AN EVALUATION OF SOUTH AFRICA'S NATIONAL DRUG POLICY; STANDARD TREATMENT GUIDELINES / ESSENTIAL DRUGS LIST AND ITS IMPACT ON RATIONAL DRUG PRESCRIBING IN PUBLIC HOSPITAL OUTPATIENT CLINICS: A CASE STUDY OF THE NORTHERN PROVINCE

by

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ABSTRACT

During the years of apartheid, South Africa developed two health care systems, public and private, that were fragmented and segregated by race. The private health care system (almost exclusively white patients) was on the same level as the tertiary care in industrialised countries, while the public health care system (almost exclusively black and coloured) was similar to the primary health care systems in many developing countries.

Even so, South Africa in 1996 was spending much more than any other African country on health care, 8.5% of the GDP per year (McIntyre 1995). The political tide turned in 1996 and with new governments came a new focus on equity of health care, access and services. Equity in health care and access are the main foci of health initiatives in South Africa.

This research evaluated the impact of the National Drug Policy (1996), and the National Drug Programme (NDP). The NDP's key component is the Standard Treatment Guidelines/Essential Drugs List (STG/EDL) to be used in South Africa's public hospitals' outpatient clinics at all levels (primary, secondary, and tertiary). This study is a cross-sectional case study that evaluates the effectiveness of the implementation of this policy through strategies to encourage prescribers to use the STG/EDL as a regular part of their prescribing repertoire. The research techniques included a combination of quantitative analyses with a drug utilisation survey (DUS) that measured adherence to rational prescribing measures, and qualitative analyses in-depth interviews with nurses, pharmacists, physicians and administrators.

The results of both the drug utilisation survey of 1,204 prescriptions from eleven clinics and 20 interviews showed that there was little evidence of rational prescribing in public hospital clinics. Overall the prescribers at the clinic level did not adhere to the NDP and rational prescribing. The one major change observed was that the hospital clinic pharmacy would substitute most brand medicines for generic ones, unless the physician formally requests the brand drug. The one clinic that was the most adherent to the rational prescribing standard had a pharmacist who was enrolled in a rational prescribing and monitoring course. In addition, the manager pharmacist developed an EDP bulletin for all the staff and encouraged the use of the Standard Treatment Guidelines Essential Drugs list for all staff in the hospital clinic.

In summary, this study shows that the major goals of the National Drug Policy (NDP), the rational prescribing of drugs and equity of access to health care and services, have note been reached. Even though there is some progress towards attaining these goals will require an effort of all stakeholders through enforceable legislation, allocated budgets, patient and prescriber education, and a bottom-up approach to policy implementation.

DEDICATION

This thesis is dedicated to the memory of two extraordinary men,
who embodied humanity, creativity, scholarship, and genius
Mr. Lauderic Rex Caton and Mr. Bernard Murray

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ACCRONYMS AND ABBREVIATIONS

APED	Association of Programmes of Essential Drugs
BDDSA	British Development Division for Southern Africa (DFID Project support office based in Pretoria)
CHD	Consultants for Health and Development (Netherlands)
COMED	Co-ordinators Committee for the Acquisitions of Medicines (DOH)
CISA	Consumer Institute of South Africa
DAP	Drugs Action Programme (WHO Headquarters, Geneva), now EDM
DFID	Department for International Development
DHS	District Health System
DOH	Department of Health (South African Ministry of Health)
EDL	Essential Drugs List
EDP	Essential Drug Programme
HOP	Head of Pharmaceutical Services (usually PEDCO's)
HST	Health Systems Trust
IDA	International Development Agency
INN	International Nomenclature Number
INRUD	International Network for the Rational Use of Drugs
KAP	Knowledge, Attitudes and Practices
MASA	Medical Association of South Africa (now South African Medical Association)
MCC	Medicines Control Council
MEC	Medical Economic Council
MEDICOS	MEDUNSA Institute for Community Services
MEDUNSA	Medical University for Southern Africa (Pretoria)
MSSS	Medical Schemes, Supplies and Services (now PPP)
NEDLC	National Essential Drugs List Committee
NDP	National Drug Policy
NHI	National Health Insurance Committee
NP	Northern Province
PASA	Pharmaceutical Association of South Africa
PEDCOs	Provincial Essential Drug Coordinators
PHILA	Public Health Intervention through Legislative Advocacy
PPP	Pharmaceutical Programmes and Planning
NDOH	National Department of Health
RAMS	Representative Association of Medical Schemes
R	South African Rand: (1998-99) 1GBP= 10 Rands
RDU	Rational Drug Use (Rational Drug Prescribing)
ReHMIS	Regional Health Management Information System
SADAP	South African Drug Action Programme (WHO; administrative /DIFID, funded)
SAMMDRA	South African Medicines and Medical Devices Regulatory Authority
STG	Standard Treatment Guidelines
UNIPAC	UNICEF Field and Fund Procurement Agency
WHO	World Health Organization
ZAR	South African Rand (also R)

DEFINITIONS

Compulsory Licensing: Allows for the cheap local manufacturing or generically equivalent drugs still protected by patents.

District Health System: A health system based on PHC is more or less self-contained. It has a well-defined population, living within a geographical region. It includes all the institutions and individuals providing health care in the district, whether governmental, social security, non-governmental, private, or traditional. The District Health System (DHS) therefore consists of a large variety of interrelated elements that contribute to health in homes, school, work placed, and communities, through the health and other related sectors. It includes self-care and all health care workers and facilities, up to and including the hospital at first referral level and appropriate laboratory, other diagnostic, and logistical support services. Its component elements need to be well co-ordinated by an officer assigned to this function in order to draw together all these elements and institutions into a fully comprehensive range of promotive, preventive, curative, and rehabilitative health activities. (Source: WHO (1992) The hospital in rural and urban districts. WHO technical report series, No 819. Geneva: 1992)

Essential Drugs: Those drugs considered to be of the utmost importance and hence basic, indispensable and necessary for the health need of the population. They should be available at all times, in the proper dosage forms, to all segments of society." Essential drugs are drugs that satisfy the health care need of the majority (90%) of the population. (WHO. *The use of essential drugs*. WHO technical report series, no 722. Geneva: 1985)

Generic Drugs: non-proprietary. A drug name not protected by a trademark. The name is usually descriptive of its chemical structure. It can be manufactured without license from the innovator company and marketed after the expiration of the patent or other exclusive rights. Generic drugs are marketed under either and International Non-proprietary Name (INN) or brand name. (WHO/DAP/98.9)

Healthlink: South African based web site that shares health information, articles, research, etc.

Hospital Types and Levels[2] :
Community Hospital- District (Level 1): Patients requiring treatment which may be adequately and appropriately provided at the first level of referral (e.g. community hospital) by a generalist with access to basic diagnostic and therapeutic facilities.

Hospital – Secondary (Regional Level 2): Hospitals providing specialist services at the provincial level. Such hospitals would be equipped with and intensive care unit.

Hospital –Tertiary (Central Level 3): Patients requiring the expertise and care associated with the specialities, sub-specialities and less common specialities (such as cardiology, endocrinology, oncology, plastic and trauma surgery, neonatology, sophisticated paediatrics and specialised imaging), or requiring access to scarce, expensive and specialised therapeutic and diagnostic equipment found only at the central or tertiary hospital.

Hospital – National (Level 4): Facilities providing quaternary health care (liver and heart transplantation)

International Nomenclature Number (INN): common, generic names to identify new pharmaceutical substances unambiguously. The selection process is conducted by an expert committee and is based on a procedure and guiding principles adopted by the WHA. The INN is recommended for worldwide use, destined to be unique and public property (non-proprietary). (WHO/DAP/98.9)

Parallel Imports: It is a means of importing drugs that are available locally at higher prices than in other countries. The importation of medicines that are manufactured, under license, by companies other than the country the country of origin. Products imported into a country without the authorisation of the right holder in that country, which have been put on the market in another country by that person or with his consent. According to the theory of exhaustion of intellectual property rights, the exclusive right of the patent holder to import the protected product is exhausted, and thus ends, when the product is first launched on the market. (WHO/DAP/98.9)

Patent: A title granted by the public authorities conferring a temporary monopoly for the exploitation of an invention. The person or company, who reveals it, furnishes a sufficiently clear and full description of it and claim the monopoly for a set number of years (usually 10-15 years). (WHO/DAP/98.9)

Poly-pharmacy: the inclusion of more than one active ingredient in a single medicinal preparation, or the prescription of too many medicines in the treatment of an individual patient.

Rational Drug Use/ Prescribing: The prescriber prescribes and the "patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community." WHO, The Rational Use of Drugs, Report of Conference of Experts, Nairobi, 25-29 November 1985.

TRIPS: The Agreement on Trade-Related Aspects on Intellectual Property Rights covers a new field in multilateral international trade law. The agreement established minimum standards of protection for the problems of international privacy and infringement of intellectual property rights. The TRIPS agreement binds the obtaining and maintenance of customs benefits in the framework of WTO to respect intellectual property rights by the State in question. It is the agreement in the Final Ac of the Uruguay Round that could have the most implications for the production of and access to drugs, particularly in developing countries. (WHO/DAP/98.9)

CHAPTER ONE

INTRODUCTION

1.1 Introduction

The focus of the current project is South Africa's recent health sector reform in 1996 that aims to address the equity and the quality of all health services, including pharmaceutical services. This health sector reform seeks to expand the capacity of South Africa to distribute medicines to previously excluded groups at a price that the National and Provincial governments can afford.

To this end in 1996, the South African government adopted a National Drug Policy (NDP) for "getting medicines to the people," regardless of residential location, race, or socio-economic status. Governments and governmental agencies, such as the British Overseas Development Agency, have supported the adoption of the NDP. Support has also come from International Organisations (World Health Organization) and people at all levels in South Africa. In spite of both international and national support for policy reform, there is continuous controversy and resistance from stakeholders, including health professionals, pharmaceutical companies, pharmaceutical organisations and others. The resistance is to:

(a) the use of the Standard Treatment Guidelines/ Essential Drug List (STG/EDL) as a tool to influence rational drug use;

(b) the means or approaches taken to implement the National Drug Policy (NDP), specifically, rational drug use (RDU) and,

(c) the appropriate means for monitoring and assessing the impact of the policy on rational drug use (RDU).

The research question posed is: "Has the implementation of South Africa's National Drug Policy (January 1996), specifically, the use of the Standard Treatment Guidelines/ Essential Drugs List,[3] [4] (for adult hospital use) resulted in rational drug prescribing in South Africa's public hospital outpatient clinics?" A cross-sectional study was designed to address this question. Both qualitative and quantitative methods were used to evaluate the impact of the implementation of the National Drug Policy (SADAP 1996).

[3] Essential Drugs List, 693 drugs for 300 medical problems and conditions. The Standard Treatment Guidelines and Essential Drugs List (STG/EDL) are combined into three books separated into three levels: primary care, hospital level (adults and paediatrics).
[4] STG/EDL were published in December 1998.

This research evaluated the effectiveness of the policy implementation strategies used to encourage prescribers to adopt the Standard Treatment Guidelines/ Essential Drug List (STG/EDL). A cross-sectional study of South Africa's Northern Province was implemented. Hospitals in six of the seven regions in South Africa's Northern Province were included in this study. Quantitative (Rational Drug Use Survey) and Qualitative (open interviews and structured observation, participant observation; and document review).

The aim of the study is to address the development, implementation and evaluation of South Africa's National Drug Policy, and in particular the use of tools such as the Standard Treatment Guidelines/Essential Drug List to impact rational drugs prescribing.

The objectives of this study include the evaluation of the policy of *Rational Drug Prescribing* within hospital clinics. Rational prescribing is the right drug, in the correct doses, for the right duration, for the correct illness. In addition, the objectives of the study are focused on the description analysis of the processes and the impact of the implementation of the National Drug Policy. The objectives will be addressed through a survey and analysis of rational drug use patterns of prescribers of various levels of outpatient hospital clinics. The second objective is to assessment of the knowledge, attitudes and practices (KAP) of health personnel (physicians, nurses, pharmacists, and administrators) toward the implementation of the NDP and their training in the use of the STG/ EDL. Third, to identification of factors, which facilitate or hinder the proposed implementation of the use of the STG /EDL for rational drug prescribing within various levels of outpatient hospital clinics. Fourth, to examine the policy implications of these research findings.

The study makes numerous potential academic and practical contributions. Little information is available on the use of STG/EDL tools to facilitate Rational Drug Use (RDU). The current research project looks to further develop appropriate methods to assess obstacles and opportunities for strengthening prescriber involvement in the goal of RDU within a wider process of organisational and institutional change in health reform.

The goals of this research include making a contribution to the data on NDP surveys in developing countries and to achieve greater conceptual clarity regarding the key dimensions and goals of implementing social policy within the health reform. This includes concepts of policy analysis of implementation and top-down approach to implementation evaluation. The practical contributions of the research will be in the form of policy implementation recommendations. Many studies have evaluated and analysed prescribing habits and drug utilisation, but few studies go further to evaluate what factors underline these results. The findings of this study will identify enabling and hindering factors to implementation of RDU tool initiatives.

The first five chapters are an introduction to the background of the Essential Drug Policies (EDP), South Africa's government, legislation and politics, the National Drug Policies in developing, and a review of policy implementation theories. The next three chapters, six through eight, are the methods and results, and the last chapters, nine and ten, are the discussion and conclusion and recommendations. In **Chapter Two**, the Background of Essential Drug Policies (EDP) is explored, and specifically, the overall drug situation and the start of EDP in Africa, especially Kenya, Zimbabwe and Tanzania. **Chapter Three** looks at South Africa's government, health and legislative and political areas are reviewed. **Chapter Four** reviews National Drug Policy Studies in Developing countries, specifically South Africa. **Chapter Five,** examines the theoretical areas of organisational change and management; implementation of social programmes; changing behaviour and RDU; and finally the pharmaceutical research that has been carried out to date in South Africa and other countries. **Chapter Six** outlines the research framework and methodology, and the initial hypotheses that were tested, the ethical and legal aspects of the research. **Chapter Seven** outlines the quantitative research results, specifically the drug utilisation survey, while **Chapter Eight** gives the results of the qualitative data, interviews and observation. **Chapter Nine** is a discussion of the findings, a look at the research outputs, its significance and its contributions. **Chapter Ten** looks at the conclusions and recommendations.

CHAPTER TWO

BACKGROUND

2.1 The Overall Drug Situation

According to the World Health Organization (WHO) approximately 1.3 and 2.5 billion people worldwide (WHO, 1988) have little or no regular access to essential drugs. In 23% of developing countries, less than 30% of the population have regular access to essential drugs. In 32% of the countries, between 30% and 60% of the population have access to essential drugs; and in 45% of the developing countries, 60-90% of the population have access. The difference in coverage is largely due to the financial situation of the country. However, finances are not the only factor. Drug policies and their implementation vary between developing countries. In 1988, 25% of countries had a well-defined national drug policy (WHO: 1988). Of the developing countries, 41% were developing a policy to increase the availability of essential drugs and 29% were considering implementing some type of essential drug policy or had no interest in an essential drug policy. In the report *The World Drug Situation*, (1988), WHO states "Although many of the 104 countries show an apparent lack of willingness to adopt a strong and effective drug policy, a majority have drug legislation as well as an essential drugs list." Drugs included on an essential drugs list differ from country to country depending on many factors such as the pattern of prevalent diseases, the type and number of available health personnel, financial resources, and genetic, demographic, and environmental factors.

Drugs alone are not sufficient to provide adequate primary health care, but they do play an important role in protecting, maintaining, and restoring health to all people. Drugs are an important part of equity and good health care for all. The concept of essential drugs emerged from two realisations. First, access to drugs for both prevention and treatment is a complex issue with multiple problems, but extended access can both reduce costs and improve treatment simultaneously. In addition, the limited resources and capabilities of the health systems in developing countries created a gap to use drugs for prevention, control and cure disease to its full extent.

This gap according to Reich (1987) has and continues to result from:

> Multiple problems in the interaction of pharmaceutical companies with social organisations of poor countries. Some companies, both domestic and international have engaged in irresponsible business practices, including misleading advertising, aggressive production, and gift-giving to physicians and pharmacists. Inadequate social infrastructure had exacerbated the problems of procurement,

> distribution and prescription, due to a lack of governmental policy, implementation difficulties, poor training of physicians and pharmacists, and ineffective management capacity. As a result, available drugs often are not appropriately prescribed or used.

The report on the *World Drug Situation* (WHO, 1988) goes on to state, "Progress is slow...Many problems remain unsolved: improvement of procurement and distribution, strengthening of the drug authority, future training of health workers, and the creation of financial mechanisms to allow the programmes to become self-sustaining. The way to success is full of pitfalls and the opposition is substantial, but success can still be achieved as long as the level of political commitment remains high."

By the end of 1999, the commitment of governments has remained about the same with 106 United Nations Member States having a National Drug Policy (NDP), while 146 of all 191 Member States have drawn up national essential drug lists (EDL) (WHO, 52:19, 1999).

The change since the 1988 report, *The World Drug Situation* (WHO, 1988) is that more governments have started the process of becoming empowered. They are now looking to learn, understand and use their legislative powers in order to increase drug availability. WHO continues to give support to member states in policy development, implementation and monitoring. However, member states have increasingly requested guidance in the area of international agreements, drug prices, innovation (patents) and local production, the use of exceptions, transfer of technology, licensing agreements and the transition period for the least developed countries.

In the World Health Assembly, (WHA52.19:1999), with the requests of Member States in mind, a resolution on the revised drug strategy was devised to address the challenges of international trade agreements, specifically Trade Related Intellectual Property (TRIPS), access to essential drugs, drug quality, and rational use of medicines. The resolution adds to the original revised drug strategy, adopted by the Health Assembly in resolution WHA39.27 in 1986, and is updated at successive annual Health Assemblies. This strategy identified principles and goals for WHO's involvement with member states and the pharmaceutical sector. Indeed, a comprehensive approach is necessary to ensure the availability and rational use of drugs (WHO, 1988).

Moreover, according to Dr. Hogerzeil, the WHO Coordinator of Policy, Access and Rational Drug Use, (WHO press release in May 2000), "some countries pay 150% to 250% of world market prices for the essential drugs, while other countries complain of unreliable suppliers and poor quality drugs. The WHO has set up an Interagency Pharmaceutical Coordination (IPC) Group, composed of pharmaceutical advisor of WHO, the United Nations International Children's Fund (UNICEF), United National Family Planing Association UNFPA, and the World Bank. The IPC has the operational principle aim to assist national government, donor agencies and other organisations."

2.2 The start of the Essential Drug Programme in Africa

Kenya, Zimbabwe, and Tanzania are the three African countries that have the longest history of implementation of an Essential Drug Programme (EDP). The EDP was developed 1981 as a formulated response to the problem that a majority of the population was not able to get affordable basic drugs within their area. The EDP started slowly and spread to rural areas until eighty-five percent of the population had access to essential drugs. Kenya, Zimbabwe and Tanzania are evaluated more closely in the following paragraphs.

Kenya

In an attempt to address the multiple problems of providing drugs, Essential Drug Programmes (EDP) were initiated in many African countries. The initial essential drugs programme in Africa was started in Kenya by the government in 1981 (WHO, 1987). Most of the drugs needed for the entire population could be found in the city of Nairobi. However, the majority of people (85%) lived in rural areas. Health care was available to the entire population, although the type and quality varied. In government health institutions, patients did not pay for outpatient consultation, treatment or medication (WHO, 1987).

The EDPs greatest advocate and active promoter was Dr. Wilfred Koinange, who was the Director of Medical Services in Kenya and also a member of WHO's Executive Board. The EDP was started, according to Dr. Koinange, because "In the past, we used to have our drugs distributed to the health centres and dispensaries by the district hospitals. What happened, obviously, was that the district hospitals first used the medicines for themselves and in the long run the health centres and dispensaries ended up with no drugs whatsoever. We wanted to correct this situation because most of our people live in the rural areas, and

the health facilities closest to them is either the dispensary or the health centre" (Essential Drug Monitor No.1, 1985). The project staff designed, developed and initiated an operation system of procurement, storage, packing and distribution, training, and information.

The first part of the analysis included the identification of common diseases in the various rural areas. Once the most common diseases were identified, a list of 30 different types of medicines was compiled and distributed to the health centres and dispensaries. The medicines were packed centrally and dispensed directly to the health units. The implementation of the EDP, especially in all the government rural health facilities was considered an immediate success.

The programme was first implemented in the rural areas because Dr. Koinange believed that the logical place to start was where the majority of people lived. One innovative intervention implemented by the consultants from both WHO and the Danish International Development Agency (UNIPAC) was the use of pre-packaged essential drugs in 'drug ration kits'. This approach was designed to improve the distribution of a limited number of essential drugs to rural health facilities. The use of rations kits comprised of essential drugs reduces losses from breakage, pilferage, and wastage. The amount of drugs to be added to the kit was determined by the number of patients at the health facility. The system proved to be a reliable and regular source of supplies of the most important medicines. The facilities received a regular supply of essential drugs at a low price. Each dispensary and health centre received a pre-packed kit that was for about 3000 patients; a reserve kit was also sent and new supplies were scheduled to arrive before previous stock ran out. This ration-kit packaging and distribution has reduced wastage and diversion of drug stocks. The cost per patent was US $0.16 at health centres and US $0.19 at the dispensaries. The per capita cost per year for the entire population was about US$0.29.

Kenya's essential drug project was the first to be evaluated in November 1984. The evaluation team found that the Kenya programme achieved many of its objectives and goals in that period of time. An additional benefit of the programme was the experience gained from using specific medications for specific illnesses that standardised some common treatments.

Dr. Koinange believed that the rational use of drugs through prescriptions and the treatment given were better with a limited list of essential drugs. Dr. Koinange stated, "I have no doubt in my own mind that the more you limit the medicines the better people know how to handle those medicines and the more efficient they are, particularly in the rural areas" (World Health Organization, Essential Drug Monitor, No.1 1985).

Zimbabwe

In the same year, 1981, the Zimbabwe government adopted an essential drug list. The goal was to address the shortage of supplies in the government medical stores, which forced health care facilities to cover their drug needs by buying in the private sector, while the costs were covered by the Ministry of Health. Zimbabwe attempted " to shift the emphasis from an elite-centred, curative, sophisticated, urban-based health care system to a majority oriented, preventive, rural-based primary health care system" (WHO, World Drug Situation, 1988). To improve this costly situation, the Zimbabwe Government proposed an essential drug list in 1981 that was published as the Essential Drug List of Zimbabwe, (EDLIZ) in 1985. Although Zimbabwe had over 2000 registered drugs, only 375 were put in the EDLIZ. Drugs not listed in the EDLIZ could be prescribed only in special cases, with the permission of the Secretary for Health. The EDLIZ was an attempt to promote the rational use of drugs. However, as shown by a survey in 1985, "personnel's use of the EDLIZ was found to be poor and none of the clinical staff had any knowledge about the prices of drugs. From the point of view of prescribing, there seems to be a need for further training in economical prescribing and dispensing, stock control, ordering, and storage." (WHO, World Drug Situation, 1988) Perhaps the programme evaluation was too early to reach definitive valid conclusions. After the survey, a training programme for the rational use of drugs was developed and carried out to cover all health care levels between 1988-1989. Zimbabwe is another good example of the perils of EDP implementation. Six years after drafting the first EDL, the Zimbabwe Government learned an EDL alone was not sufficient to insure availability of essential drugs in rural areas. The list needed to be incorporated into a National Drug Policy that includes legislation, EDP, and training.

Tanzania

In 1984, Tanzania, similar to Zimbabwe, implemented its programme on a National level. The problems that led to the implementation of a NDP were generally the same as Zimbabwe and Kenya, but the dynamics of the health systems and peoples access were different. In Tanzania, health services were provided free of charge. This policy was based on the Arusha Declaration of 1967, which served as a blueprint for Tanzania's socialism that is based on Ujama (collective work and responsibility) and self-reliance. More than 90% of the population lived within 10km of a health facility. With a decline in the health budget and lower per capita expenditure, Tanzania, like many other countries, experienced a lack of essential equipment, medical supplies and most importantly, therapeutic drugs. The Tanzanian people use the supply or the lack of drugs as a measurement of the quality of health services. This applied so closely that when the "stock of drugs runs out, there is virtually no patients, but when the Essential Drug Programme kit arrives, a crowd assembles at the dispensary"(WHO, Essential Drug Monitor, 1:1985). Procurement of drugs was done on both the national and international levels. UNICEF bought the drugs for the project, and in doing so brought down the market price of the procured generic drugs. With the co-operation and active participation of UNICEF and UNIPAC in Copenhagen, drugs were packed in kits and then shipped in containers to five destinations in Tanzania. Trucks delivered the drugs to the district headquarters, while smaller vehicles then took the drugs to various destinations. This system allowed kits to be delivered regularly to approximately 3000 health facilities. This system changed the state of the essential drug shortage in the rural areas.

Overview of the EDP in Africa

This summary of NDP implementation in the countries of Kenya, Zimbabwe and Tanzania in the 1980's gives a history of the development, implementation and impact of such programmes in a developing country context. The South African government, more than two decades later, is attempting to implement the same programmes with some of the same hurdles. Regardless of the region, many countries in Africa and all over the world adopt an EDL, but only those with a strong commitment and determination, formulate and implement a NDP that includes among other strategies an EDP. "The main reason why EDPs have not had more impact on the development of national policy within countries has

been because of a lack of willingness among governments to restrict the use of inessential drugs and introduce restrictive legislation within the private sector" (Kanji et al. 1992).

The evaluation team from WHO found that the Kenya Essential Drug programme (EDP) achieved many of its objectives and goals in that period of time. The Kenya programme began with a few districts, and slowly spread to cover all rural areas. After three years essential drugs were available to the entire rural population. Zimbabwe started their EDP in 1984. The focus was shifted from an urban-based health care system to a rural-based primary health care system that focused on preventive services. Implementation was much more difficult than anticipated and the use of the EDL alone did not bring expected results to meet the original goals. In Tanzania, although health care is free, there were difficulties with the procurement and distribution of drugs. The NDP was successfully implemented with the help of the United Nations organizations and pre-packed medicine kits.

CHAPTER THREE

SOUTH AFRICA

3.1 Background of Health Reform

During the years of apartheid, South Africa developed two health care systems, public and private, that were fragmented and segregated by race. "South Africa is not a normal society within which the usual pathologies occur. Apartheid and health were incompatible and mutually exclusive" (Simpson, 1995). Thus, the health care system reflected both industrialised tertiary care and developing country primary care. Even so, South Africa, in 1996, was spending much more than any other African country on health care, 8.5% of the gross domestic product (GDP), or £154 per person per year (McIntyre & Health Systems Trust, 1995).

When the political tide turned in 1996 a new focus on health care access and services came to the forefront. The new strategy was to increase primary health care for the masses and decrease tertiary health care coverage for the few (Equity and equality became the working foundation of health care reform in South Africa). The former (1995-1999) Minister of Health, Dr. Nkosazana Dlamini Zuma, directed the painful process of redistribution of health spending. Thus far there have been cuts in tertiary care. These resources have been shifted to provide free primary health care to children under six and pregnant women. In addition, over 500 new clinics have been built in poor areas (Economist, 1998). The new (2000-2005) Minister of Health, Dr. Manto Tshabalala-Msimang, has now turned the focus to access of drugs for AIDS by using the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) compliant measures, such as parallel import (through the Patents' Act) and compulsory licensing. The government will take advantage of cheaper imports and manufacturing cheaper generic equivalents locally. The minister states, "this is the only way that we can see at present of being able to provide medicines to people at reasonable prices" (Thom 2001).

3.1.2 Equity in Health

Equity in health is the focus of most health initiatives in South Africa. The Reconstruction and Development Programme (active until 1997, now phased out), through the Department of Health, had placed emphasis on Primary Health Care (PHC). Providing access to essential drugs is an integral part of a national health system and PHC. Now the nine individual provinces are responsible for implementing the mandates, bills, and policies that have been passed into law. National law dictates that each of the nine provinces must

implement national policies. The overall health care agenda for the Government has been to redefine the basic health services available to all while maintaining an emphasis on social justice and equity. The challenge will be to balance a basic free level of care for all, while continuing to support the highly developed tertiary care services and infrastructure.

Social class variation has been divided by race first and the economics. Most while South Africans were able to receive advances developing world health care in both the private and the segregated public hospitals. On the other hand, 'non-white' South Africans regardless of economic class were not able to access the same resources through public hospitals, but on a limited basis in private 'colored' hospitals.

Currently, South Africa has 693 hospitals, 72% public and 28% private. Public hospitals make up 75% of the 158,567 hospital beds available. Of the over 22,000 physicians practising, only 42% do so in the public sector. Four out of five patients in South Africa are treated in the public health sector. [5] in 1996, the private sector treated about 20% of the population. Total medical spending in the public and private sector is over 8% of the GDP (Economist, 1998). Although this is higher than in most middle-income countries, two-thirds of it went to a fifth of the population, largely the white population. Some argue that they deserve to get more comprehensive and better health services because they pay more taxes (Economist, 1998). The private sector "serves only 20% of the population, yet it accounts for roughly 60% of the resources spent on health. This sector has seen rampant and severe fragmentation that has resulted in the irrational use of resources, and inadequate infrastructure" (Cosser 1997, and National Drug Policy for South Africa, 1996).

3.1.3 Decentralisation of Health Resources and Services

A key feature of PHC is the decentralisation of services. Budgetary and accounting reforms are important for effective decentralisation. Decentralisation is an important part of the success of PHC policy within a country. It provides managers with both responsibility and accountability and a limited budget that allows for some flexibility to provide services. "The main public sector organisational reform already implemented in many Sub-Sahara African (SSA) countries is the decentralisation of planning and management, which aims to push responsibility for at least some decisions down the administrative hierarchy. The

preferred management level is usually the district, where the management of primary and secondary level services can be integrated and planned for a defined population. Decentralisation may also involve establishing large institutions, such as teaching hospitals, as self-managing enterprises. It is critical complementary policy for financing reforms" (Gilson & Mills 1995).

Similarly, the South African governments' decision making in health care has been decentralised. The new power focus and economic decision making lies within the districts within the provinces. At the national level public resources are allocated to the provinces, based on a formula that takes population into account. The provincial government then takes this funding and allocates it to health, education and other public services. The Provincial government determines the health focus, goals, strategies, and moneys to be allocated.

3.2 Hospital and Staff

3.2.1 Hospitals change focus

The new focus on the primary health care (PHC) approach has necessitated a shift of resources away from the hospital sector towards primary care (McMurchy, 1997). The public hospital system (academic, tertiary, secondary, community) is central to the successful implementation of the PHC approach. The Ministry of Health and specifically, Dr. Zuma, as its former Minister had been criticised for focusing on PHC at the expense of hospital care. All levels, primary, secondary and tertiary of hospital care are needed in order to care for the needs of the population. According to Dr. Zuma, there cannot be a strong primary care service without the backup of other levels of care. For the successful implementation of the PHC approach, a large proportion of existing allocations to the hospital sector will have to be re-channelled to primary health care facilities. This can only happen if hospitals make substantial savings, by improving their efficiency (National Department of Health, White paper on the Transformation of Health System, 1997).

The public hospitals have been plagued with problems of inequity, inefficiency and poor of quality services. To bring the public hospital system in line with the transformation process currently taking place in the national health system these issues must be addressed, and systematically resolved. South Africa has spent a disproportionate amount of its resources

in the hospital sector. Public acute care hospitals in 1992/3 spent R8.59 billion or 76% of the budget of total recurrent public health expenditure. This is the equivalent of approximately R200 per person in that year. A large percentage of resources for public hospitals have been spent in academic and tertiary hospitals, while they account for 38% of the beds, the acute hospital expenditure was 58% (Cossier, 1997). In spite of the resources spent, public hospitals have only 2.43 public sector beds per 1,000 population and many magisterial districts have no hospital at all.

The nine provinces within South Africa have marked differences in the availability of public sector hospitals. Mpumalanga has the lowest and Northern Cape the highest ratio of acute beds to population. Utilisation of hospital services, also show marked differences. Public hospitals in Mpumalanga, North-West and Northern Province provided less than 500 inpatient days per 1,000 population, while KwaZulu-Natal and Western Cape provided over 700 days (Cossier, 1997). Moreover, there is also a difference in the mix of public sector hospitals. Over half the beds in Gauteng and Western Cape are in academic or tertiary facilities. Conversely, Mpumalanga, and Northern Cape have virtually no tertiary beds. The Western Cape has a large number of chronic hospital beds per 1000 population (ReHMIS Survey 1992/3). Overall in 1991, there were 3.3 beds, per 1000 population. In the former homelands, however there were only 2.7 beds per 1000 population. In non-metropolitan areas the number was 4.0 compared to 7.1 in metropolitan areas. General acute beds per 1000 population, were 1.5 per 1000, while tertiary care beds were 1.9 per 1000 population.

3.2.2 Staffing

The success of health care reforms specifically the implementation of the NDP and usage by health care staff will ultimately determine the adoption of the STG/EDL. To change the foundation of health care delivery, first the environment must be altered for both staff and patients. Staff dedication and behaviour is a key to equity and the delivery of basic health care service for all. Generally, there is a shortage of most health care professionals within South Africa, but the problem is more pronounced in rural, poor and African majority Provinces. In 1990, 22,260 medical doctors were registered, 6,087 of them in medical specialities. In the metropolitan area, the ratio of population to doctors was approximately 700 per doctor. However, consistent with other figures, there are only 900 per doctor in non-metropolitan areas. In the areas that were former homelands, the estimated figure is

10,000 to 30,000 people per doctor. Seventy-seven percent of doctors live in metropolitan areas and more than 58% work in the private sector. Many doctors mix both public and private sector positions. (South African Pharmacy Council, 1998) Pharmacists show the same pattern. Generally, pharmacists are underrepresented in the public sector. Currently, only 26% of employees are in the public sector including those in administrative positions and at academic institutions. "Research conducted in 1997 showed that the percentage of pharmacists actually providing a service in this sector was between 11% and 15%" (South African Pharmacy Council, 1998:2). This is a grave matter since 80% of the population use services of public health facilities.

Most health care staff in the public sector practice in academic and tertiary hospitals. Of all the public sector health staff most work in academic or tertiary hospitals: 51% general physicians, 82% specialist physicians, 35% Nurses, and 51% pharmacists. The next highest concentration of staff is in community hospitals (Table 3.1) with general physicians (20.2%) and specialist physicians (4.1%), nurses (26.7%) and pharmacists (21.5%). The secondary and chronic hospitals have the lowest percentage of all health professionals.

Table 3.1 Distribution of Public Sector Health Care Personnel by Level of Care (1992/93)

	Pharmacists		General Doctors		Specialist Doctors		Nurses	
Facility Type	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Academic hospitals	2164	38.0	1367	63.1	21288	19.5	289	28.2
Tertiary hospitals	1287	22.6	419	19.3	17694	16.2	233	22.7
Secondary hospitals	404	7.1	122	5.6	13733	12.6	132	12.9
Community hospitals	1146	20.2	89	4.1	29049	26.7	220	21.5
Chronic hospitals	114	2.0	91	4.2	8665	7.9	44	4.3
Primary care services	575	10.1	80	3.7	18627	17.0	108	10.5
All acute hospitals	5001	87.9	1997	92.1	81764	75.0	874	85.2
TOTAL	5690	100	2168	100	109, 056	100	1026	100

Source: Regional Health Management Information System (ReHMIS) Survey, 1992/3

Note: Academic hospitals by definition will have more staff as they have both a teaching and research function. Development Bank of South Africa (1994)

In addition, substantial differences exist in staffing between the different levels of hospitals. The community and secondary hospitals have similar numbers of doctors and nurses per bed. However, in comparison to community hospitals, academic hospitals had 5 times the number of doctors per bed and 1.7 times the number of nurses, while tertiary hospitals had 2.7 times the number of doctors and 1.4 times the number of nurses. Academic hospitals have 1.8 times more doctors and 1.3 times more nurses per bed than tertiary hospitals. (Regional Health Management Information System (ReHMIS) Survey, 1992/3)

Table 3.2 Provinces Distribution of Facilities and Health Personnel 1992/93 (per 1000 population)

PROVINCE	Hospital Beds	Doctors	Nurses	Pharmacists
Eastern Cape	3.5	30.7	321.3	20.1
Mpumalanga	2.1	28.3	265.8	23.1
Gauteng	6.0	127.4	618.4	109.8
KwaZulu-Natal	3.8	53.5	431.9	28.7
Northern Cape	4.0	37.6	432.3	28.5
Northern Province	**2.5**	**15.5**	**293.2**	**7.8**
North-West	3.3	22.7	273.5	22.8
Free State	4.1	46.5	382.3	38.8
Western Cape	5.4	143.8	686.3	79.8

The distribution of facilities and health personnel between Provinces in the 1992/93 (Table 3.2) shows that Gauteng and Western Cape Provinces have the largest hospital bed per 1000 population. These provinces, mostly urbanised Gauteng and Western Cape also have the largest doctor to population ratio of 127.4 and 143.8 per 1000 population, and the largest nurse (618.4 and 686.3) and pharmacist ratios (109.8 and 79.8) respectively. In direct contrast, the mostly rural Northern Province has the lowest hospital bed to population of ratio of 2.5, only second to Mpumalanga. The Northern Province has the lowest doctor to population ratio of 15.5 and pharmacist to population ratio of 7.8. The trends of table 3.2 shows that the urban, mostly business, white majority provinces have substantial resources. The rural, agricultural, African provinces, like the Northern Province, are lacking sufficient material and human resources. This lack of adequate hospital beds

and human resources makes achieving equity in health care for all South Africans a formidable challenge.

3.3 Primary Health Care and Drugs

The restructured National Health Service in South Africa is based on a Primary Health Care (PHC) Strategy. An integral part of PHC is a comprehensive plan to evaluate and implement changes in its pharmaceutical policies through a National Drug Policy (NDP). The NDP's main goal is to make "effective, safe, low-cost drugs available and affordable to meet the needs of the entire population, and to ensure that drugs are of good quality and used rationally" (WHO, 1998c).

The National Drug Policy of South Africa aims to provide a limited number of medicines to the majority of people for prevention and treatment of disease in a PHC setting. The NDP focus is the providing of drugs that are available, affordable, and accessible and in addition the related issues of dispensing, storing, and prescribing. Availability, accessibility, equality, and sustainability are the main issues in providing drugs for the entire population at all levels of care. The limited funds available to the Health Ministry are not used in the maximum cost/benefit manner. The use of resources must be improved and wasting reduced. WHO estimates that generic prescribing from an essential drug list has the potential to save from 10 to 60 percent of spending (WHO, 1998). One of the most important foundation cornerstones for PHC is the implementation of a NDP through an Essential Drug Programme. The availability of essential drugs is of major importance in the perception of credibility of health services for patients. The selection of essential drugs list (EDL) is an important component of managing accessibility and equity in the distribution of pharmaceuticals. The EDL should be limited to drugs, which could be used in a wide range of settings from common to rare diseases and from primary to tertiary centres.

3.3.1 Pharmaceutical Reform

During apartheid, the pharmaceutical industry in South Africa thrived with both private insurers and public and private "whites only" hospitals. Since South Africa has an advanced tertiary system with a free market atmosphere, multinational pharmaceutical companies were most profitable in Africa in South Africa.

One of the largest challenges for the Department of Health, and specifically Minister Zuma, in its attempt to shift to PHC is the reform of the pharmaceutical policies in South Africa. This reform is a necessary and integral part of restructuring the health care sector that is recovering from the legacy of apartheid.

The industry enjoyed a relatively easy pricing environment with relatively no competition. However, access to drugs was a part of the apartheid system. To change history and for South Africa to provide the majority of the population with access to medicine this political and economic isolation and privilege had to change. The former Minister of Health (1995-2000),

Dr. Nkosazana Dlamini Zuma speaking about the National Drug Policy stated:
(Draft speech Dr Zuma to the 19th IFPMA Assembly, Cape Town, Wednesday 11 November 1998)

> In the past, however, drugs have not been available to all South Africans, due to the structured inequities and inaccessibility caused by apartheid. This situation will be changed through the implementation of our National Drug Policy, to develop fully the potential that drugs have to improve the health status within the available resources in a country. It is therefore incumbent on all the role players to participate fully to enable the country to provide health care for all its inhabitants.

The drug budget before 1998 of approximately R2 billion/year (US$430 million/year), (Moller 1998) for the public sector was inequitably allocated. Moreover, the selection of drugs did not reflect the health care needs of the majority of the population. The annual per capita expenditure on drugs for 85% of the population who use the public sector is R52 (US$11). For the private sector used by 15% of the population this expenditure is about R792 (US$174).) Of the Sub-African counties, twenty-three had drug consumption of less than five dollars (US$5) per person in 1990. (Essential Drug Monitor, 1998:10). In South Africa, the cost for medicines distributed in hospitals is R1.3 billion/year (US$280).

It has been estimated that 60% to 80% of the total drug procurement and distribution systems did not succeed in getting the medicines to the patients. Medicines were wasted even though there were supplies of high quality drugs in the private sector, and was a well-developed pharmaceutical industry (SADAP 2000 and BDDSA, November 1996). The use of generic drugs is relatively uncommon.

3.3.2 Generic Drugs

Generic drugs are not new in South Africa. For the past 30 years, use of generic drugs has been mostly in the public (government funded) health sector. Generics are used less frequently in the private sector. As a whole, in the private sector generics account for only 28% of drugs prescribed in South Africa at present. South Africa has a lower rate of generic prescription than many other countries (Cosser, 1997). The extension of the right to dispense drugs to all registered health care workers, linked with the wider use of the Standard Treatment Guidelines/ Essential Drugs List (EDL), make safe medicine dispensing available to more people who need it. Generics in the US and Europe typically cost 30-60% less than patented brand-name medicines. In South Africa, generics cost about 15% less (Cosser, 1997). So, generic drugs are lower in price than the name brand drug, but during apartheid the price of generic drugs in South Africa was higher than other countries because during the years of apartheid the pharmaceutical industry was protected.

Adherence to the NDP's foundation of generic prescribing using the Standard Treatment Guideline/Essential Drugs List would allow for the limited public budget for medicines to be spent in a manner that would cover more of the population. Non-adherence to prescribing generics for a majority of the population would have consequences of lessening the budget for essential brand medicines for Multi-Resistant Tuberculosis and HIV/AIDS. The cost of non-adherence is the lives of those who are not able to access basic medicinal treatment because of limited financial resources.

In an opening speech at the International Federation of Pharmaceutical Manufacturers Association (IFPMA) Bi-annual meeting in Cape Town in November 1998, Dr. Zuma stated:

> We need to lower the cost of medicines, and promote the cost-effective use of drugs. Our problems are immense, and our resources limited. We will have to make decisions in the interest of public health that you might not always like. It is our duty to rectify that unjust situation: we invite you to participate in this process. All people in this world need access to affordable, essential medicines.
>
> (Draft speech Dr Zuma to the 19th IFPMA Assembly, Cape Town, Wednesday 11 November 1998)

South Africa provides one of the largest profits for pharmaceutical multinationals of the low/middle income countries. Changes to the health and pharmaceutical legislation in South Africa would be closely watched and perhaps emulated by other countries that have many people to cover and limited public resources. All health legislation to set up options for obtaining medicines both brand and generic introduced by the National Health Department was opposed by the pharmaceutical companies. If South Africa was the first to change the rules for buying and distributing medications, then other countries would follow suite and there would be an overall reduction in pharmaceutical companies profits. Several legislative changes were initiated and fought within the courts by pharmaceutical companies.

3.4 Health Legislation, Policy and Events in South Africa (1994-2000)

1. Key Health and Drug Legislation, Policy and Events

When the new South African laws and regulations facilitate and enable the fulfilment of the NDP (Box 3.1). These regulations and laws address price control, parallel importing, international tendering, generic prescribing, prescription by nurses, dispensing by pharmaceutical technicians, generic substitution and labelling. The emphasis is on affordable drugs for a majority of the population, and actions to make it a reality. Dr. Zuma continued to encounter significant opposition over the implementation of the NDP from stakeholders, especially, multi-national pharmaceutical companies (MNCs), doctors, and pharmacists. Controversies include the promotion of generic drugs (including automatic generic substitution) instead of more expensive brand-named drugs, parallel import and intellectual property rights. South African medicines are among the most expensive in the world. This is partly a result of the MNC's operating in a sheltered and protected economic environment during the apartheid years. The MNC's enjoyed a market that did not foster competition. The submission of several Bills and statutes would have put an end to the very lucrative pharmaceutical market for many multinational companies. The specific bills that are opposed by the pharmaceutical MNC's are the Medicines and Related Substances Control Amendment Bill, and the South African Medicines and Medical Devices Regulatory Act (SAMMDRA).

In 1997, four health related Bills were introduced into Parliament: the Medicines and Related Substances Control Amendment Bill; the Pharmacy Amendment Bill; the Medical, Dental and Supplementary Health Services Professions Amendment Act; and the South African Medicines and Medical Devices Regulatory Act (SAMMDRA). Two of these Bills are now law, but as of June 2002 not all have taken effect. The Medicines and Related Substances Control Amendment Bill is under consideration by the Pretoria High court. The South African Medicines and Medical Devices Regulatory Act (SAMMDRA) was sent to South Africa's constitutional court by President Mandela, after pressure from pharmaceutical stake holders to determine its legality.

Box: 3.1 Key Health and Drug Legislation, Policy and Events in South Africa

DATE	EVENT
1994-1995	
1994	Publication of a National Health Plan (NHP) for South Africa
1994	National Drug Committee appointed
1995	Evaluation of South Africa's Drug Policy by Consultants in Health Development (CHD)
1995	National Essential Drugs Committee appointed by
1996	
February 1996	National Drug Policy for South Africa published and adopted
April 1996	Publication and Distribution of first EDL for primary care (Green Book)
September 1996	Mission to evaluate a South African Drug Action Programme by Consultants for Health and Development (CHD)
September 1996	DFID approved funding for the National Drug Programme (NDP) and the South African Drug Action Programme (SADAP)
November 1996	SADAP project started in Pretoria (1 Nov 1996 to Dec 2001)
1997	
January 1997	*Medical and Related Substances Control Amendment Act 90 of 1997*
April 1997	White Paper on the Transformation of the SA Health System
May 1997	*Pharmacy Amendment Bill of 1997* introduced
May 1997	*Medical and Related Substances Control Amendment Act 90 of 1997* tabled
1998	
January 1998	*Medical, Dental and Supplementary Health Services Professions Amendment Act 90 of 1997* passed
January 1998	*Pharmacy Amendment Act 28 or 1997* passed
January 1998	President Mandela signs *Medical and Related Substances Control Amendment Act 90 of 1997* into Law
February 1998	Pharmaceutical Manufacturing Association brings suite against SA Government.
February 1998	President Mandela sent the *Medical and Related Substances Control*
February 1998	*Amendment Act 90 of 1997* to constitutional court for repeal
February 1998	US adds South Africa put on Trade Violation 'Watch List'
March 1998	Pharmaceutical Manufacturing Association (PMA) case starts
July 1998	Compulsory community service for new physicians
November1998	*South African Medicines and Medical Devices Regulatory Authority Bill (SAMMDRA)* passes to replace *Medicines and Related Control Act of 1965* and the *Medical and Related Substances Control Amendment Act 90 of 1997*
November 1998	International Federation of Pharmaceutical Manufacturers (IFPMA) Assembly in Cape Town, South Africa
November 1998	SADAP mid-term Review
December 1998	Launch of National Drug Programme (NDP)
December 1998	Publication and Distribution of new EDL
1999	
November1999	*South African Medicines and Medical Devices Regulatory Authority Bill (SAMMDRA)* sent to court for by Mandela
2000-2001	
2000	US takes South Africa off the 'Watch List'
March 2001	Pharmaceutical Manufacturing Association (PMA) case began
March 2001	SA Health Minister, Tshabalala-Msimiang repealed the *South African Medicines and Medical Devices Regulatory Authority Bill (SAMMDRA)*
April 2001	Pharmaceutical Manufacturing Association (PMA) case withdrawn and the *Medical and Related Substances Control Amendment Act 90 of 1997* effective
December 2001	South African Drug Action Program (SADAP) direction under WHO ended.

2. Health Legislation

a) Medical, Dental and Supplementary Health Services Professions Amendment Act

The Act established a more broadly representative Health Professions' Council to replace the Interim National Medical and Dental Council of South Africa. In addition, the Act expanded the realm and powers of professional bodies for each of the various professions. Disciplinary powers are now in the authority of the professional body, rather than the Council. The Act also requires that people who register for the first time with the Council must perform remunerated community service for a year (Compulsory community services started on 1 July 1998). The Act went into effect on 23 January 1998.

b) Pharmacy Amendment Act [Act. No., 28 of 1997]

The Pharmacy Amendment Act passed in January 1998 and went into effect on 1 March 1998. It established a permanent Pharmacy Council, and also contains the provisions that relate to pharmacy education, training and practice and the licensing of pharmacists. The Act overturned the former restriction that only pharmacists may own pharmacies, although the pharmacy must be under continued supervision by a licensed pharmacist. This opening up of pharmacies is an important measure that will help in assuring that there are adequate distributions of pharmacies in rural and other under-served areas.

The second significant change is that pharmacists will now be required to dispense generics unless specifically requested not to do so by the doctor or patient. Certain provisions of the Act have not gone into effect yet, in order to allow the State to make the necessary changes with the requirements of the Act.

c) Medicines and Related Substances Control Amendment Act [Act No. 90 of 1997]

The Medicines and Related Substances Control Amendment Act (Act No. 90 of 1997) has introduced a number of cost-containment measures to bring down the cost of medicines to make health care more accessible and affordable. This legislation aims to address the growing crisis of lack of access to affordable medicine in South Africa, by promoting the use of generic medicines and by permitting the parallel importation of medicines. Act No. 90 also includes provisions to better regulate medicines in South Africa and to ensure transparency in pharmaceutical pricing by requiring the setting of a "single-exit price" and doing away with bonuses and other forms of "perverse incentives." "Currently, a

pharmaceutical company can influence a doctor or pharmacist to prescribe or dispense its products by offering cut-rate deals for a short amount of time, before raising prices once a patient has begun a course of therapy" (Medecins Sans Frontieres, 2001). Drug legislation, which had prohibited generic substitution, was revised. Drug legislation, and the Medicine and Related Substances Control Act No. 101 of 1965, and the Pharmacy Act No. 53 of 1974 prohibited generic substitution. Act 90 of 1997 included provisions for international tendering, 'parallel importation' of medicines, promotion of generic substitution, regulation of supply of medicines through bonuses, rebates and sampling, and the establishment of a pricing committee to introduce single exit pricing and other price controls. Parliament and former President Mandela passed the Act into law towards the end of 1998.

1) Minister of Health

This Act gave more power to the Minister of Health within the Medicines Control Council, which regulates medicine. But Dr. Zuma believed that although the Medicines Control Council (MCC) was generally well respected, it held too many of the former old guard that would not generally act in the interest of the majority of the population. The Minister dissolved the MCC in 1998."The MCC was staffed by white appointees of the former NP government, who nevertheless enjoyed a strong reputation among members of the medical profession" (Economist, 1998). When it was time to appoint a new Chair to the MCC, Dr. Zuma did not re-appoint the former Chair for over a decade, Professor Peter Folb[6], but appointed a new Chair. This resulted in Prof. Folb resigning from the MCC. Since then others have resigned. The former Medicines Control Council (MCC), now the Medicines Regulatory Authority (MRA) will have the task, under the new legislation, of reviewing drugs every five years, as opposed to the current once-off testing.

2) Pharmacists

The Medicines and Related Substances Control Amendment Act affected the pharmacists on various levels (Thom, 2001). First instance, Johnson the president of the Pharmacists' Association said, "bonusing and business sampling will come to an end. There will be no more grey market activity, whereby pharmacists receive "freebie" samples that are then resold." Also other incentives such as monetary reimbursement free trips and excessive gifts will also come to an end.

[6] Prof. Folb is a professor of Pharmacology at the University of Cape Town and is the Director of the WHO Collaborating Centre for Drug Policy

3) Section 15c

Section 15c is the clause that attracted the most debate internationally. It sets up a system to permit the parallel importation of medicines. Parallel importation is the practice of shopping around for the lowest world price patented products.

If a patent holder sells a product for less money in another country than in South Africa, parallel importation would allow the cheaper drugs sold in the other country market to be imported to South Africa. Johnson stated, "Without Section 15c the reference pricing means nothing. If the company refuses to bring its prices in line with the reference price, then a license can be issued to parallel import the drug from another country."

Another key issue in this court case is generic substitution. "Common in Canada, Holland, Japan, and the U.S. – of requiring that a pharmacist dispense a generic version of a medicine if it is cheaper than the branded product, unless the patient expressly forbids the pharmacist from so doing" (Medecins Sans Frontieres, MSF, 2001). The second part in the Act that went into effect requires of the pharmacist to advise patients of generic substitutes, although a doctor may indicate that the medicine may not be substituted with a generic.

A third part of the Act deals with the professional fee, stipulating that any dispenser may not make a profit on dispensing medications. The Act will also impact on the pharmaceutical industry when the Health Minister sets up the Pricing Committee. Johnson pointed out that Section 15c of the Act was crucial to empowering the Pricing Committee.

d) Pharmaceutical Manufacturers Association

On 18 February 1998, the Pharmaceutical Manufacturers Association (PMA) representing forty-two applicants representing multinational and South African drug companies, South African Subsidiaries of Pharmaceutical multinational companies, and a trade organisation brought a suit to the Pretoria High Court against the Government of the Republic of South Africa. The suit aimed to prevent the implementation of the Medicines and Related Substances Control Amendment Act, No. 90 of 1997.

The PMA sought an interdict against commencement of the Act until there was clarification of its legal status. The PMA's main objections to the Act are parallel imports[7] and patent protection[8]. If the PMA lost in the Pretoria High Court, then the Act could have be challenged through the World Trade Organisation. The Act had instigated the United States to place South Africa on a "watch list" of 32 countries that appeared to violate intellectual rights and other trade interests, specifically, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In 2000, former US President Bill Clinton took South Africa off the watch list with a residential executive order. The US Health Minister, Donna Shalala, and US Trade Minister, Charlene Barshefsky supported this order. This executive order ended the trade protection from the US government for US MNC companies. This protection placed more restrictions on parallel importing and compulsory licensing as allowed by the World Trade Organization (WTO) agreements. The South African Pharmaceutical Manufacturers Association (PMA) "argues that Section 15c is written overly broadly, in that it expands the powers of the Minister of Health to allow her to override patent protection (to issue compulsory licenses) in order to facilitate access to affordable medicines" (Medecins Sans Frontieres, 2001).

e) PMAs case against the Government and the High Court Resolution

Implementation of the Medicines Act was delayed for three years (1998-2001) after pharmaceutical companies challenged its legality in court. The PMA was especially concerned with Section 15c (Parallel importing). The case was to be heard from the 5 –13 March 2001 in front of the High Court in Pretoria. However, in April 2001, three years after the PMA action was launched in January 1998, they withdrew their court bid, and in return, the minister promised to include them in discussions on how the Act would be implemented. The Medicines and Related Substances Control Amendment Act Number 90 of 1997 went into effect.

[7] Parallel imports allow for the importation of medicines, which are manufactured, under licence, by companies in other than the country of origin.

[8] The Act has a provision for the circumvention of statutory patent protections in some circumstances. The PMA argue that it constitutes an infringement on intellectual property without compensation.

f) South African Medicines and Medical Devices Regulatory Authority Bill (SAMMDRA) 1998

In 1997, the government passed legislation – the Medicines and Related Substances Control Amendment Act (Act No. 90 of 1997) to help realise this goal by making medicines more affordable. The Medicine and Related Substances Control Amendment Act No. 90 of 1997, was sent to the constitutional courts for repeal. So a new bill, was introduced called the South African Medicines and Medical Devices Regulatory Authority Bill (SAMMDRA) 1998. The SAMMDRA replaces the Medicines and Related Substances Control Act of 1965 and the amendment of 1997.

It provides for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices. For the first time this Act includes provisions for a process to register and regulate complementary medicines. SAMMDRA created the new Medicines Regulatory Authority (MRA) that replaced the former Medicines Control Council (MCC).

Significant portions of the Medicines and Related Substances Control Act No. 90 of 1997 are also repealed by this Act. The result is that the 1998 SAMMDRA bill focuses on measures specifically aimed at ensuring that affordable medicines are made available to the public.

Less than three months after President Nelson Mandela signed the SAMMDRA bill into law, "The PMA objected to provisions, which allows for the parallel importation of drugs and generic substitution of drugs which the industry believes infringes on patent rights."

SAMMDRA's implementation was administratively bungled and was promulgated without supporting regulations, which would have left the door wide open to unregulated trading and importation of potentially lethal drugs. This caused the government to challenge its own legislation in court. The SAMMDRA legislation that former President Mandela signed into law was repealed three years later in 2001 by the High Court. The court reinstated the original 1965 act and Medicines and Related Substances Control Amendment Act No. 90

of 1997. In turn in 2001 the PMA reactivated its court challenge to the Medicines and Related Substances Control Amendment Act No. 90 of 1997.

In March 2001, the South African Minister of Health, Dr. Manto Tshabalala-Msimang, informed state law advisers that the National Health Department would repeal SAMMDRA is Medicines Regulatory Authority Act. The ordered repeal of SAMMDRA came as the pharmaceutical industry and government were in a court battle over the Medicines and Related Substances Control Amendment Act. The repeal will likely have an effect on the present court action by the pharmaceutical industry. The Democratic Alliance (DA) health spokesman, Kobus Gous said the repeal "is a constitutional and a trade matter and about the powers granted to the minister to virtually make laws to control medicines on" (the STG/EDL). He went on to say, "The pharmaceutical industry is an essential player in conquering diseases in poor countries like SA. But they have played this role reluctantly, and any compromises have had to be fought for bitterly. On the part of the minister of health, badly drawn-up legislation made legal challenge to the amendment act easy and inevitable" (Hartley, 2001).

3.5 South Africa's New National Drug Policy (1996)

South Africa in 1994 recognised that it urgently needed a written drug policy that is entrenched in legislation to ensure its fair and equal regulation. "It is necessary to ensure that all people in the country are rationally treated within necessary drugs and vaccines, to enable their protection and cure from common diseases" (National Drug Policy for South Africa, 1996). In 1995, the British former British Office of Overseas Development (ODA), now the Department for International Development (DFID), had contracted Consultants in Health and Development (CHD) to assist the National Health Insurance Committee, and to determine the cost of the essential drug needs in South Africa's primary care settings. In addition, the South African Department of Health (DOH) requested support from the DFID for the development of a national essential drug programme. A first report for such a programme, with the title, South African Drug Action Programme, (SADAP) was completed in November 1995 by CHD. Meanwhile, in the same year WHO became involved, a staff member from WHO's Action Programme on Essential Drugs, Drug Action Programme (DAP), attended a National Drug Policy Conference in South Africa and assisted in the drawing up of the NDP. The initial draft of the National Drug Policy (NDP) was prepared and workshops were held to incorporate a wide range of comments from various stakeholders. All Provincial Heads of Health ratified the National Drug Policy on 15 February 1996, and it was approved and publicly announced by the Minister of Health on 22 February 1996. The main objectives of the National Drug Policy of January 1996 (Appendix A) include health, economic and national objectives. 'Two of the five health objectives include: "to ensure *good dispensing and prescribing* practices" and "to promote *rational use of drugs* by prescribers, dispensers and patients through the provision of the necessary training, education and information."

In 1996, although the Department of Health was making steady progress towards the realisation of the National Drug Policy, it did not have the resources (staff, expertise, and finances) that were needed in order to implement the National Drug Policy. The previous years of restructuring the Department of Health and the Public Health Service had necessitated the use of most of the non-fixed public resources. The total cost of the NDP would represent 0.3% of the drug budget for South Africa, but the potential savings would

be 35% of the budget. [9] The implementation of a National Drug Policy would have very definite and concrete effects not only on the total cost, but also on the outcome of total primary care coverage for the entire population, thus having a far reaching impact on the health of the majority of the population. The merits of implementing a NDP with its major components of an Essential Drug List and Standard Treatment Guidelines were outstanding.

The Ministry of Health published the NDP in January 1996 and launched it in February 1996. The policy contains the following components: 1. Preface; 2.Objectives; 3. Legislation and regulation; 4. Drug pricing; 5. Drug selection; 6. Procurement, and Distribution; 7. Rational use of drugs; 8. Human resources development; 9. Research and development; 10. International technical co-operation; 11.Traditional medicines; and 12. Monitoring, and evaluation.

The National Drug Policy incorporates strategies for the effective application of drugs within the framework of the National Health Service (NHS). The promotion, "prevention and rehabilitative aspects of health care will receive proper emphasis and will not be made subservient to the curative aspects, with its reliance on the use of drugs. A broad approach to cost containment will be taken to ensure overall cost-effectiveness" (A National Health Plan for South Africa, 1994).

3.5.1 The South African Drug Action Programme (SADAP)

The South African Drug Action Programme was given support after the Minister of Health, Dr. Zuma made a visit to England.[10] The multinational pharmaceutical companies based in Great Britain were openly opposed to the support by DFID. Pressure was exerted on DFID to step away from South Africa's request for assistance to develop a National Drug Policy. However, the British Development Division for South Africa (BDDSA) also known as DIFID stepped in with funding for the project of the South Africa Drug Action Programme (SADAP 2000). "On the 13 of September 1996 the DFID approved the funding for the

[9] Project Memorandum, South Africa Drug Action Programme (SADAP 2000), British Development Division in Southern Africa (BDDSA) November 1996.

[10] The South African National DOH had made steady progress toward the adoption of a National Drug Policy, but was still lacking the resources (expertise and financial) that were needed.

SADAP project and requested that WHO/DAP be the executing agency.[11] " SADAP[12] is a short-term initiative to re-orient national policy toward rational drug usage" (South African Drug Action Programme (SADAP 2000), 1996). The Project's goal is to "improve the effectiveness and efficiency of health care in South Africa by providing support for the implementation of the recently formulated NDP."[13] The goal of the SADAP is "to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa, and the rational use of drugs by prescribers, dispensers and consumers" (SADAP 2000, 1996).

The project duration was initially for 50 months from 1 November 1996 until 31 December 2001. The mid-term review (November 1998), team recommended that the programme be extended for an additional 12 months. DFID financial support is channelled through the WHO to "ensure that developments under NDP conform to internationally recognised policies and practices." (South African Drug Action Programme (SADAP 2000), 1996) The DFID funded the project with GBP £3.6 million.[14] The specific areas of funding are: institutional development, legislation, quality assurance and drug regulation, financing, cost recovery, and pricing structure, drug selection, procurement, storage and distribution, rational drug use: education and training, human resource development and other activities. The funds that the DFID provided were in addition to the total contribution of the DOH of GBP £1.3 million.[15]

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[11] WHO/DAP – SADAP support mission 9-28 September 1996, mission report, unpublished

[12] The project is based within the National Department of Health in Pretoria and has three dedicated project staff members: an internationally recruited SADAP project co-ordinator who was appointed and paid by WHO as the senior advisor to the DOH for the duration of the project; a training advisor who is responsible for the development, field-testing and implementation of all training programmes at the provincial and national levels; and an office manager, who is responsible for the Project's administration.

