



UNIVERSITY OF MALAWI

College of Medicine

**An Assessment of Prescribing and Dispensing Practices in
Public Health Facilities of Southern Malawi**

By

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CERTIFICATE OF APPROVAL

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DECLARATION

I Aaron Glyn Sosola hereby declare that this thesis is my original work and has not been presented for any other awards at the University of Malawi or any other University.

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Date 15th December 2007

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ABSTRACT

BACKGROUND: The World Health Organisation estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly.

OBJECTIVE: To assess the prescribing and dispensing practices of public health facilities in the Southern region of Malawi.

METHODS: The study was cross-sectional in nature using both retrospective and prospective data from thirty (30) encounters selected by simple random sampling in 24 public health facilities. The study was based on the prescribing indicators, patient care indicators and health facility indicators as stipulated by World Health Organization.

RESULTS: A total of 24 health facilities were sampled. The study established that a high percentage of drugs prescribed are generics (99.4%). The study also established that most of the drugs prescribed are on the essential drugs list (99.6%). About one quarter of drugs were adequately labeled.

CONCLUSION: In general, the prescribing and dispensing practices in the health facilities are fairly good and are not far from the standard WHO requirements. Out of the 13 indicators, the study showed that the facilities were doing well on nine (9) i.e. average number of drugs prescribed; encounters with an injection prescribed; drugs prescribed by generic names; drugs actually dispensed; correct patient knowledge of dosage; availability of key indicator drugs; drugs prescribed on EDL and availability of prescribers. The facilities did not do well on five (5) i.e. encounters with an antibiotic prescribed; average consultation time (min); average dispensing time (min); drugs adequately labeled and availability of dispensers.

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ACRONYMS

CI : Confidence Interval

CME : Continuing Medical Education

CMS : Central Medical Stores

COMREC: College of Medicine Research and Ethical Committee

DAP : WHO's Action Programme on Essential Drugs (DAP)

DHO : District Health Office (r)

DIC : Drug Information Centre

EDL : Essential Drug List

GDP : Growth Domestic Product

H/C : Health Centre

IMF : International Monetary Fund

INN : International Non-Proprietary Name

MAX : Maximum

MDHS : Malawi Demographic and Health Survey

MEDP: Malawi Essential Drug Programme

MIN : Minimum

MOH : Ministry Of Health

MPH : Master of Public Health

MSH : Management Sciences for Health

NDF : National Drug Formulary

NDP : National Drug Policy

NGO : Non-Governmental Organisation

NMSC : National Medicines and Supplies Committee

ORS : Oral Dehydration Solution

PMPB : Pharmacy, Medicines and Poisons Board

PTC : Pharmacy and Therapeutics Committees

RDU : Rational Drug Use

SP : Sulphadoxine/Pyrimethamine

MSTG : Malawi Standard Treatment Guidelines

WHO : World Health Organisation

CHAPTER 1

1.0 INTRODUCTION

WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly (Laing RO et al. (1997). The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards. Examples of irrational use of medicines include use of too many medicines per patient ("poly-pharmacy"); inappropriate use of antimicrobials, often inadequate dosage; over-use of injections when oral formulations would be more appropriate; failure to prescribe in accordance with clinical guidelines; inappropriate self-medication, often of prescription-only medicines; non-adherence to dosing regimes.

In-order to evaluate prescribing and dispensing patterns, WHO uses 12 core indicators.(see Appendix 1)

The basic principles of prescribing are:-

- (i) to make accurate diagnosis.
- (ii) to decide whether the drug treatment is necessary.
- (iii) to choose the best available drug.
- (iv) to choose the most appropriate dosage form.
- (v) to prescribe the drug in adequate quantity.
- (vi) to monitor the treatment and;
- (vii) to inform and involve the patient.

The prescribing practices measure aspects of outpatient treatment and are measured by:

- (i) Average number of drugs per encounter, which measures the degree of poly-pharmacy (more than two drugs per encounter).
- (ii) Percentage of drugs prescribed by generic name (the drug's official or international nonproprietary name given by WHO regardless of who manufactures or markets it) which measures the tendency to prescribe by generic name which measures the cost-effectiveness of a health system to procure and use drugs.
- (iii) Percentage of encounters with an antibiotic and an injection prescribed. This measures the overall level of use of two important, but commonly overused and costly forms of drug therapy.

The purpose of dispensing is to ensure that an effective form of the correct drug is given to the right patient in the prescribed dosage and quantity with clear instructions and in a container, which maintains the potency of the drug. This can be achieved by:

- (i) Reading and understanding the prescription
- (ii) Retrieval (collecting the correct drug)
- (iii) Formulation (counting or pouring out the drug),
- (iv) Processing (correct packing and labeling the drug) and;
- (v) Delivering (giving the drug to the patient).

The dispensing practices are measured by:

- (iv) Average consultation time measures the time that medical personnel spend with patients in the process of consultation and prescribing.
- (v) Average dispensing time, measures the average time that personnel dispensing drugs spend with patients.

- (vi) Percentage of drugs actually dispensed measure the degree to which health facilities are able to provide the drugs, which were prescribed.
- (vii) Percentage of drugs adequately labeled measures the degree to which dispenser's record essential information such as name of patient, description of drug, dosage regimen, strength of the drug, precautions and total quantity dispensed on the drug packages they dispense.
- (viii) Patients' knowledge of correct dosage measures the effectiveness of the information given to patients on the dosage schedule of the drugs they receive.

In 1981, WHO's Action Programme on Essential Drugs (DAP) was established to provide operational support to countries in the development of National Drug policies based on essential drugs and to work towards the Rational Drug Use. In 1985, WHO convened a major conference in Nairobi on the rational use of drugs. In order to encourage a standard approach to measuring problems in drug use, INRUD coordinated the development of standard drug use indicators (Appendix1) and encouraged indicator studies in a number of developing countries during the period 1990-1992. An essential tool for such work is an objective method to measure drugs in health facilities that will describe drug use patterns and prescribing behaviour. (WHO/DAP,1993).

Antimicrobial resistance is an increasing problem worldwide, impacting infection control efforts and costs of antimicrobial treatment. Numerous factors contribute to the problem, including unnecessary antimicrobial prescribing by trained and untrained health workers, uncontrolled dispensing by drug vendors, poor antibiotic prophylaxis in surgery, and poor infection control practices.

In the period from 1988-92, baseline surveys were conducted by WHO in different countries. In health centres in Indonesia, patients were prescribed an average of 3.3 drugs per consultation while in Nepal, an average of 44% of drugs were prescribed by generic name and 73% of prescribed drugs were actually dispensed at the health facility. 63% of patients in Bangladesh were able to repeat the correct dosage schedule of the drugs they had received.

In Guinea, almost all the health centres and hospitals were complying with the National List of Essential Drugs. A pharmacologist, a physician and a pharmacist evaluated the Guinean prescribing and dispensing practices at a number of health units (teaching hospitals, pre-referral hospitals and health centers). The drug list was subsequently modified from 170 to 161 drugs. (Hogerzeil H V, et al, 1997)

In Nigerian health facilities, 48% of all outpatient encounters were prescribed one or more antibiotics while an injection was prescribed during 37% of all consultations and 62% of the key essential drugs were actually in stock. In Uganda, drug availability in six primary health care units, patients were dissatisfied when they were not able to obtain all drugs prescribed at a health unit. (Jitta et al, 2003). In Tanzania, an average of 88% of drugs prescribed appeared on the National Essential Drugs List while the patients spend an average of 78 seconds receiving their drugs.

In Malawi, a similar kind of survey was conducted in June, 1991 where a few core indicators were tested. During this baseline survey, the number of drugs per prescription was 1.8, percentage of antibiotics was 34%, percentage of injections was 19%, consultation time was 2.3 minutes, percentage of drugs in stock was 67% and percentage knowledge of dosage by patients was 27%. (WHO/DAP, 1993). Early studies in Yemen and Uganda have used some of the core indicators to quantify the impact of essential drugs programmes or of specific interventions within such programmes. In close collaboration with WHO, the revised indicators were then used again in Sudan, Uganda, Malawi, Nigeria and Tanzania. On the basis of these experiences, the indicators were limited to those related to facility-specific data eliminating those which had originally been included to describe the situation in the community or in the country as a whole. (Hogerzeil H V, et al,1997)

1.1 General socio-economic information for Malawi

Malawi is an African country surrounded by Tanzania, Mozambique and Zambia and has been divided into three regions namely North, Centre and South. It is also sub-divided into 27 (administrative units) districts (Figure 1). There is limited local pharmaceutical manufacturing. Medicines are procured, imported, stored and distributed through the Central Medical Stores for the public sector while a number of wholesalers serve the private-for-profit and private-not-for-profit sectors.

