CD4 count <50 cells). It is also possible that this immunological reconstitution may lead to the development of atypical presentations of some opportunistic infections.

For many opportunistic infections, including TB, there can be a transient worsening of the infection after ART initiation.[20] Such examples include mycobacterium tuberculosis (MTB), mycobacterium avium complex (MAC), pneumocystis carinii pneumonia (PCP), and cryptococcal meningitis.

Viral infections that may flare up during the first few weeks following initiation of ART include hepatitis B and C, cytomegalovirus, herpes simplex, and herpes zoster. Examples of autoimmune phenomena are psoriasis, alopecia, and thyroiditis.

This syndrome has been reported to occur in as many as 30% of patients with TB in the developed world.[21] The high prevalence of MTB in Asian countries suggests that TB-related IRS will be frequent. Studies from the region show the incidence of IRS among persons coinfected with HIV and TB and initiating highly active antiretroviral therapy (HAART) was 15.2 cases per 100 patient-years. The median days to the development of clinical IRS was 42 days (range 10-89) days.

The development of a new or recurrent opportunistic infection soon after starting ART, and as a result of the ART, does not indicate that the regimen has failed or that it should be changed. If possible, ART should be continued and the opportunistic infection treated. If not possible, ART should be temporarily interrupted, the opportunistic infection treated and the same ARV regimen restarted.

[20] DeSimone JA, Pomerantz RJ, Babinchak TJ. Inflammatory reactions in HIV-1-infected persons after initiation of highly active antiretroviral therapy. *Annals of Internal Medicine,* 2000, 133:447-54; Cheng VC, Yuen KY, Chan WM, Wong SS, Ma ES, Chan RM. Immunorestitution disease involving the innate and adaptive response. *Clinical Infectious Diseases,* 2000, 30:882-92.

[21] Narita M, Ashkin D, Hollender ES, Pitchenik AE. Paradoxical worsening of tuberculosis following antiretroviral therapy in patients with AIDS. *American Journal of Respiratory and Critical Care Medicine*, 1998, 158:157-61.

Table 20. Management of symptoms related to opportunistic infections, prophylaxis of opportunistic infections, ART and IRS

Symptom	Managing symptoms of opportunistic infections and HIV-related illness	Side-effects of ARV and opportunistic infection prophylaxis and their management	IRS (Consider during first three months on ART)
Cough, difficulty breathing	Common causes: TB, bacterial pneumonia, PCP (see Part 3)	**ART:** Stop ART if lactic acidosis suspected	IRS can be associated with PCP, TB, fungal or bacterial pneumonia
Headache	Common causes: toxoplasmosis, cryptococcal meningitis, TB meningitis, bacterial meningitis (see Part 3) Symptomatic treatment: paracetamol 1 gm every four to six hours ibuprofen 400 mg every four to six hours aspirin 600mg every four to six hours	**ART:** If on AZT or EFV, reassure that this is common and usually self-limiting but can last four to six weeks. If persists more than two weeks or worsens, call for advice or refer	Assess for toxoplasmosis and cryptococcal meningitis
Skin rash, itch	Common causes: candidiasis, penicilliosis, herpes simplex, herpes zoster, PPE, seborrheic dermatitis (see Part 3) Symptomatic treatment: emollient lotion, calamine lotion, Mild steroid creams (1% hydrocortisone. 0.01% triamcinolone), oral antihistamines	**ART:** If on EFV, give oral antihistamines and review daily. Rash is often self limiting. If on NVP or ABC, assess carefully. Stop drug if rash is moderate or severe (generalized, peeling, mucosal involvement). NFV and IDV can also cause rash. **Cotrimoxazole:** Stop if rash is moderate or severe **INH:** Stop if rash is moderate or severe	Skin conditions that can flare up due to IRS in the first three months of ART: - Herpes simplex and herpes zoster - Papilloma virus (warts) - Fungal infections - Atopic dermatitis Treat as necessary
Fever	Common causes: bacteremia, mycobacteremia, fungasemia, and others (malaria, HIV, etc.) in case of absence of localizing findings (see Part 3) Symptomatic treatment: paracetamol 1 gm every four to six hours, ibuprofen 400 mg every four to six hours, aspirin 600 mg every four to six hours	**ART:** Stop all drugs when hypersensitive reaction of ABC is suspected	Fever soon after commencing ART could be IRS (MAC, TB, CMV, HCV, HBV, cryptococcus, herpes zoster)
Diarrhoea	Common causes: bacteria and other pathogens (see Part 3) Symptomatic treatment: drink extra fluid. At least 200-300 ml in addition to usual fluid intake after each loose stool. Oral rehydration solution two to four liters per day. If persists or worsens, investigate and treat cause or give empirical therapy	**ART:** NFV commonly causes diarrhoea (less common with saquinavir) Loperamide 10-20 mg twice daily if no fever/no blood in stool If no response after two to four weeks, change ART	Temporary flare-ups of MAC or CMV may cause diarrhoea. Continue ART and treat symptomatically

Symptom	Managing symptoms of opportunistic infections and HIV-related illness	Side-effects of ARV and opportunistic infection prophylaxis and their management	Immune reconstitution syndrome (IRS)
Fatigue, pallor	If persists or worsens, check haemoglobin for anaemia caused by blood loss, MAC, HIV or other causes. Transfuse as necessary (Hb<8)	**ART:** Common for four to six weeks after starting AZT Stop AZT if severe pallor or symptoms of anaemia or low haemoglobin (<8). **Cotrimoxazole:** Stop the drug if Hb<8	Suspect MAC if fever, fatigue and anaemia. Continue ART Once CD4 >50, should resolve without treatment
Anxiety, nightmares, psychosis, depression	Care counselling and referral to specialist as needed.	**ART:** This may be due to EFV. Give at night; counsel and support patients (side-effects usually last less than three weeks). Amitriptyline 25 mg (increasing to 100 mg) once daily before bed. Call for advice or refer if severe depression, suicidal intentions, or psychosis.	These CNS effects are not associated with IRS
Neuropathy	Symptomatic treatment: amitriptyline 25 mg (increasing to 100 mg) once daily before bed. Plus analgesics as above. (It takes three weeks before amitriptyline takes effect) If persists or worsens, commencing ART may help	**ART:** Commonly caused by d4T, ddI, and ddC. Reduce dosage of d4T if possible. Add amitriptyline 25 mg (increasing to 100 mg) once daily before bed. Change ART if possible. **INH:** Give pyridoxine 100 mg daily	Not an IRS symptom
Nausea, vomiting	Symptomatic treatment: metoclopramide 10 mg tid, prochlorperazine 5-10 mg tid, chlorpromazine 25-50 mg every six to 12 hours	**ART**: Take ART with food (except ddI and indinavir). If on AZT, usually self-limiting after two weeks. Treat symptomatically. Stop ART if lactic acidosis suspected **Cotrimoxazole:** Take with food **INH:** Take at bedtime; if vomiting, stop INH	Hepatitis B and C can occur with IRS. Suspect if nausea, vomiting plus jaundice
Indigestion	Symptomatic treatment: Aluminium or magnesium sulfate tablets one to two tablets every six hours. If persists or worsens, treat for esophageal candidiasis. If no response, refer to next level	**ART:** Take ART with food, except ddI and IDV	Oesophageal candida may require treatment.
Abdominal or flank pain, and/or jaundice (yellow eyes)	Possible causes include hepatitis B and C, pancreatitis due to CMV, intestinal perforation due to CMV, hepatobiliary disease due to MAC and cryptosporidiosis.	**ART:** d4T or ddI may cause pancreatitis which requires stopping these drugs NVP (and EFV less commonly) may cause liver dysfunctions which require stopping these drugs Stop ART if lactic acidosis suspected **Cotrimoxazole**: if jaundice, stop cotrimoxazole **INH:** if jaundice, stop INH	Hepatitis B and C can occur with IRS. Suspect if nausea, vomiting plus jaundice

7) ART for infants and children[22]

Appropriate formulations for infants and children are not readily available in resource-limited settings. However, WHO recognizes that until ARV formulations are more widely available, the splitting of adult dose solid formulations may be the only way a severely ill child can receive therapy. The preferred first-line and alternate treatment for children includes:

(d4T or AZT) - 3TC – (NVP or EFV)

EFV cannot be used in children under three years of age or weighing less than 10 kg and NVP should be the non-nucleoside reverse transcriptase inhibitor (NNRTI) of choice. Some countries have developed tables of drug doses that can be administered according to weight bands. However, there is still a great deal that is unknown about ART for infants and children. Expert advice should be sought wherever possible.

The principles on which to base changes in therapy for children are similar to those applied to adults and management of toxicity is the same (see adult regimens with mild to severe side-effects and management). When toxicity is related to an identifiable drug in the regimen, the offending drug can be replaced with another drug that does not have the same side-effects.

Because of the difficulties in making a laboratory diagnosis of HIV infection in infants aged less than 18 months because of the persistence of maternal antibodies, WHO recommends that ARV initiation be divided into categories related to age. Where CD4 cell assays are available, the use of CD4 cell percentage is recommended for decision-making on ART rather than an absolute CD4 cell count because it varies less with age.

For recommendations for starting, substituting, and switching first-line ART regimens in infants and children, please refer to the WHO document entitled “Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach.”[23]

8) ART for injecting drug users

The clinical and immunological criteria for starting ART for injecting drug users do not differ from general recommendations. Special considerations for injecting drug users include:

- Dealing prospectively with lifestyle instability.
- Offering drug substitution therapies such as methadone.

[22] *Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach*. Geneva, WHO, December 2003.
[23] *Ibid*

- Optimising adherence to ART especially through developing working and trusting relationship between injecting drug users and health workers, with the possibility of directly observed treatment in closed settings (Table 14).

