

**FACTORS INFLUENCING MONITORING OF USAGE OF HERBAL MEDICINE IN KENYA: A
CASE OF MERU COUNTY, KENYA**

BY

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DECLARATION

This research report is my original work and has not been presented for the award of a degree in any other University

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DEDICATION

This project report is dedicated to my parents, who taught me that the saddest aspect of life right now is that science gathers knowledge faster than the society gathers wisdom. I also want to dedicate this report to my wife and children for the support they have given me throughout the course.

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LIST OF ABBREVIATIONS AND ACRONYMS

ASHP	American Society of Health Systems Pharmacists
CAM	Complementary And Alternative Medicine
DSHEA	Dietary Supplement Health and Education Act
EU	European Union
FDA	Food and Drug Administration
GACP	Good Agricultural and Good Collection Practices
GMP	Good Manufacturing Practice

NIH	National Institute of Health
SPSS	Statistical Package of Social Scientists
THP	Traditional Health Practitioner
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

ABSTRACT

The use of herbal medicinal products and supplements has increased tremendously over the past three decades with not less than 80% of people worldwide relying on them for some part of primary healthcare especially in developing countries. Although therapies involving these agents have shown promising potential with the efficacy of a good number of herbal products clearly established, many of them remain untested and their use are either poorly monitored or not even monitored at all. These therapies are extensively used by patients as adjuvant or as replacement treatment to the conventional prescribed drugs. More so, herbal medicine use in Kenya is amplified by the presence of traditional healers with estimates of one traditional healer present per

every 200 people. Therefore this study intended to examine the factors influencing monitoring of herbal medicine usage in Kenya. The study focused on; regulatory status of herbal medicine usage, lack of knowledge on herbal medicine, quality control of herbal medicine and beliefs on efficacy of herbal medicine. The study used a descriptive survey design and the theoretical framework of this study was Green and Kreuret's precede-precede model. The study focused on all the 67 registered herbal medicine practitioners in Meru County. The researcher conducted a census by focusing on all the 67 registered herbal medicine practitioners in Meru County. The data was collected using face to face structured interviews, focus group discussion and data analyzed using SPSS version 21. The findings were analyzed using descriptive and inferential statistics which were presented in tabular form. The results showed that herbal products are sold as herbal medicine (56.1%), dietary supplement (21.2%), food (13.6%) or functional food (9.1%). Market regulations of herbal products are good (59.1%) and ensure that the welfare of seller and buyer is taken care of. Majority of practitioners (71.2%) have good knowledge on herbal medicine but only a few pharmacists (39.4%) and physicians (36.3%) have adequate knowledge on herbal medicine usage. The administration of herbal medicine is well documented (56.1%) but monitoring of herbal products by their patients is poor (37.9%). Majority of practitioners (63.6%) are aware of the source of raw materials, how raw materials are cultivated. The findings of this study hopefully will be beneficial to policy makers in the health status, in understanding the factors that hinder monitoring of herbal medicine usage. The study will also be helpful to herbal medicine practitioners in understanding the factors that affect monitoring of herbal medicine. They will understand what they need to do in order to enhance monitoring of herbal medicine usage. The study findings will be useful to future scholars as it will add to the existing body of knowledge.

CHAPTER ONE

INTRODUCTION

1.1 Background of the study

Plants have been used for medicinal purposes long before recorded history. For

instance, ancient Chinese and Egyptian papyrus writings described medicinal uses for plants as early as 3,000 BC. Further, indigenous cultures such as African and Native American used herbs in their healing rituals, while others developed traditional medical systems such as Ayurveda and Traditional Chinese Medicine in which herbal therapies were used. Researchers have found that people in different parts of the world tended to use the same or similar plants for the same purposes (Taylor, 2013).

Herbal medicine is used currently by 75%-80% of the world population and especially in the developing countries (Kamboj, 2000). The herbal medicine in the developing countries is used for primary health care due to its cultural acceptability, better compatibility with human body and lesser side effects (Matheka and Demaio, 2013). However, in the last few years there has been a major rise in its use in the developed countries. For instance, in France and Germany herbs and herbal extracts are usually used as prescription drugs. In addition, their sales in countries of the European Union have risen from six billion dollars in 1991 to over twenty billion dollars in 2000. In the United States, herbal medicine is currently sold in health food stores and it has attained a turnover from four million dollars in 1996 to about eight million dollars in 2000. Further, in India, export of plant based crude drugs has been estimated to be around eight million dollars (Kamboj, 2000). More so, recently the World Health Organization (2013) has estimated that 80% of people worldwide rely on herbal medicines for some part of their primary health care. For instance, in Germany about 600 - 700 plant based

medicines are available and are usually prescribed by almost 70% of German physicians (Nworu and Okonkwo, 2014).

African nationals rely on traditional medicines for the cure and treatment of tropical ailments like malaria, headaches, stomach, skin diseases and many more (Maroyi, 2013). It has been estimated that about 65% to 70% of the continents population, especially in the rural areas depend on herbal medicine (Laud, 2011). This claim has been backed up by The World Health Organization (WHO) who pointed out that more than 80 % of the people in the world depend on herbal medicine (WHO, 2013).

Native doctors in Africa who have been responsible for curing people learned their trades from their ancestors who relied on herbs, tree backs and roots for the treatment of ailments (Orakpo, 2012). This method of medical care has become quite popular that it is used simultaneously with the scientific medical care in various towns and villages. For instance, in Ghana, the importance of traditional method of healing has led practitioners to set up a number of hospitals and clinics in all parts of the country. One of these medical centers is the Amin Scientific Herbal Hospital at Dome Accra that is an alternative medicine practice center that employs various forms of complementary and alternative medicines such as Psychotherapy (herbal medicine), Homeopathy, Naturopathy and Osteopathy; these Hospitals focuses on the holistic approach to healthcare (Pathar and Wagh, 2012).

In Kenya, the commonly used herbal medicines include; medicinal syrups, nutritional products, spiritual healing and relaxation techniques. These therapies are extensively used by patients as adjuvant or as replacement treatment to the conventional prescribed drugs (Matheka and Demaio, 2013). Herbal medicine use in Kenya is amplified by the presence of traditional healers with estimates of one traditional healer present per every 200 people. These traditional healers make selective use of herbal medicine, biomedical knowledge and language to enhance the perceived effectiveness of their treatments (Orakpo, 2012). The use of herbal medicine in Africa including Kenya, has been associated with cultural beliefs, age of patient, duration of illness, degree of complications, and advice from family and friends. Most importantly, the inaccessibility and shortcomings of conventional healthcare provision in Africa contribute to the high use of herbal medicine (Matheka and Demaio, 2013).

The use of herbal medicinal products and supplements has increased tremendously over the past three decades with not less than 80% of people worldwide relying on them for some part of primary healthcare. Although therapies involving these agents have shown promising potential with the efficacy of a good number of herbal products clearly established, many of them remain untested and their use are either poorly monitored or not even monitored at all. The consequence of this is an inadequate knowledge of their mode of action, potential adverse reactions, contraindications, and interactions with existing orthodox pharmaceuticals and functional foods to promote

both safe and rational use of these agents (Ekor, 2014).

Nearly one-third of the Meru population use herbs. It has been reported that 70% of the people taking herbal medicines are reluctant to tell their doctors that they use complementary and alternative medicine. This high use of herbal medicine in Meru is due to presence of plants among the Meru community especially in the Imenti forest area. There are Forty seven plant species belonging to 28 families in Meru that are being used for the production of herbal medicine that is used in Meru and other areas. This study will therefore focus on Meru County which is one of the forty seven counties in Kenya.

1.2 Statement of the problem

In many developing countries traditional medicine is still the main source of health care for about 80% of the population, because of its cultural acceptability, affordability and accessibility. This has created a need of countries to institutionalize traditional medicine in health systems. Owing to countries' efforts and calls made by the WHO Regional Office for Africa over the last two decades, more than half of the countries in the African Region have managed to develop national policies on traditional medicine; monitoring of herbal medicine use is one of the components of these policies.

Eighteen countries in Africa have developed national codes of ethics to ensure the safety, efficacy and quality of traditional medicines. However, less than half of the countries are yet to implement these policies and therefore, only a few countries have developed monitoring strategies for herbal medicine usage. More over only twenty-one

countries have developed legal frameworks that provide for; accreditation, registration of traditional health practitioners (THPs) and the establishment of a THP Council for monitoring of herbal medicine practice and products. This is because; non-regulation of traditional and herbal medicines poses a health risk to the populations Jain *et.al*/(2001).

A major concern has been that patients are replacing clinically proven conventional treatments with alternative medicines. These patients rarely disclose their alternative medicine use practices to their health care providers, an issue which calls for particular attention. More so, there is a potential risk of drug interaction when these agents are used as adjuvant to allopathic medicine. They may also interfere negatively with treatment and cause adverse effects and additional complications. It is a well-known fact that most herbal medicine agents contain active ingredients for which appropriate doses and side effects have not been determined. They are therefore likely to be administered at inconsistent doses, with the potential for fatal health effects and mortalities; hence raising the need for regular monitoring of herbal medicine usage among patients Ernst (2002).

