Comparison of antimicrobial prescribing patterns with the Standard Treatment Guidelines and Essential Drug List in Primary Healthcare facilities in Vhembe District, Limpopo Province

by

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DECLARATION

I, **Makhado Mulatedzi** hereby declare that the work on which this discussion is based is original, except where acknowledgements indicate otherwise.

This dissertation is submitted for the degree of Master of Science (Medical) in Pharmacy at the University of Limpopo. Neither the whole work nor any part of it has been submitted before for any degree or examination at this or any other university.

Signed……..…… on the ……..…….. day of ……..

DEDICATION

I dedicate this thesis to my wife, Mrs Sharon Shonisani Makhado, my parent, Mr Wilson Ntsieni Singo and my children, Thakhani Portia, Lusani Cillian and Unarine Prudence for their love, support and patience during my studies.

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EDL	Essential Drug List
MDR	Multi Drug Resistance
NDP	National Drug Policy
PHC	Primary Healthcare
PTC	Pharmacy and Therapeutic Committee
STG	Standard Treatment Guidelines
STI	Sexual Transmitted Infections
URTI	Upper Respiratory Tract Infection
UTI	Urinary Tract Infections
WHO	World Health Organization

SUMMARY

Background:

The study was conducted in primary healthcare facilities in Vhembe district in Limpopo province, South Africa. Seeing that the National Drug policy was implemented in 1996 and followed by the Standard Treatment Guidelines, it was necessary to investigate if PHC facilities are prescribing according to the guidelines. Although the data collected was from five clinics, iinformation on antimicrobial prescribing patterns is necessary for a constructive approach to the challenges that arise from the vast number of antibiotics that are available in the market and the occurrence of resistance.

Objectives:

The aim of the study was to investigate whether prescribers at Primary Health Care (PHC) facilities in Vhembe district adhered to the Standard Treatment Guidelines/Essential Drug List (STG/EDL) when prescribing antimicrobials.

Method:

Five hundred antimicrobial prescribing patterns and patient demographics were recorded from five PHC facilities (100 prescriptions in each) in the Vhembe District, Limpopo Province over a two weeks period. In all PHC facilities, data collection of prescriptions focused on the period from 01 August 2007 until the required number of 100 prescriptions was reached.

Results:

Conditions where prescriptions complied to STG/EDL were skin infections and wound 91.67% (22/24), upper respiratory tract infection 86.49% (32/37), bronchitis 80% (4/5), ear/eye infections 75% (3/4), otitis media 57.14% (4/7), sore throat/tonsillitis 56.57% (56/99), urinary tract infection 37.5% (3/8), sexual transmitted infections 37.25% (19/51), bites 33.33% (1/3), and abscesses 25% (1/4). All other remaining 18 conditions that were listed as diagnosis did not comply at all. On overall only 29.2% (146/500) of prescriptions that were evaluated complied.

Conclusion:

Antimicrobial prescribing patterns adhering to the EDL/STD were low. Attention needs to be given to the prescribing of antimicrobials.

CHAPTER 1:
INTRODUCTION

1.1 Background

This study of prescribing patterns seeks to monitor, evaluate and suggest modifications in practitioners' prescribing habits so as to make medical care rational and cost-effective (Kutty, *et al., 2003;* Shankar & Roy, 2002). Information about antimicrobial prescribing patterns is necessary for a constructive approach to challenges that arise from the multiple antibiotics that are available (Srishyla, *et al. 1994).* Excessive and inappropriate use of antibiotics in hospitals, health care facilities and the community contributes to the development of bacterial resistance (Shankar *et al., 2003*).

The state-wide surveillance of in-hospital antimicrobial utilization in South Australia has found that antimicrobial resistance is now regarded as a significant and growing threat to public health worldwide. The emergence and dissemination of antimicrobial resistant organisms are known to be associated with antimicrobial use, and various strategies have been developed in recent years to alter antibiotic usage patterns to assist in the containment of this problem (Dollman & Cooper, 2003).

Educational programmes, including the development and promulgation of evidence-based clinical guidelines; continuing education sessions and media-based programmes aimed at promoting more rational antibiotic use and feedback on prescribing to individual clinicians have been developed for use in both community and health-care settings, with variable success.

In some institutions, restrictive measures such as antibiotic cycling, formulary restriction of certain antibiotics and the implementation of stop-orders and 'prior approval' requirements, either involving computer-based programmes or requiring specialist consultation, have also been employed in an attempt to modify prescribing patterns (Dollman & Cooper, 2003).

Antimicrobial resistance is currently the greatest challenge to the effective treatment of infections globally. Resistance adversely affects both clinical and financial therapeutic outcomes with effects ranging from the failure of an individual patient to respond to therapy and the need for expensive and/or toxic alternative drugs to the social costs of higher morbidity and mortality rates, required and/or longer durations of hospitalization, increased health care costs and the need for changes in empirical therapy (Essack, 2006).

The study on monitoring antibiotic use and resistance, a pilot study conducted in Durban, South Africa found that high usage of older antimicrobial agents was seen in public sector clinics (Gray & Essack, 2005).

This study aims to compare the antimicrobial prescribing pattyerns with the STG/EDL in PHC facilities.

It is important to carry out this study in the Limpopo Province because of the following:

- The number of motivations from facilities for non formulary antibiotics is increasing.
- Antibiotic group expenditure is always amongst the first five according to usage group report from Limpopo province.

In view of the challenges from the previous studies and the spiralling cost of sourcing antimicrobials, it is imperative to determine if prescribers are indeed following the Standard Treatment Guidelines/ Essential Drug List (STG/EDL).

According to the National Prescribing Centre (National Prescribing Centre, National Health Service (NHS), 2003), antibiotic resistance makes infectious diseases more difficult to treat and prevent and this can among other factors:

- Increase the length and severity of illness experienced by individuals
- Contribute to the spread of the disease
- Lead to the use of alternative drugs with lesser known safety profiles or
- Increase the financial costs of treatment and care

According to the Limpopo Province stock usage reports for August and September 2007 (Appendix A), antibiotics were among the top items contributing to the higher expenditure of medicine procurement.

Some previous studies conducted (Bharathiraja *et al.*, 2005) revealed factors that influence antibiotic prescribing as:

- Educational qualification of the prescriber
- Experience of the prescriber
- Source of updating knowledge
- Practice setting
- Age of a child

Patient expectation and the desire to maintain the prescriber-patient relationship are widely recognised as important factors in the decision to prescribe antibiotics (National Prescribing Centre, National Health Service (NHS), 2003).

The research of antimicrobial prescribing patterns is of greater importance as the antibiotic usage in Limpopo Province is amongst the top five drug groups by value. Furthermore, training on rational prescribing was conducted between 1997 and 2000 in the province and the research will seek to investigate the adherence to STG in prescribing antimicrobials at primary healthcare (PHC) level.

Serious infections caused by bacteria that have become resistant to commonly used antibiotics have become a major global healthcare problem in the 21st century. They not only are more severe and require longer and more complex treatments, but they are also significantly more expensive to diagnose and to treat. Antibiotic resistance, initially a problem of the hospital setting associated with an increased number of hospital acquired infections usually in critically ill and immunosuppressed patients, has now extended into the community causing severe infections difficult to diagnose and treat. The molecular mechanisms by which bacteria have become resistant to antibiotics are diverse and complex. Bacteria have developed resistance to all different classes of antibiotics discovered to date (Alanis, 2005).

Studies have been conducted about the antimicrobial prescribing patterns in South Africa such as antimicrobial prescribing patterns in a group of private PHC clinics in South Africa (Katenda-Kyenda *et al.,*2007*)* and World Health Organization (WHO) study on comparison

of antimicrobial prescribing patterns in the Madibeng district with STG/EDL (WHO, 2009) and nothing similar was found for Limpopo province PHC facilities and hence the greater need to conduct similar studies in Vhembe District.

Outside South Africa, it was also found that similar studies were conducted and the examples are antibacterial prescribing in primary care (Petersen & Hayward,2007), antimicrobial prescription patterns for common acute infections in some rural and urban health facilities in India (Kumari Indira *et al.,* 2008) and challenges in antibiotic use, cost and consumption after an antibiotic restriction policy applied by infectious disease specialists (Ozkurt *et al.,* 2005).

As medicines funding is one of the challenges that are experienced on yearly basis in Limpopo province and the fact that antimicrobials represent the most expensive therapeutic group among medications used in hospitals, and their use comes at a cost, not only of the medicine itself, but of side-effects and promoting ever-growing bacterial resistance to antibiotics (Kali & Swingler, 2003), it is envisaged that the study will have a significant impact on the field.

The study is aimed at filling the gap and lead to a greater understanding of the extent of challenges on the prescribing patterns of antimicrobials in the primary healthcare facilities in Vhembe district in Limpopo province, South Africa.

Studies conducted found that:

- The overall compliance rate to STG/EDL for antimicrobials prescribed in Madibeng district in North West province, South Africa, was 67.6% (*WHO, 2009)*

- The mean number of drugs per prescription should be as low as possible since higher figures increase the risk of drug interaction, risk of bacterial resistance, non-compliance and cost (Kutty *et al.,* 2002)
- There remains a great need to restrict the use of antibiotics by doctors in general and to manage the expectations of patients over the value and necessity of antibiotics for simple infections particularly where they are of viral aetiology. There is also a need for further training of physicians, including reducing their reliance on pharmaceutical industry information, as well as legal measures to control the sale and spread of antibiotics (Balabanova *et al., 2004)*
- Quickening the availability of culture and sensitivity reports will enable the treatment to have a sound bacteriological basis. Antibiotic resistance is becoming a problem and formulation of a hospital antibiotic use policy is a matter of urgent concern. An educational programme and an antibiotic order form may be useful initiatives to reduce antibiotic use. Guidelines for antibiotic use in the community and restricting the level of health care practitioners who can prescribe antibiotics are required (Shankar *et al., 2003)*
- High levels of resistance are prevalent within public sector hospitals in South Africa. It is imperative to investigate causes and implement strategies for prevention and control in a healthcare system and South African community ill-equipped to deal with the financial, therapeutic and social implications of resistance (Essack, 2006)
- Preference for prescribing first line medicines in public/government health facilities in India matched the

availability of antimicrobials in the hospital pharmacy (Kumari Indira, 2008)

- The Durban pilot project has shown that surveillance can be done in a developing country setting, but that there are many problems that need to be overcome. The real challenge will be to make this a routine part of the health care system, so that ongoing efforts to improve antimicrobial use and to limit the spread of resistance can be planned and monitored (Gray & Essack, 2005)
- Injudicious antibiotic prescribing is rather high and should be reduced to modest levels (Ayranci *et al.*, 2005)
- It is high time that the professional bodies should take up the project of increasing awareness about antibiotic use among the practicing physicians to dispel the inappropriate information caused by pharmaceuticals and initiate necessary steps to deliver the latest advances of the knowledge to every practicing physician through academic activities in order to check over this emerging problem of antibiotic resistance (Bharathiraja *et al.*, 2005)

1.2 The aim of the study

The aim of this study was to compare the antimicrobial prescribing patterns with the STG/EDL in PHC facilities in Vhembe district, Limpopo Province, South Africa.

1.3 The objectives of the study

The specific objectives of the study were:

1) To document the antimicrobials prescribed
2) To document the indication and symptom complex for which antimicrobials were prescribed

3) To measure compliance of antimicrobial prescriptions patterns to the STG/EDL

1.4 Motivation for the study

After the implementation of the National Drug Policy (NDP) in 1996 (Department of Health, 1996), all facilities were expected to be in line with the adopted policy and hence the motivation to do research in order to verify if facilities are indeed prescribing according to the STG.

According to the study conducted on "Strategies for the prevention and containment of antibiotic resistance" it was found that the widespread use of available antibiotics has resulted in specific antibiotic resistance mechanisms in specific health care settings (*Essack, 2006).*

The NDP encourages the need to continuously embark on research on social and cultural factors which influence medicine usage. This research will assist in facilitating subsequent interventions to alter attitudes and beliefs which are found to contribute to the irrational use of drugs and to prioritize and tackle challenges of misuse which are identified as being particularly serious.

According to the Limpopo Province stock usage report for August and September 2007, items like erythromycin tablets, amoxycillin capsules and flucloxacillin capsules were among the top antibiotics used in August and September 2007.

Antimicrobial items constitute a higher percentage in expenditure and have always been in the top 5 groups of items by value and hence the need for conducting the study to determine compliance to STG.

1.5 The significance of the study

One of the health objectives of the South African NDP is to ensure the availability and accessibility of essential drugs to all citizens. This can be achieved by prescribing drugs in accordance with recommended STG/EDL (Department of Health, 1996).

The WHO Global Strategy defines the appropriate use of antimicrobial agents as "the cost effective use of antimicrobials which maximises clinical therapeutic effect while minimising both drug related toxicity and the development of antimicrobial resistance" (WHO, 2001).

National governments and health care systems can have considerable impact on limiting the emergence and development of antimicrobial resistance through the introduction of legislation and policies concerning the development, licensing, distribution and sale of antimicrobial agents National governments also have the responsibility for coordinating surveillance networks and for directing educational efforts to improve understanding about appropriate antimicrobial use (WHO, 2001).

Following the adoption of the NDP (Department of Health, 1996) and the implementation of the STG/EDL (Department of Health, 1998), it would be necessary to evaluate and conduct research on the use of antibiotics in South Africa. The STG in South Africa has been updated and the fourth edition for PHC has now been published and distributed to the provinces (Department of Health, 2008).