- Managing potential drug interactions of ARV (NVP, EFV, and RTV) with drug substitution therapies such as methadone (particularly decreased plasma levels of methadone and signs of opiate withdrawal). If a patient is on methadone and any of ARV regimens above, there will be a need to increase the dose of methadone and monitor for withdrawal signs.

Box 5. HIV/AIDS care and treatment for injecting drug users

Underlying reasons for lifestyle instability among injecting drug users include patterns of drug use, levels of drug dependence, and psychological and socioeconomic circumstances. These issues require comprehensive approach and should preferably be addressed before initiation of ART.

Substitution therapy, such as methadone maintenance, has proved effective in managing opioid dependence, improving overall health, and psychosocial stability among injecting drug users. This could optimize adherence to ART.

However, the non-participation of injecting drug users in drug substitution therapy programmes should not in itself justify exclusion from ART.

The clinical and immunological criteria for initiating ART in substance-dependent patients do not differ from those in the general recommendations.

Special considerations for this population include dealing prospectively with lifestyle instability that challenges drug adherence and accounting for the potential drug interactions of ARVs with agents such as methadone.

The co-administration of methadone with EFV, NVP, or RTV in HIV-infected individuals with a history of injecting drug use resulted in decreased plasma levels of methadone and (***DECREASED? INCREASED?***) signs of opiate withdrawal.

Patients should be monitored for signs of withdrawal and their methadone doses should be increased in appropriate increments overtime so as to alleviate withdrawal symptoms.

Personnel trained and working for harm reduction have access to and relationships with the population of injecting drug users and are able to work in a non-judgemental and trustful manner.

Careful assessment, education, and preparation of the patient before initiating treatment is key to effective HIV/AIDS treatment for injecting drug users.

The development of programmes that integrate care of drug dependence and HIV infection is encouraged.

3.5 Palliative care[24]

Palliative care usually requires a team approach including the person living with HIV/AIDS, family, caregivers, and other health and social service providers. Palliative or end-of-life care includes clinical management, social and emotional support, counselling, and spiritual care. The clinical management of palliative care will be included here. End-of-life care is in Section 4.

Symptom control

(See Section 3.3: Management of opportunistic infections, and Table 20)

Pain management: Assess the patient for pain

Determine the cause of the pain by history and examination (for new pain and any change in pain):

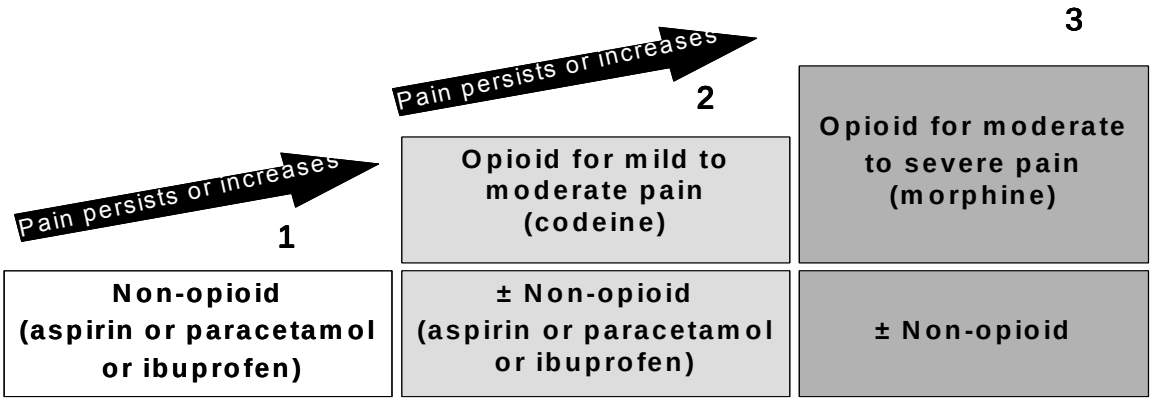
- Where is the pain? What makes it better/worse? Describe it. What type of pain is it? What are you taking now for the pain?
- Determine the type of pain—is it common pain or special pains (such as shooting nerve pain, zoster, colic or muscle spasms)?
- Is there a psychological or spiritual component?
- Grade the pain by number of fingers or pointing on a ruler or other methods

Pain management: Treat pain

- With analgesics, according to the analgesic ladder
- Reassess need for pain medication and other interventions frequently
- Repeat grading of the pain
- Investigate any new problems
- Give analgesics:
  - *By mouth*
    - If possible, give by mouth (rectal is an alternative – avoid intramuscular).
  - *By the clock*
    - Give painkillers at fixed time intervals (by clock or radio or sun).
    - Start with small dose, then titrate dose against patient's pain, until the patient is comfortable
    - Next dose should happen before effect of previous dose wears off
    - For breakthrough pain, give an extra "rescue" dose (same dosing of the four-hourly dose) in addition to the regular schedule
  - *By the individual*
    - Link first and last doses with waking and sleeping times
    - Write out drug regimen in full or present in a drawing
    - Teach about drug use
    - Check to be sure patient and family or caregiver understands
    - Ensure that pain does not return and patient is as alert as possible
  - *By the analgesic ladder (see the following figure)*:
    - Give only one drug from the opioid and non-opioid group at a time. Exception: If no codeine is given, aspirin every four hours can be combined with paracetamol every four hours. Overlap so one is given every two hours.

[24] Adapted from: *HIV/AIDS Fact Sheets for Nurses and Midwives: Palliative and Terminal Care*, Geneva, WHO, 2000; and *Palliative care: Symptom management and end-of-life care: Integrated management of adolescent and adult illness: Interim guidelines for first level facility health workers.* Geneva, WHO, November 2003.

Figure 9. The analgesic ladder



	Analgesics	Starting dose in adults	Range	Side effects/ cautions
STEP 1	**Non-opioid**			
	paracetamol (also lowers fever)	500 mg 2 tablets every 4 to 6 hours (skip dose at night or give another analgesic to keep total to 8 tablets)	Only 1 tablet may be required in elderly or very ill or when combined with opioid. Mild pain might be controlled with every 6 hour dosing	Do not exceed eight 500 mg tablets in 24 hours (more can cause serious liver toxicity)
	aspirin (acetylsalicylic acid) (also anti-inflammatory and lowers fever)	600 mg (2 tablets of 300 mg) every 4 hours		Avoid use if gastric problems. Stop if epigastric pain, indigestion, black stools, petechiae or bleeding.
	Ibuprofen (also anti-inflammatory, lowers fever, for bone pain)	400 mg every 6 hours		Max. 7 ½ tablets per day
STEP 2	**Opioid for mild to moderate pain** (give in addition to aspirin or paracetamol)			
	Codeine (if not available, consider alternating aspirin and paracetamol)	30 mg every 4 hours	30-60 mg every 4 to 8 hrs. Maximum daily dose for pain 180-240 mg due to constipation – switch to morphine	Give laxative to avoid constipation unless diarrhoea
STEP 3	**Opioid for moderate to severe pain**			
	5 mg/5ml or 50 mg/5 ml Drop into mouth. Can also be given rectally (by syringe)	2.5-5 mg every 4 hours (dose can be increased by 1.5 or doubled after 24 hours if pain persists)	According to need of patient and breathing There is NO ceiling dose	Give laxative to avoid constipation unless diarrhoea

The analgesic ladder and table are taken directly from: WHO. Palliative care: symptom management and end of life care. Integrated Management of Adolescent and Adult illness: Guidelines for first-level-facility health workers. 2003.

4. Psychological and socioeconomic support

4.1 HIV counselling and spiritual support

These standard operating practices are provided as a guide and overview. Further training to provide HIV counselling will be necessary.

People providing psychological support and HIV counselling may include people living with HIV/AIDS and their family members; friends; health workers; community volunteers; members of NGOs, CBOs, and other community groups; and spiritual leaders.

Psychological support and HIV counselling may be provided to individuals, groups, family members, and communities. Types of psychological support may change as the person adjusts to his/her diagnosis, begins treatment, or moves toward end-of-life care.

Psychological stress and HIV/AIDS

At the time of diagnosis and throughout the illness, people living with HIV/AIDS may experience:

- shock, denial, anger, fear, isolation, loss, grief, guilt, depression, anxiety, and suicidal thoughts and actions
- with each new challenge or stage of disease, these emotions can resurface

Provide emotional support

- Empathize with the concerns and fears. Provide a secure opportunity for the person to discuss his/her feelings and to experience feeling understood and accepted by a caregiver.
- Let the person know that how she/he feels is a normal reaction. Learning that others have felt the same way can reduce the sense of isolation.
- Address family issues**:**
    - Help the person understand the social and psychological implications of the result for the person living with HIV/AIDS, his/her sexual partner, family, and unborn child (if pregnant or planning a pregnancy).
    - Support the person to find strategies to involve partner and/or other family members in sharing diagnosis and responsibilities.
    - Provide support to the person living with HIV/AIDS and his/her family. Provide family counselling and coordination if necessary.
    - Help the person begin to anticipate the needs of the children and encourage children to come to HIV/AIDS day care centre or outpatient clinic for assessment.
    - Advise on family planning and HIV/AIDS prevention. Promote condom use.

Confidentiality, disclosure, and shared confidentiality

- People living with HIV/AIDS have an absolute right to confidentiality
- After careful consideration, shared confidentiality improves quality of life
- Share with family and/or friends
- Share with care providers (lay or professional)
- Members of support group
- On the whole, benefits of shared confidentiality far outweigh the risks

Elements of effective counselling

- Purposeful and specific
- Focused on a desired goal
- Involves acceptance, trust, and respect
- Consistent and accurate
- Confidential
- Sensitive and tactful
- Takes time

Common counselling errors

- Controlling, judging, moralizing, labelling, unwarranted reassurance, cajoling, non-acceptance, interrogating, and encouraging dependence

Counselling to support drug adherence (See section on adherence to ART)

Problem solving process

- Define problem from the perspective of the person living with HIV/AIDS
- Encourage open discussion
- Assess past problem-solving abilities
- Reduce problem into manageable parts
- Assess benefits and barriers
- Decide on action (identified with person living with HIV/AIDS)
- Develop action plan
- Identify resources

Support and referral

- Promote peer support
- Connect person with existing support services and community resources
- Facilitate spiritual counselling (if appropriate)
- Refer for individual and couple counselling by community or professional counsellors (where available).
- Refer to tertiary level for complex psychological and psychiatric assessment and treatment

Care for caregivers/counsellors

Psychological support and counselling is often difficult and emotionally draining. Therefore, it is essential to provide support for HIV/AIDS caregivers/counsellors by providing:

- counselling services and other forms of support;
- continuing education on issues related to HIV/AIDS;
- peer support (including emotional support and recreational and fun activities);
- a constant supply of adequate medications, supplies and equipment; and
- periodic peer review of interpersonal communication skills and strategies.