[13] The NDP's aim is to "ensure an adequate and reliable supply of safe, effective and affordable drugs of good quality to all citizens of South Africa; to promote more rational drug use and improved care; and to increase the efficiency of procurement and distribution within the public sector." South African Drug Action Programme (SADAP 2000), 1996).

[14] DFID support of £3.6 million for international technical assistance and other offshore costs (23%), national short-term advisors (29%), and other expenditures (48%).

[15] This contribution does not include other long term contributions that include secretarial support, telephone, fax, accommodation, salaries for Provincial Essential Drug Co-ordinators, training activities, and the public sector drug budget that is estimated at R2 billion/year.

The SADAP has been a semi-autonomous unit within the Chief Directorate of the Registration and Regulation Programme (RRP), and attached to the Pharmaceutical Programmes and Planning (PPP), formally called the Directorate Medical Schemes, Supplies and Services (MSSS) that will serve advisory and institutional functions. By the end of 1998, the second year, the unit activities should have been developed to the point where it could be incorporated into the Medical Schemes Supplies and Services (MSSS) and at the end of the project the DOH will take over the full funding for SADAP activities. SADAP during the first two years concentrated on aspect of the national implementation of the NDP including putting into place appropriate legislation. The second phase (2-3 years) will be to provide provinces with support in the implementation of the NDP. The implementation of the NDP and the responsibilities of both NDOH and SADAP are not well defined. The SADAP mid-term review team in 1998 proposed an organogram (Appendix B).

3.5.2 The Standard Treatment Guidelines / Essential Drug List (EDL/STG)

National Essential Drugs' List Committee and Drug Selection

The Minister of Health appoints a National Essential Drugs' List Committee (NEDLC), composed of experts from all areas of medical and pharmaceutical practice. The members are responsible for the selection of drugs to be used in the public sector[16] (Appendix C). The NEDLC drew up an EDL using generic names and based on WHO approved criteria[17]. This list was prepared for the three levels of health care providers, namely primary care, community, secondary, and tertiary hospital care. The STG/EDL was distributed to all health workers in all public settings within the country. Before the NDP with STG/EDL guidelines came into effect the Provinces could deviate from the National EDL and make Provincial Coding Lists. The current national list of essential drugs is used as a foundation

[16] The Committee will be composed of experts in all spheres of medical and pharmaceutical practice. It will include clinical pharmacists, pharmacologists, medical specialists, a paediatrician, professional nurses from community practice, medical practitioners involved in primary care practice. In addition there will be a member of a drug information centre, a member of the clinical committee of the Medicines Control Council, a health professional involved in drug management training and representatives of the provincial EDL committees. Additional members may be co-opted on an ad-hoc basis. Consultations will be undertaken with all interested parties.

[17] WHO published guidelines on formulating an EDL, the criteria are: meet the needs of the population, sufficient scientific data, substantial safety and risk/benefit ratio, mostly products containing a single pharmacologically active ingredient.

for the basic health care package of the National Health System. The STG/EDL is to be used for training doctors, nurses and other health workers in rational prescribing. In addition to the STG/EDL, a national Formulary will be created.[18]

The first EDL for primary care (popularly known as the 'green book') was published in 1996 and was distributed in all nine provinces. Since then, three STG/EDL's, one each for primary (2nd edition), paediatrics and hospital (adult) edition books were published in December 1998. The South African Drug Action Programme (SADAP) supported the development and implementation of the STG/EDL reducing the number of drugs on the ELD from 2,600 to 691 drugs (Appendix D). The use of the EDL and policy of procurement of non EDL drugs with no more than 10% of the pharmaceutical budget will shift scarce resources to benefit the majority of ailments and patients. Each province is expected to implement these polices as soon as possible. The more expensive non-EDL drugs will be phased out of the health system within an unspecified period of time. After several years, the EDL is expected to reduce the total amount of public expenditure on non-essential drugs. As a part of an EDP, generic prescribing and substitution has been launched and introduced into the public hospital sector on 3 December 1998.

At the EDL launch, in the key note address, Minister Zuma[19] (Zuma, 1998) stated:

> I believe the EDL will be printed in numbers to ensure that all prescribing personnel have access to a copy. But, I would now like to issue the following challenges to the responsible official in the Department and in the provinces. Having the book is one thing, ensuring that they are used, and the prescribers know how to use them, is another. You must therefore embark on strategies to ensure the acceptance of the essential drug concept by consumers and health personnel alike. Also, ensure that all health personnel are appropriately trained on good prescribing and dispensing practices; encourage compliance with the standard treatment guidelines among even the most traditional prescribers, develop indicators to help assess the usefulness of the EDL in achieving rational drug use and impacting positively on the drugs budget.

[18] Currently there is the South African Medicine Formulary, 4th edition 1997. A Proposal has been made to SADAP to write a primary care EDL-based Formulary by Dr. Catherine Orrell at the Department of Pharmacology at the University of Cape Town.

3.6 Rational Drug Use and Prescribing

The aim of rational drug use is "To promote the rational prescribing, dispensing and use of drugs by medical, paramedical and pharmaceutical personnel and to support the informed and appropriate use of drugs by the community" (NDP, 1996).

The National Department of Health's National Drug Policy for South Africa focuses on several areas related to the rational use of drug. The areas of focus include but are not limited to, education and training, drug information, appropriate prescribing, dispensing, and hospital therapeutic committees (NDP, 1996). The National Drug Policy's goals are to promote the rational prescribing, dispensing and use of drugs through the use of the STG/EDL as a tool by medical, paramedical and pharmaceutical personnel and to support the informed and appropriate use of drugs by the medical community. Generic prescribing is a good indicator of the rational use of drugs. The NDP aim of ration drug use could be achieved through appropriate training, the provision of scientifically validated drug information for professionals and the community, the establishment of hospital therapeutic committees, good dispensing practice, and an enhanced role for the pharmacist, and control of commercial marketing practices.

3.6.1 Appropriate or "Rational" Prescribing

The objective is "that all drugs are prescribed by generic name in accordance with recommendation standard treatment protocols and the Essential Drug List. The Department of Health will collect, evaluate and disseminate systematic data on drug utilisation to monitor and act on policy adherence" (NDP, 1996). Rational drug use includes appropriate prescribing. The goal is that all drugs will be prescribed and dispensed by generic name in accordance with the STG and EDL. Although the NDP will not have a direct effect on the private health sector, the STG /EDL use is recommended. Barriers to rational drug use include (WHO 1992a):

1) Lack of objective information and of continuing education and training in pharmacology
2) Methods of promotion employed by the pharmaceutical industry
3) Shortage of well organised drug regulatory authorities
4) Presence of large numbers of drugs on the market
5) Prevalent belief that every ill has a pill
6) Attitude of members of the medical profession, who are only too often reluctant to change their practices and view any restriction as a threat to their freedom to prescribe

According to Perez-Curvas et al (1996), Parades et al (1996), and Ofordi-Adjei et al (1996), several factors that overall agree with the WHO assessment but are stated with a different emphasis and focus on factors that influence physicians to prescribe medicines inappropriately. The factors include:

(a) Shortcomings in both the undergraduate and graduate medical education. The predominant education trend supports prescribing medicine to all patients.

(b) Lack of trustworthy clinical and pharmacological judgement. This is the most important factor in influencing physicians' inappropriate prescribing. In medical circles worldwide there is a new trend towards 'evidence-based' medicine and prescribing.

(c) Unreliable and partial sources of pharmacological information from the various methods of advertising of pharmaceutical companies.

(d) Pressure exerted by patients to receive drugs.

(e) Desire of the patient for the physician to do something and the ease of using medicines to fulfil this desire.

(f) Lack of research and continuing education.

3.6.2 Drug Information

The objective is to ensure the provision of practical and scientifically validated information on the correct handling and rational use of drugs to health personnel at all levels. This includes a regularly updated standard treatment protocols for common conditions with essential drugs. The department will produce an annual national Formulary of essential drugs for distribution to all health care providers and dispensers. The publication will include guidelines to good dispensing and prescribing and information on drug interactions (NDP, 1996).

The DOH has updated and produced a second edition (November 1998) of the STG/EDL. Sufficient quantities of these books were produced for use by physicians and nurses who prescribe, and pharmacists who work at all levels of care from primary to tertiary care in all hospitals and clinics.

3.6.3 Hospital Pharmacological Therapeutic Committees (PTC)

The objective of the policy is " to establish and strengthen the Pharmacological and Therapeutic Committee in all hospitals in the country (both public and private) in order to ensure the rational, efficient and cost-effective supply and use of drugs. These PTCs will consist of at least a senior pharmacist, a senior nurse, a senior financial officer and senior clinicians or their nominated representatives in their absence " (NDP, 1996).

In May 1998, MEDUNSA's Prof. Summers met with the Northern Province Pharmaceutical Services to discuss the: "school of pharmacy report of a workshop to consider the wider implementation of PTCs in the province and associated training needed held on 12 May 1998." (MEDUNSA Meeting programme, May 1998). The operation levels for PTCs in the province are clinics (health centre and community services), Districts (including hospitals), Hospitals (regional and tertiary), and provincial (umbrella to national). The functions and membership of the committees (Appendix E) would depend on the level they are working on: clinic, district, hospital and/ or provincial.

3.6.4 Education and Training

The objective of the National Department of Health (NDOH) is "to ensure that all health personnel involved in diagnosis, prescribing and dispensing of drugs receive adequate theoretical and practical training...A systematic and comprehensive programme of continuing education will be developed and implemented. All such initial and continued training will be developed and assessed in collaboration with health personnel at all levels " (NDP, 1996).

A systematic and comprehensive programme of continuing education will be developed and implemented. WHO/DAP have published books on training in rational drug use, but books and training are not enough to change prescribing habits on a long term basis. According to Kanji et al (1992), "DAP will need to do a lot more work before seeing a real improvement in the rational use of drugs, but in so doing is likely to be constrained by governments less interested in enhancing rational use than in supply in the essential drugs. In supplying drugs the government can gain politically, for people get the impression that the government is helping them. Enhancing rational drug use is far less rewarding activity."

3.6.5 Role of Pharmacists

The WHO has recommended a special role for pharmacists that includes quality assurance and safe and effective administration of drugs. "Pharmacists are in a strong position to promote the rational use of drugs through their extensive knowledge. Pharmacists will be involved in the multi- disciplinary approach to rational utilisation of drugs. Greater cooperation between pharmacist and other health professionals within communities and hospitals will be promoted to facilitate consensus regarding the choices of drugs and treatment protocols. Pharmacists will be required to have available scientific sources of references" (NDP, 1996). The *Dispensing* objective for the pharmacy staff is to ensure that all drugs are dispensed according to regulations and good dispensing practice. Dispensing will be in accordance with the principles already stated the in section on "The Use of Generic Drugs" (NDP, 1996).

3.6.6 Role of Patients as Consumers

The rational use of drugs aim includes "to support the informed and appropriate use of drugs by the community" (National Drug Policy, 1996). This aim was to be achieved through the education and training for the 'general public.' This goal includes, collaboration with other bodies responsible for school, adult literacy and other educational programmes to integrate in the curriculum basic education that will lead to a better appreciation of the benefits and limitations of the role of drugs in health care" (National Drug Policy, 1996).

Although on 1997 South Africa's Pharmacy Council reported that it would spend R400,000 Rand (WHO report on Public Education in Rational Drug Use: WHO/DAP/ 97.5) on patient education of rational drug use. The two patient educational programmes were: "Don't take the right medicine the wrong way" and "When receiving medicines you have certain rights." The duration of the programme is not known, as there was no data on the number of years for the project.

Considering the consumer behaviour affects the outcome of rational prescribing it is surprising that the NDP, 1996 does not include assertions of direct responsibility for patient education by provincial health departments, clinics, hospitals and health care workers. These stakeholders can share the responsibility for educating the public about the use of the

EDL, generic drugs and the importance of taking medicines as prescribed trough the use of educational materials such as poster, and leaflets. The provincial government could promote public education in rational use of drugs with news articles and radio programs.

One of the major barriers to patient education about rational drug prescribing is the high illiteracy rates and the variety of languages spoken among patients.

3.7 The Northern Province

3.7.1 Land and population (Orkin: 1995)

The land of the Northern Province covers an area of 124,000 km^2, which is 10% of the total area of South Africa. The province is divided into six regions; Bushveld, Western, Central Northern, Lowveld, and Southern (Appendix F). The population is 44 people per km^2, which is higher than the average of 34 km^2. The languages spoken include Eepedi (57%), Xitsonga (23%), and Tsivenda (12%). The population of 4,128,000 is 10.9% of the total population. Only 11% of the population live in urban areas (Table 3.3). The Northern Province is the least urbanised part of South Africa (Appendix G).

Table 3.3 Northern Province Population Data

RACE	% OF TOTAL POPUL.	% LIVE IN URBAN AREA
Africans	94.4	8
Coloured	1.9	92
White	2.7	69
Indian	0.1	92

Source: Dr. FM Orkin: 1995.

Consistent with living the mostly rural areas, few Africans (17% compared to 33% for South Africa) have running water in the households, while 93% of the White population have household water. Generally, "since Africans are the poorest race and because they represent a much larger portion of the population in the Northern Province, households in the Province are considerably less well-off, on average, than those in the country as a whole" (Orkin, 1995).

3.7.2 Health and Health Care

Life expectancy in 1991 was 62.7 years, an increase from 1980 with 60.1 years. Eighty-nine percent of the African population uses the public health facilities compared to an average of 81% for South Africa. However, more Whites also use the public health facilities (32%) compared to 20% in South Africa. In 1996 the Northern Province had 43 hospitals (including psychiatric) with 15, 549 beds in the public sector. The private sector had only 4 hospitals and a total of 216 beds. The health care services reach a majority of the population (80%). Utilisation of free Health Care Services at clinics and hospitals has

increased by 13.7% from the total attendance of 640,332 in 1996. In 1997, the total free health care (inpatient and outpatient, clinics and hospitals) was 7,448,141 visits.

Table 3.4 Free Health Care Statistics 1997

	HOSPITAL OPD	IN PATS.	*CLINIC OPD*	*FHC TOTAL*
REGION				
BUSHVELD	7,559	3,753	179,331	190,643
WESTERN	47,592	17,926	477,059	542,577
CENTRAL	173,452	59,209	435,188	667,849
NORTHERN	367,658	215,011	3,257,940	3,840,609
LOWVELD	112,584	126,654	986,510	12,225,748
SOUTHERN	109,358	60,715	810,642	980,715
TOTAL FHC	818,203	483,268	6,146,670	7,448,141

Source: MEC's Annual Report, 1997/98

The Northern Province Department of Health (NP-DOH) has produced a set of its own objectives, indicators and progress points. Specific indicators for the influence of hospital, clinics and pharmaceuticals are the financial management, development and implementation of policies, plans and legislation. The goal of the NP-DOH was to develop one hospital in each of the six regions into a fully-fledged functional secondary level facility. The Northern Province has upgraded its hospital services to include 24 hours community (level 1) hospital care service in all 37 hospitals and one secondary (Regional) hospital in each region. A total of R273 million Rand were allocated to this project. An academic hospital is now in place and has been functioning for the last year. A total of R1.3 million Rand was spent to upgrade the complex that is shared with the regional secondary hospital (MEC's Annual Report, 1997/98).

The referral system from the District hospitals (primary) to the Regional hospitals (secondary) to the Central Hospital (tertiary) has been developed and is working well. In the hospitals the average length of stay (ALOS) was 4-5 days with a 70-80% bed occupancy rate (BOR). The Northern Province has a ALOS of 5.7 and a BOR of 67.9%, below the target recommended by the Hospital Strategy Project (MEC's Annual Report, 1997/98).

Table 3.5 Hospital Performance Indicators

REGION	*ALOS*	BOR
Northern Province	**5.9**	**67.9**
Region Average		
BUSHVELD	4.0	73.8
WESTERN	5.3	63.4
CENTRAL	8.5	69.5
NORTHERN	5.4	66.1
LOWVELD	5.4	71.9
SOUTHERN	5.4	62.7

Source: MEC's Annual Report, 1997/98

The Health Care Support Services including pharmaceuticals and motor transport (ambulances) had a dedicated budget in 1997 of R1.5 million Rand. The 1998-99 expenditure on hospital support services was R101 million Rand. The specific objective of the pharmaceutical services is "to supply affordable, cost effective, accessible pharmaceuticals to all people in the Northern Province." The indicators used were: dedicated vehicles for use by all hospital pharmacies, at least two inspections per month, 90% of medicines available in-patient ready packing, 90% of orders satisfied, and 90% availability of essential drugs. All of these indicators have been met. The Standard procurement list was implemented in June 1996 and was revised in April 1997 to incorporate the level of care and was implemented on 1 January 1998. One person per clinic were trained for a total of twenty-five clinics and provincial trainers in Effective Prescribing (EP) and Drug Supply Management (DSM). In 1997, five of the six regions had met their target numbers for training.

3.7.3 Distribution and Procurement

Before the 1994 elections, provinces consolidated their fractured health care and pharmaceutical services. Provinces had their own warehouses and sent estimates of their requirements to Co-ordinators Committee for the Acquisitions of Medicines (COMED). The provinces paid the supplier directly.

The Northern Province integrated the drug supply system of four authorities to establish a single health authority. The Northern Province evaluated its system in 1994. The evaluation led to the decision in 1995 to contract out drug procurement, warehousing, and distribution of pharmaceutical supplies to a private company, Vuna Health Care Logistics (Appendix

H). Vuna works on an 8.05% commission of the value of the products. The five-year renewable contract includes a 2.2% commission for computerisation of hospital pharmacies and computer training of provincial pharmaceutical staff. (Essential Drug Monitor, 1998). Since 1996, pharmaceutical supplies have been distributed from a single depot. With the exception of receiving the goods, the provincial authority is involved in every step of procurement. The contractor's responsibility is only at the hospital level. The province is responsible for delivery to and inventory control in the clinics. At the clinic level transport and information have been difficult at best. " The Department must also ensure that the contract is carried out according to the specifications. This necessitates the active involvement of provincial staff members in the entire process from database management, and procurement to receipt and distribution" (Essential Drug Monitor, 1998:11).

3.7.4 Finances

The National government allots funds according to a formula that takes population into account while the Provincial budget is centralised. The Province then makes a budget for all public service that includes health services (Appendix I). The health budget includes pharmaceutical. Budget over spending in other areas led to the withdrawal of funds from health services (Appendix J).

The financial management for procurement of goods and services and payment of salaries and benefits has a strict mandate: "expenditure according to budget with a deviation of not more or less than 2%" (MEC, 1997). The development and implementation for policies and plans that included legislation to provide equitable health services that has been far reaching to includes a draft of a Pharmaceutical policy document.

3.8 Summary of South Africa Background

Pharmaceutical reform in South Africa started with the Primary Health Care focus with the National Drug Policy (NDP, 1996) was adopted in 1997 as a cornerstone of access and equity in health care. The NDP includes procurement, storage, distribution, and prescribing. Prescribing is the one area that is directly dependent on individual health practitioners (nurses pharmacists and physicians). The interventions have been administrative, legislative, and managerial.

The administrative intervention by the National Department of Health was the adoption of South Africa's National Drug Policy (1996). The NDP components consists of legislation and regulation, drug pricing, procurement and distribution, rational use of drugs, human resources development, research and development, international cooperation, traditional medicines and finally monitoring, and evaluation. Simultaneously, the South African Drug Action Programme (SADAP) was implemented in order to improve the procurement, distribution and rational use of drugs by prescribers, dispensers and consumers (SADAP 2000, 1996). The tools used by SADAP include baseline studies in acquisition, storage, distribution and prescribing in clinics and hospitals.

The legislative intervention included four new laws. The four new legislative interventions are: first, the Pharmacy Amendment Bill, [Act No. 28 of 1997]. Second, the Medicines and Related Substances Control Amendment [Act No. 90 of 1997]. Third, the Medical, Dental and Supplementary Health Services Professional Amendment Act (1998), and forth, the South African Medicines and Medical Devices Regulatory Authority Bill [SAMMDRA Bill, 1998]. The last five years have been tumultuous for the implementation of pharmaceutical legislation. With the repeal of SAMMDRA, the Pharmaceutical Manufacturers Association (PMA) dropped the lawsuit against the government. Thus, South Africa was designated the new world-wide testing ground for World Trade Organization (WTO) legislation, and the new vocal and active Non-Governmental Organization (NGO) for access to essential drugs, the legislative process today is still in motion.

The managerial interventions are aimed at the provincial level. The interventions include a voluntary cap on brand name drug spending of ten percent of the drug budget. Education and training has been given in Drug Supply Management and Effective Prescribing. Drug information and Prescribing tools for prescribers to encourage generic prescribing is the Standard Treatment Guidelines / Essential Drugs Lists (STG/EDL) for the primary care, paediatric hospital and adult hospital levels, and the use of Pharmaceutical Therapeutics Committees for hospital institutions.

CHAPTER FOUR

NATIONAL DRUG POLICY RESEARCH IN DEVELOPING COUNTRIES

4.1 Research on National Drug Policy, and the Essential Drug List

This section reviews the research that has been conducted on National Drug Policy (NDP), Essential Drug Programmes (EDP) and Rational Drug Use (RDU) in various developing countries, and specifically in South Africa. Research of NDP in developing countries is particularly interesting to this research to determine what has been done, and where the research gaps lie. The World Health Organization, Drug Action Programme (WHO/DAP) has been involved in promoting National Drug Policies, Essential Drugs Lists (EDL) and generic prescribing to its member states, especially the developing countries with limited budgets and large populations to serve.

4.1.1 World Health Organization and the National Drug Programmes

The WHO Action Programme on Essential Drugs is the main international force for the promotion and assistance for the formulation and implementation of National Drug Policies and Essential Drugs Programmes for their 181 member countries. The London School of Hygiene and Tropical Medicine (WHO 1989) in 1989 assessed the WHO/DAP programme and its efforts at pharmaceutical policy development. The evaluation found that the achievement of WHO/DAP was the emphasis on and the spread of the Essential Drugs List (WHO 1989). However, some of the problems included the limited adoption of National Drug Policies, weakness in the Information-Education-Communication component and a lack of focus on rational drug use. The study further revealed that WHO is effective in identifying and disseminating information on the essential elements of a NDP, but had difficulty in promoting the national implementation of new policies.

4.1.2 National Drug Policy (NDP) Research in Developing Countries

Few systematic reviews, research and analysis of national and international efforts at pharmaceutical policy development and their accomplishments have been carried out. "The analyses of pharmaceutical policy that exists rarely explore the problems of policy performance and implementation in a systematic manner" (WHO 97.6, 1997).

Moreover, there are few publications of collected essays on pharmaceutical problems in developing countries (Robles, et al 1992). WHO/DAP has conducted several studies to evaluate the impact of the NDP and prescribing practices (MOH Mozambique 1986;

Indonesia MHS 1988; Democratic Yemen 1989; and Angola 1990). Overall, the earlier studies have revealed a lack of rational drug use by prescribers.

The only published study of the evaluation of the impact of a NDP with a control group was in Yemen by a WHO/DAP staff member (Hogerzeil et al, 1989). The study found that several rational drug use indicators in the programme area were significantly difference from the 'control area' (Kanji et al 1992). Specifically the study found that the programme area had an average of 1.5 drugs per prescription, with 47.3 per cent of prescriptions containing an antibiotic and 24.8 per cent containing an injection, while in the control area 2.4 drugs were prescribed, with 66.8 per cent prescriptions with antibiotics and 57.8 per cent prescriptions with injections. The prescribing results of the intervention were significant. In the 1990's, WHO/DAP (1996a; Hogerzeil 1993) convened the only study that looked at a cross-section of countries.

4.2 Pharmaceutical Studies

4.2.1 The Twelve-Country National Drug Policy Study (WHO 1997)

The twelve-country NDP study specifically focused on comparative analysis of National Drug Policies. The WHO/DAP in collaboration with the Division of International Health Care Research in Stockholm, and the Harvard School of Public Health in Boston in 1996 conducted a comparative analysis of national drug policies (NDPs). The project was initiated in "recognition of the need to systematically evaluate national drug policies, both on the aspects of policy process and policy output, and to provide recommendations for improving policy formulation and implementation" (WHO 97.6, 1997).

The goal of the study was to assess the performance of national drug policies within the twelve chosen countries: Bulgaria, Chad, Colombia, Guinea, India, Mali, Philippines, Sri Lanka, Thailand, Vietnam, Zambia and Zimbabwe. The twelve-country research teams had two objectives. First, to identify strengths, weaknesses, and political dimensions of pharmaceutical policy formulation and its implementation within each country. The second objective was to propose effective strategies, both national and international, that could improve national pharmaceutical policy implementation. "The research provided a cross national, comparative framework and combined formative evaluation strategies (focusing

on the process of policy formulation and implementation) and a summary of evaluation strategies (focusing on policy outcomes) (WHO 97.6, 1997).

The twelve research teams used two main research tools. Standardised NDP indicators for the assessment of the NDP performance and Political Mapping for the analysis of the NDP formulation and implementation process. The preliminary methodological evaluation findings were:

- A large percentage of the indicators were useful and did not need substantial modification. Country teams constructed a few new indicators to better cover certain components of the pharmaceutical policy (e.g. rational use of drugs).
- Two country teams used political mapping to understand what had happened in the policy formulation and implementation and the reasons for successes and failures.
- The two methods used in the research were able to assess the performance of a given national drug policy and the policy process.

Comparatively the results were: "In all countries there were components of the NDP which received more attention from decision makers and senior management staff; in most of the poorest countries these components were essential drugs lists and public procurement of drugs under the (International Non-proprietary Name) INN." Also, the research clearly demonstrated that policy-making in order to be effective may be a technical process but must also be a political process. Policy-makers need both technical and political analysis in order to be effective. Policy-making does not stop with the official adoption of a policy, but must continue through the phase of implementation and evaluation (WHO 97.6, 1997). The specific lessons from the cross-national NDP analysis are:

- Certain technical components, when implemented adequately, made a difference in outcome. For example, both a bad selection of drugs and an inefficient procurement system led invariably to shortage of drugs; on the contrary, a good registration system had a positive impact on rational use of drugs.
- Countries' use of an EDL in the public sector was just a first step in improving availability and affordability. These objectives seemed more difficult to achieve in countries where the pharmaceutical market was mostly private and where there was no regulation of drug prices.
- Countries with no local industry (national or multinational) could implement the main aspects of the NDP with fewer problems.

- Improvements of the NDP through radical changes were more likely to happen when there were political windows of opportunity. When such opportunities presented themselves (e.g. new governments), it was possible to implement quick, radical and widespread changes. When such opportunities were not available, it could be better to use a systematic approach.

- Technical soundness and /or economic rationality of a policy did not always imply that the policy was politically viable.

4.2.2 The Thailand Experience: Comparative Analysis of NDP (Ratanawijitrasin, et al 1996).

The country study on national drug policy in Thailand was part of the "Comparative analysis of National Drug Policies." The Thai NDP study assessed the status of the structural and implementation process. The goals were to evaluate the policy performance and to identify areas where policy improvements could be made. The objective of the policy process study was to explain the formulation and implementation of the Generic Labelling and Advertising Policy and to identify lessons learned from this policy. The study selected 81 indicators and developed two additional outcome indicators (The NDP indicators are 129 in total). In addition, Policy Mapping was employed to look at the Generic Labelling and Advertising Policy. The analysis focused solely on the political aspects of the policy. "The purpose is to explain the political process of policy development using the Political Mapping framework with the aid of the computer program Policy Maker. In this analysis, the policy process is divided into two parts corresponding to the two policy stages: policy formulation and policy implementation. For the policy formulation period, the analysis examines the political dimension of the activities that led to the adoption of the regulation. The analysis on policy implementation period attempts to identify, from a political perspective, actions made by different players that might have resulted in the repeal of the regulation" (Ratanawijitrasin et al., 1996).

The Thailand study showed that although the structural indicators were in place with a well- established policy structure, the process and outcome indicators for the aspects of implementation of the policy lagged behind (the law enforcement is different in various jurisdictions). The National EDL covered only the public sector. More than 29,000 drugs were registered. The variety of drugs under various brand names caused confusion and increased irrational drug prescribing. Several outcome indicators on drug use have shown

that prescribers had difficulties with rational drug use. A survey found that a high percentage of child diarrhoea cases were being treated with anti-diarrhoea drugs or antibiotic preparations.

The recommendations of the indicator study included several issues that needed to be addressed.

- ***Policy Information***: There was a lack of critical policy information. An important factor to rational policy decisions is relevant, up-to-date and accurate information.

- ***Policy Implementation***: The policy implementation significantly affects the success of the policy outcome. Thus, the policy needs to be monitored regularly and emphasis placed on continuously assessing how policy activities relate to policy objectives.

- ***Decentralisation:*** provincial health offices need to be given authority, clear, and specific mandates, and support from the central agency.

- ***Dug Use:*** Irrational drug use has multiple factors: quality of products, product information, qualification of prescribers and prescribing and dispensing behaviour. The solution is to provide unbiased drug information and adequate education and training, and institute incentives to promote rational drug use.

- ***Prospective Policy:*** The policy operated in a dynamic environment, therefore it needs to be forward looking. " With the emphasis in the international platform on protection of intellectual properties and the introduction of pharmaceutical product patent in Thailand, NDP should take a prospective approach in preparing the country for possible price and affordability related problems that may become policy impediments in the future" (Ratanawijitrasin et al, 1996).

4.3 Pharmaceutical Studies in South Africa (1996-2001)

South Africa's research and monitoring needs of their National Drug Policy (NDP), Essential Drug Programme (EDP) and the use of Standard Treatment Guidelines / Essential Drug List (STG/EDL) are extensive. Research is needed to assess the direction of policy during the next NDP and South African Drug Action Programme (SADAP) review in 2000. Research will allow for a more accurate overview of the current state of the implementation of the NDP and the extent of its adoption by those who must carry out the policies in healthcare settings. A half dozen or more research projects have been carried out in the last six years on the state of pharmaceutical services (in selected provinces). The study topics have included: prescribing patterns, prescribing cost, staffing norms in the pharmaceutical sector, baseline studies for the evaluation of the implementation of the NDP in South Africa's nine provinces, rational drug training and other small studies carried out by staff and students. Many of these studies are able to assess the state of pharmaceutical services for the first time in South Africa's history.

4.3.1 Pharmaceutical Studies

The first pharmaceutical study undertaken in South Africa in 1996 was by the school of pharmacy, (MEDICOS) at the Medical University of South Africa (MEDUNSA). It was an 'Evaluation of the transformation of pharmaceutical and related services in the Northern Province'. This evaluation was the first quantified survey of its kind in any province in South Africa. The aims and objectives of the project were twofold: to determine the impact of rationalised drug procurement and distribution on the quality of pharmaceutical services in the Northern Province and to assess its impact. Second, to determine and assess the effect of an essential drugs programme on primary care services and monitor its effectiveness.

Performance indicators for six areas were evaluated: 1) selection and procurement of drugs, 2) distribution and storage, 3) rational use of medicines, 4) financial management, 5) human resource development, and 6) quality assurance. The facilities included a contracting depot, 10 hospitals, and 14 clinics were selected for inclusion by random sampling. The data were collected with collection forms and structured interviews with

staff members and patients were conducted. The results of the drug use indicators (prescriptions) in hospitals (n=300) and clinics (n=420) were:

- The average number of items per prescription in *hospitals was 2.74*, in clinics 2.36 (goal < 2.0)
- The average percentage of patients receiving at least one injection in *hospitals was 27%*, in clinics 15% (goal varies)
- The average number of patients receiving at least one antibiotic in *hospitals was 51%*, clinics 55% (goal < 25%)
- Percent of items prescribed by generic name in *hospitals was 31%*, and clinic 47%. (goal 100%)
- Percent of items prescribed appearing on EDL 1996, in clinics was 30% (goal 90%)

The awareness of the NDP and EDL were also assessed by interviews. Staff members who were:

- aware of the NDP, *hospitals 60%,* and clinics 0%.
- owning a copy of NDP, *hospital 50%*, and clinic 0%.
- able to recall three aspects from the NDP, *hospitals 10%*, and clinics 0%.
- aware of EDL 1996, *hospitals 50%*, and clinics 7%.
- owning a copy of EDL, *hospital 30%*, and clinic 0%.

Hospital staff interviewed had a higher awareness rate of both the NDP and the EDL, while those at the clinic level had almost no awareness of either. At only one clinic the NDP publication was known. Only 28% of the clinics had received a list of drugs intended for use at the clinic level. The report concluded that the areas requiring attention were injection and antibiotic use, generic prescribing, and compliance with the STG/EDL. Concerning human resources, improvements were needed in particular for staff, NDP awareness, STG/EDL training on effective prescribing, and drug supply management. Of the final eight recommendation, three were directly related to drug use and training. The recommendations were (MEDUNSA, 1997):

1. Prescribing practices must be addressed at all levels. In accordance with the National Drug Policy, a campaign to encourage generic prescribing and the use of standard treatment guidelines must be implemented. The high use of antibiotics at all levels needs attention.

2. An introduction to the National Drug Policy and the Essential Drugs List is needed for all staff, especially at Primary Care level.

3. The training of qualified Primary Health Care clinic nurses in effective prescribing and drug supply management, and of pharmacy support staff for registration purposes needs urgent attention and central policy direction.

In conclusion, Professor Robert Summers of the Medical University of South Africa (MEDUNSA) stated: "The staff at present are not trained in drug supply management, rational drug use or effective prescribing. They have a low awareness of the National Drug Policy and Essential Drugs List. Information sources in the clinics are poor."

4.3.2 South African Drug Action Programme (SADAP) Baseline Study (1996-1998)

The South African Drug Action Programme / World Health Organization (SADAP/WHO) in co-ordination with the National Department of Health and provinces, conducted a baseline study of the National Drug Policy (NDP) between 1996 and 1998 (Möller, 1998).

The intent of the study was to evaluate the efficiency and effectiveness of pharmaceutical procurement and distribution systems currently in use in the provinces with the ultimate objective of improving pharmaceutical services in the provinces, and to serve as a baseline for future studies.

The survey covered the ten key indicators of the National Drug Policy: selection, procurement, storage, distribution, quality control, information systems, facilities and equipment, cost implications, human resources development and drug use. The study examined the current state of pharmaceutical systems at various levels: depot (5), hospital (57) and clinics (120). The first survey was conducted in the Northern Province in April 1996. Staffs in clinics, mostly nursing staff in clinics and hospitals were interviewed to determine the level of knowledge about the National Drug Policy and the Essential Drug List. By 2000 eight provinces of nine have completed the local survey. Gauteng province has yet to conduct its baseline study. In addition, KwaZulu-Natal was not included in this study report because it only completed the survey in November 1998. The results were published in First Report: The Impact of the Essential Drugs Programme in Seven Provinces in South Africa, Baseline Studies April 1996 to March 1998 (October 1998). The results and recommendations are as follows (Möller, 1998):

- Awareness of the NDP: 39.2% of all persons interviewed were aware of the NDP, 29.9% had their own copy. However, only 13.8% could remember 3 key aspects from the policy. Generally, the clinic staffs were not aware of the NDP. There was an overall lack of awareness of the NDP in South Africa.

- Combination products not on the EDL were not a problem. However, a list of unwanted medicines was prepared and 75.8% of hospitals had at least one of these in stock.

- The number of items per prescription at the hospital level was 2.5 items. This high average suggests that there may be polypharmacy. Antibiotic use was a problem at all levels. On average 32.5% of patients received at least one antibiotic.

- Injection use was a problem at the hospital Out Patient Department (OPD). The Northern Province had a 27% rate.

- Concerning human resource development 7.7% of those interviewed in the hospital pharmacy received some form of Diagnosis Standards in Medicine (DSM) training, while 9.1% of those interviewed at the hospital received some training, aimed at improving the use of medicines.

- Sources of independent drug information (South African Medicines Formulary) were available to 52.7% of hospital pharmacists. While 29.9% had a copy of the Primary Health Care Formulary. The most commonly used sources were the (MIMS) Merck International Manual (which is a pharmaceutical industry publication). Only 10% of the hospital pharmacies publish a drug information bulletin or newsletter. Of those interviewed 33.7%, routinely used a drug information centre. There is an urgent need for a cross-reference guide between generic and trade name drugs at the Primary Health Care level.

The baseline study concluded with 12 recommendations, six of which were concerned with facility, inventory and storage. The other six were:

1. The general awareness of the NDP, especially al the clinic level, must improve.

2. Medicines not on the EDL must be identified and where consumption is not possible, returned to a central point for distribution.

3. Basic financial management principles must be implemented at all levels.

4. Objective drug information must be made available to all prescribers, as well as pharmacy staff.

5. Training aimed at improving supply of medicines must be designed and implemented at both the hospital and the primary care levels.

6. Training aimed at improving rational medicine use must be designed for and implemented at both the hospital and the primary care levels.

4.3.3 Pharmaceutical Services at Primary Care Clinics (Kishuna, 1994).

Aarti Kishuna (1994) studied the Pharmaceutical Services at Primary Care Clinics in KwaZulu-Natal. The research question was 'Do hospital-based pharmacists support pharmaceutical service delivery at primary health care clinics? If not, how can they?' The aims included assessing the provisions for pharmaceutical services determine whether differences exist in the provision of pharmaceutical services; identify problems associated with the provision of services. The study was conducted in three hospitals. Data collection included observations, interviews of patients, and staff (nurse, dispensing staff) and the use of three categories WHO/INRUD indicators (availability, quality, and storage; quality of dispensing practice; the experience and training of prescribers and dispensers).

The study concluded:

- Hospital based pharmacists do not support pharmaceutical service delivery at primary clinics in KwaZulu-Natal.
- Clinic staff lack training in stock management and pharmaceutical services.
- Nursing staff lacks an understanding of pharmaceutical services and is poorly trained in stock management.
- The quality of dispensing medicines was poor, especially labelling.
- Need to train personnel in ordering and storage.

In conclusion the researcher identified questions that needed further research in "order that pharmaceutical services, within the framework of PHC, becomes rational, cost-effective and appropriate to the needs of the community...Is prescribing behaviour rational in the formal health sector?"

4.3.4 Analysis of Prescription Prescribing Patterns, and Costs (Suleman, 1995)

Another academic study conducted by Fatima Suleman (1995), titled, *Analysis of Prescription Prescribing Patterns, and Costs, in Public and Private Sectors within the Durban Metropolitan Area.* It was a cross-sectional descriptive study of four patient categories within the public and private sectors of the Durban metropolitan Area (DMA) in KwaZulu-Natal. The aim of the study was to analyse prescribing patterns and their costs in the public and private sectors. WHO/INRUD prescribing indicators were used. The data was collected during 10 working days in 4 hospitals (3,589 prescriptions), 15 pharmacies (273 prescriptions) and 24 dispensaries from a medical clearing-house (212 prescriptions). A total of 4,703 prescriptions were collected for analysis. Significant differences were found. First, hospital patients (public) had an older patient profile, prescribed more drugs on average than the private sector, and had a disease profile consisting of more conditions

that are chronic. Second, dispensing doctors (private) had the highest percentage (24.4%) of prescribing generic drugs, antibiotic prescribed (33.7) and percentage of injections.

The findings, by implication warrant an in-depth qualitative study to investigate the underlying factors that affect prescribing. The recommendations are that a database be set up and used to continuously monitor drug use. Also, peer review should be introduced for prescribers, and that they be made aware of the cost implications of their prescribing. Recommendations at the end of the study were (Suleman, 1995):

- "In absence of a national database/prescription monitoring service, studies on prescribing patterns need to be carried out regularly to monitor trends or changes in prescribing behaviour."
- "The study indicated a low percentage of generic prescribing, it is recommended that prescribers be made more aware of the importance of generic prescribing prior to the proposed legislation coming into effect that all prescription sin both public and private sectors be written using the generic names of drugs."
- "As the result of drug utilisation studies (including this one) have indicated regional variation in prescribing, it is recommended that all training programmes be planned and conducted at provincial level, with appropriate aims and objectives, to ensure standardisation in the development of training programmes."
- Training for the implementation of the Essential Drugs Programme in the Northern Province January-December 1997.

Suleman, stated in her report (1995) "the document compiled by the National Department of Health advocates generic prescribing by all prescribers in accordance with the Essential Drugs List. Yet it is the dispensing doctors, rather than the public doctors, that follows this method. Also, under the section for human resource development in the NDP document, no mention is made of training prescribers with regard to generic names. Thought this may be inherent in the modules suggested for training, this factor has not been highlighted, yet it is one of the aims of the NDP to facilitate procurement, distribution, supply and use of drugs."

In conclusion (Suleman, 1995), the study highlighted two areas into which detailed research is required. The number of drugs prescribed in the public sector; qualitative studies to define the factors affecting prescribing decisions; "studies on prescribing pattern need to be carried out regularly to monitor trends or changes in prescribing behaviour and generic prescribing need to be used to ensure RDU".

4.3.5 Research in Rational Drug Use (MEDUNSA, 1998)

In response to two of the recommendations (training in Effective Prescribing and Drug Supply Management) of the first pharmaceutical study in Northern Province (1996) an intervention was undertaken by MEDICOS/ MEDUNSA (Medical University of South Africa). The intervention, a training programme, was developed, implemented and evaluated by the same group. A report, 'Training for the implementation for the Essential Drugs Programme in the Northern Province, January – December 1997' was published (MEDUNSA 1998). The report describes an intervention that was designed to implement the training and evaluate its effectiveness. The study's goal was to train one person in every Primary Health Care facility in both Effective Prescribing and Drug Supply Management. A training cascade was set up with trainers selected from various regions. In total 45 people were trained as trainers. Then 22 Effective Prescribing courses to train 450 people and 16 drug management courses that trained 339 people were conducted. After the training, research was conducted in PHC clinics in the Lowveld Region of the Northern Province. The research was a pre-test / post-test intervention study conducted on the effectiveness of the Effective Prescribing course.

A quantitative study of 90 prescriptions was assessed retrospectively for two conditions (Upper Respiratory Tract Infection and Diarrhoea & Vomiting). Also, structured patient exit interviews were conducted. The results indicated that the prescribing patterns of the intervention study group were significantly better than in the control group. The training for the study group showed that the prescribing approach taught was carried over from conditions covered (URTI) in the training to conditions not covered (diarrhoea & vomiting) in the training. The recommendations (MEDUNSA, 1998) of the study were:

1. Planning for the continuation of the project
2. Informing management of the training (for support)
3. Technical supervision and empowerment of trainers
4. Inclusion of supervisory staff
5. Training of medical practitioner in Effective Prescribing
6. Conduct a follow-up survey to measure the impact of the training intervention.

The participants of the Effective Prescribing course in their evaluation requested that additional topics to be included in the course to be: chronic patient conditions prescribing; chronic diseases, management of asthma; and more exercises for hypertension and diabetes. The other comments and suggestions included: more frequent courses, annual follow-up courses, EDL be part of PHC curriculum; doctors and pharmacists should be

trained. In addition, training could provide awareness of their preferred 'personal drugs' and 'treatment' regiments, since this will allow them a better understanding of how and why they could practice poly-pharmacy or non rational drug prescribing.

4.3.5 The Rational Drug Use Training Project (Orrell, 1998)

During the same period a Rational Use of Drugs project was conducted in two other provinces. The Rational Drug Use Training Project (1997) was based on a MSc thesis (Orrell, 1997) by Dr. Catherine Orrell (MBChB, DCH) at the University of Cape town, Department of Pharmacology. The title of the research is "T*he development, initial implementation and support of a primary health care training programme in rational drug use."*

The Rational Drug Use Training Project is a District-oriented programme designed to improve rational drug use among primary health care (nurse) prescribers in South African public sector. The Project was a train-the-trainer; district-oriented programme designed to improve rational drug use among Primary Health Clinic (PHC) prescribers in the public sector.

The project began early 1996 with the directive to improve drug use at facility-level. Baseline prescribing data was collected at three primary care facilities in December 1996, before the first set of training workshops. Data was collected again March 1997 after implementation of the training. The training was implemented in three facilities in Region B of KwaZulu-Natal. The project had three components: 1) drug use indicators adapted from those developed by WHO/INRUD, 2) two-day training workshop in rational drug use, 3) set of unbiased written resources.

The program was designed as a train-the-trainer system, training workshop in rational drug use using district staff as the trainers for twelve participants. It was a problem-based and held on-site in primary health care facilities. "The workshop was divided into four modules, which could stand-alone or be taught together. These cover principles of prescribing, use of standard treatment guidelines, principles of clinic stock management and principles of good dispensing" (Orrell, 1998).

The achievements of the workshop intervention were "significant improvements in prescribing and dispensing habits. There was an increase in the percentage of drugs prescribed by their generic names (25% to 43%, p=0.000). In addition, the training resulted in an increase in the number of medications adequately labelled (43% to 52%, p=0.0132), a decrease in the cost of prescriptions (R9.27 to R5.39, p=0.0134). In addition there was a decrease in the number of prescriptions that did not follow standard treatment guidelines at all for that diagnosis (31% to 11%, p=0.0109). The Mann-Whitney U-Test was used for statistical analysis. There were no significant changes in several important areas. First, the average number of drugs per prescription (2.76 to 2.68); and second, the percentage of drugs from the Essential Drugs List (74% to 77%); and the number of prescriptions that completely followed standard treatment guidelines (13% to 14%) (Orrell, 1998).

The problems with the implementation of the study were due to personnel. "This was a difficult study to undertake. The district trainers needed for the cascade approach were not available, and therefore clinic sisters, with full-time commitments elsewhere, where asked to be trainers for their facilities. These staffs were not people who had been trained to train. Although they fulfil their commitment to the study, they were unwilling to carry on with this additional role. The few-trained trainers moved on to other posts within a few months of the study. At this stage, therefore, the training was not sustainable."

In addition, "District staff found it difficult to function as a team. There remain many hierarchical divisions e.g. hospital-clinic, doctor-nurses, nurse-pharmacist, with poor and misunderstood communication between them. The will of district prescribing staff to learn was low. No incentives have been provided to nursing staff who are now expected to be South Africa's primary care prescribers" (Orrell, 1998). The study found five additional conclusions about drug use and prescribing (Orrell, 1998). The five conclusions are:

1. **Clear prescribing policies** for districts are not apparent.

2. A **lack of teamwork** exists. Doctors behave according to their own rules, as do nurses. The hierarchical atmosphere does not facilitate empowerment....Nurses do not feel supported by doctors.

3. **Patient demand** can be overwhelming, especially for cough mixtures and injections that promote irrational prescribing behaviour.

4. Difficulties in **implementation of treatment guidelines**. The guidelines for TB treatment were inconsistent with the packaging of the medicine received, forcing re-packing.

5. There is **limited supervision or monitoring** of drug use/ prescribing practices within the district.

Orrell stated that cooperation and links between health professions is needed not only at the hospital and clinic levels, but also the DOH and university levels. "All programmes need to be in step with the department of health. The South African Drug Action Programme is beginning this training of trainers in prescribing and drug supply management this year. The Rational Drug Use Training Project was in some senses ahead of the department for 1997. It was difficult to obtain permission for training in some provinces as we were not in step with SADAP." In addition, "Universities and other academic institutions could be rich resources for the primary care system. People need to be encouraged to share information from primary to tertiary level and vice versa. *Healthlink* helps greatly in this process." (Orrell 1998)

The researcher concluded (Orrell 1998:102), The Rational Drug Use Training Project has shown that "rational drug information, using a train-the-trainer approach, with a problem-based workshop as an intervention, quantitatively improves drug use, as described by the prescribing, dispensing and stock management drug indicators." In 1997, the Rational Drug Use Training Project expanded to eight other health districts.

4.3.6 Summary of Research Conducted in Developing Countries

Few systematic reviews, research and analysis of national and international efforts at pharmaceutical policy development (NDP) and its accomplishments have been carried out in developing countries. One published study in Yemen evaluated the impact of the NDP intervention with a control group. The results were a significant difference in rational drug use indicators between the test and controls groups.

A comparative analysis study of National Drug Policies in 1996 conducted in twelve countries to assess their performance in implementing the NDP. The research was conducted in Bulgaria, Chad, Colombia, Guinea, India, Mali, Philippines, Sri Lanka, Thailand, Vietnam, Zambia and Zimbabwe. For the study, most of the INRUD, NDP

indicators were used, while a few new indicators were added. One country, Thailand used political mapping to understand the process of policy formulation and implementation. The study showed that policy-makers need both technical and political analysis in order to implement effective interventions.

The Thailand experience showed that more than 29,000 drugs were registered. The National EDL covered only the public sector. The Thailand study showed that the NDP structural indicators were in place within the policy structure, the process and outcome indicators lagged behind, specifically, the implementation of the policy with law enforcement. The study revealed that the variety of drugs under various brand names caused confusion and increased irrational drug prescribing. Several outcome indicators also showed that prescribers had difficulties with rational drug use.

The most significant findings for the study were first; policy implementation affects the success of the outcome. The policy must be monitored regularly and continuously assessed for how the policy activities relate to policy objectives. Second, irrational drug use has multiple factors that include the quality of products, product information, qualification of prescribers and prescribing and dispensing behaviour. The solution is to provide unbiased drug information and adequate education and training, and institute incentives to promote rational drug use.

In South Africa, the first pharmaceutical study (1996) was by MEDICOS and MEDUNSA evaluated the transformation of pharmaceutical and related services in the Northern Province in order to determine first, the impact of managerial control of drug procurement and distribution.

Second, to assess the effect of an essential drug programme on primary care services. The study concluded that injection and antibiotic use, generic prescribing, and compliance with STG/EDL needed more attention. Human resource issues included staff, awareness of the NDP and STG/EDL through training on effective prescribing, and drug supply management.

The study had three main conclusions and recommendations, first, an introduction to the National Drug Policy and the Essential Drugs List. Second a campaign to encourage generic prescribing and the use of standard treatment guidelines. Third, training in drug supply management and rational drug use or effective prescribing.

SADAP Baseline survey (1996-1998) of the ten key indicators of the National Drug Policy: selection, procurement, storage, distribution, quality control, information systems, facilities and equipment, cost implications, human resources development and drug use showed that the NDP uptake was small.

The baseline study concluded with recommendations that include, medicines not on the EDL must be returned to depot, the conclusions in drug use were awareness of the NDP must improve, objective drug information must be made available, training to improve supply and prescribing of medicines and basic financial management.

A strong commitment to the National Drug Policy by the National of education, and training in essential drugs and generic prescribing with the STG/EDL as a guideline tool do show some success, but over time do not seem to remain without re-introducing the goals through administrative. The use of Pharmaco-Therapeutics Committees (PTC) with the entire hospital team represented along with the other interventions allows for a higher probability of successful NDP implementation. Overall, the earlier studies have revealed a lack of rational drug use by prescribers. What is not known is how to make generic prescribing the norm months and years after the training has occurred and the promotion of the STG/EDL is not as strong.

4.4 Gaps in Research

The gaps in the research are apparent in 'policy analysis implementation as it is related to the health policy of the South Africa National Drug Policy. The focus is based on the top-down approach to implementation theory and approach to policy analysis and evaluation. Few in-depth case studies in the implementation of the National Drug Policy (NDP) in a developing country have been competed in the last ten years. A lack of focus in the systematic in-depth evaluation of the Knowledge, Attitudes, and Practice (KAP) of those on who implement the NDP through the use of the STG/EDL on a daily basis will be one of the major evaluative components of this research. The qualitative study through interviews specifically address evaluation and analysis of the cause and effect relationship to the quantitative results of the drug utilisation. The research addresses both of these gaps.

Research that has been conducted to date in policy analysis implementation, especially as it is related to health policy and programmes outside of Europe and American is apparent after the literature review. Most studies of implementation have been conducted in the USA and Europe. Of these studies, few focus on the implementation of legislated health projects in the public sector. Few implementation studies still have been conducted in Southern Africa in the area of health programmes. The research on the impact of South Africa's National Drug Policy implementation in public hospital clinics will contribute to the literature in the Implementation Theory, with a top-down approach, school of thought. Specifically, this research project will fill some of the gaps in both the theoretical literature on policy analysis and specifically the use of implementation approach to policy analysis and evaluation.

Second, there is a lack of in-depth case studies in the implementation of the National Drug Policy (NDP) in a developing country. Existing studies have shown two main gaps. First, a political analysis of the formulation and implementation of the NDP, Essential Drug Programme (EDP) and tools that are used (STG and/or EDL). Second, an understanding and analysis of the reasons that underline the quantitative study results of the NDP, and specifically, Rational Drug Use (RDU). According to International Network of Rational Use of Drugs, INRUD, (1996), "Many studies have succeeded in documenting drug use problems, but few have examined the factors underlying these problems in a meaningful

way. Yet such studies are needed to provide policy makers and managers with useful insights into the types of interventions that might succeed in correcting these problems."

A gap exists in the systematic in-depth evaluation of the Knowledge, Attitudes, and Practice (KAP) of those on who implement the NDP through the use of the STG/EDL on a daily basis. Therefore, policy implementers have been unable to successfully develop innovative ideas and recommendations for interventions in order to improve implementation of the NDP outcomes, specifically rational drug use. This research seeks to address both of these gaps in the research genre.

CHAPTER FIVE

LITERATURE REVIEW

5.1 Introduction of Three Topics

This literature review summarises previous work on policy analysis and evaluation of the implementation of social programmes within the arena of health sector reform. A fuller understanding of organisational management and of strategies and interventions for changing behaviour will be a prerequisite for successful implementation of rational drug prescribing. Successful intervention can only be achieved through analysis of both the political and personal forces that influence the adoption of a policy change, and the interventions to address the shortcomings of the intended policy. Once this information has been collected, analysed and understood, then policy implementation is addressed through appropriate interventions.

Implementation success or lack thereof is defined by the extent to which the policy has been adopted by those who are to make it a part of their day-to- day professional lives, and the proposed interventions in order to improve compliance with the policy.

This literature review looks at four topics:

(I) Organisational Management Theories
(II) Policy and Implementation Theory
(III) Rational Use of Drugs

5.2 Organisational Management Theories

Organisational Models of Social Programme Implementation

This section reviews the literature on theoretical organisational management models, the politics of change and the psychosocial adaptations to organisational change.

An understanding of organizations is central to the analysis of policy and/or programme implementation (top-down or bottom-up approach). In the area of implementation theory the literature on organizations is diverse and contradictory (Elmore, 1953). As a result the knowledge in the field is said to be soft, as it is 'extremely difficult to use knowledge of this sort as the basis for analysis. There is no single, coherent body of organisational theory that will serve as the basis for analysis' (Elmore, 1953). Since there is not a single model to adequately represent the full complexity and breadth of the implementation process, it must be viewed from a number of different organisational models. The four models that represent the major schools of thought are (Elmore, 1953): 1) systems management model, 2) bureaucratic process model, 3) organisational development model and, 4) conflict and

bargaining model. Each model can be a legitimate analytical tool. In both the systems management model and the bureaucratic model, policy is made at the top and implemented at the bottom.

a. Systems Management Model (Elmore, 1953)

Organizations operate as rational value maximises. The structure is hierarchical control and the top management has the responsibility for policy-making. The model starts from the assumption that effective rational management is derived from goal-directed, value maximising behaviour. Success is based on the extent to which the organisation maximises performance of their goals and objectives. Every task can be carried out to its optimal end if it is allocated among the most appropriate subunits (subordinates). Implementation is carried out with a detailed set of policy objectives and performances monitoring which are adjusted when necessary to attain the organizations' goals. Because the emphasis is on hierarchical control, no allowance is made for lower-level subordinates to carry out the policy at their own discretion. Subunits are held responsible for a reaching certain goals. Managers are responsible for achieving these goals with their subunits. This is called sub-optimisation and it provides a means to exercising hierarchical control. Effective implementation requires four main ingredients: 1) clearly specified tasks and objectives that accurately reflect the intent of the policy; 2) a management plan that allocates tasks and performance standards to subunits; 3) an objective means of measuring subunit performance; 4) a system of management controls and social sanctions. The systems management model is a theoretical description of how organizations should function. It is not intended to describe reality and will work if everyone behaves according to the organisation.

b. Bureaucratic Process Model (Elmore, 1953)

In this model the organisation has two attributes, discretion and routine. The bureaucratic model assumes that the dominant characteristic of organizations is resistance to change and that it fights to remain the same. All behaviour in organizations can be attributed to the discretion exercised by individuals in their day-to-day decisions and routines. Decisions and routines are chosen to maintain or enhance their position of power. Power within the organisation is fragmented between many individuals. The more complex the organisation the more specialised the jobs and the greater control individuals will exercise over their

area of expertise. Decisions, like implementing policies, are made through controlling discretion and through changing routines.

Individuals resist the hierarchical management and try to do what they want until a way is found to make them change. Delivery of service to the client which allows for discretion and routine, is the most difficult to change. The distinctive quality of street-level bureaucracy is that discretion increases as one moves down the hierarchy. "Whether or not the policy has its intended effect on the client depends in large part on whether the force of existing routine at each level of the process operated with or against the policy." Most importantly, street-level bureaucrats are usually not included in the policy-makers' definition of policy. Instead of being thought of as being central to the implementation process, the street-level bureaucrats are ignored or thought to be external to the implementation process. "Bureaucratic coping behaviours cannot be eliminated, but they can be monitored and directed by rewarding those who most closely conform to preferred public objectives and discouraging objectionable practices" (Elmore, 1953).

c. Organisational Development Model (Elmore, 1953)

The Organisational Development Model begins from the premise that the needs of the individual, rather than those of the organisation, must be considered first. The emphasis is on individual motivation and commitment, work in-groups, and an explicit rejection of traditional notions or organisational efficiency. The organisation's function is to satisfy the psychological and social needs of individuals. The organisation should maximise individual control, participation and commitment. To achieve this, the best structure is one that minimises hierarchical control and allows for responsibility to be distributed between all individuals. Effective decision making is dependent on building consensus and on the effectiveness of those who work in a group. Strong and positive interpersonal relationships are necessary. Implementation is accomplished through consensus building and compromise between policy-makers and implementers. Work is conducted in-group. Consensus in goals, individual autonomy, and commitment to the policy are necessary. According to organisational theorist Chris Argyris (1960 & 1993) , adult behaviours like self-motivation, independence, responsibility for one's actions, courage of ones convictions, and honesty that are seen positively outside of an organisation are directly contradictory to what is expected inside an organisation. In this model, policy-making and implementation have no clear distinction. If there is a failure of implementation, it is

because of a lack of consensus and commitment within the group (Elmore: 1953). In short, implementers shape the policy, and the behaviour of the implementers is shaped by the policy. "The only way an innovation (or policy) can become established in an organisation is for the implementers to learn it, shape it, and claim it for their own" (Elmore, 1953).

d. Conflict and Bargaining Model (Elmore, 1953)

In this model, conflict and bargaining (explicit and tacit) are the foundation of organisations. Conflict and bargaining occurs within and among implementing agencies. There is not necessarily a common purpose within the organisation. Individuals in the organisation have specific interests. They compete to gain advantages and resources, and to exercise power. The distribution of power is always changing. It changes according to how power and resources are shifted to meet the goals of an individual or unit. Decision – making and implementation occurs through bargaining to reallocate resources. "Much of the behaviour in the implementation process is designed to shape the expectations of other actors...the important fact is not whether the rules are enforced or not, but the effect of their existence on the outcome of the bargaining process" (Elmore, 1953). Outcomes are a result of temporarily bargained solutions that do not necessarily reflect an agreement on common purposes. The success or failure of a social programme is dependent on the power to force individuals to conform to a single policy. Since the environment is characterised by conflict, changes are achieved through bargaining. Overall, success is measured relative to the goals and the preservation of the bargaining process itself.

The model that is most appealing for the implementation of the NDP, STG/EDL tool is the Organisational Development Model. In the attempt to change prescribing habits, the emphasis on individual motivation, personal commitment and working in-groups seems ideal. Since there are strong divisions between professionals who administer policy, prescribe, and carry out orders, this model with its co-operative approach would not be practical. The model that is the most practical is the Systems Management Model of organisations, even though it is not possible to change or control people's behaviour to the extent that their every action is oriented to utilisation and maximised towards the organisations stated goals.

e. The Psycho-social dimensions of change

Change requires the disappearance of something that was known and brings with it a sense of loss, and thus bereavement (Iles, 1997). As groups within organisations are exposed to change, reactions to loss and bereavement are well documented. The stages of grief are denial, anger, grief, resignation, and acceptance. These stages do not necessarily occur in this order or one at a time. One may go between any of these stages until the final acceptance of the loss. The evaluation of change in organisations – one of the most valuable elements of any policy and/or programme – is often neglected. The following questions are helpful in evaluating change (Iles, 1997):

Reviewing the change:

- Did the change achieve its objective?
- How closely did the actuality mirror the plan?
- How and why did it differ?
- How do the stakeholders feel about the change?
- Is there anything else that needs to be done to achieve the objectives or to influence the feelings of stakeholders?

Learning for the next time:

- What should be done differently next time?
- Why and
- how

The psychosocial dimensions of organisational management and its review of the change is helpful in directing and understanding the difference between the objective wanted and the actual outcome. Answers to these simple questions can help with the recommendations for the future and a plan of how to more forward.

Summary of Organizational Management theories

This section reviewed the models of organisational management, politics of change and the psychosocial dimensions of change within organisations.

5.3 Policy and Implementation Theory

This section reviews the literature on public policy and policy implementation theories. This research is located within the field of policy analysis through the evaluation and analysis of implementation. South Africa's NDP has a high level of government commitment. One of the goals within the NDP is rational drug prescribing to which measurable entities and explicit guiding criteria for implementation and evaluation are not clearly stated. Explicit targets have yet to be set. Walt (1994) stated: "Severe problems have been experienced in implementation of structural reforms in the absence of guiding criteria on who should execute policy change and how to implement them." The NDP Essential Drug Programme policy of using STG/EDL in all public health institutions and specifically its implementation through training to increase the adoption of this RDU tool, have yet to be clarified.

a) Policy

A definition of *policy* by Hogwood and Gunn (1984) is: "A policy usually involves a series of more specific decisions, sometimes in a 'rational' sequence (e.g. deciding there is a problem; deciding to do something about it; deciding the best way of proceeding; deciding legislation; etc.). Even when the sequence is more erratic, a policy is typically generated by interactions among many, more or less consciously related, decisions." Policy, and policy analysis has borrowed techniques from a wide variety of disciplines including political science, public administration, economics, sociology and management. For Hogwood and Gunn (1984), the role of policy analysis " is not to replace but to supplement political advocacy." Analysing public health policy requires various techniques. For Leichter (1979), a scheme for analysing public policy is using contextual health factors that never act in isolation. Instead, the factors make up a framework of analysis in which there is a continuous and simultaneous interplay of factors in both policy formulation and implementation, which must be considered and evaluated. The type of policy will have a substantial impact on the kind of political activity that is promoted by the policy making process. The extent, to which a policy seeks to introduce changes in social, political, and economic relationships, will have an equal and opposite reaction from those who do not want change.

