MEDICATION COUNSELLING PRACTICE IN COMMUNITY PHARMACIES IN LAGOS STATE, NIGERIA

BY

AJIBOYE, WALE TIMOTHY

DEPARTMENT OF CLINICAL PHARMACY AND BIOPHARMACY,

FACULTY OF PHARMACY,

UNIVERSITY OF LAGOS,

IDI-ARABA, LAGOS,

NIGERIA

MAY, 2013

MEDICATION COUNSELLING PRACTICE IN COMMUNITY PHARMACIES IN LAGOS STATE, NIGERIA

A THESIS SUBMITTED

TO

UNIVERSITY OF LAGOS,

LAGOS, NIGERIA

IN PARTIAL FULFILMENT OF

THE REQUIREMENTS FOR THE

AWARD OF DOCTOR OF PHILOSOPHY IN

CLINICAL PHARMACY

BY

AJIBOYE, WALE TIMOTHY

MAY, 2013.

SCHOOL OF POSTGRADUATE STUDIES
UNIVERSITY OF LAGOS

CERTIFICATION

This is to certify that the Thesis:

''MEDICATION COUNSELLING PRACTICE IN COMMUNITY PHARMACIES IN LAGOS STATE, NIGERIA''

Submitted to the
School of Postgraduate Studies
University of Lagos

For the award of the degree of
DOCTOR OF PHILOSOPHY (Ph.D.)
is a record of original research carried out
By:
AJIBOYE, Wale
in the Department of Clinical Pharmacy and Biopharmacy

AUTHOR'S NAME	**SIGNATURE**	**DATE**
1ST SUPERVISOR'S NAME	**SIGNATURE**	**DATE**
2ND SUPERVISOR'S NAME	**SIGNATURE**	**DATE**
3rd SUPERVISOR'S NAME	**SIGNATURE**	**DATE**
1st INTERNAL EXAMINER	**SIGNATURE**	**DATE**
2ND INTERNAL EXAMINER	**SIGNATURE**	**DATE**
EXTERNAL EXAMINER	**SIGNATURE**	**DATE**
SPGS REPRESENTATIVE	**SIGNATURE**	**DATE**

DEDICATION

I dedicate this to God, the one who gave the grace, mercy and wisdom to start, sustain and complete this work. May His name be praised forever.

ACKNOWLEDGEMENTS

My profound gratitude goes to God, who is the initiator, preserver and fulfiller of destiny. He provided the grace, mercy and wisdom to complete this study.

I also wish to appreciate my supervisor, Professor 'Fola Tayo, who provided guidance , advice and thorough supervision of this work. His style of supervision helped me to develop research and critical thinking capability. I am eternally grateful to him for being there for me even in retirement.

I appreciate Dr. B. A. Aina for being there as my co-supervisor. Similarly, the advice and counsel of the following people in the Department of Clinical Pharmacy is highly appreciated: Dr. Bukky Oyetunde, Mrs Aderemi-Williams, Dr. Arin Joda, and Dr. E. N. Anyika. I also appreciate the support of my friends Dr. Kazeem Yusuf, Dr. Giwa, and Ngozi Nwokocha.

I acknowledge the permission to use the medical library of University of North Carolina, (USA) during my stay in the university as a visiting research scholar.

Finally, my deepest appreciation goes to my wife and children for their understanding, patience, and prayers during the period of undergoing this study. Thank you!

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMS

WHO – World Health Organization

PCN – Pharmacists Council of Nigeria

USP – United States Pharmacopeia

STD – Sexually Transmitted Disease

UK – United Kingdom

USA – United States of America

NAFDAC – National Agency for Food and Drug Administration and Control

NDP – National Drug Policy

LGA – Local Government Area

ACPN – Association of Community Pharmacists of Nigeria

LSD – Least Significant Difference

FGN – Federal Goverment of Nigeria

PSN – Pharmaceutical Society of Nigeria

OTC – Over- the- Counter

FMOH – Federal Ministry of Health

ABSTRACT

Community pharmacies are major sources of medicines in most communities in Nigeria. Clients visit community pharmacies to seek help in medication therapy from community pharmacist,who has a professional responsibility to protect the public from the dangers of self medication through provision of adequate medication counselling. It is however not known to what extent community pharmacists fulfil this roles. The aim of this study was to examine the nature, extent and adequacy of medication counselling practice in community pharmacies and the factors influencing counselling practice.

A cross sectional survey of community pharmacies using simulated clients visit (Observational study) and cross sectional survey of community pharmacists using self administered questionnaire were carried out. Documents containing policy statements, laws and regulations were also reviewed. Educational intervention involving training of pharmacists in a workshop and on-site practical demonstration was carried out.

A total of 185 community pharmacies had complete data for inclusion in the analysis, representing 89.9% response rate. Pharmacist in 65 % of the pharmacies provided counselling. None of the pharmacist asked more than two questions, Information on dosage and frequency were the most (48%) frequently mentioned medication information items and information on adherence to medication least mentioned (3.6%). Only 10% pharmacies provided adequate medication counselling. Workload in the pharmacy (number of clients seen daily), and time of the day in which the pharmacy was accessed were found to be predictors of the amount of counselling offered by pharmacy staff ($R = -0.268$ & -0.329 ; $p = 0.01$ & 0.002 respectively). Weak regulatory framework on counselling practice, inadequate knowledge of medication counselling among many (72.3%) community pharmacists and lack of medication counselling guide/aids were also identified as potential factors influencing counselling practice.

Medication counselling practice in community pharmacies in Lagos State is grossly inadequate. Workload in the pharmacy, inadequate knowledge of pharmacists and weak regulatory framework should be targeted as intervention by various pharmacy and public health stakeholders in order to improve the practice.

1.0 INTRODUCTION

1.1. BACKGROUND TO THE STUDY

Medicines are the most commonly used form of healthcare treatment. They provide relief from everyday ailments to life-saving interventions for acute illness as well as support for illnesses (Quick *et al*., 2011). However, medicines must be used appropriately to maximize their potential benefits. Appropriate use of medicines requires careful instructions tailored to a patient's level of health literacy and comprehension (Murray, 2007). Insufficient medication information carries a risk of harm to the patient. Patient who lacks adequate information about their medications are more likely to experience treatment failures due to poor adherence, medication errors, and adverse events (Murray, 2007). Gandhi *et al* (2003) conducted a prospective cohort study of 661 outpatients responding to a survey to determine the rates, severity, and preventability of adverse drug events. Of the 661 participants, 25% (162) experienced adverse drug events, of which 13 % were serious and 39 % could have been made less severe or entirely prevented. Provider-patient communication was identified as a major factor responsible for many of these adverse events. Some studies have also found non- adherence rate of 50% even in life threatening situations (Quick *et al*., 2011). Causes of these adverse events include inappropriate attitudes and poor communication skills of providers, inadequate consulting time, and lack of access to printed information in simple language, such as patient leaflets or adequate labels.

Medicines are regulated commodities and can only be obtained from both public and private licensed premises. Study in Philipines shows that over 35 % of drugs in a community were purchased from registered community pharmacies (Handon,1991).

In most developing countries like Nigeria, community pharmacies are present in many urban communities where they are often seen as a convenient first point of call on advice on symptoms and other health problems. Community pharmacies differ from other drug outlets like patent medicine stores because of the presence of community pharmacists who provide professional service such as medication counselling, drug therapy consultation, health promotion advice and referrals.

The WHO Consultative Group Report (WHO, 2007a) recognizes the key role of community pharmacists in public health and use of medicines. It emphasizes their responsibility to provide informed objective advice on medicines and their use, to promote the concept of pharmaceutical care, and actively participate in illness prevention and health promotion (WHO, 2007a).

However, despite the unique position occupied by community pharmacies in the society, and the professional responsibility bestowed on the community pharmacist, important questions about the nature, extent and adequacy of medication counselling practice by community pharmacists remained unanswered. A review of literature on medication counselling practice in Nigeria shows dearth of published work in this area. The aim of this study was therefore to examine the nature, extent and adequacy of medication counselling practice by community pharmacists and to examine factors influencing it.

1.2. STATEMENT OF PROBLEM

Community pharmacies in Nigeria are one of the most important sources of medicine and also serve as the first point of call for provision of health advice. The World Health Organization unequivocally states that nearly 80% of illness episodes in most of the developing world are self-treated with modern pharmaceuticals obtained from community pharmacies (WHO, 1997).

When medicines are purchased from pharmacies, it is important that appropriate information be provided to the patient to promote safe and appropriate use. When patients are not empowered with appropriate and adequate medication information, medication related problem is inevitable. A study in US estimated the cost of medication related problems to be $177.4 billion per year (Johnson and Bootman, 1997). The incidence and the financial implication of medication related problems is expected to be high in a country like Nigeria with the challenge of low literacy level; unguided medicine advert; high rate of self-medication; limited regulation of healthcare delivery system; shortages of health professionals and adequately trained health workers (Erhun *et al*., 2001; WHO, 1997).

Therefore, giving the unique position community pharmacies occupy in the society as the major source of supply of medicine, and the association between inadequate medication counselling and medication related problems, it is important to examine medication counselling practice of pharmacists in a developing country like Nigeria.

A review of literature on the quality of community pharmacy service in Nigeria identified deficiencies in the quality of current professional practice; lack of presence of pharmacist or other trained personnel; the provision of advice for common symptoms which was not in accordance with guidelines and the inappropriate supply

of medicine (Eniojukan and Adeniyi, 1997; Ehrun, 2002 , Erhun and Osagie, 2004; Igun,1994; Oparah and Arigbe-Osula, 2002; Oreagba *et al.,* 2007). These studies evaluated the prescribing aspect in community pharmacies, management of ailment like diarrhea and sexually transmitted diseases, and supply of medicines. None of the studies evaluated the nature, extent and adequacy of medication counselling in community pharmacies.

There is dearth of published work focusing specifically on community pharmacists' counselling practice in Nigeria. Factors affecting this practice have also not been studied. No study has also examined ways of improving medication counselling practice in community pharmacies in Nigeria. Therefore, the main goal of this doctoral research is to examine the current medication counselling practice, then to understand the factors affecting the practice, and to develop, implement and evaluate intervention model to improve medication counselling practice.

1.3 AIMS AND OBJECTIVES

1.3.1. AIM OF THE STUDY

The aim of this study was to examine the nature, extent and adequacy of medication counselling practice in community pharmacies and factors influencing it.

1.3.2. SPECIFIC OBJECTIVES OF THE STUDY

1. To investigate the nature, extent and adequacy of medication counselling practice of community pharmacists.

2. To determine factors influencing medication counselling practice.
3. To develop, implement and evaluate the effect of educational intervention on medication counselling practice.
4. To determine the readability of written medication information leaflet (Drug insert).

1.4 SIGNIFICANCE OF STUDY:

This study is significant because community pharmacies represent the first point of call on health related issues for most people. According to the World Health Organization, almost 80% of pharmaceuticals found in households in developing countries are obtained from community pharmacies (WHO, 1997). Clients who visit community pharmacies expect to benefit from the professional service of the pharmacist. Secondly, adequate medication counselling has been found to improve adherence , decrease medication error and improve the overall quality of life (Murray, 2007).

The outcome of this research will serve as evidence-based information on medication counselling practice in community pharmacy. Pharmacy associations and drug regulatory bodies will find the outcome of this study as a useful database on medication counselling practice in Nigeria. At National level, the result obtained from the review of laws and regulations guiding medication counselling will be useful as a basis for review of laws and regulations on medication counselling practice in Nigeria.

1.5. RESEARCH QUESTIONS :

The following questions were answered;

1. What is the nature, extent and adequacy of medication counselling offered by community pharmacists?

2. What is the influence of various pharmacy characteristics on medication counselling practice?

3. What is the influence of various pharmacists' characteristics on medication counselling practice?

4. What is the nature and depth of pharmacists' knowledge of medication counselling and what are the factors influencing it?

5. What is the general attitude of community pharmacists to medication counselling practice?

6. What is the extent of regulatory framework on medication counselling practice?

7. What are the factors community pharmacists perceived as barriers to medication counselling and what are their suggestions on ways to improve the practice?

8. What is the effect of educational intervention on medication counselling practice?

9. What is the readability value of medication information leaflets of drugs dispensed from community pharmacies?

1.6. SCOPE AND LIMITATION OF STUDY

- This study assessed the content of information provided in community pharmacies during patient visit encounter.

- Simulated patient visit was used to gather data on current practice. A case scenario representing one of the most frequent ways by which clients present in the pharmacies was used to study current medication counselling practice.

- Only outlets identified as community pharmacies by the Pharmacists' Council of Nigeria (PCN) were included in the study. Outlets solely designated as wholesale pharmacy or not registered by PCN were excluded.

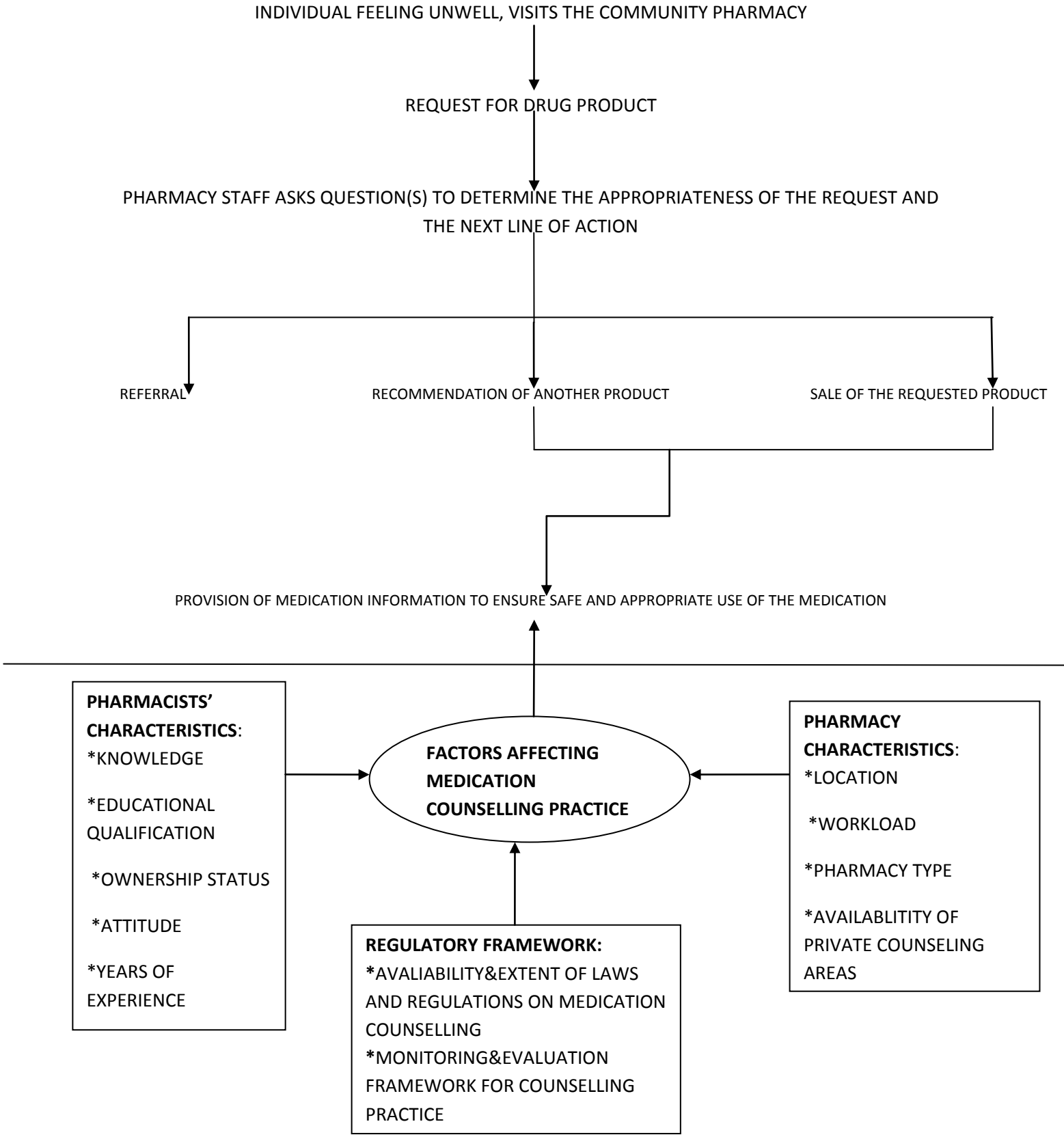
- Simulated client visit was done once due to cost involved.

- The figure for number of clients seen daily was obtained from the pharmacists, no other consistent sources of data was available to verify this.

- There was no control group for the educational intervention. A before and after study design was used.

1.7 SCHEMATIC PRESENTATION OF THE STUDY

The schematic presentation of the study is as shown in Figure 1.


INDIVIDUAL FEELING UNWELL, VISITS THE COMMUNITY PHARMACY
REQUEST FOR DRUG PRODUCT
PHARMACY STAFF ASKS QUESTION(S) TO DETERMINE THE APPROPRIATENESS OF THE REQUEST AND THE NEXT LINE OF ACTION
REFERRAL
RECOMMENDATION OF ANOTHER PRODUCT
SALE OF THE REQUESTED PRODUCT
PROVISION OF MEDICATION INFORMATION TO ENSURE SAFE AND APPROPRIATE USE OF THE MEDICATION
PHARMACISTS' CHARACTERISTICS:
*KNOWLEDGE
*EDUCATIONAL QUALIFICATION
*OWNERSHIP STATUS
*ATTITUDE
*YEARS OF EXPERIENCE
FACTORS AFFECTING MEDICATION COUNSELLING PRACTICE
PHARMACY CHARACTERISTICS:
*LOCATION
*WORKLOAD
*PHARMACY TYPE
*AVAILABLITITY OF PRIVATE COUNSELING AREAS
REGULATORY FRAMEWORK:
*AVALIABILITY&EXTENT OF LAWS AND REGULATIONS ON MEDICATION COUNSELLING
*MONITORING&EVALUATION FRAMEWORK FOR COUNSELLING PRACTICE

1.9. OPERATIONAL DEFINITION OF TERMS

Simulated Client / Pseudo-customer : Simulated client is an individual trained to present particular scenario for the purpose of evaluation of quality of service provision.

Community pharmacy: Community pharmacy is defined broadly to include all those establishments that are privately owned and whose function, in varying degrees, is to serve society's need for both drug products and pharmaceutical services.

Community pharmacist: The community pharmacist is the pharmacist responsible for pharmaceutical services in the community pharmacy.

Pharmacist: The pharmacist is the person who possesses the educational qualifications recognized by the licensing authority of a particular country, in this case the Pharmacists Council of Nigeria (PCN), and has been licensed by the PCN to practice pharmacy.

OBRA ’90: The Omnibus Budget Reconciliation Act of 1990 (OBRA '90), is a United States of America law, which mandates the pharmacist to offer to counsel patients about their prescriptions, and also specifies the components of patient counselling.

2. LITERATURE REVIEW

2.1. DEFINITIONS OF MEDICATION COUNSELLING

Researchers have tried to conceptualize the term medication counselling in their studies. One of the earliest definitions was presented by Puckett *et al*.,(1978) as ‘‘any oral and written communication(including auxiliary labels) from the practitioner relating to the drug product and its use’’. Kirking (1982) defined medication counselling as the ‘‘provision of verbal information that will help patients to use their medications properly’’. Holland (1992) defined counselling as ‘‘the process of giving professional advice about medicines and other health matters’’. According to Schommer and Wiederholt (1994), ‘‘medication counselling is the provision of advice that is the reasoned opinion of a pharmacist, is subjective, and is patient-oriented within a medication-taking context’’. Aslanpour and Smith (1997) defined counselling for

their study purposes as ‘‘the provision of information on medications and health related issues’’. The term has also been conceptualized as ‘‘the means by which one person helps another to clarify their life situation and to decide upon further line of actions’’, and its aim is to give the client an opportunity to explore , discover, and clarify ways of living more resourcefully and towards greater well-being’’. According to this definition, counselling seeks to enable or empower the patient to decide on a particular course of action and see it through (Blenkinsopp *et al*., 1999). The key point is that the counselor is helping the patient to make their own decision, even if that decision varies from that which the counselor thinks should have been made (Blenkisopp *et al*., 1999).

Advice-giving has been referred to as the transfer of information and advice about recommended actions from the pharmacist to an individual patient or customer. Ideally advice-giving should be a two-way interactive process, where the person is invited to respond and to seek further information should they need it (Blenkisopp *et al.,* 1999).

