

SESSION 4: THE COMPREHENSIVE PLAN AND NATIONAL ART TREATMENT GUIDELINES

Aim of the session:

Session 4 introduces the planning cycle and reviews the background, content and implementation progress of the Comprehensive Plan as well as staging and ART eligibility.

LEARNING OUTCOMES:

By the end of this session participants should be able to:

- ✧ Define planning and describe the planning cycle
- ✧ Describe the background to the Comprehensive Plan
- ✧ List and discuss the pillars, principles and goals of the Comprehensive Plan
- ✧ List and discuss the components of the Comprehensive Plan
- ✧ Discuss staging and ART eligibility criteria
- ✧ Discuss the principles of ART

SESSION CONTENTS:

- ✧ The principles of planning and the planning cycle
- ✧ Introducing the Comprehensive Plan
- ✧ Progress with the implementation of the Comprehensive Plan
- ✧ Challenges of the Comprehensive Plan
- ✧ Staging and ART eligibility criteria
- ✧ Understanding antiretroviral therapy

READING:

- ✧ Department of Health, Republic of South Africa. (2003) Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa. Pretoria
- ✧ Department of Health, Republic of South Africa. (2000) HIV/AIDS/STD Strategic Plan for South Africa 2000 – 2005.
- ✧ Department of Health, South Africa. (2004) Monitoring Review. Progress Report on the Implementation of the Comprehensive HIV and AIDS Care, Management and Treatment Programme. Issue 1: September 2004.
- ✧ Department of Health, Republic of South Africa. (2003) Report: National HIV and syphilis antenatal sero-prevalence survey in South Africa 2003
- ✧ Department of Health, Republic of South Africa. (2004) National Antiretroviral Treatment Guidelines. First Ed.
- ✧ Department of Health, Republic of South Africa. (2004) Format for strategic plans of Provincial Health Departments for financial years 2005/06 to 2007/08.

4.1 The principles of planning and the planning cycle

What is planning?

There are many definitions of planning and the activity of planning is used by different people in different ways. However, it is important to recognise that all planning approaches share one common element, i.e. decisions relating to the future.

Some **definitions of planning** include:

- ✧ Using information about the past and the present to make decisions that will lead to actions to improve the future.
- ✧ "Planning is a recurring process of measurement, analysis, and action designed to improve management".⁸
- ✧ "Planning is a systematic method of trying to attain explicit objectives for the future through the efficient and appropriate use of resources, available now and in the future".⁹

Why is planning important?

The outcomes of planning decisions are "plans" which are **statements of intent** concerning how resources will be used to achieve the goals and objectives stated in the plan. The Comprehensive Plan is a statement of intent about how the country will address the HIV and AIDS epidemic.

There are various approaches to planning and different approaches include elements that are common to the various models of planning. Decisions about the future require a **sequence of steps** which are depicted in a continuous cycle called the planning cycle.

