OPERATIONAL PLAN

FOR

COMPREHENSIVE

HIV AND AIDS CARE, MANAGEMENT

AND TREATMENT

FOR

SOUTH AFRICA

19 NOVEMBER 2003

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LIST OF ACRONYMS

ADR	Adverse Drug Reaction
AIDS	Acquired Immunodeficiency Syndrome
ALT	Alanine Aminotransferase
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral
ARVs	Antiretroviral Drugs
AZT	Zidovudine, Retrovir
CBO	Community-based Organisation
CPD	Continuing Professional Development
CSIR	Centre for Scientific and Industrial Research
DHIS	District health information system
DoH	Department of Health
DOTS	Directly Observed Treatment Short course
ELISA	Enzyme-linked Immunosorbent Assay
EQA	External Quality Assessment
FBC	Full Blood Count
FTE	Full-time Employee
HBC	Home-based Care
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
IT	Information Technology
JHTTT	Joint Health and Treasury Task Team
M&E	Monitoring and Evaluation
MCC	Medicines Control Council
MEC	Member of the Executive Council
MRC	Medical Research Council
NDoH	National Department of Health
NEFP	National Emergency Food Programme
NGO	Non-Governmental Organization
NHLS	National Health Laboratory Service
NHRC	National Health Research Council
NNRTI	Non-nucleoside Reverse Transcriptase Inhibitor
NVP	Nevirapine
OI	Opportunistic Infection
PCR	Polymerase Chain Reaction
PEP	Post-exposure Prophylaxis
PLWHA	People Living with HIV and AIDS
PMTCT	Prevention of Mother-to-Child Transmission (of HIV)
PPP	Public-private Partnership
QA	Quality Assurance

SAMHS	South African Military Health Services
SMT	Strategic Management Team
STI	Sexually Transmitted Infection
TB	Tuberculosis
THP	Traditional Health Practitioner
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
VCT	Voluntary HIV Counselling and Testing
VL	Viral Load
WHO	World Health Organisation
WTO	World Trade Organisation

Foreword

I would like to thank the South African Cabinet for affording me the opportunity to develop this Detailed Operational Plan on Comprehensive Care and Treatment for HIV and AIDS, after considering the Report of the Joint Treasury and Health Task Team that costed the provision of antiretroviral therapy in the public sector.

I accepted full responsibility for the development of this Plan since Cabinet asked me to do this work, and I immediately established a Task Team of various experts to assist the Department of Health in developing the operational plan.

This exercise has given the Department of Health the opportunity to review its current programmes on HIV and AIDS, Tuberculosis, Sexually Transmitted Infections, Maternal Child and Women's Health, Nutrition and Traditional Medicines.

It compelled the Department of Health to review its organisational structure and function in order to integrate and properly coordinate the implementation of its health programmes across line functions, with other relevant departments.

This work has brought into sharp focus the need for strong and sustainable partnerships in health care delivery with the private sector and civil society, in particular the fight against the spread of HIV infection and the impact of AIDS.

The plan presents various options and choices to South Africans for the care and treatment of HIV and AIDS. These options are presented in a manner that will afford Cabinet the opportunity to analyse and evaluate, through a rational framework, and to arrive at a pragmatic and defensible decision that is based on compassion, equity, justice, fairness, universal access to basic health care, and sustainability.

Dr. ME Tshabalala-Msimang
Minister of Health of South Africa

Acknowledgements

We would like to thank the Minister of Health, Dr. Manto Tshabalala-Msimang, for giving us the privilege of working on this Detailed Operational Plan for Comprehensive Care and Treatment of HIV and AIDS, and for her leadership.

We would like to thank our colleagues, the Task Team members, for accepting the responsibility to develop this operational plan and working tirelessly to get this work done effectively, efficiently and on time, often at the expense of their work and family commitments.

We would like to express our gratitude to the Department of Health for their technical and administrative support, and the various stakeholders whom we consulted during the process of developing this operational plan.

Although this plan was coordinated nationally, it was built on the hard work done by provinces that provided valuable inputs and insights to the Task Team. We therefore wish to thank the MECs for Health, the Heads of Health, the Provincial AIDS Programme Managers and health workers at the heart of the service for cooperating with this effort and making it a success, and in particular members of the public that we interacted with.

In a special way, we would like to thank the William J. Clinton Presidential Foundation, led by the Chairperson Mr. Ira Magaziner, for providing invaluable technical support to the team.

Similarly, we wish to thank Mr. Vuyo Ray Mabope, the Special Advisor to the Minister of Health, for his guidance on strategic policy issues and his editorial contribution.

Special thanks to all the patients and health personnel who agreed to participate in the development of this plan, without whom the plan would not have been possible.

We hope that all South Africans who read and implement this plan will be proud to do so and that many people living with HIV and AIDS will benefit from it.

We commit and offer ourselves, and all the Task Team members, to assist the Department of Health in whatever way possible during the implementation of this operational plan.

……..	…….
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Chairperson of the Task Team	**Coordinator of the Task Team**

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EXECUTIVE SUMMARY

Executive Summary

BACKGROUND

1. The beginnings of a coordinated public policy response to HIV and AIDS date back to 1992, with the formation of the National AIDS Coordinating Committee of South Africa (NACOSA). Progress in implementing the NACOSA plan was assessed in 1997 by the South African National STI and HIV and AIDS Review. This review identified major strengths in the response to date, but also highlighted areas for substantial strengthening and improvement.

2. Building on this review, and on an extensive consultation process, government launched its five-year Strategic Plan for HIV and AIDS in 2000. This plan provided the framework within which interventions geared towards initiating and executing a comprehensive response to the epidemic are undertaken. The strategic framework identified four key areas of intervention, namely: (1) prevention; (2) treatment, care, and support; (3) research, monitoring and surveillance; and (4) legal and human rights.

3. In April 2002, after reviewing its approach to HIV and AIDS, Cabinet reiterated its commitment to the Strategic Plan. Noting progress in the implementation of the Plan and the impact beginning to be made with regard to the prevention campaign, Cabinet decided on a number of measures to strengthen and reinforce these efforts, including:

    3.1 Strengthening partnerships, especially via the South African National AIDS Council (SANAC).

    3.2 Continued use of nevirapine in preventing mother-to-child HIV transmission, and development of a universal rollout plan.

3.3 Providing a protocol for a comprehensive package of care for survivors of sexual assault, including post-exposure prophylaxis with antiretroviral drugs.

3.4 Ensuring that no one should be turned away without appropriate treatment and management of any infection or illness, irrespective of HIV status.

3.5 Noting that antiretroviral treatment can help to improve the conditions and health of people living with AIDS if administered at certain stages in the progression of HIV and in accordance with international standards, government committed to continue its efforts to remove systemic constraints on access to these drugs.

3.6 Alongside poverty alleviation and nutritional interventions, to encourage investigation into alternative treatments, particularly supplements and medication for boosting the immune system.

4. In July 2002 government established a Joint Health and Treasury Task Team to investigate issues relating to the financing of an enhanced response to HIV and AIDS, based on the Strategic Plan as further elaborated in the 17 April 2002 Cabinet statement and the subsequent Cabinet statements of 9 October 2002 and 19 March 2003. A particular focus of the Task Team was on the second component of the Strategic Plan, namely treatment, care and support for those infected and affected by HIV and AIDS.

5. At its 8 August 2003 meeting, Cabinet received the Report of the Joint Health and Treasury Task Team (JHTTT) that was charged with examining treatment options to supplement comprehensive care for HIV and AIDS in the public health sector. This report provided options to support the strengthening of the second component of the country's five-year Strategic Plan. This included scaling up current policy interventions, and integrating additional interventions, including the option of introducing antiretroviral therapy for people with AIDS.

6. Following the discussion of this report on 8 August 2003, Cabinet instructed the Department of Health to develop a detailed operational plan on an antiretroviral treatment programme by the end of September 2003. In view of that task, the Minister of Health appointed a National Task Team on the 19th of August 2003, to assist in the development of a detailed operational plan with the following terms of reference:

6.1. Development of provincial implementation plans, including a resource and training centre in each province to help ensure the delivery of high quality treatment and care, a schedule for rollout across district hospitals and health centres and a forecast of staffing requirements. The provincial operational plans are to be based on the district health systems within each province.

6.2. Procurement and/or production of necessary medications and consumables at the lowest prices as possible and an increase in the capacity and security of the drug distribution system.

6.3. Upgrading of the national health laboratory system to handle a significant increase in diagnostic testing and monitoring of patient safety.

6.4. Elaborating an integrated nutritional programme for people living with HIV and AIDS.

6.5. Development of a research agenda to support the programme, including engagement of South African academic centres and research institutions.

6.6. Establishment of a robust system to monitor efficacy of the intervention, adverse drug events, resistance and improvement and coordination of patient information systems.

6.7. Development of staffing norms and standards for the delivery of antiretroviral therapy and assessment of human resource needs, including

health system managers, clinicians, nurses, pharmacists, nutritionists and counsellors.

6.8. Creation of a Programme Management Unit to coordinate the implementation of the programme and recommendations for its functions, structure, staffing and cost.

6.9. Development of a communications plan for health providers and the public, including what to expect from the proposed treatment programme.

6.10. Development of a detailed five-year programme budget and an estimated ten-year budget to implement the treatment programme.

6.11. Development of a detailed implementation schedule.

7. The Plan is premised on the following pillars:

7.1. Ensuring that the great majority of South Africans who are currently not infected with HIV remain uninfected. The messages of prevention and of changing lifestyles and behaviour are therefore the critically important starting point in managing the spread of HIV and the impact of AIDS. Important in supporting these efforts in the broader context are the social programmes of government and wider society that aim to reduce poverty through improving nutrition, job creation and social support, and to improve education and to bring about moral renewal.

7.2. Enhancing efforts in the prophylaxis and treatment of opportunistic infections, improved nutrition and lifestyle choices.

7.3. 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.

8. The Task Team met extensively. It held numerous discussions with representatives of all nine provinces, including several meetings with the provincial Health MECs. It also met with a wide range of stakeholders, including non-governmental organizations, professional associations, trade associations, labour organizations, research institutions, and HIV and AIDS clinicians. These meetings included visits to a wide variety of settings, urban and rural, resourced and under-resourced. Experts from the William J. Clinton Presidential Foundation assisted the Task Team, and will continue to support the implementation in the initial years as required (see Annex XV.1). In addition, the Team constituted ten working groups, each of which met on several occasions to prepare chapters of this plan.

GUIDING PRINCIPLES

9. The operational plan is guided by the following fundamental principles:

9.1 Quality of Care

9.1.1 This plan envisions significant investments to ensure that the highest available quality of care is provided to the people of South Africa in line with international and local norms and standards. The proposed scope of care for patients encompasses a broad range of treatment options that include proper diagnosis, counselling, treatment of opportunistic infections (in particular tuberculosis and sexually transmitted infections), other preventive and supportive strategies such as nutrition and nutritional supplements and traditional and complementary medicines with immune-boosting properties, as well as antiretroviral drugs for the management of AIDS.

9.1.2 Treating AIDS patients with antiretroviral drugs has been effective in prolonging the lives of people who would have progressed to stage 3 and 4 of AIDS[1]. However, the treatment of patients with antiretroviral drugs is relatively new and not a simple matter. The drugs do not cure people - they merely arrest the progression of the disease. The drugs can be toxic and have adverse side effects that may make patients temporarily sicker. In some cases, for several reasons, the drugs do not work. The improper use of these drugs can hasten the development of drug-resistant strains of the virus, thus undermining effective treatment and posing public health risks.

9.1.3 The care and treatment protocols will be based on international best practice. Accreditation procedures will help to ensure that the facilities that are approved for the provision of antiretroviral treatment are of good quality and observe the highest standards of care. In addition, extensive training and certification of health professionals will be carried out on an ongoing basis to support this treatment programme.

9.1.4 The plan also provides for extensive investments in monitoring and research to allow for continual evaluation and improvement in the quality of care. A robust monitoring system will ensure an early warning system to detect drug resistant strains of the virus, adverse drug events and drug-to-drug interactions with other Western, traditional and complementary medicines. These efforts will ensure that the best information is available for the benefit of South Africans undergoing care and treatment.

9.2 Universal Care and Equitable Implementation

9.2.1 The programme is founded upon the principle of universal access to care and treatment for all, irrespective of race, colour, gender and economic status. This is a major undertaking in a nation like South Africa, which is still suffering from the legacy of apartheid and the

extreme inequalities and disparities in health care provision. This programme attempts to address the challenge of providing services in rural and urban settings without compromising the quality of care.

9.2.2 The South African Constitution and government require that implementation of a programme of such importance be carried out in a universal and equitable manner. This operational plan aims to accomplish these goals by achieving a balance between areas that can readily implement the programme and those that need additional resources and investment to upgrade their general health capacity before they can do so. The plan takes specific account of the needs of the historically disadvantaged populations and underserved health districts.

9.3 Strengthening the National Health System

9.3.1 A fundamental principle is the strengthening of the national health system as a whole in order to ensure the effective delivery of comprehensive HIV and AIDS care and treatment. It is also essential to ensure that this plan is not implemented at the expense of other equally important healthcare priorities and programmes.

9.3.2 Prior to 1994, the provision of healthcare for the majority of South Africans was woefully inadequate and skewed. While the public health system in South Africa has made great strides since then, significant staffing and facility upgrades are still necessary to meet the health needs of South Africa's people.

9.3.3 Government is currently pursuing plans to upgrade public hospitals, consolidate the National Health Laboratory Service, refurbish and build health facilities, upgrade patient and health information systems, improve drug procurement and distribution, and enhance management systems.

9.3.4 This operational plan calls for significant additional investments to improve the capacity and capabilities of the national health care system, in particular the strengthening of human resource capacity, and providing incentives to recruit and retain health professionals in historically underserved areas.

9.3.5 Comprehensive care and treatment for HIV and AIDS needs to be delivered in an integrated fashion within a coherent overarching public health policy framework for the provision of basic social services as part of the continuum of care.

9.3.6 More than half of the total expenditures envisaged in this plan will go toward strengthening the national health system, emphasizing prevention and promoting healthy lifestyles. These funds will allow not only for the delivery of comprehensive care and treatment for those infected with HIV, but will also improve the overall capabilities of the health system.

9.4 Reinforcing the Key Government Strategy of Prevention

9.4.1 In the absence of a cure for AIDS, prevention remains the cornerstone of the country's response to HIV and AIDS. The current range of prevention strategies includes provision of barrier methods, voluntary counselling and HIV testing, prevention of mother-to-child-transmission (PMTCT), post-exposure prophylaxis (PEP), syndromic management of STIs, TB management, and a large and sustained information, education and communication campaign. Some of these strategies are critical entry points for care and treatment interventions.

9.5 Providing a Comprehensive Continuum of Care and Treatment

9.5.1 The comprehensive HIV and AIDS care and treatment programme embodied in this plan will build on the existing programmes as outlined in the five-year Strategic Plan for HIV, AIDS and STIs. Prevention of HIV infection will remain the mainstay of the programme.

9.5.2 The plan proposes to build on testing programmes to diagnose HIV infection and measure disease progression so that proper care and treatment regimens can be implemented. It includes ongoing medical services to provide treatment for opportunistic infections associated with HIV and ultimately, when necessary, antiretroviral treatment to arrest the progression to AIDS, an extensive nutrition intervention, and programmes to integrate the provision of medical care with traditional methods of healing. A full range of community support services is contemplated, including counselling, adherence support groups, community mobilisation efforts to reduce stigma and discrimination, patient transport, home and community-based care and, when necessary, palliative care.

9.6 A Sustainable Programme

9.6.1 There is currently no cure for AIDS. The best that an AIDS management programme can achieve is to prolong the lives of people living with HIV and AIDS, so that they can remain productive members of society.

9.6.2 Undertaking a programme like this therefore means committing to providing care and treatment for people over a long period. Once people enter into a comprehensive treatment and care programme, treatment must be sustained.

9.6.3 The drugs and tests required to treat an AIDS patient can run to several thousand rands per person per year, and the human and physical infrastructure necessary to sustain treatment is costly. Other nations that have undertaken comprehensive HIV and AIDS care and treatment programmes have typically had to treat and care for fewer people than is the challenge for South Africa.

9.6.4 To make this programme sustainable, it must be cost-effective and efficient, without compromising quality. Within the overall stewardship role of government, it is recommended that in order to ensure the sustainability of the programme, the biggest slice of the budget for this care and treatment programme should ideally come from the fiscus. Where appropriate the financing of the programme may be supplemented using donor resources.

9.7 Promotion of Healthy Lifestyles

9.7.1 Ultimately, any health care programme should begin with the promotion of healthy lifestyles. Good nutrition, the practice of safer sex, and effective prophylactic medical care are fundamental to good health. This remains true for all people – both to prevent the spread of HIV to those uninfected, and to sustain the immune systems of HIV-positive people for as long as possible.

9.7.2 South Africa currently has very extensive programmes to educate people on awareness about HIV infection and AIDS, including how to live healthy lifestyles to prevent the spread of the virus. Government has also been a pioneer in advocating poverty reduction and promoting good nutrition to boost the immune systems of people living with TB, HIV and AIDS and other chronic debilitating diseases.

9.7.3 This programme will be integrated with existing efforts to promote healthy lifestyles among South Africans. It will enhance these

efforts through additional investments in nutrition and traditional and complementary medicines, promoting regular exercise, supporting community-based initiatives, monitoring and evaluating the impact of health promoting activities, and intensifying information, education and communication campaigns.

9.8 Promotion of Individual Choice of Treatments

9.8.1 South Africans living with HIV and AIDS will be encouraged to make their own informed choices about the types of treatment they wish to seek. A wide range of interventions and options will be provided through this comprehensive package of care. These may include advice on general health maintenance strategies, positive living, exercise, nutrition, traditional and complementary medicines, and antiretroviral therapy. All potential clients will be informed about these care and treatment options and encouraged to make their individual informed choices.

9.9 Integration With Government Nutrition Strategy

9.9.1 Good nutrition is essential to good health. This is particularly true for people with HIV and AIDS. The South African government has in place a series of programmes to improve nutrition and food fortification among its people including those living with TB, HIV and AIDS and other chronic debilitating diseases. The new programme will be fully integrated with the existing programmes.

9.10 Ensuring the Safe Use of Medicines

9.10.1 If not administered and monitored properly, antiretroviral drugs can become less effective as drug-resistant strains of the virus develop. The drugs also have toxic side effects for some patients. The use of antiretroviral drugs in the combinations and strengths prescribed for AIDS patients is also relatively new. For all of these reasons, this plan goes to great lengths to monitor patient safety and the impact

of these measures and to emphasize the safe use of medicines and the importance of adherence to treatment.

9.11 World Health Organisation Target

9.11.1 South Africa notes the World Health Organisation's announcement of a comprehensive strategy to realize a goal of providing antiretroviral drugs to three million people worldwide by the year 2005. As a member state of the World Health Organisation (WHO) it is envisaged that there will be collaboration between this programme and WHO activities that aim to achieve the objective of providing comprehensive care for people living with HIV and AIDS, with due recognition of the complexities of programme administration.

9.12 Multi-Drug Resistant Tuberculosis

9.12.1 As with TB, poor management and poor compliance with antiretroviral therapy results in multi-drug resistant HIV, which could impact negatively on both diseases.

9.12.2 To optimise care for HIV and AIDS patients who also have tuberculosis it is important to develop and sustain joint management programmes.

9.12.3 It is also critical that effective health information is imparted to patients to ensure good patient adherence to treatment to prevent the further spread of drug resistance, as is currently being experienced with TB.

9.12.4 HIV-infected persons are at increased risk of infection caused by antibiotic-resistant microorganisms. Containment of resistance to antimicrobial agents requires the establishment of appropriate early-warning systems over seen by a dedicated team of experts. Key

elements in a containment strategy include the prudent use of antimicrobial agents, educational intervention, integrated surveillance and monitoring systems in all areas as well as good infection control practice. In addition, risk assessment and management strategies within a regulatory framework play an important role in containing antimicrobial resistance.

9.13 **Local and Regional Integration**

9.13.1 The programme will be implemented in a manner that promotes and strengthens cooperation among government departments and all spheres of government. It will also pursue collaboration and harmonisation of strategies within the Region in line with the SADC HIV and AIDS Strategic Framework and Programme of Action 2003 – 2007.

THE PLAN

10. The plan aims to accomplish two interrelated **goals**, namely:

10.1 To provide comprehensive care and treatment for people living with HIV and AIDS; and

10.2 To facilitate the strengthening of the national health system in South Africa.

11. The following **timelines** are targeted:

11.1 The goal of the Comprehensive HIV and AIDS Care and Treatment Programme is to establish a minimum of one service point in every health district (District Council or Metropolitan Council) in South Africa by the end of the first year of implementation.

11.2 The goal of the Comprehensive HIV and AIDS Care and Treatment Programme is to provide all South Africans and permanent residents who require comprehensive care and treatment for HIV and AIDS equitable access to this programme within their local municipal area within a period of five years.

12. These goals represent important milestones in the development of the programme to progressively realize the service needs and requirements of all South Africans and permanent residents within the available means and resources.

13. The goals also represent an unambiguous commitment of the South African government to care for people living with HIV infection and the impact of AIDS.

14. The achievement of these goals and targets is subject to the implementation of a holistic and integrated programme to fight the spread of HIV infection and the impact of AIDS, and the availability of adequate resources to strengthen the national health system to provide this essential service.

Continuum of Care

15. The model developed by the Actuarial Society of South Africa (ASSA2000) projects that approximately 400,000 of the HIV-positive population will develop an AIDS-defining illness during 2003 (this figure excludes members of medical schemes that might require ARVs)[2].

16. The objective of this operational plan therefore is to ensure that by 2009 all individuals requiring treatment for AIDS will be able to access comprehensive care and treatment.

17. According to the ASSA2000 model, it is estimated that by then about 1.4 million people will require ARV therapy.

18. The programme detailed in this report is focused on developing a system that safely delivers life-sustaining care and treatment, including where appropriate, antiretroviral medications.

19. The programme endeavours to respond to the holistic needs of an individual at all stages of HIV infection and attempts to slow progression and maintain the person at the highest functional level.

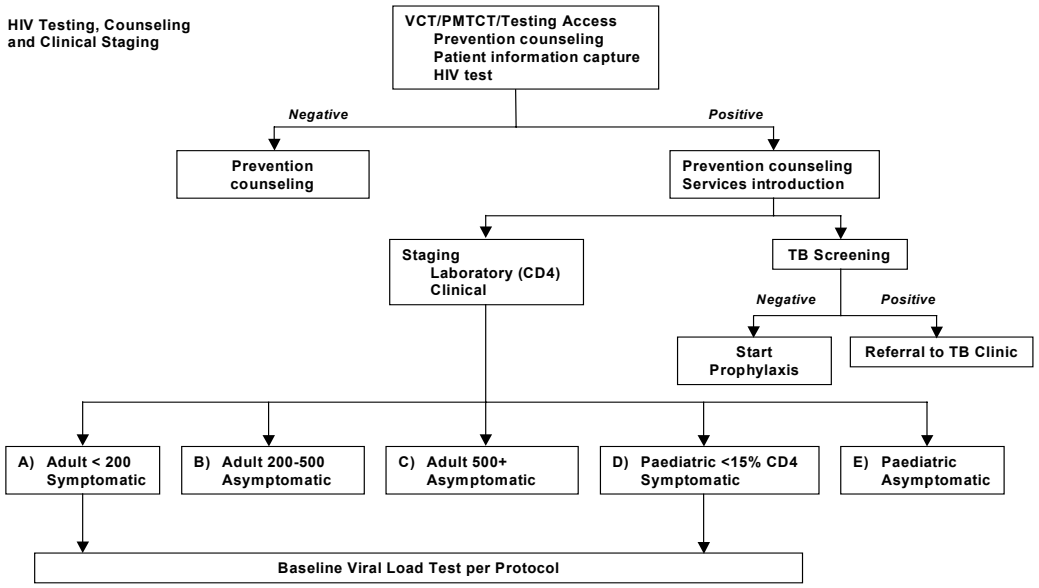
20. The programme aims to expand voluntary counselling and testing (VCT) services so that people may know their HIV status and take appropriate actions.

21. In fact, the plan proposes VCT as a crucial entry point into the care and treatment programme. Once identified as HIV-positive, patients will be assessed for their stage of illness and referred into medical care.

22. Disease staging is done with a CD4 count test and an assessment of the patient's medical history and status (see Figure 0.1).

23. Upon enrolment of a patient into an antiretroviral therapy programme, it is proposed that necessary and appropriate CD4 and viral load measurements will be done to establish the baselines. Further tests to measure the patient's response to therapy, improvement in the patient's immune system, and monitoring of drug toxicity will be done where necessary and in accordance with the recommended treatment and laboratory protocols. An ongoing surveillance programme to monitor for resistant viral strains will be instituted.

Figure 0.1: HIV Testing, Counselling and Clinical Staging



24. A fundamental commitment of this programme is to keep the HIV-negative population free of HIV infection. Therefore the prevention of HIV infection is the bedrock of government's comprehensive approach to halt the spread of HIV and the impact of AIDS. Prevention programmes will continue to deliver targeted prevention messages at service points, schools, workplaces, and within community settings. The messages will attempt to discourage high-risk activities and inform people about the risk of sexually transmitted infections.

25. HIV-positive patients seeking treatment will enter into a system of care that monitors progress of HIV infection. The envisaged system of care will focus on slowing the progression to full-blown AIDS and optimising health through the prompt diagnosis and treatment of inter-current infections, with prophylaxis as necessary. Where appropriate, patients will also have access to facilities offering routine immunizations, ongoing prevention counselling, periodic medical examinations and CD4 and viral load tests to assess their immune status. Close

monitoring of patients for TB, a common opportunistic infection associated with HIV, is part of the proposed system of care.

26 The intention is to offer counselling and the option of antiretroviral therapy to patients who are symptomatic and/or with a CD4 count less than 200 .

27 As part of the counselling and treatment process, patients will be fully informed about the benefits of restoring immune function and improving the quality of life and about serious side effects that may result from treatment with these drugs. For those patients choosing antiretroviral therapy, CD4 and viral load tests, where necessary and appropriate in the circumstances, will be administered as treatment commences. If patients are using traditional medicines, this information will be documented.

28 The programme includes supervision of patients through periodic visits to clinicians, nurses and counsellors and the administration of periodic CD4 and viral load tests and other tests as necessary according to the recommended protocols.

29 t Access to treatment will be made available to patients at service points that have been accredited to provide antiretroviral treatment and it is proposed that health professionals that have undergone training and certification procedures will be on hand to render the necessary services in accordance with the recommended treatment guidelines and protocols. Necessary and appropriate psychosocial and nutritional support of patients is an element of the programme.

30 Access to specialized consultation at secondary or tertiary institutions or care centres with strong linkages to specialist medical care may be necessary in certain instances and the programme envisages the utilisation of the appropriate referral systems for this purpose.

31 Available community care and support services such as transportation, home-based care, hospice services, etc., often provided by NGOs and CBOs, will assist in keeping people in care and encourage their adherence to treatment.

32 Nutritional support is an element of this comprehensive care and treatment programme.

33 It is envisaged that extensive information, education and communications programmes to help educate patients, families and communities about prevention and proper care and treatment for all HIV-positive South Africans will also support the programme.

Strengthening the National Health System

34 The plan provides significant investments to strengthen the national health care system overall.

35 It is the intention that through this programme, new health professionals will be added to the national health system. The addition of these human resources will strengthen the health system as a whole, by increasing its capacity to treat all patients, including those with HIV infection and AIDS-defining illnesses.

36 The programme will also pay significant attention to upgrading the skills base and competencies of health care workers within the public health system.

37 This programme will include improvements to physical infrastructure in line with current capital programmes.

38 Improved access to laboratory services and significant investments in expanding the capabilities and turnaround times of the National Health Laboratory Service are a necessary part of the programme.

39 Investments in order to upgrade the national drug distribution system as well as the patient and health information systems at all levels of the health care system are also contemplated.

40 The drug procurement strategies in this plan should allow South Africa to develop over time a fully integrated local pharmaceutical production capacity for essential medicines, including antiretroviral drugs.

41 The increasing numbers of people who will interface with the health care delivery system will present repeated opportunities to identify preventable diseases across the spectrum of illness, including non-communicable diseases such as coronary disease, hypertension, diabetes, etc. and thereby decrease morbidity and mortality in the general population.

CHAPTER SUMMARIES

42 There are a number of tasks that must be accomplished in parallel for this plan to work. Hence the plan is divided into chapters that describe these tasks. The plan also includes a detailed schedule for the next six months that describes these tasks in greater operational detail, including when they need to be completed, and who should be responsible for completing them. (See Annex A.)

43 The Task Team has gone to this level of detail because careful coordination is necessary for the plan to succeed. If one or two necessary steps are not completed on time, the whole programme may be jeopardized. The operational plan has been constructed in such a way that the risk to patients is minimised in the event that individual tasks are not completed on time. Failure to comply with committed timelines and assigned tasks will, however, lead to delays in the implementation of the programme.

44 The Task Team has designed the plan to optimise the successful implementation of the care and treatment programme for HIV and AIDS within the time frames that are envisaged, conditional upon adequate resources being made available.

45 The following summarizes the main elements of the plan.

CHAPTER I – PREVENTION, CARE AND TREATMENT

46 This chapter delineates national care and treatment guidelines that conform to the best 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.

47 Components of this continuum of care include:

47.1 Prevention strategies;

47.2 Voluntary counselling and HIV testing;

47.3 Medical care and treatment by a dedicated, trained medical team;

47.4 Psychosocial support;

47.5 Nutritional assistance;

47.6 Social support; and

47.7 Home- and community-based services.

48 The key prevention strategies are:

48.1 Voluntary Counselling and Testing

48.2 Prevention of Mother-to-Child Transmission

48.3 Information, Education, and Communication (IEC)

48.4 Management of Sexually Transmitted Infections

48.5 Supply of barrier methods such as condoms

48.6 Life skills and HIV and AIDS education

49 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.

50 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.

51 The indication for antiretroviral treatment will be based on:

a. Clinical assessment and

b. CD4 count

52 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.

53 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 importance of adherence, but also psychosocial support. The well-informed patient has the best chance pf adherence to medication.

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

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

55.1 CD4 $\leq$ 200 cells/ mm^3 and/or symptomatic, irrespective of stage; or

55.2 WHO stage IV AIDS defining illness, irrespective of CD4 count; and

55.3 Patient prepared and willing to comply with taking antiretroviral drugs.

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

56.1 CD4 < 15% and symptomatic; or

56.2 WHO Paediatric Stage III AIDS defining illness, irrespective of CD4; and

56.3 At least one responsible person capable of administering child's medication

CHAPTER II – NUTRITION RELATED INTERVENTIONS

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

58 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.

59 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.

60 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.

61 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).

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

62.1 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

62.2 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.

CHAPTER III – TRADITIONAL MEDICINE

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

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

65 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.

66 The operational plan recognizes 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.

67 The plan seeks to promote the following activities:

67.1 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;

67.2 Continued research into the safety and efficacy of traditional medicines, in particular those natural medicines with putative immune-boosting properties;

67.3 Studying interactions between drugs and traditional medicines and participation in a pharmacovigilance programme.

CHAPTER IV – ACCREDITATION OF SERVICE POINTS

68 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.

69 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, VCT, etc.

70 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.

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

72 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 programme to administer antiretroviral drugs safely and effectively.

73 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.

74 The minimum service point accreditation criteria will be applied rigorously enough 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.

75 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

CHAPTER V – HUMAN RESOURCES

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

76.1 The need to strengthen human resource capacity by recruiting and retaining additional health professionals to strengthen the healthcare delivery system.

76.2 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.

77 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.

78 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, the design and the delivery of training at the national and provincial levels.

79 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.

80 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.

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

CHAPTER VI – PROVINCIAL SITE ASSESSMENTS

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

83. 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.

84. 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.

85. Task Team projections of AIDS patient loads across the 53 districts describe an uneven distribution among sites. These projections suggest that forty-four sites should have initial ARV patient loads of fewer than 1000 individuals, and 19 should have between 1000 and 2000 persons. Fourteen other sites, primarily in urban settings, may expect over 2000 ARV treatment patients each, numbers that will likely be too great for these facilities.

86. 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.

87. 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.

CHAPTER VII – DRUG PROCUREMENT

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

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

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

    90.1 The medicines must be of the highest quality and licensed by the South African Medicines Control Council.

90.2 The medicines must be appropriate for the treatment regimens outlined in the plan.

90.3 The supply of medicines must be secure and sustainable at a volume large enough to meet the demand envisioned.

90.4 Medicines must be purchased at the lowest possible price.

90.5 Sustainable supply should be ensured through local production of antiretrovirals and sustainable financing

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

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

92.1 A regular government tender using local suppliers.

92.2 A private-public partnership/initiative.

92.3 International tendering as stipulated in section 1(4) and Regulation 3 of the Medicines and Related Substances Act 101 of 1965.

93. 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 pre-qualified suppliers.

94. 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.

95. 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.

CHAPTER VIII – DRUG DISTRIBUTION

96. This chapter provides for the upgrading of the system of distributing drugs. This will be accomplished by improving inventory management, patient prescription information and financial management systems; by investing in more secured storage facilities; by ensuring efficient and secure transportation; by training pharmacy personnel; and by improving packaging to support inventory control and ease of use by patients.

97. The drug distribution process will include:

97.1 Inventory management, patient prescription information and financial management systems at the national, provincial, and local levels.

97.2 Secure storage facilities at the central, provincial, and local levels.

97.3 Efficient and secure transport between central warehouse facilities, provincial pharmaceutical depots and public health service points.

97.4 Training of pharmacy personnel to implement inventory management practices.

97.5 Improved packaging to support inventory control and to improve patient adherence.

98. 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.

CHAPTER IX – LABORATORY SERVICES

99. This chapter deals with the strengthening of laboratory services. The guiding principles of the laboratory services component of the antiretroviral treatment programme are:

99.1 To support best practices of patient care.

99.2 To monitor patient safety for toxicity, adverse events and drug resistance.

99.3 To establish evidence-based, cost-effective and sustainable laboratory services.

99.4 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.

99.5 To improve turnaround time and review performance regularly.

100. 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.

101. 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.

102. 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.

103. 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.

CHAPTER X – SOCIAL MOBILIZATION AND COMMUNICATION

104. 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.

105. 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.

106. 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 early stages.

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

108. 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.

CHAPTER XI – PATIENT INFORMATION SYSTEMS

109. 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.

110. The specific functions of the patient information system are:

110.1 To register patients utilizing a standard Patient Record.

110.2 To collect relevant clinical care information at baseline and subsequent follow-up visits to monitor progress of patients.

110.3 To monitor adherence to treatment.

110.4 To monitor adverse drug events.

110.5 To collect other clinical, laboratory, and non-clinical data that will be useful for programme monitoring at local, provincial and national levels.

111. 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.

CHAPTER XII – MONITORING AND EVALUATION

112. 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.

113. 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.

CHAPTER XIII – PHARMACOVIGILANCE

114. 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.

115. The specific aims of the antiretroviral pharmacovigilance programme are:

115.1 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.

115.2 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.

115.3 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.

115.4 To identify, assess and communicate any new safety concerns associated with the use of antiretrovirals and other HIV medicines.

115.5 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.

115.6 To minimize the impact of misleading or unproven associations between adverse events and ARV therapy.

115.7 To detect, assess, and respond to safety concerns related to complementary and traditional medicines used in HIV-infected patients.

115.8 To establish an early warning system for resistance to antimicrobials commonly used in HIV, including, but not limited to, antiretrovirals.

115.9 To respond to unfounded and unsubstantiated claims of efficacy of untested products and treatment modalities

CHAPTER XIV – RESEARCH PRIORITIES

116. 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.

117. The research agenda also aims to answer crucial questions that will inform improvements in the quality and efficacy of the programme.

118. 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.

119. Examples of specific research topics include:

119.1 What is the most effective delivery of ARVs to persons who have progressed to a stage at which these drugs become necessary?

119.2 What are the best approaches to prevent new infections with HIV?

119.3 What are the best interventions to extend the period during which HIV-infected people can be maintained without antiretroviral drugs?

CHAPTER XV – PROGRAMME MANAGEMENT

120. The plan proposes an integrated structure for managing and coordinating programme implementation. The following principles will guide the management of this programme.

120.1 Though it will involve a significant increase in health spending, this programme will not create a parallel health system in the country. It will be integrated into the existing management of the national health system.

120.2 The programme will be integrated closely with the existing health programmes across a broad spectrum. In particular, this comprehensive care and treatment programme must integrate with prevention and education programmes.

120.3 The programme will be coordinated within a national framework to ensure uniform quality, an equitable implementation and efficiencies that can come with scale of operation. However, provinces and health districts will be responsible for on-the-ground implementation.

120.4 Programme managers will harness, where appropriate, additional skills to enhance the effectiveness of the programme's management.

121. The national Department of Health will provide assistance to provinces as required to ensure the effective implementation of the programme.

CHAPTER XVI – BUDGET

122. The plan estimates a detailed five-year budget in Chapter XVI.

123. The total costs for the rest of fiscal year 2003/4 are R296 million.

124. This figure grows to nearly R4.5 billion in 2007/8.

125. The 2007/8 figures include:

125.1 More than R1 billion for new health professionals;

125.2 About R1.6 billion for antiretroviral drugs. (The Minister will appoint a team to negotiate the best prices for purchasing antiretroviral drugs);

125.3 About R800 million for laboratory tests;

125.4 Over R650 million in additional nutritional supplements and support.

126. Over the next four and a half years, over R750 million is proposed for upgrading systems in the healthcare infrastructure in areas such as drug distribution, patient information systems and pharmacovigilance.

127. Over R300 million is proposed for new capital investments, and over R230 million for research.

128. The model used in the calculation of the budget factors in survival and mortality of people on ARVs. It also estimates the likely proportion of patients who will need to switch from regimen 1 to regimen 2 in any given year.

129. This table presents an overview of the total programme budget estimate.

Table 0.1: Total Programme Budget Estimate (Millions of Rands)

	2003/04	2004/05	2005/06	2006/07	2007/08
New Healthcare Staff	21	322	432	662	1027
Laboratory Testing	20*	152	311	520	806
Antiretroviral Drugs	42	369	725	1118	1650
Nutrition	63	343	421	532	656
Other Health System Upgrades	70	171	184	160	160
Programme Management (National & Provincial)	16	103	128	128	128
Capital Investment	30	75	100	100	0
Research	34	55	55	48	48
Total	**296**	**1590**	**2358**	**3268**	**4474**

Note: Includes R20 Million advance payment to NHLS through March '04.

PROGRAMME CHALLENGES

130. The key challenges for implementing the programme, which must be addressed to support the implementation of the programme, include:

130.1 Strengthening **prevention programmes** to ensure that the number of HIV-negative people can be maintained.

130.2 Strengthening **existing programmes** such as VCT and PMTCT, which have a synergistic effect on the provision of comprehensive care and treatment, in particular, the provision of antiretroviral therapy.

130.3 The **recruitment, training and retention** of adequate levels/tiers of health care professionals in the public service, especially in rural, remote and underserved areas.

130.4 Building strong **partnerships** between health facilities and community support structures to provide a continuum of care.

130.5 Having a strong **communication** and **community mobilisation** strategy and plan to ensure that all South Africans have adequate information on the programme.

130.6 Improving the **integration of services** at facility level, especially between the HIV and AIDS, TB and STI services.

130.7 Supporting **traditional health practitioners** and the integration of traditional and complementary medicines with Western therapies.

130.8 Strengthening the **National Health Laboratory System** to meet the demands of the programme. It requires significant investments to achieve national coverage, consolidate its operations, and improve its efficiency. We also need to pay attention to the KwaZulu-Natal provincial laboratory service, which is not yet integrated into the National Health Laboratory Service.

130.9 Ensuring good **coordination** at national, provincial and district level as it relates to human resources, training, laboratory services, pharmaceutical services, drug procurement, and information systems.

130.10 Ensuring high **quality of care and adherence** in patients treated in the private sector.

130.11 Establishing sound **pharmacovigilance** practices in the public and private health sectors.

130.12 Additional **financial resources** are needed to fund and sustain the programme.

130.13 This will be a complex programme to **manage**. A large number of tasks must be accomplished in parallel. The programme must be integrated into

the existing health care system and into the full range of existing HIV and AIDS programmes. National and provincial governments must work in close cooperation.

130.14 Obtaining good **patient information** is important both to enhance the quality of treatment at the local level, and to ensure proper management at a national level.

SCHEDULE

131. Implementation of the comprehensive HIV and AIDS care and treatment programme should occur according to the principles enunciated in this plan.

132. The implementation must be equitable. Equity can be achieved by placing greater resources, both human and financial, at the disposal of historically underserved districts. Implementation must be accomplished in a way that ensures quality of the highest available standard.

133. With this in mind, the Task Team has drawn up a schedule for implementation. The schedule involves a pre-implementation phase that will begin immediately upon a decision of Cabinet to proceed with this programme.

134. Before antiretroviral drugs can be administered safely and equitably throughout the country, there are a number of pre-implementation tasks that must be accomplished. These include:

134.1 Accreditation and strengthening of service points;

134.2 Training of health workers;

134.3 Procuring drugs;

134.4 Strengthening drug distribution systems;

134.5 Strengthening laboratory testing capabilities;

134.6 Establishing proper patient information systems.

135. These tasks are summarised in Annex A.1, which is a week-by-week schedule for the pre-implementation period with deliverables for each of the main focus areas.

136. The Detailed Implementation Plan, which follows as Annex A.2, sets out the tasks to be completed in each stage of the operational plan for each area of activity.

137. There is a task list associated with every chapter of this plan (save Chapter VI, Provincial Site Assessments and Chapter XVI, Budget).

138. Dependencies between and among tasks, and contingencies which may affect the progress of each area, are highlighted.

139. As the programme becomes more established and its results better known, it is likely that more people will enter the programme. Also, since the HIV infection rates increased rapidly from 1993 to 1998, and since it typically takes 8 to 10 years for the virus to turn into full-blown AIDS, the numbers eligible for the programme will increase over the next few years.

140. Table 0.2 presents estimates of the numbers of people that the Task Team anticipates may be eligible to enter the programme over the coming years.