In both the formulation and implementation of a policy or programme, there are four areas that must be considered in order to increase the likelihood of success. The four areas that

must be considered are the situational, structural, cultural, and environmental context (Hogwood and Gunn, 1984).

(i) Situational: Events or sudden changes like violent events, economic cycles, natural disasters, political events, technical change and policy agenda can have a large impact on the success of implementation of a new policy.

(ii) Structural: long-term characteristics and/or features the political system, economic base, social demographic composition, and natural resources.

(iii) Cultural: Values, beliefs, norms that determine interactions. These include national heritage, religion, language, political orientation, kinship, and social norms.

(iv) Environmental (International): factors that originate outside a country. These can include foreign trade, policy diffusion, international agreements, scientific knowledge, technical assistance, monetary aid, trans-national private corporations, international organisation affiliation, environmental impact, etc.

In short the formulation and implementation of a policy that is to be successful needs to take into account the situational, structural, cultural and environmental areas. Implementation is a part of policy making and also of policy analysis. Conversely, a policy is not better than its implementation (Hogwood and Gunn, 1984). Furthermore, Hill states (1993), "to understand the policy process as a whole it is necessary to give attention to policy implementation." Hill goes on to say, one is "prone to disregard was the extent to which this activity would tend to transform policy, often fundamentally. Recognition of this has given implementation studies a crucial importance in the study of the policy process." Hill (1993), states that "rather than treating implementation as the transmission of policy into a series of consequential actions, the policy-action relationship needs to be regarded as a process of interaction and negotiation, taking place over time, between those seeking to put policy into effect and those upon whom action depends."

5.3.1 Policy Implementation Theory

Implementation should establish the means to allow goals of a public policy to be realised. Policy and/or programme implementation is frequently used interchangeably. Policy implementation is usually thought to be a necessary link to and part-and-parcel of programme implementation. The policy statement of its goals, objectives and means are translated into programmes that aim to achieve the policy objectives. Therefore the study of policy implementation involves an analysis of the programmes and interventions that have

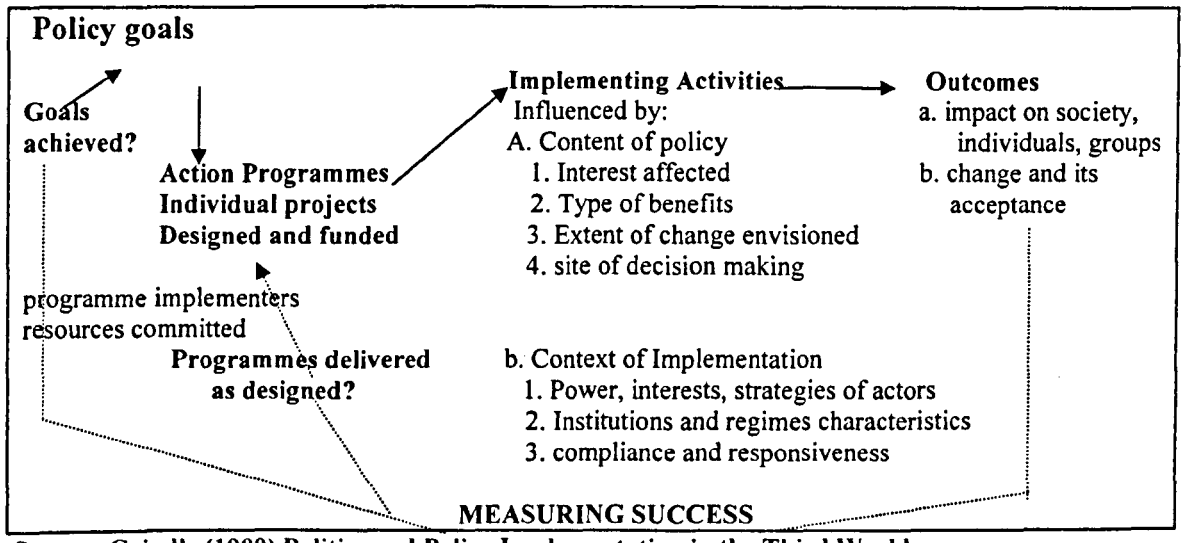
been designed to meet the policy goals. "Overall policy implementation can be evaluated by measuring program outcomes against policy goals" (Grindle, 1980). The success or failure of the implementation of the policy and/or intervention is determined by whether the programmes were delivered as intended. Implementation is a political and administrative process. The content of the public policy or programme is one of the important factors that determine the outcome and acceptance of initiatives for implementation. The most variable factor in any policy and its implementation is the stakeholders some of whom want change and others who are opposed to change. The degree of behaviour change that is necessary will affect the implementation of the policy. Also, as the number of sites for the implementation becomes more dispersed, geographically and organisationally, the execution of the programme become more complex and difficult because of the increase in the number of people and their decisions to further or hinder the policy. Hill (1993) states that when implementation involves innovation and changes that are a major departures from previous policies and practices, "there will be a particularly high probability of suspicion, recalcitrance, or outright resistance from affected individuals, groups, especially if insufficient time has been allowed for explanation and consultation or if any previous experience of change has been unfortunate. We cannot (and should not) hope ever to be free from such resistance, but we can learn the responses open to administrators from the study of individual, group, organisational, and political behaviour."

5.3.2 Implementation as a Political and Administrative Process

Implementation is an ongoing political and administrative process (Figure 5.1) of decision making by stakeholders that is influenced by both the programme and policy content, and the environmental context. Grindle (1980) perceives the implementation process as an ongoing process of decision-making that inevitable involves a large number of actors (stakeholders). In the daily processes of implementing a policy or programme, stakeholders make choices about how to implement the policy in an attempt the outcome. Each of the stakeholders has a personal interest in the success or failure of the programme or policy. The goals of various stakeholders will be in direct conflict with each other. Only some will be ale to reach their goals. Depending on the resources, power, strategies and position of the stakeholders. A full analysis of the implementation of a programme or policy must include an assessment of the stakeholders' interests, "power capabilities" and resources for achieving them. The arrows in figure 5.1 show that decisions made at one point have consequences that are important for the decisions that are made later. The arrows with the

broken line show that the political and administrative environment in which they are made influences decision outcomes.

Figure 5.1 Implementation as a Political and Administrative Process



Source: Grindle (1980) Politics and Policy Implementation in the Third World

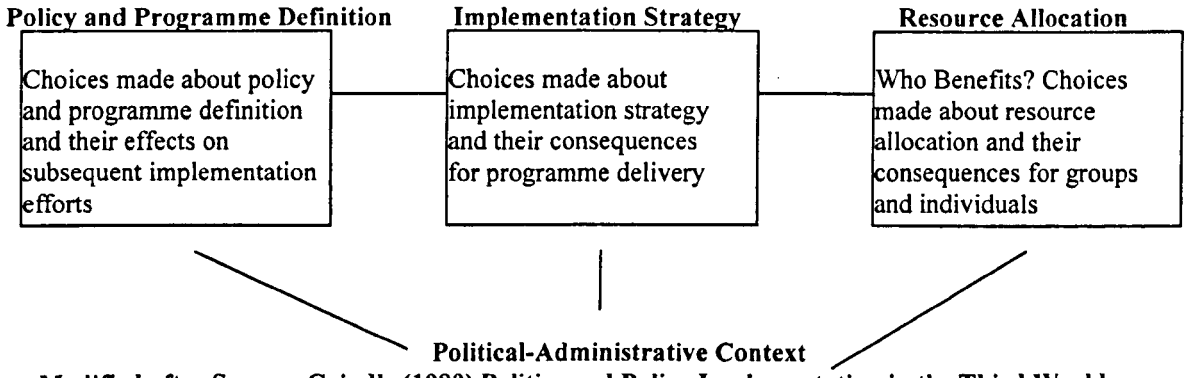
5.3.3 Challenges for Organisational and Administrative Policy Implementers

Organisational and administrative policy implementers are usually faced with two difficulties. First, how to achieve compliance with the policy, for example using the STG/EDL. Achieving compliance may entail bargaining, compromises, accommodation and great conflict. The second difficulty consists of creating a responsive environment that provides flexibility, support and feedback. . In programme /policy success "decentralisation may be a viable strategy where central authorities retain the capacity to ensure that implementing activities remain within the boundaries of the program objectives and structures" (Grindle, 1980). Simultaneously, administrators must maintain a level of control over the resources for the stated goals of the programme to be achieved.

5.3.4 Critical Choices in the Implementation Process

Implementation is an ongoing process of decision making of analysing how and why choices are made and the consequences of these choices for the implementation of the policy. The three critical choices in the implementation process (Figure 5.2) first the policy and programme definitions. Second, implementation strategy and third, resource allocation.

Figure 5.2 Critical Choices in the Implementation Process



Modified after Source: Grindle (1980) Politics and Policy Implementation in the Third World

For successful implementation, political and administrative leaders for successful implementation need to develop unambiguous goals for programmes to fulfil policies, with developmental and incremental objectives (Grindle, 1980). The choices of which organisation will implement which part of the programme goals and how, the mechanisms for accountability, monitoring, evaluation, and reporting, are all aspects of the strategic choices for implementation. Implementation is likely to be carried out by various governmental and non-governmental, national and international agencies. The choice of which agency will be responsible for which part of the implementation is critical.

5.3.5 Theories on Implementation: Top-Down and Bottom-Up Models

The two main schools of thought in implementation theory are the top-down approaches (Hogwood and Gunn:1984, Hill:1997, Sabatier:1979, Mazmanian & Sabatier:1981, and Elmore:1953) and the bottom-up approach (Hjern, and Porter, :1981; Hanf:1982, and Brinkerhoff:1991) that includes implementation policy analysis. The difference lies in who makes the policy and who has control over the implementation of the policy; management and policy-makers versus street-level bureaucrats.

a) Top-Down Approach to Policy Implementation

The top-down approach to the analysis of policy implementation (Hogwood and Gunn:1984, Hill:1997, Lipsky:1980, Elmore:1978) starts from a policy decision and focuses on the extent to which the objectives are attained over time and why. The main issues are the effectiveness of specific governmental programmes and the ability of officials to guide and constrain the behaviour of target groups. This evaluation requires an

analysis of the formally- approved objectives of officials, an evaluation of performance indicators, and an analysis of factors affecting performance.

Implementation studies carried out in the 1970's, used the top-down approach to look at factors that undermined 'the perfect implementation' and gave prescriptions about how to avoid failure of the 'perfect implementation.' Hogwood and Gunn (1984) assert that perfection is an ideal concept or an idea, but can to be achieved. In order for the ideal concept of perfect implementation to be achieved, nine preconditions would have to be accomplished. These nine preconditions are:

1. The circumstances external to the implementing agency do not impose crippling constraints.
2. Adequate time and sufficient resources are made available to the programme.
3. The required combination of resources is actually available.
4. The policy to be implemented is based upon a valid theory of cause and effect.
5. The relationship between cause and effect is direct and there are few, if any, intervening links.
6. The dependency relationships are minimal.
7. There is understanding of, and agreement on, objectives.
8. Perfect communication and co-ordination.
9. Those in authority can demand and obtain perfect compliance.

This theoretical model within top-down approach to implementation research is policy centred, rational, prescriptive, and linear. The stages for this approach are circular: formulation, implementation, evaluation, and reformulation. The goals of policy makers are accepted as valid. The "top-down approach is useful, first in cases where there is a dominant public programme in the policy area under consideration or where analyst is solely interested in the effectiveness of a programme" (Hill 1993). Sabatier (in Hill 1993) goes on to say, "the concern of top-down theorists is with the manner in which legal and socio-economic factors structure behavioural options need to be incorporated into the synthesis." The top-down approach starts with a policy decision, usually by government officials, and then asks a series of four questions (Hill 1993).

1. To what extent were the actions of implementing officials and target groups consistent with the objectives and procedures outlined in the policy decision?

2. To what extent were the objectives attained over time (i.e. to what extent were the impacts consistent with the objectives)?

3. What were the principal factors affecting policy outputs and impacts, both those relevant to the official policy as well as other politically significant ones?

4. How was the policy reformulated over time on the basis of experience?

The major proponents of the top-down theory are Paul Sabatier (1979) and Mazmanian & Sabatier (1983). The last twenty-five years has seen a large amount of research on policy implementation with a top-down perspective. Most of the research has been carried out in America and Europe. The majority of the American studies consisted in analysis of single case studies. Most concluded that the government had very little ability in or control over implementation of programmes. The second series of policy implementation studies, according to Hill (1993) were comparative in perspective and more analytical, but still had a top-down perspective. These studies, like Mazmanian and Sabatier (1983) "started with a policy decision (usually a statute) and examined the extent to which it is legally-mandated objectives were achieved over time and why." Sabatier and Mazmanian (1979,1983 cited in Hill 1993) assert that six conditions must be fulfilled for effective implementation. The first three can be influenced in the initial policy decision, while the other three are influenced by political and economic pressure that can occur during the implementation. If these conditions are met, then the behaviour of the street-level bureaucrats and target groups could be kept within acceptable limits.

The six conditions for effective implementation are (Elmore, 1993):

1. Clear and consistent objectives
2. Adequate causal theory
3. Implementation process legally structured to enhance compliance by implementing officials and target groups.
4. Committed and skilful implementing officials.
5. Support of interest groups and sovereigns
6. Changes in socio-economic conditions, which do not substantially undermine political support of causal theory.

Mazmanian and Sabatier (1983) applied and tested this framework to twenty-one studies in ten policy areas. The most important innovation of this framework is the "importance it attaches to legal structuring of the implementation process" (Hill 1993). They do not agree with the thoughts of Lipsky (1971), Berman (1995) and Elmore (1978) that it is inevitable in 'adaptive implementation' that policy-makers are forced to a large extend to accept to the behaviours and preferences of the street-level bureaucrats. Mazmanian and Sabatier (1983) reject hierarchical control. They argue that the behaviour of the street-level

bureaucrats can be kept within acceptable bounds if the six conditions for effective implementation were met over time.

According to opponents there are three problems with the top-down approach to policy implementation. First, it is questioned if top policy makers really want to and are able to set clear policy goals. Second, the goals that are set are often seen as contradictory. Policies are layered on earlier ones. Third, the normative view of the top-down approach is questioned. Why should the goal setting come from the top? Furthermore, inevitably policy must be adapted to fit the forces backed by ground-level stakeholders and street-level bureaucrats (Lipsky 1991, Berman 1978; 1980, Elmore 1978). Its opponents perceive the top- down approach to policy implementation research as weak and unresponsive. Specific criticisms are of these top-down approaches that it:

- starts from the perspective of the central decision-makers and neglects other actors (e.g. street level-bureaucrats) and the initiatives by them;
- is difficult to use in situations where there is not a dominant policy or statute;
- underestimates or completely ignores strategies used by street-level bureaucrats
- has a distinction between policy formulation and policy implementation. It ignores the possibility that organisations are involved in both stages and/or local implementing people and target groups often ignore central legislators and administrators and deal directly with one another.

b) The Bottom-Up Approach to Policy Implementation

The bottom-up approach of policy implementation research (Hjern and Porter 1981, Brinkerhoff 1996) is incremental, descriptive, and iterative. The bottom-up approach first identifies the actors involved in service delivery (local areas) and asks them about their goals, strategies, activities, and contacts. Those contacts are used to develop a network to identify local, regional, and national actors involved in planning, financing, and the implementation of both governmental and non-governmental programmes. This technique provides the bottom-up approach a mechanism for moving from the street-level bureaucrats (policy –makers, and management). It is concerned with a policy problem, but not primarily the implementation or carrying out of the policy. The focus is on understanding actor interaction in a specific policy sector.

The scholars of this approach conducted studies from 1975 to 1983, while at the Science Center in Berlin, Hjern and Porter (1981), and Hanf (1982) developed a methodology for conducting bottom-up implementation analysis. These bottom-up theorists believe that the distinction between formulation and implementation is useless (Nakamura and Smallwood 1980; Barrett and Fudge 1981; Hjern and Hull 1982). The inseparability of the formulation-implementation process is due to:

- Organisations are involved at both stages (formulation and implementation)
- Implementing groups can ignore central policy decisions
- It is difficult to isolate policy decisions and preferable to look at action and reaction (Barrett and Fudge 1981)
- Policies change as they are implemented, and so is better to evaluate 'policy evolution' (Majone and Wildavsky 1978)

These researchers believe that the bottom-up approach is more useful as it starts with a perspective of the street-level bureaucrats. The focus is on the analysis of the street-level bureaucrats who are the actors or stakeholders, and interact at the local or operational level. The focus of the bottom-up approach is on strategies that each actor uses in order to accomplish objectives. The studies that have been conducted showed that the actors often effect centrally mandated programmes in their favour to meet their own ends. Barrett and Fudge (1981in Hill) argue that "lower level actors take decisions which effectively limit hierarchical influence, pre-empt decision-making, or later policies." A case in point is Sabatier's (1993) comment on Hjern, Hanf and Porter (1978) study of the Swedish manpower training programmes, Sabatier stated the "program success was far more dependent upon the skills of specific individuals in 'local implementation structures' than upon the efforts of central government officials"

The strengths of Hjern's approach to implementation evaluation are the explicit and replicable method for identifying the implementation structure, the policy network. Second, the method begins with actors' perceived problems and the strategies that they develop to deal with them. Third, it does not start with a formal policy objective and evaluating its attainment, so they have the freedom to see all consequences of the programmes.

The limitations of Hjern's approach are the over-emphasis on the ability of the street-level bureaucrats (periphery) to frustrate the policy-makers (centre); second, the underestimation of the centre's indirect influence over the strategies and goals through its ability to change the institutional structure in which the street-level bureaucrats operate. Third, the resources of the street-level bureaucrats are taken for granted without inquiring about the how and

why of those resources. Fourth, it fails to start from an "explicit theory of factors that affects the actors. It relies on the perception and activities of actors, but does not evaluate factors that unconsciously, but directly or indirectly affect their behaviour" (Sabatier, 1993).

The respective advantages of top-down versus bottom-up approaches to implementation are dependent on the type of policy to be evaluated. The top-down approach is preferable when there is a dominant public programme or a single public agency that is under consideration or where the evaluator is interested in the effectiveness of a programme. It is best used when there is a dominant piece of legislation (statute) structuring the situation or the research funds are limited (Sabatier in Hill 1993). The bottom-up approach focuses on local implementation structures and is very good for assessing the dynamics of local variations. This is the better approach when the focus is on the inter-local variations, there is no dominant piece of legislation or there are a large number of street-level bureaucrats. If the interest is primarily in the dynamics of different local situations, the bottom-up approach is preferable.

Since the focus of this research is on the implementation of South Africa's National Drug Policy (dominant piece of legislation), tools of the Standard Treatment Guidelines/Essential Drugs List in public hospital outpatient clinics, the top-down approach is preferable.

This evaluation focuses on the impact, effectiveness, and outcome tools for rational drug prescribing in developing countries. The specific methods used will be discussed in Chapter Six, Methods.

5.3.6 Intervention of Behavioural Approach to Policy Implementation

Successful implementation of a policy should include strategies and interventions that are structured to meet the needs of the street-level bureaucrats/ stakeholders. The stakeholders translate policy into actions and ultimately outcomes. The top-down approach to evaluation of policy implementation does not take into account those who must implement the policy, even through their thoughts and behaviours can affect the success or failure of a policy. Widely accepted is the view that what happens in the implementation stage will influence the actual policy outcome. Moreover, "there are limits to what can be achieved by

manipulating structures and procedures. Human behaviour and attitude must also be influenced if policies are to be implemented." (Hogwood and Gunn 1984)

Policies are developed for and targeted towards a specific group to carry out its implementation. A good example of this is the implementation of the NDP, STG/EDL in public hospitals in South Africa. Often little attention and emphasis is given to implement the policy and actually put it into practice on a day-to-day basis. A major factor for success or failure is the acceptance of the policy. To achieve this, the stakeholders, the professional hospital staff, in this research must see a need for the change, agree to it, and then change their behaviour.

Policy acceptance needs to take place at the street-bureaucrat level, because these are the people who deliver services to the population, who have to change their behaviour (i.e. rational drug use), and who implement the policy. Not all professional hospital staff and particularly prescribers will see and adopt the policy as their own.

If the prescribing stakeholders resist the necessary change for the implementation of the policy, the policy will have a much smaller likelihood of success. Hogwood and Gunn (1984) state: "Those involved in implementing the policy who are targets of the policy may feel that they are being hustled into change because consultation has been too hurried, and the national reaction is to try to slow down the process by one mean or another."

5.3.7 Strategies for Policy Implementation and Intervention

The co-ordinated implementation model identifies three key capacities for managing changes (Brinkerhoff 1991) looking outward, looking inward, and looking ahead. Looking outward Policy makers must see beyond the boundaries of their individual organisations and become aware of who and what is out there which may have an impact, or effect on what they seek to do. This perspective includes recognising stakeholders, facilitating participation, building alliances, partnerships and forging coalitions. There is often less emphasis on looking inward, which focuses on the internal structure, systems and procedures that are needed for developing or maintaining interventions, the technical support for the implementation of a policy. Looking ahead is the ability to keep long term

goals and a change in mind, while managing the short term and is an invaluable capacity for policy implementation.

Looking inward allows the development of intervention strategies for enhancing implementation of a policy or programme and can be carried out on three levels: regulatory, administrative, and education for the design of interventions, the focus needs to be on improvement of an identified problem. To ascertain an effective intervention, a series of questions aimed at identifying the causes of the problem, the motivations and constraints of the hospital staff and their resistance to the necessary changed will be needed.

The most effective interventions combine elements from all three categories. The regulatory approach is designed to restrict decision-making and to remove choices about a behaviour (drug use behaviour from prescribers), and put them into the hands of the policy-makers and/or managers. Areas of regulatory approaches in the NDP could include market controls, licensing restrictions, prescribing and dispensing controls. Regulatory interventions are frequently easier to implement than administrative or educational interventions. However, "implementing a regulation without taking into account the understanding and acceptance of prescribers and consumers may cause unwanted side effects. For instance, generic prescribing policies are in place in public health facilities in many countries. When prescribers are not well informed about the advantages of generics, they may not comply with generic prescribing. They may also transfer their negative perceptions to patients, which will further jeopardise the implementation of the policy" (International Network for Rational Use of Drugs, 1996). The administrative or managerial approaches use processes and tolls designed to guide decision-making. Supportive processes are designed to make it easier to perform a preferred behaviour or through barriers against undesirable behaviours or practices. In prescribing practices this can include guides for prescribing and dispensing, guidelines, clinical pathways, standard order forms; systems for improving selection, procurement, and distribution of drugs; drug utilisation review combined with feedback to health care providers; and financial incentives. The educational approaches are based on communicating information and persuading health providers (prescribers) to change their behaviour. This approach is the most helpful when the problems are knowledge deficit, mistaken beliefs or biased information. Behaviour and opinions of peers can be very persuasive in changing behaviour. This intervention can be very useful if it is used in peer groups of health

providers. Each approach has various strengths and weaknesses (Table 5.1). These interventions work best when they are combined. Any intervention will need a sustained and additional effort, support, and refinements. Interventions need to be monitored, evaluated and the results disseminated so that adjustments can be made to the intervention.

Table 5.3 Strengths and Weaknesses of Intervention Approaches

Intervention	Strengths	Weaknesses
Regulatory Strategy	• Works best if safety is an issue, and problem behaviours are easy to isolate and eliminate • Frequently easy to implement • Can give powerful and rapid results • Best if combined with other approaches	• Frequently produces unexpected negative results • May be open to abuse • Often difficult to enforce • Impact difficult to measure
Administrative Approaches	• Works best when systems can be set up to make it easier to follow recommended behaviours • Can be used to support and sustain educational programmes • Very effective if target group assessed own practices • Improved supervision can have positive spin-off effects	• Open to abuse if administrative changes are not accepted by target group • Formularies, guidelines, protocols needed periodic revision • Information systems may be hard to establish and maintain
Educational Approach	• Works best if knowledge deficits are an underlying problem • Best results if message is clearly focused on specific issue • More effective with single individuals or small groups • Repetition and reinforcement of messages strengthens results	• Knowledge often cannot overcome system barriers • Disappointing results with broad messages and large groups • Can be labour intensive if there is a large target group • Transfer of staff or counter-promotion by drug companies can dissipate results

Source: INRUD (1996) How to Use Applied Qualitative Methods to Design Drug Interventions

5.4 Rational Drug Prescribing

5.4.1 Introduction

This section reviews the literature on rational drug use by health professionals and the interventions that aid in changing prescribing behaviour. The use of medication in both developed and developing countries often reveals a large discrepancy with principles of clinically acceptable practice. In developing countries the misuse of medicine ranges from travelling drug peddlers and street shops to prescribers in teaching and tertiary hospitals. Some of the commonly encountered inappropriate or irrational drug uses of prescribers include (International Network of Ration Use of Drugs – INRUD, 1996):

- Excessive use of injections where oral treatment is more appropriate;
- Multiple drug prescriptions, such as the use of several items for one condition;
- The use of drugs when no drug is indicated;
- The use of the wrong drug for a specific condition requiring drug therapy;
- The unnecessary use of drugs with adverse effects;
- The use of overly expensive drugs with cheaper alternatives.

The public health consequences of inappropriate or irrational drug use include (INRUD, 1996):

- Increased morbidity and mortality due to avoidable treatment failures;
- Increased risk of unwanted effects such as adverse drug reactions;
- The emergence of drug resistance such as Chlorolquine-resistance Plasmodium Falciparum and Penicillin-resistant gonococci;
- Waste of resources leading to increased costs and reduced availability of other vital drugs;
- Psychological effects such as when patients come to believe that there is "a pill for every ill" which may increase demand for drugs.

For many of the Third World countries, the main issue is still how to improve the availability of essential drugs, but rational drug use does not appear to be a priority for many governments (WHO, 1988). To date, in 2002 that has not changed. Hodgkin (1993) states that "rational drug policies and rational drug use are an important part of primary health care in both developing and industrialised countries, but the consequences of irrational drug use are much more serious in situations of extreme scarcity." According to WHO, "The rational use of drugs remains an area where progress is needed. There is no good system for providing objective information. In most countries, adverse reactions are not monitored and continuing education is not carried out systematically, 94% of the countries are at level 1for this indicator" (WHO report, 1988). Level 1 is the lowest level: "Continuing education is not systematic."

The contextualising, according to Kanji et al (1992) of 'rational drug use' is a major challenge to (WHO) DAP. It implies that criteria for 'rationality' cannot be defined at the national level and then applied at the district and local levels of health care. It emphasises the need for a 'bottom-up' approach to community participation, and methods that are advocated for health education in the context of PHC. In order to address the issue of rational drug use many governments have emphasised the need for further training for health personnel in health policy reform and the National Drug Programme and the use of the Standard Treatment Guideline / Essential Drugs List (STG/EDL). The essential drug concept meets with substantial resistance from those street-level bureaucrats who are to carry it out.

The availability of drugs is only one barrier to drugs getting to the population. Indeed, Foster (1991) states that "In the past few years, it has become increasingly clear that simple availability of drugs does not always solve the problem of drug use, and indeed, it often appeared in retrospect that supply wasn't the problem after all." Hogerzeil, (1991) agreeing with this view states, "adequate knowledge on rational drug use does not always result in rational prescribing behaviour. Actual behaviour is therefore preferred as a measurement." Hogerzeil (1995) concludes that, "Irrational prescribing is a global problem." Moreover, the use of the STG/EDL is not sufficient by itself to change prescribing behaviours. Training in the use of the STG/EDL, stock management, and rational drug use are all needed to allow health staff to meet the required changes. In addition other interventions including regulatory, and administrative or managerial approaches help to make a comprehensive, therefore, more likely successful intervention.

In 1993, WHO for the first time applied internationally developed indicators to investigate drug use in facilities. Before this innovation, indicators for the rational use of drugs were difficult to identify (WHO, 1988). It is not possible to quantify rational use *per se*; it has been assumed that certain mechanisms have an influence on the use of drugs before the development of indicators. Before the development of indicators, Rational Drug Use was measured by these mechanisms (WHO, 1988):

- A functioning system that regularly provides objective information on drugs to health workers and patients.
- A system of continuing education for personnel dealing with drugs.
- A monitoring system, covering adverse drugs reactions, and post-marketing surveillance.

5.4.2 Interventions to change prescribing behaviour

Indeed, changing prescribing habits is very difficult. The interventions to promote rational drug prescribing can be classified in three categories (Hogerzeil 1991) managerial, regulatory and educational. Managerial interventions include restrictions on prescribing, for example with a restrictive list, a maximum number of drugs per prescription, budgetary or cost restrictions and hospital therapeutic committees. Regulatory interventions include procedures to evaluate drugs and product information before market approval is granted; specifying a minimum level of prescriber or health facility for each drug or scheduling drugs for different sales levels. The educational interventions include objective printed materials and bulletins, seminars, and face-to-face interventions. Hogerzeil (1991), remarked that "An important observation is that printed materials alone hardly influence prescriber behaviour, and that any such influence is usually of short duration. Most of these interventions assume that the main reason for incorrect prescribing is a lack of knowledge and that if prescribers had the correct information, their prescribing would automatically improve. This is not always the case in view of the many other factors influencing prescribing, like drug promotion, patient demand, international use of placebo drugs and prescriber preference based on personal experience rather than peer reviewed standards."

"The provision of independent sources of both written and oral information on drugs to doctors can have a significant effect on prescribing"(Hodgkin 1993). According to Marinka & Reilly (1994), a framework of information to facilitate rational prescribing is needed:

- Class, generic names, and proprietary name of drug
- Therapeutic actions
- Data about unwanted effects and interactions
- Indications and contraindications
- Recommended doses and regimes
- Costs
- Significant differences from previously established drugs in the same class, or drugs with almost identical therapeutic intentions
- A risk-benefit analysis
- A cost-benefit analysis

"Both developing and industrialised countries are taking measures to promote rational prescribing. Formularies, therapeutic guidelines or limited drug lists are used to influence prescribing in advance and monitoring and auditing of prescriptions are due to evaluate in

retrospect, prescribing practices. Proven cost-effective interventions are face-to-face education focus on a particular prescribing problem in selected individuals, structured prescription forms, and focused educational campaigns together with widely discussed and frequently discussed guidelines." (Hogerzeil, 1991). Prescribing is assumed to be more rational if specific indicators have lower values. These indicators were used in a 10-country study for the external evaluation of Drug Action Programmes (DAP) of WHO. Various patterns of a lack of rational drug use were found. Moreover, "All the country studies showed that there was a lack of training and information on the rational use of drugs and that irrational use was therefore to be expected" (Kanji et al. 1992). Various groups in South Africa have initiated several programmes to encourage rational drug use for prescribers. The programmes have included the "Rational Drug Prescribing Training Program " (since January 1996); "Promoting Rational Drug Use" (27 March – 7 April 1995); "Introduction to Effective Prescribing Course" (13-15 August 1996). The longest running programme is the "Rational Drug Prescribing Training Project." It is a "train-the-trainers initiative that has been running since January 1996. It aims to encourage all prescribers at primary care level, be they nurses, pharmacists or doctors, to prescribe and dispense medicines in a safe, efficient and cost effective manner" (Orrell 1997).

The most effective training strategies (Table 5.2) to change prescribing behaviours are: Feedback with recommendations (Drug Utilisation Reviews) and Peer Group audit, for example a hospital Pharmaco-Therapeutic Committee (PTC).

Table 5.4 Summary of the impact of different educational strategies

Educational Strategy	*Knowledge*	*Prescribing*	*Costs*	*Outcomes*
Printed material,	0	- -	- -	-
Individualised Face-to face	+	++	++	0
Lectures	+	+	+	+
Raw feedback of data	-	- - -	+	*
Peer group audit	*	+	0	+
Feedback with Recommendations (DUR)	-	++++	++	*

Cell indicators: +(positive result); - (null results); 0 (inconclusive); * (no studies in this category)

Source: Davis (ed.), (1997:78) *Contested Ground.* New York: Oxford University Press.

Drug Utilisation Studies (DUS) can be used to measure the various types of prescribing behaviour interventions. In addition to training, Pharmacy and Therapeutic Committees (PTC) can be used to change prescribing behaviour. One objective of the NDP is to establish and strengthen Pharmacy and Therapeutic Committees in all hospitals in the country (both public and private) in order to ensure the rational, efficient and cost-effective supply and use of drugs. These therapeutic committees will consist of at least a senior pharmacist, a senior nurse, a senior financial officer and senior clinicians or their nominated representatives in their absence. Their terms of reference includes responsibility for:

- the accurate estimation, prompt procurement and optimal storage and supply of drugs and medical supplies
- the compilation and preparation of a hospital Formulary
- cost-effective drug use
- proper staff establishments to carry out these functions

In short, changes in the prescribing habits to incorporate rational drug use, according to Foster (1991) would allow for the "possibilities for significant savings in most areas of drug supply management and use. Potential savings from individual rationalisation measures range from 10% -60% or more. The biggest gains appear to come from better procurement and better prescribing."

As South Africa is still in the process of transforming its pharmaceutical policy, the issue of Rational Drug Use needs be at the forefront of implementation interventions. Kanji, *et al* (1992) stated in the forward of his book, *Drugs Policy in Developing Countries*, "It is important to raise the issues involved in promoting rational drug policies, especially now that Eastern Europe and South Africa are planning their new health systems."

This section reviewed the overview of rational drug use, prescribing behaviours, the framework of information to facilitate RDU and strategies for improving the acceptance of the National Drug Policy and the use of the STG/EDL.

CHAPTER SIX

METHODS

6.1 Introduction

The scope of the study is the National Drug Policy (NDP), and Essential Drug Programme (EDP) is implemented in South Africa. It focuses on the question in how far rational drug prescribing and dispensing is implemented by staff in public hospital outpatient clinics (for adults). According to Kanji *et al* (1992), "looking at prescribing practices in government health care centres seems to be the most obvious way of measuring the rational use of drugs. It is through these centres that governments intend to increase the availability of essential drugs. Education and training are most commonly directed at health centre staff and health centres often keep record of patients and prescription which can be assessed retrospectively."

To this end, this study focuses on those who implement the EDP and use the Standard Treatment Guidelines/Essential Drug List (STG/EDL) in the public hospital clinics of South Africa. The rationale for this focus is that the successful implementation depends on those who must know, understand and accept, and put into practice the EDP agenda with its use of the STG/EDL as its corner stone. The prescribers must change their behaviour in order to carry out the NDP rational drug use objectives. For those stakeholders, political jostling and competing agendas and the struggle for professional territory, autonomy, and power is likely to make the implementation of the STG/EDL extremely difficult. The National Department of Health (NDOH) has limited the amount that can be spent on drugs that are not generic or on the EDL.

The 'ten-percent' cap on ordering brand drugs not on the EDL should result in changes in the drug budget in ordering, prescribing behaviour, and rational drug use. The ten-percent cap is one of the administrative/managerial and regulatory/legislative controls that have been adopted to change prescribing. The extent of the change in prescribing behaviour with regards to this 10% cap is a focus of this study.

This research takes a look at the intent of the NDP policy and the reality of its implementation. The NDP implementation is evaluated by looking at the policy intent, with rational drug use as its main goal, and the actual practice at hospital level, and the reasons for this discrepancy. The prescribers may fear a loss of autonomy and a reduction of their effectiveness in treating patients. The implementation of the NDP should take into account these grass root stakeholders. In the final analysis, staff co-operation is the essential in

order to fully and successfully implement the NDP. The most difficult aspect of any policy is to attempt to change the behaviour of those involved.

This study looks at the EDP implementation, a policy that was conceived on a national level but must be adopted on a provincial level and carried out by individuals on a local level, by physicians, nurses, and pharmacists. Hill (1993) asserts that "on methodological grounds, implementation is better studied by looking at the efforts of those at the bottom to make sense of these new inputs from the top". This implementation is evaluated through qualitative and quantitative methods. Quantitatively, this research uses survey drug utilisation indicators, developed by WHO and International Network of Rational Use of Drugs (INRUD). These drug utilisation indicators have been used in many countries, including Africa, Zimbabwe, Zambia, Mali, and South Africa, to both evaluate and monitor National Drug Policies. This study will encompass the top-down approach to the evaluation of policy implementation (Sabatier & Mazmanian 1979, Sabatier 1986, and Mazmanian 1983). Qualitatively, this study evaluates the implementation of the NDP through open in-depth interviews with hospital clinic personnel and administrative stakeholders. The Knowledge, Attitudes, and Practices (KAP) of health professionals will be evaluated through these interviews. Consumer stakeholders were not included in this study. The three reasons that consumer / patients were not included are first, there was not a public education campaign about the use of generic medicines or the use of the EDL. Second, among those in the Northern Province there is a high literary rate, which would make using questionnaires quite difficult. Third, the consumers speak a variety of languages that would require the use of an interpreter.

6.1.1 Research Questions

The main question this research addresses is, "Has the implementation of South Africa's National Drug Policy, published in February 1996, with the introduction of the Standard Treatment Guidelines[20] /Essential Drugs List in 1998,[21] resulted in rational drug prescribing[22] in South Africa's public hospital outpatient clinics?"

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[20] Standard Treatment Guidelines (STG) was developed in 1997 for adult care.

[21] Essential Drugs List (EDL), comprised of 300 drugs linked to standard treatment guidelines for use in hospitals. As of December 1998 there are three STG/EDL's one each for adult, paediatric and primary health care, but only the adult list was used for this research.

[22] Rational Drug Use / Prescribing is defined as "patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community." WHO, The Rational Use of Drugs, Report of Conference of Experts, Nairobi, 25-29 November, 1985.

A policy analysis implementation approach guides this research of National Drug Policy ("getting medicines to the people") implementation within a developing country. The National Drug Policy was formulated on the national level by the government stakeholders, implemented on the provincial level by local department of health, and to be adopted at the point of service by prescribers.

The current political and legislative climate in South Africa continues to be fluid. Indeed, it is characterised by fast changes driven by politics within the context of health care reforms, including the NDP.

The framework for this research is a prospective policy analysis of the impact of NDP implementation. It adopts a policy analysis model of implementation with one focus on the behavioural approach. This model provides a basic and fundamental framework for considering the complex and often non-transparent inter-relationships between a number of stakeholders.

This study employed both quantitative and qualitative methods to evaluate both the impact of the implementation of the NDP with structural, process and outcome indicators and the knowledge attitudes and practice (KAP) of prescribers. The cross sectional study evaluates the implementation of the National Drug Policy (1996), Standard Treatment Guidelines /Essential Drugs List and its' impact on rational drug prescribing in South Africa's public hospital clinics.

In linking theory with field research the study focuses on three inter-linking approaches. The approaches of top-down, behavioural, and intervention policy implementation have been adopted. This study encompasses the top-down approach to implementation evaluation (Sabatier & Mazmanian 1979, Sabatier 1986, and Mazmanian 1983) that starts with a policy decision, usually by government officials, and then asks a series of 4 questions (Hill 1993):

1. To what extent were the actions of implementing officials and target groups consistent with the objectives and procedures outlined in the policy decision?

2. Is the impact consistent with the objectives?

3. What are the principal factors affecting policy outputs and impacts, both those relevant to the official policy as well as other politically significant ones?

4. How was the policy reformulated over time on the basis of experience?

The behavioural approach asserts that a successful implementation needs to include strategies and interventions that are structured to meet the needs of the stakeholders, who translate policy into action, and ultimately outcomes. Stakeholders' thoughts and behaviours can lead to success or failure of a policy. In this study attention and emphasis is placed on evaluating the extent to which prescribers believe that they are active participants in the policy implementation.

The intervention techniques to change prescribing behaviour are administrative, managerial and educational. Information and training are needed. Evaluation of the availability and type of managerial and educational interventions is an important part of this research.

In summary, the methods used to examine the implementation of the NDP policy is through both qualitative and quantitative methods. Qualitative methods are according to Mays and Pope (1999 &2000) "especially useful in looking at health services in terms of reform or policy change from the point of view of the patients, professionals and managers affected." Health care reform, and the rapid revision of legislation and the rapid implementation of new policies along with the fluidity of the political climate are some of the factors that make this research complex. In this environment the qualitative material can provide clarification not only of what is happening, but also why it is happening. The qualitative description is a prerequisite of good quantitative research, particularly in areas that have received little previous investigation (Mays and Pope, 1999 & 2000). This study evaluates the implementation of the NDP through twenty interviews with hospital clinic personnel and administrators who allowed for a more detailed and varied evaluation of health professionals' knowledge, attitudes and practices (KAP). In addition, well-recognised survey of indicators developed by WHO and INRUD was used.

6.1.2 Aim

This research addressed the void of objective information and gives an evaluation of the implementation of the National Drug Programme in developing countries, and in particular the use of tools such as the Standard Treatment Guidelines/Essential Drug List to impact rational drugs prescribing. Thus the aim of this research is to describe and analyse the processes of the implementation of the NDP and the STG/EDL (adult hospital version) and its impact on rational drug prescribing in public hospital outpatient clinics.

6.1.3 Objectives

The four objectives of the research are focused on the description analysis of the processes and the impact of the implementation of the NDP.

1. Survey and analysis of rational drug use patterns of prescribers of various levels of outpatient hospital clinics.

2. Assessment of the knowledge, attitudes and practices (KAP) of health personnel (physicians, nurses, pharmacists, and administrators) toward the implementation of the NDP and their training in the use of the STG/ EDL.

3. Identification of factors, which facilitate or hinder the proposed implementation of the use of the STG /EDL for rational drug prescribing within various levels of outpatient hospital clinics.

4. Examination of the policy implications of the research findings.

These four objectives have been met through several research methods that include primary and secondary data evaluation. The data are collected using the National Drug Policy Indicator Survey, observation and interviews. The data analysis is through the evaluation of the prescription data. Based on the findings of this study and after review of key documents, implementation interventions have been developed with will be useful for further improvement of the NDP implementation.

Table 6.1 Research Objective and Methods Grid

METHODS OBJECTIVES	*Data Collection in Outpatient Clinics*	*Data Analysis*
1.Analysis of rational drug use	NDP Indicator Survey	Evaluation of prescription data
2. Analysis of knowledge, attitudes and practices (KAP)	Open In-depth Interviews Non- participant Observation	Analysis of interviews and observations

3. Identification of factors which facilitate or prevent proposed implementation of the STG/EDL	In-depth interviews with stakeholders Non-participant Observation	Analysis of interviews and observations
4.Policy implications of the research findings.	Open In-depth interviews and result meetings with stakeholders	Document analysis

6.1.4 Hypotheses

The four hypotheses that have guided this research are:

1. The use of the Standard Treatment Guidelines / Essential Drugs List will result in an increase of Rational Drug Prescribing (RDP) in public hospital clinics at all levels.

The NDP implementing agencies:

South African Drug Action Programme (SADAP), the
National Department of Health (NDOH), and the
Northern Province Department of Health (NPDoH)

2. explicitly communicate the objectives and methods for implementation of the STG/EDL to the Head of Pharmaceutical Services (HOPS), Provincial Essential Drugs Co-ordinator (PEDCO) and personnel, who are to carry out the policy.

3. The implementation agencies' objectives, organisational structure, and programme plans reflect their goal to promote the use of the STG/EDL for RDP at all levels in the provinces in addition to providing training in its use.

4. Training and support for Rational Drug Use, specifically prescribing are encouraged and provided for all professional staff who are a part of the chain in the provision of medicines to the population.

6.1.5 Study Design

This study was designed to furnish both quantitative and qualitative information with interviews and observational and statistical data techniques. The field research design covered three approaches: (a) the application of a statistical sampling procedure for the drug utilisation study (b) participant observation at selected hospital clinics and pharmacies; and (c) the interviewing of physicians, nurses, pharmacists and administrators.

6.1.6 Research Design to Effect Policy

A longitudinal design would have allowed for the evaluation of the long-term effects of a policy. Specifically, if the policy and desired outcome and its applied changes last over

time, the best longitudinal studies are before and after an intervention for example (the NDP's, STG/EDL for hospital adult level). The longitudinal study design is said to be able to show 'the natural growth and trace patterns of change in the individual', and it is also asserted that it is the only method which can give a 'true picture of cause and effect of relationships over time (Kransz & Miller, 1991).

Since, a longitudinal study was not practical, the cross-sectional method was chosen because of limitations of time and resources, and a need for timely results to allow policy makers to change the policy implementation or content. According to Krausz & Miller (1991), "The cross-sectional design involves picking different samples or respondents, all the samples together providing thorough comparison evidence of relationships between variable or evidence of cause and change." This allows for sampling over a wide range of groups in order for the results to be applied generally. The research techniques employed were based on a cross-sectional study that encompasses three levels of hospital clinics: primary, secondary and tertiary and a variety of health personnel, administrators, pharmacists, nurses and doctors. Also this cross-sectional study collected data in eleven public hospital outpatient clinics in the Northern Province of South Africa.

6.1.7 The Case Study

The study employs a case study approach. Case study evaluations are valuable where broad. Questions have to be addressed in complex circumstances. No one method is sufficient to capture all the important aspects of an intervention, and case studies typically use multiple methods. The case study approach is "most valuable when the question being posed requires an investigation of a real life intervention in detail, where the focus is on how and why the intervention succeeds or fails (Mays and Pope, 1999 & 2000). In addition, several methods that complement the case study were employed including a survey of drug utilisation, in depth interviews, non-participant and structured observation.

6.1.8 Provincial Site Selection Criteria

Ideally, the study would be a cross-sectional study within all nine provinces. Failing this, it would be desirable to have from at least two provinces. After consultation with several people in South Africa, the Northern Province was selected for the following reasons: The Northern Province has *both* urban and rural settings with a large population of Africans, who lived in former homelands. In addition, the Northern Province has the infrastructure, experience, and co-operation of research before and since the implementation of the NDP

in 1996. Approval for this research was obtained from the Provincial Department of Health for this research.

6.2 Research Methods and Tools

In light of the objectives, hypotheses and research questions a mixture of quantitative and qualitative methodologies were chosen for this research to allow the cross validation of data with triangulation. The tools used include document analysis, an NDP survey, open in-depth interviews, structured and non-participant observation. The quantitative method of the NDP indicator survey was used to supplement the qualitative data of interviews and observation. In triangulation three or more methods are used and the results are compared for convergence or as part of a multi-method approach which examines a particular phenomenon or topic on several different levels (Mays & Pope 1999 & 2000). The triangulation of methods that was used in this research is a survey of rational drug use, participant and non-participant observation in pharmacy and therapeutic committees, open in-depth interviews of hospital personnel.

TABLE 6. 2 RESARCH QUESTIONS AND METHODS

Questions	Data Collection Method	Sources
Rational Drug Use		
1. What are the prescribing behaviours in Clinics?*	RDU Survey,	Patient Records
2. Prescribers using STG/EDL (%)?	RDU Survey, Observations	Clinics
3. Which drugs are out of stock on the day of the survey?	RDU Survey Inquiry of staff	Pharmacy records
4. Change of prescribing behaviours?	KAP, Interviews	Prescribers
5. What is the Attitudes, Knowledge, Practices towards the EDL?	KAP, Interviews	Prof. Staff
6. Is training & support in RDP given to staff?	KAP, Interviews	Prof. Staff
7. What are the factors that facilitate or prevent STG/EDL adoption?	KAP, Interviews	Prof. Staff
STG/EDL Guidelines		
8. Is the STG/EDL being used on a regular basis?	Observation	Prescribers
9. Is impartial drug information available?	Observation	Prescribers
Are prescribing books used regularly? Which books?	Observation	Prescribers
National Drug Policy		
11. What is the impact of the NDP on RDP in public hospital clinics?	KAP, interviews	Prof. Staff
12. Have NDP implementing agencies communicated the objectives and methods for implementing NDP to PEDCO, administrators, clinic personnel?	Secondary Objectives, Reports	SADAP

Notes:
Eleven prescribing indicators are Mean number of drugs, >2 drugs per prescription, percent generic, percent on EDL, percent Brand on EDL, percent of antibiotics, percent analgesic, percentage of injections, chronic illnesses: asthma, diabetes, and hypertension.

RDU Survey: Rational Drug Use Survey, KAP: Knowledge, Attitude and Practice

6.2 Methods and Tools

6.2.1 Sample

The following sampling method was used for the RDU survey in order to produce a representative sample of prescriptions. Three stratifying variables for the selections were the hospital care level (primary, secondary, tertiary), size (number of population served), the type of population served during apartheid (race) and geographical area (region) within the Northern Province. "In most of the countries, depending on the size of the region/districts, four to five geographical units are normally sufficient." (WHO, 1994). [23] The hospitals were pre-selected according to the level of service into Tertiary (academic), secondary and primary, the size, the inpatient beds and the out patient department number for both month and year, and the geographical area: the region where the hospital is located (seven areas in total). The sample was designed to include hospitals at each level, and size in each geographical area.

6.2.2 Sample Size: [24]

The research sample size is 1,204 prescriptions from eight predetermined hospitals. Of the hospitals, there is at least one located in six of the seven regions within the Province. All three levels of hospitals (primary, secondary, and tertiary), poli and specialty clinics were sampled. The hospitals were chosen on the basis of the region, the former racial status, inpatient and outpatient numbers. Finally, the hospital clinics were chosen to represent large, medium and small hospital inpatient beds and outpatient clinics. Of the thirty-six primary (community) hospitals, three were chosen. The secondary or regional hospitals are seven in total and three were chosen. The tertiary (academic) hospital complex is two physically separate hospitals in two very ethnically and economically different areas. Both hospitals were surveyed. Also there are twenty interviews from professionals: nurses, doctors, pharmacists and administrators, from one hospital at each care level (primary, secondary and tertiary).

[23] WHO, Indicators for monitoring national drug policies, 1994.

[24] WHO, Indicators for monitoring Drug Policies, recommends a sample of at least 100 prescribers. For Prescriptions take the first 30-100 or every 1 in 3.

6.2.3 Method one: NDP Indicators Survey (Collection of prescription data: Rational Drug Use Survey)

A. Pre-Data Collection Contact with Hospitals

The NDP Indicator Survey (WHO/DAP/94.12) with the Rational Drug Use (RDU) Survey was carried out at all hospital levels. Six hospitals of the eight in the study were visited before the research data collection day. In most cases formal in-person introductions were made to various hospital administrators and health care staff. These included the Medical Superintendent or the Medical Director of the hospital, the Head Matron or Head Nurse, and the head pharmacist.

Additional introductions were made in-person or by phone by the NP-DOH Research Co-ordinator, Sinah Mahlangu. In most cases the Superintendent or Matron introduced me to the head pharmacist and gave them a summary of the research that would be carried out and more importantly, an informal personal approval to encourage pharmacists' co-operation. Each head pharmacist orientated me to the process that the patient goes through from registration at the clinic to the pharmacy. All administrators and pharmacists at the hospitals were told that I would be back within a few weeks or months in order to collect the data for one day. The actual data collection day was not announced to the staff of the hospital so as not to influence prescribing behaviour.

During the visits to the hospital clinics, I observed that the record keeping methods ranged from the most sophisticated with the use of computerised data with base code readers to the most basic use of blank white paper in files without basic patient information. None of the hospitals had a data base system that would allow the data to be chosen retrospectively, for example for a particular day, month or clinic. In all the hospitals the patients' records would go through the pharmacy in order for medications to be dispensed. I concluded that it was best to collect the prescription survey data at the service point of the pharmacy, as the records came in during one entire day of the clinic and pharmacy hours.

6.2.4 Rational Drug Use Survey (RDU)

Rational Drug Use Survey allows the quantitative assessment of the adoption of the NDP through prescribing. "Today the most commonly used indicators for assessing prescribing practices are average number of drugs per prescription, percentage of prescriptions containing antibiotics and percentage of prescriptions containing an injection. The choice of these indicators had been conditioned by (a) the relative ease with which the data can be collected and (b) the excessive use of antibiotics and drugs injected. This is because the main problem associated with drug use related to over-prescribing. Thus, prescribing is assumed to be more rational if these indicators have lower values." (Kanji et al. 1992:98-99)

Outpatient prescriptions were included in this evaluation of RDU, while in-patient were excluded because the prescriptions used to ascertain the most common patient prescriptions instead of the patients who are the sickest within the inpatient setting. The hospital clinics listed in Table 6.3 were used for the RDU study and interviews of the professional staffs.

Cross-sectional prescribing data were collected giving a quantitative picture of prescribing patterns. These RDU survey data were collected during an entire day (8am to 5pm) at the pharmacy. The first patient usually came to the pharmacy no earlier than 10am, after a consultation with a nurse and/or physician. Before the first patient arrived with his/her patient file, I met with the head pharmacist and asked him to inform their staff about my presence and the research.

The goal of the research was explained and also the procedure that all patient files should be kept until the appropriate information was extracted and a copy of the prescription taken. The prescriptions and diagnosis pages were copied throughout the day at the facility. Once this was done the patient was given the file back if it was needed. Using this method, only very few files were lost.

All patient records were evaluated for appropriateness for the study, excluding pre-or-post-natal visits, children under 14 years old and in-patients. All appropriate records collected at the point of the pharmacy when the patient dropped off the record or waited to full a prescription, it was copied and given a unique number (1-1,286) in order of collection. In

addition, information on age, gender and diagnosis, were either copied or written on the copied prescription page. On the RDU survey day, the pharmacy staffs were asked to help with the interpretation of the handwriting of the prescriptions. Each pharmacy kept a one-day summary sheet of the number of clients seen and the number of medicines given. A copy of this form was obtained for each research day at the particular hospital. This sheet was used for initial evaluations of the total number of clients and the initial calculation of drug utilisation.

This drug utilisation study with rational drug use survey was carried out between September 1999 and January 2000. The data were collected during a workday at the pharmacy. The eight hospitals with eleven clinics, chosen are in different regions, their staff and clients have different socio-economic, ethnic and racial makeup, and the hospitals differ with respect to inpatient bed number, outpatient number and patient numbers treated per year (Mahlangu, 1998), and the services offered (Table 6.3).

Table 6.3 RDU Survey of Hospital Clinics (September 1999- January 2000)

LEVEL	NAME	BEDS	OPD/year	REGION	DAY
District	Van Velden	50	15,540	Lowveld	20 Jan..
Primary	F H Odendaal	201	17,477	Bushveld	12 Nov.
	Jane Furse	434	51,540	Southern	6 Oct.
Regional	Mokopane	340	31,168	Western	11 Nov.
Secondary	St. Rita's	334	100,579	Southern	5 Oct.
	Tshilidzini	450	119,247	Northern	14Oct.
Central:	Pietersburg	530	85,741	Central	Sept. &.
Tertiary	Mankweng	440	58,148	Central	Oct.

Source: Mahlangu, Sinah (1998).
Notes: Day: data collection day. OPD: outpatient department patient number per year.

The three primary care hospitals surveyed ranged from small to large, but all have only policlinics. The smallest hospital Van Velden hospital with 50 beds, and 15,540 outpatients per year was once a segregated hospital in a majority white area in the Lowveld region. F H Odendaal hospital in the Bushveld region is a hospital has 201 beds and 17,477 outpatients per year. These two previously segregated hospitals are located in white-majority population. These hospitals have the lowest of outpatients of all the hospitals surveyed. The third primary hospital surveyed was Jane Furse hospital, a former religious order hospital for the non-white poor population in the Southern region. It has 434 beds and 3 times more outpatients, than the other hospitals surveyed.

The three secondary care hospitals chosen were previously segregated black hospitals. Mokopane Hospital in the Western region had 340 beds, and an outpatient number of 31,168, while St. Rita's Hospital in the Southern region has 334 beds, but see three times more outpatients. The Tshilidzini Hospital in the northern region has 450 beds and 119,247 outpatients are seen. The two tertiary care academic hospitals officially form one complex, but are located more than a thirty-minute drive from each other in two very different areas. Pietersburg and Mankweng tertiary hospital complex are both located in the Central area in the city of Pietersburg, the largest city in the Northern Province. However, the Pietersburg Hospital is located in the city centre, while Mankweng Hospital is located outside the city centre in a former black homeland area.

The two hospitals are very different and managed separately with few shared staff or clientele. Both Pietersburg and Mankweng hospitals have Medical Directors who both are black African expatriates. Pietersburg hospital has been a traditionally segregated 'whites only' hospital that still has a high percentage of white clientele. It has two physically separate outpatient pharmacies, one for general clinics and the other for special clinics (e.g. oncology). Pietersburg Hospital has 530 beds and had 85,741 outpatients in their policlinics and their many specialty clinics that include oncology, neurology, surgery, obstetrics and gynaecology, Ear, nose and throat, psychiatry, tuberculosis, ophthalmology, dental, and others). The Mankweng hospital has been a traditionally black hospital that still has an exclusively black clientele. It only has a few specialty clinics, which are geared more towards primary health care. Mankweng hospital has 440 beds and 58,148 outpatients.

All the hospitals surveyed, except one, had a head or managerial pharmacist. Pietersburg Hospital had the highest number of specialty physicians and also pharmacists (auxiliary to managerial). On the days of data collection Pietersburg Hospital had more than 30 pharmacy staff, while Mankweng had five. All except one of the other secondary and primary hospital pharmacies had between two and five total pharmacy staff. Tshilidzini Hospital had the most under-staffed pharmacy with only two pharmacist- assistants who serviced about 250 outpatient clients daily. Also one other secondary hospital pharmacy in Jane Furse hospital was exceptional in staff numbers, with thirteen pharmacy staff, but only one educated and licensed pharmacist who had been qualified for less than a year.

6.2.5 National Drug Policy (NDP) Implementation Indicators

The National Drug Policy (NDP) indicators and questions (Appendix K) developed by the World Health Organization / International Network of Rational Use of Drugs (WHO/INRUD) has been used in a twelve country comparative study. It has also been used in studies conducted in South Africa over the last several years (Moller & Summers, 1996, Moller, 1998) Evaluation and analysis of National Drug Policy Indicators[25] serves two purposes in this research. First, it assesses the implementation of the NDP by measuring progress in key components with structural and process indicators. Second, it evaluates the outcome of NDP with outcome indicators.

6.2.6 Additional NDP Survey Outcome Indicators for Chronic Diseases (Hypertension, Asthma and Diabetes)

The South African governments Reconstruction and Development Programme (RDP) and the NDOH have chosen three major chronic diseases as priority chronic diseases. These are hypertension, diabetes, and asthma. This study evaluates these three chronic illnesses as outcome indicators in rational drug prescribing.

Upon data collection, it was apparent that all three hospital level clinics treat patients with the chronic conditions of hypertension, diabetes (insulin and non- insulin dependent) and asthma. Some hospital clinics had special days specifically for one of the above chronic conditions, but see patients with these conditions every day in all clinics. It was possible to combine the RDU survey data collection with the data collection for chronic diseases.

A) Hypertension

Hypertension is a major public health problem in South Africa, as it is in virtually all parts of the world. The WHO defines hypertension as having a blood pressure higher then 160/95 mmHg. It can be asymptomatic and requires a high level of compliance with life style changes (diet, exercise, weight control, stress control) and medication. The health risks are increased by an unhealthy life style with obesity, poor nutrition, diabetes mellitus, excessive alcohol intake, physical inactivity, and smoking. The first level of drug treatment consists in a diuretic is low-dose hydrochlorthiazide (12.5 –25 mg once a day). After three months if the blood pressure is not controlled then level 2 drugs are added, if they fail in 3

months then level 3 drugs are added. The Northern Province in 1998/99 spent R 3,995,389.16 (~£396,000) on treating hypertension (Appendix L and M).

B) Diabetes Mellitus (Types I & II)

Diabetes Mellitus is rapidly emerging as a major public health problem in South Africa. The effects of urbanisation and an unhealthy lifestyle are important contributors to the rising prevalence. Diabetes Type-II (non-insulin dependent) is often associated with obesity, hypertension, and atherosclerosis. Diabetes Type-II accounts for 80%-90% of diabetes cases. "It's a multi-faceted disorder and inflicts a tremendous economic burden on patients, families and health care providers." (Diabetes, DOH, 1998). Step one treatment for those with a certain level of glucose consists of life style modifications, which include weight control, weight loss; exercise; cessation of smoking or not starting, and a healthy diet. Step 2 treatment on the STG/EDL requires medication. The Northern Province in 1998/99 spent R 2,774,849.86 (~£275,000) on treating Diabetes Mellitus (Appendix N and O).

C) Asthma

As the environment becomes more urbanised, more people smoke, and bacterial infections become more resistant to antibiotics, the number of asthma cases in adults has increased over the years. Asthma is a paroxysmal obstruction of the airways. Air can be taken in, but it is difficult to breathe out because the airways are obstructed. In addition too patient education, drugs are given. Drugs are given as maintenance therapy and usually consist of an inhaler containing Beta-2-stimulants (Salbutamol or Fenoterol, MDI, 100-200 micrograms, every 4-6 hours as necessary). The Northern Province in 1998/99 spent R 2,451,531.66 (~£242,000) on treating Asthma (Appendix P and Q).

6.2.7 NDP Survey in Hospital Clinics

The NDP survey process and outcome indicators are determined in this study, which evaluated 1,204 prescribing encounters in eight hospitals with eleven clinic days of evaluation carried out between September 1999 and January 2000. The initial collection consisted of 1,287 prescriptions. Eighty-four prescriptions were not used because of age, date, pregnancy, or incomplete prescription information leaving a final sample size of 1,204 client prescriptions for evaluation and analysis. This is well above the WHO recommendation for a study of this kind which states that, "within these facilities, a minimum of 100 prescriptions should be included in the sample to achieve any statistically significant comparison from one year to another."(WHO 1994:43)

Although the clinic facilities differ in size and patient volume, number of staff and the use of technology all the hospital clinics in the Northern Province have the same operating routines. Patients with and without referrals go to the clinic are first seen by the nurse and then by the physician. The data from the visit is entered into the patient record along with the medication prescribed. The patients go to the pharmacy whether medications are prescribed or not in order to drop off their record. All records counted and compared to the patient outpatient list and them were evaluated for the medications prescribed or not. Pharmacies vary in their purchasing records and stock control records in both completeness and in accuracy. The main Distribution Depot, which is managed by VUNA, a private company has all records of medicine orders but would not allow the researcher access to their records.

The number of prescriptions collected for one day in all the hospital clinics had a range between 43 and a high of 226 prescriptions. The lowest numbers were both in the traditionally white primary care hospital clinics of FH Odenaal hospital with 43 prescriptions and Van Velden hospital with 52 prescriptions. The traditionally black hospital clinic of Jane Furst hospital, with about 200 outpatients per day had 123 prescriptions. The total number of prescriptions for primary hospital clinics is 214. The prescriptions in secondary hospitals were in the same range. The collection of prescriptions at St Rita's hospital yielded 142 prescriptions, Mokopani hospital 101 prescriptions, and Tshilidzini hospital 127 prescriptions.

