Monitoring and Evaluation Framework for the Comprehensive HIV and AIDS Care, Management and Treatment Plan for South Africa

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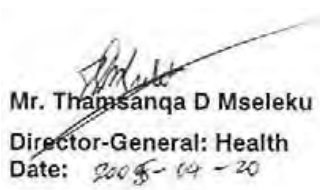
PREFACE

As HIV and AIDS epidemic continue to affect the lives of millions of people in South Africa, a growing sense of urgency has developed about the imperative need to respond to the epidemic by increasing all efforts to scale up HIV and AIDS prevention, care and support including the provision of antiretroviral treatment. In all areas of the world including South Africa, national HIV and AIDS programmes, private sector initiatives, along with countless non-governmental organisations (NGOs) and community-based organisations (CBOs), have initiated programmes to expand the response to the epidemic.

To strengthen the management of HIV, AIDS and STIs in the country, the South African Cabinet took a decision in November 2003 and approved the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa. This led to a sequence of discussions and activities aimed at laying a solid foundation for the implementation of the plan, including the development of a Monitoring and Evaluation (M&E) Framework for the programme.

This publication presents an overview of the ongoing activities starting with the outline of the early developments of public policy processes which led to the development of a detailed operational plan for comprehensive HIV and AIDS care, management and treatment and in particular the proposed Monitoring and Evaluation Framework for the plan.

It also presents a summary of input, process, output, outcome and impact indicators emanating from a two-day consultative workshop held on the 19-20 May 2004 whereby role players had the opportunity to contribute to the development of the M&E Framework and to make recommendations on a minimum set of indicators.



Mr. Thamsanqa D Mseleku
Director-General: Health
Date: 2005-04-20

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MONITORING SCHEDULE

Monitoring and evaluation is a critical component of the Comprehensive HIV and AIDS plan. The Department of Health has developed a comprehensive Monitoring and Evaluation (M&E) Framework, which is designed to measure progress towards the achievement of two interrelated goals of the Comprehensive HIV and AIDS Plan. The comprehensive M&E Framework aims to monitor the resources invested, the activities implemented, services delivered as well as evaluate outcomes achieved and long-term impact made.

Mechanisms are being put in place to improve data collection and flow to ensure quality, valid and accurate data. Existing data collection mechanisms are being enabled and new systems are being developed to respond to the data needs imposed by the plan. The mechanisms are also designed in a manner that ensures data confidentiality. Data collection, validation and use from the service point level up to the national office rely on existing expertise, commitment and dedication of members of the health team to use data collection tools and report data.

Information on indicators will be available incrementally as the data collection systems mature and grow over time. Current efforts are expended to ensure information on a primary set of selected input, process and output indicators is immediately available within six months. Some primary set indicators will be reported by gender, age-group and province.

Primary set of indicators to be reported within 6 months period
• Number of accredited service points per district
• Percentage of facilities experiencing stock out of basket of tracer drugs at any time in the last month
• Full time equivalent per category as proportion of required personnel
• Male and female condom distribution rate
• Percentage of eligible patients receiving supplement meal and micronutrient supplements
• Proportion of adult patients on antiretroviral therapy with adherence lower than 70%(unacceptable level of adherence)
• Number of CD4 counts done per month
• Number of viral loads completed per month
• Proportion of registered patients on regimen 1a or 1b, 2 or child regimen
• Percentage of patients with viral load <400 copies /ml
• Percentage of patients with CD4 > 200/mm^3
• Percentage of patients with weight gain >10% compared to baseline

It is anticipated that at least 75% of the information on the main set of indicators will be available within 24 months. Long term outcome and impact will be assessed after a long period of time following the implementation of the plan.

1. BACKGROUND ON POLICY PROCESSES AND LANDMARK EVENTS

The early developments of a coordinated public policy response to HIV and AIDS date back to principles laid out in the ANC Health Plan prior to 1994 and subsequently in the formation of the National AIDS Coordinating Committee of South Africa (NACOSA) in the early 1990s. 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.

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

Government's commitment to address HIV, AIDS and STIs in the country has been demonstrated by consistent increases in the allocation towards HIV and AIDS over the last few years. This is illustrated both by budgetary trends of the Medium Term Expenditure Framework (MTEF) related to the health budget as well as by the Enhanced Response to HIV, AIDS, STIs and TB which detailed strategies and funding requirements for HIV and AIDS particularly.

In April 2002, 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 among others, continued use of nevirapine in preventing mother-to-child HIV transmission and development of a universal rollout plan and removing systemic constraints on access to antiretroviral drugs.

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.

At its 8 August 2003 meeting, Cabinet received the Report of the Joint Health and the Treasury Task Team (JHTTT) that was charged with examining treatment options to supplement Strategic Plan 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.

Following the discussion of this strategic report on 8 August 2003, Cabinet instructed the Department of Health to develop a detailed operational plan on comprehensive care, management and treatment 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. In November the operational plan was adopted.

2. THE COMPREHENSIVE PLAN

The South African Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment holds a significant position in international public health arena largely because it is the largest and most ambitious yet in the world for HIV care.

The plan is anchored on two important pillars:
a) Must be a comprehensive programme that will include:

- 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;
- Enhancing efforts in the prophylaxis and treatment of opportunistic infections, improved nutrition and lifestyle choices;
- Effective management of those HIV-infected individuals who have developed opportunistic infections through appropriate treatment of AIDS-related conditions;
- Provision of antiretroviral therapy in patients presenting with low CD4 counts to improve functional health status and to prolong life;
- Integration of traditional and complementary medicine into the comprehensive care, management and treatment programme
- Providing a comprehensive continuum of care, support and treatment

b) Strengthening of the National Health System as a whole in order to ensure the effective delivery of comprehensive HIV and AIDS care and treatment and other equally important healthcare priorities and programmes. These include the improvement in laboratory services, in information systems, human resources and capacity development, drug procurement and distribution, etc.

3. GUIDING PRINCIPLES OF THE PLAN

The operational plan is guided by a number of important principles namely:

3.1 Quality of Care

The 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. Treating AIDS patients with antiretroviral drugs has been shown in some instances to prolong the lives of people who would have progressed to stage 3 and 4 of AIDS. The care and treatment protocols are based on international best practice. Accreditation procedures help to ensure that the facilities that are approved for the provision of comprehensive care, management and treatment are of good quality and observe the highest standards of care.

