PRESCRIBING PRACTICES IN THE SOCIAL HEALTH INSURANCE PROGRAMME AT SECONDARY HOSPITALS IN THE FEDERAL CAPITAL TERRITORY, ABUJA, NIGERIA

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KEY WORDS

Health Insurance

Rational Use

Prescribing

Essential Medicines

Generic

Cost Effectiveness

Availability

Access

Quality Services

Universal Coverage

ABSTRACT

Background

The World Health Organisation estimates that more than 50% of medicines are inappropriately used globally. The situation is worst in developing countries such as Nigeria, where irrational prescribing practices account for wastage of resources, catastrophic medicines costs and poor access to health services. In 2005, the Social Health Insurance Programme was launched as a financially sustainable model to achieve cost effective and affordable health care services including medicines. This study investigated prescribing practices and availability of medicines in the Social Health Insurance Programme in accredited public sector secondary hospitals in the Federal Capital Territory, Nigeria.

Methodology

The study is a descriptive, cross-sectional and retrospective survey of prescriptions of insured outpatients in the Federal Capital Territory, Nigeria. Four hospitals were selected by stratification of thirteen (13) public secondary hospitals in the territory into urban/peri-urban areas, followed by random selection of two hospitals from each stratum.

A total of seven hundred and twenty (720) retrospective prescription encounters of insured outpatients were systematically selected from encounters between July 2009 and June 2010 at the selected facilities. Data on prescribing practices and the extent to which prescribed medicines were provided were assessed with the use of modified WHO/INRUD indicators. Descriptive statistics were generated with Epi-info (version 3.4.3) and SPSS (version 17.0)

Results

Out of the seven hundred and twenty (720) prescriptions that were assessed analgesics/NSAID, antibiotics, antimalarials and haematinics/vitamins collectively accounted for 67.4% of the medicines prescribed.

A comparison of the results with WHO/Derived reference values showed that average number of medicines prescribed per prescription (3.5 ± 1, $p<0.001$) and the rate of antibiotic prescribing (53.7%, $p=0.009$) were higher than the WHO recommended ranges of (1.6-1.8) and (20.0-25.4%) respectively.

The use of generic names in prescribing (50.9%, $p<0.0009$) and medicines prescribed from the Essential Medicine List (74.2%, $p=0.05$) were considerably lower than the standard (100%) However, the rate of injection prescribing (12.49%, $p=0.4$) was within the recommended range (10.1–17.0%).

The study also found that 85.1%, ($p=0.001$) of prescribed medicines were dispensed, while 93.4% ($p=0.256$) of essential medicines were dispensed which was lower than the recommended standard (100%). Overall, only 58%,($p<0.0001$) of patients had all prescribed medicines completely dispensed and this was significantly lower than the desired standard (100%.) in social health insurance programmes.

Conclusions

The findings of this study show trends toward irrational prescribing practices as characterized by poly-pharmacy, overuse of antibiotics, sub-optimal generic prescribing, as well as poor adherence to the use of NHIS-Essential Medicine List. There was sub-optimal provision of prescribed medicines. These are potential threats to the scheme's goal of universal access to

health care in the year 2015. Pragmatic multi-component interventions are recommended to promote rational prescribing and improve equity in access to essential medicines.

DECLARATION

I declare that **Prescribing practices in the social health insurance programme at secondary hospitals in the Federal Capital Territory, Abuja, Nigeria** is my own work, that it has not been submitted before for any degree or examination in any University or College, and that all the sources I have quoted or used have been indicated and acknowledged as complete references.

Eunice Bosede Avong   **November 2012**

Signed…

ACRONYMS

BI   Bamako Initiative

CIA   Central Intelligence Agency DPR

DFID   Department for International Development

EDM   Essential Drug Monitor

EML   Essential Medicine List

FCT   Federal Capital Territory

MFCT   Ministry of Federal Capital Territory

FMOH   Federal Ministry of Health

GDP   Gross Domestic Product

HAI   Health Action International

HMO   Health Maintenance Organizations

ICIUM   International Conference for Improving Use of Medicines

INRUD   International Network for Rational Use of Drugs

LMIC   Low- and middle-income countries

MDG   Millennium Development Goals

MMIS   Making Medical Injections Safer

MSH   Management Science for Health

NHIF   National Health Insurance Fund

NHIS   National Health Insurance Scheme

NPC   National Population Commission

OECD   Organization for Economic Co-Operation and Development

SHIP   Social Health Insurance Programme

SIGN   Safe Injection Global Network

UNAIDS   United Nations Agency for AIDS

UNIDO   United Nations Industrial Development Organization

USAID   United States Agency for International Development

WHA   World Health Assembly

WHO   World Health Organization

WHO/DAP   World Health Organization and Action Programme on Essential Medicines

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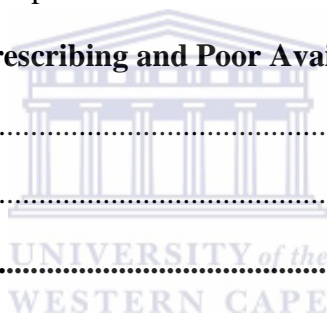WESTERN CAPE

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF APPENDICES

CHAPTER ONE

INTRODUCTION

1.1 Background

The World Health Organisation (WHO) estimates that more than half of all medicines are used irrationally (WHO, 2004a, WHO). The situation is worst in resource constrained countries where irrational prescribing practices account for more than 50% of wastage in health facilities (Quick, 2003; Holloway, 2004, WHO, 2009a; 2010a).

Rational use of medicines requires that "patients receive quality medicines, appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time and at the lowest cost to them and the community" (WHO, 1985). The objectives of rational use of medicines are to ensure safety, cost-effectiveness and the maximization of the potential values of medicines in the provision of universal access to health care (WHO, 2004b).

Irrational prescribing occurs when prescription patterns are not in conformity with WHO definition of rational prescribing given above. For example, the prescribing of too many medicines per patient and the failure to prescribe in accordance with clinical guidelines often result in widespread health hazards and shortages of medicines in health facilities (WHO, 2002; 2004a; 2009a). The financial cost incurred as a result of irrational prescribing disproportionately affects the population who also spend the largest proportion of their household income as out of pocket expenditures on prescribed medicines (Faden, *et al.*, 2011).

In Nigeria and other developing countries, poor and vulnerable people who constitute the majority in the population are often the hardest hit as they have to contend with either paying high costs for their medicines and deepening their impoverishment, or suffer catastrophic health consequences resulting from financial barriers to accessing prescribed medicines (Hogerzeil, 2004; Soyibo, *et al.*, 2005; Aina, Tayo and Taylor, 2008; Faden, *et al.*, 2011).

Over the past few decades, the Federal Government identified problems of inadequate funding and irrational use of available resources as access barriers to health services and consequently introduced several strategies including the EML, the Bamako Initiative (BI) and rhe National Medicine Policy to facilitate equitable and sustainable access to medicines.

The EML comprises of a limited range of medicines, selected on the basis of safety, efficacy and cost-effectiveness in treating prevailing health problems in the population. It was introduced in 1986 with the aim of promoting the use of affordable medicines that meet the health needs of the population in order to contain the escalating cost of health care (FMOH, 2003). In 1987, African Ministers of Health resolved in Bamako to improve the health outcome of their populations through sustainable financing of access to quality health care programmes by the process of community participation in funding and managing supplies of essential medicines. The concept, also known as the BI is based on the principle that sustainable availability and accessibility of basic essential generic medicines can be achieved by ensuring a steady supply of affordable medicines through the institutionalization of out-of-pocket payments and the medicine-revolving programme. Following the resolution, the Federal Government of Nigeria instituted this initiative in all the public health facilities across the country (Omoruan, Bamidele and Philips, 2009). Subsequent to this, the National Medicine Policy was introduced in 1990 to provide the

framework for ensuring availability of effective, affordable, safe and quality medicines at all times in all sectors of the health system (FMOH, 2004a).

However, despite these policies, access to health care services by the poor was compromised by several factors including over-prescribing and excessive use of costly medicines, which invariably escalate the costs of health services beyond the reach of the poor (Adeyi and Wouters, 1996; Uzochukwu, Onwujekwe and Akpala, 2002; Ogunbekun, Liu, 2003; Akande and Ologe, 2007).

In response to the recurrent problems of poor funding of health services and inappropriate use of available resources, the National Health Insurance Scheme (NHIS) was introduced in Nigeria in June 2005 as a financially sustainable model to address a number of challenges plaguing the health system, and to guarantee universal access to health care services, including medicines (Lecky, 2004).
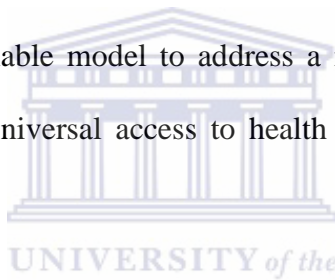
Acknowledging the importance of medicines as a major component of health care services, the scheme adopted the essential medicines concept as the most effective tool in ensuring rational prescribing, availability of medicines and equitable access to affordable medicines (WHO, 2003a; Hogerzeil, 2004). The essential medicines concept requires that the medicines listed in the EMLand recommended in the standard treatment guidelines should be the basis for prescribing and reimbursement of fees for services rendered (WHO, 2004b; 2008). Recognising that unnecessary use of services will affect the solvency and the sustainability of the scheme, the government clearly enunciated its policy for promoting rational prescribing by providing the NHIS with Operational Guidelines, an Essential Medicines/Price List and Standard Treatment and Referral Protocols. The scheme also recommended regular monitoring and audit of service

utilization to measure access and quality of health care services, including essential medicines (FMOH, 2005)

However, six years after the inception of the scheme, access to essential medicines remains a challenge with numerous reports of poor utilization of the EML (Leo and Okafor, 2012), inadequate provision of prescribed medicines and payments for services covered in the scheme (Sanusi and Awe, 2009). Deviations from combination of WHO and local standards standards for prescribing and patient care, shown in Table 1.1 are often cited as key factors contributing to poor access to prescribed medicines in public sector hospitals (WHO, 2004a; b).

Table 1.1: WHO/Reference Values for Prescribing and Patient Care (Medicines Dispensed) Indicators

Indicators	Values	Type
Average No. of Medicines prescribed	1.6 - 1.8	Derived standard
% of Prescription encounters with an antibiotic prescribed.	20.0 – 25.4 %	Derived standard
% of Prescription encounters with an injection prescribed	10.1 – 17.0%	Derived standard
% of Medicines prescribed by generic name.	100%	WHO standard
% of Medicines prescribed on EML	100%	WHO standard
% of Medicines actually dispensed	100%	WHO standard

 (WHO, 2004a: Isah , Quick, Mabadeje , Santoso and Hogerzeil, 2002)

A number of studies had been conducted to assess the NHIS programmes in the context of enrollment and service utilization rates. Akande, Salaudeen and Babatunde (2011) reported an increase in the utilization of health services in terms of the number of cases seen after

commencement of the scheme. Agba, Ushie and Osuchukwu (2010) investigated the impact of the NHIS on employees' access to health care services in Cross River State, Nigeria. However, the existing prescribing practices and the capacity of accredited health facilities in ensuring availability and equity of access to essential medicines have not been determined. These need to be investigated seeing that they are fundamental determinants of universal access to health care and key factors in assessing health system performance.

This study was carried out to assess the prescribing practices and the extent to which prescribed essential medicines are available to insured patients, with the aim of providing relevant data needed for identification of areas where rational and evidence-based interventions could guide future planning and improve management of the programme.

1.2 Country Profile

1.2.1 Demographic parameters

Nigeria is located on the West Coast of Africa, covering a land mass of 923,768 square kilometers. The country has an estimated population of 140 million and an annual growth rate of 3.2%, thereby making it the most populous African country (NPC, 2009). Nigeria is made up of 36 states and a Federal Capital Territory which are subdivided into local governments and areas councils respectively. About 55% of the population lives in the rural areas (NPC, 2009).

1.2.2 Health Status Indicators

According to the Federal Ministry of Health, Nigeria's health status indicators are among the worst in sub-Saharan Africa (FMOH, 2004b). Infant mortality rate is currently estimated at 138 deaths per 1,000, (WHO, 2009b). Life expectancy at birth is estimated at 53 years for males and

54 years for female, while under-five child mortality is estimated at 197 deaths per 1,000 live births. In comparison, life expectancy for Ghana and South Africa were estimated at 55 years and 59 years; 50 years and 52 years for males and females respectively, while estimates for under-five mortality in Ghana and South Africa are 112 deaths per 1000 and 67 deaths per 1,000 respectively (Wambebe and Ochekpe, 2011; WHO, 2009b). In the 2000 WHO Health Report Nigeria was ranked 187th position out of 191 member states in terms of health system performance and health status indicators. The high mortality and morbidity rates associated with Nigeria cannot be divorced from its health system (Omoruan, Bamidele and Philips, 2009; Sanusi and Awe, 2009).

Generally, communicable diseases are the major causes of morbidity and mortality in Nigeria. According to the FMOH (2010), malaria accounts for 60% of all outpatient cases, 30% of admissions in the hospitals and 300,000 deaths annually (FMOH, 2010; Wambebe and Ochekpe, 2011). The country ranks fourth among tuberculosis-burdened countries and accounts for 3.4 million out of the 33 million global population of people living with the Human Immunodeficiency virus/Acquired immune Deficency Syndrome (HIV/AIDS), making it the third after South Africa and India as countries with the highest populations of people living with the HIVAIDS virus in the world (UNAIDS, 2008).

1.2.3 Health Financing

Prior to the commencement of the NHIS, expenditure on health care was from a variety of sources including budgetary allocations from the three tiers of government, health insurance, private sector contributions, out-of-pocket expenses, loans and other forms of donations (WHO, 2009c; Kannegiesser, 2009; Omoruan, Bamidele and Philips, 2009). The health sector allocation

as a percentage of budget stood at 4.4% in 2005, 5.6% in 2006 and 7.28% in 2007 (WHO, 2009c)

More recent figures out the total expenditure on health at 5.8 % of the Gross Domestic Product (CIA, 2009 estimates) and public expenditure capita for health is less than US$ $ 5 (CIA, 2010 estimates). These allocations are grossly inadequate when compared to the WHO recommendation of US$ $ 34 for developing countries (Omoruan, Bamidele and Philips, 2009; Sanusi and Awe, 2009). This resulted in the population paying more than 70% of total health expenditure as out-of- pocket payments in 2006 (Kannegiesser, 2009, Omoruan, Bamidele and Philips, 2009). The inadequacy in funding of the health sector also contributed to the deteriorating public health infrastructure, decline in quantity and quality of service delivery, and loss of confidence in public sector health facilities (WHO, 2009c; 2006; Omoruan, Bamidele and Philips, 2009).
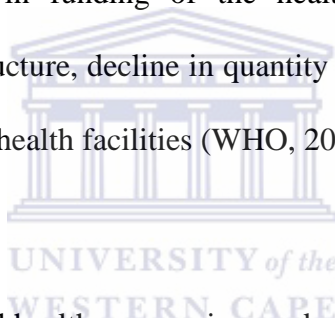
To ensure universal access to good healthcare services and reduce health care costs especially to the poor, the Federal Government established the NHIS as an alternative source of health financing through equitable distribution of healthcare costs among different income groups (Omoruan, Bamidele and Philips, 2009; WHO, 2009c).

1.3 National Health Insurance Scheme

Social health insurance is a collective health security system provided by the government that guarantees the provision of needed health care services, on the payment of token contributions at regular intervals (WHO, 2003b). The NHIS was established under Act 35 of 1999 as the corporate apex body for implementation of government goal of providing equitable access to

comprehensive quality health care services for Nigerians through various levels of social health insurance programmes (Appendix 2).

The scheme officially commenced in June, 2005 with the launching of its Formal Sector Social Health Insurance Programmes (FS-SHIP) for federal civil servants. Participation is mandatory for every organisation with ten or more employees. It entails the registration of the enrollee, the spouse and up to four biological children under the age of 18years.

Contributions in the FS-SHIP are earnings-related; it entitles the beneficiaries to equitable services in the benefits plan including access to all essential medicines recommended in the programme. Enrollees of the Organized Private Sector Social Health Insurance Programme (OPS-SHIP) have the option of choosing their preferred level of Health Care Benefits in line with their levels of contributions. Beneficiaries may access primary care services in any accredited public or private providers however; secondary and tertiary care services are accessed through the referral system (FMOH, 2005a).

Various operators have distinct roles in ensuring the achievements of the goals of the Scheme. Enrollees, in addition to their monthly contributions, pay 10% cost of prescriptions as co-payment and part of risk sharing (FMOH, 2005a).

Primary Care Providers (PCP) including the outpatient departments in the secondary and tertiary hospitals, constitute the first care contacts (i.e. gatekeepers). They provide basic services set out in the benefit package including essential medicines covered in the scheme. They also refer all procedures which require specialists' attention to secondary facilities including pharmacies, laboratories, physiotherapies and radiography centres; the tertiary health care providers such as the teaching hospitals receive referred cases from the secondary care providers.

Generally, the provision of medicines in the scheme is done by accredited pharmacies that are required to stock and dispense all generic essential medicines covered in the scheme.

Payment for services rendered at the primary level of care is in the form of monthly capitation made to physicians, which is an advance payment for the services rendered by the physicians, cost of medicines and other indirect services including laboratory and x-ray services. By this arrangement, the PCPs are required to send out prescriptions to approved pharmacies and make payments for the medicines dispensed out of their monthly capitation (FMOH, 2005a).

On the other hand, the secondary and tertiary hospitals with approved on-site pharmacies are required to stock most of the medicines covered in the scheme as well as send out prescriptions to approved private pharmacies to ensure all identified out of stock medicines are dispensed to patients (FMOH, 2005a). By this arrangement, payment for essential medicines and other services rendered at the secondary and tertiary levels of care are settled through reimbursement of fees for services (Appendix 3).

All providers in the scheme are required to maintain standard records in respect of services rendered including medicines prescribed and dispensed.

