QUALITY MANAGEMENT OF HERBAL AND TRADITIONAL MEDICINE AND HEALTHCARE PROVISION IN MUKONO DISTRICT.

BY

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A DISSERTATION SUBMITTED TO THE SCHOOL OF MANAGEMENT SCIENCE IN PARTIAL FULFILMENT FOR THE AWARD OF A MASTER OF MANAGEMENT STUDIES DEGREE IN PROJECT PLANNING AND MANAGEMENT OF UGANDA MANAGEMENT INSTITUTE (UMI)

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DECLARATION

I, Victoria Birungi Jaawe Kwesiga, declare that this is my original work and has not been submitted for the award of a degree in any other university or institution of higher learning for academic purposes.

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APPROVAL

This dissertation has been approved for submission as partial fulfillment for the award of the Master's Degree in Management Studies Project Planning and Management of Uganda Management Institute with our authority. We certify that Victoria Birungi Jaawe Kwesiga has done this work under our guidance and supervision.

NAME: MR. ANACLET MUTIBA NAMANYA

Signed……..

Date…….

NAME: DR. SSENTAMU NAMUBIRU PROSCOVIA

Signed…….

Date…….

DEDICATION

To my beloved husband, Hon. Justice John Wilson Kwesiga, and our dear children: Mary Sheila, James Wilson, Brenda Victoria, Kevin John and Michael, without whom I would not have got the courage to complete this course. I will forever be grateful and this is a family achievement for us all. Lastly I would like to thank the almighty God whose Divine mercy and love has made it possible for me to complete this study.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMS

NCRI:	Natural Chemotherapeutics Research Institute
NDA:	National Drug Authority
WHO:	World Health Organization
MOH:	Ministry of Health
PPPH:	Public Private Partnership for Health

ABSTRACT

This study investigated how quality management of herbal and traditional medicine affected health care provision in Mukono district. The objective of the study were to examine how customer satisfaction affects health care provision, to examine how conformity to standards affects health care provision, to find out how product uniformity affects health care provision and to assess how the level of quality improvement affects health care provision. Although the study findings show that the quality of herbal and traditional medicines is compromised during production thus affecting customer satisfaction, conformity to standards, product uniformity and the general quality of the drug there was still a significant positive relationship between quality management of herbal and traditional medicine and healthcare provision. The study used a descriptive case study and both qualitative and quantitative data were collected and analyzed. Data was collected using questionnaires and interviewing individuals to protect the secrecy embedded in the art of traditional practitioners practice. The main respondents were traditional health practitioners and herbal medicine consumers. Opinion leaders and policy makers and local administrators provided information to verify data from the main respondents. A check list of the local named provided by the informants were crosschecked with scientific documentation to ensure relevant information on traditional medicines for malaria was targeted. Data analysis was done using computer software SPSS 16.0. Univariate, bivariate, and multivariate analysis was used to determine the mean, correlation, and regression analysis respectively. The study confirmed that there was significant positive relationship between the independent variables used in the study and the dependent variable of healthcare quality. The study recommended that quality should not be compromised to improve health care provision through use of herbal and traditional medicine in Mukono District.

CHAPTER ONE

INTRODUCTION

1.0 Introduction

This study was done on quality management and health care provision through traditional and herbal medicine in Mukono district in Uganda. In Uganda, health care provision is undertaken both by the government (as a public sector) and the traditional and complimentary section (as the private sector). The consumers of health services have the option to choose where to get the health care services from. Often this decision is based on a number of factors such as proximity to the service centers, effective health care response and the customer satisfaction with the service provider. Malaria is the leading cause of morbidity and mortality in Uganda and is responsible for up to 40% of all outpatient visits, 25% of all hospital admissions and 14% of all hospital deaths (Uganda Ministry of Health, unpublished). The overall malaria-specific mortality is estimated to be between 70,000 and 100,000 child deaths annually in Uganda. This chapter presents the background to the study, the statement of the problem, the study purpose, objectives of the study, research questions, conceptual framework, hypothesis of the study, the significance of the study, the justification of the study and operational definition and key terms and concepts.

1.1 Background to the Study

The government of Uganda established several health care facilities to meet the needs of its people. Traditional and herbal medicines are one of the sectors envisaged to contribute to the health care services (Ministry of Health Policy Document, 2001).

The government of Uganda established public health care systems based on the then existing missionary health care systems before Uganda's political independence in 1962. Prior to that there

was the traditional medicine health care system that was used by the indigenous population and based on skills and information passed on from generation to generation. This traditional health care system was managed by persons within the community who were assigned with the tasks and responsibility to deliver the appropriate services to the population. In 1957, the colonial government of Uganda established a Witchcraft Act which was to help delineate bon-a-fide and the non-bon-a-fide practitioner. While the two systems of health care are running in parallel, they are used by the population to meet their health care needs. In 1995, Uganda established a constitution that states that it is the State's duty to ensure that all Ugandans enjoy access to health services (Republic of Uganda, 1995). The constitution expresses practical measures to ensure the provision of basic medical services population. Based on this, the government task to streamline, manage and integrate traditional medicine for health care is a task yet to be overcome. Already the Ministry of Health has in place the framework to streamline traditional medicine for health care into the mainline health care services through the establishment of the Public-Private Partnership for Health Policy (PPPH, 2012). Under this policy, traditional practitioners have a role to provide health care services through the products and services to the population.

The PPPH Policy to main streaming Traditional medicine is based on the fact that half of Uganda's populations use Traditional Medicine as their first point of contact for primary healthcare. And that the sub-sector is currently not formally recognized and is not mainstreamed in the planning, implementation and monitoring systems of the healthcare system. Most of the traditional health care practitioners used herbal medicines products.

Traditional medicine has maintained its popularity in all regions of the developing world and its use is rapidly spreading in the industrialized countries. In China, for example, traditional herbal

preparations account for 30%-50% of the total medicinal consumption. In Ghana, Mali, Nigeria and Zambia, the first line of treatment for 60% of children with high fever resulting from malaria is the use of herbal medicines at home (WHO, 2003). Over one-third of the population in developing countries lack access to essential medicines. Over a decade ago, the WHO recognized that the provision of safe and effective traditional medicines therapies could, thus, become a critical tool to increase access to health care (WHO, 2003).

Plants and their secondary metabolite constituents have a long history of use in modern 'western' medicine and in certain systems of traditional medicine, and are the sources of important drugs such as atropine, codeine, digoxin, morphine, quinine and vincristine (ESCOP,1999); (Blumenthal *et al.*, 1998); and (WHO, 1999). Use of herbal medicines in developed and developing countries has expanded sharply in the latter half of the twentieth century. Inequities in availability, accessibility and affordability of health care have increased, between as well as within populations the world over (WHO, 2008; MDGs, 2008). Recently, there has been a growing interest in Traditional medicine/Complementary and Alternative Medicine (TCAM) and their relevance to public health both in developed and developing countries (WHO, 2002). The importance of traditional medicine as a source of primary health care was first officially recognized by the World Health Organization (WHO) in the Primary Health Care Declaration of Alma Ata (1978) and has been globally addressed since 1976 by the Traditional Medicine Program of the WHO. Diversity, flexibility, easy accessibility, broad continuing acceptance in developing countries and increasing popularity in developed countries, relative low cost, low levels of technological input, relative low side effects and growing economic importance are some of the positive features of traditional medicine (WHO, 2002).

Quality management is an organization-wide approach to understanding precisely what customers need and consistently delivering accurate solutions within budget, on time and with the minimum loss to society. The term quality management has a specific meaning within many business sectors. This specific definition, which does not aim to assure 'good quality' by the more general definition, but rather to ensure that an organization or product is consistent, can be considered to have four main components: quality planning, quality control, quality assurance and quality improvement. Quality management is focused not only on product/service quality, but also the means to achieve it. Quality management therefore uses quality assurance and control of processes as well as products to achieve more consistent quality (Wikipedia. http://en.wikipedia.org/wiki/Quality_management).

Quality management of traditional and herbal medicines refers to manufacturing and handling of traditional medicines and health supplements so as to ensure that they are fit for their intended use to comply with the requirements of the National Regulatory Authority (NRA) and do not place patients or consumers at risk due to inadequate safety and quality (ASEAN, 2010). According to World Health Organization (2002: 7), "traditional medicine refers to health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being." Further the term complementary and alternative medicine (and sometimes also non-conventional or parallel) are used to refer to a broad set of healthcare practices that are not part of country's own tradition, or not integrated into the dominant healthcare system; while health care (or healthcare) is defined as the diagnosis, treatment, and prevention of disease, illness, injury, and other physical and mental impairments in humans.

Health care is delivered by practitioners (professional like doctors, nurses, traditional Birth attendants, in medicine, chiropractic, dentistry, nursing, pharmacy, allied health, and other care providers. It refers to the management of the system of health care in providing primary care, secondary care and tertiary care, as well as in public health (WHO, 2008).

In Uganda, malaria is amongst the greatest health care challenge for managers as it accounts for 25-40% of outpatients who visit health facilities and 20% of all hospital admissions (Ministry of Health, 2003). About 70 – 80% of the Ugandan population still relies on herbal/traditional medicine for day-to-day health care. The parasites which cause malaria are resistant to or are developing resistance to the most widely available, affordable and safest first line treatments such as chloroquine and fansidar (Kilama 2005; Sendagire *et al.,* 2005). In some rural areas the percentage is higher compared to 80% usage reported world-wide. The World Health Organization (WHO) had earlier estimates that the usage of traditional medicine in developing countries is 80% and the ratio of traditional medicine practitioners in Uganda to population is between 1:200 and 1:400 compared to the rate of medical practitioners that stands at 1:20,000 (WHO 2002). This is an indication that herbal medicine plays an important part in primary health care provision in Uganda and, therefore, there is a need to improve on the quality of the herbal preparations so as to improve on the quality management of the traditional herbal system.

1.2 Statement of the problem

Although production, distribution, and use of herbal medicines in Uganda have been widely adopted in treatment of various ailments, the quality of these medicines have not met the level set by the World Health Organization for Traditional Medicine Program (WHO, 2004). The status of the herbal

medicines production, distribution, and quality control in Uganda seems to be far below the WHO set standards. Monitoring of the quality of herbal medicines and thus the overall management of the traditional medicine system in Uganda is a big challenge without any standards. Medicinal plants in Uganda are mainly wild crafted (collected from the wild) with no consistency in the quality of the product or the process through which it goes through to derive the medicines. Besides, documentation and records of activities and processes in production, distribution, and use of these herbs are lacking (Mubiru *et al*., 1993). Further, herbal remedies and products based on traditional knowledge are promoted and sold in herbal clinics without registration and regulation, bringing into question the safety of some of these herbal medicines by National Drug Authority. This study was an attempt to establish whether existing traditional medicines management promotes quality of these herbs in order to meet customers' health needs within the community. This was the main reason for this study. Malaria was focused on more than the rest of other diseases because it is the leading cause of morbidity and mortality in Uganda and is responsible for up to 40% of all outpatient visits, 25% of all hospital admissions and 14% of all hospital deaths (Uganda Ministry of Health, unpublished). The overall malaria-specific mortality is estimated to be between 70,000 and 100,000 child deaths annually in Uganda

1.3 Purpose of the Study

The study examined how quality management contributes to health care provision through herbal medicines with a focus on herbals for malaria in Mukono District.

1.4 Objectives of the Study

The following were the objectives of the study:

i) To examine how customer satisfaction affects health care provision in Mukono.

ii) To examine how conformity to standards affects health care provision in Mukono.

iii) To find out how product uniformity affects health care provision in Mukono.

iv) To assess how the level of quality improvement affects health care provision in Mukono.

1.5 Research Questions

The research Questions were as follows:

i) How does customer satisfaction affect health care provision in Mukono?

ii) How does conformity to standards affect health care provision in Mukono?

iii) How does product uniformity affect health care provision in Mukono?

iv) How does the level of quality improvement affect health care provision in Mukono?