Some researchers have even questioned if the term counselling can be used to describe the information exchanged between pharmacists and customers in the context of community pharmacy (Raynor, 1996; Pilnick, 2003). According to these researchers, what pharmacists mean by counselling is the imparting of information as part of a one way process. In practice, counselling usually involves repeating verbally the information on the medicine label and giving instructions for complying with drug therapy regimens (Vainio, 2004). Therefore, one of these researchers suggests that the term concerning advice and explanation about medicines should be called medicines consultation (Raynor, 1996).

In a recent review by Shah and Chewing (2006), 'Counselling and Communication' are the two most commonly used terminologies in the studies conducted for evaluating the pharmacist-patient interaction. Within the studies reviewed by Shah and Chewing (2006), some researchers have defined pharmacist-patient communication as an information-related activity, while others focused on certain aspects of pharmacists' interpersonal behavior in addition to the information-provision activity.

One of the most comprehensive definitions was constructed by United States Pharmacopeia (USP, 2004). USP is an independent, science-based, non-profit public health organization which develops and disseminates quality standards and information about medicines. According to USP, medication counselling is an approach that focuses on enhancing an individual's problem solving skills for the purpose of improving or maintaining their quality of health and quality of life. The process emphasizes that the health professional provides and discusses medication information with the appropriate person to achieve this goal. The physical, psychological, social –cultural, emotional, and intellectual perspective as well as the health beliefs and values of the individual must be respected. The health care professional's responsibility is to support the person's efforts to develop medication management skills and to move in the direction of self-responsibility with empathy, sincerity and patience. The nature of the relationship between the patient and health care providers is interactive and constitutes a collaborative learning process for both parties.

2.1.1 MEDICATION COUNSELLING STAGES ACCORDING TO THE UNITED STATE PHARMACOPEIA

Medication counselling is viewed as a continuum of interaction between the healthcare professional and the patient. Table 1 shows key definitions related to medication counselling behavior and is designed to assist the healthcare professional in determining the stage of medication counselling. These are stages in the continuum, starting from limited interaction to involved interaction. Major emphasis has been placed on empowerment of the patient in these interactions. The interactions are considered to be generic and unrelated to the professional orientation of the information/counselling provider.

TABLE 1:MEDICATION COUNSELLING STAGES (USP MEDICATION COUNSELLING BEHAVIOUR GUIDELINE)

	Medication Information Transfer	**Medication Information Exchange**	**Medication Education**	**Medication counselling**
Level of information	Basic,brief,non-individualised	Detailed, Individualised	Comprehensive, Group or individualised	Detailed discussion and guidance
Spontaneous or planned	Most often spontaneous in response to the medication prescription	Spontaneous or planned	Planned	Planned
Objective of process	Essential information related to taking prescribed medication as directed (monolog)	Provider responds to and asks questions related to prescribed medication. (Dialog)	Collaborative learning experience and process regarding prescribed	Guidance that assists in fulfilling needs in managing medical condition and prescribed

			medication. (Conversation)	medication. (Discussion)
Product to patient	Focus is on safe and proper use of drug product	Answers and solicits questions about the drug product.Adapt information to the individual.Increases knowledge regarding proper and safe use of medication for specific condition.	Increases knowledge regarding proper and safe use of medication for specific condition	Enhances problem solving skills and assists with proper management of medical condition and effective use of medication.
Nature of relationship	Passive individual receives instruction given by the health care provider.	Questions and answers are actively exchanged between patient and provider.	Interactive learning about the implication of the medication is shared between patient and provider.	Interactive and collaborative discussion and learning between patient and provider.

2.2. BENEFITS OF MEDICATION COUNSELLING

Studies have demonstrated the effectiveness of pharmacists' provision of information. For example, a study in Memphis, Tenessee, found adherence rates of 84.7% for patients receiving a high level of information about an antibiotic drug, compared with 63% for patients receiving less information (Kessler, 1992).

Medication counselling has been shown to reduce drug related morbidity and its subsequent costs to the individual and society. It is well known that medication use problems may result not only in increased risks for the patient, but also in extra time and expense. In a California study, the cost of hospitalization of elderly patients suffering from adverse drug reactions was found to be $340.1 million (DeYoung, 1996). The cost of nonadherence to drug therapy has been estimated as 20 million lost

work days and $1.5 billion in lost earnings annually, as well as $8.5 billion in unnecessary hospital expenditures in 1986-approximately 1.7% of all health care expenditure that year.(Jackson and Hoffman, 1990; Sullivan *et al*., 1990). Overall, the annual cost of drug-related morbidity and mortality in the United States was estimated in 1997 by Johnson and Bootman to be $177.4 billion in direct health care costs (Johnson and Bootman, 1997). With costs in health care escalating each year, for individual and for health plan sponsors in government and private sector it is important that pharmacist become involved in medication counselling.

Patients find communication, interpersonal sensitivity and partnership with their health care providers to improve satisfaction; they are consequently more likely to adhere to medical advice and to recall medical information provided (Hall *et al.,* 1988; Rooter *et al.,* 1998).

Medication counselling can further assist patients with self-care. Although many conditions are self-treatable, patients often need the attention of a pharmacist. Nonprescription-drug misuse has been reported with rates varying from 15% to 66% of study groups (Flynn and Baker,2000; Leape, 2000). Self-treatment, when appropriate, can reduce the need for and costs of more formal care. As with prescription counselling, pharmacists counselling for non-prescription medications can benefit both medically and financially.

2.3. METHODS AND INSTRUMENTS USED IN EVALUATION OF MEDICATION COUNSELLING PRACTICE.

2.3.1.Methodology

Various methodologies such as telephone interview, mail survey, questionnaires, nonparticipant observer, simulated client and audio analysis have been used in the studies of pharmacist-patient interaction (DeYoung, 1996; Shah and Chewing.,2006). The pseudo-customer/simulated client method is one of the most widely used in measuring pharmacist-patient communication (Morison *et al.*, 1997).

2.3.1.1. Pseudo Customer Method

One method that can be used to assess counselling performance is the pseudo-customer method (Smith, 2002). This observational method has been proven to be a more reliable survey with respect to the accuracy and consistency of counselling activities compared

with self-completion questionnaires and diaries (Ortiz *et al*., 1998). Commonly referred to as pseudo-customers/patrons/simulated patients/standardized patients/covert participants/ mystery shoppers (Berger 2005), their use originally gained popularity in the business/marketing sector, with clients ranging from small businesses to industry leader such as McDonald's, Disney, and the Hard Rock Café (Finn and Kayande, 1999). The technique has also been adapted to assess quality of practice in the health sector (Beullens *et al.,* 1997) and for at least more than 5 decades, practice behavior in pharmacy (Wertheimer *et al.,* 1973).

In health care, the term pseudo customer or pseudo patient is commonly used overtly (i.e, the simulated patient assumes the role of a patient and the person who is being assessed is aware that this is not a genuine patient) or, covertly (i.e where the person being audited are unaware of the simulated patient's identity or purpose). The basic rationale for using covert simulated patients is that a testee's performance alters when the existence of the test is known (Watson *et al*., 2004).

A pseudo-customer is an individual trained to present particular scenario: staff whose work is being audited are unaware of the simulated patient's identity. The visit may take place at anytime within a given time frame. The pseudo-customer is trained to follow a standard script. (Puumalainen *et al*., 2008).

The first pseudo customer studies in the context of community pharmacy took place at the end of 1960s and at the beginning of the 1970s in the United States (Knapp *et al.,* 1969, Wertheimer *et al.,* 1973). The pseudo customer studies continued in the United states and in other countries to assess the quality and content of counselling practices in the community pharmacies (Rowles *et al*., 1974,Vanderveen *et al*., 1978, Vanderveen *et al.,* 1990, Goodburn *et al.,* 1991, Krska *et al.,* 1994, Willison and Muzzin 1995,

Lamsam and Kropff 1998, Lyszkiewich *et al.*, 2001,Watson *et al,*. 2002,Schatz *et al.,* 2003,Svarstad *et al.,* 2004). In Nigeria studies reporting the use of pseudo-customer method to evaluate the quality of pharmacy service in community pharmacies is scarce (Smith, 2009). A greater percentage of studies in Nigeria utilized self completed questionnaire to assess the quality of knowledge and advice provision by community pharmacists.

Pseudo-customer method has evolved since its introduction in the field of pharmacy practice research when it was mostly used to assess individual pharmacists' performances. Recent studies have used the pseudo customer as a tool to provide immediate feedback to community pharmacists during educational interventions and as a tool to change practice behavior (De Lmeida Neto *et al*., 2001, Berger *et al*., 2005).

Data collected by mystery shoppers can be reported in the form of rating scales, checklist, and open-ended responses (Finn and Kayande, 1999).The results are then used to compare the performance of particular outlets and their employees, to monitor outlet performance over time, and to identify areas where outlets are in most need of improvement. Mystery shoppers are increasingly being used to benchmark the performance of important competitors or even of outlets in other industry sectors which might provide a performance standard (Finn and Kayande, 1999).

Pseudo-customers seem to provide reasonably reliable ratings of the performance of retail outlets (Finn and Kayande, 1999). The reliability of mystery shopping data is much higher than that of customer surveys, when the data are used for the same problem of scaling outlets. There is presumably an advantage in pseudo-customer knowing they are going to be evaluating an outlet, whereas customers typically only find out after the fact when they are presented with the survey request. There may also

be further advantage in having individuals who have been trained to be observant providing the assessment (Finn and Kayande, 1999). Especially in the community pharmacy setting, a customer does not have enough knowledge to assess the professional content of advice given. A normal customer might consider friendly service as sufficient whereas pseudo-customers can assess the actual content of counselling. Krska *et al.*,(1994) concluded that determining the patient's experience of the services does not provide a time reflection of the advisory service of the pharmacist and simulations may be more accurate.

Covert pseudo-customers have face validity when the target health professional does not know or suspect that they are being confronted by a simulated patient. In a study by Watson *et al.,* (2004) only 1% of the pseudo-customer visits were detected and reported by pharmacy staff. The risk of detection is theoretically greater in pharmacies in rural area where ''new faces'' are easily spotted.

The use of objective measurement and the careful selection and training of the shoppers can increase the reliability of the method (Wilson,2001).Validity of the research findings can be improved by audio-taping the simulated patient visits. Then the tapes can be compared with the filled data collection forms (Luck and Peabody, 2002; Werner and Benrimoj, 2008).

2.3.2 Instruments to Measure Appropriateness of Medication Counselling Practice.

The literature on medication counselling specific instruments has identified issues on method of development of the instruments, validation/reliability, theoretical models and dimensions.

The evaluation of medication counselling performances requires agreement regarding the features against which performances should be assessed. ‘‘Expert panels’’ or consensus methods such as the Delphi method or the nominal group technique have been used for this purpose (Jones and Hunter, 1995; Cantrill *et al.*, 1996; Ward *et al.*, 2000). These techniques have been applied to establish criteria to assess patient counselling in the pharmacy (Ward *et al*., 2000).

The criteria developed by Ward *et al.*,(2000) combined consensus technique with the viewpoint of practicing community pharmacists. The criteria were developed by an expert panel using the nominal group technique. To ensure feasibility of the criteria, it was sent to six practicing community pharmacists. As a result, the 10 criteria developed by the nominal group were reduced to eight criteria. However, in reliability testing, predefined levels were met excluding three criteria. These criteria were rational content of advice, rational product choice and referral to another health professional. The instrument demonstrated greater reliability in assessing the process of patient counselling than the appropriateness of advice or action to be taken.

Table 2 shows a selection of medication counselling specific instruments.

Table 2. Selected Medication Counselling Specific Instruments:

Measure	Theoretical Model	Development Model	Validity/Reliability testing	Items/dimensions
1.The Purdue Pharmacist Directive Guidance (PPDG)	Inventory of socially Supportive Behaviours.	Phone Interview	Validity Testing:factor analysis. Reliability testing: Cronbach alpha	Two dimensions:Instructions(6 items) and feedback and Goal setting(4 items)
2. Criteria for assessing the appropriateness of patient counselling in community pharmacies (Ward *et al*., 2000).		Consensus method using expert panel(Nominal Group Technique)	Face,Content and consensual validity: user (community pharmacists) review . Reliability: Survey among community pharmacists.	8 items:content of advice and communication skills.
3. United States Pharmacopiea (USP) Medication Counselling Behaviour Guidelines. (USP 2004).	Definition of patient counselling :an approach that focus on enhancing individual problem-solving	USP consumer interests Health Education panel(Member representing consumers, hospital, schools of pharmacy and medicine	Validity and reliability testing: consensus method	35 items,4 dimensions 1.Introduction 2.Content 3.Process followed 4.Conclusion

	skills for the purpose of improving or maintaining quality of health and quality of life.	and drug industry)gathered existing instruments from health care institutions, pharmacy schools, and practice settings, Guidelines developed from the existing instruments.		

Source : Puumaleinen *et al.*, (2008)

2.4 QUALITY OF MEDICATION COUNSELLING PRACTICE

The quality of the content of medication counselling and communication skills used during counselling has been studied. Earlier work in the area of medication counselling focused on the rate of pharmacist-patient interaction (Krska *et al.*,1995; Laurier *et al.*,1989). Later on, research activities moved on to describe the content of pharmacist-patient interactions (Barnett *et al.*, 2000, Evans and John, 1995). While content information is critical to understanding patient counselling, an equally important aspect is the nature, or style, of the communication process. This encompasses such areas as how approachable pharmacists appear, whether non-verbal behavior is congruent with what is being said, and the overlying tone of the encounter.

Recently, more research however have focused on the aspect of appropriateness of the content of medication counselling in community pharmacies (Shah and Chewing, 2006). A study in Canada examined the content and organization of patient counselling

by community pharmacists. The study observed that pharmacists provided fairly comprehensive medication instructions to the patient actors during the study, usually beginning with name and indication of the product followed by dosing instructions and a discussion of side effects. Patients were provided with opportunity to ask questions, but generally did not have their understanding of the information explicitly verified by the pharmacist. The pharmacists tended to assume the role of expert, controlling the flow and duration of each encounter (Deschamps *et al.,* 2003). Neoh *et al* (2010) studied the nature and adequacy of information on dispensed medications delivered to patients in community pharmacies in Malaysia and concluded that most pharmacies surveyed did not provide adequate information to patients on medication use during the dispensing process.

The quality of service offered by community pharmacies have also been examined in Nigeria. Table 3.0 contains relevant studies with brief information on the specific objectives of the study, methodology and an assessment of the quality of the service.

TABLE 3.0 SUMMARY OF SELECTED PUBLISHED WORK ON MEDICATION COUNSELLING PRACTICE IN NIGERIA

S/N	**AUTHOR**	**LOCATION**	**AIMS/OBJECTIVES**	**METHODS**	**CONCLUSION**
1	Oparah and Arigbe-Osula. 2002	Benin-City	Evaluation of community pharmacists involvement in primary health care: preventive and curative services	Self-completion questionnaire,110 pharmacists	Limited involvement, especially in preventive services, infectious disease most common reason for intervention.
2.	Oparah *et al*., 2002	Benin-City	Activities of community pharmacy counter staff: Knowledge and gap	Self-completion questionnaire,201 non-pharmacist staff in 90 pharmacies	Counter staff assume roles beyond their levels of education. Poor personal control by pharmacists.
3.	Oladipo and Lamikanra. 2002	5 states in southwest.	Patterns of antibiotic purchases in community pharmacies.	Questionnaires to client(3536) in 800 pharmacies.	Study found widespread irrational sales from pharmacies.
4.	Erhun	Lagos,Osun and Oyo States	Management of STD in retail drug outlets: knowledge and	Structured self completion	Variable levels of knowledge and standards

	2002		practices	questionnaires with staff members in 180 pharmacies and patent medicine stores.	of practice reported by respondents. Author concluded that quality of care should be improved upon.
5.	Erhun and Osagie, 2004	Lagos	Prescribing and selling practices of retailers with emphasis on quality of malaria case management in drug outlets.	Self and researcher administered questionnaire to 230 medicine outlets.	Involvement of non-health professional in supply of medicine. Misconception about malaria, diagnosis and management.
6.	Igun 1994	Borno State	Reported and actual prescription for ORT for childhood diarrhea in community pharmacies and patent medicine shops.	Questionnaire survey.135 pharmacies and patent medicine shops.	A high discrepancy was reported between what respondents said they would prescribe and their actions.

2.5 FACTORS AFFECTING MEDICATION COUNSELLING PRACTICE

Studies have shown relationship between selected variables and medication counselling practice (Mason and Svarstad, 1984; Goel *et al.*, 1996 (b); Svarstad *et al.*, 2004; Tully *et al.*, 2010).

Figure 2.0 is a schematic representation of the variables that have been studied:

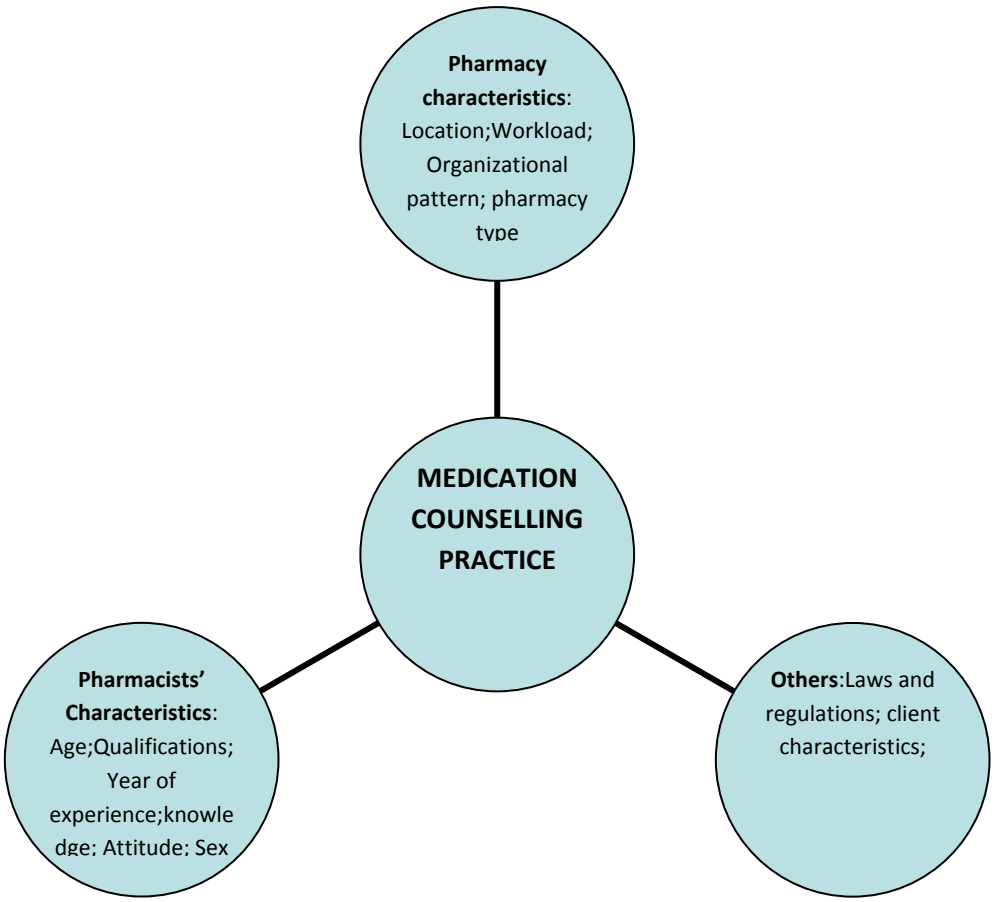


Figure 2.0 showing schematic presentation of factors affecting medication counselling practice

2.5.1 Pharmacy Characteristics and Medication Counselling Practice.

Location of pharmacy, workload, pharmacy staffing and organization pattern of community pharmacies are some of the pharmacy characteristics that have been studied. (Goel *et al.*, 1996 (a); Svarstad *et al.*, 2004; Tully *et al.*, 2010). Goel *et al* (1996a) found that location of pharmacy in a rural area or in a low-income urban neighborhood was associated with suboptimal quality of service.