A number of constraints however, exist in the control of herbal medicine use in Africa. For instance, there is lack of integration of alternative medicine therapies into African mainstream health care systems. This is despite the World Health Organization (WHO) recommendation to integrate traditional and alternative therapies into national health

care systems (WHO, 2002). Another major concern is the lack of monitoring on herbal medicine use in Africa and other developing countries, and therefore exposing the population to potential harm. Further, there exists limited quality assurance with most alternative medicine regulatory processes falling outside the scope of most government drug and therapeutic agencies in Africa. For instance, the registration of herbalists in Kenya is done by the Ministry of Social services, but in essence most of the traditional herbalists are not even aware of this. There is also limited research on herbal medicine use by people in developing countries including Kenya. More so, some alternative medicine products may also be beneficial and safe; but the lack of randomized controlled trials makes their use controversial (Matheka and Mokaya, 2012). Therefore, this study intends to examine the factors that influence monitoring of herbal medicine usage in Meru County, Kenya.

1.3 Purpose of the Study

The purpose of this study was to examine the factors influencing monitoring of herbal medicine usage in Kenya, a case of Meru County.

1.4 Objectives of the Study

The objectives of this study were;

- i. To establish how the regulatory framework of herbal medicine influences monitoring of usage of herbal medicine
- ii. To examine how awareness influences monitoring of usage of herbal medicine

- iii. To establish how quality control mechanism influences monitoring of usage of herbal medicine
- iv. To assess how beliefs on efficacy of herbal medicine influences monitoring of usage of herbal medicine

1.5 Research Questions

- i. How does the regulatory framework of herbal medicine influence monitoring of usage of herbal medicine?
- ii. To what extent does level of awareness influence monitoring of usage of herbal medicine?
- iii. How does quality control mechanism influence monitoring of usage of herbal medicine?
- iv. To what extent do beliefs on efficacy of herbal medicine influence monitoring of usage of herbal medicine?

1.6 Significance of the Study

This study will hopefully be beneficial to policy makers in the health status, in understanding the factors that hinder monitoring of herbal medicine usage. The study will offer the areas that the policy makers should focus on in enduring that usage of herbal medicine is monitored. The study will also be helpful to herbal medicine practitioners in understanding the factors that affect monitoring of herbal medicine. They will understand what they need to do in order to enhance monitoring of herbal

medicine usage. The study will also hopefully open opportunities for future researchers who would want to carry out further research monitoring of herbal medicine usage. The research will offer empirical literature for future research and create gaps for the same in the same area.

1.7 Limitations of the study

The study was limited by time but the researcher sampled the target population in order to limit the number of respondents. The study was also limited by distance of distribution of respondents and therefore the researcher ensured that there was proper scheduling which enhanced enough time to visit all the sampled respondents. Further, there was resistance of response, since a number of herbalists did not consider their medicine as alternative and a number of them conducted their businesses illegally, however the researcher assured the respondents of confidentiality and informed them that the study is purely for academic reasons only.

1.8 Delimitations of the study

The study was delimited to registered herbalists based in Meru County. The study focused on registered herbal practitioners who are based in all the nine Sub Counties of Meru County. The researcher focused only on registered herbalists since they are legal and easily identifiable.

1.9 Assumptions of the study

The researcher assumed that all the identified respondents would be supportive in

answering the questions posed and would answer questions correctly and truthfully. The study also assumed that all the herbalists are registered and are knowledgeable on the subject of herbal medicine usage.

1.10 Definition of significant terms

Efficacy	Desired quality of herbal medicine
Herbal medicine	is the use of plants to treat disease and enhance wellbeing.
Lack of knowledge	Being unfamiliar with herbal medicine usage
Monitoring	Supervising the usage of herbal medicine
Practitioners	Those persons who are selling herbal medicine
Quality control	review of the way herbal medicine is produced and sold to clients to ensure quality.
Regulation	Laws designed to control usage of herbal medicine

1.11 Organization of the study

The study was organised into five chapters. Chapter one comprised of background of the study, statement of the problem, objectives of the study, research questions, scope of the study, limitation and delimitations of the study and assumptions of the study. Chapter two of the study comprised of the literature review which presented the past study by different scholars on monitoring of herbal medicine usage. The chapter also comprised of the theoretical framework of the study and the conceptual framework.

The third chapter contain the research methodology, which was comprised of the research design, the sampling methods and the data collection and analysis methods. At the report level, this study presented the research finding and summary in chapter four and discussions, conclusion and recommendations in chapter five.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter presented a review of empirical (primary) and non-empirical (secondary) literature on the factors influencing monitoring of herbal medicine usage. The chapter covers the following specific sub-themes: regulatory framework of herbal medicine, level of awareness, quality control mechanism and status, assessment of safety and beliefs on efficacy of herbal influencing monitoring of usage of herbal medicine. The chapter also presents the theoretical frame work and conceptual framework on which the study is based.

2.2 Herbal medicine usage and monitoring

The use of herbal medicines, phytonutrients and nutraceuticals is increasing rapidly

across the world with many people now relying on these products for treatment of many health problems in various healthcare settings (WHO, 2004) The past decade has seen a tremendous flow in reception and public interest in these natural therapies both in the developing and developed countries, with these herbal medications being available in drug stores, food stores and supermarkets. It is projected that up to four billion people which is 80% of the world's population living in the developing world rely on herbal medicinal products as a primary source of healthcare and traditional medical practice which involves the use of herbs is viewed as an integral part of the culture in those communities (Mukherjee, 2002; Bodeker et al.,2005; Bandaranayake).

The use of herbal remedies has also been widely embraced in many developed countries with complementary and alternative medicines (CAMs) now becoming mainstream in the UK and the rest of Europe, as well as in North America and Australia (Anquez-Traxler, 2011). In fact, while places like the UK have a historical tradition of using herbal medicines (Nissen, 2010) the use is also widespread and well established in some other European countries (Calapai, 2008). In these developed countries the most important among many other reasons for seeking herbal therapy is the belief that it will promote healthier living. Herbal medicines are, therefore, often viewed as a balanced and moderate approach to healing and individuals who use them as home remedies and over-the-counter drugs spend huge amounts of money on herbal products. This explains in part the reason sales of herbal medicines are booming and

represents a substantial proportion of the global drug market (Kong et al., 2003).

As the global use of herbal medicinal products continues to grow and many more new products are introduced into the market, public health issues, and concerns surrounding their safety are also increasingly recognized. Although some herbal medicines have promising potential and are widely used, many of them remain untested and their use also not monitored. This makes knowledge of their potential adverse effects very limited and identification of the safest and most effective therapies as well as the promotion of their rational use more difficult (WHO, 2002). It is also common knowledge that the safety of most herbal products is further compromised by lack of suitable quality controls, inadequate labeling, and the absence of appropriate patient information (Raynor et al., 2011). It has become essential, therefore, to furnish the general public including healthcare professionals with adequate information to facilitate better understanding of the risks associated with the use of these products and to ensure that all medicines are safe and of suitable quality.

Essentially, herbal remedies consist of portions of plants or unpurified plant extracts containing several constituents which are often generally believed to work together. The recent resurgence of public interest in herbal remedies has been attributed to several factors some of which include: various claims on the efficacy or effectiveness of plant medicines; preference of consumers for natural therapies and a greater

interest in alternative medicines; erroneous belief that herbal products are superior to manufactured products; dissatisfaction with the results from orthodox pharmaceuticals and the belief that herbal medicines might be effective in the treatment of certain diseases where conventional therapies and medicines have proven to be ineffective or inadequate; high cost and side effects of most modern drugs; improvements in the quality, efficacy, and safety of herbal medicines with the development of science and technology; patients' belief that their physicians have not properly identified the problem hence the feeling that herbal remedies are another option; and a movement toward self-medication (Bandaranayake, 2006).

The increasing utilization of herbs for self-medication by patients or individuals is also attributed to a number of other reasons such as: patients being uncomfortable about discussing their medical problems and fear lack of confidentiality in handling their health information; fear of possible misdiagnosis and wrong treatment by patients with non-specific symptoms or general malaise; and lack of time to see a physician; this is usually a reason where prior visit did not yield any positive experience (Studdert et al., 1998). Furthermore, patients' freedom of choice of a practitioner is also encouraging their utilization of alternative treatments and herbal remedies, although many select herbal medicines from a deductive approach based on anecdotal information, that is, "it worked for my friend or relative" (Parle and Bansal, 2006). In addition, because of the influence of religion and greater level of spiritual consciousness, many individuals tend

to be increasingly disposed to accepting therapeutic value of a treatment based on faith or intuition rather than scientific reasoning (Astin, 1998; Zeil, 1999).