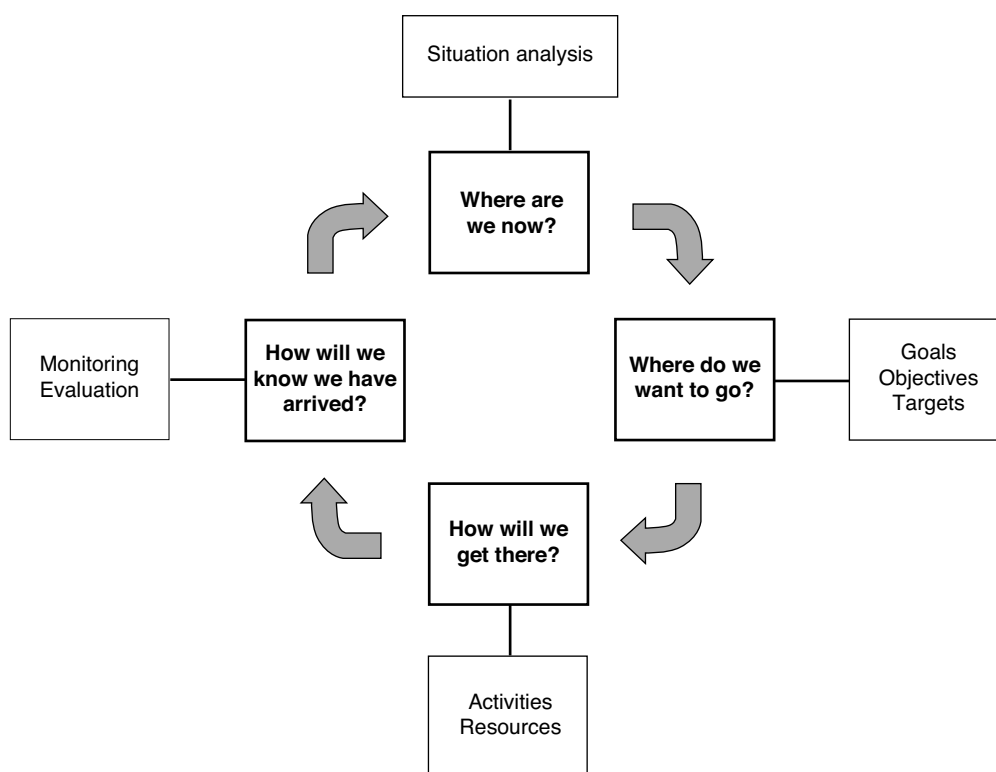
The planning cycle seeks to answer four questions:

1. Where are we now?
2. Where do we want to go?
3. How will we get there?
4. How will we know we have arrived?

⁸ Heywood, A. & Rohde, J. Undated. Using information for action. The Equity Project

⁹ Green A, 1999. An introduction to health planning in developing countries. Oxford University Press Inc. New York.

Figure 4.1: Steps in the planning cycle



1. Where are we now?

Before deciding what to do about a problem, we need to have an understanding of the situation. This is often referred to as a situational analysis. If the situational analysis does not clarify the situation sufficiently, initial planning will usually focus on further studies (research) or experimental approaches (e.g. a pilot project to get more experience/understanding). Before drawing up the national strategic plan, the situation was analysed and this information was used as the basis to go forward. If a plan is not based on a thorough assessment and analysis of the situation, the decisions and actions of the plan may not be the best ways of addressing the problem.

It is important to remember that plans addressing complex development processes must be flexible. Unexpected events and unforeseen challenges must not automatically be regarded as threats; they will often provide major new opportunities. Likewise, a conflict or contradiction erupting between stakeholders during implementation can be an opportunity to improve the plan and/or to forge new alliances if handled correctly.

Critical areas covered in a situational analysis include: demography, infrastructure, policy and political environment, health needs of the population, services available, service utilisation and resource use.

2. Where do we want to go?

After gaining a good understanding of the problem, the next step involves using this information to make decisions regarding **how the current situation needs to be changed** and improved in the future. In other words, goals must be set. Every plan should have a goal as its endpoint.

- ✧ **Goal:** the overall endpoint that the plan hopes to achieve (e.g. reduction of HIV incidence). Goals are sometimes only achieved over the longer term (5-10 years) and through the combined efforts of multiple programmes.

For example,

"...The goals of the HIV and AIDS care and treatment plan are to reduce HIV-related mortality, reduce the morbidity of HIV-infected people, and improve the quality of life of the HIV-infected..." (Comprehensive Plan, page 193).

Decisions need to be taken on how to achieve these goals. The next step is therefore to identify a set of specific things that need to happen to contribute to achieving the goal. These are referred to as objectives. Objectives address questions of "what" and "when", but not "why" or "how".

✧ **Objectives: specific achievements** that contribute to achieving the goal

The word specific is important here. While the goal is a broad statement of what we hope to achieve, objectives are more precise. Objectives are stated in terms of results to be achieved, not processes or activities to be performed. A properly stated objective is action-oriented, starts with the word "to" and is followed by an action verb.