Some studies also cited the importance of time available for counselling as one of the predictors of counselling activities in community pharmacies (Schommer *et al*.,1994, Svarstard *et al.,* 2004, Tully *et al.,* 2010). Workload in a pharmacy may vary as a result of geographical location and time of the day. For example, pharmacies located in urban central business districts may have greater workloads than those in rural areas. Urban pharmacies may have monthly (for example, after pay days), weekly (for example, on Fridays) or even daily (for example early afternoons) peak periods. In busier pharmacies during these periods of higher workload, pharmacy staff may have less time for adequately communicating with their clients, as do physicians under similar circumstances (Lipton *et al*., 1988, Goel *et al*., 1996a).

Availability and role of professional staff have been studied in Nigeria and Kenya (Oparah *et al*., 2002, Goel *et al.,* 1996a). According to WHO (1994), there is a dearth of professional staff in many developing countries, culminating in a pharmacist-population ratio of 1: 100,000.

2.5.2 Pharmacist Characteristics and Medication Counselling Practice.

Svarstad *et al.,* (2004) reported association between frequency of counselling and pharmacists' age. A correlation was also found between age and experience of pharmacist, and medication counselling practice in a study that assessed barriers to medication counselling in obese patients (O'Donell *et al.,* 2006).

In a survey of 361 retailers in Nepal, those who had completed more than ten grades and received additional training locally had more knowledge of contraindications of oral contraceptive use than those who did not (Shrestha *et al.*, 1990). In another study in Kenya, no relationship between clinical knowledge and quality of practice was detected (Goel *et al.*, 1996a). Igun (1994) reported discrepancies between what respondents said they would prescribe and their actions in a study to evaluate prescription for ORT for childhood diarrhea in community pharmacies and patent medicine shops. In India, pharmacists' inadequate knowledge and confidence were identified as some of the major barriers to medication counselling practice (Adepu and Nagari, 2009).

There is a significant relationship between the attitudes toward counselling held by community pharmacy practitioners and their actual counselling behaviors (O'Donnell *et al.*, 2006, Mason and Svarstad, 1984).

2.5.2.1: Knowledge of pharmacist and medication counselling practice.

Studies that evaluated adequacy of pharmacists' knowledge of the content of medication counselling are scarce. However in Nigeria, the knowledge of practitioners on management of conditions like malaria, STD, and diarrhea as a proxy for assessing the appropriateness of pharmacy service by community pharmacy practitioners have been evaluated (Erhun ,2002; Igun,1994).

Pharmacists need to have appropriate knowledge and skills required to provide effective and accurate patient education and counselling. They should know about their patient's culture, especially health and illness beliefs, attitudes, and practices. They should respect patient's feelings toward the health systems and roles and responsibilities for decision-making and for managing their care (Herrier and Boyce,1995). Regardless of the means, all community

pharmacists should become familiar with evidence-based knowledge of self-care medications and seize all opportunities to counsel patients regarding the selection and use of OTC products (Melissa, 2010).

Results on adequacy of pharmacists' knowledge are mixed. Evaluation of community pharmacy guideline in UK shows that pharmacists probably already have the knowledge covered by the guidelines and that failure always to apply the rigid requirements of the OTC guideline may be due to other factors (Roger *et al.,* 2004).

A study conducted by Ross-Degnan *et al.,* (1996) in two countries (Kenya & Indonesia) on diarrhea treatment in community pharmacies concluded that ''Baseline awareness of ORS and its function was high in both countries, although focus groups revealed that the staff felt that ORS was not as ''powerful'' as antidiarreal agents. Knowledge about other products, about non-pharmacologic treatments, and about the danger signs which would indicate the need for medical treatment was limited.

One of the important barriers of counselling are provider based, i.e the pharmacist. Lack of knowledge, lack of time, lack of training, lack of interest, lack of remuneration are the most important reasons expressed by pharmacist in some international studies (Rantucci, 1991). Pharmacists have also identified inadequate knowledge and confidence as one of the major barriers for offering patient counselling (Adepu and Nagavi, 2009). Studies have also linked inadequate medication knowledge to poor counselling practice. One study reported that deficiencies in the knowledge of Vitamin K-warfarin interactions could result in inappropriate patient counselling, disruptions in warfarin anticoagulant outcomes that may result in bleeds or clots and adverse medical consequences (Couris *et al*., 2000). Chalker *et al* (2000) reported a gap in drug sellers knowledge of management of STD.

In Nigeria, Erhun (2002) reported variable levels of knowledge and standard of practice in a study to assess management of STD in retail drug outlet. Another study also revealed that drug retailers have a fair knowledge of how to diagnose malaria. This study however, identified therapeutic challenges which may be overcome by suitable educational intervention to improve the knowledge and treatment practices of medicine retailers in Nigeria (Erhun and Osagie, 2004).

Assesing practitioner knowledge base has also been used as a basis of designing or developing educational intervention for improving medication counselling behavior (Ross-Degnan *et al.*, 1996, Saini *et al.*, 2006).

2.5.2.2: Attitude of Pharmacists towards Medication Counselling

Pharmacists' attitudes, as they relate to medication counselling behavior, generally have been neglected as a research focus. Attitude may have a contributory influence, or even a greater effect on pharmacist behavior than the variables identified in past studies. Using the counselling role orientation scale to measure attitude and then relating it with observed behavior, Mason *et al* (1984) demonstrate a link between pharmacists' attitudes towards medication counselling and their behaviors on all five counselling dimensions.

2.5.3: Client Characteristics and medication counselling practice

Pharmacists have reported recognition of their role to counsel patient. However, the amount and content of counselling offered to the patient is primarily determined by patient's desire and acceptance of it (Schommer *et al.*,1994). Studies focusing on patients' knowledge and

expectations of counselling services provide evidence that low patient demand for counselling from pharmacists is problematic (Wiederholt *et al*., 1992, Schommer 1994). Spencer (1974) reported that low patient expectations of pharmacist counselling services may be a reason for the lack of communication between pharmacists and patients. A study in Finland examined the myths concerning patient counselling for non-prescription medicines. The study concluded that the 'myth' that customers do not want counselling is false (Katajavuori *et al.*, 2002).

Client's social economic status and gender could also affect medication counselling (Goel *et al.*, 1996b). Local cultural norms may also influence the pharmacy staff behavior. For instance, studies from Egypt and Paraguay suggest that a male pharmacy staff person may not be able to advice effectively on gynecological problems and family planning (Sukkary, 1983).

2.5.4: Laws and Regulations on Medication Counselling.

Studies that examined the impact of regulatory framework on medication counselling practice are scarce (Smith, 2009; Goel *et al*., 1996b). It seems this area is strikingly neglected by

researchers. Few of the studies identified examined the impact of availability and enforcement of regulations and laws on medication counselling practice.

A study in United States of America examined the effect of State's counselling regulation on medication counselling practice in community pharmacies. Using three criteria (Whether or not the regulation covered all patients; Whether the regulation was relatively strict or lenient in its requirement; Whether the regulation was relatively mature or long in duration) to categorise regulatory intensity, the study revealed extraordinary variation in counselling practices under low, moderate, and high- intensity regulation. More intensive regulations increased the likelihood of pharmacist involvement in counselling, provision of risk information, assessment of shopper understanding and amount of oral information given (Svarstad *et al.*, 2004).

Erhun *et al.*,(2001) examined the impact of regulations and laws on counterfeit products in Nigeria. He observed that even though there is availability of regulation and laws, enforcement is weak.

2.6: INTERVENTION STRATEGIES TO IMPROVE MEDICATION COUNSELLING IN COMMUNITY PHARMACIES

Various strategies have been developed and tested to improve services rendered by community pharmacies. Three types of intervention strategies to improve drug use can be

distinguished: Regulatory, Managerial and Educational (Quick *et al*., 1991, Quick et al., 2011, Smith, 2009, Ross-Degnan *et al.*, 1996, DeYoung 1996).

2.6.1: Regulatory Strategies

Laws and regulations provide a framework for pharmacists to practice their profession. If patient counselling is mandated by law, it creates norms and standards for counselling practices (Puumaleinen *et al*., 2008).

In the United States, OBRA ’90 requires all pharmacists to provide counselling for Medicaid patients and all State Medicaid Agencies(SMAs) to develop and implement drug use review (DUR) programs. It also stipulates that an ‘‘offer to counsel’’ must be made, and most States require this to be done by a pharmacist, although some states allow a designate or do not address the question (Pugh,1995). According to OBRA ’90, counselling should include the name and description of medication, duration of therapy, common severe adverse effects, proper storage and refill information.

For developing countries like Nigeria, the WHO recommends the concepts of National Drug Policy (NDP) as a framework to coordinate activities of pharmaceutical sector (Quick *et al*., 2011). A National Drug Policy (NDP) is a guide for action. It specifies goals set by the government for the pharmaceutical sector, their relative importance, and the main strategies for attaining them. The main components of a National Drug Policy are legislation and regulation. The formation of a drug policy should be followed by the enactment of appropriate legislation and introduction of regulations to provide a legal basis for the policy and make it enforceable. Several legislative models and structures have been devised for the regulation of drugs. Often, laws and regulation are not enforced, and the penalties and sanctions the laws provide are not used (Quick *et al.*, 2011).

Study assessing the impact of regulatory intervention on medication counselling practice is limited. In the United States, the impact of OBRA '90 has been studied before and after the law took effect (Pugh 1995, Barnes *et al*., 1996, Lyons *et al.*, 1996, Erickson *et al*., 1998, Schatz *et al*., 2003). In general, results of these studies indicate that pharmacists are spending more time counselling patients after the law was enacted, but fall short of complete compliance (Rumore *et al*., 1995, Erickson *et al*., 1998, Schatz *et al*., 2003).

A review done by Smith (2009) on interventions to enhance role of private local pharmacies in low- and middle- income countries in public health, identified three studies that evaluated policy or regulatory interventions on a range of indicators of quality of pharmacy services and /or management of symptoms. These studies carried out in Vietnam, Thailand and Lao PDR were more wide-ranging in terms of the complexity of the intervention and /or their goals to promote more comprehensive improvement in practices in private pharmacies (Stenson *et al*., 2001, Chuc *et al*., 2002, Chalker *et al.*, 2005). The study in Lao PDR compared the effects of two levels of intervention for the implementation of regulation (Stenson *et al.*, 2001). Pharmacies in 14 districts were randomly assigned by district to active or regular groups. The intervention for the active group involved four visits comparing high-quality inspections, enforcement of regulations including the application of sanctions, ensuring a supply of up-to-date regulatory documents in each pharmacy, and using the inspection to provide information to drug sellers about any need for improvement. For pharmacies in the regular group, the intervention comprised similar components but a lower intensity, involving two visits. Outcome measures relating to the quality of services were based on the concepts of good pharmacy practice as defined by the International Pharmaceutical Federation (FIP 1998), and comprising storage of drugs, availability of essential drugs, materials and hygiene, dispensing and labeling practices and information provided to customers. Service quality on most indicators improved in both groups after the

intervention. Although there was a trend for greater improvement in the 'active' group, for most indicators the difference between the groups did not reach statistical significance. The authors concluded that there is a strong argument for governments in low-income countries to expand regulatory efforts to improve pharmacy services.

2.6.2: Managerial Strategies.

Intervention programs designed by decision makers at institutional level and professional organizations aimed at promoting rational drug use are classified as managerial strategies (Quick *et al*., 2011).

Intervention study on use of managerial strategies to promote medication counselling in community pharmacy is lacking (Smith, 2009).

In promoting rational prescribing and dispensing, few of the managerial strategies that have been tested include; Structured Order Forms, Standard Diagnostic and Treatment Guideline, Essential drug list, Course-of-therapy packaging, Kit system distribution and Effective package labeling (Grand *et al.*, 1999).

Professional organization can create national strategies to define and promote the role of a community pharmacist in health care. For example in Finland, the pharmacy organizations have been proactive in implementing the requirements of the law into practice by developing a professional strategy for community pharmacies (The Association of Finnish Pharmacies 1997). In Australia, the pharmacy profession has negotiated agreements with the government to incorporate new, remunerated professional services into community pharmacies (Robert *et al*., 2003).

2.6.3: Educational Intervention

The most commonly studied intervention strategy for improving services rendered in community pharmacy is educational method (Quick *et al.*, 1991; Grand *et al.*, 1999; Smith, 2009). Educational intervention differ in types, materials used and approaches (Quick .,*et al* 1991, Quick *et al*., 2011).

The two types of educational intervention identified in the literature are basic education and continuing professional development (Quick *et al.,* 1991). Basic education provides a foundation to promote new professional practices and behavior for pharmacy students. The content of basic education should reflect the changes in the pharmacist's professional role and take into account the new role of the patient (Newton, 1991). Continuing professional development is one way to promote the new counselling role to practicing pharmacists. In a changing, increasingly complex profession, with rapid medical and technological advances, the need for continuing professional development is evident (Rouse, 2004). Several courses have been designed to improve pharmacists' counselling skills (Lee *et al*.,1998; Kansanaho *et al*., 2003). A strong direct correlation between the number of voluntary continuing professional education undertaken and the frequency of counselling has been indicated (Holland, 1992). Continuing education is also one of the factors influencing the provision of pharmaceutical care (Odedina *et al.*, 1995).

To improve counselling practice, pharmacist's training should be systematic, taking into account the needs of the individual pharmacist and the assistants (Puumaleinen *et al*., 2008).

Various educational materials have been used to improve services. The most commonly used educational materials include standard guidelines, flow charts, newsletters, bulletins, posters and printed leaflets (Ajayi *et al.,* 2008; Okeke and Uzochukwu, 2009; Grand *et al.,* 1999, Smith, 2009).

Many developing countries have standard guidelines but evaluation of their use is few. Many studies used a before/after study design without a control (Grand *et al.*, 1999, Smith, 2009, Ajayi *et al.*, 2008). In Indonesia and Kenya, a randomized controlled study of the introduction of a guideline for diarrhea for pharmacists and drug sellers showed significant short-term improvements (Ross-Degnan *et al*., 1996). Guidelines are often not implemented, unless well-designed educational strategies are used to encourage health professionals to understand and adopt them into every day practice (Grimshaw and Russell, 1993).

Drug bulletins are supposed to be an ongoing source of objective drug information for health professionals. In Africa, few countries have a drug bulletin and production is often irregular (Health Action International 1991). In Sri Lanka, a controlled study on the use of a newsletter on antibiotics prescribing showed some improvement, but the differences were' not significant (Augunawel *et al.*, 1991).

Illustrated materials like flow charts, flyers, leaflets, posters aim to give guidance to health workers regarding the path they should follow to define the most rational course of action. Flow charts are usually focused on one illness or group of illnesses, such as diarrhea, malaria, sexually transmitted diseases, mental disorders, asthma (Grand *et al*.,1999, Quick *et al.*, 2011). Illustrated materials carrying new information that is immediately relevant to health professionals/providers may help bring about a change in behavior. In general however, printed materials may increase providers' knowledge but rarely affect actual performance when used alone. These materials are most useful when they are used in combination with other intervention strategies, especially those that involve active interactions between the party providing and the party receiving the information (Quick *et al.*, 2011, WHO/DAP 1994).

Approaches used to deliver educational intervention include : face-to-face education (educational outreach) for individual or small group, seminar/workshop, in-service training, feedback or peer review and participatory training approach. In Indonesia, a randomized controlled study found that face-to-face education was effective in shifting prescribers' practice towards the recommended norm (Santoso *et al.,* 1996). Interactional face-to-face education for the introduction of guideline in Kenya and Indonesia had significant short-term improvements in a controlled study (Ross-Degnan *et al.,* 1996). Formal training seminars to improve health workers knowledge in Kenya resulted in marked improvements, but frequent refresher courses and more supervision were recommended to further improve and sustain the results (Roosmalen ,1986). Sufficient follow-up is generally lacking, thus reducing the impact of this type of intervention (Grand *et al.,* 1999). The participatory training approach was also noted to be an important condition for the success of diagnostic counselling cards in Indonesia (Santoso *et al.,* 1996). Another study in Australia also reported an improvement in pharmacists' knowledge and skill in provision of specialized asthma care after using the participatory training approach (Saini *et al.,* 2006).

Educational intervention studies with emphasis on medication counselling in community pharmacies in Nigeria are lacking. Few studies reported educational intervention to improve sale, and recommendation of antimalarials by patent medicine sellers but not community pharmacies (Ajayi *et al.,* 2008; Okeke and Uzochukwu, 2009). In a review by Smith (2009), on intervention studies in community pharmacies in developing countries, no singular study was identified from Nigeria, confirming the dearth of work on intervention study on medication counselling in community pharmacies in Nigeria.

2.7. Readability of Medication Information Leaflet (Drug Insert)

Readability predicts relative ease with which a reader can assign meanings to words and phrases. It has both a visual and a linguistic aspects. The linguistic aspects include the length and syllabic make-up of words, as well as their likely familiarity to readers with a specified level of education. Visually, the print must be large enough and adequately spaced and sufficiently distinct from its background (Garner, 2011).

Research aimed at developing valid readability ratings has been undertaken for at least seven decades, and more than 40 measures have been published (Garner, 2011). They differ in their intended field of application, the means used to arrive at a rating and the form in which the rating is given. Most use a formula based on some combination of the number of words per sentence; word length (in terms of number of syllables or letters); and word familiarity (derived from validated lists of words according to commonness of use). For example, the Fry Readability Formula (Fry, 1967) applies a simple formula based on the ratio of words of three or more syllables in 100-word excerpts from the beginning, middle and end sections of a text. A similar approach is taken in SMOG (Simple Measure of Gobbledegook) (McLaughlin, 1969) and the Fog index (Gunning, 1968). More complex formulae are employed in two of the most commonly used measures, the Flesch Reading Ease (Flesch, 1948) score and the Flesch-Kincaid Reading Grade Level (FKRGL) (Kincaid et al., 1975). These were designed principally to assess reading texts for schools, but are also frequently used for other kind of texts including medication information leaflets.

Most countries usually set guidelines and regulations on readability and design of medicine leaflets. In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) is the body responsible for setting standards on patient information leaflets. However, there are no regulations concerning the readability of package insert of medicinal products in Nigeria.

Few studies have examined the readability of medicine information leaflets in Nigeria. Auta *et al.*, (2011) examined the readability of selected over-the-counter medicine information leaflets using the Flesch-Kincaid Grade Level Readability Test . The results showed that the mean school grade level required to read the studied leaflets was 11.9 (equivalent to Nigerian Senior Secondary School Level 3- SS3). The study concluded that medicine information leaflets should therefore be made readable to consumers given the high level of illiteracy in the country.

3.0: METHODS

3.1 Description of the Study Area and Study Setting.

Lagos State is an administrative division of Nigeria, located in the Southwestern part of the country.Lagos State is the second most populous State and arguably the most economically important State of the country. It is divided into 5 administrative divisions, which are further divided into 20 Local Government Areas(LGAs).

Community pharmacies are spread across the entire Lagos State. There are 448 registered community pharmacies in Lagos State in Dec. 2008 according to the list obtained from the Pharmacists Council of Nigeria. Community pharmacy here refers to only pharmacy outlets involved in retail distribution/sale of medicines. These outlets are expected to be supervised by a superintendent pharmacist, and assisted by other pharmacy staff which may include pharmacists (full/part-time) and non-pharmacists (shop/sales attendant, accountant). The pharmacist is the one responsible for provision of professional service including medication counselling.

3.2 Consent/Approval

A formal application for approval to carry out research in community pharmacy outlets in Lagos State was submitted to the Association of Community Pharmacists of Nigeria (ACPN) Lagos State branch. Verbal approval was granted by the executive committee of the association.

Letters of request for approval to carry out training were also submitted to the zonal group of ACPN selected for the intervention study. Advocacy visit was made to the leadership of the zonal groups to explain the objectives and format of training. This was done to mobilize members and gain commitment.

3.3: Unit of Sampling

Each community pharmacy outlet was taken as unit of sampling. Community pharmacies registered by the Pharmacists' Council of Nigeria were the target population from which samples were drawn.

3.4: Sample size calculation

The Fischer's formula for population less than 10,000 was used:

$$nf = \frac{n}{1+n/N} \qquad \text{Equation 1 (Araoye, 2003)}$$

where

nf = the desired sample size when population is less than 10,000.

n = the desired sample size when population is more than 10,000.

N = the estimate of the population size which is 448 for this study.

But Fischer's formula for population size greater than 10,000 is given by Araoye (2003) as:

$$n = z2\ p\ q / d2 \qquad \text{Equation 2}$$

where

n = the desired sample size when population is greater than 10,000.

z = the standard normal deviate,usually set at 1.96,which corresponds to the 95% confidence level.