CHAPTER 2:
LITERATURE REVIEW

2.1 Introduction

This chapter describes the literature review of some of the studies done on antimicrobial prescribing patterns. For the purpose of this study, definitions of antibiotic and antimicrobial was also elaborated and the review is in the format of definitions, antimicrobial agents, emerging antibiotic resistance, control of antibiotic resistance, approaches to optimizing antibiotic use, PHC EDL and a conclusion.

2.2 Definitions

Antibiotic is defined as a drug used to treat infections caused by bacterial and other microorganisms (Medical Dictionary, 2008).

Anti-infective: Something capable of acting against infection, by inhibiting the spread of an infectious agent or by killing the infectious agent outright. Anti-infective is a general term that encompasses antibacterials, antibiotics, antifungals, antiprotozoans and antivirals (Medical Dictionary, 2008).

Antimicrobial: A drug used to treat a microbial infection. Antimicrobial" is a general term that refers to a group of drugs that includes antibiotics, antifungals, antiprotozoals, and antivirals (Medical Dictionary, 2008).

Antibiotic resistance: The ability of bacteria and other microorganisms to withstand an antibiotic to which they were once sensitive (and were once stalled or killed outright). Also called drug resistance (Medical Dictionary, 2008).

Irrational use of medicines is a major problem worldwide. It is estimated that half of all medicines are inappropriately prescribed, dispensed or sold and that half of all patients fail to take their medicine properly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards (WHO, 2004).

2.3 Antimicrobial Agents

2.3.1 Antibiotic Use

The ten most common causes of antibacterial prescribing identified in a study (Petersen & Hayward, 2007) were:

- Upper respiratory tract infection,
- Lower respiratory tract infection,
- Sore throat,
- Urinary tract infection,
- Otitis media,
- Conjunctivitis,
- Vague skin infections without a clear diagnosis,
- Sinusitis,
- Otitis externa, and
- Impetigo.

The researchers further found that for some of these conditions over 80% of cases were being treated with antibiotics, despite the fact that guidance recommend against antibiotics for:

- Sore throat,
- Otitis media,
- Upper respiratory tract infections, and

- Sinusitis.

2.3.2 Cost

Medicines consume a significant portion of the total health care budget. Equitable access to affordable medicines remains a challenge. In accordance with the NDP, the STG and Essential Medical List ensure the cost-effective treatment options are available to citizens of the country, and seeks to build capacity in health care workers at the PHC level (Department of Health, 2008).

Antibiotics are among the most frequently used drugs worldwide. They are particularly utilized in developing countries, where an average of 35% of the total health budget is spent on antibiotics (Isturiz & Carbon, 2000).

In Limpopo Province, where the study was conducted, the antibiotics expenditure for the financial year 2007/2008 (01 April 2007 -31 March 2008), was (R32,836,327.98) 8.29% of the total issues in the province.

2.3.3 Emerging antibiotic resistance

Antimicrobial resistance is the ability of microbes, such as bacteria, viruses, parasites, or fungi, to grow in the presence of a chemical (drug) that would normally kill it or limit its growth (Dollman & Cooper, 2003).

Antimicrobial resistance is now regarded as a significant and growing threat to public health worldwide. The emergence and dissemination of antimicrobial resistant organisms are known to be associated with antimicrobial use, and various strategies have been developed in

recent years to alter antibiotic usage patterns to assist in the containment of this problem (Dollman & Cooper, 2003).

The most frequent type of resistance is acquired and transmitted horizontally via the conjugation of a plasmid. In recent times new mechanisms of resistance have resulted in the simultaneous development of resistance to several antibiotic classes creating very dangerous multidrug-resistant (MDR) bacterial strains, some also known as ‘‘superbugs’’. The indiscriminate and inappropriate use of antibiotics in outpatient clinics, hospitalized patients and in the food industry is the single largest factor leading to antibiotic resistance. In recent years, the number of new antibiotics licensed for human use in different parts of the world has been lower than in the recent past. In addition, there has been less innovation in the field of antimicrobial discovery research and development. The pharmaceutical industry, large academic institutions or the government are not investing the necessary resources to produce the next generation of newer safe and effective antimicrobial drugs. In many cases, large pharmaceutical companies have terminated their anti-infective research programmes altogether due to economic reasons (Alanis, 2005).

According to the STG/EDL MDR tuberculosis is usually the result of irregular adherence to tuberculosis treatment and is identified when there is resistance to rifampicin and isoniazid on sputum culture sensitivity testing. The current regimen is 18 – 24 months and the cure rate is only between 30 – 50% (Department of Health, 2008).

The mechanisms by which drug resistance occurs can be summarized as follows (Goodman and Gilman, 2001; Tenover, 2006):

- Antibiotic inactivating enzymes e.g. ß-lactamases, aminoglycoside modifying enzymes, chloramphenicol acetyl transferase etc.
- Impaired uptake of antibiotics which can be natural due to cell envelope characteristics. In the case of acquired resistance changes in porins may interfere with antibiotic transport.
- Drug efflux may be the operative mechanism in some cases. Mutations result in over expressions in some cases.
- Modification of the target resulting in less avid binding of the antibiotic is the mechanism seen commonly in *ß*-lactam resistance in gram positive organisms *e.g. Streptococcus pneumoniae* and *S. aureus*. An extreme example due to ribosomal modification that makes streptomycin resistant organisms uses the antibiotic as a growth factor.

  Development of an alternate metabolic pathway would allow the bacteria to grow in the presence of the antibiotic. This mechanism is seen in glycopeptide, aminoglycoside, macrolide, sulpha/trimethoprim resistance amongst others.

2.3.4 Control of antibiotic resistance

In a study conducted on the control of antimicrobial resistance (Carbon *et al.* 2002) it was found that all strategies aim at optimizing the antibiotic stress in the environment, decrease unintended interaction between antibiotics and pathogens, restrict the spread of resistant organisms and treat infections with the minimum amount of antibiotic necessary to affect cure. Towards this end a number of countries have evolved national programmes that tackle the complex issue. The common methods being focused on are:

- Surveillance of antibiotic use and resistance rates

- Optimizing antibiotic use with treatment guidelines
- Education of professionals and the public
- Prevention with infection control measures and immunization
- Industry involvement, financial resource mobilization and drug development
- Regulatory issues with central prescribing restrictions and advertising restrictions
- Audit with evaluation of interventions, audit of compliance and physician feedback
- International cooperation.

The objective will be successful if a common infection like a cold is precisely diagnosed and treated with the right antibiotic for the shortest time to ensure eradication of the bacterial infection when it occurs. We have a long way to go before we achieve this seemingly simple objective even in industrialized affluent countries.

According to a study conducted on the emerging antimicrobial resistance in bacteria with special reference to India (Raghunath, 2008), the initial steps still need to be taken. Antimicrobial resistance is a major emerging infection and needs to be tackled as such.

2.4 Approaches to optimizing antibiotic use

2.4.1 National policy and STG/EDL

To optimize antibiotic use, the WHO has recommended establishing and maintaining updated national STG's, to establish an EDL consistent with national STGs and ensure the accessibility and quality of these drugs (WHO, 2001).

On the EDL implementation strategy by different countries, the WHO Medicines Strategy 2004-2007 was developed by WHO country, regional, and headquarters staff working in essential drugs and medicines policy, in consultation with other WHO Programmes and with key development partners (WHO, 2004).

In response to these challenges, WHO provides policy guidance and country support to help improve access to essential medicines and assure their safety, quality, and rational use. Over the past four years, over 120 countries worldwide have been supported in this way. Recent achievements include:

- Implementation of a global system for monitoring country progress in medicines, including the use of household surveys, to assess the affordability, availability, source, and appropriate use of medicines
- Expansion of information on comparative medicine prices worldwide to ensure that countries and consumers do not have to pay more than necessary for essential medicines
- Revision of essential medicines selection process to ensure a more evidence-based, independent, and transparent selection process. Reasons for selection are published on the WHO Medicines Library website, together with comparative information on prices and the WHO Model Formulary
- Support to efforts to expand access to medicines — including for HIV/AIDS, TB, and malaria, and other priority diseases — through progress on critical issues such as selection, regulation, quality assurance, prices, and monitoring of trade agreements.

In responding to country needs, WHO is ensuring the implementation and monitoring of national medicines policies, with a focus on:

- Continued support to ensure that all countries develop a national medicines policy and that these are implemented, monitored, and regularly updated in line with broader health and development objectives
- Supporting countries in their efforts to use public health safeguards in international, regional, and bilateral trade agreements to improve access to priority medicines
- Promoting and monitoring: access to essential medicines as a fundamental human right; public investment in medicines R&D, especially for neglected diseases; and ethical practices in the pharmaceutical sector
- Implementation of WHO's strategy for traditional medicine to ensure affordable access, protection of intellectual property rights, and guidance on safety, efficacy, and quality assurance.

Other areas explored were ensuring equitable financing, affordability, and delivery of essential medicines (access), with a focus on:

- Expanding access to quality essential medicines for priority diseases, especially HIV/AIDS, through development and use of standard treatment guidelines, prequalification of new medicines, market intelligence on prices, and guidance on issues such as patents
- Strengthening medicines supply systems through country assessments, promotion of 'best practices', and medicines supply management training
- Promoting establishment of sustainable ways of financing medicines expenditure through health insurance schemes.

On the issue promoting therapeutically sound and cost-effective use of medicines by health workers and consumers (Rational use of medicine), the focus is on:

- Efforts to increase rational use of medicines among prescribers and consumers through working with health insurance systems to promote the use of essential medicines.
- Training, networking, and information exchange to promote the rational use of medicines in an effort to prevent deaths and illness and reduce medicines expenditure.

Some of the statistics on the implementation according to Country Progress Indicators for Expected Outcomes of WHO Medicines Strategy 2004-2007 (WHO, 2004) are shown in Table 2.1.

Table 2.1: Country progress indicators for expected outcomes of WHO medicines strategy 2004-2007

Indicator	1999 # Repor-ting	1999 %	2003 Target	2003 # Repor-ting	2003 %	Target
Countries monitoring adverse drug reactions	56/191	29%	35%	72/192	38%	45%
Countries with an official national medicines policy document—new or updated within the last 10 years	67/152	44%	55%	62/123	50%	59%
Countries with a national medicines policy implementation plan—new or updated within the last 5 years	41/106	39%	43%	49/103	48%	61%
Countries having conducted a national assessment of their pharmaceutical situation in the last 4 years				47/90	52%	58%
Countries providing free medicines for pregnant women at primary public health facilities				54/106	51%	60%
Countries with medicines legislation requiring transparency, accountability and code of conduct for regulatory work				84/114	74%	80%
Countries where less than 50% of the population has access to essential medicines	29/184	16%	14%	15/103	15%	14%
Countries with public sector procurement limited to national essential medicines list	71/133	53%	60%	84/127	66%	74%
Countries with at least 75% of public sector procurement carried out by competitive tender	81/88	92%	95%	58/70	83%	87%
Countries with DTCs in the majority of regions/provinces				32/96	33%	40%
Countries with national strategy to contain antimicrobial resistance				37/113	33%	40%
Countries that have undertaken a national assessment/study of the rational use of medicines				57/97	59%	60%
Countries with basic system for regulating pharmaceutical promotion	92/132	70%	80%	83/113	73%	76%

Source: (WHO, 2004)

In a study conducted by Krause in Burkina Faso (Krause *et al.*, 2000), the aim was to assess how the diagnosis and the treatment in rural health services complied with the STG and how patients adhered to prescriptions dispensed to them by providers.

The recommendations of this study included:

- The emphasis should be on rational diagnostic procedures in the professional training of healthcare providers and in continuous professional development
- Motivating healthcare providers should equip patients with clear drug taking information when taking their prescriptions
- Increasing and improving supervision of rural healthcare providers should enhance compliance with existing standard treatment guidelines
- Evaluation should be done on existing standard treatment guidelines for diagnosis and treatment (Krause *et al.*, 2000).

A study on drug prescribing patterns in Madurai City, India found that medical audit which seeks monitoring, evaluation and necessary modifications in the prescribing practices are necessary to achieve rational and cost-effective medical care (Kutty *et al.*, 2002).

In “child health research project special report” it was found that drug use and prescribing behaviours tend to be determined by a complex and multi-layered mix of medical, psychosocial, cultural, economic and even geopolitical factors, including:

- Access and non-access to antimicrobial drugs
- Poor diagnostic skills
- Economic factors
- Patient pressure

- Poor education of health workers
- Promotional activities of pharmaceutical companies.

Consequently, attempts to improve antibiotic use are much more complicated than the mere training of prescribers, dispensers, or users of these drugs (Radyowijati & Haak, 2002).

According to the NDP of South Africa one of the objectives for appropriate prescribing is to ensure that all drugs are prescribed in accordance with recommended standard treatment guidelines and the essential drug list. It further states that pharmacists have a special role in quality assurance and in the safe and effective administration of drugs as well as being involved in a multi-disciplinary approach to the rational utilization of drugs (Department of Health, 1996).

According to the South African NDP (Department of Health, 1996), the pharmaceutical sector, which is one of health component sector, reflected a deficiency of lack of equity in access to essential medicines. These prompted the National Department of Health to look at ways of developing and implementing the NDP that will be in line with the New Health Policy, which aims at equity in provision of health care for all citizens.