The total number of prescriptions in the secondary hospital clinics is 370. Data collection in the tertiary hospitals was done on several days in order to capture all of the important poli- and specialty clinics. The tertiary hospital complex of Pietersburg and Mankweng had a total of 620 prescriptions. At the Pietersburg hospital, the poli clinics 226 prescriptions were written; the first specialty clinic collection day yielded 78 and the second day yielded 96 prescriptions. At Mankweng the poli clinic yielded 76, while the specialty clinics day, 145 prescriptions. With both hospitals considered together there were 301 policlinic prescriptions and 319 specialty clinic prescriptions.

TABLE 6.4 HOSPITAL CLINICS SURVEY (September 1999 –January 2000)

NAME	No.	BEDS	OPD/day	REGION	Total Rx.	Analysed Rx
District or Primary Hospital Clinics					**214**	
Jane Furse	(9)	434	220	Southern	131	123
F H Odendaal	(10)	201	50	Bushvled	43	39
Van Velden	(11)	50	50	Lowveld	55	52
Regional or Secondary Hospital Clinics					**370**	
St. Rita's	(6)	334	180	Southern	158	142
Mokopane	(7)	340	200	Western	106	101
Tshilidzini	(8)	450	250	Northern	134	127
Provincial or Tertiary Hospital Clinics					**620**	
Pietersburg	(1)	530	200	Central	237 (P)	226 (P)
	(2)				79 (S)	78 (S)
	(3)				102 (S)	96 (S)
Mankweng	(4)	440	250	Central	83 (P)	76 (P)
	(5)				161 (S)	145(S)

Notes: Some of the ***Total Rx***. Prescriptions did not fulfil the criteria for inclusion in this study because of patient age, pregnancy, or incomplete prescription information. The number of prescriptions included in this study is given in the column Analysed Rx.

6.3 Interviews

Interviews are frequently used to evaluate both the implementation and the acceptance of the uptake of the NDP's rational drug prescribing policy. Interviews provide an insight into people's behaviour, thoughts, and feelings on important issues. This technique is especially good for encouraging a respondent to talk at length on a particular topic. Moreover, the successful implementation of the STG/EDL will depend on the involvement of several different interested groups. Each group may have a different interpretation of the STG/EDL implementation and its usefulness. Capturing these different views is often best achieved by using interviews or other qualitative methods with a case study design (Mays & Pope: 1999 & 2000). The open in-depth interview proved especially helpful in this research, as it allows for loosely structured open-ended questions to define the area to be explored initially. More importantly, it is a flexible and can uncover new areas or ideas that were not anticipated at the outset of the research.

The interviews allow for the evaluation of the impact of attitudes or beliefs about interventions on actual prescribing practices. The goal of the interviews was to ascertain knowledge, attitudes and practices (KAP) of hospital and administrative personnel (administrators, pharmacists, physicians and nurses) to complement the NDP indicator survey results.

The advantages of this method are that it is flexible and gives the interviewer more opportunity to ask questions. Also the personal contact enhances the possibility of good probing. Lastly, it permits the observation of non-verbal expressions of respondents. The disadvantages of this method are that it can be difficult to be a good interviewer and personal opinions may affect the interviews. In addition, it is difficult to generalise the results.

Of the eight hospitals in the RDU survey, three hospitals were selected based on region, former race segregation, hospital level, and the bed and outpatient size. Sixteen interviews with hospital staff were conducted on the same day as the Drug Utilisation Study (DUS) data collection between September 1999 and January 2000.

The INRUD recommendations from 1996, suggests to assess the KAP a minimum of three to four interviews for each group of personnel (administrators, pharmacists, nurses, and physicians). In this study twenty interviews with pharmacists, nurses, and physicians), sixteen were conducted with health professionals who work in outpatient hospital clinics and while four with administrators. Health professionals in hospital clinics were randomly asked to give an interview on the day that prescriptions were collected. In contrast, administrators were selectively chosen for interviews because of their role in the implementation of the NDP and RDU.

The interviews were guided by a set of questions adapted from INRUD (1996) (Appendix R). All the interviews started with ten basic questions that allowed for elaboration and also the possible change of focus (Appendix S). Each interviewee was told that the interview was anonymous and confidential. The names of those interviewed were not asked or recorded. During the interview the gender, age, profession and years in the profession were recorded. The interviews were conducted in a private room with a door and no other people present. Each interview was between fifteen and sixty minutes. Each interview was recorded on a separate audiotape in order to secure the data and confidentiality.

The primary care hospital chosen was Van Velden hospital where six people were interviewed. In the secondary care hospital St. Rita's four people were interviewed, and in the tertiary care hospitals, Pietersburg and Mankweng, had total of six people were interviewed. In addition four administrators were interviewed. The interviews are numbered in sequential order of the actual interview (Appendix T).

Of the sixteen interviews at the hospital clinic level, seven were at the primary care level with three physicians (all male), and two nurses (male and female) and two pharmacists (female). At the secondary care level, four interviews were conducted with one physician (male), two nurses (male and female) and one pharmacist (female). At the tertiary level, six interviews were conducted with four physicians (male), no nurses and two pharmacists (female). At the tertiary level, nurses were approached to take part in the

interview, but no interviews were successfully set up. The four administrators interviewed were male and worked at the provincial and national levels.

The administrators were asked directly for an interview and all complied with the request. From the Northern Province Department of Health (NP-DOH), both Dr. John P. McCutcheon, the Director of Health Care Support and Auxiliary Services and Danie Meyer, the Deputy Director of Pharmaceutical Services were interviewed. Also at the provincial, but private level, Mischek Dudzai, the Programme Manager of Hospital Systems for VUNA Health Care Logistics (drug depot) was interviewed. At the National level, Prof. Robert Summers, the Director of RDU training and research and Professor at Medical University of South Africa (MEDUNSA) was interviewed. Nine questions were developed for the administrators as a guide for further discussion of key issues in the implementation of the NDP, STG/EDL, RDU, and rational drug prescribing that were used as a starting point.

6.4 Structured and Non-participant Observation

An important advantage of observation is that it can help to "overcome the discrepancy between what people say and what they do," (Mays and Pope, 1999 & 2000), and give insights into the culture, thus increasing the understanding of important variables of the data collected. The areas in which this technique has been applied are informal and formal meetings and gatherings. These observations were carried out at both National and Provincial levels at the Pharmacists Society of South Africa (PSSA) (Appendix U), the South African Drug Action Programme (SADAP), Essential Drug Programme (EDP), Head of Pharmaceutical Services (HOP) and Provincial Essential Drug Programme Co-ordinator (PEDCO). Also observations were carried out at the hospital level. In these meetings I have been strictly an observer, with an overt presence. During the preliminary stage months before the stage collection stage of the research (November 1998 to March 1999) the research was based at SADAP in Pretoria located at the NDOH. During this time key stakeholders were met, pharmaceutical conferences and National EDP meetings

were attended and the hospitals were visited. These observations laid the groundwork for the field research data collection.

The three hospitals where interviews were conducted were also used for observation at the clinics and pharmacy. Three hospitals were the:

Primary or Community hospital clinic of Van Velden hospital,
Secondary or Regional hospital clinic of St. Rita's hospital and
Tertiary or Central clinics of Pietersburg and Mankweng hospitals

During the interviews and non-participant observations most administrators involved knew the aims and objectives of my research.

During the collection of some of the NDP structural and process indicators, structured observation was also used. The researcher actively looked for a copy of the STG/EDL for adults in the clinics, consulting rooms, and pharmacy. Also it was observed if prescribers used the STG/EDL. The advantages of this method were that it allowed observation of behaviour in context and it afforded the researcher the opportunity to understand factors that influence behaviour.

Observation was helpful in verifying what people do compared to what they say they do in interviews. Also it was helpful in validating data obtained by the NDP survey. The disadvantages of the method include the problem that the structured format may limit the type of information that can be collected. The presence of an observer could affect the subjects' behaviour, and thereby bias the data.

6.5 Literature Review

Review and analysis of primary and secondary information and documentary evidence shares policy statements, programme plans, parliamentary debates, published and

unpublished reports and literature, national legislation, professional journals, newspaper articles was an ongoing task throughout the research. Specifically documents from four areas were be reviewed and analysed: (i) National Drug Policy in South Africa, (ii) South Africa Drug Action Programme and (iii) Northern Province Department of Health. Since the pharmaceutical policy in South Africa is continually changing fluid a literature review was carried out continuously during the research in order to capture research, policy and other important milestones.

6.6 Data entry and analysis

The qualitative results obtained in interview and observations and the quantitative results of the drug utilisation study are analysed in chapters seven and eight respectively.

6.6.1 Drug Utilisation Study (DUS)

The quantitative data of individual prescriptions with a unique recorded number were separated by hospital name and clinic specialty. These data were then put into separate Excel files. Quantitative Analysis of the NDP survey data (structure, process and outcome) includes the evaluation of prescriptions recorded using Microsoft Excel.

For quality control, the prescription data were reviewed and evaluated for accuracy by a pharmacist from Mankweng Hospital and a physician/researcher from the University of Cape Town, Department of Pharmacology. The drug utilisation survey was analysed by using both SPSS and Stata 6 software.

6.6.2 Interviews

Each interview was recorded on audiotape and transcribed into Microsoft word format. Analysis of the data has been carried out manually and with the aid of software, called (NUD*IST) Non Numerical Data, Indexing, Searching, and Theorising, and the newer version 1.1 (April 2000) of Nvivo was employed for data analysis. Nodes, which are attributes, themes and data types were created and produced an index system. A node tree was created from the themes found in the review of the twenty interviews. The attributes, themes and data types were collated from different interviews in order to find similarities, commonalties, and contrasts of specific themes and issues. This process was done

manually and with the help of software. The software has aided in more extensive coding and theorising, linking data and ideas, and allowed for innovative approaches to asking questions.

For this analysis interviews were, categorised under various sub-topics. This technique often described as a 'cut-and-paste' process in the transcribed interviews are sorted into broad and sub-topics. Each category is labelled with an appropriate heading (e.g. Use of STG/EDL, Rational Drug Use training, pharmacy treatment committees, etc.). This was done for the responses of the different in sub-groups and commonly held beliefs, attitudes, or opinions were analysed.

6.7 Validation[26] Techniques

The main method of validation of research findings is the triangulation the use of methods (survey of indicators) and the sources of information (interviews, observation, documents, etc.). Triangulation "refers to an approach to data collection in which evidence is deliberately sought from a wide range of different, independent sources often by different means (for instance, comparing oral testimony with written records)" (Mays and Pope, 1999 & 2000).

This strategy has been used to balance the advantages and disadvantages of the various methods used in this study. Several collaborators reviewed the collected data of prescriptions for consistency and plausibility.

A seminar/workshop would be held at the Northern Province Department of Health to allow participants in the study and other interested people a forum to learn about and comment on the study findings. Those interviewed would be "the same people so that their reactions to the evolving analysis become part of the emerging research data" (Mays and Pope, 1999 & 2000). The feedback from this workshop session will serve the dual

[26] Validity is the extent to which a measurement truly reflects the phenomenon under scrutiny. (Mays and Pope, 1996)

purposes of dissemination of information and the opportunity of discussion of the research findings.

6.8 Limitations of this Study

This study focused on the Northern Province and data were collected in six of the seven regions within this province. The Northern Province is different from the other eight of South African provinces because of the high percentage of poor, rural, African population and the limited health resources.

The focus of the study was limited to the implementation of the NDP, through the use of STG/EDL and its impact on health personnel, and their knowledge, attitudes and practices at the hospital outpatient clinic level. Other factors that can influence RDU practice are drug selection, drug stock levels and procurement that are touched upon but were not evaluated in depth.

In addition, the limitations of the study include the limited focus of the Northern Province as a case study. As originally planned, with more resources of time, staff and funding, a compare and contrast study two provinces Gauteng and the Northern Province. Gauteng is the richest, most urban, and White Africans, while the Northern Province, most rural with the poorest and majority black African population. Conducting the research in both provinces with more resources would have been undertaken to show that although the two provinces are quite different in its racial, geographical and economic makeup the prescribing patterns were likely to show a lack of adherence to the National Drug Policy through rational prescribing.

If the research could be carried out again in another province I would change several features. First, I would allow for up to two years for the entire process. Second, I would collect data from more hospital clinics. Third, I would add a component to the research design to include the opinions and behaviours of patients who are prescribed generic drugs.

6.9 Legal and ethical issues

Approval for this research has been sought and granted from various official bodies. The South African Drug Action Programme in Pretoria approved access (October 1998) to its office during the initial information gathering phase of the research. The National Department of Health has given a letter of support for the research. A presentation (with visual aids) was given to the Northern Province Research Committee and the Ethics Committee at the regional Department of Health in November 1998. The former Northern Province Director of Health, Dr. Nicolas Crisp, granted permission for the research in December 1998 (Appendix V). In addition, the ethics committee of the London School of Hygiene & Tropical Medicine approved the research in September 1999.

To ensure confidentiality data protection questionnaires, surveys, diaries and other documents are stored in a private non-accessible location. The Data Protection Act will be complied with rigorously. All interviewees were guaranteed anonymity and confidentiality. A sequential interview number from one to twenty identified audio taped interviews. All interviews were recorded on a micro recorder and for each interview a separate audiotape to insure data protection and confidentiality. Interviews occurred in a private room with a door for privacy, unless the interviewee requested another location.

CHAPTER SEVEN

DRUG UTILISATION STUDY

7.1 Introduction

A total of 1,242 prescriptions from hospital records were collected and copied on the day that they were written at the hospital clinic. After further evaluation, 38 records were excluded that did not meet the age, pregnancy status or drug recording criteria and 1,204 records remained for analysis. The quantitative results will be presented in this chapter, while the qualitative results from observations and interviews will be given in the next chapter.

In this representative study of all hospital clinic levels, 1,204 records with 3,551 drugs were collected in each region of the six regions of the Northern Province. The newly created region of Bushbuck Ridge (Appendix F), former part of the Lowveld Region was not included in this study. At least one hospital was chosen in each of the seven regions. Representative hospitals were chosen for the level of care (3 Primary care (P) clinics, 3 Secondary care (S) clinics, and 5 Tertiary care (T) clinics), the region the hospital served and the population demographics as well as former segregation are in table 7.1.

The largest number of patient prescriptions were collected from *Pietersburg* hospital (clinic #1) a poli-clinic in a hospital that is integrated, but still serves mostly a white African population in the capital of the Northern Province.

The specialty clinics for adults at Pietersburg Hospital (clinic 2 & clinic 3) are true tertiary care clinics, for example oncology, surgery, cardiology, dermatology, neurology. The specialty clinics at Mankweng Hospital (clinic 5) include hypertension, asthma, and ophthalmology. The lowest number of patient prescriptions were collected from F. H Odeaal (clinic 10) a primary care clinic in a hospital that still serves mostly a white African population in a formally segregated area of Bushveld.

Table 7.1 Hospital, care level, population and region

Hospital	Clinic No	Level	Prescriptions	%	Race*	Region
Pietersburg	*1*	Tertiary – Poli	224	18.6	W	Central
	2	T-Specialty	78	6.5	W	Central
	3	T-Specialty	97	8.1	W	Central
Mankweng	*4*	Tertiary – Poli	75	6.2	B	Central
	5	T-Specialty	145	12.0	B	Central
St. Rita's'	*6*	Secondary	144	12.0	B	Southern
Mokopani	*7*	Secondary	101	8.4	B	Western
Tshilidzini	*8*	Secondary	126	10.5	B	Northern
Jane First	*9*	Primary	123	10.2	B	Southern
F. H Odeaal	*10*	Primary	39	3.2	W	Bushveld
Van Velden	*11*	Primary	52	4.3	W	Lowveld
11 Clinics	11	**5T, 3S, 3P**	**1,204**	**100**	**6B, 5W**	**6 Regions**

Note: The racial majority of the patients is designated as either Black (B) or White (W).

The 1,204 prescriptions from eight hospitals with eleven clinics are grouped by level of care into primary, secondary and tertiary. The number of prescription and the number of prescribed drugs for each level are summarised in Table 7.2. The individual clinics will be evaluated by using prescribing outcome indicators.

Table 7.2 Hospital Clinic Level, Cases and Drugs

Level	Prescriptions	Percent	Drugs	Percent
Primary	214	17.8	695	19.6
Secondary	370	30.7	1,023	28.8
Tertiary	620	51.5	1,833	51.6
Total	**1,204**	**100%**	**3,551**	**100%**

7.2 Prescribing Indicators

The South African National Drug Policy was adopted by the National Department of Health for the Provincial level in the Northern Province. Prescribing indicators are used to assess the process and outcomes of the implementation of this policy.

Both process and outcome prescribing indicators are used in this study to assess the degree of attainment of the *Rational Use of Drugs*, one of the eight objectives of the Essential Drug Program (EDP). Outcome and process indicators are used to measure the results achieved at one point in time and the changes that can be attributed to the implementation of the Essential Drug Programme, and thus the overall success of the National Drug Policy.

The eight outcome prescribing indicators provide quantitative information about the process and the extent to which South African has implemented its EDP, while the process indicator assesses the degree of functioning for the process and the achievement of specific targets (WHO/DAP/94.12).

The eight prescribing indicators were adapted for this study after a literature review to assess the degree to which the goals and targets of essential drug programme were met by prescribers.

More importantly, the indicators evaluate the prescribing behaviour at the hospital clinic level. A low mean number of drugs per prescription, high generic and EDL prescribing and a low percentage of prescriptions with antibiotics, analgesics and injections are excepted indicators of rational drug prescribing. The eight indicators will be evaluated for all prescriptions and separately for those with the chronic illnesses of hypertension, diabetes and/or asthma.

Box 7.1 Eight Evaluated Prescribing Indicators and NDP Recommended Values

1)	Mean number of drugs per prescription	(2 or less)
2)	Prescriptions with two drugs or less	(95%)
3)	Proportion of Generic drugs	(90%)
4)	Drugs on the EDL	(90%)
5)	Drugs prescribed as brand or generic on EDL	(90%)
6)	Prescriptions for antibiotic	(10%)
7)	Prescriptions for analgesics	(15%)
8)	Prescriptions for injections	(5%)

7.3 Methods of Analysis

The eight outcome indicators were analysed for each of the eleven clinics and a rank list of the clinics for these indicators was constructed. The degree of adoption of the EDP principles by clinics will be reflected in the rank list and can be quantified by an overall rank score and analysed in more detail by rank correlations.

A. Adjusted and Non-Adjusted Models of Age and Gender

The influence of several factors like age and gender on the outcome indicators was analysed using regression models (Table 7.3), a linear regression model for the mean number of drugs and logistic regression models for all other parameters.

The analysis results for the outcome indicator, "more than two drugs per prescription" using a logistic regression model are summarised in Table 7.3. The analysis, using model II is controlled for gender and age group. The coefficients in this analysis are odds-ratios. With the special parameterisation used the order of coefficients will be the rank order. The uncontrolled model shows (by definition) the same rank order as a simple ranking of proportions. The controlled model demonstrates that gender and age both have effects with increasing age, except for the oldest group, the odds ratio for more than 2 drugs rises and female patients are more likely to receive more than 2 drugs than male patients. In the adjusted rank order furnished by the controlled model the effect of age and gender of the patients has been standardised. Adjusted ranks are presented with simple ranks in the following tables.

Table 7.3 Not Adjusted and Adjusted Models of Age and Gender for Prescriptions with >2 drugs

(Model I- Not Adjusted and Model II- Adjusted, * p < 0.05, ** p < 0.01)
Note: P values of 0.000 are actually <0.001.

Model I – Not adjusted (Rx >2 Drugs)

Clinic	Coefficient	Probability
1	1.772**	0.000
2	0.414**	0.000
3	0.506**	0.001
4	1.705*	0.028
5	1.299	0.130
6	0.9023	0.538
7	0.970	0.877
8	0.706*	0.047
9	1.149	0.446
10	0.774	0.390
11	2.210**	0.009

(N=1,204)

Model II – Adjusted (Rx >2 Drugs)

Clinic	Coefficient	Probability
1	1.674**	0.001
2	0.441**	0.000
3	0.496**	0.001
4	1.940**	0.009
5	1.203	0.300
6	0.875	0.456
7	0.923	0.688
8	0.782	0.173
9	1.084	0.669
10	0.800	0.471
11	2.134**	0.014
Age Group		
15-39	0.804	0.128
40-49	0.982	0.905
50-59	1.333*	0.050
60-69	1.806**	0.001
70-79	1.488*	0.049
80-99	0.467**	0.001
Gender		
Female	1.302*	0.044

(N=1,204)

B. Correlation Matrix of Prescribing Indicators

Positive rank correlations of certain indicators, for example, a close adherence to the target mean number of drugs per prescription and the to the proportion of antibiotic prescriptions will imply a similar degree of success in the implementation of the NDP.

If individual hospital clinics have made a concerted effort to implement the Essential Drug Programme, then the indicator adherence scores (ranking is from 1 to 11, the higher the adherence, the lower score,) should have a high correlation number close to 1.0 and would be evidence of EDP implementation success. In addition, for more general evidence of programme effort and level of implementation rank correlation between hospital clinics should be positive and significant for a number of pairs of indicators. Comprehensive Correlation Matrix of Prescribing Indicators are displayed and evaluated in Table 7.24.

7.4 Analyses of Prescribing Indicators

Three analyses are used to evaluate the eight prescribing indicators and their relationship to one another in all eleven clinics for all and chronic illnesses. A Forth analysis, only for chronic illnesses and prescribing indicators by clinic level.

Each of the eight prescribing indicators is evaluated and the results are summarised in two tables. The first table evaluates the total number and proportion of the prescriptions. The second table evaluates the proportion of drugs, and also includes the "Simple Rank" for adherence to the EDP and thus successful implementation of the Essential Drug Policy, and the "Adjusted Rank," as previously described.

The eleven clinics are ranked from best to worse using the criteria of prescription indicators (Tables 7-4 to 7-33). Analysis Two evaluates all indicators (Table 7-34 to 7-35), for all the clinics and compares them to one another. The final table adds up the scores for all the prescribing indicators and gives an overall ranking for adherence to

EDP principles based on the adjusted rank. Then the clinics are ranked from the lowest score, which represents the best adherence to the EDP.

Analysis Three (Tables 7.36 to 7.37) takes the adherence scores of all the clinics and puts them into a matrix correlation table. The correlation table is produced based on the adjusted ranking of adherence. As rankings alone may fail to bring out the full story, since in any system of ranking there are those first and last, but may not fully reflect the relative portions, the evaluation will also compare means of primary, secondary and tertiary.

The degree of implementation of the policy is assured by evaluating the correlate pairs. Analysis Four (Table 7.38) evaluates the eight prescribing indicators for those with chronic illnesses (hypertension, diabetes and asthma).

This examines whether the EDP compliance measures are the same for chronic diseases, the hypothesis being that prescribing for chronic illnesses lends itself more easily to the closer adherence of the EDP practices (Tables 7.27 to 7-33).

7.4.1 Analysis One: Prescribing Indicators

Indicator One: Mean Number of Drugs per Prescription

The mean number of drugs prescribed on each prescription is an accepted indicator for rational drug prescribing with a recommended value of two drugs or less per prescription as determined by the literature. A higher number of two prescribed drugs is an indicator for poly pharmacy, which is not consistent with rational drug prescribing.

Table 7.4 Mean Number of Drugs per Prescription

Level	Pietersburg-Tertiary			Mankweng-Tertiary		Secondary			Primary			Total
No. Rx	399			220		371			214			1204
No. drugs	1156			677		1023			695			3,551
Mean No. drugs/Rx	2.83			3.07		2.75			3.24			*2.94*
Clinic	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*Sum*
No. Rx	224	78	97	75	145	144	101	126	123	39	52	1,204
No. drugs	741	173	242	231	446	391	288	344	366	123	206	3,551
Mean No. drugs/Rx	3.30	2.21	2.49	3.08	3.09	2.71	2.85	2.73	2.97	3.15	3.96	2.94

Notes: No. RX: Number of Prescriptions, No drugs: Number of Drugs,

Table 7.4 presents evidence about the extent of polypharmacy using the indicator of the mean number of drug per prescription. The primary level had the highest mean number of drugs at 3.24, when it is expected to have the lowest or at least the target of 2 or less.

All levels of care do not meet the mean drug per prescription of two or less. The range is from 2.21 to 3.96 drugs per prescription. The average for all the clinics together is 2.94, higher than the goal of 2 drugs or less. Therefore all the clinics are over-prescribing according to the EDP criteria. Surprisingly, clinic 2 a specialty clinic at the tertiary level has the lowest number of drugs per prescription showing that adherence to EDP principles is possible at all level of care and for most patients. On the other hand, clinic 11 is a primary health care facility, would be expected to prescribe fewer drugs but is actually prescribing the higher number.

Table 7.5 Rank List for Mean Number of Drugs Prescribed

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	*2*	*3*	*6*	*8*	*7*	*9*	*4*	*5*	*10*	*1*	*11*
No. Rx	78	97	144	126	101	123	75	145	39	224	52
Mean No. Drugs/RX	2.21	2.49	2.71	2.73	2.85	2.97	3.08	3.09	3.15	3.30	3.96
Coeff.	-0.649	-0.452	-0.260	-0.146	-0.145	-0.015	0.183	0.030	0.177	0.303	0.974
P Value	0.000	0.000	0.020	0.210	0.252	0.896	0.211	0.783	0.373	0.001	0.000
A- Rank	1	2	3	4	5	6	9	7	8	10	11

Notes: S-Rank: Simple Rank, A-Rank: Adjusted Rank, Coeff.: Linear Regression

In Table 7.5, the adjusted model (A-Rank) changes only slightly from the adherence (S-Rank), which do not affect the clinics mentioned. Clinic 2 and 3, both at the tertiary level, but in two separate hospitals are significantly better than the average level of prescribing.

The coefficients of the adjusted rank (A-Rank) for clinic 2 and 3 shows that they are prescribing 0.65 and 0.45 drugs less respectively, than the average. In contrast, clinic 1, a poli clinic at the same hospital as the best clinic 2, and clinic 11,at the primary care level, are prescribing significantly more drugs than average, clinic 1, 0.3 and clinic 11, 1.0 more drugs per prescription.

Indicator Two: Proportion of Prescriptions with More than Two Drugs

A second indicator for rational drugs prescribing is the proportion of prescriptions with more than two drugs, the NDP goal of being less than 5% of prescriptions with more than two drugs. If rational drug prescribing were followed it would be expected that clinics would have 95% of prescriptions with less than two drugs.

Table 7.6 Proportion of Prescriptions with More than Two Drugs

Level	Pietersburg-Tertiary			Mankweng-Tertiary		Secondary			Primary			Total
Total Rx	399			220		371			214			1204
>2 drugs	235			150		208			139			732
% Rx	58.89			68.18		56.06			64.95			60.8
Clinics	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	Sum
Total Rx	224	78	97	75	145	144	101	126	123	39	52	1,204
>2 drugs	163	30	42	54	96	83	60	65	78	21	40	732
% Rx	72.8	38.5	43.3	72.0	66.2	57.6	59.4	51.5	63.4	53.8	76.9	60.8

Notes: No. RX: Number of Prescriptions, No drugs: Number of Drugs,

Mankweng hospital clinics at the tertiary level have the highest percent, 68.18% of prescriptions with more than two drugs. In addition, consistent with the mean number of drugs in the last tables primary level of care also has a highest percent, 64.95% of prescriptions with more than two drugs. If the Evaluating individual clinics, both clinics 2 and 3 have the lowest proportion of prescriptions with more then 2 drugs with 38.5% and 43.3%, respectively. The range of prescriptions with more than two drugs is from 38.5% to 76.9% (Table 7.6). The highest proportion of prescriptions with more than two drugs was from clinic 11 with 76.9% of prescriptions. The majority of clinics have at least 50% of the prescriptions with more than two drugs. Although clinics 2 and 3 performed better than any other clinic, all have not met the standard of 95% of prescriptions with 2 drugs or less. This is clear evidence of polypharmacy, and thus a lack of rational drug prescribing.

Table 7.7 Rank of Hospitals Proportion of Prescription with > 2 drugs

S-Rank	1	2	3	4	5	6	7	8	10	9	11
Clinic	2	3	8	10	6	7	9	5	4	1	11
No. Rx	78	97	126	39	144	101	123	145	75	224	52
% Rx	38.5	43.3	51.5	53.8	57.6	59.4	63.4	66.2	72.0	72.8	76.9
Coeff.	0.443	0.499	0.782	0.771	0.889	0.929	1.084	1.206	1.907	1.684	2.143
P Value	0.00	0.001	0.171	0.394	0.503	0.688	0.711	0.293	0.010	0.001	0.014
A-Rank	1	2	4	3	5	6	7	8	10	9	11

In Table 7.7, the adjusted model (A-Rank) changes only slightly from the adherence (S-Rank). Clinics 2 and 3, both at the tertiary level, but in two separate hospitals are significantly better than the average clinic for the proportion of prescriptions with two or less drugs. The correlation for the adjusted (A-Rank) for clinic 2 and 3 show that they are 56% and 50% less likely to prescribe more than two drugs than the average. Clinic 1, and clinic 11, on the other hand – consistent with the ranking for mean number of drugs – are 68% and 114% more likely to prescribe more than two drugs than average.

Indicator Three: Proportion of Generic Drugs

A third indicator for rational drug prescribing is the proportion of generic drugs, The NDP goal being 90%.

Table 7.8 Proportion of Generic Drugs

Level	**Pietersburg-Tertiary**			**Mankweng-Tertiary**		**Secondary**			**Primary**			**Total**
No Drugs	**1,156**			**677**		**1,023**			**695**			**3,551**
No. Generic	**368**			**210**		**342**			**263**			**1,183**
% Generic	**31.83**			**31.01**		**33.43**			**37.84**			**33.31**
Clinics	***1***	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***	***11***	**Sum**
No Drugs	741	173	242	231	446	391	288	344	366	123	206	**3,551**
No. Generic	289	42	37	58	152	177	85	80	130	50	83	**1,183**
% Generic	39.00	24.27	15.28	25.10	34.08	45.26	29.51	23.25	35.51	40.65	40.29	**33.31**

The NDP goal is at least 90% generic prescribing in order to match the medicines available at the pharmacy. Instead, Table 7.8 shows that overall the primary care level has the highest percentage of generic prescription with 37.84%. However, all three levels show about a bit more than 30% of generic prescribing. These results are well below the 90% NDP goal. Generic prescribing for all the clinics is at or below 45% of the total drugs. The average for the proportion of generic drugs is even lower at 33.31%. Looking at individual clinics, the best within the group of clinics is Clinic 6 with 45.26% generic prescribing. Clinic 3, a specialty clinic at a tertiary care facility, has the lowest percentage of generic prescribing.

Table 7.9 Rank List of Hospital Clinics for Generic Drug Prescribing

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	*6*	*10*	*11*	*1*	*9*	*5*	*7*	*4*	*2*	*8*	*3*
No Generic	177	50	83	289	130	152	85	58	42	80	37
% Generic	45.26	40.65	40.29	39.00	35.51	34.08	29.51	25.10	24.27	23.25	15.28
Coeff.	1.838	1.526	1.426	1.380	1.193	1.115	0.922	0.756	0.731	0.687	0.390
P Value	0.000	0.015	0.009	0.000	0.105	0.284	0.514	0.054	0.061	0.002	0.000
A- Rank	1	2	3	4	5	6	7	8	9	10	11

Note: P values of 0.000 are actually <0.001.

In Table 7.9, the adjusted (A-Rank) and adherence (S-Rank) models have the same ranking. Clinics 6 and10, at the secondary and primary level respectively, prescribe the most generics, they are 86% and 53% more likely to prescribe generic medicines compared to the other clinics overall. Clinics 8 and clinic 3 are 31% and 61% less likely to prescribe generic drugs.

Indicator Four: Proportion of EDL Drugs

As a fourth indicator for rational drug prescribing the proportion of drugs that are on the EDL was analysed. The NDP goal for essential drug prescribing is 90% of all drugs. In addition, the proportion of essential drug prescribing is compared with generic drug prescribing.

Table 7.10 Proportion of Drugs from EDL

Level	Pietersburg-Tertiary			Mankweng-Tertiary		Secondary			Primary			Total
Drugs	1,156			677		1,023			695			3,551
No. EDL	308			158		262			208			936
% EDL	26.64			23.33		25.61			29.92			26.35
Clinics	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	Sum
Drugs	741	173	242	231	446	391	288	344	366	123	206	3,551
No. EDL	267	26	15	47	111	139	67	56	102	41	65	936
% EDL	36.03	15.03	6.19	20.35	24.89	35.55	23.26	16.28	27.87	33.33	31.55	26.35

Overall, once again the primary level has the highest proportion, 29.92% of drugs prescribed on the EDL. However, all levels have a range of EDL prescribing of 23.33 to 29.92. All fall short of the 90% goal of drugs prescribed from the EDL.

Looking at individual hospital clinics, the range of EDL prescribing (Table 7.10) is quite wide, between 6.2% for clinic 3 and 36.0% for clinic 1, both at the tertiary level. The average is 24.6% of drugs prescribed are on the EDL, far below the NDP goal of 90%. The clinic with the best adherence to EDL drug prescribing is clinic 1 with 36% of drugs prescribed. In contrast, clinic 3, the least adherent with only 6.2% of the drugs prescribed on the EDL. Overall, the evidence supports a lack of EDL drug prescribing at all levels of the study clinics.

Table 7.11 Rank List of EDL Drug Prescribing

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	*1*	*6*	*10*	*11*	*9*	*5*	*7*	*3*	*4*	*8*	*2*
No. EDL	267	139	41	65	102	111	67	51	47	56	26
% EDL	36.03	35.55	33.33	31.55	27.87	24.89	23.26	21.07	20.35	16.28	15.03
Coeff.	1.641	1.618	1.468	1.337	1.108	0.950	0.896	0.797	0.775	0.600	0.549
P Value	0.000	0.000	0.034	0.044	0.377	0.645	0.412	0.130	0.130	0.000	0.003
A-Rank	1	2	3	4	5	6	7	8	9	10	11

Note: P values of 0.000 are actually <0.001.

In Table 7.11, the adjusted (A-Rank) and adherence (S-Rank) models furnish the same rank list. Clinics 1, 6 and 10, which are at all three levels of care are significantly better than the average for the proportion of drugs from the EDL. They are 64%, 62% and 46% respectively, are more likely to prescribe drugs that are on the EDL. The least likely to prescribe drugs on the EDL are clinic 8, which is 40% and clinic 2 which is 45% less likely to prescribe drugs on the EDL.

Table 7.12 Comparison of the Proportion of Generic and EDL Prescribing

Clinic	1	2	3	4	5	6	7	8	9	10	11	Sum
Drugs	741	173	242	231	446	391	288	344	366	123	206	3,551
% Generic	39.00	24.27	15.28	25.10	34.08	45.26	29.51	23.25	35.51	40.65	40.29	33.31
% EDL	36.03	15.03	6.19	20.35	24.89	35.55	23.26	16.28	27.87	33.33	31.55	27.37
% Diff.	2.97	9.24	9.09	4.75	9.19	9.71	6.25	6.97	7.64	7.32	8.74	5.94

All EDL drugs are generic, but not all generic drugs prescribed are on the EDL. The prescribing of generic drugs and EDL drugs should be equal if only generic drugs on the EDL are prescribed. Instead all clinics have a higher percentage of generic prescribing than EDL prescribing. This is a clear indication that the EDL is not being used directly. Even more importantly, generic drugs not on the EDL are not ordered by the drug depot, are not in the hospital pharmacies, and thus should not be prescribed.

From the evaluation of the drugs prescribed it has been determined that less than 40% of the drugs prescribed are generic and even less are from the EDL are the most of the other drugs prescribed brand products that are on the EDL in generic form? The fifth indicator, the proportion of brand drugs on EDL as generic, will attempt to answer this question.

Indicator Five: Proportion of Brand Drugs on EDL as Generic Drugs

The question that now arises is "Are the drugs that are prescribed by their brand patented name, also on the EDL as generic or are prescribers requesting drugs for their patients that are not on the EDL. The NDP goal is 90% of the drugs prescribed are on the EDL, even if they are being prescribed by brand name.

Although the rate of generic prescribing is higher than the EDL prescribing, the evaluation of whether the NDP rational prescribing goal is met is not possible without looking at the proportion of drugs that are prescribed as brand and are on the EDL as generic drugs. The generic drugs at the pharmacy are usually substituted for prescribed brand drugs. The proportions of brand drugs (Table 7.13) take this factor into consideration.

Table 7.13 Proportion of Brand and Generic Drugs on EDL (EDLBRD)

Level	Pietersburg-Tertiary			Mankweng-Tertiary		Secondary			Primary			Total
Drugs	1,156			677		1,023			695			3,551
EDLBR	758			472		760			505			2,495
%EDBR	65.57			69.71		74.29			72.66			70.26
Clinics	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	Sum
Drugs	741	173	242	231	446	391	288	344	366	123	206	3,551
EDLBR	507	107	144	135	337	328	183	249	292	69	144	2,495
%EDBR	68.42	61.85	54.96	67.10	75.56	83.89	63.54	72.38	79.78	56.10	69.90	70.26

Note: EDLBR is the same as EDLBRD

The secondary level has the highest percentage, 74.29% of drugs prescribed as either brand or generic that are on the EDL. The range of drugs on the EDL as a generic equivalent for all levels is from 65.57 to 74.29%. These percentages are well below the

expected 90% that are expected when 10% of the total drug budget can be spent on drugs not on the EDL. At individual clinics, the range of EDL drugs supplied as generic despite sometimes being prescribed by brand is between 83.9 % for Clinic 6, and 55.0% for Clinic 3. As expected this is a more realistic and encouraging range from those shown in Table 7.12.

Table 7.14 Ranking of EDL/Brand Drugs (EDLBRD) in Clinics

S- Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	6	9	5	8	11	1	4	7	2	10	3
Drugs	391	366	446	344	206	741	231	288	173	123	242
EDLBRD	328	292	337	249	144	507	135	183	107	69	144
%	83.89	79.78	75.56	72.38	69.90	68.42	67.10	63.54	61.85	56.10	54.96
Coeff.	2.235	1.685	1.372	1.190	1.035	0.970	0.895	0.788	0.736	0.560	0.557
P Value	0.000	0.000	0.004	0.140	0.810	0.716	0.410	0.044	0.040	0.001	0.000
A-Rank	1	2	3	4	5	6	7	8	9	10	11

Note: P values of 0.000 are actually <0.001.

In Table 7.14, the adjusted (A-Rank) and adherence (S-Rank) models have the same ranking. Clinic 6 at the secondary level and clinic 9, at the primary level both have a high proportion of prescribed drugs that are on the EDL as generic drugs. Clinic 6 is 124% and clinic 9 is 69%, more likely respectively to prescribed drugs that are on the EDL as generic (whether prescribed by brand or generic name). Even though physicians are prescribing by brand name, if the drug is on an equal generic drug can substitute the EDL.

In contrast, clinics 10 and clinic 3 have the lowest combined prescribing and are both 44% less likely to prescribe brand or generic drugs on the EDL. More than half of the prescriptions cannot be filled with the drug intended, and the pharmacists have to substitute another similar drug for the prescribed drug.

Indicator Six: Proportion of Antibiotics Prescribed

A further indicator for rational drug prescribing is the proportion of antibiotics prescribed. The NDP goal for this indicator is less than 10%.

Table 7.15 Proportion of Antibiotics Prescribed

Level	Pietersburg-Tertiary			Mankweng-Tertiary		Secondary			Primary			Total
Drugs	1,156			677		1,023			695			3,551
No. AB	144			60		103			77			384
%. AB	12.45			8.86		10.06			11.07			10.81
Clinics	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	Sum
Drugs	741	173	242	231	446	391	288	344	366	123	206	3,551
No. AB	82	30	32	25	35	39	30	34	32	5	40	384
%. AB	11.07	17.34	13.22	10.82	7.85	9.97	10.42	9.88	8.74	4.07	4.85	10.81

Notes: P: Pietersburg, M: Mankweng, No. AB, Number of Antibiotics

In Table 7.15, the goal of prescribing no more than 10% of antibiotic drugs by the hospitals overall has been met with 10.81% prescribed. At the tertiary level, Pietersburg hospital clinics has the highest percentage of antibiotic prescribing with 12.45%, while Mankweng hospital clinics at the same level has the lowest percentage or 8.86%. The secondary level clinics also have met the target gaol with 10.06% antibiotic prescribing.

Of the individual clinics, five of the eleven clinics were over the 10% goal, but only two over 13% antibiotics. The primary clinics 9, 10, and 11 are overall the best, while the secondary clinics 6, 7 and 8 are closest to the 10% goal. Most of the tertiary level clinics that are over 10% mark. Pietersburg – tertiary clinics 1, 2 and 3 prescribe 11.07%, 17.34% and 13.22% antibiotics respectively. The Mankweng- tertiary clinic 4 fulfils that goal of 10% and Clinic 5 is close to it with 10.8% antibiotics.

Table 7.16 Ranking of Antibiotic Prescribing for Hospital Clinics

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	10	11	5	9	8	6	7	4	1	3	2
Total #	123	206	446	366	344	391	288	231	741	242	173
# AB	5	10	35	32	34	39	30	25	82	32	30
% AB	4.07	4.85	7.85	8.74	9.88	9.97	10.42	10.82	11.07	13.22	17.34
Coeff.	0.493	0.574	0.987	0.977	0.896	1.051	1.142	1.036	1.357	1.474	1.646
P Value	0.096	0.069	0.942	0.899	0.547	0.782	0.491	0.865	0.020	0.041	0.013
A-Rank	1	2	5	4	3	7	8	6	9	10	11

In Table 7.16, the adjusted (A-Rank) and adherence (S-Rank) models have the same ranking. Clinics 10 and 11, both at the primary level are ranked first and second. Clinic 10 is 50% and clinic 11 is 43%, less likely respectively to prescribe antibiotics. While clinics 1, 2 and 3 all at Pietersburg-tertiary care clinics are significantly more likely to prescribe antibiotics, Clinic 1 to 36%, clinic 3 to 47% and clinic 2 is 65% more likely.

Indicator Seven: Proportion of Analgesics Drugs Prescribed

The NDP goal of less than 15% analgesics of prescribed drugs is a further indicator of rational drug prescribing.

Table 7.17 Proportion of Analgesic Prescribed

Level	Pietersburg-Tertiary			Mankweng-Tertiary		Secondary			Primary			Total
Drugs	1,156			677		1,023			695			3,551
No. AG	264			137		249			130			780
%. AG	4.37			20.23		24.30			18.70			21.97
Clinics	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	Sum
Drugs	741	173	242	231	446	391	288	344	366	123	206	3,551
No. AG	159	52	53	54	83	86	83	80	84	24	22	780
%. AG	21.46	30.06	21.90	23.38	18.61	21.99	28.82	23.26	22.95	19.51	10.68	21.97

Notes: P: Pietersburg, M: Mankweng, No. AG, Number of Analgesics

In Table 7.17, the data for analgesic drug prescription are summarised. At the tertiary level, Pietersburg hospital clinic has the lowest analgesic prescribing with 4.37%. At all levels with the exception of secondary clinics met the 20% target goal, while the secondary was quite close at 24.30%. When looking at individual clinics, all clinics except one are over the 15% goal of prescribing analgesics. Only clinic 11 was significantly under the 15% target with 10.68% analgesic prescribing. Clinic 2 had 30.06% analgesic prescribing, double the NDP goal of 15%.

Table 7. 18 Ranking of Analgesic Drug Prescribing

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	11	5	10	1	3	6	9	8	4	7	2
Total	206	446	123	741	242	391	366	344	231	288	173
# AG	22	83	24	159	53	86	84	80	54	83	52
% AG	10.68	18.61	19.51	21.46	21.90	21.99	22.95	23.26	23.38	28.82	30.06
Coeff	0.444	0.843	0.900	0.996	0.996	1.037	1.101	1.067	1.115	1.456	1.512
P Value	0.000	0.160	0.622	0.966	0.980	0.770	0.433	0.608	0.468	0.003	0.009
A-Rank	1	2	3	4	4	6	8	7	9	10	11

Note: P values of 0.000 are actually <0.001.

In Table 7.18, the adjusted (A-Rank) and adherence (S-Rank) models have the same ranking. Clinic 11, at the primary care level is 56% less likely to prescribe an analgesic. While clinic 7 at the secondary level is 46% and clinic 2 at the tertiary level is 51% more likely to prescribe an analgesic.

Indicator Eight: Proportion of Injection Drugs Prescribed

The question answered in table 7.19 is "What proportion of the prescriptions are injections" and "does it meet the rational prescribing criteria of no more than 5% of all drugs prescribed?"

Table 7.19 Proportion of Injection Drugs Prescribed

Level	Pietersburg-Tertiary			Mankweng-Tertiary		Secondary			Primary			Total
Drugs	1,156			677		1,023			695			3,551
No. Inj.	25			15		34			10			84
% Inj.	2.16			2.22		3.32			1.43			2.36
Clinics	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	Sum
Drugs	741	173	242	231	446	391	288	344	366	123	206	3,551
No. Inj.	19	5	1	6	9	5	22	7	1	5	4	84
% Inj.	2.56	2.89	0.41	2.59	2.01	1.27	7.63	2.03	0.27	4.06	1.94	2.36

Notes: P: Pietersburg, M: Mankweng, No. Inj.: Number of Injections

At all levels, all the clinics had less than 5% injections prescribed with the exception of one. Clinic 7 has 7.6% of injection prescribing, about 50% more than the goal. The proportion of injection drugs prescribed ranges from 0.3% to 7.6%, the average being 2.4%.

Table 7. 20 Rank of Injections Prescribing in Hospitals Clinics

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	9	3	6	11	5	8	1	4	2	10	7
No. Rx	366	242	391	206	446	344	741	231	173	123	288
No. Inj	19	5	1	6	9	5	22	7	1	5	4
% Inj	0.27	0.41	1.27	1.94	2.01	2.03	2.56	2.59	2.89	4.06	7.63
Coeff.	0.157	0.212	0.759	1.157	1.231	0.995	1.446	1.377	1.317	2.474	4.303
P Value	0.045	0.092	0.543	0.766	0.555	0.990	0.173	0.441	0.539	0.047	0.000
A-Rank	1	2	3	5	6	4	9	8	7	10	11

Note: P values of 0.000 are actually <0.001.

In Table 7.20, the adjusted (A-Rank) and adherence (S-Rank) models have slightly different rankings. Clinic 9 at the primary level is ranked first and is 84% less likely to prescribe an injection. In contrast, clinics 10 and 7 are 147% and 330% more likely to prescribe an injection, respectively.

Table 7.21 Prescribing Outcomes by Clinic Level (Primary, Secondary, Tertiary)

Analysis of the eight prescribing indicators by level of care (primary, secondary and tertiary) to determine if there is a difference in the degree of implementation of the NDP Policy and EDP principles between the three levels of care.

Table 7.21 Prescribing Indicators by Hospital Care Level

Level	Goal	Primary	Secondary	Tertiary	Overall
No Drugs	-	695	1,023	1,833	3,551
Mean No	2.0	3.24	2.75	2.96	2.94
%>2 Drugs	95%	64.95	56.06	62.20	60.80
% Generic	90%	37.84	33.43	31.53	33.31
% EDL	90%	29.93	25.61	27.39	26.35
% EDLBRD	90%	72.66	74.29	67.59	70.26
% AB	10%	6.76	10.07	11.13	10.81
% AG	15%	18.71	34.34	21.88	21.97
% INJ	5%	1.44	3.32	2.18	2.36

Evaluation prescribing indicators (Table 7.21) for the three levels of care, shows that the primary level has the highest number of drugs per prescription and > 2 drugs, but the also the highest number of prescriptions with of EDL and generic prescribing. Overall the primary level has better compliance with EDL principles with the exception of prescriptions of brand drugs that are found as generic drugs on the EDL and a high absolute proportion of analgesic prescribing, although still at lowest proportion of the three levels.

The secondary level has the lowest number of drugs prescribed and prescriptions with more than two drugs but has the highest proportion of analgesics. Conversely, it has high number of EDL drugs prescribed by brand name (EDLBRD). Overall that means that more EDL drugs are dispensed, even though prescribing is by brand name. At the tertiary level, the percentage of generic drugs and of EDL drugs is lower than average, while the percentage of antibiotics is higher. This low compliance with the NDP policy and the difficulty with the implementation of the EDP principles have several reasons.

First of all it is known that specialised physicians at tertiary level are more resistant to the implementation of an EDL. Also a higher percentage of referred patients with rarer and more difficult diseases, which are possibly not covered in the Standard Treatment Guidelines (STG/EDL) and require special drugs not on the EDL.

Overall, the apparent compliance probably being more to do with the limited range of drugs available at the primary level did not adhere to prescribing indicator standards as much as expected.

The next question "Is there a difference in the eight indicators between the two tertiary care hospitals. The measure will be a direct comparison between the two hospitals with 5 clinics and the overall average for all clinics. The hypothesis is that although Pietersburg-Mankweng hospitals are considered a complex, each serves a very different population that could have a significant effect on the outcome indicators.

Pietersburg Hospital was a segregated hospital that treated only white patients. Today, it also treats black patients. It is located in the center of town, only minutes from the Provincial Department o f Health. Mankweng Hospital still treats only black patients and is located about 25 miles away from the center of the town and is surrounded by black townships.

Mankweng Hospital has the higher number of mean drugs per prescription and the higher proportion more than (>2) two drugs. Also, it has lower proportion of EDL prescribing, but the proportion of EDLBRD drugs is higher than Pietersburg. Overall, the evidence does not support that one tertiary complex is better overall.

7.4.2 Overall Ranking List of Prescribing Outcome Indicators

Analysis Two

Now that all eight prescribing indicators have been evaluated separately, and all the clinics can be ranked in a final analysis (Table 7.22). This comprehensive table sums the

separate indicator scores for a final ranking of the adherence to the EDP with adjusted coefficients. The best score would be 8 (1st rank for all 8 indicators), while the worst score would be 88 (11th rank for 8 indicators). In Tables 7.22 and 7.23, the ranking is from the most adherent to the EDP with the lowest score to the least adherent with the highest score. This overall ranking by adherence provides quantitative evidence about the extent of adoption of the EDP principles in the health care system.

Adherence Ranking (Table 7.22)

The extent of adoption of EDP principles by the different clinics that use the eight prescribing indicators is summarised in Table 7.22 using the non-corrected model.

Table 7.22 Simple Rank List for Adherence to Prescribing Indicators by Clinics

Overall Ranking	1	2	3	3	4	5	5	6	7	8	9
Clinic	6	9	5	11	10	1	8	3	7	2	4
Mean No.	3	6	8	11	9	10	4	2	5	1	7
<2 Drugs	5	7	8	11	4	9	3	2	6	1	10
Generic	1	5	6	3	2	4	10	11	7	9	8
EDL	2	5	6	4	3	1	10	8	7	11	9
EDLBRD	1	2	3	5	10	6	4	11	8	9	7
Antibiotic	6	4	3	2	1	9	5	10	7	11	8
Analgesic	6	7	2	1	3	4	8	5	10	11	9
Injection	3	1	5	4	10	7	6	2	11	9	8
Total Score	**27**	**37**	**41**	**41**	**42**	**50**	**50**	**51**	**61**	**62**	**66**

The scores range from 27 to 66. Clinic 6 has the lowest score of 27 and is ranked first for adherence to the EDP, while Clinic 4 was ranked last with a score of 66. This overall ranking using all 8 prescribing indicators summarises the data which shows that the adoption of the NDP principles Is only in the beginning stages and can be much improved in all researched clinics. These results were not unexpected or surprising.

Adjusted Ranking (Table 7.23)

The rank list of adherence to EDP principles using the eight prescribing indicators in the adjusted model is provided in 7.23. A low total score signifies good adherence, a high total score worse adherence.

Table 7.23 Rank List Using Adjusted Coefficients of Prescription Indicators

Overall Ranking	1	1	2	2	3	4	5	6	7	8	8
Clinic	6	8	3	9	5	11	10	2	1	7	4
Mean No.	3	4	2	6	7	11	8	1	10	5	9
<2 Drugs	5	4	2	7	8	11	3	1	9	6	10
Generic	11	2	1	7	6	9	11	3	8	5	4
EDL	2	10	8	5	6	4	3	11	1	7	9
EDLBRD	1	4	11	2	3	5	10	9	6	8	7
Antibiotic	7	3	10	4	5	2	1	11	9	8	6
Analgesic	6	7	4	8	2	1	3	11	4	10	9
Injection	3	4	2	1	6	5	10	7	9	11	8
Total Score	38	38	40	40	43	48	49	54	56	62	62

Table 7.23 evaluates the adjusted ranking of adherence to prescribing indicator goals. The scores range from 38 to 62. Clinics 6 and 8 have the lowest score of 38 and are ranked first, while Clinics 4 and 7 are ranked last with a score of 62.

The overall rankings in Table 7.22 and 7.23 can reveal a part of the NDP rational prescribing implementation. It shows that the goal of rational prescribing and adhering to its target goals does not appear to have taken affect by prescribers from the relative spread of the sores from 38 to 62. The primary care clinics have the highest adherence rankings and overall the lowest adherence rankings along with a tertiary clinic.

7.5 Comprehensive Correlation Matrix of Prescribing Indicators

Analysis Three

Rank Correlation Coefficients Using the Simple and the Adjusted Model

In this section, two correlation tables are calculated from the simple ranking and from the adjusted ranking of the clinics using the eight indicators for rational drug prescribing. Some clinics could be considered more successful at the implementation of the NDP than others. This would show in positive correlation of the ranks of several or all the eight prescribing indicators.

Looking at the adjusted correlation (Table 7.24) for all clinics a little closer there are some comments worth making. The high and significant correlation between mean number of drugs per prescription and proportion of prescriptions with more than 2 drugs, also between proportion of drugs prescribed generically and proportion from the ED list, are entirely expected; it would be surprising if they did not occur. No other correlations are significant. Of these most correlations with mean number of drugs and with proportion of prescriptions with more than two drugs are negative, whereas most other correlation pairs are positive.

Positive correlations are expected although most are insignificant. The absence of significant correlations suggests that there is little evidence of coherent and concerted implementation of an EDL policy. For example the weak correlation between prescribing from the ED list and reducing antibiotic prescribing (0.26) suggests that a link between improving both activities are not well established.

The negative correlations suggest that hospitals doing well by reducing polypharmacy are doing badly on generic prescribing, ED list prescribing, and antibiotic prescribing. This, of course, is further evidence against a concerted implementation of policy by suggesting that reductions in overall prescribing by some hospitals are not accompanied by reduced antibiotic prescribing or greater use of generic or ED list drugs.

Table 7.24 Correlation Coefficients of Ranked Prescribing Indicators Using Adjusted (age and gender) Model

	Mean No	>2 Drugs	Generic	EDL	EDBRD	AB	AG	INJ
Mean No	1.0000							
>2 Drugs	**0.8455***	1.0000						
Generic	-0.4909	-0.3636	1.0000					
EDL	-0.5182	-0.3818	**0.8818***	1.0000				
EDBRD	-0. 1364	-0.4455	0.4182	0.3273	1.0000			
AB	-0.5364	-0.3273	0.4364	0.2636	0.3182	1.0000		
AG	-0.5115	03141	0.4307	0.5832	0.0987	0.4576	1.0000	
INJ	0.3636	0.1182	-0.1364	-0.0727	0.4636	0.0455	0.1256	**1.0000**

Analysis three, the comprehensive correlation matrix of prescribing indicators for all the clinics showed several significant correlations. However, overall there is little evidence of a comprehensive coherent implementation of the EDP by individual clinic. Perhaps there is one level of clinics that are doing better.

To determine if there is a difference in adherence by level of care between prescribing with or without chronic illnesses, a forth analysis will look at the eight indicators by hospital clinic level.

7.6 Chronic Illnesses and Prescribing

Analysis Four

7.6.1 Introduction

Chronic illnesses have become a major factor in the morbidity and mortality of South African adults. The three chronic illnesses evaluated for this study are hypertension, diabetes, and asthma, and the combination of these illnesses.

Analysis of the prescribing pattern for these chronic illnesses using the eight prescription indicators is important to answer the question if these very common chronic illnesses are treated using STG guidelines and EDL drugs.

Overall the study population was 1,204 prescriptions from the same number of individuals. Of 1,204 people, 429, or 36.6% of patients were identified as having one or more of the three chronic illnesses evaluated. The next question was in absence of a facility/professional referral system in which patients are referred from a lower technical level of care (primary),"at what level do these patients present themselves (through formal and self-referral)? The level of care and the eight outcome indicators are important components in evaluating and comparing these chronically ill patients to the overall patient population of this study.

Table 7.25 Proportion of the Chronic Illnesses of Hypertension, Diabetes and Asthma

Level	Pietersburg-Tertiary			Mankweng-Tertiary		Secondary			Primary			Total
Total	620					370			214			1,204
Chronic	222					114			93			429
% Chron.	36.80					38.91			43.45			36.61
Clinics	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	Sum
Total	224	78	97	75	145	144	101	126	123	39	52	1,204
No Chronic	106	6	7	20	83	60	29	25	53	14	26	429
% Chronic	47.32	7.69	7.22	26.67	57.24	41.67	28.71	19.84	43.09	35.90	50.00	36.61

7.6.2 Chronic Illness, Hospital and Level of Care

According to the Primary Health Care foundation of the South African Department of Health a majority of patients, especially those with chronic illnesses should have access and be treated at the primary level. If the treatment is not successful, then a professional referral to the secondary level or tertiary level is needed.

The primary care level is expected to successfully treat the majority of cases of chronic illnesses. The secondary level is expected to have fewer cases and the tertiary level, even fewer still. This assumption is based on the theory that basic illnesses, especially chronic

illnesses are treated at the primary care level, while the more advanced diseases or unmanageable chronic cases are treated at the tertiary level. At the primary care level the common chronic illnesses of hypertension, diabetes, and asthma can be effectively followed and treated.

Table 7.26 Chronic Illness and Hospital Care Level

Level	Tertiary		Secondary		Primary		Total	
Patients	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Total Patients	**620**	**51.6**	**370**	**30.7**	**214**	**17.8**	**1,204**	**%**
Chronic Illness	222	51.7	114	33.5	93	21.6	429	90.88
>1 Chron. Illness	20	4.23	15	3.17	8	1.69	43	**9.11**
Total Chronic	**242**	**51.2**	**129**	**27.3**	**101**	**21.3**	**472**	**100**
Hypertension	173	54.4	74	23.2	71	22.3	318	**100**
Diabetes	48	52.	37	40.2	7	7.6	92	100
Asthma	21	33.8	18	29.0	23	37.0	62	100

7.5.3 Evaluation of the Eight Prescribing Indicators for Chronic Illnesses

Indictor One: Mean Number of Drugs per Prescription

The recommended value remains the same for chronic patients, two drugs or less per prescription, even though it would seem that those with chronic illnesses would need more medications.

Evaluating these chronic illnesses by level of care (Table 7.27) shows that the primary care level had at 37% the highest proportion of those with asthma. In addition, the proportion for both hypertension and diabetes was the lowest at 22.3% and 7.6% respectively. The secondary level has the lowest proportion, 29.0% of asthma. Overall, tertiary care had the highest proportion of chronically ill at 51.1% of the entire population. In addition, it has the highest proportion for hypertension, 54.4%, and diabetes 52.1%.

Table 7.27 Chronic Illnesses and the Mean Number of Drugs

S-Rank	1	2	3	4	4	5	6	7	8	9	10
Clinic	2	7	3	4	6	5	9	8	1	10	11
No Drugs	16	89	22	63	189	280	188	92	399	65	129
No RX	6	29	7	20	60	83	53	25	106	14	26
Drug/Rx	2.66	3.06	3.14	3.15	3.15	3.37	3.54	3.68	3.76	4.64	4.96
Coeff.	-0.906	-0.422	-0.568	-0.348	-0.430	-0.234	0.011	0.237	0.199	1.016	1.444
P Value	0.080	0.096	0.239	0.242	0.028	0.169	0.957	0.378	0.202	0.004	0.000
A-Rank	1	4	2	5	3	6	7	9	8	10	11

In Table 7.28, there is a difference between the adherence (S-Rank) in the simple model and the A-Rank in for several clinics, but most profoundly for clinic 7 which is ranked 2nd for adherence and 4th for the adjusted coefficient.

Clinic 2 is ranked first with 2.66 drugs per prescription, 0.9 drugs less than average. None of the clinics meet the recommended standard, although some are doing better than others. The clinics with the highest number or prescriptions are at the primary level, clinic 10 with 1.0 drugs more than average and clinic 11 with 1.4 drugs more.

Indicator Two: Proportion of Prescriptions with More than Two Drugs

Analysis of the proportion of prescriptions with more than two drugs is an important indicator for the adherence to EDP principles. The value remains the same for chronic illnesses, two drugs or less for at least 90% of the prescriptions

Table 7.28 Chronic Illness and Proportion of >2 Drugs per Prescription

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	2	3	7	8	6	4	9	5	1	10	11
No. Drug	6	7	29	25	60	20	53	83	106	14	26
No. >2	3	4	20	16	45	15	42	66	93	13	25
% >2	50.0	57.14	68.97	64.00	75.00	75.00	79.25	79.52	87.74	92.86	96.15
Coeff.	0.219	0.287	0.681	0.565	0.849	0.966	1.195	0.977	1.911	3.121	7.237
P Value	0.050	0.093	0.387	0.206	0.644	0.949	0.642	0.941	0.058	0.237	0.041
A-Rank	1	2	4	3	5	6	9	7	8	10	11

The range of prescribing more than two drugs (Table 7.28) is from 50.0% to 96.2% of all prescriptions; the average for all clinics is 90.1%. Nine of eleven clinics have more than 60% prescriptions with more than 2 drugs. Clinics 2 and 3, at the tertiary level are ranked first and second.

The adjusted (A-Rank) and adherence (S-Rank) models have the same ranking for all the clinics. Clinic 2 is ranked first and is 78% less likely to prescribe more than 2 drugs per prescription. At the opposite end of rational prescribing, clinic 11 is ranked last and is more than 7 times more likely to prescribe more than 2 drugs.

Indicator Three: Proportion of Generic Drugs

The question is "What proportion of drugs has been prescribed as generic?" The recommended value remains the same for chronic illnesses, 95% or more for generic prescribing.

