COMMON SIDE EFFECTS AND ADVERSE DRUG REACTIONS ASSOCIATED WITH HERBAL PRODUCTS IN BUSHENYI DISTRICT.

BY

MUTUMBA MUZAMIRU

A RESEARCH REPORT SUBMITTED TO SCHOOL OF PHARAMCY OF

KAMPALA INTERNATIONAL UNIVERSITY IN PARTIAL

FULFILLMENT OF THE REQUIREMENTS FOR THE

AWARD OF BACHLOR OF PHARMACY OF

KAMPALA INTERNATIONAL UNIVERSITY

FEBUARY, 2014

Declarations

I MUTUMBA MUZAMIRU, do hereby declare that this dissertation is my own work and has never been submitted to any other University or institution of learning for any Degree/Diploma/Certi icate award for which it is now being submitted for.

Signature..... date.....1/03/2014.....

Approval

This is to certify that this research proposal has been prepared under my supervision and has never been presented anywhere for other purpose and is now ready for submission to the school of pharmacy of Kampala International University

Sign..... Date .....

Dr. Godwin Okoruwa

Research Supervisor and Dean School of Pharmacy,

Kampala international University-Western Campus.

Dedication

This research work is dedicated to my Deceased Mother the late Zam Zam Nsangi and my lovely wife Kalibbala Madiinah Nakulima who has supported me throughout the entire period of study.

Acknowledgement

The completion of this work is not only a fulfillment of my dreams but also the fulfillment of the dreams of my wife and my father who encouraged and prayed for me throughout the entire period of my study.

I am indebted to my esteemed supervisor, Lecturer, and Dean School of Pharmacy for his valuable discussion and encouraging guidance which enabled me to complete this piece of work. His words of advice have been etched in my heart and I will always Endeavour to hold up his ideals.

I am also thankful to the Government of Uganda and in particular the Welfare Section of State House whose scholarship has enabled me to realize this dream.

I also thank my DHO Dr.Mubiru Wilson and my In charge Dr.Kizza Jude for the fatherly support accorded to me during my Studies.

Once again my heartfelt thanks goes to my dear wife Kalibbala Madiinah for the financial and moral support accorded to me during my time of study.

Finally, thanks goes to my classmates Wangoye Khalim and Komaketch Alfred for their invaluable contribution and support during my stay at Kampala international university.

Table of Contents

List of igures

List of tables

Abstract

A cross sectional study was conducted in Bushenyi district to review the side effects, adverse effects and the process of collecting herbal medicines between September 2013 and February 2014.

The study found out that traditional herbs were being widely used in Bushenyi district in the treatment of malaria, cough, vaginal dryness, abdominal cramps, erectile dysfunction and fevers most frequently than other conditions.

The study also found that the most common side effects were nausea and vomiting, diarrhea and headache reported by 12% of the respondents while of the respondents who reported adverse effects. Were 3(1.6%)

1.63% of the respondents reported that they were combining the herbal products with the conventional medicines.

The study concluded that; the use of traditional herbs in Bushenyi was associated with various side effects, that very few respondents did experience life threatening adverse effects with the use of traditional herbs in Bushenyi district. That most respondents were exclusively using herbal medicines alone especially for the treatment of common community ailment and inally that the process of collecting herbal drugs in Bushenyi was crude and did not follow standard guidelines

The study recommended that the government of Uganda should integrate traditional herbal medicines into the National health system in combination with National policy and regulation for products, practices and providers in order to ensure safety and quality; the use of safe, effective and quality products and practices, based on available evidence; acknowledge herbal medicines as part of primary health care and should ensure patient care by upgrading the skills and knowledge of herbalists. The government should also make provision, for research into herbal medicines since WHO fully recognizes herbal medicines as part of the health care system. And inally that the national drug authority should train the herbalists on scienti ic methods of collecting herbs.