One of the aims under the use of generic drugs (Item 4.2 of the NDP) was to achieve generic prescribing in both public and private sector, a factor that motivated the researcher to look at the current status after the implementation of the policy.

The South African Government outlined the commitment to ensure continuous availability and accessibility of medicines to all the people. The health objectives according to the NDP, 1996 were:

- Ensuring accessibility and availability of medicines to all citizens
- Ensuring that medicines that are dispensed to people are safe, effective and of good quality
- Ensuring that rational drug prescribing and good dispensing practices are observed at all times
- Promoting rational use of medicines by prescribers, dispensers and patients
- To promote the concept of patients being responsible for their health

2.4.2 Institutional guidelines

According to the South African NDP (Department of Health, 1996), in order to achieve the objectives of the NDP, not only the supply of medicine is of paramount importance but also the development of the human resource.

With rational use of drugs, the aim 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 community. This aim will be achieved by ensuring that all health care personnel that are involved in diagnosis, prescribing and dispensing are adequately trained.

More emphasis on appropriate prescribing is to ensure that all drugs are prescribed by generic name in accordance with STG/EDL. The Department of Health will collect, evaluate and disseminate systemic data on drug utilization to monitor and act on policy adherence.

Pharmacists have special roles to play in ensuring that prescribers are adhering to the STG/EDL. The South African NDP stipulated the following roles for the pharmacists:

- Promote rational use of drugs
- Ensure that medicines are of good quality, safe and effective
- Primary Health Care and Preventive Health Services
- Involvement in multi-disciplinary approach to the utilization of drugs
- Required to have scientific source of reference

2.4.3 Pharmacy and Therapeutic Committees

Pharmaceutical and Therapeutics Committee (PTC) can be defined as the committee that evaluates the clinical use of medicines, develops policies for managing medicine use and administration, and manages the formulary system (WHO, 2003).

The PTC is an essential component of a health care organization's medicine selection, use, and distribution programme. This committee has many different functions that will contribute to the goal of improving medicine selection and rational medicine use (WHO, 2003).

Many countries will spend 30 to 40 percent of their health care budgets on medicines and much of that money is wasted on irrational medicine use and inefficiencies in procurement of medicines. Other serious problems that health care organizations face includes the overuse of antibiotics, increasing antimicrobial resistance, increasing adverse drug reactions, and considerably higher costs associated with medicine use. PTC's can provide the leadership and structure to select appropriate medicines for the formulary, identify medicine use

problems, promote rational medicine use, and help reduce medicine costs to acceptable levels (WHO, 2003).

A health care organization's Pharmaceutical and Therapeutics Committee has numerous responsibilities that, when performed successfully, will have a positive impact on health care. The overall value of the PTC is not easily measured, but many authorities agree that it is one of the most important components of a comprehensive health care system. Some of the important benefits of a functioning PTC are:

- Selection of effective, safe, high-quality, and cost-effective pharmaceuticals for the formulary
- Improved medicine use, including antimicrobial use
- Management of antimicrobial resistance
- Improved quality of patient care and health outcomes
- Increased staff and patient knowledge (WHO, 2003)

According to PHC STG and Essential Medicine list in South Africa, it should be noted that the PHC essential medicine list reflects only the minimum requirements for PHC level facilities. In keeping with the objectives of the NDP, provincial and local Pharmacy and Therapeutic Committees should provide additional drugs from the Hospital level EDL based on the services offered and the competency of the staff at each facility (Department of Health, 2008).

2.5 PHC STG/EDL in South Africa

According to the South African PHC EDL (Department of Health, 2003); the supply of medicines is very crucial in order to achieve effective and efficient healthcare services to the community in the

country. The approaches used in the STG/EDL to optimize drug use at primary health care level are described below.

2.5.1 Working principles

The working principles used by the national EDL committee to come with the EDL/STG for PHC were:

- Conditions to be included are those that comprise the majority of contacts at the PHC level
- Treatment for the conditions will be initiated at the PHC level and will be competency based and not restricted to specific occupations
- Treatment will be according to the STG, which will specify both treatment and referral details
- Scheduling of drugs through drug legislation will enable health workers at primary level to access recommended drugs.

Through the STG's, the objectives of rational prescribing and optimal therapeutic outcome are virtually ensured. The use of EDL and STG's are mandatory at all public sector facilities.

2.5.2 Conditions where antimicrobials are recommended

The following sections briefly describe the conditions where antibiotics are recommended by the South African STG/EDL for primary health care (Department of Health, 2003).

Sore Throat / Tonsillitis

According to the PHC STG, tonsillitis is commonly caused by the beta-haemolytic streptococci group A and the clinical features are sore throat with pain while swallowing, inflamed tonsils with white

patches, enlarged cervical lymph nodes and often associated with sudden onset of fever (Department of Health, 2003).

Tonsillitis caused by *Streptococcus spp* must be treated with penicillin or other suitable antibiotics in order to prevent the development of rheumatic fever. Phenoxymethylpenicillin is the drug of choice to use, unless the patient has an allergy to it. It should be given by mouth twice daily for at least 10 days. Taking penicillin for shorter time periods may not completely clear up the infection.

For penicillin-allergic patients, erythromycin, oral, 6 hourly should be given before meals for 10 days in the same dosage as Phenoxymethylpenicillin. Paracetamol is given for pain relief when required to a maximum of four doses daily (Department of Health, 2003).

Cough

Coughing is a normal response to the presence of mucus or other foreign material in the airway or upper way, but persistent coughing is annoying and generally indicates irritation of the pulmonary airways (Beers *et al.*, 2006)

Likely aetiologies of cough differ depending on whether the symptom is acute or chronic. Acute cough is most often caused by Upper Respiratory Tract Infections (URTI), especially the common cold. Other causes include pneumonia, postnasal drip resulting from rhinitis or sinusitis that can be allergic, viral or bacterial in origin. Chronic cough is most often caused by chronic bronchitis, defined as the presence of productive cough over three months for two consecutive years (Beers *et al.*, 2006).

In drug treatment, cough mixtures have no effect on the course of the underlying condition. For children Tussi infants Rx, oral, 8 hourly for 3 days is the drug of choice while Expect stim Rx, oral, 10ml 8 hourly will be the treatment of choice for adults (Department of Health, 2003).

Common Cold

Colds and influenza are self-limiting viral conditions; generally symptoms begin to clear within 3 days. For common cold or flu with no complications paracetamol is the treatment of choice (Department of Health, 2003).

Colds present with nasal stuffiness and throat irritation. In addition influenza presents with headache, muscular pain and fever. Antibiotics are of no value to the treatment of the common colds and influenza (Department of Health, 2008)

Fever

Fever, i.e. temperature of 38 degree Celsius or more is a natural and sometimes useful response to infection, inflammation or infarction. Fever alone is not a diagnosis. Temperature above 40 degree Celsius needs urgent lowering with evaporative cooling. For patients with heat stroke or fever not responding to paracetamol: place patient in cool place, remove clothing, cover patient with a wet sheet or towel, keep the sheet or towel wet with regular sponging and fan the patient (Department of Health, 2008).

Fever and pain can be treated by paracetamol when required to a maximum of four doses daily (Department of Health, 2003).

Fever may be as a result of infection or one of the sequelae of tissue damage, inflammation, graft rejection, malignancy, or other disease states. A common feature of these conditions is the enhanced formation of cytokines and interferons. The cytokines increases the synthesis of prostaglandins E2 in circumventricular organs in and near to the preoptic hypothalamic area, and Prostaglandins E2, via increases in cyclic AMP, triggers the hypothalamus to elevate body temperature by promoting increase in heat generation and decrease in heat loss (Gilman *et al.*, 2001).

Upper Respiratory Tract Infection

The upper respiratory tract (URTI) consists of the nose, sinuses, adenoids, the throat, pharynx and tonsils, the middle ear and eustachian tubes therefore, the respiratory tract above the larynx is called the upper respiratory tract.

Upper respiratory tract infections include otitis media, sinusitis, pharyngitis, laryngitis (croup), rhinitis, and epiglottitis. Most nonspecific upper respiratory tract infections have a viral, not bacterial, etiology and tend to resolve spontaneously. Appropriate use of antibiotic treatment can minimize morbidity and potentially prevent complications (DiPiro *et al.*, 2005).

The term “URTI” is probably a misnomer as it incorrectly implies an absence of lower respiratory tract symptoms. URTI occurs commonly in both children and adults and is a major cause of mild morbidity. URTIs have a high cost to society, being responsible for missed work and unnecessary medical care. Occasionally they have serious

sequelae. Often regarded as trivial, URTIs do not receive serious attention in medical school curricula (Cotton *et al., 2008).*

URTI is not listed as a standalone condition in the South African STG/EDL guidelines for PHC level.

Urinary Tract Infection (UTI)

A UTI is defined as the presence of microorganisms in the urinary tract that cannot be accounted for by contamination. The organisms present have the potential to invade the tissues of the urinary tract and adjacent structures. Infection may be limited to the growth of bacteria in the urine, which frequently may not produce symptoms (Di Piro *et al.*, 2005).

The bacteria causing UTIs usually originate from bowel flora of the host. Although virtually every organism is associated with UTIs, certain organisms predominate as a result of specific virulence factors. The most common cause of uncomplicated UTIs is *Escherichia coli*, which accounts for 85% of community acquired infections. Additional causative organisms in uncomplicated infections include *Staphylococcus saprophyticus* (5% to 15%), *Klebsiella pneumoniae*, *Proteus* spp, *Pseudomonas aeruginosa* and *Enterococcus* spp (5% to 10%) (DiPiro *et al.*, 2005).

UTI is an acute condition, in most cases caused by *Escherichia coli*. Other micro-organisms may be present, especially in patients previously managed in hospitals. Uncomplicated UTIs occurs in women who are menstruating and have normal renal tracts. All other UTIs (including children and men) are seen as complicated (Department of Health, 2003).

The signs and symptoms of UTI include:

- Burning or pain on passing urine (dysuria)
- Frequent passing of small amounts of urine
- In more severe cases there is lower abdominal pain and tenderness
- Children may present with non-specific symptoms such as diarrhea and upper respiratory symptoms
- Urine may be turbid and/or bloodstained and test positive for leucocytes and nitrites

The recommended treatment protocols for UTI as per the South African STG/EDL are shown in Chapter 3 (Table 3.3).

Sexually Transmitted Infections (STI's)

The syndromic approach to STI diagnosis and management is to treat the signs or symptoms (syndrome) of a group of diseases rather than treating a specific disease. This allows for the treatment of one or more conditions that often occur at the same time and has been accepted as the management of choice. It is important to provide the patient with information and counseling on the importance of:

- Compliance with treatment
- Prevention of the complications of STI's
- Risk reduction for acquiring STI's
- Promotion and provision of condoms and demonstration of their use
- Tracing and management of sexual contacts (Department of Health, 2003)

The recommended treatment protocols for STI in South African public sector primary health care treatment facilities are shown in Chapter 3 (Table 3.4).

2.6 Conclusion

It is clear that the rational prescribing of antibiotics poses a great challenge to the community as this may lead to the development of drug resistance, a factor that may negatively affects the service delivery to the community and the already scarce resources for medicine funding.

The methodology of the study is described in the next chapter.

CHAPTER 3:
METHODOLOGY

3.1 Introduction

This chapter describes the methodology of the study to compare antimicrobial prescribing patterns with the STG/EDL in PHC facilities. The sampling method is provided, the setting is discussed and the chapter ends with discussion of the ethics of the study.

The general aim of this study was to compare the antimicrobial prescribing patterns with the STG/EDL in PHC facilities in Vhembe district, Limpopo Province, South Africa.

The specific objectives of the study were:

1) To document the antimicrobials prescribed
2) To document the indication and/or symptom complex for which antimicrobials were prescribed
3) To measure the duration of treatment, frequency of administration and generic names
4) To measure compliance of antimicrobial prescribing patterns to the STG/EDL

3.2 The design of the study

3.2.1 Research design

A retrospective, quantitative, descriptive study approach was followed.

3.2.2 Study period

The study was conducted from 20 July to 08 August 2008.

3.2.3 Setting and study site

The study was conducted in Vhembe District. This district has approximately 120 PHC facilities. The following facilities participated in the study: Makhado, Rumani, Madombidzha, Nkhensani and Tshisahulu.

Criteria of selection for the study were:

- Convenience and closeness to the researcher's residence
- Comparable monthly patient statistics

3.2.4 Sampling

A preliminary check on PHC head counts for average monthly patient's prescription showed that almost the same number of patients is seen in the facilities selected on monthly basis as reflected in Table 3.1 below:

Table 3.1: PHC headcount

PHC Clinics	Average number of patients visits per month	Number of prescriptions assessed
Madombidzha	6 008	100
Makhado	6 654	100
Tshisahulu	6 424	100
Nkhensani	6 520	100
Rumani	6 573	100

The sample size was 100 prescriptions from each of the five PHC facilities. This number was determined after taking the number of patients visiting the clinics and the average percentage of patients with prescriptions (40%) determined by previous studies in the

National Department of Health and the recommendation from the statistician into consideration.

The 100 prescriptions at each facility were selected by looking at the prescription records from the period commencing 01 August 2007, and documenting all prescriptions with at least one antibiotic until the target number of 100 was reached.