In addition to all these above-mentioned factors, the marketing strategies and efforts by various manufacturers of herbal medicines and their sales representatives have seriously projected these products into greater limelight. Various advertisements in the mass media including television and radio programmes have significantly increased consumers' awareness and given the herbal products undue respectability and credibility (Parle and Bansal, 2006). These advertisements are carefully presented to attract the different age groups of people that exist in the society. Children are encouraged to use herbs for their nutritional values to facilitate normal or healthy growth and development; young persons for their euphoric effects, supply essential ingredients to help them cope with daily stress and to prevent or slow the onset of aging; older persons for their anti-aging or rejuvenating effects and women for slimming and beauty enhancing effects (Ekor, 2013).

2.3 Regulatory framework and monitoring of usage of herbal medicines

Most of the problems associated with the use of traditional and herbal medicines arise mainly from the classification of many of these products as foods or dietary supplements in some countries. As such, evidence of quality, efficacy, and safety of these herbal medicines is not required before marketing. More so, quality tests and

production standards tend to be less rigorous or controlled and in some cases, traditional health practitioners may not be certified or licensed. The safety of traditional and herbal medicines has therefore become a major concern to both national health authorities and the general public (Kasilo and Trpsida, 2011).

The definition and categorization of herbal medicines vary from one country to another. Depending on the regulations applying to foods and medicines, a single medicinal plant may be categorized as a food, a functional food, a dietary supplement, or a herbal medicine in different countries. This introduces serious difficulty in the definition of the concept of herbal medicines for the purposes of national drug regulation while at the same time also confusing patients and consumers (WHO, 2005). In the United States, for example, natural products are regulated under the Dietary Supplement Health and Education Act (DSHEA) of 1994 (U.S. Food and Drug Administration, 2015). By definition, a dietary supplement is a product that is ingested and is intended to supplement the diet and contains a “dietary ingredient.” The dietary ingredients in these products may include vitamins, minerals, herbs, or other botanicals (U.S. Food and Drug Administration, 2012). Under the DSHEA, additional toxicity studies are generally not required if the herb has been on the market prior to 1994 (National Institute of Health (NIH) Office of Dietary Supplements, 2011). In this regard, the FDA bears the burden to prove that an herbal medicinal product or “dietary ingredient” is toxic or not safe for use. Additional major challenge in many countries is the fact that regulatory information on

herbal medicines is often not shared between regulatory authorities and safety monitoring or pharmacovigilance centers (WHO, 2014).

Until 2011, there were three possible regulatory routes by which an herbal product could reach a consumer. The unlicensed herbal remedy is the commonest route which does not have to meet specific standards of safety and quality neither is it required to be accompanied by safety information for the consumer (Raynor et al; 2011). Recently, the European Union (EU) implemented a directive after a 7-year transition period to harmonize the regulation of traditional herbal medicine products across the EU and establish a simplified licensing system in order to help the public make informed choices about the use of herbal products. This requires that all manufactured herbal products either gain a product license of the type needed to manufacture “conventional” products or become registered as a “traditional herbal medicinal product” (Routledge,2008; Raynor et al; 2011).

Like conventional medicines, licensed herbal medicines hold a product license based on safety, quality, and efficacy. Hence, it is compulsory that they are accompanied by comprehensive information such as indications, precautions, how to use the product, side effects, how to store the product and regulatory information, for safe use. This information is usually provided on a leaflet inserted into the product package (Raynor, et al; 2011). On the other hand, due to insufficient evidence of reproducible efficacy to

meet regulatory standards, license cannot be obtained for some herbal medicines to sell these products. In line with this, the Traditional Herbal Medicines Registration Scheme, which is a “simplified registration scheme,” was introduced in the UK. In this scheme, herbal medicinal products are required to meet specific standards of safety and quality, agree upon indications for use based on their traditional use and also provide information in a leaflet to promote safe use of the product by the purchaser (Raynor, et al; 2011). However, this is not the case in many other parts of the world, especially in the developing countries where many unregistered and poorly regulated herbal products are sold freely on the market with little or no restraint. Furthermore, the common misconception that natural products are not toxic and are devoid of adverse effects often lead to improper use and unrestrained intake and this has also resulted in severe poisoning and acute health problems. This misconception is not limited to the developing countries. It also exists in highly developed countries, where the general public often resorts to “natural” products without any proper awareness or information on the associated risks, particularly in the event of excessive or chronic use (UNESCO,2013).

2.4 Level of awareness and monitoring of usage of herbal medicine

Boon et.al, (2006) pointed out that most dietary supplements sold in the U.S. are purchased in pharmacies. Pharmacists, therefore, are in a good position to provide patients with information about the safety, efficacy, and potential drug interactions for

supplements at the point of purchase. Pharmacists are also best able to document supplement use in the patient's medical history and to determine the effect of alternative medications on the patient's regimen of conventional medicines. Pharmacists also have the knowledge and experience to help patients determine whether self-medication is appropriate or whether they should see a health care practitioner instead. Because of fear of disapproval, patients may also feel more comfortable telling their pharmacist, rather than their physician, that they are using a dietary supplement in addition to prescribed therapies (Cohen et.al, 2007).

However, although pharmacists are in an ideal position to provide counseling and record-keeping, it has been found out that few pharmacists or other health care professionals routinely ask about, document, or monitor patients' use of dietary supplements (Boon et.al., 2006). On the other hand, pharmacists are uncomfortable answering questions about supplements because few scientific studies are available to guide clinical discussions and decisions, and they often do not feel knowledgeable about this topic. Moreover, pharmacists might also not be familiar with professional practice standards that recommend routine inquiry, documentation, and monitoring of patients' use of supplements. As such, pharmacists who are most likely to inquire about and record supplement use work in inpatient settings, have access to evidence-based information on CAM, or have received additional training in alternative medications. Surprisingly, physicians also believe that they lack the resources and

training to respond to patients' inquiries about dietary supplements (Dunn et. al., 2005). In a recent survey in which more than 80% of the 164 respondents were general practice physicians and the remainder were mostly pharmacists, 76% said that they were "poorly informed" about herbal medicines and 46.6% said that their own knowledge on this topic was "very poor" or "quite poor." Although 77.3% of respondents said that they feared their patients would take herbal medicines without telling them, only 12.9% said that they "always" inquire about the use of dietary supplements.

In another study, more pharmacists than physicians rated their knowledge about herbal products as either "above average" or "excellent" and indicated that they could be a good alternative or adjunctive therapy to prescription medications, whereas physicians tended to state that they were either ineffective or unsafe (Dunn et. al., 2005). This difference was attributed to the pharmacists' greater familiarity and interest in dietary supplements, as well as their having more experience counseling patients on this subject. In many health care facilities, a physician's order is often required to allow patients to use a home supply of dietary supplements. Therefore, these survey findings prompt the question about whether physicians have the training and confidence to issue such an order. And hence, physicians should not be encouraged to utilize pharmacy services before ordering that a patient be permitted to take a supplement (Kemper. et. al., 2008)

Pharmacists and other health care practitioners clearly have the opportunity to reduce medical risks by increasing their knowledge and communication about dietary supplements. The American Society of Health-System Pharmacists (ASHP) agrees that pharmacists, as medication-use experts and accessible health care professionals, are uniquely qualified and positioned to identify potential adverse drug events and interactions and counsel patients on using supplements. However, despite this professional responsibility, pharmacists and other health care providers are frustrated by the lack of sound, evidence-based professional resources for reliable information about the safety and efficacy of supplements. This situation is in contrast to the wealth of available evidence about most pharmaceutical treatments, that shows that medical professionals are largely on their own when trying to understand the ingredients, proper indications, and dosages for the appropriate clinical use of supplements (Micozzi, 2003)

2.5 Quality control mechanism and monitoring of usage of herbal medicine

The quality of the source materials used in the production of herbal medicines determines to a large extent the safety and efficacy of these herbal remedies. Generally, the quality of source materials is dependent not only on intrinsic (genetic) factors, but also on extrinsic factors like environmental conditions, good agricultural, and good collection practices (GACP) for medicinal plants, including plant selection and cultivation. It is the combination of these factors that makes it difficult to perform

quality controls on the raw materials of herbal medicines (WHO, 2005). According to good manufacturing practice (GMP), correct identification of species of medicinal plants, special storage, and special sanitation and cleaning methods for various materials are important requirements for quality control of starting materials.

One of the major challenges often encountered in the quality control of finished herbal medicinal products, especially mixture herbal products, is the difficulty in ascertaining the inclusion of all the plants or starting materials (WHO,2005).Thus, the general requirements and methods for quality control of finished herbal products remain far more complex than for other pharmaceuticals (WHO, 2005). To ensure safety and efficacy of herbal medicines, therefore, WHO recommends the institution of quality assurance and control measures such as national quality specification and standards for herbal materials, GMP for herbal medicines, labeling, and licensing schemes for manufacturing, import and marketing, in countries where herbal medicines are regulated (WHO,2004).

2.6 Beliefs on efficacy and monitoring of usage of herbal medicine

The requirements as well as the research protocols, standards and methods needed for the evaluation of the safety and efficacy of herbal medicines are much more complex than those required for conventional or orthodox pharmaceuticals (Zhou et al., 2013). A single herbal medicine or medicinal plant may contain hundreds of natural constituents,

and a mixed herbal medicinal product may contain several times that number. Suppose every active ingredient were to be isolated from individual herb from which the herbal medicine is formulated or produced, the time and resources required would be tremendous. Such an analysis may practically be impossible especially where an herbal product is a mixture of two or more herbs (WHO, 2005).