1.6 Hypotheses of the study

i) Customer satisfaction has a significant positive relationship with health care provision in Mukono.

ii) Conformity to standards has a relationship with healthcare provision in Mukono

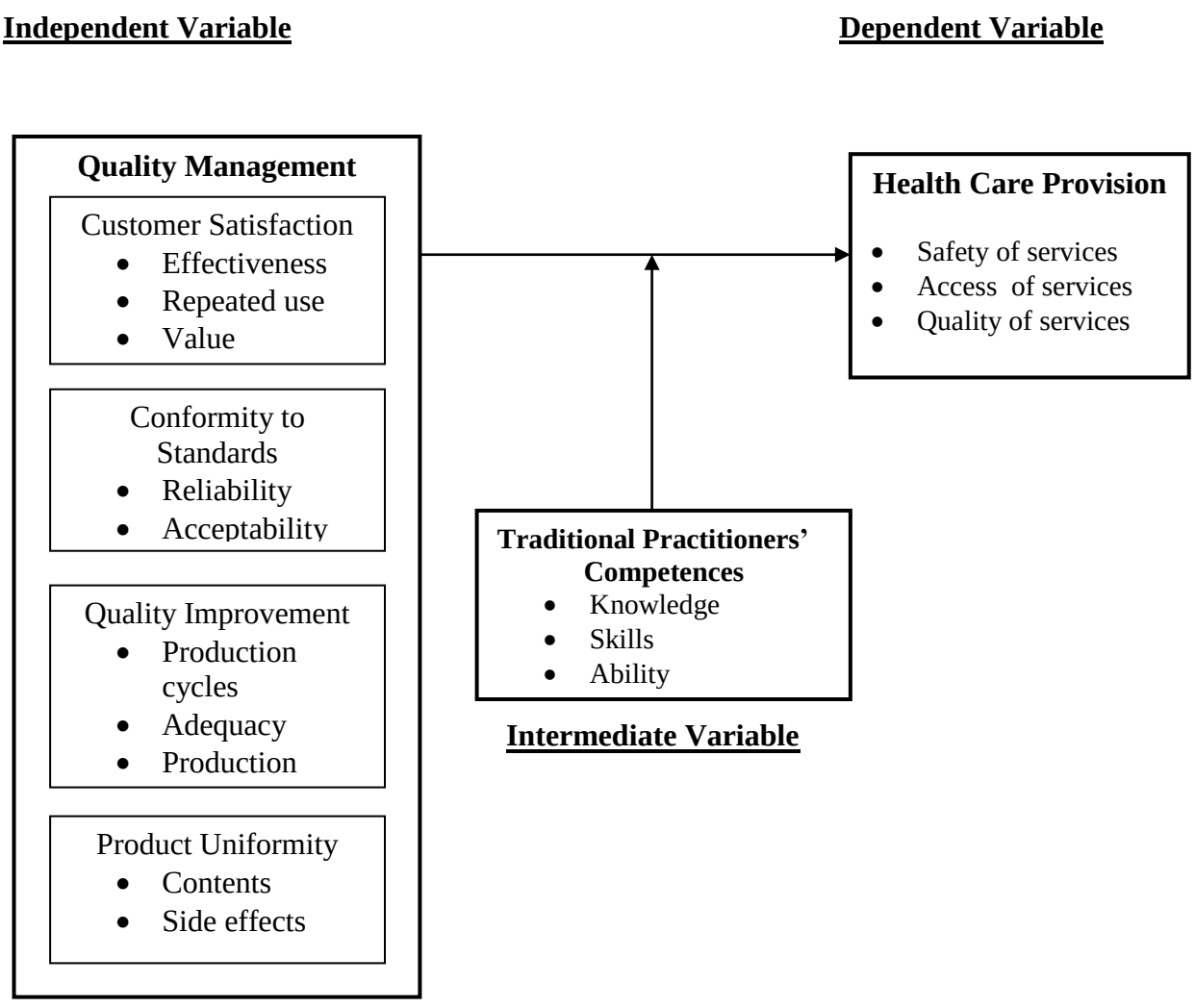
iii) There is a strong positive relationship between product uniformity and health care provision in Mukono.

iv) There is a significant relationship between quality improvement and healthcare provision in Mukono.

1.7 Conceptual Framework

The conceptual model below shows the relation between quality management as independent and health care as the dependent variables on the quality of health care using herbal medicine.

Figure 1: Conceptual framework showing the relationship between quality management and health care provision



Source: Sachs and Malaney (2002); Kilama (2005); United Nations (2005); Sendagire *et al.,* (2005); Allison *et al.,* (2001); Newton *et al.,* (2006).

The study was based on the assumption that quality management of herbal medicine, right from the production, distribution and use depends on dependent variables such as customer care, conformity to standards, quality improvement and product uniformity. The traditional practitioner's competence to undertake the different activities to translate to satisfactory healthcare service to the consumers is important. It is documented that herbal medicines do have similar acting chemicals for malaria treatment as in *Artemisia annua* that is now used to make Coartem (a modern medication use in the treatment for malaria). Issues such as dosage and drug interaction are known to affect the quality of health service. Customer satisfaction in herbal medicine health care relates to how the customer continues to use the herbal medicine product, the expression of the positive contribution of the herbal product and how the customer's positive attitude towards the herbal medicines. In a good quality managed system of herbal medicine for health care the customer expects reliable and accessible the herbal medicine is when needed. If these conditions are met, to the customer the management quality of the herbal medicine is satisfactory or good. The traditional herbal practitioners are also charged with the responsibilities and expectation to ensure that the quality improvement of the product and services meet the growing needs of the customers. There is often a deliberate effort for the producers to improve on the production cycles, the adequacy and production capacity of the herbal medicines.

1.8 Significance of the Study

i) The findings from the study are hoped to generate additional and new knowledge for researchers in the management of quality health care provision using herbal medicines in Uganda.

ii) The findings from the study are expected to generate information to influence policy in the herbal medicine healthcare management and regulation.

iii) The findings from the study are hoped to help identify mechanisms to improve management practices by traditional and herbal medicine service and product.

iv) The study findings may help generate information for use by local leaders within the district of Mukono in the quality management of traditional medicine health care for malaria.

1.9 Justification of the study

The justification for the study was because Mukono district is covered by a number of swamps leading to high rate of malarial infection. Coupled with the challenging health care needs, communities within Nyenga face inadequate healthcare facilities for malaria treatment; therefore they resort to use of herbal medicines in malaria treatment and other health care needs. Thus, this makes the issue of quality management of herbal medicines provided by traditional practitioners to ensure safety, very vital. This study was necessary to try to establish the rural community needs for health care through herbal medicine for malaria and whether the quality management matches the needs of the population.

1.10 Scope of the Study

1.10.1 Geographical Scope

The study was carried out in the rural area of Nyenga in Mukono district (Uganda). Mukono is located forty three kilometers (43) along Kampala -Jinja Highway. Nyenga has a total number of traditional practitioners registered under the Uganda Traditional Healers Association.

1.10.2 Content Scope

The study focused on finding out how quality management affects healthcare provision using herbal medicines. Focus was put on how customer satisfaction, conformity to standards, product uniformity, and quality improvement, affect healthcare provision focusing on malaria.

1.10.3 Time Scope

The study utilized data and information available on traditional medicines for the last 10 years (2003-2013). This is because it is when the NDA started implementing its policy on traditional medicines practices and control. This study was also carried out within a period of 6 months.

1.11 Operational Definitions of Terms and Concepts

Quality management of herbal and traditional medicines: Manufacturing and handling of traditional medicines and health supplements that is fit for their intended use.

Health care: The diagnosis, treatment, and prevention of disease, illness, injury, and other physical and mental impairments in humans.

Traditional medicine: Health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being.

Malaria: The major parasitic infection in many tropical and sub-tropical regions

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

The literatures reviewed are from developed countries, international reports of the World health organization for the technical aspects of health care services, and National Health Policy in reference to a developed country like Uganda, where the current study is being conducted. Theoretical literatures review on specific topics related to the independent and dependent variables are as follows;

2.1 Theoretical Review

Quality management is a central to health care provision in all health care provision and plays a pivotal role .Henceforth, the quality theory has become crucial in the way health care provision is achieved to provide a better healthcare service to the population.

This study was underpinned by Juran's (1950) quality trilogy theory that asserts that good quality management requires quality actions to be planned out, improved and controlled. The process achieves control at one level of quality performance, and then plans are made to improve the performance on a project by project basis, using tools and techniques such as Pareto analysis. This activity eventually achieves breakthrough to an improved level, which is again controlled, to prevent any deterioration. Juran believed quality is associated with customer satisfaction and dissatisfaction with the product, and emphasized the necessity for ongoing quality improvement through a succession of small improvement in projects carried out throughout the organization. He concentrated not just on the end customer, but on other external and internal customers. Each person

along the chain, from product designer to final user, is a supplier and a customer. In addition, the person will be a process, carrying out some transformation or activity.

The optimal efficacy of traditional and herbal medicine, linked to the mixture of efficacious chemical properties they contain, should be developed as both herbal formulations and medicinal chemical process to prevent deterioration of the quality of the product and thus fulfill effective service needs. In order to achieve this, concerted efforts is needed to clearly define processes and guidelines for traditional medicines and natural products research, in order to support the advancement of this important field. The development of traditional medicines should not be seen as the answer to providing cheap treatments to poor populations. It is important that such medicines are given the same scrutiny as any other pharmaceutical to ensure protection of patients from any major adverse event and also to ensure the benefits of optimal efficacy (Newton et al., 2006). Efficacy and effectiveness have rarely been demonstrated using modern scientific investigations. An evidence-based approach to this issue has only recently been implemented, and the results reveal that most herbal products have considerable knowledge gap that need to be covered before policy makers can be convinced about their efficacy. Ingredients used for symptomatic management in traditional healing are known to be used in developed countries as part of health promotion or disease prevention strategies; thus, acute treatment has been replaced by chronic exposure (Allison et al., 2001). This means that a statement about 'thousands of years of evidence that a product is safe' may not be valid for the way the product is now being used. This does not expressly mean that herbal medicine ingredients are all safe as safety of long-term use alone, cannot be assumed.

2.2 Customer Satisfaction and Health Care Provision

The resurgence of interest in traditional healing systems in the developed countries such as in Europe and North America is reflects in the need to ensure quality management of the system. In such countries, there are developed quality management document that reflect on specific products. There are pharmacopeia and herbal monographs such as the European Commission E- Monograph on selected medicinal plants; the WHO monographs Volumes 1, 2 and 3 on selected medicinal plants. These monographs act as a reference for consumers to adhere to when selecting and using herbal products. Tyler (2000) asserts that the desire to capture the wisdom of traditional healing systems has led to resurgence of interest in herbal medicines, particularly in Europe and North America. It is through such reference documentation that customers increase the use of herbal medicines based on an authenticated documentation. During the latter part of the twentieth century, increasing interest in self-medication care which relies on information from traditional healing systems and has resulted in an enormous growth in popularity of traditional healing modalities, including the use of herbal remedies; this has been particularly true in the USA.

Consumers have reported positive attitudes towards products with references in monographs and pharmacopeia, in large part because they believe them to be of 'natural' rather than 'synthetic' origin, they believe that such products are more likely to be safe than are drugs, they are considered part of a healthy lifestyle, and they can help to avoid unnecessary contact with conventional 'western' medicine. While centuries of use in traditional settings can be used as testimony that a particular herbal ingredient is effective or safe, several problems must be addressed as these ingredients are incorporated into modern practice (WHO, 2007). For example a major lacuna in Ayurveda is the lack of drug standardization, information and quality control. Most of the Ayurvedic medicines are in the form of crude extracts which are a mixture of several ingredients and the active

principles when isolated individually fail to give desired activity. This implies that the activity of the extract is the synergistic effect of its various components. In the absence of pharmacopeia data on the various plant extracts, it is not possible to isolate or standardize on the active contents having the desired effects (Sharma, 1997).

Patwardhan (2005) asserts that there have been instances in the past when a traditional context of usage of a medicinal herb has not been taken into consideration and there have been serious consequences due to this. For example, kava-kava (*Piper methysticum*) is used in the preparation of a calming traditional beverage consumed by the Polynesians during festivals, due to which the herb was picked up by drug companies for use as an anxiolytic drug. However, the drug backfired in terms of safety and led to heap-toxicity in several patients, forcing it to be withdrawn. On closer inspection the reason for the toxicity observed only in the modern derivative was pinned down to the solvent used for extraction. While the traditional preparations were water based, the modern extraction was done in acetone. In addition to kava lactones, another compound glutathione, which was found to have a role in hepato-protection, gets extracted in the water extract while it is significantly missing from the acetone extract. Glutathione reacts with the kava lactones and opens the chemical structure of the lactone rings, thus reducing the side effects.

2.3 Conformity to Standards and Health Care Provision

Standardization of several aspects such as nomenclature of medicinal plants and other resources, their collection practices, semi processes and final processing, packaging, preservation, storage, product life, labeling and modes of distribution including clinical application are needed to ensure quality, safety and efficacy of herbal medicines for malaria. The task of creating quality standards

for products starts from establishing the identity of the medicinal herb, animal part or metals and minerals, and goes onto standardizing the process, product, pharmacological activity, clinical diagnosis and finally the therapeutic interventions. To identify the raw material (a plant, for instance), a reliable traditional source – texts as well as traditional knowledge holders – must be consulted. Tradition identifies materials by vernacular names and descriptions. It is therefore necessary to carefully link the vernacular names and descriptions of plants to the appropriate botanical entity. This could be a simple or complicated exercise. For example, *Tulasi* (Sanskrit) is the vernacular name of a plant which when pointed out to a botanist would be correlated to *Ocimum sanctum* or *Ocimum tenuiflorum.*

Since biological materials possess genotypic and phenotypic variability, while establishing standards it is important to take note of traditional schemes for therapeutic classification of plants. In ancient Ayurvedic texts such as *Susrutha Samhita*, chapters have been dedicated to different kinds of classifications according to properties and contain advice about time and region of collection (*Kala* and *Desh Vichar*). Details on the different qualities of rice cultivated in different soils, milk from different animals, etc. have been described10. An interesting example pertains to the plant *Ipomea mauritiana* (Vidari). In traditional practice, the mature tubers of this plant are advised for preparation of medicine. It was found that mature tubers of the plant, *I. mauritiana* are richer in phytoconstituents than their immature counterparts. A general bioactivity assay such as the Brine shrimp bioassay indicated that the mature tubers were more active as determined by ED50 value. Another interesting example of collection standards is the case of turmeric (*Curcuma longa* L.). It is called as *rajani* or *nisa* in Sanskrit, meaning ‘night’. The rhizomes are traditionally collected during night for better therapeutic purposes. Brine shrimp bioactivity tests conducted at FRLHT indicated

that turmeric (Binzali plant) collected at night was significantly more bioactive than that collected during day. The more complex aspect of quality assurance arises in respect of standardization of the manufacturing process and finished product. The complexity arises because traditional products use a wide range of processing techniques and also dosage forms, from simple powders made from a single plant, to extracts made from many plants. The finished products may be aqueous extracts, herbal wines, herbal oils, baked products, plant starches or alkalis. These different dosage forms have been created because the end-products have differential rates and modes of bio absorption in the body. Their design indicates appreciation of pharmaco-dynamics and kinetics in Ayurveda. Standardizing all these myriad processes and products poses a real challenge to modern scientists.

