OPERATIONAL PLAN

FOR

COMPREHENSIVE

HIV AND AIDS CARE, MANAGEMENT

AND TREATMENT

FOR

SOUTH AFRICA

19 NOVEMBER 2003

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:

6.12. 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.

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

6.14. 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].

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.

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

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.

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.

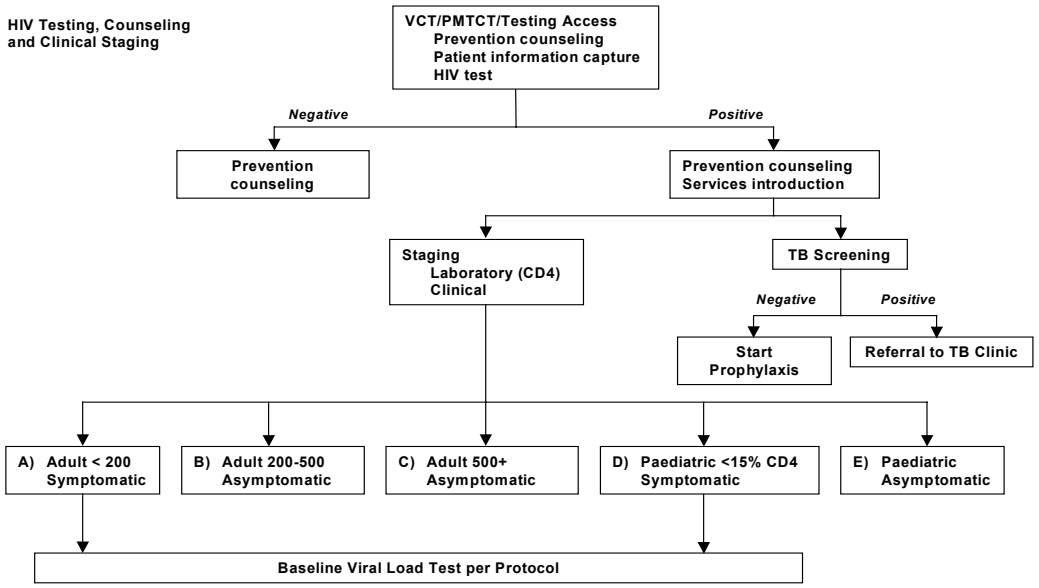
The programme aims to expand voluntary counselling and testing (VCT) services so that people may know their HIV status and take appropriate actions.

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.

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

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



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