The plan also provides for extensive investments in monitoring and research to allow for continual evaluation and improvement in the quality of care. And all these efforts will ensure that the best information is available for the benefit of South Africans undergoing care and treatment.

3.2 Universal Care and Equitable Implementation

The programme is founded upon the principle of universal access to care, management and treatment for all, irrespective of race, colour, gender and economic status. This programme attempts to address the challenge of providing services in rural and urban settings equitably without compromising the quality of care. The operational plan aims to achieve a balance between areas that can readily implement the programme and those that need additional resources and investments to upgrade their general health capacity.

3.3 Strengthening the National Health System

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 is a fundamental principle of the plan. The 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. The operational plan is reinforcing efforts to upgrade health care management information system, to improve patient tracking and referral mechanisms, and to continue with the upgrading and/or refurbishing of public hospitals, health centres and clinics, and to improve efficiency of laboratory services.

3.4 Reinforcing the Key Government Strategy of Prevention

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.

3.5 Providing a Comprehensive Continuum of Care and Treatment

The comprehensive HIV and AIDS care, management and treatment programme embodied in this plan builds on the existing programmes as outlined in the five-year Strategic Plan for HIV, AIDS and STIs. Prevention of HIV and TB infections remains the mainstay of the programme.

3.6 A Sustainable Programme

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. Once people enter into a comprehensive treatment and care programme, treatment must be sustained for the rest of their lives. 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.

3.7 Promotion of Healthy Lifestyles

Any health care programme must begin with the promotion of healthy lifestyles, which includes physical exercise, and not smoking, good nutrition, the practice of safe sex, prevention of alcohol and substance abuse 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. This programme is integrated with existing health education efforts to promote healthy lifestyles among South Africans.

3.8 Promotion of Individual Choice of Treatments

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.

3.9 Integration with Government Nutrition Strategy

Good nutrition is essential to good health. 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 is being fully integrated with the existing programmes.

3.10 Ensuring the Safe Use of Medicines

If not administered and monitored properly, antiretroviral drugs can become less effective and cause serious side effects as drug-resistant strains of the virus develop. For these reasons, the plan goes to great lengths to monitor patient safety and educate or counsel patients and asses the impact of these measures and to emphasize the safe use of medicines and the importance of adherence to treatment.

3.11 Drug Resistance

As with TB, poor management and poor compliance with antiretroviral therapy results in multi-drug resistant HIV, which could impact negatively on both diseases. To optimise care for HIV and AIDS patients who also have tuberculosis it is important to develop and sustain joint management programmes. 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.

3.12 Local and Regional Integration

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 and in the Abidjan and Maseru declarations.

4. GOALS OF THE PLAN

The plan aims to accomplish two interrelated goals, namely:

- To provide comprehensive care, management and treatment for people living with HIV and AIDS; and
- To facilitate the strengthening of the national health system in South Africa.

The National Department of Health is working closely with Provincial Departments of Health to ensure smooth implementation of the programme and the National Treasury allocated R63 million to the National Department of Health in the 2004/05 financial year.

5. MONITORING AND EVALUATION FRAMEWORK

Monitoring and evaluation is an absolute critical aspect of the plan. Good Monitoring and Evaluation (M&E) contributes to ensuring that the objectives of the operational plan are achieved. The role of M&E for planning and good financial management is emphasized in the Public Finance Management Act (PFMA).

The M&E Framework is based on the principles of monitoring and evaluation as reflected in the Health Goals, Objectives and Indicators 2001-05. Monitoring and evaluation are two complementary, but separate functions, which often serve distinct purposes. Monitoring is the routine ongoing assessment of activities applied to assess resources invested (inputs) in the programme, services delivered (outputs) by the programme and outcomes that are related to the programme. Evaluation is non-routine assessment which is concerned with evaluation of programmes impact on the health and lives of South Africans. The M&E Framework adopts a logical approach of input, process, output, outcome and impact indicators (Fig 1) to ensure ongoing monitoring and evaluation of the goals and objectives of the Plan.

The M&E Framework is designed to measure progress towards the achievement of two above-mentioned interrelated goals of the plan. Therefore, the objectives of the M&E Framework are to collect and provide information that will be used to:

- Track progress on implementation of all components of the Comprehensive HIV and AIDS Care, Management and Treatment Plan;
- Identify gaps and weaknesses in service provision;
- Support clinical management of the patients;
- Plan, prioritize, allocate and manage resources;
- Monitor the impact of HIV and AIDS on health care systems and communities; and
- Measure effectiveness of treatment.