CHAPTER ONE: INTRODUCTION

1.1 Background

Herbal medicines form a signi icant part of treatment in the world. A herbal medicine is de ined as a plant-derived product used for medicinal and health purposes (Hodges, 2002). Herbal medicines include herbs, herbal materials, herbal preparations and inished herbal products.

Over 80% of people in developing countries rely on alternative medicines, of those a signi icant proportion are experiencing an alarming danger due to impurities/adulterations of herbal medicines mixed with allopathic drugs and sold over the counter or prescribed by a practitioner of alternative medicine(WHO article WHO news story 2004; 635-636)

According to the World Health Organization (WHO) (5), because of poverty and lack of access to modern medicine, about 65-80% of the world's population which lives in developing countries depends essentially on plants for primary health care (J.B. Calixto, 2000)

In India 53.3% of traditional medicines practitioners are prescribing allopathic drugs and medicament without having the proper knowledge of allopathic drugs and medicament which is creating a lot of health hazard and economic burden to the community (WHO news story 2004; 635-636)

Uganda is not an exception since 80% of the population of Uganda relies on traditional medicines because western trained medical personnel are limited or not readily accepted by the community (Traditional medicine practice in contemporary Uganda (Anke Weisheit 2003).

A study done in western Uganda in Kabalore district revealed that 63.5% of 137 patients infected with HIV had used herbal medicines after HIV diagnosis. Same-day herbal medicines and pharmaceutical drugs use was reported by 32.8% of AIDS patients. (D. Langlois et al 2007)

However there is no scienti ic data on the safety and ef icacy of most of the traditional herbs. Furthermore both the herbalists and the local community believe herbal medicines are meant to detoxify the body and build its immunity (Observer, 2011).

There is also a general misconception that herbal medicines are free from side effects. Despite the NDA guidelines for the regulation of traditional herbal medicines local In Uganda, many challenges still stand which include;

Lack of funds to meet minimum requirements for NDA's approval. Unethical practices by herbalists including but not limited to; peddling of products with no therapeutic bene its, making unsubstantiated medical claims and adulteration of herbal products with western medicines. Uncontrolled advertising all over the country

There is wide misconception amongst herbalists that documentation requested for by NDA is intended to steal their indigenous knowledge and thus there has been hesitation to submit applications to NDA.

Haphazard manufacture and sale of herbal products, Lack of recognized body to certify herbalists who would work in herbal manufacturing facilities and herbal outlets. It is upon this background that the researcher would like to investigate the possible side effects and adverse drug reactions of commonly used herbal medicines in Bushenyi District.

1.2 Problem Statement

Since 80% of Uganda population rely on herbal medicines whose ef icacy, safety and drug interaction are not known, it is most likely that the disease burden will increase which will impact negatively on the overall economy of the country. Disease complications are also very possible since the community turns to herbal remedies for treatment of diseases such as HIV, Rabies, TB and Cancer.

There have also been documented drug interactions between herbal medicines and ARVs. The number of treatment failures for patients on HAART will increase due to increased concomitant use of herbal medicines

This will in turn necessitate patients to be switched to second line regimens which are more toxic and costly for the country.

Since there is a general misconception that herbal medicines are free from side effects, patients are most likely to perceive side effects of herbal medicines as bene icial to treating the disease or they would not distinguish between the disease and such side effects.

1.3 Purpose of the Study/General Objective

The study is meant to ind out the plant types used for herbal medicines in Bushenyi, the disease conditions claimed to be treated by the speci ic herbals, the possible side effects and adverse drug reactions.

1.4 Speci ic Objectives

1. To ind out the common side effects from use of herbal medicines in Bushenyi district.

2. To ind out the proportion of users combining herbal medicines with conventional medicines in Bushenyi district

3. To ind out the adverse drug reactions that has occurred amongst users of herbal medicines.

4. To assess the process of collection of herbal medicines being practiced by herbalists in Bushenyi district.

1.5 Study Hypothesis

Null Hypothesis: Herbal products have no side effects among the local communities in Bushenyi district.