Table 0.2: New Patients Starting ARVs and Total Cumulative Numbers on ARVs

Year	New Cases Starting ARVs	Total Cases on ARVs
2003/04	53,000	53,000
2004/05	138,315	188,665
2005/06	215,689	381,177
2006/07	299,516	645,740
2007/08	411,889	1,001,534
2008/09	551,089	1,470,510

SECTION ONE

PREVENTION, CARE AND TREATMENT OF HIV AND AIDS

Chapter I

Prevention, Care and Treatment

OVERVIEW

HIV infection typically progresses from a prolonged asymptomatic stage, during which well-being can be maintained, through to a stage at which antiretroviral drugs (ARVs) become a critical part of the care and treatment strategy. The development of an effective programme to provide antiretroviral therapy is thus a critical component of the larger comprehensive plan to care for people living with HIV and AIDS (PLWHA). People living with HIV infection should be provided with a continuum of care and support services that respond to their changing needs over the course of their infection. Components of this continuum of care include: prevention-related interventions; voluntary counselling and HIV testing (VCT); medical care and treatment by a dedicated, trained medical team; psychosocial support; nutritional assistance; social supports; and as needed, community-based services and home-based care. At the stage at which ARVs are required to maintain health, medication should be made available and accessible through a coordinated programme across levels of the public health care system including primary health care clinics, community health centres, district hospitals, and regional and tertiary care institutions.

The HIV and AIDS care and treatment programme will integrate care and treatment with prevention efforts, and link to existing HIV interventions, such as voluntary counselling and HIV testing, prevention of mother-to-child transmission (PMTCT), and TB control. Treatment efforts will be further enhanced by involvement of community-based organisations, the private sector, and NGOs that provide assistance with education and adherence as well as practical support through a caring support network. In summary, South Africans should be able to access a full array of interventions and services to address HIV and AIDS within the context of a continuum of care.

The implementation of the HIV and AIDS care and treatment programme will also have far-reaching benefits beyond the delivery of treatment-related services. Many of the

interventions in this plan will strengthen the existing public health infrastructure, including pharmacies, laboratories, transportation, information technology, referral systems, facilities and staff capacity; surveillance systems; communication systems; monitoring and evaluation capacity; and research.

The comprehensive care and treatment plan will be located within the broader HIV and AIDS strategic framework. As a pillar of the strategic framework, it needs to align itself with the other three components: prevention; monitoring, evaluation and research; and legal and human rights. Monitoring and evaluation and research are addressed in Chapters XII and XIV, respectively.

BACKGROUND AND RATIONALE

In the context of its five-year HIV, AIDS and STI Strategic Plan, government has made a wide range of HIV and AIDS-related services available. These include voluntary counselling and testing[1-4], prevention of mother-to-child transmission of HIV[5], TB and STI management and HIV post-exposure prophylaxis (PEP) for both occupational exposures and survivors of sexual assault[6], orphan care programmes and nutritional supplementation[7]. These programmes have significantly improved the lives of South Africans living with HIV and AIDS.

The integration of HIV and AIDS care and treatment within existing efforts and interventions will avert the development of vertical systems of care, and will reinforce the national strategy emphasising primary health care. Health Promotion and Quality Assurance Training Centres will provide clinical training and support for the delivery of high quality care, including antiretrovirals when indicated.

A primary goal of the plan is to preserve recent gains made in slowing the spread of HIV in South Africa. Such gains have been validated by the United Nations Joint Programme on AIDS and confirmed, particularly in the youth of this country, by the 2002 antenatal HIV survey findings which show a decline in prevalence among the age group under 20 over the last 4 years.

The key prevention interventions are:

- VCT
- PMTCT
- Information, Education, and Communication (IEC)
- STI management
- Supply of barrier methods
- Life skills and HIV and AIDS education
- TB management
- Nutrition programmes

It becomes paramount, therefore, that in the context of the comprehensive care and treatment plan, these gains are not lost to a false sense of security. The plan offers the best locally and internationally accepted standards for the clinical management of people with HIV and AIDS. However, the currently available body of evidence and knowledge on HIV and AIDS still identifies prevention as the cornerstone of any country's response and programme. Hence, the importance of prevention interventions should not be lost. Newer interventions such as those proposed in this plan will ultimately augment or maximize the impact of established interventions, not undermine them.

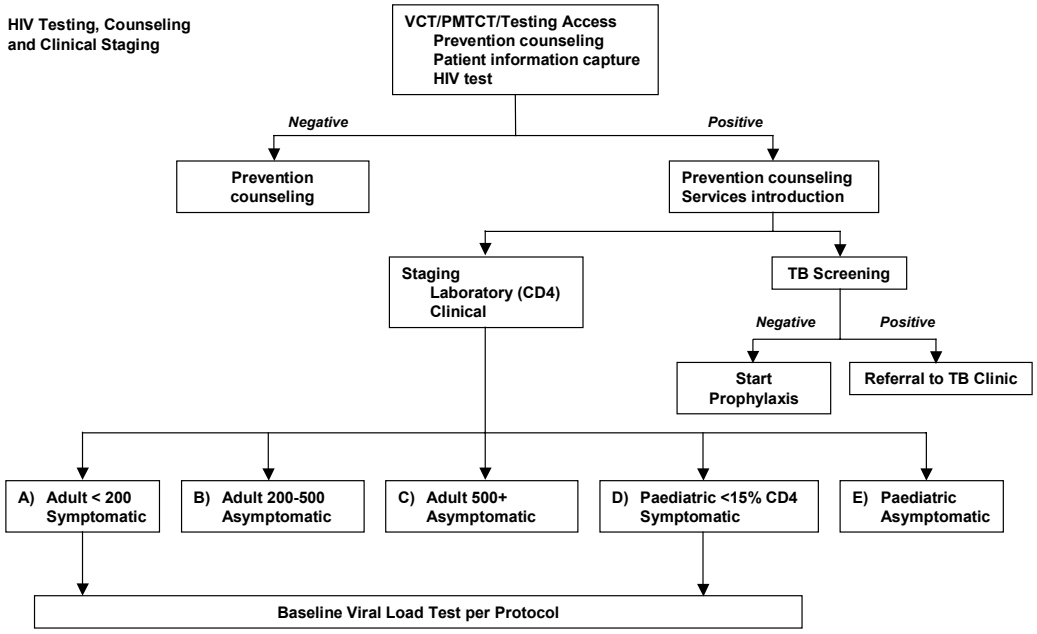
Against this background, the Joint Health and Treasury Task Team costed the implications of strengthening current prevention efforts as part of the requirements to improve our country's overall machinery in the fight against HIV and AIDS. The Joint Task Team estimated that an allocation of between R550 and R570 million per annum would achieve this objective. Such financial resources are available within the current Medium-Term Expenditure Framework and efforts have began to make them part of current initiatives, such as the national Khomanani IEC campaign.

APPROACH

1. Continuum of Care

The continuum of care has as its basis an individual who seeks out care at different levels of the health system and follows him or her through diagnosis of HIV infection and throughout the duration of the illness (see Figure 1.1).

Figure 1.1: Entry into Continuum of Care



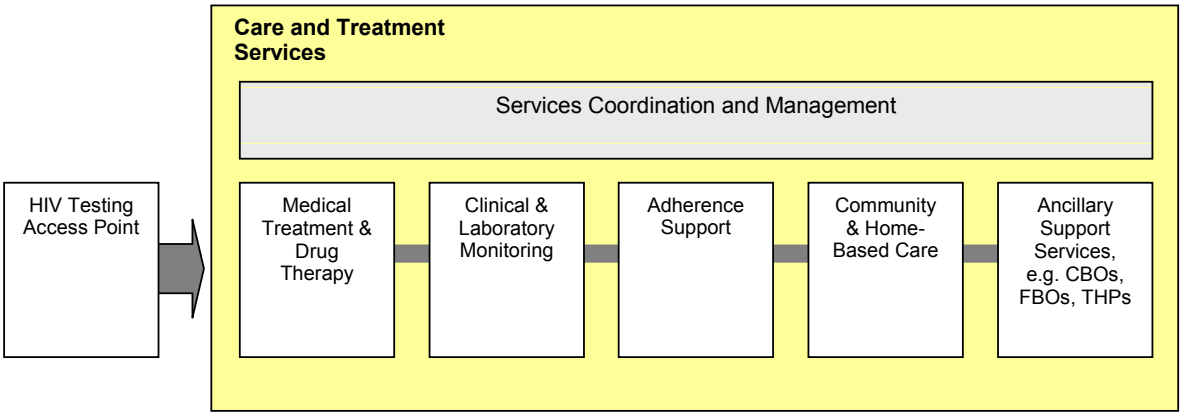
There are multiple entry points into the care delivery system, including voluntary counselling and testing venues, PMTCT programmes, clinics offering reproductive health and STI services, primary health care clinics, TB clinics, inpatient hospital settings and prisons. Following diagnosis and staging 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 (Figure 1.1).

2. Service Coordination

Over the course of diagnosis and care for HIV and AIDS, numerous providers and delivery systems interface to address patient needs. The designation of a Care Coordinator maximizes coordination of patient services, including linkages with adherence and ancillary support systems, referrals, and follow-ups with diagnostic and consultant services at other locations. Other critical linkages facilitated by nurses/counsellors include those to ancillary community-based services such as home-based care, traditional health

practitioners, hospice, and palliative care provided by a full range of NGOs, CBOs, FBOs, and support groups run by persons living with HIV and AIDS (Figure 1.2).

Figure 1.2: Continuum of Care Services



3. Referral and Consultation

For patients with complex medical needs related to HIV, it is necessary that consultation and referral mechanisms are available to ensure that appropriate patient care is delivered. Clinicians from district hospitals will initiate most requests for consultation and patient referrals. Such requests will be channelled to the appropriate district or regional hospital, following a preliminary clinical assessment. Consultative capability in the referral hospital should include: Infectious Disease Control, Internal Medicine, Neurology, Ophthalmology, Gastroenterology, Oncology and Paediatrics. When the specialist is located in a different facility, issues around transportation and follow-up need to be formalised to ensure that the recommendations by the referring clinician are carried out. The patient should be referred back to the original referring provider for continuity of medical care wherever possible.

4. Home-Based Care

NGOs and CBOs can provide care services in the home. Home-based care is a particularly useful tool to assess and support patient adherence to ARV and other therapies, including locating and reaching out to patients who miss scheduled appointments, promoting continuity of care and adherence with ARV regimens. Palliative care services can also be provided through home-based programmes working to train and support the patients' families and friends to ensure the highest achievable quality of life.

5. Prevention Counselling and Support

a. Risk Reduction

Prevention counselling is a key element of routine care provided to all patients presenting for HIV testing. For patients who test HIV-positive, repeated interaction with trusted providers enables discussion on how to avoid transmission of the virus to family, friends and partners. This includes counselling around high-risk sexual behaviours, IV drug abuse, avoiding re-infection, the diagnosis and treatment of STIs, opportunistic infections and clinical screening for TB. Patients who undergo VCT and test HIV-negative will receive prevention counselling that emphasizes behaviours that keep this population HIV negative.

b. Maximizing Health and Slowing Progression

The majority of individuals who initially test HIV-positive are likely to be asymptomatic or in earlier stages of disease. All should be embraced into a constellation of health services focused on slowing progression and helping retain the individual in care throughout his or her life. This includes activities that reduce stress, promote adoption of healthy lifestyles including proper nutrition and the use of immune boosters, cessation of unhealthy habits (e.g. unsafe sex, use of tobacco, alcohol, illicit drugs and intravenous drug use), prophylaxis of preventable opportunistic infections and early identification and treatment of TB.

c. Community-Linked Prevention Strategies

Community groups including faith and community-based organisations, workplace programmes, NGOs, traditional health practitioners, associations of PLWHA, general practitioners, and home-based care providers have a role in carrying prevention messages forward. Community-based services can do a great deal to minimize fear and discrimination, providing and reinforcing accurate information to address stigma surrounding HIV infection. Together, these mechanisms better ensure that persons living with HIV will receive ongoing information, care and support to minimize the risk of transmitting the virus to others and to maintain good health and slow progression of disease.

6. Levels of Care

a. Primary Health Care Level

Integration of HIV- and AIDS-related services into existing systems at the primary care level reinforces the national strategy for primary health care. Primary health care clinics and community health centres are the primary sites for diagnosis, staging and routine follow-up of HIV-positive patients. For patients who begin ARV treatment, these sites will provide the majority of ARV adherence monitoring and support. In some cases, where appropriate expertise exists, ARV treatment may also be initiated at the primary and community level. Additionally, individuals will receive counselling, nutritional assistance, psychosocial support and appropriate social welfare evaluation where necessary. The link between the primary health care facility and home- and community-based services is central to achieving good patient follow-up and continuity of care.

Patients who are early in the course of their infection will require less frequent laboratory monitoring, and will benefit primarily from counselling to promote prevention, good nutrition, stress reduction, and behavioural modification, as well as from appropriate immunizations against other preventable diseases. HIV-positive children should receive all routine immunizations according to standard paediatric protocols. Both adults and children should receive cotrimoxazole prophylaxis, an antibiotic which protects against pneumonia and diarrhoea, common conditions associated with HIV infection, when indicated by the degree of immune compromise. A schedule of health maintenance interventions and recommended prophylaxis is provided in Annex I.1.

For patients who meet criteria for ARV therapy (CD4<200 or symptomatic), referral to the district or regional hospital is required for the clinician's assessment and confirmation of eligibility for ARV therapy. Prior to initiation of ARV therapy, patients will be required to participate in a drug-readiness training programme and be assessed jointly by trained counsellors and/or nurses who have been closely involved with the patients and aware of individual social circumstances. This will include an assessment of any other therapies the patient may be on, such as the use of traditional medicines. Once the patient has been initiated and stabilized on ARV treatment, skilled primary health care nurses will be required to provide regular monitoring and follow-up of patients receiving ARVs in conjunction with the clinician. This will be guided by treatment protocols and training on

the side effect profiles of each antiretroviral medication. There should be ongoing communication between the primary health care facility and district hospital HIV and AIDS specialty clinic to ensure that patients are seen and monitored at appropriate intervals according to the national treatment guidelines.

Patient advocates (home-based carers, patient selected treatment 'buddies', and traditional health practitioners) will play a critical role in retention and follow-up of patients. The need for a dedicated cadre of advocates who have access to the patient on ARVs has been shown to be a critical ingredient to maximize adherence and to retain people in care[8]. These advocates also serve to help identify adverse drug events that occur between scheduled visits, and bring patients in for immediate medical attention.

b. District/Regional Hospital Level

District hospitals, and, where appropriate, regional hospitals, have been selected as the appropriate level for initiation and review of ARV treatment decisions in light of the following factors: twenty-four hour patient access; clinician availability; laboratory and diagnostic capability, either on-site or linked by a transportation system; pharmacy capability to secure and safely dispense ARVs; logistical support for regularly scheduled outpatient clinics; and clear consultation and referral lines both up to the reference hospitals and down to primary care facilities. In selected circumstances, where access to a district hospital is limited, ARV initiation may occur at lower level facilities and mobile clinics where the requisite expertise is available.

A team of health professionals with specialized training in the management and treatment of HIV infection should be responsible for delivery of care. This core team is comprised of clinicians, professional nurses, counsellors and pharmacists, with additional access to a psychologist and/or social worker, nutritionist and home-based carers. The delivery of care may take place in a dedicated HIV clinic, or be integrated within a general clinic where the full team is working together. The requirements of the HIV and AIDS care and treatment programme will necessitate the upgrading of basic infrastructure at these facilities. These upgrades will serve to strengthen the public health care system beyond HIV and AIDS.

Patients seen at district hospitals will typically be referred from primary health care facilities for initiation of ARV therapy. Patients presenting with more complex conditions can be evaluated and treated at the primary health care level, and patients referred to the outpatient department following inpatient admissions for opportunistic infections, should enter care at district hospital level. Following clinical assessment and review of laboratory data, clinicians will be able to prescribe the appropriate ARV regimen, which is to be dispensed through the hospital pharmacy. Upon the initial prescription, monthly ARV repeats should automatically be sent to the hospital pharmacy and a three-month supply maintained at the depot to eliminate risk of stock-outs. A reserve stock should be maintained at district hospitals (see Chapter VIII, *Drug Distribution*). It is necessary that patients on ARVs are seen at regular intervals by a clinician at the district hospital according to the national treatment protocol, including at least two visits during the first two months of therapy interspaced with clinic visits at the primary health care facility for side effect and adherence monitoring.

c. Tertiary Facilities

Tertiary hospitals have an important role in both training and expert clinical support to lower-level facilities. Expert clinicians should wherever possible, assist the providers at Level I and II hospitals for consultation and referral of complex patient care issues, including patients with multiple diagnoses, management of side effects and complications of therapy, and ARV regimen decision making. In any situation where treatment failure is suggested, these referral centres should guide decision-making and ARV management either directly or through consultation with the referring clinician.

7. Antiretroviral Therapy

a. Goals of Therapy

The primary goals of antiretroviral therapy are maximal and durable suppression of viral load, restoration and preservation of immunologic function, improvement of quality of life, and reduction of HIV-related morbidity and mortality. Plasma viral load is a strong prognostic indicator in disease progression, and reduction in viral load achieved with antiretroviral treatment and other therapies is correlated with substantial clinical benefits[9-15]. Suppression of plasma viral load to undetectable or low levels is a critical goal of

antiretroviral therapy, as this minimizes the degree of viral replication and potential development of resistance.

b. When to Start

The indication for antiretroviral treatment is based on clinical assessment and CD4 count. These important factors determine whether therapy should be started, or if it can be delayed. The lower the CD4 count, the higher the risk of AIDS and the more urgent the need for treatment. However, the risk of developing AIDS must be weighed against the risks of toxicity and development of resistance. Guidelines for eligibility criteria provide reference (See Table 1.1), but must be considered along with individual patient readiness for starting treatment. Patients must be prepared 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 to overcome fears. Well-informed and engaged patients are the most successful with adherence to therapy. The decision to initiate therapy must therefore be based not only on meeting the criteria and being ready to start, but also on being committed to adhering to treatment over the long term.

Patients who are acutely ill and severely immuno-compromised at the time of admission to a service point must be appropriately treated and stabilised clinically. Once stable, patients should be counselled and consent for HIV testing obtained; thereafter, treatment options must be made available, depending on clinical staging and the patient's choice.

Table 1.1: Criteria for ARV Initiation in Adults and Adolescents

ADULTS and ADOLESCENTS – including pregnant women
• CD4 $\leq$ 200 cells/ mm^3 and symptomatic, irrespective of stage, *or* • WHO stage IV AIDS defining illness, irrespective of CD4 count, *and* • Patient prepared and ready to take ARVs adherently

** Note: Treatment recommendations are based on increased (15%) probability of developing AIDS-related complications within 3 years.*

c. Adult ARV Drug Regimens

Due to the availability of approved drugs in South Africa and resource constraints, the choices of ARV regimens are not unlimited. Several factors have been considered in the selection of regimens, including safety profile, monitoring requirements, cold storage and potential for development of resistance (further elaborated in the notes for Table 1.5). A second-line regimen is available in the event of treatment failure of the first-line treatment. Men, and women of childbearing age, should be considered for regimen 1a therapy as outlined in Table 1.2. Special considerations around pregnancy are discussed below.

Table 1.2: Adult ARV Regimens and Routine Monitoring During Treatment

Regimen	Drugs	Test	Frequency
1a	d4T / 3TC / NVP	• CD4 • VL • ALT	• Staging, 6-monthly • Baseline, 6-monthly • Baseline
1b	d4T / 3TC / efavirenz	• CD4 • VL	• Staging, 6-monthly • Baseline, 6-monthly
2	AZT / DDI / Lopinavir / Ritonavir	• CD4 • FBC • Fasting cholesterol	• Staging, 6-monthly • Baseline, 1, 3, 6 mo, continue 6-monthly • Baseline only

- **Regimen 1a** – first-line for: (1) men (2) women of child bearing potential (3) pregnant women and (4) conditions where EFV is contraindicated (e.g.: psychiatric diagnosis)
- **Regimen 1b** – alternate first-line for persons who: (1) develop NVP intolerance (2) have evidence of hepatotoxicity and (3) other conditions where NVP is contraindicated. * *Avoid in pregnancy and women of childbearing potential*
- **Regimen 2** – use as (1) second-line for patients who 'fail' regimens 1a or 1b, or (2) first-line in patients who have evidence of NVP resistance prior to ARV initiation.
- ***Staging*** = initial testing for all patients after testing HIV-positive
- ***Baseline*** = testing for ARV eligible patients, at initiation of ARVs

d. Prior ARV Exposure

Individuals with prior exposure to ARVs may present for treatment. Some percentage may be at risk for the development of ARV resistance, if ARV therapy has been received for

short periods or in patterns of intermittent use, and/or if sub-optimal mono- or dual-therapy regimens were taken. These individuals should not be excluded from ARV access; however, a complete history of ARV and other therapies must be obtained to enable a rational approach to ARV regimen selection. Final decisions will largely be made at the district hospital level but should not be seen as only occurring at this level. The critical point is that recognized expert consultation be engaged in making any decisions that diverge from the written recommendations. Consultation with clinicians with experience in managing these patients is the best way to succeed in choosing the optimal regimens. This could occur at the community health centre or clinic level if the expertise is available. Decisions should be made on an individual basis. Where indicated and available, agents should be selected to which the patient has not been exposed, and/or from alternate categories where cross-resistance is unlikely[16].

e. Routine Monitoring

Regular monitoring and evaluation, both clinical and laboratory, is a critical component of management of HIV-positive patients at all stages of disease, and necessary to maximally prolong health and slow progression to AIDS-defining illnesses. Frequent monitoring affords the opportunity to reinforce messages of prevention, while enabling early detection and intervention for clinical, immunologic and psychological decline. As disease progresses, so too does the need for increased frequency of follow-up with all members and levels of the health care team. Once antiretroviral therapy is initiated, clinical and laboratory monitoring is needed to detect drug-intolerance, drug-reactions, drug toxicity, drug-drug interactions as well as treatment failure and the need to either reinforce adherence or switch regimens. Monitoring and evaluation of adherence is also critical to identify to eliminate potential or observed barriers to adherence. Thus, ongoing monitoring and evaluation, performed in the context of an integrated and comprehensive team approach to health care, will maximize the chance for treatment success.

f. CD4 and Viral Load Testing

Progression of disease and decreased durability of benefit from antiretroviral treatment and other therapies correlates with CD4 count below 200 cells/mm^3. The standard of care highlights the importance of intervening with ARV therapy before patients fall significantly below 200 CD4 cells[17]. Current recommendations do not include an

increased frequency of CD4 monitoring for patients whose CD4 count falls between 200-350 cells/mm^3; therefore, provider discretion will be necessary to consider the patients' overall rate of decline of CD4 count and duration of time before their next recommended follow-up and CD4 repeat (see Table 1.3). Acute illness or vaccination has a transient effect on both CD4 (decrease) and viral load (increase) values. Therefore, patients who present for routine CD4/VL monitoring should be re-scheduled for testing if there is a likelihood of aberrant values [1 month or more following acute illness, more than 2-3 months for TB].

Table 1.3: Staging CD4 and Viral Load Monitoring

CD4 count	Test	Frequency
> 500 cells/ mm^3	CD4	• Staging, 12-monthly
200 – 499 cells/ mm^3	CD4	• Staging, 6-monthly
< 200 cells/ mm^3 *and/or on ARVs*	CD4 VL	• Staging, 6-monthly • Baseline, 6-monthly (for regimen 1 only)

- *Staging – initial testing for all patients after HIV+ test*
- *Baseline – testing for ARV-eligible patients prior to initiation of ARVs*

g. Management of TB and HIV

TB is likely the leading cause of death among HIV-infected persons[18]. TB accounted for an estimated 30% of the all AIDS related death in 1999[19]. It has been suggested by WHO that from a global public health perspective, the effective treatment and control of TB must remain a central priority when treatment strategies for co-infected patients are being developed. However, the use of antiretroviral drugs among persons being treated for TB is complicated by overlapping toxicity profiles of some antiretroviral and anti-TB drugs, namely protease inhibitors and non-nucleoside reverse transcriptase inhibitors and the rifampicin-containing anti-TB regimen. Similarly there are concerns about drug malabsorption and complex drug-drug interactions and the occurrence of paradoxical reactions among co-infected patients (TB and HIV).

Due to the high TB and HIV co-infection rates in South Africa, many individuals who meet the criteria to receive ARVs through the Plan will have pulmonary TB[20]. Similarly, patients started on ARVs often flare with symptomatic TB as their immune status

improves (see *Immune Reconstitution Syndrome*). It is for these reasons that the antiretroviral regimens selected for this programme have options that are compatible with current TB regimens.

The current WHO guidelines for use of antiretroviral therapy in TB and HIV high burden countries recommend that until more information is available, ARVs should be initiated in TB patients with ongoing TB treatment if there is a very high risk of HIV disease progression and mortality[21]. This would occur mainly among TB patients with low CD4 T-cell count (<200 cells/mm^3). Therefore, individuals who are diagnosed with acute pulmonary TB prior to ARV initiation, should be started on appropriate anti-TB treatment (4-drug combination therapy with Rifafor) and should complete two months of therapy or longer until clinically stable, prior to starting ARV treatment. Individuals who develop pulmonary TB while on the first-line ARV regimen should be continued on their ARVs (as long as the ARVs are compatible with TB treatment): however, they should be monitored closely for development of hepatic (liver) toxicity in the context of co-administration of isoniazid (a component of the TB therapy) and a non-nucleoside reverse transcriptase inhibitor (nevirapine or efavirenz).

The usual symptoms of liver damage are non-specific initially, with fatigue and malaise predominating. This progresses to increasing fatigue, darkening of the urine colour (*coca cola* or tea coloured), lightening of the stool and jaundice. This would be preceded by elevations in ALT. If significant hepatotoxicity does develop, a switch to a rifampicin-compatible second-line protease inhibitor containing regimen may be required. This should be done in consultation with an HIV experienced provider. In patients presenting with active TB in late stage HIV (moribund) the treating clinician may not feel the patient can wait for two months of anti-TB treatment before initiating ARV treatment. This is a situation that may warrant starting both TB treatment and HIV treatment concomitantly. This should be discussed with an experienced HIV provider.

h. Immune Reconstitution Syndrome

Exacerbation of clinically occult infections (e.g. TB, CMV, fungal, toxoplasmosis) in an immunodeficient patient must be anticipated after beginning antiretroviral therapy. Patients can 'flare' with signs and symptoms of an acute opportunistic infection during the

first few weeks of ARV therapy due to an enhanced immune response. This immune reconstitution with associated clinical symptoms is not indicative of a drug failure or adverse events as a consequence of the treatment, and should not warrant considerations around switching regimens. The focus should be on diagnosing and treating the opportunistic infection. In these situations consultation with an experienced provider is warranted. It is important that a full drug history be obtained to exclude the possibility of interaction with traditional or alternative therapies.

i. Pregnant Women

Eligibility criteria for starting antiretroviral therapy (see Table 1.1) in pregnancy will not differ from other adults; however, the default first-line regimen for all women will include nevirapine as the NNRTI (non-nucleotide reverse transcriptase inhibitor) agent rather than efavirenz due to the potential of efavirenz to cause foetal abnormalities (see Table 1.2 footnote 1a/1b). All pregnant women with a CD4 <200 cells/mm3 should be started on ARVs after the first trimester. Pregnant women with CD4 counts between 200 and 350 CD4 cells/mm3 should be strongly considered for initiation of antiretroviral therapy after the first trimester, with therapy to be continued for life. Women who become pregnant while on ARVs should continue therapy without interruption, including during the first trimester. For pregnant women who test HIV-positive during labour, single-dose nevirapine will be used for PMTCT per guidelines.

8. Antiretroviral Therapy in Paediatrics

a. Diagnosing HIV in Paediatrics

Using the most widely available HIV test (ELISA), it is not possible to tell whether a newborn infant has been infected with HIV. Maternal antibodies may be present in the infant's blood for 12-18 months after birth. Thus, a child may test HIV ELISA positive prior to 15 months when they are not actually infected. Confirmation of HIV-positive status is required for ARV treatment consideration. Infants aged below 18 months presenting with suspected AIDS will require an HIV p24 Antigen test (current cost R 52.63 per test) to determine their true HIV status, due to the risk that ELISA or rapid tests may react to residual maternal antibodies. Likely numbers of babies requiring treatment in this age group have been estimated with reference to the ASSA2000 model's one-year age-band projections.

Confirmation of HIV-positive status in children over 18 months of age still requires two positive ELISA tests until HIV DNA PCR or p24 antigen test can be integrated into the system of care. HIV-infection must be suspected in children who have more than 2 hospital admissions per year for HIV complications or a prolonged hospitalisation (> 4 weeks).

b. When to Start ARVs in Children

Just as with adults, the decision to start treatment in children must take into account patient readiness along with the clinical and CD4 eligibility criteria. In the case of infants and children, 'patient readiness' refers to readiness of the responsible person who will be administering the ARV drugs. It is mandatory that at least one responsible person be present who is capable of ensuring adherence to the child's ARV schedule. Other factors that may be considered by the health care team to determine treatment readiness, include: primary health clinic attendance record, immunization record, and previous history of medication compliance (anti-TB, nutritional supplementation). Clinical and CD4 eligibility criteria for starting therapy are listed in Table 1.4.

Table 1.4: Criteria for ARV Initiation in Children < 6 Years Old

PAEDIATRIC
• 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

** Note: Treatment recommendations are based on increased (15%) probability of developing AIDS- related complications within 3 years.*

c. Paediatric ARV Drug Regimens

As is the case for adults, there are a limited number of ARV agents currently approved and available for use in children. Given these limitations, factors considered in the selection of the paediatric regimens included safety profile, monitoring requirements and potential for

development of resistance (see Table 1.5). A second-line regimen is available in the event of failure of the first-line treatment. Government will maintain one national protocol, allowing for regimens to be changed over time as clinical assessment and practice evolve.

Table 1.5: Paediatric ARV Regimens and Routine Monitoring on ARVs

Regimen	Drugs	Test	Frequency
1a	d4T/ 3TC Lopinavir/Ritonavir	• CD4 • VL • ALT • Chol/TG	Staging, 6-monthly Baseline, 6-monthly Baseline Baseline, 12-monthly
1b	d4T/ 3TC / NVP	• CD4 • VL • ALT	Staging, 6-monthly Baseline, 6-monthly Baseline, 1 m, 6-monthly
1c	d4T / 3TC efavirenź	• CD4 • FBC	Staging, 6-monthly Baseline, 1, 3, 6 mo, 6-monthly
2a	AZT / ddI Lopinavir/Ritonavir	• CD4 • FBC • Chol/TG	Staging, 6-monthly Baseline, 1, 3, 6 mo, 6-monthly Baseline, q 12 monthly
2b	AZT / ddI efavirenz or NVP	• CD4 • ALT • FBC	6-monthly Baseline, 1 mo, 6-monthly (NVP only) Baseline, 1,3,6 months, then 6-monthly

Notes:

- *d4T syrup requires refrigeration. If no refrigerator at home, switch d4T to AZT. Clinician discretion to substitute ABC for d4T in infants > 3 months of age.*
- *NVP - Choice between first-line regimens is informed by: (a) previous exposure to NVP within last 12 months consider lopinavir/ritonavir; (b) children without history of NVP exposure can receive regimen 1b or 1c, 2b is 2nd line if regimen 1a was given*
- *efavirenz - limited to children >3 yrs of age and >13 kg.*
- *For drug failure criteria in paediatrics refer to: Continuum of Care Building for HIV - Paediatric Section, developed by the national Department of Health*
- *'Staging' – initial testing for all infants/children after confirmed HIV-positive*
- *'Baseline' – for ARV eligible children at time of ARV initiation*
- *(See Annex I.6 for paediatric ARV detailed dosing and drug information)*

d. Cotrimoxazole Prophylaxis

There is overwhelming evidence that cotrimoxazole prophylaxis prevents *pneumocystis carinii* pneumonia, a common opportunistic infection in HIV infected infants. Cotrimoxazole prophylaxis also protects against selected invasive bacterial disease. Prophylaxis should start in infants born to HIV-positive mothers after 6 weeks of age (See Table 1.6), and should be continued until risk of HIV exposure has ceased and HIV infection has been ruled out (e.g. negative ELISA after 15 months of age or HIV PCR after 1 month of age).

Table 1.6: Cotrimoxazole Use in HIV-positive Children

Who Should Receive Cotrimoxazole Prophylaxis?	
• Infants (> 6 weeks) born to an HIV-infected woman irrespective NVP use for PMTCT • Infants (> 6 weeks) confirmed HIV-positive during first year of life by DNA PCR • Clinical diagnosis of HIV infection and positive serology • Children (> 12 months), with symptomatic HIV disease or AIDS-defining illness (WHO category II or III) should continue Cotrimoxazole prophylaxis for life.	
When Should You Start Cotrimoxazole Prophylaxis?	
• At 6 weeks of age for infants born to an HIV-positive mother • At any time when the infant/child fulfils the initiation criteria	
Cotrimoxazole Dosage (5mg/kg trimethoprim + 20mg/kg sulphamethoxazole)	
Weight	**Dose**
• < 5 kg • 5 – 9.9 kg • 10 – 14.9 kg • 15 – 21.9 kg • > 22 kg	• 2.5 ml daily • 5 ml daily • 7.5 ml daily • 10 ml or 1 tablet daily • 15 ml or 1.5 tablets daily

e. Nevirapine resistance

Resistance monitoring is critical in infants exposed to nevirapine in the PMTCT programme, as nevirapine resistance mutations have been seen in almost half of babies exposed to nevirapine through PMTCT[22]. Guidelines and recommendations will be updated as new information from sound studies becomes available. Until further

evidence, nevirapine will remain available as an agent in the first-line regimen recommended for use in children but lopinavir/ritonavir may be substituted for nevirapine in first line regimen when clinically indicated (Table 1.5 footnotes 1 and 2).

9. Changing or Stopping Antiretroviral Treatment

a. Treatment Failure – Changing Regimens

Treatment failure can be defined as virologic, immunologic and/or clinical. Treatment failure results from failure to suppress viral replication with the development of viral resistance. Primary virologic failure is less than 1-log (10 fold) drop in viral load after 6-8 weeks of therapy. Secondary virologic failure is 1-log (10 fold) increase in from lowest recorded level. Immunologic failure is defined as a 30% drop in CD4 count from peak value or a return to pre-ARV baseline or lower. Clinical failure is progression of disease with the development of opportunistic infections or malignancy occurring 3 months or more after initiation of ARV therapy.

Clinical failure must be distinguished from Immune Reconstitution Syndrome. A favourable CD4 T-cell response can occur with incomplete viral load suppression and might not indicate an unfavourable prognosis. The urgency of changing therapy in the presence of low-level viraemia is tempered by this observation. Continuation of existing therapy does not lead to rapid accumulation of drug-resistant virus in every patient. A reasonable strategy is maintenance of the regimen, with redoubled efforts at optimising adherence and increased monitoring. If it is determined that a patient should switch regimens due to treatment failure, there should be a switch from their first-line combination to a completely new standardized second-line regimen.

b. Drug Toxicity or Intolerance – Single Substitutions and Interruptions

Patients with a good response to an ARV regimen including adequate viral suppression may develop signs of drug intolerance or drug toxicity. If this toxicity is clearly linked with a single drug in the regimen, that drug can be discontinued and replaced with a substitute according to the national protocol. Should toxicities develop or side effects occur which are intolerable enough to compromise adherence, and a specific agent cannot be identified, switching the entire regimen may be appropriate.

In the situation where a patient does not have adequate viral suppression, and a serious toxicity or intolerance develops, it is recommended that the entire regimen be switched. If a low-grade toxicity or intolerance occurs and a temporary interruption in therapy is planned, the entire regimen must be stopped at the same time regardless of whether the offending agent is identified. On resolution of the side effect, all agents should be restarted together under close monitoring.

c) Salvage Regimens

A patient's best chance of good clinical outcomes is when the first line treatment is successful. A second line regimen, whilst still effective, is typically less so than the first line, as the virus may have developed resistance to this class of drugs. If the second line of drugs fails, then salvage therapy may have to be considered. This is highly specialised treatment, requiring referral to a higher-level facility. Salvage regimens are expensive and their clinical benefit may be limited.

From a cost and equity point of view, the greater the number of patients that go on salvage therapy, the fewer the number of patients who will be put onto basic treatment. Hence it would currently not be advisable to provide salvage therapy in the South African public sector. It may be considered as a future option when new laboratory technologies and new drugs become available.

10. Adverse Events Reporting

Identification of a potential adverse drug event by any member of the health care team should be brought to the attention of the primary provider, and when deemed appropriate, reported by the provider to the Pharmacovigilance Unit at the national level using the Medicines Control Council (MCC) adverse drug reaction reporting protocol. The Pharmacovigilance Unit will provide a standardized protocol outlining the grading and reporting criteria for adverse events (AEs). (See Chapter XIII, *Pharmacovigilance*.)

11. Patient Drug-Readiness Training

For individuals who are ARV eligible (CD4 $\leq$ 200 and/or symptomatic) and preparing to begin treatment, specific education or drug-readiness training is essential to provide the knowledge to enable individuals to take ownership of their own health and prolongation of

their lives. Adequate time, qualified knowledgeable staff, well developed training materials and adequate facilities are needed to conduct such programmes. Nurses and/or counsellors may facilitate training. Current recommendations suggest 3-times weekly training sessions to occur prior to drug initiation. Basic topics recommended for inclusion:

- Positive living – dealing with stigma and discrimination, legal issues, disclosure, and healthy lifestyle including good nutrition.
- Basics of HIV and AIDS
- Opportunistic infections – prophylaxis and treatment
- Care and treatment for HIV and AIDS – including ARVs
- ARV side effects
- ARV adherence

12. Adherence

a. Purpose

Adherence to ARV treatment is essential to maintain long-term health benefit and avoid development of drug resistance[23, 24]. It is not possible for health care providers to reliably predict which individuals will ultimately be adherent to their treatment plan, as adherence does not correlate with gender, cultural background, socio-economic or education level, or language barriers between provider and patient. It is therefore essential to provide all patients with a comprehensive plan to support adherence that utilizes multiple strategies and all members of the health care team, as well as family and community.

b. Adherence Assessment and Monitoring - Role of the Health Care Team

Evidence indicates that adherence wanes as time progresses. Thus, monitoring and support of adherence is essential. New diagnoses or symptoms can influence adherence. For example, depression might require referral, management, and consideration of the short- and long-term impact on adherence. A trusting relationship between the patient and members of the health care team is essential. Optimal adherence requires full participation by the health-care team, with every patient interaction representing an opportunity for reinforcement. Supportive and non-judgmental attitudes and behaviours will encourage patient honesty regarding adherence and problems. Clinicians should commit to communication between clinic visits, ongoing adherence monitoring, and timely response

to adverse events or interim illness. Interim management during clinician vacations or other absences must be clarified with the patient. Adherence support must be intensified when sub-optimal adherence is identified (e.g. investigate new barriers, more frequent visits, enlist support of family/friends, review teaching, increase home visits, etc.). For all health care team members, specific training regarding ARV treatment and adherence should be offered and updated periodically. (See Table 1.7 for adherence support methods)

Table 1.7: Adherence Strategies

Strategies to Promote Adherence
• Spend time and have multiple encounters to explain goals of therapy and need for adherence. • Consider monitoring of medications such as cotrimoxazole or other surrogate prior to ARV initiation. • Negotiate a treatment plan that the patient can understand and to which he/she commits. • Encourage disclosure to family or friends who can support the treatment plan. • Inform patient of potential side effects – severity, duration, and coping mechanisms. • Establish 'readiness' to take medications before ARV initiation. • Provide adherence tools where available: written calendar of medications, pill boxes. • Encourage use of alarms, pagers or other available mechanical aids for adherence. • Avoid adverse drug interactions; full disclosure for over-the-counter drugs and traditional medicines. • Anticipate, monitor and treat side effects. • Include adherence discussions in support groups. • Develop links with community-based organizations to support adherence. • Encourage links with support groups. • Create links with patient advocates.

13. Traditional Medicine

Health seeking behaviours are largely affected by cultural norms and personal belief systems. A large percentage of patients have deeply rooted traditions around maintenance of health and treatment of illness, and utilise traditional health practitioners as their first

point of contact for health care. Traditional health practitioners hold positions of authority within the community and their advice is widely respected. As a well-established and accepted form of health care in South Africa, it is essential that traditional medicine and its practitioners be recognized, respected, and engaged in coordinating care for HIV-positive patients that wish to utilize both disciplines. Traditional practitioners may play an important role in raising public awareness and promoting acceptance of VCT as well as adherence to TB and antiretroviral therapy. (See Chapter III, *Traditional Medicine.*)

14. Care for Caregivers

For persons involved in care for patients with HIV and AIDS, both paid and volunteer, burnout is a common issue due to the tremendous emotional and psychological stress that accompanies work where recurrent illness, hardship and death is a constant. Due to the acute needs of the patients, the needs of staff looking after them are often overlooked. Additionally, many staff members are themselves infected and affected by HIV and AIDS, making their work doubly challenging. Provision of time and structured programmes for debriefing and grief management for staff members, especially after loss of patients who were well known and close to staff, is particularly helpful. Given constraints on time, resources, and availability of trained psychologists and counsellors, co-workers and peers can play an important role in support. Developing staff support programmes will help facilities attract and retain personnel and will have benefits that stretch far beyond the HIV and AIDS care and treatment programme (See Chapter V, *Human Resources and Training*). The Department of Health is currently developing guidelines to improve working conditions for caregivers.

Motivated and talented persons who have committed their lives to caring for persons living with HIV and AIDS are essential and precious commodities; therefore, these persons should be supported to the extent that resources allow. Each facility and HIV health care team must develop strategies and programmes that meet the individual needs of their site and team members. Availability of antiretroviral treatment for all persons in advanced stages of HIV infection, including health care professionals, may decrease stigma and discrimination for staff who are HIV-positive, and promote disclosure and support amongst peers.

SPECIAL CONSIDERATIONS

South African Military Health Service

The South African Military Health Service (SAMHS) plans to implement a comprehensive HIV and AIDS care and treatment programme for military personnel and their dependents. This programme will complement existing programmes focused in SAMHS on prevention, diagnosis and treatment of opportunistic infections and sexually transmitted infections, prophylaxis in instances of occupational exposures such an injuries and in instances of sexual assault, PMTCT, and nutritional supplementation. SAMHS is participating in a research project that will involve ARVs. The implementation of antiretroviral treatment is expected to commence in January 2004. Prior to that time, training of SAMHS medical personnel in the safe and correct use of ARVs will take place, in collaboration with the national Department of Health. Plans will also be finalized for the purchase of necessary laboratory equipment and antiretroviral drugs in concert with the Department. Those HIV-positive persons completing their military service will be referred into ongoing care to ensure the continued benefit from care and treatment services.