M & E APP ROAC

INDICATORS

DATA SOURCES

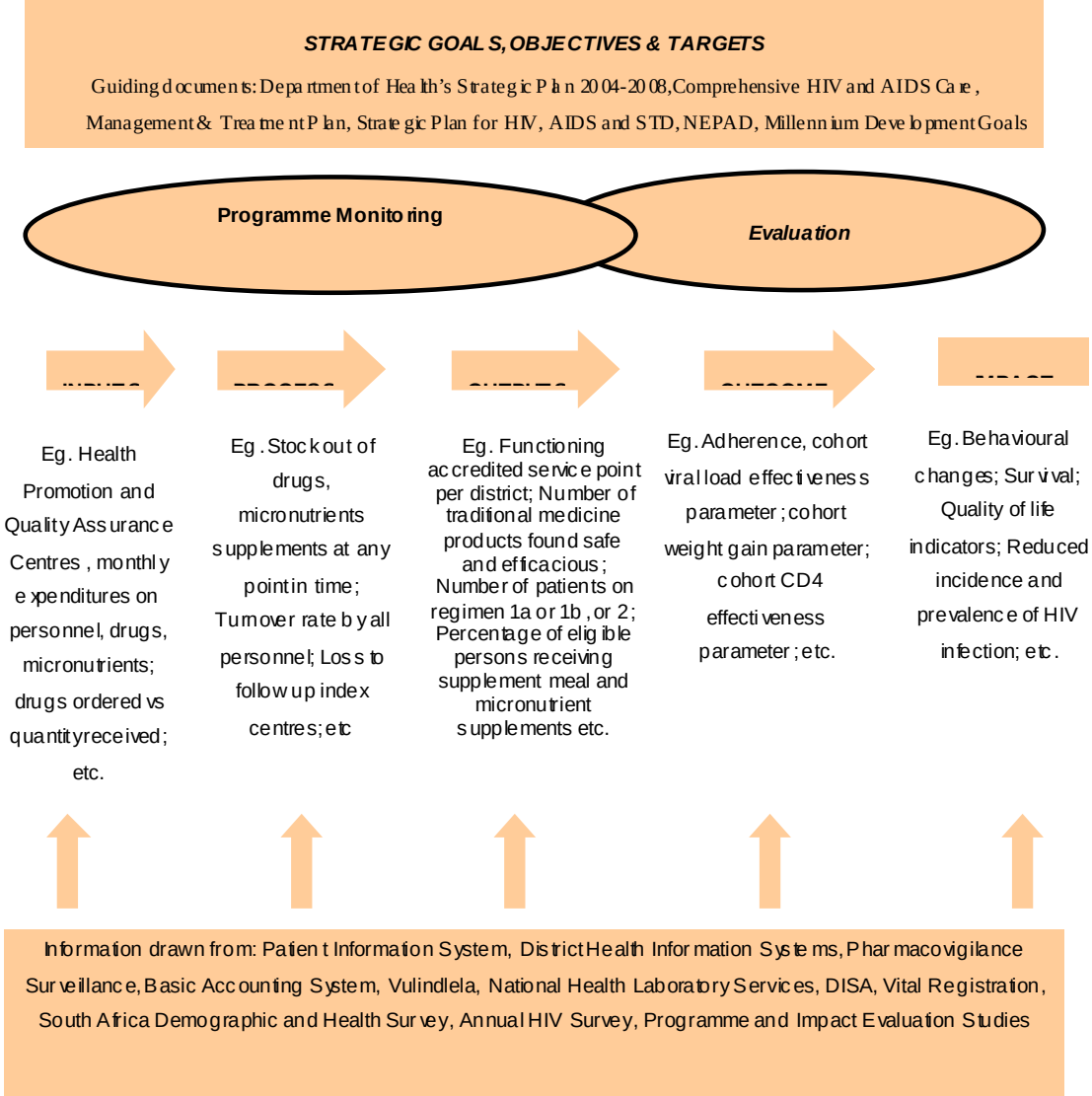

Figure 1: Monitoring and Evaluation Framework: Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment of South Africa

A minimum set of indicators is proposed taking into consideration the principles of universal access and equitable implementation, quality of services, continuum of care, efficiency, sustainability, affordability, compliance, safe use of medicines, integration and strengthening of health systems. The indicators can be subdivided into two broad arms, namely operational outputs and patient outcome indicators.

A two-day consultative workshop was held on the 19-20 May 2004 in Johannesburg to make recommendations on a minimum set of indicators from a wide list of proposed indicators. Ninety-one (91) role players and experts from diverse professions, disciplines, governmental, non-governmental, local and international and donor organizations attended the workshop.

The workshop gave participants an opportunity to contribute in developing the M&E Framework of the Plan and making recommendations on a minimum set of indicators to be considered, tools to be used to collect data and frequency of data collection.

Frequency of data collection will vary with the type of indicators. For example, indicators such as expenditure, availability of drugs and nutrition supplements, number of CD4 tests done can be collected on monthly basis while some indicators can be calculated on quarterly, yearly or 5-yearly.

Data sources will include systems such as Patient Information System, National Health Laboratory Information System', Pharmacovigilance Surveillance System, District Health Information Systems, Routine Data, Basic Accounting System and programme and impact evaluation research. Patient data will be stored in a Master Patient Index whereas programmatic indicators data will be kept on M&E database. Efforts are underway to ensure that the various systems with patient linked data are harmonised and even linked. It is also important that the upgrade of the information systems and harmonisation of tools and indicators is supplemented with on-site support to ensure the use, accurate and quality data. It is also requires dedication and commitment on every role player to collect and use information.

An illustration of a simplified and clearly defined information and data management procedures is presented on *Figure 2*. Agreed upon data management protocols are a necessary requirement at service point, district, provincial and national level. The protocol should not only describe the data flow but also state the operational procedures on secure storage, access and confidentiality annexure. It is important that data is verified and used firstly at the primary point of collection prior to being submitted to the next levels.

Data collected at various entry points will be captured and stored at a central data point within a service point to support patient and programme management at that level and to monitor material usage, services outputs and performance. Data will then be submitted to the next levels including the district, provincial and national offices. Indicators will allow disaggregation by location in terms of service point, district municipality, province and national; and/or social defined groupings in terms population group, gender, age, education level and employment.

5.1 Implementation Challenges

This framework will provide the basis for monitoring risk related to achieving good patient outcomes and providing good clinical and health practice. In addition this framework will be able to identify important challenges to implementing the plan. The challenges that are already glaringly clear relate to ensuring appropriately adequate human resources, finance and infrastructure, narrowing the gap in resource availability between provinces, timely reporting and so on.