Alternative hypothesis: The use of herbal medicines is associated with side effects among the local communities in Bushenyi district.

1.6 Study Justi ication

Numerous studies have been carried out in various parts of Uganda about the use of herbal medicines. However no studies have been done to exhaustively identify the herbal medicinal plants commonly used in Bushenyi District, their side effects, and adverse drug reactions. This study is therefore important in that it is intended to identify the commonly used herbal medicines in Bushenyi district, their possible undesirable effects, and ind possible solutions to address such problems.

CHAPTER TWO: LITERATURE REVIEW

Virtually all herbal remedies can cause allergic reactions and several can be responsible for photosensitization E. Ernest (2000).

Although herbs are often believed to be "natural" and therefore safe, many dangerous and lethal side effects have recently been reported, including direct toxic effects, allergic reactions, effects from contaminants and interactions with drugs and other herbs. Stephen Bent, Richard KO, pharmD, PhD (2004)

According to Frederick W. Fraunfelder, MD (2004), herbal medicines and nutritional supplements for example chamomile, canthaxanthine, Datura, Echinacea purpurea, Ginkgo biloba, licorice, niacin, vitamin A are all associated with clinically signi icant ocular side effects.

B. Niggeman, C. Gruber(2003) also reported that organ toxicity had been observed associated with various herbal preparations involving the liver, kidneys and the heart. The authors further stated that herbs and drugs could also interact the same way drug/drug interactions occurred.

A study done in UK revealed that 26% of patients using both conventional OTCs and herbal remedies would consult their GP for a serious ADR to OTC medicines but not a similar ADR to a herbal remedy, whereas 0.8% of respondents would consult their GP for a serious ADR to a herbal remedy but not a similar ADR to conventional OTC medicine. J. Barnes et al, (1998)

Non-steroidal anti-in lammatory drugs (NSAIDs), particularly aspirin, have the potential to interact with herbal supplements that are known to possess antiplatelet activity (ginkgo, garlic, ginger, bilberry, dong quai, feverfew, ginseng, turmeric, meadowsweet and willow), with those containing coumarin (chamomile, horse chestnut, fenugreek and red clover) and with tamarind, enhancing the risk of bleeding.

Acetaminophen may also interact with ginkgo and possibly with at least some of the above herbs to increase the risk of bleeding. Further, the incidences of hepatotoxicity and

nephrotoxicity may be augmented by acetaminophen when concomitantly used with the potentially hepatotoxic herbs Echinacea and kava, and with herbs containing salicylate (willow, meadowsweet), respectively. The concomitant use of opioid analgesics with the sedative herbal supplements, valerian, kava and chamomile, may lead to increased central nervous system (CNS) depression. The analgesic effect of opioids may also be inhibited by ginseng. W. Abebe (2002).

Concurrent use of herbs may mimic, magnify, or oppose the effect of drugs Adriane Fugh-Berman, MD (2000)

Although herbal medications are considered 'natural' products that may have some bene its, adverse effects such as increased bleeding tendencies and drug interactions are associated with their use.

Anesthetists and surgeons must be familiar with the effects of herbal medicines and should speci ically enquire about the use of herbal medicines during pre-operative assessment. Currently available data suggest that all herbal medicines should be ceased 2 weeks before surgery.

Patients undergoing surgery are exposed to a far greater number of pharmacological agents than in their everyday life. There is therefore a greater potential for interactions between herbal medicines and drugs.

Currently, the American Society of Anesthesiologists recommends that patients cease herbal medicines at least 2 weeks before surgery. There is also a concern that the long-term use of echinacea (i.e. > 8 weeks) may result in immunosuppression, which may in turn result in an increased risk of surgical complications such as poor wound healing and infection.

Signi icant changes in heart rate and blood pressure during anaesthesia in patients taking herbal medicines such as ginseng have been reported.

