

CONTINUE DAY 2

Activity: Starting the day

Time: 15 min

Method: plenary discussion and facilitator presentation

Facilitator's instructions

- ❖ Address any logistical and administrative issues.
- ❖ Ask two participants to give a brief overview of the previous day.
- ❖ Allow time for questions.
- ❖ Provide an overview of the activities for the day.

Activity 4 - Progress with the implementation of the Comprehensive Plan

Time: 20 min

Method: facilitator presentation and plenary discussion

Aim: to create awareness of progress with the implementation of the comprehensive plan at national and local levels

Facilitator instructions

- ❖ Give a presentation summarising the Progress Report on the implementation of the Comprehensive Plan
- ❖ Invite a provincial representative to give a brief presentation on the provincial progress in the implementation of the Comprehensive Plan
- ❖ Invite participants to briefly share progress at their own sites

Facilitator's Notes

Country-wide progress with implementation by September 2004

(Refer to page 2 of the Progress Report)

- ❖ Accreditation of 132 health facilities (expected to expand to most facilities over time)
- ❖ 50 of the 53 district municipalities have one service point providing services
- ❖ Over 11,253 patients including children on ARVs
- ❖ A total of 20 laboratories performing CD4 tests

- ❖ 7 laboratories performing viral load tests
- ❖ A M&E framework and indicators established for monitoring both patient progress and programme performance
- ❖ Patient forms for data collection developed

Activity 5 - Challenges of the Comprehensive Plan

Time: 20 min

Method: facilitator presentation and plenary discussion

Aim: to create awareness of challenges to the implementation of the Comprehensive Plan

Facilitator instructions

- ❖ Give a presentation on the challenges documented in the Comprehensive Plan
- ❖ Invite participants to briefly share challenges experienced at their own sites

Facilitator Notes

Challenges to implementation of the Comprehensive Plan

(Refer to page 48 of the Comprehensive Plan)

- ❖ Strengthening prevention programmes
- ❖ Strengthening existing programmes, e.g. VCT, PMTCT
- ❖ Recruitment, training and retention of health professionals
- ❖ Building strong partnerships between health facilities and community support structures to promote a continuum of care
- ❖ Having a strong communication and community mobilisation strategy
- ❖ Improving integration of services at facility level, especially between HIV and AIDS, TB and STI services
- ❖ Support and integration of traditional health practitioners and complementary medicines
- ❖ Strengthening the National Health Laboratory System to meet demands
- ❖ Ensuring good coordination at national, provincial and district level
- ❖ Ensuring quality of care and adherence in the private sector
- ❖ Establishing sound pharmacovigilance practices in public and private sectors
- ❖ Obtaining sufficient financial resources

- ❖ Obtaining good patient information to enhance quality of treatment at local level and to ensure proper management at national level

ANNEX TO SESSION 4: SUMMARY OF THE COMPREHENSIVE PLAN

Prevention, Care and Treatment

This chapter delineates national care and treatment guidelines that conform to the international and local norms and standards and best practice. These guidelines and performance standards are applied uniformly throughout the country. These include standard treatment guidelines, laboratory diagnostic tests, drug protocols, frequencies and types of visits with health professionals and other standards for the care and treatment of people living with HIV and AIDS.

Components of this continuum of care include:

- ❖ Prevention strategies;
- ❖ Voluntary counselling and HIV testing;
- ❖ Medical care and treatment by a dedicated, trained medical team;
- ❖ Psychosocial support;
- ❖ Nutritional assistance;
- ❖ Social support; and
- ❖ Home and community-based services.

The key prevention strategies are:

- ❖ Voluntary Counselling and Testing (VCT)
- ❖ Prevention of Mother-to-Child Transmission (PMTCT)
- ❖ Information, Education, and Communication (IEC)
- ❖ Management of Sexually Transmitted Infections (STIs)
- ❖ Supply of barrier methods such as condoms
- ❖ Life skills and HIV and AIDS education

There are multiple entry points into the care delivery system, including voluntary counselling and testing services, PMTCT programmes, clinics offering reproductive health and STI services, primary health care clinics, TB clinics, inpatient hospital settings and prisons.