Psychological support and education

Psychological support and education usually involves helping people develop new behaviours and/or making behaviour changes (see strategies for behaviour change in HIV prevention Section 4). Education for people with HIV/AIDS can be provided individually or in groups.

Individual education for people living with HIV/AIDS

- An effective interpersonal relationship should first be developed.

- Assess the learning needs of the person living with HIV/AIDS.
- Assess his/her prior learning history (how does he/she usually learn best?).
- Assess the psychological state of the individual (e.g. motivated, depressed, angry, distracted, overwhelmed etc.) This will influence how much he/she can learn.
- Fit the pace and method of teaching to the individual's psychological state, learning needs and most suitable learning method(s).
- Use a variety of educational tools (see below).
- Promote empowerment and personal control for learning.
- Encourage and reinforce learning over a few sessions (if possible). Assess knowledge prior to starting each new session.
- Assess (evaluate) adequate learning before concluding education sessions.

Group education

- Develop a good rapport with the group before starting the education session.
- Assess group knowledge before starting each new session.
- Assess the learning needs of the group.
- Encourage group participation.
- Promote empowerment and personal control for learning.
- Use various educational tools to meet the needs of different types of learners.
- Reinforce learning over a few sessions.
- Motivate and encourage participants.
- Assess (evaluate) adequate participant learning prior to concluding education sessions.

Establishing support mechanisms

Promote:

- support from family members and/or primary caregivers/support people;
- peer support from other people living with HIV/AIDS;
- group support from others involved in HIV/AIDS care and treatment; and
- development of networks for people living with HIV/AIDS.

Teaching aids

It is important to work with the person living with HIV/AIDS to determine which teaching aids are more likely to help in his/her particular circumstance. Also remember that some people living with HIV/AIDS are illiterate and visual aids can be most important. People living with HIV/AIDS can create or choose the teaching aids that best suit them.
Teaching aids may include:

Pamphlets Calendars Videos/films Plays/drama	Posters Pill boxes Fridge magnets Photographs	Games Story-telling Colour charts Slide presentations	Puppet shows Recorded activities of the people living with HIV/AIDS)

Community education

- Make sure messages are positive; do not give fear messages
- Provide messages to reduce stigma and discrimination
- Create messages that are clear, attractive and responsive to the cultural and educational level and needs of the target audience

HIV/AIDS messages (not using fear) can be distributed at:

- recreation centres and recreational gatherings (e.g. picnics, sports events, national holidays, special events, and fairs);
- schools and job sites;
- shopping centres;
- health facilities, community centres, and places of worship;
- public places such as parks and markets; and
- through newspaper/magazine articles, radio, and television.

4.2 End-of-life care

End-of-life care strives to:

- meet physical, psychological, social, and spiritual needs, while remaining sensitive to personal, cultural, and religious values, beliefs, and practices;
- affirm the right of the individual and family to participate in informed discussions and make treatment choices;
- provide pain relief and symptom control (see palliative care in Section 3);
- prevent dehydration;
- offer support to family and loved ones during terminal illness and bereavement;
- provide practical support and anticipatory guidance to people living with HIV/AIDS and their loved ones; and
- maintain comfort and dignity .

End-of-life care for family strives to:

- provide referral and/or guidance on making a will; and
- advocate for inheritance rights, particularly for women and children; and
- develop plans to care for orphans and vulnerable children.

Making a will strives to:

- help to make clear what a person wishes to happen after his/her death;
- ensure that property, land, and valuables are passed on to people in accordance with the wishes of the person living with HIV/AIDS;
- make clear who has custody of children;
- specify who will ensure the will is acted upon (trustees or executors); and
- provide instructions about funeral arrangements.

To be valid, a will must usually be:

- written in permanent ink or typed;
- signed by the dying person and clearly dated;
- witnessed by persons present at the time of signing and dating (those who benefit from the will should not be witnesses); and
- written when the person is of sound mind, and not being forced to do so by someone else.
- The person must not be under the influence of heavy sedating medications such as morphine at the time of writing or signing the will.

Support healthy lifestyles:

4.3 Social welfare and legal support

These standard operating practices are provided as a guide and overview. People providing social welfare and legal support may include health workers; social workers;

lawyers; people living with HIV/AIDS; their family members and friends; community volunteers; members of NGOs, CBOs, and other community groups; and spiritual leaders.

Social welfare and legal support may be provided to individuals, groups, and family members. Types of social welfare and legal support may change as the person adjusts to his/her diagnosis, begins treatment, or moves toward end-of-life care. Strategies to support people living with HIV/AIDS and family members to access social welfare and legal support include:

- assessing the socioeconomic status of the person living with HIV/AIDS and his/her family;
- promoting involvement of people living with HIV/AIDS;
- providing referral to social welfare services, if necessary;
- referring to CBOs, NGOs, CHBCs, and others to provide: (a) basic necessities of daily living (e.g. food, clean water, shelter and clothing) and/or (b) access to a subsistence allowance;
- providing access to health care (diagnosis and treatment) free of charge or at subsidized rates, including access to essential drugs;
- advocating for or using local schemes for free or subsidized clinical services;
- developing or referring to programmes for income-generating activities;
- providing access to basic materials for income-generating activities (seeds, fabric, herbs, traditional medicines, craft supplies etc);
- promoting micro-credit banking and provide micro-credit banking information and credit applications;
- providing small business education; and
- developing marketing strategies for selling products.

Care for orphans and vulnerable children

- Provide access to schooling for both boys and girls (e.g. fee waivers, tax exemption)
- Establish access to free or subsidized school uniforms, school supplies, and school meals
- Encourage orphans to stay with extended family, if appropriate, or within their traditional cultural community
- If child-headed households, provide support for all children in the family to attend school and/or job training
- Provide social welfare support as necessary

Legal support

- Advocate for laws that protect the inheritance rights of children and women
- Challenge laws that lead to abuse of vulnerable women and children

4.4 Nutritional and daily living support

Nutrition support

HIV infection and ART result in a range of complicated nutritional issues for people living with HIV/AIDS, and there is growing evidence that nutritional interventions influence health outcomes. Nutrition is the cornerstone of HIV/AIDS care and treatment and nutrition interventions should be included at all stages of treatment and care. This will require a variety of interventions at each stage of HIV disease progression. These interventions include:

- promoting links between food security and poverty alleviation programmes;
- developing links between food programmes and HIV/AIDS care and treatment programmes;
- coordinating nutrition interventions at district level;
- promoting community nutrition interventions (where appropriate);
- establishing individual and group nutrition education and counselling sessions;
- educating people living with HIV/AIDS and their family members on food hygiene, water safety, food budgeting, and healthy eating at first visit;
- discussing food security, food programmes, and food supplementation as necessary;
- educating people living with HIV/AIDS and family members on adequate hand washing, covering open cuts and sores, cleanliness of food preparation surfaces and utensils, safe storage of food, and cooking food at high enough temperatures to avoid bacterial contamination;
- continuing to discuss food security and adequate, safe nutrition at each health care visit;
- providing education and support to people living with HIV/AIDS and their family members on nutrition-related symptom management;
- educating and supporting people living with HIV/AIDS and their family members on adequate nutrition while taking pharmaceutical treatments for opportunistic infections (e.g. when to take food, what foods to avoid with certain medications, food supplementation etc.);
- educating and supporting people living with HIV/AIDS and their family members on adequate nutrition and ART regimens, taking into account particular dietary restrictions;
- managing nutritional deficiencies of ART side-effects, including treatment of wasting;
- suggesting food supplementation if necessary; and
- supporting and educating people living with HIV/AIDS and their family members when nasogastric (NG) feeding or total parental nutrition (TPN) is required.

Daily living support

Support for daily living improves quality of life for people living with HIVAIDS and their family members and includes adequate psychological and socioeconomic support, nutritional support, and support for healthy living. Promoting healthy living includes:

- promoting adequate rest and activity;
- educating, supporting, and encouraging self care;
- encouraging recreation and play;
- promoting and encouraging support for people living with HIV/AIDS (individual and group);
- Encouraging meditation, massage, relaxation, and spirituality, if appropriate;
- supporting avoidance of risk behaviours, including drug and alcohol abuse (see HIV prevention section 5);
- involving locally respected traditional healers;
- promoting effective herbal remedies; and
- providing information, education, and communication materials that promote quality of life and effective daily living while reflecting local customs and literacy levels.