3.3 Data collection

3.3.1 Data collection procedure followed

This study was carried out in the rural region of the Vhembe District in the Limpopo Province, South Africa, over a period of two weeks. All five clinics were assessed using PHC facility data collection form (Appendix B) in order to determine the compliance of prescribing patterns to the STG/ EDL.

All PHC clinics were informed at least two weeks before the expected date of data collection. Communiqué was through clinic telephone numbers, cellphone numbers of clinic supervisors and physical visit by delegated colleague.

3.3.2 Collection of data

- Records from patients' prescriptions book from the five participating PHC facilities were used. Data of 100 antimicrobial prescriptions were obtained and recorded using the PHC Facility Data Collection forms from each participating PHC facility.
- The age and gender of patients, patient diagnosis and symptom complex, duration of treatment, drugs prescribed, strength and

frequency were recorded as entered on the PHC facility data collection form.

3.4 Data consolidation, analysis and interpretation

Results were tabulated, a descriptive statistical analysis was performed and findings were presented graphically.

The recorded diagnosis and symptoms were grouped according to EDL/STG index. The total number of prescriptions dispensed for each indication were counted and expressed as percentages of the total number of prescriptions. For conceptual simplicity and to provide sufficient numbers of episodes for analysis, different diagnoses were combined into complexes. For example, the diagnosis for pain related conditions were combined together as miscellaneous pain for the analysis. A complete list of diagnoses and complexes are shown in Chapter 4 (Table 4.4).

The data were then sorted in excel format in accordance to what was to be analysed. Different graphs and tables were extracted from the excel spreadsheet and they are reflected in the document.

3.5 Gold standards for treatment

As a next step, the prescriptions were analyzed for compliance with the South African STG/EDL for PHC level. Antimicrobial patterns of prescriptions were compared to the recommendations indicated in the STG/EDL. Table 3.2 gives a reference of the relevant pages.

Table 3.2: Conditions where antibiotics should be used at PHC level

Antibiotic Agent	**Conditions**	**EDL 2003 page number**
Amoxycillin	abscess, dental, gingivitis, acute, necrotising, ulcerative, severe malnutrition, valvular heart disease and congenital structural heart disease, impetigo, eczema, atopic, eczema, acute, moist or weeping, athlete's foot – tinea pedis, measles (children with bronchitis or otitis media), acute infective bronchitis, pneumonia, pneumonia , mild in adults, otitis media, acute, sinusitis, acute, pneumonia, prophylactic treatment to prevent infection only if the hand is bitten or for extensive wounds requiring surgery	10, 13, 58, 80, 85, 87, 91, 92, 146, 199, 212, 213, 243, 246, 258, 277
Phenoxymethyl-penicillin	rheumatic fever, acute, tonsillitis, bacterial	79, 249
Erythromycin	dental abscess and gingivitis (penicillin allergic patients)	10, 14
	acute rheumatic fever, boil abscess, impetigo and cellulitis (penicillin allergic patients), acute, moist or weeping eczema and tinea pedis (penicillin allergic patients), measles, vaginal discharge/lower abdominal pain in women, genital ulceration in man and women, inguinal swelling in men and women, interpretation of syphilis serology (penicillin allergic patients), pneumonia in children and adults, conjunctivitis, otitis externa, otitis media, acute sinusitis, bacteria tonsillitis, animal and human bites and herpes zoster (penicillin allergic patients except for conjunctivitis and herpes zoster)	79, 84, 86, 87, 91, 92, 146, 151, 153, 155, 156, 159, 212, 213, 230, 242

Antibiotic Agent	Conditions	EDL 2003 page number
Metronidazole	dental abscess, acute gingivitis, chronic diarrhoea in adults, bacillary dysentery, giardiasis, urethral discharge/burning micturition in men, vaginal discharge/lower abdominal pain in women and animal and human bites	10, 14, 30, 31, 33, 150, 151, 278
Ciprofloxacin	bacillary dysentery, urinary tract infection, urethral discharge, vaginal discharge/ lower abdominal pain in women, painful scrotal swelling, prophylaxis of meningococcal meningitis	32, 130, 150, 151, 155, 183
Benzathine Benzylpenicillin	acute rheumatic fever, genital ulceration, inguinal swelling, interpretation of syphillis serology, bacterial tonsilitis	79, 152, 153, 156, 249
Benzylpenicillin	pneumonia	213
Doxycycline	acne vulgaris, malaria, urethral discharge/ burning micturition in men, vaginal discharge/ lower abdominal pain, inguinal swelling, painful scrotal swelling, interpretation of syphillis serology, tick-bite fever, chronic bronchitis and emphysema	82, 138, 139, 140, 143, 150, 151, 153, 155, 156, 157, 159, 199
Ceftriaxone	acute diarrhoea, shigellosis, typhoid fever, failure to thrive, neonatal emergencies, acute pyelonephritis, UTI, STI, acute bacterialmeningitis, severe pneumonia, gonococcal conjunctivitis, cough associated with difficulty in breathing, penetrative sexual abuse	26, 32, 39, 58, 111, 128, 130, 151, 182, 183, 214, 229, 258, 302

Antibiotic Agent	Conditions	EDL 2003 page number
Flucloxacillin	boil abscesses, otitis externa	84, 241
Metronidazole	dental abscess, gingivitis, chronic diarrhoea in adults, amoebic dysentery, giardiasis, STI, bites and stings	10, 14, 30, 31, 33, 150, 151, 278

Tables 3.3 and 3.4 shown below are for drug treatment protocols for UTI and STI in accordance with the Standard Treatment Guidelines (Department of Health, 2003). This is a gold standard against which the prescribing patterns observed in the 500 prescriptions evaluated were measured. Of all the conditions (diagnosis complex) that were listed, only the treatment protocol of UTI and STI were depicted on a tabular form according to the PHC EDL (Department of Health, 2003)

Table 3.3: Drug Treatment protocol for UTI

Condition	**Drugs**
Uncomplicated UTI in adult women, excluding pregnant women:	ciprofloxacin, oral, 500 mg as a single dose
Recurrent UTI in women and all males:	ciprofloxacin, oral, 250 mg, 12 hourly for 7 days
Children	nalidixic acid suspension, oral, 250 mg/ 5mL, 6 hourly for 5 days _ children 2 to 5 years : 250 mg/dose 5 mL _ children over 5 years : 375 mg/dose 7.5 Ml
Pregnant women, if severely ill, before referral:	ceftriaxone, IM, 1000 mg

All children less than 2 years and those with UTI and abdominal pain, persistent vomiting or failure to show appropriate weight gain pattern should be referred (Department of Health, 2003).

Table 3.4: Drug treatment protocol for STI

Option 1: Non-pregnant woman with a vaginal discharge and no pain on moving the cervix **Syndromic approach:**	**Option 2: Pregnant woman with a vaginal discharge and no pain on moving the cervix**
ciprofloxacin, oral, 500 mg immediately **and** • doxycycline, oral, 100 mg 12 hourly for 7 days **and** • metronidazole, oral, 2 000 mg immediately or • metronidazole, oral, 400 mg 12 hourly for 7 days	ceftriaxone, IM, 125 mg immediately **and** • erythromycin, oral, 500 mg 6 hourly for 7 days **and** • metronidazole, oral, 400 mg 12 hourly for 7 days
Option 3: Clinical evidence of vaginal candidiasis	**Option 4: Non-pregnant woman with pain on moving the cervix**
If there is clinical evidence of vaginal candidiasis then add to the treatment used in options 1 or 3: • clotrimazole, 500 mg inserted in the vagina at night as a single dose	ciprofloxacin, oral, 500 mg immediately **and** • doxycycline, oral, 100mg 12 hourly for 14 days **and** • metronidazole, oral, 400 mg 12 hourly for 14 days

In pregnant women, lower abdominal pain related to pelvic infection is rare. If present, these patients are usually seriously ill and require referral (Department of Health, 2003).

3.6 Ethics Approval

Permission for the research was obtained from the Provincial Ethical Committee (Appendix C) and the appropriate healthcare service managers, after approval by the University of Limpopo's Medunsa Campus Research and Ethics Committee (Appendix D). Patient anonymity was guaranteed throughout the study as no names were recorded in the PHC facility data collection form.

The site visit started with the explanation of why their clinics were selected and the steps that were followed until the approval was

granted to authorize the conducting of study in the province by Head of Department of Health and Social Development. The study was explained to clinic staff members and it was stressed that the study was retrospective without recording names of patients and it was not for the evaluation of their services. Appointments were made with each clinic to avoid disruptions to their daily activities.

Clinic staff members were encouraged to ask any questions for clarity before data collection commenced. Data collected were captured in an excel spreadsheet.

3.7 Conclusion

To conclude, the above mentioned research methodology was used successfully in conducting the study. The findings are presented in the next chapter.

CHAPTER 4:
RESULTS

4.1 Introduction

The results are presented as figures and tables and represent the different indicator/variables tested /used during the study. Each indicator was individually reported on and discussed using the guidelines.

From the data collected, results will be presented in the format of demographics, number of items per prescription (overall and breakdown per PHC facility), generic prescribing (overall and breakdown per PHC facility), duration of treatment, frequency of prescription, indications recorded on prescriptions, compliance with STG per PHC facility, number of antibiotics per prescription per PHC facility and most frequently used antibiotics.

The distribution of diagnosis of patients prescriptions which were evaluated are shown in (Table 4.1).

4.2 Demographics characteristics of the study population

Table 4.1: Demographics characteristics of the study population

Age group	Male	Female	Total	Percentage
0 - 10 Years	69	71	140	28.00%
11- 20 years	52	69	121	24.20%
21 - 30 years	31	54	85	17.00%
31 - 40 years	25	43	68	13.60%
41 - 50 years	10	30	40	8.00%
51 - 60 years	5	13	18	3.60%
> 60 years	6	6	12	2.40%
Unknown (Old)	2	14	16	3.20%
Total	200 (40%)	300 (60%)		

4.3 Number of items per prescription

All 500 prescriptions contained antibiotics and the overall number of items per prescriptions for the 500 prescriptions evaluated was 2.656. Number of items per prescription breakdown in five PHC facilities was Nkhensani 2.57, Madombidzha 2.54, Makhado 3.01, Rumani 2.4 and Tshisahulu 2.77.

4.4 Generic prescribing of all items evaluated

Of the 500 patients evaluated, 1326 items were prescribed and 26.77% (355/1326) of those were prescribed using generic name.

Table 4.2: Generic prescriptions of items evaluated

Clinic Name	Prescriptions evaluated	Number of items prescribed	Number prescribed using generic name	Number of items per prescription	Number of Prescriptions where frequency of dosage was indicated	Duration of treatment indicated
Makhado	100	299	153 (51.17%)	2.99	114 (38.13%)	0
Madombidzha	100	254	31 (12.20%)	2.54	121 (47.64%)	0
Tshisahulu	100	276	30 (10.87%)	2.76	258 (93.48%)	3 (1.09%)
Rumani	100	240	48 (20%)	2.4	204 (85%)	0
Nkhensani	100	257	93 (36.19%)	2.57	248 (96.5%)	165 (64.2%)
Total	**500**	**1326**	**355 (26.77%)**	**2.652**	**945 (71.27%)**	**168 (12.67%)**

Nkhensani had 36.19% (93/257), Madombidzha 12.2% (31/254), Makhado 51.17% (153/299), Rumani 20% (48/240), Tshisahulu 10.87% (30/276) of prescriptions that had generic name indicated.

4.5 Duration of treatment

Of the 500 prescriptions that were evaluated, a total of 1326 medicines were prescribed and 12.67% (168/1326) of the total scripts had duration of treatment specified.

Duration of treatment was only indicated in two PHC facilities and they were Tshisahulu with 1.09% (3/276) and Nkhensani with 64.2% (165/257). Makhado, Madombidzha and Rumani had 299,254 and 240 prescriptions respectively and none of them had duration of treatment specified.

4.6 Frequency of dosage

Frequency of dosage was recorded in 71.27% (945/1326) of the total prescriptions that were evaluated. Nkhensani had 96.5% (248/257), Madombidzha 47.64% (121/254), Makhado 38.13% (114/299), Rumani 85% (204/240), Tshisahulu 93.48% (258/276) of prescriptions that had frequency of dosage indicated.

4.7 Indications recorded on prescriptions

The most common conditions for which an antibiotic was prescribed were:

- Sore throat/ tonsillitis 19.8% (99/500)
- Flu 14.2% (71/500)
- Cough 14.2% (71/500)
- Sexually transmitted infections 10.2% (51/500)
- Upper respiratory tract infections 7.4% (37/500)

- Skin infections/infection/wound 5% (25/500)
- Chest pain 4.2% (21/500)
- Miscellaneous pain 4.2% (21/500)
- Headache 3.4% (17/500)
- Abdominal pain 3% (15/500)

4.8 Compliance with STG/EDL

Compliance with STG is tabulated according to: overall compliance with STG, by diagnostic group (Complex) and by PHC facility.

The following conditions listed in the data were not listed as conditions or diagnosis in the South African STG/EDL guidelines:

- Upper respiratory tract infection (Upper respiratory conditions are listed individually)
- Assault
- Hot body (may be referring to fever)

4.8.1 Overall compliance with STG

The following graph (Figure 4.1) indicates compliance of prescription containing antibiotics with STG for all PHC facilities.