Correctional Services

There are approximately 180,000 prisoners in South Africa. The number of HIV-positive prisoners is unknown. Correctional Services is not currently within the public health sector, but relies on referrals to public facilities for clinician care. In order to offer HIV and AIDS care and treatment, tight linkages with the public health system will be needed, so that patients requiring evaluation for antiretroviral therapy can be appropriately assessed and started on ARVs by skilled clinicians. The health care team will refer prisoners back to Correctional Services for ongoing primary care follow-up for HIV, with referrals for specialized care in public facilities according to national treatment guidelines. Upon discharge from Correctional Services, clear referral to ongoing care is to be formalized to ensure continuation of therapies and reinforcement of prevention counselling and support.

ADMINISTRATIVE STRUCTURE

Administrative systems will be put in place to support the planning, implementation, monitoring and evaluation of the integration of antiretroviral treatment within comprehensive integrated systems of care (see Chapter XV, *Programme Management*).

Chapter II

NUTRITION-RELATED INTERVENTIONS

OVERVIEW

The relationship between HIV and AIDS and poor nutrition has been well established[1]. Infection with HIV exacerbates the impact of poor nourishment, while poor nutrition hastens the progression of HIV infection to AIDS, wasting and death. Opportunistic infections and their associated symptoms limit food intake and intensify resting energy demands, increasing nutritional needs. HIV-related symptoms such as anorexia, nausea, vomiting, malabsorption, and diarrhoea further worsen poor nutrition. For undernourished HIV-infected people, the resulting downward spiral of inadequate nutritional intake, inability to maintain weight and lean tissue mass, micronutrient deficiency, and increased susceptibility to opportunistic infections accelerates the development of AIDS. This decline ultimately leads to malnourished, HIV-infected people who become economically unproductive and unable to control their illness. Similar principles apply to TB, where nutritional deficiencies also accelerate disease progression, and impair response to medications.

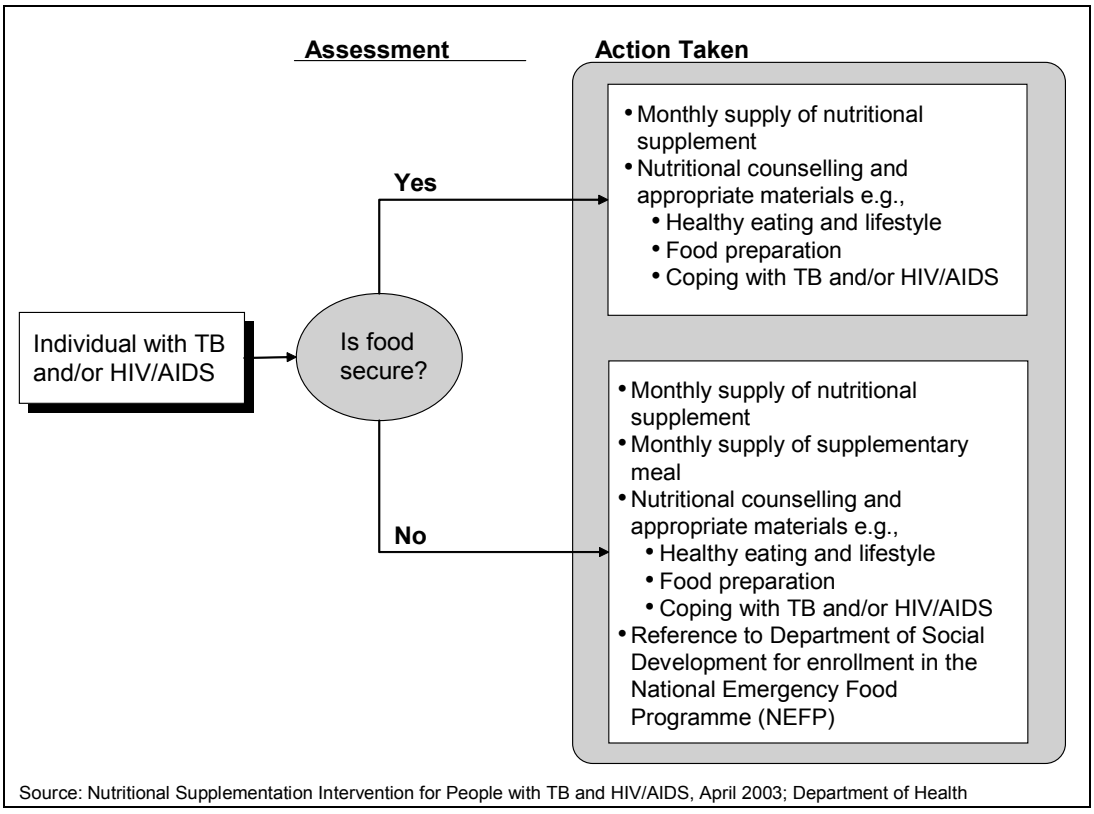
BACKGROUND AND RATIONALE

The South African government seeks to implement a comprehensive nutritional programme with the introduction of HIV and AIDS care and treatment. The implementation of the nutrition supplementation intervention will be within the broad existing government policies and strategies aimed at eradicating poverty, providing better nutrition, and promoting healthy lifestyles in both HIV-negative and HIV-positive populations.

Existing integrated nutrition programmes include the National Emergency Food Programme (NEFP) to alleviate food insecurity and the Nutrition Supplementation Intervention for TB and HIV-infected individuals, which provides supplement meals and micronutrients. These programmes have facilitated improvements in food intake for many South Africans, and have encouraged the establishment of sustainable projects such as vegetable gardens and small-scale poultry farming. These programmes are examples of

joint collaborations among the departments of Health, Social Development, and Agriculture. For maximum impact, these programmes must be integrated and expanded to cover the nutritional needs of all those infected with TB and HIV. The Department of Health 2003 guidelines initiated the provision of supplement meals and micronutrients to all people with TB, HIV and AIDS along two broad options, delineated in Figure 2.1.

Figure 2.1: Nutritional Response to HIV and AIDS



Source: Nutritional Supplementation Intervention for People with TB and HIV/AIDS, April 2003; Department of Health

The HIV and AIDS care and treatment programme will assist many people in these groups to participate in existing nutritional programmes, as well as extend nutritional services to additional groups.

APPROACH

TB and HIV Infected Individuals

In South Africa, both TB and HIV infection occur among adult and paediatric populations that already suffer from inadequate nutrition. Food choice may be affected by a number of factors, including knowledge and sources of information, socio-economic status, and

manifestations of TB or HIV infection. In these undernourished groups, both TB and HIV infections progress rapidly, exacerbating immune deficiency and increasing susceptibility to further infection. Current scientific evidence indicates that an optimal nutritional status with adequate vitamin and mineral levels delays the progression to AIDS[2]. For the majority of South Africans living with early HIV infection, achieving and maintaining a healthy nutritional status will be instrumental in slowing the progression of disease, and delaying the time until treatment with ARVs becomes necessary.

The importance of good nutrition in patients dually infected with HIV and TB cannot be overemphasized. These patients are at highest risk for malnourishment secondary to their disadvantaged state. Through this programme, those without food security will receive vitamin supplementation, as well as referral to existing nutritional services for TB and HIV patients.

HIV-Positive Infants and Children

HIV-positive infants and children face a confluence of three powerful nutritional challenges, namely high nutritional needs to sustain their high growth rate, rapid progression to AIDS associated with significant wasting; and an immature, compromised immune system, with increased risk for opportunistic infections and diminished nutritional intake. Consequently, all HIV-positive children under the age of 14 years who enrol at service points should receive nutritional packages consisting of vitamin syrup and a supplement meal.

In addition, caretakers of HIV-positive infants and children will need to be well informed on nutritional management. Appropriate counselling should be included in regular paediatric clinic visits. In addition, particular efforts should be made to identify households headed by children, and connect them to the network of available nutritional services, specifically those located in the Departments of Health, Agriculture and Social Development.

HIV-Infected Pregnant Women

Recent scientific evidence shows that providing HIV-infected pregnant women with a multivitamin supplement that contains vitamins B, C and E, along with iron and folate,

reduces the potential for vertical transmission of HIV[3]. All seropositive pregnant women should therefore receive micronutrient supplements as part of their care and treatment programme. In addition, those with need should receive supplement meals to ensure their food security.

It has also been established that HIV can be transmitted through breast milk[4]. HIV-infected, lactating mothers will therefore receive appropriate counselling to facilitate informed decision-making, particularly in discordant situations where the newborn child is not infected with HIV. Counselling sessions for pregnant women will focus on:

- Risks and benefits of various infant feeding options, i.e. exclusive breast-feeding vs. exclusive formula feeding vs. mixed feeding.
- For the mothers who choose to use formula, proper preparation, feeding and storage processes.
- Appropriate foods for the mother to eat.

Infant formula may be available to all those who might require it. This is intended particularly in instances where the mother is HIV-positive and the child remains HIV-negative following delivery, in order to decrease the risk of vertical transmission that could occur through breast milk.

Nutritional Supplementation for Persons Receiving ARV Treatment

The HIV and AIDS care and treatment programme envisages the provision of supplement meals to all people with clinical AIDS who are malnourished and are eligible for ARVs, and who do not have access to a secure food supply. Individuals with AIDS who are not food insecure, and who receive care and treatment through a service point, should be referred to one of the appropriate existing nutritional programmes for additional nutritional support, if indicated.

Nutritional Issues Related to the Use of Antiretrovirals

From a clinical perspective, adequate nutrition, appropriate micronutrient supplementation, and the treatment of clinical malnutrition will significantly enhance the effects of antiretroviral treatment and treatments for opportunistic infections.

Some licensed antiretrovirals have food requirements, stemming from the effect of food on drug absorption through the gastrointestinal tract. Table 2.1 summarizes the food requirements for the first and second regimen drugs selected for South Africa. This interdependency of nutrition and ARV treatment emphasises the importance of integrating the ARV programme with nutritional services for maximal clinical benefit.

Table 2.1: Food Requirements for ARVs selected for use in South Africa

Regimen	Generic name	Food Requirement
1st line	Stavudine (d4T)	Take without regard to meals.
1st line	Lamivudine (3TC)	Take without regard to meals.
1st line	Efavirenz (EFV)	Avoid taking after high fat meals.
1st line	Nevirapine (NVP)	Take without regard to meals.
2nd line	Zidovudine (AZT)	Take without regard to meals.
2nd line	Didanosine (ddI)	Take 1 hour before or 2 hours after meal.
2nd line	Lopinavir / Ritonavir	Moderate fat meal increases absorption of capsules and solution. Take with food.

Source: Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, Department of Health and Human Services (US), 2002.

The steadfast national attention to nutritional needs is expected to have a significant positive impact on people living with HIV and AIDS, including those on ARVs.

Comprehensive Nutritional Counselling Services

In addition to the targeted interventions described above, all persons attending service points for HIV care should receive counselling and materials on healthy eating and lifestyle, food preparation and coping with infection. Nutritional counselling for HIV-infected patients helps them to effectively manage their illness, and to understand the wide array of nutritional programmes available to them to help them meet nutritional needs. Elements to be included in counselling and education include basic nutritional education, including weight maintenance; food safety; food strategies that employ locally available foods; and the provision of appropriate recipes. Communities will be targeted with general information on nutrition, with particular emphasis on HIV and AIDS-specific needs, and referral to home-based care programmes.

Coordination with Integrated Nutritional Programmes

This programme is central to the coordination of nutritional care for HIV-infected patients. Available service point nutritionists should provide regular assessments of patients' nutritional needs, evaluate food and supplement needs of patients, and, where necessary and appropriate, refer patients to Social Development and appropriate food security programmes, such as the National Emergency Food Programme (NEFP). The integration of HIV service points with these programmes is expected to augment their effectiveness and assist in their ability to manage additional demand.

SPECIAL CONSIDERATIONS

Accreditation

Assessment of nutritional plans will be part of the service point strengthening and accreditation process (see Chapter IV, *Accreditation of Service Points*).

ADMINISTRATIVE STRUCTURE

National Level

The Department of Health will be responsible for setting nutritional guidelines, coordinating interdepartmental nutritional programmes, and developing nutritional training materials. It is expected that as implementation occurs, provinces will assume administration of the nutritional components of the programme in conjunction with the existing Department of Health initiatives.

Specifically, the national Department of Health will remain responsible for:

- Reviewing the specifications of supplement meals;
- Setting the standard level of the multivitamin/mineral syrup or tablet;
- Reviewing criteria for nutritional supplementation;
- Ensuring that reliable suppliers are identified;
- Developing and updating training materials regarding nutritional assessment, nutrition counselling and education (healthy eating and lifestyle); and
- Coordinating with the Departments of Social Development and Agriculture to ensure adequate coverage of NEFP throughout all service points.

Provincial Level

Each province will be responsible for comprehensive planning to address nutritional needs related to the implementation of the HIV and AIDS care and treatment programme.

The provincial offices will be responsible for:

- Ensuring that staff are appropriately trained in nutrition assessment;
- Ensuring uninterrupted supply of nutrition supplements (supplement meals and micronutrients);
- Follow-up of clients and monitoring of nutritional status;
- Providing nutrition support, especially to in-patients (taking into consideration ability to eat and providing the appropriate feeding regimen and recognising food and ARV interaction);
- Ensuring that secure storage is available and distribution of supplies tallies with supplies received.

Local Level

Dieticians will be required at the district and service point level. These dieticians should be employed wherever possible at accredited delivery points within a district to implement the nutrition supplementation intervention. The dieticians should link with community liaison officers and/or community health workers at the surrounding community health centres and clinics. They should also be responsible for training nurses and community liaison officers, who should also have responsibility for assessing the nutritional status of patients.

PROGRAMME ASSESSMENT

The impact of this programme will be determined by regular review by the provincial Nutrition sub-directorates in conjunction with the Cluster for HIV and AIDS. Nutrition has been identified as a priority research issue for this programme - findings will inform future nutritional interventions. Through these efforts, the impact of the nutritional programme on HIV-related morbidity and mortality can be assessed to determine the relationship between increased access to food, and the ability of HIV-infected individuals to lead healthy lives.

Chapter III

Traditional Medicine

OVERVIEW

The majority of South Africans consult traditional health practitioners on a regular basis for problems of health and disease. These practitioners utilise scientific methodologies that stretch back thousands of years. Often the traditional health practitioner is the first port of call for someone sick with HIV or AIDS. An operational plan for comprehensive HIV and AIDS care and treatment in South Africa must acknowledge traditional medicine as an important modality of treatment for HIV and AIDS – a modality that patients are free to choose, and to discuss with biomedical health practitioners without fear of stigma and being ostracised.

The continuum of care developed for the HIV and AIDS care and treatment programme therefore should involve traditional health practitioners as an essential and irreplaceable component of the comprehensive care provided. As HIV and AIDS care and treatment expands throughout the nine provinces, traditional health practitioners will no doubt continue to play their historic role in treating and caring for all patients, including those infected with HIV. Moreover, traditional health practitioners can enhance the implementation of the antiretroviral therapy component 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 continuing their acknowledged mission in improving patient well-being and quality of life.

Traditional health practitioners tend to adopt a more holistic approach to health promotion and disease management, an approach that is more appropriate to the problem of immune deficiency wherein virologic assaults upon the immune system are compounded by immune exhaustion from concomitant infections, psychological stress such as that due to social isolation, under-nutrition, alcohol abuse, and behaviours that compromise immune recovery such as repeat exposure to HIV and sexually transmitted infections. A holistic

approach to living with HIV and AIDS is known to be a key factor for success in living a longer, healthy life with the syndrome.

South Africa will not be unique in incorporating traditional medicines into the national health system. In the USA and Europe the majority of patients living with AIDS use complementary medicines. In India and China parallel systems of ayurvedic and other traditional medicines are extensively used with good results in the treatment and care of people living with HIV and AIDS. Agencies such as the National Centre for Complementary and Alternative Medicine of the National Institutes of Health of the USA; and the Indian Council on Medical Research have extensive research projects in the use of traditional medicines for AIDS care.

BACKGROUND AND RATIONALE

Estimates suggest that more than 200,000 traditional health practitioners are active throughout the country, and many have joined national, provincial, or local organisations designed to facilitate communication among members and advocate for relevant health concerns with government and in public contexts. It is estimated that 80% of South Africans consult traditional health practitioners, often as their first response to a health problem. Additionally, it is estimated that up to 97% of people with HIV and AIDS first use complementary or traditional medicine, and consultation with a biomedical practitioner is often sought only if problems persist[1,2,3].

Government recognises the significance of traditional health practitioners in communities and in the health care sector, and several years ago began developing a process of certifying these professionals as legitimate health care workers. A Traditional Health Practitioners Bill has been tabled in Parliament, and when enacted will result in the formation of a council of traditional health practitioners similar to those that regulate the registration and practice of other health professionals. In this way members of the public will be assured of the training and expertise of a traditional healer, provided he or she is currently registered. Currently, the Medicines Control Council has expert committees on Complementary and African Traditional Medicines that advise on the regulation and registration of safe, effective and high quality traditional medicines.

In addition to the integration of traditional health practitioners into the public health care system, government has supported formal research and development of traditional medications (plant pharmacology) in the Medical Research Council and other institutions for more than seven years; in the Centre for Scientific and Industrial Research (CSIR); and within the science system generally. This research has included studies on the extraction of active chemical moieties from plants used as traditional medicines—those specifically of South African origin—and complementary medicines from other countries and customs. Clinical trials with natural plant products have also been supported, as have investigations of plants believed to have immune-boosting properties in people living with HIV and AIDS. Efforts also are underway to expand the availability of medicinal plants through horticultural programmes established by various government agencies.

National and international NGO sectors, including the World Health Organisation, have also recognised the significance of traditional health practitioners as health care workers. Traditional health practitioners have been involved in HIV prevention and treatment activities for nearly a decade, affirming their skills in the health field as well as their status within communities. Similarly, traditional health practitioners have been providing care and management of HIV-infected patients, although this has typically occurred outside the realm of government or NGO programming.

APPROACH

Traditional Health Practitioners therefore are an essential part of the continuum of care; and they are keen to play a role in the implementation and expansion of this comprehensive model throughout South Africa. Several stages of development are necessary to realise the collaboration of traditional health practitioners and biomedical workers.

Expanding Dialogue Between National and Provincial Traditional Health Practitioner Organisations and Conventional Medical Practitioners

Efforts to bring together traditional health practitioners to increase their involvement in health care programmes are already underway. Several traditional health practitioner

organisations have been in discussion with government concerning a variety of health care issues and programmes to which traditional health practitioners have begun to contribute.

In the context of the comprehensive care and treatment programme, traditional health practitioners can be significant assets in the implementation phases of the programme. Over the long term, the nature of collaboration between traditional and conventional medicine can be further strengthened, depending on the emerging needs of the HIV-infected population, and of South Africans in general. Guidelines addressing HIV-related care, consistent with the Primary Health Care Manual for Traditional Health Practitioners, will be compiled and widely disseminated. Along with this general approach, more specific efforts will engage traditional health practitioners as formal collaborators in the clinical management of HIV-infected patients through this programme.

Involvement of Traditional Health Practitioners in the Programme

Traditional health practitioners already have training in HIV-related care. This training could be expanded to involve aspects of the clinical roles necessary for successful HIV and AIDS care and treatment, including prevention, treatment, adherence, general counselling, toxicity monitoring, and patient education. This specialised training will require the involvement of traditional health practitioners in the implementation process, enabling them to rapidly mobilise patients and communities over the first several months of the programme. The intention is not, however, to train them to use antiretrovirals.

An expert team of representatives from the Department of Health, the national Strategic Management Team, provincial programme implementation units, biomedical practitioners, and traditional health practitioners will convene to define the role of traditional health practitioners within the care and treatment programme. This group will produce a report, describing the diversity of expertise and activities of traditional health practitioners in South Africa, the current status of collaboration with biomedical practitioners in prevention, care and treatment practices, remuneration issues, and the aspects of traditional medicine that might enhance HIV care. This report will provide a baseline upon which to develop systems for further collaboration. It will also define the level of interest of traditional health practitioners in becoming involved in this programme.

Development of Enhanced Referral Systems

An open channel of communication among the different providers engaged by patients is a prerequisite to the optimal care of HIV-infected persons, and of patients generally. Given the widespread consultation with traditional health practitioners, it will be important to establish means of communication regarding the different interventions that may be pursued by patients. While referral systems and networks among biomedical practitioners generally permit routine follow-up of clients, traditional health practitioners have a comparable system, but little is known of these systems and the two networks have never been linked. This is a critical connection, since traditional health practitioners are often more deeply embedded within local communities. The programme seeks to encourage biomedical workers and traditional health practitioners to connect their referral systems and learn to make effective use of these expanded networks. If obstacles to using referral mechanisms prove insurmountable, the team will develop a different model that will be both bi-directional and functional for all care providers.

Protocols will also be developed to evaluate how best to engage with traditional health practitioners to guide implementation of the HIV and AIDS care and treatment programme in communities. These protocols will evaluate methods and strategies to assess community infrastructure, and to assess the special skills offered by traditional health practitioners and the expectations of traditional health practitioner regarding collaboration with biomedical providers. The biomedical practitioners will also be assessed in order to determine the comparable range of their skill sets and their expectations for working with traditional health practitioners. These protocols will also define techniques for appropriate initial contacts, for collecting interview and group information, and for reporting these results back to the community. Once complete, protocols will be piloted in at least two communities in order to ascertain their suitability for more widespread use. The expert team will review the results of these pilots, and suggest modifications as appropriate. Communication strategies will also facilitate the participation of traditional health practitioners in the continuum of care, and educate communities and biomedical professionals about the nature and benefits of traditional practices, in general.

Development of Quality Assurance (QA) Mechanisms

Methods for quality assurance around the practice of traditional medicine as it relates to HIV and AIDS care and treatment will need to be formalized, consistent with those of traditional health practitioners organisations. This effort will be linked to this programme's monitoring and evaluation process (see Chapter XII, *Monitoring and Evaluation*). Traditional medications will also need to be incorporated into the pharmacovigilance process, including the development of a national database on phytovigilance, including the interactions between ARVs and traditional medicines (see Chapter XIII, *Pharmacovigilance*).

Training Activities and Priorities

Health Promotion and Quality Assurance Training Centres ("Quality Training Centres") should incorporate information about traditional practices in their training programmes (employing resources made available from the National Reference Centre for Traditional Medicines). These trainings should be bi-directional, serving to inform biomedical practitioners of the role and methods of traditional practice, particularly their communication skills with patients, as well as providing traditional health practitioners with information on ARVs and HIV care. Resolution of contradictory recommendations made by traditional health practitioners and biomedical practitioners should be facilitated by these trainings.

Relevant trainings are currently offered through the different traditional health practitioner organizations, and these curricula will be standardized and made available to the Quality Training Centres to avoid unnecessary new programming. Traditional medicine experts should work with the Quality Training Centres to regularly update curricula and trainings as new relevant information becomes available. Linkages with traditional health practitioner organizations that conduct training will need to be formalized in collaboration with the Quality Training Centres, and these organizations should assume responsibility for conducting training sessions. When possible, the local traditional health practitioner organization will be used; otherwise, expertise from a different region will be utilised until local capacity reaches competency.

SPECIAL CONSIDERATIONS

Research

Research related to traditional medicine is largely supported by the Medical Research Council (MRC) and the Centre for Scientific and Industrial Research (CSIR), as well as various other academic institutions. In the future, research information will be collated and disseminated by the recently established National Reference Centre for African Traditional Medicines. This research programme involves the isolation of compounds in medicinal plants and the development of high quality total extracts from plants that produce favourable health outcomes in traditional practices. Additional research issues are expected to include a variety of behavioural studies, including the effects of traditional health practitioners in the delivery of care, the perceptions of traditional health practitioners within different practitioner and community groups, the evolution of traditional health practitioner community status in conjunction with collaborative work, and the evolution of traditional health practitioner practices as this system expands. Research into traditional medicines that are claimed to have immune–boosting properties in PLWHA are being investigated. The Research Cluster will consider expanding the research agenda to include study of a wider diversity of plants from a broader geographic area, and will seek to prioritise this research, develop concept papers and requests for applications (RFA), and pursue appropriate levels of supportive funding through the MRC (see Chapter XIV, *Research Priorities*).

Although traditional health practitioners frequently see HIV-infected patients, the collaboration with traditional health practitioners outlined above suggests that contact between HIV-infected patients and traditional health practitioners becomes routine, particularly where a traditional health practitioner is serving not only as an adherence or drug toxicity monitor, but also as a care and treatment provider. These efforts may strengthen the implementation of the Traditional Healers Bill, promote their organisation, bring acceptance to the traditional practice and support their work.

PROGRAMME ASSESSMENT

The Department of Health will collaborate with the Traditional Health Practitioners Interim Council, and its permanent successor, to ensure ongoing collaboration on implementation of programmes and projects.

SECTION TWO

HUMAN RESOURCES AND FACILITIES

Chapter IV

Accreditation of Service Points

OVERVIEW

In order to expand access to comprehensive care and treatment for HIV and AIDS, it will be necessary to involve large numbers of health care facilities of various sizes and capabilities throughout the country. The engine that will power this undertaking is a plan to strengthen the ability of the public health system to effectively screen, monitor and care for HIV-positive patients, and to certify service points that are eligible to provide ARVs. A service point is a defined geographical area that has the capacity to meet the requirements of accreditation through a single hospital or clinic or through the aggregated facilities and their support services (e.g. laboratories, referral systems, transport, VCT, etc.) within a defined catchment area. In other words, it is a single point or a grouping of health facilities, which combined meet the accreditation criteria, and which could include NGOs, private clinics or corporations. This accreditation process, while taking into account many aspects of the service point, is intended to specifically assess the readiness of the service point and its staff to provide HIV care, including ARVs, and its ability to expand these services. As such, it is not a substitute for, nor is it intended to replace, existing and more comprehensive hospital and clinic accreditation procedures. However, it is anticipated that strengthening of all aspects of HIV care will strengthen overall health infrastructure and services.

The strengthening and accreditation process must be rigorous, to ensure quality HIV and AIDS care, but must at the same time be flexible enough to account for differences in facilities' baseline size, organisation, available personnel, and infrastructure. The Service Point Assessment and Accreditation Guide (Annex IV) is the tool that will be used to initially assess service points, and to reassess them every two or three years thereafter. While the minimum accreditation criteria may seem stringent at first, they largely coincide with current standard operating procedures and practices at public health care facilities in South Africa. After the initial assessment, a service point-specific strengthening plan, based on identified short-, intermediate-, and long-term needs, will be written in

collaboration with the service point. Some facilities will not immediately be able to meet the accreditation criteria. In these cases, appropriate resources should be deployed to meet the target of establishing at least one service point in every health district by the end of the first year of the programme.

APPROACH

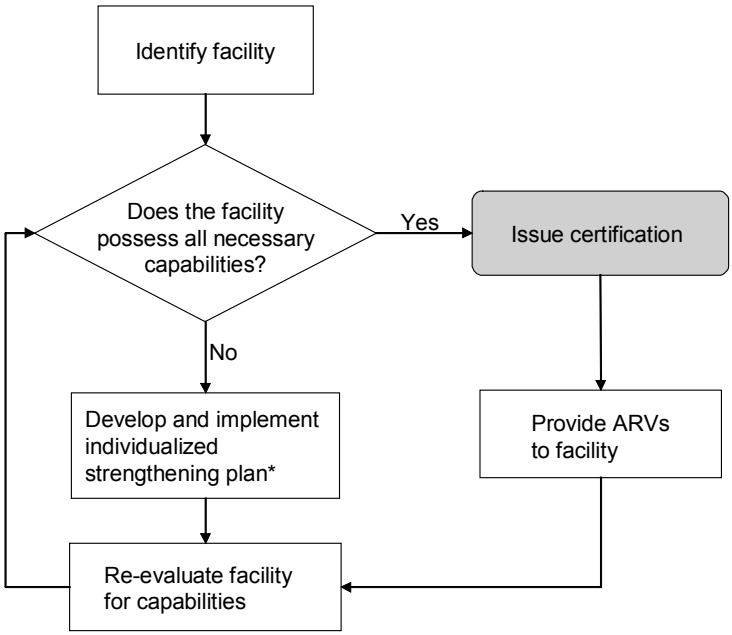
Selection of Service Points and the Strengthening Process

The provinces will be responsible for identifying the projected numbers and locations of service points for programme implementation, within the context of the principle of ensuring equitable access to comprehensive HIV and AIDS care and treatment at the provincial and district levels. These must be approved by the MEC for Health in each province.

During the initiation of the plan, the Strategic Management Team (SMT) (see *Chapter XV, Programme Management*) will supervise the service point assessments and the subsequent strengthening and accreditation process. The SMT will use its discretion in determining whether to work with any third parties to support the assessment and accreditation process in order to expedite implementation.

The strengthening and accreditation process is outlined in Figure 4.1. It is designed to start ARV provision as soon as possible at service points meeting, or close to meeting, accreditation criteria, while at the same time strengthening the remaining service points that have been assessed but have not been accredited.

Figure 4.1: Preparing Facilities For Accreditation



* Includes recruiting and training HCWs, obtaining equipment and improving overall facilities
Source: Team proposal

Service point assessments will be performed during visits by a national team including at least one clinical expert (clinician or senior nurse) and one administrator with project management experience. This team will assist the provincial team in writing a service point-specific strengthening plan immediately after the assessment. This strengthening plan will be the main tool in preparing service points for providing ARVs. It will also assign responsibility for each implementation step and develop a timeline.

It is important to assess and, where needed, strengthen service points sufficiently far in advance to ensure that they can meet the goals of the HIV and AIDS care and treatment plan in a timely manner. This advance preparation is particularly important for service points needing recruitment of additional personnel and/or construction work to expand their facilities. It is important to note that the assessment and strengthening efforts are not restricted to the hospital or clinic setting, but encompass the full continuum of care. For example, an analysis of available VCT and home-based care (HBC) services within the service point area must be undertaken and a plan drawn up for increasing the number (or

effectiveness) of these services if necessary. These activities will require coordination with various sections of the DoH, community leaders and NGOs.

The strengthening plan and subsequent deployment of appropriate resources are intended to enable a service point to meet the accreditation requirements summarised below and described in greater detail in Annex IV.2. The strengthening plan will provide detailed strategies to meet the requirements. The plan will encourage maximum integration with, and improvement of, existing healthcare resources. In addition, a service point should have flexibility to tailor the way it proposes to meet a specific requirement in a manner that reflects the service point's needs and characteristics.

Accreditation Requirements

The following criteria summarise the conditions necessary at a service point to ensure high quality comprehensive HIV and AIDS care and treatment.

1. Presence of a service point project manager, who will supervise programme conduct and expansion. Where practical and effective, a project manager may supervise programme conduct and expansion for more than one service point.
2. Availability of a trained care team on-site with representation of all relevant professions (clinicians, nurses, and counsellors), easy access to trained laboratory, pharmacy and nutritional staff, and links to NGOs and other service providers. The care team should consist of sufficient staff in appropriate ratios to manage the projected number of patients.
3. Implementation and maintenance of current standards of care as provided by the National Treatment Policy Guidelines.
4. Access to care 24-hours a day at the service point, or in the direct vicinity, with coverage relationships explicit to both facility staff and patients.
5. A staff recruitment, training and skills development plan in place for health care workers responsible for HIV and AIDS care and treatment (including volunteers and lay counsellors) based on initial needs and projected long-term patient numbers.
6. Appropriate numbers of consultation, treatment and counselling rooms should be available to assure patient confidentiality, based on projected patient numbers.

7. Access to appropriate laboratory services, which have appropriate equipment, trained operators, and an effective maintenance plan, overseen by the NHLS. Adequate specimen preparation protocols should be in place for service points accessing laboratory services outside their own facilities.
8. Secure and adequate pharmacy storage, and sufficient cold-chain capacity, appropriate to handle Schedule 5 drugs. (See Chapter VIII, *Drug Distribution.*)
9. Adherence to drug dispensing Standard Operating Procedures (SOPs) for OI prophylaxis and treatment, and ARVs.
10. Access to patient nutritional status assessment and nutritional support.
11. Existing links with on-site and/or proximal VCT centres, antenatal clinics, FP clinics, TB clinics, STI clinics, TB/HIV demonstration districts, and any other patient referral facilities, to ensure that HIV-positive patients are formally referred to the accredited service point.
12. A PMTCT programme in place for service points providing antenatal care and a referral system in place for sites without antenatal care facilities.
13. Formal referral systems and links with other operations within the service point (in-patient wards, other clinics, support units) and outside expertise (secondary/tertiary care facilities and sub-specialties, including neurology, ENT, ophthalmology, oncology, pulmonary and infectious diseases).
14. Referral systems and linkages with community resources (NGOs, CBOs, HBC, faith-based organisations, PLWHA groups, traditional health practitioners, community leaders, industry, and other support organisations) that complete the continuum of medical care and support services.
15. Linkages in place with support organisations and NGOs to ensure continuous care and support in the home and community, including support groups, adherence support, educational activities, bereavement counselling and family support.
16. A system in place to track patients/treatments.
17. A system in place to maintain medical records and to transmit core data to a central data collection point.

18. A system in place to ensure that durable equipment is appropriately inventoried and service and maintenance agreements are in place. Where equipment is needed, the service point shall have a plan for procuring and installing the equipment.
19. 24-hours post-exposure prophylaxis (PEP) access, according to the latest national guidelines.
20. A plan for channelling into the care system HIV-positive blood donors, patients treated with PEP, and prison populations identified as HIV-positive.
21. Established links with the provincial HIV and AIDS Unit to coordinate briefing of local officials and to streamline input from local advisory committees.
22. Identification of technical assistance needs in administrative and various other technical areas, including medical training.
23. Participation in IEC activities, in particular by enlisting resources to help educate patients, families and communities about the basics of HIV and AIDS care and treatment, the role that ARV treatment can play, and the difficulties inherent in lifelong treatment for affected individuals and their families.

The Accreditation Process

The minimum service point accreditation criteria must be rigorous enough to ensure quality HIV and AIDS care, including ARV management, while remaining flexible enough to 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 in order to assist them in meeting the minimum criteria for accreditation. A project manager will be designated to participate in the writing of the service point strengthening plan and take responsibility for the plan's implementation and supervision. The result of a service point going through this process will be to improve the capacity and quality of other services offered at a service point, not just its capacity and quality for HIV and AIDS care and treatment. The accreditation process will be repeated every two or three years to ensure continuing quality of care as the programme expands.

ADMINISTRATIVE STRUCTURE

Responsibility for the accreditation process lies with the national Strategic Management Team (SMT). Initially, for the first few months, accreditation will be done directly from the national Department of Health by teams commissioned by the SMT. After this period, provincial accreditation groups will be formed and will carry out accreditation and strengthening activities under standards set by the national Department. Over time this activity will form part of the general quality assessments in the public health sector.

The issues the SMT will want to see addressed in an accreditation application will include:

- Quality – Does the service point have a treatment system in place that will ensure quality health care for HIV and AIDS patients?
- Quantity – Is the point ready and willing to treat an agreed upon number of HIV-positive individuals upon certification, and to increase the patient load as the staff gains experience and the facility is upgraded as need be?
- Accountability – Are protocols and procedures in place to ensure that funds, equipment, and medicines are properly used and accounted for?
- Successful implementation of the service point strengthening plan, if necessary, after deployment of adequate resources

If a point is deemed by the accreditation team not to have yet met the accreditation criteria, an appeal may be submitted to the SMT. The SMT will be responsible for determining next steps.

PROGRAMME ASSESSMENT

The programme's success will be measured by the number of service points accredited within designated timeframes, and progress against the principle of offering equitable access to a comprehensive continuum of services. For example, by the end of the first year of the programme, a minimum of one site should be in place per health district, and multiple points in some districts with large AIDS populations. Assessment will also consider population size when targets are created.

Chapter V

Human Resources and Training

OVERVIEW

The human resources and training strategy for this operational plan is founded upon four core principles: 1) quality of care; 2) investments to more generally benefit the public health system; 3) equitable access; and 4) feasibility in delivering the continuum of care and treatment services to the target number of patients. The Task Team developed this human resources plan based on advice from provincial officials, and best-practice experience in South Africa and other countries.

South Africa's public health care system is already challenged by inadequate resources and a significant burden of disease. Nevertheless, it remains possible to meet the goals of this plan through a combination of training, targeted recruitment, private sector participation, retention strategies, multi-skilling, and the adjustment of roles and responsibilities of the available health care workers to best match the needs of the programme. The additional human resources needed to begin implementation is intended be made available through active recruitment of new personnel and implementing strategies to retain the existing public sector workforce.

To implement the programme, provinces will require additional funding to upgrade their human resources in health. Within recommended guidelines for minimum personnel requirements for each service site, the provincial health managers should be able to utilise the additional funding to hire additional personnel, contract with private sector personnel, or put in place incentives to retain workers. Additional funds will also be required for training of existing clinicians, nurses, pharmacists, counsellors and affiliated health care workers. The implementation needs for the plan can be met, but this will require support from national level that leverages the strengths of the health care system, while seeking creative and innovative solutions for staffing and skill shortages.

This should not be a vertical programme. HIV and AIDS prevention, care and treatment must be tightly woven into the overall public health system. Investments made in human resources and training to get HIV-positive patients into the care they need before they become sick will in the longer-term benefit the public health care delivery system. Further, new staff needed for this programme will also provide support in filling gaps in other areas of health care delivery. The health personnel added by this plan, will be located in district hospitals and community health centres and clinics, and will serve all patients, not only HIV-positive and AIDS patients. Thus, in tackling the challenges for HIV and AIDS care and treatment, human resources for the entire public health system in South Africa will be enhanced.

BACKGROUND AND RATIONALE

General Context of Human Resources in Health

Matching workforce capacity with the skilled human resource needs of the operational plan represents a significant challenge for programme implementation. Significant shortages of professional nurses, medical officers, lay counsellors, and managerial/administrative personnel exist. The retention of trained personnel is a challenge throughout the public health system. Health care workers move from one province to another for family and career opportunities. Other countries actively recruit them, with recruiting firms offering attractive incentives and financial packages to relocate abroad. Rural areas face even bigger challenges for attracting and retaining qualified staff.

The impact of HIV and AIDS on the health sector has strained an already overburdened system. According to the September 2003 Department of Health report, *Essential Health Care for All South Africans*, admissions to public hospitals have increased by over 100,000 per year between 1994 and 2002.

The recommendation for additional human resource capacity to support the implementation of this plan is made in the context of:

- An already overburdened and under-resourced public health service;
- Patients requiring hospitalisation and treatment for other medical conditions are presently crowded out by ill HIV and AIDS patients; and

- ARV treatment is lifelong resulting in a cumulative increase in the number of patients that will require care and treatment over time.

Operational Plan: Patient Targets

A detailed analysis, including provincial visits, was conducted to determine the level of human resources needed for implementation. Provinces submitted proposals on their requirements for additional staffing needs. These proposals were reviewed and adjusted by the Department of Health to allow a standardised approach to estimate staff requirements. (See Chapter XVI, *Budget*.)

Estimates of the underlying demand for AIDS care and treatment have been drawn from the ASSA2000 model, as used by the JHTTT. Based on these epidemiological estimates, ranges for patient demand and achievable treatment coverage have been discussed with provinces to form the basis for provincial planning. The midpoint of the range is reflected in Table 5.1 below.

Patient demand was translated into total patient visits as shown in Table 5.2, using the care model in Chapter I, *Prevention, Care and Treatment.*

Estimates of core staffing requirements per service site and workload per category of health care worker, shown in Table 5.3 and 5.4, were used to determine the total number of full-time equivalent (FTE) personnel that would be needed for the plan (Table 5.4). During the first phase, a buffer has been factored into the workload assumptions, acknowledging that it will take some time and experience before staff consistently reach these productivity benchmarks.

The above estimates will require close monitoring during the implementation and where necessary adjustments to these estimates will be made.

Table 5.1: Total Patients receiving CD4 tests and ARV Treatment by Year*

Year	Patients receiving CD4 tests	ARV Patients	Total
2003/04	212,000	53,000	265,000
2004/05	628,705	188,665	817,370
2005/06	1,078,446	381,177	1,459,623
2006/07	1,497,580	645,740	2,143,320
2007/08	2,167,834	1,001,534	3,169,368

**Note: This table represents the mid-point of the range of patients projected using the ASSA2000 model to access the system for CD4 tests and ARV treatment.*

Table 5.2: Patient Visits per Year

Year	Patient Visits
2003/04*	265,353
2004/05	3,592,428
2005/06	7,088,948
2006/07	11,661,119
2007/08	17,848,642

** This represents a 3-month period.*

Table 5.3: Core Staffing Requirements Per Service Site to Treat 500 Patients with ARVs

Category of Staff	Minimum (FTE)
Medical Officers	1
Professional Nurses	2
Pharmacists	1
Dieticians/Nutritionists	1
Social Workers	.5
Lay Counsellors	5
Administrative Clerks	1
Data Capturers	1
Total	**12.5**

Table 5.4: Workload By Category of Health Care Worker, by Patient Contact-hours per Day

	Long Visits				Short Visits			
	Assumption Visits ppy	Total patient visits / worker / yr	Visit length (hours)	Visits / day	Assumption Visits ppy	Total patient visits / worker / yr	Visit length (hours)	Visits / day
Medical Officers	2	1458	0.75	6.3	2	1458	0.25	6.3
Professional Nurses	10	2431	0.5	10.6	2	486	0.25	2.1
Enrolled Nurses	12	4375	0.25	19.0	0	0	0	0.0
Assistant Nurses	12	4375	0.2	19.0	0	0	0	0.0
Pharmacists	1	729	0.33	3.2	0	0	0	0.0
Pharmacist Assistants	12	8751	0.2	38.0	0	0	0	0.0
Dieticians	2	2917	0.5	12.7	0	0	0	0.0
Social Workers	2	2917	0.5	12.7	0	0	0	0.0
Counsellors	24	1750	1	7.6	0	0	0	0.0
Admin Clerks	12	4375	0.25	19.0	0	0	0	0.0

**Note: These estimates are based on worker productivity as implementation scales up. It is assumed that productivity will be lower in the initial phase, as staff members will have less experience in delivering care and number of patient visits per day may evolve over an initial implementation period.*
This table provides a breakdown of the total number of patient visits each health care worker will likely see, detailed by "long visits" for new patients and "short visits" for existing patients/patients with few complications.

In total, 1,786 FTEs will be needed for HIV and AIDS care and treatment by April 2004, 6,233 FTEs total by March 05, and 13,805 FTEs by March 08. Table 5.4 summarizes the total number of personnel required per category during these time periods. The estimates for staffing are calculated using the estimated number of persons with HIV and AIDS reflected in Table 5.5.