According to Shia *et al.*, (2007), when traditional medicine is practiced outside its original context and practiced as complementary or alternative medicine, there is a need for increased vigilance due to differing population characteristics, modification of formulations and methods of the transported knowledge. According to WHO, as a general rule evaluation of herbal medicines for malaria should take care of its medical, historical and ethnological background of herbal products and traditional experience of its use. European Union is adopting a traditional use registration procedure for herbal medicines. Similarly many other countries are introducing such systems. Safety monitoring for herbal medicines is also increasing. Adverse experiences from plants such as Aristolochia, drug interactions of St. Johns wort and toxicity of Kava-kava have increased awareness among public and scientific community. Under reporting and poor quality of data provided by users are major challenges for regulators (Barnes, 2007). Countries with their own traditional medical systems are more likely to measure risks against benefits. Also in countries where herbal medicines for malaria

are recently becoming popular, safety is often considered prime compared to efficacy like in the USA (Shia *et al.*, 2005).

Monitoring of practitioners is also done in various countries by checking their usage of medicines and medical procedures, re-registration after a given number of years, medical supervision by allopaths and introduction of voluntary self-regulation systems. Often ambiguities in regulations strain referrals and relationship of conventional practitioners and herbal medicines for malaria practitioners. Non-disclosure of complementary therapies used along with conventional medicines by patients during allopathic consultation is as high as 77% which stymies efficacy assessment of therapies. Concern about negative responses, a perception that physicians need not know about therapies outside their domain, and physicians do not elicit questions about other therapies are considered reason for non-disclosure (Bodeker *et al.*, 2007: 14). Other reasons could be that the patient did not consider complementary interventions as serious medical methods and lack of awareness about consequences of drug interactions. This fact points to a need to strengthen physician-patient relationship and building awareness about the potentials and likely problems of such therapies both among patients and conventional medical practitioners. There has been no development of alternate standards and methods at any national or international level. Thus there are also differing risk assessments in different regions for herbal medicines for malaria. Like in other products, varying regulations in different countries often create double standards for export and domestic consumption of herbal products especially in developing countries. In many countries usage in tradition is considered a reason for exemption from strict safety regulations for herbal medicines for malaria, which may not be valid in all instances (Bodeker *et al.*, 2007).

Food & Drug Administration (2002), also noted that one of the most difficult issues to contend with in translating traditional herbal practices into conventional 'western' medicine is the individualization of prescriptions containing multiple other ingredients. There is little incentive for standardization of products for a mass market, when the intention has been to provide an individual prescription. To the small grower or the traditionally trained herbalist, standardization means understanding the growth conditions, the time of harvesting, the manner of extraction or other preparation of material so that a reliable (albeit small amount of) active ingredient can be offered to people. To the manufacturer or distributor of large quantities that will be sold in a supermarket or a health food store, standardization refers to industrial production under defined conditions, using so-called Good Manufacturing Practices (GMP) akin to those used for drug production.

WHO (2000) asserts that in many cases, a single plant species has several different commercial or medicinal names in different regions. Several distinct species are often used under the same drug name. Another problem relates to adulteration in the market samples. In other words, authentication of the botanical identity and ascertaining the genuineness of drug is great concern in practical situation. To some extent, it can be overcome by drug characterization which is done by estimating their active principles, recording the anatomical features under microscope and their curative effects by clinical trials. When the botanical identity of the plant is controversial, it is better to go for estimation of the therapeutic agent responsible for the curative effect ascribed to the species. The species rich in the ascribed compound should be taken as the genuine drug, those with relatively small amounts may be accepted as substitute of the original drug, and those lacking the required constituents may be rejected.

It is important for world-class pharmacognosy and pharmacology laboratories dealing with traditional knowledge products to have modern quality assurance standards based on the sophisticated qualitative standards built up over centuries within traditional health cultures themselves.

2.4 Product Uniformity and Health Care Provision

Most of the herbal drugs produced currently in the developing countries generally lack proper quality specification and standards and therefore, have no consistency in quality in batch to batch products. Most of these drugs do not have well defined and characterized composition. The three pillars of ideal herbal drug and their rational use are quality, safety and efficacy. The herbal medicines for malaria used to be an individual based treatment regime wherein the traditional physicians used handpicked plant materials to prepare drugs/formulations to treat their patients. Over 80 per cent of the raw material required for herbal medicines for malaria/ herbal medicines used to be collected from wild resources. With the increase in demand of medicinal plants for the commercial herbal medicine sector led to the indiscriminate and unscientific collection without any consideration for the quality of the material collected.

A common argument is that the optimal efficacy of these plant-based products is inherently linked to the mixture of efficacious chemical entities they contain and hence they should be developed as both herbal formulations and also form the basis of medicinal chemistry programmes. Concerted efforts should be made to clearly define processes and guidelines for herbal medicines for malaria and natural products research, in order to support the advancement of this important field. The development of herbal medicines for malaria should not be seen as the answer to providing cheap

treatments to poor populations. It is important that such medicines are given the same scrutiny as any other pharmaceutical to ensure protection of patients from any major adverse event and also to ensure the benefits of optimal efficacy (Newton *et al.,* 2006).

WHO (2001) state that without GMP products cannot be expected to be of required standards and quality. The concept of safety is almost non-existent in many developing countries. Safety requirements with respect to buildings, machinery and staff have to be introduced and if possible, safety manuals have to be prepared in order to focus the attention of the management and staff on these issues. Stringent requirements are being introduced presently to safeguard the environment, to reduce pollution caused by use of synthetic materials and to conserve the biodiversity. Hence eco-audit procedures will be required for safeguarding environmental damage. Organic production will reduce the risks of contamination of products and the environment with synthetic chemicals.

There is one basic difference of outlook between the Ayurvedic and modern Allopathic system regarding the therapeutic use of drugs. While in Ayurveda, whole drug is used; in Allopathy the isolated active ingredient present in the drug is used. Ayurvedic drugs act moderately and gradually, but Allopathic drugs react severely and quickly. Charak asserts that the four standards for effective herbal medicines for malaria include; should be grown in proper season; attain maturity in taste, potency and smell; smell, appearance and taste and touch remains unvitiated by the effect of weather, fire, air and insects; fresh. But Sushruta has propounded a general principle regarding acceptability of plants for use as medicine. A drug may be accepted for use whether it is new or old provided its odour has not vitiated and its taste not deteriorated.

2.5 Quality Improvement and Health Care Provision

Quality is defined in a variety of ways. While there is some agreement that quality embodies notions of efficiency, effectiveness and consumer satisfaction (Lethbridge *et al.,* 1996). By *quality improvement,* we mean the ongoing, systematic process of using quality measurements to identify problems and to implement strategies to improve the quality of care, usually within specific organizational entities, such as a group practice, a health plan, a hospital, a public health department clinic, or a community-based clinic. The objective is to identify the causes of variation in the processes and outcomes of care and to strive continuously for higher levels of performance (Berwick *et al.,* 1990).

A number of plans and cycles can be used in an ongoing way in order to apply quality improvement. One example is PDSA (plan-do-study-act) cycle, also known as the Shewhart or Deming Cycle. In this cycle, the first step is to plan a change designed to improve a product or process. The second step is to implement the change. The third is to observe the positive and negative results of the change. The fourth step is to adopt the change or abandon it or execute the cycle again, possibly under different environmental conditions (Levin, 1994). On a more concrete level, Baker (1997) outlines a series of steps that a health promotion organization considering quality improvement might follow. The first step according to Baker, is to identify the desired outcome, the second step is to decide the focus or population of interest, which could range from a particular set of clients to the broader community. Third is to specify how to recognize whether a change is an improvement by developing measures to test that change. The fourth step is to identify what you might do differently, that is, what changes you might try to create improvement, and then engage in tests of change where you try out these changes to see if they result in improvement.

It is now well known that the therapeutic activity of a medicinal plant is due to the presence of certain biologically active chemical constituents, which are either primary or secondary metabolites. The expression of many of these compounds particularly those of the secondary metabolite category are controlled and conditioned by a variety factors such as its genetic predisposition, habitat of the plant agro climatic conditions, season and also the stage of growth and development of the plant. The Traditional Indian System of Medicines like Ayurveda, Siddha, Unani and Amchi provided specific instructions for collection by indicating location/edaphic conditions, habitat, seasonal and even the stage of the plant growth and developmental stage. Scientific investigations now provide ample evidence to the fact that there is a flux of change in the presence of very many of these chemical constituents, particularly those of the secondary metabolites, in such varied conditions described above. Therefore, it is extremely important to establish the reference samples and to determine the quality parameters of the medicinal plants.

In the whole process development of herbal drug/product based on traditional knowledge needs proper taxonomically identified safe raw material and scientific validation of the products. Further get constant supply of right raw material whether procured from wild or cultivated and their storage one has to follow. Good Agriculture Practices (GAP), Good Collection Practices (GCP), Good Ethical Practices (GEP), Good Procurement Practices (GPP), Good Safety Practices (GSP) (Pesticide, heavy metal, microbial load as per WHO guidelines) and Good Storage Practices (GSP). Quality control of the phyto-products for human consumption and world market can be ensured by maintaining the quality of raw material adequacy of processing technology and quality of the finished products. Thus, the quality concept commences right from the choice of authentic and improved seeds (varieties) to the post-harvest treatment of the raw material and to the process

control for avoiding contamination. As such for developing phyto-products, WHO's, Good Manufacturing Practice (GMP) must be followed to satisfy the ISO 9000 certification.

CHAPTER THREE

METHODOLOGY

3.0 Introduction

This chapter presents a description of research methodology that was used to undertake the study. It covers the research design, study population, sampling design and size, data sources, data collection instruments, reliability and validity of research instruments, measurements of research variables, data processing/analysis, and limitations to the study.

3.1 Research Design

A case study descriptive design was used in conducting the study. This design was opted for because it helped the researcher to carry out in-depth investigation in order to gain insight into larger cases. Both quantitative and qualitative approaches were used during data collection, as these helped in describing the characteristics of an event in determining the degree of relationships between variables (Amin, 2005; Sekaran, 2003). It also explored how the influence on quality health care, through a series of activities, affected the outcome of health care services. Through interviews and discussions, this approach helped the researcher to gain deeper understanding of the relationship between quality management of herbal and traditional medicine and healthcare provision in Mukono district.

3.2 Study Population

The study focused on traditional medicine practitioners and customer/recipients who consume and use these medicines to treat mainly malaria. The study population involved a census of 47 registered herbal medicines for malaria practitioners and 46 consumers/recipients of herbal medicines for malaria and three (3) opinion leader/policy makers. A total population of 96 was used for this study.

3.3 Sampling Techniques and Procedure

3.3.1 Sample Size and Selection

A total sample of 96 respondents was used in this study in line with Krejcie and Morgan (1970) table guide for sample selection which states that "a sample will always be selected as a representative of the given population. Considering that the ratio of traditional practitioners to the population in Uganda is estimated to 1 to 200 to 1:400 (WHO, 1995), the samples ratio of 47 practitioners to 46 consumers were deemed average for the study. Simple random sampling method was used in selecting respondents from each of the respondent category making a total of 96 respondents. See Table 1 below.

Table: 1 Sample Size and Selection

Category	**Population**	**Sample Size**	**Sampling Technique**
Traditional Medicine Practitioners	60	50	Simple Random
Recipients/users of traditional medicine	70	46	Simple Random
Total	**130**	**96**	

Source: Natural Chemotherapeutic Laboratory Wandegeya, using Krejcie & Morgan (1970) technique.

3.4 Data Collection Methods

3.4.1 Questionnaire Survey

Primary data was collected using structured questionnaires administered to registered traditional practitioners of the local traditional healers association and recipients/consumers of the traditional

medicines used in treatment of malaria. The respondents included specifically herbal medicines for malaria practitioners who have been dealing in herbal medicines in treating malaria.

3.4.2 Interviews

This method was used to collect data from traditional medicines practitioners and their users. Face-face contact with the respondents was encountered. This allowed for in-depth analysis of the research concept in order to get the expected information and data relevant for this study.

3.5 Data Collection Instruments

3.5.1 Questionnaires

Self-administered 5 point likert– type closed Questionnaires were used to collect data from the herbal medicines practitioners and consumers (herbal medicine consumers/recipients). The questionnaires contained short structured questions with answers provided on a 5-likert scale of strongly agree, agree, not sure, disagree, and strongly disagree.

3.5.2 Interview Schedule

Structured interview guide was also used in this study. This method of data collection was used in order to get on-spot answers and views of the respondents involved in the study. Pre-planned meeting and discussions were used to generate information from secondary sources. Field survey reports and published reports were used to correlate data collected.