4.5 Stigma and discrimination reduction

Stigma and discrimination in health care settings and the community: Existing human rights instruments confirm that discrimination against people living with HIV/AIDS – including those who are injecting drug users and sex workers, family members or those thought to be HIV infected – is a violation of their human rights. Strategies that help reduce stigma and discrimination include:

- Promoting and supporting active involvement of people living with HIV/AIDS in HIV/AIDS-related activities
- Creating a safe and supportive environment to encourage people living with HIV/AIDS to disclose their HIV status
- Providing attitudinal HIV-related training and support to health workers and others involved in HIV/AIDS care and treatment based on sound medical, social and psychological knowledge and evidence
- Integrating comprehensive HIV/AIDS care and treatment that are "friendly" to people living with HIV/AIDS within existing health systems
- Developing discharge and referral systems that specifically avoid stigmatizing people living with HIV/AIDS
- Ensuring codes of ethics and professional conduct measures are in place and enforced by providing sufficient penalties for violations
- Providing community HIV/AIDS education and sensitization
- Promoting open dialogue and life-skills education and counselling that focuses on how people living with HIV/AIDS, family members and affected children can cope with stigma and discrimination
- Advocating and promoting strict universal precaution practices (see HIV prevention Section 5)
- Providing post-exposure prophylaxis (PEP) (see HIV prevention Section 5)

Stigma and discrimination in the religious sector: Churches, mosques, religious schools, lay groups, religious NGOs, ecumenical groups, and other religious groups have far-reaching influence on individuals, families, and communities. Key responses to help reduce stigma and discrimination within religious sectors[i] include:

- Ensuring religious leaders are "AIDS-competent" by including HIV/AIDS-related subjects into pre- and in-service training.
- Integrating holistic HIV/AIDS care and support programmes in service and education activities including life-skills for youth, home-based care, support groups for HIV infected and affected persons, and support for orphans.
- Identifying religious language and doctrines that are stigmatizing. Promote alternative language that is caring and non-judgemental.
- Promoting humanitarian, ethical and spiritual values of compassion for marginalized and stigmatized groups.

5. HIV prevention

HIV prevention must be linked to HIV/AIDS care and treatment. This can be achieved through:

- Increased access to HIV testing and social marketing that promotes testing and counselling to persons without HIV symptoms who are not accessing services.
- Promotion of HIV transmission prevention strategies in the community.
- Promotion of and increased access to affordable condoms.
- Promotion of strategies to prevent transmission of sexually transmitted diseases in the community and access to testing and treatment for sexually transmitted infections.
- Scale up comprehensive HIV/AIDS prevention services to injecting drug users, particularly methadone maintenance and other drug detoxification, peer outreach, needle and syringe programmes, etc.
- Scale up targeted peer outreach, condom promotions and treatment of sexually transmitted infections to sex workers and other vulnerable groups (e.g. injecting drug users and men who have sex with men).
- Scale up programmes to prevent mother-to-child transmission.
- Promotion of universal care and health worker safety in health and home-based care settings.
- Increased access to post-exposure prophylaxis for health workers.

1) HIV prevention and vulnerable populations

- Identify vulnerable populations at the district/intermediate level (e.g. sex workers, homosexual men, injecting drug users, poor and destitute people, children, ethnic minorities etc.)
- Target HIV prevention to vulnerable populations (avoiding fear messages)
- Promote peer education and counselling/support
- Improve access to HIV/AIDS treatment and care to vulnerable populations
- Develop outreach HIV/AIDS care and treatment programmes

2) HIV prevention and behaviour change

Factors that promote behaviour change include:

- wanting to appear responsible and trustworthy;
- wanting to protect others;
- wanting to protect health;
- fearing social/community sanctions for self and family; and
- expressed desire to change behaviour.

Strategies to support behaviour change involve:

- assessing behaviour change triggers;
- choosing goals and dividing into sub-goals;
- developing a behaviour change contract;
- starting small and building on success;
- choosing behaviour change reminders;
- identifying people to support behaviour change;
- if necessary, challenging and confronting risk behaviour; and
- encouraging and rewarding success.

3) Counselling on safer sex and providing condoms

Remember that sexual activities could be heterosexual or homosexual, and that homosexuality is often a hidden practice. Counselling on safer sexual practices includes:

- Counselling on options for sexual expression
- Asking how feasible it might be to:
    - delay sexual activity
    - reduce the number of sexual partners (optimal: staying faithful to one partner)
    - use condoms: (a) using model to demonstrate correct use; (b) explaining that condoms should be used before any penetrative sex, not just before ejaculation; (c) explaining how to negotiate condom use; (d) providing free condoms; and (e) using water-based lubricants
- Counselling on less risky sex: choose sexual activities that do not allow semen, vaginal fluid, or blood to enter the mouth, anus, or vagina of the partner
- Counselling and educating on behaviour change strategies and encourage healthy lifestyles
- For men, also emphasizing not having sex with teenagers or young girls. Counter the myth that this cleanses HIV infections
- Encouraging disclosure and shared confidentiality
- Encouraging partner and friends to be tested
- Responding to concerns about sexual function

4) Harm reduction

Harm reduction activities for injecting drug users include:

- Advocating for reduction in barriers to HIV prevention (especially legal)
- Explaining the risks in sharing needles, syringes, razor blades, or tattoo equipment
- Encouraging HIV-positive injecting drug users to use sterile injecting equipment
    - Each time they inject
    - Do not pass on used needles and syringes to others
    - Make sterile needles and syringes available
- Checking for common infections such as local abscesses, pneumonia, TB, and hepatitis
- Other strategies that have proved effective in HIV prevention and harm reduction include:
    - Education, especially peer education and counselling
    - Remove barriers to access to use of sterile equipment (especially police and legal barriers)
    - Increased drug treatment availability, accessibility, and options; referring when available
    - Increased access to primary health care, particularly through services designed to be “friendly” to, and appropriate for, the IDU community
- Helping people living with HIV/AIDS stabilize their lifestyles. Integrate care and prevention with drug substitution and other treatment and support services
- Being aware that some medications may induce withdrawal if people living with HIV/AIDS are on methadone:
    - rifampicin
    - ART, including EFV, NVP, and PIs
- Special considerations for ART:
    - EFV and NVP can decrease plasma levels of methadone and lead to opiate withdrawal. People living with HIV/AIDS should be monitored for

signs of withdrawal and their methadone dose should be increased as required to alleviate withdrawal symptoms.
- Link to rehabilitation centres for injecting drug users and sex workers
- Provide adequate referral and follow-up between rehabilitation camps and HIV/AIDS care and treatment programmes
- Expand outreach activities to increase access/utilization of HIV prevention for marginalized people living with HIV/AIDS

5) Promoting universal precautions

Universal precautions should be used with all patients, in all settings, at all times, regardless of the diagnosis. Universal precaution strategies include:

- careful handling and disposal of sharps (safe disposal receptacles for sharps, needles, and syringes; scooping and replacing needle caps is suboptimal);
- hand-washing with soap and water before and after all procedures and upon removal of gloves;
- use of protective barriers such as gloves, gowns, aprons, masks, goggles and boots for direct contact with blood and other body fluids;
- safe disposal of waste contaminated with blood or body fluids;
- proper disinfection/sterilization of instruments and other equipment; and
- proper handling of soiled linen.

6) Providing post-exposure prophylaxis

Post-exposure prophylaxis is the management and treatment of health workers who are possibly exposed to HIV in the workplace.

- Treatment of exposure site
  - Skin: Wash skin immediately with soap and water for three minutes.
  - Eyes: Rinse eyes immediately with eye-wash solution or normal saline.
  - Mouth: Spit out immediately. Rinse mouth several times with water or saline solution.
- Reporting exposure: Have adequate reporting forms
  - Date and time of the exposure
  - Details about the procedure being performed
  - Details of the exposure
  - Details about the exposure source
- Assessment of risk
  - Deep, skin-penetrating injury with a large-bore needle or sharp object with visible blood and source patient known to have HIV (highest risk)
  - Contact with mucous membrane and non-intact skin: eyes, mouth, skin rash, scratch, abrasion (minimal risk)
  - Contact with normal unbroken skin (no risk)
- Counselling of health worker
  - *Pretest counselling*: (see testing and counselling: Section 2). Include rationale for post-exposure prophylaxis and the risks and benefits of receiving it.
  - *HIV tests*: Ideally, HIV tests should be done for a minimum of six months following exposure.
  - *Post test counselling*: If the test is HIV negative, caution about the “window period” and the need for prevention measures such as condom use, possible cessation of breast feeding and strict universal precautions for at least six months. If positive, follow recommendations for post-exposure prophylaxis
  - *Confidentiality:* Post-exposure prophylaxis management should be kept strictly confidential

- Treating with ARV (if appropriate)
  - Start post-exposure prophylaxis as soon as possible (one to two hours following contact), or within 72 hours, if possible. Follow recommended ARV regimen available in country (usually triple combination therapy)
- Documentation of the incident

Post-exposure prophylaxis should also be available for people who have suffered rape or sexual abuse and for those who had unprotected sexual intercourse with an unknown partner in high-HIV-prevalence settings. Strategies to be used in such circumstances include:

- Counselling. Often someone of the same sex with specific sexual abuse training is helpful.
- Treating with ART if appropriate.
- Reporting the incident while protecting confidentiality.

7) Advising people living with HIV/AIDS on how to prevent other infections

- Avoid sexually transmitted infections and re-infection with other strains of HIV
- Use safe drinking water
- Eat well-cooked meals
- Wash fruit and vegetables (with safe drinking water)
- Avoid other people with infections such as colds, flu, boils, impetigo, herpes zoster, and chickenpox
- Practice good hand-washing: after using toilet, preparing food, coughing or sneezing, touching genitals, handling garbage, after touching blood, semen, vaginal fluids, or faeces
- Use topical antiseptic for cuts (after washing)
- Use an insecticide-treated bed net to prevent malaria

8) ART and HIV prevention

- Promote HIV prevention in all HIV/AIDS care and treatment programmes
- If person living with HIV/AIDS is on ARV therapy: warn they can still transmit HIV infection and can be re-infected themselves: promote and provide condoms and educate on all other aspects of HIV prevention
- Providing ART encourages renewed commitment HIV prevention as well as to accessing HIV/AIDS treatment and care

9) Prevention of mother-to-child transmission

Current data suggests that about two thirds of those infected through mother-to-child transmission are infected during pregnancy and around the time of delivery. The remaining third are infected through breast milk.

