

SECTION ONE

PREVENTION, CARE AND TREATMENT OF HIV AND AIDS

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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 testing¹⁻⁴, prevention of mother-to-child transmission of HIV⁵, TB and STI management and HIV post-exposure prophylaxis (PEP) for both occupational exposures and survivors of sexual assault⁶, orphan care programmes and nutritional supplementation⁷. 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.

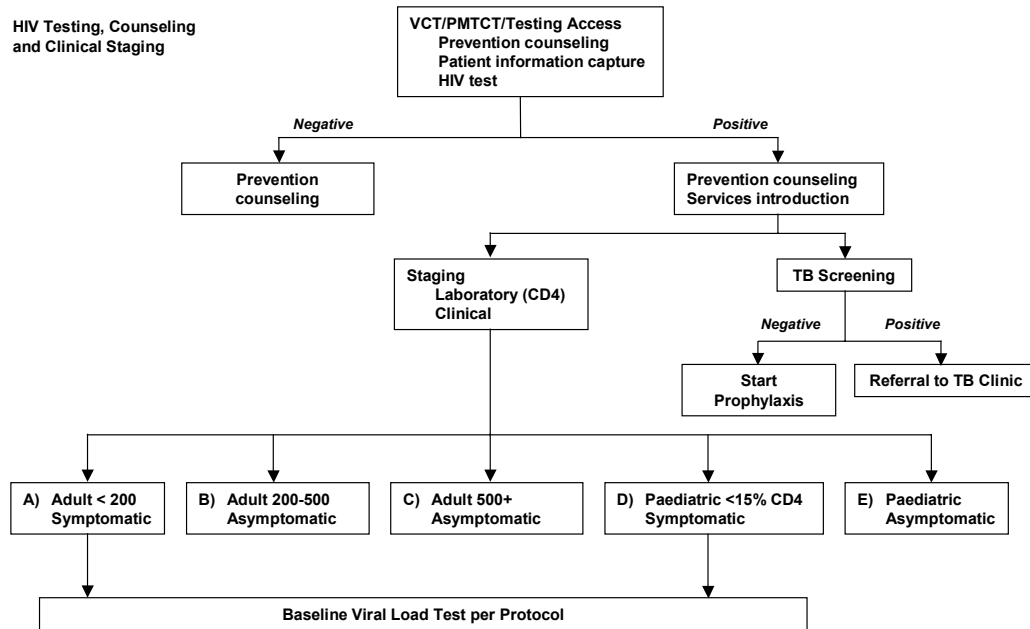
Against this background, the Joint Health and Treasury Task Team costed the implications of strengthening current prevention efforts as part of the requirements to improve our country's overall machinery in the fight against HIV and AIDS. The Joint Task Team estimated that an allocation of between R550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



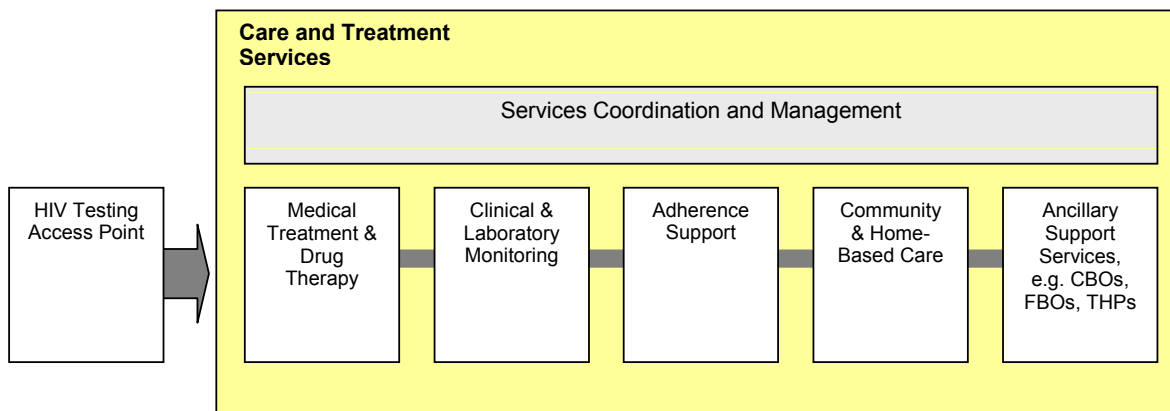
There are multiple entry points into the care delivery system, including voluntary counselling and testing venues, PMTCT programmes, clinics offering reproductive health and STI services, primary health care clinics, TB clinics, inpatient hospital settings and prisons. Following diagnosis and staging 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 care⁸. 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 benefits⁹⁻¹⁵. 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 |
|--|
| <ul style="list-style-type: none"> • CD4 \leq 200 cells/ mm³ and symptomatic, irrespective of stage, <li style="text-align: center;"><i>or</i> • WHO stage IV AIDS defining illness, irrespective of CD4 count, <li style="text-align: center;"><i>and</i> • 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 | <ul style="list-style-type: none"> • CD4 • VL • ALT | <ul style="list-style-type: none"> • Staging, 6-monthly • Baseline, 6-monthly • Baseline |
| 1b | d4T / 3TC / efavirenz | <ul style="list-style-type: none"> • CD4 • VL | <ul style="list-style-type: none"> • Staging, 6-monthly • Baseline, 6-monthly |
| 2 | AZT / DDI / Lopinavir / Ritonavir | <ul style="list-style-type: none"> • CD4 • FBC • Fasting cholesterol | <ul style="list-style-type: none"> • 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 unlikely¹⁶.