In most countries, herbal medicines and related products are introduced into the market without any mandatory safety or toxicological evaluation. Many of these countries also lack effective machinery to regulate manufacturing practices and quality standards. These herbal products are continuously made available to consumers without prescription in most cases and the potential hazards in an inferior product are hardly recognized (Bandaranayake, 2006).

Over the past decade, the use of herbal medicines represents approximately 40% of all healthcare services delivered in China while the percentage of the population which has used herbal medicines at least once in Australia, Canada, USA, Belgium, and France is estimated at 48%, 70%, 42%, 38%, and 75%, respectively (Foster et al.,2000). In spite of the positive perception of patients on the use of herbal medicines and alleged satisfaction with therapeutic outcomes coupled with their disappointment with conventional allopathic or orthodox medicines in terms of effectiveness and/or safety the problem of safety of herbal remedies continues to remain a major issue of concern

(Abbot and Ernst, 1997).

The general perception that herbal remedies or drugs are very safe and devoid of adverse effects is not only untrue, but also misleading. Herbs have been shown to be capable of producing a wide range of undesirable or adverse reactions some of which are capable of causing serious injuries, life-threatening conditions, and even death. Numerous and irrefutable cases of poisoning have been reported by scholars such as Vanherweghem and Degaute (1998); Cosyns et al., Ernst (2002). For instance, the toxicity evaluation of the poly-herbal formula known as Yoyo "Cleanser" Bitters, conducted by Ekor et al., (2010)) in a laboratory, was prompted by an unpublished case report of a young male adult who had been on self-medication with this herbal product and was subsequently admitted to the hospital on account of liver failure. Yoyo "Cleanser" Bitters is one of the herbal remedies that is widely advertised in the various Nigerian media and as such has gained so much public acceptance over time and continues to enjoy increased patronage among consumers, especially in the southwestern part of the country. The study revealed that this herbal formula was capable of elevating plasma levels of liver enzymes and inducing hypokalemia following 30 days administration in rats.

Further, Auerbach et al. (2012) reported an association between traditional herbal medicine use and the development of liver fibrosis among study participants in Uganda.

A number of Chinese herbal medicines and other herbal medicines from different parts of the world have also been implicated in cases of poisoning. Many of them have been shown to contain toxic compounds which are capable of reacting with cellular macromolecules including DNA, causing cellular toxicity, and/or genotoxicity (Rietjens et al., 2005).

2.7 Theoretical framework of the study

The study was guided by the Precede-Proceed Model. The Precede-Proceed model is a cost-benefit evaluation framework, which helps health program planners, policy makers, and other evaluators to analyze situations and to design health programs efficiently (Green, 2005). It provides a comprehensive structure for assessing health and quality of life needs, and for designing, implementing, and evaluating health promotion and other public health programs to meet those needs. One purpose and guiding principle of the Precede-Proceed model is to direct initial attention to outcomes, rather than inputs. It guides planners through a process that starts with desired outcomes and then works backwards in the causal chain to identify a mix of strategies for achieving those objectives. A fundamental assumption of the model is the active participation of its intended audience; that is, that the participants ("consumers") will take an active part in defining their own problems, establishing their goals, and developing their solutions.

In precede-proceed model, health behavior is regarded as being influenced by both individual and environmental factors, and hence has two distinct parts. First it is an educational diagnosis which is '*PRECEDE*', an acronym for Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation. Second it is an ecological diagnosis which is '*PROCEED*' for Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development (Freire and Runyan, 2006).

The PRECEDE-PROCEED model is a participatory model for creating successful community health promotion and other public health interventions. It is based on the premise that behavior change is by and large voluntary, and that health programs are more likely to be effective if they are planned and evaluated with the active participation of those people who will have to implement them, and those who are affected by them. Thus health and other issues must be looked at in the context of the community. Interventions designed for behavior change to help prevent injuries and violence, improve healthy behaviors, and those to improve and increase scholarly productivity among health education faculty (Freire and Runyan, 2006).

2.8 Conceptual framework

A conceptual framework on which this study is based appears as Figure 1

INDEPENDENT VARIABLES

Regulatory status
-Classification of herbal products
-Marketing regulation

Level of awareness
-Knowledge among pharmacists
-Knowledge among physicians
-Documentation and

DEPENDENT VARIABLE

Monitoring usage of herbal medicine
a) Documentation of patients' usage
b) Licensing of practitioners
c) Documentation

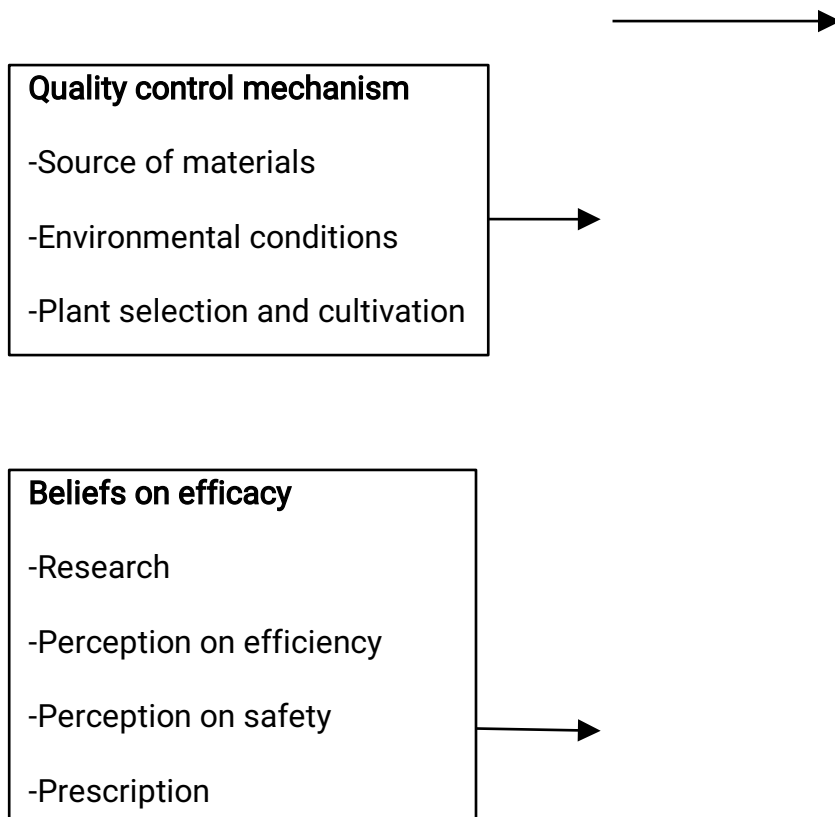


Figure 1: Conceptual framework

2.8.1 Explanation of conceptual framework

The independent variable of this study was factors influencing, which will be made up of regulatory status of herbal medicine, lack of knowledge on herbal medicine, beliefs on efficacy of herbal medicine and quality control. On the other hand the dependent

variable of the study was monitoring of herbal medicine usage.

2.9 Knowledge gap

The study reflects on the factors influencing monitoring of herbal medicine usage in Meru County namely regulatory framework, level of awareness, quality control mechanism and beliefs on efficacy of herbal medicine. The study has not considered how practitioner professional qualification influences successful monitoring of herbal medicine usage. There is therefore the need to carry out further research on the influence of practitioner professional qualification on monitoring of herbal medicine usage in Kenya.

2.10 Summary of literature review

This chapter presented a review of empirical (primary) and non-empirical (secondary) literature on the factors influencing successful monitoring of herbal medicine usage. The chapter covered empirical literature on regulatory framework of herbal medicine, level of awareness, quality control mechanism and beliefs on efficacy of herbal influencing monitoring of usage of herbal medicine. The chapter also presents the Precede-Proceed Model as theoretical frame work of the study. The chapter also discussed the conceptual framework of the study.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter outlined the research methodology which was used to find answers to the research questions. The research design, target population, sampling technique and sample size, data collection methods, instruments of data collection, reliability and validity of the data collection instruments and finally the data analysis techniques were presented in the chapter and ethical considerations.

3.2 Research Design

A research design is a plan, a roadmap and blueprint strategy of investigation conceived so as to obtain answers to research questions; it is the heart of any study (Kothari, 2004). The study used descriptive survey design. The descriptive survey design was selected because it is suitable for gathering of data and basically describes the characteristics of the population (Mugenda and Mugenda, 2003). Descriptive study also involves an assessment of the situation of affairs describing, analyzing and reporting conditions that exist or that existed (Kothari, 1993). The researcher chose this type of research design because the study intended to generate information on the factors that hinder successful monitoring of herbal medicine usage.

3.3 Target Population

Oso and Onen (2005) defined target population as the total number of the subjects of interest to the researcher. This study focused on 67 registered herbal medicine

practitioners in Meru County. The study focused on the registered practitioners since they were the only ones operating legally in the county. These practitioners were found in; chemists, supermarkets, exclusive herbalists and herbal medicine outlets.