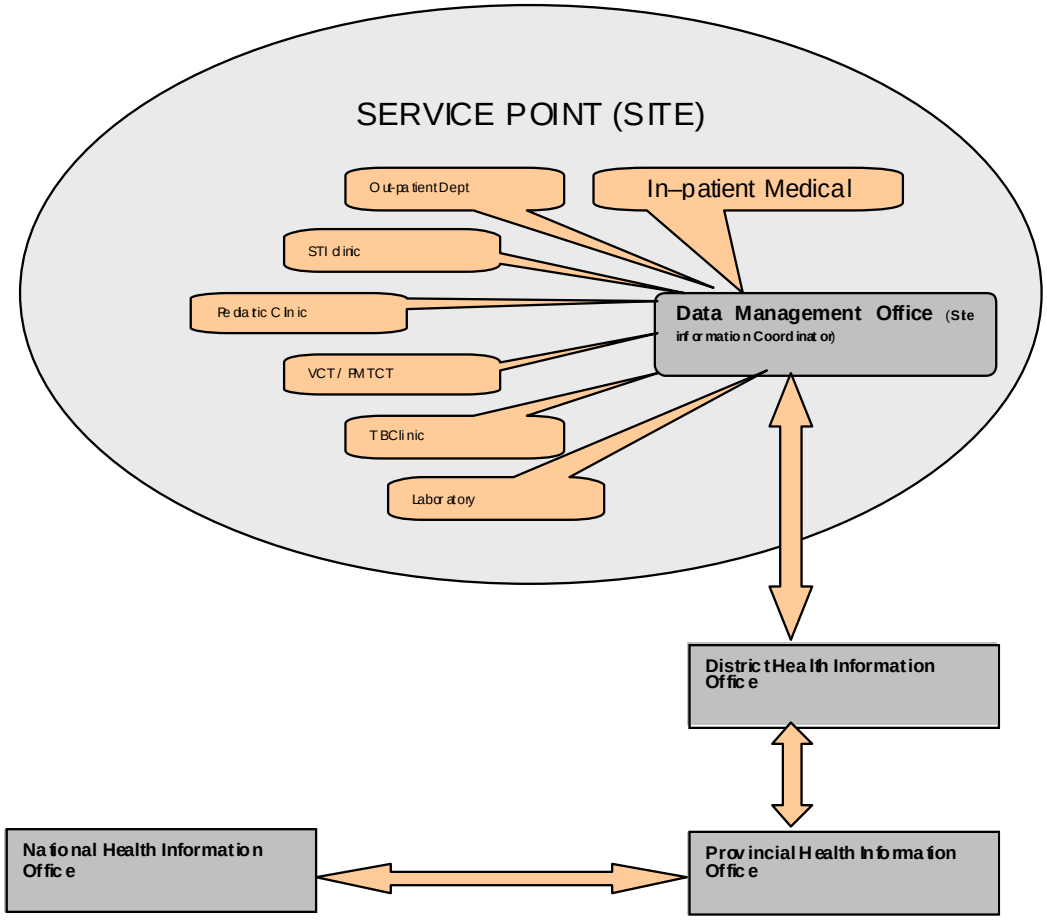

Figure 2: Simplified Data Flow Diagram

6. CORE SET OF INDICATORS

A core set of indicators has been extracted from a wider set of programmatic indicators. The set is recommended for purposes of reporting on the Comprehensive HIV and AIDS Plan to Cabinet, National Health Council and other relevant authorities.

Table1: Core Set of Indicators	Frequency[1]
• Monthly expenditures on personnel, drugs, micronutrient supplements and nutrition supplements, laboratory services, information systems	Monthly
• Unit price trends for drugs year on year – periodic	Annually
• Functioning accredited service point per district	Quarterly
• Number of service points with functional information systems in the country	Annually
• Percentage of facilities experiencing stock out of basket of tracer drugs at any time in the last month – not periodic	Monthly
• Full time equivalent per category as proportion of required personnel	Monthly
• Percentage of staff per category trained and certified per category by quality assurance and health training centres	Quarterly
• Male and female condom distribution rate	Monthly
• Percentage of eligible patients (HIV positive, patients on antiretroviral therapy, children diagnosed with HIV, pregnant women) receiving supplement meal and micronutrients supplements	Annually
• Proportion of clients HIV pre-test counselling (excluding antenatal)	Monthly
• STI partner treatment rate	Monthly
• Proportion of treatment start among TB smear positive	Quarterly
o Number of traditional medicine products found safe and efficacious	
o Percentage of patients using any traditional and complimentary medicines	Monthly
• Proportion of adult patients on antiretroviral therapy with adherence lower than 70%(unacceptable level of adherence)	Quarterly
• Proportion of registered patients on regimen 1a or 1b, 2 or child regimen	Monthly
• Cohort Viral Load Effectiveness Parameter	Annually
• Cohort CD4 Effectiveness Parameter	Annually
• Cohort Weight Gain Parameter	Annually
• Cause specific Mortality rate - treatment (children and adults)	Annually
• Specific mortality rate attributable regimen (1a, 1b, 2)	Annually
• Cause Specific mortality rate -Traditional Medicine (TM)	Annually
• Specific morbidity due to interaction ART and TM.	Annually
• Survival rates	Two yearly
• Percentage of people who report to have obtained information on HIV and AIDS from health promoters, mass media and Khomanani	5 yearly
• Percentage of people who both correctly identify ways of preventing the sexual transmission of HIV and who reject major misconception about HIV transmission or prevention.	5 yearly

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7. INPUT, PROCESS AND OUTPUT INDICATORS

This section describes the input, process and output indicators to be used to monitor budgeting and expenditure, human resources and training indicators, drug procurement and distribution, nutrition related interventions, and laboratory services.

[1] The frequency of reporting indicated in all indicator tables in this document would become effective after mid 2005 because ongoing development in data collection and flow mechanisms.

7.1 Budget and Expenditure Indicators

Funding is one of the most important inputs into the Plan that will be closely monitored. These will be monitored also by source of funding in terms of provincial, conditional grants and donor funding.

Table 2: Budget and Expenditure

	Frequency
• Monthly expenditures on e.g. personnel, drugs, micronutrient supplements and nutrition supplements, laboratory services.	Quarterly

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7.2 Human Resources and Training Indicators

Effective delivery of the Plan depends on the availability of adequate numbers of appropriately trained doctors, pharmacists, nutritionists/dieticians, professional nurses and counselors at the service points. The availability of such a health team is one of the minimum criteria for a service point to be accredited.

A minimum of 1 full time (FTE) medical officer, 2 FTE professional nurses, 5 FTE lay counselors, 1 FTE nutritionist/dietician and 0.5 FTE social worker is required to treat and care for 500 patients. Indicators to be used to monitor this component are as follows: -

Table 3: Human Resources and Training	Frequency
• Full time equivalent per category as proportion of required personnel	Monthly
• Annual turnover rate by category	Annually
• Percentage of staff per category trained and certified per category by quality assurance and health training centres	Quarterly
• Number of quality assurance and health training centres established in each province	Annually
• Number of people per category planned to be certified by quality assurance and health training centres.	Quarterly

7.3 Accreditation of Service Points

Access to care, management and treatment of highest available quality will be made available at services points accredited. A service point is defined as a group of network of linked health facilities within a clearly demarcated health district called a health district that is coterminous with district or metropolitan council area. A health district should have at least one health service point. Physical access and functionality of accredited service points will be monitored to ensure that services provided are of high quality.