Objectives must be **SMART**:

- S - Specific:** Is the objective specific – does it cover only one rather than multiple activities?
- M - Measurable:** Can the objective be measured or counted in some way?
- A - Achievable:** Is the objective actually doable – can it be achieved?
- R - Relevant:** How important is the objective to the work we are doing? How relevant is it to achieving our goal?
- T - Time-bound:** Does the objective give a timeframe by when the objective will be achieved?

Note: The most common time-frames in planning in South Africa relate to one-year "business" plans, the three-year Medium Term Expenditure Framework (MTEF), and the ten-year strategic planning.

3. How will we get there?

After deciding **what** needs to be achieved, decisions need to be taken on how to achieve the objectives in order to reach the goal, i.e. what activities and resources are required? Required resources are often referred to as inputs. Activities refer to a set of tasks or processes that need to be accomplished and involve the drawing up of an operational plan or a work plan. The resources needed to carry out each activity must be identified.

4. How will we know we have arrived?

The final step of the planning cycle involves **monitoring and evaluation** of the implementation of the plan. This provides the basis for the next situational analysis and injects new information into the planning cycle. Monitoring and evaluation is a critical step in the planning cycle and is dealt with in more detail in session 5

4.2 Introducing the Comprehensive Plan

Introduction

During the last two decades, the HIV and AIDS pandemic has claimed millions of lives and has had an impact on the lives of millions of others, inflicting pain and grief, causing fear and uncertainty and threatening or causing economic devastation for many families and communities. Despite efforts to contain the epidemic, **HIV prevalence has increased significantly in South Africa over the last decade**. Consequently, a growing sense of urgency has developed about responding to the epidemic. The need was recognised for scaling up of HIV and AIDS prevention, care and support interventions, including the provision of antiretroviral treatment. The Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa represents such a

response.

Development of the Comprehensive Plan

- ✧ In 1992, early developments of a coordinated public policy response to HIV and AIDS began with the formation of the **National AIDS Coordinating Committee of South Africa (NACOSA)**.
- ✧ In 1997, progress in implementing the NACOSA plan was assessed by the South African National STI and HIV and AIDS Review.
- ✧ In 2000, building on this review, the South African government launched its five-year **Strategic Plan for HIV and AIDS and STI**.
- ✧ In April 2002, the Cabinet noted that antiretroviral treatment can help to improve the health of people living with AIDS.
- ✧ In July 2002, the government established a Joint Health and Treasury Task Team to investigate issues relating to the financing of an enhanced comprehensive response to HIV and AIDS, based on the Strategic Plan of 2000.
- ✧ In November 2003, the government approved the **Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa**.

Overview of the Comprehensive Plan

The Comprehensive Plan is a detailed document describing a wide-ranging response to HIV and AIDS. An overview of the Plan may be gained by reviewing the pillars, guiding principles and goals. The contents page (i) provides an outline of the various components of the plan.

Pillars of the Comprehensive Plan

(Refer to page 15 of the Comprehensive Plan)

The pillars can also be viewed as the main strategies of the plan.

- ✧ Ensuring that the great majority of South Africans who are currently not infected with HIV **remain uninfected**.
- ✧ Enhancing efforts in the **prophylaxis and treatment** of opportunistic infections, improved nutrition and lifestyle choices.
- ✧ Effective management of those HIV-infected individuals who have developed **AIDS-defining illnesses**, through appropriate treatment of AIDS-related conditions (including the possibility of using antiretroviral therapy in patients presenting with low CD4 counts to improve functional health status and to prolong life), and suitable palliative and terminal care where treatment has run its course.