3.4 Sampling Procedure and sampling size

Sampling is a procedure, process or technique of choosing a sub-group from a population to participate in the study (Ogula, 2005). A sample is a smaller group or sub-group obtained from the accessible population (Mugenda and Mugenda, 2003). This study took all the 67 practitioners which is a 100% representation of the population since the population is small and easily accessible. This study therefore, took a census of the 67 practitioners from Meru County. According to Hardy and Dooley (2007), when the sample is small it is important to take the whole population to determine the needs of an organization.

3.5. Research Instruments

The research instruments in this study included face to face interviews and focus group discussions.

3.5.1 Face to Face interviews

The researcher intended to select interviews as the instruments of data collection, since the study is qualitative in nature, interviews allowed the researcher to probe for responses and collect in depth information. The main advantage of the face-to-face interview was the presence of the interviewer, which made it easier for the respondent to either clarify answers or ask for clarification for some of the items (Dialsingh, 2008)

3.5.2 Focus Group Discussion

The researcher used Focus group as instrument of data collection. Focus groups discussion revealed a wealth of detailed information and deep insight. It created an accepting environment that puts participants at ease allowing them to thoughtfully answer questions in their own words and add meaning to their answers (Eliot and Associates, 2005).

3.6 Validity of the Instruments

Validity is the degree to which the test items measure a particular quality for which the test was designed (Kothari, 2004). Validity of the instruments was established by availing the research instruments to peers and a panel of experts from the Department of Extra-Mural Studies who established its validity in order to ensure that the face to face interview instrument and focus group instrument included adequate and representative set of items which contain the dimension and elements of concepts under study. The panel ensured that the items adequately represented concepts that covered all relevant issues under investigation, which complies with recommendations by Mugenda and Mugenda (2008). To achieve content validity, the researcher sought assistance from the university supervisor on various sections in the interview schedule which were the primary instruments for data collection. Adjustment was made to accommodate the recommendations.

3.7 Reliability of the Instruments

Reliability of data is the consistency of measures in a study (Bryman and Bell, 2003). It is the degree to which research instruments yields consistent results of data after trials. In this study, the researcher used test reliability of data by using pilot test method on the interview schedule. Pilot studies comprising of Three (3) practitioners who were selected randomly to carry out the pilot study of the interview schedules before the

main interviews was conducted. To avoid bias, the three practitioners who were chosen from a neighboring county hence did not participate in the main study.

3.8 Data Collection Procedures

The researcher acquired an introductory letter from the university to present to the respondents in the herbal medicine outlets as a means of verifying that the research is for academic purposes only. The researcher then sought permission from the Department of Health, Meru County to conduct the research. The researcher then visited registered practitioners in chemists, supermarkets, and exclusive herbal medicine outlets to familiarize with the herbal medicine outlets and notify practitioners of the intended study. The researcher then embarked on administering of data collection instruments to the herbal medicine practitioners in the County. The instruments were administered and data collected the same day. This study collected qualitative and quantitative data.

3.9 Data Analysis and Presentation

The data generated from the study was analyzed on the basis of specific objectives both quantitative and qualitative techniques. Data organization started with coding of the question items, and then coded data was tabulated in computer program statistical package for social sciences (SPSS vs 21). Quantitative data was analyzed using both descriptive and inferential statistics. On the other hand, content analysis was conducted on the qualitative data.

3.10 Ethical considerations

All respondents were treated with courtesy and respect in order to avoid misunderstanding between the enumerators and respondents and they were informed

of the purpose of the study. The study avoided asking personal questions that could invade into the respondents' privacy.

3.11 Operation definition of variables

This section presents the objectives of the study in a tabular form, by identifying the indicators of the variables that the researcher used, the data collection method, the scale to be applied in measuring the variables and data analysis procedures used. Operational definition of variables is shown on Table 3.1.

Table 3.1 Operationalization definition of variables

Objectives	Type of Variable	Indicator(s)	Data collection method	Measurement Scale	Data Analysis
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To establish how the regulatory framework influences monitoring of usage of herbal medicine	Independent Regulatory framework	<ul style="list-style-type: none"> a) Classification of herbal products b) Marketing regulations c) Production and testing regulation 	Interviews	<p>Nominal</p> <p>Ordinal</p> <p>Nominal</p>	<p>Descriptive</p> <p>Inferential</p>
To examine how level of awareness influences monitoring of usage of herbal medicine	Independent Level of awareness	<ul style="list-style-type: none"> a) Knowledge among pharmacists b) Knowledge among physicians c) Documentation and monitoring patients 	Interviews	<p>Ordinal</p> <p>Ordinal</p> <p>Nominal</p>	<p>Descriptive</p> <p>Inferential</p>
To establish how quality control mechanism influences monitoring of usage of herbal medicine	Independent Quality control mechanisms	<ul style="list-style-type: none"> a) Source of materials b) Environmental conditions c) Plant selection and cultivation 	Interviews	<p>Nominal</p> <p>Nominal</p> <p>Nominal</p>	<p>Descriptive</p> <p>Inferential</p>

<p>To investigate how beliefs on efficacy of herbal medicine influences monitoring of usage of herbal medicine</p>	<p>Independent</p> <p>Beliefs on efficacy of herbal medicine</p>	<p>a) Research</p> <p>b) Perception on efficiency</p> <p>c) Perception on safety</p> <p>d) Prescription</p>	<p>Interviews</p> <p>Focus group</p>	<p>Nominal</p> <p>Ordinal</p> <p>Ordinal</p> <p>Nominal</p>	<p>Descriptive</p> <p>Inferential</p>
<p>Monitoring of usage of herbal medicine</p>	<p>Dependent</p> <p>Monitoring of usage of herbal medicine</p>	<p>a) Documentation of patients' usage</p> <p>b) Licensing</p> <p>c) Visiting of public health officials</p>	<p>Interviews</p>	<p>Nominal</p> <p>Nominal</p> <p>Nominal</p>	<p>Descriptive</p> <p>Inferential</p>

CHAPTER FOUR

DATA ANALYSIS, PRESENTATION AND DISCUSSION

4.1 Introduction

This chapter contains data analysis, presentation and interpretation of findings. The study investigated the factors influencing monitoring of the usage of herbal medicine in Kenya, a case of Meru County. The chapter discusses results of the study under the following headings: questionnaire return rate, demographic characteristics of the respondents and objectives of the study namely regulatory framework of herbal medicine, awareness, quality control mechanism and beliefs on efficacy of herbal medicine influencing monitoring of the usage of herbal medicine in Meru County.

4.2 Questionnaire Return Rate

The questionnaire return rate was 98.5 %, as 67 herbal medicine practitioners were interviewed. As Mugenda and Mugenda (2003) has stated, a response of 50% is considered good.

4.3 Demographic Characteristics of the respondents

This section discusses the practitioners' gender, where they would be classified and period in practice of herbal medicine.

4.3.1 Study responses by gender

The practitioners were asked to indicate their gender. The responses are shown in

Table 4.1.

Table 4.1 Gender of herbal medicine practitioners

Gender	Frequency	Percentage
Male	29	43.9
Female	37	56.1
Total	66	100.0

The study findings indicated that 56.1% of the practitioners were males while 43.9% were females. The findings show that the number of female herbal medicine practitioners were more than that of males in Meru County.

4.3.2 Classification of herbal medicine practice

The practitioners were asked to classify their herbal medicine practice and responses are shown in Table 4.2

Table 4.2 Classification of herbal medicine practice

Classification	Frequency	Percentage
Chemist	24	36.4
Supermarket	19	28.8
Herbal medicine outlet	23	34.8
Total	66	100.0

The findings show that 34.8% of practitioners stock their herbal medicine in chemists while 34.8% of practitioners stock their herbal medicine in herbal medicine outlets. The study shows that herbal medicine is stocked in chemists, herbal medicine outlets and in supermarkets.

4.3.3 Period in practice of herbal medicine

The practitioners were asked to indicate their period in years they have practiced herbal medicine. The responses are shown in Table 4.3.

Table 4.3 Number of years practicing of herbal medicine

Number of years	Frequency	Percentage
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Number of years	Frequency	Percentage
Less than 1 year	11	16.7
1-5	39	59.1
6-10	10	15.2
More than 10	6	9.1
Total	66	100.0

The findings indicated that 59.1% of the practitioners have been in herbal medicine practice for 1-5 years within only 9.1% of practitioners have been in herbal medicine practice for more than 10 years. The study therefore shows that many herbal practitioners (90.9%) joined herbal practice less than 10 years ago.

4.4 Regulatory framework of herbal medicine influencing monitoring of usage of herbal medicine

In this section, the researcher sought to categorize the herbal products sold, rate the marketing regulation of herbal products and rate the testing process of the herbal products sold.

4.4.1 Categorization of herbal products that are sold

The herbal medicine practitioners were asked to categories the herbal products they sell. The responses are shown in Table 4.4.