1.2 Demographic parameters

The World Health Report (2007)(Appendix2) stipulates that the population was 12,884,000 in 2006 and the annual growth rate was 2.2%. The life expectancy was 35.0 years for males and 34.8 years for females in 2002 (DHS 2004). The fertility rate was 6.3, which is one of the highest in southern and eastern Africa (MICS, 2006). In terms of education, over 82% of children, who are primary school age (6-13), attend primary or secondary school (MICS, 2006). The literacy rate is 70.7 % (UNESCO Institute for Statistics, 2007).

1.3 Key health information

Malaria is the leading cause of outpatient visits estimated at 40% (MDHS, 2004). Maternal mortality rates are some of the highest in the world at 984 deaths per 100,000 births in 2004 (MDHS, 2004). The infant mortality rate is 76 per 1,000 births in 2004 (MDHS, 2004). The under-five mortality rate is 133 per 1,000 births (MDHS, 2004). Acute respiratory infections, diarrhoea and malaria are the major causes of childhood mortality. The HIV/AIDS prevalence for people aged 15-49 is 12% (MDHS, 2004). Over 100,000 people are on ARV (Malawi MOH HIV/AIDS Unit report, 2006). These facts and figures reflect the lack of access and use of health services especially pharmaceutical care as well as the poverty that drives the illnesses.

The Malawi Essential Drugs Programme (MEDP) introduced the 1st edition of the Malawi Standard Treatment Guidelines (MSTG) and the National Drug List in 1990 and the Malawi Prescriber's Companion (MPC) in 1993. These documents are supposed to be reviewed every four (4) years in order to accommodate new drug molecules and treatment guidelines but the last time they were reviewed was in 1998. (Malawi MOH, 1998)

The study was conducted in selected public health facilities of the Southern Region of Malawi (Figure 1 for map of Malawi).

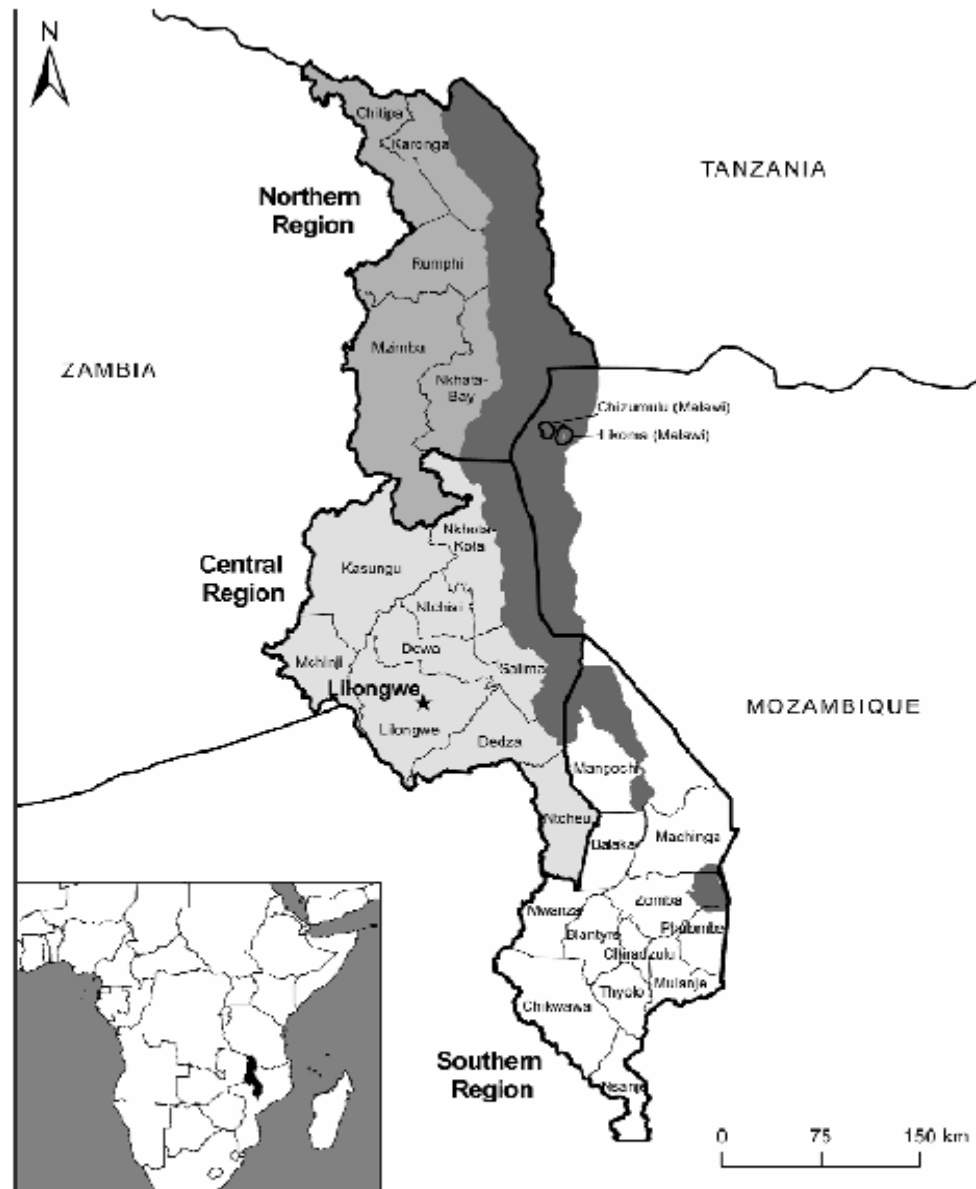


Figure 1: Map of Malawi showing Districts and Regions

The study assessed whether the dispensing and prescribing habits in the health facilities were appropriate or not—depending on National or WHO standards.

1.4 Study rationale

This was a unique study because no study had been undertaken for all the thirteen (13) indicators at once in Malawi except for WHO which did one (1) indicator at a time and just did quite a few in 1991. The study may inform the Ministry of Health, World Health Organization, health planners, health providers, medical training institutions and other health related non-governmental organizations, the shortfalls in the prescribing and dispensing practices in Malawi so that the health providers can improve these practices by modifying the existing weaknesses and malpractices.

CHAPTER 2

2.0 STUDY OBJECTIVES

2.1 Broad objective

The main objective of the study was to assess the prescribing and dispensing practices of public health facilities in the Southern Region of Malawi.

2.2 Specific objectives

The specific objectives of the study were :

- to determine whether drugs were prescribed in adequate quantities with the most economical and appropriate dosage form in health facilities in conformity with the Malawi National Drug Policy.
- to examine whether the drugs that had been prescribed were actually dispensed in adequately labeled packages and that patients understood the information given during consultation and dispensing of drugs.
- to determine whether all the necessary health system support tools such as drugs, staff and medical literature for delivering health services were in place at the health facilities.
- To evaluate the indicators which were not evaluated by WHO in 1991 namely (i) % of drugs prescribed by generic name (ii) Average dispensing time (sec) (iii) % of drugs actually dispensed (iv) % of drugs actually dispensed (v) % availability of EDL or formulary (vi) % of drugs prescribed on EDL (vii) % of available prescribers (viii) % of available dispensers.

- to identify weaknesses and make recommendations on how to improve the prescribing and dispensing practices in the public health facilities.

CHAPTER 3

3.0 STUDY METHODS

A cross-sectional study was conducted in public health facilities in the Southern Region of Malawi. Firstly, the health facilities were stratified into Central hospital, District hospital and health centre, then the health centres were selected by simple random sampling whereby in each district, all health centres (sampling frame) were assigned numbers from 1 (one) to the last number of the health center on a piece of paper. Then any column from the Random Sampling Numbers was selected and numbers were selected where the middle row of the table met this column and proceed downwards. Any two numbers (health centers) that are within the range of the sampling frame were selected without replacement while discarding those that were outside. This was done for all the 12 districts, all district hospitals (sampling frame) were assigned numbers from 1(one) to the last number of the district hospital on a piece of paper. Then any column from the Random Sampling Numbers was selected and numbers selected where the middle row of the table met this column and proceed downwards, any two numbers (district hospitals) that were within the range of the sampling frame was selected without replacement while discarding those that were outside. Similarly, for the 2 central hospitals, one central hospital was selected using the same random sampling method without replacement.