These estimates assume no diminution of work for health professionals in the short-term through this programme. It is anticipated that these patients will visit their health professional less frequently for infections and complications associated with their HIV status. Thus, while this recruitment model assumes all ARV-related treatment as additional workload for health professionals in the system, in fact a great deal of this work is likely to replace existing time with the same patients.

Longer term, ARV treatment will require a substantial increase in human resources, notwithstanding this substitution. People will be living longer and the number of AIDS patients will increase significantly. Patients with other conditions who are now "crowded out" of hospitals by AIDS patients will continue to present themselves for care.

Table 5.5: Total Additional Staff to be Recruited

Category of Staff	Through March 04 (# FTE)	April 04-March 05 (# FTE)	April 05-March 08 (# FTE)
Medical Officers	76	271	628
Professional Nurses	228	813	1,883
Enrolled Nurses	152	542	1,255
Assistant Nurses	152	542	1,255
Pharmacists	76	271	314
Pharmacist Assistants	76	271	314
Dieticians/Nutritionists	76	136	314
Social Workers	38	136	314
Lay Counsellors/CHWs	760	2,710	6,275
Administrative Clerks	152	542	1,255
Total	**1,786**	**6,233**	**13,805**

Operational Plan: Roles

At the outset, medical officers situated at district hospitals will be the central health care providers for prescribing ARV treatment, in coordination with primary health care staff at accredited service points (see Chapter I, *Prevention, Care and Treatment*). The authority to prescribe ARVs will be limited to medical officers who have been certified in clinical issues associated with ARV use. Registered professional nurses with additional training in clinical assessment, diagnosis, treatment and care are a critical part of the programme, at both the district hospital and community health centres and clinics and within their existing role as primary health care workers. Dieticians/nutritionists will be required for direct patient counselling and oversight of the nutritional supplementation programme. Lay counsellors and community health workers (CHWs) will be required for a broad range of support roles, ranging from ongoing prevention, pre- and post-test counselling and ARV adherence counselling. Roles and responsibilities will be reviewed on an ongoing basis to determine the most appropriate utilization of health care workers. New laboratory staff will be required to perform the increased volumes of specialized HIV testing (see Chapter IX, *Laboratory Services*). Facility, data and programme managers will be

required for administration and oversight, particularly at the provincial and national levels (see Chapter XV, *Programme Management*).

APPROACH

Human resource and training needs are interconnected and are therefore presented together in an integrated strategy. The needs and approach for the short term, are described first, and are followed by recommendations for the longer term.

HR and Training Strategy and Options during Programme Initiation

To begin delivering HIV and AIDS care and treatment at the outset of implementation, designated service points will utilize existing experienced personnel with additional human resources to fill service gaps. Funding to replace full-time equivalent (FTE) personnel deployed for this purpose is included in the budget of this plan and will be made available to provinces.

The first priority for this phase of implementation will be to establish a comprehensive national training programme to include all categories of health care workers and support personnel required for the provision of HIV and AIDS treatment and care and with a wide geographic coverage. Service point accreditation will be tied to certification of the core team of health care workers. Certification can be achieved through the completion of the didactic portion of training followed by a clinical mentoring programme for the medical officer to be completed once ARV treatment commences at the service point.

A strategy to ensure that all students who graduate from health academic institutions at the end of 2003 have received a short, intensive course on providing a comprehensive package of care for HIV and AIDS must be developed and implemented immediately.

Training Needs

Standardised training programmes for health care workers will be developed on a national basis and implemented locally. The initial focus of this effort will be to develop basic competencies required of all health care workers that will directly deliver the required continuum of comprehensive services for HIV and AIDS care and treatment. Going

forward, the emphasis will be broadened to support ongoing HIV training and clinical support for health care workers, including continuing professional development (CPD) programmes that will update the training of health professionals on the latest developments in HIV and AIDS care and treatment nationally and internationally.

The Cluster for Human Resources and the Cluster for HIV, AIDS and TB will initially coordinate the national strategy for these training and education activities, to ensure that all training and education activities are coordinated and synchronised to coincide with other parts of the implementation plan, with a view that the Human Resource Cluster will assume full responsibility for these functions in the future. The Human Resource Cluster will identify core competencies required for the provision of HIV and AIDS care and treatment as defined in the national protocol, and match these to the scopes of practice of each category of health care professional. The intention of this framework is to facilitate the delivery of care by a multi-disciplinary team that understands each other's roles and responsibilities. Further, this framework should highlight areas where flexibility can be allowed across categories of health care workers to fulfil functions in cases where there are gaps in personnel (e.g. who fulfils the nutritional counselling role in the absence of an on-site nutritionist?).

Each province must designate an interim training coordinator from existing personnel to take responsibility for ensuring that training needs are identified and staff are fully prepared for the launch of the programme. The provincial training coordinator will work closely with the Clusters and medical advisors in the development of a strategic training plan for the province.

The provincial training coordinator will work closely with the Clusters and the provincially based medical advisors in the development of a strategic training plan for the province. The medical advisor with the provincial training coordinator is responsible for delivering the nationally defined curriculum to the site staff, especially clinicians and nurses. The medical advisor defines the specific knowledge gaps and over the course of three months delivers this tailored curriculum in the facility setting.

Training courses should be developed and scheduled immediately thereafter, based on existing curricula for the comprehensive care and treatment programme for persons with HIV and AIDS established in South Africa and elsewhere. Medical officers, nurses, pharmacists and lay counsellors at initial service points should complete training on a priority basis. Training should be delivered by experts in HIV and AIDS care and treatment, in collaboration with local and international partners. Discussions and collaboration for the long-term sustainability of the training programmes will commence at the outset especially with statutory health professional councils, educational authorities and education and training providers.

Comprehensive and concise training courses with standardized curricula will be developed to provide all current health professionals with the specialized knowledge and skills to provide comprehensive services for persons infected with HIV and AIDS using ARVs. A component of all training and certification programmes is the requirement for continuing re-certification, to ensure expertise as standards of HIV and AIDS care and treatment evolve.

In each province, all health facilities, health care workers and support personnel will be briefed and provided with comprehensive information regarding the implementation of the plan, with specific emphasis on the service sites identified, the referral systems and the criteria for referral.

Long-term professional training should be an extension of the short-term process defined above. This training must focus not only on the comprehensive approach to HIV and AIDS prevention, treatment and care, but also on the broader spectrum of diseases that will allow qualified assessment of other disease categories and treatment strategies for both adults and children. Specific attention to the integrated management of childhood illnesses, management of TB, malaria, sexually transmitted infections, and gender-related issues must be included in all the basic curricula of health professional training. Specific curricula and CPD programmes will be developed in collaboration with the health professional councils in South Africa.

The general challenge of raising the standard of all existing CPD programmes remains. The mechanisms for maintaining educational standards and ensuring quality of education presently promoted through the South African Qualifications Authority (SAQA) will be utilised to ensure that the training in HIV and AIDS care and treatment will be formally registered as unit standards in comprehensive HIV and AIDS prevention, care and treatment. These unit standards will be utilised for both CPD and to enhance existing pre-professional programmes, provided by universities and colleges, medical schools, schools and colleges of nursing, pharmacy colleges and other health professional schools. In addition it is envisaged that all training provided to lay counsellors and community health workers will be formalised through a similar process of registering unit standards on the appropriate level of the National Qualifications Framework, to facilitate career advancement for these categories of health workers.

Training of Health Care Workers

An intensive training course to prepare clinicians and selected senior professional nurses to deliver comprehensive HIV and AIDS clinical care, inclusive of antiretroviral therapy, should be developed. Training is targeted at medical officers, general practitioners, medical specialists and selected nurse specialists. Training should utilize didactic teaching and interactive discussion.

Basic Competency on Completion of Training Course

It is envisaged that the following basic competencies will be covered in the training course:

- Understand natural history of HIV disease
- Diagnose and manage opportunistic infections
- Initiate and manage antiretroviral therapy
- Utilize referral and consultation mechanisms

Training programme – Curriculum Components

The curriculum components are as follows:

- Unit 1: HIV Care and Treatment Programme
    - Programme overview
    - Levels of care - referrals

- Staff roles and responsibilities
- Expert support
- Documentation and reporting
- Universal precautions – occupational risks, PEP

- Unit 2: HIV Basics
  - Epidemiology
  - Immunology, virology
  - Natural history of disease – signs and symptoms, staging

- Unit 3: Management of the HIV-positive Patient
  - Counselling – prevention
  - Nutrition
  - Infant feeding choices
  - Recognition and integration of traditional medicine

- Unit 4: TB and Opportunistic Infections
  - TB management
  - OI prophylaxis
  - OI treatment

- Unit 5: Antiretroviral Drugs
  - Introduction
  - Initiation – criteria and drug selection
  - Special considerations – pregnancy, prior ARV exposure, concurrent TB treatment
  - Adherence
  - Monitoring
  - Drug interactions
  - Side effects – identification, management
  - Resistance
  - Immune Reconstitution Syndrome
  - Pharmacovigilance – documentation and reporting

- Unit 6: Paediatric HIV and AIDS
  - Progression of disease

- ARV treatment
- Assessment and monitoring

Medical Officers

Medical officers who complete the short intensive didactic HIV and AIDS training course will be certified to prescribe antiretroviral drugs within the context of a clinical mentoring programme. (See Annex V.2 for a description of required competencies and training modules for clinician training.) Medical officers will be certified to prescribe ARVs independently after completing this programme, which entails:

- Evaluating 10 ARV-eligible patients jointly with an assigned clinical mentor;
- Evaluating 10 ARV-eligible patients, with on-site mentor consultation; and
- Evaluating 10 ARV-eligible patients, with off-site mentor consultation and written or oral review of the follow-up plan.

It is expected that the requirements for certification can be completed over the course of two clinical sessions. Clinical mentors authorized to mentor and certify clinicians will be selected from the pool of acknowledged clinical HIV experts from both within and outside South Africa. For medical officers with established expertise in ARV treatment, clinical mentors will have discretion to adjust the numbers of patients evaluated in order to obtain certification. The standardised curriculum will apply to private medical practitioners to ensure quality care and treatment in the private sector as well.

Clinical Mentor Training

All mentors will undergo the basic training outlined above and in addition should receive specific training that will include skills required for mentoring. Authorisation to mentor and certify training will be on completion of a suitable mentorship training programme.

Nurse Training

Professional nurses will need to complete a training course based on a standardized HIV nursing curriculum and case studies (see Annex V.3). A set of training materials and protocols for nurses will need to be provided at service points to assist nurses during normal patient care for persons on ARV treatment. The Health Promotion and Quality

Assurance Training Centres will need to establish ongoing clinical consultation and in-service support in each province.

Lay counsellors and community health workers

Excellent HIV training programmes already exist for lay counsellors. More than 5,000 counsellors in 1,569 VCT centres throughout the country have received HIV training; nearly all of the initial service points have trained VCT counsellors in place. These individuals will be called upon to play a critical role in prevention care and treatment, specifically in the areas of ARV adherence and counselling of new patients. To perform these new functions, experienced VCT counsellors will need to receive an additional one-day of training in ARV treatment and adherence counselling. Other community based health workers i.e. DOTS workers and community health workers, including home based carers, who have not completed initial VCT training will be needed for both on-site care and outreach. These counsellors will be required to complete a more extensive training programme in the history of HIV disease, pre- and post-test counselling, drug readiness training and palliative care. (See Annex V.4 for complete list of topics.) Additional training in ARV adherence and counselling of new patients should be provided for existing mentors providing support to VCT counsellors.

Administrative staff

One day of training will be needed for administrative staff, clerks and data capturers. Training will cover such areas as relate to the specific responsibilities of the staff. For instance, training for administrative support staff would cover HIV and AIDS basics, basic communication skills, procedures to follow and track patients that do not keep appointments, completion of forms, patient confidentiality, and appropriate interactions with patient and family. Data capturers will need to be trained on specific data needed for patient tracking and monitoring and evaluation purposes, as well as how to use the software selected for this purpose.

Nutritionist and dietician training

Nutritionists and dieticians have an important role to play focused on maximizing nutritional status of PLWHA. Dieticians should oversee the implementation of the nutritional supplementation programme at accredited service points. The Directorate of

Human Resources Development, in collaboration with the provinces and with existing providers of educational programmes, will prepare a standardized curriculum for nutritionist/dietician training.

Human Resource Strategies

In preparation for the introduction of the programme, a core team of health professionals will be identified at each of the service points designated for early implementation. To be accredited, each service point must have a minimum core team available and responsible for HIV and AIDS care and treatment which shall consist of a minimum of 1 FTE medical officer, 2 FTE nurses, 5 FTE lay counsellors/community health workers, and 1 FTE pharmacist. In addition, 1 FTE administrative clerk and 1 FTE data capturer will be needed per service point. This staffing norm is based on the HR needs to treat 500 patients. Where personnel are available, this core team will also include 1 FTE nutritionist or dietician and 0.5 FTE social worker. If these categories of workers cannot be readily obtained, the functions they perform may be incorporated into the tasks of existing health care workers during a transitional period, and a plan will be established for building this capacity over time.

Recruitment of Health Personnel

The training of new lay counsellors and the recruitment of additional administrative support staff should not pose too much difficulty provided that the mechanisms to appoint them exist. All new personnel appointed will require training according to the guidelines described above.

Provincial Heads of Health must review current capacity against the need for initial implementation and submit plans to the Department of Health for funds to meet additional staffing needs. Based on the review by the Department, funds will be made available and the provinces will exercise discretion to fill gaps using strategies most appropriate for their given context. Options for recruiting health care workers include:

1. **Target community service graduates and new placements –** Upon completion of training, many health care workers must complete one year of community service. Of the workers needed for the core HIV and AIDS teams, medical officers,

pharmacists, and nutritionists/dieticians participate in community service. (Nurses, lay counsellors and community health workers do not participate in community service programmes currently.) The class of 2003 will complete the programme in November and December and are about to enter the workforce. If provinces actively recruit these graduates and ensure that the vacant posts are identified or new posts are created, it may still be possible to attract these graduates to fill needed functions.

The class of 2003 will be placed in late October and November for community service beginning January 2004. The window for affecting these decisions is very narrow. However, with quick and concerted action at the national and provincial levels, it may be possible to create additional community service posts for the service points that could use additional support for functions that can be handled by junior staff (see Table 5.6).

Table 5.6: Community Service Class of 2003 and Placements for 2004

	Community Service Class of 2003	Community Service Placements for 2004
Medical Officers	1,100	1,100
Pharmacists	350	350
Nutritionists/dieticians	150	150

2. **Recruit from pool of new nursing graduates –** The estimated 6,000 nursing students, pupil nurses and pupil nursing auxiliaries completing training offer a potential pool of new recruits.

3. **Community service for nurses –** presently nurses completing training do not perform community service. The projected target date for community service for nurses can be adjusted to meet the need for additional nurses required.

4. **Establish targeted bursaries** - The establishment of bursaries for targeted groups of potential health professionals, especially in the more scarce categories, may assist in ensuring that the medium- and long-term human resource needs can be

met. These bursaries would be granted in the years after community service requirements are completed, on the condition that students receiving bursaries commit to working in the public health service for one year for each year of bursary received. Funds will need to be made available for these bursaries. For example these bursaries can be awarded to medical students in the fourth and fifth years of training for the academic year starting January 2004. In two and three years these professionals should be available to work in the public health service for at least two to three years. Bursaries can also be made available for trainee pharmacists and nutritionists.

5. **Create preferential registration for qualified foreign workers who commit to work in designated service points –** In order for foreign health care workers to seek employment in South Africa, they must apply to the Department of Health for approval before they register with the relevant health professional council. Each year, hundreds of applications are received from nurses and clinicians. For example, during the first half of 2003 alone, 561 applications for registration were submitted from foreign nurses; 58 were reviewed and approved. The review process tends to be slow and restrictive. The Department of Health could adapt this registration process to meet the needs of this programme, by offering preferential registration to qualified health professionals who are prepared to work in the designated service points.

6. **Recruit retired health care professionals** - Advertise posts to attract professionals that are presently not actively employed to assume work in the public sector on a flexible basis e.g. a sessional, part-time or full-time employment with flexible working hours.

7. **Extend over-time hours** – Existing personnel may be available to perform additional work if they are granted permission to perform overtime work for additional remuneration.

8. **Review policy of rotation for nurses** – It is current practice in many provinces for nurses to rotate into a different function on a 10-week basis. This practice has the

potential to cause service disruptions. While in the long run, it is a goal to have all nurses trained in HIV care and treatment, in the near term, it is more critical to build up the skills of the core team of health care workers by keeping them in that role for a longer period of time.

A review of work practices, skills, roles and responsibilities against the care framework would ensure optimal utilization of existing workers. This review would highlight functions that might be performed by lower categories of health workers and mid-level professionals or support personnel in order to free up clinicians for the essential clinical aspects of treatment and care.

9. **Increase retention of existing health care workers -** Retention of existing and new workers is an important short- and long-term goal. Strategies already identified by the Department for increasing retention include:
   - Retention incentives to include rural allowances for selected categories of health workers, additional remuneration for scarce skills, mentorship/support mechanisms, providing occupational health services and support programmes for employees, and time off for study.
   - Provision of care and treatment for health care workers with HIV and AIDS within the health care sector. This will serve immediately to diminish losses.
   - Support programmes to assist health professionals to cope with burnout.

10. **Capacity development and support to non-governmental organisations, faith-based organisations and community-based organisations** - These organisations are vital for assisting with community mobilisation support programmes, education and communications programmes, programmes to integrate education and prevention with treatment, adherence support, support groups, home-based and palliative care and other related activities. The personnel involved in providing the required services to support this plan require training in the standardised training programmes. In addition, many of these organisations require capacity building in management, writing of funding protocols and financial management. As many of these organisations are dependent on government and donor grants, lack of

capacity in management and finance could compromise their ability to obtain government and donor support. Capacity-building initiatives for these groups is important to ensure the services required for the continuum of care at a community level.

11. **Establish public-private partnerships** – HIV and AIDS is a national priority. The engagement of private sector partners to assist with addressing the challenges of provision of care and treatment is essential.
    - **Incorporate HIV care into work-based health care programmes.** Currently the private sector (especially large industries) provides work-based health care for their employees. These services are often well resourced and provide primary health care services to employees that would normally utilise the public sector. Entering into partnerships with these industries to support the implementation of this plan for their existing workers that may require HIV and AIDS care and treatment could prevent these workers from flooding the public health facilities. In addition, these industries could provide support in areas where the existing public health care services cannot meet all the requirements for the continuum of care.
    - **Utilise clinical expertise in the private sector**. There are private sector medical professionals who may be utilised to support the public health care delivery system in South Africa. To tap into this resource, provinces could contract with specialists and skilled clinicians or sessional private practitioners to fill vacant posts that cannot be filled by full-time public sector personnel. The basis of all contracts must ensure that health care delivery will occur at an accredited public service point, health practitioners must be trained and certified in accordance with the standardised training programmes and all care and treatment would be delivered in accordance with national treatment guidelines established under this plan.
    - **Education and training of professional nurses.** The majority of professional nurse training currently occurs in the public sector. The lack of availability of clinical facilities for the midwifery component of professional nurse training presents an obstacle. Through a public-private

partnership, this obstacle could be overcome, resulting in a greater supply of professional nurses to provide health care in South Africa.

- **Private sector practitioners.** Due to limited medical aid coverage for HIV and AIDS treatment, many patients on ARV treatment commenced by private practitioners will seek the continuation of treatment in the public sector. To ensure that the treatment of these individuals is not compromised, it is essential that the national treatment guidelines also apply to the private sector. Discussions with health professional councils, associations, the Board of Health Care Funders and other stakeholders to reinforce the implementation of the national guidelines should commence immediately to develop mechanisms to facilitate the training of private practitioners in the standardised training programmes.

12. **Other Supports -** In addition to measures aimed at recruiting and retaining personnel, back-up support services will be provided to enhance the productivity and effectiveness of health professionals in the programme.

    - **Phone-based Clinical Consultation**: "The Clinical HIV Treatment Help Line" - Each service point should have backup through medical expertise and referral networks at the provincial level. To provide additional backup for health-related questions that cannot be answered at this level, a clinical consultation line will be established prior to the start of treatment to assist health practitioners. This line, which will be staffed during normal work hours, will provide clinical consultation to all health care workers involved in HIV and AIDS care and treatment, including clinicians, nurses, and pharmacists. Detailed information on how to contact this consultation line will be included in all established training courses, and will be posted prominently at all initial service points. The Department of Health HIV, AIDS and TB Cluster will coordinate staffing, in consultation with national and international experts in HIV care.

    - **Mentorship for Lay Counsellors** - The VCT programme has introduced a mentorship and support programme for lay counsellors. This programme

will be strengthened to include the support required by lay counsellors and community based workers in their role in the implementation of this plan.

HUMAN RESOURCE NEEDS FOR 2005-2008

Over the longer term, the Department of Health will need to employ additional strategies to expand the skilled labour force for health in general, and for HIV and AIDS care and treatment, in particular. Table 5.7 below demonstrates that by March 2005, 6,233 health care FTEs will be needed, growing to 13,805 by March 2008. With the exception of nutritionists and pharmacists, new hires represent from 4 to 8 percent of the current in-post workforce. Recruiting and hiring these additional health workers will require creative solutions, and yet should be achievable. The number of new dieticians and nutritionists increases the existing workforce in this category by 25 percent, and for pharmacists more than doubles the numbers. Hiring these categories of workers may require a re-evaluation of pay scales. It may also require looking at ways to increase enrolment and class size in allied health programmes to prepare today for the need in a few years' time.

Table 5.7: Number of FTEs Needed

	April 04-March 05		April 05-March 08	
	# FTEs needed	New HCWs as % of current workforce	# FTEs needed	New HCWs as % of current workforce
Medical Officers	271	3.8%	628	8.8%
Professional Nurses	813	2.0%	1,883	4.7%
Enrolled Nurses	542	2.6%	1,255	6.1%
Assistant Nurses	542	1.9%	1,255	4.4%
Pharmacists	271	21.9%	314	25.4%
Pharmacists Assistants	271	N/A	314	N/A
Dieticians	136	51.0%	314	118.4%
Social Workers	136	N/A	314	N/A
Counsellors	2,710	N/A	6,275	N/A
Admin Clerks	542	N/A	1,255	N/A
TOTAL	**6,233**		**13,805**	

Funding to each province under this plan will be sufficient to hire or contract with health care workers in each of these categories to meet the targets in the table above. Funding decisions will include an explicit goal of redistribution of resources to underserved provinces to redress former inequalities. The staff to be hired under this programme will likely not work exclusively with PLWHA. Rather, it is the intention of this programme to integrate the service into the general health infrastructure. As such, hiring additional medical officers, nurses and other categories of workers will benefit the overall public health system.

Longer-Term Strategies for Increasing the Health Care Workforce

1. Increase production of health professionals - The national Department of Health should engage academic and training institutions to increase the intake of students in accordance with the projected needs of provincial and national human resource plans. Special attention should be given to increasing the number of medical graduates, professional nurses, enrolled nurses and nursing auxiliaries, pharmacists, post basic pharmacist assistants and nutritionists by increasing the number of trainees. The Health and Welfare SETA learnership programmes could provide a useful conduit for increasing training nurses and pharmacist assistants.

2. Increase public health employment opportunities - Additional posts should be created for pharmacist assistants, enrolled nurses and community service health personnel.

3. Create new categories of health care workers - Create the category of phlebotomist and develop certification requirements for blood collection. The placement of phlebotomists within the public sector is likely to free medical practitioners and nurses to assume more of their clinical functions.

Coordinate with existing DoH activities around the creation of mid-level positions for dieticians/nutritionists and psychologists.

4. Explore changes in the practice of care - Steps to redefine work definitions and scopes of practice could increase the efficiency of health delivery.

- Review the scopes of practice for most health professional groups with respect to skills and functions e.g. review the training and scope of enrolled nurses to perform intake assessments.
- Enhance the skill set developed for enrolled and auxiliary nurses during pre-professional education to meet the specific needs of HIV care and treatment.
- Establish cross-training programmes to promote multi-skilled healthcare workers
- Improve the model of how HIV care is delivered by the health worker in various categories in South Africa based on operational research.
- Review the different categories of community based health care workers i.e. DOTS workers, home-based carers, community health workers and lay counsellors to ensure that their roles and responsibilities are clearly developed and rationalised where necessary.

5. Employee retention strategies - Retention of trained health care providers should be achieved in part through the use of incentives targeted particularly to rural and underserved areas and improving working conditions for health workers in rural health services.

- Evaluate the potential of offsetting loans established during the pursuit of professional degrees. This may likewise serve to make these positions more desirable and to enhance retention.
- Establish provider incentives (e.g. adjustment of pay scales, professional advancement additional payment for scarce skills). Other creative mechanisms should be explored on an ongoing basis.
- Develop and enhance existing employee support programmes.
- Increase initiatives to recognise service excellence through awards such as the Khomanani Health Worker Excellence Award and the Cecilia Makiwane Award for nurses.

6. Recruit qualified overseas clinicians and health professionals

- Establish twinning programmes with international centres of excellence. Current twinning programmes could be expanded to include programmes with international centres of excellence in the field of HIV and AIDS treatment and care. South African service sites could aim to become international centres of excellence for HIV and AIDS treatment and care themselves in the near future
- Explore the repatriation of South African health care workers currently working outside the country.

- Put in place government-to-government agreements for work exchange programmes for health care workers.

SPECIAL CONSIDERATIONS

There are a few other issues that should be addressed to assure that human resource needs for the plan are met.

Laboratory training

The NHLS laboratories are staffed by highly skilled laboratory technologists and technicians, and there is currently sufficient human resource capacity to perform nearly one million CD4 count assays per year. Nonetheless, vacancies exist for phlebotomists, technologists and technicians, particularly in peripheral laboratories, and the expanded volume of laboratory assays required to support the ARV treatment plan will require an increase in laboratory staffing over five years. To address these human resource needs, the NHLS should establish a national training centre at the National Institute for Communicable Disease.

While NHLS will need to train its professional laboratory staff, health professionals at service points will also require basic laboratory skills - the initial collection, processing and handling of blood samples from HIV-infected patients. Training in blood handling and safety for service site health professionals should thus be part of the nationalized curriculum.

Certification

Health professionals who complete an approved training curriculum will be certified as proficient in HIV care and service delivery. Demonstration of a sufficient roster of certified health professionals will be necessary for service points to be accredited, and consideration for streamlined certification will be given to those professionals who have established experience in HIV and AIDS care (see Chapter IV, *Accreditation of Service Points*).

ADMINISTRATIVE STRUCTURE

Department of Health Human Resources Cluster

The Human Resources Cluster will be responsible for management of the operational plan's human resource deployment, and will pay particular attention to initial deployment. The HIV, AIDS and TB Cluster will oversee and coordinate the HIV training activities described above (see Chapter XV, *Programme Management).* The development of curricula for health care workers will emit directly from the standard of care defined through the guideline process. The Cluster will also establish a regular newsletter and a website containing HIV care updates and other clinical information relevant to HIV practitioners informed by Helpline inquiries.

Health Promotion and Quality Assurance Training Centres (Quality Training Centres)

Quality Training Centres within each province will coordinate HIV training activities at the provincial and local levels. These may be based in a single institution or across multiple institutions. The centres will work closely with a clinical consultant team to implement training programmes based on a standardized national curriculum, particularly during the inception of the programme. The HIV, AIDS and TB Cluster will need to assign clinical experts in HIV care to assist provincial Quality Training Centres in implementing training programmes and provider certification, as necessary.

National Health Laboratory Service

Laboratory training should be established by the NHLS. The HIV, AIDS and TB Cluster will coordinate laboratory staffing issues with the NHLS, to ensure that unexpected human resource needs at NHLS do not delay the initial implementation.

PROGRAMME ASSESSMENT

The Human Resources Cluster will monitor the ongoing human resource needs of the treatment programme. It is envisaged that the staffing ratios and funding assumptions that underlie this plan will be reviewed in March 2004 and October 2004, and annually thereafter in light of the patients being served, to ensure that quality patient care is provided, that training is adequate and that equity is achieved in human resources

deployment. The competency of health care workers will also need to be reviewed to ensure that skills are both learned and retained. In addition, operational research will need to be conducted to determine how best to maximize use of available human resources by skills and functions.

Chapter VI

PROVINCIAL SITE ASSESSMENTS

OVERVIEW

The Task Team met on several occasions with officials of all nine provinces to discuss implementation of comprehensive HIV and AIDS care in their provinces. At the invitation of the Task Team, each province produced a preliminary treatment implementation plan. In addition, the Task Team, with experienced AIDS clinicians from the Clinton Foundation, have visited 77 service points, including at least one in every health district, to identify health facilities that will be capable of delivering ARVs to patients within 12 months. These service points were selected in consultation with provincial officials as sites likely to be able to introduce comprehensive HIV and AIDS care within the next twelve months. Teams visited 33 sites in August and September, and 44 sites in October. We have concluded from these visits that it should be possible to begin treatment in every health district at these sites within a 12-month period. Considerable technical assistance will be necessary in some of these sites, however, to help them prepare.

SITE ANALYSIS

The Task Team used a general questionnaire to guide the initial site visits in August and September. For the October visits, the Task Team used the accreditation criteria detailed in Chapter IV. All of the sites visited possess the fundamental laboratory, pharmacy, and human resource capabilities necessary to initiate comprehensive treatment. However, while some of the sites, with a limited amount of assistance, can begin to deliver ARV treatment within the next few months, other sites will require greater assistance to reach full capacity in 12 months.

Table 1 lists all the sites. Those marked "1" should be ready to deliver effective care within a few months. Their staff will require training, the appropriate patient information and measurement and evaluation systems must be installed, and some minor upgrades are necessary in other areas. But these all can be readily accomplished in a short period of time. Those marked "2" will require greater technical assistance and in some cases

investments to upgrade various aspects of their programmes and facilities, in addition to training. Many also must increase their staff. The operational plan provides for this technical assistance and investment through the accreditation process. Many of these facilities could be ready by the first quarter of 2004 and others may require several months to be ready.

The readiness of facilities must be judged in relation to the number of people that the service point may have to serve. The Task Team has made rough estimates of the number of eligible patients that may seek treatment during the first few months of the programme in each health district (Table 6.2).

These rough estimates are based on antenatal rates and the number of people in each health district. The Task Team used the ASSA study to estimate how many of those who are HIV-positive have developed AIDS and how many might be eligible for ARV treatment. International experience suggests that about 20% of those eligible patients will seek treatment in the first several months of the programme.

Based on this analysis, it appears that most of the centres visited by the Task Team should be able to handle patient loads. Forty-four of the sites should have initial patient loads of under 1000 people seeking ARV treatment, and 19 facilities should have initial patient loads of between 1000 and 2000. There are areas where the patient load may be over 2000, which would likely be too great for the facilities visited. Of these, five are in Gauteng and five in KwaZulu-Natal, primarily in urban areas, and one each in Limpopo, the Eastern Cape, the North West and Mpumalanga.

The SMT, in cooperation with health district officials will identify additional service points in these areas in order to achieve better ratios of potential patients per facility. Many of these areas are heavily populated with multiple hospitals and other health facilities, so we believe that finding these sites will not be difficult. The Task Team is also mindful of the fact that a number of the service points in rural health districts with smaller populations may still need special assistance in order to serve a dispersed population. Transportation needs have been built into budgets for those regions.

Table 6.3 lists potential service points identified by provincial officials that have not been visited by the Task Team. A number of these may also be able to achieve readiness, and some are in districts that appear to be under-serviced in this analysis.

ASSESSMENTS

The site assessments conducted by the Task team focused in five areas.

The first area addressed facility context in terms of total population served, number of facilities referring to the location, and the tertiary or regional hospitals to which the site referred patients for specialty care.

The second area focused on current HIV and AIDS services, inclusive of VCT, PMTCT, TB management, STI management, post-exposure prophylaxis (occupational and rape), nutrition, HIV clinic, and ARV treatment. Questions targeted the presence and availability of these programmes on-site or at referral locations.

The third area addressed laboratory status at the facility. Questions were asked about the presence of a laboratory, equipment inventory, staff, utilization of NHLS or outside laboratories, and capacity to conduct CD4 and viral load tests.

A similar set of questions regarding pharmacy comprised section four. Issues included the presence of a pharmacy on-site, the inventory and ordering systems, dispensing practices, storage and security procedures, staff, and current stock of ARVs and Fluconazole/Diflucan.

The fifth section sought responses regarding the current status of or potential to meet the requirements for several issues identified in the accreditation criteria. Questions focused on the potential for adequate and appropriate clinic space, the HIV clinical core-team personnel, access to 24-hour care, access to expert consultative care, management and support staff, systems for patient intake and referral, the patient information system, support and information / education / communication services, and linkages to provincial HIV and AIDS offices.

There are three areas that require special attention, namely human resources, laboratories and pharmacies.

Human Resources

Staff at all of the facilities have considerable experience with HIV-infected patients. The large majority of inpatients and many of the outpatients are HIV-positive, and most facilities have in-house VCT or PMTCT programmes. This range of experience however, rarely includes the use of ARV medications. Some medical officers manage patients on ARVs, but these providers are extremely small in number and the skill level is limited. Virtually none of the nursing staff have any practical experience with ARVs.

The need to train health professionals is the primary limitation to the initial phase of ARV treatment. Some sites have one or more medical officers who have experience with HIV patients and with some ARV treatments. Conversely, other sites do not currently have medical officers with any experience and will need significant assistance to reach treatment capacity. Compounding these personnel gaps are the accompanying laboratory and pharmacy staffing needs. To ensure high quality care, the training of health professionals will require an initial didactic curriculum followed by an ongoing mentoring process, involving experienced AIDS clinicians and nurses, which will last for several months.

Nearly all facilities also have formal linkages to expert consultants for sub-specialty care. Ongoing training of staff and treatment experience throughout the health care system will enable local and national consultative networks to become more effective to serve the needs of the larger patient population.

Many of the sites will have to recruit new health professionals either as permanent hires or as contractors. In most cases the major difference between those service points ready to start treatment immediately and those requiring more time, is a lack of human resources.

This operational plan recommends a number of strategies for dealing with this issue and provides adequate budget to do so. The exact means that will be employed to solve the human resource shortage will differ from one health district to the next.

Laboratories

Nearly all sites visited during these assessments possessed on-site laboratories. These laboratories conduct a spectrum of routine tests, and courier systems are used to transport specimens to larger laboratories for the more rarely used tests (e.g. CD4 and viral load). These systems have functioned for years and possess demonstrably successful records. All of these laboratories and courier systems have some capacity to support the initial phase of ARV implementation in each district. As the patient population grows, however, resource input at some locations will have to increase rapidly to address space and equipment requirements. These latter facilities will be targeted to meet the 12-month timeframe.

Pharmacies

All hospital facilities visited possess pharmacies and can dispense Schedule 5 drugs. In addition, these pharmacies currently stock ARV medications for post-exposure prophylaxis and, in many instances, for PMTCT programmes. Once drugs are available widely, current pharmacy capacity can support the initial phase of HIV and AIDS care and treatment implementation. Limitations at some facilities will be reached very quickly, however, as the treatment population grows. Resource inputs to these latter sites will be used to prepare for ARV treatment capacity in 12 months.

In more general terms, pharmacies have some flexibility since the provincial depots will manage the pre-packaging and delivery of ARV medications to individual patients (see Chapter VIII, *Drug Distribution*). Facility pharmacies will not have to store, package, and dispense large quantities of bulk drugs. Some storage capability will be required, however, to hold packages for patients who lack accessible addresses. Hospital pharmacies also can support health centres that currently lack capacity for this early stage of implementation.

HIV AND AIDS CARE AND TREATMENT IMPLEMENTATION

Assessments of service points confirm that existing laboratory and pharmacy capacity can support some level of implementation effort, and that human resource limitations pose the most significant barrier. Recruitment of staff and intensive training programmes can surmount these limitations. At some sites, the assistance needed is limited, and ARV treatment can begin in a matter of a few months; at other sites, more time and assistance will be required to reach a level of competency to commence treatment. Nutrition, administrative support, and patient information systems also will build on existing structures, and expand to manage the growing patient populations. Ancillary services should be addressed through both facility and community programmes.

We are confident that at least one facility in each district will be delivering HIV and AIDS care and treatment within 12 months. In those districts with a greater anticipated patient load implementation efforts will focus on ensuring the capacity for ARV care in more than a single facility within the 12-month period.

A second potential pool of initial ARV implementation facilities includes sites identified by provinces for the first phase of development, but that were not subjected to the current assessment evaluations (Table 6.3). These additional sites might be incorporated in the initial implementation to buttress the early expansion. The accreditation team will conduct more formal assessments at these other sites.

Table 6.1: Facility readiness for HIV and AIDS Care and Treatment

PROVINCE	Districts	Facility Name	Facility Type	Readiness*
Eastern Cape	Cacadu / Western	Settlers	Regional	1
	Amatole	Celicia Makiwane/Frere	Tertiary	1
	PE: Nelson Mandela	Dora Nginza	Regional	1
	Chris Hani / North East	Frontier	Regional	2
	Ukhahlamba	Umlamli/ Empilisweni	District	1
	OR Tambo	Umtata General	Regional	1
		St Elizabeth	Regional	1
	Alfred Nzo / EG Kei	Rietvlei	District	2
Free State	Xhariep	Diamant	District	2
	Motheo	Pelenomi	District	2
		National	District	1
		Universitas	Regional	2
	Lejwe Le Putswa	Bongani	District	1
		Thusanong	District	2
	Thabo Mofutsanyane	Elizabeth Ross	District	1
		Phekolong	District	2
	Northern Free State	Boitumelo	Regional	2
Gauteng	Ekurhuleni	Natalspruit	Regional	2
	City of Johannesburg	Helen Joseph	Regional	1
		Coronation	Regional	1
		Discoverer	Health Centre	2
	Tshwane/ Metsweding	Garankuwa	Regional	1
	West Rand	Leratong	Regional	1
	Sedibeng	Kopanong	District	2
KwaZulu-Natal	EThekwini	King Edward	Secondary Care	1
		RK Khan	District/Regional	1
	Ugu	Murchison	District	1
		Port Shepstone	Regional	2
	Umgungundlovu	Greys/Edendale	Regional	1
	Uthukela	Ladysmith	District	1
	Umzinyathi	Dundee	District	2
		Church of Scotland	District	1
	Amajuba	Newcastle	District/Regional	2
		Madadeni	District/Regional	1
	Zululand	Nkonjeni	District	2
	Umkhanyakude	Mosvold	District	1
		Mseleni	District	1
	Uthungulu	Ngwelezane	Regional	1
		Empangeni	District	2

Readiness: **1** = Site is ready to start ARV-roll-out in a couple of months with limited input to reach capacity for ARV treatment. **2** = Site requires higher levels of input to ensure that capacities can support treatment programmes in 12 months.

PROVINCE	Districts	Facility Name	Facility Type	Readiness*
KwaZulu-Natal	iLembe/King Shaka	Stanger	District/Regional	2
	Sisonke / East Griqualand	Usher Memorial	District	2
Limpopo	Sekhukhune	Matlala	District	2
		St Rita	Regional	2
		Hlogotlou	Health Centre	2
		Jane Furse	District	2
	Bohlabela	Mapulaneng	Regional	1
		Tintswalo	Regional	1
	Mopani	Nkhensani	District	2
	Vhembe	Elim	District	2
		Musina	Health Centre	2
	Capricorn	Mankweng	Tertiary	1
		WF Knobel	District	2
	Waterberg	Mokopane	Regional	1
		Warmbaths	District/Regional	1
Mpumalanga	Eastvaal	Evander	District	2
		Bethal	District	1
	Nkangala	Witbank	Regional	1
	Ehlanzeni	Rob Ferreira	Regional	1
		Themba	District	2
North West	Bojanala	Rustenburg	Regional	2
	Central	Mafikeng/Bophelong	Regional	1
	Bophirima	Taung	District	2
	Southern	Klerksdorp/Tshepong	Regional/Tertiary	1
Northern Cape	Kgalagadi	Kuruman	District	2
	Namakwa	Springbok	District	1
	Karoo	De Aar	District	2
	Siyanda	Gordonia (Upington)	Regional	2
	Francis Baard	Kimberly	District	1
Western Cape	West Coast	Vredenburg	District	1
	Boland	TC Newman	Health Centre	1
	Overberg	Hermanus	District	2
	Garden Route / Klein Karoo	George	District/Regional	1
	Central Karoo	Beaufort West	Health Centre	2
	City of Cape Town	Hout Bay	Health Centre	1
		Langa	Health Centre	1
		Khayelitsha	Health Centre	1
		Gugulethu	Health Centre	1

***Readiness:** **1** = Site is ready to start ARV-roll-out in a couple of months with limited input to reach capacity for ARV treatment. **2** = Site requires higher levels of input to ensure that capacities can support treatment programmes in 12 months.