Following diagnosis and staging of HIV infection, individuals may be referred for antiretroviral therapy and/or prophylaxis for opportunistic infections, or routine follow-up and monitoring for patients with less advanced disease. However, patients will still have the right to choose the treatment of their choice.

The indication for antiretroviral treatment will be based on:

- a. Clinical assessment and
- b. CD4 count

These important factors determine whether therapy should be started. The lower the CD4 count and the higher the viral load, the higher the risk of AIDS and the more urgent the need for treatment.

The risk of developing AIDS, however, must be weighed against the risks of adverse events and development of resistance. Patients must be prepared to make choices, and for a lifelong commitment to taking ARVs, which may require not only education to gain understanding of potential side-effects and the importance of adherence, but also psychosocial support. The well-informed patient has the best chance of adherence to medication.

The specific antiretroviral drug regimens that are recommended for the various groups of patients are discussed in detail in Chapter I of the Comprehensive Plan.

The criteria for initiation of antiretroviral therapy in non-pregnant adults and adolescents are:

- ✧ CD4 < 200 cells/ mm³ and/or symptomatic, irrespective of stage; or
- ✧ WHO stage IV AIDS defining illness, irrespective of CD4 count; and
- ✧ Patient prepared and willing to comply with taking antiretroviral drugs.

The criteria for initiation of antiretroviral therapy in children under 6 years are:

- ✧ CD4 < 15% and symptomatic; or
- ✧ WHO Paediatric Stage III AIDS defining illness, irrespective of CD4; and
- ✧ At least one responsible person capable of administering the child's medication

Nutritional Related Interventions

This chapter advocates for a significant increase in nutritional programmes available to people who are HIV-positive or who have developed AIDS.

These programmes provide nutritional supplements and in some cases food to people in need in order to help sustain their overall health and strengthen their immune systems, and to help them tolerate the antiretroviral and other drugs they may take.

The plan envisions significant new expenditures for this programme because from a clinical perspective, adequate nutrition, appropriate micronutrient supplementation, and the treatment of malnutrition are important in the treatment of AIDS.

All persons attending service points for HIV and AIDS care and treatment will receive counselling and information on healthy eating and lifestyle, food preparation and coping with HIV-related disease.

Nutritionists that are available at the service point will provide regular assessments of the nutritional needs of patients, evaluate their food and supplement needs and, where necessary, refer patients to appropriate food security programmes in the Departments of Health, Social Development and Agriculture, such as the National Emergency Food Programme (NEFP).

Specifically, two nutritional interventions are included in the operational plan:

- ✧ Provision of food support (composite meals) for members of defined patient groups who are malnourished and do not have access to secure food supply; and in addition
- ✧ High-dose vitamin supplementation for defined patient groups such as HIV-positive pregnant women, people with active tuberculosis and/or TB/HIV co-infection and HIV-positive children under 14 years of age.

Traditional Medicine

Many South Africans use traditional health practitioners, and the care they receive from these practitioners must be factored into the systems of care.

This chapter recommends support for traditional medicine and the integration of traditional healing methods into the comprehensive care and treatment programme.

In addition, research into the safety and efficacy of traditional medicines may yield beneficial findings for future treatments, especially as these medicinal plant products are proving to have immune-boosting properties.

The operational plan recognises that traditional health practitioners can enhance the implementation of this plan by mobilising communities, drawing patients into testing programmes, promoting adherence to drug regimens, monitoring side effects, sharing their expertise in patient communications with biomedical practitioners, and vice versa, and in continuing their acknowledged mission in improving patient well-being and quality of life.

The plan seeks to promote the following activities:

- ✧ Joint training programmes between clinicians and traditional health practitioners to share knowledge and facilitate the prompt identification of life-threatening illnesses and to strengthen referral mechanisms to benefit patients;
- ✧ Continued research into the safety and efficacy of traditional medicines, in particular those natural medicines with putative immune-boosting properties;
- ✧ Studying interactions between drugs and traditional medicines and participation in a pharmacovigilance programme.

Accreditation of Service Points

This chapter establishes norms and standards for the accreditation of service points to ensure that comprehensive HIV and AIDS care and treatment of the highest available quality, as envisaged in the care and treatment plan, can be delivered.