A schedule to visit the facilities was prepared and the officers-in-charge were informed on the month their facility would be visited. Permission was sought first from the Ministry of Health, Zonal Health Office (South) and the officers in-charge of the health institution

before conducting the survey. Twenty four (24) health facilities in total were assessed instead of the 27 planned, because three (3) health centres were not open on the day of the visit. The patients were interviewed after obtaining their approval through the Consent Form (Appendix 9). A convenience sampling method was used for obtaining a sample of patients at each institution. Convenience sampling is a method by which, for convenience sake, the study units that happen to be available at the time of data collection are selected. Patients were then selected by choosing the first patient, and then followed by the next patient until 30 patients were selected sequentially per encounter per site. Thirty (30) encounters in a facility were sampled which was amounting to 720 encounters in total for all facilities.

Two (2) health centres were randomly selected from each of the 12 districts. These were Bvumbwe, Khonjeni, Chifunga, Tulonghondo, Chonde, Kambenje, Kalembo, Mbela, Kukalanga, Monkey-Bay, Matawale, Namasalima, Nainunje, Ntaja, Namitambo, Nkalo, Ngabu, Zingwangwa, Phalombe, Lundu and Sorgin. One (1) Central (referral) hospital (Queen Elizabeth Central Hospital) and two (2) District hospitals namely Thyolo and Machinga. It was envisaged that 27 health facilities would be surveyed but only a total of 24 were surveyed due to closure of two (2) facilities and unavailability of medical personnel at the other one.

3.1 Data collection

Data was collected by a Pharmacy Technician who had been adequately trained on how to collect data. Thirty (30) encounters in a facility for all the 24 facilities were sampled for a period covering one year, which was amounting to 720 encounters in total for all facilities.

3.1.0 Prescribing indicators

The prescribing indicators measure aspects of outpatient treatment. All the four indicators below were collected retrospectively from the out-patient registers (they record date, name of patient, age, diagnosis and treatment). The data was recorded or collected according to the following indicators on a prescribing indicator form (Appendix 3).

- (i) Average number of drugs per encounter, which measures the degree of poly-pharmacy (more than two drugs per encounter). This was done by dividing the total number of different drug products prescribed, by the number of encounters surveyed.
- (ii) Percentage of drugs prescribed by generic name (the drug's official or international nonproprietary name given by WHO regardless of who manufactures or markets it) which measures the tendency to prescribe by generic name which measures the cost-effectiveness of a health system to procure and use drugs. This was calculated by dividing the number of drugs prescribed by generic name, by the total number of drugs multiplied by 100.
- (iii) Percentage of encounters with (1) an antibiotic prescribed.
(2) an injection prescribed.

This measures the overall level of use of two important, but commonly overused and costly forms of drug therapy. They were calculated by dividing the number of patient encounters during which an antibiotic or injection were prescribed, by the total number of encounters surveyed, multiplied by 100.

- (iv) Percentage of drugs prescribed from essential list or formulary, which measures the degree to which practices conform to national drug policy. It was calculated

by dividing the number of products prescribed which were listed on the essential drugs list by the total number of products prescribed, multiplied by 100.

3.1.1 Patient care indicators

These address key aspects of what patients experience at health facilities and how well they have been prepared to deal with pharmaceuticals that have been prescribed and dispensed. All data needed to measure patient care indicators for each facility were recorded and summarized on the patient care form (Appendix 4)

- (i) Average consultation time measures the time that medical personnel spend with patients in the process of consultation and prescribing. This was observed and time recorded using a stopwatch between when the patient entered and left the consultation room. It was calculated by dividing the total time for a series of consultations by the number of consultations.
- (ii) Average dispensing time, measures the average time that personnel dispensing drugs spend with patients. This was done by observing and recording the time when a patient submits the prescription to the dispenser of drugs on the counter and the time the patient leaves the (counter) dispensary. It was calculated by dividing the total time for dispensing drugs to a series of patients, by the number of encounters.
- (iii) Percentage of drugs actually dispensed measure the degree to which health facilities are able to provide the drugs which were prescribed. It was measured by dividing the number of drugs actually dispensed at the health facility by the total number of drugs prescribed, multiplied by 100.

- (iv) Percentage of drugs adequately labelled measures the degree to which dispenser's record essential information such as name of patient, description of drug, dosage regimen, strength of the drug, precautions and total quantity dispensed on the drug packages they dispense. It was measured by dividing the number of drug packages containing at least patient name, drug name and when the drug should be taken, by the total number of drug packages dispensed, multiplied by 100.
- (v) Patients' knowledge of correct dosage measures the effectiveness of the information given to patients on the dosage schedule of the drugs they receive. This was measured by dividing the number of patients who could adequately report the dosage schedule for all drugs during exit interviews, by the total number of patients interviewed, multiplied by 100.

3.1.2 Health facility indicators

Three important components which influence the ability to prescribe drugs rationally are the availability of qualified prescribers and dispensers, adequate supply of essential drugs and access to unbiased information about these drugs. The data for the health facility indicators was recorded on the facility summary form (Appendix 5).

- (i) Percentage availability of a copy of essential drugs list or formulary is indicative of the extent to which copies of the national essential drugs list or local formulary are available at health facilities. The Essential Drugs List or formulary was checked in the consultation room or dispensing area or drugstore. It was calculated by dividing the total number of health facilities that have the

Essential Drugs List or formulary by the total number of facilities surveyed, multiplied by 100.

- (ii) Percentage of available key drugs is a measure of the availability at the health facility of key drugs recommended for the treatment of some common ailments such as malaria, pneumonia, anaemia and diarrhoea. This was collected from the drugstore. This was done by dividing the number of available key drugs from the checklist by the total number of drugs on the checklist multiplied by 100 (Appendix8).

The actual drugs that were checked were: Paracetamol tablets, Ferrous Sulphate + Folic Acid tablets, Albendazole tablets, SP tablets, ORS and Cotrimoxazole tablets.

- (iii) Percentage availability of qualified prescribers (clinicians who write prescriptions). This was obtained by asking the health workers whether they are or have qualified clinicians. It was calculated by dividing the total number of health facilities that have qualified clinicians by the total number of facilities surveyed, multiplied by 100.
- (iv) Percentage availability of qualified dispensers (pharmacy personnel who issue out drugs to patients). This was obtained by asking the health workers whether they have qualified pharmacy personnel. It was calculated by dividing the total number of health facilities that have pharmacy personnel by the total number of facilities surveyed, multiplied by 100.

3.2 Data analysis

The necessary data on prescribing indicators, patient care indicators and facility indicators was calculated and summarized on the appropriate forms (See appendices). The information that was collected was for a period of 12 months (July, 04 to June, 05). After the data had been collected from each facility, the results were entered and aggregated onto a facility indicator reporting form (Appendix6) and consolidation form (Appendix7) and then transferred into a computerized version of the form. Both tabular and graphic presentations were used from the quantitative data. Mean (average), minimum and maximum values and the confidence intervals for indicators were generated using Epi-info 2002 version 2 of 2003 software. Bar and pie graphs were created using Microsoft Excel that showed the number of facilities at different levels of each indicator and how the facilities might vary. From the data, p-values and confidence intervals were calculated. A CHI-Square was used and considered p-values $\angle 5\%$ as being statistically significant. The results were compared with the baseline information of another survey that was conducted by WHO in June, 1991 for Malawi, results of other developing countries and the WHO standard measures.

3.3 Ethical considerations

The study was not expected to raise any significant ethical issues because the methods of study are regularly employed in research in Malawi. The issues studied fall within the regular activities and mandate of the Ministry of Health (MOH). However, permission was sought and obtained from Ministry of Health, Zonal Health Office (South) and district

health authorities and respondents themselves before the actual survey could be conducted. The privacy of subjects being interviewed and the secrecy of the information from registers and relevant documents were of paramount importance. Before interviewing the subjects, an informed consent was sought from first, the In-charge of the facility and secondly, through a Consent Form, the subject to be interviewed. Confidentiality was assured for all information collected and no reference was made to specific patients or study units. Similarly, College of Medicine Research and Ethical Committee (COMREC) reviewed and approved this study.

3.4 Limitations of the Study

In undertaking the study, the following limitations were encountered:

- Since the study only covered public health facilities in one region, there was no comparison with the Private sector and mission hospitals in all the regions where the results could be different especially in the number of drugs prescribed.
- The baseline survey that was conducted by WHO in June, 1991 and WHO standard measures did not cover all the core indicators. Hence it was difficult to compare the results of all the indicators.
- The Consent Form could distort the validity of the results since the subjects would be operating from an experimental (non-ideal) environment.
- Observer bias could be introduced by observing the health workers, as they could not work as normal due to the investigators' presence. This could distort the validity of the results since the workers would be operating from an experimental (non-ideal) environment.