P =the proportion in the target population estimated to have a particular characteristics.If there is no reasonable estimate,then use 50% (i.e 0.50).

q = 1.0 – p = 0.50

d = Degree of accuracy desired, usually set at 0.05

Therefore,

n = (1.96)2 (0.50) (0.50) / (0.05)2 = 384

Substituting this in equation 1,gives

384 / 1+384/448 = 384 / 1+ 0.859 = 207

The required sample size is 207

3.5: Sampling

A combination of stratified and random (multi-stage sampling) sampling method was employed as the sampling method.

Step 1 :

Using the names and addresses of community pharmacies obtained from the PCN, the outlets were sorted out into their respective Local Government Areas.

Step 2:

In order to obtain the number of pharmacies to be sampled per LGA, a multiplication factor was obtained by the formula below

Sample size/ Target population = 207/448 = 0.46

This factor was then used to obtain the number of pharmacies to be sampled per LGA. (Fig 3.1)

Table 4 Target population and sample size of community pharmacies per LGA

S/N	Local Government Areas	Target Population	Sample size

1	APAPA	17	8
2	IKEJA	53	24
3	EPE	2	1
4	MUSHIN	6	3
5	IKORODU	28	13
6	OSODI-ISOLO	48	23
7	IFAKO-IJAYE	21	10
8	LAGOS MAINLAND	24	11
9	SOMOLU	16	7
10	ALIMOSHO	44	20
11	AGEGE	20	9
12	AJEROMI-IFELODUN	6	3
13	LAGOS-ISLAND	18	8
14	OJO	12	6
15	KOSOFE	36	17
16	ETI-OSA	11	5
17	BADAGRY	4	2
18	IBEJU-LEKKI	14	6
19	AMUWO	22	10
20	SURULERE	46	21
	TOTAL	448	207

Step 3:

After calculating the sample size per LGA, the pharmacies to be visited were then selected through balloting (Simple random sampling).

3.6: Selection of drug of focus

Antimalarial was adopted as the therapeutic class of focus. This was based on the following reasons;

- Malaria remains a major public health problem in Nigeria. Malaria is endemic in Nigeria, responsible for over 300,000 deaths annually (WHO 2007b).

- Antimalarials are one of the most commonly purchased medicines from community pharmacies in Nigeria (Oshikoya *et al*., 2007).

- Previous antimalarials were rendered impotent due to development of resistance fuelled by irrational use (Ajayi *et al*, 2008).

- Effective medication counselling has been proven to promote rational use and good treatment outcome (Ajayi *et al.*,2008).

The Federal Ministry of Health in 2006 adopted the WHO recommendation that stipulates the use of Artemisinin based combination drugs for treatment of malaria. Subsequently, Artemether-lumefantrine combination drug was chosen as the combination of choice for treatment of malaria in Nigeria (FMOH, 2006). Artemether-Lumefantrine was therefore chosen as the drug of focus for this study.

3.7: Selection of simulated client scenario.

Community pharmacists were asked to identify the most frequent ways patients/clients self medicate in community pharmacies. Responses obtained showed that most individual comes into the pharmacy to request for product. Therefore 'Request for product scenario' was chosen as the simulated scenario for this study.

3.8: Development of Criteria for assessing adequacy of medication counselling for Artemether-Lumefantrine combination drug:

Literature search and expert review method was used to develop the criteria.Through literature search, medication information items were identified for Artemether-Lumefantrine combination drugs. Only medication information items obtained from randomized controlled studies were included. A potential drug interaction between Artemether-Lumefantrine was not included because no invivo study was found to justify the inclusion. A total of 10 major items were generated. A team of reviewers comprising of 1 clinical pharmacy lecturer, 1 clinical pharmacology lecturer and 1 community pharmacist/public health practitioner was constituted to review the medication information items to identify only items required to ensure safe and proper use of the drug [USP Medication Counselling Behavior Guideline Stage 1]. After the review,5 items were identified. These include information on :

1. Dosage
2. Frequency of use
3. Duration of use
4. Special precaution specifically related to ''take after fatty food''.
5. Instruction to promote adherence; ''ensure you complete your medication even if you feel better.''

Adequate medication counselling was defined as provision of ≥ 4 medication information.

Table 5.0 SUMMARY OF STUDY 1-5.

	STUDY 1	STUDY 2	STUDY 3	STUDY 4	STUDY 5
STUDY DESIGN	Cross-sectional survey of community pharmacies	Cross-sectional survey of community pharmacists	Review of documents.	Evaluation of Readability of medicine information leaflets	Educational Intervention
OBJECTIVE	To determine nature, extent and adequacy of medication counselling. To determine influence of pharmacy characteristics on medication counselling . [Research Objective 1 & 2]	To determine influence of pharmacists' characteristics on medication counselling. To determine pharmacists opinion on barriers to medication counselling. [Research objective 2]	To determine factors affecting medication counselling practice : availability and extent of regulatory framework on medication counselling. [Research objective 2]	To determine the readability of medicine information leaflets dispensed from community pharmacies. [Research objective 3]	To determine the impact of educational intervention on medication counselling practice. [Research objective 4]
SAMPLE SIZE	207	Pharmacists in all the 207 pharmacies in study 1	Laws, regulation, policy statements and guidelines on pharmacy practice.	Medicine information leaflets of brands of artemether-lumefantrine (drug of focus in this study).	48 community pharmacies (selected from the 207 pharmacies)
SAMPLING METHOD	Simple random sampling	Purposive	Purposive	Purposive	Purposive
RESEARCH INSTRUMENT	Simulated client visit with Observer report Form	Self completed questionnaire for pharmacists	Medication counselling regulatory framework indicators	Flesch-Kincaid readability test	Training of pharmacists in a workshop followed by on-site practical demonstration

3.10: STUDY 1. SURVEY OF COMMUNITY PHARMACIES (OBSERVATIONAL STUDY)

Objectives:

- To determine the nature, extent and adequacy of medication counselling practice.
- To determine factors affecting medication counselling : Influence of pharmacy characteristics.

Study Design:

Cross sectional survey of community pharmacy outlets using the pseudo-customer method [Observational, Cross sectional design].

Data Instruments:

Development of Pseudo-customer Scenario:

Request for product was chosen as the dispensing scenario. The scenario was developed to capture/collect data on the following:

- The nature, extent and adequacy of medication counselling provided by community pharmacist.
- Pharmacy characteristics : measures of workload; availability of private counselling area; pharmacy location.

Simulated Client Scenario

- ❖ The simulated client; an adult of 18-25years of age enters the pharmacy, ask to see the pharmacist. He/She then request for a pack of Artemether – lumefantrine tablet (e.g Coartem, Lonart tablet).
- ❖ The simulated client will take note mentally of the following;

- Any question(s) asked by the pharmacist.
- Any advice on how to take the medication including dosage (number of tablets), frequency, (how often) and duration (how long).
- Any advice on precautions like before or after food, if after food what type of food.
- Advice on adherence : Ensure you complete your medication,
- and any other advice giving by the pharmacist.

❖ The simulated clients will also take note of the following; number of client(s) waiting to be attended to; number of staff on duty; estimated duration of interaction and time of visit.

❖ The simulated client will accept the product and pay for it if offered for sale.

❖ After leaving the pharmacy, the simulated client will complete the Observer Report Form .

Quality Control of the Research Instruments: Validation and Reliability

- The pseudo-customer scenario and the Observer Report Form were written out into a manual which was circulated to 2 clinical pharmacy lecturers for face and content validity.
- Selection of pseudo-customers: Undergraduate students in the Faculty of Pharmacy were selected and trained to act as pseudo-customers for data collection.
- Training of data collectors (Pseudo-customer): The data collectors were trained using the training manual and role play. The training was done over a period of 5 hour by the researcher. During the training, they were informed of possible questions that could be asked by the pharmacist and what response to provide.

- Scenario was pretested in few community pharmacies and appropriate adjustment made.

Data Collection:

The community pharmacy outlets randomly selected were visited by a pseudo-customer. The pseudo-customer enters the pharmacy and then plays out the scenario. After purchasing the drug he/she then fills the Observer Report Form after exiting the pharmacy. Where the pharmacist was not available, the simulated client enquired when the pharmacist will be around and then repeated the visit.

Data Processing:

- Questions asked by the pharmacist were analyzed using the criteria for assessing appropriateness of self medication developed by Ward *et al* (2000).
- Medication information provided were analyzed using the criteria developed in this study for assessing adequacy of medication information for Artemether-Lumefantrine combination drugs. Provision of ≥ 4 medication information will be regarded as adequate medication counselling practice.

- Influence of Pharmacy Characteristics on Medication counselling practice:
    - Location: Two groups were compared; pharmacies in LGA categorized as urban and those in LGA categorized as rural.

- Workload in the pharmacy: number of clients seen daily, number of clients at the pharmacy waiting area, number of pharmacists on duty and time of visit. The actual numbers of these measures will be used for analysis.

- Availability of private counselling area : Two groups were compared: pharmacies with private counselling area were compared with those without counselling area.

Data Analysis:

- Statistical package for Social Science (SPSS) version 15.0 was used for analysis.

- P-value of 0.05 and below was considered statistically significant.

- Descriptive Statistics: Summary of tables, frequency, mean and bar charts were generated.

- Inferential Statistics: Multiple regression model; One-way ANOVA; Correlation coefficient; Independent t-test were used as Test of Association between variables.

3.11 : STUDY 2- SURVEY OF COMMUNITY PHARMACISTS

3.3.1 : Objectives:

- To determine factors affecting medication counselling: Influence of pharmacists' characteristics;

- To determine adequacy of pharmacists' knowledge.

- To determine pharmacists' general attitude to medication counselling.

- To determine pharmacists' opinion on barriers to medication counselling and strategies to strategies to improve counselling practice.

Study Design:

A cross sectional survey of pharmacists in selected community pharmacies using pretested validated questionnaire.

Data Instrument:

A pre-tested standard self administered questionnaire was developed as data collection instrument to capture;

- Pharmacists' demographic data
- Community pharmacy characteristics
- Pharmacists' knowledge of medication counselling;
- Pharmacists' general attitude to medication counselling

- Pharmacists' perspective of barriers to medication counselling and strategies that can be used to improve counselling practice.

Development of Questionnaire on Knowledge, Attitude and Barriers to Medication Counselling:

Knowledge: Questions to assess the knowledge of medication counselling information specific for artemether-lumefantrine was developed using case study format. The 2 major areas of medication counselling assessed were questions to ask when a patient presents in a pharmacy to request for a product of Artemether-lumefantrine and, medication information that should be provided following sale of this product. The use of case study format is a standard way of assessing knowledge (Couris, 2000).

Attitude: A 7-item questions to assess the general attitude of pharmacists towards medication counselling was developed. The questions were developed to assess attitude of pharmacists towards:

- Role and importance of medication counselling.
- Readiness/Willingness to accept medication counselling as a professional responsibility and be made accountable for doing it.
- Readiness/Willingness to overcome barriers to medication counselling.

The 5-point Likert scale was used as the format for questions on attitude.

Pharmacists' opinion on barriers to medication counselling and strategies to improve counselling practice: After a thorough search of the literature, 8 barriers to medication counselling practice and 7 strategies to improve counselling practice were identified. These items were framed into questions and pharmacists were expected to rate each of these items on a scale of 1 to 5 based on the extent to which they constitute barriers to medication counselling in their practice or the extent to which the strategies will help improve counselling practice in their pharmacy.

Reliability and Validity of Questionnaire to assess Knowledge, Attitude and Barriers to medication counselling practice:

Face and content validity of the questionnaire was assured through a 2 step process. One, through a thorough search of the literature to ensure that all aspects pertaining to barriers and strategies to overcome them were captured. Clinical pharmacy staff both within and outside the Faculty of Pharmacy, University of Lagos were then asked to review the questionnaire to ensure both face and content validity.

The questionnaire was pre-tested in some selected pharmacies around Ikeja LGA. This resulted in minor modification of the final instrument. The pharmacies used for pre-testing of questionnaire were excluded from the sample for the actual study.

A cronbach alpha (α) of 0.721 was calculated for reliability.

Data Collection:

All selected community pharmacies were visited to administer the questionnaire to all categories of pharmacists (Superintendent pharmacist, staff pharmacist, & part time pharmacist). Visits were repeated to ensure that all pharmacists engaged in the sampled community pharmacies filled the questionnaire.

Data Processing:

Knowledge of the content of medication counselling:

The medication counselling 'questions' and 'information' were analysed using the criteria developed by Ward *et al* (2000) and the criteria developed in this study for artemether-lumefantrine combination drugs respectively.

Attitude towards medication counselling:

Each of the 7 attitude questions were analysed separately.

Barriers to medication counselling and strategies that can be used to improve counselling practice:

The mean rating for each of the barriers / strategies were computed. Actual value were compared. Post hoc analysis was also carried out to determine differences in rating amoung pharmacists with different demographic characteristics.

Data Analysis:

- Descriptive statistics: Summary of tables; Frequency, and mean.
- Inferential statistics: Correlation coefficient , independent t- test, LSD post hoc analysis were used to test for association/relationship.

3.12: STUDY 3: EVALUATION OF REGULATORY FRAMEWORK ON MEDICATION COUNSELLING

Objective:

To determine factors affecting medication counselling practice: Availability and extent of regulatory framework on medication counselling practice in community pharmacies.

Study Design:

Review of publications on laws and regulations by PCN/PSN/FGN on pharmacy practice in Nigeria. Review of checklist used by Pharmacists Inspection Committee for monitoring of community pharmacy activities in Lagos state.

Data collection Instrument:

After a thorough literature search, the following questions were developed to assess the availability and extent of regulatory framework on medication counseling practice;

- Is there any instruction on when a pharmacist is expected to counsel?
- Is there a list of what a pharmacist is expected to say when counselling patient?
- Is there a provision for when a pharmacist is required to counsel and when he/she can delegate to other pharmacy staff ?
- Is there a process for assessing, monitoring and enforcing counselling requirements?
- Is there a rule that specify what functions unlicensed personnel may perform under the supervision of a pharmacist ?
- Is there a rule that specifies liability for not performing counselling function (for non-prescriptions and prescription medicines) ?

Using the regulatory framework questions, data capturing form was then developed to collect data.

Data Collection:

Five publications containing laws/regulations, policy statements and guidelines on pharmacy practice in Nigeria were identified;

-Pharmacists Council of Nigeria Act 1992 [Ref ; PCN.ReC.001 Year of publication- July 2009].

- Code of Ethics for Pharmacists in Nigeria. [Year of publication- 2005].

- 4-Part Compendium of minimum standards for the assurance of pharmaceutical care in Nigeria. [Ref;PCN.MoR.005. Year of publication- 2009].

-National Drug Policy [Year of publication- 2005].

-Compilation of Law on Pharmacy practice [Ref; PCN.ReC.003. Year of publication- July 2009].

These documents were reviewed using the regulatory framework questions developed and the results documented in the data capturing form.

3.13: STUDY 4 – READABILITY OF MEDICATION INFORMATION LEAFLET (DRUG INSERT)

Objective:

- To determine the readability of medication information leaflets

Study Design:

Evaluation of selected medication information leaflets for artemether-lumefantrine combination drugs using the Flesch-Kincaid Grade Level readability test.

Data collection:

Eight medicine information leaflets were randomly selected from the range of artemether-lumefantrine combination drugs dispensed from community pharmacy dispensed in study 1.Information on the leaflets were transcribed into Microsoft office word 2007. The transcribed documents were imported into online readability software on 'online-utility.org' to generate readability grade level for each leaflet.

Statistical Analysis:

The readability score obtained indicate US grade level at which a reader can understand the document. The US grade level score obtained were compared with the Nigerian educational level to be able to draw inference (Table 6). The number of leaflets corresponding to the different Nigerian educational level was also computed.

Table 6. United States of America grade level and the corresponding educational level in Nigeria

US Grade Level	Nigerian Education Level	
1	Primary 1	Primary education
2	Primary 2	
3	Primary 3	
4	Primary 4	
5	Primary 5	
6	Primary 6	
7	Junior Secondary 1	Junior secondary school
8	Junior Secondary 2	
9	Junior Secondary 3	
10	Senior Secondary 1	Senior secondary school
11	Senior Secondary 2	
12	Senior Secondary 3	
13	Tertiary	Tertiary education
14	Tertiary	
15	Tertiary	
16	Tertiary	

Source: Auta *et al* 2011

3.14: STUDY 5: EDUCATIONAL INTERVENTION STUDY

Objective:

-To develop, implement and evaluate the impact of educational intervention on practice of medication counselling.

Study Design:

Before and after outcome measure. Medication counselling practice were measured at baseline and then measure at 1 month and 6 month post intervention.

Intervention Model:

- Training of pharmacists in an interactive workshop followed by on-site demonstration. Pharmacists were trained in an interactive workshop. This was then followed up by distribution of posters containing detailed medication information on Artemether-Lumefantrine.

Study Population/Sample size/Sampling

Pharmacies in a zonal chapter of ACPN which were part of the previously sampled community pharmacies used for study 1 and 2. A total of 42 pharmacies were identified and included in the study.

Outcome Measures:

- Practice score : total number of appropriate medication information provided to simulated client.

Baseline Evaluation of Outcome measures: This had earlier being carried out in study 1 and 2.

Development of intervention model: The framework for planning intervention study described by Quick *et al* (1991) was used as a basis for development of the educational intervention model used in this study (Figure 3).

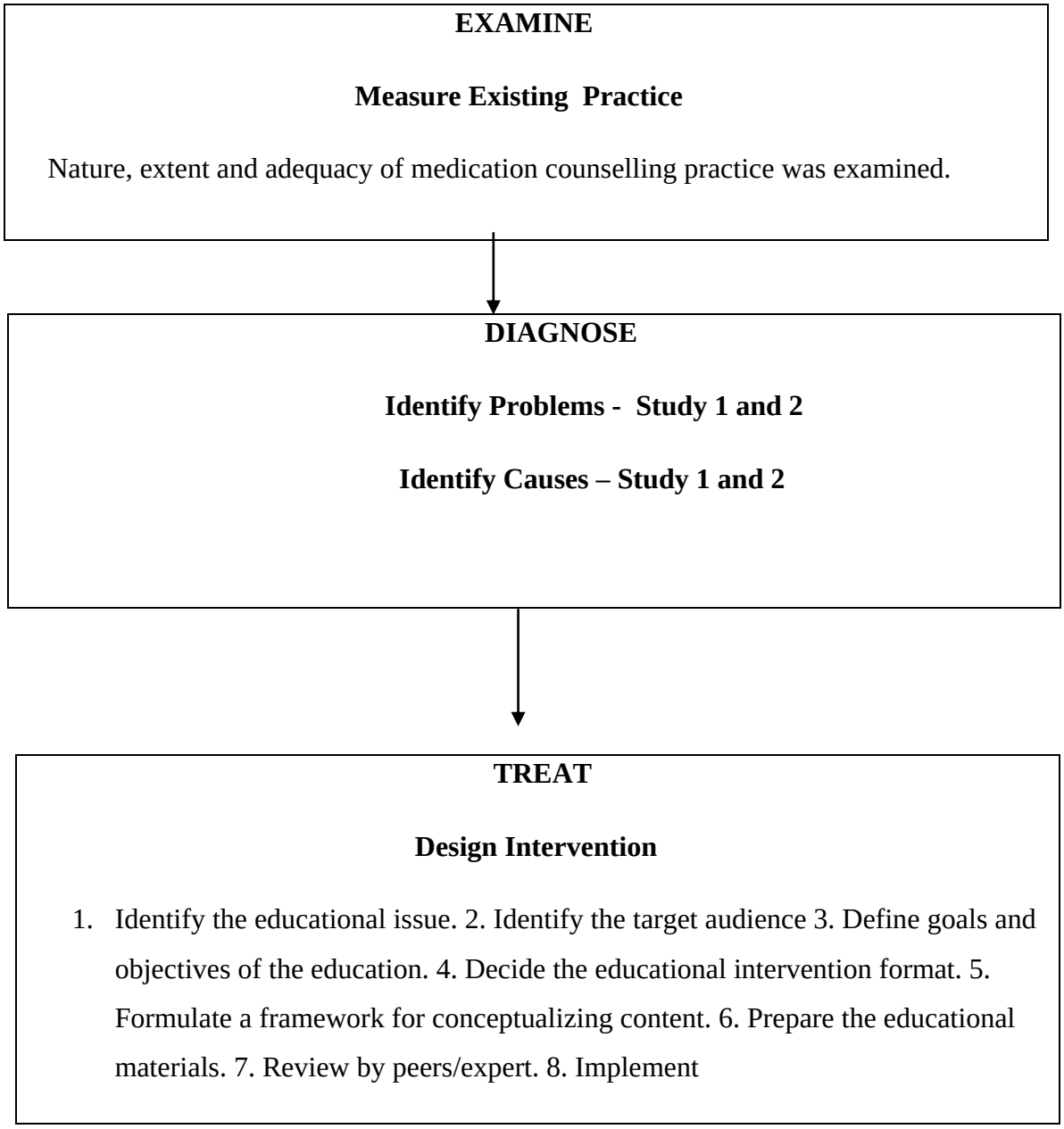


Figure 3 showing framework for the intervention study.