A distinction must be made whether: (a) ART prophylaxis is required for mother and child, or (b) the mother requires ART for maternal health (HIV/AIDS clinical stage, CD4 count, total lymphocyte count) (see ART standard operating procedures). If the mother and possibly the child require ART, then the standard operating procedures for adults/adolescents and for children should be followed. For asymptomatic, HIV-infected pregnant women, prevention of mother-to-child transmission should be initiated.

Provision of ARV drugs for preventing mother-to-child transmission:

(Please refer to Annex D)

Preventing mother-to-child transmission and breast-feeding
Current estimates suggest that approximately one third of HIV infection from mother to child can be transmitted through breast milk. It is therefore important to help the mother (and possibly father) make an informed decision about infant feeding. These choices are:

- exclusive replacement feeding; and
- exclusive breast-feeding.

Exclusive replacement feeding provides the most protection for the child. However, in resource-limited settings, exclusive replacement feeding may not be possible or advisable for a variety of reasons. Therefore, the next best alternative is exclusive breast-feeding. *Mixed feeding should be discouraged.*

Support for women using replacement feeding includes:
- discussing strategies to avoid breast-feeding, including issues related to stigma and family pressure;
- helping with the practicalities and resources required;
- demonstrating and discussing safe preparation and administration of feeds, including volumes and frequency of feeds (if possible, conduct home visits to counsel and support women who are not breast feeding); and
- monitoring child for diarrhoeal disease and seeking early health care support if it develops.

Support for women who are exclusively breast-feeding includes*:*
- discussing strategies to facilitate exclusive breast-feeding, including issues related to family pressure, milk supply and demand, and coping with a crying infant
- examining breasts for signs of poor attachment (sore/cracked nipples, engorgement, etc.);
- helping with correct attachment of infant to the breast; and
- discussing safe transition from breast to replacement feeding (weaning).

ANNEX A

An example of framework for country action on HIV/AIDS care and treatment

1. Political commitment, coordination, and management, including:

- obtaining commitment of national and local decision-making bodies;
- establishing and strengthening central units to manage and coordinate HIV/AIDS care and treatment;
- involving the community and people living with HIV/AIDS in every aspect and in every step of HIV/AIDS care and treatment;
- developing a care and treatment plan with ambitious national targets for spreading the use of ART;
- developing administrative and funding mechanisms to support local actions; and
- involving and monitoring the private sector.

2. Uninterrupted supply of affordable HIV medicines and diagnostics. Steps may comprise:

- including HIV medicines, including ARV medicines, in the National Essential Drug List;
- developing capacity for price negotiation with pharmaceutical companies;
- reviewing and improving national legislation and regulations that affect generic production and importation;
- addressing issues of intellectual property, including public health safeguards; and
- strengthening supply management including selection, procurement, distribution, and use.

3. Scaling-up ART integrated into continuum of care

- Identify service delivery model with emphasis on partnership mechanisms (such as day care centres) between public health services, clinical services, peer support groups, and CBOs/NGOs at district/intermediate level with referral to/from provincial/tertiary and health centre/home-community levels.
- Develop technical guidelines and operational procedures including package of services and activities at each level (mobilization and coordination of key players, including people living with HIV/AIDS; HIV testing and counselling; clinical care; psychological and socio-economic support; and HIV prevention).
- Develop and support human resources for implementation, including establishment of unified training program.
- Strengthen laboratory services, including quality assurance.
- Conduct costing and explore appropriate financing options, including incentives for health workers.

4. Ensuring equitable access to care and reducing stigma and discrimination

- Overcome financial barriers (user charges, insurance, and poverty exemptions).
- Overcome health service barriers (discrimination in health facilities, health service quality, etc.).
- Overcome policy and social barriers, including stigma and discrimination (injecting drug users, sex workers, homeless, paid plasma donors).
- Overcome geographical barriers (coverage, transportation).
- Overcome information and communication barriers (testing and counselling; information, education, and communication; and health-seeking behaviours).

5. Responding to diverse and changing situations

- Develop a patient monitoring system linked to drug supply.
- Develop a national programme-monitoring system that tracks the progress and supports adequate and timely actions.
- Support local monitoring and responses.
- Establish ARV drug resistance surveillance.
- Conduct operational research.

6. Accelerating HIV prevention

- Develop and integrate HIV prevention interventions into care and treatment from HIV testing and counselling through the continuum of chronic care management.
- Emphasize prevention with access to ARV.

ANNEX B

First-line ARV drug interactions[25]

If patient is taking:	Do not co-administer with these drugs (Call for advice for alternative treatment)	Other cautions
NVP	Rifampicin Ketoconazole	Do not rely on oestrogen-based oral contraceptives – switch to another form of contraception or use additional protection If on methadone, will need to increase its dose. Monitor for withdrawal signs.
3TC	No major drug interactions	
d4T	Do not give with AZT (ZDV)	Higher risk of d4T neuropathy when also taking INH
AZT (ZDV)	Do not give with d4T or ganciclovir	Higher risk of anaemia when also taking aciclovir or sulfa drugs
EFV	Diazepam (OK for convulsions in emergency) Other benzodiazepines other than lorazepam Phenobarbitol Phenytoin Protease inhibitor ARVs	Do not take with high-fat meals. If on methadone, will need to increase its dose. Monitor for withdrawal signs.

[25] *Chronic HIV care with ARV therapy: Integrated management of adolescent and adult illness: Interim guidelines for first level facility health workers.* Geneva, WHO, December 2003.

ANNEX C

The following is a draft version of the new WHO Paediatric Clinical Staging, which is being finalized. Updated information is available at http://www.who.int/3by5/***.***

WHO PAEDIATRIC CLINICAL STAGING (Draft)

For use in those 12 years or under with confirmed laboratory evidence of HIV infection; HIV Antibody where age >18 months, DNA or RNA virological testing for those age <18 months.

STAGE 1	
Asymptomatic Persistent generalized lymphadenopathy (PGL)	Hepatosplenomegaly
STAGE 2	
Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, 2 or more episodes in any 6 month period)Papular pruritic eruptions Herpes zoster (1 or more episodes in 6 months) Recurrent oral ulcerations (2 or more episodes in 6 months) Lineal gingival Erythema (LGE)	Angular chelitis Parotid enlargement Seborrhoeic dermatitis Extensive Human papilloma virus infection or Molluscum infection (more than 5% body area or disfiguring) Fungal nail infections
STAGE 3	
Unexplained moderate malnutrition[26] not adequately responding to standard therapy Unexplained persistent diarrhoea (more than 14 days) Unexplained persistent fever (intermittent or constant, for longer than 1month) Oral candidiasis (outside neonatal period) Oral hairy leukoplakia Pulmonary TB[27] Severe recurrent presumed bacterial pneumonia (2 or more episodes in 6 months)	Acute necrotizing ulcerative gingivitis/periodontitis Lymphoid interstitial pneumonitis (LIP) Unexplained Anaemia (<8gm/dl), neutropenia (<1,000/mm$^{3)}$ or thrombocytopenia (<30,000/ mm$^{3)}$ for more than 1 month Chronic HIV associated lung disease including brochiectasis HIV related cardiomyopathy or HIV related nephropathy
STAGE 4	
Conditions where a presumptive diagnosis can be made using clinical signs or simple investigations: Unexplained severe wasting or severe malnutrition[28] not adequately responding to standard therapy Pneumocystis pneumonia Recurrent severe presumed bacterial infections (2 or > episodes within one year e.g. empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia) Chronic orolabial or cutaneous Herpes simplex infection (of more 1 month duration) Extrapulmonary TB Kaposi's sarcoma Oesophageal Candida CNS Toxoplasmosis HIV encephalopathy	*Conditions where confirmatory diagnostic testing is necessary:* CMV infection (CMV retinitis or infection of organ other than liver, spleen, or lymph nodes onset at age 1 month or more) Cryptococcal meningitis (or other extrapulmonary disease) Any disseminated endemic mycosis (e.g. extra-pulmonary Histoplasmosis, Coccidiomycosis, Penicilliosis) Cryptosporidiosis Isosporiasis Disseminated non-TB mycobacteria infection Candida of trachea, bronchi or lungs Acquired HIV related recto-vesico fistula Cerebral or B cell non-Hodgkin's Lymphoma Progressive multifocal leukoencephalopathy (PML)
STAGE ON ARV TREATMENT	

[26] Defined as very low weight for age - http://www.who.int/child-adolescent-health/publications/CHILD_HEALTH/WHO_FCH_CAH_00.1.htm or page4

[27] TB may occur at any CD4 count and CD4 % should be considered where available

[28] Definition :very low weight or visible severe wasting or oedema of both feet Ref: http://www.who.int/child-adolescent-health/publications/CHILD_HEALTH/WHO_FCH_CAH_00.1.htm

Presumptive Stage 4 diagnosis in children less than eighteen months old where virological confirmation of infection is not available
In a HIV seropositive infant less than 18 months symptomatic with 2 or more of following; oral thrush, +/- severe pneumonia,+/- severe wasting/malnutrition, +/-severe sepsis[29], severe immunosuppression should be suspected and ARV treatment is indicated CD4 values where available should be used to guide decision making CD4% below 24 requires urgent ARV treatment Other factors that support diagnosis of stage 4 HIV infection in an HIV seropositive infant are recent maternal death or advanced HIV disease in mother.

Explanatory Notes

The clinical staging system for children is designed to:

1. Provide simple guidance to assist clinical care providers in determining when to start, substitute, switch or stop ARV therapy in HIV infected children, as outlined in WHO guidelines for a public health approach. It is also designed to harmonize with HIV and AIDS case surveillance and enable monitoring of trends in the magnitude and severity of HIV related disease.

2. Be used where HIV infection is confirmed by HIV antibody or virological testing. In children under 18 months virological diagnostic methods are recommended.