- A major limitation in realizing some of these potentials is the absence of WHO reference values which would serve as a yardstick to assess the prescribing practices as well as evaluate interventional and supervisory efforts.

CHAPTER 4

4.0. STUDY RESULTS

It was envisaged that 27 health facilities would be surveyed but only a total of 24 (1 (one) Central hospital, two (2) District hospital and twenty-one (21) health centres) were surveyed due to closure of two (2) facilities (no medical assistant at Tengani in Nsanje and Mfera in Chikwawa) and unavailability of medical personnel (Mpassa in Phalombe, there was a funeral). However, the team managed to interview all health workers and participants in the facilities visited. The participants to the study were mostly women, educated up to standard 8 (480 [67.5%] out of 720), who came with a sick minor to the health facility. When they were asked a question in English, they responded in the same language though in a disjoint English phraseology. There was only one pharmacist in these public health facilities who was based at referral hospital and most of the pharmaceutical services were provided by Pharmacy Technicians and Pharmacy Assistants with little or no supervision.

4.1 Prescribing Indicators

4.1.0 Average number of drugs per encounter

In Table 1 and Figure 2, the average number of drugs per encounter was 2.1 at 95%CI (2.0, 2.2) drugs. Referral hospital had a higher (2.7) number of drugs prescribed than the WHO standard (1.6-1.8).

Table 1 : A TABLE SHOWING COMPARATIVE CORE DRUG INDICATORS FOR THE STUDY AND THEIR MEAN FOR DIFFERENT LEVELS OF HEALTH CARE

					Mean Core Drug indicator according to Level of Health Care		
Indicator	WHO Standard Values	Study findings at 95% Confidence Interval	WHO Baseline study (Malawi)-06/ 91	p-value (study Vs WHO standard) at 95%	Referral Hospital	District Hospital	Health Centre
Average number of drugs prescribed	1.6 - 1.8	2.1 (2.0, 2.2)	1.8	0.01	2.7	2.1	2.1
% of drugs prescribed by generic names	100.0	99.4 (99.1, 9.7)	-	-	100.0	100.0	99.3
% of encounters with an antibiotic prescribed	20.0 - 26.8	63.9 (57.1, 70.7)	34.0	0.0001	33.3	33.3	65.4
% of encounters with an injection prescribed	13.4 - 24.1	26.0 (19.6,32.4)	19.0	0.02	40.0	1.7	27.6
Average consultation time (min)	-	2.1 (1.8, 2.4)	2.3	0.04	1.1	1.6	2.2
Average dispensing time (sec)	-	58.4 (44.0, 72.8)	-	-	31.3	34.7	62.0
% of drugs actually dispensed	-	97.1 (95.5, 98.7)	-	-	100.0	91.3	97.6
% of drugs adequately labeled	-	25.4 (14.6, 36.2)	-	-	71.7	56.3	20.2
% correct patient knowledge of dosage	-	80.6 (75.3, 85.9)	27.0	0.0001	86.7	76.7	80.7
% availability of EDL or formulary	-	75.0	-	-	-	-	-
% availability of key indicator drugs	-	84.5 (81.5, 87.5)	67.0	0.001	85.7	85.7	84.3
% of drugs prescribed on EDL	100.0	99.6 (99.4, 99.8)	-	-	100.0	100.0	99.5
% of available prescribers	-	95.8	-	-	-	-	-
% of available dispensers	-	13	-	-	-	-	-

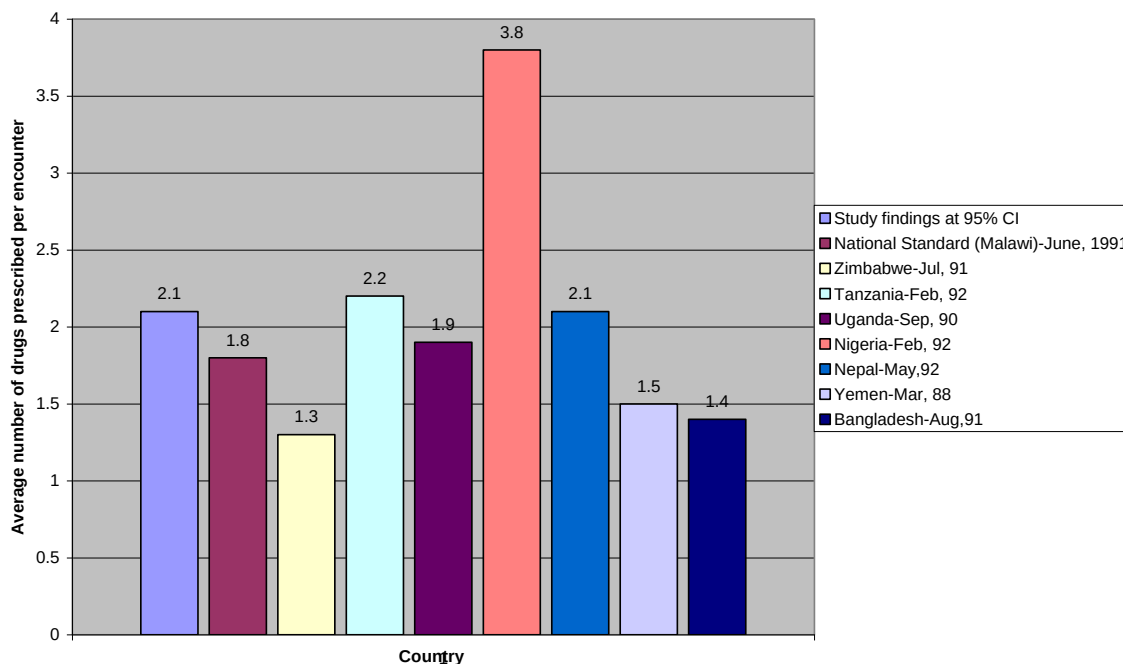


FIGURE 2: A GRAPH SHOWING COMPARISON OF AVERAGE DRUGS PRESCRIBED PER ENCOUNTER FOR DIFFERENT DEVELOPING COUNTRIES

4.1.1 Percentage of drugs prescribed by generic name

In Table 1 and Figure 3, the average percentage of generic drugs prescribed was 99.4%. All drugs prescribed by District hospitals and Referral hospitals (100% respectively) were generic drugs.

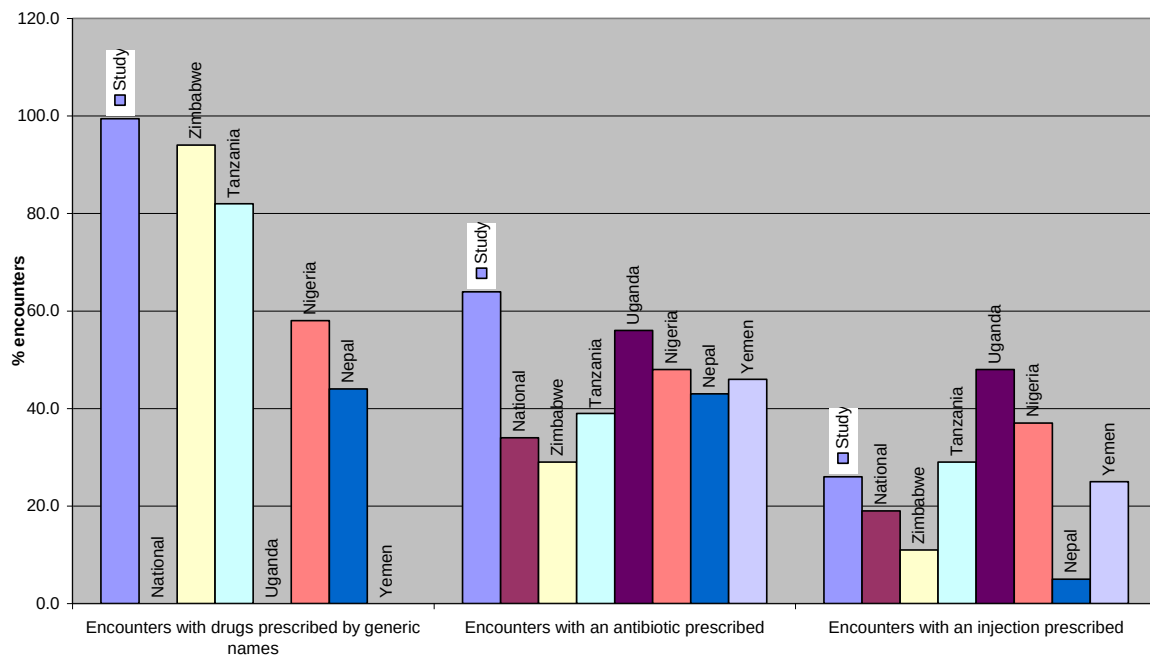


FIGURE 3: A GRAPH SHOWING GENERIC NAME, ANTIBIOTIC AND INJECTION USAGE IN DIFFERENT DEVELOPING COUNTRIES

4.1.2 Percentage of encounters with an antibiotic and injection prescribed

In Table 1 and Figure 3, the percentage of patients receiving antibiotic was 63.9% with a 95% CI (57.1, 70.7)%. Antibiotic prescribing was much higher (65.4%) in the health centers as compared to District and Referral hospital (33% respectively) but both are higher than the WHO standard. From Figure 4, the bulk of about 30% - 50% antibiotics were being used by 58% of the facilities (almost half of the facilities).