Educational Intervention Design:

Objective : To improve provision of oral medication counselling practice in community pharmacies through provision of educational intervention.

Target audience: Pharmacists

Intervention Format: Training of pharmacists in an interactive workshop, followed by on-site demonstration.

Framework for content of educational materials: Materials for the interactive workshop were developed using the National Malaria Treatment Guideline, Criteria for assessment of self-medication developed by Ward *et al* (2000) , and Criteria for assessment of adequacy of medication counselling for artemether-lumefantrine combination drug developed in this study. The major highlights of the workshop include: Importance of appropriate medication counselling; review of outcome of study 1 and 2(feedback); medication counselling information for artemether-lumefantrine combination drug; criticality of each medication information to outcome of therapy.

Validation of Educational Intervention Materials: The following educational interventional materials were reviewed by a clinical pharmacy lecturer and clinical pharmacology lecturer for face and content validity:

-Manual and slides for pharmacists' interactive workshop.

- Pictorial posters for pharmacies.

Implementation :

Pharmacists were trained during the monthly continuing education meeting. A pictorial poster emphasizing the 5 essential medication information for artemether-lumefantrine was developed for on-site practical demonstration.

Post-Intervention evaluation of outcome measures:

- Simulated client visit was repated for all pharmacies included in the intervention group at 1 month and 6 months post workshop / onsite training.

Data Processing and Data Analysis:

The baseline and post intervention score for medication counselling practice was processed and computed. The data were computed for significance difference between baseline and 1 month and 6 month, and between 1 month and 6 months.

4.0 RESULTS

4.1 Demographic profile of community pharmacies and community pharmacists.

A total of 185 community pharmacies were identified as having complete data for analysis, representing 89.8 % response rate. The demographic data of the pharmacies and community pharmacists in these pharmacies are as shown in Table 7 and 8.

Table 7: Demographic profile of community pharmacies.

Pharmacy Characteristics	**Frequency (%)**
Type of pharmacy	
Independent (1 pharmacy)	160 (86.5)
Multiple (number of pharmacies ≥ 2)	25 (13.5)
Location of pharmacy	
Urban	155 (83.8)
Rural	30 (16.2)
Operating hours per day (hours)	
1- 12 hours	79 (42.8)
≥13 hours	106 (57.2)
Estimated average daily patronage	
1 – 50 clients	80 (43.7)
51 – 100 clients	60 (32.8)
≥101 clients	43 (23.5)
Private counselling area	
Available	170 (91.9)
Not available	15 (8.1)

The demographic profile of the pharmacies sampled shows that majority of the pharmacies are located in the urban area and also have a private counselling area. Only few of the pharmacies have avarage daily patronage of $\geq$100 patients.

4.1.1 Demographic data of Community Pharmacists

A total of 225 community pharmacists (from 185 pharmacy outlets) responded to the pharmacists' questionnaire. Their demographic profile is as shown in Table 8.

Table 8: Demographic profile of selected community Pharmacists in Lagos State

Demographic data	**Frequency (%)**
Years of experience	
1 – 10 years	101 (47.6)
11 – 20 years	53 (25.0)
≥ 21 years	58 (27.3)
Pharmacists Status	
Pharmacy Owner	152 (67.6)
Staff pharmacist	48 (21.3)
Locum pharmacist	16 (7.1)
Location where pharmacists practice	
Rural	37 (16.5)
Urban	187 (83.5)
Pharmacy Type	
Independent	177 (79)
Multiple (≥ 2)	47 (21)
Educational qualification	
1st Degree (B.Pharm) only	177 (78.7)
Postgraduate qualification(s)	43 (9.1)

The demographic profile of pharmacists sampled shows that almost half of the respondents have 1-10 years experience. Pharmacy owners constitute a greater percentage of the respondents and majority of the pharmacies are located in the urban areas.

4.2. Nature, Extent and Adequacy of Medication Counselling Practice in Community Pharmacies.

Pharmacists in most (65%) of the pharmacies provided counselling (asked question(s) and / or provided medication information). The types of questions asked by pharmacists during the counselling episode are as shown in Fig 4. Majority of the pharmacists who asked question(s) wanted to know 'who' the medication requested is meant for, and 'what symptom' necessitated the request for the medicine, however none of them enquired how long the symptoms have been present.

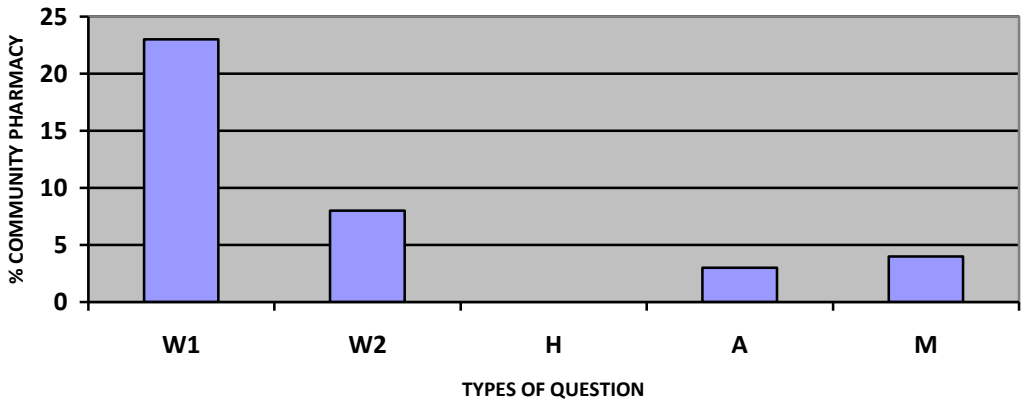


Fig 4. Showing types of counselling questions asked by pharmacist

Key:

W1- Who is the patient

W2- What are their symptoms

H – How long have the symptom been present

A – Actions already taken

M – Medications already taken

Sixty three percent of pharmacists did not ask any question before sale of the medicine- Figure 5. The highest number of questions asked was also limited to 2.

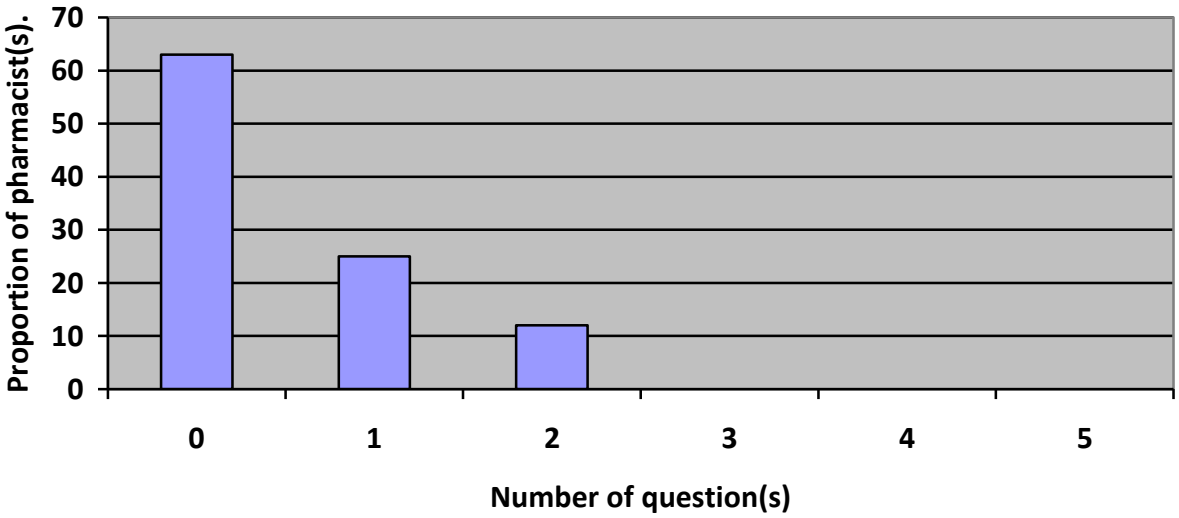


Figure 5. Showing the number of counselling questions asked by pharmacists.

Pharmacists in forty- eight percent (48%) of the pharmacies provided medication information. Information on dosage and frequency was provided by all the pharmacists, while only 3% provided information on adherence. All patients that received information on dosage (how many tablets to take) were also told the frequency (how often to take them).(Fig 6).

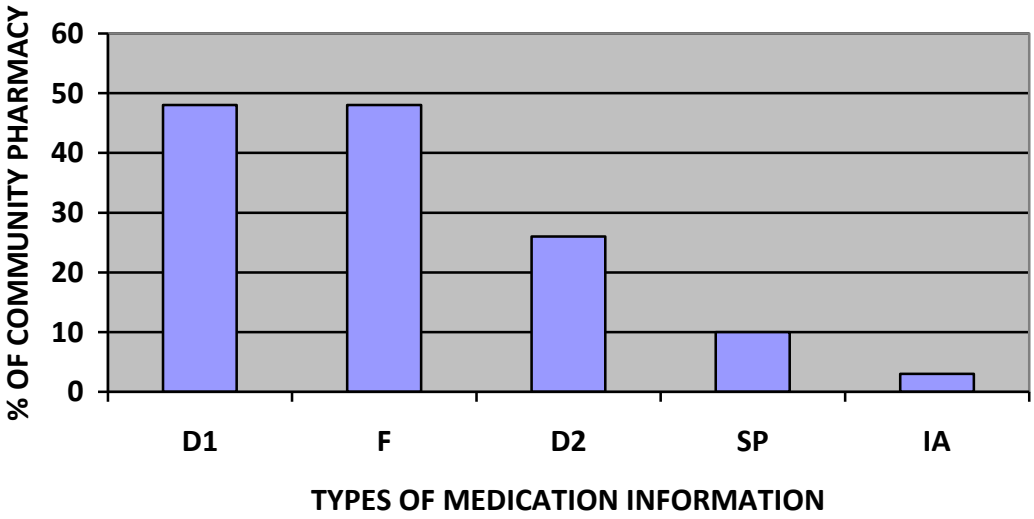


Figure 6. Showing types of medication information provided by pharmacists.

Key:

D1 – Dosage (How many tablets to take)

F – Frequency (How often to take them)

D2 – Duration (For how long)

SP – Special Precaution (Take immediately after food, especially fatty food)

IA – Information on Adherence (Ensure you complete your medication).

The highest number of medication information provided by pharmacist was 3, and only few (10%) pharmacists provided ≥ 4 medication information.-Figure 7.

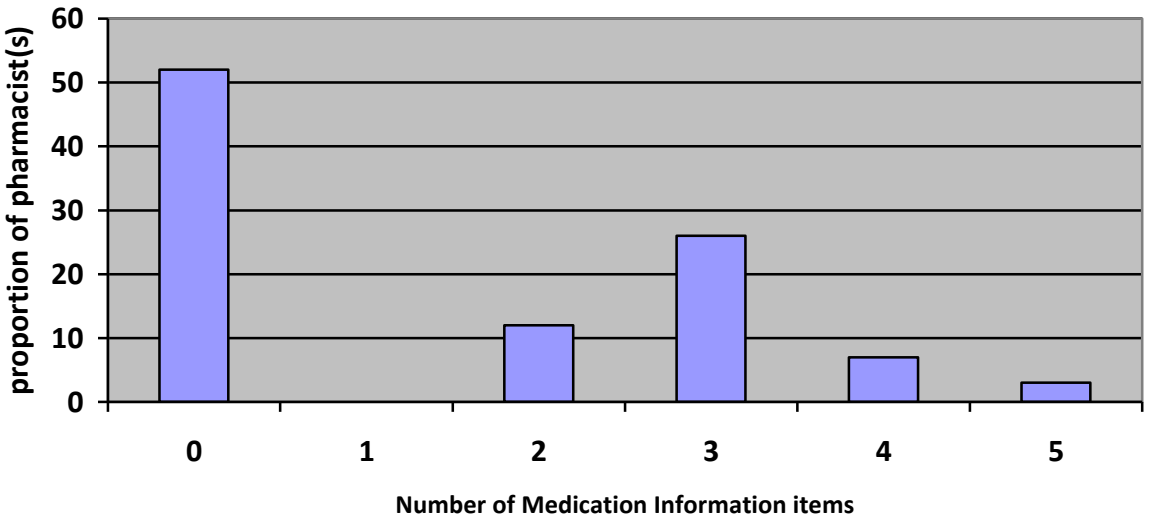


Figure 7. Showing number of medication information items offered by pharmacists.

An average of 2.4 minutes was spent during the counselling session and the amount of counselling items was related to the duration of interaction (R=0.295, p= 0.001). All the counselling episode resulted in the sale of the requested medication.

4.3. Factors influencing medication counselling practice

4.3.1 Influence of Pharmacy Characteristics on Medication Counselling Practice

4.3.1.1 Workload in the pharmacy

Data for different measures and determinants of workload in the community pharmacy were collected; number of clients seen daily, number of clients in the waiting area at the time of visit, number of pharmacy staff on duty, and time of the day in which the pharmacy was visited. A multiple regression analysis was performed to examine the relationship between the extent of medication counselling (dependent variable), and the various measures of workload (independent variables). Table 9 shows there exist a significant relationship between the various variables of workload and medication counselling practice.

Table 9. Analysis of Variance Technique

Model	Sums of Squares	Df	Mean Square	F	p-value
Regression	42.489	4	10.622	4.262	0.003
Residual	219	180	2.492		
		184			

The coefficient of the variables (Table 10) also shows that, number of clients seen daily and time of the day in which the pharmacy was visited significantly contributed to the extent of medication counselling offered ($p<0.01$). There was also a negative relationship between number of clients seen daily and extent of counselling offered, indicating that as the number of clients seen daily increases the extent of medication counselling offered decreases. In addition there was a progressive decrease in the extent of counselling as the day progressed. Two of the variables, number of clients in the pharmacy waiting area and number of staff on

duty did not influence medication counselling. This shows that number of clients seen daily and time of the day in which the pharmacy was visited are both predictors of medication counselling practice in community pharmacies. The significance value (p value) of both variables shows that time of the day has higher predictive value compared with the number of clients seen daily.

Table 10. Multiple Regression Model showing influence of various measures of workload on medication counselling practice.

Model	**Unstandardized Coefficients**		**Standardized Coefficients**	**p-value**
	Beta	**Std. Error**	**Beta**	
(Constant)	4.703	1.150		
Number of clients seen daily	-0.009	0.003	-0.268	0.010
Number of clients in the pharmacy waiting area	0.016	0.084	0.021	0.853
Number of pharmacy staff on duty	0.100	0.122	0.091	0.418
Time of the day in which pharmacy was visited.	-0.223	0.070	-0.329	0.002

4.3.1.2 Location of Pharmacy

A total of 30 (16.2%) pharmacies were located in the rural areas, while 155 (83.8%) were located in urban areas. The mean counselling scores for both categories of pharmacies are 1.53 and `1.97 respectively.

Pharmacies in the rural areas and those in the urban areas do not differ significantly in their medication counselling practice.(Independent t-test: t=1.436,df=183,p=0.153)- Table 11.

Table 11. Test of association between location of pharmacy and medication counselling practice

Location of pharmacy	**Frequency**	**Mean Counselling Score (n ±)**	**Independent t-test and p-value**
Rural	30 (16.2%)	1.53 ± 1.252	t- 1.436 p- 0.153
Urban	155 (83.8%)	1.97±1.587	

4.3.1.3 Availability of Private Counselling Area

Pharmacies with designated private counselling area were more likely to ask the client questions compared to those without counselling area (p-0.000). However, no significant difference was found between the extent of medication information offered by pharmacy staff in both group of pharmacies (t-0.568, df = 183 ;p-0.571) – Table 12.

Table 12. Test of association between availability of private counselling area and medication counselling practice

Private counselling area	**Mean counselling score**	
	Counselling questions (n ± SD)	**Medication information (n ± SD)**
Available	0.21±0.479	0.91±1.547
Not Available	0.00±0.000	0.64±1.120
Independent t-test	1.425	0.568
p-value	0.000	0.571

4.3.1.4 Pharmacy Type (Independent versus Multiple)

No significant difference was found between the counselling practice of staff working with Independent pharmacy and those working with multiple outlets, both in the amount of questions asked (t-0.33,df=183, p-0.973), and medication information provided (t-0.196, df=183, p-0.844) – Table 13.

Table 13. Test of association between pharmacy type and medication counselling practice.

Type of pharmacy	Mean counselling score (n ± SD)	
	Counselling questions	Medication Information
Independent	0.24±0.517	0.94±1.519
Multiple	0.23±0.599	0.86±1.460
Independent t-test	0.33	0.198
p-value	0.973	0.844

4.3.2 Influence of Community Pharmacists' Characteristics on Medication Counselling Practice.

4.3.2.1 Pharmacists' Years of Experience.

Pharmacists' years of experience did not influence the amount of questions asked (F- 0.508, p- 0.611), the amount of medication information provided (F- 2.610, p-0.103), and the total questions plus medication information offered (F-2.191, p-0.142) - Table 14.

Table 14. Test of association between pharmacists' years of experience and medication counselling practice.

Pharmacists' years of experience	**Mean counselling score (n ± SD)**	**ANOVA and p- value**
1- 10 years	1.74 ± 1.11	
11- 20 years	1.95 ±1.31	F = 2.191
≥ 21 years	1.87 ±1.15	p-0.142

4.3.2.2 Pharmacists' Designation.

The designation of pharmacists seems to have a significant influence on the amount of questions asked, and the amount of medication information provided. Locum pharmacists provided more medication counselling (mean counselling score=3.52) than staff pharmacists (Mean counselling score=2.58) and pharmacy owners (mean counselling score=1.18). There was a significant difference between medication counselling offered by different categories of pharmacists (F- 8.878; p-0.002) – Table 15.

Table 15. Test of association between pharmacists' designation and medication counselling practice.

Pharmacists' designation	Mean counselling score (n ± SD)	ANOVA and p-value
Pharmacy Owner	1.18 ±1.30	F= 8.878 p-0.002
Staff Pharmacist	2.58±0.926	
Locum Pharmacist	3.52±0.707	

4.3.2.2 Pharmacists' Qualification

Having additional degree did not influence the counselling practice of the pharmacists. Pharmacists with basic pharmacy degree and the ones with postgraduate qualification(s) did not significantly differ in their counselling practice (t -0.932; p- 0.363) – Table 16.

Table 16. Test of association between pharmacists' educational qualification and medication counselling practice

Educational qualification	**Mean counselling score (n ± SD)**	**Independent t-test and p-value**
Basic pharmacy degree	2.25 ±0.65	t-0.932
Post-graduate qualification	3.40 ±1.10	p-0.363

4.3.2.3. Pharmacists' knowledge of medication counselling

4.3.2.3.1 : Pharmacists' knowledge of the content of medication counselling- Counselling Questions

The types of counselling questions pharmacists said they would ask is as shown in Fig 8. Majority (68.9%) of community pharmacists said they would ask 'what symptoms' necessitated request for the drug, however, only few (13.3%) pharmacists thinks getting information on 'how long the symptoms have persisted' is vital.