The Health Maintenance Organizations (HMOs) are statutorily empowered to supervise the activities of health care providers to ensure conformity with set standards. Their roles also include payment of monthly capitation to the PCPs and reimbursement of fees for services to secondary and tertiary health providers (FMOHa, 2005). The over-all regulation of the scheme rests with the NHIS Council (Awosika, 2005).

1.4 Study Setting

The Federal Capital Territory (FCT), where this study was conducted is located in North central part of Nigeria (Fig 1.1). It occupies a land mass of $8000km^2$ and consists of six area councils namely Abaji, Bwari, Gwagwalada, Kuje, Kwali and Abuja Municipal Area Council (AMAC) which is the capital of Nigeria (FCT Baseline Data, 2009).

Following the move of the seat of power from Lagos to Abuja in December 1991, the FCT experienced a population growth rate of 20 to 30% per year. According to available information, the population now stands at 1.4 million, which is equivalent to 1% of the total population of the country (NPC, 2009). The rapid growth exceeded government's capacity to accommodate everyone within the city. Consequently, area council workers, the poor and low income earners who cannot afford the cost of living in the capital city, reside in the peri-urban areas of the territory. The peri-urban areas are densely populated and poorly developed in terms of infrastructure; this makes their population more susceptible to communicable diseases compared with the urban dwellers (Ogunbekun, 1996; FCT Baseline Data, 2009).

The territory has 434 primary health care centres, several private hospitals, 13 public sector secondary hospitals, two public sector tertiary hospitals and over 100 registered pharmacies (FCT Health Report, 2006). All the public secondary and tertiary hospitals are participants in the health insurance scheme whilst, the primary health centres still need to be accredited to participate in the scheme.

The public sector secondary hospitals are managed by the Health and Human Services Secretariat (HHSS) and as at December 2006, the HHSS had 290 medical doctors and 160 Pharmacists including pharmacy technicians as its staff (FCT Health Report, 2006). The facilities

have a large population of health insurance outpatients in attendance. Of the 13 hospitals, AMAC has seven with 100-150 patients attending the general outpatient department daily, of whom 10-20 patients are health insurance outpatients. Each of the remaining five area councils has at least one hospital in its satellite towns with 20-40 patients attending the general outpatient department daily, of whom 5-10 patients are health insurance outpatients (FCT Health Statistical Bulletin, 2009).

Each of the hospitals has an accredited pharmacy department that is dedicated to rendering pharmaceutical services to only insured patients. Designated prescription sheets branded NHIS, are used for prescribing medicines for all social health insurance patients and duplicates of these prescription sheets are kept separately from other prescription sheets in the pharmacy stores. The pharmacy departments also ensure that designated logbooks on medicine utilization are kept as recommended by the NHIS.
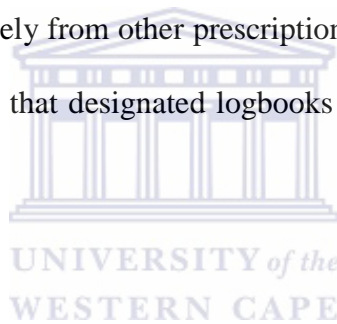
Fig. 1.1 Map of FCT area council towns and Abuja city (phase I and II)

1.5 Problem Statement

Studies have found that up to 40% of the health budget of developing countries is spent on medicines procurement, and more than half of the procured medicines are wasted through irrational prescribing practices which in turn, affect access to health services (MSH, 1997; WHO, 2004a; b; 2006). Over the past few decades, several cases of irrational use of medicines, over-prescribing and medicines shortages have been reported in health facilities in Nigeria, in spite of the various initiatives designed by the government to promote appropriate prescribing and access to essential medicines, particularly in public health facilities (Uzochukwu, Onwujekwe and Akpala 2002; Akande and Ologe, 2007).

Although, the recently adopted NHIS was established with the necessary tools and regulatory framework for ensuring rational prescribing and access to essential medicines, findings from surveys of health consumers' perceptions and newspapers reports have highlighted cases of poor quality services, medicine shortages and unofficial payments for services that ought to be covered by scheme premiums (Sanusi and Awe, 2009; Okon, 2010; Onyedibe, Goyit and Nnadi, 2012). These revelations have generated concerns about the ability of the scheme meeting its objectives of providing equitable access to quality and cost-effective medicines to all health seeking scheme members. This study was undertaken to provide insights into prescribing practices within the scheme, and the extent to which essential medicines are prescribed by health providers and dispensed to patients.

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

Over the past few decades, the WHO and International Network for Rational Use of Medicines (INRUD) have collaborated with countries, including Nigeria, to conduct research and formulate policies on medicines usage and the development and application of appropriate interventions to promote rational use of medicines use (WHO, 2004b; 2008; 2010).

This chapter defines some concepts underpinning the rational use of medicines with a focus on the global problems of irrational prescribing as well as its attendant consequences. The chapter also illustrates the prevalence of different forms of irrational prescribing practices in various settings and countries, and summarizes the literature on the WHO initiatives for promoting rational use of medicines and their effects on availability of medicines and access to cost effective quality health care services.

It concludes by describing the innovative impacts of social health insurance on prescribing practices and access to essential medicines in different countries and then describes the NHIS framework for ensuring rational prescription, cost containment and availability of prescribed medicines in the FS-SHIP in Nigeria.

2.1 Concept of Rational Use of Medicines

The current global focus on health-related Millennium Development Goals (MDG) has once again brought to the fore the need to promote rational use of medicines and ensure sustainable

availability of medicines: in facilitating universal access to quality cost-effective health care (WHO, 2004b; 2010b).

The definition of Rational Use of Medicines emanated from the Conference of Experts in the Rational Use of Medicines (ICIUM) held in Nairobi in 1985 (WHO, 1985) and according to these experts, the requirements of the rational use of medicines can only be fulfilled, if the processes of medicines uses are appropriately followed by prescribers, dispensers and the community (Laing, Hogerzeil, and Ross-Degnan, 2001; Brunthland, 2003).

Rational use of medicines in the context of the prescribers, entails that the prescriber takes the necessary steps to make an accurate diagnosis, decide whether medicines treatment is necessary or not, select the best available medicines, choose the most appropriate dosage form, prescribe the medicine in adequate quantity to the right patients and monitor the treatment (Laing, Hogerzeil, and Ross-Degnan, 2001; Brunthland, 2003; Neyaz, *et al.*, 2011). Irrational prescribing comprises of practices which are at variance with the WHO criteria for appropriate prescribing including the use of medicines when no medicine therapy is indicated, poly-pharmacy or over-prescription of medicines, overuse or under use of antibiotics and other anti-infective agents, indiscriminate use of injections and overuse of multivitamins and tonics for malnutrition. Other examples include unnecessary use of expensive medicines, the use of medicines with doubtful or unproven efficacy and non-compliance with the National Medicines List of Formulary (Greenhalgh, 1987; Laing, 1990; Hogerzeil, Bimo and Laing, 1993; WHO, 2004a).

2.2   Scope of Irrational Medicines Use

According to information available from the WHO experts, more than half of all medicines in the world are used inappropriately (Greenhalgh, 1987; Laing, 1990; WHO, 2004a). Irrational use of

medicines is a global public health problem affecting developed countries including Australia, Canada and the USA as well as developing countries including Nigeria, South Africa, Pakistan and China (Hogerzeil, 1995; WHO, 2004a; Kumari, *et al.*, 2008; Sun, *et al.*, 2009). Unfortunately, the problem is more pronounced in developing and resource-constrained countries (WHO, 2004a; b).

There has been a general misconception that the problem of irrational use of medicines is due to inappropriate use by consumers (Greenhalgh, 1987; Hardon and Le Grand 1993). However, a review of the literature indicates that inappropriate prescribing of medicines in public and private health facilities is the greatest contributor to the global problem of medicine use (Hogerzeil, 1995; Gupta, *et al.*, 1997; Haldar, *et al.*, 2011). It permeates the three tiers of health care primary, secondary and tertiary health facilities (Odunsanya, 2004; WHO, 2004a; Awad, Ball and Eltayeb, 2007), both urban and rural areas (Ross and Macleod, 2005; Dutta and Chakraborty, 2010) and the different categories of physicians, even though Hogerzeil (1995) argued that the practice is more frequent with general practitioners.

2.3 Manifestations of Irrational Prescribing Practices

Medicine use studies conducted in different parts of the world provide evidence of various forms of irrational prescription patterns, including poly-pharmacy, indiscriminate use of antibiotics, overuse of injections of injections, unnecessary use of branded medicines and poor use of essential medicine lists (WHO, 2004a; 2009c).

2.3.1 Poly-pharmacy

Poly-pharmacy is the simultaneous use of multiple medicines per patient. Appropriate prescribing requires that patients should be given the medicines needed and the number be kept

as low as possible (Pavin, *et al.*, 2003; Laing, Hogerzeil, and Ross-Degnan, 2001). The practice of poly-pharmacy is widespread in developing countries as a result of attempts by health personnel to treat presumptive diseases without recourse to performing diagnostic test (Uzochukwu *et al* 2011)..

Studies conducted in developing countries have revealed several examples of poly-pharmacy in prescription encounters of public health facilities, with some facilities having an average of more than 3.0 medicines per prescription encounter. For example, Mohlala, *et al.*, (2010) reported an average of 3.2 medicines per prescription in some public facilities in two provinces in South Africa. Kumari, *et al.,* (2008) reported an average of 3.1 medicines per encounter in several public health facilities in Lucknow District, India, while Haldar, *et al.,* (2011) reported an average of 3.7 medicines per encounter in a survey of prescriptions from four randomly selected Central Government Health Scheme dispensaries in Kolkata, India.

Several studies conducted in Nigeria also revealed the prevalence of poly-pharmacy in prescriptions from outpatient departments in health facilities. For example, in a study conducted to evaluate the effects of the BI medicine revolving fund on rational use of medicines in Eastern Nigeria, Uzochukwu, Onwujekwe and Akpala (2002) reported 5.3 medicines per prescription. Akande and Ologe (2007) surveyed the prescription patterns of a secondary public hospital in Ilorin, Nigeria, and concluded that poly-pharmacy was prevalent amongst the physicians. The report of Enato and Chima (2011) on medicine utilization patterns and patient care practice at the Federal Medical Center, Lokoja, in Kogi State of Nigeria revealed prescribing patterns with a high tendency of poly-pharmacy.

2.3.2. Indiscriminate Use of Antibiotics

Since the discovery of antibiotics, there has been tremendous reduction in infectious disease related mortality and morbidity diseases particularly in developing countries (Kakkilaya, 2006). Unfortunately, there are reports of widespread misuse and overuse of these life saving agents (Sivagnanam and Mohanasundaram, 2004; Kakkilaya, 2006; Dong, Yan and Wang, 2008). Currently, it is estimated that antibiotics account for 25-75% of all prescribed medications globally and they are the second most common category of medicines used in developing countries (Hogerzeil, Ross-Degnan and Laing, 1993; Akande and Ologe, 2007; WHO, 2010b). However, evidence has shown that significant proportions of antibiotics received by patients in developing countries are unnecessary (Holloway, 2004; WHO, 2009a).

The WHO/INRUD initiated several intervention programmes with the aim of ensuring appropriate use of antibiotics and optimizing their usefulness in combating infectious diseases, particularly in developing countries where they are most needed considering the prevalence of communicable diseases in the countries (WHO/DAP, 1993; WHO, 2002; Holloway, 2004; WHO, 2004b; 2008; 2009c). Unfortunately, reports from these countries consistently reveal widespread misuse and overuse of antibiotics by prescribers (Holloway, 2002; Quick; 2003; WHO, 2004b). In a study conducted in 680 primary health clinics in Western China, antibiotics were prescribed in 48.43% of the prescriptions surveyed (Dong, Yan and Wang, 2008). Similarly, antibiotics were prescribed in 28.3% and 68.1% of the prescriptions surveyed in Western Nepal and South Africa respectively (Ghimire, *et al.* 2009; Mohlala, *et al.*, 2010).

The prevalence of inappropriate use of antibiotics has also been widely reported in studies conducted in Nigeria. For example Uzochukwu, Onwujekwe, and Akpala (2002) revealed that

72.8% of prescriptions surveyed in health centers implementing the BI contained antibiotics, while Akande, Ologe and Medubi (2009) observed an overuse of antibiotics in University of Ilorin Teaching Hospital, Ilorin, Nigeria, where it was revealed that 83.5% of the prescriptions had at least one antibiotics prescribed. Several authors have noted the unnecessary and wasteful use of antibiotics in the treatment of common diseases like malaria, fever, sore throat and other cases where there are no clinical indications for their use (Nwoilsa, Erinuagha and Ofoleta 2006; Onwujekwe, *et al.*, 2009**;** WHO, 2009a; Oshikoya and Senbanjo, 2010; Moorthi, *et al.*, 2011).

2.3.3   Overuse of Injections

Clinically, injections are the most appropriate dosage form when immediate physiological action is required however; the use of injections is irrational when safer and more cost-effective routes of administration are available (2004a). To discourage unnecessary use of injections, a Safe Injection Global Network (SIGN) was established by the WHO in collaboration with countries and other international agencies with the aim of promoting and training health staff on rational and safer use of injections (Miller and Pisani, 1999).

In spite of these measures, available information has shown that 15 billion injections are used annually in the world, the situation is worse in developing and transitional countries, which currently account for 70% of injection use in the world (Quick, *et al.*, 2002; WHO, 2000a; Castrillo, Noel and Van Roekel, 2009; 2010b). In a comprehensive situation assessment of injection practices in primary health care hospitals in Bangladesh, Chowdhury, *et al.,* (2011) found injections prescribed in 78% of the prescriptions surveyed. Overuse of injections in health facilities have been widely reported in studies conducted in Nigeria. According to Holloway (2004), about 38% of primary health care patients in Nigeria received injections and

Ugochukwu, Onwujekwe and Akpala (2002) found that a high proportion of patients (64.7%) were given injections in the BI health centres in South East of Nigeria.

A consistent area of concern to the WHO is that the vast majority, estimated at about 90%, of the injections given in low income countries are unnecessary and unsafe (Quick, *et al.,* 2002; WHO, 2004b; Castrillo, Noel, and Van Roekel, 2009). For example in Nigeria, available evidence has shown that more than 70% of injections prescribed in Nigeria are not necessary (Quick, *et al.,* 2002; Holloway, 2004; Odunsaya, 2004).

The wide spread use of injections in developing countries could be attributed to patients' preference for injections in the belief that injections are more effective than oral dosage forms, and the subsequent desire of physicians to satisfy patients' requests. Notwithstanding the reasons given for irrational use of injections, Quick, *et al.* (2002) argued that significant number of injections used in developing countries could have been given in oral dosage form.

2.3.4. *Unnecessary Use of Branded Medicines*

Given the importance of medicines in health care, the policy priority of WHO is to ensure available and equitable access to affordable medicines (WHO, 2004b). To achieve this, the WHO advocated for the use of generic names as a policy for the procurement and prescribing of medicines in health facilities, bearing in mind that generics are usually cheaper than originator brand products (Laing, Hogerzeil, and Ross-Degnan, 2001). The generic names of medicines are the International Non-proprietary Names (INN) or official names of medicines. Despite this fact, studies have shown that substantial proportion of the medicine budget in low and middle income countries is wasted on originator brand products in public health facilities (WHO, 2010b).

Assessments of prescriptions in developing countries revealed mixed findings on the compliance rates of countries with generic prescribing policies (WHO, 2004b). According to available evidence, while Mozambique and Zimbabwe have been able to attain a level of more than 90% of generic use of medicines in 1995 (WHO, 2004a), findings some developing countries showed much high proportions of originator brand names in the prescription encounters. In a prospective surveillance of drug prescribing and dispensing in the outpatient department a teaching hospital in Western Nepal, Ghimire, *et al.,* (2009) observed only 13% of medicines were prescribed by generic name. Fattouh and Abu-Hamad, (2010) also found generic names used in only 5.5% of all the medicines prescribed in the prescriptions surveyed in government primary care clinics in the Gaza Strip..

Similar studies conducted in Nigeria demonstrated that the use brand names in prescribing was common in all public health facilities in the country. For example, assessments carried out by Akande and Ologe (2007) in public health facilities in Nigeria revealed that the percentage of medicines prescribed with generic names was as low as 41.9%. Similarly, Eze, and Olowu, (2011) found that use of generic names in 48.9 % of medicines prescribed in their study on prescribing patterns and use of medications in elderly outpatients in a tertiary hospital in Nigeria. While Enato and Chima (2011) observed that 37 % of medicines were prescribed using generic names.

2.3.5 *Poor Use of Essential Medicines List*

The WHO estimates that more than 50% of the population of developing countries lack regular access to medicines needed for the treatment of diseases (WHO, 2004a). To facilitate equitable and sustainable access to affordable medicines, the WHO in 1977 recommended the use of

medicines listed on an EML to guide in prescribing and facilitate access to medicines needed by the population (WHO, 2004a).

Whilst it is currently estimated that over 70% of WHO member states now have national EML, the influence of EML on the prescribing practices of physicians remain poor in some countries (WHO, 2007a; Ahmed and Islam, 2012). A systematic review of the patterns of use of medicines in primary health care settings in 104 low and middle income countries (LMIC) showed an increase in the percentage of medicines prescribed from EMLfrom 70% in 1990 to 87% in 2009 (Holloway, Ivanovska and Ross-Degnan, 2011). In an assessment of prescribing habits conducted in public and private health facilities in two provinces in South Africa, Mohlala, *et al.* (2010) showed that there was optimal use (92.6%) of medicines on the EML. A similar study in southwest Ethiopia revealed that the rates of medicines prescribed from the EML in the selected health facilities ranged from 89.09% to 91.85% (Angamo, Wabe and Raju, 2011).

However, reports on use of medicines in some developing countries showed several cases of suboptimal use of the essential medicine list. For example, a study on antibiotic prescribing behavior of consultants in different localities of Pakistan, showed that only 30% of medicines prescribed were on the essential medicine list (Riaz, *et al.*, 2010). In western Nepal, Ghimire, *et al.* (2009) found that the percentage of medicines prescribed from the EML in a teaching hospital in the country was poor at only (32.8%)..