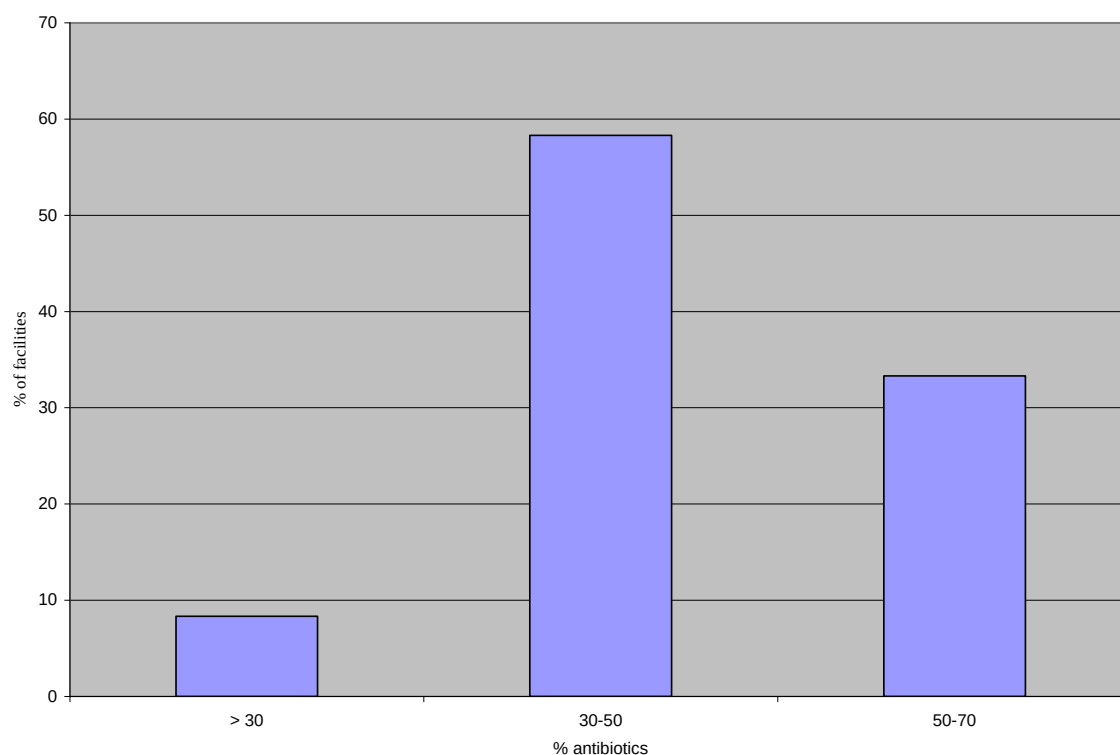


FIGURE 4: A GRAPH SHOWING SAMPLE-WIDE DISTRIBUTION ANTIBIOTIC USE

The average percentage of patients receiving one or more injections at the facilities was found to be 26.0% at 95% CI (19.6, 32.4) %. Almost 54.2% of the facilities were prescribed 20% - 50% of the injection (Figure 5). Injection use is very high (40%) in the Referral hospital as compared to the lower levels. But overall injection use (26.0%) was not significantly different from the WHO standard of (13.4-24.1%).

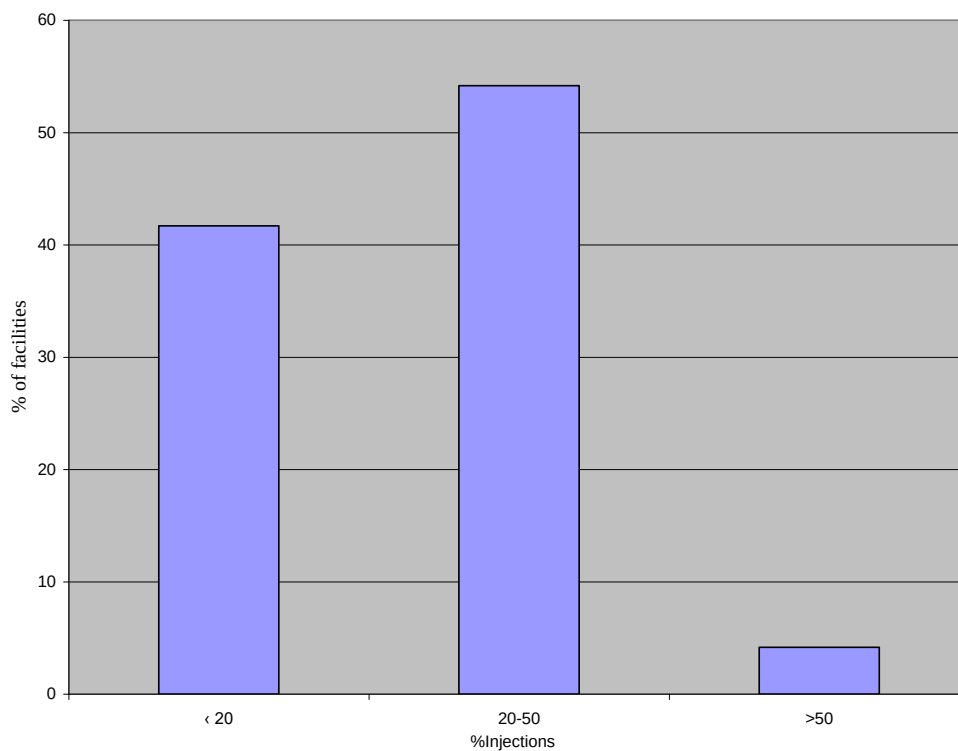


FIGURE 5: A GRAPH SHOWING SAMPLE-WIDE DISTRIBUTION OF INJECTION USE

4.1.3 Percentage of drugs prescribed from essential list or formulary

From Table 1, the average percentage of drugs prescribed that was on the Essential drugs list of Malawi in the health facilities was 99.6% at 95% CI (99.4, 99.8)%. 75% of the health facilities had between 99%-100% of drugs, which were on the EDL.

4.2 Patient care indicators

4.2.0 Average consultation time and dispensing time

The average consultation time was 2.1 minutes at 95% CI (1.8, 2.4) minutes. In Appendix1, the average dispensing time for facilities was 58.4 seconds at 95% CI (44.0, 72.8) seconds.

4.2% of the facilities were dispensing in more than 120 seconds while almost half (45%) of the facilities were dispensing in less than 40 seconds. The Referral hospital had the lowest consultation and dispensing times of 1.1minutes and 31.3 seconds respectively than the other levels. There was no difference in consultation time between the baseline survey (2.3 min) and the consultation time (2.2 min) of the study of health centers. The health centers took ample time to dispense drugs to the patients than the other levels of care. The District and Referral took less time (almost half of the time taken by health centre).