Table 4.4 Categorization of herbal products that are sold

Policy	Frequency	Percentage
Food	9	13.6
Functional food	6	9.1
Dietary supplement	14	21.2
Herbal medicine	37	56.1

Total	66	100.0
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From the findings, 56.1% of the practitioners indicated that herbal products are sold as herbal medicine while others sell herbal products as dietary supplement (21.2%), food (13.6%) or functional food (9.1%). Herbal medicine is gaining popularity.

4.4.2 Rating of marketing regulation of herbal products in Kenya

The practitioners were asked to rate the marketing regulations of herbal products and then justify the rating. The responses are recorded in Table 4.5 and Table 4.6 respectively.

Table 4.5 Rating of marketing regulation of herbal products in Kenya

Rating	Frequency	Percentage
Very good	10	15.2
Good	39	59.1
Just okey	12	18.2
Bad	5	7.6
Total	49	100.0

From the study, 59.1% of practitioners believed that the marketing regulations of herbal products are good with only 7.6% of practitioners believing that the marketing regulations of herbal products are bad. Therefore, 92.8% of practitioners believed that the marketing regulations of herbal products are either good, just ok or very good.

Table 4.6 Justification of why marketing regulation of herbal products in Kenya are good

Survival of branches	Frequency)	Percentage
Owners sell their products with ease if	13	19.7

Survival of branches	Frequency)	Percentage
registered		
Conduct a regular check up of the products found at the self	25	37.9
Minding the welfare of the seller and buyer	20	30.3
They ensure safety of customers	8	12.1
Total	49	100

The marketing regulations of herbal products are considered to be good since regular check of herbal products is conducted regularly to ascertain quality as indicated by 37.9% of practitioners while 30.3% of practitioners indicated that market regulations of herbal products ensure that the welfare of seller and buyer is taken care of.

4.4.3 Awareness of production process of products sold

The practitioners were asked whether they were aware of the production process of products they sell and their responses were recorded in Table 47.

Table 4.7 Awareness of production process of products sold

Survival of branches	Frequency)	Percentage
Yes	34	51.5
No	32	48.5
Total	49	100

From the study, 51.5% of the practitioners indicated that they are aware of the production process of herbal products they sell. The study shows that slightly less than half of the practitioners (48.5%) are not aware of the production process of the herbal products they sell.

4.4.4 Rating of testing process of the herbal products sold

The practitioners were asked to rate the testing process of herbal products they sell and their responses were recorded in Table 4.8.

Table 4.8 Rating of testing process of products you sell

Rating	Frequency)	Percentage
Very good	6	9.1
Good	47	71.2
Just okey	13	19.7
Total	49	100

The practitioners (71.2%) indicated that the testing process of herbal products they sell is good with only 9.1% of the practitioners rating the testing process as very good. Therefore all practitioners rated the testing process as either good, just okey or very good.

4.5 Level of awareness influencing monitoring of usage of herbal medicine

In this section, the researcher sought information concerning knowledge of herbal medicine by practitioners, pharmacists and physicians. The researcher also sought information on whether the administration of herbal medicine is documented and whether the use of herbal medicine by patients is monitored.

4.5.1. Rating of practitioners knowledge on herbal medicine

The practitioners were asked to rate their knowledge on herbal medicine and responses are shown in Table 4.9

Table 4.9 Practitioners knowledge on herbal medicine

Rating	Frequency)	Percentage
Very well	6	9.1
well	47	71.2

Rating	Frequency)	Percentage
Just okey	12	18.2
Not well	1	1.5
Total	49	100

From the findings, 71.2% of practitioners indicated that their knowledge on herbal medicine is well while only 1.5% of practitioners indicated that their knowledge on herbal medicine is not well. Therefore, 98.5% of practitioners have knowledge on herbal medicine and can advise herbal medicine patients.

4.5.2 Level of agreement on awareness and monitoring of usage of herbal medicine

The practitioners were asked to indicate the rating of pharmacists and physicians knowledge of herbal medicine, whether administration of herbal products is documented and whether use of herbal products by patients is monitored and responses are shown in Table 4.10.

Table 4.10 Level of awareness and monitoring of usage of herbal medicine

Issues	Yes		No	
	Frequency	Percentag e	Frequency	Percentag e
Pharmacists are knowledgeable on herbal medicine usage	26	39.4	40	60.6
Physicians are knowledgeable on	24	36.4	42	63.6

herbal medicine usage				
Do you document administration of herbal medicine among patients who buy from you	37	56.1	29	43.9
Do you monitor how your patients use herbal medicines	25	37.9	41	62.1

From the study, 39.4 % of practitioners agreed that pharmacists are knowledgeable on herbal medicine usage and 36.4 % of practitioners agreed that physicians are knowledgeable on herbal medicine usage. Therefore majority pharmacists (60.6%) and physicians (63.7%) do not have knowledge on herbal medicine usage. From the study, 56.1% of practitioners indicated that administration of herbal medicine is documented and only 37.9% of practitioners indicated that they monitor use of herbal products by their patients.

4.6 Quality control mechanism influencing monitoring of usage of herbal medicine

In this section, the researcher sought to rate the awareness of materials used in manufacturing herbal medicine, the environmental conditions in which herbal medicine raw materials are grown, awareness of how raw materials are cultivated and whether involved in discussing plant selection to be used in making herbal medicine.

4.6.1 Rating of the source of materials used in manufacturing herbal medicine

The practitioners were asked to rate the awareness of the source of materials that are used in manufacturing herbal medicine and responses are shown in Table 4.11.

Table 4.11 Awareness of the source of materials used in manufacturing herbal medicine

Rating	Frequency	Percentage
Very well	9	13.6
Well	42	63.6
Just okey	14	21.2
Not well	1	1.5
Total	49	100

From the findings, 63.6% of practitioners indicated that they are aware of the source of materials used in manufacturing herbal medicine while 1.5% of practitioners indicated that they are not well aware of the source of materials used in manufacturing herbal medicine. Therefore, 98.5% of practitioners are aware of the source of materials used in manufacturing herbal medicine.

4.6.2 Rating of the environmental conditions in which herbal medicine raw materials are grown

The practitioners were asked to rate the environmental conditions in which herbal medicines raw materials are grown and responses are shown in Table 4.12.

Table 4.12 Rating of environmental conditions in which raw materials for herbal medicine are grown

Environmental conditions	Frequency	Percentage
Very well	13	19.6
Well	43	65.2
Just okey	10	15.2
Total	66	100

From the study, 65.2% of practitioners indicated that the environmental conditions in which raw materials are grown are well while 19.6% of practitioners indicated that the environmental conditions in which raw materials are grown are very well.

4.6.3 Awareness on how raw materials are cultivated and involvement in discussing plant selection to be used in making herbal medicine

The practitioners were asked to indicate whether they are aware of how raw materials are cultivated and whether they are involved in discussing plant selection to be used in making herbal medicine. Table 4.13 shows the responses.

Table 4.13 Awareness of how raw materials are cultivated and involvement in discussing plant selection to be used in making herbal medicine

Issues	Yes		No	
	Frequency	Percentage	Frequency	Percentage
Whether aware of how raw materials are cultivated	41	62.1	25	37.9
Whether involved in discussing plant selection to be used in making herbal medicine	13	19.7	53	80.3

From the findings, 62.1% of practitioners indicated that they are aware of how raw materials of herbal medicine are cultivated while only 19.7% of practitioners indicated that they are involved in discussing plant selection to be used in making herbal medicine. Most of the practitioners (80.3%) are not involved in discussing plant selection to be used in making herbal medicine.

4.7 Beliefs on efficacy of herbal medicine influencing monitoring of usage of herbal medicine

This section sought to establish whether herbal medicine practitioners were involved in research on herbal medicine, whether research is experimental, opinion on efficiency of herbal products, opinion on safety of herbal products and whether patients buy herbal medicine with prescription.

4.7.1 Whether involved on conducted research on herbal medicines, whether research was experimental and whether patients buy herbal medicine with prescription

The practitioners were asked to indicate whether involved on conducted research on herbal medicines, whether research was experimental and whether patients buy herbal medicine with prescription. Table 4.14 shows the results.

Table 4.14 Involvement in research and whether patients buy herbal medicine with prescription

Issues	Yes		No	
	Frequency	Percentage	Frequency	Percentage
Whether involved on conducted research on herbal medicines	20	30.3	46	69.7
Whether research was experimental	13	19.7	53	80.3
Whether patients buy herbal medicine with prescription	32	48.5	34	51.5

From the findings, 30.3% of practitioners indicated that they were involved in conducting research on herbal medicines and only 19.7% of practitioners indicated that

the research was experimental. From the study, 48.5% of practitioners indicated that patients buy herbal medicine with prescription. The study shows that 51.5% of practitioners indicated that patients buy herbal medicine without prescription.

4.7.2 Why patients buy herbal medicine without prescription

The practitioners were asked to indicate why patients would buy herbal medicine without prescription and responses are shown in Table 4.15.