3. Encourage clinical care providers to consider diagnostic testing for HIV for children with Stage 3 or 4 clinical events

4. Classify disease in a progressive sequence from least to most severe, with each higher clinical stage having a poorer prognosis. Once a stage 3 clinical condition has occurred, the prognosis remains that of stage 3 and does not improve, even with resolution of the original condition, or appearance of a new stage 2 clinical event. ARV therapy improves the prognosis. Further evidence is required to determine the significance of staging events once on ARV treatment.

5. Be used with reference to CURRENT clinical events, meaning clinical events that have been diagnosed or are being managed at this episode. 'Current clinical event' is taken to include any time from initial assessment and diagnosis through to immediate management and follow-up for the clinical event.

6. Be considered in relation to previous clinical events, such as reported TB, severe pneumonia, PCP or other conditions. This is RETROSPECTIVE clinical staging and requires caution. Children reporting stage 2, 3 or 4 clinical events should have the diagnoses reviewed by HIV care providers to make appropriate clinical care decisions and other prophylaxis, and the need for ARV treatment. ANY reported history of a stage 3 or 4 diagnosis should have immediate assessment by or referral to HIV care providers able to initiate ARV treatment.

7. Be used to guide clinicians in assessing the response to ARV treatment, particularly where viral load and or CD4 count/percent are not widely or easily available. Treatment failure may be suggested by new or recurrent stage 4 events, and new or recurrent stage 2 or 3 events may suggest poor response to treatment (potentially due to poor adherence). Note that clinical events in the first 3 months of starting ART may be due to immune restoration

[29] Presumptive diagnosis of stage 4 disease in seropositive children < 18 months requires confirmation with HIV virological tests as soon as possible or repeat HIV antibody test after 18 months of age.

disease (IRD) not poor response to ART. TLC is not currently recommended for monitoring therapy.

The accompanying tables are provide further detail of the current clinical event, and how it may be diagnosed clinically or with basic laboratory or radiological capacity, or require more sophisticated investigations . Some conditions are not possible to diagnose without some laboratory or radiological investigation, and this is indicated in the table. Accepted clinical practice may be to make a presumptive clinical diagnosis. HIV infected children with any signs or symptoms of HIV should be given cotrimoxazole prophylaxis. CD4 values and their relation to immunological status are provided to assist clinical decision-making and link with monitoring, and surveillance.

WHO Recommendations upon Antiretroviral therapy (ART) '**Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach'** are at **:** http://www.who.int/3by5/publications/documents/arv_guidelines/en/

Revisions to the clinical staging system for children mean that these are to be replaced by the following:

- Clinical stage 4 disease requires ARV therapy as soon as is possible irrespective of age, CD4 % or TLC
- Clinical stage 3 disease requires urgent consideration of ARV therapy, although CD4 (percent) and age may guide the urgency to start
- A presumptive diagnosis of stage 4 disease in an HIV exposed infant <18 months requires ARV therapy
- Pulmonary TB and other stage 2 & 3 conditions occur in the absence of HIV infection
- Pulmonary TB and many skin and oral conditions occur across the spectrum of immune function
- Further specifications are usually available in National ARV treatment guidelines

IMMUNOLOGICAL CATEGORIES FOR PEADITRIC HIV INFECTION

IMMUNE STATUS	Age less than 12 months	Age 13 months or more
Not considered to have significant immunosuppression	30 % or more	25% or more
Evidence of mild immunosuppression	< 25-29%	20-24%
Evidence of advanced immunosuppression	20-24%	15-19%
Evidence of Severe immunosuppression	< 20 %	< 15%

PROPOSED REVISED CLINICAL DEFINTIONS FOR PEADITRIC HIV INFECTION

Indication to start ARV therapy in HIV infected children:
Stage 3 and 4 disease

Indication for cotrimoxzaole prophylaxis:
HIV infected- any signs or symptoms suggestive of HIV or clinical stage 2, 3 or 4
HIV exposed until HIV infection definitively ruled out

ANNEX D

Clinical situations and recommendations for the use of ARV drugs in pregnant women and women of childbearing potential in resource-constrained settings [30]

Clinical situation	Recommendation
A: HIV-infected women with indications for initiating ART who may become pregnant	First-line regimens: AZT + 3TC + NVP or d4T + 3TC + NVP EFV should be avoided in women of childbearing age, unless effective contraception can be ensured. Exclude pregnancy before starting treatment with EFV.
B: HIV-infected women receiving ART who become pregnant	**Women:** Continue the current ARV regimen* unless it contains EFV, in which case substitution with NVP or a PI should be considered if the woman is in the first trimester. Continue the same ARV regimen during the intrapartum period and after delivery. **Infants:** Infants born to women receiving first- or second-line ARV treatment regimens: AZT for one week or single-dose NVP or single-dose NVP plus AZT for one week.
C: HIV-infected pregnant women with indications for ART	**Women:** Follow the treatment guidelines as for non-pregnant adults. EFV should not be given in the first trimester. First-line regimens: AZT + 3TC + NVP, or d4T + 3TC + NVP Consider delaying initiating ART until after the first trimester, although for severely ill women the benefits of initiating treatment early clearly outweigh the potential risks. **Infants:** AZT for one week or single-dose NVP or single-dose NVP plus AZT for one week.**
D: HIV-infected pregnant women without indications for ART	▪ **Women:** AZT starting at 28 weeks or as soon as feasible thereafter; continue AZT during labour, plus single-dose NVP at the onset of labour. **Infants:** Single-dose NVP plus AZT for one week** Alternative regimens (not in order of preference) ▪ **Women:** AZT starting at 28 weeks, or as soon as feasible thereafter; continue in labour **Infants:** AZT for one week** ▪ **Women:** AZT + 3TC starting at 36 weeks, or as soon as feasible thereafter; continue in labour and for one week postpartum **Infants:** AZT + 3TC for one week ▪ **Women:** Single-dose NVP **Infants:** Single-dose NVP
E: HIV-infected pregnant women who have indications for starting ART but treatment is not yet available	Follow the recommendations in clinical situation D, but preferably use the most efficacious regimen that is available and feasible
F: HIV-infected pregnant women with active tuberculosis	If ART is initiated, consider***: AZT + 3TC + SQV/r or d4T + 3TC + SQV/r If ART is initiated in the third trimester, AZT + 3TV + EFV or d4T + 3TC + EFV can be considered. If ART is not initiated, follow the recommendations in clinical situation D.
G: Pregnant women of unknown HIV status at the time of labour or women in labour known to be HIV-infected who have not received ARV drugs before labour	If there is time, offer HIV testing and counselling to women of unknown status and if positive initiate intrapartum ARV prophylaxis. If there is insufficient time for HIV testing and counselling during labour, then offer testing and counselling as soon as possible postpartum and follow the recommendations in clinical situation H. Recommended regimens (not in any order of preference):

[30] *Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: Guidelines on care, treatment and support for women living with HIV/AIDS and their children in resource-constrained settings*. Geneva, WHO, 2004.

	▪ **Women:** Single-dose NVP; if imminent delivery is expected, do not give the dose but follow the recommendations in clinical situation H. **Infants:** Single-dose NVP. ▪ **Women:** AZT + 3TC in labour and AZT + 3TC for one week postpartum. **Infants:** AZT + 3TC for one week.
H: Infants born to HIV-infected women who have not received any ARV drugs	**Infants:** Single-dose NVP as soon as possible after birth plus AZT for one week If the regimen is started more than two days after birth, it is unlikely to be effective.

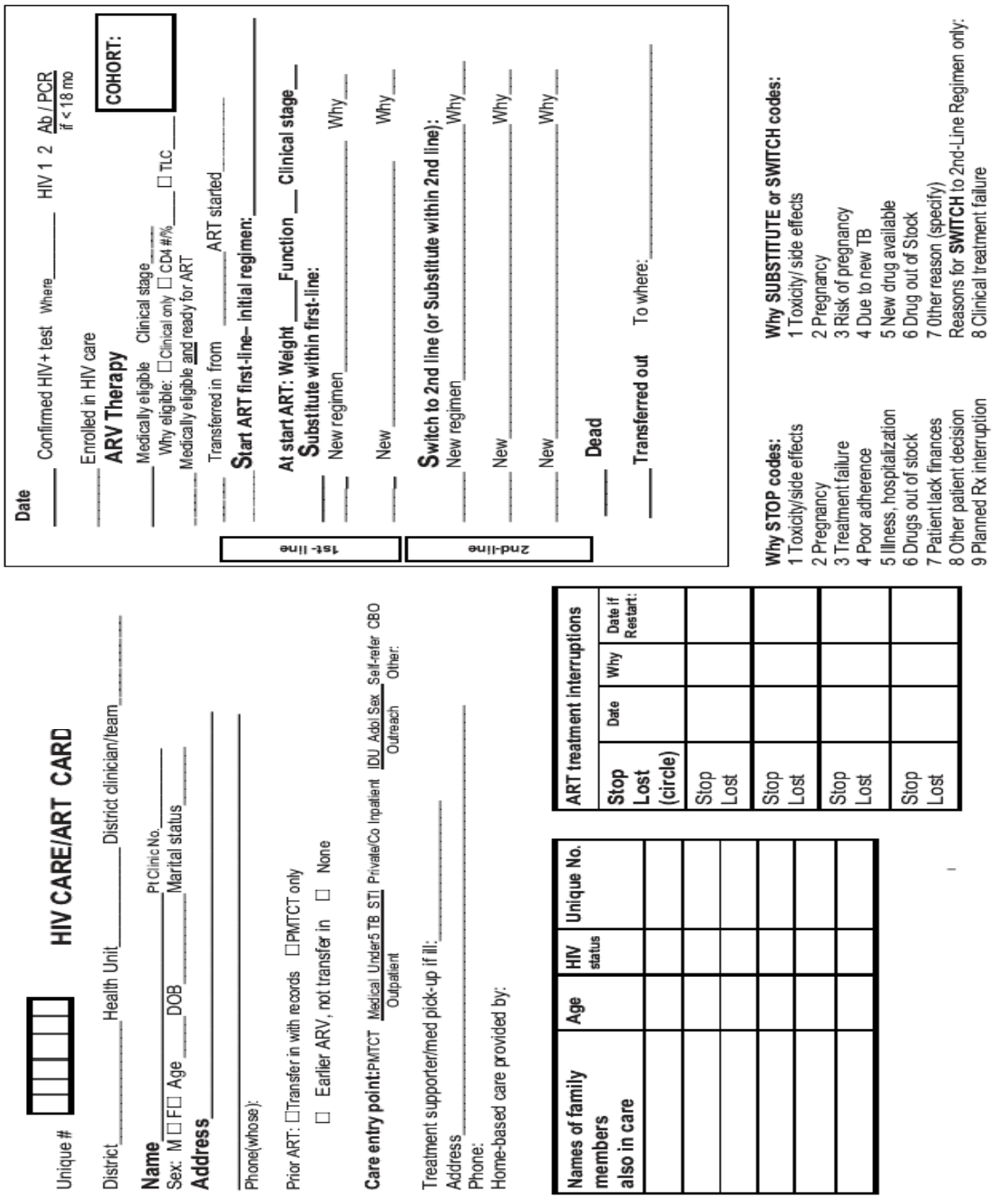
* Conduct clinical and laboratory monitoring as outlined in the 2003 revised WHO treatment guidelines.