3.6 Validity and Reliability of the Research Instruments

Validity and reliability are very important concepts in the acceptability of the use of an instrument for research purposes. Validity refers to the appropriateness of the instrument while reliability refers to its consistency in answering whatever it was sent out to measure. Usually they are established before the research process.

3.6.1 Validity of Instruments

Closed questionnaire was developed in harmony with the guidelines specified by Sekaran (2000). First, an item analysis was done to verify the items in the instrument and a pre – test was carried out to check validity and reliability so as to minimize on vagueness of the results generated. Content Validity Index was measured by declaring the valid items to total number of items. The formula for the content Validity Index (CVI) according to Amin (2005) is:

CVI= No. of items declared valid/total no. of items.

If the instrument has an average index of 0.7 or above it is accepted as valid (Amin, 2005).The content validity index was computed and elicited results are presented in table 2.

Table 2: Content Validity Index results

Research instruments	Total No. of items in the instruments	Number of instruments rated as valid	Content Validity Index(CVI)
Questionnaire	40	35	0.875
Interview guide	12	10	0.833

Source: Primary Data

Table 2 shows that CVI of the questionnaire was 0.875 and the interview guide was 0.833, CVI of each instrument was above 0.7, was concluded that all instruments used to collect the data for this study were valid.

3.6.2 Reliability

According to Amin (2005), reliability refers to the dependability or trustworthiness in the context of measuring instruments. It is the degree to which the instrument consistently measures what it is intended to measure. Reliability was obtained by using Cronbach's coefficient test as stated in the following formula:

$$\alpha = \frac{K}{K-1}\left[\frac{1-\sum \delta^{2} k}{\delta^{2}}\right]$$

Where:

α = Alpha coefficient

δ^{2} = Variance of the total test

$\sum \delta^{2} k$ = Sum of variances of the k questions in the instrument

K = Number of questions in the research instrument

Reliability (internal consistency and stability) of the instruments was tested using Cronbach's Alpha Coefficient which should be above 0.5 (50%) (Cronbach, 1946). The researcher tested inter–item consistency reliability to ensure that there was consistency of respondents' answers to all items in the measure. The findings of the reliability test showed that all the variables were above the accepted alpha coefficient of 0.5 (50%). This is shown in Table 3.

Table 3: Reliability Coefficient Results

Variables	No of Items	Cronbach Alpha Items
Quality Improvement	13	.717
Customer Satisfaction	10	.826
Conformity To Standards	10	.894
Product Uniformity	12	.816
Healthcare Provision	11	.713

Source: Primary data

Table 3 above shows that responses to the questionnaires in relation to the variables selected were valid as the figures were all below one.

3.7 Procedure of Data Collection

The researcher obtained an introductory letter from the Uganda Management Institute, which was presented to political and civil leaders of the municipality. Permission and cooperation to carry out the research was then sought

3.8 Data Analysis

Data was analyzed and interpreted using both qualitative and quantitative techniques of analysis.

3.8.1 Qualitative Data Analysis

Qualitative data was collected through recording the opinion statements from secondary data source. The data was used for discussion in the study.

3.8.2 Quantitative Data Analysis

Data collected from the primary source was compiled, sorted, edited for accuracy and clarity, classified, coded into a coding sheet and analyzed using a computerized data analysis package/tool known as SPSS 16.0. Univariate, bivariate, and multivariate analysis was used to determine the mean, correlation, and regression analysis respectively. Graphs, frequencies and distribution tables (represented as figures) were used in data presentation and a conclusion to the study was drawn.

3.9 Measurements of the Research Variables

Quality management was measured using the dimensions of quality control and quality assurance as developed by Patwardhan (2005); Shankar *et al.*, (2006). Traditional practitioners' competence was measured using the dimensions of knowledge (level of education), experience and excellence of workers, ability and skills as developed by Sveiby (2001); McClelland (1998); Torkington and Hael (2008); Woodruffe (2002).Health care provision was measured using the dimensions of effectiveness, efficiency, and safety as developed by WHO (2007); Sharma (1997).

3.10 Limitations of the study

The following problems were encountered in this study:

It was apparent that some respondents withheld some vital information due to fear; though this was overcome by assurance of confidentiality on all the information that was provided.

Some of the respondents did not have enough time to provide all responses fill to the questionnaires and this affected the quality of the data being sought for this study. There were shortcomings on the accuracy of the research tools and methodology (due to langue and interpretation) that was overcome by correlating the primary data with the secondary data that exist on herbal medicines for malaria.

CHAPTER FOUR

PRESENTATION, ANALYSIS AND INTERPRETATION OF RESULTS

4.0 Introduction

In this chapter, the results and interpretation of the research respondents are presented. The presentation is guided by the research objectives and as a result, the statistics are a reflection of what it takes to answer the research questions. Chapter four of this study presents the background information of the respondents including gender category, level of education, job position, and years in service of the Staff. The response rate by the respondents was ninety percent

4.1 Response Rate

The research set out to collect data from various categories of respondents who are involved in processing and consumption of traditional medicines. 47 traditional practitioners and 46 consumers/recipients/users of traditional medicines responded in this study as shown in the table below:

Table 4: Response Rate

Category	**Population**	**Sample Size**	**Response rate**
Traditional Medicine Practitioners	60	50	83.3%
Recipients/users of traditional medicine	70	46	66%
Total	**130**	**96**	74%

Source: Primary data

4.2 Background and characteristics of respondents

The background information of the respondents included the gender, level of education, work tenure, and roles of respondents.

4.2.1 Distribution of respondents by Gender

Gender equality in any social and economic development project is considered paramount for the success of any project. It is necessary to involve both males and females in equal proportion. This study explored the involvement of gender in the activities of herbal medicines and the results are show as follows;

Table 5: Proportion of Gender and Respondents Category

			Respondents Category		**Total**
			Recipients	**Practitioners**	
Gender	Male	Count	28	38	66
		Column %	**60.94%**	**76.0%**	68.8%
	Female	Count	18	12	30
		Column %	**39.1%**	**24.0%**	**31.3%**
Total		Count	**46**	**50**	**96**
		Column%	**47.9%**	**52.1%**	**100.0%**

Source: Primary data

Table 5 indicates that there were more practitioners (76%) interviewed than consumers/recipients (61%). Amongst the practitioners there were more male as compared to female. Whether this finding has direct relation to the responsibilities or the opportunities for the gender to influence quality management of herbal medicine is a significant area to be explored. The gender proportion of more males than female is also reflected in the percentage recipient (38% male; 12% female). This study captured more male Practitioners respondent as compared to the female respondent. While on the other side there were more female consumers/recipients respondents than the male recipient's respondent of herbal medicines for malaria. This implies that quality management through herbal and traditional medicine is more embraced by males than their female counter parts in provision of health care in treatment of malaria.

4.2.2 Distribution of respondents by Level of Education

Formal education is necessary to enable individual read and write to communicate and share knowledge within a community. The study explored the level of formal education of the respondents as shown below.

The finding in the table 6 below shows the level of education of the respondents.

Table 6: Proportion of Highest Level of Education of Respondents

			Respondents Category		
			Recipients	**Practitioners**	**Total**
Education Level	No Formal Education	Count	11	27	38
		Column %	**23.9%**	**54.0%**	39.6%
	Primary Level	Count	22	15	37
		Column %	**47.8%**	**30.0%**	38.5%
	O - Level	Count	9	4	13
		Column %	**19.6%**	**8.0%**	13.5%
	Diploma	Count	4	4	8
		Column %	**8.7%**	**8.0%**	8.4%
Total		Count	**46**	**50**	**96**
		Column%	**47.9%**	**52.1%**	**100.0%**

Source: Primary data

From the finding in table 6 above, majority (54%) of the practitioners had no formal education, while there were only 24% of the consumers/recipients in this category. Further analysis also indicates that 48% of consumers/recipients who responded had attained primary level of education while the practitioners comprised 30%. The findings also indicate that there were 20% of consumers/recipients who had attained ordinary level of education and the practitioners comprised only 8%. The result also shows that 8.7% of consumers/recipients and 8% of practitioners who responded had attained diploma level of education. This implies that most of those who responded in the study were primary level certificates holders who could either read or write in the local language and would mean that they were capable of keeping records of their data for management purposes.

4.2.3 Period of Dealing with Herbal medicines for malaria and Respondent Category Distribution

Table 7 below shows the period for which the respondents were engaged in providing health care using herbal medicines for malaria.

Table 7: Period of Dealing with Traditional Medicines and Respondent Category Distribution

			Respondents Category		
			Recipients	Practitioners	Total
Period spent in practicing and dealing with Traditional Medicines	1 – 5 years	Count	19	25	44
		Column %	41.3%	50.0%	45.8%
	6 – 10 years	Count	13	16	29
		Column %	28.3%	32.0%	30.2%
	11 – 15years	Count	14	9	23
		Column %	30.4%	18.0%	24.0%
Total		Count	46	50	96
		Column%	47.9%	52.1%	100.0%

Source: Primary data

The finding in table 7, indicated that majority (50%) of practitioners and 41% of consumers/recipients who responded had dealt with herbal medicines for malaria for a period of 1-5 years, while there were 28% consumers/recipients and 32% of practitioners who had dealt with

herbal medicines for malaria for 5-10 years. Further analysis from the table 7, also indicates that there were 30% of consumers/recipients and 18% of practitioners who responded had dealt with herbal medicines for malaria for 10-15 years. This implies that most of the respondents had dealt with herbal medicines for malaria for 1-5 years as shown by the results. This means that the practitioners were in experienced in handling and dealing with traditional medicine, which could escalate the problem of quality and standards.

In quote, one respondent had to say that "there is no established period for which practitioners should deal with herbal medicine to provide effective service. However, the longer the period of dealing with herbal medicine the more chances the practitioner has to perfect and improve on formulation and monitoring and evaluating his/her practice. It all depends how active the practitioner works. Working every day for a five months week may be better than working once a year for five years".

4.2.4 Level of Information and Instruction in the Use of herbal medicines for malaria and Respondent Category Distribution

Traditional and herbal medicine practice is widely reported to be handed from generation to generation, the process of information exchange depends largely on apprenticeship which quite often takes time (WHO, 2004) however there are cases of herbal medicine use that takes place through verbal instruction that nay be a one time off or through repeated hearing of the same information.

The finding in table 8 indicates whether the consumers/recipients and practitioners who responded had received training in dealing with herbal medicines for malaria.

Table 8: Training in the Use of Traditional Medicines and Respondent Category Distribution

			Respondents Category		
			Recipients	**Practitioners**	**Total**
Received Training in the use of traditional medicines	Yes	Count	21	13	34
		Column %	**45.7%**	**26.0%**	35.4%
	No	Count	25	37	62
		Column %	**54.3%**	**74.0%**	64.6%
Total		Count	**46**	**50**	**96**
		Column%	**47.9%**	**52.1%**	**100.0%**

Source: Primary data

From the finding table 8, majority (54%) of the consumers/recipients and 74% of the practitioners who responded had no Information and Instruction in the Use of herbal medicines for malaria prior to their use, while 48% of consumers/recipients and only 26% of practitioners had informal Information and Instruction in the Use of traditional medicines in healthcare provision. This implies that majority of the respondents had no Information and Instruction in the use of herbal medicines for malaria. This could limit their understanding and knowledge towards proper quality management of traditional medicines, which compromises its efficacy and safety.

4.2.5 Practitioners' Role within Herbal Medicine Practice Setting

Traditional and herbal medicine processing involves a number of activities which often involve different roles and sometimes specialties. The more specialized the practitioner is the more the

chance that he/she will adhere to quality controls and therefore quality management of the herbal health care delivery. For example, correct identification, appropriate harvesting of a medicinal plant and the consequent drying or extraction of the products translates to the quality of the service and management controls.

The finding in table 9, below shows the roles played by practitioners who responded in the study.

Table 9: Practitioners' Role within Herbal Medicine Practice Setting

		Frequency	Valid Percent	Cumulative Percent
Valid	Research & Packaging	25	50.0	50.0
	Processing	16	32.0	82.5
	Extracting	9	18.0	100.0
	Total	**50**	**100.0**	

Source: Primary data

The results in table 9 above indicate that majority (50%) of the practitioners who responded were involved in research and packaging, while 32% were involved in processing. Only 18% were involved in traditional medicine extraction as shown by the results above. This implies that majority of the practitioners took on the roles of research and packaging in a traditional medicine setting.

4.3 Factor Analysis

Factor analysis was used to extract the most important factors that measured the study variables. These factors explained patterns of correlation between the dependent and independent variables. The principal component analysis extraction method and varimax rotation methods were used to extract and reduce on the many items into few and relevant factors that can be worked on. Only factors with Eigen values greater than 1 (one) were extracted and correlation coefficients of +/- 0.3 were deleted from the rotated component matrix table. The extracted factors were used to fit the regression models. The rotated component matrix for each variable is outlined below;

4.3.1 Quality Control Management

The principal component analysis was used to analyze the eighteen (18) dimensions of quality control management. The dimension was related to the quality establishing if there were standards set by the practitioners in the production system.