The most important surgical interaction is unanticipated excessive bleeding associated with garlic, ginkgo biloba and ginger. The peri-operative use of NSAIDs is increasing. The use of NSAIDs in a patient taking herbal medicines such as garlic, gingko and ginger may cause increased peri-operative bleeding. Kam, (2002)

A study conducted by Angelo.A.Izzo et al revealed that interaction between anherbal medicines and cardiovascular drugs was a potentially important safety issue. Angel, et.al reported that Warfarin was found to interact with old curbicin.

Fenugreek,garlic,danshen,devil's claw,don quai,papaya,ginkgolycium,mango, resulting into over anticoagulation and with ginseng,green tea,soy and st.Johns wart causing decreased anticoagulation effect.

The same study revealed that Gum guar,St John's wart,siberian ginseng and wheat bran were found to decrease plasma digoxin concentration.

Aspirin interactions included spontaneous hyphema when associated with ginkgo and increased bioavailability when combined with tamarind. Decreased plasma concentration of simvastatin or lovastatin was observed after coadministration with wheat bran and St.John's wart respectively.

Other adverse events included hypertension after co-administration of ginkgo and a diuretic thiazide, hypokalemia after liquorice and antihypertensive.

Wide spread use of herbal medications among pre-surgical population may have negative impact on perioperative patient care Michael. et al (2001)

Morbidity and mortality associated with herbal medications may be more likely in the perioperative period because of the polypharmacy and physiological alterations that occur. Such complications include myocardial infarction, stroke, bleeding, inadequate oral anticoagulation, prolonged or inadequate anesthesia, organ transplant rejection, and interference with medications indispensable for patient care Michael. K et al (2001)

CHAPTER THREE: STUDY METHODOLOGY:

3.1 Study design

The study was a survey involving questionnaires to both the herbalists and the participants from the community.

Self administered questionnaires were used for both the herbalists and participants who could not read or write while the participants who could read and write completed the questionnaires under the guidance of the principle researcher.

3.2 Study setting

The study involved visiting the herbalists at their respective places of practice. Visits were made to the participant's places of work and homes. However some participants were organized into groups.

3.3 Study population

The estimated population igure for Bushenyi district in 2011 was 260,800 people. Out of this igure it was assumed that 35% of the people are above 15years of age.

Therefore the study population is 35% of 260800 which is 91280.

3.4 Sample size

Slovene's formula was used to estimate population sample size.

$$n = \frac{N}{1 + N(e)^2}$$

Where n is the sample size, N is the population size and e is the level of precision which is 5% while 1 is constant.

3.4.1 Inclusion Criteria

Only participants who had used herbal medicines before, above 15 years, mentally stable and regular users of herbal medicines for both infectious diseases and chronic illnesses were included in the study.

3.4.2 Exclusion Criteria

Persons under 15 years of age and people who had never used herbal medicines did not participate in this study.

3.5 Sampling techniques

Simple random sampling was used in the study.

3.6 Data collection procedures

The researcher used guided structured questionnaires. This method is suitable for the subjects who are not able to read.

3.7 Data Analysis procedures

Data was analyzed using Statistical Product for social scientist (SPSS, V16).

3.9 Ethical Considerations

The purpose of the study was explained to the participants and their anonymity was not disclosed for privacy purposes. Participants were not coerced since they chose voluntarily to participate in the study.

3.10 Limitation to the study

The respondents found it challenging to differentiate between adverse drug reactions and side effects of herbal medicines.