Table 6.2: Projected AIDS Patient Loads by District and Facility

PROVINCE	Districts	Facility Name	Facility Type	Potential AIDS Patient Load by Facility During First Six Months*
Eastern Cape	Cacadu / Western	Settlers	Regional	467
	Amatole	Celicia Makiwane / Frere	Tertiary	2634
	PE: Nelson Mandela	Dora Nginza	Regional	1735
	Chris Hani / North East	Frontier	Regional	1499
	Ukhahlamba	Umlamli / Empilisweni	District	251
	OR Tambo	Umtata General	Regional	1433
		St Elizabeth	Regional	1433
	Alfred Nzo / EG Kei	Rietvlei	District	1157
Free State	Xhariep	Diamant	District	390
	Motheo	Pelenomi	District	650
		National	District	650
		Universitas	Regional	650
	Lejwe Le Putswa	Bongani	District	913
		Thusanong	District	913
	Thabo Mofutsanyane	Elizabeth Ross	District	877
		Phekolong	District	877
	Northern Free State	Boitumelo	Regional	1207
Gauteng	Ekurhuleni	Natalspruit	Regional	5186
	City of Johannesburg	Helen Joseph	Regional	2528
		Coronation	Regional	2528
		Discoverer	Health Centre	2528
	Tshwane/Metsweding	Garankuwa	Regional	4913
	West Rand	Leratong	Regional	1922
	Sedibeng	Kopanong	District	1869
KwaZulu-Natal	Ethekwini	King Edward	Secondary Care	4777
		RK Khan	District/Regional	4777
	Ugu	Murchison/Port Shepstone	Regional	2227
	Umgungundlovu	Greys/Edendale	Regional	3560
	Uthukela	Ladysmith	District	1579
	Umzinyathi	Dundee	District	508
		Church of Scotland	District	508
	Amajuba	Newcastle	District/Regional	837
		Madadeni	District/Regional	837
	Zululand	Nkonjeni	District	2521
	Umkhanyakude	Mosvold	District	838
		Mseleni	District	838
	Uthungulu	Ngwelezane	Regional	1250
		Empangeni	District	1250
	iLembe/King Shaka	Stanger	District/Regional	1615
	Sisonke / East Griqualand	Usher Memorial	District	736

PROVINCE	Districts	Facility Name	Facility Type	Potential AIDS Patient Load by Facility During First Six Months*
Limpopo	Sekhukhune	Matlala	District	334
		St Rita	Regional	334
		Hlogo Tlou	Health Centre	334
		Jane Furse	District	334
	Bohlabela	Mapulaneng	Regional	350
		Tintswalo	Regional	350
	Mopani	Nkhensani	District	2043
	Vhembe	Elim	District	616
		Musina	Health Centre	616
	Capricorn	Makweng	Tertiary	830
		WF Knobel	District	830
	Waterberg	Mokopane	Regional	563
		Warmbaths	District/Regional	563
Mpumalanga	Eastvaal	Evander	District	1525
		Bethal	District	1525
	Nkangala	Witbank	Regional	2403
	Ehlanzeni	Rob Ferreira	Regional	1460
		Themba	District	1460
North West	Bojanala	Rustenburg	Regional	3646
	Central	Mafikeng/Bophelong	Regional	1865
	Bophirima	Taung	District	876
	Southern	Klerksdorp / Tshepong	Regional/Tertiary	1986
Northern Cape	Kgalagadi	Kuruman	District	258
	Namakwa	Springbok	District	105
	Karoo	De Aar	District	107
	Siyanda	Gordonia (Upington)	Regional	163
	Francis Baard	Kimberly	District	364
Western Cape	West Coast	Vredenburg	District	107
	Boland	TC Newman	Health Centre	289
	Overberg	Hermanus	District	104
	Garden Route / Klein Karoo	George	District/Regional	233
	Central Karoo	Beaufort West	Health Centre	30
	City of Cape Town	Hout Bay	Health Centre	395
		Langa	Health Centre	395
		Khayelitsha	Health Centre	395
		Gugulethu	Health Centre	395

Note: ASSA figures for each province and antenatal prevalence rates for districts were used to estimate the potential patient loads. These are very rough estimates.
1) District populations were multiplied by antenatal rates to obtain estimates of HIV infection; these calculations normally will be too large for an accurate population figure, because antenatal rates are typically higher than population rates.
2) Percent distribution of infections within province were determined by summing projections and dividing by the total. Assuming a stable relationship between antenatal and population

prevalences, these proportions will reflect the population pattern as well.
3) These proportions were multiplied by the number of ASSA AIDS cases to estimate the actual total number of AIDS cases by district.
4) District AIDS numbers were multiplied by 20% for an estimate of the number of entries into care during the initial months of the care and treatment programme.
5) Patient load figures for districts in which more than one facility was assessed were divided equally among the facilities. Actual distributions will depend on a number of factors beyond these simple calculations.

Table 6.3: Sites Identified by Provinces for Initial HIV and AIDS Care and Treatment Implementation and Current Assessment Visit Status

Province	District	Facility	Assessments Conducted
Eastern Cape	OR Tambo	Umtata Hospital Complex	□
	Amatole	Frere / Makiwane Hospital Complex	□
	PE: Nelson Mandela	Dora Nginza Hospital Complex	□
Free State	Lejwe Le Putsha	Bongani (Welkom) Hospital	□
	Thabo Mofutsanyana	Elizabeth Ross Hospital	□
	Motheo	National Hospital	□
Gauteng	Johannesburg Metro	Johannesburg Hospital	
		Hillbrow CHC	
		Helen Joseph Hospital	□
		Coronation Hospital	□
		Discoverer Clinic	□
		Chris Hani-Baragwanath Hospital	
		Lillian Ngoyi Clinic	
		Zola Clinic	
	West Rand	Leratong Hospital	□
		Carletonville Hospital	
		South Clinic	
	Ekurhuleni	Natalspruit Hospital	□
		Tembisa Hospital	
		Daveyton Main Clinic	
	Sedibeng	Sebokeng Hospital	
		Kopanong Hospital	□
		Empilisweni Clinic	
	Tshwane/Metsweding	Pretoria Academic Hospital	
		Kalafong Hospital	
		Laudium Clinic	
		Garankuwa Hospital	□
		Soshanguve II Clinic	
KwaZulu-Natal	EThekwini (Metro)	King Edward Hospital	□
		Prince Mshiyeni Memorial Hospital	
		Mahatma Ghandi Memorial Hospital	
	Ethekwini (Metro)	Addington Hospital	
		RK Khan Hospital	□
	Ugu	Port Shepstone Hospital	□
		Murchison Hospital	□

Table 6.3: Sites Identified by Provinces for Initial HIV and AIDS Care and Treatment Implementation and Current Assessment Visit Status

Province	District	Facility	Assessments Conducted
KwaZulu-Natal	Ugu	GJ Crookes Hospital	
	Ilembe/King Shaka	Stanger Hospital	□
	Amajuba	Madadeni Hospital	□
		Newcastle Hospital	□
	Umzinyathi	Church of Scotland Hospital	□
	Zululand	Vryheid Hospital	
		Benedictine Hospital	
		Nkonjeni Hospital	□
	Umgundundlovu	Grey's Hospital	□
		Edendale Hospital	□
		Northdale Hospital	
	Uthukela	Ladysmith Hospital	□
		Escourt Hospital	
	Uthungulu	Ngwelezane Hospital	□
		Lower Umfolozi/Empangeni Hospital	□
		Nkandla Hospital	
	Umkhanyakude	Bethesda Hospital	
		Mosvold Hospital	□
		Manguzi Hospital	
		Mseleni Hospital	□
Limpopo	Capricorn	Polokwane/Mankweng Hospital Complex	□
		WF Knobel Hospital	□
		Lebowakgomo Hospital	
		Seshego Hospital	
	Bohlabela	Mapulaneng Hospital	□
		Tintswalo Hospital	□
	Sekhukhune	St. Rita's Hospital	□
		Hlogo Tlou Hospital	□
		Matlala Hospital	□
		Mecklenburg Hospital	
	Vhembe	Siloam Hospital	
		Elim Hospital	□
		Messina Hospital	□
		Tshilidzini Hospital	
	Mopani	Nkhensani Hospital	□
		Letaba Hospital	
		Maphutha Malatji Hospital	
	Waterberg	Mokopane Hospital	□
	Waterberg	Warmbaths Hospital	□
		George Masebe Hospital	

Table 6.3: Sites Identified by Provinces for Initial HIV and AIDS Care and Treatment Implementation and Current Assessment Visit Status

Province	District	Facility	Assessments Conducted
Mpumalanga	Gert Sibande	Evander Hospital	□
		Bethal Hospital	□
	Ehlanzeni	Rob Ferreira Hospital	□
	Nkangala	Philadelphia Hospital	
		Witbank Hospital	□
Northern Cape	Frances Baard	Kimberley Hospital	□
	Siyanda	Gordonia (Upington) Hospital	□
North West	Southern	Klerksdorp/Tshepong Hospital Complex	□
	Central	Mafikeng/Bophelong Hospital Complex	□
	Bojanala	Rustenburg Hospital	□
	Bophirima	Taung Hospital	□
Western Cape	Metro	Khayelitsha Clinics x 3	□
		Gugulethu Clinic	□
		Tygerberg Hospital	
		Groote Schuur Hospital	
		Red Cross Memorial Children's Hospital	
		GF Jooste Hospital	
		Langa Washington Road Clinic	□
		Hout Bay Main Road Clinic	□
		Hottentots Holland Hospital	
		Mitchells Plain CHC	
	Garden Route/Klein Karoo	George Hospital	□
	Boland/Overberg	Worcester Hospital	
		Paarl Hospital	

SECTION THREE

OPERATIONAL ISSUES: DRUGS AND LABORATORIES

Chapter VII

Drug Procurement

OVERVIEW

A central component of expanded HIV and AIDS care and treatment is the production, procurement and supply of medicines, in particular antiretrovirals. To support the operational plan, the drug procurement system must achieve the following general objectives:

- Medicines must be of the highest quality and 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 significant demand envisioned.
- Medicines must be purchased at the lowest possible price.
- The sustainable supply should be ensured through local production of antiretrovirals and sustainable financing.

The framework for the procurement of ARVs has been designed to meet these objectives. This framework is also guided by principles of good procurement practices, sound financial management and accountability and compliance with good quality standards.

BACKGROUND AND RATIONALE

Historically the cost of ARVs has restricted access to ARV therapy to a limited number of patients with AIDS. Though the introduction of equivalent generic products has substantially lowered the market price for these medicines, they are still prohibitively expensive for the vast majority of people who need them. The current market for ARVs in developing countries is small and fragmented. As a result, the production system for these medicines is sub-scale and high cost. Producers have not had the demand or predictability that they need to organize efficient production systems.

The South African pharmaceutical market is characterised by high import penetration, with a significant volume of products coming in as finished products, with limited local

generic production.

The current tender process for pharmaceuticals allows for split contracts among suppliers of critical items that address prevalent conditions and priority programmes. This approach enhances continuity and sustainability of supplies.

Medicines that are procured in the country including antiretrovirals should be registered by the Medicines Control Council and must meet standards of quality, efficacy and safety.

This plan takes into consideration the declarations of the SADC Health Ministers agreed to at two meetings held in Pretoria on the 17th June 2000 and in Durban on the 8th July 2000. These related to legislative and regional legal regimes that will ensure the availability of technologies and drugs at affordable prices for treatment, including bulk purchasing of drugs and manufacturing of generic medicines in the region. The first meeting developed principles that would be used in any negotiations with the companies and these are:

- The prime focus of the negotiations must remain on Sub-Saharan Africa where the magnitude of the problem is greatest.
- WHO should become the convening agency for these negotiations in the light of its broad health mandate and the greater opportunity for representivity that it can provide through the World Health Assembly.
- The negotiations should address the overall provision of care for HIV and AIDS-related conditions and must include a consideration of all the elements related thereto viz. health infrastructure, diagnostic kits, pharmaceuticals and the technology that would ensure that these can be safely and effectively administered.
- All proposals should be centred around the principle of sustainability and on this basis, seek to make drugs both affordable and accessible.
- Health ministries should define all research priorities based on local conditions and national objectives.
- Those options open to Member States under TRIPS (parallel importation and compulsory licensing), should not be compromised.
- Member States should not be required to assume the responsibility of ensuring that these products do not leave their markets.

In particular, at the second meeting held in Durban, Ministers reaffirmed that HIV and AIDS is a serious developmental issue and that therapy for HIV and AIDS-related conditions should be delivered through sustainable health systems. Ministers further

directed that a minimum package of services that can be used by SADC countries when negotiating as individual countries or as a collective with pharmaceutical companies should be developed. The package would not focus only on the provision of antiretroviral drugs, but would address issues of HIV and AIDS-related infections in a holistic way, therefore including aspects such as laboratory support, treatment of opportunistic infections, infrastructure, capacity building and monitoring of drugs, especially antiretroviral drugs.

APPROACH

The national procurement of ARVs will operate on several principles. Firstly, the supply of ARVs must be of high quality and suppliers must have the technical know-how to produce specific treatment regimens and a long-term commitment to deliver high quality pharmaceuticals consistently. Manufacturers of the medicines must conform to national and international quality standards and be able to produce adequate quantities of medicines into the future. The procurement of ARVs must also be flexible; as new and better medicines are introduced, or as the treatment regimen of a particular patient is changed over time, adjustments must be made.

Secondly, there must be a competitive market for the production of ARVs. Engaging with a number of competing manufacturers will further drive price reductions. As more suppliers qualify for tenders, it is envisaged that additional competition will create downward price pressure. A number of viable and competing manufacturers will also guarantee security of supply should any supplier fail for any reason.

Thirdly, ARVs must be affordable and legislative provisions exist to ensure access to affordable medicines. One method of promoting low cost medicines is to maximize the volume of demand by aggregating orders within the country and possibly with other countries in the procurement of ARVs. An additional way to promote efficient production is to commit to long-term supply agreements. Both methods enable investments in large-scale production facilities and significant reductions in cost by manufacturers. On the basis of cost analyses, a maximum forward price can be set along a diminishing cost curve. This will further reduce prices with increased total purchasing volume.

Fourthly, the supply of ARVs must be uninterrupted to meet the treatment needs of patients. There is always a risk of failure in the supply chain of pharmaceuticals. It is intended that the procurement plan coordinates a sustainable supply through the participation of viable suppliers, and local production of finished products and active pharmaceutical ingredients.

To achieve these goals, the following processes are planned.

Appointment of Negotiating Team

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

The negotiating team appointed by the Minister should be composed of people with the following skills and expertise:

- Knowledge of the tendering process
- Knowledge of procurement and Treasury regulations
- Knowledge of Competition Commission rules and regulations
- Knowledge of the cost and pricing structure and pricing models of the pharmaceutical industry
- Knowledge of the strategic and policy positions of the South African government regarding the pharmaceutical sector
- Knowledge of trade and legal issues

Procurement Mechanisms

There are at least three options by which procurement processes could be put into operation, namely:

- A regular government tender using local suppliers.
- A public-private 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 the regular national government tender procurement pre-qualification procedures be used. In the case of ARV procurement, a substantive

contractual agreement for sustainable supply of medicines would require a longer-term agreement than the standard two-year tender agreement as well as more flexible terms to allow for changes in drug regimens within an existing procurement agreement. This would also enable the department to negotiate diminishing cost curves as volumes increase.

If the usual tender process is unsuitable, ARVs could be purchased through a public private partnership (PPP) with specified suppliers, in accordance with Treasury regulations, led by the Department of Health. The PPP could be established to administer the tendering process for ARVs and to coordinate a sustainable and competitive long-term market for ARV production. While this mechanism allows greater flexibility in the tender process, the establishment of the PPP may involve delays.

International tendering may be considered in accordance with Section 1(4) and Regulation 3 of the Medicines and Related Substances Act 101 of 1965 as amended if such medicine;

- is essential for national health as approved by the Minister,
- can be obtained at a lower price outside the Republic and
- is registered by the Medicine Control Council (MCC)

International tendering or procurement however implies that continuous quality monitoring capacity must be strengthened to ensure that imports are not sub-standard and the possibility of counterfeiting is guarded against.

Pooled Procurement

Coordinating procurement with other countries provides manufacturers the volume required to achieve maximum economies of scale. This would allow for dramatically lower prices, enabling the government to realize one of the core goals of ARV procurement. Enhancing the total size of the ARV market also provides greater opportunity for competition, economic sustainability, and secure supply by multiple manufacturers. Pooled procurement could also be considered within the framework of the SADC Ministers' statement entrenching cooperation in strengthening local production and access to affordable medicines. Though this type of buying group has advantages, it requires careful management of country specific contracts.

Security of Supply and Local Production

To secure the long-term sustainable supply of ARVs, local production should be enabled through transfer of technology and production of active pharmaceutical ingredients (APIs) in South Africa. Local production policy should be aimed at establishing local production capacity that builds on existing realities of our investment drive and development initiatives. The strengthening of the industrial pharmaceutical and technological base in South Africa will respond to the NEPAD initiative and ensures that South Africa assumes an international market role.

Tender Process

The tender process consists of four stages. It is expected that the tender process will take about twelve weeks. A lead-time of two to four weeks may be required after the first orders are placed.

1. Supplier pre-qualification

All suppliers with MCC-approved drugs will be invited to participate in the pre-qualification process. All suppliers will be required to meet national and international standards in order to be qualified to tender to supply South Africa with ARVs. Pre-qualification is open to any manufacturer of ARVs, including companies producing generic, branded, and/or patented medicines. The criteria will include:

- MCC product registration and licensing of suppliers and distributors
- Pre-qualification standards (WHO or MCC approval)
- Financial viability
- Manufacturing quality, capacity and scale
- Cost transparency
- Agreement to price ceilings
- Commitment to establishing integrated production in South Africa
- Compliance with local regulations e.g. Black Economic Empowerment (BEE), Preferential Procurement Act etc.

2. Request for proposal and tendering (RFP)

Consistent with the notion of a partnership, a request for proposals will be developed to ensure procurement needs are met with the least cost and disruption to production. The RFP will establish:

- Product specifications
- Unique identification
- Volume of ARV supply for tender
- Duration of supply
- Substitution of medicines to alternative regimens
- Forward price setting according to a diminishing scale curve
- Annual review of costs of production and future prices
- Currency denomination
- Bid bonds
- Contingencies and risks assumed by each party
- Minimum inventories
- Distribution

3. Contracting

The final stage of the procurement transaction is negotiation, agreement on final terms and completion of the purchase contract.

4. Monitoring and evaluation

Contracts completed under the procurement process must be actively managed, monitored and evaluated for compliance with agreed to performance criteria and cost effectiveness.

Under this process it is envisioned that dedicated amounts of demand, e.g. 100,000 patient-dose-years, will be offered for tender to supply ARVs over a fixed period extending up to five years. To ensure adequate ongoing supply of ARVs by multiple manufacturers the total volume of any tender may be apportioned amongst bidders. During the fixed tender term, one drug regimen may be substituted for another regimen set at a different forward price curve depending on the clinical needs of the population.

SPECIAL CONSIDERATIONS

Regulatory Considerations

For both imported and locally produced medicines, it is important to have a robust regulatory and legal framework for the manufacture, sale, distribution and use of medicines, including ARVs, to underpin the long- term security of supply.

Regulatory Context for Supply

Like all medicines, ARVs must meet the normal standards for drug regulation and approval. All suppliers must include the following criteria for tendering:

1. Establish a legal presence in South Africa, i.e. appoint and designate a natural person who resides in the Republic to be responsible under local law
2. Use premises licensed for warehousing and distribution by the Director-General: Health
3. Gain approval as a pharmacy with the Pharmacy Council. From May 2004 the Medicines Control Council (MCC) will be responsible for licensing manufacturers, wholesalers, distributors, importers, and exporters.
4. Register the product with the MCC.

Accelerated Registration Processes

It is important to reduce administrative delays in the registration and approval of any new medicines that may improve health outcomes and mitigate drug resistance. All medicines procured must be registered by the MCC. Registration with the MCC is a thorough and occasionally time-consuming process. Fast track procedures are in place for expediting MCC approval.

Intellectual Property Considerations

All ARVs on the market are still under patent protection. The maintenance of intellectual property rights is essential to foster innovation and industrial development, however, the costs of patented medicines may prevent equitable access to essential medicines. The introduction of ARVs to the care and treatment of HIV and AIDS must comply with South African medicines law, patent law, and international obligations under the Trade Related Intellectual Property Rights (TRIPS) agreement. There are several ways in which access within existing laws can be facilitated.

Voluntary licenses

In cases where medicines can be obtained at a lower price, generic manufacturers can apply for voluntary licenses from patent holders. The disadvantage with voluntary licenses is that they are granted by the patent holders, who may or may not cooperate. Secondly, prices generally do not fall substantially where there is only one generic on the market. Prices come down with more competition. Thirdly, voluntary licenses may have strings attached e.g. royalties or restrictions with regard to whom products can be sold to.

So far, only one generic company has been granted a voluntary licence by two patent holders. This option may not be very useful as it is weighted heavily on the goodwill of the patent holder who may also have an interest in a viable market share. There are two further options to ensure a sustainable and affordable supply of necessary medicines as outlined in 2 and 3 below.

Compulsory licenses

The Patent Act provides for granting of a compulsory license by the Patent Commissioner, where demand for a patented ARV is not being met to an adequate extent and on reasonable terms. International legal norms provide further guidance regarding the granting of compulsory licenses. In cases of national emergency or where a product is for public non-commercial use, TRIPS allows the use of a patented product without the authorization of the patent holder. The detailed operation of this provision in the case of HIV, TB, and malaria has been reaffirmed and elaborated by the World Trade Organisation (WTO) Council for TRIPS. Most recently, the WHO has declared access to antiretroviral treatment by HIV and AIDS sufferers a global health emergency. A legislative amendment to the Patent Act to introduce compulsory licensing in the case of national emergency and public non-commercial use would be one way to further reinforce the comprehensive legal environment to enable broad access to affordable medicines and to facilitate secure and sustainable local supply.

The underpinning principle in the granting of compulsory licenses is that the patent holder is abusing his/her patent rights by maintaining an unaffordable price. This therefore implies that there must be negotiation with the patent holders to lower prices to an affordable level. The advantage with this option is that it opens the market to any generic

manufacturer. The disadvantages are that it may take a few months (three to four) to set it up and the patent holders may appeal to the Patent Commissioner on the basis of their not abusing their patent rights e.g. by granting voluntary licenses or bringing their prices down through the preferential price framework. This may therefore lead to protracted negotiations, appeals and delays.

Parallel importation

To enable the supply of more affordable medicines and to protect the health of the public, the Minister of Health may grant a permit that allows parallel importation of medicines. In this case, the Minister may determine that patent rights relating to a medicine patented in South Africa do not apply and the medicine can be imported. This provision is applicable and better invoked where the patent holder is abusing his/her patent rights by maintaining unaffordable prices. If parallel importation is invoked, it must be clearly demonstrated that there is no other option to access affordable medicines. Though this provision is at the behest of the Minister of Health, it may have wider trade related implications. It may also have a negative impact on the prevailing South African manufacturing capacity. The Doha and Cancun discussions however lessen this risk. The Department has all along been stating that this would be a last resort, after having exhausted all other negotiations to make medicine affordable. If this provision is invoked, communication in this regard is necessary. Secondly, parallel importation would be open to other players, beyond government in line with administrative justice and fairness. This implies that the monitoring arm of the Medicine Regulatory Authority must be vigilant and ensure that sub-optimal products are not imported into the country.

Regulation 7 of the Medicines and Related Substances Act stipulates that the permit granted by the Minister under this provision will be valid for two years and proof of registration of the product in the country of origin by a regulatory authority recognized by the MCC must be furnished. The person seeking a permit must also furnish documentary proof of the lowest price at which the medicine is currently sold in South Africa as well as the price at which it will be sold in South Africa. To ensure safety and efficacy, all parallel imported drugs must be registered with the MCC.

The principles outlined above, which aim at making medicine more affordable, will be extended to all essential medicines, in the spirit of the minimum package as stated by the SADC Ministers.

ADMINISTRATIVE STRUCTURE

Interdepartmental Leadership

An interdepartmental group will be established to oversee the implementation of the ARV procurement system. The Pharmaceutical Policy and Planning Cluster within the Department of Health will manage day-to-day operations in coordination with the Negotiating Committee. The Cluster will be responsible for managing tenders, aggregating provincial orders, placing order directly with suppliers, and ensuring that appropriate payment systems are in place.

Quality Assurance

Quality assurance (QA) for all companies registered by the MCC is administered by the MCC. The MCC inspects premises, determines Good Manufacturing Practice (GMP) standards, and recalls defective products. For purchased medicines, random product sampling is required. At present there is a need to strengthen the QA laboratory facilities at two centres, based in Cape Town and Johannesburg.

PROGRAMME ASSESSMENT

The effective management of the ARV procurement process requires routine, detailed analysis of the procurement portfolio and processes themselves. This review should include:

- Monitoring and evaluation data
- Review of market dynamics for ARVs
- Procurement patterns and irregularities
- Total volumes of procurement
- Analysis of prices paid
- Analysis of any hidden costs
- Management costs, times and other metrics
- Contractual performance

- Management of supplier relationships/ performance

Chapter VIII

Drug Distribution

OVERVIEW

An efficient and secure process for storage, distribution and appropriate utilisation of antiretroviral medications (ARVs) will be put in place in the public health system to ensure a reliable supply of medicines at all levels of distribution to avoid "stock-outs" and to prevent shrinkage and re-exportation.

To meet these two aims, 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).

BACKGROUND AND RATIONALE

Each province operates its own drug depot that provides drug storage and distribution services to the public health centres in the province. There are a total of 11 provincial drug depots, including one per province, except Western Cape and Eastern Cape, which each have two. Some have strong security mechanisms and inventory-tracking information management systems in place, while others do not. Those that do not have these systems experience higher rates of theft and stock-outs.

It is estimated that in the public health sector, a significant amount of pharmaceutical products procured is lost during the process of distribution and storage. While some of this high shrinkage risk can be attributed to the product being damaged or stocked inappropriately in the drug depots or the service point pharmacies, or during the process of

delivery, the majority is attributed to theft of product. Because of the very high market value of ARVs in Europe and the United States, and because of the lack of availability of the medicines in other African nations with a high prevalence of HIV and AIDS, large-scale theft for re-exportation presents a serious risk.

APPROACH

Provincial Level Depots

Drug storage

This Programme will need to ensure that existing Standard Operating Procedures at the provincial level depots are followed. ARV medicines will be managed administratively as "Schedule 5" medicines, with some additional requirements:

- An up-to-date register with a detailed listing of all products received and distributed, as well as every prescription dispensed.
- Inventory storage in a secure location, with access restricted to the person designated as responsible for the Schedule 5 stock (e.g. pharmacist, manager, specified ARV handler). The definition of a secure location is, at minimum, a padlocked room that is caged, (caged ceiling, four walls) and has a concrete floor and for pharmacies is either a caged room or a locked box.
- Order processing at depots may only be handled by the depot pharmacist, manager or specified ARV handler.
- Whether the delivery service is a government-owned system or an out-sourced courier service, the delivery service will be required to sign the shipment in and out directly in the presence of the depot pharmacist, manager or specified ARV handler. Contracts will have to be put in place between the provincial depots and their delivery services to ensure proper service, including the introduction of severe penalties in the event that an order is mishandled by the delivery service.
- Rooms where ARVs are stored will need to have air conditioning. Some ARVs, such as paediatric formulations in syrup form, will need refrigeration.

In any location where stock is stored and distributed, audits will be required every three months.

Inventory management

To ensure proper supply of ARVs to the public health service points, provincial depots will be required to process and ship an order within two business days (48 hours) of receipt. In addition, for exceptional cases where there is a local emergency, mechanisms

will be put in place that should allow orders to be processed and shipped within four hours.

Given the volume of medicines that are likely to be ordered, the number of service points, and the need for rapid turn-around, it will be necessary to place and track orders electronically within three to five years. IT systems in each provincial depot will need to be upgraded over the initial years of the programme to include high-speed Internet connectivity, and symbology-based technologies for electronic parcel tracking. Symbology-based technologies that identify the drug, the source, the destination and the patient through a patient identification number will enable the department to meet the drug handling requirements without all the manual record keeping. There still will be paper based tracking systems in facilities that do not have computer systems or reliable access to electricity.

Within five years, it is expected that this upgrading will be completed and each provincial warehouse should have one IT person on staff to maintain the ordering and processing system. An additional investment in an advanced inventory tracking system at the central procurement, provincial depot and local health facility levels should also occur to improve visibility into the drug supply at the national, provincial and local levels, and prevent stock-outs. The system should contain the following functionality:

- When stock runs low at the service points, the system will notify the provincial depot and/or the manufacturer that more stock needs to be sent.
- When the stock runs low at the provincial depot level, the system will trigger a notification to the manufacturer that more stock needs to be sent.
- In the event that stock runs low at a provincial depot and the main manufacturer is not able to supply the order, even with the contingency supply requirements, the system will: 1) check the stocks of other provincial depots to see if they are over-stocked, and trigger re-route of some of that stock to the provinces that are under stocked; 2) send an order to a secondary set of manufacturers asking for an expedited supply of the medicines.

These investments in information technology will not only improve the system to manage ARVs, but should improve inventory tracking for the entire drug distribution network.

Pharmacies at the Public Health Service Point Level

There are pharmacies in all of the district hospitals and most of the community health centres. In order to accommodate the ARV Programme, investments in infrastructure and human resources will be required for up to 90 percent of these sites.

Site Accreditation

Every health facility pharmacy that wishes to dispense ARVs will need to be accredited. Minimum standards will include, but not be limited to, the following:

- Implementation of the Standard Operating Procedures for receiving, storing and dispensing Schedule 5 medicines, including the security standards described for provincial depots.
- A minimum level of buffer stock (at programme initiation, this will be four weeks' supply; by the end of year 5, it decreases to two weeks).
- A registered pharmacist on-site.

Physical Plant Upgrades

Most public health pharmacies will have to upgrade their facilities to deal with the demands of storing and dispensing large amounts of ARVs. Site upgrades will include an expansion of storage facilities for Schedule 5 medicines and investments in the IT infrastructure to allow for online order placement and prescription information collection and management. In addition, pharmacies will need adequate rooms for patient counselling. This should strengthen pharmaceutical care throughout all services rendered.

Prescription Tracking

A significant portion of the population moves between their homes and a separate place of work. To ensure uninterrupted access to needed medications, it will be important for individuals to be able to get prescriptions filled as they move throughout the country. Therefore, a system needs to be in place to track prescriptions throughout the country. A software module will have to be added to the inventory management system discussed in the provincial level depot section to track patient movement throughout the system (see Chapter XI, *Patient Information Systems*). This will improve tracking and follow up for all patients on chronic medication, including TB patients.

SPECIAL CONSIDERATIONS

Contingency Stock Plans

In order to minimize potential disruptions to ARV programme implementation, a contingency stock plan has been considered. Drug manufacturers will be required to keep a two month supply of stock on hand in their local warehouses. This requirement will help to minimize the chance of stock-outs in the country while at the same time lessening the storage demands of the provincial depots and public health pharmaceutical facilities.

Packaging to Optimise Adherence

The provincial depots have a role to play in the packaging of ARVs to improve overall drug adherence. For example, using a system that is already in place in a few of the provincial depots, packaging all the separate ARVs from a single regimen into one box or bag can greatly improve the dispensing and administering of the drug. As the IT systems improve, printing the name of the prescription recipient on each package at the warehouse or depot before it arrives at the local pharmacy will greatly improve the security and accurate dispensing of the medicines at the pharmacies. This also allows for the introduction of direct-shipping options to prescription recipients. As the number of individuals on ARVs increases over time, consideration might be given to the development of capacity to provide the type of individualized, large-volume packaging that is required through contracts with local suppliers. This can be extended to other high value items and specialised treatment regimens.

ADMINISTRATIVE STRUCTURE

In order to ensure the proper implementation of the drug distribution component of the ARV programme implementation, the Pharmaceutical Policy and Planning Cluster will manage the following structures:

- The Committee for Medical Provisioning (COMED) will determine the standard operating procedures as they relate to inventory management, security, and distribution of all medicines including ARVs to all public health pharmacies.
- The Heads of Pharmaceutical Services Forum will assess training programmes and materials, and ensure proper budgets are in place to deliver on the drug distribution plan.

- The Pharmaceutical Policy and Planning Cluster will oversee the pharmacy accreditation process, developing a strategy to ensure that accreditation can happen in a timely manner. Other activities will include development of standards for tracking and tracing of medicines

PROGRAMME ASSESSMENT

The Pharmaceutical Policy and Planning Cluster will assess the programme on an ongoing basis, to ensure that set goals are met. Specifically, at depot level, the goals are to:

- Keep shrinkage of ARVs below 0.5%.
- Process orders within 48 hours.
- Maintain a minimum of 6-week stock at the provincial depot level.

At the pharmacy level, the goal is zero stock-outs and shrinkage below 0.5%. Manufacturers will be measured based on meeting expected lead times, the quality and completeness of orders, and the maintenance of a continual 6-week stock in local warehouses.

At facility level, the ultimate goal is to ensure that records of patients' medication profiles are kept to facilitate counselling on drug use, follow-up of patients on chronic medication that default, reporting of adverse events and adverse reactions and to link all pharmacy activities to a patient information system.

Chapter IX

Laboratory Services

OVERVIEW

Laboratory diagnosis of HIV infection, staging of disease progression, and monitoring of therapies, including management of antiretroviral toxicities and the response to therapy are essential components of HIV care and treatment. The significant current expense of these tests mandates a careful assessment of the required tests and their use. Price negotiations with suppliers are ongoing.

The laboratory services established as part of this programme incorporate the best available evidence and international guidelines in order to establish a judicious laboratory plan. Moreover, the high volumes that will be required to support the HIV and AIDS care and treatment programme make significant reductions in the price of CD4 and viral load tests likely.

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

- To support best practices of patient care.
- To monitor for the development of drug resistance.
- To establish evidence-based, cost-effective and sustainable laboratory services.
- To expand currently available capacity within the NHLS to offer best support to the clinical services.

The National Health Laboratory Service (NHLS) will take responsibility for the laboratory services as required to support the HIV and AIDS care and treatment programme. Although the NHLS has a strong infrastructure base, additional infrastructure and capital equipment expenditure will be required to support the programme's laboratory needs, as will targeted improvements in sample collection, specimen transport, laboratory training, and information systems. Initial working capital will be required to support initial implementation operations. The NHLS could contract out work to the private laboratories

as a contingency measure.

The NHLS operational plan is outlined at the end of this chapter, following a brief summary of the laboratory services to be provided under the care and treatment plan and a brief discussion of additional laboratory issues relevant to the HIV and AIDS care and treatment programme.

BACKGROUND AND RATIONALE

Laboratory Services to Support HIV Care and Treatment

A set of diagnostic assays is central to HIV care and treatment, in accordance with national and international guidelines:

- HIV diagnostic tests (rapid tests, ELISAs, and infant diagnostics)
- CD4 counts
- Viral loads (currently by quantifying HIV RNA. Other technologies may become available.)
- Toxicity assays (such as FBC and ALT)
- Resistance monitoring
- Diagnostics for opportunistic infections

Clinical Monitoring Protocol

The NHLS laboratory services will follow the requirements dictated by the ARV treatment clinical protocols (see Chapter I, *Prevention*, *Care and Treatment*). The protocol for clinical monitoring of HIV disease has been evolving since the mid-1990s, when antiretroviral drugs to treat HIV infection and new laboratory assays - particularly viral loads - were first introduced. While there is consensus on some issues, there is as yet no well-established protocol for laboratory and clinical monitoring. Recent guidelines were set forth by the World Health Organization and by the United States Public Health Service, but revisions of these recommendations are expected in the near future. In order to remain vigilant of new developments in monitoring, the Department of Health will develop periodic updated guidelines for the ARV treatment programme. (See Chapter I, *Prevention*, *Care and Treatment*, and Chapter XII, *Monitoring and Evaluation.)*

CD4 Count and Viral Load

The CD4 count assay is the cornerstone of HIV disease monitoring. CD4 counts provide an assessment of the immune system in HIV-infected patients and are used to track both the decline in immune function in untreated patients, and the rise in immune function following the initiation of ARV treatment. A CD4 count below 200 cells/mm^3 will be the major laboratory determinant of entry into ARV treatment until further evidence indicates otherwise, and CD4 counts will also determine the need for specific interventions to prevent opportunistic infections.

To perform these tests the NHLS will require significant investment in laboratory infrastructure, capital equipment and ongoing operational expenditures. Based on current projections, a cumulative total of between 14 and 20 million CD4 counts will be performed after the first five years of the ARV programme. To meet these targets, infrastructure and equipment to support CD4 count testing will need to be developed in all NHLS regions. Of the NHLS sites selected for CD4 testing, capacity is currently available in Cape Town, Durban, Johannesburg and Bloemfontein. To meet targets, CD4 laboratories will be established in Nelspruit, Polokwane, Umtata, Ngwelezana, and Port Elizabeth. New sites in Newcastle, Port Shepstone and Tshepong could be established by the fifth year of the programme to handle the projected increased needs.

Specimen transport capacity to ensure timely delivery of samples to the designated CD4 laboratories will be upgraded where necessary. Overall CD4 testing capacity will need to be expanded approximately six to eight-fold after five years. Training will have to be expanded to equip the new technical staff required (see the outline of the NHLS operational plan below).

Viral load assays measure the amount of HIV present in the plasma of an infected individual. They serve three functions: as a marker of progression from HIV infection to AIDS; as a measure of the response to ARV treatment; and as a sentinel indicator for development of treatment failure, possibly due to drug resistance. The assays are technically complex to perform, and require sample separation within eight hours of collection and subsequent sample refrigeration. Based on current projections, a cumulative total of approximately three million viral load assays will be performed after

the first five years of the programme.

Of the NHLS sites selected for viral load testing, capacity is currently available in Cape Town, Durban, and Johannesburg. To meet targets, viral load laboratories will be established in Bloemfontein, Umtata, Ngwelezana and Polokwane, as well as one additional site to be determined based on need. To maximize cost effectiveness and thus reduce costs to the DoH, viral load and CD4 testing will remain centralized as far as possible, particularly in the fist five years of the project, or until the technology changes sufficiently to permit cost effective service to be offered closer to the point of service.

The NICD would form an additional facility to handle any specimen demand in excess of current capacity. A detailed table of facilities upgraded to perform these two assays by year is included in the summary of the NHLS operational plan.

South Africa's CD4 and viral load volumes will likely expand the global market for these assays by 50-100 percent. In order to minimize the budgetary impact, significant price reductions can be achieved through strategic partnerships with international manufacturers of the CD4 and viral load testing equipment and reagents. These partnerships should involve not merely volume discounting, but innovative ways to reduce the costs of production and distribution and guarantee supply, and the development of local manufacture of consumables or reagent kits will be explored. Such partners may be used to fast track new technology for African and global use. Commercial partners should be selected on their ability to provide the highest quality equipment and test kits using protocols designed for resource-constrained settings, at affordable pricing.

Toxicity Monitoring/Pharmacovigilance

The existing infrastructure of the NHLS is sufficient to handle the routine assays used for toxicity monitoring, particularly given the anticipated upgrades to several previously disadvantaged district and central laboratories, and to specimen transport capacity that will take place within the ambit of this project. As the programme expands additional infrastructure development of district laboratories and service sites for routine haematology and chemistry is anticipated, particularly in provinces where current peripheral laboratory capacity is limited.

The clinical monitoring protocol calls for laboratory assays to monitor the toxicities of the antiretroviral medications. These include monitoring for the development of liver toxicity after the initiation of the first ARV regimen, and testing for anaemia and cholesterol abnormalities for patients receiving the second regimen. These assays are technically simpler (and therefore less expensive) than CD4 and viral load testing, and are currently performed routinely by the NHLS. In addition, it is anticipated that other tests to monitor potential toxicities not identifiable through routine screening will be clinically indicated for a subset of patients (such as pancreatitis, lactic acidosis, and glucose intolerance). The ability to perform these assays on an as needed basis has been budgeted into the laboratory component of the programme, based on projections of the frequency of ARV side effects. (See Chapter XIII, *Pharmacovigilance.*)

APPROACH

The availability of high quality laboratory services is an essential component of the HIV and AIDS care and treatment programme. There are a number of key principles that apply. Testing will need to be performed using the best international standards. Investment in high quality laboratory infrastructure will have to be made to monitor patient safety, response to therapy and eligibility for ARV therapy. This investment will also improve access to laboratory services nationally. Although national standards will proscribe certain tests, these tests will need to be available as clinically indicated. In addition, price negotiations should be conducted to achieve lower prices for higher volumes of tests being performed.

National Health Laboratory Services (NHLS) Operational Plan

The NHLS will provide the laboratory services for the ARV programme within the resources available to it. This is in accordance with legislation currently in effect in South Africa. Should the NHLS infrastructure prove inadequate for the workload, work could be contracted out to the private pathology sector by the NHLS. In reviewing its capacity to meet the needs of the programme, the NHLS has identified seven priority areas for development:

- Enhancing laboratory infrastructure to support CD4 count and viral load testing.

- Improving specimen transport infrastructure in currently under-serviced areas.
- Improving information technology and laboratory information systems to facilitate transfer of patient details and results between clinical service sites and the laboratories. This will also permit improved data mining capability.
- Upgrading district hospital infrastructure where necessary for basic laboratory assays and specimen processing.
- Expanding laboratory staff training to support increased need for viral load and CD4 testing, quality assurance and information technology.
- Implementing dried blood spot technologies for support of VCT external quality assessment (EQA).
- Identifying and supporting research priorities in affordable HIV related diagnostics, monitoring and surveillance.

Support for the NHLS in each of these priority areas is included in the operational plan and outlined briefly here.

Laboratory Infrastructure to Support CD4 Count and Viral Load Testing

Implementation of the ARV treatment programme nationally will require expansion of central laboratory facilities extending into all regional divisions of the NHLS. The facility expansion plan will be reassessed regularly by NHLS in coordination with the Department of Health, particularly in the first phase of the programme when uptake may be variable across the provinces. By increasing capacity at existing facilities and diverting specimen transport, the NHLS can flexibly meet unexpected increases in demand. By the third phase of the programme, sufficient capacity should exist in each province to meet local/regional CD4, viral load, and toxicity testing needs.

Specimen Transport Infrastructure

CD4 counts and particularly viral load assays have unique specimen handling constraints, further complicating laboratory operations. A comprehensive plan to identify geographic areas and existing laboratories needing specimen transport upgrades has been conducted by the NHLS. Areas in need of additional transportation resources (including four-wheel drive vehicles) will be prioritised, in order to ensure that laboratory services are equitably distributed and do not hinder programme implementation. Specimen transport should be monitored and addressed on an ongoing basis by the NHLS. In addition, technologies to reduce the impact of specimen transport issues, such as dried blood spots for viral load

assays and point-of-care diagnostics, will be developed, evaluated, and implemented as they become available.

Information Technology (IT) and Laboratory Information Systems (LIS)

The existing laboratory information system in place at NHLS laboratories will be expanded to meet the needs of the ARV treatment programme. This will facilitate improved turn-around-times. Data mining will also be possible within the existing Laboratory Information System (LIS). Computer hardware and licensed software will need to be brought into several existing peripheral laboratories, to improve the interface with the rest of the NHLS. Implementation of the IT expansion also encompasses system installation and LIS training for laboratory personnel. The existing LIS infrastructure will also be utilised by the NHLS to monitor laboratory ordering practices and laboratory costs, as well as regional uptake of laboratory services. (For further details, see Chapter XI, *Patient Information Systems*, and Chapter XII, *Monitoring and Evaluation*). This data will be communicated to the DoH. Demographic details and laboratory results may also readily be accessed in NHLS data repositories for additional analyses.

District Hospital Infrastructure

In addition to the creation of additional central laboratories for CD4 count and viral load testing, several district hospitals may be upgraded to enable CD4 count and viral load testing based on demand. While essential laboratory assays (such as HIV ELISAs, FBCs, or liver enzymes) are already well established and generally sufficient for the needs of this project, upgrades will be implemented where necessary. Such upgrades will need to be undertaken in order to ensure that laboratory services are available in geographical settings appropriate to demand across the country.