A service point is defined as a group or network of linked health facilities within a clearly demarcated geographical area called the health district that is coterminous (shares the same boundaries) with the district or metropolitan council area, which together meet the requirements of accreditation outlined in Chapter IV, through a single hospital (or clinic) or through aggregated facilities and their support services, within a defined catchment area. Essential support services include laboratories, referral systems, transport, and VCT. (rather list all than use "etc").

The plan also provides for technical assistance and financial resources to assist managers and clinicians at these service points to meet the accreditation requirements in a timely fashion.

Greater financial resources and technical assistance will be directed towards historically disadvantaged and underserved areas of the country to promote a more equitable implementation of the programme.

The process to accredit and certify service points will be driven by a plan to strengthen the ability of the public health system to effectively screen, diagnose, treat, care for and effectively monitor the progress and safety of HIV-positive patients, and to certify service points that are eligible to provide antiretroviral drugs. This approach is necessary because of the complexity of the safe and effective administration of antiretroviral drugs.

The Department of Health will inspect every facility that has been identified to provide this service in every health district to ensure that it complies with the accreditation requirements contained in Chapter IV, using the Service Point Assessment and Accreditation Guide in Annex IV.

The minimum service point accreditation criteria will be applied rigorously to maintain the quality of HIV and AIDS care and treatment, including the management of an antiretroviral programme. At the same time, the process will allow for creativity and initiative in addressing service point specific baseline conditions.

Additional financial and technical resources will be deployed to service points in resource-constrained or underserved areas to assist them in meeting the minimum criteria for accreditation as quickly as possible. This will include the allocation of resources to assist traditional health practitioners.

Human Resources

This chapter addresses two very important components of the programme, namely:

- ✧ The need to strengthen human resource capacity by recruiting and retaining additional health professionals to strengthen the healthcare delivery system.
- ✧ A training programme for health professionals, including traditional health practitioners, to be implemented as part of the service point accreditation process in order to prepare South African clinicians, nurses, counsellors, pharmacists and other

health professionals to deliver high quality care.

- ✧ Establishment of regional training centres.

Staffing norms to deliver comprehensive HIV and AIDS care are discussed in detail in Chapter V. The gap between the current staffing levels and the essential staffing levels has been calculated based on potential workloads per health professional. Numbers and categories of staff needed have been estimated for service points in each health district.

The training programme will be extended progressively throughout the country and certification will be provided to professionals who successfully complete training. Training involves a short intensive formal module as well as ongoing mentoring. This mentoring will be provided by experienced health professionals and consultation through a “clinical HIV and AIDS treatment help line” and other methods to provide support for practicing clinicians. South African and international experts will be mobilised to assist in the planning, design and delivery of training at national and provincial levels.

The Comprehensive Plan proposes strategies for increasing the number of health professionals in order to successfully implement the programme, and indicates the financial resources necessary to do so.

The Comprehensive Plan advocates increasing utilisation of private sector health professionals in the national health system, additional incentives to attract health professionals to underserved areas, and measures to retain health professionals in the public health sector.

Overall, the plan should result in an increase in the availability of health professionals in the national health system, benefiting all patients.

Provincial Site Assessments

The Comprehensive Plan proposes service implementation in at least one service point in every health district in the country within the first 12 months.

Initial assessments conducted at 77 facilities provided information regarding site readiness for initiating HIV and AIDS care and treatment. All sites accredited possessed the basic elements of human resource, laboratory, pharmacy, and ancillary services capacity. Requirements to reach a level of service competency vary significantly among these locations.

The plan calls for the investment of technical assistance and financial resources in these sites to reach appropriate capacities. This assistance will result in the commencement of programmes within a few months at some locations and well within the 12-month period at others.

The Task Team, in cooperation with health district officials and provincial AIDS managers, will identify additional service points in these areas to achieve better ratios of potential patients per facility.

The Task Team also recognized that some rural areas with widely dispersed populations encounter equally difficult circumstances in the delivery of HIV and AIDS care and treatment. Additional facilities and transportation services will have to be introduced if these special conditions are to be addressed.

Drug Procurement

This chapter establishes a system of drug procurement that attempts to secure antiretroviral drugs at prices well below current best international prices. This purchasing system should result eventually in the creation of fully integrated production facilities for these drugs in South Africa.