Table 4.3: Compliance per PHC facility

Name of clinic	Number of prescriptions	Number of Rx Complying	% of Rx complying per PHC facility
Tshisahulu	100	12	12%
Rumani	100	28	28%
Nkhensani	100	51	51%
Makhado	100	30	30%
Madombidzha	100	25	25%
Total	**500**	**146**	**29.2%**

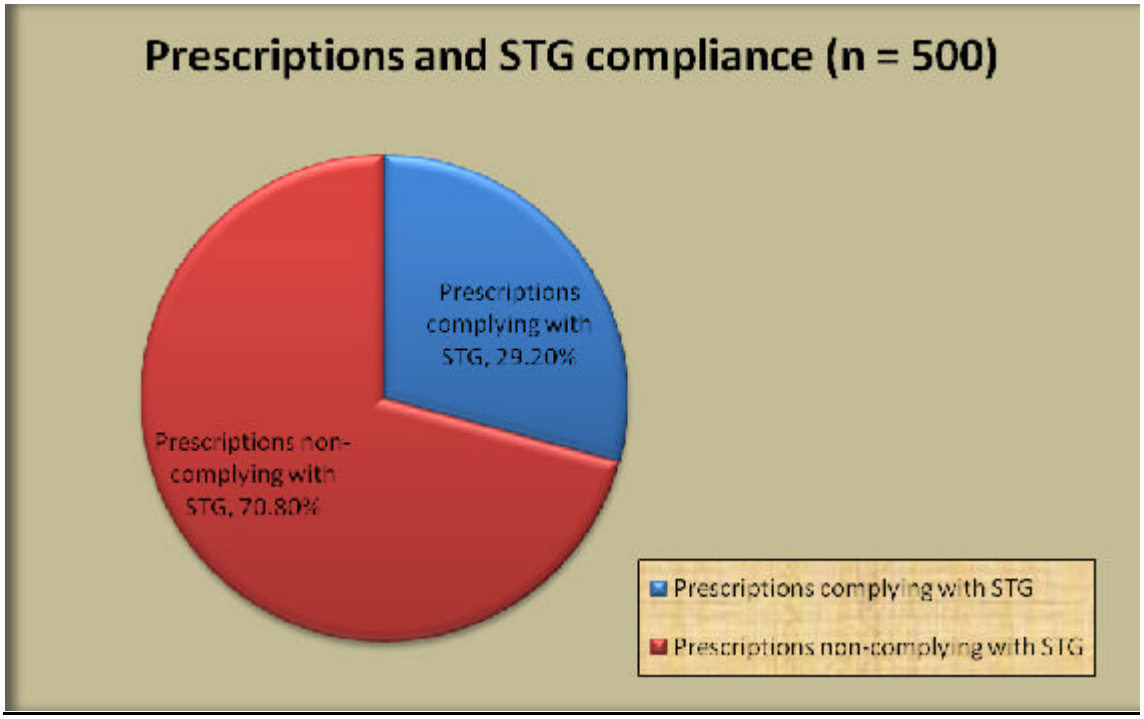

Figure 4.1: Prescriptions and STG compliance

Of the 29.2% prescriptions that were found to be complying, the highest compliance to STG/EDL guidelines was for the treatment of:

- Skin infections/infection/wound 92% (23/25)
- Respiratory tract infections 86.49% (32/37)
- Bronchitis 80% (4/5)
- Ear/eye infections 75% (3/4)
- Otitis media 57.14% (4/7)
- Tonsillitis/sore throat 56.57% (56/99)
- Urinary tract infection 37.5% (3/8)
- STI 37.25% (19/51)
- Bites 33.33% (1/3)
- Abscesses 25% (1/4)

In addition, antibiotics were used for the following conditions in non-compliance with STG:

- Abdominal pain
- Allergy
- Chest pain
- Chickenpox
- Common cold
- Cough
- Diarrhoea
- Ear/eye pain
- Fever
- Flu
- Headache
- Hypertension
- Miscellaneous pain
- Rash
- Ring worm
- Vomiting

It was found that the presence of fever (hot body) and cough increased the likelihood of antibiotic being prescribed. This is largely due to the fact that the prescribers tend to consider fever (hot body) and cough as a sign of bacterial infection, which is not always the case (Bharathiraja, 2005).

4.8.2 By diagnostic group

Table 4.4 depicts the symptom/diagnosis complex of all 500 prescriptions that were evaluated from the participating PHC facilities.

Table 4.4: Primary related diagnosis in study patients with prescriptions containing antibiotics

Symptom Complex/Diagnosis	Number of Rx	Number of RX Complying
Abdominal pain	15	0
Abscesses	4	1
Allergy	1	0
Assault	3	0
Asthma	6	0
Bites	3	1
Bronchitis	5	4
Chest pain	21	0
Chickenpox	2	0
Common Cold	8	0
Cough	71	0
Diarrhea	4	0
Ear/Eye infections	4	3
Ear/Eye pain	8	0
Fever	2	0
Flu	71	0
Headache	17	0
Hypertension	2	0
Miscellaneous Pain	21	0
Otitis media	7	4
Rash	2	0
Ringworm	1	0
Sexual transmitted Infections	51	19
Skin infections/infections/wound	25	23
Sore Throat/tonsillitis	99	56
Upper respiratory tract Infection	37	32
Urinary tract infection	8	3
Vomiting	2	0
Total	500	146

4.9 Antibiotics use

Figure 4.2 indicates percentages of prescriptions containing an antibiotic complying to STG/EDL per PHC facility that participated in the study.

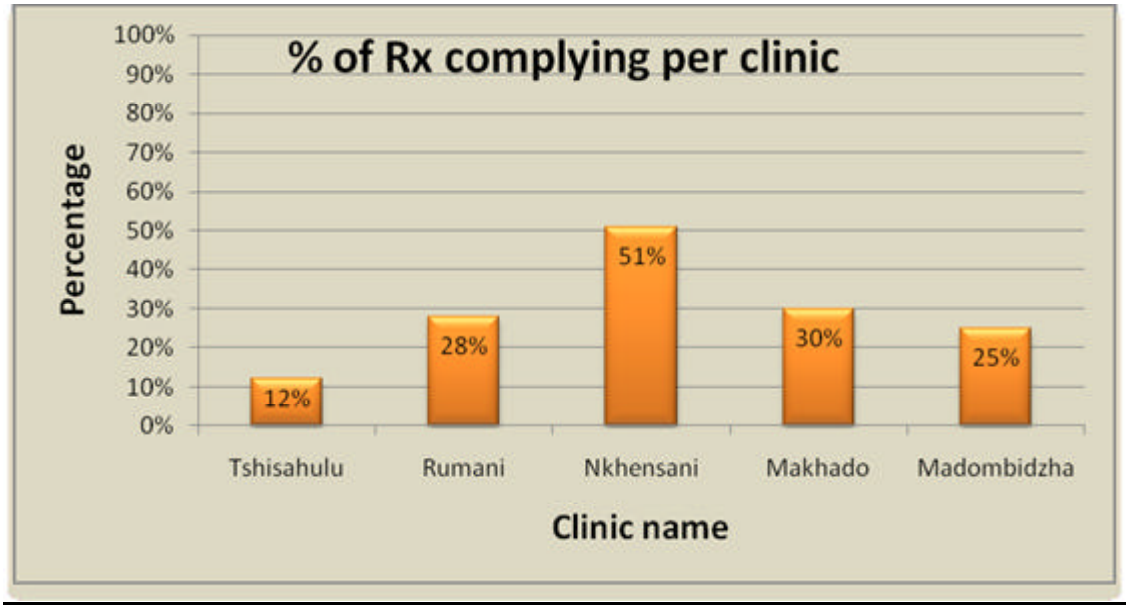

Figure 4.2: Percentage of prescriptions containing an antibiotic complying per PHC facility (clinic)

4.9.1 Number of antibiotics per prescription

On average, 1.7 antibiotics were prescribed per prescription in this study. Figure 4.3 depicts the breakdown in percentages at which the number of antibiotics were prescribed.

Table 4.5: Number of antibiotics per prescription

Clinic	One Antibiotic	Two Antibiotics	Three Antibiotics	Four Antibiotics	Total
Tshisahulu	87	10	3	0	100
Rumani	87	9	4	0	100
Makhado	84	11	5	0	100
Madombidzha	86	12	1	1	100
Nkhensani	90	6	4	0	100
Total	434	48	17	1	500

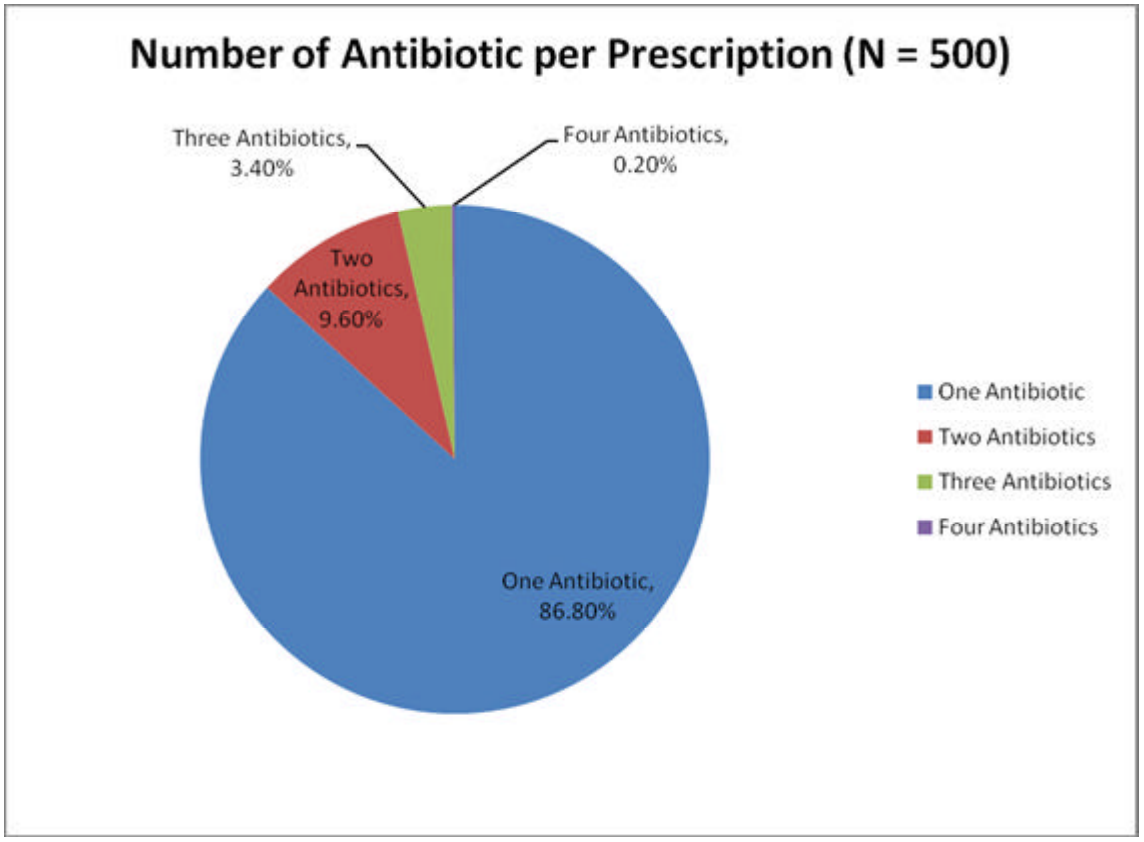

Figure 4.3: Percentage of antibiotics prescribed per patient (n=500)

Figure 4.3 depicts the number of antibiotics prescribed: A single antibiotic was prescribed in 434 (87%) patients while two antibiotics were prescribed in 48 (10%) patients. Three antibiotics were prescribed in 17 (3%) patients while four antibiotics were prescribed in one patient.