** Continuing the infant on AZT for four to six weeks can be considered if the woman received antepartum ARV drugs for less than four weeks.

*** ABC can be used in place of SQV/r; however, experience with ABC during pregnancy is limited. In the rifampicin free continuation phase of tuberculosis treatment, an NVP containing ARV regimen can be initiated.

ANNEX E

HIV care/antiretroviral therapy card and report forms[31]



HIV CARE/ART CARD

Unique # ☐☐☐☐☐☐

District_____Health Unit_____District clinician/team_____

Name_____PI Clinic No._____

Sex: M ☐ F ☐ Age____DOB_____Marital status_____

Address_____

_____

Phone(whose):

Prior ART: ☐Transfer in with records ☐PMTCT only

☐ Earlier ARV, not transfer in ☐ None

Care entry point:PMTCT Medical Under5 TB STI Private/Co Inpatient IDU Adol Sex Self-refer CBO Outpatient Outreach Other:

Treatment supporter/med pick-up if ill:_____

Address_____

Phone:

Home-based care provided by:

Names of family members also in care	Age	HIV status	Unique No.

ART treatment interruptions			
Stop Lost (circle)	Date	Why	Date if Restart:
Stop Lost			
Stop Lost			
Stop Lost			
Stop Lost			

Date

_____ Confirmed HIV+ test Where_____ HIV 1 2 Ab / PCR if < 18 mo

_____ Enrolled in HIV care

ARV Therapy **COHORT:**

_____ Medically eligible Clinical stage_____

_____ Why eligible: ☐Clinical only ☐ CD4 #/%_____ ☐ TLC_____

_____ Medically eligible and ready for ART

_____ Transferred in from _____ ART started_____

_____ **Start ART first-line– Initial regimen:**_____

1st-line

_____ **At start ART: Weight ____Function ___ Clinical stage___**

_____ **Substitute within first-line:**

_____ New regimen_____ Why___

_____ New _____ Why___

2nd-line

_____ **Switch to 2nd line (or Substitute within 2nd line):**

_____ New regimen_____Why___

_____ New_____Why___

_____ New_____Why___

_____ **Dead**

_____ **Transferred out** To where:_____

Why STOP codes:
1 Toxicity/ side effects
2 Pregnancy
3 Treatment failure
4 Poor adherence
5 Illness, hospitalization
6 Drugs out of stock
7 Patient lack finances
8 Other patient decision
9 Planned Rx interruption
10 Other

Why SUBSTITUTE or SWITCH codes:
1 Toxicity/ side effects
2 Pregnancy
3 Risk of pregnancy
4 Due to new TB
5 New drug available
6 Drug out of Stock
7 Other reason (specify)
Reasons for **SWITCH** to 2nd-Line Regimen only:
8 Clinical treatment failure
9 Immunologic failure
10 Virologic failure

[31] WHO, UNAIDS, USAID, CDC, HRSA, GFATM. Interim patient monitoring guidelines for HIV care and ART: based on the WHO patient ART-monitoring meeting, Geneva, 29-31 March 2004.

Unique # ☐☐☐☐☐ **HIV CARE/ART CARD** ___ **Name**_____

Date Check if scheduled. Write in alternate pick-up if ill	Follow-up Date	Duration since last starting ART/ since starting current regimen	**Wt**	**Pregnant** PMTCT? Due date or **FP**— no FP/ yes: Methods **If child: Height**	Function Work Amb Bed	**WHO** Clinical **Stage**	TB Status	Potential SIDE EFFECTS	New OI, Other PROBLEMS	Cotrimoxazole Adhere /Dispense		Other meds dispensed	**ARV drugs** Adherence	Dispense	CD4	Hgb, RPR, TLC, other lab	Refer or consult or link/ provide Hospital clinic no.
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► Follow-up Education, Support and Preparation for ARV Therapy

	Date/Comments	Date/Comments	Date/Comments
Educate on basics, prevention, disclosure: Basic HIV education, transmission			
Prevention: abstinence, safer sex, condoms			
Prevention: household precautions, what is safe			
Post-test counselling: implications of results			
Positive living			
Testing partners			
Disclosure			
To whom disclosed (list)			
Family/living situation			
Shared confidentiality			
Reproductive choices, prevention MTCT			
Child's blood test			
Progression, Rx: Progression of disease			
Available treatments/prophylaxis			
Follow-up appointments, clinical team			
CTX, INH prophylaxis			
ART preparation.....initiation.....support, monitor.....: ART– educate on essentials (locally adapted)			
Why complete adherence needed			
Adherence preparation Indicate visits			
Indicate when READY for ART; DATE/result clinical team discussion			
Explain dose, when to take			
What can occur, how to manage common side effects			
What to do if one forgets dose			
What to do when traveling			
Adherence plan (schedule, aids, explain diary)			
Treatment supporter preparation			
Which doses, why missed			
ARV support group			
How to contact clinic			
Home-based care, support: Symptom management/palliative care at home			
Caregiver Booklet			
Home-based care– specify			
Support groups			
Community support			

FACILITY: HIV Care (pre- ART) REGISTER Treatment Unit_

Registration								Fill when applicable							ART						
Date start chronic HIV care	Patient clinic ID No.	NAME IN FULL Upper Space: surname Lower Space: first name	Age	Sex	Address	HIV+ date	Entry point- from where	CTX Start Date / Stop Date	Fluconazole Start Date / Stop Date	INH Start Date / Stop Date	TB Rx Start Date / Stop Date	Pregnancy Date Date, PMTCT No/A	If patient is DIED before starting ART, write DIED and Date	Indicate if LOST or TO (Transfer Out) before starting ART and Date	Date medically eligible for ART	Clinical stage at start of ART	Why medically eligible: Clinical only CD4# TLC	Date eligible & ready for ART (after adherence preparation and clinical team meeting)	Date eligible & ready & selected by committee for ART	Date ART started (transfer to ART register)	ART number

COHORT: Year ______ Month ______

ART Register 2004-2005

Registration and Personal Info.								Status at start ART				Fill when applicable					1st Line Regimen		2nd Line Regimen	
ART Start Date	ART No.	Why Eligible (Transfer In)	Patient's Clinic ID	Name Surname Given name	Sex	Age	Address	Functional status	Weight (kg)	WHO clinical stage	CD4	CTX Start date Stop date	Fluconazole Start date Stop date	INH Start date Stop date	TB treatment Start date Stop date	Pregnancy Due date PMTCT link	Original Regimen	Substitutions 1st: Reason / Date 2nd: Reason / Date	Regimen	Switches, substitution 1st: Reason / Date 2nd: Reason / Date

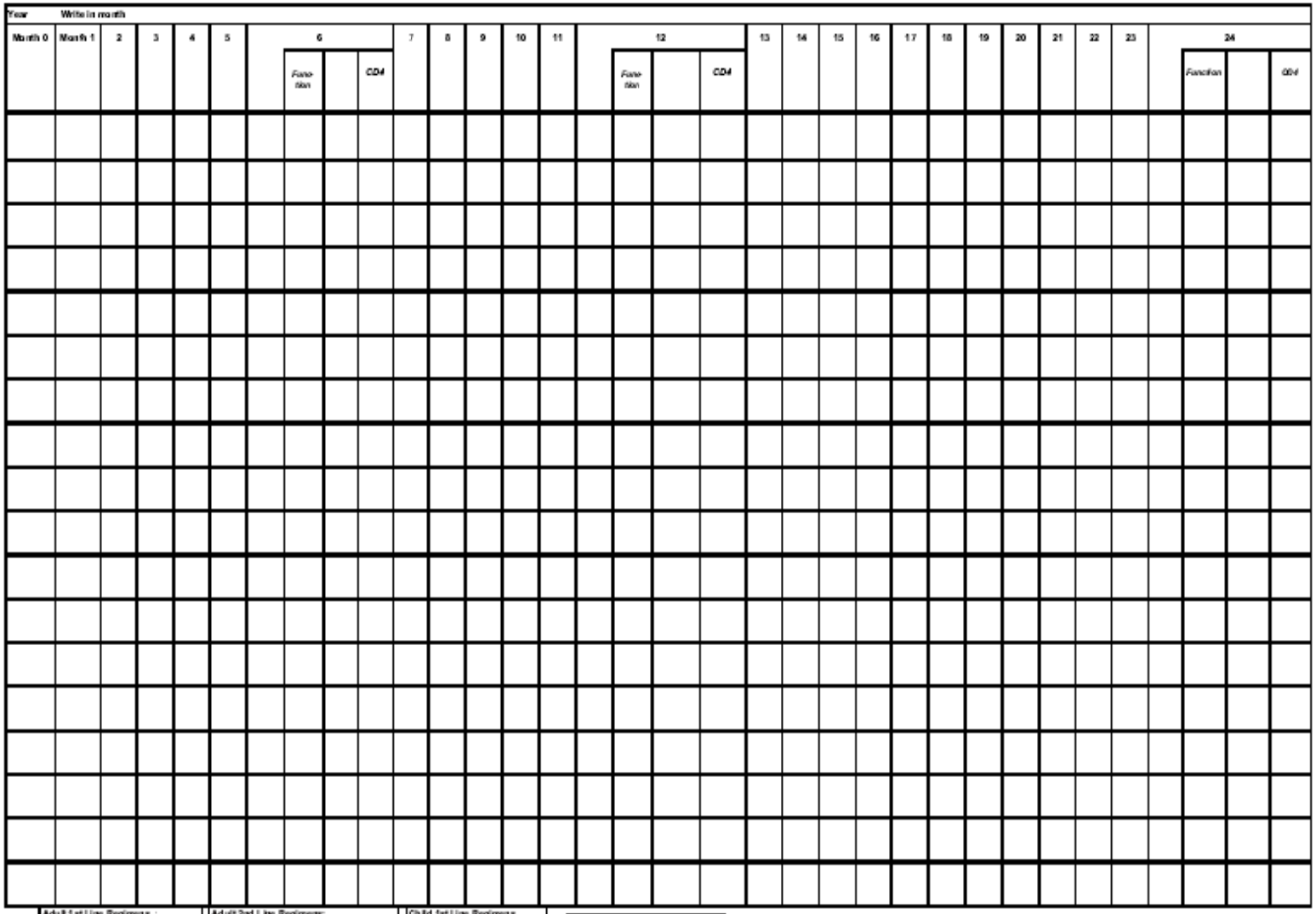
Why Eligible :
1 Clinical only
2 CD4
3 TLC
If Transfer In (TI), where ART