The procurement system also seeks to support an adequate and sustainable supply of these drugs by involving multiple competing suppliers and multiple production locations.

To support the operational plan, the procurement system for these medicines must achieve the following objectives:

- ✧ The medicines must be of the highest quality and licensed by the South African Medicines Control Council.
- ✧ The medicines must be appropriate for the treatment regimens outlined in the plan.
- ✧ The supply of medicines must be secure and sustainable at a volume large enough to meet the demand envisioned.
- ✧ Medicines must be purchased at the lowest possible price.
- ✧ Sustainable supply should be ensured through local production of antiretrovirals and sustainable financing.

The Minister of Health will appoint a negotiating team to implement the procurement strategy recommended in this plan.

There are at least three options by which this tender process could be put into operation:

- ✧ A regular government tender using local suppliers.
- ✧ A private-public partnership/initiative.
- ✧ International tendering as stipulated in section 1(4) and Regulation 3 of the Medicines and Related Substances Act 101 of 1965.

The Task Team recommends that government invite all bidders, and pre-qualify those that meet its criteria. There will then be an open tender among these prequalified suppliers.

The introduction of ARVs to the care and treatment of HIV and AIDS must comply with South African patent law and international obligations under the TRIPS agreement. However, the prices of patented and/or branded drugs supplied by the pharmaceutical manufacturers will prevent equitable access to necessary drugs for South Africans.

Recent international trade agreements and the South African law provide a number of ways to address this dilemma. Therefore, if it is deemed necessary, the government may consider the implementation of measures such as voluntary licensing, compulsory licensing and parallel importation to purchase drugs at affordable and favourable prices.

Drug Distribution

This chapter provides for the upgrading of the drug distribution system. This upgrade will be accomplished by improving and extending current systems.

The drug distribution process will include:

- ✧ Inventory management, patient prescription information and financial management systems at the national, provincial, and local levels.
- ✧ Secure storage facilities at the central, provincial, and local levels.
- ✧ Efficient and secure transport between central warehouse facilities, provincial pharmaceutical depots and public health service points.
- ✧ Training of pharmacy personnel to implement inventory management practices.
- ✧ Improved packaging to support inventory control and to improve patient adherence.

The theft of medicines from the public sector remains a major challenge, especially when dealing with expensive medicines that have a high value both in developed and developing countries. The plan proposes major investments in the distribution and secured storage of medicines. It is also proposed that the number of pharmacists in the public sector is substantially increased.

Laboratory Services

This chapter deals with the strengthening of laboratory services.

The guiding principles of the laboratory services component of the antiretroviral treatment programme are:

- ✧ To support best practices of patient care.
- ✧ To monitor patient safety for toxicity, adverse events and drug resistance.
- ✧ To establish evidence-based, cost-effective and sustainable laboratory services.
- ✧ To provide high quality laboratory services in all parts of the country, and to strengthen access to these services in rural, remote and underserved areas.
- ✧ To improve turnaround time and review performance regularly.

A network of laboratories belonging to the publicly owned National Health Laboratory Service will be responsible for laboratory tests, with the National Institute for Communicable Diseases playing the role of a National Reference and Training Centre.

The Comprehensive Plan calls for a significant upgrading of the National Health Laboratory Service in order to provide better coverage and better training for laboratory personnel in the country.

It proposes a significant expansion in specific capabilities to perform the CD4 and viral load tests that are essential for high quality HIV and AIDS care and treatment.

The plan also envisages improved efficiency and improvements in procurement mechanisms that

should lead to significantly lower prices for these laboratory tests. These material improvements in the laboratory infrastructure as well as the efficiency gains will benefit the whole public health system.

Social Mobilisation and Communication

This chapter proposes the implementation of a comprehensive communications and community mobilisation programme to ensure that administrators of all relevant government programmes, health care providers, people living with HIV and AIDS and their families, and caregivers, are fully knowledgeable about all key provisions and requirements of the Comprehensive Plan, as well as their respective roles and responsibilities.

The communications plan also focuses on educating people who will be initiating antiretroviral drugs and their families on what to expect from the treatment and what they must do to make it successful. Finally, and of equal importance, the plan integrates prevention messages into programme communications. The plan also proposes significant investments in community support programmes for those being treated for AIDS.