Table 10: Factor Analysis Results for Quality Control Management

Quality Management	Product Uniformity	Quality Improvement	Customer Satisfaction	Conformity to Standards
All our products have been processed under the same guidelines and methods	.720			
All our products have always had the right and standard content	.867			
We have always used the same process in extracting raw materials from medicinal plants	.883			
All our products have always had uniform packages	.707			
All our products have always been process under standard quality specification	.802			
All production of our traditional medicines is guided by standard safety manuals	.767			
All our medicines always go through quality measurements during their processing	.815			
All our medicines have always followed specific processing time during production		.766		
We always follow good manufacturing practices during our production processes		.880		
We always use safe raw material in medicine production		.811		
We always use the right raw material in medicine production		.789		
There has always been adequacy in our medicine processing		.776		
There has always been increased demand for our existing traditional medicines			.880	
All our medicines have always had value as perceived by the consumers			.725	
Customers prefer our medicines to other artificial medicines on the market			.791	
All our products have always got expiry dates				.707
We always identify the right medicinal plants in production of our products				.710
We have always had better collection practices of raw materials used in producing medicines				.726
Eigen Values	**19.138**	**5.006**	**3.63**	**3.426**
Variance %	**42.529**	**11.124**	**8.067**	**7.614**
Cumulative %	**42.529**	**53.653**	**61.72**	**69.334**

Source: Primary data

Factor analysis in table 10 above showed that the total success of quality control management is enhanced by product uniformity which highly contributes to improved healthcare provision. This analysis is important for herbal medicines for malaria practitioners and national drug authority in Uganda because it helps in defining the magnitude of quality control management to the responsible policy makers. Eighteen (18) items constituting 69% of the total variance of quality control management were extracted using the varimax rotation method to obtain individual contribution of the four constructs of quality control management. It was found out that product uniformity (19%) contributed more to quality control management, followed by quality improvement (5%), customer satisfaction (4%), and conformity to standards (3%) respectively.

4.3.2 Health Care Provision

The principal component analysis was used to analyze the Eleven (11) dimensions of healthcare provision. This is shown in table 11.

Table 11: Factor Analysis Results for Health Care Provision

Health Care Provision	**Safety**	**Access**	**Affordability**
The herbal medicines for malaria that I have ever used has always been safe	.778		
I have never developed any complication after using herbal medicines for malaria	.578		
The herbal medicines for malaria that I have ever used have high level of effectiveness	.587		
Many consumers of herbal medicines for malaria that I have ever used have always given it complements	.890		
I always get herbal medicines for malaria at my reach when I need it		.703	
The herbal medicines for malaria that I need are always available in the market		.760	
I can always get herbal medicines for malaria that I use at any time		.885	
I have always easily accessed all herbal medicines for malaria that I need		.717	
The suppliers of herbal medicines for malaria have always made it available at any time		.639	
I am always able to afford all the herbal medicines for malaria that I need			.777
The price of traditional medicine that I use has always been fair			.876
Eigen Values	**6.382**	**1.120**	**1.096**
Variance %	**58.018**	**10.178**	**9.960**
Cumulative %	**58.018**	**68.196**	**78.156**

Source: Primary data

Factor analysis in table 11, above shows that what matters most in healthcare provision through use of herbal medicines for malaria was safety of the medicines. Eleven (11) items constituting 78% of the total variance of healthcare provision were extracted using the varimax rotation method to obtain individual contribution of the three constructs of healthcare provision. It was found out that safety

(58%) contributed more to healthcare provision, followed by access (11%), and affordability (10%) respectively.

4.4 Descriptive for the Variables under Study

Descriptive statistics were generated to indicate the means and standard deviations of the variables under study as seen in table 9 below.

4.4.1 Customer Satisfaction

A questionnaire was used on consumers/recipients to determine whether they were satisfied with herbal medicines in treatment of malaria compared to other medicines on the market, and results were indicated in table 12.

Table 12: Description for Customer Satisfaction

	N	Min	Max	Mean	Std. Deviation
We always afforded herbal medicines for malaria compared to other medicines on the market	46	1.00	5.00	3.70	1.31
I have frequently used herbal medicines for malaria when I am sick	46	1.00	5.00	3.89	1.11
I have always easily had access and use to herbal medicines for malaria in past years	46	1.00	5.00	3.73	1.37
I have always preferred herbal medicines for malaria to other medicines on the market	46	1.00	5.00	3.76	1.25
Many people in my home area always use herbal medicines for malaria when they fall sick	46	1.00	5.00	3.58	1.32
I have always appreciated using herbal medicines for malaria in treating my sickness in the past years	46	1.00	5.00	3.80	1.19
The herbal medicines for malaria that I have ever used has always had rapid action on my sickness	46	1.00	5.00	3.83	1.27
I have never complained after using herbal medicines for malaria in the past years	46	1.00	5.00	3.67	1.35
I have been healed by herbal medicines for malaria that I have always used in the past years	46	1.00	5.00	3.84	1.38
There has always been availability of herbal medicines for malaria whenever I need them	46	1.00	5.00	3.85	1.28

Source: Primary data

From table 12 above, the consumers/recipients were neither agreed nor disagreed whether they had always afforded herbal medicines for malaria compared to other medicines on the market (mean 3.70). They were also not sure about frequently using herbal medicines for malaria when sick (mean 3.89). They were also not sure on always easily having access and use to herbal medicines for malaria in past years (mean 3.73). The study also revealed that the respondents were not sure on their preference for herbal medicines for malaria to other medicines on the market (mean 3.76). further analysis also showed that the respondents were neither in agreement nor disagreement about many people in their home area always using herbal medicines for malaria when they fall sick (mean 3.58). they were also not sure about having always appreciated using herbal medicines for malaria in treating sickness in the past years (mean 3.80) and that the herbal medicines for malaria that they have ever used has always had rapid action on my sickness (mean 3.83). the respondents were also not sure whether they have never complained after using herbal medicines for malaria in the past years (mean 3.67) and also having been healed by herbal medicines for malaria that they have always used in the past years (mean 3.84). Furthermore the consumers/recipients were also not sure about availability of herbal medicines for malaria whenever they needed them (mean 3.85).

4.4.2 Conformity to Standards

A questionnaire was used on consumers/recipients to determine whether herbal medicines in treatment of malaria conformed to standards compared to other medicines on the market, and results were indicated in table 13

Table 13: Conformity to Standards

	N	Min	Max	Mean	Std. Deviation
All the herbal medicines for malaria that I always use are effective	46	1.00	5.00	3.57	1.17
I have always used herbal medicines for malaria which are properly labeled	46	1.00	5.00	2.57	1.13
I always get proper prescription when I buy any traditional medicine	46	1.00	5.00	3.76	1.17
I have always had ease of using herbal medicines for malaria in the past years	46	2.00	5.00	3.69	1.04
I have always verified all the herbal medicines for malaria that I consume	46	1.00	5.00	3.63	1.22
All herbal medicines for malaria that I have always bought are picked from a good storage point	46	1.00	5.00	3.63	0.95
All herbal medicines for malaria that I have always used has never caused me harm	46	1.00	5.00	3.63	1.24
I am always served herbal medicines for malaria by a qualified practitioner	46	1.00	5.00	3.40	0.86
All herbal medicines for malaria that I have ever consumed had expiry dates inscribed on them	46	1.00	5.00	3.38	1.30
The herbal medicines for malaria that I always buy have preservatives	46	1.00	5.00	3.35	1.12
I have always bought all my herbal medicines for malaria from a specific distribution point	46	1.00	5.00	2.50	1.31

Source: Primary data

Analysis from table 13 above, shows that consumers/recipients of herbal medicines for malaria were not sure about all the herbal medicines for malaria that they always use being effective (mean 3.57), however, they disagreed about using herbal medicines for malaria which are properly labeled (mean 2.57). The result also indicated that the consumers/recipients were not sure about always getting proper prescription when they buy any traditional medicine (mean 3.76), and were not sure of always having ease of using herbal medicines for malaria in the past years (mean 3.69). Further analysis shows that they were also not sure about always verifying all the herbal medicines for

malaria that they consume (mean 3.63), and also that all herbal medicines for malaria that they have always bought are picked from a good storage point (mean 3.63). They were also not sure about all herbal medicines for malaria that they have always used has never causing harm (mean 3.63) and also about always being served herbal medicines for malaria by a qualified practitioner (mean 3.40). analysis from the results also indicates that the consumers/recipients were not sure about all herbal medicines for malaria that they have ever consumed had expiry dates inscribed on them (mean 3.38), the herbal medicines for malaria being preserved (mean 3.35), and that they disagreed about buying all herbal medicines for malaria from a specific distribution point (mean 2.50).

4.4.3 Product Uniformity

A questionnaire was used on consumers/recipients to determine whether herbal medicines in treatment of malaria were uniform compared to other medicines on the market, and results were indicated in table 14.

Table 14: Description for Product Uniformity

	N	Min	Max	Mean	Std. Deviation
The prescription of the herbal medicines for malaria that I always use has never changed	46	1.00	5.00	3.04	1.23
The taste of herbal medicines for malaria that I always use has never changed in the previous years	46	1.00	5.00	2.20	1.11
The package of herbal medicines for malaria that I always use has never changed in the past years	46	1.00	5.00	3.13	1.11
The appearance of herbal medicines for malaria that I always has remained the same	46	1.00	5.00	3.20	1.22
The smell of herbal medicines for malaria that I always use has never changed in the past years	46	1.00	5.00	3.25	1.10
The content of herbal medicines for malaria that I always use has not been altered	46	1.00	5.00	3.37	0.93
The quality specification of herbal medicines for malaria that I always use has never changed	46	2.00	5.00	2.44	1.01
The quantity/weight of herbal medicines for malaria that I always use has been the same	46	1.00	5.00	3.22	1.01
The names of herbal medicines for malaria that I always use for specific sickness has never changed	46	1.00	5.00	3.46	1.24
The formulation of all herbal medicines for malaria that I have ever used has never changed	46	1.00	5.00	3.36	1.07

Source: Primary data

Further analysis from table 14 above, shows that the recipient were not sure whether the prescription of the herbal medicines for malaria that they always use had never changed (mean 3.04), but they were in disagreement about the taste of herbal medicines for malaria that I always used never changing in the previous years (mean 2.20). further analysis also showed that the consumers/recipients were not sure about the package of herbal medicines for malaria that they always use never being changed in the past years (mean 3.13), the appearance always remaining the same (mean 3.20), the smell always not changing in the past years (mean 3.25), and that the content of herbal medicines for malaria that always use had not been altered (mean 3.37); but they were in

disagreement about the quality specification of herbal medicines for malaria never changing (mean 2.44). The result also indicates that consumers/recipients were not sure about the quantity/weight of herbal medicines for malaria that they always use being the same (mean 3.22), the names not changing (mean 3.46), and the formulation never being changed (mean 3.36).

4.4.4 Quality Improvement

A questionnaire was used on consumers/recipients to determine whether there was quality improvement in herbal medicines in treatment of malaria compared to other medicines on the market, and results were indicated in table 15.

Table 15: Description for Quality Improvement

	N	Min	Max	Mean	Std. Deviation
The herbal medicines for malaria that I have always used has never had any side effect on me	46	1.00	5.00	3.43	1.17
I have always gained satisfaction after using herbal medicines for malaria	46	1.00	5.00	3.76	0.99
All the herbal medicines for malaria that I have always used have proved to be safe	46	1.00	5.00	3.66	1.03
The raw material used in processing herbal medicines for malaria that I use is always the same	46	1.00	5.00	3.69	0.87
The herbal medicines for malaria that I use have always been freshly processed	46	1.00	5.00	3.67	1.06
The herbal medicines for malaria that I use have always been blended to the required standard	46	1.00	5.00	3.57	1.13
There has always been reliability of all herbal medicines for malaria that I have ever used	46	1.00	5.00	3.70	0.92
I have always experienced immediate relief from my sickness after using herbal medicines for malaria	46	2.00	5.00	3.89	0.88
The traditional practitioners have always reviewed the content of their medicines that I use	46	1.00	5.00	3.63	0.93
All herbal medicines for malaria that I have ever used have been credible in curing my sickness	46	1.00	5.00	3.72	1.19

Source: Primary data

The results from table 15 above shows that the consumers/recipients of herbal medicines for malaria were not sure whether there had never been any side effect (mean 3.43), and were also not sure about gaining satisfaction after using herbal medicines for malaria (mean 3.76). The consumers/recipients were also not sure about all herbal medicines for malaria proofing to be safe (mean 3.66), the raw material used in processing always being the same (mean 3.69), and always being freshly processed (mean 3.67). further analysis of the results still showed that the consumers/recipients were not sure about the medicines that I use they being blended to the required standard (mean 3.57), its reliability (mean 3.70), experiencing immediate relief from sickness after use (mean 3.89), reviewing the content (mean 3.63), and that all herbal medicines for malaria being credible in curing sickness (mean 3.72).

4.4.5 Healthcare Provision

A questionnaire was used on consumers/recipients to determine whether herbal medicines used in treatment of malaria was used in health care provision compared to other medicines on the market, and results were indicated in table 16.