Guiding principles of the Comprehensive Plan

(Refer to page 16 of the Comprehensive Plan)

- ✧ Quality of Care
- ✧ Universal care and equitable implementation
- ✧ Strengthening the National Health Care System
- ✧ Reinforcing the key government strategy of prevention
- ✧ Providing a comprehensive continuum of care and treatment
- ✧ A sustainable programme
- ✧ Promotion of healthy lifestyles
- ✧ Promotion of individual choice of treatments be consistent in this list with upper/lower case
- ✧ Integration with government nutrition strategy

- ✧ Ensuring the safe use of medicines
- ✧ World Health Organisation target
- ✧ Multi-Drug Resistant (MDR) Tuberculosis
- ✧ Local and regional integration

Goals of the Comprehensive Plan

(Refer to page 24 of the Comprehensive Plan)

- ✧ To provide comprehensive care and treatment for people living with HIV and AIDS, and
- ✧ To facilitate the strengthening of the National Health Care System in South Africa.

Components of the Comprehensive Plan

(Refer to page (i) of the Comprehensive Plan)

The Comprehensive Plan is organised into six sections and sub-divided into sixteen chapters. Each chapter represents a component of the Plan.

SECTION ONE – PREVENTION, CARE AND TREATMENT OF HIV AND AIDS

- I Prevention, Care and Treatment
- II Nutrition-Related Interventions
- III Traditional Medicine

SECTION TWO – HUMAN RESOURCES AND FACILITIES

- IV Accreditation of Service Points
- V Human Resources and Training
- VI Provincial Site Assessments

SECTION THREE – OPERATIONAL ISSUES: DRUGS AND LABORATORIES

- VII Drug Procurement
- VIII Drug Distribution
- IX Laboratory Services

SECTION FOUR – COMMUNITIES

- X Social Mobilisation and Communications

SECTION FIVE – INFORMATION, MONITORING & RESEARCH

- XI Patient Information Systems
- XII Monitoring and Evaluation
- XIII Pharmacovigilance
- XIV Research Priorities

SECTION SIX – MANAGEMENT AND BUDGET

XV Programme Management

XVI Budget

4.3 Progress with the implementation of the Comprehensive Plan

Country-wide progress in 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

4.4 Challenges of the Comprehensive Plan

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 COMPONENTS OF THE COMPREHENSIVE PLAN

1. 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 VCT 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 to antiretrovirals. Patients must be prepared to make choices and to make a lifelong commitment to taking ARVs, which may require not only education to gain understanding of potential side-effects and 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 child's medication

2. 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 patients' nutritional needs and 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.

3. Traditional Medicine

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

4. 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.

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 the historically disadvantaged and underserved areas of the country to promote the 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 administering antiretroviral drugs safely and effectively**.

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

5. 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 this 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. It 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 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.

It advocates increasing the 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.

6. Provincial Site Assessments

The 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 provide information regarding site readiness for initiating HIV and AIDS care and treatment. All sites possess 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 capacity. 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.

7. Drug Procurement

This chapter establishes a system of drug procurement that attempts to secure antiretroviral drugs at prices well below current 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 maintenance of strong intellectual property rights is essential to foster innovation and industrial development. 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 may 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 and expedient, 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.

8. Drug Distribution

This chapter provides for the upgrading of the system of distributing drugs. This 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 as well as increasing dramatically the number of pharmacists in the public sector.

9. 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 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 total public health system.

10. 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 this 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** in the communications programme. The plan also proposes significant investments in community support programmes for those being treated for AIDS.

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

11. 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 standardised, 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.

12. 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.

13. Pharmacovigilance

The plan proposes a comprehensive programme of pharmacovigilance in order to monitor the **efficacy** of the drugs that are being used. In particular, this 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 post-marketing 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 HIV, including, but not limited to, antiretrovirals.
- ✧ To respond to unfounded and unsubstantiated claims of efficacy of untested products and treatment modalities

14. 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?

4.5 Staging and ART eligibility criteria

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.

4.6 Understanding Anti-Retroviral Therapy

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) · ddI (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/ ddI/ 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 and 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.