CHAPTER FOUR: STUDY FINDINGS

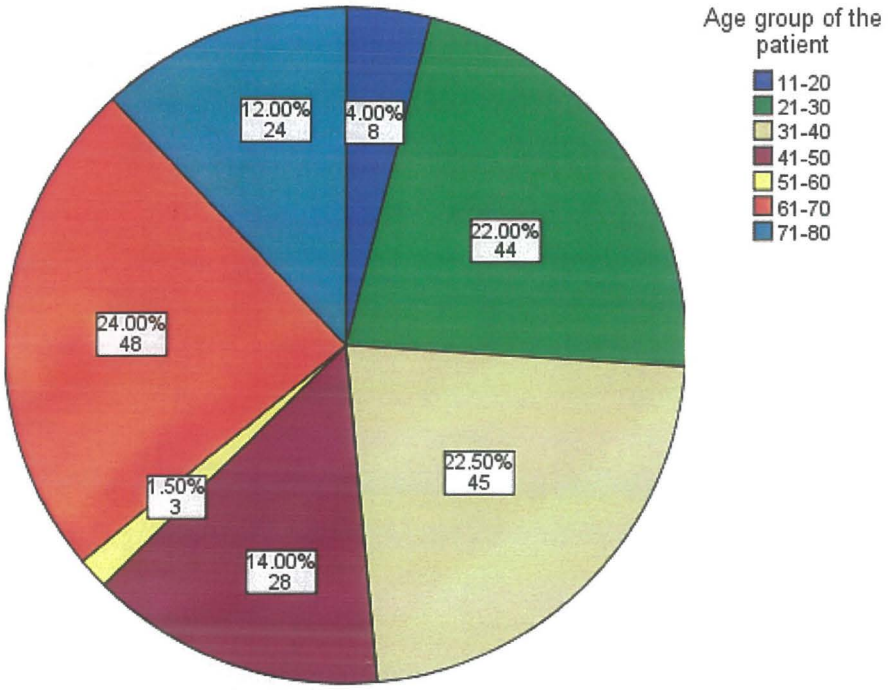
4.0 General Introductions

This chapter presents the indings and results of the study according to the speci ic study objectives. Findings and results are presented in form of graphs, charts, table and descriptive statements.

4.1. Bio Data

4.1 Age

Figure 1: Age distribution of Respondents



The figure above shows that majority of the respondents involved in this study were 61-70 years old, 48(24%), followed by the 31-40 years age groups 45(22.5%)., 21-30, 44(22%).

4.1.3 Occupation and education levels

Table 1: Occupa on and Educa on Level of Respondents

		level of education					
		None	Primary	Secondary	Tertiary Institution	University	Total
upation of respondents	Student	0	3	3	6	6	18
	Peasant farmer	10	22	19	7	3	61
	House wife	13	20	10	3	0	46
	Casual laborer	0	6	0	0	0	6
	Employed	2	2	6	18	4	36
	Business	3	15	12	3	0	33
ɪtal		**28**	**62**	**50**	**37**	**13**	**200**

The above table shows that of the 200 respondents, 62 had stopped at primary level of education, 50 at secondary and 37 had reached tertiary level. 13 respondents had reached university level of training, whereas 28 did not have any formal education.

In-terms of occupation, the table shows that, majority were unemployed, 125. In the unemployed class are the housewives, students and peasants. However 75 participants were employed and this class included teachers, casual laborers and business men and women.

4.1 Common Side Effects

4.1.1. Common Products

Table 2: The common herbal products used by respondents

		number		
		N	Percent	Percent of Cases
herbal product	Ekokorutanga,Rusharira (Aloe Ferox)	93	15.2%	46.5%
	Niim(Azadirachta indica)	51	8.3%	25.5%
	Embirirbiri(Crassocephalum vitellinum)	23	3.8%	11.5%
	Omujaaja(Ocimum suave)	97	15.8%	48.5%
	Omuko(Erithrina Abyssinica)	35	5.7%	17.5%
	omuboroboro(Nuxia congesta)	22	3.7%	72.0%
	Omunyaara(Spathodea Campanulata)	38	6.2%	19.0%
	kivu(solanecio cydonifolious)	6	1%	3.0%
	Omubirizi Vernonia amygdalina	144	23.5%	
	Tangawuzi(Ziniber officinale)	105	17.2%	52.5%
	mautatembwa(zonothoxylum gilletti)	20	3.3%	10.0%
Total		612	100.0%	306.0%

a. Dichotomy group tabulated at value 1.