Laboratory Staff Development

The laboratory expansion also necessitates a significant expansion in the numbers of trained laboratory personnel, particularly with respect to CD4 and viral load testing. Technical laboratory training for laboratory technologists and technicians is currently coordinated through the NHLS, the professional registration bodies, and technical training institutes. Training capacity will be enhanced by the establishment of a national training centre at the NICD (National Institute for Communicable Diseases) campus in

Johannesburg. Educational and training efforts will be coordinated with the appropriate certification boards and will be determined by the laboratory-specific human resource needs in each region. Training manuals and short courses on laboratory techniques associated with the ARV treatment programme have been developed and are currently available through the NHLS. In addition, the companies supplying equipment and reagents for the viral load testing should offer equipment and assay-specific training. (For further details, see Chapter V, *Human Resources and Training)*.

Dried Blood Spot Technologies for VCT External Quality Assessment

As support for the VCT needs associated with the ARV treatment programme, an external quality assessment (EQA) programme for rapid HIV test kits will be developed. This EQA programme will take advantage of advances in dried blood spot (DBS) technology. Specimens collected as dried blood spots for EQA at service sites and VCT centres can be collected, stored, and shipped to the NICD laboratories for EQA cheaply and reliably. Establishment of an expanded EQA Programme will include improvements in basic infrastructure, additional training for laboratory staff, training for VCT site staff on DBS sample collection, and capital equipment and reagent purchases, including DBS punch elution equipment and DBS packets for VCT sites.

Research

A research programme focused on operational questions central to the ARV programme and on the development of affordable technologies for HIV laboratory services will need to be established within NHLS. Research will include developing methods for improving laboratory services. The research agenda should include resistance monitoring, strategies for optimal ARV laboratory monitoring, and clinical utility of assays at each time point during treatment, the appropriate laboratory evaluation at the initiation of therapy, and the development of new, inexpensive methods for CD4 count and viral load determination. Further details of the research programme can be found in Chapter XIV, *Research Priorities*.

SPECIAL CONSIDERATIONS

Laboratory aspects of Voluntary Counselling and Testing (VCT)

The VCT programme will be an important point of entry into the ARV treatment programme. The existing VCT programme now encompasses 1,625 sites and nearly 5,000 trained VCT counsellors. With the introduction of antiretroviral therapy, it is anticipated that demand for VCT services will increase significantly. Coordination between the ARV treatment programme and the VCT programme will be established to ensure that there is appropriate procurement of HIV testing kits and ready supply at VCT sites. In addition, the NHLS will expand their external quality assessment (EQA) programme for the HIV rapid test kits now in widespread use throughout the VCT initiative. Moreover, contingency plans to address either excess demand or low uptake of ARV treatment programme services need to be coordinated between the VCT and ARV treatment programmes. This may require increased HIV ELISA testing capacity within the NHLS.

Resistance monitoring

As the affordable range of antiretroviral drugs available for use against resistant virus is limited, ensuring that development of drug resistant HIV in patients receiving ARVs is minimized is a high priority of this programme. Resistance monitoring has been established as part of the monitoring and evaluation of this programme, as well as a high priority for research (see Chapter XII, *Monitoring and Evaluation*, and Chapter XIV, *Research Priorities*). The National Institute for Communicable Diseases can support the research needs for resistance testing, which is technically complex. The Department of Health will be responsible to review and report regularly on developments in the field of resistance monitoring, including opportunities for price reductions and the establishment of guidelines for the use of resistance assays.

Opportunistic infection diagnostics

Several laboratory tests are commonly ordered in the context of HIV care to diagnose HIV-related opportunistic infections. Current capacity exists within the NHLS to support these assays, including cryptococcal antigen tests, tests for cytomegalovirus, hepatitis and herpes viruses, and others. The Department of Health, in coordination with the NHLS, will undertake periodic review of OI diagnostics.

Infant diagnostics

Standard HIV antibody test kits (i.e. rapid tests and antibody ELISAs) cannot reliably diagnose HIV infection in infants until approximately 18 months of age. Assays that may be used to determine whether an infant born to an HIV-infected mother is infected prior to 18 months of age include P24 antigen serology and HIV DNA PCR. While available in many laboratories within the NHLS, these assays are not always in routine use. Strategies for infant diagnostics are currently coordinated by the PMTCT programme. It is recommended that a Paediatric Monitoring Task Force be established, and charged with coordinating protocols for infant diagnostics and monitoring with the PMTCT programme and the NHLS.

ADMINISTRATIVE STRUCTURE

The National Health Laboratory Service (NHLS) will implement the laboratory component of the ARV programme.

Because of the cost of laboratory testing and the scope of laboratory services in the ARV programme, the laboratory component represents a significant fraction of the overall budget, despite the development of a monitoring protocol that attempts to minimize unnecessary testing without compromising clinical care. Strategic partnerships with suppliers that include centralized purchasing, predictable volumes and innovative cost reduction initiatives are expected to lead to cost reductions in the necessary equipment and reagents. Procurement plans will be coordinated with NHLS and the Department of Health as the project progresses. These may change with time depending on changes in pricing structures and availability of new technologies.

PROGRAMME ASSESSMENT

The SMT will monitor the laboratory costs of the ARV treatment programme on a regular basis, and will meet regularly with NHLS executives to review data on laboratory utilization, turn-around times, patient friendliness, costs, and new diagnostic assays. The Department of Health will assess the protocols used for initiating ARV therapy and for monitoring patients receiving ARVs on an ongoing basis, including reviewing laboratory

monitoring protocols, based on new developments in HIV laboratory technologies and evolving international guidelines.

SECTION FOUR

COMMUNITIES

Chapter X

Social Mobilisation and Communications

OVERVIEW

The success of the proposed HIV and AIDS care and treatment plan will be facilitated by a well-defined social mobilisation and communications strategy. This strategy includes an external information, education and communications (IEC) strategy linked with a social mobilisation component that together articulate the implementation goals.

Research has shown that susceptibility to HIV infection is related to a wide range of factors, such as poverty, culture, gender relations, and lack of education. Raising awareness is but one aspect of HIV prevention. Prevention also requires strategies and interventions that support behaviour change, particularly access to services, a supportive environment, and positive social norms.

Increasingly in South Africa HIV and AIDS communication campaigns are focusing on "care" as well as "risk reduction" as areas of intervention. This reflects the progression of the HIV and AIDS epidemic to the point that a significant proportion of the population is directly affected. HIV and AIDS intervention campaigns are therefore about developing a range of strategies and interventions that will support behaviour change.

Successful implementation of the various elements of this operational plan will require a communication strategy that involves a wide range of government sectors and non-governmental organizations at the national, provincial and local levels.

The specific aims of this communication plan are to ensure that all relevant government programmes, health care providers, PLWHA, their families, care-givers and stakeholders are fully knowledgeable about all of the key provisions and requirements of the plan, as well as their respective roles and responsibilities.

The communication plan should endeavour to ensure that PLWHA are informed of care, treatment and support resources available through national and local programmes. It should include the creation of a supportive and safe environment for people living with HIV and AIDS, largely through educational programmes that address stigma and discrimination. As always, communication efforts must continue to focus on preventing further infections among people who are free of this disease, and reducing the risk of HIV transmission by those who are infected.

BACKGROUND AND RATIONALE

A comprehensive communication strategy provides basic HIV and AIDS information, and promotes available services and advocacy efforts. Basic informational activities include mass media messaging; distribution of small media (such as leaflets and posters); and social mobilisation activities. Promotion of services will focus on interventions such as condom use, voluntary HIV counselling and testing, an AIDS Helpline, the use of ARVs and treatment of opportunistic infections, and sexually transmitted infections.

The communication strategy will serve as a vehicle for supporting the following HIV prevention and education priorities:

- Healthy lifestyle choices, and how they can help prevent HIV infection.
- The importance of testing to learn one's HIV status.
- The reduction of stigma at a societal level, to ensure that all those HIV-positive individuals who desire to will enter into a system of prevention and care.

Guiding Principles

Two groups of factors are critical to the success of a communications strategy:

Content

- A balance between prevention and care, so as not to undermine current gains and efforts.
- Clear communication to the effect that not all HIV-positive persons require antiretrovirals.
- Information on where service is provided in each of the nine provinces, and what it entails.
- The importance of a healthy lifestyle in slowing progression from HIV to AIDS.

- Clear guidelines and messages on nutrition.
- The importance of adherence for those on treatment.

Process

Effective communication requires a market segmentation approach, whereby different groups are differentially targeted in both method and substance. This communications plan will need to be designed to meet the needs of seven key target groups. Each of these groups will be directly affected by the plan and play a vital supporting role in implementation. These sectors are:

- Three tiers of government: Ongoing communication to political leaders and key decision-makers with regard to plan implementation, as well as the development of key messages for their constituencies.
- Affected individuals, including PLWHA: These core beneficiaries will be provided with content addressing their specific information and education needs.
- General public: General information regarding the programme, including messages on stigma and discrimination.
- Health care providers and traditional health practitioners: Tools and information that support the work of these practitioners will help support integration of services at the community level.
- Families/caregivers of people living with HIV and AIDS
- NGOs and other groups providing services to people living with HIV and AIDS
- Sectors of civil society

APPROACH TO COMMUNICATION

To achieve its goals, the communications plan will pursue a combination of strategies that include augmentation of the existing communication and social mobilisation capacity at the national and provincial departments of Health. Particular attention will be focused on ensuring that communication strategies are integrated into existing efforts and lead to an overall systems improvement.

The current government campaigns have achieved a number of successes in both the development and implementation of their objectives. The ARV communication campaign should build on these achievements, implementing a more intensive public campaign to

increase and maintain uptake around VCT, and the rollout of the comprehensive treatment programme.

The scope of work for the treatment campaign should be organised in three components: public awareness (mass communication), small media material and social mobilisation.

Mass communication campaigns should aim to raise awareness and provide a backdrop for complementary communications, small media and interpersonal activities, such as the AIDS Helpline and VCT services. A major thrust of the campaign will be the use of traditional broadcast media, with the bulk of spending on radio and outdoor advertising.

Small media material is crucial in the rollout of the ARV programme. It includes the development of posters, leaflets, guidelines and strategic documents and should be available in at least 5 of the 11 official languages.

This material is intended to support interactive activities such as health care worker training and patient counselling, and can also be used at clinics and events. The provision of appropriate small media products allows for dialogue to be supported by objective information, and also empowers many individuals and organisations to offer accurate information in relation to ARVs.

Social mobilisation is central to implementation of a comprehensive HIV and AIDS care and treatment plan. The implementation of the plan should expand on the existing sector advocacy activities, such as national, provincial, and district AIDS councils, faith-based organisations, women's organisations, men's groupings, and celebrities, to reach a broad range of South African society.

Social mobilisation is a critical component of any media campaign aimed at mobilising people and communities to action. It provides visible on-the-ground presence for the campaign and its messages.

The overarching goals of social mobilisation efforts are to ensure that PLWHA have access to care and treatment programmes and adequate support structures in their local

communities, and that stigma and discrimination experienced by PLWHA are eliminated or reduced, thereby reducing social isolation and increasing the likelihood of adherence. These goals will be achieved through community networks that address these issues, with emphasis on providing supportive networks to those on ARV treatment and their families.

APPROACH TO SOCIAL MOBILISATION

Because HIV and AIDS care and treatment are community-based, involvement of the existing community structures is critical to success. Essential elements to include in social mobilisation include:

Utilisation of existing structures, such as AIDS Councils

The community-mobilising effort should utilise and expand on existing mechanisms and structures that relate to HIV and AIDS. The creation of a subcommittee of the provincial AIDS Council on community mobilisation will be necessary prior to commencement of treatment. This subgroup could include representatives of the provincial departments of Health and Social Development, relevant NGOs, faith-based organisations, celebrities and PLWHAs, as well as representatives of the traditional leadership and traditional health practitioners.

Pre-Implementation Requirements

Prior to the initiation of comprehensive care and treatment, it will be essential to raise community awareness not only about access to the treatment programme, but also about HIV and AIDS more broadly. Currently, many misconceptions remain that may deter persons from accessing care. The pre-implementation phase for social mobilisation should include identification and evaluation of existing community mobilisation programmes, and active involvement of traditional health practitioners, trade unions, local community leaders and the business sector as partners. This should include establishment of regular meetings of these entities to set up a community support system that effectively coordinates efforts, refers persons to care, and refers individuals back to community support mechanisms.

Dissemination of information related to the existence of the programme can be achieved with the help of these community groups, and should also make use of the mass media campaign, including radio, TV, and print media in locally relevant languages to increase understanding about HIV transmission and how it causes disease; prevention; and treatment care and support. Care must be exercised to ensure that communications are reflective of local sensitivities.

Implementation Requirements

ARV treatment programmes will need to be linked to community services, many of which are outside of the traditional health care system. A system of referrals from community centres to the health care system and from the health care system back to community centres to allow clinic service coordinators to assist patients and their families in accessing community services will need to be established as part of the continuum of care at the district level.

Treatment literacy curricula will be developed and will include teaching people with HIV and AIDS about the importance of good nutrition, healthy lifestyles, preventing infection and re-infection. Additionally, education about side effects is an important goal, as knowledge of early signs of side effects has proven effective in improved health outcomes. Patients who are knowledgeable about side effects are more likely to seek medical attention earlier, when lower cost solutions are still possible.

Key messages

The approach adopted shall be relevant to previous campaigns, and shall incorporate research into message development, and evaluation outcomes.

AIDS Helpline: Promotion of an anonymous 24-hour multi-lingual counselling service which provides information on ARVs, i.e. who will qualify, where the services will be and what to expect.

Promoting voluntary counselling and testing: Promotion of VCT services to the general public, including promoting the advantages of HIV testing, the counselling (pre- and post-test) that is provided, and encouraging post-test support.

Care and Support: Promotion of treatment, care and support services in health facilities and communities (including ARV treatment). This is aimed at encouraging health-seeking behaviour, and adopting caring attitudes towards people seeking assistance from health care services.

Stigma and Discrimination: Promotion of activities and campaigns that address acceptance, openness and information of social welfare benefits available.

The communication campaigns need an approach that recognizes all the challenges of diversity, yet must have communication strategies that are holistic and integrated.

Requirements for effective internal communications

1. Equip the Department of Health with the infrastructure necessary to take lead responsibility for the internal communications and IEC efforts related specifically to the implementation of the plan.
2. Establish regular face-to-face or teleconferencing group briefing sessions between key Department of Health staff and identified communications contacts for each provincial Health Department on the implementation details of the plan.
3. Enhance the existing communications capacity within all provincial health departments to ensure on-going communications with district/local health care providers on implementation progress.
4. Establish a regular electronic (e-mail), newsletter and web-site briefing and announcement system within the Department of Health to provide weekly update information on the Plan to provincial and district level public health care administrators and health care workers.
5. Develop a system that informs key relevant government departments (Finance, Social Development, Education etc.) about the implementation activities, to ensure multi-sectoral participation.

Requirements for effective external communications

The immediate strategies developed to address the communication goals will need to be focused on enhancing the existing Department of Health capacity for organising and managing public media campaigns. The campaign efforts should reflect both a clear understanding of the implementation goals and the needs and challenges facing those at risk or living with HIV and AIDS. The communication strategies are as follows:

1. Strengthen and expand existing communication capacity within the Department of Health and its HIV and AIDS Cluster and the Communications Cluster to coordinate an ongoing public awareness and education programme (integrated with and informed by existing IEC efforts) for the plan.
2. Develop a comprehensive communication strategy organised around the priorities of preventing the further spread of HIV infection, promoting and supporting access to VCT and HIV care and treatment at the community level, enhancing treatment literacy and treatment adherence among people affected by HIV and AIDS, and eradicating stigma and discrimination against PLWHA.
3. Enhance the formal structures ensuring full participation of individuals infected and affected by HIV and AIDS in the design and implementation of all relevant communication campaigns.
4. Ensure that print, radio, broadcast and other electronic news media at the national, provincial and community levels are effectively utilised to promote the communication priorities.

Resource needs for the above four strategies include increased budgeting for enhanced communication activities.

To support and implement the above strategies, the communications plan will rely on print and electronic media, community radio, Internet access, special events, speakers' bureaus, print and electronic advertising (paid and donated), distribution of small print education materials and community-level outreach.

The communication channels will be determined by the focus of the campaign message and the intended target group/stakeholder. In addition, it is important that the mass media campaigns, supporting materials and channels are well tailored to conform to the culture, social norms and language of the target groups. Finally, the communication campaign efforts will need to be designed to support the social mobilisation programmes envisaged in the implementation plan. These efforts will work hand in hand in promoting broad access to HIV and AIDS prevention, care and treatment, improving treatment adherence and health outcomes.

ADMINISTRATIVE STRUCTURE

Communication efforts will be coordinated by the national Department of Health in conjunction with provincial Health Departments. Resource needs to support the government communications programme will include additional dedicated communications staff for the Department of Health and related IT support as reflected above. Within each province an additional 1.5 FTEs will be required to support the internal communication efforts.

PROGRAMME ASSESSMENT

The communications programme will need to include a monitoring and evaluation (M&E) component to measure the programme's overall effectiveness and to identify needed improvements and modifications. The M&E effort will be coordinated with the existing Cluster for Health Information, Evaluation and Research.

Government Management Communications Systems

A tailored monitoring and evaluation system will have to be integrated into the governmental management communications system to assess the effectiveness of information flow and consistency of understanding among the national, provincial and municipal public health departments. The M&E data will be critical in identifying bottlenecks and gaps that might undermine effective implementation.

Communications Programme

The Department of Health will need to know whether the public awareness and social mobilisation campaigns are effective in achieving the appropriate outcomes in the intended target groups or sectors. The M&E system will ensure that specific measurable objectives are built into the major mass media campaigns and that clear analysis is fed back to the programmes for continuous improvement.

Specific messages will be developed for the public information, education and communications campaigns based on the goals. Appropriate and effective messages for the IEC effort will be developed based on formative evaluation research with specific target groups and stakeholders.

In conclusion, the ARV campaign should comprise a mass media campaign utilising cost-effective approaches to reaching appropriate target audiences. It should have key focus areas with at least one key message/theme for each focus area, and an appropriate and cost-effective media strategy. The social mobilisation component is crucial in the broader context of the proposal.

A multi-tiered communications intervention is going to be vital for the country's ongoing response in the ARV programme.

SECTION FIVE

INFORMATION, MONITORING AND RESEARCH

Chapter XI

Patient Information Systems

OVERVIEW

The patient information system is designed 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 are:

- To register patients utilizing 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 need to be developed as an integral part of existing health information systems in South Africa. The system will need to be integrated into existing data collection systems, and will be standardized across all facilities in the programme. Basic data should be collected at the facility level, analysed for local use, and passed on to the provincial and national levels for programme monitoring and evaluation.

BACKGROUND AND RATIONALE

The national health information system is made up largely of three sub-systems: hospital information systems, a district health information system, and a disease notification system. All but the latter should be adapted for the ARV treatment programme.

Hospital-Based Systems

Patient information systems in hospitals vary across facilities, ranging from large, sophisticated systems such as Medicom and Meditech, through homegrown systems such as the Patient Administration and Billing system (PAAB), to manual paper-based systems.

The systems share a certain degree of similarity, but are not always compatible. Although there has been an attempt to standardize these systems, this has not been fully achieved.

The following is a listing of the information systems that are currently in place in the provincial hospitals:

- PAAB is implemented in a number of hospitals in Gauteng, Mpumalanga and North West.
- Medicom is implemented at 9 hospitals and 5 clinics in Gauteng and at Inkosi Albert Luthuli hospital in KwaZulu-Natal.
- Delta 9 is implemented in Limpopo and clinics in Eastern Cape.
- Systech is used in 3 academic hospitals in the Western Cape.
- Oasis is used in 6 hospitals in the Northern Cape.
- Meditech in used in 3 hospitals in the Free State.

District Health Information System

The District Health Information System (DHIS) has been developed primarily to provide core information for primary health care administration. It collects basic facility information, including rosters of hospitals, health centres, and clinics, as well as a number of specific modules. A Hospital Module contains information on utilisation, bed occupancy and length of stay. A PMTCT Module and a Patient Module have been developed over the past year.

APPROACH

The ARV treatment programme will modify the PAAB module as the standard for data collection. Provinces may adapt this module onto their existing systems, provided this adaptation collects the standardized information. Where the use of electronic systems is still limited, or where the electronic PAAB module cannot be integrated into existing hospital information systems, a paper-based version of the modified PAAB system will be used. These paper-based data will be converted into an electronic file, to be used for monitoring and evaluation at provincial and national levels. As the programme is implemented, paper-based systems will ultimately need to be replaced entirely by electronic records. A standard patient information form and basic dataset will need to be adapted in all provinces to ensure standardisation.

Data Modules

The major component of the modified PAAB form will be known as the "Patient ARV Treatment Report Form," and will contain the following unique modules. These modules are designed to contain the minimal essential information necessary to ensure good patient outcomes and efficient programme administration.

Patient registration

All patients entering the programme should be registered using the national identification number (ID), surname and date of birth. The ID number will used as a patient identifier across all systems at every level of health care and in any province to avoid duplication and repetition of procedures. The system should be able to identify nationality or residence status as well as medical insurances/schemes.

Demographic data contained in the Patient Registration Form include:

- Names and surname
- Address/telephone
- Date of birth: dd/mm/yy
- Identification number
- Gender
- Marital status
- Next of kin
- Population group
- Employment
- Education
- Name of local and district municipality
- Province
- Citizenship/Residence status
- Facility

Medical history/examination

At the first visit following registration, a form will be administered to capture a patient's medical history, including previous illnesses, hospitalisation, date of HIV diagnosis, date

and location of VCT, current medications, symptoms, and ARVs taken previously, including nevirapine. For women, current or planned pregnancy, access to PMTCT services and access to contraceptives will be assessed.

A baseline examination of patients will also include vital signs, weight and details of any abnormalities of the eyes, oropharynx, lymph nodes, lungs, heart, abdomen, extremities, etc. This information will be captured in the baseline medical history/examination form.

At each follow-up clinic visit, an abbreviated version of the medical history/examination form will be completed. It will include:

- Vital signs
- Interim medical history, including: illnesses, hospitalisations and visits with specialists
- Current ARVs prescribed, if any
- Assessment of ARV adherence, if taking ARVs
- Assessment of ARV side effects, including: rash, weight changes, abdominal pain, and nerve pain in the hands and feet
- Allergies and current non-ARV medications

If the patient is admitted to a hospital or treated in outpatient specialist clinics, a medical history/examination form should be completed there as well. Upon completion of treatment or hospital discharge a summary record should be generated automatically by the PAAB system to enable verification by medical records staff and enable completion of any missing information.

Laboratory and other diagnostic information

The results of laboratory tests and other diagnostic evaluations performed either at the implementation site or at designated laboratories should be captured as part of the patient record. At a minimum, the patient information system should capture the results of the CD4 cell count, viral load, and other basic tests, including those used to identify potential adverse reactions to ARVs. The frequency of these tests will be determined by the treatment protocols for ARV management. The NHLS will also retain patient laboratory information as part of its laboratory information system (LIS).

Pharmacy and pharmacovigilance

Data captured as part of the patient medical record will support drug dispensing for inpatients and outpatients. This part of the patient record will interface with a separate pharmacy database, which will provide for entry of prescriptions and medication orders at outpatient clinics or wards. On entry of prescription, the pharmacy database will display other drugs that have been prescribed to a particular patient. The system will need to have a controlled procedure for the authorization of all issued drugs and will maintain a separate register or controlled drugs and narcotics.

For inpatients, the National Health Care Management Information System (NHC/MIS) should maintain patient medication profiles and prepare medication administration schedules with days, times, and dosages. It should also check for allergies or sensitivities, possible drug interactions, contraindications, over dosages, and special instructions, taking into account the route, dosage, forms and times of administration. Information on adverse drug events should be captured.

Specific data elements collected in the pharmacy database will need to be coordinated with the Pharmacovigilance unit (see Chapter XIII, *Pharmacovigilance*), and will include:

- Medications
- Date treatment was commenced
- Date treatment was terminated
- Reasons for treatment termination: (e.g. patient defaulted, patient decision, patient lost to follow-up, adverse drug reactions, patient died)
- Adverse drug reactions
- Treatment adherence information

The system should, on completion of the summary or abstract of treatment details, have the tools to render the record non-modifiable. From then on, the NHC/MIS should maintain that as part of medical history, accessible to authorized users.

Service utilization

The modified PAAB system will have to permit scheduling of appointments and follow-up visits. The appointments may be given either for a specified time or for a time-bracket and

should enable a conscious overbooking and the handling of emergencies. The system should be able to detect appointment conflicts, enable rescheduling of appointments and hospital clinics, cancellation of appointments, and track non-compliance with scheduled visits.

The system will need to fully support the processing of admissions, discharges and transfers of inpatients, including emergency admissions. Discharges should be entered either at the nurse's station or the medical records office. The system should generate a discharge summary, especially for patients that were referred from other levels. Visits to specialists, laboratories and general clinics will need to be recorded, with recognition of first visit and subsequent visits. The system should permit recording of actual/scheduled information along with defaulters to ensure production of accurate monthly utilization reports.

IT Development

As the programme moves beyond the initial phase, and the number of sites increases, there will be a significant expansion of reporting points requiring investment in health information infrastructure to upgrade electronic information systems, computer hardware and software, and to enable effective interface with laboratory and pharmacy information systems.

ADMINISTRATIVE STRUCTURE

Within each facility, a clerk should complete patient registration, and the clinician or nurse attending the patient should complete clinical records. At each additional point of contact in the facility (laboratory, pharmacy, etc.) a patient-linked record will need to be completed and integrated into the patient's file. If paper forms are used, a data clerk should complete electronic entry. Each facility will have a clear information flow protocol, and checks to ensure that all records pertaining to the programme are collated at the close of each day. One individual at each facility should be assigned as the data/M&E officer to conduct checks and ensure completeness of data entry.

Data entry manuals and guides for data entry and completion should be developed at the national Strategic Management Team (SMT) and made available to facilities.

At the district level, a single M&E officer should ensure that data from each facility are collated and completed. Abstracts of these data should be made available to facilities, to the provincial office, and to the national office. The information to be passed back to facilities, the districts, and the provinces will be established by the Department of Health as part of the Monitoring and Evaluation activity (See Chapter XII, *Monitoring and Evaluation*). A succinct newsletter or 'monitor' will be developed and circulated to all participating facilities and provincial offices as a feedback mechanism to track progress in the programme. The M&E office will be responsible for all aspects of the data collection and management process.

Finally, simple modifications of the DHIS Hospital, PMTCT and Patient Modules will need to be made to collect information on utilization rates, ARV distribution, and other information relevant to the ARV treatment programme administration not obtainable directly from the modified PAAB patient record system.

PROGRAMME ASSESSMENT

The success of the patient information system initiative depends on strong coordination at the central level (via the Cluster of Health Information, Evaluation and Research and the NHISSA committee), collaboration with the provincial health information teams, and the availability of adequate resources including personnel, training time and equipment at the district and service point level

Progress of the patient information programme will be assessed using the following measures:

- Number (and percentage) of sites using the national system
- Number (and percentage) of sites reporting complete minimum data set
- Speed and accuracy of reporting
- Progress toward migration to national system
- Progress toward complete integration of existing systems.

The Cluster of Health Information, Evaluation and Research will conduct an evaluation at the national level.

Chapter XII

Monitoring and Evaluation

OVERVIEW

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. The success of this operational plan requires the establishment of a monitoring and evaluation (M&E) system at the outset, to monitor implementation and ensure these goals are met. Ongoing monitoring will be critical to inform activities and allow adjustments to implementation. The M&E system will 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 national M&E unit will coordinate M&E units in each of the provinces that link with M&E efforts at the district level. Programme staff at each level will manage M&E processes and data, and will be placed nationally, in each of the nine provinces, and in the districts. Data collected by clinicians at service points will be aggregated at the district level, and incorporated into central databases housed at the provincial M&E units. Existing staff will be used to the widest extent possible. As enrolments grow over the course of the programme, additional support will be brought into the system. The overall objective of the M&E system is to provide information to maximize the programme's likelihood of success, and the achievement of the basic goals emphasised throughout this plan.

BACKGROUND AND RATIONALE

The standard public health M&E framework describes a straightforward relationship among factors that lead to the achievement of a programme's goals. Indicators associated with these factors can be measured, and then used to document how successfully goals are accomplished. These factors can be segregated into four levels: Inputs include basic personnel, consumables, equipment, and other infrastructure dedicated to support activities

or services. Outputs comprise those activities and services, and might include patient care, staff trainings, education campaigns, and support services. Changes in behaviour, skills, or health status as a result of the programme's activities and service constitute Outcomes. Over time and from the perspective of a population rather than an individual, the composite effect of outcomes results in major shifts in health patterns. These shifts are identified as Impacts, and in this case might include decreased mortality and morbidity, improved quality of life, or reduced transmission of HIV. Each of these factors can be subjected to monitoring and evaluation that can rapidly inform the future inputs, outputs, outcomes and impacts and lead to enhanced care delivery and programme effectiveness. Existing surveys and other research studies will be utilised as evaluation tools.

The ultimate success of an M&E programme depends on the ability to access and evaluate the above data. In this regard, M&E is dependent on the quality of data collection. The proposed national plan provides a unique opportunity to gather data efficiently, and on an unprecedented scale, and to use the M&E effort to inform the future direction of this programme, and of similar programmes emerging elsewhere.

APPROACH

Reaching the goals of the HIV and AIDS care and treatment programme requires the successful coordination of a diverse array of activities, and their timely, ongoing evaluation. The data relevant to monitor the critical health care indicators will derive from information gathered routinely in the course of care, and, when necessary, by appropriately designed studies. These uncomplicated data can also be used to monitor the large-scale accomplishments, to manage national programme activities, and to guide adjustments to national programme components.

Input and Output Indicators

The national M&E unit will define a core list of indicators, consistent with this operational plan and with the delivery of HIV care. Recommended output indicators for each plan component, representing the national and provincial implementation of services and activities, are listed in Table 12.1.

Table 12.1: Output Indicators for Monitoring and Evaluation

Care and treatment	Percent of functional programmes; health outcomes
Nutrition	Percent of programmes providing nutrition support
Traditional medicine	Number of service points with referral linkages
Strengthening and accreditation of service points	Number of accredited service points
Drug procurement	Level / percent of drug procurement systems in place
Drug distribution	Level / percent of drug distribution systems in place
Laboratory services	Number of accredited labs performing CD4 and viral load testing
Human resources and training	Number of certified health professionals; percent of posts filled
Communications	Percent of communication programmes completed
Community mobilisation	Percent of community mobilisation programmes completed
Patient information systems	Percent of facilities with functional systems
Pharmacovigilance	Number of pharmacovigilance monitoring systems in place
Research priorities	Number of research projects initiated
Programme management	Number of provincial management structures in operation

Input data will not be collected routinely at the national and provincial levels, given the tremendous quantity of information involved. Input data are available at the district level and will be abstracted to address specific evaluation questions.

The results of the programme's activities and services constitute outcomes, and the composite effect of these activities on health patterns constitutes impacts. For example, outcomes might include the change in the number of trained health care professionals who demonstrate improved skills, the change in the number of labs producing higher quality results, or the change in the number of HIV-positive persons in care and treatment. While the potential number of outcomes and impacts that might be evaluated is large, the national M&E effort will focus only on those associated with the delivery of care and its consequences, as listed in Table 12.2.

Monitoring of outcomes and impact

Table 12.2: Outcome and Impact Indicators for Monitoring and Evaluation

Indicators
• Number of people tested • Percent of people testing HIV-positive • Number of HIV-positive people in care and staged • Number of eligible patients receiving ARVs • Number of persons on ARVs with undetectable VL • Time between meeting staging criteria and receipt of ARVs • Mean change in CD4 among persons on ARVs • Rate of opportunistic infections among HIV • Average weight gain of patients on ARVs • Percent of patients on first, second regimen • Number of adverse events* • Prevalence of resistant strains (sentinel study) • Number and duration of inpatient visits • Number of casualty visits • Quality of life and score on Karnofsky Index • Number of AIDS-related deaths

*Note: Numbers collected on these indicators can be used with appropriate denominator data to calculate percentages. *Data will be collected by the Pharmacovigilance Unit and shared with the M&E office.*

At a national level, the composite picture reflecting these health improvements will document the level of achievement of the operational plan's goals. For example, prevalence of OIs, average weight gain, mean change in CD4 counts, quality of life scores, and mortality rates will be used to document realisation of the goals of reduced morbidity, increased quality of life, and decreased mortality. National profiles indicating improved survival and a better life for South Africans will represent the principal impacts of this programme.

Training

It will be essential to ensure that there are adequately trained personnel to manage the M&E function. National and provincial M&E unit members will collaboratively define their specific training and technical assistance needs during the onset of programme implementation. Expert training in establishing M&E systems is readily available. A team from the national M&E unit responsible for maintaining straightforward curricula

will oversee the development of provincial M&E teams. The provincial teams will be responsible for basic skills development for providers and data managers within each district and service point. The national office will conduct annual training for provincial teams; as the programme unfolds, these sessions will focus on updates and issues pertinent to programme success.

The national M&E unit will conduct training for the provincial teams early during implementation. At this time, the framework of the entire project will be reviewed, and issues specific to the M&E effort addressed. Relevant curricula will be introduced for use by the provincial teams when working with district and service point staff, which will be modified based on feedback from initial trainings to reflect local needs. Provincial teams will use these revised materials to begin training sessions at the district and service point level. These sessions for both care providers and other staff will address the principles of monitoring and evaluation and describe the assistance available from provincial and national M&E units.

Data Management

The management of data at national and provincial levels will require establishment of appropriate IT and database capabilities. An extensive use of information technology is projected, and full implementation over time will require considerable resources. The proposed electronic Patient Information System will require time to implement successfully, and this delay may result in initial data collection on paper at the district and health facility levels.

Data Collection Processes

Implementation plan goals and core indicators identified at the national level will guide the M&E activities in the provinces and the districts. Additional indicators might be monitored at the provincial or district level, to address local questions, but only data for national indicators will be submitted to the national M&E unit. Health care indicator data will be abstracted from the Patient Information System, while programme implementation indicators will be obtained from aggregated administrative data summaries.

The majority of primary data will be gathered from service point patient and administrative records. Patient data will be linked on the basis of unique, confidential identifiers, whereas programme information will be summarized into monthly totals. This information will be submitted to the provincial office and consolidated with data from other districts. Provincial M&E units will gather data on implementation activities, including training and other programmes based at the provincial level. These data will be submitted to the national office, where all provincial information will be combined. Other primary data will also be gathered at the national level, tied to the activities conducted within the national venue.

The actual data collection process will evolve in conjunction with the development of the Patient Information System (see Chapter XI, *Patient Information Systems*). Consequently, the initial data collection system will be a combination of paper forms and electronic media, the latter linked to existing patient data systems.

The M&E data system also will become the basis for more concentrated work, providing a foundation for sentinel or other surveillance studies and for formal research. These latter studies will build upon the M&E system and augment inferences obtained from this evolving health care system. Decisions regarding access to these data and to service points will follow the formal procedures outlined by the national SMT and the Health Information, Evaluation and Research Cluster, which coordinates the research agenda (see Chapter XIV, *Research Priorities*). Research findings that impact the M&E systems will be made available and utilised to fine-tune the M&E framework; this will create a productive bi-directional relationship between M&E and research.

SPECIAL CONSIDERATIONS

In conjunction with this M&E programme, one priority sentinel study will need to be introduced at the outset of the implementation plan to function as an early warning system for the emergence of drug resistance. This early warning system will, in turn, provide a measure of the success of the ARV treatment programme. The significant negative consequences associated with drug resistance are profound and require very close monitoring as the care and treatment programme rolls unfolds across the country.

This sentinel study, which represents a link between the research, pharmacovigilance, and M&E programmes, will be situated in a number of sentinel sites, chosen for their potential to rapidly yield resistance information. Two different cohorts are to be monitored in this study. The first group will include individuals who are currently receiving ARV treatment. These persons will be monitored for the emergence of resistance, as indicated by treatment failure. A second group will include persons who are verified as recent infections, through the use of detuned assays to identify new infections. These persons will need to undergo specialized resistance testing to ascertain the presence of, and by inference, the recent transmission of resistant strains.

ADMINISTRATIVE STRUCTURE

The general configuration of the M&E system follows the tiered structure of the national health care system. Overall coordination and support for M&E will rest with the M&E Unit and with the national Department of Health.

Within the M&E system, roles and responsibilities are defined according to the level of the health care system and the programme activities. Overall responsibility rests with the national M&E unit. While the various roles taken by the national office are replicated at each lower level, the scope of responsibilities will differ. The national M&E unit will define the core indicators to be used for national programming. Aggregate M&E data will be collected and managed by this office, and regular reports will be disseminated to, and reviewed with, the provinces and other appropriate agencies of government. This feedback will prove vital to programming, offering guidance for the modification of provincial activities. The national M&E office will create and sustain a training and technical assistance capacity, offering support to provincial and district offices. Partnerships with external entities will be emphasized both to increase capacity for care delivery and research, and to utilise additional expertise for training and technical assistance activities. When appropriate, national dissemination activities will target national and international outlets and journals.

Comparable roles and responsibilities will be situated at the nine provincial M&E units. The scope of these activities will be smaller, although the primary roles will remain the same. Each province will work with district and other local constituencies to define any additional indicators to supplement those developed by the national SMT. Provincial aggregate data will be collected and maintained at this level, and reports will provide feedback to the districts and to the national office. Ongoing dialogue and feedback between the national and district M&E units will ensure the successful implementation of programme and M&E activities. The province will provide training and technical assistance to the districts when requested, although some requests will be better served by national training and technical assistance programmes.

At the district level, M&E responsibilities include support for service point activities and for submission of information to the provincial office. Districts will work closely with service points to support programming and M&E, and to define specific aspects for the local effort. Some districts may choose to add indicators to those defined by the province and by the national office. Districts will manage data for their administrative areas, conducting the first phase of electronic data entry and initial stages of aggregation for the provincial office. Training and technical assistance requests to the district will be screened according to the capacity of the district, and many of these requests are expected to receive support from the provincial and national offices.

In addition to the M&E structure integrating the national programme, provinces, and health districts, the national M&E office will coordinate linkages with PLWHA groups; the private sector; NGOs; bilateral, multilateral and private funders; South African universities and research institutions; and international universities. These additional linkages will serve as a platform to share information, to standardize and coordinate effort, and to provide a framework for more focused research. This part of the M&E system is designed to facilitate partnerships to expand the delivery of care.

Human resource needs for the M&E system target two primary areas: programme management and data management/analysis. Programme management personnel requirements occur throughout the system. Data management requirements are tied to the evaluation of the large data sets. Specific personnel requirements of the M&E programme

include an M&E specialist in the national office. This person will be supported by a data manager, an epidemiologist/statistician, and a behavioural/social scientist. The provincial units will be led by an M&E specialist and supported by an epidemiologist/statistician and a data manager/data entry person. At the district level, a single person will oversee the M&E system. This individual should manage the local M&E effort, manage the data collection process, and act as liaison with the province. Preceding the implementation of the new Patient Information System, the M&E coordination office, with NHISSA representatives, will ensure that appropriate data hardware and software are in place. The district M&E officer will circulate among the service sites to enter information into an electronic format. This procedure will permit the retention of forms at the service sites, and limits the data entry process and need for specialised skills until an electronic system is fully implemented.

Data forms will include only unique patient identifiers, ensuring confidentiality above the district level. One additional staff position is required at the district level, although some exceptions might be made where districts include only a small number of service points. Under these circumstances, an existing district staff worker can initially assume these duties. It is anticipated that this process will evolve as growing enrolments lead to a greater need for dedicated positions.

Personnel requirements at the level of individual service points will be limited. An existing staff person can assume responsibility for the assembly of information for submission to the district office. In the future, this responsibility may demand considerable time and, consequently, the creation of a new position.

Chapter XIII

Pharmacovigilance

OVERVIEW

The plan highlights the need for a comprehensive pharmacovigilance programme as an integral part of the antiretroviral programme. Historically, the reporting of adverse drug reactions for all medicines has been poor, and remains limited in the case of antiretroviral agents. Pharmaceutical companies conduct and report required regulatory monitoring, but individual practitioner reports are less common. Health professionals are more likely to identify and report adverse drug reactions if they have sufficient knowledge and the ability to identify, manage and prevent such reactions. The need for ongoing training and aggressive advocacy is essential.

The goal of the pharmacovigilance programme is to ensure the safe and effective use of ARVs and other medicines commonly used in HIV and AIDS patients. Ultimately, pharmacovigilance should improve patient well-being and public health. The approach will involve regulatory activities performed by the Medicines Control Council, and active surveillance and training through the clinical pharmacology departments of medical schools attached to health facilities, including those in underserved areas. The pharmacovigilance units will be identified based on their technical capacity, ability to provide broad-based support to underserved areas, and ability to facilitate collaboration among the relevant departments of involved institutions.

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 treatment 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 (see Chapter XII, *Monitoring and Evaluation*)
- To respond to unfounded and unsubstantiated claims of efficacy of untested products and treatment modalities

BACKGROUND AND RATIONALE

Current Status of Pharmacovigilance Activities in South Africa

A regulatory infrastructure for pharmacovigilance activities in South Africa has been established since 1987. The Medicines and Related Substances Control Act (101 of 1965) mandates that applicants for registration should submit adverse drug reaction forms associated with the use of their products without delay. There is also limited experience reporting some serious adverse events as part of clinical trials. Further clarifications and more comprehensive requirements were included in recent legislation, providing clear instructions for voluntary reporting of any adverse drug reactions associated with the use of medicines registered in South Africa. An Adverse Drug Reaction (ADR) reporting form is attached as Annex XIII.1. A national adverse drug reaction reporting database (ADRI) has also been developed, compatible with the World Health Organization's pharmacovigilance database. All ADRs reported in South Africa are fed into an international pharmacovigilance database housed in Uppsala, Sweden.

Pharmacovigilance of the HIV and AIDS Care and Treatment Programme

The potential impact of ARV-related adverse effects on our population needs to be carefully monitored and considered. The risk of previously undiscovered or poorly documented adverse effects, long-term toxicities, teratogenicity and new drug-drug or

drug-food interactions also need to be carefully investigated in the South African population.