Table 4: Accreditation of Service Points	Frequency
• Functioning accredited service points per district	Quarterly

7.4 Nutrition Related Indicators

The plan recognizes the role of good nutrition and household food security among those infected with TB and HIV, and those who are on antiretroviral therapy. Amongst others, the nutrition interventions consist of nutritional assessment, the promotion of healthy diet, and free micronutrient supplements and supplement meals. Based on the nutrition

assessment and household food security, access to free micronutrient supplements and supplement meals will be for patients who are on antiretroviral therapy, children diagnosed with HIV, pregnant women who are HIV positive and persons infected with TB and HIV. The availability of stocks and coverage of nutritional interventions should be monitored on the one hand and the relationship between nutrient intake, healthy diet, weight gain and disease progression should be measured on the other hand. Proposed indicators to be used for nutrition are shown below:

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Table 5: Nutrition related interventions indicators	Frequency
• Percentage of accredited service points that receive the quantity of supplement meals ordered	Monthly
• Percentage of accredited service points that receive the quantity of micronutrient supplements ordered	Monthly
• Percentage of accredited service points that experience being out of stock of supplement meals at any time	Monthly
• Percentage of accredited service points that experience being out of stock of micronutrient supplements at any time	Monthly
• Number of supplementary meals available and issued per month	Monthly
• Number of micronutrient supplements available and issued per month	Monthly
• Percentage of eligible patients (patients on antiretroviral therapy, children diagnosed with HIV, pregnant women who are HIV positive and persons infected with TB and HIV) receiving supplement meal and micronutrient supplements	Monthly
• Proportion of patients who experience specific food-drug interactions	Biennially
• Average intake of proteins /micronutrient supplements	Biennially

7.5 Drug Procurement and Distribution Indicators

Drug procurement aims to ensure availability of medicines of highest quality, a secure and sustainable supply at volumes large enough to meet the demand, purchase at the lowest possible price, local production and sustainable financing. Drug distribution aims to establish an efficient and secure process for storage, distribution and appropriate utilization in order to avoid stock outs and prevent shrinkages and re-exportation. Proposed indicators are: -

Table 6: Drug Procurement and Distribution	Frequency
• Unit price trends for drugs year on year – periodic	Annually
• Percentage quantity of drugs purchased vs. quantity contracted – periodic	Annually
• Percentage of accredited service points experiencing stock out of drugs at any time in the last month	Monthly
• Percentage of facilities experiencing stock out of TB drugs at any time in the last month	Monthly
• Percentage of facilities experiencing stock out of basket of tracer drugs at any time in the last month	Monthly
• Percentage quantity of drugs ordered vs. quantity received (service level)	Monthly
• Percentage orders received within the contracted lead time	Monthly

7.6 Laboratory Services Indicators

The National ART Guidelines state clearly when and on whom the individual laboratory tests are to be done. CD4 cell count, viral load, full blood count, ALT, fasting cholesterol, triglycerides and fasting glucose are the absolute minimum tests required for staging,

regular monitoring and assessment of treatment outcome. The laboratory services are provided by the National Health Laboratory Services. The objectives of laboratory services component are : -

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

Monitoring quality assurance and efficient performance of the laboratories is of paramount importance and indicators for laboratory services have been developed as follows: -

Table 7: Laboratory Services	**Frequency**
• Percentage of laboratories performing within EQA standards	Quarterly
• Percentage of CD4 counts results received by clinician < 6 days	Monthly
• Percentage of Viral loads results received by clinician < 6 days	Monthly
• Number of corrective actions taken on turn around time by NHLS	Quarterly
• Number of CD4 counts completed per Month	Monthly
• Number of CD4 counts results <200/Month	Monthly
• Number of CD4 counts results <50 per Month	Monthly
• Number of CD4 counts <15% per Month	Monthly
• Number of viral loads completed per Month	Monthly
• Number of ALT tests per month	Monthly
• Number of FBC done per month	At baseline, 3 months, 6 monthly
• Number of fasting cholesterol and triglyceride tests done	At baseline, 6 months & then annually
• Number of fasting glucose tests done	At baseline, 6 months & then annually

7.7 Patient Information System, Monitoring and Research

Information system must be strengthened at all accredited service points. Research to answer questions relevant to systemic, clinical and programmatic aspects of the Comprehensive HIV and AIDS Plan will be conducted. Proposed indicators on Patient Information System, Monitoring and Research include:

Table 8: Patient Information System, Monitoring and Research	**Frequency**
• Number of service points with functional information systems in the country	Annually
• Availability of output and outcome indicators	Quarterly
Proportion of research questions on research projects have been commissioned	Annually
• Project proposal approved by research priority area per year	Annually
• Project proposals funded by research priority area per year	Annually
• Research projects completed by research priority area per year	Annually

• Studies published per year by research priority area per year	Annually
• Percent budget allocated for research on the Comprehensive HIV and AIDS plan per financial year	Annually

Table 9: Progress Monitoring Indicators	Frequency
• Monthly returns on 10 core indicators by Province	Monthly
• Monthly returns on patient laboratory profile from NHLS	Monthly
• Full provincial monthly reports received	Monthly
• Monthly monitoring feedback distributed to each province	Monthly
• Indicators booklets distributed to each province	Annually
• Availability of data collection system in all provinces	Annually
• Provincial training for data collection system	Monthly

A research governance framework has been developed to support the research programme for the comprehensive HIV and AIDS care, management and treatment plan. Research will in turn generate important data and information for monitoring and evaluation of the programme.

One of the goals for the Comprehensive Plan is strengthening of health systems. Proposed indicators for strengthening of the health systems include:

Table 10: Health Systems Strengthening Indicators	Frequency
• Percent of facilities with systems that supports quality service delivery	Annually
• Facilities with working referral system	Annually
• Availability of policies, plans, guidelines that promote access to HIV and AIDS services	5 yearly
• Number of service points with functional information systems in the country	Annually
• Facilities submitting completed routine management information system (MIS) report on time	Monthly
• Facilities using information to monitor performance	Annually
• Facilities with adequate storage for all supplies	Annually
• Proportion of established Provincial AIDS Council sub-committees on Community mobilization	Annually

8. PATIENT OUTCOME AND IMPACT INDICATORS

The sections deals with outputs, outcome and impact indicators. These indicators are concentrated mainly, but not limited to, in components such as pharmacovigilance; social mobilisation and communication; and prevention, care and treatment.