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/mm³. The standard of care highlights the importance of intervening with ARV therapy before patients fall significantly below 200 CD4 cells¹⁷. Current recommendations do not include an

increased frequency of CD4 monitoring for patients whose CD4 count falls between 200-350 cells/mm³; 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 <i>and/or on ARVs</i> | 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 persons¹⁸. TB accounted for an estimated 30% of the all AIDS related death in 1999¹⁹. 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 TB²⁰. 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 mortality²¹. This would occur mainly among TB patients with low CD4 T-cell count (<200 cells/mm³). 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 Rifampin) 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 |
|---|
| <ul style="list-style-type: none"> • CD4 < 15% and symptomatic <p style="text-align: center;"><i>or</i></p> <ul style="list-style-type: none"> • WHO Paediatric Stage III AIDS defining illness, irrespective of CD4 % <p style="text-align: center;"><i>and</i></p> <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • CD4 • VL • ALT • Chol/TG | Staging, 6-monthly Baseline, 6-monthly Baseline Baseline, 12-monthly |
| 1b | d4T/ 3TC / NVP | <ul style="list-style-type: none"> • CD4 • VL • ALT | Staging, 6-monthly Baseline, 6-monthly Baseline, 1 m, 6-monthly |
| 1c | d4T / 3TC efavirenz | <ul style="list-style-type: none"> • CD4 • FBC | Staging, 6-monthly Baseline, 1, 3, 6 mo, 6-monthly |
| 2a | AZT / ddI Lopinavir/Ritonavir | <ul style="list-style-type: none"> • CD4 • FBC • Chol/TG | Staging, 6-monthly Baseline, 1, 3, 6 mo, 6-monthly Baseline, q 12 monthly |
| 2b | AZT / ddI efavirenz or NVP | <ul style="list-style-type: none"> • 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? | |
|---|---|
| <ul style="list-style-type: none"> • 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? | |
| <ul style="list-style-type: none"> • 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 |
| <ul style="list-style-type: none"> • < 5 kg • 5 – 9.9 kg • 10 – 14.9 kg • 15 – 21.9 kg • > 22 kg | <ul style="list-style-type: none"> • 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 PMTCT²². 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 |
|--|
| <ul style="list-style-type: none">• 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 as 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 established¹. 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.

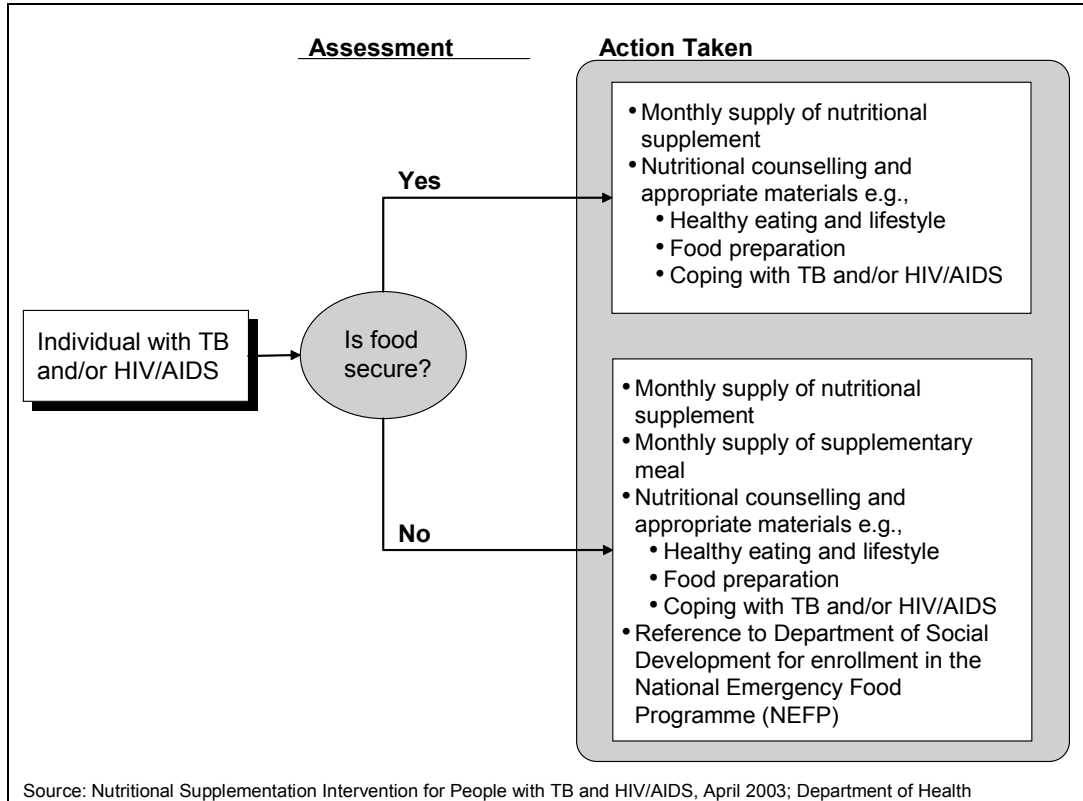
BACKGROUND AND RATIONALE

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



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 AIDS². 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 HIV³. 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 milk⁴. 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.