Table 7.29 Chronic Illness and Proportion of Generic Drugs

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	2	10	6	4	7	1	11	5	3	9	8
No. Drug	16	65	189	63	89	399	129	280	22	188	92
No. Generic	9	35	96	30	42	188	53	106	8	60	19
% Generic	56.25	53.85	50.79	47.62	47.19	47.12	41.09	37.86	36.36	31.91	20.65
Coeff.	1.610	1.700	1.448	1.186	1.270	1.210	0.911	0.831	0.785	0.649	0.359
P Value	0.307	0.030	0.023	0.487	0.258	0.122	0.613	0.184	0.559	0.009	0.000
A-Rank	2	1	3	6	4	5	7	8	9	10	11

The range of prescribing of generic drugs (Table 7.29) is from 20.7% to 56.3% of all prescriptions. The average of generic prescribing is 42.2%, well below the recommended value of 95% of all drugs. Clinic 2 at the tertiary level, and Clinic 10, at the primary care level are ranked first and second for adherence with 56.3% and 53.9% generic prescribing respectively. The lowest level of generic prescribing is 20.7% by clinic 8, at the secondary level.

The adjusted (A-Rank) and adherence (S-Rank) models have slightly different rankings for all the clinics. Clinic 10 is 70% and clinic 2 is 61% more likely to prescribe the average generically. Clinic 8 is 64% less likely to prescribe generically.

Overall, the evaluation of prescribing for chronic illnesses does not show evidence of higher generic prescribing than the general study population.

Indicator Four: Proportion EDL Drugs

The question is "What proportion of drugs prescribed for those with chronic illnesses are on the EDL?" The recommended value remains the same for chronic illnesses, 90% or more for EDL prescribing.

Table 7.30 Chronic Illnesses and Proportions of EDL Drugs

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	1	2	10	6	7	3	4	11	9	5	8
No. Drug	399	16	65	189	89	22	63	129	188	280	92
No. EDL	181	7	27	78	35	8	21	41	52	76	14
% EDL	45.36	43.75	41.54	41.27	39.33	36.36	33.33	31.78	27.66	27.14	15.22
Coeff.	1.611	1.387	1.397	1.357	1.287	1.182	0.961	0.902	0.723	0.704	0.351
P Value	0.000	0.484	0.177	0.064	0.242	0.686	0.879	0.595	0.061	0.019	0.000
A-Rank	1	3	2	4	5	6	7	8	9	10	11

Note: P values of 0.000 are <0.001.

Table 7.30 the range is from 15.22% to 45.36% of drugs prescribed that are on the EDL. All clinics fall below the recommended value of 90%. The clinic closest to this goal is still 50% below the rational drug prescribing target.

Clinic 1, at the tertiary level, is ranked first for both adherence and adjusted ranking with 45.36% of drugs prescribed on the EDL. Clinic 8, at the secondary level, is ranked last with only 15.22% of drugs prescribed from the EDL.

The adjusted (A-Rank) and adherence (S-Rank) models have slightly different rankings for the proportion of EDL drugs. Clinic 1 is 61% more likely to prescribe drugs on the EDL, while clinic 8 is 65% less likely to prescribe drugs on the EDL.

The goal for prescribing drugs from the EDL at least 90%, but the results show that the clinic with the highest proportion of EDL prescribing is still 50% lower than desired. The other prescribers in the other ten clinics are off the mark by 50% to 80%. Treatment of chronic illnesses using the Standard Treatment Guidelines (STG) and EDL drugs was expected to be higher than for all illnesses together, since the treatments are widely accepted and the necessary EDL drugs are readily available. But, surprisingly, analysis of the prescribing pattern for chronic illness shows that the implementation of the STG/EDL has not been as successful as expected.

Indicator Five: Proportion of Brand and Generic Drugs on EDL

The question is "What proportion of brand and generic drugs prescribed for those with chronic illnesses are on the EDL?" The recommended value is 95%. Prescribing in brand name is acceptable if there is a generic equivalent drug on the EDL, which can be dispensed. Which name is used for a drug is not important as long as it is on the EDL, and the patient gets the drug intended.

Table 7.31 Chronic Illness and Proportions of Brand & Generic (EDLBRD) Drugs on the EDL

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	6	8	4	9	3	7	5	1	11	10	2
No. Drug	189	92	63	188	22	89	280	399	129	65	16
No. EDLBRD	167	76	52	154	18	71	222	289	93	39	9
% EDLBRD	88.36	82.61	82.54	81.91	81.82	79.78	79.29	72.43	72.09	60.00	56.25
Coeff.	2.087	1.379	1.449	1.233	1.645	1.193	1.141	0.759	0.746	0.409	0.375
P Value	0.002	0.233	0.245	0.293	0.332	0.3497	0.423	0.048	0.151	0.000	0.038
A-Rank	1	4	3	5	2	6	7	8	9	10	11

Note: P values of 0.000 are <0.001.

The range of brand and generic drugs (EDLBRD) prescribed on the EDL (Table 7.31) is from 56.3% to 88.4% of all drugs. The average proportion of drugs prescribed from the EDL is 77.6% of all drugs. Clinic 6, at the secondary level, is ranked first with 88.4% for prescribing (brand and generic) that are on the EDL. Clinics 10, at the primary level with 60% of drugs on the EDL and clinic 2 at the tertiary level with 56.3% of drugs prescribed on the EDL are ranked last.

The ranks in the simple (S-rank) and the adjusted model (A-Rank) differ slightly for clinics 3, 4 8 and 9. This difference does not affect the overall results. Prescribers at Clinic 6 are more than 100% more likely to prescribe drugs (brand or generic) on the EDL. Clinics 10 and 2 are about 60% less likely to prescribe drugs on the EDL.

The target for prescribing drugs in brand or generic name that are on the EDL is 90%. The results show that the clinic with the highest proportion of drugs prescribed on the EDL is still slightly 12% below the desired 90%. The other prescribers in the other ten clinics are off the mark by 20% to 60%. Thus, after accounting for those who use brand name or generic drugs, there is little evidence that the NDP is being successfully implemented through dispensing generic drugs.

Indicator Six: Chronic Illness and Proportion of Antibiotics

The question is "What proportion of antibiotics are prescribed for those with chronic illnesses?" The recommended value is less than 5%. The prescribing of antibiotics for those with chronic illnesses should be very low, if antibiotics are prescribed for bacterial infections.

Table 7.32 Chronic Illness and Proportions of Antibiotic (AB) Drugs

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	4	9	6	8	11	1	10	7	5	2	3
No. Drug	63	188	189	92	129	399	65	89	280	16	22
No. AB	0	1	4	2	3	10	2	3	10	1	4
% AB	0.00	0.53	2.12	2.17	2.33	2.51	3.08	3.37	3.57	6.25	18.18
Coeff.	0	0.655	2.271	2.936	3.260	3.224	4.016	5.078	4.621	8.971	40.408
P Value	0	0.648	0.139	0.115	0.040	0.001	0.043	0.005	0.000	0.023	0.000
A-Rank	1	2	3	4	6	5	7	9	8	10	11

Note: P values of 0 and 0.000 are <0.001.

In table 7.32 the range of antibiotic drugs prescribed is from 0% to 18.18% drugs. Clinics 4 and 3, both at the tertiary level are at the opposite ends of the prescribing range and will be evaluated in detail. Clinic 4, the Mankweng hospital specialty clinic for chronic illnesses, ranks first for adherence with no antibiotics prescribed. On the other end, Clinic 3, the Specialty clinic for Pietersburg Hospital is ranked last with 18.18% antibiotics prescribed.

All but two of the eleven clinics were below the recommended 5% antibiotic prescribing, but clinic 2 is nearly 8 times more likely and Clinic 3 is almost 40 times more likely to prescribe an antibiotic to those with chronic illnesses than the other clinics. This evidence supports a fairly comprehensive adoption the rational antibiotic prescribing for the subgroup of patients with chronic illnesses or the inappropriateness of antibiotics for those conditions.

Indicator Seven: Chronic Illness and Proportion of Analgesic Drugs

The question is "What proportion of analgesic drugs are prescribed for those with chronic illnesses?" The recommended value is lower than or equal to the general study population, at 15%. Effective treatment of chronic illness would eliminate the pain associated with the illness, and the number of analgesics for those with chronic illnesses should be very low.

Table 7.33 Chronic Illness and Proportion of Analgesic (AG) Drugs

S-Rank	1	2	3	4	5	6	7	8	9	10	11
Clinic	2	11	10	7	5	8	6	1	3	9	4
No. Drug	16	129	65	89	280	92	189	399	22	188	63
No. AG	1	12	7	13	44	15	32	69	4	41	15
% AG	6.25	9.30	10.77	14.61	15.71	16.30	16.93	17.29	18.18	21.81	23.81
Coeff.	0.391	0.607	0.720	0.954	1.024	1.179	1.154	1.187	1.272	1.570	1.856
P Value	0.320	0.102	0.398	0.877	0.907	0.570	0.525	0.332	0.645	0.031	0.039
A-Rank	1	2	3	4	5	7	6	8	9	10	11

The range of analgesic drugs prescribed (Table 7.33) is from 6.3% to 23.8% of all drugs. The overall proportion of analgesic drugs, Clinic 2 is ranked first with 6.3% of analgesic prescribing, prescribers at Clinic 2 are % less likely to prescribe analgesics. On the other hand, clinic 4 is ranked last with 23.8% of the drugs prescribed were analgesics. Indicator Eight: Chronic Illness and Proportion of Injection Drugs.

The question is "What proportion of injection drugs are prescribed for those with chronic illnesses?" The value is lower than expected or equal to the general study population, at 5% of all drugs prescribed. The hypothesis that is prescribing injections for those with chronic illnesses should be very low, because effective treatment of the chronic illness should be possible by oral medication.

Six clinics (2, 3, 6, 9, 10 & 11) did not prescribe any injections and two (clinics 4 & 8) prescribed only one injection. The other three clinics prescribed 5 injections (1.25%) for clinic 1, (1.07%) 3 injections for clinic 5 and 4 injections (4.49%) for clinic 7.

7.6.4 Overall Ranking List of Prescribing Outcome Indicators by Level of Adherence

Now that all eight prescribing indicators for chronic illnesses have been evaluated separately, all the clinics are ranked for all the indicators except injections, in a final table below (7.34). The overall ranking by adherence provides separate quantitative evidence to support or negate findings about the extent and pattern of adoption of EDP principles for those with chronic illnesses. The ranking is from the most adherent to the EDP,

which has the lowest score to the least adherent with the highest score. The clinics are presented in their care level categories, because in the treatment of chronic illnesses, the level of care is an important factor in evaluating prescribing. Since the indicator of prescribing injections was not ranked, it has been taken out of this set of analyses.

Table 7.34 Chronic Illnesses and Ranking of Prescribing Indicators Adherence

Clinic	6	2	7	4	3	10	1	8	5	9	11
Mean No.	3	1	4	5	2	10	8	9	6	7	11
>2 Drugs	5	1	4	10	2	10	8	3	7	9	11
Generic	3	2	4	4	9	1	5	11	8	10	7
EDL	4	3	5	7	6	2	1	11	10	9	8
EDLBRD	1	11	6	3	2	10	8	4	7	5	9
Antibiotic	3	10	8	1	11	7	5	4	8	2	6
Analgesic	6	1	4	11	9	3	8	7	5	10	2
Total Score	25	29	35	41	41	43	43	49	51	52	54
Overall Ranking	1	2	3	4	4	5	5	6	7	8	9

A majority of the chronic illnesses should be treated at the primary care level and should only be referred to tertiary level clinics, as the disease becomes more complex and difficult to treat. The primary care level clinics (9-11) should be able treat many patients with a limited number of generic drugs and should rank in the top three for compliance. But, Clinic 10 ranks sixth and Clinics 9 and 11, rank tenth and eleventh.

Conversely, prescribers at the tertiary level are expected to have a lower adherence score because of their specialty training and consistent exposure to new brand drugs and usually more difficult and rare diseases. But contrary to this expectation, clinic 2 a tertiary specialty was ranked second overall. Specifically, Clinic 2, ranked first for the lowest mean number of drugs, the lowest percentage of prescriptions with more than 2 drugs and the lowest number of analgesics prescribed, and ranked second for the higher proportion of prescribing generic drugs, and third for EDL drugs.

Ranked first for overall adherence to the EDP is Clinic 6 at the secondary level. Clinic 6 is ranked first in only one category, the proportion of brand and generic drugs prescribed on the EDL (EDLBRD). In all other categories the clinic scored third or higher. The key to being ranked first overall is that all the indicators are ranked no higher than 6. As a result it is overall the best compared to the other ten clinics.

Table 7.35 Ranking of Coefficient Indicators (A-Rank) of Prescribing Indicators for Chronic Illnesses

Clinic	6	2	7	4	3	10	1	8	5	9	11
Mean No.	3	1	4	5	2	10	8	9	6	7	11
>2 Drugs	5	1	4	10	2	10	8	3	7	9	11
Generic	3	2	4	4	9	1	5	11	8	10	7
EDL	4	3	5	7	6	2	1	11	10	9	8
EDLBRD	1	11	6	3	2	10	8	4	7	5	9
Antibiotic	3	10	8	1	11	7	5	4	8	2	6
Analgesic	6	1	4	11	9	3	8	7	5	10	2
Total Score	25	29	35	41	41	43	43	49	51	52	54
Overall Ranking	1	2	3	4	4	5	5	6	7	8	9

7.5.5 Comprehensive Correlation Matrix of Prescribing Indicators

Finally, two correlation tables (7.36 and 7.37) summarise the evaluation of the prescribing patterns for those with chronic illnesses. They are produced from simple (S-Rank) ranking for adherence and an adjusted (A-Rank) ranking by evaluating the correlate pairs of NDP indicators.

The question, " Is there evidence of a concerted and coherent implementation process of the EDP when prescribing for those with chronic illnesses?

The expected value would be positive correlation coefficients across the range of indicators if the implementation of the EDP policy were coherent.

For this analysis, ranks of the seven prescribing indicators for the eleven clinics are entered into the analysis program Stata 6.0. If the implementation of the NDP policy is being executed in a consistent way, the ranks for several or all indicators should correlate. Tables 7.36 and 7.37 show the simple and adjusted correlation tables.

Table 7.36 Chronic Illness and Simple Model of Correlation Coefficient of Prescribing Indicators

	Mean No.	>2 Drugs	Generic	EDL	EDLBRD	AB	AG
Mean No.	1.0000						
<2 Drugs	**0.8794***	1.0000					
Generic	0.3266	0.0789	1.0000				
EDL	0.1974	0.0818	**0.7981***	1.0000			
EDLBRD	0.1884	-0.2636	-.04210	-0.4636	1.0000		
AB	-0.3230	-0.3455	0.1491	-0.2909	0.5909	1.0000	
AG	-0.0897	-0.0545	0.4122	0.2182	**-0.7000***	-0.5000	1.0000

Note: * significance to 0.005.

The correlations for chronically ill patients show a similar lack of evidence for a coherent EDL policy as seen in the all-patients table although there are subtle differences. There is a single significant correlation apart from the two expected values; that between ED list prescribing (even though prescribed by brand name) and analgesic prescribing. The correlation is strongly negative but the correlation pair is not particularly meaningful, especially since the other (EDL) Essential Drugs List/analgesic correlation does not concur with it; it being weakly positive. It could be that the significant correlation has arisen by chance even though the statistical test suggests otherwise.

Other correlations are weak and positive and negative values appear to be distributed fairly randomly in the table, without the bunching of negative values associated with polypharmacy seen in the all-patients table. For chronic patients therefore, there does seem to be a correspondence between those hospitals better at reducing polypharmacy being those better at generic and ED list prescribing – but it is a weak effect and still does not hold for antibiotic prescribing.

The correlation table of simple rank (adherence) (7.36) shows the expected correlations of "Mean No. of Drugs" with "More than 2 drugs." Unexpected was the negative

correlation between "Proportion of brand and generic drugs on the EDL (EDLBRD)" with the percentage of analgesics prescribes.

When adjusted for age and gender (Table 7.37), the similar results are found. For, the adjusted ranks there is slightly more scattering of the negative correlations. In summary, evidence of a concerted implementation effort when prescribing for those with chronic illnesses is weak.

Table 7.37 Chronic Illness and Adjusted Model of Correlation Coefficient of Prescribing Indicators

	Mean No.	>2 Drugs	Generic	EDL	EDLBRD	AB	AG
Mean No.	1.0000						
>2 Drugs	**0.7909***	1.0000					
Generic	0.2091	-0.0273	1.0000				
EDL	0.2182	0.0091	**0.8364***	1.0000			
EDLBRD	0.3364	0.3182	-0.4364	-0.3364	1.0000		
AB	-0.3636	-0.4091	-0.2182	-0.2455	0.3818	1.0000	
AG	-0.0818	-0.0273	0.5545	0.2636	**-0.7182***	-0.5545	1.0000

Note: * significance to 0.005.

7.6.5 Chronic Illnesses and Prescribing Indicators by Clinic Level (Primary, Secondary, Tertiary)

This final analysis evaluates chronic illnesses and prescribing indicators by clinic level (Table 7.38). The eight prescribing indicators are evaluated by level of care (primary, secondary and tertiary) to show if there is a difference in chronic care prescribing between the three levels of care. The question is "If individual clinics have not adopted EDP principles is there evidence that different levels of clinic (primary, secondary, tertiary) have done so to a different degree?

Table 7.38 Chronic Illnesses and Prescribing Indicators by Clinic Level

Level	Primary	Secondary	Tertiary	Average
Chronic	101	129	242	472
% Chronic	21.1	27.3	51.2	100
Mean No	4.33	3.25	3.19	3.5
>2 Drugs	95.2	83.2	82.7	90.0
Generic	42.2	39.4	45.0	42.1
EDL	33.6	31.9	37.1	35.2
EDBRD	71.3	83.5	74.4	77.6
AB	7.3	10.1	20.0	10.1
AG	63.9	56.7	62.3	51.6
INJ	0	7.0	3.0	3.3

Evaluation of the eight indicators for the three levels of care (Table 7.38) shows that similar to the overall results of all patients (Table 7.22) the primary level care level has the highest number of drugs per prescription and of more than 2 drugs. It also had the lowest level of antibiotic and injection prescribing. In addition, like the overall patient evaluation, the primary care level once again had the highest proportion of analgesic prescribing. The most noticeable indicators that are supportive evidence of a beginning implementation of EDP principles are antibiotics and injection prescribing.

The secondary care level had the lowest proportion of generic and EDL prescribing. While, similar to the overall study population, it has the highest proportion of Brand + generic drugs (EDLBRD) that are on the EDL. Most striking is that the secondary care level has the highest proportion of injections much higher than the primary and tertiary levels. The low percentage of prescribing generic and EDL and high injection prescribing shows that EDP principles have not been adopted at the secondary level. For the tertiary care level, more difficult to treat diseases and a hither resistance towards implementation of the EDL, it was expected that the compliance with EDP principles analysed by using the prescribing indicators for chronic illnesses would be lower. Instead, the results show that the tertiary care had the lowest mean number of drugs and proportion of prescriptions with more than two drugs per prescription. In addition it also had the highest proportion of generic, EDL, and antibiotic prescribing.

Overall, the evidence supports that on the tertiary level there is overall appropriate prescribing which could be interpreted as a small shift towards the adoption of EDP principles for patients with chronic illnesses, while at the primary and secondary level there is show little evidence of rational prescribing for those with chronic illness.

Chapter Eight

Interviews and Structured Observations

8.1 Introduction to Qualitative Results

This chapter presents data from the interviews and structured observations. The in-depth interviews were conducted with 20 health professionals who work in or with the Northern Province hospital clinics as nurses, pharmacists, physicians and administrators at various levels of care.

Interviews were conducted with nurses, pharmacists, physicians and administrators to gather information about their perceptions of the STG/EDL. The acceptance of the STG/EDL and the knowledge, attitudes and practices in these different groups of health professionals are important factors for prescriber compliance and the practical implementation of the NDP.

This chapter presents the interviews of health service providers and administrators. Health professionals that work in hospital clinic nurses, physicians and pharmacists were interviewed between October and November 1999 at the hospital on the day that prescribing data were collected. The interviews were conducted individually about their experiences of learning about and using the EDL Demographics of these respondents are provided in Box 8.1. The second set of interviews was conducted with health administrators who work on the provincial and national level.

In this chapter only issues concerning the implementation of the NDP raised in these discussions are identified. Summary details of the administrators interviewed are provided in Box 8.2. Interviews were conducted in a private room within the health facility with the health providers and at various locations with the administrators. Health providers were and recruited for the interviews on the basis of level of facility and type of provider.

Box 8.1 Interviews with Health Professionals

- **16 respondents: 9 male and 7 female**
  - **3 Nurses (1 male, 2 female)**
  - **5 Pharmacists (all female)**
  - **8 Physicians (all male)**
- **Age range: 20-60+**
- **Level of service: 6 work in Primary, 3 Secondary, and 7 Tertiary Hospital Clinic**
- **Years of experience: had between 3 had >1 year; 0 had1-5 years; 7 had 6-10 years; 4 had 11-20 years; 1 had 20+ years.**

The four administrators interviewed were chosen for their role in the implementation of various aspects of the NDP and RDU in the Northern Province. The administrators were asked directly for an interview and all complied with the request. From the Northern Province Department of Health, both the Director of Health Care Support and Auxiliary Services and the Deputy Director of Pharmaceutical Services were interviewed. Also at the provincial, but private level, the Programme Manager of Hospital Systems for VUNA Health Care Logistics (drug depot) was interviewed. At the National level, the Director of RDU training and research and Professor at MEDUNSA was interviewed.

Box 8.2 Interviews with Administrators

- **4 Respondents: all male**
  - **2 pharmacist**
  - **1 physician**
  - **1 manager**
- **Age range: 2 are 40-59, and 2 are 60+**
- **Level of responsibility : 3 Provincial, 1 National**
- **Years of experience: more 1 with 6-10 years, 3 with than 16 years,**

The interviews were conducted to gain a better understanding of the underlying reasons for the results of the drug utilisation study data of 1,204 prescriptions. The four main areas explored in the interviews are demographic data, knowledge, attitudes, and practices of the hospital clinic staff.

The nature of the interviews was informal, based on a guiding list of questions (Appendix S), rather than a structured questionnaire. The intention of the interviews was to allow the interviewees to discuss their own experiences assessing and using the EDL

and rational prescribing guidelines. Interviews with health professionals who work at the clinic level focused on their experiences with the implementation of the EDL.

The interview with health administrative, in contrast, were focused on the plans of implementation, and the four areas of review, knowledge, the EDL for adults at hospital level, including Budget limitations for non-EDL drugs, Pharmaceutical Therapeutic Committees (PTC), and Peer Review (PR). The topic "attitude" will include attitudes to the implementation of the EDL and brand drugs; training, PTC, and PR. "Practices" will include the multiple issues of prescribing.

In both groups of interviewees the discussion also raised come issues about public hospital care, financing and the mandated policy from the national level that is implemented at the provincial and local levels. In short, the hospital staffs were interviewed with a focus on their knowledge, attitudes and practices of RDU, while the administrators were interviewed with a focus on the understanding of the implementation of the National Drug Policy and Rational Drug Use.

After literature review and preliminary discussion with health professional and administrators, the three main topics of Knowledge, Attitudes and Practices, were chosen to evaluate the understanding of the National Drug Policy. And further, the Rational Drug Use implementation process as experienced by the professionals themselves and the intentions of the implementation to be carried out by the administrators.

8.2 NURSES

8.2.1 1Introduction

In hospital clinics, unlike many primary and rural clinics, nurses do not prescribe medicine, because usually a physician is available. Nurses, by law may prescribe a basic level of drugs, diagnose diseases and determine if a referral to a secondary or tertiary hospital clinic is needed.

8.2.2 Nurses Knowledge of EDL

To assess knowledge about the STG/EDL, the nurses were asked, "Were you or your colleagues informed about the new STG/EDL?'

All the nurses interviewed said that they knew very little about the use of the new STG/EDL at the hospital clinic level. When asked if they were informed about the use of STG/EDL for adults at the hospital level (1998) the responses included,
"Not yet. (I-11)," and "Just a little. We didn't get that much information. "(I-5).
Although nurses were not formally informed about the STG/EDL their Attitudes and Practices are an important factor in determining the success of NDP implementation.

8.2.3 Nurse Attitudes and Practices

Most of the nurses who shared their attitudes about the use of the EDL and training also talked about their role and its connection with other staff, pharmacists and physicians. The attitudes are developed especially within the responses about their professional practice. The practice issues include a) change in the work environment, b) EDL use, c) training, and the use of d) Pharmaco-Therapeutic Committee (PTC) and Peer Review (PR). Each will be looked at sequentially.

a) Change in Nurses Work Environment

Successful implementation of the EDL, as a cornerstone on diagnosis and treatment of adults in the hospital clinic, would translate in a noticeable change the work environment would be noticeable not only for nurses, but also their health professional colleagues. The question, is *'Has the EDL affected the way you work?'*

The responses varied from no change to a significant change in the work environment.

One of the changes is the new EDL (1998) for the hospital level stressed health education for patients and at times not prescribing a medicine. However, nurses feel the pressure of patients demands for a drug, without the drug they fell that they have not received treatment. One nurse stated,

"Our problem is that patients are used to drugs, and when you give them health education you know they don't (want it). For example for a cough and sniffles, this one says you must boil water, to get them (to) drink. So patients like the P.H. (public health worker to) give them drug, not, you know, health education. They are getting used to it now." (I-2)

One nurse responded to the question of change in the work environment by stating that the changes were not significant.

"No, not so much. Sometimes there seem there is (no) time to talk about this (EDL), because there are a lot of people. We see a lot of patients. I think there's not much time to talk about it. It seems, when I checked the new one there was no effect. There was not (a) lot of difference It seems as if some of the things (on the new EDL) are (the) non-drug treatment it emphasises, but I think it is additional." (I-2)

While the nurse (I-2) did not believe that the EDL had an effect on their working environment, it did have an impact.

"This new one (STG/EDL) has more health education to tell these people what they can do at home. So this new one talks more of health education"(I-5).

Another nurse stated, "It has made a difference. I think the EDL is very much advantageous because it's simple. According to me it's simple. The MIMS is very complicated. We use it when we want some of the drugs. MIMS is drug orientated, but this EDL, having this EDL is simple, even though we can not use it most of us. It is simplified ...I think even this EDL must be for nurses really. ..." (I-2).

When asked if they use other materials for diagnosis and prescribing and if they prefer these materials. One response was:

"We have got some notes. We've got some MIMS. We have got some journals from workshops. We have some papers from workshops. Those are very good, because everything is covered. But it is not enough. I think the EDL can do a lot. It is guiding us how to prescribe. "(I-2).

In summary, for nurses, the effect of the EDL in the work environment is non-existent to small. Since, by law nurses can evaluate and prescribe for patients with minor ailments, they feel that in order to do their job well, they need to be included in the adoption of the STG/EDL. The EDL did not bring changes in the way they practice or their environment. The EDL is seen as simple and advantageous with more drugs on the list, and a new emphasis on prevention.

b) Training in EDL

Training to increase nurses' knowledge about and the use of the EDL for Primary Health Care (1996 Edition) for the primary health care started at the local clinic level in 1996 (MEDUNSA, 1998). The question is ' *Were you or your colleagues trained to use the new EDL?'*

Nurses are the professional cornerstones of most community and many primary hospital clinics, especially in majority black populous or rural areas. Nurses must examine, diagnose, prescribe, and follow-up with patients who are rarely able to get a consultation with a physician. Thus, nurses are usually the first to diagnose and treat patients. One nurse stated,

"I think we need to have ...a lot of time (for training), because we are the (main) people who are staying with the patients. So, but, it seems that some times they ignore us the nurses." (I-6)

All the nurses responded that they were not trained to use the new EDL. However, all believed that training was imperative to their effective nursing skills. One explained,

"...Nurses who are prescribing need some sort of training. It might be a week or two or three. Even if when we go to school for this nursing. The schools are not the same. Some emphasise pharmacology, some emphasise diagnosis, so what we have here (training for) all people working in the primary health (care, who are) prescribing and diagnosing.

Some times the most (difficult) problems are the drugs because the drugs are very dangerous. So when need to insure a form of training to all the people working here." (I-2)

Another nurse agreed, "*These people must teach (the use of the EDL), we (need) education so that we are able to (do) what is expected" (I-5).*

One nurse spoke of the need for EDL training in the context of nurse autonomy to service patients, the conflict over professional lines of service, and a team approach. The nurse states,
"We see patients. Now we can diagnose patients. We can see (patients who have the) most simple diseases, minor aliments. I think they must allow nurses to decide what they must do. But not only decide (treatments from) the pharmacist, the doctors, but (also) we nurses. I think because we are doing primary health care nursing, then some of the work is advanced because we diagnose." (I-2)

When asked about whom should be trained in using the EDL, all the nurses interviewed thought that all healthcare workers should be trained.

"I think (training should be) for both doctors and nurses. Really we must cope with the changes, new technical (materials). Yea, (all the) time, things are changing. But if we really took some steps with the changes things will be much easier for us" (I-11).

In summary, overall nurses believe that training is an important component of fulfilling their professional role. However, at all levels, few nurses at the hospital level were trained or educated about the adult hospital STG/EDL.

c) *Pharmaco-Therapeutic Committee (PTC) and/or Peer Review (PR), Interdisciplinary meetings*

The two questions are First, 'Have you heard about the PTC committees and/or Peer Review? Second, 'Should there be interdisciplinary meetings? If so, with whom, and how often?'

The Pharmaco-Therapeutic Committee and Peer Review are interventions that allow for the participants to assess their peers and learn from one another. Hospitals staff is amenable to participating in an inclusive PTC or PR are more likely to conform and co-operate in working as a team, and to adopt RDU prescribing and training recommendations.

Nurses interviewed were supportive of having PTC in which the entire health team that would include physicians would actively participate in assessing difficulties with treatments and prescribing. The PTC is useful for both the staff and patients.

"Maybe we prescribe drugs that are not effective, or even we see their problems. Since I have been in this field I can detect what these doctors are doing. I can detect very quickly if the doctor is doing something very good. And even he can detect if I am doing good or bad. So if we have meetings I think it will be better. The care of the patient will be highly improved. " (I-2)

Currently, nurses are not usually included in PTC or other treatment – prescribing meetings. To meet as a multi-professional team is better not only for the staff, but also for the patients.

"They need to be there, the doctors and pharmacists. I think the pharmacist is a ref. (referee). Even the doctors do not know drugs, the pharmacists, (and) only the pharmacist know(s) drugs very (well). We diagnose patients, and prescribe medicines, but most of the time, our pharmacists know the drugs. It would be very interesting if the pharmacists talked with the doctors." (I-2)

Although PTCs with a multi-professional team are recognised by health professional to be a great benefit, it is not occurring.

"It is not happening because some of the doctors are not aware that we can even do (prescribing), If we can come together to discuss (prescribing), then in time we will be very careful for what we are doing. The (PTC) I think (will) improve our communication and care for patients."(I-2)

The PTC meetings with PR are effective when conducted monthly, with representation from all staff. PTCs improve staff communication, prescribing, and patient care.

Summary of Nurse Interviews

The three nurses interviewed, work at all three hospital levels and have between six and sixteen years of experience. Nurses at all three levels said that they did not have useful knowledge about the EDL. Thus far their work environment had not changed as a result of its implementation. The new EDL has more drugs on the list, but it has a public health oriented emphasises on both prevention and health education for patients. Overall, the nurses interviewed stated that they think that the STG/EDL is simple and advantageous.

In summary, nurses would like to be trained in the use of the STG/EDL. Training would allow nurses to respond to the change positively. Also, they would like to actively participate with other health care providers on the hospital PTC committee. In order to promote improved communication, effective prescribing, monitoring, and thus improved patient care.

8.3 PHARMACISTS

8.3.1 Introduction

Pharmacists were asked the same questions **(Appendix S)** as nurses, with additional attention to the change in their work environment. The work environment change includes, filling all prescriptions with generic drugs, regardless of how it was written. Pharmacists face pressure from both physicians and patients to order brand name drugs, not on the EDL with the 10% of total pharmaceutical budget and to give the rugs in the colour and size that they know.

8.3.2 Pharmacists' Knowledge

The first question asked in the interview is first, '*Were you or your colleagues informed about the new STG/EDL?*'

All, but one of the hospital pharmacists said that they were informed about the new EDL. One pharmacist stated,
"A regional pharmacist told me about it and then she gave me a book." (I-15) Another agreed, *" I think we were informed by our senior pharmacist from head office that we were going to launch it (EDL) officially. So we knew about it before it came" (I-8). Only one pharmacist interviewed, said "No, I did not hear anything about it (EDL)." (I-1)*

Pharmacists were expected by hospital administrators to distribute the set of STG/EDL books, and to encourage and promote its use. Yet, none of the pharmacists felt that they had a part in either its development or implementation of the STG/EDL. One pharmacist said,
"I think they (hospital staff) should (have been) consulted. All the nursing staff, the professional staff, (and) the pharmacist especially." (I-1)

Second, 'Do you know about motivating for drugs and the 10% cap on ordering non-EDL drugs?'
All pharmacists had knowledge of the 10% budget restriction on non-EDL medicines and the "Motivation," the procedure for physician to request drugs not on the EDL. All, but one pharmacist had knowledge of the use of Pharmaceutical Therapeutic Committees (PTC), while no pharmacists knew about 'Peer Review.'

Overall, pharmacist had knowledge about the new STG/EDL, the 10% budget cap on non-EDL drugs and PTC.

8.3.3 Pharmacists Attitudes

a) Usefulness of EDL

The questions are "Do you or your colleagues use the STG/EDL?" and "Are there advantages to using the EDL? Why or why not?"

All of the pharmacists interviewed said that the new STG/EDL is useful for themselves and for other health professionals. Pharmacists use the set of new STG/EDL books regularly. Pharmacists interviewed believed that the STG/EDL is useful for ordering drugs, staying within a budget, and decreasing the number of drugs prescribed in each patient encounter.

Useful for hospitals and clinics

The use of the STG/EDL is good for "basic health care and they are using it at the clinics. You get the general prescribing there and general regime for all our clinics and hospitals. So you don't get the 'our clinic is going to order something different now' They have got their regime to stick to for reference." (I-16)

Decreases polypharmacy and Cost- Effective

"It has made it much better. The EDL has curbed many things like polypharmacy. We used to get prescriptions with thirteen items on, four antibiotics. Most recent it has cut out and so economically we are saving in a way. Because you know for three antibiotics you can give only one according to the guidelines." (I-8) Another pharmacist agreed, *"It's cost effective." (I-8)*

Useful, but not used by Physicians

Although pharmacists believe that the new EDL has promoted overall significant changes, they also believe that physicians are not using the EDL. This opinion is based on their observation of the prescriptions that come into the pharmacy. One commented,

"Most of them (physicians) don't comply with the EDL. Most of them, I can say sixty percent." (I-1)

When asked if the book was used by and useful for physicians, a pharmacist said, it is useful *"just have the book around. We've got boxes and boxes, all the EDL's are there (in the office). In principle they should use it, maybe they don't have time to look up the drug. But in principle, each and every doctor has it. Our interns, even the students" (were given a set of (STG/EDL) (I-8)*

8.3.4 Pharmacists Practice

Five areas of practice were covered. Four foci were specifically on the STG/EDL, while the other focus was PTC and peer Review. The STGEDL questions about the manner in which the EDL has affected the work environment, if they were trained in its use, if they use it regularly, and if it is advantageous to use the STG/EDL. The other foci are is PTC and Peer Review.

a) Work environment

Pharmacists at the public hospitals were the first to see and experience a change in their work environment, and their practice as a result of the use of the STG/EDL.
The work environment evaluation includes 1) Training, 2) Use of STG/EDL Use, 3) Generic Substitution and 'Motivation.' 4) Non EDL Drugs cap of >10% of the total budget. Pharmacists are expected to be the gatekeeper for the ordering and dispensing of EDL and brand drugs.

When asked had the implementation of the EDL made the job any different. *'Has the EDL affected the way you work?'*
"It has, it is easier for me what is on the EDL because it is on code. For me, when it is not on code, and with a limited budget. It doesn't really sit well "(I-15).

b) Training

The question is 'Were you or your colleagues trained to use the new STG/SDL?'

Pharmacists interviewed, with the exception of one, have had no or very little training on using the new EDL. *"There was no training there. No they would give a (EDL) list...."(I-1)*

Another concurred,

"We only received the new book from our regional pharmacist about three months ago. And they were handed out to all the doctors. But we were to go through them by ourselves. No, we did not get any formal (training). I think that they did send some documentation to us.'(I-16)

Most pharmacists agreed that training would be helpful not only for themselves, but also for other staff.

"Yes, it would be helpful. Unfortunately, we were not trained, on the EDL. It was just (there and) we had to use it, but there was no training involved. Yea, definitely (the training would help) it's never too late... You can train primary health care nurses. It is important to train your doctors, to train your pharmacists. Basically, those people are the ones that are directly involved with prescribing" (I-8).

While only one pharmacist said that physicians did not need to be trained on the use of the EDL or rational prescribing.

"No I don't think they really do. We've got very intelligent (physicians), So it is not really necessary to discuss the EDL. They read it and they keep to it. They just do it on their own. It's self-explanatory. I know that the regional pharmacist asked (the medical director) if he thought it was necessary to give a talk about it. He said that everyone must read it first, then if they have suggestions then we can top it up on my suggestion. So everybody (has an EDL), there are six or seven doctors on the staff and the HIZ doctors " (mandatory service internship for new physicians) (I-15).

Training could be the key to bring acceptance, ownership and compliance.

"Maybe if they can be trained (pharmacist and physicians) they would understand it differently" (I-1).

c) EDL Training and Chronic Illness Patients

Pharmacists, like nurses thought that the EDL is especially useful and beneficial for chronic patients.

"Most of the time, like here in our hospital, most of the patients are referred to the clinic some to collect their chronic (illness) medicine. Most of the chronic patients just some come here to collect their medicine. Most of the chronic patients see the nurses. The kind

of chronic patients that are seen are " hypertensive, asthmatic, diabetic. Even rheumatic arthritis patients. Even the fact that those nurses at the clinic, they are prescribing. So they can benefit a lot of they can go, if the nurses have training" (I-1).

d) Use of EDL

The questions are first, 'Do you or your colleague use the EDL?' Second, 'Are there advantages to using the EDL? Why or why not?

Pharmacists use the STG/EDL for various functions including, a guide for what is in the pharmacy, and a guide for generic substitution.

Pharmacists use STG/EDL to interpret prescriptions that listed brand name drugs so that they could substitute the appropriate generic drugs. When a prescription is sent to the pharmacy with brand name drugs, then the pharmacist has several options. First to send it back to the physician for a clarification of the drug they desire, or second, the pharmacist substitutes a generic drug. One pharmacist said that she goes back to the physician often for clarification. I go back to the physician, *"if we have any drug falling in the same category. But, you have to consult the doctor first. But some of the things we just give. If they say (a brand drug), we give the generic. It depends on the substitution" (I-1).*

e) Generic Drugs

The work environment for the pharmacists did not show a great change with the introduction of the STG/EDL. The exception is a physician wants a drug that is not on the EDL, then they should complete a 'motivation' form to request the drug. Instead, usually the physician asks the pharmacist to order the drug but also to fill out the motivation form. It is difficult for pharmacists to deny a request.

Of the pharmacists interviewed, half believe that generic substitution has changed the way that they work in the pharmacy.

f) Generic drugs and Physician Pressure

A pharmacist who is also a provincial administrator reflecting on pharmacists filling brand name prescriptions with generic medicines stated,

"I think that has always been the problem of pharmacists and I don't think that they see it as difficult. I think it is a measure of the degree of the failure of the EDL to penetrate to whoever is prescribing. Because one of the basic ideas is to (encourage) more generic prescribing and that hasn't always happened. And it is also an issue of advertising of the user who would rather have their prescribing in a name of a particular brand, and many of our medical staff in particular I think are convinced the propriety brand are different from the generic, which is so untrue. I think that advertising, rather than logic is being subject (of prescribing rather than) evidence based medicines."(I-17)

g) Motivation for brand drugs and Physicians

Physicians who want brand drugs not on the EDL must fill out a 'motivation' form (Appendix W), but many will not and expect the pharmacist of order the drug because they want it. A pharmacist from a tertiary institution said,

Physicians "do have to motivate because we find that most of the time what they need is not on the hospital code. So they ...fill in a motivation form. (They must explain) why they want that particular drug, why they can't use the drugs that are available and then we send it to our depot. (I-1)

h) Patients and Generic Substitution

The new STG/EDL has changed patients' perceptions about drugs. They do not like getting drugs that perhaps they have not seen before. "Now that the patient does not get a brand name drug but a generic it is a problem also. I can give you an example with asthma patients.

"They would say, 'no I get this type of pump.' 'Then- the asthma 'medicine, it doesn't work.' (You tell them) 'it is just a different company.' But they will say, 'not this (generic, it) doesn't work. I want this'. In this case there is nothing you can do. You just tell the patient, ' no, this one is the same. It is just from a different company.' But it's hard, really. It happens (all) most every day. Especially if we see this community (African, poor & rural). I can say about 60% or our community don't read. (I-1)

Patient education about generic drugs has been promoted through posters. Other patient education could support all hospital clinic health staff who feel obliged to give the patient the medicine that they know and want. Patient education is an important component of rational prescribing.

In summary, the two areas in the work environment that were most affected for pharmacists are first, generic substitution and second, the 10% budget cap on non-EDL drugs to encourage cost-effective prescribing and dispensing.

i) Pharmaco – Therapeutic Committee

The Questions are, *First, 'Have you heard about PTC committees or Peer Review? Second, 'Should there be interdisciplinary meetings? If so, with whom and how often?'*

Pharmacists interviewed said that they were aware of PTC committees, but have not been actively included.

"We used to have meetings though I must admit, it was called 'Doctors Meetings,' they use to invite pharmacists. In fact all the pharmacists. It turned out to be more of a doctor's thing and we had... sit there and they would discuss the cases they had, ...' it didn't involve us, you know, so we had to withdraw. But, it was interesting in a way. If there (is) a new drug on the market they would tell you it was there. It was a nice forum. But unfortunately it was more for doctors." (I-8)

Another said that they were using some form of team meetings to discuss prescribing, packing, dispensing, and the EDL.

"At this stage we have to discuss (these topics) in our meetings now and give feedback according to the EDL. Some of our doctors we get back (to them about their prescribing. I'll take an example, Flagyl, for an STD use, it is a standard dose of 5 (mg) and we get a packet of five and some of the doctors still prescribed (other doses) and we have to do re-packing" (I-16).

For drugs not on the STG/EDL, "when (there is a) Pharmaco-Therapeutics Committee (PTC), they sit (and) talk about it, (if) they feel that really there is a need then the drug is given out, but strictly on motivation" (I-8).

One pharmacist interviewed thought that pharmacists and physicians need to work together, but have not in the past. This creates an additional challenge to the effective EDL implementation at the hospital level.

"I can say I think the main problem is that they (physicians) are not used to working with pharmacists. This hospital had hospital assistants, not pharmacists. There were no pharmacists. Most of the pharmacists that you see (are) assistants (that) are doing the dispensing. So they are not used to working with the pharmacists. (Physicians) just write the prescription and they are used to that it goes through to (what they) want" (I-1).

Pharmacists believe that all health staff should be trained. Further they believe that they and the physicians must work together as a team to get the right medicine to the patient. Use were not well known overall none of the pharmacists talked about peer review. All, but one said they had knowledge of Pharmaceutical Therapeutic Committees (PTC).

8.3.5 Summary of Pharmacist Interview

Overall, pharmacist had knowledge about the new STG/EDL, PTC and Peer Review, and the 10% budget cap on non-EDL drugs. Most pharmacists were given documentation about the adoption of the new EDL, but only one pharmacist had formal training. Pharmacists were expected not only to give out the STG/EDL set, but also provide encouragement, consultation and informal training on its use. The overall attitudes towards using the EDL was positive as a guide of what was on code and for cost-effective budgeting Pharmacists believe that it helped to decrease polypharmacy and the limit ordering of non-generic drugs. Both the work environment and practice of pharmacists have changed as a result of the EDL. Pharmacists are experiencing pressure from both the patients and physicians to order and dispense brand drugs.

Pharmacist believe that training and the use of a PTC committee for all staff would be helpful, and relieve them of some of the pressures as the enforcer of generic drug use and the gate-keeper to brand drugs. Moreover, PTC inter-disciplinary committees would help to encourage the whole team, physician, nurse, administrator and pharmacist to work together, and provide the best treatment and rational prescribing.

8.4 PHYSICIANS

8.4.1 Introduction

To determine the knowledge, attitudes and practices, physicians were asked the same questions as nurses and pharmacists. However, the interview emphasis for physicians was the use of the EDL and other materials that include the South African Medicines Formulary (SAMF) and Merck Manual (MIMS) and their prescribing practices (number, generic, brand, and motivation for drugs).

8.4.2 Physician Knowledge

In implementing the STG/EDL physicians would have been informed, and even given a formal introduction and training at a staff meeting. The first step of implementation is to find those who are carrying out the policy information.

The questions were asked to assess physicians' knowledge of the STG/EDL. First, 'Were you or your colleagues informed about the EDL?' and second, 'Do you know about 10% cap on ordering drugs and motivating for drugs?' Third, 'Do you know about PTC committees or Peer Review?'

a) 'Were you or your colleagues informed about the new STG/EDL?

All physicians received a set of STG/EDL, but only seven of the nine had knowledge about the use the new STG/EDL. Of the nine physicians interviewed, seven said they had knowledge of the new STG/EDL for adults at hospital level.

'Do you know about 10% cap on ordering drugs and motivating for drugs?

For budget limitations, no physician had knowledge of the 10% budget restriction on non-EDL medicines. Conversely, all the physicians interviewed had knowledge of motivating for drugs not on the STG/EDL. The methods used for improving and monitoring prescribing, PTC, Peer Review, 10% budget cap were not well known overall none of the physicians talked about peer review and only two said that they had knowledge of Pharmaco-Therapeutic Committees (PTC).

Do you know about Pharmaco-Therapeutic Committees or Peer Review?'
Only four of the seven physicians interviewed had knowledge of Pharmaco- Therapeutic Committees, only one has knowledge about 'Peer Review and thought that it should be used.

Overall, few physicians had knowledge of PTC and, while none had knowledge about the use of Peer review, or budget limitation of 10% cap on brand drugs.

Physician Attitudes and Practices
The attitudes and practices of the STG/EDL are paired in this evaluation because Their attitude directly shows itself in practice and ultimately in prescribing.

8.4.3 Physician Practice
Overall a majority of the physician felt that there was not a change in their work environment or the way that they practised. Few, (two) physicians said that generic substitution changed the way in which they prescribed. None of the physicians' interviews had directly participated in either PTC or Peer Review process, although two physicians had heard of it, and one was in the initial process of setting one up at a hospital level.

A. Physician's Environment and Prescribing Practice
1. Work Environment
'Has the EDL affected the way you or your colleagues work?'

The EDL was produced to change the way physicians and other health professionals prescribe treatment and medication. The areas of the work environment that could be affected by the adoption of the EDL are centred around prescribing, training, and the use of PTC and/ or Peer Review.

Nonetheless, the work environment for the physicians interviewed did not show a great change since the introduction of the EDL for adults at the hospital level. The manner in which physician prescribe, usually brand drugs did not change. When physicians wants a drug that is not on the EDL or in the pharmacy, then theoretically they must put in a motivation form to request the drugs and justify why they need that particular drug and can not use the drugs on the EDL. Overall, five physicians believe that there is a change in their environment in which they practice. Only, two physicians believe that generic substitution change the way that they prescribed. When one interviewee was asked if the book affected what he prescribes he responded:

"Not really, because I was always used that in practice. I know which drugs were the most competent ones. What it did (was) to give me extra drugs that we did didn't have access to previously. (I-7)"

Another physician was asked if he thought the 'EDL changed the way he or his colleagues worked' he said,

"I don't think it is much better. I have been working for ten year so I have quite clear ways of treating patients you understand (I-13)."

Once again, the overall the work environment for physicians had not changed since the implementation of the EDL.

2. Prescribing Practice

a. Usefulness of EDL

The attitudes of the physicians towards the EDL, patient demand, budget restrictions directly affect their prescribing practices. The questions asked are: '*Are there advantages to using the EDL? Why or why not?*'

Few physicians think that the EDL is useful for them personally. Although, they do think it is useful for others, especially as a guide of available medicines, standard treatments, and for cost-containment. The usefulness of the EDL as a guideline and for cost-effective prescribing is explored further.

Only one physician said he uses the EDL regularly.

"I always used that (EDL) in practice. I knew which drugs were the most competent ones. And what it did was give me extra drugs that we didn't have access to previously (I-12)."

b) The EDL is useful, but not for me

The use of the EDL with its generic drugs is a managerial method to change prescribing practices and specifically to bring about rational prescribing. The other physician who uses the EDL was trained in a tertiary hospital in the richest province in the country. He uses it as a guideline for what is available and its generic name.

Most physicians think that the EDL is useful, for other inexperienced physician and other hospital staff, but not for them. Seven of the eight physicians said that the EDL is not useful for them. The overall view of EDL usefulness is summed up by one physician, *"I don't really think so. No"*(I-14). Another physician said:

"I have been working for ten year so I have quite clear ways of treating patients. But, this has nothing to do with a drug list as such. This is just a question of how to get started. You do everything, gynaecology, paediatrics, surgery, so it is very difficult to get started. Once you have a book that really has all these major important cases listed out with suggestions for treatment, perhaps it (will) help you a lot. But when it is independent for the essential drug list it could be another drug list as well." (I-13)

One physicians' statement that apply to most physicians attitude is:
"Most of the drugs should be on the EDL, but it doesn't affect me (I-7)," stated
"I must say, not all physicians are using it. They are still going back to their own lists and drug treatment schedules. They don't really consult this book, I wish they (would) do it."(I-12)

Although think that the EDL is a good source for them, many physicians think that it would be good for others to use, especially if they also work in private practice.

"There is a difference because those who are in private practice basically prescribe in brand names boxes and they are pushing that name."(I-4)

Physicians, especially those at the tertiary level, work in both private and public practices. Most physicians think that overall the EDL is useful for others, but not for themselves. When asked if the EDL was useful for him personally, he responded

"I don't really think (so). But this has nothing to do with a drug list as such. This is just a question of how to get started. In our hospital you deal with all different kinds of diseases. You do everything, gynaecology, paediatrics, surgery, so it is very difficult to get started. Once you have a book that really has all these major important cases listed

out with suggestions for treatment perhaps it helps you a lot. But when it is independent for the essential drug list it could be another drug list as well." (I-13)

When asked about the use of the EDL, a specialist stated,

"There are advantages. I am the only oncologist in this whole province, so it would be very difficult if there's an EDL for my field. I would rule out myself in any case. I think it has not affected me very much. My field is so specialised and the drugs that I use, I am not very concerned about the other drugs. And here in Pietersburg the situation is that I actually decide for myself what I want to use"(I-7).

Only two of the seven physicians said that they use the EDL and it is helpful. One physician who uses the STG/EDL has been worked in primary health care for more then fifty years, participated was on the first committee that put out the first EDL for primary care. He said,

"Yes. I use it. (The EDL) has been compiled by people who are really experts in health care. The people that compiled this are the best in health care, in the country. I trust them and I think it is a good thing." (I-12)

c) EDL Useful as pharmacy stock guidelines and cost effectiveness

Physicians think that the EDL is an 'advantage' as 'good guidelines,' and a tool for 'cost effective' prescribing. The STG/EDL is useful for other professionals, including young physicians. As a guideline,

The EDL "would be good if we could use structured regimes. If we use the same regime then you could start to do a study. They are much more accurate if people have used the same medications. (I-6)"

Another physician said,

"this is a good guideline for the young and not experienced doctors. It is a good guideline to know what is available in the country. But that's it.

For cost effective prescribing, the use of the EDL allows for 'cost effective' prescribing.

(The EDL) 'makes it more cost effective and makes it more easy for inexperienced doctors. For those two benefits I think it is a good thing to have, but not for experienced doctors." (I-13)

Several other physicians, without prompting identified the cost-effectiveness of using the EDL.

"I personally think we (the EDL committee) have gone through to make things very simple and very cost effective"(I-6). Moreover, another said, "The standard treatment guidelines, we have standardised our drug list which makes it much more cost-effective." (I-12)

A general practitioner stated,

"I have not used it that much. I would think that here is an advantage to using that one because perhaps to contain the costs of the hospitals and to know what's available, then you know what to prescribe. Unlike coming out with something that you know is standard, but you don't know what to prescribe. Otherwise you don't know what to prescribe and you what's available to prescribe..." (I-9)

d) Use of Other Materials for Prescribing

Physicians prefer to use other professional resource materials when prescribing. These include the South African Medical Formulary (SAMF) and the Merck Manual (MIMS). The book that is used the most, predictably is not the EDL but the SAMF and MIMS.

" All are using MIMS. All the consulting (doctors) are using MIMS and we use the Oxford, but that is more for treatment or stuff like that or signs and symptoms (I-14)."

e) EDL Usefulness Summary

Overall, physicians' attitude towards the EDL is a good reference guide that is cost-effective guide that can be useful to new physicians, patients, and all other health care personnel.

They generally do not think that the guide is helpful to them personally. Most physicians know that the pharmacist will substitute the brand drug prescribed for a generic drug unless they submit a motivation form. Physicians' attitudes are necessarily linked to their type and level of practice. Physicians may think that the EDL is useful for others and not themselves. The self-reported practices in the next section will evaluate the environment and the prescribing practices.

Overall, physicians say that they use and do not use the EDL. Those who use the EDL the advantage is a list of drugs that are stocked in the hospital pharmacy. Overall, the EDL has not changed the environment for the manner in which physician work. There are advantages to using the EDL that are minimal, namely as a list of drugs available and treatment for chronic illness with know effective and standard regimens.

II. Physicians Practice

Many physicians, as a result of both their knowledge and attitudes have not changed their prescribing, diagnosis or treatment regimes. A more detailed look at prescribing, training and PTC/ Peer Review should give some clues about why the environment has not changed.

The hospital adult level EDL has 694 drugs and combinations (National Department of Health, 1998a). The questions are, first, *'Do you use the EDL?' Second, 'Has the EDL affected the way you prescribe?', Third, ' Do you prescribe from the EDL?', Forth, 'Do you usually prescribe by brand name or generic name?'* Physicians described their own 'Self-reported prescribing practices' (Table 8.1) during the interviews.

Table 8.3 Physician Self-Reported Prescribing Practices

Physicians	Number	Percent
	8	**100**
Prescribing		
Use EDL	2	37
Do Not Use EDL	5	63
Generic	1	13
Brand	3	38
Motivate	1	13
Poli pharmacy	0	0
Public/Private	1	13

a. Prescribing by Generic Name

Physicians self reported prescribing practices revealed that only one physician interviewed said when prescribing, *"I tend to use generic" (I-4).* Another physician who does not prescribe by generic name thought that it is good to use generic names so that the pharmacist knows exactly what the physician wants to give the patient.

"...Sometimes you prescribe something and they don't have (it), they are out of stock and there is an equivalent that you can use. So these types of patients they refer (back) to you, so you have to prescribe something else." (I-4)

Most physicians have their favourite drugs and will write it on the prescription whether it is available by brand name or not.

"We know what we want to prescribe and then we look at what is available" (I-14).

Almost all the physicians prescribe by brand name in the public and private sectors, that they the public and private sectors. Only one physician simultaneously works in both while the other seven physicians only in the public sector. The use of generic medications is standard in the public sector, yet the EDL/STG has not encouraged help physicians to prescribe by generic name.

"Maybe it's better to use generic names because they (pharmacist) know that. So if you are using a trade name chances are that they will tell you, 'you know it's not here.' Or else they give a generic instead of tossing the patient back and forth." (I-4)

Since most physicians know that if a brand name drug is prescribed, the pharmacy will dispense the generic equivalent. *"I think that the pharmacy give the patient the generic anyway, whatever we prescribe" (I-14).*

b. Prescribing by Brand Name

Brand name prescribing is so common and can be fully adopted less than a year out of medical school regardless of the practice setting. A young physician interviewed in his first year out of medical school stated writing prescriptions by generic name, but changed to writing prescriptions in brand name, even though his first job out of medical school was in a primary health care hospital. I asked him how he was trained in medical school. He responded,

"In medical school you basically use generics. After you get to the ward you write Renitec instead of hydrochlorothiazide (for hypertension). Basically pharmacology is based on generic names." (I-4)

When I asked the young physician, how this change in prescribing occurred, he recognised the change and was visibly surprised, when he understood that he was using

almost exclusively brand name. He said that every month the pharmaceutical companies put on lectures and invite the physicians. He has been to these meeting and learned about the latest drug on the market. He went on to say,

"We know that it quickly spreads, to use the trade names (I-4)."

The young physician interviewed works under the most experienced physician of the physicians' interviews, more than 50 years in primary care facilities. He uses the EDL and encourages the young physicians under his direction to do the same. He tries to be a role model and positive influence, of EDL for generic prescribing.

"They don't want to change. They don't use generic prescriptions here. I am trying to teach the young doctors to do that now "(I-12).

Overall physicians are give reinforcement through pharmaceutical seminars and generally find it easier to remember the short and memorable brand names when prescribing.

"We mostly prescribe in brand names, only because it's easier. It is easier to write 'Renitec', than 'Enalapril'. I wouldn't mind prescribing all generics. It's just that we know the trade names better than we know the generic. But we should actually prescribe generic I think "(I-14).

c) 'Motivating' for non-EDL Drugs

Those who prescribed by brand name or generic continued with very little change. Only one physician said that he 'motivates' for a brand name drug. Three physicians said that they regularly prescribe brand name drugs, while five admitted to be non-compliant in suing the EDL. The positive answer to both the use the EDL and simultaneously, not compliant shows the difficulty physicians have in adopting the use of the EDL

d) Prescribing Antibiotics

The over prescribing of antibiotics is an indication of polypharmacy and counter indication to rational drug prescribing. On the subject of antibiotics, one physician stated,

"I am in favour that junior doctors should not be prescribing expensive medications, particularly expensive antibiotics. I think in general (that) antibiotics are over-prescribed. They're expensive and I don't think we do enough cultures as a back up to find our what organisms we are treating and what its sensitivities are" ((I-6).

e) Prescribing influences

Patients Demand

Patient demand is a driving force behind how physicians prescribe. For some the issues surround meeting the demands of their patients. A physician, when asked if training would help in resisting patient demand, and instead rely on evidence based medicine.

"No I'm not too sure. I think the main issue for just us doctors is the response (from patients). The (reason that we) prescribe so many drugs? We have patients who want drugs (I-4)."

Patients feel that if you do not give them a drug after the visit then they feel that you *"haven't done something for them (I-4)."*

The expectation of patients for drugs shapes prescribing for some physicians. One physician explained,

"A *patient comes in with hypertension. You say, 'OK, I'm not going to give you any drug. Come back in two weeks.' 'Oh no doctor, but I want (a specific drug).' Then they develop a reflexive pain. 'Ah I have pain here, there and there.' Then you give them a panadol (I-4)"* (brand name for paracetamol –generic form for pain).

f) EDL Useful for Chronic Patients

Several physicians identified the advantage of using the STG/EDL as a good guideline to know what is available, and a good tool for cost effective treatments, especially for people who have chronic illnesses. The STG can help to assess the level of the chronic illness, the type of treatment and be cost effective.

One physician stated,

"Chronic diseases, hypertension, diabetes, I personally think we have gone through (the assessment of effective treatments) to make things very simple and very cost effective."(I-6)

Another physician stated on using the EDL and cost effectiveness, *"...In medical school we were taught primary, secondary and tertiary and it didn't make much sense until one gets to the hospital you know hypertension and all those preventable diseases and all that training was not in vain. If you can apply (this) then you can save those people a lot of money. If you can treat the priority risk, usually people take care of themselves. Usually there is (not) much budget for insurance reimbursement (I-4)."*

Several of the physicians interviewed cited the use of the EDL is especially beneficial to patients with chronic illnesses and those who need set regimes.

"I am from a tertiary institution from a richer province that has housing all these pills. So when I got here I saw these guys have this. I think that the patient feels as well, (if) the doctor checks" (the EDL) (I-4)

"I think there are advantages. The book is supposed to be like a guide managing patients, but each patient is difference. Sometime (there are) one or two things inside the EDL that go with what I have learnt. You know I went to the U.S. to train and I do thinks more along those lines. Maybe there are some strategies here pertaining to the people here. So, I wouldn't like to go against it." (I-9)

The STG/EDL can also be used to not only for drug and treatment protocols, but also for ideas of disease prevention for chronic patients.

"Perhaps we ought to be more organised and formulated. We as prescribers often don't know what is available and we can't see how we prescribe. Chronic diseases, hypertension, diabetes, I personally think we have gone though (drug protocols) to make things very simple and very cost effective. Rather than treating hypertension for years and years, we want to be doing more assessments and saying 'why does this patient have high blood pressure.' Is there an underlying renal disease, (or) a tumour? How is the blood pressure changing with exercise? Simple life activities changes the probability, we don't pay enough attention to those things...(I- 6)

8.4.4 Summary of Physician Prescribing

To summarise physician prescribing, overall, seven of eight physicians work only in the public sector where generic drugs are the norm. Yet all physicians, except one in the public sector prescribe by brand name. Only one person said that he motivates for brand drugs not on the EDL.

"It's the RTC factor, you know, 'resistance to change'. You get use to a certain system of medical care and you stick to it if it works. They don't want change." (I-12)

I. Training and Pharmaco-Therapeutic Committees

To address rational prescribing, physicians' training, and Pharmaco-Therapeutic Committees with Peer Review can have a substantial influence in not only providing

information, but also changing perceptions and behaviours about using the EDL and generic drugs.

a) Training

'Were you or your colleagues trained to use the new EDL?'

The literature on rational drug prescribing recognises that materials alone, such as an EDL list will not change prescribing behaviour and the National Drug Policy states that training is of primary importance, each province is left to find the monetary and staffing resources in order to implement training. Formal and systematic training of physicians has yet to be either developed or instituted. One physician said that training was not done because he believes that the EDL *"is so comprehensive and clear that you can use that for the basis of your treatment"(I-12).*

Without exception all physicians interviewed thought that training in rational drug prescribing, the use of EDL for generic prescribing, is a good idea and is of value for others, especially the nurses, pharmacists, and young physicians, but not for themselves. An example is, *"But to say we need training for all doctors, I'm not sure (I-4)."*

Many physicians believe that training would not make a difference in physician prescribing. One physician said succinctly, *"No, it won't " (I-7).* A medical director thinks, "young doctors should be trained "from day one...before the reps (pharmaceutical representatives) get to them" (I-11).

Another physician said,

"From my perspective, I don't think any training would be necessary. But if people think that they need to guide us here and there I would appreciate it. For nurses I think it would be helpful on how to prescribe (I-4)."

In short, one physician stated with accuracy"

"Honestly, I don't know anything about the EDL. I just saw that, so it didn't really take hold. So if they want to implement it strictly then there should be training, especially for the nurses and the doctors who are going to use this one" (I-10).

c) Pharmaco-Therapeutic Committee (PTC)

Clearly, physicians believe that they do not need "training", but are willing to take suggestions especially from each other through peer review. If it comes from an outside source other than other highly respected physicians, then it is not seen as credible, and valuable.