Table 4.15 Why do patients buy herbal medicine without prescription

Reason	Frequency	Percentage
Most of the products do not require prescriptions	12	18.2
There are inadequate number of prescribers	24	36.4
Most patients believe on over counter consultations	10	15.2
Treated as an illegal medicine	1	1.5
Not applicable	19	28.8
Total	66	100

The study shows that 36.4% of practitioners indicated that patients buy herbal medicine without prescription because there is inadequate number of prescribers while 15.2% of practitioners indicated that patients buy herbal medicine without prescription because of over the counter consultations.

4.7.3 Opinion on efficiency and safety of herbal products

The practitioners were asked to indicate their opinion on efficiency and safety of herbal products and responses are shown in Table 4.16 and Table 4.17 respectively.

Table 4.16 Opinion on efficiency of herbal products

Services	Frequency	Percentage
Very efficient	18	27.3
Efficient	39	59.1
Sometimes efficient	9	13.6
Total	66	91.8

From the study, 59.1% of practitioners indicated that herbal products are efficient while 27.3% of practitioners indicated that herbal products are very efficient.

Table 4.17 Opinion on safety of herbal products

Activity	Frequency	Percentage
Very safe	23	34.8
Safe	36	54.5
Sometimes safe	7	10.6
Total	66	85.7

From the study, 54.5% of practitioners indicated that herbal products are safe while 34.8% of practitioners indicated that herbal products are very safe.

4.8 Monitoring of usage of herbal medicine

This section sought to establish whether herbal medicine usage poses public health dangers, whether conducted independent testing of herbal medicine that you sell and an independent testing of herbal medicine you have conducted.

4.8.1 Public health dangers posed by Herbal medicine usage

The herbal medicine practitioners were asked to indicate whether herbal medicine

usage poses public health dangers and whether conduct independent testing. The responses are shown in Table 4.18.

Table 4.18 Whether herbal medicine usage poses public health dangers

Issues	Yes		No	
	Frequency	Percentage	Frequency	Percentage
Whether herbal medicine usage poses public health dangers	10	15.2	56	84.8
Whether conduct independent testing of herbal medicine	9	13.6	57	86.4

From the study, 84.8 % of practitioners indicated that herbal products do not pose public health dangers while only 13.6% of practitioners have conducted independent testing of herbal medicine. This shows 86.4% of practitioners have not conducted independent testing of herbal medicine.

4.8.2 Independent testing of herbal medicine conducted

The practitioners were asked to indicate the independent testing of herbal medicine they have conducted and responses are shown in Table 4.19.

Table 4.19 Independent testing of herbal medicine conducted

Type of testing	Frequency	Percentage
Aloe-Vera and amaranth	4	6.1
Aloe-Vera and neem tree	3	4.5
Aloe vera, Omega-3, Ginseng, panax	2	3.0
Not applicable	57	86.4
Total	66	100

From the study, 6.1 % of practitioners indicated that they have conducted independent testing on Aloe-Vera and Amaranth, 4.5 % of practitioners indicated that they have conducted independent testing on Aloe-Vera and Neem tree and 3 % of practitioners indicated that they have conducted independent testing on Aloe-Vera ,Omega-3,Ginseg and Panax.

4.8.4 Comments by herbal medicine practitioners

The herbal medicine practitioners were asked to comment on issues of herbal medicine practice and responses are shown in Table 4.20.

Table 4.20 Comments

Comments	Frequency	Percentage
Conduct more research on herbal medicine	41	62.1
Government to make more awareness about herbal medicine	14	21.2
More shops dealing with herbal need to be opened	9	13.6
The body governing herbal should enhance monitoring	2	3.0
Total	66	100

From the study, 62.1 % of practitioners indicated that more research on herbal medicine

need to be conducted, 21.2% of practitioners suggested that government to make awareness about herbal medicine while 13.6% of practitioners suggested that more shops dealing with herbal medicine need to be opened.

4.9 Summary of the Chapter

The data collected was analyzed using Statistical Package for Social Sciences and tables were used to present data in APA table format. The questionnaire return rate was 98.5 %, as 67 herbal medicine practitioners were interviewed. The chapter discussed results of the study under the following headings: questionnaire return rate, demographic characteristics of the respondents and objectives of the study namely regulatory framework of herbal medicine, awareness, quality control mechanism and beliefs on efficacy of herbal medicine influencing successful monitoring of usage of herbal medicine in Meru County.

CHAPTER FIVE

SUMMARY OF FINDINGS, DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter focuses on the summary of findings of the study which formed the foundation for discussions. The discussions provided a firm basis upon which

conclusions and recommendations were advanced to address the factors influencing monitoring of the usage of herbal medicine in Kenya, a case of Meru County. It also includes with suggested areas for further research.

5.2 Summary of Findings

The summary of findings presented is based on the four objectives of the study.

5.2.1 Regulatory framework of herbal medicine influences monitoring of usage of herbal medicine

The study has shown that herbal products are sold as herbal medicine (56.1%), dietary supplement (21.2%), food (13.6%) or functional food (9.1%). The marketing regulations of herbal products are good (59.1%) while some practitioners believed that the marketing regulations of herbal products are just okey or very good. The marketing regulations of herbal products are considered to be good since regular check of herbal products is conducted regularly to ascertain quality and market regulations of herbal products ensure that the welfare of seller and buyer is taken care of.

The practitioners (51.5%) indicated that they are aware of the production process of herbal products they sell. The practitioners (71.2%) further indicated that the testing process of herbal products they sell is good with only 9.1% of the practitioners rating the testing process as very good.

5.2.2 Level of awareness influencing monitoring of usage of herbal medicine

The study has shown that 71.2% of practitioners indicated have good (well) knowledge on herbal medicine. The study has also shown that only 39.4 % of pharmacists are knowledgeable on herbal medicine usage and 36.4 % of physicians are knowledgeable on herbal medicine usage. Therefore majority pharmacists (60.6%) and physicians (63.7%) do not have knowledge on herbal medicine usage. The administration of herbal

medicine is documented (56.1%) and only 37.9% of practitioners indicated that they monitor use of herbal products by their patients.

5.2.3 Quality control mechanism influences monitoring of usage of herbal medicine

The study has shown that practitioners (63.6%) are aware of the source of materials used in manufacturing of herbal medicine and practitioners (65.2%) indicated that the environmental conditions in which raw materials are grown are well. The practitioners (62.1%) further indicated that they are aware of how raw materials of herbal medicine are cultivated and only 19.7% of practitioners are involved in discussing plant selection to be used in making herbal medicine.

5.2.4 Beliefs on efficacy of herbal medicine influencing monitoring of usage of herbal medicine

The findings has shown that 30.3% of practitioners are involved in conducting research on herbal medicines and only 19.7% of practitioners indicated that the research involved in was experimental. The practitioners (51.5 %) believed that patients buy herbal medicine without prescription. This is because the number of prescribers is inadequate and too the patients prefer over counter consultations. The study has also shown that herbal products are efficient (59.1%) and safe (54.5%).

5.3 Discussion of Findings

A discussion of findings of the study is presented based on the objectives of the study.

5.3.1 Regulatory framework of herbal medicine influences monitoring of the usage of herbal medicine

The study has shown that herbal products are sold as herbal medicine, dietary supplement, food or functional food. This collaborates study by WHO (2005) who stated that depending on the regulations applying to foods and medicines, a single

medicinal plant may be categorized as a food, a functional food, a dietary supplement, or a herbal medicine in different countries. The marketing regulations of herbal products are good. The marketing regulations of herbal products are considered to be good since regular check of herbal products is conducted regularly to ascertain quality and market regulations of herbal products ensure that the welfare of seller and buyer is taken care of. This agrees with Raynor et al; (2011) who stated that until 2011, the unlicensed herbal remedy which did not have to meet specific standards of safety and quality reached customers without even been accompanied with safety information for the consumer make for him to make informed choices about the use of herbal products.

The herbal practitioners indicated that they are aware of the production process of herbal products they sell and also indicated that the testing process of herbal products they sell is good. This testing of herbal products ensures safety. This agrees with Kasilo and Trpsida (2011) who reported that the safety of traditional and herbal medicines has therefore become a major concern to both national health authorities and the general public

5.3.2 Level of awareness influencing monitoring of the usage of herbal medicine

The study has shown that 71.2% of practitioners indicated have good (well) knowledge on herbal medicine. The study has shown that majority pharmacists (60.6%) do not have knowledge on herbal medicine usage. This study agrees with study by Boon et.al., (2006) who stated that although pharmacists are in an ideal position to provide counseling and record-keeping, it has been found out that few pharmacists routinely ask about, document, or monitor patients' use of dietary supplements due to lack of knowledge on herbal products.

The study has further indicated that that majority of physicians (63.7%) do not have knowledge on herbal medicine usage. This study is supported by Dunn et. al., (2005) who stated that surprisingly, physicians also believe that they lack the resources and training to respond to patients' inquiries about dietary supplements from herbal products.

The administration of herbal medicine is documented (56.1%) and only 37.9% of practitioners indicated that they monitor use of herbal products by their patients. This compromises the safety of herbal products. This agrees with Raynor et al., (2011) who stated that It is common knowledge that the safety of most herbal products is compromised by lack of suitable quality controls, inadequate labeling, and the absence of appropriate patient information and follow up.