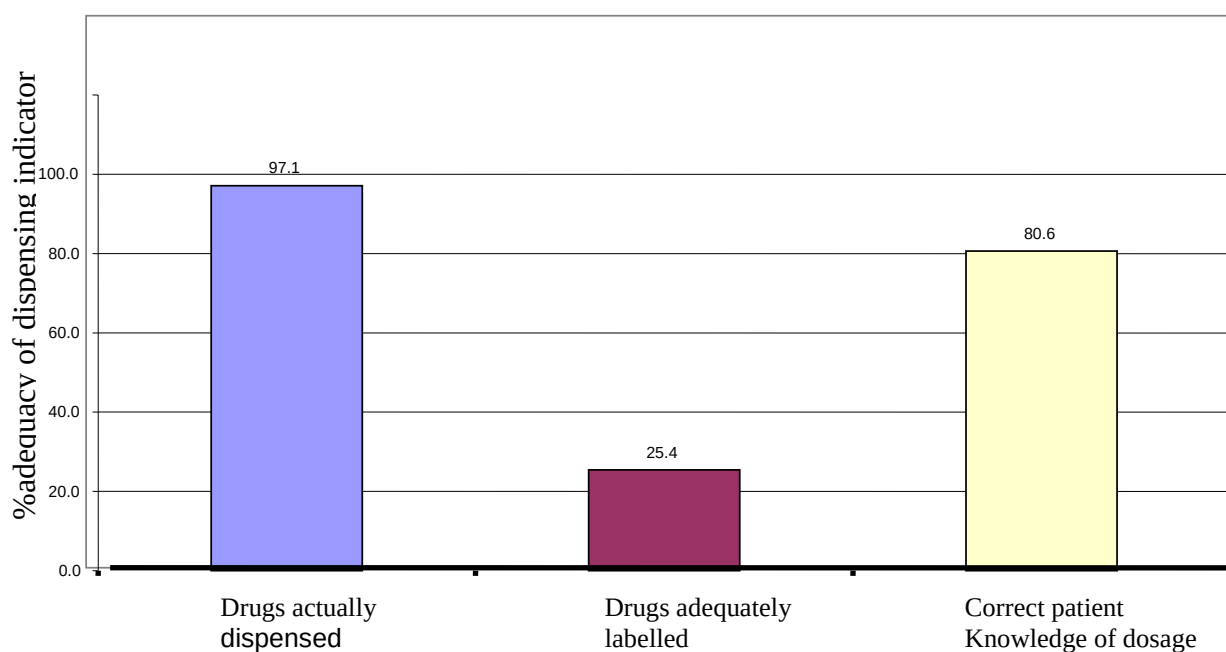


FIGURE 6: A GRAPH SHOWING ADEQUACY OF DISPENSED DRUGS, LABELLING OF DRUGS AND DOSAGE KNOWLEDGE OF PATIENTS

4.2.1 Percentage of drugs actually dispensed, adequately labeled and patients'

knowledge of correct dosage

In Table 1, the Referral hospital dispensed all the drugs that were prescribed than the other two levels. In Table 1 and Figure 6, the average adequacy of labeling of drugs was 25.4% with a 95% CI (14.6, 36.2) %. Proper labeling at the Referral was done in almost three-quarters of the dispensing packets as compared to the other levels of care. However, the average adequacy of patient knowledge at the public health facilities was 80.6% at 95% CI (75.3, 85.9)%. The knowledge by patients in the Referral hospital was comparatively higher (86.7%) than the other levels. However, the overall adequacy of knowledge by patients was high in all levels. Even the layout of the dispensary where people queue one after another to receive medicines was not conducive to counseling.

4.3 Health facility Indicators

4.3.0 Percentage of available key drugs

In Table 1 and Figure 7, the percentage of available key drugs was 84.5% with a 95% CI (81.5, 87.5)% .It is also seen that almost 80% - 90% of the key drugs were available in 75.0% (3 in 4) of the facilities. This availability was not significantly different in all levels of care.

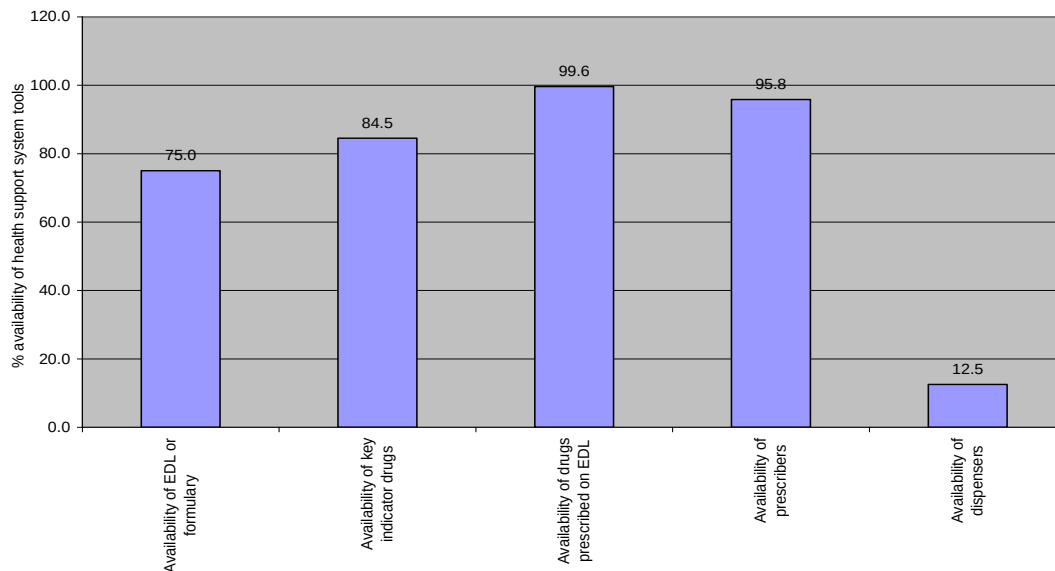


FIGURE 7 :A GRAPH SHOWING AVAILABILITY OF HEALTH SYSTEM SUPPORT TOOLS IN THE HEALTH FACILITIES

4.3.1 Availability of qualified prescribers and qualified dispensers

In Table 1 and Figure 7, the percentage of facilities with EDL, facilities with prescribers and facilities with dispensers were 75.0%, 95.8% and 12.5% respectively. Figure 7 shows that in three – quarters (3 in 4) of the facilities, EDL was available while in most of the facilities there were prescribers who could be either medical assistants or clinical officers or doctors. In Figure 8, it was only in 13% of the facilities that had qualified dispensers.

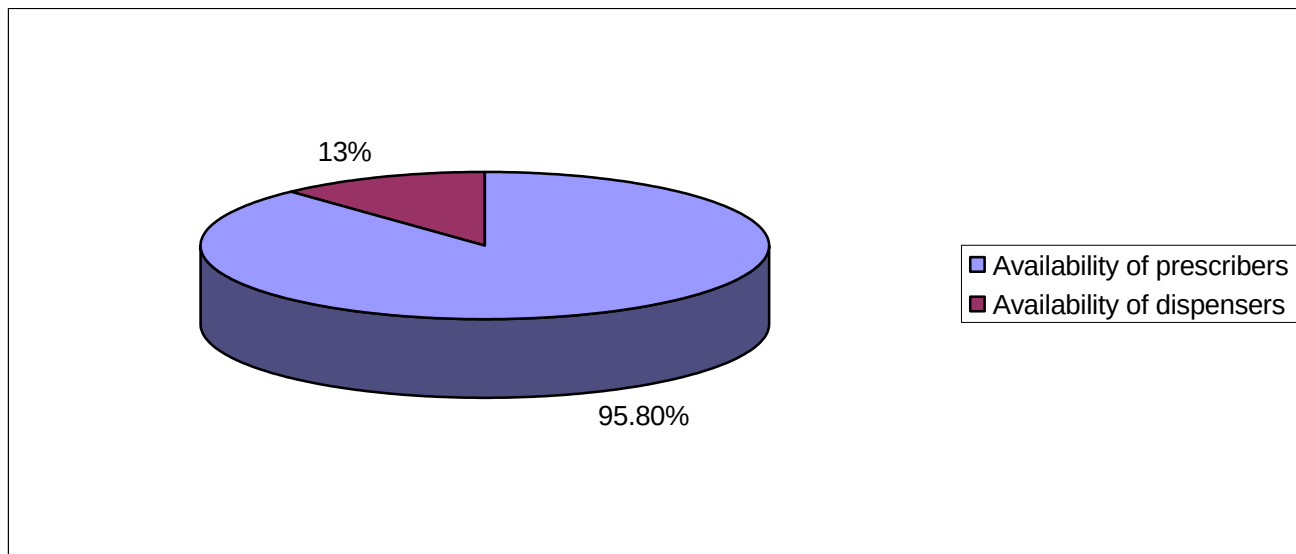


FIGURE 8:A GRAPH SHOWING AVAILABILITY OF PRESCRIBERS AND DISPENSERS

The unqualified dispensers, mostly hospital attendants, are of low calibre and didn't understand the usefulness of drug management, counseling and communication. When the investigators asked the attendants on whether they had attended any course in drug management, very few (3%) responded affirmatively and those who did, after asking them to simulate counseling on certain drugs, lacked technical insight in dispensing practices.