From table 2 above, most respondents agreed that they had at least taken Omubirizi 144 respondents, Tangawuzi(Ziniber of icinale) 105 respondents, Omujaaja(Ocimum suave) 97 respondents Ekokorutanga/Rusharira 93 respondents , followed by Niim(Azadirachta indica) 51 respondents, Omunyaara(Spathodea Campanulata) 38 respondents.

4.2.2. Common disease treated by the herbal medicines

From the table below, 141 respondents reported treating malaria with traditional herbs, followed stomach pain 27 and cough 24 respondents.

Other ailments that were being treated by traditional herbs are loss of appetite 18, ulcers 16, allergy and burns, 3 respondents each.

4.2.3: common methods of collecting herbal medicines

Data about the collection process for herbal medicines was assessed from the herbalists during the course of the study. Of the 10 herbalists visited , one herbalist was collecting the traditional herbs from his established garden. The others were collecting from the wild gardens. However, the entire 10 herbalist agreed that at one point collected herbs from either their gardens or from the wild gardens.

Table 3: Common disease and herbal products used to treat them

		what disease condition did you use the product for								
		Malaria	Fever	Stomach pain	loss of appetite	cough	Allergy	ulcer	burns and wounds	Total
Which of the following products have you used?	Ekokorutanga(Aloe Ferox)	39	0	6	0	0	3	0	3	48
	Niim(Azadirachta indica)	22	0	0	3	3	0	0	0	28
	Embirirbiri(Crassocephalum vitellinum)	9	0	0	0	0	0	0	0	9
	Omuko(Erithrina Abyssinica)	0	3	0	0	9	0	10	0	22
	Omujaaja(Ocimum suave)	0	6	12	15	3	0	3	0	39
	omuboroboro(Nuxia congesta)	0	0	3	0	3	0	0	0	9
	Omunyaara(Spathodea Campanulata)	3	0	3	0	0	0	3	0	9
	Omubirizi(Vernoia amygdalina)	68	3	0	0	3	0	0	0	30
	Tangawuzi(Ziniber officinale)	0	0	3	0	3	0	0	0	6
Total		141	12	27	18	24	3	16	3	200

Table 4: Common Side e ects of the commonly used herbal products

		Which side effects did you experience while using the herbal product?			
		vomiting	nausea	diarrhea	Total
ı of the following ıcts have you used?	Ekokorutanga(Aloe Ferox)	13	38	41	92
	Niim(Azadirachta indica)	6	22	9	37
	Embirirbiri(Crassocephalum vitellinum)	13	3	3	19
	Omuko(Erithrina Abyssinica)	0	9	0	9
	Omujaaja(Ocimum suave)	7	3	9	19
	omuboroboro(Nuxia congesta)	0	0	0	0
	Omunyaara(Spathodea Campanulata)	0	3	3	6
	Omubirizi(Vernoia amygdalina)	30	33	12	75
	Tangawuzi(Ziniber of icinale)	0	3	0	3
ıl		**69**	**105**	**77**	**260**

The most common side effects were, nausea reported by 105 respondents, Diarrhea reported by 77 respondents and vomiting with 69 respondents, followed by diarrhea reported by 33 respondents and least reported side effects was stomach pain.

44.5% of Ekokurutrutanga/Rukaka (Aloe ferox) users reported getting Diarrhea while 41.3% reported nausea, 14.1% reported vomiting.