4.9.2 Most frequently used antimicrobials

Table 4.6: Antibiotics chosen in order of preference in treating conditions by most common member within each class

Abdominal pain (n=17)	**Abscesses (n=5)**	**Bites (n=4)**
Amoxicillin = 70.59%	Amoxicillin = 20.00%	Amoxicillin = 25.00%
Doxycycline = 11.76%	Flucloxacillin = 40.00%	Flucloxacillin = 50.00%
Erythromycin = 5.88%	Phenoxymethylpenicillin = 40.00%	Phenoxymethylpenicillin = 25.00%
Ceftriaxone = 5.88%		
Metronidazole = 5.88%		
Assult (n=3)	**Asthma (n=6)**	**Allergy (n=1)**
Flucloxacillin = 100.00%	Amoxicillin = 66.67%	Amoxicillin = 100.00%
	Phenoxymethylpenicillin = 33.33%	
Bronchitis (n=5)	**Chest pain (n=20)**	**Chickenpox (n=2)**
Amoxicillin = 80.00%	Amoxicillin = 95.00%	Phenoxymethylpenicillin = 100.00%
Phenoxymethylpenicillin = 20.00%	Erythromycin = 5.00%	
Common Cold (n=8)	**Cough (n=72)**	**Diarrhoea (n=4)**
Amoxicillin = 50.00%	Amoxicillin = 84.72%	Amoxicillin = 75.00%
Pheoxymethylpenicillin = 50.00%	Erythromycin = 5.56%	Erythromycin = 25.00%
	Phenoxymethylpenicillin = 9.72%	
Ear/Eye infections (n=4)	**Ear/Eye pain (n=9)**	**Flu (n=75)**
Amoxicillin = 75.00%	Amoxicillin = 77.78%	Amoxicillin = 78.67%
Ceftriaxone = 25.00%	Erythromycin = 11.11%	Ceftriaxone= 2.67%
	Ciprofloxacin = 11.11%	Erythromycin= 2.67%
		Phenoxymethylpenicillin = 14.67%
		Benzylpenicillin = 1.33%
Headache (n=17)	**Miscllaneous Pain (n=24)**	**Upper Respiratoty Tract Infection (n=39)**
Amoxicillin = 82.35%	Amoxicillin = 54.17%	Amoxicillin = 48.72%
Phenoxymethylpenicillin = 17.65%	Flucloxacillin = 20.83%	Erythromycin = 2.56%
	Doxycycline = 8.33%	Flucloxacillin = 2.56%
	Erythromycin = 4.17%	Phenoxymethylpenicillin = 43.59%
	Phenoxymethylpenicillin = 12.50%	Benzylpenicillin = 2.56%
Urinary Tract Infection (n=12)	**Sore Throat/Tonsilitis (n=104)**	**Sexual Transmitted Infections (n=107)**
Ciprofloxacin = 16.67%	Amoxicillin = 41.35%	Amoxicillin = 2.80%
Amoxicillin= 33.33%	Metronidazole = 0.96%	Ceftraxone = 2.80%
Ceftraxone= 8.33%	Benzathin Penicillin = 5.77%	Flucloxacillin = 1.87%
Doxycycline = 25.00%	Erythromycin = 1.92%	Doxycycline = 33.64%
Erythromycin = 8.33%	Phenoxymethylpenicillin = 50.00%	Erythromycin = 11.21%
Metronidazole = 8.33%		Phenoxymethylpenicillin = 0.93%
		Ciprofloxacin= 21.50%
		Metronidazole = 24.30%
		Benzathine Penicillin =0.93%
Skin infections/wound (n=26)	**Otitis Media (n=7)**	**Vomiting (n=2)**
Amoxicillin = 15.38%	Amoxicillin = 57.14%	Amoxicillin = 50.00%
Flucloxacillin = 73.08%	Flucloxacillin= 14.29%	Erythromycin = 50.00%
Phenoxymethylpenicillin = 7.69%	Phenoxymethylpenicillin = 28.57%	
Metronidazole = 3.85%		
Ringworm (n=1)	**Hypertension (n=2)**	**Rash (n=1)**
Flucloxacillin = 100.00%	Amoxicillin = 100.00%	Amoxicillin = 100.00%

The most widely prescribed antibiotics for bites, bronchitis, common cold, asthma, cough, flu, headache, upper respiratory tract infections and otitis media were amoxycillin followed by

phenoxymethylpenicillin. In overall amoxicillin appeared more frequent with 57% (285/500) of all prescriptions followed by phenoxymethylpenicillin with 21.8% (109/500) of prescriptions.

CHAPTER 5:
DISCUSSION OF RESULTS

5.1 Introduction

In this chapter discussion will resemble the structure of the results and it will be in the order of demographics characteristics of the study population, number of items per prescription (overall and breakdown per PHC facility), generic prescribing (overall and breakdown per PHC facility), duration of treatment, frequency of prescription, indications recorded on prescriptions, compliance with STG per PHC facility, number of antibiotics per prescription per PHC facility and comparison of data with general accepted guidelines.

5.2 Demographic characteristics of the study population

Highest rate (28%) of antimicrobial prescription was observed in children of age group from birth to 10 years followed by the age group of 11 to 20 years with 24.2%. The results are similar to the study conducted in India on antimicrobial prescriptions patterns for common acute infections in some rural and urban health facilities of India (Kumari, 2008). This sort of age related difference in antimicrobial prescriptions had been reported by other authors as well (Nyquist, 1998). There were 3.2% (16/500) of prescriptions where age was not indicated or being reflected as “pensioner” on the prescription book.

According to South Africa’s Identification Act number 68 of 1997, the Director-General shall assign an identity number to every person whose particulars are included in the population register (Department of Home Affairs, 1997). This means that systems are already in place with regard to all South Africans citizens to have an identification

document and at this stage there should not be person that are classified as “old” more in particular because all pensioners need to produce their identity document before they could be registered for monthly grant.

5.3 Number of items per prescription

The mean number of drugs per prescription should be as low as possible since higher figures increase the risk of drug interaction, risk of bacterial resistance, non-compliance and cost. Our data can be used by prescribers for making an appropriate revision in their prescribing pattern (Kutty *et al.*, 2002).

The average number of drugs per prescription in an audit is an important index of the scope for review and educational intervention in prescribing practices. It is preferable to keep the number of drugs per prescription as low as possible to minimize the risk of drug interactions, development of bacterial resistance and institutional costs (Stratton, *et al., 1993).*

The average number of items per prescription was found to be 2.6, a figure which is lower than Limpopo’s provincial average of 3.5 for the same period in 2007 (Limpopo Province Department of Health, 2007) The lowest average number of items per prescription per facility was recorded at Rumani PHC facility with the highest being Makhado with 3.01 items per prescription. Indications are that, more time should be dedicated for empowering the prescribers on rational prescribing workshops as well as emphasizing the introduction of district pharmacy and therapeutic committee that will also provide support in monitoring and evaluation.

5.4 Generic prescribing

The NDP requires that all drugs be prescribed by generic name. In this study it was found that only 26.77% (355/1326) of items were prescribed by generic name. To comply with the NDP, more efforts should be put in place to ensure that prescribers are following the guidelines. In some instances, prescribers are still using brand names which have long been discontinued or no longer kept in the public sector, a challenge that needs to be addressed by all healthcare workers.

PHC facility breakdown on generic prescribing revealed that only one facility had more than 50% of items prescribed on generic name, with the other four having recorded relatively low percentages as reflected by the results. The NDP is aiming at achieving generic prescribing in both the public and the private sectors which translate into more strategies that should be put in place to achieve the objectives (Department of Health, 1996).

5.5 Duration of treatment

The quantity dispensed or duration of treatment was only indicated in 12.67% of prescriptions (168/1326). It is very much important to indicate the duration or quantity as patients need to comply with the prescribed treatment.

Nkhensani was one of the two PHC facilities where duration of treatment was indicated and the recorded figure was 64.2% as compared to the insignificant figure of 1.09% recorded for Tshisahulu and none for other three PHC facilities. Due to the low number of prescriptions evaluated per facility, it may be that there was one prescriber who was on duty at Nkhensani for the same period where

the data were collected. In general, there are still challenges of recording duration of treatment or quantity dispensed and further studies need to be conducted on a larger scale to determine the reasons for not documenting details of treatment duration when prescribing.

Duration of treatment is necessary especially with antibiotics even if the symptoms of the patient's illness have disappeared and he/she feels better before he/she has completed the antibiotic course. A person who has been prescribed an antibiotic should therefore make sure to take all of it, at the intervals the prescriber specified as failure to complete the full course of the antibiotic prescribed allows the stronger disease-causing microorganisms to survive, reproduce, and eventually become resistant to the antibiotic.

5.6 Frequency of dosing

For all prescriptions evaluated, 71.27% had frequency of dosage (dosing interval) indicated, a situation that need to be encouraged more in particular as two of the five PHC facilities had percentages of less than fifty. Although this does not reflect good or bad counselling on prescribed medicines, it may be interesting to determine if patients in PHC facilities are indeed counselled on the correct use of their medicines.

Documentation of dosing frequency is a necessity in all spheres of medicine dispensing and this was further emphasized on the South African NDP (Department of Health, 1996). To achieve optimal percentages in this regard, more support from the hospital where the PHC is attached should be given to prescribers. Staffing is one of the area which is often pointed as the major reasons that deter the

prescribers in following the guidelines and hence the need to look at qualitative research for augmentation of the study as well as finding ways to improve the current situation.

5.7 Indications recorded on prescriptions

From the results it is clear that prescribers at PHC facilities were recording either the symptoms or diagnosis. It has been highlighted that majority of indications which were recorded are not even appearing in the STG/EDL book as diagnosis and this can only highlight the extent of the challenges encountered in PHC facilities. The way prescriptions are recorded differs with PHC facility to another as some do record everything according to the STG/EDL. This further substantiates the need for the support by pharmacists at the PHC as well as continuous assessment on the compliance by prescribers to STG/EDL.

5.8 Compliance with STG

According to the NDP, all prescriptions should comply with the STG at PHC level (Department of Health, 1996).

From the results of this study, it was evident that only 29.2% of prescriptions with antibiotics from the Vhembe district in the Limpopo Province of South Africa complied with the STG. Similar study on comparison of antimicrobial prescribing patterns in the Madibeng District (North West Province, South Africa) with the STG/EDL found an overall compliance of 68% (WHO, 2009).

Failure to comply with STG/EDL guidelines, as indicated above may lead to drug resistance, poor patients care and unnecessary expenditure in an already resourced stretched environment.

In comparing with the EDL/STG guidelines, in most of the evaluated prescriptions:

- Erythromycin as an example is normally reserved for penicillin–allergic patients but it is topping the antibiotic list in Limpopo Province usage report for August and September 2007, an issue that needs further investigation
- Most conditions in PHC level that needs antibiotics are treated with amoxicillin but the report showed flucloxacillin and erythromycin as the top antibiotics used by value (Appendix A). According to the EDL, flucloxacillin should be used in boil abscesses and Otitis externa (Department of Health, 2003)

From the five PHC facilities that were evaluated, Nkhensani clinic recorded the highest percentage of compliance with STG, the reason of which is not known as this was not part of the objective of the study. The possible reasons may however range from existing prescribers in Nkhensani having undergone the training course on effective prescribing before, prescribers who were trained have left the system in the other facilities, new prescribers who have joined the department in other facilities that scored lower percentages and non-availability of certain medicines as outlined in the STG at the time of prescribing and dispensing. The percentage difference amongst the facilities on compliance to STG should be part of the objectives in future similar studies.

5.9 Number of antibiotics per prescription

The average number of antibiotics items per prescription for the 500 prescriptions that were collected was 1.17, a figure which is less than that of the study on prescribing patterns in Western Nepal, which was

1.7 numbers of items per prescription (Shankar *et al.*, 2003). Although the average number of items per prescription seems to be low in the study, the figure could have been much lower if it were not for irrational antibiotics prescribing to most of the conditions.

This indicator attempts to describe prescriber behaviour, since too high (or too low) an average number prescribed can indicate poor prescribing practices. These practices can be explained by lack of pharmaceutical information and education, or by chronic lack of supplies that force health workers to prescribe what is available. Additional information is necessary to explain the cause of the prescribing practices observed (Management Sciences for Health, 1995).

5.10 Most frequently used antibiotics

As shown in Table 4.6, according to (Balabanova *et al.*, 2004) there remains a great need to restrict the use of antibiotics by prescribers in general and to manage the expectations of patients over the value and necessity of antibiotics for simple infections particularly where they are of viral aetiology. There is also a need for further training of prescribers, including reducing their reliance on pharmaceutical industry information, as well as legal measures to control the sale and spread of antibiotics.

5.11 Conditions where antibiotics were prescribed

It is clear from Table 4.4 that guidelines are not followed and this may explain why antibiotic expenditure cost is spiralling in Limpopo Province. The significance of this is that patients are prescribed antibiotics when it is not necessary and this does not help curtailing the chance of developing drug resistance. In overall, patients are not given the quality of service that they deserve and the funds used may have been channelled to the other programmes within the directorate.

5.12 Description of other conditions where antibiotics were prescribed frequently

Cough

In all prescriptions for cough and common cold which were evaluated, none of them complied with the STG as all patients had antibiotics which are not according to the STG/EDL. Tussi Infants and Expect Stim are treatment that should be used. In summary, antibiotics are not needed to treat such conditions (Department of Health, 2003).

Fever

The results indicated that none of the patients who had fever as diagnosis complied with the STG. Fever is actually the body's natural way of defending itself from invaders like viruses and bacteria, because many of them cannot survive in the body due to the high temperature caused by a fever. High body temperatures also signal

infection-fighting cells of the immune system such as phagocytes, neutrophils, and lymphocytes to defend and help fight off infections.

According to the 2008 edition of PHC EDL, fever can be a symptom of other conditions such as otitis media, pneumonia, acute bacterial meningitis, mumps, measles, prostatitis, urinary tract infection, boil and abscess (Department of Health, 2008).

In another study, it was found that the presence of fever and cough increased the likelihood of antibiotic being prescribed. This is largely due to the fact that the prescribers tend to consider fever and cough as a sign of bacterial infection, which is not always the case (Bharathiraja R, 2005)

CHAPTER 6:
SUMMARY, CONCLUSION AND RECOMMENDATIONS

6.1 Introduction

This chapter includes a summary where the objectives are weighed against the key findings, limitations of the study and the study is evaluated in terms of the contribution to rational antibiotic prescribing in the Limpopo Province.

The chapter concludes with recommendations which could be applied in future practice of healthcare professionals.

6.2 Limitations of the study

The following limitations to the study were identified:

- Low number of prescriptions evaluated per facility due to time constraints
- The study did not look at co-prescribed drugs as it mainly concentrated on antibiotics

6.3 Recommendations

The following recommendations arose from the study:

- Increase and improve supervision to prescribers in primary level to enhance compliance with the existing guidelines. This can be done by encouraging pharmacists to pay support visits to PHC facilities, Conducting Monitoring and Evaluation as well as including clinic supervisors in the district or hospital Pharmaceutical and Therapeutic Committee meetings.