At the time of the survey none of the hospitals in the Northern Province had an active Pharmaco-Therapeutic Committee. One of the primary care hospitals, the medical director had been involved in the development of the first EDL, actively used the hospital EDL and encouraged the five physicians practising under him to do the same, with little success. He has decided to start a PTC committee.

"We are in the process of establishing one now. You know its something new... We have had a meeting about that to get it off the ground (I-12)."

A physician that practices a specialty at the tertiary level is reluctant to use PTC committees for Peer Review. He stated:

"In theory it (peer review) is a good thing. Again one has to take and think very carefully about the context in which the patients, uh are judged on. To give you another example, a lot of this stuff (cases) I see here is very complex. It's were the other people in secondary hospitals in the province here, say Tshilidzini, Letaba, Mokopani don't feel happy with all these complications or complex things. My results often look a bit shabby, but then I look at what I have treated. So when someone comes in as a peer reviewer and says look your results are not as good as someone in a secondary hospital. I might appear to have bad results. I think often you must look at the context of (who) the patient is (and) in what situation we work " (I-6).

The medical director is the driving force to put the PTC in place and has taken on the sole ownership in decision-making about who will make up the committee.

"I have decided that the pharmacy should be represented, the doctors, the nurses and the financial manger" (I-12).

At the time of the survey, the secondary hospitals did not have a PTC committee and those interviewed did not know about PTC committees. At the tertiary hospital level a PTC was established and met for a short time, but was stopped.

"We had a failed therapeutic committee, a provincial therapeutic committee, which did not get off the ground because we organised it from the head office and the specialists did not come as required. It must be organised by a group that deals with the university and so on" (I-17).

In summary, physicians need training through an academic or medical professional institution. I asked which university would organise the new PTC and was told,

"MEDUNSA, where many of these specialists are trained. So now we have moved it into the academic field, which again will be more acceptable to the specialists because now this is a more academic exercise. And so their training outreach will be providing additional vehicles with the idea of establishing outreach for training. I think this will help a lot to break down the resistance to a logical approach to prescribing" (I-17).

8.5 Summary of Interviews with Nurses, Pharmacists and Physicians

A review of the interviews with the nurses, pharmacists and physicians show a common theme of not being informed about or trained to use the new EDL. All healthcare workers received a EDL set of 3 books: primary care, hospital care: paediatric and adult. With exception of the pharmacists, few nurses and physicians use the EDL books on a daily basis.

Nurses and pharmacists think that all health workers should be trained, while without exception physicians thought that they did not need training, however other health care workers need training in using the EDL and rational prescribing. The research has shown some evidence that many physicians do not know much about efficient prescribing, but rely on their early-formed prescribing regimes.

The use of the EDL has changed the work environment for nurses and pharmacists, but not for physicians. The change includes a ready-made procurement list, cost reduction, and a decrease in polypharmacy. Also, pharmacists have learnt to take a brand or trade name prescription and interpret the generic drug that can be substituted. Overall all health professionals believe that a PTC committee would be helpful and most believed that it should include all professionals.

Some physicians think that Peer Review that can occur during a PTC meeting can be helpful in promoting rational drug prescribing. PTC committees could also help to support prescribers in their attempt to implement rational prescribing with patients. This is especially important for patients with chronic illnesses in clinics that do not want the generic drugs, which were once dispensed as a brand. Some refuse to take the generic medicine prescribed because it does not look like the one that they are used to. Patient education about generic drugs and the new EDL has been limited to posters put up in the clinics. The questions that are evoked for administrators are what were the preparations and planning for the EDL, what were the implementation challenges and what is the vision of the future.

8.6 Administrators

8.6.1 Introduction

After the interviews with hospital staff were reviewed, and new questions about the implementation of the EDL were apparent, including questions about planning, preparation, and implementation of the EDL guideline use and training at the national, provincial and local levels.

Four administrators who are responsible for various arms of provincial and national offices that co-operate best answered these questions. The questions (Appendix S) are based on preparation, planning and challenges to the EDL implementation.

The three main areas of foci are (1) Preparation and planning for implementation, (2) Challenges to EDL implementation and (3) Visions and plans for the future.

8.6.2 Preparation and Planning for EDL

National, provincial and individual hospital planning, not only for implementation, but for evaluation is important for the NDP and specifically for the STG/EDL will take hold. A National plan for the implementation of the NDP, EDL at the provincial and local levels allows for the successful adoption of rational prescribing.

a) National Planning

South Africa's government continues to change and adapt to the new circumstances. However there was not an implementation plan that South Africa's nine provinces could adopt. When asked why there was not a plan, an answer was

"Because there isn't generally that service, South Africans' don't plan. You get certain perceptions it is a very poor strategic planning. There is no regional planning philosophy." (I-20)

Although the National Drug Policy was well stated, and adopted nationally, specific plans for implementation of its various components, including rational drug use was the responsibility of the nine Provincial governments. Lack of planning,

"I think there are two reasons for that. Previously there was no type of initiative or incentive to train or to plan. Things just kind of went along half-hazardly. So there's no culture of planning. And secondly, particularly in the last three years there have been ever diminishing resources. There is more and more work and few and fewer people in the public sector...OK, so now all you get (is) time to do is your service work. You don't have time to plan. You don't have reason to have lack of planning, but it doesn't mean that people haven't wanted to plan. But the two things, lack of culture of planning and lack of time to actually sit down on one side and plan something instead of (responding to) the service demands. " (I-20)

A pharmacist, professor, and developer-trainer of rational prescribing, stated that the national government, specifically the health department lacked planning for the implementation of the EDL.

"I think that, I am not talking about the Northern (Province) Government now, I am talking about National – The lack of planning. There have been no integrated effort, starting from the hospital level, the two volumes, you know the paediatric and the adult guidelines for hospitals. They were launched in December 1998. Now what happened when they were launched there was no declaration beforehand to say that we are going to have a launch date at such and such a time. Before that launch date we should have really been developing an implementation program to train people and when the document came people could start to use it. But now they've got a book which some of them use, in some (cases) use in the wrong fashion because they haven't been trained to do so."(I-20)

b) Provincial Planning

Was there a Provincial implementation plan of the NDP, EDL at the provincial and local levels?

The lack of strategic planning for the implementation of the NDP and the use of the STG.EDL to encourage cost-effective prescribing is not only at the national level, but also at the provincial level at the Northern Province Department of Health.

"I don't think there was anything specifically envisioned for any province because there was only about two or three months before the launch occurred. Nobody had any idea that it would actually be launched in December 1998. There was a major thrust within their EDL committee and the central government. The planning within the provinces should be developed by through a process: this is what we are going to do about it. We are going to have training programs in the hospitals. These are the people who are

responsible for it. You are going to develop this. You are going to do that. The target dates, the number your going reach is... The lack of planning is in general. To lesser an extent because the Northern province (had a) very good strategic leader as you know ...Nicholas Crisp (former Northern Province Health Director) and during that period a lot of progress made including a lot of this training that you've got in the book (nurses and pharmacists). So that was 1997, 1998, 1999." (I-20)

The launch of the EDL for paediatric and adult levels was planned hastily and was not communicated to the Provinces and regions in an effective manner. Therefore, it was not possible to plan an implementation strategy at both the hospital and clinic level.

"The lack of medium term planning. Short term, it no good planning short term because it's on you before you know it. You've got to plan for a few years. That is what we are trying to do, get a longer-term view." (I-20)

So, hospital pharmacists were sent boxes of EDL and were not told what to do with them, who to give them to or how to introduce them to their staff.

"Yea, well then that was about when people, people then might not have known there was going to be a hospital edition launch, except the people involved. Because again there is poor communication down to the service level, down to the provinces. We know have the PEDCO's, Provincial Essential Drug Co-ordinator. Each province has one, but the provinces differ in the effectiveness in which those PEDCO'S disseminated information into their structure." (I-20)

Moreover, an administrator said,

"At the hospital clinic level we did not envision any training. We thought that speaking to the doctors we might change their attitudes and in some hospitals it does work. But in other hospitals, not.

Another administrator agrees,

"Basically in hospital clinics there has been much clearer services within the hospital premises. The implementation has been far lower than it has in the primary health care community in the districts. So basically there is still a lot of work to be done at hospital level." (I-20)

At the primary health clinic level there was some planning for training nurses. As a carryover benefit from the fist EDL in 1996,

"I think in the clinics we have managed to succeed purely by we have managed to put out a clinic list and we managed to train the nurses at clinic level on effective prescribing and prescribe according to the list. So I think there we barley covered the list." (I-18)

Overall, planning and implementation of the EDL was not done on the national, provincial, or hospital level. As a result the EDL guidelines are rarely used by prescribers in hospital clinic and the implementation has not met the targets of rational drug prescribing set by the national government have not been met.

c) What percentages of the prescribers and pharmacist have been trained?

"But after we did the Effective prescribing for nurses, we got a very clear signal from the nurses that the doctors need to train because they are now in conflict with the doctors even at hospital level. Because some nurses are also prescribing at hospital level and that is were we realise that we really need to train the doctors in effective prescribing." (I-18)

"And the other organisation that has been helpful in many of the programs is SADAP. They contract training providers, which we were one. They put out a tender and we bid. So we bid for some training programs. But again, there is no medium term strategy for that. You know, nobody said, we want to, in 1999 or 2000, we want to train 30 people in each province. We did that in '98 and '97, a little bit in '99. But long term, there is no long-term vision of where we are going. "(I-20)

Part of the support is from the University of the North and we are very lucky and SADAP also gives us support. If we can work together we should manage put it (Physician rational prescribing training) through." (I-18)

The Northern Province Department of Health (NPDoH) looks to professional trainers who have carried out various training projects before with some success. Nationally, the MEDUNSA School of Pharmacy staff are consultants to provinces that want their medical staff trained in pharmaceutical management and/or rational prescribing.

8.6.3 Challenges of NDP and EDL Implementation

"What have been some of the biggest challenges to implementation?"

Besides the lack of preparation and planning, the other challenges of the NDP and EDL implementation according to the four administrators includes ten main areas, with training as the most multifaceted challenge. The ten area are: (a) Diminished Resources of Staff and Budget, (b) Distribution and Stock Control, (c) Beliefs and Attitudes of staff, (d) Resistance to Change: EDL adoption and compliance, (e) Communication, (f) Partnerships of health professionals, (g) Patient demands, and (h) Prescribing: interventions and (i) Training of staff will be looked at in detail with questions that look at the vision, implementation, numbers trained and the challenges. In the training of staff additional challenges were identified: (1) budget, (2) development of materials, (3) logistics, (4) administration, (5) selection of participants, and (6) resistance.

(a) Diminishing resources: Staff and Budget

1. Staffing

Diminishing resources of professional staff and budget is a challenge to EDP implementation. All over South Africa, a shortage of professional staff is apparent. The shortage is more severe in rural areas with a largely poor Black population, like the Northern Province. Most professional health posts are not filled. Those who are professionally trained leave for better working conditions and salaries. The Northern Province Department of Health (NPDoH) administrator of pharmaceutical services stated,

"there's 40 vacant (pharmacist) posts. So the number of posts (for the Northern Province public sector) is actually one hundred. The number of people in those posts in any particular time is sixty (pharmacists). Few-trained pharmacists are willing to work in public service hospitals for less pay" (I-20).

"I just need what everybody else needs. I just need more people, two or three more (full-time) people...I have to find people. I've got to find the money. My job is not to cut the money. It is to help them. If I am going to provide training for people in other provinces I need people to do that, whether they are provincial people or my people"(I-20).

2. Budget

The Pharmacology Department Staff from the MEDUNSA were engaged (1999) in the preliminary designs of a rational prescribing program for physician in the Northern Province.

"Really (it) takes months of develop a good training program and test it"(I-20)
Still, the design, pilot test, and implementation of a rational prescribing program is costly. At the time of the research the staff did not have a budget to complete the course development project for physicians.

A drug management course was offered to pharmacists with,

" a three year grant. Now is the year 2000 and its still going on outside funding. So, you've got no kind of long term...(funding) I cant give anybody job security. ."(I-20)

The MEDUNSA administrator was asked how much does it cost for the program and how much does it cost per participant, to train a doctor in effective prescribing. The answer was,

"Ah, we don't know how much its going to cost to train the doctors because it will be in- service training, its not going to be taken out of the working environment. I don't think that costly. To develop a program is going to cost about $70, 000 dollars. There is a lot of pre testing and tests to be done" (I-18).

Funding has been sought through South African Drug Action Programme (SADAP). *Once the program to train physicians is developed and tested then, the program costs should go down " because then the basic training cost will be at the hospital level where we will have training as part of the CET" (Continuing Education Training) (I-18).*

(b) Distribution and Stock control

An administrator that works as a bridge between the central supply depot (Vuna Health Care and hospital pharmacists said that one of the biggest challenges to the EDL implementation was

"each (hospital) was very different from the other. So it was quite challenging in that way, really different from the other. The people are different." (I-19)

The Vuna depot staff have regular training sessions for all the management pharmacists who work in the public hospitals. The training is in

"stock control, (and) the Provincial (procurement and storage) policies. We take groups of ten. We provide the accommodation and meals and we go through our stock control software and provincial policies a one-week training. Training never ends anyway because we have on-site training when ever there are changes to the software." (I-19)

The VUNA project manager visits each of the Northern Provinces forty hospital pharmacies every month and more frequently if needed. The manager puts a priority on keeping contact with the pharmacists. This contact is a very good support for pharmacists and helps them to know what is new, and then to disperse the information to hospital staff. The challenge for the VUNA manager is to keep up regular contact with each pharmacy manager at the hospital, and provide training to each pharmacist on a regular basis and ongoing. Currently, there are two VUNA managers to cover all forty hospitals each month.

(c) Beliefs of staff

For all staff, the desire to help patients with what is available, especially drugs is the one most often used.

"In clinics the biggest challenge is, one of the biggest challenges is trying to teach nurses (and physicians) that not every illness has to be treated with medicine." (I-18)

With patient demand for medicine it is extremely difficult to convince the patient that they have been seen and heard without leaving with medicine. In addition, one administrator admitted,

"Well, what worries me is that I think that we have at many of our clinics a demoralised otherwise ineffective staff who may be using this as an excuse and saying look we don't have many medicines" (I-17).

1. Resistance to Change: EDL adoption and compliance

The implementation of the EDP was to distribute the 3-book set to all professional hospital personnel at all hospital levels the expectation is that they will not comply with it.

"I think that the secondary and tertiary care hospitals are relatively new to the province and you will find that you will find in your research that it hasn't complied easily. That is only my impression"(I-17).

Physicians, especially at the secondary and tertiary care levels work both in the private and public sectors, although it is officially not allowed. Most physicians work in the private sector and have access to all brand drugs and usually use a limited set of drugs for particular illnesses. The prescribing behaviour from the private sector is carried over to the public sector. Physician prescribe brand drugs in the public sector because

"It is an issue of the effective (of) advertising on the users. (Physicians) would rather have their prescribing in a name of a particular brand. Many of our medical staff in particular, I think is convinced the proprietary brands are different from the generic, which is so untrue. I think that advertising, rather than logic or evidence based medicine" (I-17).

When the same doctor who functions in a variety of settings is in the

"hospital clinics, it's the ultimate in 'doctor know best.' He is used to using this for this condition. All of a sudden, if you take it away, he feels that there is no medicine. Then you have a major, major upset. This has been one of the biggest challenges. Physicians that can adopt the EDL list as their own and agree to using it because they feel that it is the best for their patients can only do so if they believe that they have been involved. Most of the specialist also involved with MEDUSA, so they do their training." (I-18)

The specialists from the tertiary hospitals are involved in drawing up a provincial medicine code.

"I have drafted a list of all the medicines we have on our Provincial code and what level they are available, and ask them to comment to them. That's how we involve them. But we have a provincial committee meeting, so we start with getting the specialist involved. But they are very reluctant at this stage. It is causing a bit of a problem. I definitely think that this will be a problem starting the treatment of AIDS." (I-18)

To get not only physicians, but all hospital staff to adopt the changes.

"(It) can't be top-down, you have to be participatory. (I-20)

"At hospitals it is more difficult. Doctors don't like to be (told how to) prescribe. At this stage we are developing, with MEDUNSA, a program to teach doctors 'Effective Prescribing', as a part of continuing professional development." (I-18)

The specialists from the tertiary hospitals are involved in drawing up a provincial medicine code.

"I have drafted a list of all the medicines we have on our Provincial code and what level they are available, and ask them to comment to them. That's how we involve them. But we have a provincial committee meeting, so we start with getting the specialist involved.

But they are very reluctant at this stage. It is causing a bit of a problem. I definitely think that this will be a problem starting the treatment of AIDS." (I-18)

(e) Poor communication

Communication of policy from the National to Provinces to Regions governments to the Department of Health and then to the hospitals and clinics has been a very serious problem from the onset of the EDL implementation. The top-down approach has failed. Communication about the NDP policy was to be transmitted from the Regional Department of Health to the Provincial Essential Drug Coordinators (PEDCOs):

"PEDCO'S and down to the district and the facilities. You know again (that) communication has not been a good aspect of South African health care, management information, (and) communication (from) the National Department of Health to the "PEDCO'S, and down to the district and the facilities. You know again (that) communication has not been a good aspect of South African health care, management information, (and) communication systems of care" (I-20).

(f) Pharmacists changing role between Partnership & Interventions

The pharmacist has changed with the implementation of the EDL in hospitals. The role of the pharmacists continues to change. Now the pharmacist manager is held accountable for interpreting prescriptions written in brand name, dispensing in generic, budgeting, spending, ordering and stock, their role has become more complex. Pharmacists are expected to get *"out of the cocoon to start acting as managers. "*

Pharmacists are expected to be the gatekeeper to the medicines ordered, but many pharmacists adopt the tactic: *"If it not on the list, but the doctor says he wants it. I'm not going to argue with the doctor." (I-18)*

Pharmacists intervene in what is prescribed because:

"Sometimes the prescription goes to the pharmacist instead of having the generic from the EDL. It will have a brand name on it. Then the pharmacist has to interpret that ...I think that has always been the problem of pharmacists and I don't think that they see it as difficult. I think it is a measure of to a degree of the failure of the EDL to penetrate to whoever is prescribing. Because one of the basic ideas is generic prescribing and that hasn't always happened."(I-17)

In addition to the prescriber, the pharmacist must explain educate and assure both the physician and patient that the generic medicine is equal in quality and will work just like

the brand drug. The pharmacist's role has now taken on more responsibility, with few tools to keep the prescribing and budget in control.

(g) Patient Demands

The cornerstone of healthcare in South Africa is 'access and equity' in the health services and treatments is a policy that has been in place for several years, since 1995. Many patients have high expectations to get the treatment and medicine that they had been missing for most of their lives. Access, includes treatment with brand drugs. Patient demand for drugs has added to the EDL implementation challenges.

Patient education about the EDL, generics, and medicines had not been planned or carried out. Generally, patients go to the hospital clinic not only for diagnosis, and treatment, but for medication. Patients have a newfound belief that they should have access and equity to both services and medications. Many believe that they should have access to what had been denied, for most this is a brand name drug, not a generic drugs. Patient demand is one factor that drives prescribing and also makes it difficult to implement the use of the EDL. The implementation of the use of the EDL is difficult according to one nurse, who said,

A "major implementation constraint or challenge is that people demand medication. They demand a lot of medication but don't understand that good treatment is sometimes not to give medicine. They don't understand that antibiotics shouldn't be always given. In any case, the (staff) feel constrained and this upsets the whole purpose of the EDL." (I-17)

Patients go to hospital clinics in order to get the best access not only a diagnosis, but medicines. When they believe there is not medicine, then they do not go to the clinic.

"The interesting thing is that the community believes that we have no medicines at our institutions. This is frustrating because we believe we do have medicines." (I-17)

At times the stocks are low or absent of even the basic medications for chronic illnesses, for example, hydrochlorothiazide for hypertension, and when this occurs the information is spread to the community quickly.

To review, the challenges of EDL implementation are: (a) the diminishing resources, especially staff and budget, (b) Distribution and stock control, (c) Beliefs of the staff about the usefulness of the EDL, (d) Resistance to EDL adoption, thus lack of compliance, and (e) poor communication at and between all levels of staff, (f) Pharmacists changing role between Partnership & Interventions, and (g) Patient demand for drugs at every visit and the demand for brand drugs. These seven factors have contributed to the difficulty in implementing the use of the STG/EDL at public hospital facilities. The seven challenges to implementation of prescribing interventions can be partially met with the managerial use of (h) Pharmaco-Therapeutic Committees (PTC), Peer Review (PR) and, (i) training in effective prescribing and/ or Evidence Based Medicine. The challenges to training will further be reviewed.

(h) Prescribing Interventions: PTC and Training

Pharmaco-Therapeutic Committee (PTC)

A version of the Pharmaco-Therapeutic Committee (PTC) was started at the tertiary level, but because of staff resistance it was abandoned.

"Yes, it is (a PTC), but we are not calling it that. We had a failed therapeutic committee, a provincial therapeutic committee, which didn't get off the ground because we organised it from the head office, and the specialists did not come as required. It must be organised by a group that deals with the university and so on" (I-17).

After mandating the PTC from the 'Head Office' provincial level, now an approach of engagement is used to get physicians to participate and own the process.

"Yes, we tried something new with the Pietersburg-Mankweng Complex with the head of specialities to give them guidelines for certain diseases and started to the specialities first. It's a bit of another approach, but we still need a PTC, which will decide on everyday 'motivations'. We never had a tertiary complex and its still developing and new ideas for a lot of people and they see it (PTC) as a whip, and not as a tool."(I-18)

With input from physicians on all levels, the new PTC will be more accepted, and perhaps will be used not only for treatment and drug reviews, but also peer review by all clinical staff.

The new PTC will attempt to implement a team approach to treating the patient. The focus is on 'Partnerships.' The training of pharmacists, nurses, physicians, and administrators attempts to foster this partnership.

Partnership is "not normally in the public sector. I think the problem is that they haven't got much experience with each other. Neither group know the other groups strengths and weaknesses. The last program, we had a tremendous kind of results. The relationships were starting to develop amongst the pharmacists and the doctors were amazing. They didn't have to worry about the other stuff. They were there to work together and suddenly, 'You know let's work it through together.' It is an important principle." (I-20)

(i) Training of Staff

The questions about training were: *First, what type of training was envisioned? Second, Has the training envisioned been implemented for prescribers and pharmacist? Third, Has the training envisioned been implemented for prescribers and pharmacists? Fourth, What percentage of prescribers has been trained? Fifth, What are some of the restraints to training?* The 1998 EDL for paediatrics and adult hospital use was new. The first EDL (in the early 1990s) was only for primary health care and used only by PHC nurses in local clinics.

"You put STG and EDL together there is a special case. I think we have to answer that specifically because that is new in terms of some treatments. And I think hasn't been a treasured part of the system (I-17).

Training of staff is one of the interventions used to get staff to understand, adopt and comply with the NDP concept of generic and rational prescribing.

"Well the first thing is to train the prescribers in the use of the Standard Treatment Guidelines, Essential Drug List because they haven't received any training in either the philosophy or the practice of the STG/EDL. So the main objective, the main requirement at the moment is training medical physicians" (I-20)

According to the administrators interviewed, ideally courses should be developed for a team of nurses, pharmacist and physicians.

"Yea, we are talking about a team which would be a pharmacist, one or two doctors in the hospital and the nurse to work together. Trying to get them into the team approach. They have got to talk to each other. "(I-18)

The restraints of resources, staff, and budget to implement training have been a major challenge at the hospital clinic level. The EDL implementation success is

"largely dependent on the training. The training has gone reasonably well. And particularly the rational prescribing courses with MEDUNSA (Medical University of South Africa, School of Pharmacy), which is in the region of three or four hundred, classified (as) management. The training has extended to hospital staff, three or four hundred is still a need for more extensive training of hospital staff, plus nurses and doctors." (I-17)

In the Northern Province, the two main courses that MEDUNSA have taught to health personnel (except physicians) mostly to nurses in primary health care clinics, and some hospital pharmacists in drug management and rational prescribing. Most of the training for nurses at the local clinic level occurred in 1996-1997.

"I know that in our first year in operation (1996) we were most effective and we had two courses, rational drug use training for eight or nine hundred (800 or 900) people" (I-17).

Later pharmacist, and managers were also trained, but very few, about 50 in total (MEDNSA, 1998). The Pharmacists were trained in:

"drug management, because its no good at all in telling people how to handle the essential drug list if they run out of drugs. But of course recognising that the other influences are not just prescribing but life style changes. Or other influences." (I-17)

Training the health care staff in the Northern Province has four major challenges: Budget, (2) Logistics: who, when and where, (3) Development of materials and courses, and (4) Resistance.

I. Training Challenges

The four training challenges identified by administrators were first, the inadequate budget for projects and staff. Second the need to develop course materials for promotion of the EDL and Rational Drug Prescribing; third, and the logistics of who can be trained, at

what time and place for how long, and fourth challenge is the resistance to change among the staff. Each of these challenges is explored.

1. Budget

The first training challenge is the lack of a specific budget for carrying out training in Drug Management and Rational Prescribing. *Sources of Funding for Training*

Training has not been pursued with targets and fixed money. The budget for training is pursued a course by course, piecemeal manner. A MEDUNSA administrator said,

"The budgeting is annual, and there's not provision long-term strategic training, which includes human resource development. There that was a deliberate attempt by the Northern Province working with us, that was worked into the plan. Nobody since then has planned a cohesive planning in the Northern Province" (I-20).

A budget for training on the EDL and rational drug prescribing is

"Just what we have negotiated from the DIFID funds (SADAP). The training budget, is not a specific amount per year. It is what we have on an ad hoc basis had paid for the specific training we set up. So, even the pre budget amount we are sharing nationally" (I-17).

The Northern Province Pharmaceutical Services Director was asked, "What do you think your budget was last year for training?" His response was,
"I haven't got a clue. I haven't got a training budget at all. It is a decision of human resource development. Although the NPDoH Pharmaceutical Director and PEDCO is very astute and aware of drug spending, he is not aware of what the training budget was or the number of those trained last year" (I-18).

The Northern Province Department of Health does not have a defined budget line for training that is within their department or control.

"There are little pools of money .The budget for training health staff for compliance to the EDL is obtained through several sources. "We do have a budget in the provincial office under Human Resources and Development, which we can access, but it is very difficult sometimes to get access to that money"(I-18).

"We, we have to some extent been funded and supported by the Northern Province and we believe that will continue" (I-20).

Also, funding comes from specific grants from the South African Drug Action Programme (SADAP). The SADAP has money specifically for training that must cover

the activities in all nine provinces. Most of the training grants have gone to the consultant team at MEDUNSA for work in several provinces.

"Sometimes we ask SADAP for funding if the region can not pay. Some regions pay out of their budget. In service training is complicated in that with the regions there is a lot of them" (I-18).

"With regard to the academic side that is funded partly from the provincial budget partly from a direct national fund and the core redistributed fund which (was) to build a tertiary complex, because this province did not have a tertiary complex. Then there is also a fund which has changed names, a 'top slice' fund for academic training, tertiary training. I can't put a total figure to all these funds. The department has always decided that primary health care should be the main thrust of this department for this under-resource province with a rural population with quite basic health needs. But most of our money is going to tertiary. It is a little bit illogical, because they say that we should have primary health care, but we actually spending it on tertiary. And we neglect the secondary. It is not a good balance."(I-17)

The cost of training one person for one or two courses, 'Drug Management' or 'Rational Prescribing' cost about

"R250 per day, which is for the ten days, two thousand-five hundred (R 2,500) for the entire course. In fact the accommodation and everything was extra. If you translate that into dollars it is not a great deal. Everything like that it works out to be R250-R300 a day for training. The courses were "funded from the Province, the (Northern) Province found the money for that. There was money within the provincial budget" (I-20).

Each time that the NPDoH requests the 'Drug Management' or 'Rational Prescribing' course, the requesters and the course organisers start their search for funding. The lack of planning and budget exclusively for training also affects the staffing for the training programs.

"We had a three year grant. Now is the year 2000 and it's still going, and its still going on outside funding. So, you've got no kind of long term...I cant give anybody job security. The regular staff they've got it but the other thing you know I can see that we are funded for two years. So for two years, after two years I don't know before that. That is where I am at the moment." (I-20)

Budget, staffing, training are all interconnected. Now that he new EDL has been introduced into hospitals,

"the service needs is huge. The starting (salary) levels are low, and the resources and preparation of the training program are also low because to have a proper program you need to have someone full time and you know everybody's got their own program. In our program, basically (we) present or prepare pharmaco training for the pharmacist and practitioner. Our jobs, all the direct things that we do, are funded from the outside and the pharmacy training development project. That's all outside funding. Now I keep something like you know four or five full time people funded on those project from outside funding but I've got to develop a variety of programs for that purpose"(I-20).

In summary, training of the staff has four major challenges. First, the restraints of budget and staff, second, the time and cost for development of materials and courses, third, training logistics, and forth, the staff resistance to change in prescribing and procedures. Although training to adopt the EDL or change prescribing behaviour was an intricate part of the South African National Drug Policy (NDP 1996), a fixed budget line, along with Provincial DOH or regional strategic plan for this sole purpose of training was not added. Instead, administrators of the Northern Province must seek funding on a project by project basis from various small provincial and national funds. Since there is not a set budget, the Provincial Director of the Pharmacy Services had no knowledge of the total spending on training for the years 1998-99 or 1999-2000. The administrators said the budget for in-service training is limited to what can be found in other non-centralised monetary resources. The application process for funding is often complicated, tedious, and difficult because of the various criteria and restrictions for funding. Thus programs that are developed, staffed, implemented and at times evaluated in a non-centralised strategic manner.

(2) Logistics

The third training challenge is the logistics of training staff away from the hospital. Training in one of the two courses in drug management or rational prescribing is either one or two weeks long. Staff must take off this time go to another town and stay for the entire course. In many hospitals with the shortage of staff taking a professional out of the hospital for several days could mean the closing or cancellation of services. Staff, who must take off work time for training, are reluctant. This is a big challenge to promoting training. Although the training is valuable, it is attended at a high price.

"To take people away for training is the problem because we have a shortage of all physicians here. If you are a nurse, sometimes you are the only nurse you can't take off. Or if you've got only one doctor or two doctors in the hospital, one is on call for 24 hours a day, for seven days. And the pharmacist is the same, if you have one pharmacist in the hospital pharmacy, many of them. And set up a pharmacist for a week. So it becomes a problem the shortage. Maybe we could make it so that the pharmacist will help us. And them you are stuck with another problem, accommodation for them" (I-18).

Speaking about the rational prescribing course, the course developer believes that the length of the two-week course is necessary,

"Well, that one we probably do a week (then wait several weeks and then do another) week because the first week really teaches them methodology. Understanding and being able to investigate the way in which the medicines are being used, in fact more on research methodology type of programs. But then because of the way we train we always train with the ideology to do the job (by) the time that they go away they have designed a project that they take back to their service. They then have to do an initial investigation during the interim. And they come back for the second week they actually present the results. We then have a discussion on the results. We then give them the next stage. We teach them to do intervention, to improve the situation." (I-20)

Overall, the time factor is critical to training. Staffs who have had training have had to take one or two weeks away from work and home. Most public hospital systems in the Northern Province are understaffed, and thus cannot afford to allow staff to go away for training.

(3) Development of Materials and Courses,

The third training challenge is the development of rational prescribing materials specifically for physicians. The materials used for the two courses of Drug Management is geared to pharmacists, while Rational Prescribing course was developed for primary care nurses, but is used for all nurses and pharmacists. The programmes for nurses, pharmacists have unique components that have allowed for some success. However, the lack of materials and courses for physicians has become one of the challenges to rational drug prescribing.

In the last four years nurses have had the most training. Now the focus is shifting to pharmacists and physicians. Courses materials must also be developed for,

"the new training trend has been to "work in pairs. We try to develop a partnership between the pharmacist and the doctors and try to train the pharmacist and doctors together in rational drug use. Overall we may have trained about twenty doctors and twenty pharmacists together. Now, they will at least be comfortable working with each other, other than in a direct service environment. So they know they will be able to work together in a training environment. " (I-20)

The development of course materials for physicians that appeal to both the professional level and responsibilities of the various staff while imparting the most important aspects of evidence- based medicine, cost-effective prescribing and dispensing. In order to accomplish this goal the courses must be developed for nurses, pharmacist and physicians to be trained separately or as a multi disciplinary team. Courses for each of the professions will be looked at sequentially.

a. Courses for Nurses

Training courses for nurses had been the main focus after the introduction of the first primary health care STG/EDL in 1996.

"We did train in the first year (1997) nearly four-hundred nurses in effective prescribing, and the second year (1998) just trained seventy. We had to slow down a bit on 'Effective Prescribing' for nurses at clinic level because they were going through a lot of training in the last two years. By the time they get back to their working station they have forgotten what they've learned. We decided to scale down a little bit until other people have finished the (other courses)" (I-18).

b. Courses for Pharmacists

More pharmacists, than physicians have been trained in 'Drug Management and Supply,' and 'Rational Drug Prescribing,' but still too few have had either course.

"Pharmacists who work in the public sector are about '300. I don't know how many hospitals there are in the Northern Province, but we certainly haven't reached the pharmacists in every hospital. We might have reached a majority of them. I can't tell you. I mean I should, but I can't"(I-20).

He went on to say,

"We have had pharmacists passing through our system. They come from a different point of view. These two training courses, 'Effective Prescribing,' which is concentrated on a few common conditions. (It is) Sort of an algorithm approach of how you would approach those conditions. It is not extensive yet. It really was meant to be the principle (of the course) and from that you can use the EDL booklets"

Pharmacists are expected to be managers and have been trained thus far,

"Probably we have reached 40 pharmacists over two years (1997-99) in the Northern Province. At the moment there is around 60-65 pharmacists in the public sector in the Northern Province. Well,(the) pharmacist we have trained, more as mentors or guides for the medical practitioners. We taught the pharmacist, in 'Drug Supply and Management' and 'Effective Prescribing. So they know what the parameters are for good drug use. They are also in the position to evaluate the data, the prescribing data and give feedback that says basically 'why does every patient that comes into this clinic or into this hospital given an antibiotic?' Obviously that is a bad practice. So we train them to do that" (I-20).

To meet the new demands, the NP would like to implement another training program designed for pharmacists to gain additional managerial skills.

"I am also looking at another type of training for pharmacists. Training them to become managers in the future. We want to give pharmacists management training. This course will help them to improve hospitals prescribing because they will be taught, pharmaco-economics, the basics of being managers and communications skills" (I-18).

The course aims to assess the difficult task of pharmacist as the gatekeepers to brand drugs. The course goals is to give pharmacists more confidence to allow them to be more assertiveness with prescribers who ask for drugs not on the EDL, and who want to motivate for other more expensive brand drugs, when there is a suitable drug on the EDL.

The training will take place in "the hospital situation for work-study. In the first 18 months, the target number of pharmacist to be trained is "approximately forty). It will take them about 18 months. Upon completion of the training, pharmacists "will receive a management certificate from MEDUNSA, and the University of the North. Only, *"once you have done the training and the pharmacist managers course you can apply" for a pharmacy manager position. If you haven't got this certificate, then you can not become a pharmacy manager" (I-18).*

Funding for the new pharmacist management training course has been sought from SADAP. Even so, pharmacists
"will have to pay for it." The exact cost of the course is not known yet, *"the relevant funding will cut down the costs. They (the pharmacists) will just have to pay for the training materials. I think that it will be between R2,500 and R4,000 Rand" (£250 to £400 GBP for each pharmacist). Many will not be able to meet the cost of training, so they will able to apply for a bursary to help to defray the costs" (I-18).*

c. Courses for Physicians

The National Department of Health and the NPDoH, as a result of poor planning,

"at the hospital clinic level, did not envision any training. We thought that speaking to the doctors we might change their attitudes. I n some hospitals it does work. But in other

hospitals not. But after we did the 'Effective Prescribing' for nurses, we got a very clear signal from the nurses that the doctors need to train because they are now in conflict with the doctors even at hospital level. Because some nurses are also prescribing at hospital level and that is were we realise that we really need to train the doctors in effective prescribing." (I-18)

Currently there is not a course for rational prescribing for physicians.

"At hospitals it more difficult. Doctors don't like to be (told how to) prescribe. And our first thing is that at this stage we are developing with MEDUNSA a program to teach doctors on effective prescribing as a part of continuing professional development. At this stage my application is with SADAP asking for funding through actually finance the budget with SADAP everything in place now I just have to develop the program" (I-18). MEDUNSA is now setting up a continuing education course. It will be "voluntary, but because we are going to put is as a part of the CET (continuing education training) for the doctors might fall for it because they get points" (I-18).

The exact type of training that physicians will have in rational prescribing is still not known.

"No. I don't think I have too many details. I think that it will be in-service. It will be monitored by the professionals themselves, so that they can see what they're doing. In other words it will be active participation. It is not going to be something which is presented to them in the form of a course or a lecture program, but actually involved in participation." The training will occur "within their work environment "The basis training cost will be a the hospital level were will have training as part of the CET (Continuing Education Training). The designers of the intervention believe that face to face and active participation will it work, "because there will be a run through a cascade, like how we do all our training. We train the trainers, and then they train others, so it goes down into their service row" (I-20).

The exact location of the first Programme implementation for physicians is not known. *"I don't have the hospitals yet. I just know that it's the Northern Province" (I-20).* The cost also has not been worked out.

"Ah, we don't know how much its going to cost to train the doctors because it will be in service training, its not going to taken out of the working environment. I don't think that costly. To develop a program as such will is going to cost about $70, 000, there is a lot of pre testing and tests to be done" I-18).

The development of the course for physicians will be developed, and tested in

"three stages because clearly you have to do a pilot program, you've got to develop your materials, pilot test, redefine, review, improve and then take it to the next stage. I don't know what the costing might be of the two stages. I don't have any figures. But I do know

that we are looking for support." (I-20) the NP Pharmaceutical Director, has "submitted my application to SADAP for funding (I-18). If the funding were available right away, "It shouldn't take two months to develop the program. We have the background of what we want to do, we've got the material attached we just have to put the materials together and train the trainers. And then we need to test it before we use it in other hospitals...The whole process of the development; the test and evaluation of a physician rational prescribing course will be pursued vigorously. "We really want to push hard. It shouldn't take us more than six months "(I-18).

"The prospects of getting a person who is qualified to train physicians full time is a difficult task that is made more difficult because of budget constraints." (I-20)

Overall courses in evidence based medicine and effective prescribing for nurses, pharmacists and physician are thought to be needed by the interviewees with the exception of physician who believe that others, including physicians could use training, but they do not need it. Administrators who would like the physicians to adopt cost-effective prescribing, at the time of the interviews were at the initial conception stage. The best mechanism (Continuing education credits, On-house rounds, PTC, peer review, etc.) to implement training is for physician. For nurses, several courses were given for a cascade training effect that did not occur. Training was given to one pharmacist per hospital, but almost all of them need to have managerial training.

With all the challenges to implementation, the administrators were asked about their vision for the future of EDL implementation and training for the future and how that can make the vision a reality.

Resistance to prescribing interventions (EDL/STG Use, Training, and PTC)

Resistance to prescribing interventions include the use of the STG/ EDL, training, and PTC committees. Nurses and pharmacists have generally been enthusiastic about participating in training, but physicians have consistently stated that others need it, but they personally do not need to have training.

According to Administrators and physicians themselves, many physicians, especially specialists, do not believe that the EDL has the medicines that they use regularly use for

their patients. In addition, the list does not always coincide with the actual dosage of medicines that are available in the hospital pharmacy.

"The EDL list talks about the medicines to comply with the EDL. The medicine will come in 2.5mg, and the EDL will say to use 10mg. Some find it very confusing, even the doctors. If a patient needs 5 (mg), what do you do? Do you give them two 2.5 (mg) or do you give them a single 5 (mg)? This is causing a bit of a problem, even at the tendering site there is a conflict, and frustration" (I-18).

The EDL covers many of the tertiary illnesses, but it does not cover the most common illness in psychiatry, dermatology, oncology or immunology (HIV/AIDS). On the EDL/STG there are

"Very few dermatology and oncology (medicines) at this time. That is an area that they will have to look at. Psychiatric medicine is a bit of a problem. So, psychiatric doctors are really up in arms with us. Many physicians believe that the EDL advisory committee was not made up of colleagues in their professions. There is also a general feeling that they weren't consulted about the changes to the drug lists. Many physicians have adopted their own ways of getting around the use of only medicines on the EDL. We think there will be changes. Fortunately, within the province we can make up our own list. So we are doing that. (I-18)

Many physicians have their favourite personal list of drugs that they use and do not want to change. They are resistant to any form to intervention that focuses on prescribing change.

"Well training is a part of the problem, but I think that old habits die very hard. If you have always treated with brand (medicine) then you go on doing it. But if some outside body says that it is better for the patients, and believe strongly in certain medications. Advertising or some other forms can increase this...(brand name prescribing influence). So, I think that, not here but in other places, it shows that doctors tend to prescribe from a very limited range of drugs." (I-17)

Rational Drug prescribing course developers believe that once a specific program is developed from an academic medical department, the resistance to use generic drugs and prescribing will be lessened.

"One obstacle is that doctors see themselves as superior. What we've got now is a tertiary complex with specialists. We have various communities with various professors who are starting now to look at local application of various conditions and prescribing treatment. This is not very far off the ground, but is a major set (of priorities) in the last weeks, which I hope will get done faster. These people are academics, and they will be accepted by the doctors. We are hoping that this is the way we will get the training accepted by the doctors, rather than using our present pharmacist-nurses approach."(I-17)

This academic rational prescribing approach for physicians is likely to be developed and is implemented with the use of the PTC committee.

In brief, the resistance to change, being told how to practice medicine, though prescribing is resisted by almost all physicians. In addition, specialists believe that the EDL does not list medicines that they need for their practice especially in psychiatry, dermatology, oncology, infectious diseases, and immunology. In response to the mandated prescribing, physicians have found various ways of getting around or ignoring the use of the EDL. The way forward seems to be a new emphasis on physicians who are clinicians and academics that can bridge the gap between the administration and the prescribers.

8.6.4 Administrators Vision for the future

The last questions asked to administrators to assess their vision of the future were "What do you envision for prescribers and pharmacist a year from now, and how can you get closer to making this a vision a reality?"

The administrators who were asked about their vision for the future, most comments were based on the use of the EDL, multi-team practice at the hospital level, training in rational prescribing, and an updated STG/EDL every two to three year. The new STG/EDL should include medicines in specialty areas that are lacking in the 1998 version. Once the 1998 STG/EDL is updated, then once again the focus must turn to the implementation of its use at all hospital levels.

"Well if I could have my professional pharmacist trained this year (1999), I think in a year or two we should be able to have trained the new doctors because we feel that is where we can make a big savings at this stage. But we are not just looking at doctors; we see the training for the doctor prescriber is a team effort within the hospital with the pharmacist actively involved. But I think that within a year or two we should have at least one team per hospital trained" (I-18).

The number of physicians that would need to be trained is about 500 in total.

"Well, you know I think that we will be implementing something constructive. The first thing obviously is to increase their sensitivity or awareness to the current difficulty both in terms of therapeutics. Secondly, from the financial point of view. Although the drug companies would not have you believe that good therapeutics often go hand in hand with cost management. They would tell you that you must use the best expensive drug. That is nonsense. So what I am saying that good therapeutics and good cost management go together. So if you can be sensitise the prescribers to both issues and show them that their patients are not going to be any worse off with good prescribing rather than with fashionable prescribing, then we would have achieved a lot. We have to change that whole attitude because they have been so conditioned by the industry, even during their undergraduate training. They have a major role in developing pure (brand prescribing) practice because of their direct interest in making profits. They are there for the shareholders. They are not there for the patients" (I-20).

The Northern Province has about 500 physicians in both public and private practice.
"All 500 need to be trained. Whether we would train all 500 in one year, I think it is unlikely. So, it would be a two year three year period" (I-20).

In summary, for administrators the lack of preparation and planning created additional challenges to local EDL implementation. The vision for the future includes addressing ten challenges listed below and individualised training and courses for nurses, pharmacist and physician. In addition, multi-team practice and PTC meetings, EDL/STG updates (every 2-4 years) will aid in the NDP implementation of Rational Drug Prescribing.

8.7 Structured Observations

8.7.1. Observations in Health Facilities

As part of the Drug Utilisation Study (DUS) evaluation during the facility visits, interviews and structured observation were used to determine first, the availability of EDL. Second the availability of impartial drug list. The set of three books (STG/EDL, 1998) for Primary Health Care, Paediatric Hospital Care and Adult Hospital Care were delivered to all Northern Province hospital pharmacies in the study. The 'pharmacy management' staff had various methods of distributing the books. As confirmed in interviews and by observation most doctors, who are the primary prescribers, pharmacists and nurses in hospitals received the entire set.

Structural observations at the facilities helped to answer several questions. First, is the EDL available for staff use? Second, are the STG/EDL present being used? If so, by whom, at which level, and how? Third, is there other impartial drug information available and accessible for reference? Fourth, Does the facility have its own drug bulletin? Fifth, what drugs on the STG/EDL are not available on the day that the survey was conducted?

a. STG/EDL available for staff use

All nurses, pharmacist and physicians were said to be given the set of STG/EDL books at all three hospital clinic levels. At one tertiary level pharmacy, there were large boxes of STG/EDL books in a copy/storage room. They were available for in all hospital clinics observed, bur rarely used. The availability of the STG/EDL along with the number of prescribers having direct access to a National Drug Formulary has a direct effect on the potential for prescribers to prescribe rationally.

b. Use of STG/EDL

The physical presence of the STG/EDL with the person or in the physician office, examining room, nurses desk, pharmacy, etc. is good indication that the book is being used for patient consultation. If the STG/EDL book were used regularly, then it would show warn or bent pages and other indications that it had been used. Instead, almost all of

the books used by physicians and some nurses looked new. It was apparent that the books had not been regularly used by some nurses and only two physician observed and interviewed. In contrast, the book was found in constant use at most of the pharmacies observed in the study.

8.7.2 The Use of Other Impartial Drug Information

Both the primary and the tertiary hospital clinics that were observed did not have impartial drug information with the exception of several textbooks and the EDL. At tertiary hospitals, pharmaceutical companies provided most of the drug information. Partial drug information was the norm.

In contrast, the secondary hospital clinic (#6) had impartial drug material and its own regular EDL bulletin for all the staff (Appendix X). At the time of data collection, the pharmacist manager was enrolled in the 'Rational Prescribing' Course given by MEDUNSA. The pharmacist produced a monthly EDL bulletin for the hospital personnel as a way to impart information on EDL changes and the rational for the changes.

8.7.3 Training of Staff

In the quantitative analysis, the hypothesis that the availability or lack of training and/ or impartial drug information contributes to irrational drug prescribing.

In addition to impartial drug information and a hospital level drug bulletin, the availability of training sessions can positively contribute to promoting rational drug prescribing. The assessment is determined by number of training session on drug use for prescribers in the last year, out of average number of training sessions organised in the past three years give a good indication of the actual population coverage of training. This includes the number of prescribers that have attended at least one training session in the last year, out of total number of prescribers surveyed.

8.7.4 Summary of Observations

Overall the staff did not feel or behave as if the use of the EDL was beneficial to them or the patients with the exception of pharmacist who used it to substitute brand name drugs on prescription with generic drugs. In order for the health staff to use the EDL and prescribe rationally they must believe and feel that they have a part in the development, implementation of the EDL and the evaluation of their peers.

8.8 Summary of Qualitative Chapter

The quantitative chapter explored the knowledge, attitudes and practices of the hospital staff and administrators through observation and interviews that allowed the staff to give their views in their own words. First the demographic information of nurses, pharmacists, and physicians was collected. The main group of questions centred on Knowledge, Attitudes and Practices with the EDL, Peer Review, PTC and training. The practice questions centred on changes in the work environment, including use of EDL, generic substitution and prescribing.

Not all staffs were officially informed about the implementation of the new EDL and the Policy to prescribe drugs by generic name on the EDL. Some staff were sent a memo, while others were given the set of three EDL books. All the staff interviewed, with the exception of one, had not received training in the use of the EDL, evidence-based medicine or rational prescribing.

Overall, the nurses and pharmacists thought that the EDL and training in effective prescribing was useful for all professional staff, while physicians thought that it is useful for other physicians, but not them. Consistently, with this view, the work environment changed for both nurses and pharmacists, but not for physicians, since the official launch of the EDL.

After sixteen of the hospital staff were interviewed, new questions arose. Specifically, questions concerning plans for implementation, training, and visions for health staff and training in the future. Thus, specific administrators were chosen in order to answer the questions about a national or provincial plan for the implementation of the NDP and EDL, as well as the percentages of the prescribers and pharmacists who have been trained. These administrators were asked about what they consider to be the biggest challenges to the implementation of the NDP and EDL. Their answers can be categorised as follows:

(1) Diminishing resources, (2) Distribution and Stock Control, (3) Resistance to Change, (4) Beliefs of staff, (5) Communication, (6) Partnership of health professionals, (7) Patient Demands, (8) Prescribing interventions, (EDL, generic dispensing, and PTC), and (9) Training of staff.

The administrators concluded that training must be directed to a particular professional audience through professional channels that are acceptable within the profession. Once this criterion is met there are still six challenges to training staff that include (1) budget, (2) material development, (3) logistics, (4) administration, (5) participant selection, and (6) resistance.

Administrators envisioned training for prescribers and pharmacists, as a means to make the vision a reality. Envisioned is a budget line funding for trainers, courses and interventions that are tailored to the specific health care audience (physicians, nurses, pharmacists, administrators, and consumers). The courses would encourage team care at the hospital level and the use of inter-disciplinary practice and PTC meetings. In addition, the EDL must be updated regularly.

Observation of the study facilities revealed that although all the staff was given a set of EDL with the exception of the books. The pharmacies also had the ELD set of books, but they were not present in other parts of the hospital clinic. Only one prescriber interviewed in a secondary hospital carried the books with him. At the same hospital, the pharmacy manager produced an EDL bulletin for health professionals on a regular basis and had other independent drug literature available.

In order to explore the link between the qualitative and the quantitative data in chapters seven and eight, the drug utilisation and prescribing will be analysed and discussed in chapter nine, to answer the basic eight questions on the answers of which additional inquiry and analysis will be based. These basic questions were how many drugs were prescribed, how many drugs were from the EDL, generic, brand, antibiotic, analgesic,

injections. The answers to these questions were also evaluated for chronic illness in chapter seven.

CHAPTER NINE

Discussion

9.1 Introduction

This chapter will review the objectives of this thesis and summarise the findings. The aim of the research was to assess the availability of objective information about the South Africa's National Health Policy and evaluation of the top-down approach to its implementation. In top-down planning, "setting goals, identifying options, and choosing among options all occur at the senior level. Top-down planning is more appropriate for strategic planning, in which the basic mission and goals must be defined". Top-down planning requires input from all levels. Top-down planning is less appropriate for operational and project planning, in which the purpose and major goals are clear.

The overall objective of this thesis was to evaluate the implementation of South Africa's National Drug Policy (NDP), the use of the Standard Treatment Guidelines/ Essential Drugs List (STG/EDL) and its impact on rational drug prescribing in public hospital outpatient adult clinics. The main question is has the implementation of South Africa's National Drug Policy and the use of the STG/ EDL resulted in rational drug prescribing in South Africa's hospital outpatient clinics, specifically in the Northern Province?

9.2 Analysis of Drug Utilisation Study (Objective One)

The first objective was to survey and analyse patterns of drug prescribing at three levels of outpatient hospital clinics. The Drug Utilisation Survey *(DUS)* focused on eight Prescribing Indicators at eleven clinics in eight hospitals. The eight indicators were 1) mean number of drugs, 2) prescriptions with two drugs or less, 3) proportion of generic drugs, 4) proportion of drugs on EDL, 5) proportion of drugs prescribed as brand or generic on EDL, 6) proportion of antibiotics, 7) proportion of analgesics, and 8) proportion of injections. These indicators were evaluated for the overall population and in addition for patients with chronic illnesses.

The results of the DUS study showed that overall the three levels of care were quite similar in their adherence to EDL principles with the following exceptions. The primary care levels overall showed better compliance to EDL principles, although still not

meeting the EDP goals. This small success at the primary care level can be attributed to familiarity with a limited number of generic drugs, a limited stock, and introduction of the EDP concepts and training many years before the implementation of the NDP for all levels.

The overall ranking for rational prescribing of the eleven hospital clinics did not show a specific pattern. Hospital clinic #6, St. Rita, a secondary hospital was ranked first for adherence to prescribing indicators. In contrast, clinic #7, Mokopani, also a secondary hospital and #4 Mankweng, a tertiary poli-clinic ranked last in adherence.

St. Rita's clinic #6 ranked first of the eleven clinics, in both adherence and by the coefficient evaluation. It ranked first for generic (GEN) prescribing, and the number of drugs prescribed by brand name on the EDL as generic (EDLBRD). St Rita's clinic ranked second for the number of drugs prescribed on the EDL.

St. Rita's first rank is not a surprise when reviewing the interviews and observations during the data collection. The Managerial Pharmacist at St. Rita has a firm commitment to the use of generic drugs, the EDL and rational prescribing. At the time of the interview she was preparing a small DUS study for her class in Rational Prescribing. In addition she produced a monthly newsletter on rational prescribing (Addendum X). The nurses and physicians who used the STG/EDL and carried it around during their patient visits shared this commitment to generic prescribing.

9.2.2 Chronic Illnesses and comparison with overall prescribing indicators

Generally, the majority of chronic illnesses should be treated at primary care facilities and only the more complex cases should be referred to a tertiary care facility. Of the general study population, 39.2% had a documented chronic illness of hypertension, diabetes and/or asthma or a combination of these illnesses.

In contrast to the goal of treatment of chronic illnesses by Primary Health Care facilities, 54% of those with hypertension and 52% of those with diabetes were treated at tertiary care facilities and only 37% of those with asthma were treated at primary care facilities.

Overall as for the general population, the clinics that were the least adherent for those patients with chronic illnesses were both at the primary care level, Jane Furst hospital clinic #9 and van Velden hospital clinic #11. (Comment: Misleading – does not allow for different sample sizes)

Once again, St. Rita's clinic #6 ranked first overall, even though they ranked first only once in prescribing drugs by brand name, which are on the EDL as generic (EDLBRD). St Rita's clinic ranked second for the number of drugs prescribed on the EDL. Ranked second overall, Pietersberg poli-clinic #2, ranked first in mean number of drugs, prescriptions with two or less drugs, and the proportion of analgesics prescribed, but it also ranked last in prescribing drugs by brand name that are on the EDL as generic (EDLBRD) and antibiotics.

Prescribing for those with chronic illnesses did not show better rational drug prescribing or a concerted effort to adopt the use and principals of the EDL at any of the three levels. Evaluating the prescribing indicators by facility level for those with chronic illnesses is similar to the overall results. At the primary care level the mean number of drugs was the highest, but in contrast to this the level of prescribing antibiotics and injections were the lowest. Overall this evidence does support the hypothesis that at the tertiary level there is a trend towards the adoption of EDP principles, while at the primary and secondary level there is little evidence of adoption the EDP.

9.2.3 Comprehensive Correlation Matrix of Prescribing Indicators

For both the general population and those with chronic illnesses the pattern of the comprehensive correlation matrix was the same. The high correlations between the mean number of drugs and prescriptions with two or less drugs and between prescribing from the EDL and generic are expected. Worth noting is that there are no other significant correlations. In summary, there is little evidence of a concerted implementation of the EDL policy.

9.2.4 Knowledge, Attitudes, and Practices of Health Professionals (Objective Two)

The second objective was to assess the knowledge, attitudes and practices (KAP) of health professionals (nurses, pharmacists, physicians and administrators) concerning the implementation of the NDP and their training in the use of the STG/EDL.

Interviews

Overall, the interviews with nurses, pharmacists, and physicians show a common experience of not being informed about or trained to use the new EDL, although all of them said that they received the set of three books. Although every health care provider received the books, most pharmacists but only a minority of nurses and physicians use the EDL as part of their working routine.

The implementation of the EDL in general has slightly changed the working environment for nurses and pharmacists, but not for physicians. These changes in the professional environment for nurses include the addition of public health issues and non-drug treatments, and for pharmacists automatic generic substitution, a ready-made procurement list for ordering, cost reduction, and a decrease in polypharmacy.

Nurses and pharmacists believe that all health professionals need the EDL and training in rational drug use, while physicians believe that the others need training while they do not. In addition all health professionals believe that a multi-teamed PTC committee would be beneficial to both staff and patients.

The different groups of health care providers had different challenges with the EDL, generic drugs and rational prescribing. These will be summarised separately.

a) Nurses

Nurses were given the new STG/EDL for hospital adult care. None were given a briefing about when or how to use it. All were given books, but none of them had training on rational prescribing or the use of the new STG/EDL.

Overall nurses, who were given the first primary health care EDL (the green book) in 1995, thought the STG/EDL was simple, useful and advantageous because it included preventive care and public health tips. Even with the use of the new EDL, few felt as if their work environment had changed as a result of its implementation. However, all felt that they did not have the knowledge needed to use the STG/EDL to their full advantage. All expressed that they would like to be trained. In addition, they thought that active participation, for example in Pharmaco-Therapeutic Committees (PTC), as a part of a health care team would give them the input that they need and also allow for better patient care.

b) Pharmacists

All pharmacists said that they had received the set of STG/EDL books. All had knowledge about the new STG/EDL because they were expected to give these books to all health personnel and to inform them about their use. Nonetheless, only one pharmacist interviewed, at St. Rita's Hospital, had formal training in Rational Drug Prescribing.

Pharmacists are expected to be the gatekeeper of the drugs available from the pharmacy and to educate the prescribers on how to use the EDL and write prescriptions with generic names. Pharmacists found the EDL was a positive guide that helped them to limit the amount of drugs ordered that are not on the EDL. They use the EDL as a way to reduce pressure from both patients and physicians to order and dispense brand drugs. In addition, pharmacists use the EDL as a guide of what to order.

The pharmacist is expected to stay within the budget, while supplying all the drugs needed for all the specialities, to order mostly generic drugs, to spend only 10% of the budget on brand drugs, to motivate prescribers to use drugs on the EDL, and generally act as enforcer. Nonetheless, only one pharmacist received formal training on how to fulfil

these duties. Pharmacists would like to receive formal training and also to be active within inter-disciplinary PTC committees.

Currently, the pharmacist is expected to be the manager, gatekeeper, accountant, and teacher, and to motivate the staff to adopt the EDP and rational drugs prescribing, all with little or no training in management, rational prescribing or budgeting.

c) Physicians

All physicians interviewed received a set of STG/EDL books. The overall knowledge of physicians about the use of the new STG/EDL, motivating for generic drugs, Peer Review and Pharmaco-Therapeutic Committees (PTC) are limited. Of the physicians, two said that they did not have knowledge of the new EDL and generic prescribing. In contrast, all physicians know about 'motivating' for drugs not on the EDL, while none had knowledge about the 10% budget cap on ordering drugs not on the EDL. One physician talked about Peer Review and only four said that they had knowledge about PTC committees. None of them had participated in either a Peer Review or PTC committee. The Pietersburg Hospital administration said that they once had a PTC committee that failed because of its focus only on physicians' experiences with patients. The administration will attempt to set up a multi-team PTC.

The working environment for physicians should have changed as a result of the EDL adoption, for example by prescribing more generic drugs, less poli-pharmacy, participation in training, PTC committees and Peer Review. Physicians said that their environment had not changed since the introduction of the EDL.

Most physicians interviewed thought that the EDL was not useful for them or their practice. Only one physician changed the way he practised medicine by prescribing by generic name. The only change for some physicians is that now when they order brand drugs, they must fill out a justification form to 'motivate' the pharmacist to order the brand drug for a particular patient. The most telling interview was with a young physician who was practising medicine at a primary care hospital for less than a year. He said that

in his six years of medical school in South Africa he learned to prescribe only by generic name. Within less than a year and with medical seminars sponsored by drug companies only once a month, he prescribed by brand name most of the time.

Several physicians thought the EDL is useful for young and /or inexperienced physicians or as a list of what is available in the pharmacy. Physicians interviewed did not experience a change in their work environment, although two physicians said that generic substitution changed the way they prescribe. Overall physicians said that the EDL is a simple and cost-effective reference tool that is good for young physicians, patients, especially those with chronic illnesses, and other staff who should be trained to use it. However, they do not think that it is a helpful guide for them personally and thus it has not influenced their prescribing practices. Physicians interviewed overall did not adopt rational prescribing practices like using generic names or prescribing fewer drugs including antibiotics, analgesics, and injections. Physicians practice, diagnosis, prescribing or treatment regimes overall had not changed. As one administrator summarised the physician practice environment, "It's the RTC factor, resistance to change" (I-12).

9.3 Administrators

After the interviews with the hospital clinic staff, administrators were interviewed to gain a better understanding for the planning, preparation, and implementation goals of the NDP and the evaluation of the degree of success. The three main foci were I) preparation and planning for implementation, II) challenges to EDL implementation, and III) visions and plans for the future.

9.3.1 Preparation and Planning

Overall strategic or programme planning and implementation of the EDL did not occur on the national, provincial or hospital levels. Administrators stated that there was no implementation plan because in South Africa's health care system ' there is no culture of planning'. The planning for the implementation of the NDP was left to the Provincial Departments of Health (DOH) within the nine provinces. The new EDL was launched in

a ceremony in Pretoria on 3 December 1998 by the National DOH, but the Nine Provincial DOH were not informed in advance. Thus there was no time to prepare the drug depots, pharmacists, and prescribers. Boxes of EDL books were sent to pharmacists without information, guidance or training.

9.3.2 Challenges to the NDP and EDL Implementation

The lack of preparation and planning are the cause of the current challenges that have impeded the successful implementation of the NDP. This topic will be explored in detail in the third objective, which identified factors that had hindered or facilitated the implementation of the NDP, and of rational prescribing or the use of the STG/EDL.

9.3.3 Factors Hinder or Facilitate NDP Implementation (Objective Three)

The third objective of this thesis was to identify factors that facilitate or hinder the implementation of the NDP, the rational prescribing of drugs, and the use of the STG/EDL. Factors that hinder the implementation of the NDP and rational prescribing include a lack of strategic and programme implementation planning on the National and Provincial levels, diminishing resources of staff and budget, distribution and stock control, patient demands, communication, staff resistance to change, lack of training and continuing education. For this discussion several of these factors will be analysed in more detail.