Table 16: Description for Healthcare Provision

	N	Min	Max	Mean	Std. Deviation
The traditional medicines that I have ever used has always been safe	46	1.00	5.00	3.00	0.92
I always get traditional medicines at my reach when I need it	46	2.00	5.00	3.32	0.86
The traditional medicines that I need are always available in the market	46	1.00	5.00	2.24	0.90
I can always get traditional medicines that I use at any time	46	1.00	5.00	2.92	0.84
I am always able to afford all the traditional medicines that I need	46	1.00	5.00	3.24	0.90
The price of traditional medicine that I use has always been fair	46	1.00	5.00	3.28	0.80
I have never developed any complication after using traditional medicines	46	1.00	4.00	2.84	0.86
I have always easily accessed all traditional medicines that I need	46	1.00	5.00	3.20	1.03
The traditional medicines that I have ever used have high level of effectiveness	46	2.00	5.00	3.48	0.76
Many consumers of traditional medicines that I have ever used have always given it complements	46	2.00	5.00	3.36	0.66
The suppliers of traditional medicines have always made it available at any time	46	1.00	5.00	3.32	1.03

Source: Primary data

The results from table 16 above, shows that the consumers/recipients were not sure about herbal medicines for malaria being safe (mean 3.00), and also about it when they need it (mean 3.32). The analysis also shows that the consumers/recipients were not sure about herbal medicines for malaria that they need always being available in the market (mean 3.24). However, they disagreed about always getting herbal medicines for malaria that they use at any time (mean 2.92), but again were not sure about being always able to afford all the herbal medicines for malaria that I need (mean 3.24), the price of traditional medicine that they use being always fair (mean 3.28). They were in disagreement about never developing any complication after using herbal medicines for malaria (mean 2.84), but were again indifference about always easily accessing all herbal medicines for

malaria that they need (mean 3.20). They were also not sure about the herbal medicines for malaria that they have ever used being highly effective (mean 3.48), and consumers always giving complements (mean 3.36), and about the suppliers of herbal medicines for malaria always making them available at any time (mean 3.32).

4.5 Correlation Analysis

The relationships between study variables are established by running a correlation analysis and since the study had relationship objectives, the study variables quality control management and healthcare provision relationships were established using Pearson's correlation. The results of the correlation analysis are indicated in table 17.

Table 17: Showing the Relationship between the Study Variables

	1	2	3	4	5
Quality Improvement (1)	1.000				
Customer Satisfaction (2)	.480**	1.000			
Conformity to Standards (3)	.540**	.303*	1.000		
Product Uniformity (4)	.406**	.445**	.343*	1.000	
Health Care Provision (5)	**.370***	**.599****	**.615****	**.494****	1.000
** Correlation is significant at the 0.01 level (2-tailed).					
* Correlation is significant at the 0.05 level (2-tailed).					

Source: Primary data

4.5.1 Relationship between Customer Satisfaction and Health Care Provision

According to table 17 above, there is a significant positive relationship between the independent variable and dependent variable ($r = .599$, P value <0.01). This means that there is a significant positive relationship between customer satisfaction and healthcare provision. Healthcare provision lies in the multi-dimensional nature of better customer satisfaction. Customer satisfaction determines the demand for a particular product or service. Without customer satisfaction, there is no healthcare provision through herbal medicines for malaria because there would be no consumers of these herbs and herbal medicines for malaria.

Hypotheses testing

The study tested hypotheses as a way of accepting or rejecting them. This was the basis on which the analysis was based from where the conclusions were drawn.

Hypothesis One:

This hypothesis predicted that customer satisfaction has a significant positive relationship with use of traditional and herbal medicines in health care provision.

α level: $\alpha = 0.01$ Null hypothesis:

Ho:

Customer satisfaction has no significant positive relationship with use of traditional and herbal medicines in health care provision in Mukono district.

H1:

Alternate hypothesis:

There is a significant relationship between them

The hypothesis was tested using Pearson's coefficient of rank correlation and the results are summarized in table 17.

Table 17 shows that there is a strong significant positive relationship between customer satisfaction in use of traditional and herbal medicines in health care provision in Mukono district ($r = 0.599$; p value = 0.01). Since the correlation was found to be significant, the null hypothesis (Ho) was accepted and the alternate hypothesis (H1) which does not recognize the existence of significant relationship between customer satisfaction and health care provision was rejected.

4.5.2 Relationship between Conformity to Standards and Health Care Provision

From Pearson's Correlation table 17 above, there is a significant positive relationship between the independent variable and the dependent variable (r = .615, P value <0.01). This implies that there is a significant positive relationship between conformity to standards and improved healthcare provision. The key factors in conformity to standards are the efficacy of the herbs and herbal medicines for malaria used in provision of improved healthcare provision. Poor standard herbs and herbal medicines for malaria compromise the quality of healthcare provided to the society.

Hypothesis Two:

Null hypothesis:

Ho:

Conformity to standards has no significant positive relationship with use of traditional and herbal medicines in health care provision in Mukono district.

H1:

Alternate hypothesis:

There is a significant relationship between them

α level: α = 0.01

The hypothesis was tested using Pearson's coefficient of rank correlation and the results are summarized in table 17.

Table 17 shows that there is a strong significant positive relationship between conformity to standards in use of traditional and herbal medicines in health care provision in Mukono district (r = 0.615; p value = 0.01). Since the correlation was found to be significant, the null hypothesis (Ho)

was accepted and the alternate hypothesis (H1) which does not recognize the existence of significant relationship between conformity to standards and health care provision was rejected.

4.5.3 Relationship between Product Uniformity and Health Care Provision

From Pearson's Correlation table 17 above, there is a significant positive relationship between the independent variable and dependent variable ($r = .494$, P value <0.01). This means that there is a significant positive relationship between product uniformity and improved healthcare provision. Herbal medicines for malaria practitioners with superiority in provision of uniform products to provide improved healthcare encourages people to use more of their products hence increased demand. Inefficient herbal medicines for malaria blending and processing may compromise product uniformity which affects improved healthcare provision.

Hypothesis Three

Null hypothesis:

Ho:

Product uniformity has no significant positive relationship with use of traditional and herbal medicines in health care provision in Mukono district.

H1:

Alternate hypothesis:

There is a significant relationship between them

α level: $\alpha = 0.01$

The hypothesis was tested using Pearson's coefficient of rank correlation and the results are summarized in table 17.

Table 17 shows that there is a strong significant positive relationship between product uniformity in use of traditional and herbal medicines in health care provision in Mukono district (r = 0.494; p value = 0.01). Since the correlation was found to be significant, the null hypothesis (Ho) was accepted and the alternate hypothesis (H1) which does not recognize the existence of significant relationship between product uniformity and health care provision was rejected.

4.5.4 Relationship between Quality Improvement and Health Care Provision

According to table 17 above, there is a significant positive relationship between the independent variable and dependent variable (r = .370, P value <0.05). This means that there is a significant positive relationship between quality improvement and healthcare provision. Quality improvement determines how healthcare can be provided to the people in treating different diseases. Quality determines the efficacy and safety of the herbs and herbal medicines for malaria in provision of improved healthcare.

Hypothesis Four

Null hypothesis:

Ho:

Quality improvement has no significant positive relationship with use of traditional and herbal medicines in health care provision in Mukono district.

H1:

Alternate hypothesis:

There is a significant relationship between them

α level: α = 0.05

The hypothesis was tested using Pearson's coefficient of rank correlation and the results are summarized in table 17.

Table 17 shows that there is a moderate significant positive relationship between quality improvement in use of traditional and herbal medicines in health care provision in Mukono district (r = 0.370; p value = 0.01). Since the correlation was found to be significant, the null hypothesis (Ho) was accepted and the alternate hypothesis (H1) which does not recognize the existence of significant relationship between quality improvement and health care provision was rejected.

4.6 Regression Analysis

Multiple regression analysis was used to find out the influence of the independent variable on the dependent variable. The dependent variable considered was improved healthcare provision through herbs and herbal medicines for malaria. Table 18 below presents the regression model of the variables.

Table 18: Regression between the Study Variables

Coefficients					
	Unstandardized Coefficients		**Standardized Coefficients**	**t**	**Sig.**
Model	**B**	**Std. Error**	**Beta**		
(Constant)	.179	.586		.306	.761
Customer Satisfaction	.326	.141	.313	2.307	.027
Conformity To Standards	.560	.128	.511	4.389	.000
Product Uniformity	.246	.111	.259	2.217	.033
Quality Improvement	.045	.128	.048	.348	.730
Dependent Variable: Health Care Provision					

	R square	**Adjusted R Square**	**F Change**	**Sig. F Change**
	.604	.560	13.747	.000

Source: Primary data

The regression result showed that about **56%** of the variations in use of herbs and herbal medicines for malaria in treating malaria were explained by a combination of customer satisfaction, conformity to standards, product uniformity, and quality improvement which constitutes quality control management. This means that about **44%** of the variations remain unexplained by this study. This could be determined by other factors.

CHAPTER FIVE:

SUMMARY, DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.0 Introduction

This chapter discusses the findings, conclusions, recommendations and suggestions of areas for further study. The study is divided into three sections; discussions of results, conclusion and recommendations. The findings are discussed in reference to the research objectives.

5.1 Summary of Findings of the Study

The followings were the summary of the findings from the study results. There is a significant positive relationship between customer satisfaction and healthcare provision. Further analysis also indicates that there is a significant positive relationship between conformity to standards and improved healthcare provision. The results also show that there is a significant positive relationship between product uniformity and improved healthcare provision. There is also a significant positive relationship between quality improvement and healthcare provision.

5.2 Discussion of the Findings

5.2.1 Relationship between Customer Satisfaction and Health Care Provision

The correlation coefficient in figure 11 above showed that there was a significant positive relationship between customer satisfaction and healthcare provision. According to Tyler (2000) the desire to capture the wisdom of traditional healing systems has led to resurgence of interest in herbal medicines, particularly in Europe and North America, where herbal products have been incorporated into so-called ‘alternative’, ‘complementary’, ‘holistic’ or ‘integrative’ medical systems. During the latter part of the twentieth century, increasing interest in self-care resulted in an enormous growth in popularity of traditional healing modalities, including the use of herbal

remedies. Consumers have reported positive attitudes towards these products, in large part because they believe them to be of 'natural' rather than 'synthetic' origin, they believe that such products are more likely to be safe than are drugs, they are considered part of a healthy lifestyle, and they can help to avoid unnecessary contact with conventional 'western' medicine. WHO (2007) asserts that while centuries of use in traditional settings can be used as testimony that a particular herbal ingredient is effective or safe, several problems must be addressed as these ingredients are incorporated into modern practice.

5.2.2 Relationship between Conformity to Standards and Health Care Provision

The correlation coefficient showed that there was a significant positive relationship between conformity to standards and improved healthcare provision. Standardization of several aspects such as nomenclature of medicinal plants and other resources, their collection practices, semi processes and final processing, packaging, preservation, storage, product life, labeling and modes of distribution including clinical application are needed to ensure quality, safety and efficacy of herbal medicines for malaria. The task of creating quality standards for products starts from establishing the identity of the medicinal herb, animal part or metals and minerals, and goes onto standardizing the process, product, pharmacological activity, clinical diagnosis and finally the therapeutic interventions.

According to Shia *et al.*, (2007), when traditional medicine is practiced outside its original context and practiced as complementary or alternative medicine, there is a need for increased vigilance due to differing population characteristics, modification of formulations and methods of the transported knowledge.

According to WHO, as a general rule evaluation of herbal medicines for malaria should take care of its medical, historical and ethnological background of herbal products and traditional experience of its use. European Union is adopting a traditional use registration procedure for herbal medicines. Similarly many other countries are introducing such systems. Safety monitoring for herbal medicines is also increasing. Adverse experiences from plants such as Aristolochia, drug interactions of St. Johns Wort and toxicity of Kava-kava have increased awareness among public and scientific community. Under reporting and poor quality of data provided by users are major challenges for regulators (Barnes, 2007). Countries with their own traditional medical systems are more likely to measure risks against benefits. Also in countries where herbal medicines for malaria are recently becoming popular, safety is often considered prime compared to efficacy like in the USA (Shia *et al.,* 2005). There has been no development of alternate standards and methods at any national or international level (Bodeker *et al.,* 2007).

Food & Drug Administration (2002), also noted that one of the most difficult issues to contend with in translating traditional herbal practices into conventional 'western' medicine is the individualization of prescriptions containing multiple other ingredients. There is little incentive for standardization of products for a mass market, when the intention has been to provide an individual prescription. To the small grower or the traditionally trained herbalist, standardization means understanding the growth conditions, the time of harvesting, the manner of extraction or other preparation of material so that a reliable (albeit small amount of) active ingredient can be offered to people. To the manufacturer or distributor of large quantities that will be sold in a supermarket or a health food store, standardization refers to industrial production under defined conditions, using so-called Good Manufacturing Practices (GMP) akin to those used for drug production. WHO (2000)

asserts that in many cases, a single plant species has several different commercial or medicinal names in different regions. Several distinct species are often used under the same drug name. Another problem relates to adulteration in the market samples. In other words, authentication of the botanical identity and ascertaining the genuineness of drug is great concern in practical situation.