Safety profile of ARVs

Antiretrovirals are internationally recognized for their positive impact on life expectancy in HIV-infected people. In recent years, however, concerns among communities and health professionals about the safety of combination ARV therapies have been raised. ARVs are also known to cause serious, and sometimes fatal adverse effects. Toxicities such as lactic acidosis and other metabolic derangements, haematological toxicity, serious skin reactions, liver toxicity (hepatotoxicity), and neurotoxicity result from the ARVs selected as part of first and second regimens. Table 13.1 lists the expected rates of known acute toxicities. Moreover, some ARVs have important drug interactions that can render the ARVs or other medicines ineffective or enhance their potential for side effects.

Table 13.1: Expected Rates of Toxicities for ARVs used in Programme Regimens

ARV drug	System Affected/Toxicity					
	Haem	Hepatic	Pancreatic	Skin	Metabolic	Neurologic
Stavudine	+	++++	++++	-	Lactic acidosis	++++
Lamivudine	++	++	+++	++	Lactic acidosis	+++
Efavirenz	+	++	-	++++	-	Wide range
Nevirapine	++	+++	-	++++	-	+
Didanosine	+	+++	+++	-	Lactic acidosis	++++
Lopinavir/ Ritonavir	+	++	+	++	Lipid/glucose abnormalities	++
Zidovudine	++++	++	-	-	Lactic acidosis	-

Scale: ++++ >10% +++ 5-9% ++ 1-4% + <1% - Not reported or rare

The National Adverse Drug Event Monitoring Centre in Cape Town has received a total of 83 adverse drug reaction reports associated with the use of one or more antiretroviral medicines. Table 13.2 provides a breakdown of the number of reports received for individual ARVs (noting that more than one drug may be suspected in a single case).

Table 13.2: Number of ADR reports associated with ARV agents

Antiretroviral Agent	Number of Reports
Abacavir / Ziagen	8
AZT / Retrovir / Combivir	17
3TC / Lamivudine / Combivir	51
Efavirenz / Stocrin	25
d4T / Stavudine / Zerit	24
DdI / Didanosine / Videx	19
Lopinavir-Ritonavir / Kaletra	3
ddC / Hivid	3

Documented in the National ADRI database (as at 30 August 2003)

This relatively low number of reports on ARVs suggests the possibility of significant underreporting, but could also reflect the relatively small number of patients currently on ARVs. Training clinicians to better recognize and evaluate drug-related conditions is crucial to establishing a systematic reporting of ADRs.

To address these issues, the pharmacovigilance plan will evaluate long-term toxicities, potential for teratogenicity, drug-drug and drug-food interactions, and the impact of complementary and traditional medicines and additional drugs. The programme should improve and expand on the existing pharmacovigilance system to detect and evaluate previously unknown or poorly understood safety concerns associated with ARV use.

This plan, while focusing on the requirements for an ARV surveillance programme, will also consider the general pharmacovigilance needs of the country, particularly those likely to enhance the safety of medicines in patients with HIV and AIDS. While pharmacovigilance activities in South Africa have typically had a regulatory focus, the ARV pharmacovigilance programme should augment the general clinical care of patients on ARVs.

Antimicrobial Agents

HIV-infected persons are at increased risk of infection caused by antibiotic-resistant microorganisms. Containment of resistance to antimicrobial agents requires the establishment of appropriate early-warning systems over seen by a dedicated team of experts. Key elements in a containment strategy include the prudent use of antimicrobial agents, educational intervention, integrated surveillance and monitoring systems in all areas as well as good infection control practice. In addition, risk assessment and management strategies within a regulatory framework play an important role in containing antimicrobial resistance.

APPROACH

The national pharmacovigilance programme will pursue a phased plan of action over the coming three years, reflecting short, medium, and long-term goals.

Priorities

- Training and information support for health care teams and strengthening of the existing spontaneous reporting system. Advocacy on pharmacovigilance and ADR reporting can be initiated as part of enhancing spontaneous adverse event reporting. Strengthening the MCC and its regulatory infrastructure should be initiated in the first few months.
- Strengthening regulatory infrastructure and further provision of online support, including the development of a database that will be functional in 2005.
- Initiation of focused surveillance and novel pharmacovigilance methods for addressing key research questions, including maternal and perinatal surveillance and phytovigilance

Activities

- Enhance national spontaneous reporting system with active feedback to decision-makers, prescribers, reporters, patients and the public.
- Develop and improve regulatory procedures to support the defined objectives.
- Further development of a sustainable, functional, user-friendly database to support activity 1.
- Provision of unbiased, evidence-based information on the safety profile of ARVs, the safe and effective use of ARVs and the management of potential complications.
- Introduce targeted sentinel surveillance systems to evaluate signals of safety issues of potential public health importance (e.g. high risk groups such as pregnant women,

infants, HIV/TB co-morbidity). This will include resistance monitoring and documentation of trends to facilitate an early warning system.

- Develop novel pharmacovigilance methods to complement and support spontaneous reporting and sentinel surveillance systems.
- Develop key indicator(s) for estimating the prevalence of drug-related morbidity and mortality.
- Develop a phytovigilance programme for safety monitoring of complementary and African traditional medicines.

SPECIAL CONSIDERATIONS

Pharmacovigilance of Traditional and Complementary Medications

In the South African context, phytovigilance includes the safety of complementary African traditional medicines. Any phytovigilance plan should involve traditional and alternative health practitioners and should recognize the pivotal roles of the Traditional Health Practitioner Council and the Allied Health Professions Council.

There are several challenges associated with developing a phytovigilance system in South Africa, particularly given the early stages of regulation of complementary and traditional medicines. A National Reference Centre has been established, as a partnership among the DoH, MRC and the CSIR. Among other functions, this centre will serve the purpose of testing traditional and herbal products that make medicinal claims. Special attention must be given to building expertise and developing novel monitoring systems to assess risks and benefits of traditional and complementary medicine.

ADMINISTRATIVE STRUCTURE

Pharmacovigilance activities will continue to be maintained by the Medicines Control Council. The MCC will work with the national pharmacovigilance unit in Cape Town, as well as with two new focused pharmacovigilance units established at academic departments, including clinical pharmacology departments at MEDUNSA and in the Free State. Findings pertinent to the success of the HIV and AIDS care and treatment programme will be communicated directly to the Department of Health.

PROGRAMME ASSESSMENT

The following factors are critical to the success of the pharmacovigilance plan:

- Adequate funding and resources
- Support from the provinces
- Capacity development
- Collaboration and communication with key organizations and individuals in the public and private sector
- Ongoing assessment of the programme will be under the purview of the MCC.

Chapter XIV

Research Priorities

OVERVIEW

Research is a critical element of the plan for Comprehensive Treatment and Care for HIV and AIDS. The objective of the research agenda is to conduct studies whose answers will define the most effective provision of HIV and AIDS care and treatment, and guide programme implementation. Further new solutions for HIV and AIDS are needed as there is still no cure for AIDS, and it still proves impossible to eradicate totally the HIV virus from an infected individual, despite the progress in the past five years in the development of new antiretroviral drugs.

With regard to effective delivery of the antiretroviral drugs some of the critical questions to be asked would 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, nutritional or otherwise, to extend the period in which HIV-infected people can be maintained without antiretroviral drugs - arresting progression to AIDS? The challenge is to protect the immune system from the depredations inflicted upon it by HIV infected CD4+ cells during the 5–14 years between initial seroconversion and AIDS. In Africa this decline seems to be more rapid than in developed countries.

When eventually the patient ‘s immune system has been extensively destroyed and their CD4+ count drifts below 200 per ml, the research challenge becomes one of optimising delivery of currently available interventions such as antiretrovirals, nutritional interventions, antimicrobial prophylaxis and treatment of opportunistic infections, as well as the place of traditional and complementary medicines. Such research would include development of enhanced diagnostic and monitoring technology; new and improved drug regimens; better use of health systems to deliver these drugs; and behavioural research to improve compliance with medication regimens. This is the main thrust of the research

agenda: to conduct studies whose answers will define the most effective provision of HIV and AIDS care and treatment, and guide programme implementation.

The operational plan also seeks to engender research into one of the most important research question in AIDS: how to protect the immune system from continuing destruction caused by HIV-infected cells and other possible factors such as micronutrient deficiency, malnutrition, concomitant infection with other viruses and bacteria, and psychological stress.

Finally research in this programme on 'immune reconstitution' should be supported, including the effectiveness of putative immune modulators from traditional and complementary medicines – interventions that might permit AIDS patients to live out a normal and healthy lifespan despite continuing infection with HIV.

BACKGROUND AND RATIONALE

The scope of the treatment effort being undertaken creates an opportunity to understand the impact of ARVs in a largely treatment-naïve population. The information currently available on the use of ARVs derives from studies not representative of the South African situation, where local factors, including poverty, endemic clades of HIV, local host genetics, and the impact of co-infections with other pathogens such as tuberculosis remain to be evaluated. At the most basic level, formal research will be essential to understand the effectiveness, safety, and appropriateness of ARV use, and to refine the HIV and AIDS care and treatment programme moving forward. ARV use in South Africa is limited, indicating the need to monitor closely treatment effects when these drugs are made available in the public sector. The considerable research infrastructure available at multiple sites in South Africa, together with the strong research leadership from South African investigators, provide a sound platform upon which to rapidly develop a research programme that runs concomitantly with the implementation of antiretroviral therapy.

Rational development of a successful research agenda requires the ability to accurately track care delivery, during programme implementation. The health system's performance in delivering care is the essential component of any health programme, including this one.

The implementation of the ARV plan will inform the research used to guide this programme.

The establishment of a high-quality, accurate database that includes all persons initiating ARV treatment is central to this research effort (see Chapter XI, *Patient Information Systems*). Targeted sample collection and storage will be essential for addressing some basic research questions. Funding will be needed to support both human resources and infrastructure, including storage facilities. Mechanisms will be established for investigators to submit research proposals for consideration to a representative review panel with a transparent review process that will prioritise competing research projects and access to data. Linkages to established research programmes (such as the MRC, South African AIDS Vaccine Initiative, academic research programmes, Comprehensive International Programme on Research on AIDS, and International AIDS Clinical Trials Group) will provide synergy and prevent duplication of effort. The research programme will be flexible, such that it can respond to newly arising issues and provide guidance for future efforts.

The substance of the research agenda is based on extensive use of quantitative and qualitative methods. While quantitative research is essential to assess the success of specific aspects of the programme, added strength derives from associated qualitative studies. Qualitative and behavioural research provides greater insight into clinical decisions. Qualitative research also gives voice to individuals, families, communities, and illuminating circumstances. Qualitative information from HIV-infected individuals is particularly critical to the success of the programme, as the introduction of HIV and AIDS care and treatment constitutes an entirely new future for the HIV-infected population. Care and treatment will also alter the relationships among the infected and their families, communities, and care providers.

APPROACH

Clinical Research

Most data that guide the use of ARVs have been generated in the setting of developed countries, and have focused on different strains of virus than those responsible for the

South African epidemic. Although there is no question that ARVs can be life extending, the optimal use of these drugs has not been determined in the South African setting. Operational research to define best practices in similar settings has been limited. The performance of VCT sites to diagnose HIV infection and laboratory facilities to monitor resistance and the response to treatment are critical to the success of the programme. Development and use of new diagnostic tests for CD4, viral load, and resistance monitoring, and new parameters on the timing, frequency and location of laboratory monitoring, need to be evaluated.

A significant concern of the ARV programme is the development of resistance and the transmission of resistant strains of the virus. There is a clear, immediate need to research and develop an early warning system that indicates the onset of resistance, both at the service point level and at a national level.

The impact of antiretroviral medications on adolescent growth and development in naïve populations is a unique area of inquiry. Little has been published on the interplay of these medications on post-pubescent physiology, including issues around contraception.

Epidemiological Research

Epidemiological research will constitute an important aspect of the research agenda. This area of research will augment information that is currently collected in routine reporting systems and research projects which constitute HIV and AIDS surveillance systems. These include studies such as the Department of Health annual prevalence surveys, Behavioural Surveillance, Youth Risk Surveillance surveys and HIV incidence studies. Epidemiological studies include studies that add information on the progression of the HIV and AIDS epidemic. Data collected in this ARV programme will provide important epidemiological data on morbidity and mortality related to AIDS. Epidemiological studies will be able to provide more detailed information on HIV and AIDS associated morbidity, mortality and disability in the context of the overall burden of disease in South Africa.

Health Systems Research

Health systems research will include a broad range of issues including questions related to activities aimed at improving the health system's capacity to handle the increased service

requirements established by the implementation plan. Research projects may define how best to facilitate the integration of ARV programmes with general health services and with other HIV-related programmes, to avoid the creation of vertical, specialised operating silos among programmes. Specific projects will for instance evaluate whether the initial implementation, as well as integration with existing programmes at the service points, will de-stigmatise and de-mystify HIV care. Special attention will be given to identifying impact of ARV roll out on treatment behaviours, and concerns and strategies related to available HIV therapy in the workplace. Studies will also assess how the HIV and AIDS care and treatment plan affects other health programmes.

HIV Prevention Research

Prevention of HIV infection is the foundation for management of HIV and AIDS. Prevention can be augmented through a successful treatment plan. The classical method of preventing viral infection is vaccination. However as yet no HIV vaccine exists, and current progress suggests that it will be at least 5–10 years before an effective vaccine is available. The well known maxim that 'the only vaccine for HIV is prevention' still rings true; and behavioural science research to investigate how to enable people to protect themselves from HIV infection (through modification of sexual behaviour, use of condoms, microbicides, diaphragms etc.) is a key priority in HIV and AIDS research.

Behavioural Research in Prevention, Treatment and Care

HIV and AIDS is as much a psychosocial phenomenon as it is a biomedical phenomenon. Thus, the behavioural science research agenda is critical to providing insights leading to the discovery of improved treatment regimens for HIV-infected individuals. For the behavioural science research agenda a high priority is (a) designing, implementing and evaluating HIV sexual risk-reduction programmes to prevent the acquisition of HIV; (b) elucidating factors associated with adherence to antiretroviral medication and designing adherence programmes; (c) making antiretroviral medication more easily accessible; (d) reducing stigma associated with being at risk and living with HIV and AIDS. Priority behavioural research objectives for each of the following sections have been identified and are listed in the annexes (Annex XiV.1).

AIDS in South Africa is a disease that is transmitted primarily by social interactions between sexual partners. These risky sexual behaviours can be changed. Effective primary prevention programmes to prevent the further spread of HIV can assist people in making and sustaining behavioural changes that reduce the probability of transmission of HIV. A critical component of the behavioural science research agenda is to discover how to change behaviours and conditions that lead to HIV transmission including preventing their initiation and maintaining protective behaviours once they are adopted. Currently, behavioural interventions are the only effective way of slowing the spread of HIV. Cumulatively, meta-analyses evaluating the efficacy of HIV prevention studies, provide strong empirical evidence that interventions designed for individuals are efficacious in reducing high risk sexual behaviours.

Subsequent to identifying risk factors, HIV prevention research efforts must address issues related to the initiation and maintenance of HIV and AIDS risk-reduction efforts. This process requires moving beyond HIV and AIDS prevention programme efforts that only focus on providing information, education and communication (IEC). Moving beyond the IEC agenda requires the development of evidence-based HIV prevention programmes. Moreover, interventions designed to enhance adherence to antiretroviral therapy must be a research priority.

Rapid advancement of meaningful and effective HIV related social and behavioural science research requires further development of methodological tools, including those for evaluating HIV prevention interventions. As methodology represents the essential building blocks of intervention research it needs to be given special attention. Research methods are required to increase recruitment, retention and compliance to protocols for adherence and HIV prevention research. Adherence and HIV prevention intervention efficacy should be evaluated by using rigorous research methods, including randomised controlled behavioural trials. Evaluations of behavioural intervention studies should use self-reports of behavioural outcomes, as well as, HIV sero-incidence data and other biological markers as outcome measures. In addition to assessing intervention efficacy, researchers should assess the cost-effectiveness of prevention programmes. Finally, more research is needed to address the pressing ethical issues in the conduct of adherence and HIV prevention research.

Social Research

The impact of HIV and AIDS is experienced not only be individuals, but also by families, communities, and societies. The effects of the epidemic at all of these levels must be understood and monitored so that strategies can be developed to prevent household, social, and economic disintegration. The predominant mode of HIV transmission in South Africa is heterosexual transmission. Thus, designing interventions involving both partners of the couple to enhance their communication skills and facilitate partner norms supportive of safer sex is critical. There has been increasing recognition of the importance of the family in preventing and adapting to HIV prevention efforts. Families may include consanguine relationships, extended families, and kin sharing similar values and norms. Fostering family norms supportive of safer sex and adherence, providing HIV and AIDS education within the context of the family, and enhancing communication skills between parent and their children to dialogue about HIV prevention can be effective strategies. Effective interventions at the community level involve the community (neighbourhoods, social network members, organizations, institutions) as a partner and can enhance community norms supportive of safer sex and adherence. Societal level interventions involves modifying economic, legal, policy, and regulatory practices such that they may facilitate safer sex and therapeutic efforts.

Women experience HIV and AIDS differently than men do in a number of important respects, some of which are physiological and some of which are social. Women progress to AIDS at lower viral load levels and higher CD4 counts than do men. Women are more vulnerable to HIV as a result of cultural attitudes, social and economic position. This may be partly explained because context of heterosexual relationships and social arrangements are often characterized by gender inequality in which women have less power than men further exasperates their risk of HIV. It is important to understand the socially constructed aspects of male and female relationships including economic dependence, political decision making, access to health services, and education that may influence access to antiretrovirals and practice of safer sex efforts. HIV infected pregnant women have received a great deal of attention, however, this has mostly focused on their role in preventing transmission to their offspring. Greater attention must be given to the women themselves.

There has been a growing recognition that many individuals at risk of HIV and who become infected with HIV are also afflicted by a number of co-morbid conditions including other infectious diseases (hepatitis, sexually transmitted diseases, tuberculosis), substance abuse, mental illness, malaria (and other disease prevalent in South Africa) and poverty. Research needs to test the efficacy and effectiveness of interventions that simultaneously address multiple diagnoses and risk and improve HIV treatment adherence. In addition to assessing the efficacy of the interventions, research is needed to understand and improve the organization, management, access, delivery, cost-effectiveness, and cost-utility of health care, family planning, social services, drug treatment services, alcoholism treatment that reduce HIV risk behaviours and transmission.

Support research for the development, evaluation, diffusion and adoption of strategies to increase early identification, to improve treatment adherence, and to prevent or minimize the negative physical, psychological, cognitive and social consequences of HIV including stigmatisation of persons with or at risk for HIV infection. Support research strategies for promoting effective health care utilization among all persons with HIV infection and for promoting modifications in the health care delivery system to develop more effective, culturally sensitive methods to better serve treatment needs of infected populations.

Specific Research Projects

Within the framework of these three areas, there are a number of research questions that are of highest priority (note that this list assumes that a national treatment cohort with a uniform database will be established; thus, this is not listed as a specific objective). These include:

HIV/TB Co-infection

The burden of co-infection with TB presents a specific challenge in terms of treatment of HIV infection. Guidelines for initiation of therapy and for initial treatment regimens have been derived from settings lacking a high burden of TB infection. However, in South Africa, it is estimated that over 55% of persons with HIV infection may also have clinical tuberculosis[1]. The optimal timing of treatment of TB and HIV in co-infected persons and the optimal regimens for effective treatment remain to be determined. Thus operational

research to answer the following critical questions must be part of the initial ARV implementation plan:

- *What is the best treatment strategy for HIV-infected TB patients?*
- *What are the ARV regimen options that are most effective in the setting of concomitant clinical TB?*
- *Does malaria have an effect on ARV therapies?*

Opportunistic Infection

Research on opportunistic infections, and the mechanisms of infection and treatment should be an important component of the research agenda. A number of important research questions will arise, including:

- *What is the incidence/prevalence of various opportunistic infections in South Africa*
- *Do clinical course/severity and response to treatment differ from study populations in other geographic areas*
- *What is the role of co-infection with sexually transmitted infections (such as HSV2) on -infections with HIV*

Drug Resistance

One of the major threats to future treatment options for HIV infection is the development of antiretroviral drug resistance. Use of sequential monotherapy and dual therapies, and inadequate adherence to triple combination therapies has resulted in widespread emergence of multi-drug resistance in developed countries. Surveillance studies have indicated transmission of drug resistant viruses that compromise options for treatment of newly diagnosed infections. Success of the ARV treatment programme in South Africa will depend on the potency of the regimens used and proper adherence to these regimens. Moreover, the impact of widespread nevirapine use in PMTCT programmes on development of resistant mutations needs to be determined. Thus operational research to answer the following critical questions must be part of the initial ARV rollout plan:

- *What is the impact of nevirapine PMTCT programmes on subsequent treatment of women and their children?*
- *What is the evolution of drug resistance in the treated population as the programme is rolled out?*
- *What is the prevalence of drug resistance in the untreated population (i.e., how much drug resistant virus is being transmitted)?*

What Are the Optimal Efficacy and Toxicity Monitoring Approaches in the South African Context?

Most studies of ARVs have been performed in settings in which resources for monitoring efficacy and toxicity have not been limited. This has led to frequent monitoring, but the optimal frequency of monitoring has not been determined in a prospective controlled fashion, nor has the cost effectiveness of different monitoring schedules been determined. In addition, as the cost of ARVs drops, it is expected that a major economic burden will be the cost of diagnostic tests. Many new approaches to more economical monitoring, both through new monitoring techniques and through adjustment of monitoring schedule, are being developed. However, the impact of these new approaches on the quality of care delivered has not been determined. Thus a major important focus of initial research efforts should be to determine the optimal means of monitoring treatment. Operational research issues related to this effort include:

- *What is the optimal use and frequency of CD4 testing?*
- *What is the optimal use and frequency of viral load testing?*

What Are the Behavioural/Social Issues That Affect Success of Treatment Efforts?

The ultimate success of ARV treatment programmes is highly dependent on strict adherence to treatment regimens. Although there are clear data indicating that high levels of adherence to ARVs can be achieved in resource limited settings, the relative efficacy of different approaches to maximize adherence has not been determined. Moreover, the impact of new programmes for HIV and AIDS treatment on other aspects of the health

care delivery system has not been defined. Operational research issues related to behavioural/social issues include:

- *What are the optimum strategies to maximize and monitor drug adherence?*
- *What is the effect of the availability of ARVs on uptake of VCT?*
- *What is the effect of the ARV programme on sexual behaviour?*
- *What is the effect of the ARV programme on stigmatisation?*

What Are the Optimal ARV Regimens and Treatment Strategies?

Studies that have determined optimal regimens for treatment of HIV infection have largely been conducted in resource rich settings, where access to frequent laboratory monitoring is readily available. In these settings there nevertheless remain a number of inadequately addressed questions. The optimal use of ARV regimens in settings where resources are more limited, and where nutritional challenges and co-infections are more prevalent, remain to be determined. These factors pose a new set of research questions, which include:

- *What effect do different CD4 counts have on treatment outcomes as it relates to initiation of therapy?*
- *What to start: Should the initial regimen be non-nucleoside reverse transcriptase inhibitor (NNRTI) based or protease inhibitor (PI) based?*
- *When to change: Should clinical, CD4 or VL indications be used to determine when to change therapy?*
- *What to do in pregnancy? What are the optimal first and second line regimens in pregnancy?*
- *What to do in paediatric infection? What are the optimal first and second line regimens in paediatric infection?*

What is the Role of Nutrition in Health Maintenance in HIV Infected Persons?

HIV infection drives a hypermetabolic state with resultant weight loss and reduction in muscle mass and subcutaneous fat. With advanced HIV disease, micronutrient deficiencies may supervene, exacerbating the immune deficiency state, and increasing susceptibility to opportunistic infections. There is therefore a need to determine the following:

- *What are the optimal approaches to the delivery of essential nutritional elements to PLWHAs?*
- *To what extent do nutrition programmes prolong the period of time prior to the need for ARV treatment?*
- *Does nutritional supplementation affect the frequency of occurrence of opportunistic infections?*
- *Does nutritional supplementation augment adaptive and innate immune responses?*

What is the role of traditional and complementary medicines in treatment of AIDS?

Claims have been made, in South Africa and other African countries, that various African traditional medicines are able to restore immune function, with many impressive case reports that attest to improved clinical state, rising CD4+ count, and reduced viral load in people living with AIDS who take these medications. Other 'immunopotentiators' that have been investigated in the USA include interlukines, structured treatment interruption, Chinese herbs, lentinin (shitaki mushrooms), and other cytokines in general. Traditional healer therapies might have some immuno-restorative qualities.

Research would focus on:

- safety and toxicity of such traditional medicines
- clinical efficacy in controlled clinical trials – some of which are already underway
- drug-drug interactions with ARVs

Does Advanced HIV Infection and AIDS Impair Absorption of Drugs?

This has not been extensively studied but there are indications that anti-TB medications may be malabsorbed in patients with advanced HIV disease and AIDS. The public health implications of low drug serum levels include the possibility of MDR-TB associated with HIV infection. Similarly, ARVs may also be malabsorbed, predisposing to sub-therapeutic doses, and drug resistance. The research questions posed by this observation include:

- *Determination of the bio-availability of antiretroviral drugs and anti-TB medications among HIV-infected TB patients compared with non-HIV infected TB cases.*
- *Is malabsorption related to the degree of immune deficiency in HIV-infected persons?*
- *What is the effect of intestinal parasites on drug absorption.*

Determinants of and interventions against progression of HIV to AIDS

HIV infection typically leads to severe immune deficiency associated with the loss of CD4 T-lymphocyte populations. Although progression rates in South Africa are not known, studies in other settings indicate that HIV infected individuals will progress to clinical AIDS and death within 7-10 years. In 20% of persons this occurs within 5 years and sustained asymptomatic states without a significant decline in CD4 T cell occur in about 2% of investigated populations. There are no such data in areas of the world hardest hit by this epidemic. The factors that influence these very different disease rates are unclear, but may relate to host genetic factors, different genetic features of the infecting virus strain, and the host immune response. These observations indicate that specific aspects of the human immune system may hold important determinants for disease progression. The key research questions for predominantly treatment-naïve populations include:

- *Determination of the benefits of population-level screen for genetic determinants of progression to assist in applying appropriate interventions at the appropriate times.*
- *Determination of the utility of immune-stimulants and modulators to assist in preservation of a stable host immune system and hence slow the progression to AIDS and delay the time until ARVs are needed.*

- *Determination of the effects of ARV treatment on immune reconstitution*
- *What are the mechanisms by which the small proportion of HIV infected cells are able to induce apoptosis of other uninfected CD4+ cells – a key research question that emerged from the discussions of the International Presidential AIDS Panel in South Africa in the year 2000 - the so called 'bystander effect'*

Improving HIV care and treatment through adjunctive immune modulation

The use of HAART has been advocated as the most important intervention for HIV and AIDS. However there remain practical and virological limitations of the current regimens. Strategies that simultaneously investigate the potential for a combined virological approach and immune modulation aimed at improving control of viremia need to be explored. The pertinent questions include:

- *Determination of the effect of immune modulation as an adjunct to HAART on survival, improved and sustained protective immune systems as evidenced by slower progression to AIDS and the decline of the incidence of opportunistic infections.*
- *Will adjunctive immune modulation impact on immune recovery or are there critical states of immune destruction which are irreversible?*
- *What proportion of the infected population will be most responsive to immune modulators and are there surrogate predictors?*
- *Can immune modulation potentially replace HAART or reduce dependence on HAART?*

Cancer

Kaposi sarcoma and Non-Hodgkin's Lymphoma are the main cancers in AIDS with cervical cancer in women with human papilloma virus being the third. This is especially common in South Africa where cervical cancer is the leading cancer in women.

- *Basic incidence/prevalence data, and information on progression is needed*
- *Studies on diagnosis and treatment are needed.*

SPECIAL CONSIDERATIONS

In addition to the highest priority research issues that will be addressed immediately, additional research issues of high merit will be considered for future study. It is expected that funds for these projects will be obtained from sources outside of the current programme. These issues include:

1. What is the role of traditional and complementary medications in the context of HIV care and ARV treatment?
2. What are the gender-specific differences in natural history of HIV disease and response to treatment? (For the former, a natural history cohort of HIV infected, untreated should be established.)
3. What are the metabolic complications of ARV treatment in the South African population?
4. Does micronutrient supplementation improve clinical disease outcomes for PLWHA?
5. What is the cost-effectiveness of ARV treatment in South Africa?
6. What are the optimal models of care for urban and rural health care facilities?
7. To what extent can one identify markers of good outcome of treatment in the early stages of intervention; likewise can one define markers of bad outcome that can allow for early intervention to improve outcome?
8. What is the overall effect of the HIV and AIDS care and treatment programme on access to health care?
9. What is the impact of the HIV and AIDS care and treatment programme on attitudes of health care providers, and on retention of health care workers?
10. Various research questions are identified in other chapters of the Operational Plan, such as the pharmacovigilance, traditional medicines and nutrition chapters.

ADMINISTRATIVE STRUCTURE

The research programme will be coordinated through the Health Information, Evaluation and Research Cluster at the national Department of Health.

Research Oversight

Although it is critical to the success of the programme that oversight of the research agenda remains the preserve of the Department of Health, appropriate mechanisms will be found to ensure an efficient mechanism for managing research. It is equally critical that the operational plan be subjected to ongoing critical evaluation by independent investigators. This will ensure a careful and dispassionate assessment of the HIV and AIDS care and treatment programme.

Review of Applications

A rigorous and transparent peer review process will be used to ensure that all proposals are relevant to the interests of patients and of government; are of the highest scientific quality; are conducted by scientists competent to the task; and have been authorized by the appropriate institutional review boards. Peer review could be facilitated through existing peer review mechanisms such as those of the Medical Research Council (MRC).

Allocation of Support

Recommendations for funding will be made by the Research Advisory Committee and approved by the Department of Health. Funds to support research questions deemed to be highest priority will be provided through government and other supporters.

Dissemination of Research Findings

Appropriate mechanisms will be established to disseminate the results of this research, facilitated by regular reports from funded investigators. Emphasis will be placed on using research findings to improve and strengthen the programme.

Sources of Funding

It is expected that networks similar to the clinical trial consortia will be established for the research programmes described above, and that twinning with external organizations will have immense capacity to leverage direct funding and strengthen research capacity. New funding strategies will also be developed.

Partnerships

The Health Information, Evaluation and Research Cluster at the national Department of Health will create and maintain links with local, regional and international organizations, institutions and collaborating partners. These linkages will facilitate exchange of ideas, especially among health systems with experience in operational research on ARV implementation.

In the field of diagnostics, especially in high TB- and HIV-burden countries, the Bill and Melinda Gates Foundation initiative, the Foundation for Innovative New Diagnostics (FIND), is expected to expand its current efforts into the development of new diagnostics to improve TB diagnosis among HIV-infected persons. It has to be emphasised that there is a need for new affordable diagnostics for HIV and other opportunistic infections that can potentially be adapted for use at programme level in resource-limited settings.

PROGRAMME ASSESSMENT

Formal review of the research agenda as well as of the management structure will be performed on a yearly basis by an independent panel comprised of scientists with expertise in HIV and AIDS. This panel will report to the Minister of Health.

The HIV and AIDS care and treatment plan also represents a unique opportunity to collect data that will inform not only South Africa's programme, but nascent programmes to expand HIV and AIDS care and treatment throughout sub-Saharan Africa and other affected regions of the world.

SECTION SIX

MANAGEMENT AND BUDGET

Chapter XV

Programme Management

The Importance of Effective Management

The comprehensive HIV and AIDS Care and Treatment Programme will require energetic and disciplined management. A large number of people must complete tasks and their work must be integrated together in a timely fashion for the programme to succeed.

This will be particularly important in the first few years of the programme. A management failure to execute one part of the plan could jeopardize the execution of all parts. Health professionals can be trained, facilities upgraded for treatment, patient information systems ready to go, but if the capacity to administer CD4 tests is not ready, or one of the necessary ARV drugs is not delivered on time, the whole programme can be delayed. This may occur if any of the multiple essential elements of the plan are not executed efficiently.

This operational plan is designed so that patients will not be put in jeopardy through management failure. Facilities will not be allowed to administer antiretroviral drugs until they are accredited as ready and their staff are properly trained. Drugs will not be made available until they are properly tested and can be securely distributed. Patients will not be given drugs until they are counselled, tested and have community support structures in place to assist them. However, the programme could suffer serious delays, waste significant resources and cause considerable disruption to the nation's health care system if not managed properly.

The management annex of this plan (Annex A.2) details the tasks that need to be performed to implement this programme successfully. This annex also proposes a week-by-week initial schedule for the performance of those tasks in order to help ensure that the various actions necessary for successful implementation occur in tandem. This annex has been computerized and will serve as a tool for management of the project. It will require

continual revision and updating as the project proceeds, but will provide a way to keep managers at all levels working from the same management plan.

Programme Management Principles

There are a number of principles that will guide the management of this programme.

1. Though it will involve a significant increase in health spending, this programme will not create a parallel health system in the country. It will be integrated into the existing management of the national health system.

2. The programme will be integrated closely with the existing health programmes across a broad spectrum, including HIV, AIDS, STI and TB management. In particular, this comprehensive care and treatment programme will integrate with prevention and education programmes.

3. The programme will be coordinated within a national framework to ensure uniform quality, an equitable implementation and efficiencies that can come with scale of operation. However, provinces and health districts will be responsible for on-the-ground implementation.

4. Programme managers will utilise, where appropriate, partnerships between the public and private sector to enhance the effectiveness of the programme's management.

5. The national Department of Health will provide assistance to provinces as required to ensure effective implementation of the programme.

Management Structure

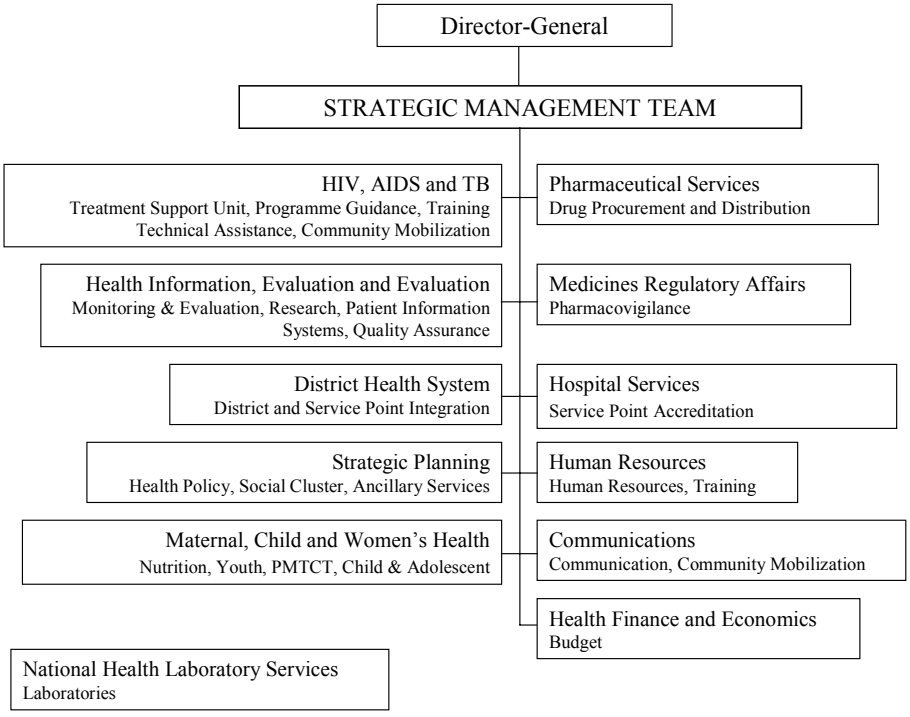
Management of the programme will ultimately be the responsibility of both national and provincial authorities. Some tasks such as procurement and distribution of drugs, laboratory testing, organization of research, pharmacovigilance, information systems and monitoring and evaluation will be managed nationally. Other tasks such as oversight of care and treatment protocols, human resource development and training and certification

of facilities will be implemented locally under frameworks and accreditation established nationally. Still other activities such as mobilisation of community support groups will be coordinated at the provincial level.

National Management

At the national level, the coordination of this programme will be through the existing Strategic Management Team (SMT). The SMT consists of all Cluster Managers in the Department of Health, and is chaired by the Director-General (see Figure 15.1). The SMT already meets on a bi-weekly basis, and this platform will be used to drive implementation, with guidance from the HIV, AIDS and TB Cluster.

Figure 15.1: Strategic Management Team

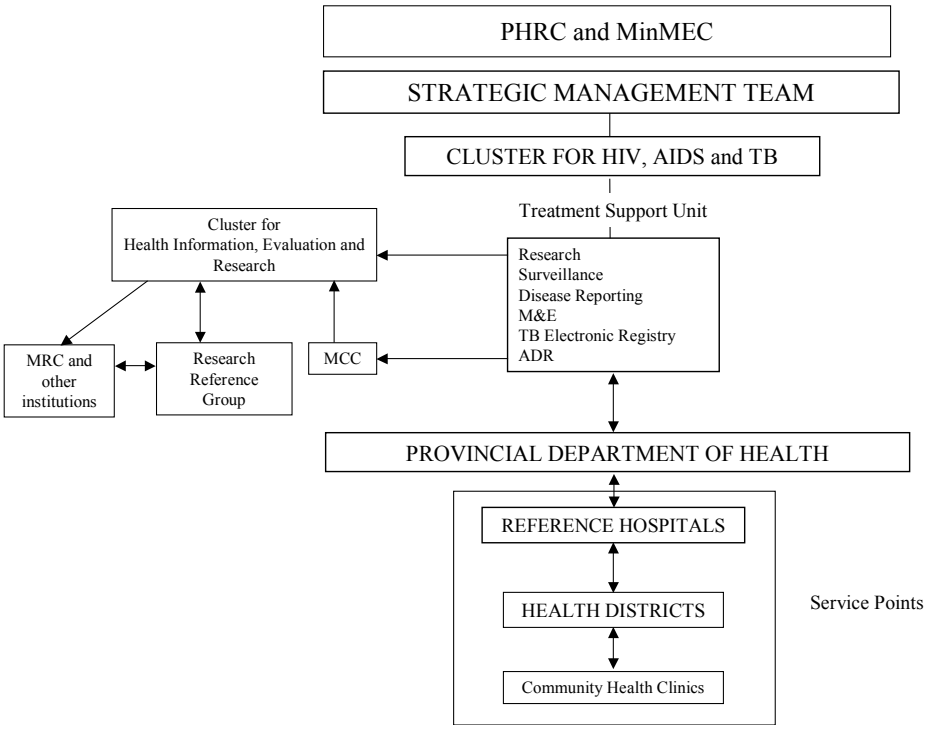


The Clusters that constitute the Strategic Management Team will require additional resources, both human and financial, to implement the various functions contained within the programme. These requirements are planned for in the budget.

The work of the SMT will be informed by a dynamic flow of information between provincial Health Departments and the national Department of Health (see Figure 15.2). Systems already in place will be vital to the quick identification of emerging issues that require attention and a rapid response. Information from service points at the community level, received and managed at the health district level, will capture critical clinical and programme-level issues involved with delivery of the programme. The health districts and tertiary level/reference hospitals are in turn closely interfaced with provincial Health Departments, with reporting relationships that broadly inform programme planning, management and budget activities.

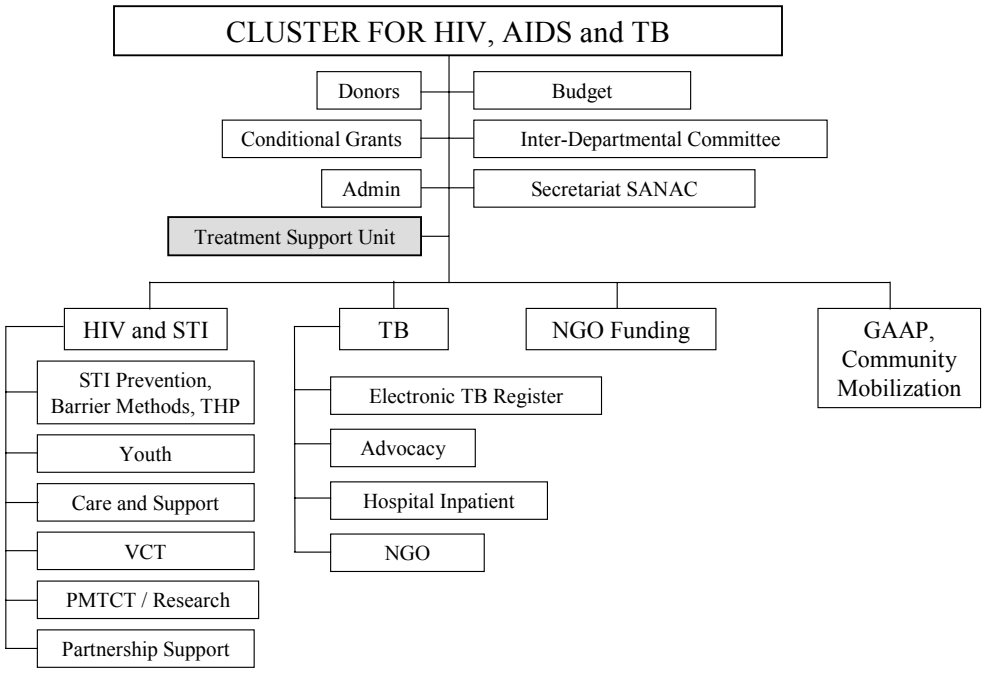
The SMT will report to the PHRC and MinMEC on the progress of implementation. Disease reporting, routine surveillance and a resistance surveillance system, and monitoring and evaluation data will continue to be reported to the Health Information, Evaluation and Research Cluster. Reports of adverse drug reactions will be directed to the pharmacovigilance programme of the Medicines Control Council for further evaluation. Health systems, behavioural and clinical research studies will also be enhanced by the wealth of data that will come forward to the Health Information, Evaluation and Research Cluster from multiple levels of the public health system.