The factors that have helped to facilitate the NDP implementation and rational prescribing include continuing education in 'Rational Prescribing and Drug Supply Management' for the pharmacist manager. At the same clinic, a regularly published bulletin and a commitment by the nurses and physicians to use the EDL as a tool for rational and cost-effective prescribing.

a) Factors that Hinder NDP Implementation

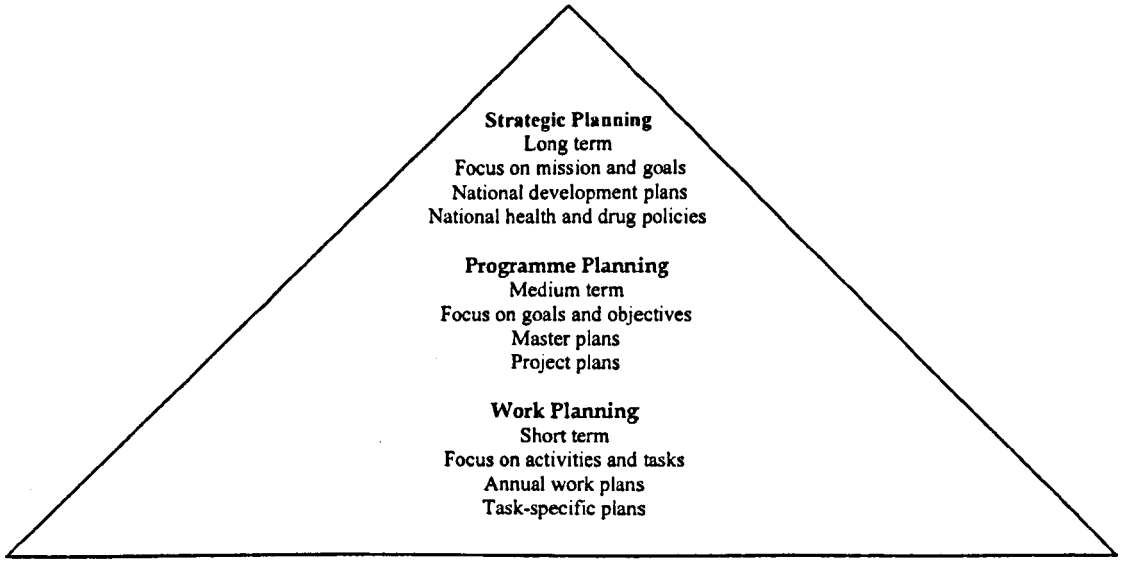
Factors that hinder the implementation of the NDP and rational prescribing at the national level are the neglect of allocating resources to the implementation process and the non-

existent promotion of the NDP implementation for health care workers in all nine provinces. Making a policy at the national level with little input from those who need to enforce it at the provincial, local and public health institutions has led to only minimal success. The main factors that will be explored in this discussion are a) the lack of implementation planning, b) distribution and stock control, c) staff resistance, d) patient demands, and e) the lack of training and continuing education.

b. Lack of Implementation Planning

The lack of implementation planning including strategic and programme implementation planning for the NDP has resulted in an ineffective tool and limitations on what could be accomplished. Planning is defined as "the first step in the management cycle, the process of assessing needs, establishing goals, setting objectives and targets, and determining the strategies, responsibilities, and resources needed to achieve the objectives" (DSM, 1997). To maximise the chances of successful implementation of a plan, those involved in the practical implementation of this plan should participate in the plan formulation. It is important to establish the planning team at the outset. For strategic planning, this team should include policy makers and senior staff. For programme and work planning this should include all involved key people in the unit. The three levels of planning differ in their purpose, level of detail and time frame (DSM, 1997)

Figure 9.1 Levels of Planning: the Planning Pyramid



During the planning process four key questions need to addressed at all three levels. (DSM, 1997)

1. Where are we now? Assessment of the current situation and needs

2. Where do we want to go? Statement of intent to describe the expected outcomes: mission, goals, and objectives. Objectives are the results that the plan seeks to achieve defined by the mnemonic 'SMART':

Specific: to avoid differences of interpretation

Measurable: to enable monitoring and evaluation

Appropriate: in relation to overall objectives or goals

Realistic: available resources

Time-bound: deadlines

3. How will we get there? Methods used for achieving specific targets, objectives and goals:

Strategy: Promote rational prescribing through strengthening formal education, continuing education, and supervision.

Activity: Conduct a workshop on rational prescribing.

Tasks: Prepare session notes and overhead transparencies at least four weeks before workshop.

4. How will we know when we have arrived? Monitoring and evaluation of the achievement of objectives and long-term goals. Indicators help to measure changes directly and indirectly and also used to assess the extent to which the targets and objectives are being attained.

c. Distribution and Stock Control

Vuna Healthcare Logistics is a private for-profit company, which was contracted by the Northern Province DOH to control the orders, distribution, and training for pharmacists who were to be the gatekeepers to the Northern Province hospital pharmacies. One project manager had contact with all the pharmacy managers during their intense one-

week course on Provincial ordering policies and the software for stock control training at Vuna headquarters and afterwards with on-site training. In addition, Vuna published its own bulletin 'Vuna Vision' (Appendix Y) to keep pharmacists and health care providers informed about staff, drug changes, and policy changes.

Although the ordering and stock system is set up to capture mistakes and correct them quickly, several hospital pharmacies were found to be lacking in basic generic drugs in doses needed during the Drug Utilisation Study (DUS). The most striking example of the failure of this system was at the tertiary complex Mankweng Hospital, which serves a mostly black patient population.

During the DUS at the hospital pharmacy it was found that hydrochlororthiazide (HCTZ), a generic medicine for hypertension was not in stock that day. Most of the 173 people (54.4%) with one or more of the three chronic illnesses were seen at the tertiary care facility at Mankweng, where the basic drug for treatment of hypertension was not available. When I asked the pharmacist why the drug was not available, I was told that there were several problems. First, when a drug is out of stock, many times the pharmacy staff must pick up the drugs and there is not sufficient staff or vehicles to complete this task. Second, when an entire stock of drugs are ordered and received, the hospital pharmacy must then supply the primary health care clinics.

To compound the difficulties, the depot has not been able to find a supplier of the drug with 12.5mg of hydroclorothiazide (HCTZ), even though the STG/EDL states that this is the correct dosage to treat hypertension. Instead, Vuna orders the available 25mg of HCTZ. Most patients do not cut them in half. Instead they take the whole pill that contains double of what is needed.

d. Staff Resistance

Staff resistance to change was expected, especially after they had not been included in the formulation, implementation or evaluation of the NDP. The STG/EDL books, generic medicines and restrictions on brand medications are seen as just another mandate from

the top administration in Pretoria that will pass when the political situation changes and posts are given to new people with new agendas. The largest resistance comes from professionals who work in secondary and tertiary institutions and mostly from physicians. Professionals, especially physicians believe that they should not be told how to practice medicine. Although only several physicians admitted in the formal interview that they work in both public and private practice, many physicians consider this an economic necessity. Understandably, this creates a conflict of how physicians practice medicine, diagnose and treat patients. In private practice, physicians are expected to use the best treatments and drugs available, but in public practice they are expected to use only some treatments and generic drugs.

This resistance manifests itself in a lack of rational prescribing, which can negatively affects patient care and cost effectiveness. The prescribing study showed that overall there was very little evidence that the NDP implementation was taken up by health care professionals. These results are consistent with a study conducted in South Africa two years before the NDP implementation. This study, reviewed in chapter four (Orrell, 1998), concluded:

1. No clear prescribing policies for districts exist.

2. Lack of teamwork. Doctors behave according to their own rules, as do nurses. The hierarchical atmosphere does not facilitate empowerment. Nurses do not feel supported by doctors.

3. Patient demand can be overwhelming, especially for cough mixtures and injections, and promotes irrational prescribing behaviour.

4. Difficulties in the implementation of treatment guidelines. The guidelines for TB treatment were inconsistent with the packaging of the medicines that required re-packing.

5. Staff resistance could be reduced through the implementation of several initiatives, including, but not limited to, independent drug information, for example bulletins, books, and centers. In addition, Pharmaco-Therapeutic Committees, Peer Review and continuing training and education would also reduce resistance to these changes.

e. Patient Demands

Education of the public about the implementation of the NDP and the use of generic drugs also was also not planned. Many patients have been denied both medical care or prescription drugs for most of their lives. Now, they demand to have access and equity of medical treatment including brand name drugs. Patients perceive the brand drugs as being better and the generic drugs as being not as good. Patients in hospital clinics included in this study get their medicines without a fee.

Generally, patient demand is one factor that increases the number of drugs prescribed. If a certain drug is not prescribed, the patient believes that they did not receive correct treatment. In addition, patients see antibiotics as the cure-all pill for illnesses. Many patients go to the clinic with a certain drug name already in mind and they believe that if they do not receive this drug the treatment will not be effective.

Most patients go to the clinic mainly for drugs, not for diagnosis and non-drug treatment. During this study, when hypertensive patients went to Mankweng Hospital for their monthly dose of hypertension medication, hydrochlorothiazide, and found it was not in stock, they believed that the hospital did not have drugs at all. It is likely that this false information spread throughout the community quickly. One administrator said, "the interesting thing is the community believes that we have no medicine at our institutions. This is frustrating because we believe we do have medicines" (I-17). When there is no medicine at the clinic for their illness, many patients either change the way they medicate themselves or go to traditional healers to medicate their illness.

f) Lack of Training and Continuing Education

For the implementation of the NDP, the National Department of Health committed to "a systematic and comprehensive programme of continuing education which would be developed and implemented to "ensure that all health personnel involved in diagnosis, prescribing and description of drugs receive adequate theoretical and practical training". In addition, all initial and continued training would be developed and assessed in collaboration with health personnel at all levels (NDP, 1996).

To date there is no official continuing education system on the rational use of drugs for prescribers and dispensers. Health personnel have not "received any training in either the philosophy or the practice of the STG/EDL" (I-20) according to one administrator. It is understood that NDP implementation success "is largely dependent on training" (I-17).

Several courses in Rational Prescribing and Drug Supply Management have been given, even though only a few of the hospital clinic staff in the Northern Province had been trained. The challenges for staff training are budget, logistics, and course materials and staff resistance. The National Department of Health claimed to be committed to "a systematic and comprehensive programme of continuing education" without giving funding or guidance about how to find funding for the implementation of the training. The difficulty is that the "budget is annual, and there's not a provision of long-term training, which includes human resource development" (I-20).

The only source of funding that was not from the Provincial budgets was from SADAP. Only one stakeholder, MEDUNSA, provided training and sought funding from SADAP as well as from the Provincial Health Departments to train a limited number of people in all nine provinces.

In addition, the logistics of having a class during normal working hours, outside of the hospital, perhaps in another province for one or two weeks is a strain on the already limited human resources of hospitals. Most physicians have many patients and not much time, so the pharmacy manager is usually the only qualified person. Shortage of staff, the demand of time, and the lack of funding contribute to the fact that training and continuing education is virtually non-existent in the Northern Province.

A randomised controlled study (MEDUNSA, 1997) conducted by MEDUNSA and SADAP in all nine provinces of South Africa showed that the Effective Prescribing Training produced significant improvement in prescribing practices of primary care nurses. This short course given by Pharmacy staff for primary health care nurses on

rational drug use, supply and management was successful. The costs of the courses are usually paid through grants provided by SADAP and/or the provincial budget. Enrolment in the course is decided by the head of the pharmaceutical department within the provincial department of health. MEDUNSA held workshops for health care workers and administrative staff that were attended by 156 participants in 1998 bringing the total number to 508 countrywide.

In the Northern Province, by the end of 1999, a total of 159 people have been trained in effective prescribing and 419 in drug supply management. Of those trained by 1998, one was a pharmacist, twenty-six were pharmacist assistants, nurses and health service managers. In 1998 refresher courses were conducted in the Northern Province that included an Effective Prescribing course attended by 14, Drug Supply Management courses attended by 8 and Training of Trainers attended by 26 people (MEDUNSA 1998). A Drug policy course was conducted in 1998 and once again in 2000 by MEDUNSA with an international faculty for 30 participants from twelve countries. The topics offered for health care personnel by the MEDUNSA School of Pharmacy staff are:

a) Training of Trainers in Drug Supply Management (1 week)
b) Effective Prescribing (1 week)
c) Promoting Rational Drug Use (2 weeks)
d) Drug Policy Issues (2 weeks)

In order to address the lack of continuing education and training for health professionals several points are important. First, a designated budget for NDP and EDL training with designated targets and outcomes is essential. Second, materials and courses specifically for Pharmacist Managers and for Physicians have to be developed. Third, the logistics of training have to be addressed enabling health professionals to participate on a regular basis.

b) Factors that Facilitate NDP Implementation

Factors that facilitate the implementation of the NDP and rational prescribing at the national level will be explored in this discussion are a) Independent Drug Information, b)

Drug Bulletins, c) Drug Information Centre, d) Standard Treatment Guidelines /Essential Drugs List, and e) Pharmaco-Therapeutic Committees and Peer Review.

a. Independent Drug Information

Independent drug information is one component of promoting Rational Drug Use. The NDOH foci included producing independent drug information. The sources of independent drug information include a drug bulletin for health personnel and administrators, an independent drug information service, and a regularly updated STG/EDL for distribution to all health care providers and prescribers.

b. Drug Bulletin

An independent drug bulletin giving the latest information about drugs added or removed from the EDL, doses, and case studies could be beneficial to hospital personnel, prescribers, administrators and patients. To date there is no independent and objective drug bulletin in South Africa.

c. Drug Information Centre

A Drug Information Centre is located in the Pharmacology Department at the University of Cape Town in South Africa. Several pharmaceutical companies finance the centre. Mostly health professionals who are in the more developed areas of South Africa and have access to a phone with long-distance services use this service. As a result of limited resources the drug information centre is not able to provide regular information on drugs to prescribers and dispensers in the nine provinces of South Africa.

d. Standard Treatment Guidelines /Essential Drugs List

The NDOH of South Africa compiled and published its first National Standard Treatment Guidelines and Essential Drug List (STG/EDL) for primary health care in 1996. Since then it has produced a follow-up STG/EDL in 1998 for primary health care and added two additional books one each for paediatric and adult patients at the hospital level. The methods to promote STG/EDL adherence include (DSM, 1996).

The goal of the NDOH was to publish new books every two years to incorporate drugs that were reviewed and deemed necessary for inclusion in order to meet the needs of the population. Since the 1998 set of STG/EDL were published and given to all public health care personnel, another set has not been produced.

From interviews conducted for this study, the staff believed that the EDL was a good guideline about what was in store at the pharmacy. Yet, that it was lacking in medicines for entire categories of illnesses, including dermatology, psychiatry, oncology, infectious diseases, just to name a few.

Since the promised inclusion of additional drugs from evidence based medicine has not happened and the STG/EDL has not been updated for six years, prescribers feel they have only few options, other than prescribing and if necessary 'motivating' for drugs not on the EDL.

To reach the goal of limiting brand drugs to no more than 10% of the entire pharmaceutical budget, the system of adding medications and publishing lists every two years would have been imperative.

Since the NDOH has not followed through with their commitment to update and publish the STG/EDL every two years, prescribers have started using pharmaceutical sponsored references which are usually free, heavily subsidises and up to date. The most popular books used by health professionals are the South African Medical Formulary (SAMF) and the Merck Manual (MIMS).

e. Pharmaco-Therapeutic Committees and Peer Review

The PTC is responsible for developing policies and procedures to promote rational drug use. Members of the PTC should include representatives from the medical, pharmacy, and nursing staffs, administrators, and the quality assurance coordinator. Its functions include:

1. Management of the approved drug list (STG/EDL)

2. Ongoing drug utilisation review (Rational Prescribing)
3. Medication error reporting and monitoring (Patient Care)

The drug use process has the four components prescribing, preparation and dispensing, medication administration, and monitoring the effects of drugs. The first two areas were analysed for this research. Drug prescriptions in hospitals are mostly the responsibility of the physician who is in charge of the patient's care. Frequently, these physicians prescribe and order medicines not on the EDL. The responsibility for assuring appropriate prescribing within the hospital falls within the domain of medical staff committees, which can include a PTC. The policies and procedures for medicine preparation and dispensing by pharmacists should be reviewed and approved by the PTC (DMS 1996).

In the Northern Province, Pharmaco-Therapeutic Committees (PTCs) were initiated and held only at the tertiary level. After a short period the PTC ceased to exist. The reinstatement of the PTC committees was said to be underway at the time of the interviews. The PTCs would have a new approach concerning its staff make-up and its goals.

9.4 Visions and Plans for the Future

For administrators who are responsible for the implementation of the NDP, the vision and plans for the future all centred around strategic and programme planning, budget and goals for training staff.

Specifically the administrators saw strategic and programme planning and the encouragement of team committees for the training of health professionals as important factors. Training would increase sensitivity and awareness about prescribing. In addition, they felt that rational prescribing, good therapeutics and cost effectiveness are inseparable. The goal would be to train all pharmacists and all 500 physicians in public and private practice in the Northern Province. Also the STG/EDL should be updated at least every two years.

These goals for the future are attainable with commitment to not only theoretical improvements, but also allocation of financial resources in order to fulfil the goals of the NDP implementation.

CHAPTER TEN

Conclusions and Recommendations

10.1 Health Policy Implications (Objective Four)

This chapter will outline the implications of these findings for health care policy and suggest an agenda for future research.

The fourth objective is to examine the health policy implications of these research findings. Policy implementation is an intricate part of programme implementation. The South African government first had to change the legislation to harmonise with the National Drug Policy formulation and implementation.

Legislative groundwork must be implemented before policy and programme implementation and evaluation can occur once again. Once this has been completed successfully, then the strategic planning for programme development, implementation and evaluation can take priority. The commitment of resources, both staff and finances are imperative for success.

10.1.1 Legislation

In order to implement a National Drug Policy in South Africa, the legislative ground had to be changed to redefine roles, responsibilities and the use of resources for both public and private entities. These changes were accomplished through changes and updates to previous legislation and the introduction of new legislation.

The four health legislation bills that were introduced into Parliament in 1997-1998 are:

1. The Pharmacy Amendment Act [Act No. 28 of 1997]
2. Medicines and Related Substances Amendment Act [Act no. 90 of 1997]
3. The Medical, Dental and Supplementary Health Services Professions Amendment 1998
4. South African Medicine and Medical Devices Regulatory Act (SAMMDRA) 1998

Of these bills the most important and influential for success of the NDP are the Medicines and Related Substances Amendment Act [Act no. 90 of 1997] and the South African Medicine and Medical Devices Regulatory Act (SAMMDRA).

The Pharmaceutical Manufacturers Association (PMA), three years after taking the government to the Pretoria High Court (2001) in order to stop the adoption of the Medicines and Related Substances Amendment Act [Act no. 90 of 1997], withdrew its complaint and the Act went into effect. Meanwhile, with the assistance of SADAP, the DOH formulated and passed the South African Medicine and Medical Devices Regulatory Act (SAMMDRA) to replace the Medicines and related Substances Control Act of 1965 and the amendment of 1997. This act is specifically aimed at ensuring affordable medicines for the public.

The PMA objected to the provisions that allow parallel importation and generic substitution of drugs and the government challenged it own legislation and the law was stuck down. Then the PMA reactivated its original court challenge to the Medicines and Related Substances Amendment Act [Act no. 90 of 1997]. Today as a result of these legislative failures, South Africans are living with legislation from the original 1965 Act brought into effect by the governments and sentiments of apartheid, without the 1997 amendments.

10.1.2 Policy and Programme Implementation

The policy statement of its goals, objectives and means are translated into programmes that aim to achieve the policy objectives. Thus the study of policy implementation involves the analysis of the programmes and interventions that have been designed as vehicles for the policy.

a) Resources for NDP Implementation

The National Department of Health instituted the NDP and expected the Provincial Departments of Health to find the resources in their tight budgets for the training of staff and patients about the use of generic drugs, the EDL and the 10% cap on brand drugs.

The NDOH gave a mandate without considering the lack of resources. For Provinces that have few private hospitals or paying patients, the NDP could have been a life-line for 'getting medicines to the people' and promoting rational prescribing, but without staff and financial resources specifically allocated to the NDP, patient education and rational prescribing, there was only very limited implementation of the NDP.

b) Staff Adoption of NDP

The most variable and unpredictable aspect of implementation of the NDP was the attitudes and practices of the stakeholders, nurses, pharmacists and physicians. The large degree to which the stakeholders would have to change their behaviour had a direct effect on the NDP policy implementation. Nurses' and pharmacists' prescribing behaviours were affected the least, as they were able to adapt the most. While physicians' prescribing behaviours were affected the most and the most difficult to change as seen in the research results. Without convincing physician of rational prescribing, the success of the NDP implementation has been limited.

In addition, the staff need access to updated STG/EDL information on a monthly basis and new lists yearly that can be accessed on-line or an updated set of books every two years as originally intended. The last update was in 1998. They are already five years out of date.

In conclusion the legislation failed, the resources of staff and money were not allocated for implementation, and a set of books was not enough to change perceptions or behaviours or staff of patients.

To improve the National Drug Policy and the National Drug Programme implementation, the policy recommendations are:

1. Legislation on health and drug policy be revised, evaluated for constitutional rigor and passed by the policy makers within the South African government.

2. A dedicated set budget (no matter how small) from the National Department of Health be allocated to each Provincial Department of Health for training in the NDPs goals of rational prescribing, drug supply management, and patient education.

3. The continued implementation of the NDP through the bottoms-up approach to policy (from the health workers to administrators to policy makers) to re-evaluation and implement rational drug prescribing and the use of an STG/EDL.

4. The National Department of Health develops a continuing education course for physicians with direct physician-to-physician feedback, a course for pharmacy managers and nurses be developed and that full time trainers implement this education.

5. Education of consumers about rational prescribing and the EDL through Posters and radio announcement to combat the barrier of illiteracy and medicine demands.

6. The STG/EDL is updated every two years in paperback and every year online.

10.2 Recommendations for future research

The research agenda for South Africa as it adopts NDP tenants and evaluate implementation are varied. Research projects could include:

1. Intervention study: Intended versus actual behaviour regarding drug use.
2. Evaluation of the use and impact of the STG/EDL
3. A study of where and how guidelines have been used, what factors are conducive or obstructive to their use and whether they had any impact on drug prescribing practices.
4. Evaluation of the impact of drug bulletins on rational drug prescribing.
5. Evaluation of the impact of public education on the acceptance of generic drugs.

6. Cost effectiveness of different intervention strategies, such as face to face, interactive group discussions (PTC), and feedback from prescribers.

7. Interventions addressing other problem drugs, such as painkillers, vitamins, coughs and colds, or injections. More intervention research is needed on drugs, which are not essential but widely prescribed and utilised.

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APPENDICES

APPENDIX A

SOUTH AFRICA'S NATIOANL DRUG POLICY

The initial draft of the NDP was prepared and workshops were held to incorporate a wide range of comments from various stakeholders. All Provincial Head of Health ratified the National Drug Policy on 15 February 1996, and it was approved and publicly announced by the Minister of Health on 22 February 1996. The main objectives of the National Drug Policy (January 1996) include health, economic and national objectives.

Health objectives:

1. To ensure the *availability and accessibility* of essential drugs to all citizens
2. To ensure the *safety, efficacy, and quality* of drugs
3. To ensure *good dispensing and prescribing* practices
4. To promote *rational use of drugs* by prescribers, dispensers and patients through provision of the necessary training, education and information
5. To promote the concept of *individual responsibility* for health, prevention and informed decision making

Economic Objectives:

1. to lower the cost of drugs in both the private and public sectors
2. to promote the cost-effective and rational use of drugs
3. to establish complementary partnership between Government bodies and private providers in the pharmaceutical sector.
4. To optimise the use of scarce resources through co-operation with international and regional agencies

National Development Objectives

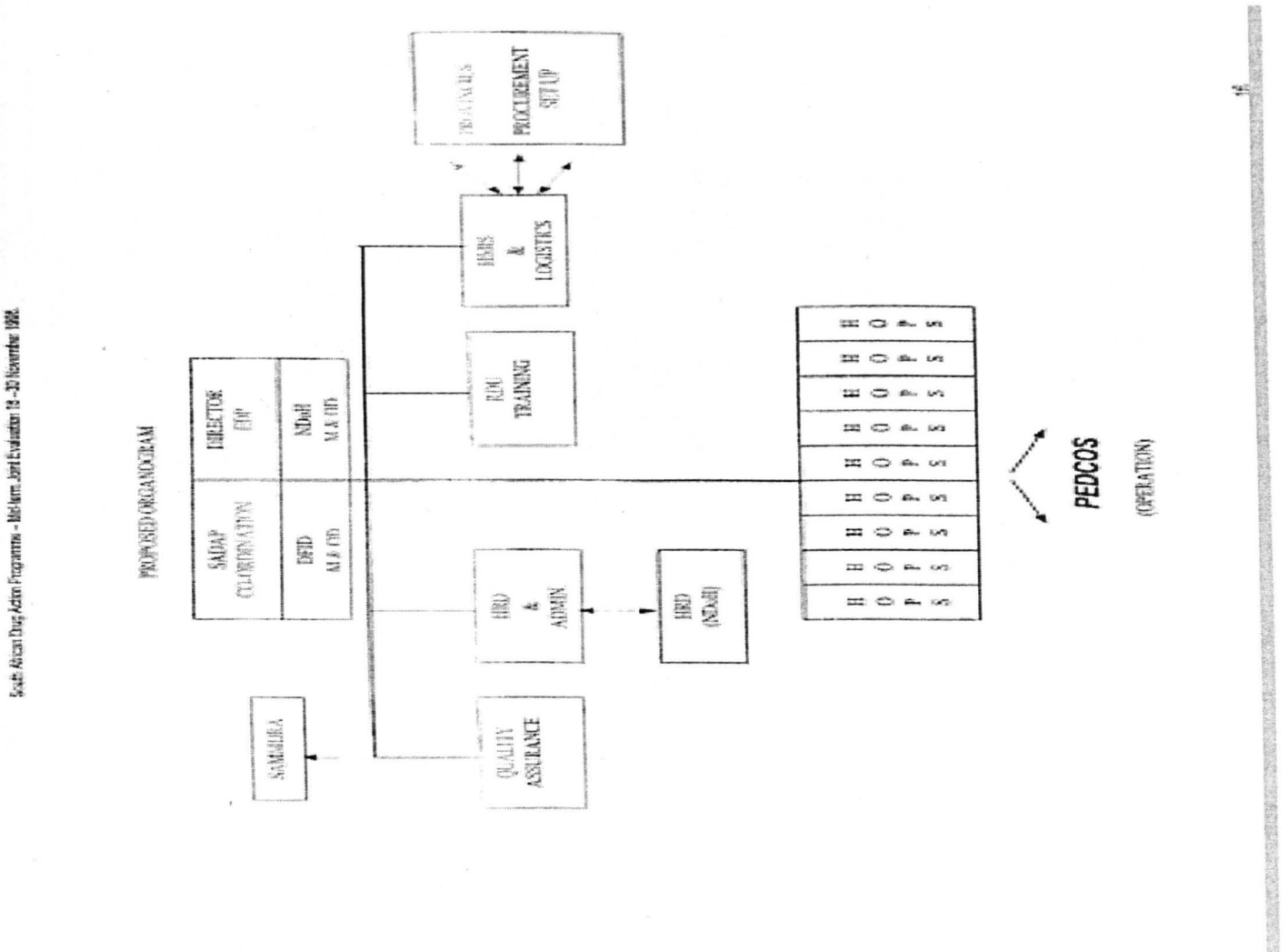
1. to improve the knowledge, efficiency and management of pharmaceutical personnel

2. To re-orient medical, paramedical, and pharmaceutical education toward the principles underlining the National Drug Policy

3. To supply the development of the local pharmaceutical industry and the local production of essential drugs

4. To promote the acquisition, documentation and sharing of knowledge, and experience through the establishment of advisory groups in rational drug use, pharmaco-economics and other areas of the pharmaceutical sector.

APPENDIX B
Proposed Organogram of NDP/ EDP Implementors (SADAP and DOH)



APPENDIX C

SELECTION OF EDL DRUGS

The selection of drugs on the National Essential Drugs List [1] will be based on the following criteria:

- must meet the health needs of the majority of the population sufficient proven scientific data must be available regarding the effectiveness of any such product should have a substantial safety and risk/benefit ratio

- the aim, as a general rule will be to include, as far as possible, only products containing single pharmacologically active ingredients.

- combination products may, as an exception, be included where patient compliance becomes an important factor or two pharmacologically active ingredients are synergistically active in a product when two or more drugs are equivalent in the above respects, preference will be given to those which have:

    1. the best cost advantage
    2. the best pharmacokinetic properties
    3. has been the best researched
    4. the best patient compliance
    5. the most reliable local manufacturer

Note: In exceptional circumstances, drugs outside the essential drugs list may be requested for specific patients. A standardized procedure for such requests will be developed. Care will be taken to ensure that a minimal portion of the drugs budget is spent on such drugs. These drugs will be included on a supplementary list for that facility, drawn up and regularly reviewed by the Pharmacy and Therapeutics Committee of the facility concerned.

APPENDIX D
LIST OF EDL DRUGS FROM ADULT HOSPITAL CARE
STG/EDL 1998

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ESSENTIAL DRUGS LIST

HOSPITAL LEVEL

A ALIMENTARY TRACT AND METABOLISM

A01 Stomatological preparations
- Chlorhexidine gluconate mouthwash 0.2%
- Nystatin lozenges 100 000 IU

A02 Antacids, drugs for treatment of peptic ulcer and flatulence
- Aluminium hydroxide 250 mg/mag trisilicate 500 mg tab
- Aluminium hydroxide susp 300 mg/5 mL
- Cimetidine tab 200 mg
- Cimetidine tab 400 mg
- Omeprazole 20 mg cap (example of class)
- Simethicone
- Sucralfate tab 1 g

A03 Antispasmodic and anticholinergic agents and propulsives
- Glycopyrronium bromide inj 0.2 mg/mL
- Hyoscine butylbromide inj 20 mg/mL
- Metoclopramide inj 10 mg/2 mL
- Metoclopramide tab 10 mg
- Propantheline bromide tab 15 mg

A06 Laxatives
- Glycerine suppositories adult
- Glycerine oral solution
- Lactulose oral syrup 3.3 g/5 mL
- Liquid paraffin
- Magnesium sulphate oral powder BP
- Paraffin liquid
- Sennosides A and B in alcohol 7 % (v/v)
- Sennosides A and B tab 7.5 mg

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- Sodium phosphate 6(
- mg/mL 135 mL enem
- Sorbitol 70 %

A07 Antidiarrhoeals, in anti-infective ager
- Loperamide tab 2 mg
- Prednisolone retention enema 20 mg/
- Sulfasalazine tab 500 mg

A09 Digestives, including enzymes
- Pancreatin cap 300 mg

A10 Drugs used in diabetes
- Glibenclamide tab 5 mg
- Gliclazide tab 80 mg
- Glipizide tab 5 mg
- Insulin biphasic 100 units/mL
- Insulin intermediate acting 100 units/mL
- Insulin long acting 100 units/mL
- Insulin rapid acting 100 units/mL
- Insulin short acting 100 units/mL
- Metformin tab 500 mg
- Metformin tab 850 mg
- Tolbutamide tab 500 mg

A11 Vitamins
- Ascorbic acid inj 500 mg/5 mL
- Ascorbic acid tab 100 mg
- Calciferol 50 000 IU
- Calcitriol cap 0.25 mcg
- Nicotinamide tab 100 mg
- Pyridoxine tab 25 mg

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- Thiamine inj 100 mg/mL
- Thiamine tab 100 mg
- Thiamine tab 50 mg
- Vitamin B complex inj 2 mL
- Vitamin B complex tab
- Vitamin B12 inj 1 000 mcg/mL

A12 Mineral supplements
- Calcium carbonate tab
- Calcium chloride inj 1g/10 mL 10 %
- Calcium gluconate inj 1g/10 mL 10 %
- Magnesium sulphate inj 50 %
- Potassium chloride inj 10 mL 15%
- Potassium phosphate inj
- Potassium supplement inj 1g
- Potassium supplement tab (not enteric coated)
- Sodium bicarbonate inj 8.5 %
- Sodium bicarbonate powder
- Sodium chloride 0.45 %
- Sodium chloride 0.9 %
- Sodium chloride 5 %
- Sodium citrate powder

B BLOOD AND BLOOD-FORMING ORGANS

B01 Antithrombotic agents
- Heparin sodium 1 000 IU/mL
- Heparin sodium inj 25 000 IU/mL
- Heparin sodium inj 5 000 IU/mL
- Streptokinase inj 1 500 000 IU/vial
- Warfarin tab 5 mg

B02 Antihaemorrhagics
- Amino caproic acid inj 250 mg/mL
- Amino caproic acid tab 500 mg
- Vitamin K1 inj 10 mg/mL

B03 Antianaemic preparations
- Epoetin alpha inj 2 000 IU/0.5 mL

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- Ferrous sulphate oral 200 mg (65 mg elemental iron)
- Folic acid tab 5 mg

B05 Plasma substitutes and perfusion solutions
- Amino acids with dextrose with or without electrolytes (several formulations)
- Dextrose 10 %
- Dextrose 20 %
- Dextrose 35 %
- Dextrose 5 %
- Dextrose 5 %/sodium chloride 0.9%
- Dextrose 50 %
- Electrolyte/trace element formulation
- Mannitol inj 12.5 g/50 mL 25 %
- Ringer-Lactate solution
- Soya oil 10 % /phospholipid/glycerol emulsion
- Soya oil 20 %/phospholipid/glycerol emulsion
- Soya oil emulsion/medium chain triglycerides 10 %
- Soya oil emulsion/medium chain triglycerides 20 %

C CARDIOVASCULAR SYSTEM

C01 Cardiac therapy
- Adenosine inj 6 mg/2 mL
- Amiodarone inj 150 mg/3 mL
- Amiodarone tab 200 mg
- Atropine inj 0.5 mg/mL
- Atropine inj 0.6 mg/mL
- Bretylium tosilate inj 50 mg/mL
- Digoxin inj 0.5 mg/2 mL
- Digoxin tab 0.25 mg
- Dobutamine inj 250 mg/20 mL
- Dopamine inj 200 mg/5 mL
- Dopamine inj 40 mg/mL
- Etilefrine HCl inj 10 mg/mL
- Glyceryl trinitrate inj 10 mg/10 mL
- Glyceryl trinitrate inj 25 mg/5 mL

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APPENDIX D

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Glyceryl trinitrate tab sublingual 0.5 mg
Isoprenaline inj 0.2 mg/mL
Isosorbide dinitrate tab 40 mg
Isosorbide dinitrate tab sublingual 5 mg
Isosorbide mononitrate tab 20 mg
Phenylephrine inj 10 mg/mL

C02 Antihypertensives
Amlodipine tab 10 mg
Amlodipine tab 5 mg
Dihydralazine inj 25 mg
Diltiazem tab 60 mg
Hydralazine tab 25 mg
Methyldopa tab 250 mg
Prazosin tab 1 mg
Prazosin tab 2 mg
Prazosin tab 5 mg
Reserpine tab 0.1 mg
Sodium nitroprusside infusion 100 mg

C03 Diuretics
Furosemide inj 10 mg/mL
Furosemide tab 40 mg
Hydrochlorothiazide tab 12.5 mg or 25 mg
Spironolactone tab 25 mg

C07 Beta blocking agents
Atenolol inj 5 mg/10 mL
Atenolol tab 100 mg
Atenolol tab 50 mg
Carvedilol tab 25 mg
Esmolol inj 10 mg/mL
Propranolol inj 1 mg/mL
Propranolol tab 10 mg
Propranolol tab 40 mg

C08 Calcium channel blockers
Nifedipine cap 5 mg
Nifedipine longacting tab 30 mg
Verapamil inj 2.5 mg/mL
Verapamil sustained release tab 120 mg
Verapamil tab 40 mg
Verapamil tab 80 mg

C09 Agents acting on the renin-angiotensin system
Perindopril tab 4 mg (example of class)
Ramipril tab 1.25 mg (example of class)
Ramipril tab 5 mg (example of class)

D DERMATOLOGICALS

D02 Emollients and protectants
Ung. Emulsificans Aqueous (UEA)

D04 Antipruritics and topical anaesthetics
Lidocaine gel 2 %
Lidocaine topical spray 10 mg/metered dose

D05 Antipsoriatics
Coaltar 2%/Salicylic acid 2% ointment BP
Dithranol 0.1 % in white paraffin
Salicylic acid 2 % in white paraffin

D06 Antibiotics and chemotherapeutics for dermatological use
Mupirocin ointment 2 %
Silver sulfadiazine cream 1 %

D07 Corticosteroids, dermatological preparations
Betamethasone 10 % in UEA
Betamethasone 20 % in UEA
Betamethasone valerate cream 0.1 %
Betamethasone valerate ointment 0.1 %
Hydrocortisone cream 1 %
Hydrocortisone ointment 1 %

D08 Antiseptics and disinfectants
Cetrimide solution 1 %
Chlorhexidine cream 1 %

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Chlorhexidine solution 0.5 % in water
Ethyl alcohol
Hydrogen peroxide 3 % (10 volume)
Polyvidone iodine cream 5 %
Potassium permanganate solution in water 0.01 %

D10 Anti-acne preparations
Benzoyl peroxide topical gel 10 %
Benzoyl peroxide topical gel 5 %

D11 Other dermatological preparations
Bichloracetic acid
Podophyllin 25% in compound benzoin tincture
Trichloracetic acid

G GENITO-URINARY SYSTEM AND SEX HORMONES

G02 Other gynaecologicals
Dinoprostone (prostaglandin E2) tab 0.5 mg
Oxytocin inj 10 IU/mL
Oxytocin inj 5 IU/mL

G03 Sex hormones and modulators of the genital system
Clomifene tab 50 mg
Cyproterone acetate tab 10 mg
Estrogen conjugated inj 25 mg/vial
Estrogen/progesterone (HRT)
Estrogens conjugated tab 0.625 mg
Estrogens conjugated tab 1.25 mg
Ethinylestradiol tab 0.02 mg
Ethinylestradiol tab 0.5 mg
Levonorgestrel 0.05/0.075/0.125 mg/ethinylestradiol 0.03/0.04/0.03 mg (triphasic)
Levonorgestrel 0.05/0.125 mg/ethinylestradiol 0.05 mg (biphasic)
Levonorgestrel 0.15 mg/ethinylestradiol 0.03 mg
Medroxyprogesterone acetate inj 150 mg/mL
Medroxyprogesterone tab 10 mg
Norethisterone 1 mg/estradiol 2 mg tab
Norethisterone tab 5 mg
Norgestrel 0 mg/0.5 mg/estradiol 2 mg/2 mg
Norgestrel 0.5 mg/ethinyl oestradiol 0.05 mg
Oestradiol valerate tab 1 mg
Progesterone inj
Testosterone esters 100 mg/mL

G04 Urologicals
Finasteride tab 5 mg
Mist Pot Cit BP
Nalidixic acid tab 500 mg
Oxybutynin tab 5 mg

H SYSTEMIC HORMONAL PREPARATIONS, EXCLUDING SEX HORMONES

H01 Pituitary and hypothalamic hormones
Desmopressin intmasal solution 0.1 mg/mL
Octreotide inj 50 mcg/mL

H02 Corticosteroids for systemic use
Betamethasone inj 3 mg/mL
Dexamethasone inj 4 mg/mL
Dexamethasone tab 0.5 mg
Fludrocortisone acetate tab 0.1 mg
Hydrocortisone sodium succinate inj 100 mg
Hydrocortisone tab 10 mg
Methylprednisolone inj 40 mg/mL
Prednisone tab 5 mg

H03 Thyroid therapy
Carbimazole tab 5 mg
Levothyroxine tablet 100 mcg
Levothyroxine tablet 50 mcg
Lugol's iodine drops

H04 Pancreatic hormones

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APPENDIX D

Glucagon 1 mg/vial

H05 Calcium homeostasis

Alendronic acid tab 10 mg
Pamidronic acid inj 15 mg/5 mL

J GENERAL ANTI-INFECTIVES FOR SYSTEMIC USE

J01 Antibacterials for systemic use

Amikacin inj 100 mg/2 mL
Amikacin inj 500 mg/2 mL
Amoxicillin cap 250 mg
Amoxicillin cap 500 mg
Ampicillin inj 1 g/vial
Ampicillin inj 500 mg/vial
Benzathine benzylpenicillin inj 1.2 MU/vial
Benzylpenicillin inj 1 MU/vial (=600 mg)
Cefazolin inj 500 mg/vial
Cefotaxime inj 1 g/vial
Cefoxitin inj 1 g/vial
Ceftazidime inj 1g/vial
Ceftazidime inj 250 mg/vial
Ceftazidime inj 500 mg/vial
Ceftriaxone inj 1 g/vial
Chloramphenicol cap 250 mg
Chloramphenicol inj 1 g/vial
Ciprofloxacin infusion 2 mg/1 mL
Ciprofloxacin tab 500 mg
Ciprofloxacin tab 750 mg
Clindamycin cap 150 mg
Clindamycin inj 150 mg/mL
Cloxacillin inj 250 mg/vial
Cloxacillin inj 500 mg/vial
Doxycycline cap 50 mg
Doxycycline cap/tab 100 mg
Erythromycin inj 1 g/vial
Erythromycin stearate tab/cap 250 mg

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Flucloxacillin cap 250 mg
Fusidic acid tab 250 mg
Gentamicin inj 40 mg/mL
Gentamicin inj 80 mg/mL
Imipenem 500 mg/cilastatin 500 mg/vial
Metronidazole supp 500 mg
Neomycin tab 500 mg
Ofloxacin infus 200 mg/100 mL
Phenoxymethylpenicillin tab 250 mg
Piperacillin inj 4 g/vial
Procaine penicillin inj 3 MU/10 mL
Sodium fusidate IV infus 500 mg
Sodium fusidate tab 250 mg
Tetracycline cap 250 mg
Tobramycin inj 40 mg/2 mL
Tobramycin inj 80 mg/2 mL
Trimethoprim 80 mg/sulfamethoxazole 400 mg tab
Trimethoprim tab 100 mg
Vancomycin inj 1 g/vial
Vancomycin 500 mg/vial

J02 Antimycotics for systemic use

Amphotericin B inj 50 mg/vial
Amphotericin B loz 10 mg
Clotrimazole vaginal tablet 100 mg
Fluconazole cap 150 mg
Ketoconazole tab 200 mg

J04 Antimycobaterials

Clofazimine cap 100 mg
Dapsone tab 100 mg
Ethambutol tab 400 mg
Isoniazid tab 100 mg
Rifampicin 120 mg/INH 60 mg/pyrazinamide 300 mg/ethambutol 200 or 225 mg
Rifampicin 150 mg/INH 100 mg
Rifampicin 300 mg/INH 150 mg

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Rifampicin inj 600 mg/vial
Rifampicin cap 600 mg
Streptomycin inj 1 g/3 mL

J05 Antivirals for systemic use

Aciclovir infusion 250 mg/vial
Aciclovir tab 200 mg
Famciclovir tab 250 mg
Lamivudine tab 150 mg
Valacyclovir tab 500 mg
Zidovudine tab 100 mg

J06 Immune sera and immunoglobulins

Anti-D-immunoglobulin inj 100 mcg/2 mL
Boomslang antivenom inj
Clostridium Botulinum trivalent antitoxin
Hepatitis B immunoglobulin inj 200 IU/2 mL
Polyvalent antivenom inj
Rabies immunoglobulin (RIG) inj
Scorpion antivenom inj
Spider antivenom inj
Tetanus immunoglobulin human inj 250 IU/2 mL (TIG)
Varicella zoster immunoglobulin inj

J07 Vaccines

BCG vaccine
Haemophilus influenzae type b conjugated vaccine (Hib) inj
Hepatitis B vaccine inj
Pneumococcal vaccine inj 0.5 mL
Rabies vaccine inj
Rubella vaccine inj
Tetanus toxoid 10Lf/0.5 mL (tetanus adsorbed toxoid vaccine)TT inj

L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

L01 Cytostatic agents

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Adriamycin (doxorubicin)
Asparaginase
Bleomycin
Busulfan
Carboplatin
Chlorambucil
Chlormethine (nitrogen Mustard)
Cisplatin
Cyclophosphamide
Cytarabine
Daunorubicin
Docetaxel
Etoposide (VP 16)
Fluorouracil
Hydroxycarbamide (hydroxyurea)
Ifosfamide
Lomustine
Melphalan
Methotrexate
Mitomycin
Mitoxantrone
Procarbazine
Thiotepa
Tretinoin (all trans retinoic acid)
Vinblastine
Vincristine
Vinorelbine

L03 Immunomodulating agents

Interferon alpha

L04 Immunosuppresive agents

Azathioprine tab 50 mg

M MUSCULOSKELETAL SYSTEM

M01 Anti-inflammatory and antirheumatic products

Ibuprofen tab 200 mg

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APPENDIX D

Ibuprofen tab 400 mg

Indomethacin cap 25 mg
Indomethacin supps 100 mg
Penicillamine tab 300 mg

M03 Muscle relaxants
Alcuronium inj 10 mg/2 mL
Dantrolene inj 20 mg/70 mL
Pancuronium bromide inj 4 mg/2 mL
Suxamethonium chloride inj 100 mg/2 mL
Vecuronium bromide 4 mg/mL
Vecuronium bromide inj 10 mg/5 mL

M04 Antigout preparations
Allopurinol tab 100 mg
Colchicine tab 0.5 mg
Probenecid tab 500 mg

N CENTRAL NERVOUS SYSTEM

N01 Anaesthetics
Atracurium inj
Bupivacaine inj 0.5 % without adrenaline
Bupivacaine inj 0.5 % with dextrose
Droperidol inj 2.5 mg/mL
Etomidate inj 2 mg/mL
Fentanyl inj
Halothane inhalation liquid
Isoflurane inhalation liquid
Ketamine inj
Lidocaine inj 0.5 %
Lidocaine inj 1 %
Lidocaine inj 2 %
Lidocaine inj 2 % with adrenaline
Lidocaine inj 5 % with dextrose
Propofol infusion 10 mg/mL
Thiopental sodium inj 0.5 g/vial

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N02 Analgesics
Aspirin soluble tab (scored) 300 mg
Codeine phosphate tab 30 mg
Dihydroergotamine inj 1 mg/mL
Ergotamine 1 mg/caffeine tab 100 mg
Morphine inj 10 mg/mL
Morphine tab 10 mg
Paracetamol 500 mg/codeine phosphate 10 mg tab
Paracetamol tab 500 mg
Pethidine inj 100 mg/2 mL
Pethidine inj 50 mg/ mL

N03 Antiepileptics
Carbamazepine susp 100 mg/5 mL
Carbamazepine tab 200 mg
Ethosuximide cap 250 mg
Phenobarbital tab 30 mg
Phenytoin cap/tab 100 mg
Phenytoin inj 250 mg/5 mL
Valproate sodium tab 200 mg
Valproate sodium tab 500 mg

N04 Antiparkinsonian agents
Benzhexol tab 2 mg
Biperiden inj 5 mg/mL
Biperiden tab 2 mg
Bromocriptine tab 2.5 mg
Levodopa 100 mg/carbidopa tab 25 mg tab
Levodopa 200 mg/benserazide 50 mg tab
Orphenadrine tab 50 mg

N05 Psycholeptics
Clonazepam tab 0.5 mg
Clonazepam tab 2 mg
Diazepam inj 10 mg/2 mL
Diazepam tab 2 mg
Diazepam tab 5 mg

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Flupentixol decanoate depot inj 20 mg/mL
Fluphenazine decanoate inj 25 mg/mL
Haloperidol inj 5 mg/mL
Haloperidol tab 0.5 mg
Haloperidol tab 1.5 mg
Haloperidol tab 5 mg
Lithium carbonate tab 250 mg
Lorazepam inj 4 mg/mL
Lorazepam tab 1 mg
Lorazepam tab 2.5 mg
Midazolam inj 5 mg/5 mL
Oxazepam tab 10 mg
Oxazepam tab 15 mg
Oxazepam tab 30 mg
Zuclopenthixol acetate inj 50 mg/mL

N06 Psychoanaleptics
Amitriptyline tab 10 mg
Amitriptyline tab 25 mg
Clomipramine tab 25 mg
Fluoxetine cap 20 mg
Imipramine tab 10 mg
Imipramine tab 25 mg

N07 Other nervous system drugs
Alfentanil 0.5 mg/mL
Neostigmine bromide 0.5 mg/mL
Physostigmine inj 0.5 mg/mL
Pyridostigmine bromide tab 60 mg
Sevoflurane liq
Sufentanil 5 mcg/mL

P ANTIPARASITIC PRODUCTS

P01 Antiprotozoals
Chloroquine tab 200 mg (base 150 mg)
Metronidazole infusion 500 mg/100 mL
Metronidazole tab 200 mg

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Primaquine phosphate tab 13.2 mg (base 7.5 mg)
Quinine inj 300 mg/mL
Quinine sulphate tab 300 mg
Sulfadoxine 500 mg/pyrimethamine 25 mg tab

P02 Antheimintics
Albendazole tab 200 mg
Praziquantel tab 600 mg

R RESPIRATORY SYSTEM

R01 Nasal preparations
Oxymetazoline nosedrops 0.05 %

R03 Anti-asthmatic agents
Adrenaline inj 1 mg/mL
Aminophylline inj 250 mg/10 mL
Budesonide inhaler 100 mcg/actuation
Budesonide inhaler 200 mcg/actuation
Fenoterol inhaler 100 mcg/inhalation
Fenoterol UDV solution 0.5 mg/2 mL
Fenoterol UDV solution 1.25 mg/2 mL
Hexoprenaline infusion 25 mcg/10 mL
Ipratropium bromide metered dose inhaler 40 mcg/ actuation
Ipratropium bromide respirator solution 0.25 mcg/mL
Ipratropium bromide UDV solution 0.25 mg/2 mL
Salbutamol metered dose inhaler 100mcg/actuation
Salbutamol nebules 2.5 mg/2.5 mL
Salbutamol nebules 5 mg/2.5 mL
Theophylline sustained release tab 200 mg
Theophylline sustained release tab 300 mg

R06 Antihistamines for systemic use
Chlorpheniramine tab 4 mg
Promethazine inj 25 mg/mL
Promethazine tab 10 mg
Promethazine tab 25 mg

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APPENDIX D

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S **SENSORY ORGANS**

S01 **Ophthalmologicals**

Acetazolamide inj 500 mg
Acetazolamide tab 250 mg
Aciclovir eye ointment 30 mg/g
Chloramphenicol eye drops 0.5 %
Chloramphenicol eye ointment 1 %
Cyclopentolate 0.2 %/phenylephrine 1 % eye drops
Dexamethasone eye drops 0.1 %
Dipivefrine eye drops 0.1 %
Flurbiprofen eye drops 0.03 %
Gentamicin eye drops 0.3 %
Lanolin anhydrous liquid eye ointment 3 %
Pilocarpine eye drops 1 %
Tetracaine eyedrops 5 mg/mL
Tetracycline eye ointment 1 %
Timolol eye drops 0.25 %
Timolol eye drops 0.5 %

V **VARIOUS**

V03 **All other therapeutic products**

Acetylcysteine inj 2 g/10 mL
Charcoal activated oral
Citric acid powder
Deferoxamine mesylate inj 500 mg
Dicobalt edetate inj 300 mg/20 mL
Dimercaprol inj 50 mg/mL
Disulfiram tab 400 mg
Electrolyte solution
Ipecacuanha syrup BP
Methionine powder
Methylene blue
Naloxone inj 0.4 mg/mL
Sodium nitrite 3 % inj 10 mL
Sodium polystyrene sulphonate powder
Sodium thiosulphate inj 50 %

V08 **Contrast media**

Barium sulphate powder 98 g/100 g
Barium sulphate susp enema 93 g
Iohexol 300 mg I/mL
Meglumine amidotrizoate 66 g/sodium amidotrizoate 10 g
Meglumine iothalamate
Sodium iopodate cap 500 mg
Sodium iothalamate infus 20 % 250 mL

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ICD NUMBERS

ICD-10	Guideline
N91-N93	Abnormal uterine bleeding
O04	Abortion, complicated, therapeutic, legal
L70	Acne
E	Acromegaly
E27	Adrenal insufficiency
F10.1	Alcoholism
A06.4	Amoebic liver abscess
O99.0	Anaemia in pregnancy
D64.9	Anaemias
	Anaesthetics
R57.9	Anaphylactic shock/Shock
F41.9	Anxiety disorder, generalised
J45	Asthma, acute
J45	Asthma, chronic persistent
N40	Benign Prostatic Hyperplasia
E51.1	Beriberi
F31.9	Bipolar disorder
T63.4	Bites and stings
N39.4	Bladder Dyskinesia
J47	Bronchiectasis
T30.0	Burns, complicated
B37.9	Candidiasis, systemic and others (in HIV)
I49.9	Cardiac arrhythmias
I50.9	Cardiac failure syndrome
L03.9	Cellulitis/Erysipelas/Pyoderma (Impetigo)
J44.9	Chronic obstructive airways disease
K51.9	Colitis, ulcerative
B59	Community acq. pneumonia and Pneumocystis carinii pneumocystosis (in HIV)
Q24.9	Congenital heart disease, adults
K56.4	Constipation / faecal impaction
K50.9	Crohn's disease
B45.9	Cryptococcal meningitis in HIV
E24.9	Cushing's disease
F34.0	Cyclothymic disorder
E84.9	Cystic fibrosis
F03	Delirium
F03	Delirium, non psychiatric
O24.9	Diabetes and glucose intolerance in pregnancy
E23.2	Diabetes insipidus, central
E11	Diabetes mellitus
E16	Diabetes, pancreatic
E11.2	Diabetic renal disease
A05.9	Diarrhoea, infective / Food poisoning
E87.4	Disorders of acid-base balance
B45.7	Disseminated cryptococcosis incl. Meningitis (in HIV)
E87.5/6	Disturbances in potassium balance
E78	Dyslipidaemia

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APPENDIX E

FUNCTION AND MEMBERSHIP FOR PTC COMMITTES AT FOUR LEVELS

CLINICS/COMMUNITY SERVICES (Primary Care Hospitals)

FUNCTION

- Committee to familiarise providers with NDP (EDL/STG)
- Compile formulary form EDL for local use
- Provide comments and feedback on EDL to the PTC
- Share the information with district PTC
- Educate and create an awareness among practitioners about EDL.

MEMEBERSHIP

- PHC practitioner (1)
- DHWS- one member (TLC)
- District pharmacist ex officio
- Medical doctor

DISTRICT (Secondary Care Hospitals)

FUNCTION

- Flow of information
- Communication process
- Hospital formulary and other items
- Capacity building
- Advisory
- Monitor and evaluation of drug use
- Budget control
- ADR (monitor and record)

MEMBERSHIP

- Superintendent
- Pharmacist
- Matron
- Secretary
- Community matron
- Medical officer
- Ad hoc member
- Community representative

REGIONAL (Tertiary Hospitals)

FUNCITONS

- Evaluate, implement and promote decision taken by provincial PTC (including protocols and local restrictions)
- Educate – rational cost-effective prescribing
- Provide information resources
  Customised needs (relevance)
  Information bulletin (regular)
- Monitor prescribing pattern with the objective of budget control (e.g antibiotic use, key drugs)
- Collaborate / liaise with existing committees (information control etc.) and establish surgical and management (budget)
- Prepare, evaluate and submit non-formulary requests form clinicians

PROVINCIAL (Department of Health)

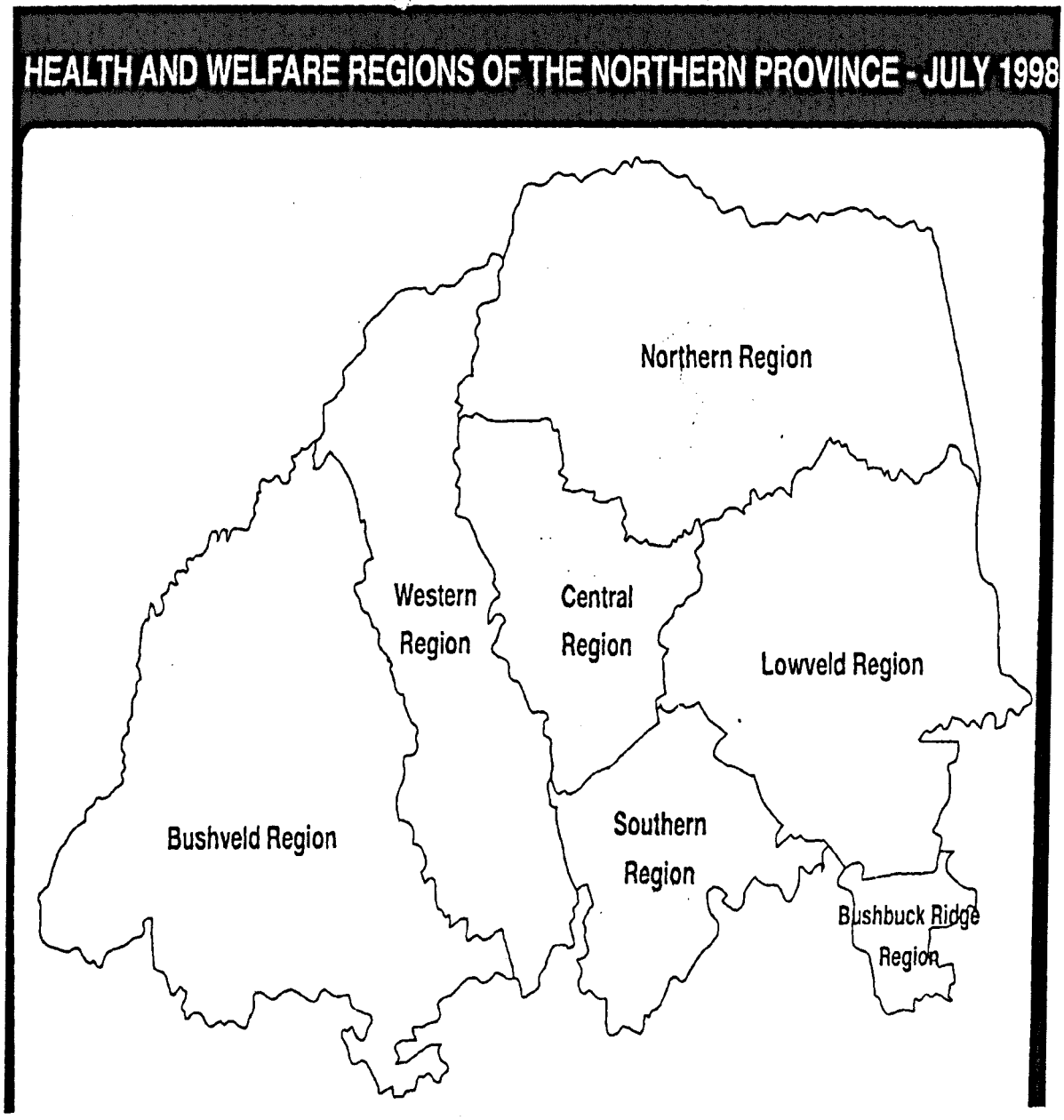
FUNCITONS

- Review national EDLs
- Review drug purchases in light of budgetary restrictions
- Coordinate drugs appropriate to level of care
- Decide on additions and deletions to procurement list
- Make recommendations to national EDL process and facilitate national consultation
- Facilitate decision on whether to withhold treatment for certain conditions
- Facilitate DUEs and reviews of antibiotics resistance patterns
- Supervise and monitor other PTCs

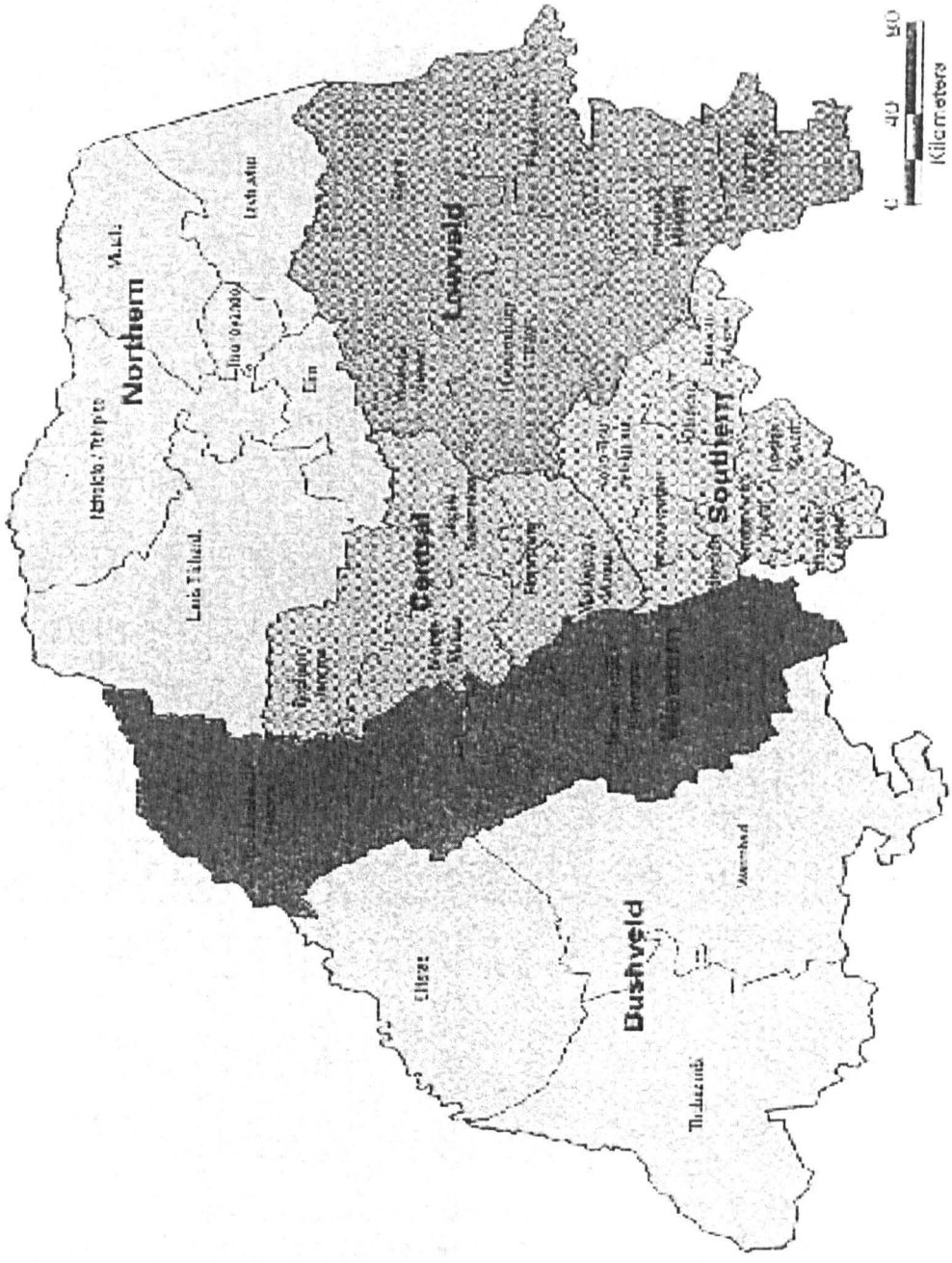
MEMBERSHIP

- Head of Pharmaceutical Services
- Procurement manager
- Pharmaco-economist
- Clinical pharmacologist / pharmacist
- Medical specialists (physician, paediatrician, surgeon, family medicine, co-opted specialists)
- PTC specialist
- Other co-opted members
- Secretary (professional
- Regional Representative

APPENDIX F
Health and Welfare Regions of the Northern Province



APPENDIX F
Map of the Northern Province with six regions



APPENDIX G

FACTS AND FGURES ON NORTHERN PROVINCE AND SOUTH AFRICA

POPULATION	NORTHERN PROV.	SOUTH AFRICA
Female	57	51
African	95	76
Non urban	89	50
Young (>15yrs)	48	40
No formal education	27	13
Females	19	11
Males	32	15
Unemployed	41	29
Employment informal	25	17
Earn > 999 R/month	33	31
AFRICANS		
Female	41	31
Live in brick house	63	73
Live in shack	3	7
Live in traditional house (hut)	28	14
Electricity	31	51
Running water	17	33
Flush toilet	9	22
Telephone	12	32
Use public health facilities.	89	81

Source: Living in the Northern Province. Selected findings of 1995 October Household Survey. Central Statistics Service (CSS),1998, Dr. FM Orkin, Pretoria).