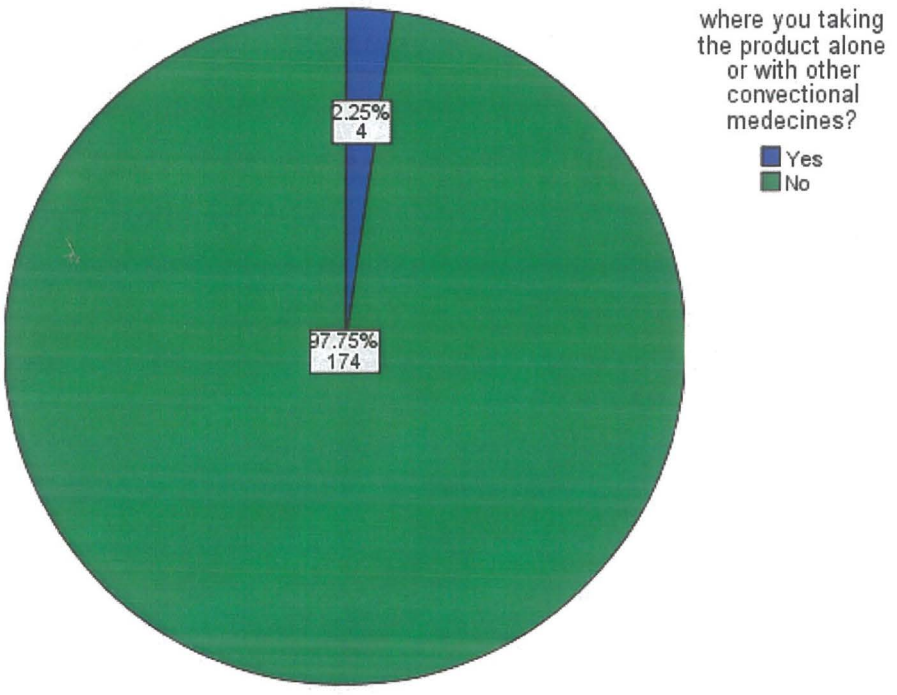
Vernonia amygdalina(Omubirizi) had nausea as the commonest side effect with 26.4% occurrence followed by vomiting at 24% and then diarrhea at 9.6%.

For Neem, 37 out of 51 users reported the side effects of nausea 22 respondents, diarrhea 9 respondents and vomiting 6 respondents.

Spathodia campanulata had the lowest incidence of side effects with only 6 out of 38 respondents reporting side effects.

However Nuxia congest(Omuboroboro) did not have any side effect amongst its users.

Figure 3: propor on of respondents taking herbal drugs in combina on with conven onal medicines



In the figure 3 above, of all the 200 respondents reporting side effects, 3(1.69%) of the respondents reported that they were combining the herbal products with the conventional medicines, 174(97.7%) reported that they did not combine the herbal products with any conventional

medicines. The remaining 22 did not mention whether thy combined the herbal products with conventional medicines or not.

As shown by the table 5 below, very few respondents reported having had any adverse reactions with the herbal medicines. The adverse drug reactions reported were; Urticaria with 2 respondents pruritus, 1 respondent, and photosensitivity 1 respondent.

All the respondents who experienced adverse effects stopped the medication.

Table 5: The adverse e ects, side e ects and steps taken by respondents

		Frequency	Percent	Valid Percent	Cumulative Percent
adverse effects	Photosensitivity	1	.005	.005	.005
	Urticaria	2	.01	.01	015
	Pruitus	1	.005	.005	.02
	None of the adverse effects	196	99.98	99.98	100.0
	Total	200	100.0	100.0	
Total		200	100.0		

Table 6: what respondents did a er experiencing side e ects

		Frequency	Percent	Valid Percent	Cumulative Percent
adverse effects	continued with medications	86	44.5	44.5	44.5
	stopped taking the herbal product	87	45	45.0	89.5
	reported to the herbalist	2	1	1	90.5
	went to the hospital	18	9.38	9.32	100.0
	Total	193	100	100.0	

CHAPTER FIVE: DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS:

5.0 General Introdcutions

In this chapter, the reader is introduced to the discussions and arguments behind the research indings. The discussions are basically focused on the study objectives. However some other indings are also highlighted in the discussions.