8.1 Prevention, Care and Treatment Indicators

The prevention, treatment and care component aims to ensure that service points provide access to a full array of interventions and services within a context of continuum of care. The full array of interventions and services include voluntary counselling and HIV testing (VCT), prevention of mother to child transmission of HIV (PMTCT), tuberculosis control, treatment and prevention of sexually transmitted infections, nutrition assistance, antiretroviral therapy, psychosocial support, community based services and home based care. The target is to have at least one service point within a health district offering these services.

The development of indicators for the prevention, treatment and care component prompted a review of the existing indicators for VCT, PMTCT, STI and TB with a view to have a combined minimum dataset that will be collected at both primary health care facilities and hospitals. The combined PHC and hospital minimum dataset will use the District Health Information System Software for the following indicators: -

Table 11: VCT, PMTCT, STI and TB	Frequency
• Incidence of STI treated new episode	Monthly
• Incidence of male urethritis syndrome treated new episode	Monthly
• STI partner notification rate, tracing & treatment rates	Monthly
• Male and female condom distribution rate	Monthly
• Proportion of clients HIV pre-test counselling (excluding antenatal)	Monthly
• HIV testing rate (excluding antenatal)	Monthly
• HIV prevalence among clients tested (excluding antenatal)	Monthly
• Proportion of antenatal clients tested for HIV	Monthly
• Syphilis prevalence among antenatal clients tested	Quarterly
• Nevirapine uptake rate among babies born to women with HIV	Monthly
• Nevirapine dose to baby coverage rate	Monthly
• Prophylaxis among rape victims -proportion	Quarterly
• Prophylaxis among occupation HIV exposure cases- proportion	Quarterly
• TB case finding index	Quarterly
• Proportion of treatment start among TB smear positive	Quarterly
• Incidence of INH preventive therapy start in HIV positive	Monthly
o Incidence of cotrimoxazole prophylaxis rate in HIV positive.	Monthly

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Indicators that would be used to measure not only access but also immediate outcomes and impact will be collected at accredited service points. These indicators are a combination of output and outcome indicators. Proposed indicators are: -

Table 12: Antiretroviral Therapy	Frequency
• Assessment first visit	Monthly
• Total assessment visits	Monthly
• Proportion CD4 turn-around > 6 days	Monthly
• Known-death rate during readiness assessment	Monthly

• Number of Registered patients	Monthly
• Proportion of patients assessed eligible for treatment	Monthly
• Total number of visits by patients on antiretroviral therapy	Monthly
• Patient transfer out rate	Quarterly
• Known-death rate among patients on antiretroviral therapy	Annually
• Total number of registered patients on antiretroviral therapy	Monthly
• Stop index	Quarterly
• Loss to follow up index	Quarterly
• De-registered patients index	Quarterly
• Proportion of registered patients on regimen 1a or 1b	Monthly
• Proportion of registered patients on regimen 2	Monthly
• Proportion of registered patients on any child regimen	Monthly
• ART Adherence last 3 days proportion 100%	Quarterly
• Scheduled dose defaulting rate regimen	Quarterly
• Cohort Viral Load Effectiveness Parameter	Monthly
• Cohort Weight Gain Parameter	Monthly
• Adult cohort WHO Stage Parameter	Monthly
• child cohort WHO Stage Parameter	Monthly
• Cohort CD4 Effectiveness Parameter	Monthly
• Incidence of STI treated new episode among patients on antiretroviral therapy	Monthly
• Proportion of adult patients on antiretroviral therapy with adherence greater or equal 90%	Quarterly
• Proportion of adult patients on antiretroviral therapy with adherence lower than 70%(unacceptable level of adherence)	Quarterly
• Proportion of patients registered who missed one dose or more in the last 3 days	Monthly
• Average number of year lived while on treatment.	Two yearly

These indicators will be calculated from the data collected using a set of patient forms, namely, the Patient Demographic Form, the ART Baseline Form, and the ART Follow-up Form.

8.2 Traditional Medicine

The indicators were developed to monitor the collaboration between health systems and Traditional Health Practitioners in implementing the comprehensive HIV and AIDS Plan. Proposed indicators on traditional medicine include:

Table 13: Traditional medicine	Frequency
o Percentage of patients using any traditional and complimentary medicines	Monthly
o Percentage of Registered Traditional Health Practitioners trained on treatment and care of patients	Quarterly
o Percentage of patients referred by Traditional Health Practitioners to service points	Quarterly

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8.3 Social Mobilisation and Communications Indicators

The success in implementation will be facilitated by a well-defined social mobilization and communications strategy. The strategy includes external information, education and communications (IEC) strategy linked with social mobilization component that together articulate the implementation goals. The specific aims of the communication strategy are

to ensure that all relevant government programmes, health care providers, people living with HIV and AIDS), their families, care givers and stakeholders are fully knowledgeable about tall the key provisions and requirements if the plan as well as their respective roles and responsibilities. It is the objective of this component to create a supportive and safe environment for people living with HIV and AIDS largely through educational programmes that address stigma and discrimination.