- Educational strategies to modify prescribing practices and strengthen prescriber-patient relationships might improve compliance and decrease drug waste.
- Establishment of functional Pharmaceutical and Therapeutic Committees in hospitals which will in turn support PHC facilities will be of great importance.
- As factors that influence the decision to prescribe antibiotics were not looked at, it would be a good idea for future studies to also concentrate on the main reasons for irrational antibiotic prescribing.

6.4 Conclusion

The study investigated the prescribing patterns of antibiotics by healthcare professionals at PHC level in Vhembe District of the Limpopo Province in South Africa.

In overall, adherence to standard treatment guidelines is still a major challenge as reflected by 29.2% (146/500) compliance of all prescriptions evaluated that were according to the protocols. The majority of prescriptions were for conditions where antibiotics are not indicated or for conditions that are not even listed in the STG/EDL guidelines and efforts to strengthen STG/EDL compliance and the consequences of non compliance should be a priority.

It can be concluded that rational use of antimicrobials in primary care should be encouraged and the reasons for the observed deviations in prescribing according to the STG/EDL need further evaluation.

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APPENDICES

Appendix A

Number	August 2007 Stock Usage Report			September 2007 Stock Usage Report		
	Generic Name	Quantity	Value	Generic	Quantity	Value
1	Efavirenz 600Mg Caps	14289	R 2,021,175.06	Vaccine Hib-O.T.P 10 Dose	3230	R 341,376.15
2	Vaccine Hib-O.T.P 10 Dose	4313	R 1,265,434.20	Norethisterone Inj 200Mg/ml Long-Actin	1009	R 655,581.52
3	Norethisterone Inj 200Mg/ml Long-Acting	1484	R 928,075.62	Vaccine Rabies 2.5Ml/dose Vial + Dil.	5162	R 575,795.84
4	Baby Formula	11731	R 726,036.80	Lamivudine Tabs 150Mg	14156	R 487,540.44
5	Trifluoperazine Tabs 5Mg (Pnp 28)	68450	R 699,350.00	Baby Formula	3227	R 482,411.80
6	Lamivudine Tabs 150Mg	16925	R 594,776.35	Thermometer Non-Mercury	4002	R 473,836.80
7	Nifedipine Tabs 30Mg Slow Release	25323	R 589,691.53	Perindopril Tabs 4Mg	35590	R 468,479.14
8	Thermometer Non-Mercury	3655	R 551,065.20	Nifedipine Tabs 30Mg Slow Release	11940	R 447,983.97
9	Perindopril Tabs 4Mg	43679	R 505,067.74	Budesonide M.D.I 200Mcg 200Dose	9062	R 406,493.37
10	Nifedipine Tabs 60Mg Slow Release	7642	R 457,632.22	Nifedipine Tabs 60Mg Slow Release	6004	R 359,699.64
11	Budesonide M.D.I 200Mcg 200Dose	10423	R 451,930.89	Risperidone Tabs 2Mg	1593	R 311,192.55
12	Vaccine Rabies 2.5Ml/dose Vial + Dil.	3799	R 438,844.64	Salbutamol M.D.I. 100Mcg 200 Dose	20265	R 284,419.28
13	Stavudine Caps 30Mg	238047	R 434,680.04	Cosmos Compound Syr 100Ml	166091	R 273,730.42
14	Vaccine Hepatitis B Peed 10 Dose Vial(mult	2556	R 429,819.10	Sanitary Towels Maternity With Loops	13671	R 258,564.49
15	Salbutamol M.D.I. 100Mcg 200 Dose	24578	R 344,952.23	Stavudine Caps 30Mg	10717	R 242,030.79
16	Risperidone Tabs 2Mg	1640	R 320,374.00	Erythromycin Tabs 250Mg (Pnp 20)	27566	R 238,663.04
17	Vaccine Measles Live Atten 10 Dose + Diluc	8067	R 317,673.00	Vaccine Hepatitis B Peed 10 Dose Vial	474	R 234,729.60
18	Test H I V Initial	907	R 286,412.96	Insulin Actraphane Hm 10Ml	5490	R 231,829.10
19	Insulin Actraphane Hm 10Ml	7736	R 283,967.22	Sevoflurane	115	R 231,344.30
20	Cosmos Compound Syr 100Ml	171653	R 276,818.02	Amoxycillin Caps 250Mg (Pnp 15)	97950	R 199,142.24
21	Metformin Tabs 850Mg	6586	R 243,682.00	Ibuprofen Tabs 200Mg (Pnp 15)	188672	R 195,464.19
22	Oral Contraceptive Monophasic Low	561	R 237,885.70	Flucloxacillin 250Mg Caps 20	24896	R 194,686.88
23	Overshoes Single Use All Sizes	4381	R 229,546.50	Oral Contraceptive Monophasic Low	516	R 189,960.90
24	Medroxyprogesterone Inj 150Mg/ml 1Ml	735	R 220,546.14	Medroxyprogesterone Inj 150Mg/ml 1Ml	470	R 186,811.32
25	Oral Contraceptive Triphasic Low	11886	R 216,181.90	Mist Tussi Infans Mist 100Ml	116712	R 182,460.48
26	Sanitary Towels Maternity With Loops	44001	R 213,768.90	Phenoxymethyl Penicillin Tabs 250Mg (I	40624	R 176,714.40
27	Ibuprofen Tabs 200Mg (Pnp 15)	203545	R 210,872.62	Valproate / Valproic Acid Tabs 300Mg	1710	R 176,469.10
28	Flucloxacillin 250Mg Caps 20	26903	R 209,780.59	Gown Hospital Short Sleeves Universal	2260	R 164,227.50
29	Valproate / Valproic Acid Tabs 200Mg	2964	R 208,667.84	Zidovudine Tabs 300Mg	26733	R 163,072.63
30	Vaccine Oral Polio Trivalent 10 Dose 10	1156	R 205,897.50	Aluminium Hydrox Magnesium Trisil Tat	218223	R 158,469.42
31	Valproate / Valproic Acid Tabs 500Mg	1196	R 194,553.32	Ampicillin Inj 500Mg	15894	R 150,791.50
32	Erythrolevjin Tabs 250Mg (Pnp 20)	22813	R 191,775.62	Valproate / Valproic Acid Tabs 200Mg	2124	R 148,595.04
33	Gown Hospital Short Sleeves Universal	2316	R 185,625.00	Metformin Tabs 850Mg (Pnp 56)	17337	R 143,162.03
34	Miconazole Nitrate Oral Gel 30Gm	3857	R 176,300.28	Valproate / Valproic Acid Tabs 500Mg	862	R 140,221.54
35	Haemosolvate Factor 8 500Iu 10Ml	207	R 174,184.29	Test H I V Initial	13239	R 139,679.82
36	Mist Tussi Infans Mist 100Ml	108436	R 172,653.91	Glove Examination Latex Medium	8344	R 138,339.18
37	Amoxycillin Caps 250Mg (Pnp 15)	89469	R 171,323.42	Form Patient Referral	82863	R 132,300.00
38	Bandage Cotton Crepe 100Mm	5456	R 169,936.04	Paracetamol Syr 120Mg/5Ml 50Ml	121584	R 128,759.57
39	Ampicillin Inj 500Mg	17237	R 163,362.02	Oral Contraceptive Triphasic Low	4957	R 126,561.60
40	Glove Examination Latex Medium	6716	R 161,081.84	Miconazole Nitrate Oral Gel 30Gm	2768	R 125,269.96
41	Rif 150 Inh 75 :50	3518	R 157,958.20	Nevirapine Tabs 200Mg	2858	R 121,436.42
42	Haloperidol Tabs 5Mg	2196	R 155,928.00	Paracetamol Tabs 500Mg (Pnp 10)	1042619	R 120,820.17
43	Test Strip Blood Glucose (One Touch)	1807	R 148,536.08	Ceftriaxone Inj 1G	11698	R 118,502.40
44	Rif 300 Inh 150 :50	4150	R 145,167.00	Test Strip Blood Glucose (One Touch)	1391	R 115,306.13
45	Valproate / Valproic Acid Tabs 300Mg	1378	R 141,387.13	Paclitaxel 100Mg Injection	133	R 113,764.08
46	Baby Formula Lactose Free	5897	R 140,167.50	Metronidazole Inj 500Mg/100ml I.V.	7439	R 113,655.06
47	Efavirenz Caps 200Mg	588	R 134,480.88	Bag Brown No: 4	42399	R 112,382.10
48	Erythropoietin Inj 4000Iu/ml	445	R 133,691.48	Haemosolvate Factor 8 500Iu 10Ml	131	R 110,232.57
49	Metformin Tabs 850Mg (Pnp 56)	15837	R 130,070.06	Bandage Cotton Crepe 100Mm	2752	R 109,958.26
50	Swabs Gauze Absorbent 100Mmx100mm 8	23088	R 125,195.06	Swabs Gauze Absorbent 100Mmx100m	19252	R 106,388.56
51	Phenoxymethyl Penicillin Tabs 250Mg (Pnp 4	28542	R 124,197.70	Bandage Compression Porous Elastic 7	4148	R 105,307.20
52	Glove Examination Latex Large	7378	R 122,319.86	Carbamazepine Tabs 200Mg (Pnp 84)	9031	R 101,141.66
53	Metronidazole Inj 500Mg/100ml I.V.	8254	R 119,421.26	Rif 150 Inh 75 :50	12791	R 96,735.10
54	Bag Brown No: 4	9203	R 117,682.33	Dorzolamide Eye Drops 20Mg/ml 5Ml	1132	R 96,733.36
55	Dapsone Tabs 50Mg (Pnp 56)	12486	R 116,981.33	Co-Trimoxazole Tabs 480Mg (Pnp 20)	51752	R 87,887.10
56	Dorzolamide Eye Drops 20Mg/ml 5Ml	1398	R 115,796.34	Ketorolac Trometh Preserv 5Ml Eye Drops	2614	R 87,449.92
57	Oxytocin Inj 10Iu 1Ml	3998	R 115,053.64	Chlorhexidine Scrub 4% 500Ml	9031	R 87,264.80
58	Paracetamol Syr 120Mg/5ml 50Ml	185087	R 111,343.83	Phenoxymethyl Penicillin Susp 250Mg/5	16511	R 86,637.11
59	Stavudine Caps 40Mg	4591	R 110,706.88	Erythromycin Susp 125Mg/5ml 100Ml	12572	R 86,547.20
60	Aluminium Hydrox Magnesium Trisil Tabs	33093	R 110,180.71	Glove Surgical Latex Long Size 7.0	1604	R 84,868.26
61	Ceftriaxone Inj 1G	10700	R 108,926.03	Mask Respirator M.D.R-Tb	4739	R 84,622.85
62	Cimetidine Tabs 400Mg	349937	R 108,467.23	Chlorpheniramine Syr 2Mg/5ml 50Ml	61290	R 84,570.47
63	Vaccine Diphtheria Tetanus Pertussis 10 Do	345	R 106,846.50	Ferrous Sulphate Co Tabs (Pnp 28)	1406322	R 83,908.38
64	Flucloxacillin Susp 125Mg/5ml 100Ml	10745	R 104,925.34	Water For Inj 10Ml (Plastic)	1512	R 83,692.56
65	Glove Surgical Latex Long Size 7.0	1758	R 104,881.18	Insulin Actraphane Hm 3Ml Penfoil	847	R 81,627.10
66	Orpheradrine Tabs 50Mg (Pnp 28)	20748	R 103,875.04	Oxytocin Inj 10Iu 1Ml	9053	R 81,574.60
67	Bag Plastic Tablet White 1034Mm X 120Mm T	93	R 103,522.95	Flucloxacillin Susp 125Mg/5ml 100Ml	9033	R 80,903.42
68	Cloxacillin Caps 250Mg	1790	R 102,669.20	Stavudine Caps 40Mg	3891	R 80,019.87
69	Vaccine Tetanus Adsorbed 10 Dose	868	R 100,360.00	Orpheradrine Tabs 50Mg (Pnp 56)	9510	R 80,009.10
70	Glove Surgical Latex Long Size 7.5	1676	R 99,235.96	Hydroxyethyl Starch 130/0.4 6% And Sc	1106	R 80,778.17
71	Water For Inj 10Ml (Plastic)	1391	R 98,842.90	Cloxacillin Inj 500Mg	402	R 80,626.00
72	Intravenous Cannula 24G	2571	R 98,350.00	Orpheradrine Tabs 50Mg (Pnp 28)	16978	R 80,127.60
73	Incontinence Diaper Adult, Small	1576	R 97,592.64	Hydrochlorothiazide Tabs 25Mg (Pnp 28	89829	R 84,439.50
74	Rif 150 Pza 400 Inh 75 Eth 275 84	7757	R 97,512.95	Rif 300 Inh 150 :56	2335	R 81,678.30
75	Co-Trimoxazole Tabs 480Mg (Pnp 20)	51800	R 96,667.10	Haloperidol Tabs 5Mg (Pnp 28)	3381.39	R 81,627.66
76	Paracetamol Tabs 500Mg (Pnp 10)	169457	R 96,262.63	Glove Surgical Latex Long Size 7.5	1352	R 80,051.92