Figure 15.2: Information Flow



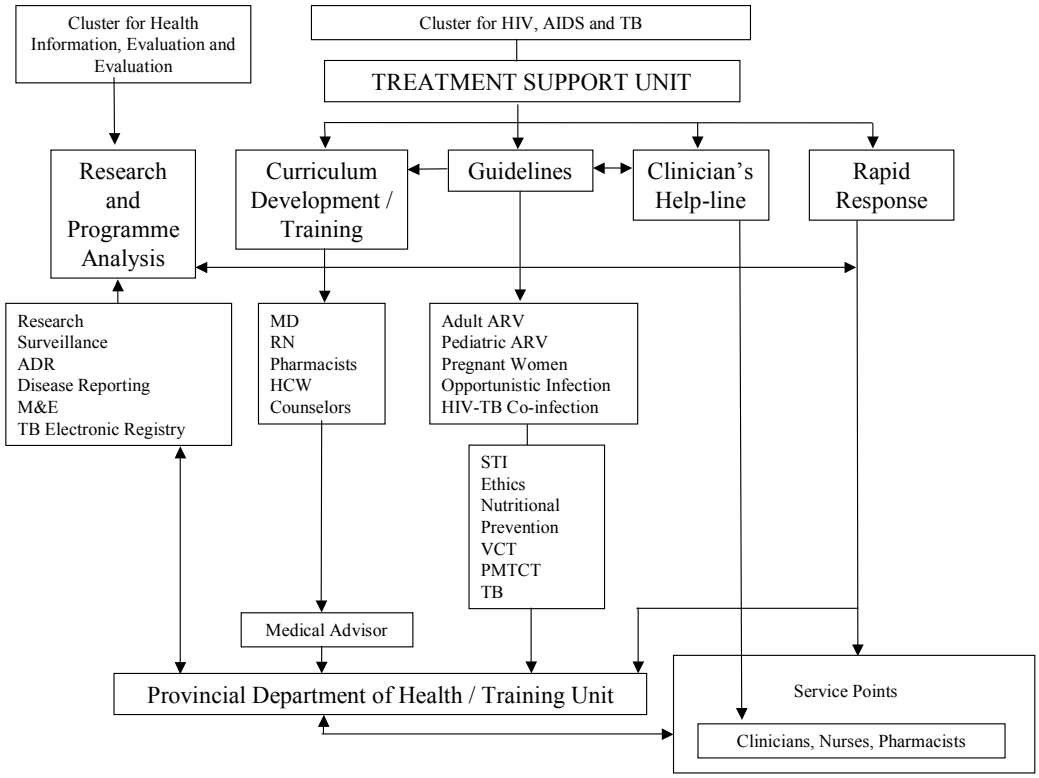
Within the SMT, the Cluster for HIV, AIDS and TB will continue to serve as a focal point for the oversight of HIV, AIDS, STI and TB programmes. Current programmes under the Cluster form the fabric of the national response to HIV and AIDS, to which treatment with antiretrovirals will now be added (see Figure 15.3). The Cluster also includes the Secretariat for the South African National AIDS Council (SANAC) and the Inter-Departmental Committee, which have important roles in informing and coordinating policies and programmes that respond to HIV and AIDS. The Department of Health also has a direct relationship with the Social Cluster to ensure effective information flow and coordination with other government departments.

Figure 15.3: Cluster: HIV, AIDS and TB – Office Structure



Additional responsibilities will be required to strengthen the Cluster in the implementation of this programme, including the establishment of a Treatment Support Unit in the Cluster to oversee the new functions (see Figure 15.4):

Figure 15.4: Treatment Support Unit



Guidelines Review and Development: The current Care and Support sub-directorate within the HIV, AIDS and TB Cluster will need to be strengthened to define and regularly update treatment guidelines for the management of HIV, AIDS, TB and STIs. These will include guidelines for the use of ARVs in adults, adolescents and pregnant women; use of ARVs in paediatric HIV infection; prophylaxis and treatment of opportunistic infections; and use of ARVs in patients with HIV and TB co-infection. In addition, this sub-directorate will need to convene expert panels of HIV specialists and researchers from within South Africa to regularly review and evaluate new clinical information related to the treatment of HIV infection.

Curriculum Development and Training: The Cluster will have responsibility for reviewing national curricula and training materials that have been developed on the treatment and care of HIV, STIs and TB, and develop new training modules on ARV therapy management. Specific curricula for clinicians, nurses, pharmacists, nutritionists, counsellors and community health workers will need to be developed, along with

continuous professional development programmes to update and reinforce the knowledge and skills acquired. These educational materials will be the basis for training programmes used to certify clinicians and train other health care professionals as part of the requirements for accreditation of service points. The Cluster will also have to provide ongoing support and technical assistance to provinces as they develop and implement training centres and provincial training plans.

Clinical HIV Treatment Helpline: A clinical consultation phone line will be established to assist health care workers involved in HIV and AIDS care and treatment, including clinicians, nurses and pharmacists, address clinical questions related to patient care. Staffing of the Helpline will be coordinated within the Cluster, in consultation with national and international experts in HIV care.

Rapid Response Capability: A rapid response technical assistance capability will be put in place within the Cluster to address emerging problems that cover the breadth of care and treatment programme issues that may arise in the course of implementation. The information pathway from service points through the district and provincial level can bring problems rapidly to the attention of the office of the Cluster, where the Cluster can quickly draw on a faculty of experts from around the country to help define the problem and the solution. This ability to mobilize and intervene early can preclude the development of adverse outcomes.

Provincial Management

The implementation of the national HIV and AIDS care and treatment programme within existing programmes and service points will be directed by the provincial Health Departments. Each provincial government will need to integrate within its management structure a defined capacity to oversee and monitor all aspects of the delivery of HIV-related care and treatment services, as part of broader health care services. This would include oversight of human resource development, training, and community mobilisation and communication activities, in addition to clinical services. A medical advisor will need to be made available to each province to assist in developing and carrying out training activities and mentoring support, with an immediate focus on those clinical staff serving in proposed initial service points. Provinces will also require ongoing technical assistance

and support from the SMT as they implement the accreditation process and address crosscutting issues, such as laboratory and pharmacy systems, that require national leadership.

To begin implementing the programme quickly, a number of people could be hired on a temporary basis to initiate the programme while longer-term recruitment takes place.

The SMT will be responsible for overseeing the successful implementation of all aspects of the management plan. They will exercise programmatic control over expenditures associated with the programme and will ultimately be responsible for its success.

Public-Private Cooperation

This programme is designed for implementation in the public sector. However, just as HIV does not observe national borders, the virus does not distinguish between those South Africans who utilise the public health system and those who have private insurance and use private clinicians and hospitals.

HIV and AIDS are national problems that require a coordinated national response. Though government will not directly oversee nor fund care and treatment for HIV and AIDS in the private sector, it should attempt to ensure that the standards it establishes for quality and accreditation in the public sector are replicated in the private sector. Similarly, the pharmacovigilance, monitoring and evaluation and research agendas should be coordinated with the private sector, to help ensure success of national AIDS treatment. Drug resistance can develop in private sector patients as easily as in those treated in the public sector.

Public-private cooperation will also be helpful for the implementation of the public sector programme itself. Private NGOs and companies can assist government with community mobilisation and support programmes, education and communications programmes, and programmes to integrate education and prevention with treatment and other health-promoting activities.

Finally, mechanisms that support contractual arrangements between public health facilities and health professionals and managers in the private sector may assist provincial health authorities to augment their human resource capabilities and facilitate a more rapid and successful implementation of the plan.

Management Review

The Strategic Management Team will ultimately be responsible for the accomplishment of the tasks defined in this plan and for revising both the plan's objectives and the management and task plan as necessary. The SMT should regularly publish reports on programme progress.

Chapter XVI

Budget

OVERVIEW

This chapter presents a national budget detailing the resource requirements for implementation of all aspects of the operational plan. It incorporates information on each dimension of the proposed comprehensive care and treatment plan, including provincial service delivery and infrastructure, procurement, system strengthening and programme management. These are combined to provide a uniform estimate of the resources required to support the comprehensive HIV and AIDS care and treatment plan over a five-year period.

BACKGROUND AND RATIONALE

The report of the Joint Health and Treasury Task Team (JHTTT) presented estimates of the likely cost of implementing a comprehensive care and treatment package to meet the specific health care needs of people with HIV and AIDS. The overall budget presented below can be compared directly with the total cost estimates presented in the JHTTT report for the "100% coverage / Best Prices" scenario. The development of the budget for the operational plan flows directly from this earlier work, but the Task Team has used a more detailed estimation of programme implementation and infrastructure strengthening requirements. The Task Team has also used updated price and cost data in several key areas where the situation has evolved.

The Task Team used the estimates of the underlying demand for AIDS care and treatment from the ASSA2000 model, as did the JHTTT. Based on these epidemiological estimates, ranges for patient demand and achievable treatment coverage have been discussed with provinces to form the basis for provincial planning. Models developed for use in the JHTTT (*GOALS SA* and related costing models) have then been used to evaluate the costs of nutritional supplementation and support, diagnostic testing and laboratory monitoring, and of treatment with antiretroviral drugs, based upon planning ranges for demand agreed with provinces. These models also incorporate all revisions and improvements to care

protocols. The staffing and infrastructure requirements presented in provincial plans have been analysed, and form the basis for a standardised and equitable approach to allocating resources for health system strengthening; this approach seeks to provide the resources required by all provinces to successfully implement the comprehensive HIV and AIDS care and Treatment plan, while also targeting additional resources to strengthen health systems in those provinces whose current resource base and capacity is relatively low. Resource estimates for national functions and activities have been developed on the basis of detailed assessment of plans for each component.

As described in the JHTTT report, there are a number of essential links between an expanded care and treatment programme and other aspects of HIV-related and general health care programmes, although these may operate and be budgeted for independently of the care and treatment programme. The JHTTT report noted the fundamental importance of maintaining and strengthening an effective HIV prevention programme, and that the availability of resources for prevention must not be compromised by the expansion of the care and treatment response. Similarly, the integrated care and treatment programme has organic links and inter-dependencies with programmes such as PMTCT, VCT, STIs, HBC, and the National Tuberculosis Control programme. However, all of these programmes will remain operationally distinct, and are therefore not included in the budget presented in this chapter. Standard treatment of opportunistic infections and complications of AIDS will also continue to take place in the wider primary health care and hospital system.

Over the last two years, substantial additional funds have been provided via the provincial Equitable Share and the HIV and AIDS Conditional Grant to cover the growing costs of AIDS care in hospital, primary health care and home-based care, and these already committed funds continue to grow over the MTEF period. The JHTTT report concluded that these funds were likely to be sufficient to cover the costs of non-antiretroviral care for people with AIDS (primarily treatment of opportunistic infections and palliative care) during the phase-in period of the comprehensive care and treatment plan.

While the budget presented below makes provision for substantial strengthening of staffing in the general health system, and of infrastructure specifically required to implement the integrated care and treatment plan, it does not address the issue of large-

scale physical facility upgrades or new builds for clinics or hospitals, as significant capital programmes exist already for this purpose.

Demand Estimates and General Assumptions

Underlying the general analysis of resource requirements is a set of estimates of the likely need for AIDS care and treatment across the population. These are based on the ASSA2000 model output for each province, excluding the proportion of persons who are members of medical aids (i.e. who do not require publicly funded health care). While Figure 16.1 shows how planned numbers of patients accessing antiretroviral therapy rise as a proportion of new AIDS cases, Table 16.1 below shows the number of new AIDS cases projected by province for the next five years.

Figure 16.1: New Patients Starting ARVs vs. New AIDS Cases Per Year.

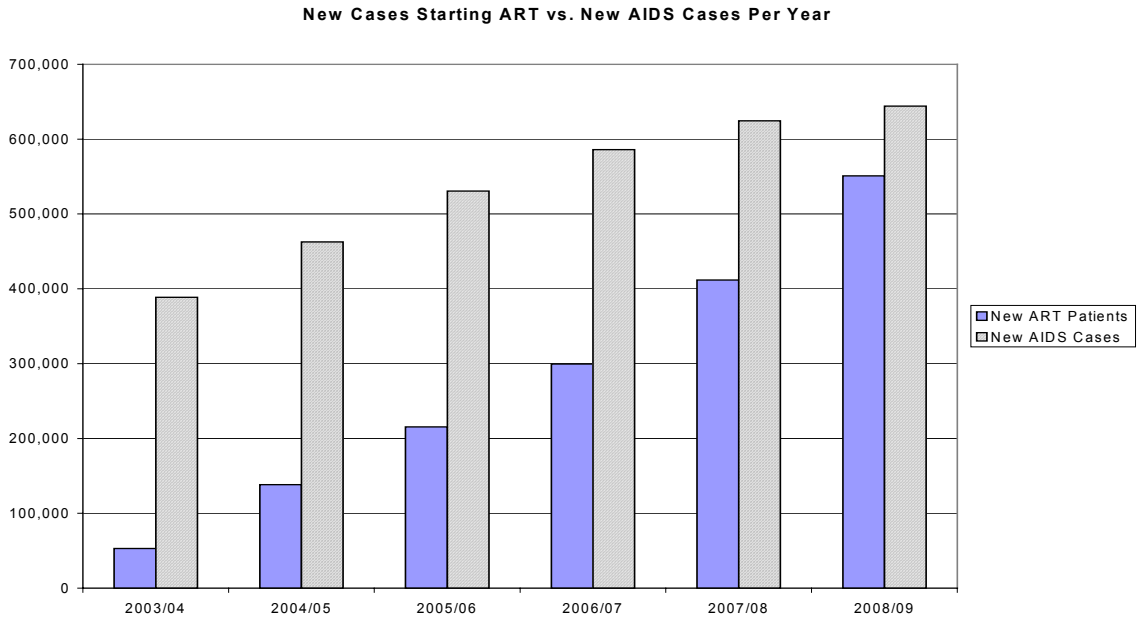


Table 16.1: Estimated New AIDS Cases by Province (excluding Medical Aid)

Province	2003	2004	2005	2006	2007
Eastern Cape	48,758	60,228	71,975	83,259	93,278
Free State	29,310	34,987	40,128	44,247	46,960
Gauteng	64,150	77,036	88,638	97,751	103,429
KwaZulu-Natal	124,511	144,430	160,930	172,311	177,547
Limpopo	34,823	42,507	50,190	57,311	63,296
Mpumalanga	38,670	44,649	49,673	53,336	55,403
Northern Cape	3,948	4,977	6,039	7,057	7,949
North West	36,155	43,545	50,421	56,106	60,079
Western Cape	8,376	10,482	12,664	14,803	16,779
South Africa	**388,701**	**462,841**	**530,658**	**586,181**	**624,720**

Note: These figures are not cumulative.

Over the planning period, the objective of the programme is to ensure that an increasing proportion of new AIDS patients are able to access antiretroviral treatment. As shown in the chart above, this proportion grows from zero (the current position) until 86% of new AIDS patients access ARV therapy by 2008/09. In nations that have been providing ARVs for many years, between two-thirds and three-quarters of patients estimated to be eligible for treatment actually participate in treatment. Therefore, this 86% figure is likely to prove more than full coverage. It is possible that a high percentage of people might choose to participate in the first five years of the programme, which could raise the cost of the programme in those years.

Based upon this estimate of underlying need, resource requirements have been calculated on the basis that the content of care and treatment protocols then drives resource utilisation. These requirements are described thematically in the sections that follow. All budget and cost estimations are presented in 2003 Rands.

Strengthening and Upgrading the Health System

A fundamental prerequisite to implementing this operational plan is ensuring the upgrading of the health system. At the core of improving the health system's capability is the need to ensure the availability of appropriate human resources, and to ensure that personnel are appropriately skilled and trained. Staffing requirements and training were addressed and costed in the JHTTT report, but more detailed cost estimates have been prepared as part of the process of developing this operational plan. Other necessary

system upgrades that require additional resources include the upgrading of pharmacies, patient information and monitoring systems, and the capabilities of the National Health Laboratory Service. Over the first five years of the integrated care and treatment plan, fully 36% of all expenditure will be devoted to strengthening the health system.

Staffing Requirements

As part of the development of their provincial plans, provinces submitted detailed proposals on their requirements for additional staffing to implement the integrated care and treatment plan. This encompassed health professionals, management personnel, counsellors and administrative support at all levels. Staffing requirements for programme management at the provincial level are addressed separately in the programme management section below. The Task Team analysed provincial plans and developed a standardised approach to estimate staff requirements. The Task Team determined the numbers of health professionals and supporting staff required per site for initial implementation and then used staff:patient ratio models for subsequent years. In order to ensure that provinces with low healthcare staff:population ratios receive targeted additional support, a weighting factor was applied to estimates of staff requirements. This weighting factor is based on the distance of each province from the national mean staff:population ratio for a set of key health professionals (medical officers and specialists, pharmacists, nurses and dieticians). Provinces below the national mean receive enhanced funding for key posts, while provinces above the mean receive proportionately less funding (reflecting the fact that a limited proportion of increased treatment workload can be met from their proportionately larger pool of existing staff). This weighting factor therefore serves to improve inter-provincial equity; enhance the capacity of poorer provinces to move ahead with implementation; and enhance the multiplier effect of the programme to benefit general health services in poorer provinces.

Funding requirements for additional staff have been calculated based on estimates of recruitment lead times. New staff hired at the beginning of the programme are assumed to be in post by February 2004; new staff joining the programme in FY 2004/05 are estimated to be in post on average by June 2004. In all subsequent years, full year funding for new staff has been provided for. Based on this approach, the estimated budget

required for the employment of additional staff to implement the integrated care and treatment plan is as follows (Table 16.2):

Table 16.2: Total Additional Staffing Costs (Millions of Rand)

Province	2003/04	2004/05	2005/06	2006/07	2007/08
Eastern Cape	2.5	40.0	55.5	97.2	159.9
Free State	1.3	21.3	28.3	40.4	62.5
Gauteng	2.7	46.5	61.9	79.4	106.5
KwaZulu-Natal	6.2	108.0	143.9	208.9	320.7
Limpopo	1.9	38.0	48.5	81.5	131.9
Mpumalanga	2.3	31.1	41.8	69.3	108.1
Northern Cape	1.2	4.5	6.0	8.2	13.0
North West	1.4	24.7	35.8	63.1	101.7
Western Cape	1.2	8.1	10.8	14.1	22.4
Total	**20.7**	**322.2**	**432.4**	**661.9**	**1,026.7**

Table 16.3 summarises the cumulative number of additional staff by category:

Table 16.3: Total Additional Staff (FTEs) to be Recruited

Employees	To March 04	April 04-March 05	April 05-March 08
Medical Officers	76	272	725
Professional Nurses	228	816	2,175
Enrolled Nurses	152	544	1,450
Assistant Nurses	152	544	1,450
Pharmacists	76	272	363
Pharmacist Assistants	76	272	363
Dieticians/Nutritionists	76	136	363
Social Workers	38	136	363
Counsellors	760	2,720	5,800
Admin Clerks	152	544	1,450
Total	**1,786**	**6,256**	**14,500**

Provinces will have discretion in the use of funds to procure additional staff inputs to support the programme; funds earmarked for expanding human resources may be used in any of the following ways:

- Employment of new staff
- Funding of community service personnel deployed to support the programme
- Overtime payments for health professionals already in post

- Contracting with private practitioners who have successfully met the programme's training and certification requirements
- Recruitment of foreign doctors

Upgrading Facilities and Pharmacies

While the implementation of the HIV and AIDS care and treatment plan will not require any significant new building or major upgrades to the physical infrastructure of health facilities, there will be a need for minor works and improvements at many sites and some procurement of capital equipment. In particular, many pharmacies are likely to require improved physical security measures and provision of secure storage space. Provincial capital planning is at a preliminary stage only, and most provinces are not yet able to provide detailed plans at facility level. Therefore, the Task Team proposes to hold a capital budget at national level, against which provinces will be able to bid for eligible upgrading projects. This mechanism will actively support provinces with poorer facility infrastructure and project management capacity to develop and execute project proposals. This capital fund will require R10 million in 2003/04, R75 million in 2004/05, and R100 million per year for the two succeeding years, after which point major capital upgrading should no longer be necessary.

Upgrading Patient Information, Monitoring and Evaluation Systems

Strengthening patient information systems will be an important part of the successful management of the programme. Information system strengthening will improve patient care and provide the backbone of effective quality assurance, programme and adverse events monitoring, and will maximise the efficiency of ordering and procurement systems. The Task Team estimates that R20 million per year will be required for each full year of the plan to support strengthening of patient information, monitoring and evaluation systems.

Upgrading the National Health Laboratory Service

The National Health Laboratory Service will require R20 million in capital and development funding at the beginning of the programme, to procure essential diagnostic equipment and to train key personnel. In addition to these capital funding requirements, NHLS has indicated a need for an advance payment of R20 million to purchase reagents

and consumables in bulk as the programme commences. The cost of tests conducted would then be drawn down against this advance payment.

Maintaining Health After HIV Infection

The JHTTT Report considered in detail the services and interventions required to maintain good health in HIV-positive patients and to delay the onset of opportunistic infections and AIDS. The JHTTT report costed these requirements, and they are contained in the "Non-ARV" component funded via general health services. This plan focuses on two main elements requiring additional resources to maximise the health and healthy years of life attainable by people infected with HIV, namely:

- Nutritional support
- Diagnostic monitoring of CD4 counts

Nutritional Support and Supplementation

Two nutritional interventions have been 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 a secure food supply
- High dose vitamin supplementation for defined patient groups (HIV-positive pregnant women, people with active TB and/or TB-HIV co-infection, HIV-positive children under fourteen years)

Table 16.4 describes the four target groups and the interventions to be received by each:

Table 16.4: Nutritional Supplement Protocol

Target Group	Composite Meals	Micronutrient Supplementation
HIV-infected children under 14 years of age	Yes Assumes 10% of children likely to display growth failure	Yes Paediatric syrup
HIV-infected mothers enrolled in PMTCT	Yes Assumes 25% may be food insecure	Yes Capsules
Tuberculosis patients in TB programme	Yes Assumes 25% may be food insecure	Yes Capsules
People receiving antiretroviral therapy	Yes Assumes 25% may be food insecure	Not indicated in this patient group

The Task Team assumes that 25 percent of patients may require meal supplementation (based on recent food security surveys), at a monthly cost of R56.40 per person. Vitamin supplementation has been costed on the current prices of special formulations; for adults, a monthly supply of vitamin capsules costs R40, and a month's supply of paediatric syrup currently costs R60. The Task Team considers these prices excessively high. Implementation of the nutrition component should be preceded by intensive negotiation and creation of competitive conditions to achieve significant price reductions. Notwithstanding these issues, the total additional costs of the nutritional support component are as follows:

Table 16.5: Total Costs of Nutrition Support and Supplementation

Years	R-Millions
2003/04	63
2004/05	343
2005/06	421
2006/07	532
2007/08	656
2008/09	798

Diagnostic Monitoring Following Diagnosis of HIV Infection

Once a person has been identified as HIV-positive, he or she should enrol in a high-quality care programme in order to receive appropriate advice on healthy living, prophylaxis against common opportunistic infections, and routine monitoring of health status. This

will also allow timely commencement of antiretroviral therapy when required. The revised treatment protocol recommends that this diagnostic monitoring incorporate routine measurement of CD4 count. In HIV-positive but asymptomatic individuals presenting to the care programme, CD4 count will be measured annually in individuals with CD4 >500. In those in whom CD4 count has fallen below 500, this would step up to six-monthly monitoring of CD4; once CD4 count falls below 200, antiretroviral treatment would commence. A one-third reduction in the price of CD4 testing has already been achieved since the finalisation of the JHTTT report. Numbers of patients presenting for care will be determined largely by the success of communication efforts and by the capacity of the VCT programme to provide initial diagnosis of HIV infection; clearly there is a degree of uncertainty surrounding the level of uptake which can be achieved. A relatively conservative scenario has therefore been used in which demand for diagnostic monitoring starts from a fairly small base, but over time assumes a majority of HIV-positive persons are enrolled in effective care programmes. The costs of laboratory diagnostic monitoring for this testing are as follows (Table 16.6):

Table 16.6: Cost of Diagnostic Monitoring of Asymptomatic HIV+ Patients

Years	R-Millions
2003/04	4
2004/05	45
2005/06	84
2006/07	126
2007/08	186
2008/09	249

Comprehensive Care and Treatment Plan

Implementation of the HIV and AIDS care and treatment plan, which includes the introduction of antiretroviral treatment, will require funding for two main elements: diagnostic monitoring of patients on therapy, and the antiretroviral drugs themselves. The additional staff described in Table 16.3 are adequate to support the care and treatment plan at the levels of coverage proposed. The treatment package will be supported by a major training effort, monitoring and evaluation, and research (the resource requirements of which are described below). Table 16.7 shows the total number of patients enrolled in the care programme by year, split between those who are receiving periodic CD4 counts, but

whose CD4 remains above 200, and those patients with CD4 <200 who will commence antiretroviral therapy.

Table 16.7: Total Patients Enrolled in Care Programme and ARV Treatment

Years	Patients CD4 >200	Patients on ARVs	Total in Programme
2003/04	212,000	53,000	265,000
2004/05	628,705	188,665	817,370
2005/06	1,078,446	381,177	1,459,623
2006/07	1,497,580	645,740	2,143,320
2007/08	2,167,834	1,001,534	3,169,368

The ultimate cost of care and treatment is a function of two cost drivers: the components of the care protocols in use, and the number of patients receiving care. The costs of care protocols are described below in detail. Estimates of patient demand (see Table 16.8 and Table 16.9) have been developed using the ASSA2000 model as a starting point for discussion with provinces; an upper and lower boundary for expanding coverage for each province was delineated (accounting for different levels of readiness and to accommodate the inherent uncertainty regarding patient uptake) to ensure that provinces will move within a reasonably consistent range to expand coverage, while allowing some degree of flexibility. Retaining flexibility within the programme budget to accommodate uncertain overall uptake levels and differential rates of progress between provinces will be of fundamental importance to the ultimate success of the programme. Proposed mechanisms to facilitate flexibility in budgeting are discussed later in this chapter. The budget for laboratory monitoring and antiretroviral treatment presented below is based upon the following estimates of uptake, based on provincial plans and target ranges as described above. The aim is to achieve universal coverage of new AIDS cases by the end of FY 2008/09 (excluding Medical Aid members).

The model used in the calculation of the budget factors in survival and mortality of people on ARV therapy. It also estimates the likely proportion of patients who will need to switch from regimen 1 to regimen 2 in any given year, assuming that, for every year spent on regimen 1, there will be a 24% probability that, by the end of that year, the patient will have switched to regimen 2.

Table 16.8: Planned Number of Patients on Antiretroviral Treatment

Years	New Cases Starting ARVs	Total Cases on ARVs
2003/04	53,000	53,000
2004/05	138,315	188,665
2005/06	215,689	381,177
2006/07	299,516	645,740
2007/08	411,889	1,001,534

Table 16.9: Expected Total Number of Cases on Antiretroviral Treatment by Province

Provinces	2003/04	2004/05	2005/06	2006/07	2007/08
Eastern Cape	2,750	15,626	38,826	72,411	121,804
Free State	2,127	11,883	24,415	42,065	66,555
Gauteng	10,000	45,000	77,358	112,840	149,851
KwaZulu-Natal	24,902	74,208	202,057	353,600	496,584
Limpopo	6,965	21,494	41,479	72,150	116,419
Mpumalanga	1,934	10,767	26,782	48,105	77,061
Northern Cape	790	2,492	4,907	8,698	14,282
North West	1,808	10,426	26,744	49,289	80,890
Western Cape	2,728	5,728	11,072	21,084	37,078

Note: These figures total to a slightly higher number in each year than those in Table 16.8, based on slightly different assumptions in some provinces on the number of AIDS patients who will be eligible for the programme.

The total number of planned cases on treatment falls within the range of likely total ARV cases estimated in the JHTTT report "100% Coverage" scenario, namely between 918,000 and 1,200,000 cases by 2007/08.

Laboratory Monitoring for Antiretroviral Therapy

The revised care and treatment protocol for diagnostic monitoring of patients on ARVs has been costed using revised prices negotiated with the National Health Laboratory Service. The costs per patient per year of the monitoring protocols accompanying each of the drug regimens are presented in Table 16.10a:

Table 16.10a: Laboratory Monitoring Costs of Each Regimen

Rands per patient/year	
Regimen 1 - efavirenz	820.00
Regimen 1 - nevirapine	926.68
Regimen 2	231.76

Infants aged below 18 months presenting with suspected AIDS will require an HIV p24 Antigen test (current cost R 52.63 per test) to determine their true HIV status, due to the risk that ELISA or rapid tests may react to residual maternal antibodies. Likely numbers of babies requiring treatment in this age group have been estimated with reference to the ASSA2000 model's one-year age-band projections. While the absolute number of babies projected to develop AIDS increases over time, the proportion of total AIDS cases in this age group actually declines, due to improved coverage of Prevention of Mother to Child Transmission services and the impact on fertility of HIV itself. It is assumed that, as coverage builds up, babies will present in proportion to the overall ratio of 0-18 month old cases to total cases. Using this assumption, the approximate number of 0-18 month olds requiring p24 Antigen testing will be as follows:

Table 16.10b: Laboratory Monitoring Costs for Infants Under 18 Months

	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09
Infants <18 months	3,825	8,382	11,203	13,656	16,913	20,924
Total Cost (R millions)	0.2	0.4	0.6	0.7	0.9	1.1

This cost is a small fraction (less than 1%) of the overall cost of laboratory monitoring. Thus, even if larger numbers of infants presented for care in the early stages of the programme, these costs would easily be accommodated within the overall amounts budgeted for laboratory monitoring.

Given the planned volume of patients on antiretroviral therapy, the total budget required for laboratory monitoring over the planning period is as follows (Table 16.11):

Table 16.11: Total Cost of Diagnostic Monitoring of Patients on ARVs

Years	R Millions
2003/04	13
2004/05	108
2005/06	227
2006/07	394
2007/08	620
2008/09	917

Antiretroviral Drugs

Very significant price reductions have been achieved through negotiations since the finalisation of the JHTTT report. Table 16.12 shows the prices that are currently available, those that should be negotiable in the first year of the programme, and the further reductions in price that will be negotiable by Year 5:

Table 16.12: Drug Prices per Patient per Year

Rands per patient/year	Current	Year 1	Year 5
Regimen 1 efavirenz	4,211.71	3,916.75	2,139.00
Regimen 1 nevirapine	1,473.13	1,405.85	1,078.13
Regimen 2	10,334.55	6,572.25	3,079.13

Drug costs for the first three months of the programme have been budgeted at current prices. However, there is a strong possibility that further reductions can be achieved even within this timeframe. Given planned volumes of patients on antiretroviral therapy, the total budget required for drugs will be as follows (Table 16.13):

Table 16.13: Total Drug Costs

Years	R Millions
2003/04	42
2004/05	369
2005/06	725
2006/07	1,118
2007/08	1,650

Programme Management

Successful implementation of all aspects of the integrated care and treatment plan will require additional programme management resources at both national and provincial levels.

National Strategic Management Team

The comprehensive care and treatment programme for HIV and AIDS will require an energetic and disciplined management team. A management failure to execute one part of the plan could jeopardise the execution of all parts. The funding requirements for additional resources at the national level is set out as follows:

- The establishment of a Treatment Support Unit within the Cluster HIV, AIDS and TB
- Strengthening of national Department of Health units providing direct support for the programme, such as drug procurement, pharmacovigilance, and monitoring and evaluation
- Task-specific funding required for successful oversight

Management Structure

Additional national DoH staff is required to support the implementation of the comprehensive care and treatment programme (Table 16.14):

Table 16.14: National Department of Health Additional Funding (Rand)

Requirements	2003/04	2004/05	2005/06	2006/07	2007/08
Personnel	1,300,000	5,100,000	5,100,000	5,100,000	5,100,000
Non-personnel	572,921	2,291,682	2,291,682	2,291,682	2,291,682
Total	**1,872,921**	**7,391,682**	**7,391,682**	**7,391,682**	**7,391,682**

Task-specific funding required for successful oversight

Additional funds must be added to carry out the following functions described in the operational plan:

- National care and treatment – encompassing activities such as protocol and guideline development, certification of sites, and provincial liaison.
- Training and human resource issues – development of teaching and training materials, conducting and coordinating training. In addition, in the early years a mentoring programme will ensure adequate support to health professionals.
- Drug procurement and distribution – added capacity required to deal with procurement and distribution together with the introduction of more sophisticated

mechanisms to track the distribution and enhance the security of drugs, especially ARVs.

- Pharmacovigilance programme – strengthening of national oversight of pharmacovigilance, specifically monitoring of resistance and adverse drug reactions, together with the establishment of two new research units to complement the existing unit in Cape Town.
- Patient information systems and monitoring and evaluation – enabling the tracking of patients through the system together with assessing outcomes of the programme requiring investment in IT infrastructure (hardware and software).
- Research – conducting a research programme that integrates different pieces of research to maintain a high quality programme but also to ensure that the policy direction of the programme is well guided.
- Communication – investment in infrastructure to ensure adequate and appropriate information is communicated to the public, including updating existing information and education programmes to include the benefits and risks of ARVs.
- Community mobilisation – targeted programmes with NGOs and CBOs to ensure that communities are informed of the benefits and roles that they can play in reducing infections, improving health outcomes and encouraging HIV testing.

The funding requirements to carry out these tasks and functions effectively are outlined in Tables 16.15 and 16.16 below. Table 16.16 further splits the costs of these tasks between recurrent elements and start-up and investment costs; the latter might be especially suitable for discrete funding by interested donors. The requirements to start the programme are R114m for the remainder of 2003/04, growing to R350m in 2007/08.

Table 16.15: National Programme Implementation and Health System Capability Upgrading Costs (Millions of Rands)

	2003/04	2004/05	2005/06	2006/07	2007/08
National Treatment and Care	3.0	5.0	5.0	5.0	5.0
Community Mobilisation	10.0	40.0	50.0	60.0	60.0
Training and HR					
Training	8.0	12.0	15.0	15.0	15.0
Mentoring	10.0	40.0	40.0		
Drug Procurement & Distribution	2.0	4.0	4.0	10.0	10.0
Pharmacovigilance					
National unit	2.5	5.0	5.0	5.0	5.0
University-based units	12.5	15.0	15.0	15.0	15.0
Patient Information (incl. M&E)					
Operational requirements	5.0	10.0	10.0	10.0	10.0
Infrastructure/equipment	5.0	10.0	10.0	10.0	10.0
Research					
NDoH priorities	14.0	20.0	20.0	13.0	13.0
General research	20.0	35.0	35.0	35.0	35.0
Communications	12.0	30.0	30.0	30.0	30.0
Total	**104.0**	**226.0**	**239.0**	**208.0**	**208.0**

Table 16.16: Split of Funding Requirements Between Recurrent and Start-up Investment for Health System Capability Upgrading (Millions of Rand)

	2003/04	2004/05	2005/06	2006/07	2007/08
National Treatment and Care	3.0	5.0	5.0	5.0	5.0
Recurrent	1.5	2.0	2.0	2.5	3.5
Start-up and Investment	1.5	3.0	3.0	2.5	1.5
Community Mobilisation	10.0	40.0	50.0	60.0	60.0
Recurrent	5.0	25.0	40.0	60.0	60.0
Start-up and Investment	5.0	15.0	10.0	0.0	0.0
Training and HR	18.0	52.0	55.0	15.0	15.0
Recurrent	2.0	7.0	7.0	7.0	9.0
Start-up and Investment	16.0	45.0	45.0	5.0	6.0
Drug Procurement and Distribution	2.0	4.0	4.0	10.0	10.0
Recurrent	0.0	2.0	2.0	2.0	2.0
Start-up and Investment	2.0	2.0	2.0	8.0	8.0
Pharmacovigilance	15.0	20.0	20.0	20.0	20.0
Recurrent	2.0	3.5	7.5	10.0	10.0
Start-up and Investment	13.0	16.5	12.5	10.0	10.0
Patient Information (incl. M&E)	10.0	20.0	20.0	20.0	20.0
Recurrent	2.5	10.0	10.0	10.0	10.0
Start-up and Investment	7.5	10.0	10.0	10.0	10.0
Research	34.0	55.0	55.0	48.0	48.0
Recurrent	14.0	20.0	20.0	20.0	20.0
Start-up and Investment	20.0	35.0	35.0	35.0	35.0
Communications	12.0	30.0	30.0	30.0	30.0
Recurrent	2.5	4.0	4.0	4.0	26.0
Start-up and Investment	9.5	26.0	26.0	26.0	4.0
Total	**104.0**	**226.0**	**239.0**	**208.0**	**208.0**
Recurrent	**30.8**	**78.6**	**97.6**	**120.6**	**145.6**
Start-up and Investment	**73.2**	**147.4**	**141.4**	**87.4**	**62.4**

Provincial Management Capacity

Each province will require additional staff to drive implementation successfully (Tables 16.17-16.19). Each provincial government will need to integrate within its management structure a defined capacity to oversee and monitor all aspects of the delivery of HIV-related care and treatment services, as part of broader health care services. This would include oversight of human resource development, training, and community mobilisation and communication activities in addition to clinical services. Detailed consideration was given to the needs of provinces, the pace of their planned implementation, and their

current levels of capability. All provinces have been allocated management and administrative support in relation to their planned number of sites. Provinces with more limited resources at present have also been allocated further staff to ensure that implementation can be driven forward effectively. All provinces have been allocated a non-staff budget to support day-to-day programme management activities, and to fund limited local communications activities.

Table 16.17: Provincial Programme Management–Personnel Budget (Rands)

Provinces	2003/04	2004/05	2005/06 onward
Eastern Cape	895,092	7,336,554	9,782,072
Free State	639,351	3,740,204	4,986,939
Gauteng	799,189	5,898,014	7,864,019
KwaZulu-Natal	1,118,864	7,336,554	9,782,072
Limpopo	895,092	7,336,554	9,782,072
Mpumalanga	895,092	5,898,014	7,864,019
Northern Cape	639,351	3,740,204	4,986,939
North West	735,254	7,336,554	9,782,072
Western Cape	799,189	5,178,744	6,904,992
Total	**7,416,473**	**53,801,396**	**71,735,195**

Table 16.18: Provincial Programme Management–Non-Personnel Budgets (Rands)

Provinces	2003/04	2004/05	2005/06 onward
Eastern Cape	723,773	3,834,139	4,445,518
Free State	659,838	2,935,051	3,246,735
Gauteng	699,797	3,474,504	3,966,005
KwaZulu-Natal	779,716	3,834,139	4,445,518
Limpopo	723,773	3,834,139	4,445,518
Mpumalanga	723,773	3,474,504	3,966,005
Northern Cape	659,838	2,935,051	3,246,735
North West	683,813	3,834,139	4,445,518
Western Cape	699,797	3,294,686	3,726,248
Total	**6,354,118**	**31,450,349**	**35,933,799**

Table 16.19: Total Provincial Programme Management Budget (Rands)

Provinces	2003/04	2004/05	2005/06 onwards
Eastern Cape	1,618,864	11,170,693	14,227,590
Free State	1,299,189	6,675,255	8,233,673
Gauteng	1,498,986	9,372,518	11,830,023
KwaZulu-Natal	1,898,581	11,170,693	14,227,590
Limpopo	1,618,864	11,170,693	14,227,590
Mpumalanga	1,618,864	9,372,518	11,830,023
Northern Cape	1,299,189	6,675,255	8,233,673
North West	1,419,067	11,170,693	14,227,590
Western Cape	1,498,986	8,473,430	10,631,240
Total	**13,770,591**	**85,251,745**	**107,668,993**

Summary of Budget Requirements

The total budget requirements for this programme are estimated below (Table 16.20).

Table 16.20: Total Programme Budget Estimate (Millions of Rands)

	2003/04	2004/05	2005/06	2006/07	2007/08
Service Staff	21	322	432	662	1,027
Laboratory Testing	20*	152	311	520	806
Antiretroviral Drugs	42	369	725	1,118	1,650
Nutrition	63	343	421	532	656
Health System Capability Upgrading	70	171	184	160	160
Programme Management (National and Provincial)	16	103	128	128	128
Capital Investment	30	75	100	100	0
Research	34	55	55	48	48
Total	**296**	**1,590**	**2,358**	**3,268**	**4,474**

** Includes R20 million advance payment to NHLS*

Sensitivities

The Task Team sees the following sensitivities in its estimates. Savings are likely in the budget as laboratory costs are reduced through efficiencies and nutrition costs are reduced through more aggressive price negotiations. In the last two years of the budget, the Task Team assumes a higher proportion of the eligible people accessing ARVs than is typical internationally. In the first two and a half years, the Task Team assumes a gradual build up to the proportions (Table 16.1). If a higher proportion of eligible people access ARVs in the first few years, it is possible that the cost of the programme will be as much as 10%, or, in the extreme, 20% higher than in the budget summary during 2004/05 and 2005/06.

The budget is calculated and based on international tendering as the means of procuring drugs. Should this not be the route chosen, it must be noted that the drug cost component could rise and based on prices currently available in South Africa, this could increase by between 45-115%, depending on volumes of different combinations purchased.

Routing of Funds

Early discussions, including the Medium Term Expenditure Committee (MTEC) hearings with national departments, indicate that National Treasury has accepted the principle that programme funding:

- Must be additional to existing resources; and
- Would need to flow through direct NDoH transfers via a combination of conditional grants to provinces and direct national procurement of key inputs (e.g. drugs and laboratory services).

This would be required in the initial years of the programme to assure successful implementation and equitable provision across provinces, and to ensure steady progress is being made toward realization of provincial plans. Specific mechanisms for the routing of funds are presented below (Table 16.21):

Table 16.21: Funding Mechanisms for HIV and AIDS Care and Treatment

Programme	Funding Mechanism
Drug Procurement	Direct National Procurement
Drug Distribution	Conditional Grant
Laboratory Monitoring	Direct National Procurement
Nutrition Support	Conditional Grant
National Programme Management	Direct National Procurement
Provincial Programme Management	Conditional Grant
Regional Training Centres	Conditional Grant
Training	Direct National Procurement
Pharmacovigilance	Direct National Procurement
Medicines Regulation	Direct National Procurement
Additional Personnel – Health Facilities	Conditional Grant
Infrastructure – Health Facilities	Conditional Grant

Given the considerable uncertainties surrounding the levels of uptake and the pace of rollout, the funding arrangements for the programme will require considerable flexibility. In particular, two approaches will merit careful consideration.

- Significant funds should be held in reserve centrally to be reallocated in line with actual progress as implementation unfolds (a contingency reserve).
- There should be flexibility to roll over funds that are unspent due to slower-than-expected uptake and rollout.

Furthermore, any conditional grant funding will be designed to be as flexible as possible, and onerous or time-consuming administrative procedures will be avoided, while still ensuring that funds are spent against designated tasks and activities. The key determinant here will be adherence to the operational plans developed by each province, and demonstrated implementation progress against a set of key performance indicators.

Endnotes

KEY DOCUMENTS

The following documents were consulted widely in the development of the operational plan:

- National HIV and Syphilis Antenatal Sero-Prevalence Survey in South Africa, 2002. Department of Health, 2003
- Full Report of the Joint Health and Treasury Task Team Charged with Examining Treatment Option to Supplement Comprehensive Care for HIV/AIDS in the Public Health Sector. Department of Health, 2003
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