Functional Status:
1 Work
2 Ambulatory
3 Bedridden

Reasons for regimen change
1 Toxicity/side effects
2 Pregnancy
3 Risk of pregnancy
4 Due to new TB
5 New drug available
6 drug out of Stock
7 Other reason (specify)
Reasons for Switch to 2nd-Line Regimen
8 Clinical treatment failure
9 Immunologic failure
10 Virologic failure

Follow-up Status at end of each month:
On treatment (current regimen abbreviation) or
DEAD
STOP pid ART (continued on other care)
Lost (not seen since....?)
Transferred Out (TO)- to where

If follow-up status is "STOP", then add reasons (and weeks if later restarted)
1 treatment Failure
2 poor Adherence
3 toxicity, complications
4 illness, Hospitalization
5 patient lacked financial Resources
6 other patient Decision
7 Planned treatment interruption (put reason
8 Drugs Out of Stock
9 Other



Adult 1st Line Regimens :
1a(30) = d4t(30)-3TC-NVP
1a(40) = d4t(40)-3TC-NVP
1b(30) = d4t(30)-3TC-EFV
1b(40) = d4t(40)-3TC-EFV
1c = AZT-3TC-NVP
1d = AZT-3TC-EFV

Adult 2nd Line Regimens:
2a=60 AZT -DDI (250)-LPV/r
2a=60 AZT-DDI (400)-LPV/r "
2b(30) d4T(30)-DDI(250)-LPV/r
2b(60) d4T(40)-DDI(400)-LPV/r "
2c
3 - Third line, salvage""

Child 1st Line Regimens
4a d4T-3TC-NVP
4b d4T-3TC-EFV
4c(18-24 mo): AZT-3TC-NVP
4c 2-5 yr: AZT-3TC-NVP
4c >5 yr AZT -3TC-NVP
4d AZT-3TC-EFV

Child 2nd Line Regimens
5a d4T- DDI-NFV
5b AZT-DDI-LPV/r

Monthly, Facility-Based HIV Care/ART Reporting Form

Month:	Year:
Grantee:	Facility:
Location:	Country:

1. HIV care (non-ART and ART) - new and cumulative number of persons enrolled			
	Cumulative number of persons ever enrolled in HIV care at this facility at beginning of month	New persons enrolled in HIV care at this facility during the month	Cumulative number of persons ever enrolled in HIV care at this facility at end of month
1. Males (>14 years)	a.	g.	m.
2. Non-pregnant females (>14 years)	b.	h.	n.
3. Pregnant females	c.	i.	o.
4. Boys (0-14 years)	d.	j.	p.
5. Girls (0-14 years)	e.	k.	q.
Total	f.	l.	r.
	Total number of persons who are enrolled and eligible for ART but have not been started on ART		s.

2. ART care - new and cumulative number of persons started			
	Cumulative number of persons ever started on ART at this facility at beginning of month	New persons started on ART at this facility during the month	Cumulative number of persons ever started on ART at this facility at end of month
1. Males (>14 years)	a.	g.	m.
2. Non-pregnant females (>14 years)	b.	h.	n.
3. Pregnant females	c.	i.	o.
4. Boys (0-14 years)	d.	j.	p.
5. Girls (0-14 years)	e.	k.	q.
Total	f.	l.	r.
	No.of persons on ART and already enrolled in program who transferred into facility in last month		s.
	Number of persons who restarted ART during the last month, after stopping ART for at least 1 month		t.
	Number of baseline CD4$^+$ counts for persons who started ART in the last month		u.
	Median baseline CD4$^+$ count for persons who started ART in the last month		v.

3. Change in CD4$^+$ count (optional) and adherence to ART for 6-month and 12-month cohorts		
For persons who have completed	6 months of ART	12 months of ART
Cohort started in (month/year)	a.	i.
Number of persons in cohort	b.	j.
Number of baseline CD4$^+$ counts	c.	k.
Median baseline CD4$^+$ count	d.	l.
	after 6 months of ART	after 12 months of ART
Number of persons in cohort	e.	m.
Number of CD4$^+$ counts	f.	n.
Median CD4$^+$ count	g.	o.
Number of persons who picked up ARVs each month for 6 months	h.	
Number of persons who picked up ARVs each month for 12 months		p.

4. ARV r+C88egimen at end of month	Male	Female		
On 1st-line ARV regimen				
4.1 Adults (>14 years)				
d4T-3TC-NVP	a.	j.		
d4T-3TC-EFV	b.	k.		
ZDV-3TC-NVP	c.	l.		
ZDV-3TC-EFV	d.	m.		
	e.	n.		
	f.	o.		
	g.	p.		
	h.	q.		Total number of adults on 1st-line regimen
Adults on 1st-line regimens	i.	r.	s.	
4.2 Children (0-14 years)				
d4T-3TC-NVP	a.	k.		
d4T-3TC-EFV	b.	l.		
ZDV-3TC-NVP	c.	m.		
ZDV-3TC-EFV	d.	n.		
	e.	o.		
	f.	p.		
	g.	q.		
	h.	r.		Total number of children on 1st-line regimen
Children on 1st-line regimens	i.	s.	u.	
Adults and children on 1st-line regimens	j.	t.	v.	Total adults and children on 1st-line regimens
On 2nd-Line ARV regimen				
4.3 Adults (>14 years)				
ZDV-ddI-LPV/r	a.	j.		
d4T-ddI-LPV/r	b.	k.		
	c.	l.		
	d.	m.		
	e.	n.		
	f.	o.		
	g.	p.		Total number of adults on 2nd-line regimen
Adults on 2nd-line regimens	h.	q.	r.	
4.4 Children (0-14 years)				
d4T-ddI-NFV	a.	k.		
ZDV-ddI-LPV/r	b.	l.		
	c.	m.		
	d.	n.		
	e.	o.		
	f.	p.		
	g.	q.		Total number of children on 2nd-line regimen
Children on 2nd-line regimens	h.	r.	u.	
Adults and children on 2nd-line regimens	i.	s.	v.	Total adults and children on 2nd-line regimens
Adults and children on 1st- and 2nd-line regimens	j.	t.	w.	Total adults and children on 1st- and 2nd-line regimens

5.1 Number of persons who did not pick up their ARV regimens	Male	Female	5.2 Of those who did not pick up regimen in last 1 month (optional)	Total number of adults and children
1. For last 1 month (only)	a.	e.	1. Lost to follow-up	a.
2. For last 2 months (only)	b.	f.	2. Who died	b.
3. For last 3 or more months	c.	g.	3. Who stopped ART	c.
Subtotal	d.	h.	4. Who transferred out	d.
Total number of persons who did not pick up their ART regimens		i.		

6. Number of personnel trained in HIV care during the month	Physicians	Nurses	Other staff	Subtotal
1. ART clinical care	a.	e.	i.	m.
2. Non-ART clinical care	b.	f.	j.	n.
3. Adherence counseling/support	c.	g.	k.	o.
4. Other types of training	d.	h.	l.	p.
			Total personnel trained	q.

Report on Treatment Status/Outcomes for Cohorts on ART for (circle): 6 months 12 months 24 months 36 months

District: **Date:** Only include monthly cohorts who have reached this duration on ART.

	for cohort starting ART:	*Jan-04*	*04-Feb*	*04-Mar*	*04-Apr*	*04-May*	*04-Jun*	*04-Jul*	*04-Aug*	*04-Sep*	*04-Oct*	*04-Nov*	*04-Dec*
X	**Started on ART in this clinic**												
Y	**Transfers In**												
Z	**Number in Cohort**												
H	**Continuing on Original 1st Line Regimen**												
I	**Substituted to Alternative 1st Line Regimen**												
J	**Switched to 2nd Line Regimen**												
D	**Stopped**												
E	**Died**												
F	**Transferred Out**												
G	**Lost ***												

Percent of cohort alive and on ART

[(H + I + J) / Z * 100]

CD4 median or proportion ≥200												
Functional Status												
Proportion Working												
Proportion Ambulatory												
Proportion Bedridden												

100%