77	Zidovudine Tabs 300Mg	52209	R 95,152.78		Test Malaria Rapid P. Falciparum	516	R 77,400.00
78	Hydrochlorothiazide Tabs 25Mg (Prp 28)	100897	R 94,843.18		Vaccine Oral Polio Trivalent 10 Dose Vi	452	R 76,692.20
79	Glove Surgical Latex Long Size 8.0	1295	R 94,188.14		Glove Examination Latex Large	126364	R 74,522.61
80	Cloxacillin Inj 500Mg	438	R 93,274.28		Baby Formula Lactose Free	3133	R 74,338.70
81	Cefuroxime 125Mg/5ml Susp 50Ml	2198	R 92,316.90		Metformin Tabs 850Mg (Prp 28)	332554	R 73,280.84
82	Vaccine B C G 20 Dose Vial + Diluent	545	R 92,116.90		Amoxycillin Susp 125Mg/5ml 75Ml	29212	R 73,198.43
83	Sodium Alginate Gel 25G	1247	R 91,173.10		Acyclovir Eye Oint 3%	504	R 71,316.00
84	Bandage Cotton Crepe 50Mtr	28168	R 90,803.82		Immunoglobulin Anti-D Amp 2Ml	218	R 71,063.64
85	Dressing Wound Absorbent Non-Adhered 1	245	R 89,143.25		Svt Polyest 1/2Tp 45Mtr (Sherodkar)	410	R 70,700.00
86	Rif 150 Pza 400 Inh 75 Eth 275 100	1271	R 88,868.32		Bag Sterilization No 7	61158	R 67,590.40
87	Chlorhexidine Scrub 4% 500Ml	22719	R 88,336.60		Hydrocortisone Inj 100Mg/2ml	1455	R 67,439.25
88	Nevirapine Tabs 200Mg	2079	R 88,306.71		Vitamin Multiple Caps Adults	111925	R 67,339.03
89	Amoxycillin 500Mg Caps (Prp 15)	59400	R 86,877.55		Tranexamic Acid Inj 100Mg/ml 5Ml	334	R 67,140.68
90	Clozapine Tabs 100Mg	663	R 86,190.90		Syringe Safety 5Ml 21Gx40mm Needle	21056	R 66,965.04
91	Zuclopenthixol Acetate Inj 50Mg 1Ml	1755	R 84,484.86		Rif 150 Pza 400 Inh 75 Eth 275 100	953	R 66,633.76
92	Insulin Actraphane Hm 3Ml Penset	811	R 83,776.30		Vaccine Tetanus Adsorbed 10 Dose	287	R 63,720.20
93	Dressing Wound Absorbent Non-Adherent 1	421	R 81,537.53		Immunoglobulin Human Normal 5G 200	55	R 63,706.50
94	Erythromycin Susp 125Mg/5ml 100Ml	10658	R 80,973.40		Sodium Hyaluronate 18Mg/ml 0.4Ml Syr	615	R 63,670.15
95	Test H I V Confirmation	3310	R 80,907.75		Rif 150 Pza 400 Inh 75 Eth 275 60	1198	R 63,661.72
96	Chlorpheniramine Syr 2Mg/5ml 50Ml	52430	R 80,860.58		Carbamazepine Tabs 400Mg C R	23317	R 63,400.18
97	Oral Contraceptive Monophasic High	149	R 79,880.70		Budesonide M D I 100Mcg 300Dose	1695	R 62,410.85
98	Paclitaxel 100Mg Injection	70	R 79,517.20		Intravenous Cannula 24G	451	R 61,775.80
99	Carbamazepine Tabs 200Mg (Prp 84)	6918	R 77,792.91		Ibuprofen Tabs 200Mg (Prp 84)	13070	R 61,167.80
100	Povidone Iodine Solution Spray 100Ml	1994	R 77,135.90		Pouch Ostomy One Piece 20-60Mm Op	3256	R 60,230.70

Appendix B

Primary Healthcare Facility Data Collection Form

Name of the Primary Healthcare Facility:_____.

Date of collection:_____.

Patient number	Gender	Age	Diagnosis/ Symptom Complex	Drugs Prescribed	Strength	Frequency	Duration	Rx Complied with STG/ EDL

Appendix C

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH AND SOCIAL DEVELOPMENT

Enquiries: Malomane EL

Ref: 4/2/2

9 April, 2008

Mr Makhado M

University of Limpopo Medunsa Campus

Dear **Mr Makhado M**

Comparison of anti-microbial prescribing patterns with the standards treatment guidelines and essential drug list (STG/EDL) in primary healthcare (PHC) facilities in Vhembe district

- Permission is hereby granted to **Mr Makhado M** to conduct a study as mentioned above
- The Department of Health and Social Development will expect a copy of the completed research for its own resource centre after completion of the study.
- The researcher is expected to avoid disrupting services in the course of his study
- The Researcher/s should be prepared to assist in interpretation and implementation of the recommendations where possible
- The Institution management where the study is being conducted should be made aware of this,
- A copy of the permission letter can be forwarded to Management of the Institutions concerned

HEAD OF DEPARTMENT
HEALTH AND SOCIAL DEVELOPMENT
LIMPOPO PROVINCE

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Appendix D

UNIVERSITY OF LIMPOPO

Medunsa Campus

UNIVERSITY OF LIMPOPO

MEDUNSA CAMPUS RESEARCH & ETHICS COMMITTEE

FACULTY OF HEALTH SCIENCES

CLEARANCE CERTIFICATE

P O Medunsa
Medunsa
0204
SOUTH AFRICA

Tel: 012 - 521 4000
Fax: 012 - 560 0086

MEETING: **01/2008** **PROJECT NUMBER: MCREC/H/03/2008: PG**

PROJECT **Title:** Comparison of anti-microbial prescribing patterns with the standard treatment guidelines and essential drug list (STG/EDL) in primary healthcare (PHC) facilities in Vhembe district

Researcher: Mr. M. Makhado
Supervisor: Prof. A.G.S. Gous
Co-supervisor: Ms. E. A. Helberg
Hospital Superintendent: EK Motlanthe
Other Involved H.O.D's: MP Setsiba (Pharmaceutical Services)
Department: Pharmacy
School: Health Care Sciences
Degree: PhD (Pharmacy)

DATE CONSIDERED: February 07, 2008

DECISION OF THE COMMITTEE:

REPC approved the project.

UNIVERSITY OF LIMPOPO
2008 -02- 13
RESEARCH
Medunsa Campus

DATE: February 13, 2008

PROF GA OGUNBANJO
DIRECTOR: RESEARCH & CHAIRPERSON

Note:	**i)**	**Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.**
	ii)	**The budget for the research will be considered separately from the protocol. PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.**

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Appendix E

Pharmaceutical Services Data Collection Tool - Limpopo Province 2007/2008	
Month:_____.	
HOSPITAL PHARMACY DETAILS	
Hospital Name	
Name of Pharmacy Manager	
Number of Pharmacists	
Number of Community Service Pharmacists	
Number of Interns	
Number of Registered Pharmacists Assistants	
Number of Unregistered Pharmacists Assistants	
Number of active beds	
Number of Fixed Clinics	
Number of Mobile Clinics	
HOSPITAL AND CLINICS PERFORMANCE DATA PART 1	
Number of Outpatients Prescriptions	
Number of Outpatients Items	
Number of Outpatients Items per Prescriptions	
Number of Inpatients Prescriptions	
Number of Inpatients Items	
Number of Inpatients Items per Prescriptions	
Number of Chronic Referral	
Number of Chronic Referral Items	
Number of Chronic Referral Items per prescription	
Issue Value: Inpatients	
Issue Value: Outpatients and Chronics	
Issue Value: Casualty/OPD	
Issue Value: Theatres	
Issue Value: Wards	
Issue Value: Clinics	
Issue Value: Home Based Care	
Issue Value: Emergency Services	
Issue Value: ARV Drugs	
Issue Value: Others	
HOSPITAL AND CLINICS PERFORMANCE DATA PART 1 cont.	
Clinic Stock Availability (%)	
Value of expired stock: Pharmacy	
Value of expired stock: Clinics	

Value of Expired Stock : Wards	
Total Value of Expired Stock	

HOSPITAL AND CLINICS PERFORMANCE DATA PART 2	
Number of Bed Days	
Number of Major Operations	
Number of Minor Operations	
Patient Day Equivalent (PDE)	

HOSPITAL AND CLINICS PERFORMANCE DATA PART 3			
Number of DTC meetings held during the month			
Copy of DTC minutes attached	Yes	No	
Number of Supportive Clinic Visits (Inspection)			
Total Clinics Headcount			
Total Monthly Budget Allocated			
Value of Stock Received from Suppliers			
Commulative Allocated Budget			
Cummulative Value of Stock Received from Suppliers			
% Spent on Accumulative compared to Actual Accumulative Budget			

FLUCONAZOLE (DIFLUCAN) DONATION STOCK			
Total Stock Received this month (Number of tablets)			
Total Number of Tablets used this month			
Total Number of Tablets damaged/lost this month	Yes	No	
Total Number of Tablets Redistributed to other institutions this month			
Stock remaining (Number of Tablets)			
Total Number of OC Patients treated this month			
Total Number of CM Patients treated this month			
Total Number of Patients treated this month			

PDSX SYSTEM UPDATES	
Date of Last PDSX Update	
List of Top 10 Antibiotics by Value	Attach Lists
List of Top 10 Pharmaceutical and Surgical Items by Value	
List of Items Overdue for more than 30 Days	

ARV QUANTIFICATION - DATA SHEET

Estimated Monthly Adult Patients Intake			
Regimen 1	**Male**	**Female**	**Total**
Total Number of Adults who Collected Treatment			
Total Number of Children who Collected Treatment			
Number of Patients: < 40kg			
Number of Patients: >= 40kg and < 60kg			
Number of Patients: >= 60kg			
Number of Pregnant Patients: < 40kg			
Number of Pregnant Patients: >= 40kg and < 60kg			
Number of Pregnant Patients: >= 60kg			
ART (Patients) Adult on Regimen 1a			
ART (Patients) Adult on Regimen 1b			
Regimen 2			
Number of Patients: < 60kg			
Number of Patients: >= 60kg			
ART (Patients) Adult on Regimen 2			
Estimated Monthly Post Exposure Prophylaxis (PEP) Patients			
Estimated Monthly PMTCT Patients (Mothers)			
ART (Patients) Adult on Other Regimens			

Estimated Monthly Pediatric Patients Intake			
Regimen 1	**Male**	**Female**	**Total**
ART(Patients) Children on Regimen 1: **Age =< 3 Years (Without TB)**			
ART(Patients) Children on Regimen 1: **Age =< 3 Years (With TB)**			
ART(Patients) Children on Regimen 1: **Age > 3 and =< 5 Years**			
ART(Patients) Children on Regimen 1: **Age > 5 and =< 9 Years**			
ART(Patients) Children on Regimen 1: **Age > 9 and =< 14 Years**			
Number of Patients (Age > 9 and =<14 Years): < 40kg			
Number of Patients (Age > 9 and =<14 Years): >= 40kg and < 60kg			
Number of Patients (Age > 9 and =<14 Years): > 60kg			

Estimated Monthly Pediatric Patients Intake cont.			
Regimen 2			
ART(Patients) Children on Regimen 2: **Age =< 3 Years**			
ART(Patients) Children on Regimen 2: **Age > 3 and =< 5 Years**			
ART(Patients) Children on Regimen 2: **Age > 5 and =< 9 Years**			
ART(Patients) Children on Regimen 2: **Age > 9 and =< 14 Years**			
Number of Patients (Age > 9 and =<14 Years): < 60kg			
Number of Patients (Age > 9 and =<14 Years): > 60kg			

AVERAGE AVERAGE PATIENTS WEIGHT AND HEIGHTS			
Regimen 1			
Average Patient Weight - Regimen 1 (Age =< 3 Years,without TB)			
Average Patient Height - Regimen 1 (Age =< 3 Years,without TB)			
Average Patient Weight - Regimen 1 (Age =< 3 Years,with TB)			
Average Patient Height - Regimen 1 (Age =< 3 Years,with TB)			
Average Patient Weight - Regimen 1 (Age > 3 and =< 5 Years)			
Average Patient Height - Regimen 1 (Age > 3 and =< 5 Years)			
Average Patient Weight - Regimen 1 (Age > 5 and =< 9 Years)			
Average Patient Height - Regimen 1 (Age > 5 and =< 9 Years)			
Regimen 2			
Average Patient Weight - Regimen 2 (Age =< 3 Years)			
Average Patient Height - Regimen 2 (Age =< 3 Years)			
Average Patient Weight - Regimen 2 (Age > 3 and =< 5 Years)			
Average Patient Height - Regimen 2 (Age > 3 and =< 5 Years)			
Average Patient Weight - Regimen 2 (Age > 5 and =< 9 Years)			
Average Patient Height - Regimen 2 (Age > 5 and =< 9 Years)			
Estimated Monthly PMTCT Patients (Children)			
ART(Patients) Children on Other Regimens			
Total Number of Patients Adhering to Treatment			
Total Number of Patients who Missed Treatment			
List of ART Drugs Out of Stock any time during the month			
List of TB Drugs Out of Stock any time during the month			
Record of Co-Trimoxazole Out of Stock at any time during the month	Yes	No	
% Quantity of ART Drugs Ordered Vs Quantity Received			