CHAPTER 5

5.0 DISCUSSION

From Table 1, the average number of drugs prescribed of 2.1 was significantly different from the WHO standard of and baseline survey of 1.8 of 1991 with $p < 0.01$. This shows that the therapeutical training that prescribers undergo might not have been consistent and that the prescribing habits tend to use less prescribing information from Standard Treatment Guidelines. This may be due to a number of factors notably overuse of antibiotics, injections, analgesics, NSAIDs and multivitamins.

The percentage of antibiotic use had almost doubled from 34.0% to 63.9% with $p < 0.0001$. This shows that the antibiotic use has significantly increased over the years. However, this could be attributed to the HIV/AIDS pandemic since opportunistic infections are mostly treated by antibiotics. There was unacceptably high use of antibiotics (63.9%) and unless prompt measures are taken to improve the prescribing habits and the use of these types of drugs, there is little doubt that Malawi will face serious problems of increasing resistance to currently cost-effective antibiotics and increased costs and risk to the patient from the overuse of injections.

Comparatively, there was a relatively low usage but no significant change of use of injections 26% with a $p < 0.02$ which has increased from 19%. This is comparatively not different from the WHO standard. Most of the patients that visit the Referral hospital are referred from health centers. Hence the high use of injections in the Referral hospital could be attributed to the numerous admissions that occur after consultation. Transmission of

diseases such as HIV/AIDS, Hepatitis B through re-utilization of needles and accidental needle pricks amongst health workers should have led to a decline in the popularity of injections. However, this is not the case as injection use is still the preferred route of drug administration. This could be due to inadequate availability of syringes and needles over the past four years. Almost half (54%) of the facilities were prescribed almost half of the injections. This could indicate that due to the small number of injections used, the large number of antibiotics being administered could be oral antibiotics especially the syrups such as amoxicillin syrup, erythromycin syrup and many more. Injection misuse, including overuse and unsafe practices, can transmit blood-borne pathogens.

The average percentage of generic drugs prescribed (99.4%). (Table 1) which is in line with the Malawi Government policy through the National Drug Policy (1991) that all drugs procured by Central Medical Stores should be generic in order to capitalize on their cheaper cost. The high percentage of drugs prescribed by generic name and from EDL clearly shows that the procurement and utilization of drugs in Malawi may be cost-effective. High quality generic drugs have equivalent efficacy and generally cost less than brand name alternatives. If product quality can be assured, then efforts to promote generic prescribing and generic substitution at the point of dispensing will result in more cost-effective care

The same generic drugs were also found in the Essential Drug List (99.6%).

Almost three-quarters of the facilities had almost 100% of the drugs which were on EDL. (Table 1 & Figure 7). This might be because the Malawi Government through Central Medical Stores had made it possible that all the drugs in the Central Medical Stores

catalogue should come from the EDL and that all public health facilities should always procure drugs from Central Medical Stores.

Most prescribers in health facilities may not necessarily have used EDL because it was outdated. The Malawi Standard Treatment Guidelines (MSTGs) and Malawi Essential Drugs List (MEDL) currently in use were last revised in 1998. The status of EDL in the facilities was reasonably available. This may have augmented the adequate knowledge of the patients on dosage regimen and the prescribing of generic forms of drugs by clinicians. Disease control programmes have come up with new treatment protocols requiring review and incorporation in the MSTG.

The average consultation time of 2.1 minutes with $p < 0.04$ shows that it has not significantly changed from the WHO baseline survey of 1991 of 2.3 minutes. It was short due to the long queues and increased disease burden at the health facilities. Proper diagnosis and counseling may not be achieved within this short period of time. The short consultation time for Referral hospital could be due pressure of workload since in Malawi Referral hospitals serve both outpatients and in patients. The movement (brain drain) of medical personnel from the public sector might have created a big shortage. In addition to this, most of the prescribers have not been trained in effective communication since it was not included in their curriculum at the college level.

The average dispensing time of 58.4 seconds (under a minute) was too short to effectively label, dispense and counsel the patients on the appropriate use of medicines. This could be

due to the fact that there was no counseling by unqualified dispensers (who were not Pharmacists) and that most of the drugs were pre-packed in the drugstore before the patient came. The quality of dispensing is likely to be affected by the level of training of the dispensing staff. Most of the countries were above 1 minute (Hogerzeil H V, et al, 1997). The shorter period for the upper two health care levels was due to workload by medical personnel as compared to health centers.

The high number of health facilities with prescribers was due to the resumption of training of clinicians at the College of Health Sciences and College of Medicine. Unlike dispensers (13% availability), their numbers were too small in the health facilities due to lack of school of Pharmacy during the period of the study and the fact that the pharmacy assistant course at the college of Health Sciences was stopped long time ago. Physicians are often highlighted as the final pathway for nearly all professional decisions about the use of health resources. Yet with respect to drugs, pharmacists and other dispensers are in many cases the final link between the medication and the patient.

The percentage of drugs actually dispensed was very similar to the drugs being prescribed because it's the same person who is ordering, prescribing and sometimes dispensing.

The (25.4%) of drugs that were adequately labeled, may be contributed to by the high numbers of untrained dispensers (13% of facilities had dispensers) who could not package and label the drugs properly. Even the high workload could be another contributing factor. The high number of properly labeled dispensing packets in Referral hospital could be due to availability of Pharmacy Technicians and Pharmacy Assistants who were dispensing the

medicines. While in the lower levels, hospital attendants who had never attended any drug management course were dispensing the drugs.

The average adequacy of patient knowledge at 80.6% shows that it has increased (trebled) significantly to the national WHO baseline study of 1991. Patient knowledge had also been increased due to an increase in adult literacy rate from 39% in 1991 to 70.7 % in September, 2007 (World Health Report 2007). Many people have become reasonably knowledgeable in many issues including medication. In addition to this, the media (both electronic and print) may have also contributed considerably by informing the public through the radio, newspapers and television on the issue of medication. Many factors contribute to inadequate patient knowledge, among them the quality of the consultation and the information about the prescribed medicines given by the consulting health worker. Despite the fact that the mean consultation and dispensing time were significantly shorter at the referral hospital than at district hospital and health centres, the patient knowledge of drugs dispensed was significantly higher in patients at referral hospital than at district hospital and health centres. This may be because the consulting and dispensing staff at referral hospital are better trained than those at health centre. The higher knowledge on dosage information at the Referral hospital could be due to the fact that all Referral hospitals in Malawi are located in the main cities. Therefore, most of the patients in urban are more educated than the rural areas where most District hospitals and Health centers are. Hence, the patient-dispenser interaction was therefore very poor. There was no time to ask the patient to repeat the dosage regimen in order to confirm whether it was clear.

The availability of a copy of essential drugs list was moderately high. Since government priority in selecting drugs to be procured was not in line with health facility requirements during the period of study; the availability of key drugs in the health facilities was moderately high. Communicating effectively with patients and drug packaging and labeling can also play a role in patient compliance. There is a relationship between labeling of drugs and patient knowledge (Figure 6). Properly labeled drugs enhance or promote good patient knowledge. Dispensers play a significant role in communicating with patients on how to take the drugs to ensure compliance with drug therapy. This can be done during dispenser-patient contact.

The percentage availability of key indicator drugs had significantly increased from 67% during the WHO baseline survey of 1991 to 84.5% with $p < 0.001$. However, the limited number of key drugs could not give a true impression. Some of the critical surgical items and reagents could be out of stock at the time of the survey. Bias of health worker observing could contribute to improper information given by the participants; consultation and dispensing times might be affected as well.

CHAPTER 6

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Drugs were being procured and prescribed in adequate quantities and in the most cost-effective way though antibiotics were being prescribed in an irrational manner. There was a drastic increase of patient knowledge on how to take medication by patients despite poor labeling by the dispensers. Health support system tools that help with proper delivery of health systems were available in terms of key drugs, medical literature and medical personnel except dispensers (Pharmacists, Pharmacy Technicians and Pharmacy Assistants) who were not adequately available. The indicators that were not assessed in 1991 by WHO were done in this study. Out of the 13 indicators, the study showed that the facilities were doing well on nine (8) i.e. average number of drugs prescribed; encounters with an injection prescribed; drugs prescribed by generic names; drugs actually dispensed; correct patient knowledge of dosage; availability of key indicator drugs; drugs prescribed on EDL and availability of prescribers. The facilities did not do well on five (5) i.e. encounters with an antibiotic prescribed; average consultation time (min); average dispensing time (min); drugs adequately labeled and availability of dispensers.