APPENDIX H
VUNA Healthcare Logistics Newsletter

VUNA VISION

WE KEEP YOU UP-TO-DATE

VUNA HEALTHCARE LOGISTICS VOLUME 1 MAY 1999

EDITORIAL

Our first Newsletter was distributed during January, but very little feedback was received from hospitals. Thank you to those of you who did respond.

There are so many facets of Pharmacy and Primary Health Care that are of interest to us all - please share your knowledge and experience with us. In our first Newsletter, Phokae Hasting informed us about the support staff training to be implemented, and in this Newsletter we include some information on inspections by the Pharmacy Council, with reference to the Good Pharmacy Practice (GPP) document, which is a requirement at all pharmacies, and can be obtained from the Council.

Hospital pharmacies are also supposed to conform to certain minimum standards. I have the opportunity, as an inspector of the Council, to do inspections of quite a few Hospital pharmacies, and must admit that in some cases the standards of facilities and systems do not compare well with the requirements, or give a true reflection of a professional service at all times.

We would like you to let us have your views on this matter - are we giving a service as required by the Council as set out in the GPP guidelines and the National Drug Policy, is the supervision of staff and control of Pharmaceuticals and Surgical sundries done as required, and if not, why not?

What are the problems you are experiencing, what is being done or what can be done to overcome these, so that the service can take its rightful place among the Health professions.

Remember - you might have the problem or need information, but someone else could just have the solution or information you need.

This is your Newsletter - please make use of it.

Greetings

Almero Mathews
Editor

STOP PRESS! STOP PRESS! NORTH WEST TENDER AWARDED.

We are thrilled to announce that Vuna Healthcare Logistics has been granted the tender for the North West Province. This includes the procurement, warehousing, distribution and management of information systems.

As called for in the tender, a situational analysis and recommendations on a repacking unit and a medicine delivery system from hospital to clinic, will be actioned.

VHL in partnership with the Provincial Executives has already initiated a project management team to ensure the smooth implementation of the specifications and requirements of the tender in the province.

Vuna Healthcare Logistics offers a wide range of pharmaceutical and healthcare support services. A member of the Thebe Group of Companies, VHL is a non-racial, non-sexist organisation, which is committed to promoting first class, affordable healthcare for all South Africans.

STAFF ANNOUNCEMENT: DEPUTY CHIEF EXECUTIVE

It gives us great pleasure to announce the appointment of Bada Pharasi as the Deputy Chief Executive of Vuna Healthcare Logistics with effect from 18 January 1999. Bada will join the Board of Directors of the company as Managing Director.

Bada Pharasi is well known within the Pharmaceutical industry in Southern Africa and is joining the company from the national Department of Health where he was the Chief Director, Registration and Regulation. His portfolio also included the licensing of electromedical devices and the regulation of the food industry through the Directorate of Food Control.

Bada holds a M.Pharm degree in Pharmacy, which he obtained at the Medical Academy in Sofia, Bulgaria.

Please join us in welcoming Bada on board and wishing him a long, successful and satisfying career with the company.

KNOW YOUR DEPOT STAFF

Bertie Botha, VHL Branch Manager, Northern Province Pharmaceutical Depot - Pietersburg.

Barend Petrus (Bertie, as we all know him) Botha was born on the 8th September 1960 in Koster, North West Province. He grew up in the Swartruggens district, west of Pretoria, and matriculated from Hoërskool Piet Potgieter in Potgietersrus. He attended the University of Pretoria, where he obtained his degree in Pharmacy in 1983.

Bertie enjoys 4 x 4 and other outdoor activities and is a keen squash player. He is married to Mariaan and they have twin daughters - Marialdi and Sunrun, aged 5.

NPPD STOCK AVAILABILITY

July 1998 - January 1999

Items	July 98	Aug 98	Sept 98	Oct 98	Nov 98	Dec 98	Jan 99
Critical/Essential Items	88.0%	93.8%	94.6%	93.8%	93.4%	93.6%	92.9%
All items	87.1%	85.1%	87.6%	88.0%	95.3%	91.8%	88.4%

Compiled by: Bertie Botha

NEWS FROM THE PHARMACY COUNCIL

- THE INSPECTORATE -

Appointment of inspectors:

An inspector is considered inter alia on the exposure that a pharmacist has had in terms of the different sectors of pharmacy practice. The wider the exposure, the better equipped such person will be to perform inspections on behalf of Council. An inspector is appointed for a period of one year in a specific area and should preferably not be involved in community pharmacy in that area.

Inspection types:

The core Good Pharmacy Practice in South Africa document with the annexures for hospital and community pharmacy is used as a guide for the inspector. These guidelines were also used to compile the new questionnaires for both hospital and community pharmacies that have been in use since the beginning of 1999.

Council appointed inspectors, namely performs four kinds of inspections:

Premises inspections.

Monitoring inspections.

Training inspections.

Disciplinary inspections.

The role of the inspector:

An inspector should not only identify areas for improvement in a pharmacy, but also encourage and guide the profession to attain the goals of acceptable practice standards as set out in the Good Pharmacy Practice guide of Council in an informative and educational way. The inspector fulfils an important communication role between the Council and the profession and is considered an ambassador of the Council.

J.De Beer - Manager Registrations and Inspections.

VHL TRAINING

Training is one of the most important aspects of how VHL is delivering the solution in the public-private sector partnership.

VHL thought it necessary to prepare all support staff for the Pharmacist Assistant course, which will follow in the near future.

Mr Almero Mathews was approached to draw up the necessary training material, and the VHL Depot Pharmacists are presenting the training.

Staff agreed to three hours training weekly, pending the completion of operations, and written and oral tests are done monthly to monitor the progress.

The first four modules, namely: ordering, receiving, stock-take and warehouse storage conditions, have already been completed. All legal aspects and regulations, Good Pharmacy Practice, Good Manufacturing Practice, the National Drug Policy, the VHL distribution contract, Tender Board and Treasury regulations, as well as Standard Operating Procedures for the warehouse, form an integral part of the training material.

This kind of training makes the staff more aware of the ethics and responsibilities pertaining to the scope of pharmacy.

Compiled by: Bertie Botha, VHL Pietersburg

NOTIFICATION OF DEATH

Mr JL Pitlo, a General Assistant at Pietersburg Hospital passed away on the 15th January 1999 after a short period illness. May his soul rest in peace.

PHARMACY OF THE YEAR AWARDS 1998/9

A. Northern Province

A panel consisting of VHL staff, and the Department's Principal and Chief Regional Pharmacists did preliminary evaluations. The top performers and the previous years top two were through to the final round. The final evaluations were done from the 16th - 18th November 1998, and the results are, in order of performance, as follows:

1. Voortrekker Hospital Pharmacy
2. Tshilidzini Hospital Pharmacy
3. Warmbaths Hospital Pharmacy
4. Ellisras Hospital Pharmacy
5. Siloam Hospital Pharmacy
6. Seshego Hospital Pharmacy
7. M.L.Malatji Hospital Pharmacy

B. Mpumalanga Province.

Nominations were received from the Regional Pharmacists, and evaluations done during June 1998 by VHL staff and Regional Pharmacists. The results were, in order of performance, as follows:

1. Middelburg Hospital Pharmacy
2. Babereon Hospital Pharmacy
3. Bethal District Pharmacy
4. Shongwe Hospital Pharmacy
5. Lydenburg Hospital Pharmacy
6. Embhalem Hospital Pharmacy

CONGRATULATIONS TO ALL!

WORDS OF WISDOM

Do not brag about your plans for tomorrow - wait and see what happens. Don't praise yourself; let others do it.

Proverbs 27:1,2

APPENDIX H

DID YOU KNOW?

172 people died of malaria in the country last year, of which 39 people were from the Northern Province.

25092 cases of malaria were reported countrywide, of whom 3674 were from the Northern Province.

Extract from: Die Pos 29/1/99

COLD CHAIN NEWS

Recently two representatives from the Northern Province Pharmaceutical Services attended a training course on the technical aspects of vaccine procurement; storage and distribution aimed at district level.

The objectives of the training course that was funded by the South African Drug Action Programme was to introduce the participants to:

1. Basic principles of cold chain management
2. Basic principals of vaccine procurement
3. Minimum requirements for record keeping
4. Standard procedures for the disposal of clinical waste
5. Notification and monitoring of adverse events.

The main overall objective of the course was to prepare an action plan for pharmaceutical services to improve cold chain management at district level.

The first Northern Province Technical Cold Chain training course is planned for the end of April 1999. The target group for this course will be pharmaceutical and primary health care management at district level. The Southern part of the Province will be targeted first.

Any enquiries on the course can be done with Mr D van Wyk at 015-223 0325.

LETTER RECEIVED FROM SAAHIP

Dear Mr Renier Botha -

Vuna Healthcare Logistics

On behalf of SAAHIP it gives me great pleasure to thank you for attending the meeting to establish a branch for SAAHIP in Mpumalanga. As you have experienced, it was a most successful occasion. Hospital and Institutional Pharmacists joined hands to make this a historical day.

VHL has again showed its trust in Pharmacists and in what they do, by your company's generous contribution to sponsor this occasion. This was highly appreciated.

Thank you for your positive message, you will surely always be counted as part of this team!

Regards, Karin Erasmus
(Chairperson SAAHIP Mpumalanga)

GOING HOME

Ms Cathy Lynch, a pharmacist at Tshilidzini has gone back to Queensland, Australia, after serving the Province for two years. During her stay at Tshilidzini, Cathy, together with her motivated assistants, ensured that the computerisation of the hospital pharmacy ran smoothly. This placed Tshilidzini in line to receive an award as one of the best-managed pharmacies in the Province.

In addition to her pharmacy managerial duties she became a Drug Supply Management Trainer for the Northern Region. By the end of 1998 she and Mr Makhado (pharmacist at Siloam) trained a total of 203 nursing and pharmacy personnel in DSM.

Cathy will be sadly missed in the Province.

Compiled by: Emily Rasengane

PROMOTING RATIONAL DRUG USE (PRDU COURSE)

The PRDU course was held for the first time in the Northern Province at the Protea Park Hotel in Potgietersrus. The course was offered by Medical university of South Africa (MEDUNSA). The first part of the course was held on the 14-18 September and the second and last part on the 19-23 October 1998.

Doctors, professional nurses and pharmacists from all seven regions participated in the course plus three pharmacists from the Western Cape. Three of the province's professionals helped facilitate some of the sessions. They are Judith Muhlarhi (Nkhensani Hospital), Margareth Thupana (Southern Region) and Razeeya Khan (Pietersburg Hospital).

The main objective of the PRDU course is to guide professionals to identify and make interventions whenever drug use problems occur in our hospitals. At the end of the workshop each region formulated a proposal on how to address selected drug use problems, for example the Western Capes' Proposal Title is: Improving Correct Use of Metered Dose Inhalers in Adult Patients with Moderate and severe Asthma, requiring continuous Therapy, in the Western Cape. The results of this study will be published for all interested parties.

Compiled by: ME Rasengane

LITERACY TRAINING AT THE N.P. DEPOT BY VHL

The training commenced in December 1998. Students were identified through assessments and were placed according to the levels of their communication skills in English. The facilitator was identified and underwent the necessary training.

There are twenty-three students. Two on Basic Oral Level, eleven on Level 1, three on Level 2 and seven on Level 3. The N.P.P.D Adult centre is also registered with the Independent Examination Board. We would like to wish Level 1 good luck on their coming examinations.

This training has recently commenced in Mpumalanga.

Compiled by: Mavis Selvane

FAREWELL TO THE NORTHERN PROVINCE

After working for 2 years in the pharmacy at Tshilidzini Hospital in Region 4, I said goodbye to return home to Australia.

My time spent here has been VERY busy, and the pharmacy has progressed a long way. It is now fully computerised, and is the only department in the whole hospital to be so.

The past two years have seen the implementation of many new policies, procedures, and standard treatment guidelines. This has been an excellent start on the road to providing an efficient cost-effective service to the community.

It has been a rare opportunity to work in a rural setting but at the same time have the support of excellent technology. In so many ways, the contrast here reflects the changing face of South African society. Working at Tshilidzini Hospital has given me an insight into the importance of Primary Health Care programmes. The clinics in this region are very busy and provide an excellent service to the community. This service can only be maintained with the support of the pharmacy and its staff.

I take this opportunity to thank everyone who has helped me during the last two years. Working at Tshilidzini Hospital has been very different to my previous position, so along the way, I have asked for help and advice from many people, and assistance has always been forthcoming. In particular, I would like to thank Mr Meyer, Mr van Wyk, Mrs Bettie Labuschagne, the regional pharmacist for Region 4, Mr Makhado from Siloam Hospital, and the staff of VHL who have been of great assistance and support. I will always look back on these two years with fond memories.

I wish everyone well in their future efforts to implement the new standard treatment guidelines.

Cathy Lynch

ON THE LIGHTER SIDE:

During the preliminary evaluation of pharmacy support personnel, I encountered some humouristic phrases, amongst all the serious facets of 'Pharmacy'.

Q: What is the expiry date of a medicine?
A: It is no longer good
A: The medicine does not work any more.
A: The medicine is finished.

Q: What is a split tender?
A: A tender that no longer exists
A: A tender that is in two ways
A: Two types of tenders with different names

Compiled by: Lynne Ras

JOKE

A man walks into a pharmacy and asks to speak to the pharmacist.

"Morning Sir, how may I help you?"

"I need some uh, uhm, uhh, um, um....."

"Yes?"

"I need some uh, uhm.... Acetylsalicylic Acid tablets please"

"Oh, you mean Aspirin?"

"Yes! Gee, you know, I can never remember that name!"

EDITORIAL PANEL

All letters for publication must please be signed with full name, telephone number and address. No letters that are slanderous or political will be published. Letters can be posted to: The Editor, Vuna Vision, P O Box 388, Nylstroom, 0510, or any of the sub-editors via the Distribution Depots.

NB:
Due to limited space, some articles have regrettably been edited or shortened while trying to retain the essence of their contents.

Editor.

APPENDIX H

DID YOU KNOW?

172 people died of malaria in the country last year, of which 39 people were from the Northern Province.

25092 cases of malaria were reported countrywide, of whom 3674 were from the Northern Province.

Extract from: Die Pos 29/1/99

COLD CHAIN NEWS

Recently two representatives from the Northern Province Pharmaceutical Services attended a training course on the technical aspects of vaccine procurement; storage and distribution aimed at district level.

The objectives of the training course that was funded by the South African Drug Action Programme was to introduce the participants to:

1. Basic principles of cold chain management
2. Basic principals of vaccine procurement
3. Minimum requirements for record keeping
4. Standard procedures for the disposal of clinical waste
5. Notification and monitoring of adverse events.

The main overall objective of the course was to prepare an action plan for pharmaceutical services to improve cold chain management at district level.

The first Northern Province Technical Cold Chain training course is planned for the end of April 1999. The target group for this course will be pharmaceutical and primary health care management at district level. The Southern part of the Province will be targeted first.

Any enquiries on the course can be done with Mr D van Wyk at 015-223 0325.

LETTER RECEIVED FROM SAAHIP

Dear Mr Renier Botha -

Vuna Healthcare Logistics

On behalf of SAAHIP it gives me great pleasure to thank you for attending the meeting to establish a branch for SAAHIP in Mpumalanga. As you have experienced, it was a most successful occasion. Hospital and Institutional Pharmacists joined hands to make this a historical day.

VHL has again showed its trust in Pharmacists and in what they do, by your company's generous contribution to sponsor this occasion. This was highly appreciated.

Thank you for your positive message, you will surely always be counted as part of this team!

Regards, Karin Erasmus
(Chairperson SAAHIP Mpumalanga)

GOING HOME

Ms Cathy Lynch, a pharmacist at Tshilidzini has gone back to Queensland, Australia, after serving the Province for two years. During her stay at Tshilidzini, Cathy, together with her motivated assistants, ensured that the computerisation of the hospital pharmacy ran smoothly. This placed Tshilidzini in line to receive an award as one of the best-managed pharmacies in the Province.

In addition to her pharmacy managerial duties she became a Drug Supply Management Trainer for the Northern Region. By the end of 1998 she and Mr Makhado (pharmacist at Siloam) trained a total of 203 nursing and pharmacy personnel in DSM.

Cathy will be sadly missed in the Province.

Compiled by: Emily Rasengane

PROMOTING RATIONAL DRUG USE (PRDU COURSE)

The PRDU course was held for the first time in the Northern Province at the Protea Park Hotel in Potgietersrus. The course was offered by Medical university of South Africa (MEDUNSA). The first part of the course was held on the 14-18 September and the second and last part on the 19-23 October 1998.

Doctors, professional nurses and pharmacists from all seven regions participated in the course plus three pharmacists from the Western Cape. Three of the province's professionals helped facilitate some of the sessions. They are Judith Muhlarhi (Nkhensani Hospital), Margareth Thupana (Southern Region) and Razeeya Khan (Pietersburg Hospital).

The main objective of the PRDU course is to guide professionals to identify and make interventions whenever drug use problems occur in our hospitals. At the end of the workshop each region formulated a proposal on how to address selected drug use problems, for example the Western Capes' Proposal Title is: Improving Correct Use of Metered Dose Inhalers in Adult Patients with Moderate and severe Asthma, requiring continuous Therapy, in the Western Cape. The results of this study will be published for all interested parties.

Compiled by: ME Rasengane

APPENDIX I
PHARMACEUTICAL EXPENDITURE PER PROVINCE 1998/99

Province	Per Capita Health Expenditure	Population	Pharmaceutical Expenditure	Per capita Expenditure	%of Health on Pharmaceuticals
Gauteng	773	7,171,000	471,775,685	65.79	7.60%
Free State	510	2,470,000	159,876,721	64.73	8.70%
Western Cape	707	4,118,000	190,976,916	46.38	4.90%
Kwazulu-Natal	418	7,073,000	316,480,381	44.74	7.90%
Eastern Cape	444	5,865,000	198,837,284	33.90	12.70%
Northern Cape	543	746,000	19,999,998	26.81	6.60%
North West	417	3,043,000	80,000,000	26.29	6.30%
Mpumalanga	263	2,646,000	60,420,152	22.83	10.70%
Northern Province	**309**	**4,927,368**	**100,724,860**	**20.44**	**8.50%**
National	487	38,059,368	1,599,091,997	42.02	8.21%

APPENDIX J
NORTHERN PROVINCE PHARMACEUTICAL EXPENDITURE 1998/99

ANTIBIOTICS

	Expenditure	Group Total	% of Expend
Amoxycillin Caps 250Mg	1,293,516.88		
Phenoxymethyl Penicillin Tabs 250Mg	1,176,382.44		
Erythromycin Tabs 250Mg (Prp 20)	1,148,048.67		
Oxytetracycline Polymixin Eye Oint 5G	1,046,614.19		
Phenoxymethyl Penicillin Susp 250Mg/5ml	898,610.65		
Ceftriaxone Inj 250Mg	886,119.92		
Cefoxitin Inj 1G	755,811.00		
Amoxycillin Susp 125Mg/5ml 75Ml	739,347.32		
Cloxacillin Caps 250Mg	719,193.45		
Cloxacillin Susp 125Mg/5ml 100Ml	716,814.49	17,264,834.11	23.83 %

DROPS, AEROSOLS AND INHALANTS

	Expenditure	Group Total	% of Expend
Salbutamol Inhaler Complete 100Mcg 200 D	800,266.68		
Beclomethasone Inhaler Complete 50Mcg	494,108.28		
Sodium Hyaluronate 10Mg/ml Inj 0.5Ml Syr	240,437.48		
Sodium Cromoglycate Eye Drops 2% 10Ml	173,016.00		
Flurbiprofen Eye Drops 0.3Mg/ml 5Ml	128,058.96		
Levobunolol Eye Drops 0.5% 7.5Ml	109,170.47		
Antazoline Naphasoline Eye Drops 15Ml	91,033.12		
Betaxolol Eye Drops 5Mg/ml 5Ml	88,584.68		
Ipratropium Udv 0.5Mg/2ml	83,450.15		
Ipratropium Inhaler Complete 200Dose	82,580.43	3,000,850.93	4.14 %

FAMILY PLANNING

	Expenditure	Group Total	% of Expend
Norethisterone Inj 200Mg/ml Long-Acting	3,737,694.18		
Oral contraceptives	1,592,599.44		
Medroxyprogesterone Inj 150Mg/ml 1Ml	1,476,256.00		
Intra Uterine Device 375	3,732.44		
Intra-Uterine Device Short	1,387.64		
Desogestrel Oestradiol Tabs 150/20Ug (Me	91.21	6,811,760.91	9.40 %

ALCOHOL, AETHER AND

GLYCERINE			
	Expenditure	Group Total	% of Expend
Alcohol 96% 25L	70,408.40		
Ether Technical 500Ml	3,914.84		
Glycerine B. P 500Ml	2,871.85		
Ether Technical 25L	1,673.40	78,868.49	0.11 %

APPENDIX K
NDP EVALUATION INDICATORS AND QUESTIONS

INDICATORS

I. Structural Indicators

Data Source: Analysis of Documents

- Drug regulatory authority whose mandate includes registration and inspection
- A Licensing system to regulate the sale of drugs
- Pharmacist legally entitled to substitute generic drugs for brand name products
- Legal provisions for penal sanctions
- Control on drug promotion based on regulations and consistent with the WHO Ethical Criteria for Medicinal Drug Promotion
- National essential drugs list (EDL) using INN officially adopted and distributed countrywide
- Official committee whose duties include updating the national essential drugs list (EDL)
- Formal procedures for registering drugs
- Drug regulation committee
- Drugs usually procured in the public sector though competitive tender
- Procurement in the public sector limited to drugs on the national essential drugs list (EDL)
- National publication (formulary/bulletins/manuals, etc) revised within the past five year, providing objective information on drug use
- National therapeutic guide with standardized treatments
- The concept of essential drugs part of the curricula in the basic training of health personnel
- Official continuing education system on rational use of drugs for prescribers and dispensers
- Drug information unit

II. Health Facility Indicators

Data Source: Prospective NDP Indicators, collected at facility visits
Analysis of facility indicators of EDL drug use

- Availability of Standard Treatment Guidelines? Essential Drugs List
- Availability of impartial drug information

III. Prescribing Indicators

Data Source: prospective (facility visit) and retrospective (baseline studies by MEDUNSA)

- Percentage of drugs prescribed by generic name
- Percentage of drugs prescribed from essential drugs list
- Percentage of drugs prescribed by brand name, but dispensed as generic
- Assessment of three rational drug prescribing indicators:

1. Percent of prescription with one of more injectables
2. Percent of prescriptions with one or more systemic antibiotics
3. Average number of items per prescription

IV. Process Indicators:

Qualitative information on the processed by which a nation drug policy is implemented. The indicators assess the degree of functioning for the processes in the seven key components and the progress being achieved over the time towards specific goals.

- Number of drugs from the national essential drugs list (EDL) prescribed, out of total number of drugs prescribed.
- Number of drugs from the national essential drugs list (EDL) sold, out of total number of drugs sold.
- Number of prescribers having direct access to a (national) drug formulary, out of total number of prescribers surveyed
- Number or training session on drug use for prescribers in the last year, out of average number of training sessions organised in the past three years.
- Number of prescribers have attended at least one training session in the last year, out of total number of prescribes surveyed.

QEUSTIONS

Structural Questions[1]

Qualitative information to assess the pharmaceutical system's capacity to achieve its policy objectives. These indicators are intended to check if the structures necessary to implement a pharmaceutical policy exits. These structural indicator questions are answered with a "Yes or No" based on information available at the central level (WHO, 1994).

1. Are pharmacists legally entitled to substitute generic drugs for brand name products?

2. Is there control on drug promotion based on regulations and consistent with the WHO Ethical Criteria for Medicinal Drug Promotion?

3. Is there a National essential drugs list (EDL) using INN officially adopted and distributed countrywide?

[1] From WHO, Indicators for Monitoring National Drug Policies, 1994

4. Is there an official committee whose duties include updating the national essential drug list(s) (EDL)?

5. Are drugs usually procured in the public sector though competitive tender?

6. Is procurement in the public sector limited to drugs on the national essential drugs list (EDL) ?

7. Is there a National publication (formulary/bulletins/manuals, etc) revised within the past five year, providing objective information on drug use?

8. Is there a National therapeutic guide with standardized treatments?

9. Is the concept of essential drugs part of the curricula in the basic training of health personnel ?

10. Are there official continuing education system on rational use of drugs for prescribers and dispensers?

11. Is there a drug information unit?

Process Questions:

Process questions will provide qualitative information on the processes by which the National Drug Policy is implemented. The indicators assess the degree to which activities are being effectively implement and the progress over time. Process information can be used by national-decision makers to monitor the progress in the implementation of drug policy with reference to goals and targets established at the national level. This information is available through either the central level and/or obtained trough surveys (WHO, 1994). For this research project, the latter will be used.

12. What is the availability of key drugs on EDL (list 20-30 drugs to be constructed[2])?

13. What is the availability of copy of essential drugs lists?

14. What is the availability of Standard Treatment Guidelines?

15. What is the availability of impartial drug information?

16. What Percentage of drugs are prescribed by generic name?

17. What Percentage of drugs are prescribed from essential drugs list?

18. What Percentage of drugs prescribed by brand name, but dispensed as generic?

19. Assessment of three rational drug prescribing indicators:

[2] WHO has a list of 10 drugs that is used for PHC facilities. Perhaps this list can be used as a guideline for a new list that is tailored to the hospital adult level.

a. What percentage of prescriptions with one or more systemic antibiotics?
b. What number of drugs prescribed are from the national essential drugs list (EDL)?

20. What number of training session on drug use for prescribers occurred in the last year, out of average number of training sessions organised in the past three years?

21. What number of prescribers have attended at least one training session in the last year, out of total number of prescribers surveyed ?

22. What is the number of special hospital pharmacy and therapeutic committees?

23. What is the number of resource books / drug use information? (Can three major sources of information be found relatively easily in the facility?)

24. What is the number of drug bulletins/newsletters published in the province?

4.4 Outcome Questions[3]

Outcome indicators measure the results achieved and the changes that can be attributed to the implementation of a national drug policy. They measure the effects of implementation on the overall objectives of the national drug policy, but for this research, it will measure the 'rational use of drugs.' This information is available at the central level and /or obtained through survey (WHO, 1994). Eight outcome indicators were chosen: 5 from WHO/INRUD and 3 specifically for this study)

25. What is the average number of items per prescription?

26. What percentage of prescription are antibiotics?

27. What is the average cost per prescription?

28. What is the percentage of adherence to the EDL/STG? **(Drug and dose)**

29. What is the percentage of generic prescribing?

30. What is the number of adults with hypertension are receiving the protocol treatment based on the STG/EDL?

31. What is the number of adults with diabetes type II are receiving the protocol treatment based on the STG/EDL?

32. What is the number of adults with asthma are receiving the protocol treatment based on the STG/EDL?

[3] Several of these outcome indicators were used in the evaluation of the EDP baseline studies conducted by SADAP and MEDUNSA.

APPENDIX L
Hypertension Treatment
Essential Drugs List Hospital - Adult

3.9. HYPERTENSION Treatment guidelines		
	Management	**Comments**
Non-drug treatment	Extensive health education is necessary. This is baseline treatment Lifestyle modification Moderate exercise	**Referral criteria** • If the patient is compliant with therapy, and the blood pressure is refractory while on drugs from three different classes, one of which being a diuretic. • All cases where secondary hypertension is suspected. **Special investigations**: These are indicated in complicated hypertension and where secondary causes are suspected, especially in young adults, sudden onset of moderate to severe hypertension and first onset after the age of 50 years. Also indicated when complicated by target organ involvement.
Drug treatment	Diuretics: Hydrochlorothiazide, oral, 12.5 mg daily. In patients with fluid retention: increase to 25 mg daily.	First line therapy for all patients To reduce blood pressure to less than 140/90 mm Hg in all patients, and to less than 160/95 mm Hg in the elderly with no co-morbidity.
	Furosemide, oral, 40–120 mg daily, if unresponsive to above	For eodamatous subjects or those in CCF or resistant or in renal failure.
	Reserpine, oral, 0.1 mg daily	Continued from primary care as additional therapy.
	Atenolol, oral, 50 mg daily, can be increased to 100 mg daily in patients with insufficient beta blockade	In addition to hydrochlorothiazide May be beneficial in the following conditions: Angina, after myocardial infarction, tachydysrhythmias, and pregnancy
	ACE-inhibitors e.g. Perindopril, oral, 4 mg daily	Use if target blood pressure is not achieved with the above-listed medications. Also for: Heart failure Left ventricular hypertrophy. After myocardial infarction (remodelling prevented) Diabetes with micro-albuminuria
	Alpha blocker e.g. Prazosin, oral, 1–5 mg 2–3 times daily, maximum dose: 20 mg daily. Start with low dose, titrate	Use for chronic renal failure and heart failure This is a third-line anti-

	upwards. A first dose hypotensive effect can occur.	hypertensive drug
	Calcium channel blockers e.g. Verapamil, oral, 40–80 mg 3 times daily or Verapamil sustained release, oral, 120–360 mg one or twice daily Nifedipine*, oral, 5 mg, can be repeated. Short term, emergency use only) or Nifedipine long-acting, oral, 30–90 mg daily	Extra benefits: Angina pectoris, peripheral vascular disease, in elderly patients, systolic hypertension These drugs are metabolically neutral *Nifedipine is a third-line drug used for emergency lowering of blood pressure.

APPENDIX M

EXPENDITURE ON HYPERTENSION 1998 / 1999
NORTHERN PROVINCE PHARMACEUTICAL SERVICES

GENERIC NAME	UNITS ISSUED	COST
Amiloride 2.5Mg Hydrochlorothiazide 25Mg	184,000	7,643.36
Amiloride 5Mg Hydrochlorothiazide 50Mg	6,549,061	138,461.56
Atenolol Tabs 50Mg	537,208	49,354.14
Atenolol Tabs 100Mg	348,068	49,007.82
Captopril Tabs 25Mg	4,400,932	855,767.77
Disopyramide Caps 100Mg	12,500	3,591.52
Enalapril Tabs 5Mg	414,680	127,533.00
Enalapril Tabs 10Mg	762,720	435,792.00
Enalapril Tabs 20Mg	308,560	352,200.00
Hydralazine Tabs 10Mg	95,500	3,726.40
Hydralazine Tabs 25Mg	103,500	3,821.71
Hydralazine Tabs 50Mg	140,000	9,525.54
Hydrochlorothiazide Tabs 25Mg	5,698,980	201,565.45
Indapamide Tabs 2.5Mg	6,540	632.54
Methyldopa Tabs 250Mg	12,110,000	1,374,664.19
Nifedipine Caps 10Mg	1,844,462	236,778.73
Nifedipine Caps 5Mg	292,200	41,580.03
Nifedipine Tabs 60Mg Slow Release	300	550.00
Perindopril Tabs 4Mg	90	47.76
Prazosin Tabs 1Mg	57,300	5,497.02
Prazosin Tabs 2Mg	77,000	12,398.21
Prazosin Tabs 5Mg	45,630	21,040.32
Quinapril Tabs 10Mg	1,120	440.00
Reserpine Tabs 0.25Mg	478,296	23,770.09
ANNUAL PROVINCIAL COST		**3,955,389.16**

APPENDIX N

DIABETES TREATMENT

6.5. DIABETES MELLITUS Treatment guidelines		
	Management	**Comments**
Non-drug treatment	Education for self-care and to prevent complications Dietary therapy and weight loss is the corner stone of treatment of patients with NIDDM (Type 2) Increased physical activity within limits.	Definition A syndrome caused by a relative or absolute deficiency of insulin. Pathogenesis Insulin deficiency can be either primary or secondary. Types Non-Insulin Dependent Diabetes Mellitus (NIDDM) (Type 2) Insulin-Dependent Diabetes Mellitus (IDDM) (Type I) Pancreatic diabetes mellitus Referral criteria • Serious complications • Associated diseases • Pregnancy (see appropriate guideline) • If condition is difficult to control.
Drug treatment	One drug initially, but combine with metformin or insulin if targets are not achieved. Oral anti-diabetic agents: Sulphonylureas: e.g. Tolbutamide, oral, 250 mg 2–3 times daily, up to 1 500 mg/day OR Glipizide, oral, , 2.5 mg once to twice daily, up to 30 mg/day OR Gliclazide, oral, 40 mg once to twice daily, up to 320 mg/day OR Glibenclamide, oral, , 2.5 mg once to twice daily, up to 15 mg/day	Monitor response clinically and by blood glucose Use if glycaemic targets are not reached after lifestyle modification for 3 months OR in newly diagnosed patients with very high blood glucose levels (15–20 mmol/L) who are not dehydrated or in keto-acidosis. These drugs stimulate insulin secretion. Hypoglycaemia can be a problem. NB. Not to be used in pregnancy or in impaired renal or hepatic function. Caution with long-acting drugs in elderly people.
	AND/OR Biguanides: Metformin, oral 500 or 850 mg 1–3 times daily, total maximum daily dose: 3 000 mg	Use if glycaemic targets are not reached after lifestyle modification for 3 months OR in newly diagnosed patients with very high blood glucose levels (15-20 mmol/L) who are not dehydrated or in keto-acidosis They enhance insulin action peripherally. They are useful in obese patients.
	OR Insulin: - insulin protocols: Very rapid acting: onset of action: 10 min, peak action: 1 hour, duration of action: 3 hours; injections daily, immediately prior to meals.	Use for: • All Type I diabetics (IDDM) • Type 2 diabetics (NIDDM) with poor glycaemic control on oral agents; or during stress or intercurrent illness or infections or peri-operative, after trauma, during pregnancy, with

	Short-acting: onset of action: 30 min, peak action: 2–5 hours, duration of action: 5–8 hours, injections daily, 30 min prior to meals. Intermediate-acting: onset of action: 1–3 hours, peak action: 6–12 hours, duration of action 16–24 hours, injections: 1–twice daily. Biphasic mixtures e.g. 30/70, onset of action: 30 min, peak action: 2–12 hours, duration of action: 16–24 hours, Injections: once to twice daily.	pancreatitis, severe organ failure and in hyperglycaemic emergencies. Titrate dose according to blood glucose response
Ketosis:	Electrolytes and fluids: Sodium chloride solution 0.9%, IV, 1–2 L initially, followed by sodium chloride solution 0.45%. Potassium to be monitored and given if necessary. When blood glucose reaches 10–14 mmol/L change to dextrose 5% in water to prevent hypoglycaemia. Insulin, regular, IV, titrate according to response, given hourly and change to SC 4–6 hourly until a decision is made for further treatment Sodium bicarbonate 8.5% for IV use, guided by bicarbonate deficit as estimated e.g. HCO3 = 0.50 x weight (kg) x desired HCO3 - deficit. Monitor carefully during treatment. Titrate dose to pH.	To be given only in exceptional cases as correction of dehydration usually makes this unnecessary. To be prescribed by a specialist only

APPENDIX O

EXPENDITURE ON DIABETES 1998/1999
NORTHERN PROVINCE PHARMACEUTICAL SERVICES

GENERIC NAME	UNITS ISSUED	COST
Acarbose Tabs 50Mg	1,800	630.00
Glibenclamide Tabs 5Mg	3,594,650	110,254.09
Gliclazide Tabs 80Mg	1,160,712	164,405.98
Glipizide Tabs 5Mg	1,700	184.91
Insulin 100iu/ml	89,910	1,480,450.94
Insulin Inj Device 3Ml Cartridge	1	11.25
Insulin Needles	70,600	15,206.76
Insulin Syringes	962,962	298,210.04
Metformin Tabs 850Mg	1,693,800	151,150.00
Test Strip Blood Gluc(haemo) Visual Or R	3,550	3,592.60
Test Strip Blood Gluc.(Lenstr.)Sg018	142,250	87,742.45
Test Strip Blood Glucose (Ames)	247,000	172,900.00
Test Strip Glucose In Blood (Refloflux	4,950	3,719.65
Test Strip Glucose In Blood (Accutrend)	38,750	29,697.24
Test Strip Glucose In Urine (Lenstrip)	93,350	17,641.50
Test Strip Glucose Ketones Protein Suo15	162,700	38,598.60
Test Strip Glucose Prot.Ket.(Combur 9	524,500	152,728.35
Test Strip Glucose Protein Ketones	127,500	37,639.00
Tolbutamide Tabs 500Mg	87,800	10,086.50
ANNUAL PROVINCIAL COST		**2,774,849.86**

APPENDIX P
ASTHMA TREATMENT

10.2. ASTHMA, CHRONIC PERSISTENT Treatment guidelines		
	Management	**Comments**
Non-drug treatment	Patient education Psychological support	Referral criteria • · To assess and confirm diagnosis when in doubt • · To optimise therapy • · To treat complications • · Patients not responding to optimal therapy • · Acute severe non-responding attacks of bronchospasm
Drug treatment Maintenance therapy:	Beta-2-stimulants, e.g. Salbutamol or fenoterol, MDI,100–200 micrograms, 4–6 hourly as necessary OR Salbutamol, nebulised, 2.5-5 mg undiluted given over 3 minutes, repeat 4–6 hourly OR Fenoterol, nebulised, 1.25-2.5 mg undiluted given over 3 minutes, repeat 4–6 hourly. AND/OR Ipratropium bromide, MDI, 40–120 micrograms 6–8 hourly	The doses of beta-stimulant MDIs, i.e. 100-200 micrograms 4–6 hourly should not be exceeded in chronic asthma except in acute severe attacks, as higher doses may be hazardous, especially in the elderly and those with cardiac disease. Concomitant use of preparations of the same pharmacological classification is hazardous and must be avoided. Nocturnal asthma is usually indicative of poor control and treatment adjustment should be considered. Exercise-induced asthma may be an isolated symptom of asthma and may require the use of an inhaled beta-2-stimulant 15-20 minutes before the exercise. To be prescribed by a specialist only.
	PLUS, IF REQUIRED Budesonide, inhaled, 200 micrograms twice daily, if no peak flow or other lung function test assessment available. Higher doses should be based on lung function test and evidence of clinically meaningful response. PLUS, IF REQUIRED Prednisone, oral, 5–10 mg/day, or 15 mg on alternate days. Doses of 20–40 mg daily for 7 days may be needed for short term exacerbations in patients not responding to the above.	Dosages of more than 800 micrograms per day are reserved for pulmonologist only, and should not normally be used, as higher dosages cause significant metabolic adverse effects. All inhaled corticosteroids should be administered via a spacer. Cromoglycate and nedocromil have no improved benefit over corticosteroids.
	Theophylline slow release, oral, initially 400 mg/day in 2-3 divided doses 8-12 hourly, followed by increments of 150-200 mg/day every third	Higher dosages of theophylline should be guided by blood level monitoring. The elderly are more susceptible to theophylline toxicity and theophylline dosages need to be reduced by about

	day until a maximum dose of 14 mg/kg/day, or a maximum of 900 mg/day, has been achieved.	30% Combinations of xanthine derivatives with ephedrine-like substances and sedatives have no place in the treatment of asthma.
Intercurrent bacterial infections:	Antimicrobials may be used for 7–10 days, e.g. Doxycycline, oral, 100 mg twice daily OR Amoxicillin, oral, 500 mg 8 hourly OR Trimethoprim/sulfamethoxazole 80/400mg, oral, 1 tablet twice daily.	

APPENDIX Q
EXPENDITURE ON ASTHMA 1998/ 1999
NORTHERN PROVINCE PHARMACEUTICAL SERVICES

GENERIC NAME	UNITS ISSUED	COST
Aerochamber Adult	170	4,505.00
Aerochamber Child	396	21,166.13
Aerochamber Neonate	141	7,559.01
Beclomethasone Inhaler Complete 50Mcg	70,592	494,108.28
Beclomethasone Rotacaps 100Mcg	5,880	2,860.62
Beclomethasone Rotacaps 200Mcg	1,560	1,068.08
Budesonide Inhaler 200Mcg 300Dose	333	10,926.03
Fenoterol Udv 1.25Mg/2ml	420	399.14
Fluticasone Diskhaler	36	529.20
Fluticasone Disks 250Mcg	938	4,355.00
Ipratropium Inhaler Complete 200Dose	4,830	82,580.43
Ipratropium Udv 0.25Mg/2ml	31,500	33,157.62
Ipratropium Udv 0.5Mg/2ml	63,420	83,450.15
Ketotifen Fumarate Syr 200Ml	1,598	78,659.15
Salbutamol Inhaler Complete 100Mcg 200 D	164,892	800,266.68
Salbutamol Rotacaps 200Mcg	29,340	7,732.79
Salbutamol Rotacaps 400Mcg	3,360	1,247.68
Salbutamol Rotahaler	600	9,000.00
Salbutamol Syr 2Mg/5ml 500Ml	6,723	50,124.10
Salbutamol Tabs 4Mg	1,981,000	75,136.59
Salbutamol Udv 2.5Mg/2.5Ml	51,864	37,993.16
Salbutamol Udv 5Mg/2.5Ml	15,655	13,270.73
Sodium Cromoglycate Inhaler Complete 5Mg	9	427.05
Sodium Cromoglycate Spinhaler	99	1,490.94
Theophylline Caps 60Mg (Anhydrous)	11,100	3,355.90
Theophylline Caps 125Mg (Anhydrous)	38,040	11,703.64
Theophylline Syr 200Ml	84,678	287,630.31
Theophylline Tabs 200Mg (Anhydrous)	1,257,000	127,731.98
Theophylline Tabs 250Mg (Anhydrous)	155,000	10,306.14
Theophylline Tabs 300Mg (Anhydrous)	1,241,500	188,790.13
ANNUAL PROVINCIAL COST		**2,451,531.66**

SAVINGS
ON METERED DOSE INHALERS

Beclomethasone Inhaler Complete 50Mcg	70,592	560,500.48
Salbutamol Inhaler Complete 100Mcg 200 D	164,892	1,203,711.60
TOTAL FOR CURRENT PROTOCOL		1,764,212.08

Budesonide 200cmg 300dose	11765	469,436.80
Salbutamol Inhaler 100Mcg 300 Dose	109928	1,021,231.12
TOTAL FOR NEW PROTOCOL		1,490,667.92

POSSIBLE SAVING	**273,544.16**

GENERIC NAME	UNITS ISSUED	COST
Aerochamber Adult	170	4,505.00
Aerochamber Child	396	21,166.13
Aerochamber Neonate	141	7,559.01
Ketotifen Fumarate Syr 200Ml	1,598	78,659.15
Salbutamol Syr 2Mg/5ml 500Ml	6,723	50,124.10
Salbutamol Tabs 4Mg	1,981,000	75,136.59
Theophylline Syr 200Ml	84,678	287,630.31
ANNUAL PROVINCIAL COST		**524,780.29**

SAVINGS ON METERED DOSE INHALERS

Beclomethasone Inhaler Complete 50Mcg	70,592	560,500.48
Salbutamol Inhaler Complete 100Mcg 200 D	164,892	1,203,711.60
TOTAL FOR CURRENT PROTOCOL		1,764,212.08

Budesonide 200cmg 300dose	11765	469,436.80

Salbutamol Inhaler 100Mcg 300 Dose	109928	1,021,231.12
TOTAL FOR NEW PROTOCOL		1,490,667.92

Saving on MDI	273,544.16
	524,780.29
POSSIBLE SAVING	**798,324.45**

APPENDIX R
INRUD QUESTIONS

QUESTIONS TO GUIDE QUALITATIVE ASPECTS OF THE STUDY

(Source: INRUD, How to use Applied Qualitative Methods to Design Drug Use Interventions, 1996:2-7 and 2-8)

Describes the Problem in Greater Detail

1. Do practices vary greatly by location, health facility, or health provider?
2. Do deficits in knowledge contribute to problem practices?
3. What specific areas of knowledge are deficient: diagnostic procedure, drug efficacy, drug dosing, etc.?
4. Do health providers think their practices are the same or different from their peers?
5. Do problem practices vary by diagnosis, type of patient, time of month, etc.

Feasibility of Proposed Intervention

6. Are there severe constraints in the work environment that would prevent health providers from changing their behaviour?
7. Are there proper drugs available at all times?
8. Are health providers interested in improving their practices?
9. Are the administrative authorities supportive of the types of changes proposed?

Target the Intervention

10. Are there features of the social, cultural, or behavioural context that could be used to influence the practices of individual health workers?
11. Are there particular people whose opinion is especially influential with health providers?
12. Would it be possible to recruit these opinion leaders to assist in implement the intervention?
13. Is it possible to reduce the general problem of interest to more specific behaviours or practices that it would be easier to change?

Define Specific Intervention Messages

14. Can specific myths about practice be identified that it is possible do debunk with scientific facts?

15. Are there specific areas of miscommunication between administrators and health providers (pharmacists, doctors, nurses)?

16. What kinds of educational material are available to health providers?

17. When health providers or patients have changed in the past, what was it that caused them to change?

18. How do health workers respond to prototype intervention material?

To Decide Format and Style of Intervention

19. What source of information do health providers use to learn about health problems or drugs?

20. What educational programmes have health workers already attended?

21. What model of continuing education is most highly rated: group seminars, workshops, visits by medical experts, etc?

22. How often do health workers interact with drug company representatives?

23. Is information from drug companies considered to be biased?

24. Do health workers have access to any unbiased sources of drug information?

25. Are there any ways for health workers to review their practices for the problem of interest: regular utilization reports, practice audits, practice & therapeutic committees, departmental reviews, etc.?

26. How do health workers respond when they are given summaries of their own practices?

APPENDIX S
Guiding Questions for Interviews

Questions for Health Personnel

1. Were you or your colleagues informed about the STG/EDL?
2. Were you or your colleagues trained to use the new STG/EDL?
3. Has the STG/EDL affected the way you work?
4. Are there advantages to using the STG/EDL? Why or why not?
5. Do you know about 10% cap on ordering drugs and motivating for drugs?
6. Have you heard about PTC committees?
7. Should there be interdisciplinary meetings? If so, with whom and how often?
8. Is there something that we have not discussed, that you think is important?

Questions for Administrators

1. What is your view about the implementation of the STG/EDL in hospital clinics thus far?
2. What have been some of the biggest challenges to implementation?
3. What type of training was envisioned?
4. Has the training that was envisioned been implemented for prescribers and pharmacists?
5. What percentages of the prescribers and pharmacists have been trained?
6. What are some of the restraint to training?
7. What do you envision for prescribers and pharmacist a year from now?
8. How can you get closer to making this vision a reality?
9. Is there an area that I have not covered, that you think is important?

APPENDIX T
List of Interview

Interview	Gender	Age	Yrs. Exp.	Level	Venue
NURSES					
II	Female	26-35	11-16	Sec.	St. Ritas
V	Male	36-40	6-10	Tert.	St. Ritas
XI	Male	26-35	11-16	Prim.	FH Odeaal
PHARMACISTS					
I	Female	>25	<1	Tert.	Mankweng
III	Female	26-35	6-10	Sec.	St. Ritas
VIII	Female	26-35	6-10	Tert	Pietersburg
XV	Female	51-60	20+	Prim	FH Odeaal
XVI	Female	>25	<1	Prim	FH Odeaal
PHYSICIANS					
IV.	Male	26-35	6-10	Sec.	St. Ritas
VI.	Male	36-45	11-20	Tert.- Surgery	Pietersburg
VII.	Male	41-50	11-20	Tert.-Oncology	Pietersburg
IX.	Male	26-35	6-10	Tert.- Int. Med	Pietersburg
X.	Male	26-35	6-10	Tert.	Pietersburg
XII.	Male	60+	40+	Prim	FH Odeaal
XIII.	Male	26-35	6-10	Prim	FH Odeaal
XIV.	Male	26-35	>1	Prim	FH Odeaal
ADMINISTRATORS					
XVII	Male	51+	16+	Prov	DoH
XVIII	Male	41-50	16+	Prov	DoH
XIX	Male	41-50	6-10	Prov.	Vuna
XX	Male	51+	16+	National	Univ.

Notes :
Surg.= Surgerty
Oncol. = Oncology
Int. Med. = Internal Medicine
Derm = DermatologyX.

Northern Province

Department of Health

Pharmaceutical Services Conference

16,17 & 18 April 1999

Printed & Sponsored By

VUNA HEALTHCARE LOGISTICS

APPENDIX U
Pharmacist Society of South Africa Conference - Observation

Dr W Bannenberg

You are cordially invited to attend the Northern Province Pharmaceutical Services Conference.

Venue: Mopani Rest Camp – Kruger National Park

Date: 16, 17 & 18 April 1999

Gate Arrival: This invitation and a positive identification will allow you free entrance at Phalaborwa Gate only.

Registration: Please report to the reception at Mopani Rest Camp on arrival.

Dress Code: "Semi – Formal" during conference sessions. Formal (Suit & Tie) at the formal dinner on 17 April 1999.

Overnight Accommodation:

One single bed per invitation will be reserved for the 16th & 17th April 1999.

Note: You are invited as a special guest to the conference. Traveling time from Phalaborwa Gate to Mopani Rest Camp is a minimum of two hours.

Sponsors
(in alphabetical order)

Bayer (Edms) Bpk

Boehringer Ingelheim

Convatec

Hoechst Marion Roussel Ltd

Johnson & Johnson

Macmed Healthcare

Pharmacare Ltd

Roche Products

Schering (Pty) Ltd

Smith & Nephew Ltd

Vuna Healthcare Logistics

Queries

D van Wyk	082 458 0104
J van der Nest	082 550 3001

APPENDIX U

Pharmacist Society of South Africa Conference - Observation

16 APRIL 1999

10H00 Tea / Coffee and Biscuits

10H30 Welcome and In House Arrangements Mr D van Wyk

10H40 Opening of the Conference Dr J Mc Cutcheon

SESSION 1

11H00 Mudslinging
Chair: Mr Makgopa
Panel: VHL – Mr B Botha, Ms L Ras & Mr M Dudzai

13H00 ***LUNCH***

SESSION 2

14H00 Pharmacy Council:
a. New Regulations
b. Staffing Norms
c. Pharmacy Assistant Training
d. Community Service for Pharmacists
Chair: Ms M Thupana
Panel: Mr J du Toit (Registrar Pharmacy Council)

15H30 ***TEA***

SESSION 3

15H45 Report on NP Pharmaceutical Services Survey
Chair: Ms B Labuschagne
Panel: Ms H Möller

SESSION 4

17H00 Integration of PHC (Chronic Diseases) and Pharmacy
Chair: Ms M Rasengane
Panel: Ms E Kotzenberg

19H00 ***BRAAI AT THE BOMA***

17 APRIL 1999

06H30-07H15 ***BREAKFAST***

SESSION 5

08H00 The Role of the Pharmacist in Public Health Care
a. The District Pharmacist
b. The Regional Pharmacist
c. SAAHIP
Chair: Ms R Abrie
Panel: Mr A Gray – President SAAHIP

10H00 ***TEA***

SESSION 6

10H15 Management of Asthma and the use of Inhaled Corticosteroids
Chair: Mr E Langa
Panel: Prof. A Gouws

12H15 Sponsors Hour — Hoechst Marion Roussel, Johnson & Johnson, Roche, Schering

13H00 ***LUNCH***

SESSION 7

14H00 Expenditure 1998/1999 Mr D Meyer

15H00 ***TEA***

SESSION 8

15H15 Budget 1999/2000 Mr D Meyer

16H45 Closure Mr K McCullough

17H00 In House Arrangements Mr J van der Nest

19H00 ***FORMAL DINNER***

APPENDIX V
Letters for support of Research in South Africa

Northern Province
DEPARTMENT OF HEALTH & WELFARE

TEL: (0152) 291 2637
(0152) 295 2851/2
(0152) 295 2987/8
FAX: (0152) 291 5961
(0152) 291 5146

PRIVATE BAG X9302
PIETERSBURG
0700

Enquiries : Sinah Mahlangu

Reference : Research & Quality Improvement
1 December 1998

Ms Ariel King

South African Drug Action Programme

273 Proes Street

PRETORIA

0001

Dear Ms King

AN EVALUATION OF THE FORMULATION AND IMPLEMENTATION OF THE NATIONAL DRUG POLICY, ESSENTIAL DRUG LIST AND STANDARD TREATMENT GUIDELINES IN PUBLIC HOSPITALS. A CASE STUDY OF GAUTENG AND NORTHERN PROVINCES

1. Permission is hereby granted to conduct a study on the above topic in the Northern Province
2. The Department of Health & Welfare needs a copy of the research findings for its own resource centre.
3. The researcher should be prepared to assist in interpretation and implementation of the recommendations where possible.
4. Implications: Permission should be requested from regional and institutional management to do research.

Sincerely,

Nicholas Crisp 02/12/98.

SUPERINTENDENT_GENERAL
DEPARTMENT OF HEALTH & WELFARE
NORTHERN PROVINCE

DR JAN MOOLMAN BUILDING
34 HANS VAN RENSBURG STREET
PIETERSBURG 0700

APPENDIX V
Letters for support of Research in South Africa

DEPARTMENT OF HEALTH

Verw/Ref:

AAN/TO: CHIEF DIRECTORS

From/Van: CHIEF DIRECTOR: REGISTRATION AND REGULATION

Enquiries: OMB PHARASI

Your ref:

Telephone: 312-0355

Dated:

Office No: 923 H

Date:

RE: RESEARCH: MS A KING

TO WHOM IT MAY CONCERN

This is to introduce to you Ms Arial King, PhD student at the London School of Hygiene and Tropical Medicine. Ms King is doing her PhD on the implementation of the South African National Drug Policy, and specifically she will investigate the impact of the introduction of the Essential Drug List for hospitals in the Northern and Gauteng Provinces.

I recommend that you support Ms King in her research efforts as the topic is of importance.

Kind regards

CHIEF DIRECTOR: REGISTRATION AND REGULATION
DATE: 12/1/99

APPENDIX W
Motivation Form for Ordering Brand Drugs

Department of Health and Welfare: Northern Province

NAMED PATIENT MOTIVATION FOR A NON-FORMULARY MEDICINE OR SURGICAL MATERIAL REQUEST

Kindly complete all sections. Please contact your pharmacist for assistance. Submit completed form to pharmacy.

To: The Secretary,
Provincial Therapeutics Committee/Therapeutics Control Committee

From: ..... hospital/district manager Tel:..... Fax..... Order no.....

Note: a) If more than one drug required for same condition, complete a separate motivation and attach.
b) For surgical materials, complete only the sections marked with an asterisk (*).
c) Department of Health & Welfare does not accept liability for unlicensed indication(s).

1. Patient details (please complete all fields)

Name ..... Age .....

Sex ..... Ward type (surgical etc.)..... Patient No ....

2. Medication required

Indication/condition.....

3. Tender details: Tender number RT...../..... Spec. No..... Item No. ..... Price...../.....

4. Is treatment for this indication approved/licensed by MCC? YES / NO

If "NO: are you prepared to accept liability? YES / NO

SAMF/ATC or pharmacological classification .....

*Approved name ..... *Proprietary name .....

Strength ..... Dose .....

Dose form ..... *Treatment period .....

*Quantity required .....

Note: chronics patients initially 2 months supply. Doctor to review patient after 1 months Rx. Then max. 3 months supply Thereafter, renew motivation.

*Current/previous treatment .....

.....

.....

*Reason why patient requires new treatment (attach copy of laboratory *antibiogram* if requesting an anti-infective agent) .....

.....

.....

APPENDIX W
Motivation Form for Ordering Brand Drugs

5. ***Drug utilisation data***

Is product listed in most recent edition of publications listed below?

SAMF (3rd ed.) YES / NO WHO Essential Drug list (1996) YES / NO

Reason for this request			*Reference(s):*
a.	Improved cost/benefit ratio	YES / NO	.....
b.	Improved benefit/risk ratio	YES / NO	.....
c.	Branded/proprietory product	YES / NO	.....

If a branded/proprietary product is requested, kindly supply details and references of bio-availability data .....

.....

d.	Increased potency/efficacy	YES / NO	.....
e.	To improve compliance	YES / NO	.....
f.	Special pharmacokinetics	YES / NO	.....
g.	Alternative not in formulary	YES / NO	.....

If alternative product not in formulary then please state what procedures/interventions etc. were previously used at your hospital .....

.....

h. Other (please specify) .....

Date ...../ ...../ ..... Prescribers signature .....

Note: 1. Only criteria based motivations will be considered.

2. Items required for emergency use will be referred to a Peer group, all others to next PTC meeting.

Approved	*Approved* .....
(Chairman: Hospital TCC)	(Secretary: Hospital TCC)

6. ***For PTC/TCC use only***

Formulary alternative	*List No.*	*Cost: formulary item*	*Cost: requested item*
1.....	.....	.....	.....
2.....	.....	.....	.....

7. PTC recommendation(s) Approved: YES / NO Reason/comments .....

.....

Date ...../...../..... Chairman .....

APPENDIX W
Motivation Form for Ordering Brand Drugs

PIETERSBURG HOSPITAL

APPLICATION FOR A RESTRICTED CODED ITEM

DATE: 20/09/19 REQUISITION NUMBER: .....

ITEM	(TABLET) / LIQUID / INJECTION / ETC.	STRENGTH	QUANTITY REQUIRED
REFLEX		500 mg	21

WARD / SECTION	NAME OF PATIENT	AGE	HOSPITAL NO. OF PATIENT	CLASSIFICATION OF PATIENT	DOSE	DURATION OF TREATMENT
GOPD	ELIZABETH SEBOLA	27yrs.	MV85008570		500mg tds	1/52

MOTIVATION: NOT RESPONDING TO USUAL GENERAL ANTIBIOTICS - ?AUGMENTIN COMPLEX.

ORDERED BY: (please print) MOLOMO J.J RANK: REGISTRAR SIGNATURE: .....

HEAD OF DEPARTMENT: (please print) ..... RANK: ..... SIGNATURE: .....

THIS FORM MUST BE SENT TO THE PHARMACY WITH THE PATIENT'S FILE

30 x 250mg Amoxycillin

MOTIVATION: NOT RESPONDING TO USUAL GENERAL ANTIBIOTICS - ?AUGMENTIN COMPLEX.

ORDERED BY: (please print) MOLOMO J.J RANK: REGISTRAR SIGNATURE: .....

HEAD OF DEPARTMENT: (please print) ..... RANK: ..... SIGNATURE: .....

THIS FORM MUST BE SENT TO THE PHARMACY WITH THE PATIENT'S FILE

30 x 250mg Amoxycillin

APPENDIX X
St. Rita's Newsletter

EDP NEWS

Contents

Cough mixtures - why are there no cough mixtures on the EDL?

In order to understand the logic behind the exclusion of cough mixture from the EDL we need to know more about coughing and why people cough.

Why do people cough?

Coughing is a useful reflex that helps the body to clear the air passages of foreign bodies or sputum. A foreign body inhaled can be mechanical like dust or chemical e.g. cigarette smoke. Natural secretions like sputum or phlegm increase when the patient suffers from a cold an allergy or asthma. A cough is said to be productive when sputum or phlegm is coughed out, clearing the breathing passages. Coughing is therefore a natural response to expel irritant or harmful substances from the airways. A cough also warns us that there is something in the air that is irritating to the airways.

Cough has been reported to be one of the most frequent reasons for a patient to visit a healthcare provider. In Australia it is the single most common reason for a patient to visit a doctor and accounts for more than 10% of all visits. American statistics have shown that coughing is among the five most common reasons for patients to visit a doctor and that it accounts for 30 million office visits a year in the US.

Cough mixtures are advertised all over - how can you say it does not work?

Many common respiratory conditions where coughing is prominent are self limiting -

APPENDIX X
St. Rita's Newsletter

Enclosed please find:
1.Clinic reference list
2.EDP news
3.Evaluation results

2ND EDL AVAILABLE

By now all clinics should have their copies of the second edition of the EDL.EDL now includes diagnostic flow diagrams to help you to determine whether to treat or refer.

The other very helpful feature is that the doses of medication for children are more specific.

CHANGES TO THE EDL

All tablets and syrups used for the management of Asthma are now phased out.Only inhalers are available.Please check the EDL for the management of Asthma.
There are no cough mixtures on the EDL.Check EDP news for more information.

TB REGIME

A combination of Rifampicin,Pyrizinamide,Isoniazid and Ethambutol is now available.These combination is called Rifater 4 and will be used to treat some patients.

BUDGET

Your monthly and yearly allocation of the budget has been given to you.This will help you to control your own clinic budget.
Check your invoice everytime you receive stock.

APPENDIX X
St. Rita's Newsletter

STOCK ABOUT TO EXPIRE

If some medications are about to expire and will not used before theexpiry date,please return them to the pharmacy a month before expiry.

GENERICS

Let's go Generics.
Let us get used to the generic names.Always use generic names during prescribing and arrangement of the pharmacy/medical cupboard.Use the attached reference list when problems are accountered with generic names or call the pharmacy.

APPENDIX X
St. Rita's Newsletter

NGWARITSI MAKHUDU

THAMAGA TUBATSE

STEELPOORT DISTRICT

CLINIC REFERENCE LIST

GENERIC NAMES	TRADE NAMES
Amoxycillin	Amoxil
Ciprofloxacin	Ciprobay
Cloxacillin	CLoxin
Co-Trimoxazole	Bactrim,Purbac,Cozole
Doxycycline	Doxycin
Erythromycin	Purmycin,Emu-V
Griseofulvin	Griseofulvin
Phenoxymethylpenicillin	Pen VK
Aluminium&magnesium	Gelusil
Aspirin	Aspirin
Atenolol	Tenbloka
Chlorpheniramine	Allergex
Folic&Ferrous fumarate	Fefol