Findings from the WHO sponsored baseline assessment of the Nigerian Pharmaceutical sub-sector showed that more than 90% of prescribed medicines were listed in the EML (FMOH/WHO, 2002). The study conducted by, Onwujekwe and Akpala (2002) equally reported high proportion (93%) of medicines prescribed from the EML in facilities operating the BI

medicine revolving scheme, however, the proportion was much lower (21%) in facilities outside the BI scheme. Another study conducted by Enato and Chima (2011) reported that only 82.3 % of medicines prescribed at the Federal Medical Center, Lokoja were from the EML.

2.4   Consequences of Irrational Prescribing Practices

Quality health services necessitate the maximization of the potential benefits of medicines while minimizing their hazardous effects. The problems associated with irrational prescribing of medicines have resulted in significant public health issues with regards to their implications on health outcomes, household and national expenditure on health and access to medicines.

2.4.1. Health Implications

The practice of poly-pharmacy has been found to be associated with risks of medication errors and unnecessary toxicity arising from medicine interactions, which may result in hospitalization and potentially life threatening effects (Neyaz, *et al.,* 2011). The prevalence of hospitalization resulting from adverse drug reaction has been estimated to range from 5% to 16% in developed countries and 10 to 30% in developing countries (Hasford, *et al.*, 2002; Iribhogbe and Agbaje, 2011). Whilst the prevalence of death resulting from adverse drug reaction in developing countries is unavailable for comparison; the review of White, Araekelian and Rho (1999) on the implications of medicines use problems showed that adverse medicines reactions are the 4th-6th leading cause of death in USA.

The public health threat associated with irrational use of injections is a major cause of concern amongst medical experts. The risks are obvious in patients' vulnerability to transmitting or contracting three preventable primary blood borne viral (BBV) diseases namely; Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus; in addition to

the risk of tissue toxicity from local irritations and shocks associated with irrational use of injections (Holloway, 2004).

According to WHO (2000a; b), several cases of paralytic polio in children were the consequences of unsafe use of injections by health care workers. This report is supported by evidence from the WHO's Global Burden of Disease study which revealed that annually, 32% cases of Hepatitis B Virus (HBV), 40% of new Hepatitis C Virus (HCV) infections and 5% of new HIV infections in developing and transition countries were associated with contaminated syringes and needles when administering injections (WHO, 2000a; b; Logez, *et al.*, 2004).

Another source of public health concern is the increasing emergence of bacterial resistance to first-line antibiotics that has been linked with continued misuse of antibiotics in health settings (WHO, 2005b; Shittu, *et al.*, 2009; Onipede, Onayade and Elusiyan, 2009; Vila and Pal, 2010). This is particularly problematic in developing countries where there are reported cases of therapeutic failure resulting from 70-90% resistance rate to original first-line antibiotics, which are commonly used for the treatment of dysentery, pneumonia, gonorrhoea and hospital infections (Shittu, *et al.,* 2009; Onipede, Onayade and Elusiyan, 2009; Vila and Pal, 2010). This invariably exacerbates the infectious disease related morbidity and mortality associated with developing countries, especially amongst the poor and vulnerable population who cannot afford the higher costs of second and third generation antibiotics (WHO, 2005b; Vila and Pal, 2010; Vila and Tibor, 2010).

2.4.2. Cost Implications

Evidence has shown that the misuse and overuse of injections and antibiotics exert unnecessary financial burden on household, hospital and government expenditure on medicines. Additional

costs are borne for administering injections to patients and switching to second or third line antibiotics in the event of resistance to first line antibiotics (Holloway, 2004). The author also noted that additional cost is also required for treatment of medicines-related morbidity. For example, Geer, *et al.*, (2011), reported that USD 22469 was spent on hospitalization of patients presenting with adverse medicine reactions (AMRs) in Kashmir. In Nigeria, Oshikoya, *et al.* (2007) found that USD 15, 466:60 was spent on the treatment of pediatric AMRs in a tertiary health facility in Lagos.

Holloway's review estimated that irrational use of medicines and its attendant effects results in the wastage of between 50–70% of the government expenditure for medicines in developing countries (Holloway, 2004). A study on cost implication of irrational use of chloroquine in Lagos State government public hospitals in Nigeria revealed that 90% of the cost of procured chloroquine injection was lost to irrational prescribing (Aina.,Tayo and Taylor, 2008). According to experts on rational use of medicines, the cumulative cost of additional services and interventions from medicine toxicity may be unaffordable by the poor in developing and resource-constrained countries (Le Grand, Hogerzeil and Haaijer-Ruskamp, 1999; EDM, 2003; Holloway, 2005).

2.4.3. *Effects on Availability and Universal Access to Health*

Rational use of medicines has been identified as one of the four medicines-specific factors that will ensure that medicines are accessible to people whenever and wherever they are needed. There is evidence to suggest that irrational prescribing practices and it attendant problem of medicine shortages partly accounts for the high proportion (estimated at over 50%) of populations of developing countries that lack access to essential medicines needed for quality

health services (MSH, 1997; Uzochukwu, Onwujekwe and Akpala, 2002; EDM, 2003; Aina, Tayo and Taylor, 2008).

2.5   Initiatives for Promoting Rational Use of Medicines

To ensure safe and cost-effective access to medicines and quality health service delivery, the WHO introduced a range of initiatives to facilitate optimal use and sustainable accessibility of quality medicines. These initiatives include the Essential Medicine Concept (EMC), the use of WHO/INRUD standard tools and indicators for measuring medicines utilization rate and Social Health Insurance Concept.

2.5.1. Essential Medicines Concept

The introduction of the Essential Medicine Concept (EMC) was informed by the need to guide member states in formulating policies that would assist health personnel, as well as consumers, in fulfilling the requirements of rational use of medicines, ensuring access to services and improving the health of the population (WHO, 2004b).

Essential Medicines (EMs) are "those medicines that satisfy the health needs of the majority of the population which should be available at all times, in adequate amounts and in the appropriate dosage forms at a price the community can afford" (WHO, 1987). According to the concept, careful selection and use of a limited range of medicines will results in higher quality of care, more rational prescribing, cost-effectiveness and better management of available health resources (Laing, Hogerzeil and Ross-Degnan, 2001). The components of EMC include the following: essential medicines list, standard treatment guidelines and use of generic medicines.

2.5.1.1 Essential Medicines List

In 1977, the WHO drew up the first Essential Medicines Model List comprising of 208 medicines selected on the basis of safety, approved efficacy and cost-effectiveness in treating the world's most common diseases to serve as a guide for member states in development of their Essential Medicine Lists or institutional formularies (HAI/WHO, 2000; Laing, Hogerzeil and Ross-Degnan, 2001). Additional criteria considered for the development of the country lists include the prevailing disease patterns of the country, changes in public health priority and levels of health facilities (WHO, 2002; Liu, 2003; Hogerzeil, 2004). The listed medicines form the EML of the country respectively. The WHO recommends regular updating of the list in view of innovative therapeutic options and the need for better medicines to cope with emerging new diseases, antimicrobial resistance and other health problems (HAI/WHO, 2000).

The WHO and experts in rational medicines use programme maintain that the use of an EML as policy tool for procurement of medicines, health insurance reimbursement, and training and supervision of health workers will ensure rational use of medicines, sustainable affordability and availability of medicine as well as facilitate universal access to quality health care (Laing, Hogerzeil and Ross-Degnan, 2001, WHO, 2008). There is evidence to show that the introduction of the EML significantly improved prescribing practices in many countries, resulting in improved availability of essential medicines, decreased the production and utilization of medicines of doubtful effectiveness in many developing countries (Le Grand, Hogerzeil and Haaijer-Ruskamp, 1999; Liu, 2003; Hogerzeil, 2004; 2006)

2.5.1.2 Use of Standard Treatment Guidelines

Standard Treatment Guidelines (STGs) are defined as systematically developed statements that are intended to enhance knowledge and aid physicians in making appropriate decisions for specific clinical circumstances; with the objectives of ensuring rational use of medicines, cost effectiveness, quality health care and improved health outcome (Liu, 2003). They are recommended for prescribers to guide in making appropriate diagnosis and specific prescribing practices (Liu, 2003). Evidence has shown that the use of STGs have helped to standardize treatment and proved to be effective in preventing wastage and improving prescribing quality, availability of medicines and better health outcome in many settings (Hogerzeil, 1995; Le Grand, Hogerzeil and Haaijer-Ruskamp, 1999; Laing, Hogerzeil and Ross-Degnan, 2001; Quick, 2001).

2.5.1.3 Generic Medicines

The concept of rational use of medicines seeks to prevent unnecessary use of branded medicines where generic medicines of proven efficacy are available (WHO, 2004b). Generic names are the official International Non-Proprietary Names (INN) or shortened scientific names assigned to medicines globally. Generic medicines are bio-equivalent to their originator brand products in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use (Kings and Kanava, 2002).

According to the concept, the use of generic medicines in procurement, prescribing and dispensing will ensure cost containment and regular availability in health facilities since they are cheaper, easier to identify and accessed globally than the branded equivalents (Laing, Hogerzeil, and Ross-Degnan, 2001; Quick, 2001; Kings and Kanavo, 2002). In addition, available information has shown that generic medicines have enabled some countries to spend their limited

resources efficiently in procuring more medicines so that a wider coverage of patients would be achieved (Liu, 2003).

2.5.1.4 *Impacts of Essential Medicine Concept*

It has been found that appropriate application of all the components of the essential medicines concept in medicine utilization programmes has synergistic effects in achieving the collective goals of ensuring cost effectiveness of services, medicine availability and equity in access to quality health services (Hogerzeil, Walker and Sallami, 1989; Quick, 2001). Studies conducted in low and middle income countries including India, Iran and Yemen; estimated that the introduction of the national EML, generic prescription policy and treatment guidelines in health facilities led to great improvement in prescribing practices. It was estimated that savings from such improvement could constitute up to 30–70% of the national expenditure for medicines which could further be used to procure more medicines for more patients without affecting health outcome (Hogerzeil, Walker and Sallami, 1989; Chaudhury, *et al.*, 1997; Le Grand, Hogerzeil, and Haaijer-Ruskamp, 1999; Quick, 2001; WHO, 2004).

In Nigeria, there are mixed reports regarding the impacts of the components of essential medicines concept on prescribing practices across different public health settings. Some studies have shown that the implementation of the concepts in Nigeria has significantly improved the use of EML, prescription of generic based medicines and availability of essential medicines in health facilities (Uzochukwu, Onwujekwe and Akpala, 2002; Enato and Chima, 2011). However, evidence from other studies suggest that poly-pharmacy and unnecessary use of antibiotics remained a recurring medicine use problem in some public health facilities in Nigeria (Akande and Ologe, 2007; Akoria and Isah, 2009; Adebayo and Hussain, 2010).

2.5.2   *Measuring Prescribing Practices*

Periodic monitoring and evaluation of medicines utilization practices are fundamental steps in identifying and quantifying potential medicines use problems and appropriate interventions in the health system (MSH, 1997; WHO/DAP, 93). According to Liu (2003), regular medicine utilization review could eliminate unnecessary and inappropriate use of medicine, which would result in reduced medicine-induced hospitalizations, unnecessary costs for medicines and improve quality of care. Hogerzeil (1995) asserted that assessment of medicine utilization cannot be effectively done without appropriate methodology and reference standards for measuring the degree of deviation from acceptable norms and for making comparisons between facilities, regions and countries.

To assist member states in ensuring consistent, valid and standard identification and quantification of medicines use problem, the WHO Drug Action Programme on essential medicines (WHO/DAP) and International Network for Rational Use of Medicines (INRUD) developed sets of standard core and complementary indicators, which have been tested and recommended for medicines use studies in general out-patient departments (WHO/DAP, 1993; Hogerzeil, Ross-Degnan and Laing, 1993; Adebayo and Hussain, 2010). The core indicators consist of prescription indicators, dispensing and patient care indicators, and health facility indicators. The indicators have been used globally for assessing current medicines use practices, identifying potential medicines use problem and appropriate interventions where applicable. In addition, they are internationally endorsed for comparison of medicine use patterns across countries (WHO, 2002; 2004a; 2007b).

These tools have been successfully used in medicines utilization reviews programme globally (2002). Hogerzeil (1995) noted that medicine utilization review have resulted in substantial cost savings and improved the standards of health care services in developed countries including the Netherlands, Mexico, the United Kingdom and the Medicaid programme of the USA (Hogerzeil, 1995). Several researchers have used these tools to successfully conduct studies on medicine utilization patterns in developing countries including Nepal (Ghimire, *et al*., 2009), Pakistan (Hafeez, *et al.*, 2004), India (Karande, Sankhe and Kulkarni, 2005; Kumari, *et al.*, 2008; Bhartiy, *et al.*, 2008; Gaash, 2008), South Africa (Mohlala, et al., 2010), Ghana (Bosu and Ofori-Adjei, 2000) and Nigeria (Uzochukwu, Onwujekwe and Akpala, 2002; Akande and Ologe, 2007; Adebayo and Hussain, 2010).

To further encourage a standard approach in comparison of measuring medicine use problems in countries, it was recommended that the standard value for percentages of medicines prescribed by generic names and from essential medicine list should have a desirable optimal value of 100%, which is regarded as the WHO standard values. However, the variations in countries' disease patterns necessitated the development of reference values for average number of medicines per encounter, percentage encounter prescribed injections and percentage encounter prescribed antibiotics based on countries specific morbidity patterns (Isah, *et al.*, 2002; WHO, 2004a).

Several countries have generated local standards for these three indicators and the derived local standards have been used in combination with the WHO optimal values mentioned above (as WHO/Derived Reference Values) for measuring the degree of deviations in findings from studies on medicines utilization patterns in health facilities. Examples of such researches include studies

conducted in Malawi and Nigeria (Sosola, 2007; WHO/FMOH, 2002; Akoria and Isah, 2009; Enato and Chima, 2011; Eze and Olowu, 2011; Tamuno and Fadare, 2012).

2.5.3   *The Concept of Social Health Insurance*

In response to the recurring problems of poor funding and ineffective management of resources, the world health organization advocated for the institutionalization of Social Health Insurance Programmes (SHIPs) as alternative financing options for achieving universal access to health care stipulated in the MDGs (Brundtland, 2001; Hogerzeil; 2004; ICIUM, 2004; WHO, 2004b; 2005a). The prepayment system of SHIPs "*allows the healthy to subsidize the sick, and through income-based premiums, the rich to subsidize the poor. Both shifts imply that health care becomes more affordable for the poor and the sick*" (Brundtland, 2003; WHO, 2004b:64). Funds pooled from various categories of contributors has the potential to increase the level of resources available for health care, ensure sustainable financing of medicines and guarantees equitable access to essential medicines at all times (Brunthland, 2000; Hogerzeil, 2004; WHO, 2004b).

Evidence presented at the Second International Conference on Improving the Use of Medicines (at Chiang Mai, Thailand, 30 March – 2 April 2004), which was supported by the WHO, reaffirmed the effectiveness of health insurance in promoting appropriate use of medicines and improving access to cost-effective health care through effective use of the essential medicines concept (WHO, 2007a). Consequently, the Sixtieth World Health Assembly in resolution WHA60.16 urged member states to consider developing, strengthening and implementing, where appropriate, the application of an EML into the benefit package of existing or new insurance funds (WHO, 2007a). This, according to the WHO, would accelerate their progress towards the attainment of universal access to medicines and health care (WHO, 2005a).

The recommendation was based on the concept that health insurance is associated with various administrative and managerial approaches to programmes that control cost, influence rational use of medicines and ensure availability of medicines (WHO, 2004b). Such strategies include collation of data on their enrollees, health service providers, services utilized and expenses incurred. These enable the monitoring and tracking of information on medicines utilization and cost of services with the objectives of designing policies and strategies that will ensure appropriate use of medicines (Carapinha, *et al.*, 2010; Faden, *et al.*, 2011).

Insurance programmes also define medicines benefits and coverage limit, terms of re-imbursement to consumer and health care providers. In some countries, including Nigeria, the system implements Separation of Prescribing and Dispensing policy (SPD), which aims at reducing potential conflict of interest and expenditures on medicines, and promoting appropriate use (Faden, *et al.*, 2011). Other strategies include; claims verification, cost sharing system such as co-payment and capitation system of paying providers. In addition, the system uses STG, generic medicines based formularies, and generic reference pricing which is used as the basis for calculating copayment and re-imbursement of fee for services (Hogerzeil, and Ross-Degnan, 2001; Carapinha, *et al.*, 2010; Faden, *et al.*, 2011).

There is a substantial evidence that suggests that these strategies had led to more rational use of medicines, expanded medicine benefits and cost containment of expenditure of medicines in health insurance programmes of some developing countries including Iran, Thailand, Taiwan and Philippines (Yesalis, Norwood and Lipson, 1994; Dong, *et al.,* 1999; EDM, 2003; WHO, 2004b; Hogerzeil, 2004; Chu, Liu and Romeis, 2008; Faden, *et al.*, 2011).

2.6 Prescribing In Health Insurance Settings

Reports from previous studies have demonstrated large variations in prescription patterns in health insurance settings. There is ample evidence that suggest that social health insurance schemes were associated with the observed increase in the number of essential medicines prescribed, increase in the number of medicines prescribed with their generic names; and a reduction in antibiotics and injections prescribed in some parts of China and Lao People's Democratic Republic (Dong, *et al.*, 1999; Syhakhang *et al*, 2011). However, a few studies in some developing countries contradict the positive findings on the effects of health insurance on prescribing practices. For instance, a study conducted in Shandong Provinces of China to assess the prescribing patterns in health insurance operating facilities confirmed this theory. The results revealed that over use of antibiotics, injections, and poly-pharmacy were common in townships and village hospitals with and without health insurance programme (Sun, *et al.*, 2009).