Social mobilization will aim to reach a broad arrange of South African society to mobilize people and communities to action. The aim of social mobilization is to ensure that people living with HIV and AIDS have access to care and treatment programmes and adequate support structures in their local communities. The indicators on social mobilization and communications will assess the extent of reach to the communities and some of these indicators may be collected through household or population-based surveys. The proposed indicators include:

Table 14: Social Mobilisation and Communications	**Frequency**
• Proportion of clients receiving home based care assistance for the first time	Annually
• Proportion of clients served by the Community based care around the accredited service points	Annually
• Number of referrals between service points and community based organisations	Annually
• Number of clients served by Home based care around the accredited service points	Annually
• Proportion of established Provincial AIDS Council sub-committees on Community mobilization	Annually
• Percentage of people who report to have obtained information on HIV and AIDS from health promoters, mass media and Khomanani	5 yearly
• Percentage of people who know about the comprehensive HIV and AIDS care, management and treatment plan	5 yearly
• Percentage of people who both correctly identify ways of preventing the sexual transmission of HIV and who reject major misconception about HIV transmission or prevention.	5 yearly

8.4 Pharmacovigilance Indicators

The plan proposes a comprehensive programme of pharmacovigilance in order to monitor the efficacy of the drugs that are being used and in particular to monitor adverse events. The specific aims of the antiretroviral pharmacovigilance programme are: -

- To determine the burden of drug related morbidity and mortality in patients with HIV and AIDS, particularly associated with ARV use, and develop measures to minimize their impact;
- To provide training and information to health personnel and patients on the safe use of antiretrovirals and other medicines commonly used in HIV infected and AIDS patients;
- To develop systems to asses the risks and benefits of treatments commonly used in patients with HIV, STIs, and TB, including over the counter medications / phyto-therapeutic agents;
- To identify, assess and communicate and new safety concern associated with the use of antiretrovirals and other HIV medicines;

- To support the regulatory and public health decision making through an efficient, national post-marketing system, monitoring the quality, benefits and risk or harm associated with ARVs and other medicines currently used in the health sector;
- To minimize the impact of misleading or unproven associations between adverse events and ARV therapy;
- To detect, assess and responds top safety concerns related to complementary and traditional medicines used in HIV-infected patients;
- To establish an early warning system for resistance to antimicrobials commonly used in HIV, including, but not limited to antiretrovirals; and
- To respond to unfounded and unsubstantiated claims of efficacy of untested products and treatment modalities.

Representative sentinel surveillance sites will be selected form the service points implementing the Plan. Specially designed forms will be used to collect information on adverse events. Proposed indicators on pharmacovigilance were presented at the workshop, they include:

Table 15: Pharmacovigilance	**Frequency**
• Percentage of spontaneous adverse events (ADE) reports	Annually
• Percentage of ART related ADE experienced at sentinel sites in children	Annually
• Percentage of ART related ADE experienced at sentinel sites in adults	Annually
• Number of patients on treatment with regimens that had to be switched due to serious ADE	Annually
• Percentage of patient discontinuing ART due to ADE	Annually
• Specific mortality rate attributable to specific drugs	Annually
• Specific mortality rate attributable to ART regimen (1a, 1b, 2)	Annually
• Specific morbidity rate attributable to ART regimen (all severe & mild cases)	Annually
• Regimen change rate	Annually
• Discontinuation of treatment rate	Annually
• Adherence rate to treatment	Annually
• Cause specific mortality rates (ART and TM)	Annually

9. CONCLUSION

The Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment holds a significant position in international public health largely because it is the largest and most ambitious yet in the world for HIV and AIDS care. It also provides for extensive investments in monitoring, evaluation and research to allow for continual evaluation and improvement in the quality of care. And all these efforts will ensure that the best information is available for the benefit of South Africans undergoing care and treatment. It is against this background that the release of this Monitoring Framework is intended at sharing the information that relates to issues that are relevant to various aspects of the plan.

10. REFERENCES

1. National Antiretroviral Treatment Guidelines, *National Department of Health, South Africa 2004*
2. Operational Plan for the Comprehensive HIV and AIDS Care, Treatment and Management for South Africa; *National Department of Health, South Africa 2003, http://www.doh.gov.za*
3. Research Governance Framework, *Department of Health Report.*