Experience in other countries demonstrates that such social mobilization and communication programmes play an essential role in promoting proper use of drugs and in assisting people to overcome the difficulties associated with treatment, particularly in early stages.

The Government Communication and Information System (GCIS) will be an important partner in the implementation of this communication and community mobilisation strategy and plan.

The media is another important partner in this initiative as it has the potential to communicate a message of hope to the nation and to keep the public informed about the achievements and challenges experienced in implementing the programme.

Patient Information Systems

This chapter proposes to upgrade patient information systems in the national health system. Effective patient information systems are necessary to ensure that a standardized, effective and efficient system for data collection, collation, monitoring, and feedback is in place to facilitate programme implementation, ensure good quality care, and achieve good patient/programme outcomes.

The specific functions of the patient information system are:

- ✧ To register patients utilising a standard Patient Record.
- ✧ To collect relevant clinical care information at baseline and subsequent follow-up visits to monitor progress of patients.
- ✧ To monitor adherence to treatment.
- ✧ To monitor adverse drug events.
- ✧ To collect other clinical, laboratory, and non-clinical data that will be useful for programme monitoring at local, provincial and national levels.

The patient information system will be developed as an integral part of the existing health information system. Information technology upgrades will occur to enable a standard electronic and paper-based patient information system to meet patient care objectives.

Monitoring and Evaluation

This chapter proposes that a comprehensive monitoring and evaluation effort be integrated into programme implementation. Ongoing monitoring will be critical to measure the outcomes of the programme and the impact of this intervention. The monitoring and evaluation system will be developed to collect data relevant to all resources invested in the programme, services provided by the programme, outcomes related to the programme, and the overall impact of the programme on public health and quality of life.

The monitoring and evaluation system will monitor the programme in order to institutionalise the systematic process of continuous improvement by reviewing programme performance. This will be done through the collation of data from all programme sources such as patient information systems, research audits and through monitoring tools.

Pharmacovigilance

The plan proposes a comprehensive programme of pharmacovigilance in order to monitor the efficacy of the drugs that are being used. In particular, the pharmacovigilance programme monitors adverse events.

The specific aims of the antiretroviral pharmacovigilance programme are:

- ✧ To determine the burden of drug-related morbidity and mortality in patients with HIV and AIDS, particularly associated with ARV use, and develop measures to minimize their impact.
- ✧ To provide training and information to health personnel and patients on the safe use of antiretrovirals and other medicines commonly used in HIV infected and AIDS patients.
- ✧ To develop systems to assess the risks and benefits of treatments commonly used in patients with HIV, STI and TB, including over the counter (OTC) medication / phyto-therapeutic agents.
- ✧ To identify, assess and communicate any new safety concerns associated with the use of antiretrovirals and other HIV medicines.
- ✧ To support regulatory and public health decision-making through an efficient, national surveillance system, monitoring the quality, benefits and risk or harm associated with ARVs and other medicines currently used in the health sector.
- ✧ To minimize the impact of misleading or unproven associations between adverse events and ARV therapy.
- ✧ To detect, assess, and respond to safety concerns related to complementary and traditional medicines used in HIV-infected patients.

- ✧ To establish an early warning system for resistance to antimicrobials commonly used in treating HIV, including, but not limited to, antiretrovirals.
- ✧ To respond to unfounded and unsubstantiated claims of efficacy of untested products and treatment modalities

Research Priorities

The plan envisages a research programme that focuses on practical questions that are necessary for better understanding and improving the provision of comprehensive HIV and AIDS care and treatment.

The research agenda also aims to answer crucial questions that will inform improvements in the quality and efficacy of the programme. It focuses largely on health systems questions such as the most effective delivery mechanism for antiretroviral drugs, the best approaches to preventing new infections, the best interventions to extend the period in which HIV-infected people can be maintained without antiretroviral drugs, the optimal use of nutrition interventions in the management of HIV patients, and the optimal use of traditional medicines.

Examples of specific research topics include:

- ✧ What is the most effective delivery of ARVs to persons who have progressed to a stage at which these drugs become necessary?
- ✧ What are the best approaches to prevent new infections with HIV?
- ✧ What are the best interventions to extend the period during which HIV infected people can be maintained without antiretroviral drugs?