The report of a study on Philhealth insurance programme in Philippines also showed that the scheme was marred with overcharging, excessive admission, irrational prescribing practices and high co-payment (WHO, 2004b).

A similar study conducted in Iran to ascertain the impact of interactive programme on rational prescribing by physicians in social health insurance settings showed high use of antibiotics, corticosteroids and injections by physicians (WHO, 2003b; 2009d; Hosseini, Banihashemi and Darbooy, 2011). This is not surprising given the fact that many insurance schemes in developing countries lack appropriate framework for monitoring the activities of providers who can easily engage in irrational prescribing (Brundtland, 2001). A report by Bjerrum (1998) found that poly-

pharmacy was frequent in county health insurance services of Funen in Denmark; confirming the existence of irrational prescribing in health insurance programmes in some developed countries.

2.6.1 Framework for Appropriate Prescribing in Social Health Insurance Programmes in Nigeria.

To effectively prevent irrational use of services in the scheme introduced in Nigeria, the NHIS-council developed a set of tools and regulations including Operational Guidelines, Essential medicines and price list and NHIS Standard Treatment and Referral Protocol (STG) which are provided to accredited providers. These tools were intended to assist stakeholders in delivering cost effective services (FMOH, 2005a; b; c). The operational guidelines strongly emphasize on strict adherence to the concepts of rational use of medicines, and compliance with specifications in the guidelines is mandatory to qualify for re-imbursement of fees for services rendered.

2.6.2 Studies in Social Health Insurance Setting in Nigeria

There is a dearth of studies on prescribing practices in the Social Health Insurance Programmes in Nigeria, though there have been reports of shortages of medicines, non reimbursement for medicines paid by insured patients and non referral of prescriptions to accredited private pharmacies (Uwagu, 2009, Sanusi and Awe, 2009). The few studies conducted in health insurance accredited health facilities reported poor availability of medicines and various forms of irrational prescribing. For instance, a qualitative research carried out in Oyo State in Nigeria revealed that 72% of the respondents wanted discontinuation of the programme attributing their action to poor services from providers, shortages of medicines and unofficial payments for services covered in the benefits package (Sanusi and Awe, 2009). Another study conducted by Adebayo and Hussain, (2010) on the patterns of prescription at the Nigeria army hospitals at

Kano, Yaba and Lagos, found an average of 2.8 ± 1.5 medicines per prescription encounter, 49.3% of medicines prescribed with their generic names and 28.1% of prescription encounters containing at least one antibiotic.

However, there are several limitations in these studies which necessitate further research. For example, the qualitative research conducted by Sanusi and Awe (2009) failed to assess the prescribing and dispensing practices as possible causes of shortages of medicines and poor services. The results of the studies conducted by Adebayo and Hussain (2010) were not analysed in relation to the WHO/Derived Reference Values for Nigeria (Isah, *et al.*, 2002). In addition, the results cannot be generalized to health insurance programme because the sampling methodology did not exclude prescription sheets of uninsured patients.

CHAPTER THREE

METHODOLOGY

3.0 Introduction

Chapter three introduces the aims and objectives of this study. It describes the study population and justifies the choice of study design, sampling methods, data collection techniques as well as determination of sample size. The methodological processes including the measures undertaken to fulfill the requisite ethical issues, recruitment of data collectors, pre-testing of tools and the documentation of data on the data collection forms are extensively discussed in this chapter. The chapter then describes the procedure employed for management and analysis of data, the methods of results presentations; and concludes by describing the measures undertaken to ensure validity and reliability of data.
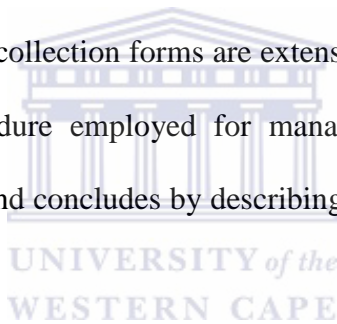
3.1 Aim of the study

To investigate prescribing practices in the Social Health Insurance Programme in accredited public sector secondary hospitals in the Federal Capital Territory, Nigeria.

3.2 Objectives

1. To describe prescribing practices in the Social Health Insurance Programme in accredited public sector secondary hospitals in the Federal Capital Territory, Nigeria.
2. To identify and quantify irrational prescribing of medicines in the Social Health Insurance Programme in Federal Capital Territory, Nigeria.

3. To measure the percentage of prescribed essential medicines that was dispensed to beneficiaries of the Social Health Insurance Programmes in Federal Capital Territory, Nigeria.

3.3 Study Design

This study used a cross-sectional, descriptive methodology to survey retrospective records of prescription sheets of Social Health Insurance enrolees in accredited public sector secondary hospitals in the Federal Capital Territory, Nigeria. The choice of cross-sectional design was based on its ability to identify and quantify the variables contributing to medicine use problems (Grimes and Schulz, 2002; Beaglehole, Bonita and Kjellstrom, 2006). Second, it meets the WHO's recommendation that cross-sectional study designs can be used to study the trend in the use of medicines for one year to ensure equal representative samples and arrive at valid results devoid of biases (WHO,1993). The feasibility of generalizing the findings from cross-sectional studies to the study population is high (WHO/DAP, 1993; Durrheim and Painter, 2006; Park, 2007). Third, a review of literature on the use of medicine practices suggests that most baseline studies or studies on the prevalence of irrational use of medicines in Nigeria and other parts of the world used cross-sectional study designs (Uzochukwu, Onwujekwe and Akpala, 2002; Holloway, 2002; Araoye, 2003; Akande and Ologe, 2007; Adebayo and Hussain, 2010).

A retrospective data collection technique was employed to review the prescription encounters. This permitted examination of past trends in the use of medicines within a year and helped minimise bias due to seasonality and variations in the medicine supply cycle. The review of literature on prescribing practices revealed that a substantial number of studies conducted in Nigeria relied on retrospective review of patient records for collection of a large amount of data (Uzochukwu, Onwujekwe and Akpala, 2002; Akande and Ologe, 2007; Adebayo and Hussain, 2010).

3.4 **Study Population**

The study population consisted of the following:

a). All the 13 functioning public sector secondary hospitals managed by the Health and Human Services Secretariat (HHSS), Federal Capital Territory, Abuja. They constituted the primary unit of study. The initial plan was to use all the 14 public sector hospitals in FCT as the study population, however, according to information from the FCT Health Research Committee, only 13 of the 14 hospitals were operational. The newly constructed hospital at Karu has not commenced operational activities at the time of the survey.

b) The prescription encounter records of the NHIS out-patients representing a mix of health problems and ages constituted the secondary unit of study.
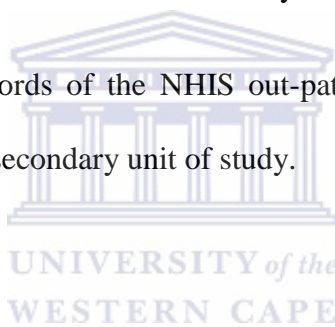
3.5 Sampling Procedure

3.5.1 Determination of Sample Size

a) Four public sector hospitals were selected as the primary unit for this study.

b) A total of Seven hundred and twenty (720) copies of prescription encounters were selected retrospectively from the selected secondary hospitals as the secondary unit of study. This sample size was well above the WHO specification for a cross-sectional survey of prescribing practices, which stipulates a minimum of 600 prescription records for 20 hospitals, or 100 records for a single health facility. The decision to use a large sample size was to ensure effective representative of all the variations in the study population (at a confidence interval of plus or minus 5% error and at 95% confidence level) as well as to further enhance the validity of data (Hedges, 1978; WHO /DAP, 1993; Durrheim and Painter, 2006).

3.5.2 *Sampling of Hospitals*

To generate representative samples, a Multistage sampling technique was used for the selection of the hospitals:

First, 13 secondary care hospitals were stratified into urban/peri-urban areas.

a) Six urban hospitals which have high concentration of patients in attendance with 80-150 patients per day and 10-20 insured patients in attendance per day. These include: Wuse, Garki, Asokoro, Kubwa, Maitama and Gwarinpa hospitals.

b) Seven peri-urban- hospitals which have low concentration of patients in attendance with at least 20-40 patients per day and 5-10 insured out-patients in their daily attendance register, they consist of Abaji, Bwari, Nyanya, Karshi, Kuje, Kwali and Rubochi hospitals. Each peri-urban area is not more than one hour drive from the urban area.
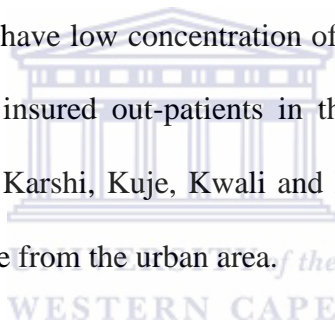
Second, two hospitals were randomly chosen from each of the strata. This was done by writing the names of the hospitals in each group on small pieces of folded paper in two separate bowls; thereafter, one of the data collectors randomly picked two of the folded pieces of papers from each of the two bowls. Hospitals were coded according to the stratum from which they were selected. The two hospitals generated from the peri-urban stratum were coded PAH and PBH; while hospitals selected from the urban stratum were coded UAH and UBH.

3.5.3 *Sampling of Prescription Encounters*

The prescription encounters of the Social Health Insurance out-patients from July 2009 to June 2010 constituted the sampling frame. Copies of the prescription sheets from each hospital were

gathered and sorted in monthly order. Indelible and torn prescriptions sheets were excluded from the sampling process; the remaining were counted and recorded for each month.

Fifteen prescriptions were systematically selected from each of the 12 months. The sampling interval was determined by dividing the total number of prescription encounters recorded for a given month by the number of cases needed per month. The random number used as the starting point for each selection was determined by throwing a dice. The derived number was used repeatedly to systematically select 15 prescription sheets for each month of encounter for a year (June 2009 to July, 2010) until 180 prescription encounters were selected per hospital, and 720 prescriptions for the four hospitals. This method has been employed in previous studies in Nigeria (Castrillo, Noel, and Van Roekel, 2009).

3.6 Data Collection

3.6.1 Data collection instruments

The WHO/DAP INRUD standardized methodology, tools and indicators recommended in the WHO guidelines on "How to investigate medicine use in health facilities" (WHO/DAP, 1993), were adapted and used in this study.

The modified tools consisted of three forms:

Data Compilation Form 1: This form was modified to capture data on patients' identifier codes, names of medicines prescribed, route of administration and formulation type, the number of medicines actually dispensed per prescription encounter and number of prescriptions referred to other accredited pharmacies (Appendix 4).The design of the form also helped in quality checking, tracking and tracing missing data.

Prescribing and Dispensing Indicators Form 2: This form was restructured to record the detailed information on patterns of prescribing and dispensing of medicines. The recorded data included the number of medicines prescribed per encounter, encounters with injection or antibiotics prescribed number of medicines prescribed from the NHIS Essential Medicines Formulary, number of generic medicines prescribed per encounter, number of medicines dispensed in hospitals under study and the number of medicines dispensed through referral of prescriptions to accredited pharmacies outside the hospitals (Appendix 5).

Facility Summary Form 3: This form was also modified to describe all analytical results on the prescribing indicators including average number of medicines per encounter, percentage of medicines prescribed by generic name, percentage of encounter with antibiotic prescribed, percentage of encounters with injection prescribed, percentage of medicines prescribed from the NHIS Essential Medicine Formulary, percentage of prescribed medicines dispensed at the selected hospital and percentage of prescriptions referred (Appendix 6).

3.6.2. *Preparations* for Data Collection

Prior to the commencement of data collection, extensive preparatory activities were carried out to facilitate smooth data collection processes. The activities include the following:

3.6.2.1 *Visits to stakeholders*

Key health insurance stakeholders including the NHIS corporate office, FCT Health and Human Service Secretariat and some HMOs were visited to inform them of the study and to seek their support and participation. A copy of the proposal was submitted to each of them, this resulted in the release of letters of approval for the research from the Health and Human Service Secretariat, FCT, Abuja; and support from the NHIS corporate head quarters.

The letter of approval for the research was presented to each of the Chief Pharmacists in the selected hospitals; this was aimed at ensuring adequate notification of the purpose and methods of the study and to seek their support. The Chief Pharmacist and staff of the pharmacy units in each of the selected facility responded positively as was evidenced in the assistance given in identifying and arranging the required prescription copies and interpreting information on prescription sheets or dispensing logbooks when necessary. The visitation to the hospitals also provided opportunity to introduce the data collectors, confirm availability of required records and estimate the time required to conveniently collect data from each of the facility without disturbing the routine works of the pharmacy units.

3.6.2.2 Selection and Training of Data Collectors

A team of data collectors comprising health professionals including the principal investigator, two pharmacists, a microbiologist and two pharmacy technicians were engaged and trained on the data collection process. Each of the data collectors has a minimum of five years work experience in reading and dispensing prescriptions in various hospitals and pharmaceutical outlets. Their knowledge of pharmaceutical terms enhanced accurate extraction of information from prescription records and interpretation of prescriptions.

All data collectors were trained together in three training sessions. The training covered the following topics: how to effectively use the research tools, the types of data to be extracted from prescriptions sheets, how to identify prescribed medicines, route of administration, medicines dispensed and referred, and how to record them on the appropriate column of the data collection tools. Other components of the training included sampling procedures, ethical issues and confidentiality in handling administrative and clinical documents and research findings.

At the end of the training, data collectors were divided into two teams. A team was assigned to the urban hospitals while the other covered the peri-urban hospitals. A survey schedule was arranged for each facility to ensure that the chief investigator fully participated in collection of data from each study facility to enable effective supervision.

3.6.2.3 Data Collection Guidelines

To avoid ambiguity in collection of data, each data collector was given a copy of the NHIS-EML formulary as the reference list for identifying what constitute generic medicines and antibiotics, and measuring the number of medicines prescribed from NHIS-EML list. In addition, a protocol was designed to assist in interpreting unclear prescription and identifying the data to be collected (Appendix 7). A list of abbreviated names of medicines commonly used by prescribers in Nigeria was given to the data collectors for easy identification of such medicines (Appendix 8)

It was also decided that collection of data should take place between 11a.m. and 1:30 p.m. from Tuesday to Thursday every week. The choice of this period was based on the fact that Mondays were very busy days, and the hours between 9 a.m and 11 a.m was the peak of activities in the NHIS dedicated pharmacy units; which usually open for activities from 8:30 a.m and closes 2:00 p.m.

3.6.2.4 Pre-Testing of Instruments and Procedures

The tools used in this study were pre-tested in one of the hospitals not selected for the study. The field test offered an opportunity to identify problems associated with the sampling procedures and completion of the instruments. To ensure reliability of data and content validity, the feedback from the pre-testing was used to further modify the study instruments. The *Prescribing and Dispensing Indicators Form 2* was modified to capture additional data on prescribed

essential medicines dispensed, while the *Facility Summary Form 3* was re-designed to capture data on the proportion of prescribed essential medicines dispensed and the proportion of prescription encounters having all prescribed medicines completely dispensed to insured patients.

3.6.3 Data Collection Procedures

The retrospective data on prescription encounters were collected within two months, from March 7th to May 5th 2011, with the aid of the three WHO adapted data collection instruments described above. All information on medicines prescribed and referred were abstracted from the sampled prescription encounters and documented on the corresponding portion on the *Data Compilation Form 1*. In this study, referral was defined as prescriptions containing prescribed medicines not completely dispensed in the study facilities. These were assessed to determine if the prescribed essential medicines were dispensed in other accredited providers as stipulated by the guidelines.

Detailed information describing the prescribing patterns and the extent to which the hospitals ensure that prescribed medicines were available to patients was extracted and entered into the designated section of *Prescribing and Dispensing Indicators Form 2* for each facility.

Availability of medicines was assessed by:

First, measuring the number of medicines dispensed in the study facilities by tracing the name of patients, date of prescription and names of medicines prescribed on each sampled prescription to the corresponding details on the dispensing logbooks to determine the number of medicines dispensed.

Second, determining the number of medicines dispensed through the process of referral to other accredited providers. This was done by identifying prescriptions with prescribed essential medicines not completely dispensed thereafter, we requested to review pharmacy records to determine the number referred to other providers and the number of re-imbursement made in respect of the referred prescriptions.

To facilitate statistical analysis, the documentation of information such as prescriptions with antibiotic or injection prescribed and prescription referred were assigned with the codes "0" or "1" on the respective column in the *Prescribing and Dispensing Form 2*. The code "0" infers that no antibiotic or injection was prescribed, and no prescription was referred to any accredited pharmacy; on the other hand, the code "1" indicates that an antibiotic or injection was prescribed. In terms of dispensing of prescription, "1" also infers that a patient was referred to another facility to get his/her remaining prescribed medicines dispensed. The numerical variables including number of medicines prescribed or dispensed, number of medicines prescribed from the EML, and number of prescriptions referred were not assigned with codes.

The summary results of all the findings in the study per facility were transferred to the relevant sections on the *Facility Summary Form 3*.

3. 7 Data Management

At the end of the data collection, completed forms were brought to a central place for further review and data cleaning. All detected inaccurate entries or missing data were corrected using the prescription identifier code to trace the corresponding sampled prescription encounter (Joubert and Erhlich, 2007). Data were entered into Microsoft Excel^{TM} spreadsheets over one week by two dedicated typists and cleaned to ensure that unknown values did not appear in the

data set. Thereafter, data were imported into Epi-info version 3.4.3 for further cleaning and quality checks to ensure completeness and consistency.

3.8 Data Analysis

Epi-info version 3.4.3 and SPSS (Statistical Program for Social Science, version 17.0) were employed to generate means (average), percentages, range, confidence intervals and *p*-values. One-way ANOVA was used to determine the statistical difference among the means of the four hospitals, followed by Chi-Square tests to determine the statistical significance of the differences in the percentages of the prescribing indicators. *P*-values < 5% were considered as statistically significant.