5.3.3 Quality control mechanism influences monitoring of the usage of herbal medicine

The study has shown that practitioners (63.6%) are aware of the source of materials used in manufacturing of herbal medicine. It is important to know the source of herbal raw materials for the practitioner to determine the quality of herbal products. This agrees with WHO (2005) report that the quality of the source materials used in the production of herbal medicines determines to a large extent the safety and efficacy of these herbal remedies. The practitioners (65.2%) indicated that the environmental conditions in which raw materials are grown are well. The practitioners (62.1%) further indicated that they are aware of how raw materials of herbal medicine are cultivated. This further agrees with WHO (2005) who reported that the quality of source materials is dependent not only on intrinsic (genetic) factors, but also on extrinsic factors like environmental conditions, good agricultural, and good collection practices (GACP) for medicinal plants, including plant selection and cultivation.

5.3.4 Beliefs on efficacy of herbal medicine influencing monitoring of usage of herbal medicine

The findings have shown that 30.3% of practitioners are involved in conducting research on herbal medicines. Such researches are complex because it may involve more than one herb. This is supported by Zhou et al., (2013) who stated that the requirements and research protocols, standards and methods needed for the evaluation of the safety and efficacy of herbal medicines are much more complex than those required for conventional or orthodox pharmaceuticals. The practitioners (51.5%) believed that patients buy herbal medicine without prescription. This is because the number of prescribers is inadequate and too the patients prefer over counter consultations. However selling herbal products without prescriptions pose hazards to patients. This agrees with study by Bandaranayake (2006) who reported that herbal products are continuously made available to consumers without prescription in most cases and the potential hazards in an inferior product are hardly recognized. The study has also shown that herbal products are considered to be efficient (59.1%) and safe (54.5%). The study agrees with UNESCO (2013) who reported that in many parts of the world, there is a common misconception that natural products are not toxic and are devoid of adverse effects often leading to improper use and unrestrained intake and this has also resulted in severe poisoning and acute health problems.

5.4 Conclusion of the study

The study concludes that regulatory framework, level of awareness, quality control mechanism and beliefs on efficacy of herbal medicine influence successful monitoring of herbal medicine usage.

It can be concluded that herbal products are sold mainly as herbal medicine, though some herbal products are sold as dietary supplement, food or functional food. The

marketing regulations of herbal products are good since regular check of herbal products is done to ascertain quality. Market regulations of herbal products ensure that the welfare of seller and buyer is taken care of. The practitioners are aware of the production process of herbal products and the testing process of herbal medicine is good.

It can also be concluded that majority of practitioners have good (well) knowledge on herbal medicine but only a few pharmacists and physicians have adequate knowledgeable on herbal medicine usage. The administration of herbal medicine is well documented and but monitoring of herbal products by their patients is poor.

It is also concluded that majority of practitioners are aware of the source of materials used in manufacturing of herbal medicine, aware of how raw materials of herbal medicine are cultivated but only a few of them are involved in discussing plant selection to be used in making herbal medicine. The environmental conditions in which raw materials are grown are well.

It is concluded that only a few herbal practitioners (30.3%) are involved in conducting research on herbal medicines and the research was not experimental (80.3%). Most patients buy herbal products without prescription because the number of prescribers is inadequate and most patients prefer over counter consultations. The herbal products are efficient and safe.

5.5 Recommendations

On the basis of the results of this study the recommendations are as follows:

1. Market regulation of herbal products should be done to ascertain the quality of herbal products on the shops and ensure that the welfare of the seller and buyer is taken care of.
2. The practitioners should be aware of the production and testing process of herbal products.

3. The pharmacists and physicians need to attend seminars and workshops in order to understand usage of herbal products by patients since herbal products are gaining popularity in the last 10 years.
4. The practitioners should document administration of herbal medicine and monitor usage of herbal products by the patients.
5. The practitioners should be aware of the source of materials used in manufacturing of herbal medicine, aware of how raw materials of herbal medicine are cultivated and be involved in discussing plant selection to be used in making herbal medicine.
6. The practitioners should be involved in researches on herbal products which should mainly be experimental.

5.6 Suggested areas for further Research

Following are suggested areas for further study

1. Research should be carried out on the factors influencing monitoring of herbal medicine usage in other parts in the Country.
2. A study to establish the influence of practitioners' professional qualification on monitoring of herbal medicine usage in Kenya.
3. Research should be conducted on the factors influencing increased usage of herbal products by patients in Kenya.

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APPENDICES

APPENDIX 1 LETTER REQUESTING FOR TRANSMITTAL TO THE RESPONDENTS

TITUS KIIO

P.O.Box 1762 -60200

MERU

Cellphone; 0724855509

Dear Sir/Madam,

I am a graduate student undertaking a degree in Master of Arts in Project Planning and Management of the University of Nairobi and I am conducting a research study entitled “**Factors influencing monitoring of herbal medicine usage in Kenya, a case of Meru**”

County”.

You have been selected to assist in providing the required information because your views are considered important to this study.

Please note that any information given will be treated with utmost confidentiality and will only be used for the purpose of this study.

Thank You.

Yours faithfully

Titus Kiio

APPENDIX 2: INTERVIEW SCHEDULE

Section 1: Demographic characteristics of respondents

1. What is your gender?

Male [] Female []

2. Where would you classify your herbal medicine practice?

Chemist [] Supermarket [] Herbal medicine outlet [] Other []

3. If other, kindly specify_____

4. How long have you practiced herbal medicine sale?

Less than one year [] 1-5 years [] 6-10 years [] More than 10 years []

Section 2: independent variables

Part 1: Regulatory framework and monitoring usage of herbal medicine

1. Where would you categorize the herbal products that you sell?

Food []

Functional food []

Dietary supplement []

Herbal medicine []

2. How would you rate marketing regulation of herbal product in Kenya?

Very good [] Good [] Just o.k [] Bad [] Very bad []

3. Justify your answer

above_____

4. Are you aware of the production process of products you sell?

Yes [] No []

5. How would you rate the testing process of products you sell?

Very good [] Good [] Just o.k [] Bad [] Very bad []

Part 2: Level of awareness and monitoring of usage of herbal medicine

1. How would you rate your knowledge on herbal medicine?
Very well [] Well [] Just o.k. [] Not well [] Very poor []
2. Do you think that all pharmacists are knowledgeable on herbal medicine usage?
Yes [] No []
3. Do you think that all physicians are knowledgeable on herbal medicine usage?
Yes [] No []
4. Do you document administration of herbal medicine among patients who buy from you?
Yes [] No []
5. Do you monitor how your patients use herbal medicines?
Yes [] No []

Part 3: Quality control mechanism and monitoring of usage of herbal medicine

1. How would you rate your awareness of the source of materials that are used in manufacturing herbal medicine?
Very well [] Well [] Just o.k. [] Not well [] Very poor []
2. How would you rate the environmental conditions in which herbal medicine raw materials are grown?
Very good [] Good [] Just o.k. [] Not good [] Not aware at all []
3. Are you aware of how raw materials of herbal medicines are cultivated?

Yes [] No []

4. Are you involve in discussing plant selection to be used in making herbal medicine?

Yes [] No []

Part 4: Beliefs on efficacy and monitoring of usage of herbal medicine

1. Are you aware of any research conducted on the herbal medicine you are involved with?

Yes [] No []

2. If yes, was the research experimental?

Yes [] No []

3. What is your opinion on the efficiency of herbal products?

Very efficient [] Efficient [] sometimes efficient [] Slightly inefficient []
Inefficient []

4. What is your opinion on the safety of herbal products?

Very safe [] safe [] sometimes safe [] Slightly safe [] unsafe []

5. Do patients buy herbal medicine with prescription?

Yes [] No []

6. If no above, explain why?

Section 3: Dependent variable

1. How often do you document patients' usage of herbal medicine?

Very often [] Often [] slightly often [] Not often [] Never []

2. Do you think herbal medicine usage poses public health dangers?

Yes [] No []

3. Do you conduct independent testing of herbal medicine that you sell?

Yes [] No []

4. List any two independent testing of herbal medicine you have conducted

i.....

ii.....

5. Give any other information

Thank you for your cooperation

APPENDIX 3: Focus Group Discussion

1. How would you categorise the herbal products sold in various places?
2. How would you rate marketing regulation of herbal product in Kenya?
3. How would you rate the testing process of products you sell?
4. Do you think that all pharmacists and physicians are knowledgeable on herbal medicine usage?
5. Do you document administration of herbal medicine among patients who buy from you?
6. Do you monitor how your patients use herbal medicines?
7. How would you rate your awareness of the source of materials that are used in manufacturing herbal medicine?

8. How would you rate the environmental conditions in which herbal medicine raw materials are grown?
9. What is your opinion on the efficiency of herbal products?
10. What is your opinion on the safety of herbal products?
11. Do patients buy herbal medicine with prescription?
12. Do you think herbal medicine usage poses public health dangers?
13. Do practitioners conduct independent testing of herbal medicine that they sell?

Thank you for your cooperation