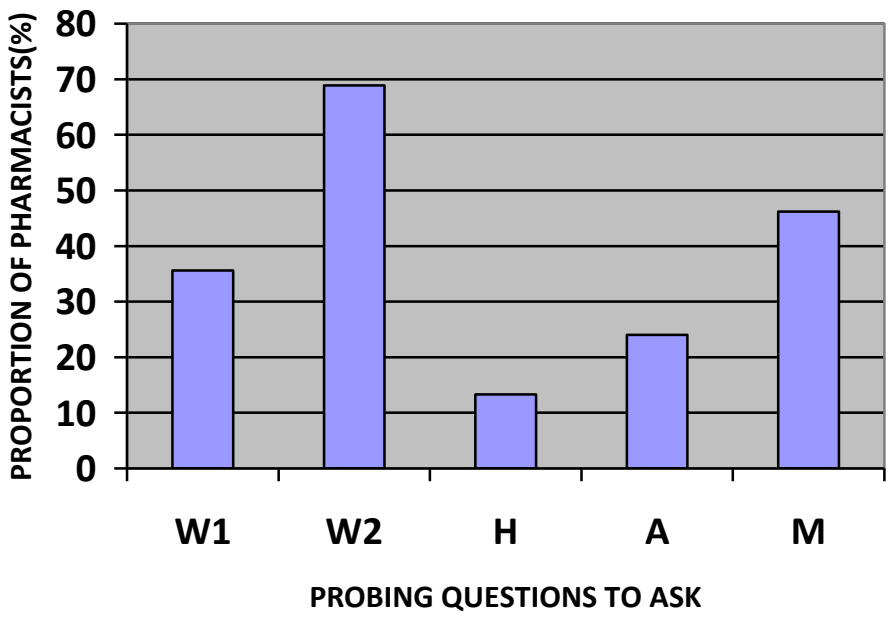


Fig 8. Showing Pharmacists' knowledge of counselling questions

KEY:

W1- Who is the patient?

W2 – What are their symptoms?

H – How long have the symptoms been present?

A – Actions already taken?

M – Medications already taken

Knowledge score for Counselling Questions : Most (35.6%) pharmacists had a knowledge score of 2 on a scale of 1-5. None (0%) had a score of 5.

4.3.2.3.2. Pharmacists' Knowledge of medication information.

Most (≥ 75%) pharmacists demonstrated adequate knowledge of dosage and frequency of the medication.(Fig 9). However, information on adherence was the least mentioned by most of the pharmacists.

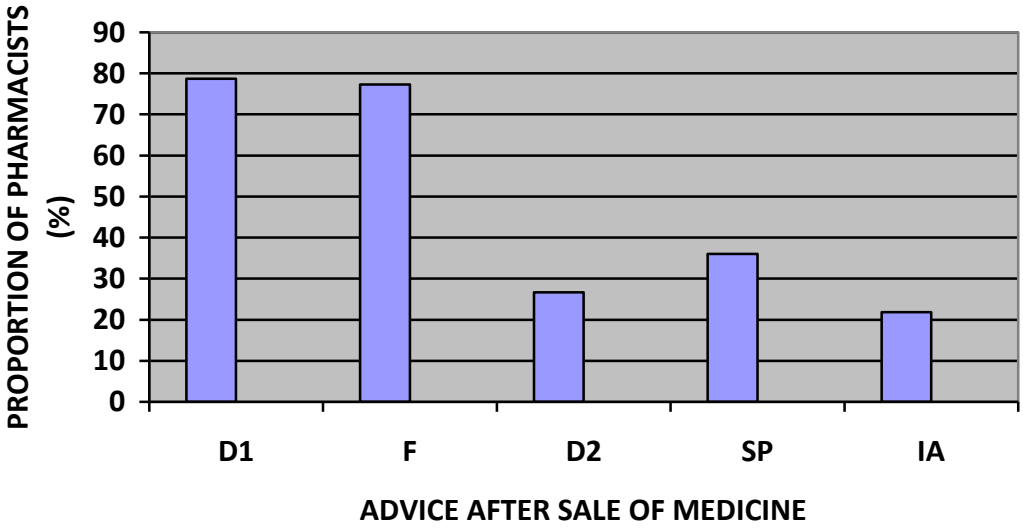


Fig 9. Showing pharmacists' knowledge of medication information

KEY:

D1 – Dosage (How many tablets t take)

F – Frequency (How often)

D2 – Duration (For how long)

SP – Special Precaution (Take immediately after food)

IA – Information on Adherence (Ensure you complete your medication)

Knowledge Score for medication information: Most (76.8%) pharmacists had a knowledge score of ≤3 on a scale of 1-5. Only 23.3 % were found to have adequate knowledge of medication information (score of ≥ 4).

4.3.2.3.3 Test of association between knowledge of medication counselling and pharmacists'

years of experience.

The mean knowledge score for pharmacist with less than 10 years experience was found to be 4.59 , while pharmacists with 11-20 years experience and those greater than 21 years experience were found to be 4.77 and 4.58 respectively.

Pharmacists' years of experience did not have any influence on their knowledge of medication counselling.(F=0.442,p=0.644) – Table 17.

Table 17. Test of association between knowledge of pharmacists and their years of experience

Years of Experience	Proportion of Pharmacists (%)	Mean Knowledge score (n ± SD)	ANOVA and p-value
1-10years	101 (44.9%)	4.59±1.150	
11-20years	53 (23.6%)	4.77±1.115	F-0.442 p-0.644
≥21years	58 (25.8%)	4.58±1.348	

4.3.2.3.4. Association between Knowledge of medication counselling and pharmacists' designation.

The mean knowledge score for pharmacy owner, staff pharmacists and locum pharmacists were found to be 4.65, 4.57, 4.60 respectively.

The status of pharmacists did not significantly affect their knowledge of medication counselling.(F=0.80, p= 0.923) – Table 18.

Table 18. Test of association between knowledge of medication counselling and pharmacists' designation

Pharmacist Ownership status	Proportion of pharmacists (%)	Mean knowledge score (n ± SD)	ANOVA and p-value
Pharmacy owner	152 (67.6%)	4.65±1.120	F-0.80
Staff Pharmacist	48 (21.3%)	4.57±1.065	p-0.923
Locum pharmacist	16 (7.1%)	4.60±1.549	

4.3.2.3.5. Test of association between knowledge of medication counselling and pharmacists' educational qualification.

The mean knowledge score for pharmacists with only first degree was found to be 4.61 while pharmacists with postgraduate degree had mean knowledge score of 4.74.

There was no significant difference between the knowledge of pharmacists with only first degree and those with additional qualification(s).(t=0.583, p= 0.561) – Table 19.

Table 19. Test of association between knowledge of medication counselling and educational qualification.

Educational qualification(s)	**Proportion of pharmacists (%)**	**Mean knowledge score (n ± SD)**	**Independent t-test and p-value**
Basic pharmacy qualification (B.Pharm/PharmD)	177 (78.7%)	4.61±1.232	t-0.583 p-0.561
Basic pharmacy degree + post graduation qualification	43 (19.1%)	4.74±1.32	

4.3.2.3.6. Correlation between pharmacists' knowledge and medication counselling practice

Correlation coefficient analysis was carried out to examine the correlation between what pharmacists said they would do (knowledge of questions to ask and medication information to provide) and what was actually offered in practice. Though their mean knowledge score was found to be higher than the mean practice score, however, no consistent relationship was found between pharmacists' knowledge and practice.(Mean Score for knowledge- 4.87; Mean score for practice- 2.38; (r=0.156, p-0.524).

4.3.2.4. Attitude of Pharmacists- General Attitude To Medication Counselling practice.

Most (99%) pharmacists believe medication counselling is a professional responsibility that should be performed at all times. In addition, (95%) agreed that the Pharmacists Council of Nigeria should make medication counselling compulsory for all pharmacists. However, pharmacists were divided on whether not performing counselling should attract liability – Table 20.

Pharmacists also expressed positive attitudes towards counselling clients. Many (87%) agreed their counselling is not dependent on patients consent. Majority (84%) agreed that patients should be counseled regardless of whether they request for it or not, and even if it is a drug they are familiar with.

Table 20. Attitude of Pharmacists to medication counselling practice

S/N	Attitude Items	% Responses				
		SA	A	UD	DA	SD
1.	Medication counselling is a professional responsibility of pharmacists that must be performed at all times.	95.6	4.0	0.4	-	-
2.	Medication counselling should be made compulsory for every community pharmacists by PCN	56.8	37.8	2.3	2.3	0.9
3.	Pharmacist should be sanctioned for not providing medication counselling	12.4	38.1	28.9	18.3	2.3
4.	Pharmacist should take responsibility for medication errors caused inadequate medication counselling	35.0	44.6	10.8	7.7	1.8
5.	My counselling depends on the consent of the patient.	0.9	8.8	3.7	64.5	22.1
6.	When patients do not demand for medication information, it is not necessary to bother them with counselling.	0.9	2.2	3.1	59.2	34.5
7.	Patients do not need counselling on medicine they are familiar with.	0.9	9.0	6.3	61.3	22.5

KEY:

SA – Strongly Agree

A – Agree

UD – Undecided

DA – Disagree

SD – Strongly Disagree

4.3.3: Availability and extent of regulatory framework on medication counselling

Five publications containing Laws, Regulations, Policy Statements and Guidelines on pharmacy practice were identified and reviewed using six quality indicators specific for regulatory framework on medication counselling (Appendix IV).

Two of the 5 publications (majorly policy statements) provided information on when the pharmacist is expected to counsel and what he is expected to say. However, these two documents do not contain information on when a pharmacist can delegate counselling to other pharmacy staff, and process for monitoring / enforcing counselling requirements. None of the Laws and Regulations on pharmacy practice has provision on liability for not performing counselling function.

4.3.4: Pharmacists' Perceived Opinion on Barriers to Medication Counselling Practice and Strategies that can be used to improve the practice.

4.3.4.1: Pharmacists' perceived opinion on barriers to medication counselling practice

Pharmacists' response showed that Workload in the pharmacy, Lack of medication counselling aids, Lack of appropriate drug information/reference books, and Lack of private counselling area are the four topmost barriers to medication counselling practice in community pharmacies. Table 21 shows the mean rating (on a five-point scale where 1=no influence and 5=highest influence) for each of the barriers.

Table 21. Pharmacists' rating of barriers to medication counselling practice

Barriers to medication counselling	**Mean rating ± SD** n= 225
1.Lack of compensation for counselling service	2.49±1.417
2.Workload in the pharmacy	3.30±1.236
3.Lack of expertise in medication counselling	2.78±1.148
4.Low expectations or lack of patient demand for counseling	2.45±1.257
5.Lack of interest in medication counselling	2.66±1.467
6.lack of private counselling area	2.83±1.484
7.Lack of appropriate drug information source/reference books	2.89±1.514
8.Lack of medication counselling aids	2.90±1.376

4.3.4.1.1. LSD post hoc differences in pharmacists' rating of barriers to medication counselling practice

Community pharmacists with different designation (pharmacy owner/ staff pharmacists / locum pharmacists) significantly rated workload in the pharmacy, lack of private counselling area, lack of appropriate drug information references and lack of medication counselling aids differently (p-0.042, p-0.014, p-0.047 & p-0.005 respectively). Post hoc analysis shows that pharmacy owners and staff pharmacists contributed to this significant difference for 'workload in the pharmacy'. For differences in rating of 'lack of private counselling area', locum pharmacists rated this barrier differently from other pharmacists.

Community pharmacists with different years of experience rated workload in the pharmacy, lack of demand by patient, and lack of private counselling areas differently (p-0.000, p-0.005, p- 0.002). Post hoc analysis shows that pharmacists of different years of experience all rated workload in the pharmacy differently. Pharmacists with ≥21years of experience rated lack of demand from patient differently from others. Pharmacists with 1-10years and 11- 20 years of experience both rated lack of private counselling area differently compared to their counterpart with >21years experience.

Community pharmacists with different practice location rated lack of demand by patient differently. Pharmacists in rural areas rated this barrier higher than pharmacists in the urban areas (3.00 vs 2.34; p-0.003).

Community pharmacists with different educational qualification rated 'lack of compensation for counselling' differently. Pharmacists with postgraduate education rated this barrier higher than pharmacist with basic pharmacy degree (3.02 vs 2.36; p- 0.007).

4.3.4.2: Pharmacists' suggestions on strategies to improve medication counselling practice.

Pharmacists rated practical training on medication counselling, followed by provision of counselling area, and availability of drug specific counselling guide/aid as the three topmost strategies that can be used to improve medication counselling practice in community pharmacies. Table 22 shows the mean rating (on a five-point scale with 1=no influence and 5=highest influence) for each of the strategies.

Table 22. Pharmacists' rating of strategies to improve medication counselling practice

Strategies to improve medication counselling practice	**Mean rating ±SD** n= 225
1.Increased staffing in pharmacy	3.60±1.344
2.Provision of counselling area	4.20±1.064
3.Compensation for counselling	3.42±1.442
4.Practical training on medication counselling	4.28±0.979
5.Stricter regulation that makes it mandatory for pharmacists to counsel patients	3.74±1.205
6.Greater support from pharmacy management for counselling activities	3.97±1.069
7.Availability of drug specific counselling guide/aids	4.08±1.068

4.3.4.2.1: LSD post hoc differences in pharmacists' rating of strategies to improve medication counselling practice.

Community pharmacists with different designation rated 'practical training on medication counselling' differently (p-0.041). Post hoc analysis shows that locum pharmacists contributed significantly to the differences in rating of this strategy.

Community pharmacists of different location of practice rated 'provision of private counselling areas differently (p-0.040). Pharmacists in the rural areas rated this strategy higher than those in the urban areas (4.53 vs 4.14 on a scale of 1-5).

Community pharmacists with different educational qualification rated 'compensation for counselling service' differently. Pharmacists with postgraduate education rated this strategy higher than their counterpart with basic pharmacy education (3.83 vs 3.31; p-0.036).

4.4.Readability of Medication Information Leaflet (drug insert)

The Flesch-Kincaid grade level of the studied leaflets is as shown in Table 23

Table 23. Flesch-Kincaid grade level for Artemether-Lumefantrine combination drugs leaflets.

S/n	Trade Name of Artemether-Lumefantrine combination drugs	Flesch-Kincaid grade level (US grade level)	Flesch-Kincaid grade level (Nigerian educational grade level)
1.	**A-L 1**	18	18
2.	**A-L 2**	18	18
3.	**A-L 3**	14	14
4.	**A-L 4**	16	16
5.	**A-L 5**	19	19
6.	**A-L 6**	16	16
7.	**A-L 7**	18	18

Table 24. Percentage of Artemether-lumefantrine drug leaflets readable at different educational system.

Nigerian educational level	**Flesch- Kincaid Test %**
1. Junior secondary school	0
2. Senior secondary school	0
3. Tertiary (graduate)	43
4. Post- graduate	57

4.4: Educational Intervention to Improve Medication Counselling Practice.

Post intervention assessment of practice at 1-month and at 6-months shows significant improvement in medication counselling practice. (p=0.000 at 1 month, and p=0.000 at 6 months). No significant difference in counselling practice was observed between 1 month and 6 month post intervention (p – 0.673) - Figure 10.

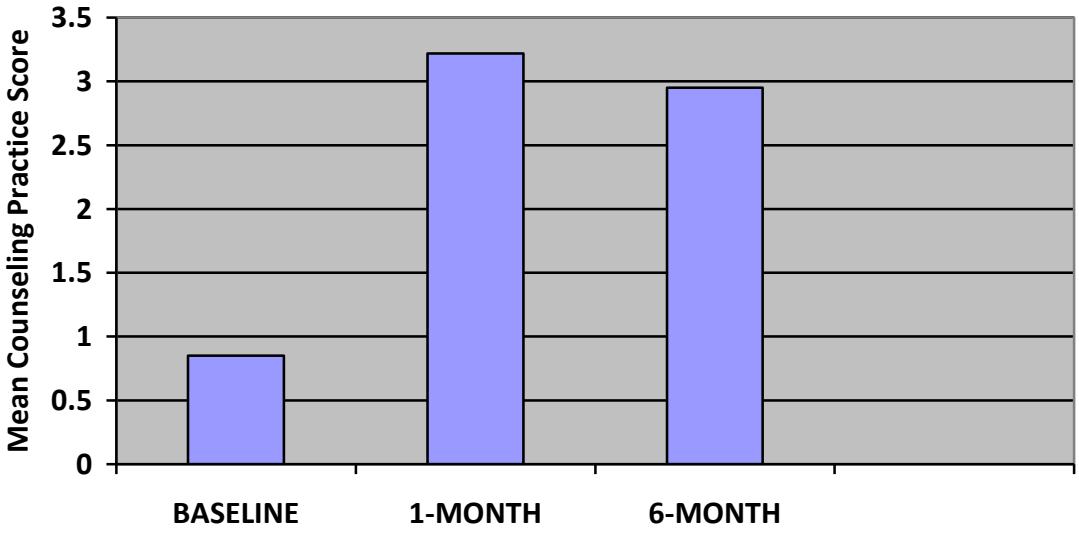


Figure 10. Showing Mean Medication Counselling Practice Score at baseline and at different post intervention stages.

5.0 DISCUSSION

5.1 Nature, Extent and Adequacy of Medication Counselling Practice in Community Pharmacies:

The results of this study reveal that most (63%) of the pharmacists did not ask any question before offering the drug for sale. Sigrist (2002) observed the same practice in an observational study in Switzerland. The study indicated that, direct sale, which refers to a sale without discussion except to mention the price of the product was a common practice for non-prescription drugs. Asking appropriate questions provides the opportunity to interpret patients' symptoms and determine appropriateness of self-medication. When a non-prescription medicine is requested by name in a pharmacy, it should not be assumed that the enquirer has adequate knowledge of the medicinal product. This is expedient especially in Nigeria with less than optimal regulatory control of advertisement/promotion. The populace is exposed to drugs advert through - billboards, print or electronic media- without an opportunity to ask questions. Community pharmacists should bear this constraint in mind and be willing to ask appropriate questions, and give counsel at every available opportunity.

The results also show that 90% of community pharmacists did not provide adequate medication information following sale of the medicine. Noeh et al (2010) reported similar findings in Malaysia. Provision of adequate medication information is required to engender safe and appropriate use of medicine. Insufficient medication information carries a risk of harm to the patient. Murray (2007) reported that patients who lack adequate information about their medications are more likely to experience treatment failures due to poor compliance, medication errors, and adverse events. If community pharmacists provide adequate medication information to patients, it will go a long way to engender patient

adherence, prevent medication error, and position community pharmacist as promoter of public health.

5.2 Factors affecting Medication Counselling Practice:

5.2.1. Pharmacy characteristics

The results of the observational study (simulated client) produced two significant findings; firstly, workload in the pharmacy (number of clients seen daily) and time of access were both found to be predictors of the extent of medication counselling. This result is similar to that of Tully *et al* (2010), who found that workload in the pharmacy predicted poor counselling practice in Swedish community pharmacies. Workload in the pharmacy is one of the most frequently cited environmental factors influencing medication counselling practice (De Young 1996). Secondly, no significant relationship was found between location of pharmacy and medication counselling practice. This result is contrary to that obtained by Goel *et al* (1996a), who found that location of a community pharmacy in a rural area or in low-income urban neighborhood in Kenya was associated with suboptimal medication counselling practice. The probable factors responsible for this observation is that rural pharmacies practice in a professionally isolated environment , and also that they may be less active in organizing continuing education programs. The interpretation of the influence of location on medication counselling should be done with caution, since there are other secondary factors associated with various types of locations. The result obtained in this study may be due to the fact that previous classification of Rural /Urban has been overtaken by progressive development over time. This assumption is consistent with recent description of Lagos State as majorly urban (Lagos State Government official website). The present work however could provide a baseline data for regulatory authorities in planning intervention strategies.

5.2.2. Pharmacists' characteristics

It is disturbing that majority (77%) of community pharmacists do not possess adequate knowledge to give adequate counsel following sale of the medication. Adequate knowledge is an important determinant of quality practice (Kroeger *et al*., 2001). A deficient knowledge base adversely affects quality of practice. A deficiency in pharmacists' knowledge could account for the high percentage of inadequate counselling practice reported in this study. This corroborate Kroeger *et al* (2001) and Nasir *et al* (2011) who both reported that lack of adequate knowledge is a contributing factor to poor advice offered by drug sellers. No relationship was found between knowledge of pharmacists and their educational qualification, years of experience, and pharmacists' status; p=0.561, 0.644, and 0.923 respectively. This result indicates an urgent need to address this deficiency.

5.2.3. Regulatory framework on medication counselling

The result obtained from evaluation of regulatory framework on medication counselling practice shows that key elements of an effective framework for regulating medication counselling practice in community pharmacy are missing. There seems to be little effort to address key important aspects of regulation that will guarantee control of medication counselling practice in community pharmacies in Nigeria. For instance, two of the publications (Code of Ethics for Pharmacists and PCN Act 1992) noted that pharmacists should provide counselling for clients visiting their pharmacies, and also listed what counselling information to provide, it however did not make any distinction between what should be the amount and extent of information to provide for various categories of medicines (vis-à-vis prescription medicine, refill or OTC). Information on liability for not

providing medication counselling was not mentioned in any of the publications. This result shows that regulation is weak and may be a potential factor influencing counselling practice.