Summary statistics of means and percentages of medicines prescribed were used to describe and quantify the prescribing practices in relation to the degree of poly-pharmacy, the tendency to prescribe by generic names, the overall level of use of antibiotics and injections; and the degree to which prescriptions conformed to the Essential Medicine List as indicated by the NHIS-medicine formulary. The statistical measures were also applied to determine the extent to which hospitals were able to provide the medicines which were prescribed, and the proportion of patients who have all their medicines completely dispensed.

Findings were presented in the form of tables and bar charts to display the different levels of each indicator for each facility, and comparisons were made with findings from previous studies in Nigeria and other developing countries. The rationality of prescribing and availability of medicines were determined by comparing the results with the WHO/Derived Reference Values which consist of the WHO standards values and local standards derived for two states in Nigeria (Table 4.1).

3.9 Validity

Validity is the ability of a study to measure what it intends to measure to give a sensible result (Beaglehole, Bonita and Kjellstrom, 2006). A range of checks were undertaken in this study to ensure validity of data.

To ensure content validity, pharmaceutical reference books including EMDEX (The complete Drug Formulary for Nigeria's Health Professionals) and Martindale Extra Pharmacopeia were used as guides to determine the generic equivalent of all prescribed branded medicines in order to ascertain their availability in the EML. The appropriateness in the use of prescribed medicine was determined by using the NHIS-Essential Medicine Formulary.

The coding of each prescription encounter was structured in such a way that information bias due to missing data, or wrong data documentation was minimised by ensuring ambiguous data were further clarified by tracking the number of data on the form to the corresponding prescription sheets with the use of assigned codes and subsequently correcting the entries until clarity of the data was captured.

Confounding occurs when a third variable is strongly associated with the study variables in the study population thereby making it difficult to determine the factors truly responsible for the results obtained in a study (Joubert and Erhlich, 2007). In this study, potential confounding bias were minimized by using the NHIS Essential Medicines Formulary as terms of reference, therefore all medicines in semblance with antibiotics such as anti-protozoas and anthelmintics, which were not considered as antibiotics in the NHIS formulary were not regarded as such; however, all combination medicines and topical agents containing antibiotics were regarded and counted as antibiotics.

Selection bias was minimized by ensuring that only prescription encounter records of social health insurance patients from the general outpatient department were included in this study.

The adoption of retrospective data collection techniques also reduced conceptual biases that could have risen from seasonal variation, interruption of medicine supply, and the susceptibility of information biases arising from change in prescribers' attitude in the presence of researchers (WHO/DAP, 1993).

3.10 Reliability

Reliability demonstrates the extent to which the instruments or tools yield the same results on repeated trials under the same setting (Beaglehole, Bonita and Kjellstrom, 2006). Studies have shown that random sampling and measurement error are major factors that influence the reliability of any given research (Myer and Karim, 2007; Joubert and Erhlich, 2007).

In this study, the use of large sample size of 720 prescription encounter records and multi-stage sampling technique helped to ensure equal representation of the various variables in the study population and minimized errors from random sampling error (Grimes and Schulz, 2002; Beaglehole, Bonita and Kjellstrom, 2006). Measurement errors were minimized with the use of the WHO standardized measuring tools and indicators; which were adapted and pre-tested before the commencement of data collection in health facilities.

3.11 Generalizability of Results

The results of this study are only applicable to the study population, however, the generalizability of the findings to the NHIS formal sector health insurance programne in other public sector secondary hospitals was enhanced by the choice of study facilities which are

affiliated to more than 50% accredited HMOs for formal sector scheme and the use of a large sample size which ensured good representation of insured patients.

3.12 Ethical Consideration.

Ethical clearance and approval for this study was first given by the Health Research and Ethics Committees of the University of the Western Cape and the NHIS corporate headquarters. Thereafter, ethical permission to conduct the research in the selected hospitals was granted by the Health Research Ethics Committee in FCT through the Chairman; the Secretary of Health and Human Services - under whose authority these hospitals function (Appendix 9). In addition, the NHIS corporate headquarter was also informed and their consent was solicited before the commencement of the study.

Confidentiality of the names of the selected hospitals and the insured patients was maintained by assigning codes to each of the selected hospitals and prescription encounter sheets. The data collection forms also reflect the codes of the selected hospitals and prescription encounter sheets so that information from the sampled prescription encounter sheet was documented against the corresponding codes on the data collection forms. The privacy of data was further assured by ensuring that data was stored in the computer with a password known only to the researcher and hard copies of data collected were stored in a safe at all times and will be destroyed after a period of five years.

Copies of this study will be submitted to the University of the Western Cape in partial fulfillment of the requirements for the Masters in Public Health degree. Also, soft copies would be disseminated to the NHIS corporate headquarters, heads of all the 13 secondary hospitals through

the Secretary of Health and Human Services; and all the HMOs affiliated to the study facilities (Appendix 10).

CHAPTER FOUR

RESULTS

4.0 Introduction

In this chapter, the findings of this study on prescribing practices and availability of essential medicines are presented. The study was conducted in four selected public sector hospitals in the Federal Capital Territory, Nigeria, two peri-urban and two urban hospitals identified as PAH, PBH and UAH, UBH respectively. The study sampled 180 prescription encounters from each of the four hospitals selected for the study. Overall, 720 prescription encounters were examined and the information analyzed with the use of the WHO prescribing and dispensing indicators. The results are presented as averages, percentages and frequency of distribution of variables as tables and charts. The rationality of prescribing was determined by comparing results with the WHO/Derived Reference Values as detailed in Table 4.1 (WHO, 2004, Isah, *et al.*, 2002). The first section of this chapter describes the WHO/Derived Reference Values, followed by a description of prescription patterns across the four hospitals and concludes by describing the extent of availability of prescribed medicines to patients.

4.1 Description of WHO/Derived Reference Values

Table 4.1: WHO/Derived Reference Values for Prescribing and Patient Care (Medicines dispensed) Indicators

Indicators	Values	Type
Average No. of Medicines prescribed	1.6 - 1.8	Derived standard
% of Prescription encounters with an antibiotic prescribed.	20.0 – 25.4 %	Derived standard
% of Prescription encounters with an injection prescribed	10.1 – 17.0%	Derived standard
% of Medicines prescribed by generic name.	100%	WHO standard
% of Medicines prescribed on EML	100%	WHO standard
% of Medicines actually dispensed	100%	WHO standard

(WHO, 2004a: Isah, Quick, Mabadeje, Santoso and Hogerzeil, 2002)

Table 4.1 shows the WHO/Derived Reference Values which are a combination of the WHO standard values and local standards derived from two states in Nigeria; they were used in determining the appropriateness of prescribing patterns and the degree of availability of medicines in this study.

The WHO global standard values for percentages of generic medicines prescribed from the EML and medicines dispensed are an optimal value of 100% each. However, based on morbidity patterns and the results of a study conducted in two states in southern Nigeria, the values derived for the average number of medicines prescribed, percentage of prescriptions with antibiotics and injections prescribed are within the ranges of 1.6-1.8, 20.0- 25.4% and 10.1-17.0% respectively.

The wide range assigned to the indices of antibiotics and injections is due to the prevalence and severity of communicable diseases and other local factors which may influence the indices in varying degrees.

4.2 Description of the Patterns of Prescribing

The following section provides an overview of prescribing patterns in the social health insurance programme in accredited public sector hospitals in FCT, Abuja. The section identified the nature and magnitude of irrationalities in the prescription encounters of insured patients.

Table 4.2: Frequency of medicines prescribed per encounter (n=2517)

No. of Medicines Per Prescription Encounter	PAH		PBH		UAH		UBH		OVERALL	
	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%
1	2	1.1	2	1.1	4	2.2	0	0	8	1.1
2	22	12.2	46	26	39	21.7	21	11.7	128	17.8
3	48	26.7	72	40	56	31.1	54	30	230	31.9
4	75	41.7	47	26	51	28.3	59	32.8	232	32.2
5	30	16.7	10	5.6	22	12.2	35	19.4	97	13.5
6	3	1.7	3	1.7	8	4.4	11	6.1	25	3.5
Total	180	100	180	100	180	100	180	100	720	100

One of the most commonly used indicators for determining rational prescribing is the number of medicines prescribed per encounter. The frequency of the number of medicines prescribed per encounter in the study population is presented in Table 4.2; and it ranged from one to a maximum of six medicines per encounter. In PAH, PBH and UAH hospitals, the prescription encounters resulted in one or more prescribed medicines; however, in UBH the number of prescribed medicines per encounter ranged from 2 to 6. Overall most encounters resulted in three

or four prescribed medicines, with almost one third of encounters resulting in three prescribed medicines and another third in four prescribed medicines.

The study also revealed that 81.1% of the study population had three or more medicines prescribed. Further analysis showed that PBH exhibited the highest poly-pharmacy with 88.3% of its entire prescription encounters having three or more medicines prescribed; this was followed by PAH (86.8%), UAH (76.0%) and PBH (73.4%).

Table 4.3: Mean number of medicines prescribed per prescription encounter (n = 2517)

Hospital	Number of Prescription Encounters	Number of Medicines Prescribed	Mean Number of Medicines Prescribed	Minimum	Maximum
PAH	180	658	3.7 ± 1	1	6
PBH	180	566	3.1 ± 1	1	6
UAH	180	612	3.4 ± 1	1	6
UBH	180	681	3.8 ± 1	2	6
OVERALL	720	2517	3.5 ±1	1	6

Analysis of Variance (F) = 13.2,   p< 0.001

Table 4.3 shows that the average number of medicines prescribed per encounter in the study population was 3.5±1 compared to the WHO/Derived Reference Values which ranged from 1.6 - 1.8. The average number of medicines prescribed per encounter varied between the hospitals from a minimum average of 3.1 found in PBH to a maximum average of 3.8 found in UBH. A significant difference (p< 0.001) was found and the results show that PBH, with a mean of 3.1 had the least tendency towards poly-pharmacy compared to the other hospitals.

Table 4.4: Most commonly prescribed medicine categories (n=2517)

Categories of Medicines Prescribed	OVERALL		PAH		PBH		UAH		UBH	
	%	Rank	%	Rank	%	Rank	%	Rank	%	Rank
Analgesics/NSAID	19.2	1	19.1	2	21.2	2	18.3	1	18.4	1
Antibiotics	17.6	2	18.5	3	22.8	1	15.7	3	14.2	4
Antimalarials	17.3	3	19.6	1	17.8	3	13.2	4	18.2	2
Haematinics/Vitamins	13.3	4	9.4	4	12.2	4	16.2	2	15.3	3
Antihypertensives	6.6	5	3	9	2.8	7	10.1	5	9.5	5
Antihistamines	4.3	6	5.6	5	5.5	6	3.6	7	2.5	9
Anti-flagellates	3.6	7	3.5	8	2.3	9	4.1	6	2.9	8
Anti-ulcers	3.5	8	4	6	2.7	8	2.6	9	4.6	6
Sedatives/ Tranquilizers	2.1	9	2.4	11	9	5	2.1	10	2.1	10
Anthelmintics	1.8	10	3	9	1.7	11	2	11	1.8	11
Antidiabetics	1.7	11	0.8	12	0.4	13	2.3	8	3.4	7
Antifungals	1.6	12	1.7	7	1.5	12	1.6	12	1.4	12
Corticosteroids	1.2	13	0.8	13	1.8	10	1.3	13	1.2	13

The most commonly prescribed medicine categories are ranked according to their frequency in Table 4.4. Analgesics/NSAIDs were the most prevalent medicine category accounting for 19.2% of the total medicines prescribed in the four hospitals. The four most frequently prescribed categories of medicines were analgesics/NSAID, antibiotics, antimalarials and haematinics/vitamins, they constituted 19.2%, 17.6%, 17.3% and 13.3% of the 2517 medicines prescribed across the four hospitals respectively; and collectively accounted for 67.4% of the overall medicines prescribed. These four categories of medicines comprised the top four categories across all four hospitals. The findings with regard to the use of anti-infective and anti-parasitic agents revealed that antimalarials, antibiotics and antiflagellates were on the top-ten list of commonly prescribed medicines in all four hospitals, however, anti-fungal agents were also amongst the top ten medicines categories in PAH, and anthelmintics were on the top ten list in

PAH and UBH facilities. Overall, antibiotics (17.6%), antimalarials (17.3%), anti-flagellates (3.6%) and anthelmintics (1.8%) accounted for 40.3% of the total (2517) medicines prescribed in the study population.
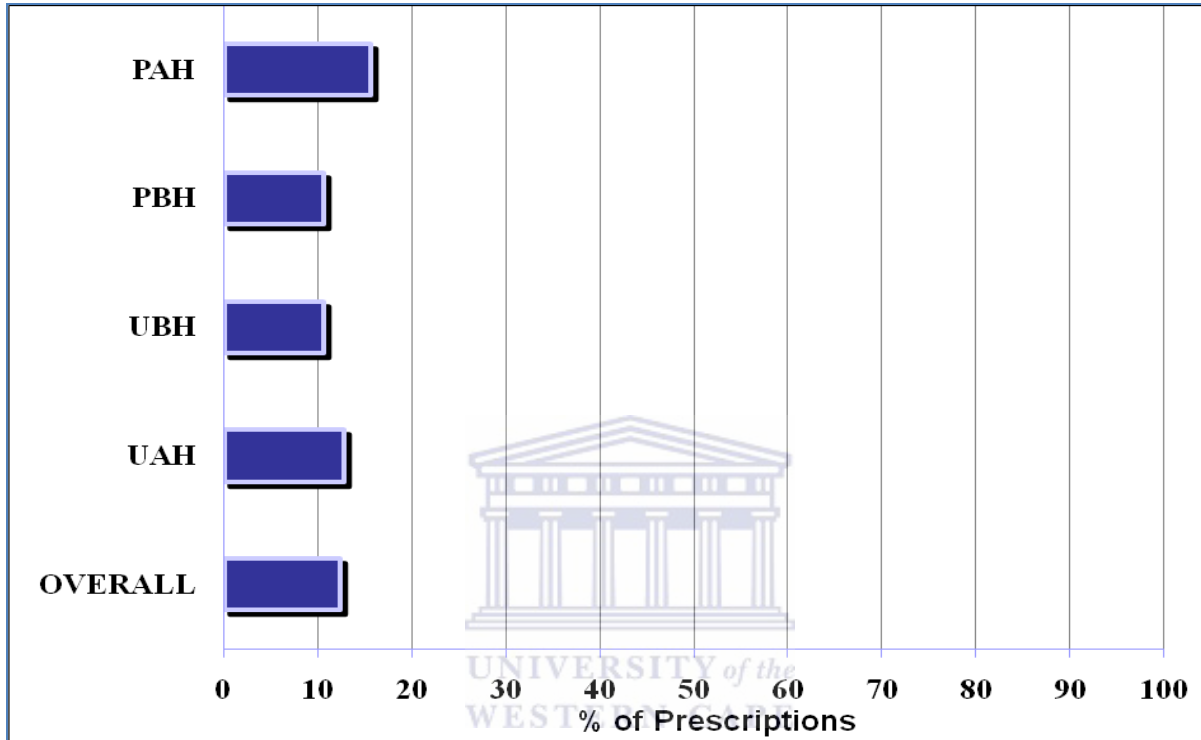
Chi- X^2= 2.8, p= 0.4

Figure 4.1: Percentage of prescription encounters with injections prescribed (n=720)

The study found an average of 12.49% (95% CI of 10.1-15.0) of the study population received one or more injections (Figure 4.1). This result shows that the overall rate of injection used in the four hospitals was lower than the standard requirement of the WHO/Derived Reference Value (13.4 – 24.1%). Although there was no significant difference (p= 0.4) found in the use of injections across the hospitals, the highest proportion of prescription encounters with an injection

was found in PAH (15.6%), followed by UAH (12.8%). PBH and UBH had the lowest proportion of injection prescription encounters at 10.6%.

PERCENTAGE	PAH	PBH	UAH	UBH	OVERALL
	55	62.8	48.3	46.7	53.7
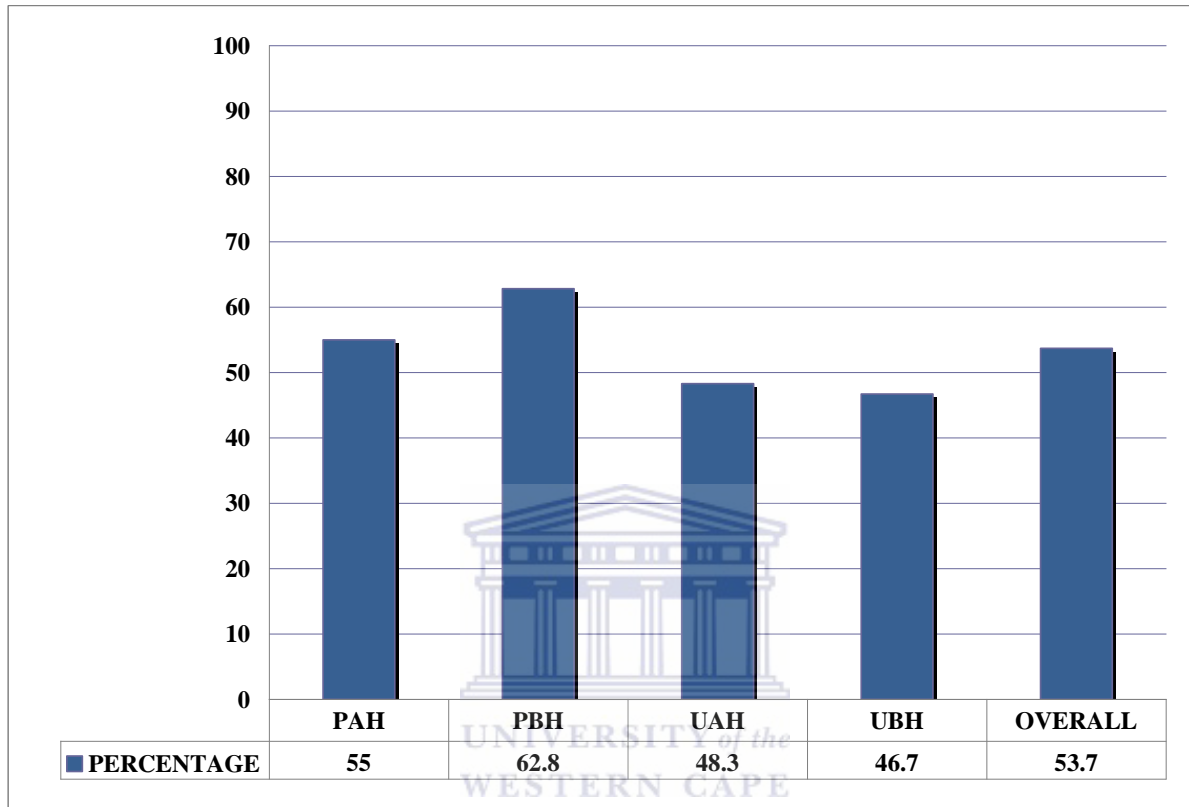
Chi-square ($X^2 = 11.7$), p= 0.009

Figure 4.2: Percentage of prescription encounters with antibiotics prescribed (n=720)

The study findings on antibiotics utilization showed that just over half (53.7%) of the patient encounters resulted in an antibiotic prescription (at 95% confidence interval (CI) (49.9-56.9%) compared to 20-27% in WHO/Derived Reference Values (Fig.4.2). The results showed that PBH had the highest rate (62.8%) of patient prescription encounters with antibiotics prescribed (p=0.009) while UBH had the lowest rate (46.7%)

The statistically significant (p=0.009) difference observed in the prescription encounters with antibiotics prescribed across the four facilities indicated that at PBH antibiotics were significantly more frequently prescribed to patients than at the other three facilities.