5.2.3 Relationship between Product Uniformity and Health Care Provision

The correlation coefficient in figure 16 above also showed that there was a significant positive relationship between product uniformity and improved healthcare provision. WHO (2001) states that most of the herbal drugs produced currently in the developing countries generally lack proper quality specification and standards and therefore, have no consistency in quality in batch to batch products. Most of these drugs do not have well defined and characterized composition. The three pillars of ideal herbal drug and their rational use are quality, safety and efficacy. A common argument is that the optimal efficacy of these plant-based products is inherently linked to the mixture of efficacious chemical entities they contain and hence they should be developed as both herbal formulations and also form the basis of medicinal chemistry programmers. Concerted efforts should be made to clearly define processes and guidelines for herbal medicines for malaria and natural products research, in order to support the advancement of this important field. The development of herbal medicines for malaria should not be seen as the answer to providing cheap treatments to poor populations. It is important that such medicines are given the same scrutiny as any other pharmaceutical to ensure protection of patients from any major adverse event and also to ensure the benefits of optimal efficacy (Newton *et al.,* 2006)**.**

WHO (2001) state that without GMP products cannot be expected to be of required standards and quality. The concept of safety is almost non-existent in many developing countries. Safety requirements with respect to buildings, machinery and staff have to be introduced and if possible, safety manuals have to be prepared in order to focus the attention of the management and staff on these issues.

Charak also asserts that the four standards for effective herbal medicines for malaria include; should be grown in proper season; attain maturity in taste, potency and smell; smell, appearance and taste and touch remains uni vitiated by the effect of weather, fire, air and insects; fresh. But Sushruta has propounded a general principle regarding acceptability of plants for use as medicine. A drug may be accepted for use whether it is new or old provided its odor has not vitiated and its taste not deteriorated.

5.2.4 Relationship between Quality Improvement and Health Care Provision

The correlation coefficient in figure 16 above also showed that there was a significant positive relationship between quality improvement and healthcare provision. According to Lethbridge *et al.*, (1996), quality is defined in a variety of ways. While there is some agreement that quality embodies notions of efficiency, effectiveness and consumer satisfaction. By *quality improvement, it* means the ongoing, systematic process of using quality measurements to identify problems and to implement strategies to improve the quality of care, usually within specific organizational entities, such as a group practice, a health plan, a hospital, a public health department clinic, or a community-based clinic. The objective is to identify the causes of variation in the processes and outcomes of care and to strive continuously for higher levels of performance (Berwick *et al.,* 1990).

A number of plans and cycles can be used in an ongoing way in order to apply quality improvement. One example is PDSA (plan-do-study-act) cycle, also known as the Shewhart or Deming Cycle. In this cycle, the first step is to plan a change designed to improve a product or process. The second step is to implement the change. The third is to observe the positive and negative results of the change. The fourth step is to adopt the change or abandon it or execute the cycle again, possibly under different environmental conditions (Levin, 1994).

On a more concrete level, Baker (1997) outlines a series of steps that a health promotion organization considering quality improvement might follow. In the whole process development of herbal drug/product based on traditional knowledge needs proper taxonomically identified safe raw material and scientific validation of the products. Further get constant supply of right raw material whether procured from wild or cultivated and their storage one has to follow. Good Agriculture Practices (GAP), Good Collection Practices (GCP), Good Ethical Practices (GEP), Good Procurement Practices (GPP), Good Safety Practices (GSP) (Pesticide, heavy metal, microbial load as per WHO guidelines) and Good Storage Practices (GSP). Quality control of the phyto-products for human consumption and world market can be ensured by maintaining the quality of raw material adequacy of processing technology and quality of the finished products. Thus, the quality concept commences right from the choice of authentic and improved seeds (varieties) to the post-harvest treatment of the raw material and to the process control for avoiding contamination. As such for developing phyto-products, WHO's, Good Manufacturing Practice (GMP) must be followed to satisfy the ISO 9000 certification.

Theoretically, Juran (1950) asserted that good quality management requires quality actions to be planned out, improved and controlled. The process achieves control at one level of quality performance, and then plans are made to improve the performance on a project by project basis, using tools and techniques such as Pareto analysis. This activity eventually achieves breakthrough to an improved level, which is again controlled, to prevent any deterioration. For the case of quality management and health care provision through herbal medicines for malaria is not known.

5.3 Conclusions

The conclusion of the study was based on the study objectives as stated below;

5.3.1 Customer Satisfaction and Health Care Provision

From the quantitative analysis, the finding from the research indicates that much as there is a significant positive relationship between customer satisfaction and healthcare provision there is still inadequate customer satisfaction due to the way the herbs are processed and handled.

From the qualitative analysis, the finding from the research indicates that many people used traditional herbs in treatment of malaria. Healthcare provision lies in the multi-dimensional nature of better customer satisfaction. Customer satisfaction determines the demand for a particular product or service.

5.3.2 Conformity to Standards and Healthcare Provision

From the quantitative analysis, the finding from the study also indicates that much as there is a significant positive relationship between conformity to standards and improved healthcare provision there is still laxity in conforming to standards thus compromising quality. This could be due to lack of training.

From the qualitative analysis, the finding indicates that the traditional medicine was preserved by adding food supplements and were prescribed based on artificial measures, and stored in clean shelves.

The key factors in conformity to standards are the efficacy of the herbs and herbal medicines for malaria used in provision of improved healthcare provision.

5.3.3 Product Uniformity and Healthcare Provision

From quantitative analysis, the study results also indicate that much as there is a significant positive relationship between product uniformity and improved healthcare provision uniformity among herbal products is still poor due to the poor methods used during compounding.

From the qualitative analysis, the practitioners asserted that sometimes they had problems with poor mixtures, contents, and formulation, thus affecting the blending and processing of the herbal medicine.

Herbal medicines for malaria practitioners with superiority in provision of uniform products to provide improved healthcare encourages people to use more of their products hence increased demand.

5.3.4 Quality Improvement and Health Care Provision

From the quantitative analysis, the study results also indicate that much as there is a significant positive relationship between quality improvement and healthcare provision, quality generally is still being compromised due to ignorance thus a need for the national drug regulatory agency to conduct more sensitization awareness.

From the qualitative analysis, the practitioners asserted that some customers had complained about contamination cases due to the numerous production cycles.

Quality improvement determines how healthcare can be provided to the people in treating different diseases. Quality determines the efficacy and safety of the herbs and herbal medicines for malaria in provision of improved healthcare.

5.4 Recommendations

5.4.1 Customer Satisfaction and Health Care Provision

The traditional medicine practitioners should ensure that there herbs and medicines are of great quality in order to satisfies their customers in health care provision.

5.4.2 Conformity to Standards and Healthcare Provision

The traditional medicine practitioners should also ensure that the traditional herbs and medicines used in treatment of malaria conforms to the expected standards by preserving and storing the medicines under prescribed temperature.

5.4.3 Product Uniformity and Healthcare Provision

The traditional medicine practitioners should ensure that all the traditional herbs and medicines are formulated using same mixtures, contents, and formulation, in order to avoid compromise with the uniformity of the medicines.

5.4.4 Quality Improvement and Health Care Provision

The traditional practitioner should ensure that contamination of the herbs and medicines are controlled as they go through different stages of production.

5.5 Contributions of the study

From the results generated from this study, contributions drawn were as follows;

- The study has shown that customer satisfaction determined by quality.
- The study has also indicated that quality is achieved through planned and controlled quality management.
- The study has also indicated that optimal efficacy of medicines is achieved by efficiency in mixing of the different contents.
- The study results have also indicated that herbal medicines have to go through the same scrutiny as any other pharmaceutical to ensure quality and protection of patients.
- Further analysis from the study has also shown that quality traditional medicines and herbs can be used in treating chronic and acute infections.

5.6 Areas for Further Research

Future research can be done in the following areas:

- The impact of information sharing in improving quality of herbal medicines for malaria in Uganda
- The impact of capacity building on herbal medicines for malaria extraction and processing in Uganda
- The impact of practitioners' competence on quality of herbal medicines for malaria
- Investigating the management challenges in the concurrent use of modern medicines and herbal medicines for malaria treatment in Uganda

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APPENDIX 1: HERBALIST BEING TRAINED ON HOW TO HANDLE TRADITIONAL MEDICINES

Source: NCRL Herbalist Training report. 2012.

APPENDIX II: SAMPLES OF HERBAL MEDICINES

	
Sampled bottled herbal medicines (liquid form)	Herbal powders packing in different forms (powder, capsules (bottom left; tablets (bottom right).

Source: The Cross-Cultural Foundation of Uganda, 2008

www.crossculturalfoundation.or.ug. Promoting Herbal Medicine in Uganda.

APPENDIX III: PLANTS COMMONLY USED FOR THE TREATMENT OF MALARIA

Plants commonly used for the treatment of malaria Species; family;	Plant family	Local names	Part used
Acacia seyal	Mimosoïdeae;	Gacia	B
Albizia zygia	Mimosoïdeae	Nongolongo	1
Allium cepa	Alliaceae	Obutungulo	Bu
Azadirachta indica	Meliaceae;	Neem	L
Cajanus cajan	Fabaceae	Nkolimbo	L
Carissa edulis	Apocynaceae	Muyonza	S
Chenopodium ambrosioïdes	Chenopodiaceae		L
Chenopodium opulifolium	Chenopodiaceae		L
Citrus sinensis	Rutaceae	Mucungwa	1
Coffea canephora Froehner	Rubiaceae		L
Combretum molle	Combretaceae		L
Conyza sumatrensis	Asteraceae		1
Flueggea virosa	Euphorbiaceae	lukandwa	R
Harrisonia abyssinica	Simaroubaceae		L
Jatropha curcas	Euphorbiaceae	Kirowa	L
Kalanchoë densiflora	Crassulaceae		1
Lantana camara	Verbenaceae		L
Leonotis nepetifolia	Lamiaceae		L

Mangifera indica	Anacardiaceae	Muyembe	L / Bk
Melia azedarach L.;	Meliaceae;	Lira	1
Momordica foetida	Cucurbitaceae	Ebombo	L
Moringa oleifera	Moringaceae	Moringa	L
Ocimum gratissimum	Lamiaceae	Mujaja	L
Talinum portulacifolium	Portulacaceae	Mpoza;	L
Tamarindus indica	Caesalpinioïdeae	Nkoge	1
Vernonia amygdalina	Asteraceae	Mululuza	L
Zanthoxylum chalybeum	Rutaceae		R
Aristolochia ringens		kipapula	S
Schuria pinnata	Asteraceae	kwinini	W
Aloe sp	Aloeaceae	kigagi	L

APPENDIX IV: QUESTIONNAIRE FOR PRACTITIONERS

Semi-structured questionnaire for officials at Mukono District and respondents.

Introduction

Dear Sir/Madam. I am Kwesiga Birungi Jaawe Victoria, a student at Uganda Management Institute pursuing Master's Degree in Management studies. I am undertaking a research on Quality Management of Herbal and Traditional Medicine and Healthcare Provision in Mukono District.

The findings of this study will be submitted to the Higher Degree Department, Uganda Management Institute for the award of a master's Degree in Management Studies, Project Planning and Management. In order to achieve the aims and objectives of the study, you are kindly requested to provide appropriate information. The findings are purely for academic purposes and the information provided will be treated with utmost confidentiality.

SECTION A: Background/Biographical data of respondents

Please Tick appropriately

1. Gender Male _____ Female _____

2. Highest level of Education

   i) ‘‘O’’ Level and below _____ ii) ‘‘A’’ Level _____ iii) Diploma _____

   iv) Degree _____ v) Postgraduate _____vi) others (Specify)

3. What is your role within this herbal practice setting? _____

4. For how long have you practiced dispensing traditional medicines?

   i) 1 – 5 years _____ ii) 5 – 10 years _____ iii) 10 – 15 years _____iv) Above 16 years

5. Do you hold any certificate in traditional medicine practice?

   Yes _____ No _____

SECTION B:
Please select option(s) that suits your level of agreement on each of the following questions.