Generally speaking, regulation is the basic device employed by most governments in both developed and developing countries to modify the behavior of drug system (Quick *et al*, 2011). If patient counselling is mandated by law, it creates norms and standards for counselling practices (Puumaleinen *et al*, 2008).

The result of this study should serve as evidence for action by relevant pharmacy regulatory authorities and other stakeholders involved in regulation or control of community pharmacy practice. There is an urgent need to take a pragmatic step towards developing a regulatory framework that would guide medication counselling practice in community pharmacies in Nigeria. This will go a long way to improve the practice.

5.2.4. Pharmacists' opinion on barriers to medication counselling and strategies that can be used to improve counselling.

Pharmacists' self-report also identified workload in the pharmacy as the topmost barrier to medication counselling practice in community pharmacy. This result is consistent with that obtained in the observational study (simulated client study) and may suggest the real threat of workload to adequate medication counselling practice. Pharmacists also viewed lack of medication counselling aids as one of the barriers influencing medication counselling practice. This finding underscores the importance of having consensus guidelines on medication counselling for specific disease conditions or for drugs that are frequently purchased from community pharmacies. For example, malaria is a major public health issue and artemether-lumefantrine has been adopted by Nigeria as the drug of choice for treating it.

Having a consensus guideline on how to counsel patients presenting with symptoms of malaria or self medicating with antimalarial will go a long way to assist community pharmacists in meeting their professional obligation of providing adequate counselling to their clients. Professional organizations like Pharmaceutical Society of Nigeria (PSN) and Association of Community Pharmacists of Nigeria (ACPN) must take up this challenge of collaborating with pharmacists in academia to develop medication counselling aids that will help community pharmacists to improve on their counselling responsibility.

Pharmacists suggested practical training on medication counselling, provision of counselling area and availability of drug specific counselling guide/aid as strategies that can be used to improve medication counselling practice. Again, this shows consistency in what pharmacists cited as barriers and what they also think will be the strategies to improve medication counselling practice in community pharmacies, especially with respect to the availability of counselling guide / aids. This study being the first to obtain perspective of community pharmacists in Nigeria on barriers to medication counselling and strategies to improve it will provide a baseline data for action for all relevant stakeholders. The call for practical training on medication counselling by community pharmacists is an important issue that should be considered by pharmacy regulatory and professional bodies concerned with the basic and mandatory continuing education of pharmacists. There is a need to establish procedures for development, dissemination, utilization and revision of (community pharmacy specific) standard treatment guidelines/best practice guidelines. This will enhance community pharmacists' confidence in providing medication counselling to their clients. Grimshaw and Russel (1993) reported that the use of standard treatment guideline (STGs), clinical policies, treatment protocols or best-practice guidelines, structured approaches to diagnosis & therapy, all have considerable potentials to promote rational drug use.

5.3. Readability of medication information leaflets (drug insert).

Result obtained shows that majority of the medication information leaflet could only be read by persons with tertiary education. This is quite challenging and portends a great danger to public health. According to the 1996 census, a greater percentage of Nigerians were reported to have secondary school education as their highest educational qualification, implying that only a smaller percentage of the population will find the medicine information leaflets useful.

Medicine information leaflet is a major source of information on medicine for the client who may have no other source of information. Patients who can read medicines information leaflets generally have improved awareness of medication use, are more likely to be completely satisfied with their treatment, know the name of their medicine, and are more aware of the possible adverse drug reactions (Wiederholt *et al*., 1983). Medicine Information leaflets have also been shown to improve compliance of short term antibiotic treatment (George *et al*., 1983). Therefore, it is mandatory that it be client friendly. In a situation such as found in this study, the public may be at a preventive and unnecessary risk.

Regulatory bodies like NAFDAC will need to come up with guidelines on the standards expected of medicine information leaflets in order to safeguard the health of the citizens.

5.4. Educational Intervention to Improve Medication Counselling Practice.

The result of the intervention study shows that educational intervention can improve medication counselling practice. There was a significant improvement in practice at 1 month and 6 month post intervention. No significant difference was seen between the practice score at 1 and 6 month. This result is consistent with that obtained by Ross-Degnan *et al* (1996).

A few issues are highlighted from this work: Post intervention practice score shows that some of the pharmacies did not provide adequate counselling even though there was a significant difference between the practice score at baseline and at post intervention. This may suggest that improving knowledge and skill of practitioners alone may not be sufficient to permanently change behavior. A multi-interventional approach that incorporates educational intervention with enactment and enforcement of regulation on medication counselling could achieve a sustainable improvement in quality of medication counselling offered in community pharmacies. This position is consistent with the result obtained by Svastard *et al*.,(2004) and Chuc *et al*., (2002) , who observed that use of multidimensional interventional approach led to an increase in quality of service offered by private pharmacies.

The inability to use a control group may also limit the possibility of ascertaining that the effect produced after the intervention was absolutely due to the educational intervention.

6.0: CONCLUSION AND RECOMMENDATIONS

6.1. CONCLUSION

The following can be concluded from this study;

- Medication counselling offered by community pharmacists is inadequate, limited in nature and extent.

- Workload in the pharmacy is a predictor of extent of medication counselling offered by community pharmacists.

- Pharmacists' knowledge of medication information is inadequate.

- Regulatory framework on medication counselling is weak, lacking essential elements of quality regulatory framework.

- Medication information leaflets dispensed from community pharmacies can only be comprehended by individuals with tertiary education.

- Training of pharmacists in a workshop followed with on-site practical demonstration can improve medication counselling practice.

6.2. RECOMMENDATIONS

The following are recommended :

- Pharmacy organization must seek for ways to improve medication counselling in the community pharmacies.

- Individual pharmacist and pharmacy organizations must develop strategies to reduce workload in the pharmacy so as to improve medication counselling practice. Practical suggestions include automation of dispensing process, stock management and labelling.
- Pharmacists' continuing education program must be reviewed and made more relevant.

- Pharmacy regulatory bodies must urgently review laws and guidelines on pharmacy practice to incorporate regulatory framework on counselling.

- Pharmacists in academia can collaborate with those in practice to produce medication counselling guidelines.

- Training of pharmacists in a workshop in addition to on-site practical demonstration can be used to improve both knowledge and practice of medication counselling.

7.0. CONTRIBUTIONS TO KNOWLEDGE

This study:

1. Developed a set of ‘rapid assessment medication counselling indicators’: an instrument that can be used for rapid assessment of professional service offered in community pharmacies.

2. Established the basis for review of pharmacy laws and regulations guiding medication counselling practice in community pharmacies.

3. Indicated deficiency in community pharmacists’ knowledge and practice of medication counselling: An important basis for review of both basic and continuous pharmacy education.

REFERENCES

Adepu, R., and Nagavi, B. G. (2009). Attitude and behaviours of practicing community pharmacists towards patient counselling. *Indian Journal of Pharmaceutical Sciences,* **71**(3): 285-289.

Ajayi, I. O., Falade., C. O. and Bamgboye, E. A. (2008). Assesment of a treatment guideline to improve home management of malaria in children in rural south-west Nigeria. *Malaria Journal,* **7:**24-32.

Angunawela, I. I., Diwan, V. K. and Tomson, G. (1991). Experimental evaluation of the effect of drug information on antibiotic prescribing: a study in out-patient care in an area in Sri Lanka. *International Journal of Epidemiology*, **20:** 558-564.

Araoye, M.O. (2003). Sample size determination in Araoye, M. O (Eds) Text Books of Research Methodology with Statistics for Health and Social Scientists, Nathadex, Ilorin-Nigeria, pp. 117-120.

Aslanpour Z, and Smith, F. J (1997). Oral counselling on dispensed medication: a survey of its extent and associated factors in a random sample of community pharmacies. *International Journal of Pharmacy Practice*, **5**:57–63.

Auta, A., Shalker, D., Dayam, D. W. and Banwat, S. (2011). Readability of over-the-counter medicine information leaflets in Nigeria. *International Journal of Pharmaceutical frontier Research,* July-Sep, **1**(2): 61-67.

Barnes, J. M., Riedlinger, J. E., McCloskey, W. W. and Montagne M. (1996). Barriers to compliance with OBRA´90 regulations in community pharmacies. *Annals of Pharmacotherapy*, **30**:1101–1105.

Barnett, C. W., Nykamp, D. and Ellington, A. M. (2000). Patient guided counselling in the community pharmacy setting. *Journal of American Pharmacists Association*, **40**, 765-772.

Berger K, Eickhoff C, and Schulz M (2005). Counselling quality in community pharmacies: implementation of the pseudo customer methodology in Germany. *Journal of Clinical Pharmacy and Therapeutics*, **30**:45–57.

Beullens, J., Rethams, J. J., Goedhuys, J., and Buntinx, F. (1997). The use of standardized patients in research in general practice. *Family Practice*, **14**: 58-62.

Bexell, A., Lwando, E., Tembo, S., von Hofsen, B. and Diwan, V. Does information improve prescribing practice and patient management in primary health care? Report from an intervention study carried out in 16 health centres in Lusaka, Zambia. In: East and Central African Regional Essential Drugs Programme Training Project, 1991-1994.

Blenkinsopp, A., Panton, R. and Anderson C. (1999). Health promotion for pharmacists. 2nd edition. University Press, Oxford.

Cantrill, J. A., Sibbald, B. and Buetow, S. (1996). The Delphi and nominal group techniques in health services research. *International Journal of Pharmacy Practice*, **4**:67–74.

Chalker, J., Chue, N. T. K., and Falkenberg, H. (2000). STD management by private pharmacies in Hanoi: practice and knowledge of drug sellers. *Sexually Transmitted Infection Journal,* **76**, 299-302.

Chalker, J., Ratanawijitrasin, S., Chuk, N. T. K., Petzold, M. and Tomson, G. (2005). Effectiveness of a multi-component intervention on dispensing practices at private pharmacies in Vietnam and Thailand- a randomized controlled trial. *Social Science & Medicine*, **60**, 131-141.

Chuc, N. T. K., Larsson, M., Do, N. T., Diwan, V. K., and Tomson, G. B. (2002). Improving private pharmacy practice: A multi-intervention experiment in Hanoi, Vietnam. *Journal of Clinical Epidemiology***, 55**, 1148-1155.

Couris, R. B., Tataronis, G. R., Dallal, G. E. and Blumberg, J. (2000). Assesment of Healthcare Professionals' knowledge about Warfarin-Vitamin K Drug-Nutrient Interactions. *Journal of the American College of Nutrition*, **19**(4) ,439-445.

Cranor, C. W. & Christensen, D. B. (2003). The Asheville Project:short-term outcomes of a community pharmacy diabetes care program. Journal of American Pharmacy Association, **43**(2):149-159

De Almeida Neto, A. C., Kelly, F. and Benrimoj, S. I. (2001). Shaping practice behaviour: novel training methodology. *International Journal of Pharmacy Practice*, **9**:203–210.

De Young, M., (1996). A review of the research on pharmacists'- patient communication-views and practices. *American Journal of Pharmaceutical Education*, **60**:60-76.

Deschamps, M., Dyck, A., & Taylor, J. (2003). What are we saying? Content and organization of patient counselling by community pharmacists. *Canadian Pharmaceutical Journal*, **136**(6), 42-47.

Eniojukan, J. F. and Adeniyi, A. (1997). Community Pharmacists and primary health care programme. *Nigerian Journal of Pharmacy*, **28** (2): 21-24.

Erhun, W .O. (2002). Management of sexually transmitted diseases in retail drug outlets in Nigeria. *Journal of Social and Administrative Pharmacy*, **19**:145-150.

Erhun, W. O., and Osagie, A. (2004). Management of malaria by medicine retailers in a Nigerian urban community. *Journal of Health & Population in Developing Countries*, **8**:1-6.

Erhun, W. O., Babalola, O. O. and Erhun, M. O. (2001). Drug regulation and control in Nigeria:The challenge of counterfeit drugs. *Journal of Health & Population in Developing Countries.* **4**(2):23-24.

Erickson, S. R., Kirking, D. M. and Sandusky M. (1998). Michigan Medicaid recipients' perceptions of medication counselling as required by OBRA´90. *Journal of American Pharmaceutical Association* **38**:333–338.

Evans, S., and John, D. (1995). A preliminary investigation of the interactions between UK and US community pharmacists and their prescription clients. *International Journal Pharmacy Practice*, **3:** 157-162.

Finn, A., and Kayande, U. (1999). Unmasking a phantom: a psychometric assessment of mystery shopping. *Journal of Retailing***, 75**: 195-217.

FIP (1998). Good Pharmacy Practice in Developing Countries. Recommendation for Stepwise Implementation. Report of a working group. The Hague. International Pharmaceutical Federation. Available at www.fip.org. Accessed Oct 2009.

Flesch, R. (1948). A new readability yardstick. *Journal of Applied Psychology*, **32**: 221-233.

Flynn, E. A., and Barker, H. (2000). Medication Errors Research. In: Cohen M, ed., Medication Errors: Causes, Prevention and Risk Management. American Pharmacists Association, Jones and Barlett, Boston, MA, p. 61-63.

FMOH (2006). Federal Ministry of Health , Nigeria. The pattern of transmission of malaria in Nigeria. Revised National Health Policy. Available from Federal Ministry of Health , Abuja . Nigeria.

Fry, E. (1967). A readability formula that saves time. *Journal of Reading*, **11**: 513-516.

Gandhi, T. K., Weingner, S. N. and Borus, J. (2003). Adverse drug events in ambulatory care. *New England Journal of Medicine*. **348** (16):1556-1564.

Garner, M., Ning, Z. and Francis, J. (2011). A framework for the evaluation of patient information leaflets. Health Expectations. Blackwell publishing Ltd.

Goel, P. K., Ross-Degnan, D., McLaughlin, T. J and Soumerai, S. B. (1996a). Influence of location and staff knowledge on quality of community pharmacy prescribing for childhood diarrhea in kenya. *International Journal for Quality in Health Care*, **8**(6):519-526.

Goel, P., Ross-Degnan, D., Berman, P. and Soumerai, S. (1996b). Community pharmacies in developing countries: a behavior and intervention framework. *Social Science & Medicine,* **42**:1155-1161.

Goodburn E, Mattosinho S, Mongi P and Waterston T (1991). Management of childhood diarrhoea by pharmacists and parents: Is Britain lagging behind the Third World? *British Medical Journal*, **302**:440–443.

Grand Le, A., Hogerzeil, H. V., and Ruskamp-Haaijer, F. M. (1999). Intervention research in rational use of drugs: a review. *Health Policy and Planning*, **14**(2), 89-102.

Grimshaw, J. M. and Russel, I. T. (1993). Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet*, **342**: 1317-1322.

Gunning, R. (1968). The FOG index after twenty years. *Journal of Business Communication*, **6:** 3-13.

Hall, J. A., Rooter, D. L., and Katz, N. R. (1988). Meta-analysis of correlates of provider behaviour in medical encounters. *Medical Care*, **26:** 657-675.

Handon, A. (1991). Confronting ill health: Medicines, self-care, and the poor in Manila. Quezon City; Philippines: Health Action International.

Health Action International. Educational tools and activities to enhance a rational use of drugs. Amsterdam, 1991. Working documents.

Herman, C., and Rodowskas, C. (1974). The development and testing of a methodology to measure the attitudes of pharmacists towards clinical pharmacy. *Drug Intelligence and Clinical Pharmacy*, **8**, 238-241.

Herrier, R. N., and Boyce, R. W. (1995). Does counselling improve compliance? *Journal of American Pharmacists Association,* **35**: 11-20.

Holland R. (1992). Voluntary continuing professional education and patient counselling in Australia. *American Journal of Pharmaceutical Education*, **56**:363–367.

Hopper, E. M., Comstock, L. M., & Goodwin, J. M. (1982). Patient characteristics that influence physician behaviour. *Medical Care*, **20**: 630.

Igun, U. A. (1994). Reported and actual prescription of rehydration therapy for childhood diarrhea by community pharmacists in Nigeria. *Social Sciences & Medicines*, **39**:797-806.

Jackson, R., and Huffman Jr. D. (1990). Patient compliance: The financial impact on your practice. *National Association of Retail Druggist Journal,* **112** (7): 67-71.

Johnson, J. A., & Bootman, J. L. (1995). Drug –related morbidity and mortality: A cost of illness model. *Archives of Internal Medicines*, **155**, 1949-1956.

Johnson, J. A. and Bootman, J. L. (1997). Drug related morbidity and mortality and the economic impact of pharmaceutical care. *American Journal of Health System Pharmacists*, **54**:554-558.

Jones, J., and Hunter D. (1995). Qualitative Research: Consensus methods for medical and health services research. *British Medical Journal*, **311**:376–380.

Kansanaho, H., Pietilä, K., and Airaksinen, M. (2003). Can a long-term continuing education course in patient counselling promote a change in the practice of Finnish community pharmacists? *International Journal of Pharmacy Practice,* **11**:153–160.

Katajavuori, N. M., Valtonen, S. P., and Pietila, K. M. (2002). Myths behind patient counselling: A Patient Counselling Study of Non-presciption Medicines in Finland. *Journal of Social and Administrative Pharmacy*, **19** (4): 129-135.

Kessler, D. (1992). A challenge for American Pharmacists. *Annals of Pharmacotherapy*, **32** (1): 33-36.

Kincaid, J. P., Fishburne, R. P., Rogers, R. I. and Chissom, B. S. (1975). Derivation of New Readability Formula for Navy Enlisted Personnel. Millington, TN: Navy Research Branch.

Kirking, D. (1982). Evaluation of an explanatory model of pharmacists' patient counselling activities. *Journal of Social & Administrative Pharmacy***, 2:**50-56.

Knapp, D. A., Wolf, H., Knapp, D. E. and Rudy, T. A. (1969) The pharmacist as drug advisor**, 9:**502.

Kroeger, A., Ochoa, H., Arana, B., Diaz, A., Rizzo, N. and Flores, W. (2001). Inadequate drug advice in the pharmacies of Guatemala and Mexico: the scale of the problem and explanatory factors. *Annals of Tropical Medicine & Parasitology*, **95** (6) :605-616.

Krska, J., Greenwood, R. and Howitt, E. P. (1994). Audit of advice provided in response to symptoms. *Pharmacy Journal*, **252**:93– 96.

Lagos State Goverments' official website. Avalaible at http://www.lagosstate.gov.ng/index. Accessed 2011.

Lamsam, G. D., and Kropff, M. A. (1998). Community pharmacists' assessments and recommendations for treatment in four case scenarios. *Annals of Pharmacotherapy*, **32**:409–416.

Laurier, C., Archambaull, A. and Contandriopoulos. (1989). Communication of verbal information by community pharmacists. *Annals of Pharmacotherapy***, 23**, 862-868.

Leape, L. L. (2000). A Systems Analysis Approach to Medical Error. In: Cohen, M. (ed)., Medication Errors: Causes, Prevention and Risk Management. American Pharmacists Association, Jones and Bartlett, Boston, MA. P.2.1-2.10.

Lee, A. J., Borham, A., Korman, N. E., Keeney, B. E. and Mock, D. E. (1998). Staff development in pharmacists-conducted patient education and counselling. *American Journal of Health System Pharmacists* **,55**:1792–1798.

Lipton, H. L., and Lee, P. R. (1988). Drugs and the Elderly: Clinical, Social and Policy Perspective. Stanford University press, Stanford.

Luck, J., and Peabody, J. W. (2002). Using standardised patients to measure physicians' practice: Validation study using audio recordings. *British Medical Journal*, **325**:679–683.

Lyons, R. F., Rumore, M. M. and Merola, M. R. (1996). An analysis of drug information desired by the patient (Are patients being told everything they wish to know under OBRA´90?) *Journal of Clinical Pharmacy and Therapeutics*, **21**:221–228.

Lyszkiewicz, D., Gerichhausen, S., Björnsdottir, I., Einarson, T., Koren, G. and Einarson, A. (2001). Evidence based information on drug use during pregnancy: a survey of community pharmacists in three countries. *Pharmacy World and Science,* **23**:76–81.

Mason, H. L. and Svarstad, B. L. (1984). Medication counselling behaviours and attitudes of rural community pharmacists. *Drug Intelligence and Clinical Pharmacology*. **18**:409-414.