Table 4.5: Medicines prescribed with generic names (n = 2517)

Hospital	Number of Medicines Prescribed (n)	Number of Medicines Prescribed with Generic Names	% of Medicines Prescribed with Generic Names
PAH	658	348	52.9
PBH	566	311	54.9
UAH	612	280	45.8
UBH	681	344	50.5
OVERALL	**2517**	**1283**	**50.9**

Chi-square (X^2) = 16.5, p= 0.0009

The results of analysis of the use of generic names in the study population are presented on Table 4.5. It revealed that the average percentage of generic medicines prescribed was 50.9% at (95% CI of 45.8-54.9) which is far below the WHO recommendation of (100%). The prescribing of medicines with generic names varied from a minimum of 45.8% at UAH to a maximum of 54.9% observed at PBH. A statistically significant difference (*p*<0.0009) was found in the use of generic medicine names across the hospitals, and UAH was responsible for the observed difference by having the lowest propensity to prescribe with generic names.

Table 4.6: Medicines prescribed from essential medicines list or formulary (n= 2517)

Hospital	Number of Medicines Prescribed *(n)*	Number of Medicines on EML	% of Medicines on EML
PAH	658	471	71.6
PBH	566	445	78.6
UAH	612	458	74.8
UBH	681	495	72.7
OVERALL	2517	1869	74.2

Chi-square (X^2) = 7.7 p= 0.05

The analysis in terms of medicines prescribed from the EML showed (Table 4.6) that these hospitals had between 71.6% - 78.6% of medicines prescribed from the NHIS-EML with no significant difference (*p* =0.05) found among the four hospitals. Overall, 74.2% (at 95% CI, 71.6-78.6) prescribed medicines were on the EML, suggesting a shortfall of 25.8% compared to the WHO target (100%) for this indicator.
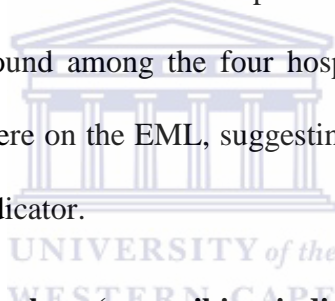
Table 4.7: Summary of overall values (prescribing indicators) compared with Reference Standards (n=720)

Indicators	n=	Overall Observed Values	WHO/Derived Reference Values	*p*-value (*p*)
Average No. of medicines prescribed	n=2517	3.5	2	*p*<0.001
% of Encounters with an antibiotic prescribed.	n=720	53.2	20 - 27	*p*=0.009
% of Encounters with injection prescribed	n=720	12.4	13.4 – 24.1	*p*=0.4
% of Medicines prescribed by generic name	n= 2517	50.9	100%	*p*=0.0009
% of Medicines prescribed from EML	n= 2517	74.2	100%	*p*=0.05

Table 4.7 presents a summary of overall study findings on prescription indicators in comparison with the WHO/Derived Reference Values. *P-values* < 5% indicate statistically significant difference in prescription of medicines across the hospitals.

4.3 Description of Proportion of Medicines Available To Beneficiaries.

This section describes the extent to which prescribed medicines were available to patients in the hospitals under study using a range of indicators.

Table 4.8: Total medicines dispensed (n = 2517)

Hospital	Number of Medicine prescribed *(n)*	Number of Medicines Dispensed	% of Medicines Dispensed
PAH	658	625	94.9
PBH	566	504	89
UAH	612	487	79.6
UBH	681	526	77.2
OVERALL	**2517**	**2142**	**85.1**

Chi-square (X^2) = 60.2, p= 0.001

As can be seen in Table 4.8, the percentages of prescribed medicines actually dispensed in PAH (94.9%) and PBH (89.0%) almost correspond to the total number of medicines prescribed. Overall, the percentage of prescribed medicines actually dispensed in the study population was 85.1% at 95% CI (77.2-94.9%) as against 100% targeted by World Health Organization.

Significant differences (*p*=0.001) were observed in the values obtained across the hospitals which varied from 77.2% (UBH) to a maximum of 94.9% found in PAH. The study found that UAH and UBH dispensed lower percentages of prescribed medicines than the remaining two

hospitals. It should be noted that the proportion of medicines dispensed consist of both essential medicines and those not on the EML.

Table 4.9: Essential medicines dispensed (n=1869)

Hospital	Number of Medicines Prescribed on EML	Number of Essential Medicines Dispensed	% of Essential Medicines Dispensed
PAH	471	454	96.3
PBH	445	432	97
UAH	458	424	92.5
UBH	495	434	87.7
OVERALL	**1869**	**1744**	**93.4**

Chi-square (x^2) = 0.129, p= 0.256

Table 4.9 shows the extent to which prescribed medicines on EML were dispensed relative to those prescribed on EML. No statistically significant difference (p= 0.256) was observed in the proportion of essential medicines dispensed among the hospitals. However, PBH had the highest percentage (97.0%) while the lowest tendency to dispense prescribed essential medicines on NHIS-EML was found in UBH (87.7%). Ideally, all prescribed medicines on the NHIS-EML should be dispensed; this is nevertheless a reasonable percentage. In this study, the overall percentage of prescribed essential medicines dispensed was 93%.

	PAH	PBH	UAH	UBH	OVERALL
■ ALL PRESCRIBED MEDS. DISPENSED	82	71	41	37	58
■ NOT ALL PRESCRIBED MEDS.DISPENSED	18	29	59	63	42
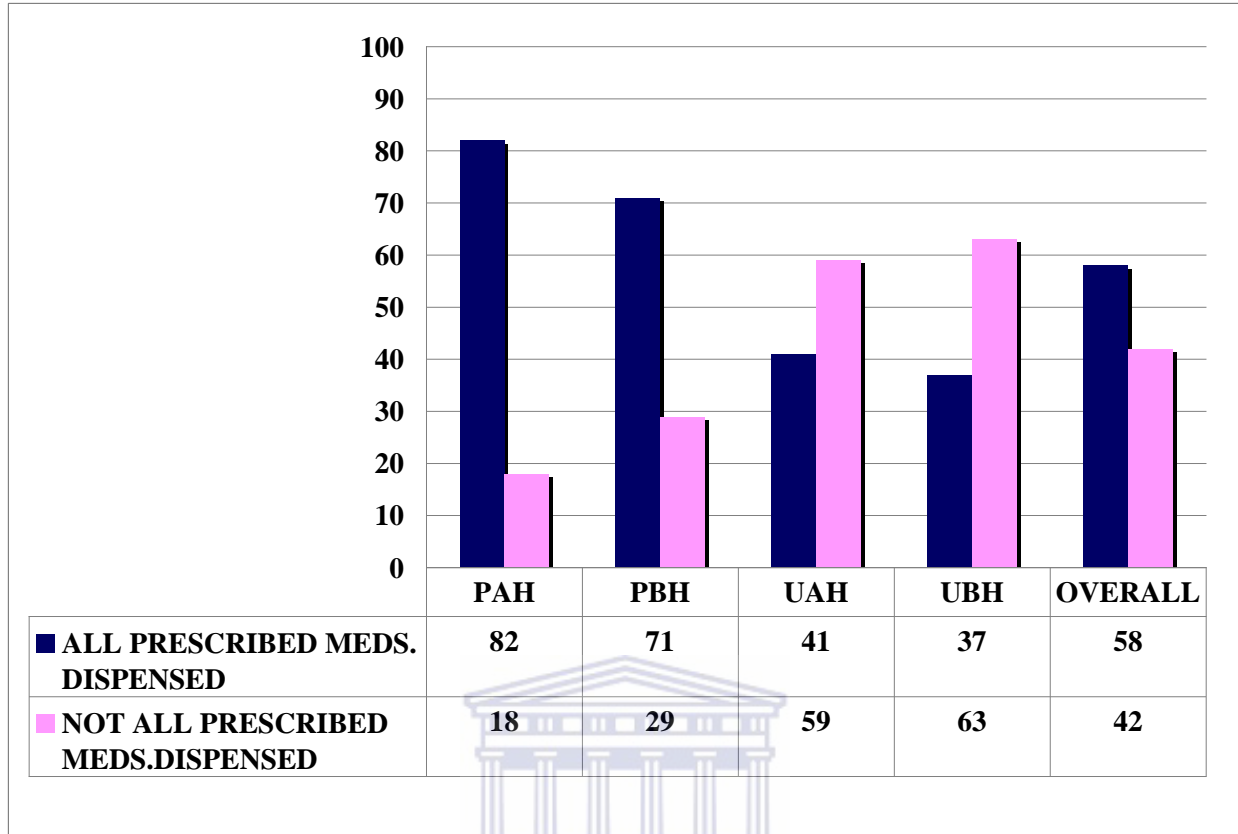
Chi-square ($X^2 = 109.4$), p< 0.001

Figure 4.3: Percentage of patients having all prescribed medicines dispensed (n=720)

Further analysis of medicines dispensed was carried out to reveal the proportion of patients who had all their medicines dispensed to them across the hospitals (Fig.4.3). Overall, only 58% of 720 patients' prescription encounters had all their prescribed medicines completely dispensed, which is far short of the target of 100% access to prescribed medicines envisaged (WHO, 2004a).

There was a significant ($p<0.0001$) difference in number of prescription encounters with all prescribed medicines completely dispensed among the hospitals. The study found that the propensity of patients having all their medicines completely dispensed was lower in the patients

who visited the two urban hospitals, UAH (41%) and UBH (37 %), than those who visited the two peri-urban hospitals. Conversely, PAH (82%) had the highest tendency to completely dispense all medicines prescribed per prescriptions.

	PAH	PBH	UAH	UBH	OVER ALL
% Prescriptions not Completely Dispensed	18	29	59	63	42
% Referred or Re-imbursed	0	0	0	0	0
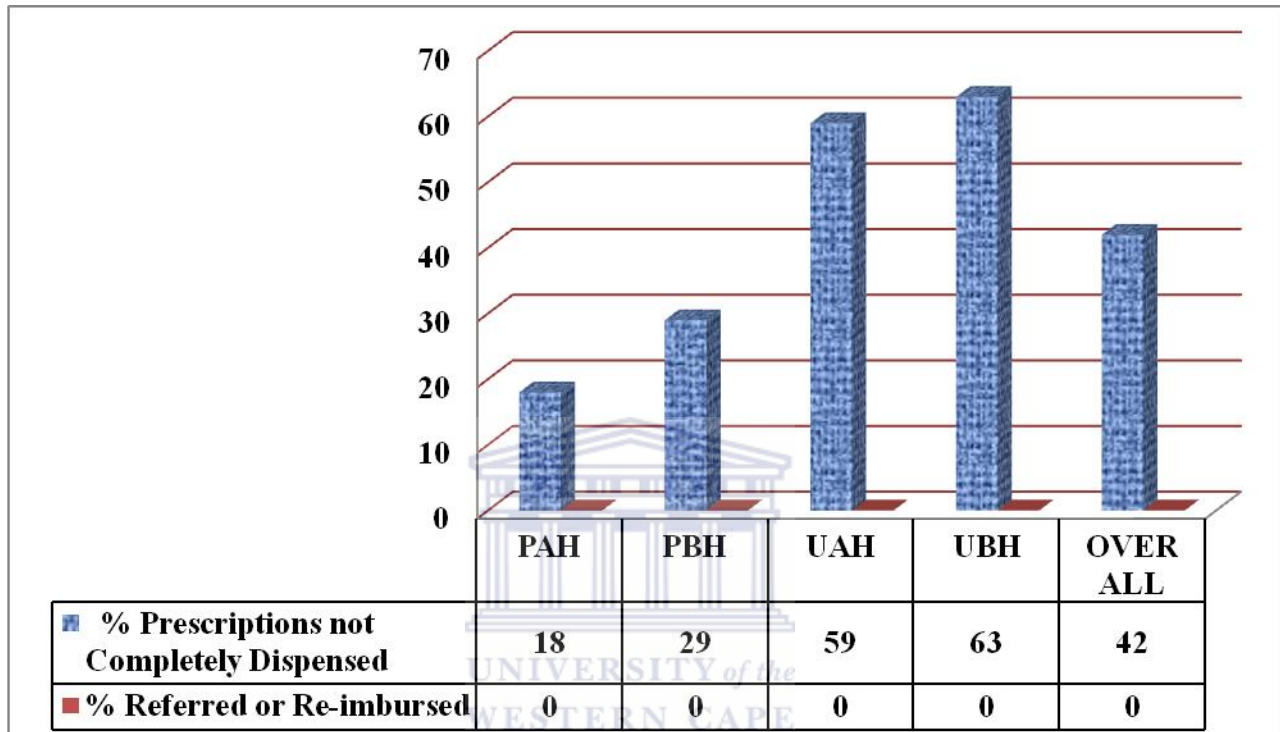
Chi-square ($X^2 = 109.4$), p< 0.001

Figure 4.4: Utilization rate of referral/reimbursement process (n=720)

Ideally, a secondary public sector hospital with an in-house pharmacy should ensure that all prescribed essential medicines are dispensed to patients by releasing unfilled prescriptions to accredited pharmacies outside the hospitals and thereafter reimbursing the cost of the medicines dispensed to the patients to the referred pharmacy. Where the cost of the prescription was paid by the patient, then reimbursement should be made directly to the patient. Figure 4.4 shows the utilization rate of the process of referring patients' prescriptions to accredited pharmacies and reimbursement of out-of-pocket expenditures on prescribed essential medicines.

The study found that UBH (63%) had the highest number of patients' prescription encounters with prescribed medicines not completely dispensed, while the lowest was observed at PAH (18%). Overall, 42% of the 720 patients did not have all their prescribed medicines completely dispensed. It was observed that none of the hospitals referred or reimbursed patients for out-of-pocket expenditure on prescribed medicines covered by the scheme.

Table 4.10: Summary of Medicines Received by Insured Patients

Indicators	Overall Observed Value	Ideal Value	*p*-value (*p*)
% of overall medicines dispensed	85.1	100%	p= 0.001
% of EMs dispensed relative to medicines prescribed on EML.	93	100%	p= 0.256
% of prescriptions with all prescribed medicines completely dispensed.	58%	100%	p< 0.001

Table 4.10 summarises the dispensing of prescribed medicines to patients in the study. A *p*-value < 5% indicates statistically significant difference in the dispensing of prescribed medicines across the hospitals.

Table 4.11: Summary of Results

Hosp.	Average Medicines Prescribed	of% of PXNs with Injections	% of PXNs with Antibiotics	% of PXNs Generics Medicines Prescribed	of% Medicines EML	of% of Total on Medicines Dispensed	% of Total % completely Dispensed	% of PXNs Prescribed Ems Dispensed	of% of Medicines Referred
PAH	3.7 ± 1	12.4	55	52.9	71.6	94.9	82	96.3	0
PBH	3.1 ± 1	10.6	62.8	54.9	78.6	89	71	97	0
UAH	3.4 ± 1	12.8	48.3	45.8	74.8	79.6	41	92.5	0
UBH	3.8 ± 1	10.6	46.7	50.5	72.7	77.2	37	87.7	0
OVER ALL	3.5 ±1	15.6	53.7	50.9	74.2	85.1	58	93.4	0
Min.	1								
Max.	6								
WHO/Derived Reference Values (ideal Values)	1.6 - 1.8	10.1 – 17.0%	20.0 – 25.4 %	100%	100%	100%	100%	100%	100%

Legend: PXN =Prescriptions

4.4 Summary

Table 4.11 summarises the findings for the main study variables in each of the four hospitals and overall, together in a comparison with the WHO/Derived Reference Values. The results found that 720 prescription records sampled for study contained 2517 prescribed medicines.

The overall average number of medicines prescribed per prescription encounter was 3.5 ±1 ($p< 0.001$). Injections were prescribed in 15.6 ($p= 0.4$) of the encounters, while more than half, 53.7% ($p=0.009$) contained at least one antibiotic. Overall, 50.9% ($p<0.0009$) of the medicines were prescribed by generic names while 74.2% ($p=0.05$) of prescribed medicines were from the EML.

The study also found that 85.1% ($p=0.001$) of overall prescribed medicines were dispensed by on-site pharmacies, specifically, out of the total essential medicines prescribed, 93.4% ($p= 0.256$) was dispensed. Overall, only 58% ($p<0.0001$) of 720 patients' prescription encounters had all prescribed medicines completely dispensed.

In conclusion, the results of this study were considerably different to the WHO/Derived Reference Values. The appropriateness of prescribing and the implications of these results on access to health care and health outcome in the National Health Insurance Programme will be discussed in the next chapter.