Some more studies are needed which may include in-patient wards, private clinics, mission hospitals and coverage of all the regions. The findings and recommendations of this survey should facilitate efforts to build on the significant progress already made in improving drug management in Malawi by strengthening institutional and human resource capacity to

manage pharmaceutical supplies, service provision and regulation at all levels of the healthcare system. There were good prescribing and dispensing practices at the district level as compared to referral and health center. This could be contributed by the overload of patients in both the referral hospital and Health centers as well as lack of adequate medical staff in the health centers.

Ministry of Health should use validated drug management and core drug indicators as part of monitoring and evaluating the implementation of National Drug Policy. To promote improvements in the quality of health care, which meet specific policy objectives, indicators should be continually reviewed. They should be designed to measure trends in drug management, prescribing, and dispensing in both the public and private sectors. Implementation should be based on local evidence and should include interventions on multiple levels of the health care system; and should also be long-term since implementation takes time, continued stakeholder commitment, and adequate human resources. In general, the prescribing and dispensing practices in the health facilities are fairly good and are not far from the standard WHO requirements.

Sufficient evidence is now available to persuade policymakers that it is possible to promote rational drug use. If such effective strategies are followed, the quality of health care can be improved and drug expenditures reduced.

6.1 Recommendations

In view of the above findings and discussions, the following recommendations are made:

1. Ensure that antibiotic prescribing is in line with the Malawi Standard Treatment Guidelines. Identify and develop interventions for implementation to address the significant increase in the number of antibiotics prescribed per patient. This may be achieved through:
 - Promotion on the use of MEDL in both the public and private sector through regular distribution and training of all relevant health workers.
 - Limiting prescription of antibiotics by level of prescriber; this includes limiting certain antibiotics to being available only with a prescription and not available over-the-counter;
 - In order to control the overuse of antibiotics in a health facility, all recommended prescribers should submit their names and signatures to the Pharmacy Department. Any prescription whose name and signature of prescriber does not appear on the list should be rejected.
 - Review membership of the National Medicines and Supplies Committee (**NMSC**) and its Terms of Reference. This committee should categorize antibiotics according to level of health care. It should advise health workers on the dangers of prescribing high level before the lower level antibiotics to avert development of resistance. In addition, there should be support on the regular update, production and distribution of the MSTG, MEDL, Malawi National Formulary and Prescribers Companion.

- Treatment guidelines and training courses should emphasize on the importance of correct labeling and instructions to patients when antibiotics are prescribed.
 - Institutionalise Continuing Pharmaceutical and Medical Education activities for the training of practicing health workers.
2. Ensure that patients are diagnosed and assessed adequately. This may be achieved through:
- Training of adequate clinicians who may in turn ease the congestion in the hospitals.
 - Intensify disease prevention and control campaigns in order to sensitize the general public on good hygiene practices. Hence, this may reduce disease burden and in turn lessen congestion in the health facilities.
 - Conduct frequent refresher courses for clinicians on proper prescribing and counseling of patients.
3. Ensure that all the medicines dispensed are adequately labeled and that all the information on dosage regimen, side effects and refill are effectively conveyed to the patient or caretaker.
- Develop, disseminate and enforce clear guidelines and training on the importance of labeling for dispensed medicines on good dispensing practices for all dispensing personnel.
 - The Malawi College of Health Sciences should resume the training of Pharmacy Assistants to increase the numbers of Pharmacy Technicians and Assistants.
 - Ensure revision of the curricula of all pharmaceutical training courses for students involved in dispensing to adequately cover rational use of drugs.

- Ensure the regular inspections, evaluation and monitoring of premises and personnel where dispensing operations are performed.
- Ensure that drugs in the public and private sector are dispensed by the holders of a valid dispensing license.

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APPENDICES

APPENDIX 1

TABLE SHOWING HEALTH INDICATORS FOR MALAWI

Total population	12,884,000
Population Growth (2005) (annual %)	2.2
GDP per capita (Intl \$, 2004)	519
Life expectancy at birth (2005) (years)	40.2
Healthy life expectancy at birth, m/f total (years, 2005)	35.0/34.8
Child mortality (2005) (per 1000)	109
Adult mortality m/f (per 1000)	663/638
Total health expenditure per capita (Intl \$, 2003)	46
Total health expenditure as % of GDP (2003)	9.8
The literacy rate (2005) (% of population ≥ 15 years of age that can read and write)	70.7
Prevalence of HIV/AIDS,(2005) total (% population aged 15-49)	14.1

(World Health Report 2007)

APPENDIX 2

PRESCRIBING INDICATOR FORM

Location: _____ Date: _____ Investigator: _____

No	Type of treatment	Age (Yrs)	# Drugs	# Generics	Antibiotics (0/1)*	Injection (0/1)*	# On EDL
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
26							
27							
28							
29							
30							
Total							
Average							
Percentage				% of total drugs	% of total cases	% of total cases	% of total Drugs

* 0=NO, 1=Yes

APPENDIX 3
PATIENT CARE FORM

Location: _____ Date: _____ Investigator:

No	Patient Identifier	Consulting time (min)	Dispensing time (sec)	# drugs prescribed	# drugs dispensed	# adequately labeled	Knows dosage (O/1)*
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
26							
27							
28							
29							
30							
Count							
Total							
Average							
%				% Prescribed	% Dispensed	% adequately labeled	% Cases knows

* O=No, 1=Yes

APPENDIX 4

FACILITY SUMMARY FORM

Location: _____ Date: _____ Investigator: _____

Qualified prescribers available at facility (0/1)	
Qualified dispensers available at facility (0/1)	
Essential Drug List/Formulary available at facility? (0/1)	
Key drugs in stock to treat important conditions:	<u>IN STOCK(0/1)</u>
Cotrimoxazole 480mg	
Paracetamol 500mg	
Aspirin 300mg	
Ferrous sulphate + Folic acid	
Albendazole	
Sulphadoxine/Pyrimethamine (SP)	
Oral Rehydration salts (ORS)	
% Drugs in stock	%

APPENDIX 5
FACILITY INDICATOR REPORTING FORM

Location: _____ Date: _____ Investigator : _____

		This facility	National Standard
# of Cases	Prescribing		
	Patient care		
Average number of drugs prescribed		%	%
% of drugs prescribed by generic names		%	%
% of encounters with an antibiotic prescribed		%	%
% of encounters with an injection prescribed		%	%
Average consultation time		Min	Min
Average dispensing time		Sec	Sec
% of drugs actually dispensed		%	%
% of drugs adequately labeled		%	%
% correct patient knowledge of dosage		%	%
% availability of EDL or formulary		%	%
% availability of key indicator drugs		%	%
% of drugs prescribed on EDL		%	%
% of available prescribers		%	%
% of available dispensers		%	%

COMMENTS:.....

.....

SIGNATURES:.....

APPENDIX 6

DRUG USE INDICATORS CONSOLIDATION FORM

[illegible]

APPENDIX 7
CHECKLIST FOR KEY DRUGS

1. Diarrhea	- Oral Rehydration Salts (ORS);
2. Acute Respiratory Tract infections	- Cotrimoxazole tablets
3. Malaria	- Sulphadoxine/Pyrimethamine (SP) tablets
4. Anaemia	- Ferrous sulphate + Folic acid tablets
5. Worm infestation	- Albendazole tablets
6. Analgesics	- Paracetamol tablets

APPENDIX 8

PARTICIPANT'S CONSENT FORM

STUDY TITLE: The assessment of prescribing and dispensing practices in the public health facilities of Southern Malawi.

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In partial fulfillment of a Master of Public Health (**MPH**), every student is required to survey and submit a dissertation on a chosen topic related to health. Consequently, I have decided to embark on a study entitled 'The assessment of prescribing and dispensing practices in the public health facilities of Southern Malawi'. This will try to rectify shortfalls in the prescribing and dispensing practices in Malawi.

The investigator would, therefore, like to request your voluntary participation in this study where you will be asked questions related to prescribing and dispensing; Out patient registers, standard treatment guidelines and drugstore checked; health passport book checked for diagnosis, drugs prescribed and dispensed. The final copy of the dissertation will be sent to you after approval from College of Medicine. I guarantee that the information will be treated with strict confidence.

If you solemnly and sincerely accept to participate in this study, sign below:

I,....., after carefully understanding the procedures, hereby voluntarily agree to participate in this study.

(Participant)

Signature:..... Date:.....

Name:.....Signature:.....Date:.....

(Officer-In-Charge of facility)

Name:..... Signature:..... Date:.....

(Zonal Officer-South East)

Name:..... Signature:..... Date:.....

(Deputy Director-Clinical Services(MOH)