McLaughlin, H. G. (1969). SMOG grading : a new readability formula. *Journal of Reading*, **12:** 639-646.

Melissa, M. D. (2010) Patient counselling: A Pharmacist in every OTC Aisle. *US Pharmacist*, **35**(4): (OTC Trend Suppl):9-12.

Morison, L. J., Colman, A. M,. and Preston, C. C. (1997). Mystery customer research: cognitive processes affecting accuracy. *Journal of Market Research Sociology*, **39**:349-355.

Murray, M. D. (2007). Medication Instruction by pharmacists: Making good on an offer. *New England Journal of Medicine,* **68**(5):343-345.

Nasir, T. W., Raju, N. J. and Angamo, M. T. (2011). Knowledge, attitude and practice of patient medication counselling among drug dispensers in North West Ethiopia. *Journal of Applied Pharmaceutical Science,* **1**(7):85-90.

Neoh, C. F., Hassali, M. A., Shafie, A. A. and Awaisu, A. (2010). Nature and adequacy of information on dispensed medications delivered to patients in community pharmacies: a pilot study from Penang, Malaysia. *Journal of Pharmaceutical Health Services Research,* **24**: 56-74.

Newton G. (1991). Pharmaceutical education and the translation of pharmaceutical care into practice. *American Journal of Pharmacy Education*, **55**:339–344.

O'Donnell, D., Brown, C. M., & Dastani, H. B. (2006). Barriers to counselling patiemts with obesity: A Study of Texas Community Pharmacists. *Journal of American Pharmacists Association,* **46**(4) 465-471.

Odedina, F. K., Segal, R. and Hepler, C. D. (1995). Providing pharmaceutical care in community practice: differences between providers and non-providers of pharmaceutical care. *Journal of Social and Administrative Pharmacy,* **12**:170–180.

Okeke, T. A. and Uzochukwu, B. (2009). Improving childhood malaria treatment and referral practices by training patent medicine vendors in rural south-east , Nigeria. *Malaria Journal*, **8**: 260-268.

Oladipo, O. B, and Lamikanra, A.(2002). Patterns of antibiotic purchases in community pharmacies in south western, Nigeria. *Journal of Social and Administrative Pharmacy*, **19**:33-38.

Oparah, A. C, Enato, E. F. O, and Odili U. V. (2002). Activities of community pharmacy counter staff in Benin City, Nigeria. *Journal of Social and Administrative Pharmacy*, **19**:141-144.

Oparah, A. C., and Arigbe-Osula, E. M. (2002). Evaluation of community pharmacists' involvement in primary health care. *Tropical Journal of Pharmacy Research*, **1**:67-74.

Oreagba, I. A., Ashorobi, R. B., Olayemi, S.O., Oparah, C. A. and Awodele, O. (2007). Case management of children with malaria in a Nigerian community. *International Journal of Pharmacy of Pharmacy Practice*, **15**:1-3.

Ortiz, M., Walker, W. L. and Thomas, R (1998). Comparisons between methods of assessing patient counselling in Australian community pharmacies. *Journal of Social Administration and Pharmacy*, **6**:39–48.

Oshikoya, K. A., Njokanma, O. F., Bello, J. A. and Ayorinde, E. O. (2007). Family self-medication for children in an urban area of Nigeria. *Paediatric and Perinatal Drug Therapy*, **8**(3):124-130.

Pilnick, A. (2003). "Patient counselling" by pharmacists: four approaches to the delivery of counselling sequences and their interactional reception. *Social Science and Medicine* **56**:835–849.

Podhipak, A., Varavithya, W., Punyaratabandhu, P., Vathanophas, K., and Sangchai, R. (1993). Impact of an educational program on the treatment practices of diarrhoeal diseases amoung pharmacists and drug sellers. *South Asian Journal Of Tropical Medicine and Public Health*, **24**, 32-39.

Puckett, F. J., White, S. J., Mossberg, H. E. and Matchett, J. A. (1978). Pharmacist-patient counselling practices. *Contemporary Pharmacy Practice***, 5**:67–71.

Pugh, C. B. (1995). Pre-OBRA `90 Medicaid survey: How community pharmacy practice is changing. *Annals of Pharmacotherapy*, NS**35**:17–23.

Puumalainen, I. I., Peura, S. H. and Kansanaho, H. M. (2008). Progress in patient counselling practices in Finnish community pharmacies. *International Journal of Pharmacy Practice.* **13**:145-151.

Quick, J. D., Laing, R. O. and Ross-Degnan, D (1991). Intervention research to promote clinically effective and economically efficient use of pharmaceuticals. International Network for Rational Use of Drugs. *Social Science and Medicine*, **35**:1329-1341.

Quick, J. D., Rankin, J. R., Laing, R. O., O'Connor, R. W., Hogerzeil, H. V., Dukes, M. N G. and Garnett, A. (eds.) (2011). Managing Drug Supply. 4th edition. Connecticut, USA, Kumarian Press.

Rantucci, M. (1991). Patient counselling, How to make it happen in your pharmacy. *Australian Pharmacist*, **15**. 163-167.

Raynor, D. K. (1996). Time to redefine "counselling"? *International Journal of Pharmacy Practice*, **4**:185–186.

Roberts, A., Benrimoj, S. I., Chen, T., Williams, K. and Aslani, P. (2003). An investigation into business and professional facilitators to change for the pharmacy profession in light of the third Guild/Government Agreement.Pharmacy Practice Research, Faculty of Pharmacy, University of Sydney.

Roger, J., Richard, G., & Nicky B (ed) (2004). Oxford Textbook of Primary Medical Care, 1, 113.

Roosmalen, J. V. (1986). Effectiveness of seminars in training rural health workers. *Tropical Doctor*, **16**: 90-92.

Rooter, D. L., Hall, J. A., and Merisca, R. (1998). Effectiveness of interventions to improve patient compliance: A meta-analysis. *Medical Care*, **36,** 1138-1161.

Ross-Degnan, D., Soumerai, S. B., and Goel, P. (1996). The impact of face-to-face educational outreach on diarrhea treatment in pharmacies. *Health Policy and Planning,* **11**:308-318.

Rouse, M. J. (2004). Continuing professional development in pharmacy. *American Journal of Health-System Pharmacists,* **61**:2069-2076.

Rowles, B., Keller, S.M. and Gavin, P. W. (1974). The pharmacist as compounder and consultant – a 100 pharmacy study. *Drug Intelligence and Clinical Pharmacy***, 8:**242–244.

Rumore, M. M., Feifer, S. and Rumore, J. S. (1995). New York City pharmacists and OBRA ´90: One year later. *Annals of Pharmacotherapy*, **35**:29–34.

Saini, B., Smith, L., and Carol, A. (2006). An Educational Intervention to train community pharmacists in providing specialised Asthma care. *American Journal f Pharmaceutical Education,* **70**(5):Article 118.

Santoso, B., Suryawati, S., and Prawitasari, J. E. (1996). Small group intervention versus formal seminar for improving appropriate drug use. *Social Science and Medicine*, **42** (8): 1163-8.

Schatz, R., Belloto, R. J Jr., White, D. B. and Bachmann, K. (2003). Provision of drug information to patients by pharmacists: the impact of the Omnibus Budget reconciliation Act of 1990 a decade later. *American Journal of Therapeutics*, **10**:93–103.

Schommer, J. C. (1994). Ohio pharmacists' conceptual views and experiences regarding patient counselling. *Drug Information Journal*, **28**:765-775.

Schommer, J. C. and Wiederholt, J. B. (1994). Pharmacists' perceptions of patients' need for counselling. *American Journal of Hospital Pharmacists*, **51**(4): 478-485.

Shah, B., and Chewning, B. (2006). Conceptualizing and measuring pharmacist-patient communication: a review of published studies. *Research in Social & Administrative Pharmacy*, **2:**153-185.

Shrestha, A., Kane, T., and Hamal, H.(1990). Contraceptive social marketing in Nepal: Consumer and retailer knowledge, needs and experience. *Journal of Biosocial Science*, **22**: 305-312.

Sirgrist, T (2002). Changing pharmacists' and pharmacists' practice in dealing with direct request for non-prescription analgesics. *International Journal of Pharmacy Practice*, **10**:23-29.

Smith, F. (2002). Research methods in pharmacy practice. First edition. The Pharmaceutical Press, London 2002.

Smith, F. (2009). Private local pharmacies in low- and middle-income countries: a review of interventions to enhance their role in public health. *Tropical Medicine and international Health,***14**(3):362-372.

Spencer, E. (1974). The attitudes of ambulatory patients toward a hospital-based pharmacy service: The patient as consultant. *Drug Intelligence & Clinical Pharmacy,* **8,**710-716.

Stenson, B., Syhakhang, L., and Lundborg, C. S (2001). Private pharmacy practice and regulation: A randomised trial in Lao PDR. *International Journal of Technology Assessment in Health Care,* **17,** 579-589.

Sukkary, S. (1993). The role of the pharmacists in basic health care in Egypt- a micro view. In an overview of Pharmacies, Pharmacists and the Pharmaceutical Distribution System in Egypt [Edited by Cole, H. E, Smith, R. H., & Sukkary, S] Mimeo. Futures Group, Washington, DC.

Sullivan, S. D., Kreling, D. H., and Hazlet, T. K. (1990). Noncompliance with medication regimens and subsequent hospitalization : A literature analysis and cost of hospitalization estimates. *Journal of Research in Pharmaceutical Economics*, **2** (2): 19-34.

Svarstad, B. L., Bultman, D. C. and Mount, J. K. (2004). Patient counselling provided in community pharmacies: Effect of state regulation, pharmacist age, and busyness. *Journal of American Pharmacy Association*, **44**(1):22-29.

The Association of Finnish Pharmacies: Guidelines for Professional Community Pharmacy. Helsinki 1997.

Tully, M. P., Gyllenstrand-Beckman, A. and Bernsten , C. B. (2010). Factors predicting poor counselling about prescription medicines in Swedish community pharmacies. *Patient Education and Counselling*, **18** (1);3-6.

USP (2004). United States Pharmacopeia (USP) Medication Counselling Behaviour Guidelines. Accessed: http://www.usp.org, June 4, 2009.

Vainio, K. (2004). Developing patient counselling in Finnish community pharmacies. Kuopio University Publications A. Pharmaceutical Sciences 78. University of Kuopio.

Vanderveen, R. L., Adams, C. and Sandborn, M. (1978). The pharmacist as drug consultant - five years later. *Drug Intelligence and Clinical Pharmacy*, **12:**718–719.

Vanderveen, R. L and Jirak, J. L. (1990). The pharmacist as health consultant – ten years later. *Annals of Pharmacotherapy*, **24**:833–836.

Ward, P. R., Bissell, P. and Noyce, P. R. (2000) Appropriateness measurement:application to advice-giving in community pharmacies. *Social Science & Medicine*, **51** (3):343-59.

Watson, M. C, Bond, C. M., Grimshaw, J. M., Mollison, J., Ludbrook, A., and Walker, A .E. (2002). Educational strategies to promote evidence-based community pharmacy practice: a cluster randomized controlled trial (RCT). *Family Practice*, **19**:529–536.

Watson, M. C., Skelton, J. R., Bond, C. M., Croft, P., Wiskin, C. M., Grimshaw, J. M. and Mollison J (2004). Simulated patients in the community pharmacy setting. Using simulated patients to measure practice in the community pharmacy setting. *Pharmacy World and Science*. **26**:32–37, 2004.

Werner, J. B., and Benrimoj, S. I. (2008). Audio taping simulated patient encounters in community pharmacy to enhance the reliability of assessments. *American Journal of Pharmaceutical Education*, **72** (6): Article 136.

Wertheimer, A. I., Shefter, E, & Cooper, R.M. (1973). More on the pharmacist as a drug consultant: three case studies.*Drug Intelligence & Clinical Pharmacy Journal***, 7** : 58-61.

WHO, (1994). World Health Organization Action Programme on Essential Drugs. Guide to good prescribing. WHO/DAP/94.11.

WHO, (1997). World Health Organization. Public education in rational drug use. WHO/DAP/97.5. Geneva.

WHO, (2007a). World Health Organization. The role of pharmacists in health care systems. Report of a WHO Consultative Group, New Delhi, India. 2007.

WHO, (2007b). World Health Organization Fact Sheet. Available at: www.who.int.org. Accessed Dec 2009.

Wiederholt, J. B., Clarridge, B. R. & Svarstad, B. L. (1992). Verbal consultation regarding prescription drugs: Findings from a statewide study. *Medical Care*, **28:**765-775.

Willison, D. J. and Muzzin, L. J. (1995). Workload, data gathering, and quality of community pharmacists' advice. *Medical Care*, **33**:29–40.

Wilson, A. M. (2001). Mystery shopping: Using deception to measure service performance. *Psychology and Marketing*, **18**:721–734.

Appendix I

Simulated Client Scenario

- ❖ The simulated client; an adult of 18-25years of age enters the pharmacy,ask to see the pharmacist. He/She then request for a pack of Artemether – lumefantrine tablet .
- ❖ The simulated client will take note mentally of the following;
- Any question(s) asked by the pharmacist.
- Any advice on how to take the medication including dosage (number of tablets), frequency, (how often) and duration (how long).
- Any advice on precautions like before or after food.
- Advice on adherence : Ensure you complete your medication,
- and any other advice giving by the pharmacist.
- ❖ The simulated clients will also take note of the following; number of client(s) waiting to be attended to; number of staff on duty; estimated duration of interaction and time of visit.
- ❖ The simulated client will accept the product and pay for it if offered for sale.
- ❖ After leaving the pharmacy, the simulated client will complete the Observer Report Form .

Appendix II

OBSERVER REPORT FORM

1.NAME OF PHARMACY_____

2.LGA_____

3.Were you asked question(s) during counselling ?: Yes_____ No_____

4. If answer to question 3 is Yes, state the question(s) below

_____

_____

5.Were you given advice on;

(i) Dosage : Yes_____ No_____

(ii) Frequency: Yes_____ No_____

(iii) Duration : Yes_____ No_____

(iv) Take immediately after fatty food Yes_____ No_____

(v) Ensure you complete your medication Yes_____ No_____

6. Any other advice different from the 5 items listed in 5 above? if Yes, outline below:

_____

7. Estimated duration of interaction in minutes _____

8. Number of clients in the pharmacy waiting area _____

9. Number of staff on duty _____

10. Time of the day in which pharmacy was visited _____

11. Is there a designated counselling area in this pharmacy _____

12. Were you offered privacy during counselling _____

APPENDIX III

COMMUNITY PHARMACISTS QUESTIONNAIRE

PHARMACIST AND PHARMACY CHARACTERISTICS

1. Year of graduation: _____
2. Qualification(s):
   1st Degree: ☐ B. Pharm
   2nd Degree: ☐ (M. Pharm, M.Sc, MBA, FWAPCP)

3. Are you; Pharmacy Owner ☐
   Staff pharmacist ☐
   Locum pharmacist ☐

	YES	NO
4. Have you attended any workshop/seminar/training on patient counselling since graduation	☐	☐
5. Were you taught patient counselling in your undergraduate days	☐	☐

If answer to question 5 is Yes, kindly answer the question 6;

6. Does the teaching included practical exposure (Experiential learning)	☐	☐

7. For how long is your Pharmacy opened in a day? _____hours
8. In your own estimate how many customers visit your Pharmacy in a day? _____
10. Kindly tick the reference books available in your Pharmacy

(a) British National Formulary Year:_____ ☐
(b) EMDEX ☐
(c) AHFS Drug Information ☐
(d) Counselling Patients on their Medication ☐
(e) British Pharmacopoeia ☐
(f) Martindale ☐
(g) Others, pls Specify _____

BARRIERS TO MEDICATION COUNSELLING IN COMMUNITY PHARMACIES

Rate the following factors on a scale of 1 – 5 in order of their influence as barriers to patient counselling in your practice:

Key to rating:

1 represents : No influence

5 represents: Highest influence

		1	2	3	4	5
(1.)	Lack of compensation for counselling service	☐	☐	☐	☐	☐
(2)	Busyness of Pharmacy(Lack of time)	☐	☐	☐	☐	☐
(3)	Lack of expertise in medication counselling.	☐	☐	☐	☐	☐
(4)	Low expectations or lack of patient demand for medication counselling.	☐	☐	☐	☐	☐
(5)	Lack of interest in medication counselling	☐	☐	☐	☐	☐
(6)	Lack of private counselling area	☐	☐	☐	☐	☐
(7)	Lack of appropriate drug information sources/reference books	☐	☐	☐	☐	☐
(8)	Lack of medication counselling guide/aids	☐	☐	☐	☐	☐

STATEGIES TO IMROVE MEDICATION COUNSELLING IN COMMUNITY PHARMACIES

Rate the following strategies on the extent to which they could help improve medication counselling in community pharmacies

Key to rating:

1- represents : Not at all
5- represents : To a great extent.

	1	2	3	4	5
(1) Increased staffing in pharmacy	----	----	---	----	----
(2) Provision of counselling area	-----	-----	----	----	----
(3) Compensation for counselling service	-----	------	-----	----	----
(4) Practical training on medication counselling	-----	------	-----	----	-----
(5) Stricter regulation that makes it mandatory for Pharmacist to counsel patient.	-----	-----	-----	----	-----
(6) Greater support from pharmacy management For counselling activities.	------	------	------	-----	-------
(7) Availability of drug specific counselling guide/aid	------	-------	--------	-----	-------

KNOWLEDGE OF MEDICATION COUNSELLING

Below is a case scenario commonly encountered in community pharmacies. The case scenario is followed by questions; kindly write your response in the space provided.

Case Scenario :

A 24 year old man walks into your Pharmacy to request for a pack of Artemether-Lumefantrine combination drug.

What question(s) would you ask the patient:

If you decide to offer the requested drug for sale, what information would you give the patient along side the sale of the medication to ensure safe and effective use of the drug:

ATTITUDE TOWARDS MEDICATION COUNSELLING

Kindly tick the response that best represent your own sincere opinion on each of the statements below;

Keys:
SA - Strongly Agree
A - Agree
UD - Undecided
DA - Disagree
SD - Strongly Disagree

S/N	Attitude Items	Responses				
		SA	**A**	**UD**	**DA**	**SD**
1.	Medication counselling is a professional responsibility of pharmacists that must be performed at all times.					
2.	Medication counselling should be made compulsory for every community pharmacist by PCN					
3.	Pharmacists should be sanctioned for not providing medication counselling					
4.	Pharmacists should take responsibility for medication errors caused inadequate medication counselling					
5.	My counselling depends on the consent of the patient.					
6.	When patients do not demad for medication information, it is not necessary to bother them with counselling.					
7.	Patients do not need counselling on medicine they are familiar with.					

Appendix IV : Data collection form for determination of availability and extent of laws and regulation medication counselling practice.

		Q1	Q2	Q3	Q4	Q5	Q6
Publications on laws, regulation, policy statements, and guidelines on pharmacy practice	1,Pharmacists' Council of Nigeria Act 1992	No	No	No	No	No	No
	2.Code of ethics for Pharmacists	Yes	No	No	No	No	No
	3. Four-part Compendium for the Assurance of Pharmaceutical Care in Nigeria.	Yes	Yes	No	No	No	No
	4.National Drug policy	Yes	Yes	No	No	No	No
	5.A Compilation of Pharmacy, drugs and related Laws and Rules	No	No	No	No	No	No

KEY:

Q1- Is there any instruction on when a pharmacist is expected to counsel?

Q2- Is there a list of what a pharmacist is expected to say when counselling a patient?

Q3- Is there a provision for when a pharmacist is required to counsel and when he/she can delegate to other staff?

Q4- Is there a process for assessing, monitoring and enforcing counselling requirements?

Q5- Is there a rule that specifies what functions unqualified personnel may perform under the supervision of a pharmacists?

Q6- Is there a rule that specifies liability for not performing counselling functions?

No- Not Available

Yes- Available

Medication Counselling Information for Artemether-lumefantrine Combination Drugs

ENSURE YOU TAKE APPROPRIATE NUMBER OF TABLETS

Based on Formulation and Weight

TWICE A DAY

Morning and Evening

FOR 3 DAYS

TAKE EACH DOSE WITH FATTY FOODS

E.g. A glass of Milk, Butter, Egusi Soup etc.

ENSURE YOU COMPLETE YOUR MEDICATION;

This will help kill all the malaria parasites