CHAPTER FIVE

DISCUSSION

5.0 Introduction

The Social Health Insurance Programme was introduced in Nigeria to provide quality and accessible health care to all Nigerians at an affordable cost. Since its inception in June 2005, there is no information on prescribing practices or the availability of medicines to insured consumers. This study attempted to investigate prescribing practices as well as availability of medicines in accredited public sector secondary hospitals in the Federal Capital Territory, Nigeria between July 2009 and June 2010.

This chapter presents the interpretation of the findings of this study, compares the results with previous studies and discusses the implications of the trends in prescription patterns and availability of essential medicines in this setting.

5.1 Description of Prescribing practices

The findings of the study revealed considerable irrational prescribing practices in the form of poly-pharmacy, overuse of antibiotics, as well as poor use of generic medicines and those on EML. However, injections were found to be prescribed within the optimal range provided by the Reference Values. The detailed results of the prescription indicators and their implications are discussed below.

5.1.1 Tendency to Poly-pharmacy

5.1.1.1 Categories of Medicines Prescribed

The analysis of data on the categories of medicines prescribed revealed the predominance of anti-infective agents, analgesics/NSAID and vitamins/haematinics amongst the top ten categories of medicines prescribed at all the hospitals. They accounted for 67.4% of the medicines prescribed in the overall study population (Table 4.4). These findings are consistent with those reported in previous studies by Akande and Ologe (2007).

The high proportion of prescribed anti-infective agents (40.3%) observed in the overall study population correlates with the prevalence of infectious and parasitic diseases in the study area (FCT Health Report, 2006; WHO, 2007c). The rationale for the high proportion of vitamins/haematinics (9.4%-16.2%) is outside the scope of this study; however, studies have shown that they have little or no medical importance except where anaemia is suspected. Evidence has shown that these categories of medicines are often abused by prescribers who use them to gratify patients' desire for medicines and this could be a possibility in this setting too (Neyaz, *et al.,* 2011).

5.1.1.2 Average Number of Prescribed Medicines

A breakdown of the number of medicines prescribed per encounter found that 80% of the overall prescription encounters contained three or more medicines (Table 4.2), while the overall average number of prescribed medicines per encounter, 3.5 SD ±1 (Table 4.3), exceeds the range recommended in the WHO/Derived Reference Values (1.5-1.8) and the average (1.3-2.3) reported in research conducted in some developing countries (Hogerzeil, and Ross-Degnan, 2001). These values indicate a high tendency towards polypharmacy in providers' prescribing

practices. Possible reasons for the observed polypharmacy could be due to demands from patients as reported in a study conducted in China where it was shown that insured patients are more likely to demand for certain types of medicines including painkillers, antibiotics and vitamins (Moreira, *et al.*, 2006). Similarly, the high use of anti-infective agents, multivitamins and analgesics/ (NSAID) (32.5%) as observed in this study (Table 4.4) could have likely contributed to the high averages observed in this study. These results are consistent with findings in other countries that health insurance tends to increase medicine utilization (Moreira et al, 2006).

Poly-pharmacy and unnecessary prescription of medicines have serious potentially economic and health implications for social health insurance programmnes. First, poly-pharmacy and unnecessary use of vitamins, tonics, antibiotics and adjuvants may cumulatively increase the expenditure on medicines and the cost of co-payments paid on prescribed medicines. Studies on the RAND health insurance experiment showed that hhigh co-payment on services may deter the vulnerable and low income earners from accessing basic services which may invariably result in poor health outcomes (Leighton 1996; Hudman and Molly, 2003; EDM, 2003; Goldman, Joyce and Zheng, 2007; Lu, *et al.*, 2008). In addition, high co-payments exert financial constraints on government funding of the scheme. For example, the US Centre for Medicare and Medicaid Services reported that the USA spends US$50 billion annually on polypharmacy on the nation's health care plan (Bushardt, *et al.*, 2008). Such financial cost may be unaffordable in Nigeria, particularly in view of the report that the scheme is grossly underfunded (Anyene, 2011). In addition, these patients are more likely to be hospitalized in the event of medicine toxicity and antimicrobial resistance, resulting from irrational prescribing (Moreira et al, 2006).

Second, the current study also found that 81.1% of the study population had three or more medicines prescribed suggesting that at least large numbers of patients were exposed to the risks of medicines toxicity resulting from adverse reactions and poor patient compliance, which are associated with a high pill burden. Of particular concern are people living with HIV/AIDS who are at high risk of adverse medicine reactions as a result the burden of antiretrovirals (ARVs) and other regimen used in control and treatment of HIV/AIDS (Clarke et al. 2008; Seden et al., 2009). The side effects and economic burden of purchasing ARVs combinations as well as the inconveniences of the dosage regimen tend reduce adherence rate in people living with HIV/AIDS (UNAIDS, 2008; Clarke et al. 2008).

5.1.2. Injections Prescribed

In this study, the overall rate of injections (10.5% in Fig. 4.1), is within the optimal range in the WHO/Derived Reference Values (10.1-17.1). This should be lauded. A comparison of this result with findings from previous studies conducted in Nigeria indicates that there is a decline in the use of injection (Ugochukwu, Onwujekwe and Akpala, 2002; Akande and Ologe, 2007). The decline could be attributed to the positive impact of government interventions which has increased prescribers and members of the public awareness of the risks associated with unnecessary use of injections. For instance, the compliance of prescribers with the policy change from chloroquine to artemisinin-based combined therapy (ACT) for treatment of malaria could have drastically reduced the use of chloroquine injection (FMOH, 2010b).

5.1.3 Use of Antibiotics

The overall percentage of patients receiving antibiotics (53.7% in Fig. 4.2) was found to be unacceptably high when compared with the recommendation in the WHO/Derived Reference Values which ranged from 20-24%. A slightly lower value of 51.0% was reported in a study recently conducted in similar

settings by Ehijie and Chima (2011). Comparison with findings from other countries shows that the use of antibiotics in this study is higher than the values (50%) reported in Nepal, but lower than the value (68.1%) was reported by Mohlala, *et al.*, (2010) in South Africa.

The high utilization of antibiotics observed in this study could be attributed to the prevalence of communicable diseases in Nigeria and inadequate knowledge of prescribers on appropriate use of antibiotics (WHO, 2002; WHO, 2007c; Oshikoya, Senbanjo and Sodipe, 2009). Previous studies in Nigeria have shown that a substantial proportion of antibiotics prescribed for outpatients in public health facilities were for prophylaxis, diseases of non-bacterial aetiology like cough and fever, and other presumed diseases without sufficient diagnosis (Odunsanya, 2004; Nwolisa, Erinuagha and Ofoleta 2006; Onwujekwe, *et al.*, 2009; Erah and Ehiagwina, 2010; Oshikoya and Senbanjo, 2010).

Given the importance of antibiotics in combating infectious diseases in high-burdened countries like Nigeria, the irrational use of antibiotics observed in this study has the tendency to reduce the therapeutic effectiveness of antibiotics as a result of emergence of bacterial resistance to antibiotics; this predisposes patients to the risk of treatment failure. The consequences are higher with people living with HIV/AIDS seeing that they need to take antibiotics daily to prevent or treat HIV-related opportunistic infections. This may necessitate switching to more expensive antibiotics in the process of treating resistant strains (Pavin, *et al.*, 2003; Holloway, 2004; 2005; Erah and Ehiagwina, 2010). Available evidence has shown that antibiotic-resistant infections are the principal cause of death in AIDS (UNAIDS, 2008).

5.1.4 Generic Prescription

Previous studies conducted to determine the rate of generic prescription in Nigeria have reported values in the range of 37.0-54.8%, which are considerably lower than the suggested target of 100% by the WHO (Hogerzeil; 2000; Erah, Olumide and Okhamafe, 2003; WHO, 2004a;

Akande and Ologe, 2007; Adebayo and Hussain 2010; Enato and Chima, 2011). In this study, only 50.9% (Table 4.5) of the total medicines prescribed were written in their generic names. This value is lower than those obtained in health insurance programmes of China and Iran (Sun, *et al.*, 2009; WHO, 2009d). The low percentage of generic medicines indicates high use of branded medicines which is likely to be due to the influence of pharmaceutical marketers; and poor perception of the safety and quality of generic medicines by physicians (Holloway, 2000; King and Kanavos, 2002; Ijoma, *et al*, 2010: Leo and Okafor, 2012).

Other studies have also shown that the preference for branded products could be attributed to providers' perceptions that generic names are unattractive and difficult to remember, and the profit margin and demand for generic medicines are low (Abdelmoneim, Tayeb and Omer, 1999; Chen , *et al.*, 2011).

Notwithstanding the reasons given for the poor use of generic medicines, unnecessary use of expensive branded medicines will led to the depletion the capitation that could have been used to procure more of clinically equivalent generic medicines for wider coverage of insured patients (Hogerzeil, 2004). In addition, the provision of branded products to insured patients may result in higher co-payments, which can disproportionately affect low income earners (Chen, *et al.*, 2011). Patients may also resort to purchasing prescribed branded medicines on their own when health facilities are not sufficiently stocked to dispense the generic equivalents listed on the EML. In particular, there is a high tendency that the health outcome of low income earners who may not have the financial means to purchase prescribed branded products will be affected negatively (Adebayo and Hussain, 2010; Chen, *et al.*, 2011). The use of brand products in a social health insurance programme is therefore inappropriate and ineffective in ensuring availability of medicines and equal access to cost effective essential medicines.

5.1.5 Medicines Prescribed on Essential Medicine List

Good use of the EML will to an extent, determine which prescribed medicines will be dispensed to insured patients. Ideally, all prescribed medicines should be on the NHIS-EML to facilitate access to the required ones. However, evaluation of the extent of physician adherence to the NHIS-EML found that the range of the percentage (71.6-78.6%: Table 4.6), of medicines prescribed from the NHIS-EML was significantly lower than 100% recommended by the WHO. Higher values ranging between 82-97% were reported in previous studies conducted in other parts of the country a few years earlier (Akoria and Isah 2001; FMOH/WHO 2002; Ugochukwu, Onwujekwe and Akpala, 2002). The comparison of these results with those from other developing countries found that higher values were obtained in Zimbabwe 100%, (WHO, 2004a) and Ghana 97% (Bosu and Ofori-Adjei 2000). Further investigation is suggested to elucidate on the observed decline in the use of medicines on the EML in a social health insurance setting.

The study also observed that the percentages of medicines prescribed on the NHIS-EML in all the hospitals, 71.6-78.6% are relatively higher than the corresponding percentages of medicines prescribed in generic names. This suggests that a significant proportion of prescribed branded products have their generic equivalent in the NHIS-EML. This pattern of prescription is grossly irrational as patients would likely pay higher co-payments on prescribed brand products which have generic equivalents listed in the NHIS-EML. Equity in health insurance would require an increased utilization of generic essential medicines to ensure effective use of scarce resources in providing access to all. Therefore, the low prescription of medicines on the EML strongly suggests a negative impact on equity in access to health care.

Poor availability of EML in public health facilities has been cited as one of the reasons for poor use of medicines on the EML (Chedi, Abdu-Aguye and Kwanashie 2010). However, some studies have shown that even when copies of the EML are available, some prescribers still rely on proprietary reference books and advertisements in medical journals, which are inadequate sources of information needed for appropriate prescribing (Akande and Aderibigbe, 2007; Oshikoya, Senbanjo and Sodipe, 2009; Adebayo and Hussain, 2010).

The poor use of medicines on the EML observed in this study could also be attributed to the delay in updating national EML and NHIS- Formulary. Available information suggests that some countries like Nigeria do not comply with the WHO recommendation that countries should update their national EML regularly (Akter, *et al.*, 2012).

After seven years of the usage of its 2003 fourth edition of the national EML, Nigeria published its current edition (Fifth Edition) in October, 2010. The fifth edition contains Artemisinin Combination Therapy in line with the current malaria treatment policy, and other WHO therapeutic options for treatment of emerging diseases. On the other hand, the current NHIS-Medicines Formulary and treatment guidelines which were based on the fourth edition (2003) of the national EML is yet to be updated to incorporate newer medicines listed in the fifth edition.

These could have promoted the prescription of medicines particularly antimalarials that are not listed in the NHIS-Formulary.

5.2 Availability of prescribed medicines to insured patients

The finding with regards to availability of medicines for health insurance patients are described with the following indicators: percentage of total medicines dispensed, percentage of essential medicines dispensed and the proportion of patients having all prescribed medicines dispensed.

5.2.1. Aggregate Medicines Actually Dispensed in Study Hospitals

A high percentage of prescribed medicines were actually dispensed 85% (Table 4.8) to insured patients at the study facilities' pharmacies. This result is consistent with the general belief that health insurance schemes are associated with increased percentages of prescribed medicine actually dispensed (Frenk, Gomez-Dantes and Knaul, 2009). However, the result is lower than 100% suggested by WHO and the value (87%) obtained in the surveys conducted in 1982-2006 in some Sub-Saharan Africa countries WHO (2009a).

Nevertheless, the result suggests a slight improvement on the values reported by Tetteh and Adeya (2005) in a study conducted to assess the availability and use of antimalarial medicines in some public hospitals in Nigeria. The result is an indication that there was adequate supply of various medicines in the study facilities. Other possible reasons for these improved figures could be that prescribers were better informed of the type of medicines in stock and consequently prescribed accordingly (Holloway, 2000).

5.2.2 Essential Medicines Dispensed

An important finding in this survey is that only 87% of prescribed essential medicines were dispensed to patients (Tables 4.9). Ideally, all prescribed essential medicines should be dispensed. The shortfall in the proportion of prescribed essential medicines dispensed could be an indication of inadequate stocks of essential medicines recommended in the NHIS-medicines formulary. Another possible reason that could explain the sub-optimal proportion of prescribed essential medicines dispensed is insufficient funding of the scheme. According to Onwuka, (2008) allocations from the pool of employers' contributions for health insurance falls short from the amount needed to meet the aspirations of the population. Thus if complete access to recommended essential medicines is to be achieved, additional funding may be required. It

should be noted that currently, federal civil servants who are major beneficiaries of the FS-SHIP are yet to contribute their 5% shares to the scheme (Ogundipe, 2009). One way of improving on funding is to expedite action on commencing the deduction of employees' contribution (5% of basic salaries) to the scheme.

5.2.3. Proportion of Patients Having All Prescribed Medicines Dispensed

Although the percentage of prescribed medicines dispensed to patients provides an indication that a large proportion of the products are dispensed to patients, further analysis showed that the medicines were not equitably available to all the patients as only 58% (Figure 3) of the insured patients had all their prescribed medicines completely dispensed, while the remaining 42% had at least one prescribed medicines not dispensed.

Possible reasons for this poor performance could partly be due to prescription of medicines outside the benefit coverage or non-compliance of the study facilities to refer patients to accredited pharmacies outside the study facilities.

There is a tendency that medicines not dispensed included essential medicines, and their non-availability, therefore, constituted access barrier to quality health services. This implies that the affected patients (42%) would have to bear the financial burden of purchasing such medicines on their own (Pavin, *et al.*, 2003). Studies have shown that patients' whose prescriptions are not completely dispensed, are three times more likely to purchase less than the required quantity of medicines prescribed (Saradamma, Higginbotham and Nichter, 2000). In this scenario, disproportionately affected low income earners may resort to borrowing to purchase the medicines which may further impoverish the households' income or may completely forego treatment, thereby worsening their ailments (OECD/WHO, 2003b; Pavin, *et al.*, 2003).

5.2.4 *Prescriptions Referred and Dispensed in Accredited Off-site Pharmacies:*

Evidence from Taiwan suggests that compliance with the principle of the SPD policy, which requires the release of prescriptions by providers to accredited private pharmacies, resulted in more rational prescribing and a significant decrease in expenditure on medicines (Faden, *et al.*, 2011). Similarly in the NHIS programme, the extent to which prescribed medicines are provided to insured patients is dependent on the ability to have all prescribed medicines dispensed in the accredited pharmacy unit of hospitals visited by patients or accredited off-site pharmacy when prescriptions are released to them.

The result of this study showed that none of the study facilities released their prescriptions to accredited private pharmacies when the pharmacy units could not provide all prescribed medicines to the insured patients (Figure 4). This implies that insured patients were left to source unavailable prescribed essential medicines on their own. This invariably shifted the cost of prescribed essential medicines to patients.

Considering the overall proportion of patients without essential medicines, referring them to accredited private pharmacies would have increased the number of patients having access to all prescribed EMS, improving their health outcomes and reducing the economic hardship of sourcing medicines on their own (Pavin, *et al.*, 2003).

The non-referral of these patients also exposed them to the risk of purchasing poor quality medicines from non-professional medicine dealers and denied them the opportunity to access standard dispensing practices and other pharmaceutical services offered freely by professional Pharmacists in accredited pharmacies (FMOH, 2005a). This is inconsistent with the objectives of

the scheme as ensuring compliance of providers to release prescriptions to pharmacies to dispense is an important policy directive.

5.3 Implications of Irrational Prescribing and Poor Availability of Medicines

The irrational prescription and poor availability of medicines found in this study have several implications on providers, in this case the SHIP and patients.

5.3.1 Implications for Providers

According to King and Kanavos, (2002), efficient allocation of health insurance funds is achieved with rational prescribing of available medicines. Given that health insurance systems are characterized with fix tariffs for recommended medicines and capitation of services, the use of brand medicines, overuse of antibiotics, low use of generic medicines and polypharmacy as observed in this study, likely increase providers' expenditure on medicines and may result in short falls on the capitation received (WHO, 2010). This will invariably make the scheme unprofitable and unsustainable for the health providers (Dong, *et al.*, 1999; Mills, *et al.*, 2005).