Options are:

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

5. Strongly Agree
4. Agree
3. Not sure
2. Disagree
1. Strongly Disagree

	Customer Satisfaction					
A1	There has always been increased demand for our existing traditional medicines	1	2	3	4	5
A2	Our customers always appreciate the effectiveness of our traditional medicines	1	2	3	4	5
A3	There is always regular use of our traditional medicines by most people	1	2	3	4	5
A4	There have always been no complaints on the quality of our traditional medicines	1	2	3	4	5
A5	All our medicines have always had value as perceived by the consumers	1	2	3	4	5
A6	We have always made all our medicines available based on the market demand	1	2	3	4	5
A7	Our medicines have always been easily accessible by all customers	1	2	3	4	5
A8	Customers prefer our medicines to other artificial medicines on the market	1	2	3	4	5
A9	Our medicines have always been affordable by all customers	1	2	3	4	5
A10	Many customers have frequently used our medicines in the past three years	1	2	3	4	5
	Conformity to Standards					
B1	All our products have always got expiry dates	1	2	3	4	5
B2	We always identify the right medicinal plants in production of our products	1	2	3	4	5
B3	We always ensure that all our products are properly preserved	1	2	3	4	5
B4	All our traditional medicines have always been properly labeled	1	2	3	4	5
B5	All our traditional medicines have always been subject to verification and inspection	1	2	3	4	5
B6	All our products have always had better distributions modes	1	2	3	4	5
B7	All our existing products have always had the right names inscribed on them	1	2	3	4	5
B8	All our products have prescriptions on them for ease of use by customers	1	2	3	4	5

B9	All our products have always been properly stored under the required conditions/temperature	1	2	3	4	5
B10	We have always had better collection practices of raw materials used in producing medicines	1	2	3	4	5
	Product Uniformity					
C1	All our products have been processed under the same guidelines and methods	1	2	3	4	5
C2	All our products have always had the right and standard content	1	2	3	4	5
C3	We have always used the same process in extracting raw materials from medicinal plants	1	2	3	4	5
C4	All our products have always had uniform packages	1	2	3	4	5
C5	All our products have always had standardized processing	1	2	3	4	5
C6	All our products have always been process under standard quality specification	1	2	3	4	5
C7	All our existing products have always had consistent quality	1	2	3	4	5
C8	There has always been use of the right composition in producing our traditional medicines	1	2	3	4	5
C9	All our products have always been produced under standardized formulation	1	2	3	4	5
C10	There has always been no adverse effects of our products on consumers	1	2	3	4	5
C11	Our products have always had the same smell and appearance	1	2	3	4	5
C12	All production of our traditional medicines is guided by standard safety manuals	1	2	3	4	5
	Quality Improvement					
D1	All our medicines always go through quality measurements during their processing	1	2	3	4	5
D2	All our medicines always have uniform product processing criteria	1	2	3	4	5
D3	All our medicines go through all the set production cycles	1	2	3	4	5
D4	All our medicines have always satisfied the interests of the customers	1	2	3	4	5
D5	We always consider chemical constituents in production of all our medicines	1	2	3	4	5
D6	All our medicinal plants have always been harvested at the right time and season	1	2	3	4	5
D7	All our medicines have always followed specific processing time during production	1	2	3	4	5
D8	We always follow good manufacturing practices during our production processes	1	2	3	4	5
D9	We always carry out scientific validation during our traditional medicine production	1	2	3	4	5
D10	We always use safe raw material in medicine production	1	2	3	4	5
D11	We always use the right raw material in medicine production	1	2	3	4	5
D12	There has always been adequacy in our medicine processing	1	2	3	4	5
D13	We always ensure that all raw materials are treated to avoid contamination	1	2	3	4	5

APPENDIX V: QUESTIONNAIRE FOR RECIPIENTS

Dear Respondents,

You are kindly requested to complete this questionnaire appropriately and the information provided will be treated with utmost confidentiality.

Please Tick appropriately

BACKGROUND INFORMATION

1. Gender Male _____ Female _____

2. Highest level of Education

   i) ‘‘O’’ Level and below _____ ii) ‘‘A’’ Level _____ iii) Diploma _____

   iv) Degree _____ v) Postgraduate _____v) others (Specify)

3. For how long have you been using traditional medicines?

   i) 1 – 5 years _____ ii) 5 – 10 years _____ iii) 10 – 15 years _____ iv) Above 16 years

4. Have you ever been educated on use of traditional medicines?

   Yes _____ No _____

Please select option(s) that suits your level of agreement on each of the following questions.

Options are:

Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

5. Strongly Agree

4. Agree

3. Not sure

2. Disagree

1. Strongly Disagree

	Customer Satisfaction					
A1	I have always afforded traditional medicines compared to other medicines on the market	1	2	3	4	5
A2	I have frequently used traditional medicines when I am sick	1	2	3	4	5
A3	I have always easily had access and use to traditional medicines in the past three years	1	2	3	4	5
A4	I have always preferred traditional medicines to other medicines on the market	1	2	3	4	5
A5	Many people in my home area always use traditional medicines when they fall sick	1	2	3	4	5
A6	I have always appreciated using traditional medicines in treating my sickness in the past years	1	2	3	4	5
A7	The traditional medicines that I have ever used has always had rapid action on my sickness	1	2	3	4	5
A8	I have never complained after using traditional medicines in the past three years	1	2	3	4	5
A9	I have been healed by traditional medicines that I have always used in the past three years	1	2	3	4	5
A10	There has always been availability of traditional medicines whenever I need them	1	2	3	4	5
	Conformity to Standards					
B1	All the traditional medicines that I always used have always strong action on me.	1	2	3	4	5
B2	I have always used traditional medicines which are properly labeled	1	2	3	4	5
B3	I always get proper prescription when I buy any traditional medicine	1	2	3	4	5
B4	I have always had ease of using traditional medicines in the past years	1	2	3	4	5
B5	I have always verified all the traditional medicines that I consume	1	2	3	4	5
B6	All traditional medicines that I have always bought are picked from a good storage point	1	2	3	4	5
B7	All traditional medicines that I have always used has never caused me harm	1	2	3	4	5
B8	I am always served traditional medicines by a qualified practitioner	1	2	3	4	5
B9	All traditional medicines that I have ever consumed had expiry dates inscribed on them	1	2	3	4	5

B10	The traditional medicines that I always buy have preservatives	1	2	3	4	5
B11	I have always bought all my traditional medicines from a specific distribution point	1	2	3	4	5
	Product Uniformity					
C1	The prescription of the traditional medicines that I always use has never changed	1	2	3	4	5
C2	The taste of traditional medicines that I always use has never changed in the previous years	1	2	3	4	5
C3	The package of traditional medicines that I always use has never changed in the past years	1	2	3	4	5
C4	The appearance of traditional medicines that I always has remained the same	1	2	3	4	5
C5	The smell of traditional medicines that I always use has never changed in the past years	1	2	3	4	5
C6	The content of traditional medicines that I always use has not been altered	1	2	3	4	5
C7	The quality specification of traditional medicines that I always use has never changed	1	2	3	4	5
C8	The quantity/weight of traditional medicines that I always use has been the same	1	2	3	4	5
C9	The names of traditional medicines that I always use for specific sickness has never changed	1	2	3	4	5
C10	The formulation of all traditional medicines that I have ever used has never changed	1	2	3	4	5
	Quality Improvement					
D1	The traditional medicines that I have always used has never had any side effect on me	1	2	3	4	5
D2	I have always gained satisfaction after using traditional medicines	1	2	3	4	5
D3	All the traditional medicines that I have always used have proved to be safe	1	2	3	4	5
D4	The raw material used in processing traditional medicines that I use is always the same	1	2	3	4	5
D5	The traditional medicines that I use have always been freshly processed	1	2	3	4	5
D6	The traditional medicines that I use have always been blended to the required standard	1	2	3	4	5
D7	There has always been reliability of all traditional medicines that I have ever used	1	2	3	4	5
D8	I have always experienced immediate relief from my sickness after using traditional medicines	1	2	3	4	5
D9	The traditional practitioners have always reviewed the content of their medicines that I use	1	2	3	4	5
D10	All traditional medicines that I have ever used have been credible in curing my sickness	1	2	3	4	5

APPENDIX VI: INTERVIEW GUIDE FOR PRACTITIONERS

Dear Respondents,

You are kindly requested to provide responses to questions in this guide to enable the interview successful. All information provided will be treated with utmost confidentiality.

1. **Customer Satisfaction**

a) In your opinion do many people often use traditional medicines in treatment of malaria?
……
b) According to your experience is traditional medicine more effective in treatment of malaria?
……
c) How have you dealt with customers' complaints in the past years?
……
d) What has always been customers' comment towards use of traditional medicines in comparison to use of artificial medicines in treatment of malaria?
……

2. **Conformity to Standards**

a) What has been NDA opinion on operation of your traditional medicines' outlet in the past years?
……..
b) In your opinion how have you preserved your traditional medicines in past years?
……..
c) How have you handled the issue of prescriptions of your traditional medicines in the past years?
……..
d) According to your opinion what kind of storage have you been subjecting your traditional medicines to?
……..

3. **Product Uniformity**

a) In your opinion what are some of the challenges you experience while processing your traditional medicines?
……..
b) According to your experience how do you handle the issue of poor mixtures and contents?
……..
c) What has been the impact of poor formulation during your production process?
……..
d) What safety standards do you have in place to consider during medicines production process?
……..

4. **Quality Improvement**

a) In your opinion what has been the main complaints about your traditional medicines?
……..
b) What are some of the cycles through which your medicines go through, briefly explain?
……..
c) What are some of the contamination issues that you have experienced during production?
……..
d) What are some of the criteria you take to ensure that the raw material used in production is the right one?
……..

APPENDIX VII: INTERVIEW GUIDE FOR RECIPIENTS

Dear Respondents,

You are kindly requested to provide responses to questions in this guide to enable the interview successful. All information provided will be treated with utmost confidentiality.

5. Customer Satisfaction

a) In your opinion how has traditional medicines help cure you sickness compared to artificial medicines?
……

b) Why do you prefer traditional medicines in treating your sickness compared to other medicines?
……

c) How easily do you always access traditional medicines?
……

d) What do people in your society say about traditional medicines?
……

e) How do you compare the costs of traditional medicines to artificial medicines which you have ever used?
……

6. Conformity to Standards

a) How do you describe your experience with traditional medicines in terms of side effects?
……..

b) How do you describe the ease of use of traditional medicines in terms of prescriptions and safety?
……..

c) What are some of the issues you have experienced with storage of traditional medicines?
……..

d) How do you recognize that the traditional medicines that you always use are not expired?
……..

7. Product Uniformity

a) In your opinion is the taste of some of traditional medicines that you have used the same?
……..

b) What is your opinion on the weight and quantity of traditional medicines that you have repetitively used?
……..

c) In your opinion how has the Knowledge and by products of traditional medicines that you have ever used been of use to you?
……..

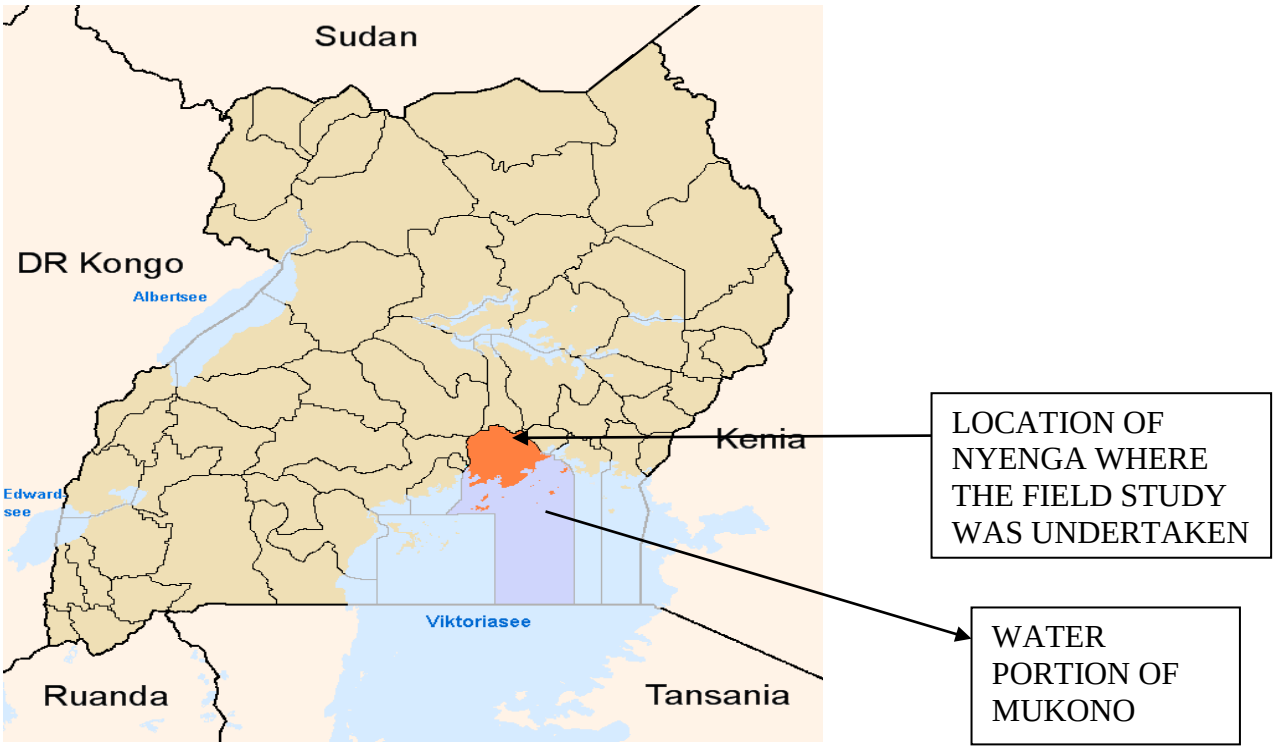
d) What has been your experience with smell of traditional medicines that you have repetitively used?
……..

8. Quality Improvement

a) In your opinion what has been the quality of traditional medicines that you have ever used?
…….....

b) What is your comment on the reliability and effectiveness of herbal and traditional medicine?
……..

APPENDIX VIII: MAP OF UGANDA SHOWING THE LOCATION OF MUKONO DISTRICT, NYENGA



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31 August 2012

TO WHOM IT MAY CONCERN

MASTERS IN MANAGEMENT STUDIES DEGREE RESEARCH

Ms. Victoria Birungi Jaawe Kwesiga is a student of the Masters Degree in Management Studies of Uganda Management Institute 23rd intake 2010/2011 specializing Project Planning and Management, **Reg. Number 10/MMSPPM/23/069.**

The purpose of this letter is to formally request you to allow this participant to access any information in your custody/organisation, which is relevant to her research.

Her Research Topic is: ***"Quality Management and Health Care Provision Through Herbal and Traditional Medicine in Mukono District-Uganda "***

Benon C. Basheka (PhD)
HEAD, HIGHER DEGREES DEPARTMENT