Activity 6 - Staging and ART eligibility criteria

Time: 20 minutes

Method: facilitator presentation and plenary discussion

Aim: To increase awareness of the clinical staging criteria for ARTs

Facilitator notes

Staging is the process of classifying people living with AIDS into groups based on the level of depletion of their immune system. Staging can be done through the use of clinical case definitions that assess symptoms and signs or through the use of laboratory tests such as the CD4 count.

The CD4 count is a count of the CD4 T helper lymphocytes in the blood. The CD4 cells are destroyed by the virus, resulting in their numbers gradually decreasing over time.

There are 4 clinical stages of AIDS:

(Refer to WHO staging systems in appendix 1 and 2 of the South African National Antiretroviral Treatment Guidelines for details.)

- ❖ Stage 1: the first signs are usually enlarged lymph glands
- ❖ Stage 2: symptoms and signs include weight loss, minor skin infections, shingles and recurrent upper respiratory infections may appear.
- ❖ Stage 3: symptoms and signs include severe weight loss, chronic diarrhoea, oral candidiasis and lung infections (TB / pneumonia)
- ❖ Stage 4: the end stage when almost any infection can occur as well as cancers such as Kaposi's sarcoma.

In settings where CD4 count laboratory tests can be done, clinical staging is almost always supplemented by laboratory CD4 count diagnosis.

Medical eligibility criteria related to staging

Based on the South African National Antiretroviral Treatment Guidelines, a person living with HIV and AIDS is eligible for ART treatment when:

- their CD4 count is less than 200/ml irrespective of clinical stage, or
- they are in WHO clinical stage 4 irrespective of CD4 count.

Patients with CD4 counts higher than 200/ml and/or who are in clinical stages 2 and 3 are followed up through regular monitoring in wellness clinics.

Activity 7 - Understanding Anti-Retroviral Therapy

Time: 30 minutes

Method: facilitator presentation

Aim: to provide overview of important concepts surrounding ART

Facilitator notes

Definition

ART represents the term "Antiretroviral Therapy" and is a shorter version of the term HAART which stands for "Highly Active Antiretroviral Therapy". ARV stands for the term "Antiretroviral" but the acronym ARVs is often used to refer to antiretroviral drugs. (The term antiretroviral is used because HIV is a retrovirus.)

Combination Therapy

HIV multiplies in the blood by making copies of itself or “replicating” itself. HIV is a fast replicating virus and

mutations often arise in the replication / copying process. Mutations may result in a particular drug losing its effectiveness, since the part of the virus that the drug was acting on has now changed.

ART is a ‘combination therapy’ involving the combination of three or more anti-HIV drugs that block different points of the HIV replication cycle. Three drugs are used in order to reduce the rate at which the virus can develop resistance to any one drug when used alone or in dual therapy.

Currently there are four groups of antiretroviral drugs that can be used for ART. ART regimens are usually selected to include three or more ARV drugs from different groups. (This is often referred to as a “cocktail” of drugs.) The South African National Antiretroviral Treatment Guidelines makes use of three of the available drug groups for the three ART regimens provided for in the guidelines, namely:

- 1a. First line regimen for adults and adolescents including women on contraception
- 1b. First line regimen for women in whom contraception is not guaranteed
2. Second line regimen for everybody who fails on any of the first line regimens and is still eligible for treatment

According to South Africa’s national guidelines the selection criteria for ART is as follows:

Medical criteria:

- ❖ CD4 count <200 cells/mm irrespective of WHO stage

OR

- ❖ WHO Stage IV disease irrespective of CD4 count.

Psycho-social considerations (not exclusion criteria):

- ❖ Demonstrated reliability, i.e. patient has attended three or more scheduled visits to an HIV clinic.
- ❖ No active alcohol or other substance abuse.
- ❖ No untreated active depression.
- ❖ Disclosure: it is strongly recommended that patients have disclosed their HIV status to at least one friend or family member OR have joined a support group.
- ❖ Insight: patients have to accept their HIV-positive status. They need to have insight into the consequences of HIV infection and the role of ART before commencing therapy.

- ❖ Patients should be able to attend the antiretroviral centre on a regular basis to have access to services that are able to maintain the treatment chain. Transport may need to be arranged for patients in rural areas or for those far away from the treatment site.