DRAFT

DATA FLOW AND DATA MANAGEMENT PROTOCOL

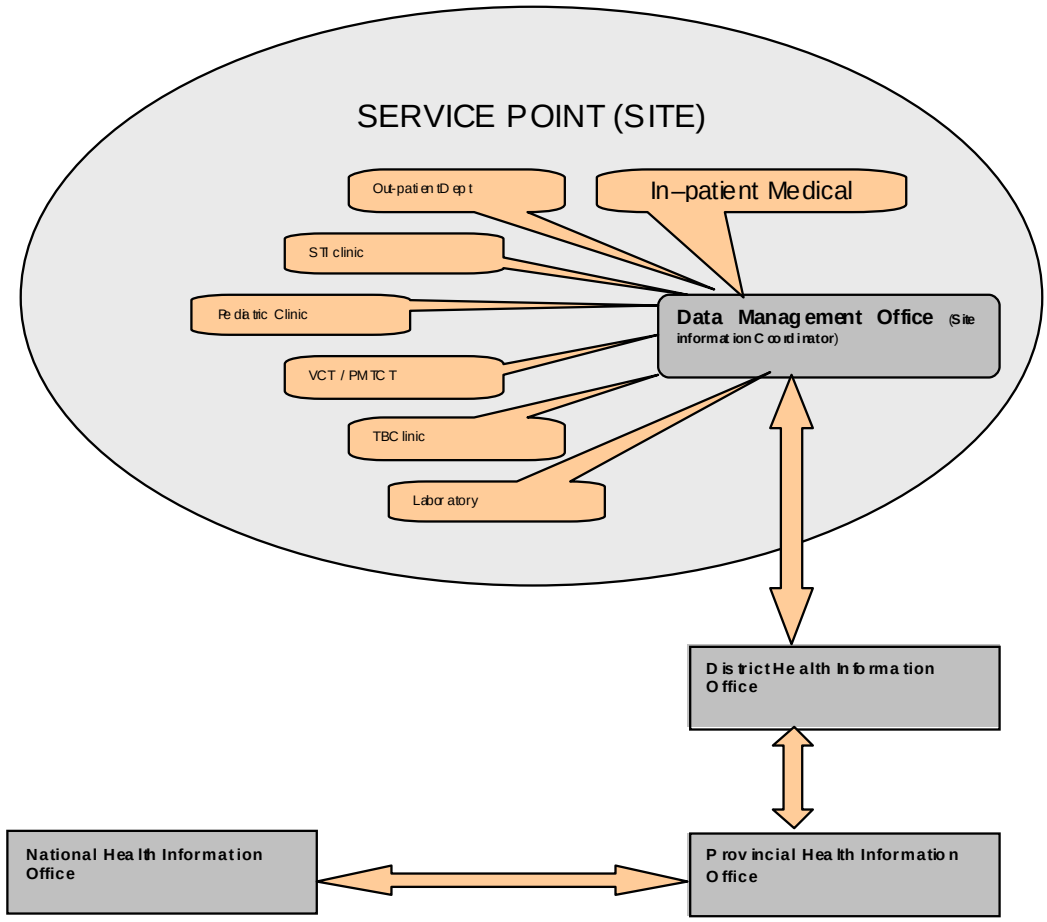
COMPREHENSIVE HIV AND AIDS CARE, TREATMENT AND MANAGEMENT PROGRAMME

DATA FLOW AND DATA MANAGEMENT PROTOCOL

1. Each facility should have a central data capture point equipped with efficient security system, e.g. in look-up rooms, etc.
2. Each facility should have a well-defined data management protocol and data flow protocol from different peripheral data capture points (satellite clinics) (e.g. TB, PMTCT, VCT, Laboratory, etc) to the central data capture.
3. For confidentiality reasons, the facility should have in place a safe and reliable data keeping and filling system (for both electronic and paper based data) which clearly outlines all security measures.
4. Time frames and frequencies as to when and how often are data forms sent to the central data capture point from each peripheral data capture points (satellite clinics) should be clearly set.
5. All computers dedicated only for the comprehensive HIV and AIDS programme should be protected with relevant passwords to improve patient information confidentiality.
6. Only health workers and data capturers/information officers permanently designated to work with patient information should be identified and be given access the data. However patient information should be limited for access depending on the level of authenticity and a sworn security clearance should be obtained for each person having access to the data.
7. Time frames and frequencies as to when and how often are patient information data sent to the district information office should be clearly set by the facility health information office and the district health information office.

8. Each district and provincial health information office should have an efficient storage and security system, e.g. in look-up rooms, etc.
9. Each district and provincial health information office should have a well-defined data management protocol and data flow protocol from different peripheral data capture points.
10. Each district information office should have clearly set time frames and frequencies outlining when and how often are patient information data sent to provincial health information office.
11. Provincial information office should have clearly set time frames and frequencies outlining when and how often are aggregated patient information data sent to the national office.

DATA/INFORMATION FLOW CHART



Roles and Responsibilities

This document outlines the roles and responsibilities at different levels in relation data flow and data management in relation to the Comprehensive HIV and AIDS Plan. The following principles are to be followed: -

- Data will be collected using both paper-based and electronic Patient Information System at the service points;
- Completed paper forms must be kept in patient folders and stored in a secure place;
- Data flow will start from the service points and will be sent through the district and provincial offices to the national office;

- Data accuracy and completeness must be maintained at all times;
- Health personnel responsible for data collection, entry and use should ensure that the confidentiality of patients' records is maintained at all service points.
- Each level must create a database with a back-up system for data storage.

Service Points

- At the service points, members of the core health team will complete the forms;
- All completed forms should be sent to the central data office at the service points;
- The data capturer will capture data from the forms electronically into the patient information system;
- The data managers will ensure the data are accurate and complete.
- The data managers will ensure that data are signed off to the district or province weekly (preferably every Thursday)
- A register of data received, captured and submitted must kept;
- No data and completed forms will be submitted without the Programme Manager's approval
- At each service point, programme managers and members of the core health team are encouraged to analyse, interpret and use data locally, for their planning purposes.
- All personnel who have access to the data must sign a confidentiality form.
- A list of all personnel who have access to patients records and data must be maintained

District Offices

- The District Health Information Officer will capture data onto the district health database and also makes backups;
- The District Health Officers will be responsible for verifying the quality and accuracy of data;
- Data will be submitted to the provincial offices on weekly basis. A register of data received and submitted must kept;
- The district offices are encouraged to analyse, interpret and use data locally, for their planning purposes.

- All personnel at district office who have access to the data must sign a confidentiality form
- A list of all personnel who have access to patients records and data must be maintained

Provincial Offices

- The Provincial Information Officer should make data verifications and checks for correctness and accuracy.
- Then the data will be recorded on the provincial database.
- A register of all data received from Service Point and submitted to the National offices must kept
- Provincial level data must be stored in a secure place with backups.
- Access to databases at provincial level will be strictly restricted.
- All personnel at provincial office who have access to the data must sign a confidentiality form
- A list of all personnel who have access to patients records and data must be maintained

National Level

- At the National office, data from provinces will be confidentially kept on the database in the Monitoring and Evaluation Unit
- Access to databases at national level will be strictly restricted
- All personnel at national office who have access to the data must sign a confidentiality form
- A list of all personnel who have access to patients records and data must be maintained

Data Security and Access

Data security

- Unauthorised disclosure of personal data or aggregated data by a person designated for data entry or processing is not allowed and could result in appropriate action being taken against the said person.

- Any personal data or aggregated data either in paper form or in electronic form should be stored in a secure place and should not be duplicated unnecessarily
- All persons designated to work and have access to data either in paper form or electronically are responsible for ensuring that any personal data or aggregated data which they hold is kept securely to ensure that:
    - There is no unauthorised access to or alteration or destruction of the data
    - There is no unauthorised disclosure, either orally or in writing, of the data
    - There is no accidental loss or destruction of the data
    - There is no accidental disclosure, either orally or in writing, of the data (to any unauthorised third party).
- Appropriate security measures shall be taken against unauthorised access to, or unauthorised alteration, disclosure or destruction of, the data.
- As a minimum standard:
    - Access to computers and manual files containing personal or aggregated data should restricted to authorised staff only.
    - Access to the information should be restricted on a "need-to-know" basis in accordance with a clearly defined data management protocol.
    - Computer systems containing personal or aggregated data should be password protected.
    - Information on screens or on forms should be kept hidden from callers to data capturing offices.
    - There should be a back-up procedure in operation.
    - All waste papers, printouts, etc. should be disposed of carefully.

Access requests

- Any requests for access to personal data or aggregated data either in paper form or in electronic form should be made in writing, where appropriate, to the office of the Chief Director: Health Information, Evaluation and Research.
- The office of the Chief Director: Health Information, Evaluation and Research will be responsible for establishing the identity of the enquirer and initiating, where appropriate, a request for such data which will be deemed relevant to provide.

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