5.3.2 Implications for Patients

It is widely acknowledged that consumers place a high value on availability of medicines and it has been shown to increase patient satisfaction and confidence in the health care system (Faden, *et al.*, 2011). The findings of this study with regards to poor availability of prescribed essential medicines, the possibility of high co-payments and the burden of out-of-pocket payments for unavailable products without re-imbursement, suggest that patients may lose confidence in the scheme's potential to meet their medicines needs (Kreling, 2000; WHO, 2009a). In addition, the heavy out-of-pocket expenditure on medicines which the scheme promised to address, is still in existence as a high proportion of patients (42%) were left to access unavailable prescribed

medicines without any recourse to re-imbursing them. This observation was similarly reported by Awe and Sanusi (2009) where 80% of people sampled had no confidence in the scheme due to unnecessary payment for medicines and services already covered by capitation.

5. 3 Limitations of Study

The current study only describes irrational prescribing practices amongst the sampled hospitals; the cross-sectional design used in this study does not permit the detection of aetiological reasons for prescribing (Grimmes and Schuz, 2002).

Also, availability of medicines was measured based on medicines received by patients without giving prominence to other contextual factors that could have affected the extent to which prescribed medicines are dispensed to insured patients. In spite of these limitations, this study provides the baseline data for further research to facilitate intervention needed to promote rational prescribing and availability of essential medicines in the social health insurance system in Nigeria. In addition, as the first study on prescribing practices and availability of medicines in the National Health Insurance Scheme in Nigeria, the study has contributed to knowledge on prescribing practices and access to essential medicines in health insurance programmes in developing countries by explicitly focusing on only the prescription encounter records of insured outpatients.

5.4 Summary

The findings of this study when compared with the WHO/Derived reference values shows that the prescribing practices in the social health insurance scheme programs of the study facilities were characterized by poly-pharmacy, overuse of antibiotics, low use of generic medicines, and suboptimal use of medicines on NHIS-medicines formulary. Inadequate provision of prescribed

essential medicines was evident in all the study facilities. The policy recommendation for improving rational prescribing and availability of prescribed essential medicines will be discussed in the next chapter.

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CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.0. Introduction

This chapter draws conclusions on the findings of this study, in relation to standard measures of rational prescription and availability of medicines, and the implications for the Social Health Insurance Programme operational in public sector secondary hospitals in the Federal Capital Territory, Nigeria. This chapter concludes with recommendations for policy considerations.

6.1 Conclusion

The findings of this study show trends towards irrational prescribing practices as characterized by poly-pharmacy, over use of antibiotics, sub-optimal generic prescribing as well as poor adherence to the use of the NHIS-EML. However, the use of injections was found to be appropriate, which is laudable. This indicates that the National Health Insurance Scheme has not achieved good prescribing practices in this study population. These findings are in line with the growing body of evidence of existence of inappropriate prescribing practices in health insurance programmes that are not adequately monitored (Bruntland, 2003).

This study also provides evidence that many insured patients (42%) in the study settings did not have all their prescribed medicines dispensed. There was sub-optimal provision of essential medicines and prescriptions were not referred to accredited private pharmacies, signifying access barriers to essential medicines and pharmaceutical care. This is a pointer to inadequacy in the
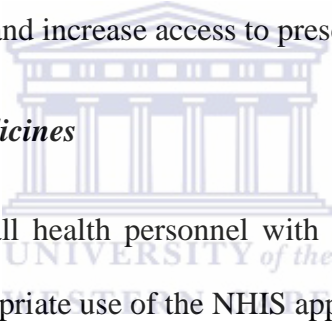
scheme's ability to ensure compliance to its operational guidelines and to actualize its objectives of equity in access to essential medicines.

The prescribing practices and the inequity in access to prescribed medicines as observed in this study constitute a threat to the scheme's goal of achieving universal access to health care in the year 2015. Pragmatic interventions should be deployed towards promoting rational prescribing as well as increasing equity in access to essential medicines.

6.2   Recommendations

In the light of the findings of this study, the following recommendations are suggested to improve the quality of prescribing and increase access to prescribed medicines in the SHIP.

1) Training on rational use of medicines

a) Providing regular training for all health personnel with an emphasis on the importance of rational use of medicines and appropriate use of the NHIS approved formulary.

b) Regular dissemination of the NHIS operational guidelines, NHIS price list and NHIS treatment protocols to all prescribers and dispensers.

2) Monitor medicines utilization patterns

a) Evaluating data reported by providers to identify medicines use problems and opportunities for interventions.

b) Regular supervision and monitoring of dispensing practices to ensure compliance with the standard specifications for provision of prescribed essential medicines to insured patients.

c) Enforcing compliance with standard specifications for dispensing by removing non-compliant providers from participation in the scheme.

3) Ensure Sustainable Availability and Access to Essential Medicines

a) Strengthening the HMOs to effectively supervise and monitor pharmaceutical procurement and management activities to ensure uninterrupted supply and availability of essential medicines at health facilities.

b) Updating the NHIS medicine formulary and treatment guidelines to harmonize with the current 5th edition (2010) of the national EML.

c) Increasing the sources of funding including the commencement of payment of beneficiaries (federal civil servants) contributions (5% of employee basic salary) to the scheme.

4) Public Awareness

Increase public awareness on the benefits of health insurance, consumers' right to essential medicines and the dangers of irrational use of medicines.

5) Areas of Further Research

a} Research is required to explore the impact of morbidity patterns on prescribing practices of prescribers attending to insured patients in the study hospitals in order to identify appropriate interventions for promoting rational prescribing.

b) Research is also required to understand additional contextual factors that could constitute access barriers to medicines in the study hospitals and to identify appropriate interventions for increasing availability and access to essential medicines.
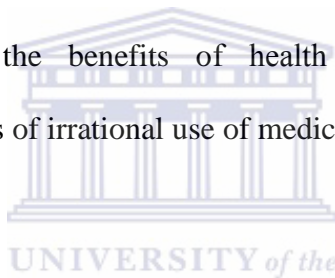
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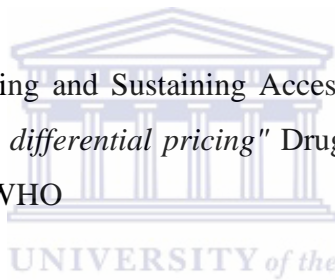
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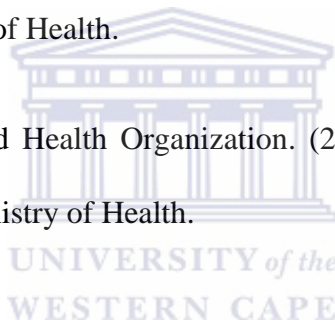
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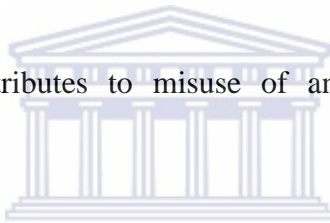
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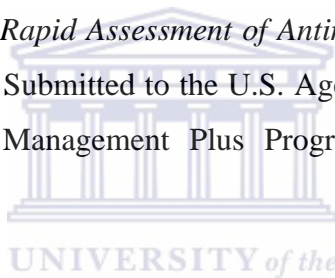
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Appendix-1

Nigeria's health and socioeconomic indicators

INDICATORS	ESTIMATE
Demographic Indicators	
Total population (2001)	155,215,573
Annual growth rate	3.2%
Urban population	50%
Socio-economic Indicators	
Gross Domestic Product (GDP) per capita	$ 2,500
Total expenditure on health as a percentage of the GDP (2000)	5.8%
Population below poverty line (CIA, 2007 est.)	70%
Gross national income per capita (PPP international $)	1,980
Total expenditure on health per capita (Intl $, 2009)	136
Total expenditure on health as % of GDP (2009)	5.8
Health Structure	
Physician density physicians/ 1,000 population (2008)	0.395
Hospital bed density/1000 population (2004 estimate)	0.53
Health Status Indicators	
Life expectancy at birth for males	53
Life expectancy at birth for females	54
Under 5 Mortality Rate (per 1,000 children)	138
People living with HIV/AIDS	3.4Million

Sources: *Nigeria demographic and health survey 2010, CIA 2009, Human Development Report 2010, Federal Ministry of Health, Report (2010) and WHO, 2009b Report.*

Appendix 2:

Programmes Categories of National Health Insurance Scheme

A1) Formal Sector Health Insurance Programme

- Federal Civil Service Social Health Insurance Programme(FS- SHIP)
- Organized private sector Social Health Insurance Programme (OPS-SHIP)
- Armed forces, police and allied services Social Health Insurance Programme
- Students of tertiary institution Social Health Insurance Programme(TI-SHIP)
- Voluntary contributors: These are interested individuals such as Retires (who wish to continue with the NHIS formal sector programme), Nigerian's in Diasporal, employees with less than ten (10) employees or self employed persons.

A2) Informal Sector Social Health Insurance Programmes

These include:

- Rural Community Social Health Insurance Programme
- Urban self employed Social Health Insurance Programme
- Vulnerable group Social Health Insurance Programme
- Children Under-Five Social Health Insurance Programme
- Prison Inmates Social Health Insurance Programme

Appendix-3:

Transfer of National Health Insurance Funds From N.H.I.S. To Providers

CONTRIBUTIONS (GOVT. PUBLIC SECTOR)

RESERVE FUNDS

(Security Fund) for

Equalization

NHIF

NHIS (ADMIN COST)

HMO

CASE PAYMENT

CAPITATION

FEEE-FOR- SERVICE

Tertiary Providers

Primary Providers

Secondary Providers

Specialist Hospitals

Pharmacies

Dentistry

Laboratories

Physiotherapies

Radiography centre
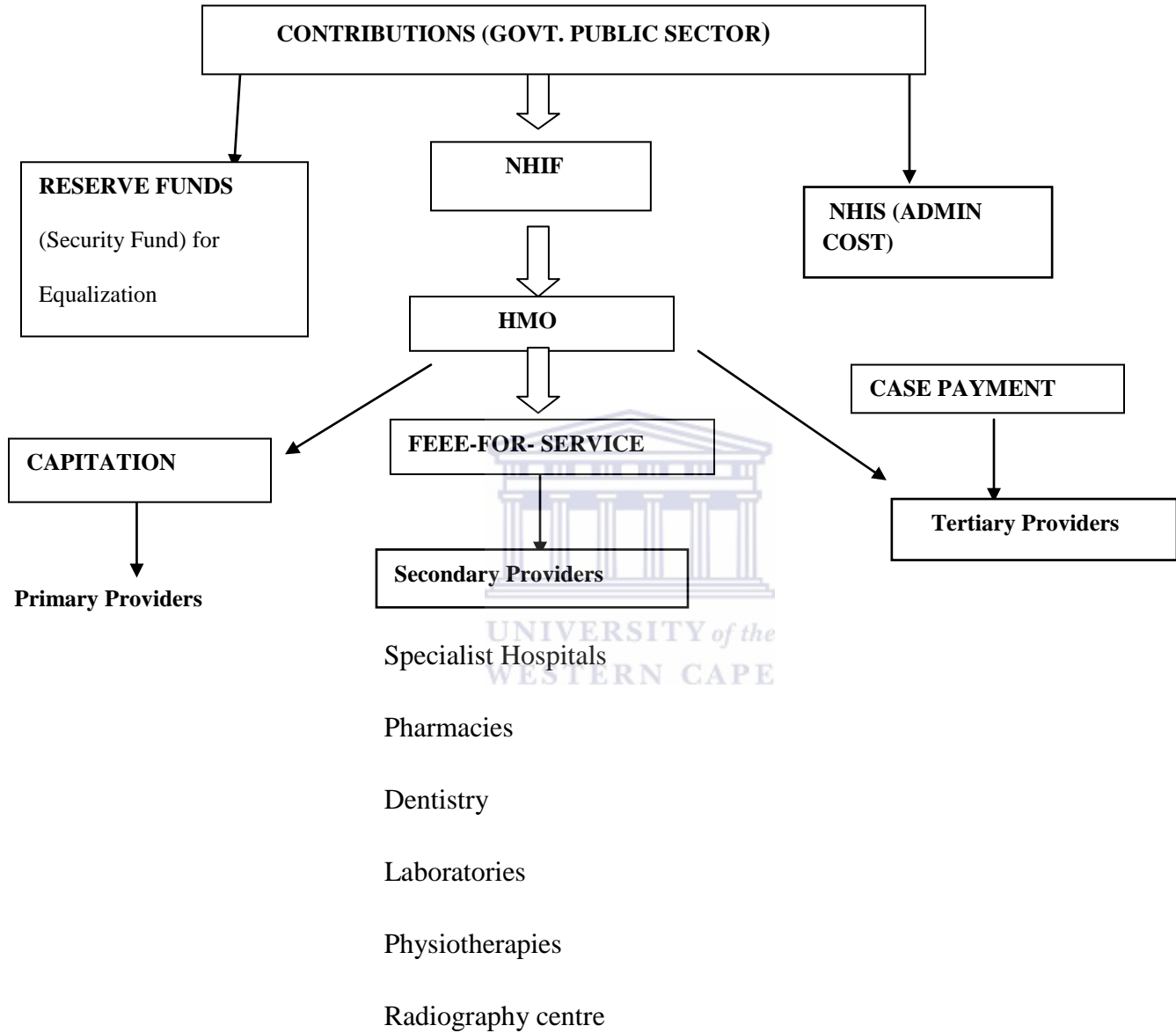
(FMOH, 2005a)

Appendix 4

Data Compilation Form 1

Facility (coded name): _____

Investigator: _____

Month of Investigation_____

Serial Nos	Date of prescription	Code for Patient's Name	NHIS Code	Names of Medicines prescribed	Route of administration	Number of medicines Dispensed	Number of medicines Referred
1				1) 2) 3)			
2							
…15							

Appendix 5

Prescribing and Dispensing Indicators Form 2

Facility (coded name)_____   Month of Investigation_____

Investigators_____

Nos.	Patient's Code	Date of prescription	No. Of medicines prescribed	No. Of generic medicines prescribed	Antibiotic prescribed Yes=1, No=0	Injection prescribed Yes=1, No=0	No. Of prescribed medicines on EML	No. Of prescribed medicines dispensed	No. Of prescribed Essential medicines dispensed	No. Of prescriptions Referred
1										
15										
TOTAL	X		A	B	C	D	E	F	G	H
AVERAGE			A/X							
PERCENTAGE				% of Total Medicines	% of Total Patients	% of Total Patients	% of Total Medicines	% of Total Medicines	% of Total Medicines	% of Total Patients
TOTAL		H								

Appendix 6

Facility Summary Form

Date: _____

Hosp.	Average of Medicines Prescribed	% with Injections	% with Antibiotic	% Generics Medicines	% of Medicines on EML	% of Total Medicines Dispensed	% of Prescribed EMs Dispensed	% of Prescriptions Completely dispensed	% of Medicines Referred
PAH									
PBH									
UAH									
UBH									
OVER ALL									
Min.									
Max.									

Appendix 7

Data Collection Guidelines

1. Medicines classified as antibiotics were medicines classified as antibiotic on NHIS Essential Medicines List.

2. Injections used for vaccination and family planning were excluded from being measured in this research.

3. Prescribed brand products which have their generic equivalent in the EML was regarded as medicines prescribed from the EML.

4. A product comprising of two or more medicines for instance multivitamins, were considered as one.

5. All suspensions or tablets prescribed concurrently with the injection components, such as a prescription containing paracetamol tablets and suspension together; were considered as a single entity and counted and recorded as one in the data compilation sheet.

6. Measurement of generic name indicator was based on the name used in the prescription and not the names of the product dispensed.

7. Abbreviated names of generic medicines commonly used by prescribers in Nigeria were counted as generic medicines during the data analysis process.

Appendix 8

Common Abbreviations used in prescribing medicines

GENERIC MEDICINE IN NHIS-EML	COMMON NAMES OR ABBREVIATION
Paracetamol	PCM, P/cmol
Multivitamin tab	M/Vt M/Vite
Vitamin B Complex	B.Co, Vit-BCO
Vitamin C or Ascorbic acid	Vit-C
Acetyl Salicylic Acid	ASA
Mist. Magnesium Trisilicate	MMT
Cough Expectorant Elixir	Cough Syrup
Tetracycline Cap	TCN
Ciprofloxacin	Cipro
Amoxycillin	Amoxyl

Appendix 9

ETHICAL APPROVAL LETTER

FEDERAL CAPITAL TERRITORY
HEALTH RESEARCH ETHICS COMMITTEE
Research Unit, Room 10, Block A Annex, HHSS
FCT Secretariat No. 1 Kapital Street Area II, Garki, Abuja - Nigeria

Name of Principal Investigator:	**Eunice Bosede Avong**
Address of Principal Investigator:	AO3, Lt. Col. Okoli Street, Nig. Army Post Housing Scheme, Kurudu, Abuja
Date of receipt of valid application:	15/12/2010

NOTICE OF APPROVAL AFTER COMMITTEE REVIEW
Protocol Approval Number: FHREC/2011/01/4/28- 02-11

TITLE: Prescribing Practices in the Social Health Insurance Programme at Secondary Hospitals in the Federal Capital Territory, Nigeria
The research described in the submitted protocol has been reviewed.
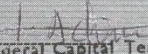
Documents Reviewed:
(1) Application form; including;
* Curriculum Vitae of the Investigators
(2) Research Protocol including;
* Brief participants Information Sheet
* Questionnaire

On the basis of the review, this application has been **approved** by the Committee (FHREC). Subsequent changes are not permitted in this research without prior approval by the FHREC.

This approval dates from 28/02/2011 to 27/02/2012. Note that no participant accrual or activity related to this research may be conducted outside of these dates. All informed consent forms used in this study must carry FHREC assigned protocol approval number and duration of FHREC approval of the study.

The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the code including ensuring that all adverse events are reported promptly. The FHREC reserves the right to conduct compliance visit to your research site without previous notification.

In multiyear research, endeavour to submit your annual report to the FHREC early in order to obtain renewal of your approval and avoid disruption of your research. At the end of the research, a copy of the final report of the research should be forwarded to FHREC for record purposes.

Federal Capital Territory
Health Research Ethics Committee
Ilaumbiela S. Adechinas
Secretary, FHREC
For: Chairperson FHREC
APPROVED
February 28, 2011 Date