ART Drugs

Table 4.1: Currently available ARV drugs by drug group/class

Nucleoside reverse transcriptase inhibitors	Non-nucleoside reverse transcriptase inhibitors	Protease inhibitors	Fusion and attachment inhibitors
<ul style="list-style-type: none"> · AZT (ZDV, zidovudine) · ddl (didanosine) · ddC (zalcitabine) · d4T (stavudine) · 3TC (lamivudine) · Abacavir · Tenofovir (a nucleotide) · AZT/3TC combination · AZT/3TC/Abacavir combination · Emtricitabine (FTC) · Truvada (combination of Emtriva and Viread) · Epzicom (combination of abacavir and 3TC) 	<ul style="list-style-type: none"> · Nevirapine (NVP) · Delavirdine (DLV) · Efavirenz (EFV). 	<ul style="list-style-type: none"> · Saquinavir (SQV) · Indinavir (IDV) · Ritonavir (RTV) · Nelfinavir (NFV) · Amprenavir (APV) · Lopinavir (LPV) · Atazanavir (TAZ) · Fosamprenavir (908) 	<ul style="list-style-type: none"> · Enfuvirtide (T-20)

Recommended ARVs contained in National ART Guidelines

Table 4.2: Recommended regimens in adults

Regimen	Drugs
1a	d4t / 3TC/ efavirenz
1b	d4t / 3TC/ NVP
2	AZT/ ddl/ lopinavir/ ritonavir

Table 4.3: Paediatric first-line therapy – Regime 1

	6 months – 3 years	> 3 years old and >10kg
First-line	Stavudine (d4T) Lamivudine (3TC) Lopinavir/ritonavir	Stavudine (d4T) Lamivudine (3TC) Efavirenz

Table 4.4: Paediatric second-line therapy – Regime 2

	6 months – 3 years	> 3 years old and >10kg
First-line	Zidovudine (AZT) DDI Nevirapine	Zidovudine (AZT) DDI Lopinavir/ritonavir

Adherence

Adherence means taking one's medication the way it is supposed to be taken. Although this sounds easy, in many situations it is not. ARVs need to be taken every day, at specific times of the day, with or without certain kinds of food, and throughout a person's life.

Resistance

When ARVs are not taken properly, the body may not have adequate levels of the drug at all times and this will result in allowing the virus to multiply and often mutate and become resistant to the drugs. Since the drugs belong to groups, resistance to one drug often means resistance to all drugs in that group and sometimes to other groups as well.

Treatment failure

Treatment failure occurs when the ARVs that a patient is taking are no longer effective in suppressing the multiplication of HIV. This happens as a result of the virus becoming resistant to the drugs.

Patients who fail on the first line regimen can be switched to the second line regimen if the failure was not as a result of poor adherence. When the adherence problems have been managed and patients are still failing on therapy, then they can be switched to the second regimen. Patients who fail on second line therapy will be discontinued on ART and started on palliative therapy.

Adverse reactions and side effects

Apart from failure, patients may also be switched from first line to second line regimen or have their ART treatment stopped when they react adversely or experience severe side effects to the drugs they are taking. Although the ART regimens chosen for South Africa have fewer than average side effects, they can still occur. Common side effects or adverse reactions include:

- ✧ Early (within days):
gastrointestinal complaints (stomach aches, constipation, nausea), skin rashes, hypersensitivity (allergic) reactions, jaundice, anaemia, etc.
- ✧ Delayed (months to years):
neuropathy (numbness in the hands and feet), lipodystrophy (abnormal fat distribution), lactic acidosis (metabolic derangement), osteoporosis (thinning of bones), dizziness, nightmares, pancreatitis.

Specific follow-up visits are recommended for all patients on ART as a standard measure for preventing or predicting side effects through clinical and laboratory assessments.

Most of the less serious side effects can be managed without stopping the patient's ART treatment, but the more serious side effects often require substituting problem drugs, switching regimens altogether or stopping the patient's ART treatment. Details of these are provided in the guidelines document.

Treating Children

Children are one of the target groups in ART treatment programmes. However, their enrolment into ART continues to lag behind that of adults. National paediatric guidelines for the management of children are being finalised.