5.0 Demographic Findings

The study attracted 200 respondents of which the majority were 61-70 years old, 48(24%), followed by the 31-40 years age groups 45(22.5%), then 21-30 years old 44(22%) then 41-50 years 28(14%), then 71-80 years24 (12%). The least number of respondents were 51-60 years old, 3(1.5%) and 11-20 years old 8(4%).

In terms of gender, 132(66%) of the respondents were males followed by the females 68(34%). In terms of education level, 62 of the respondents had stopped at primary level of education, 50 at secondary and 37 had reached tertiary level. 13 respondents had reached university level of training. Whereas 38, the lowest number have not had any formal education.

In-terms of occupation, the table shows that, majority of the participants were unemployed, 125(62.5%) while 75(37.5%) were employed. Amongst the unemployed group were students, house wives and peasants while in the employment category was teachers, business men and casual laborers.

5.2.1 Discussions of objective one:

The most common side effects amongst herbal users in Bushenyi district were Nausea vomiting and Diarrhea. However occurrence of adverse effects was negligible.

Diarrhea was mostly experience with Aloevera (Rukaka or Rusharira).

This is in agreement with the publication in the Journal of environmental science and health where it is stated that ingestion of Aloe vera was associated with diarrhea and electrolyte imbalances.

The diarrhea is possibly due to aloin and emodin which are known to have irritating potential which may result into nausea and abdominal cramping.

Nausea and vomiting were possibly due to the very bitter taste of the freshly prepared aloevera juice.

However Vernonia amygdalina ranked second in causing nausea and vomiting as well.

5.2.2 Discussions of objective two:

There are severe side effects or adverse effects associated with the herbal medicine documented by many scholars. However this study revealed that the herbal medicines used in Bushenyi to treat common illnesses had not caused severe adverse drug reactions.

This is in line with the publication in the Brazilian Journal of medical and Biological research where it is clearly stated that adverse effects of phytotherapeutic agents are less frequent compared to synthetic drugs although such effects really exist.

5.2.3 Discussions of speci ic objective three

This study found out that only 3 herbal users (1.5%) combined the herbal products with the conventional medicines, 174 (87%) reported that they did not combine the herbal products with any

conventional medicines while 13(10%) of herbal user did not indicate whether they were combining herbal medicines with conventional medicines.

This was possibly due to the fact that most herbal users had confidence in the traditional herbs whereas others had access only to herbal medication.

5.2.4 Discussions of Objective four:

The study revealed that at least 10% of the herbalists were collecting the traditional herbs from his established garden. The others were collecting from the wild gardens and 100% of the herbalists agreed that at one point collected herbs from either their gardens or from the wild gardens.

This is however, not in line with the recommendation of the National Drugs Authority on the use of traditional medicines in Uganda, in which it is recommended that: It is desirable that cultivation and collection of medicinal plants, as the starting materials for herbal medicines should follow the guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. (In this respect WHO (GACP) will be followed). The processes of collecting the herbs in Bushenyi were shown not to follow any of such guidelines.

Whether there is enough care while packing and transporting the herbs to the point of processing and administration was quite well beyond the scope of this study.

The researcher however, observed that there were limited applications of scienti ic process in the process of collecting herbs in Bushenyi district.

5.2.5 Discussion of objective Five

The study found out that majority of respondents 87 (45%) stopped the herbal products after experiencing side effects, followed by 86 (44.5%) of the respondents who continued with the medications. The least number of respondents 2 (1%) of the respondents who experienced side effects reported to the herbalist and only18 (9.38%) went to the hospitals. This figure is lower than

that from a study done in UK where 30.3% of the patients would consult their general practitioner in case of side effect either to a herbal drug or to a conventional medicine.

The small numbers of patients who went to hospitals was due to the fact that herbal drugs are usually used on self treatment and therefore the patients were not aware that they could consult a health worker in case of minor and serious side effects to herbal drugs.

However it is not clear why the herbal users did not consult the herbal practitioner from whom the remedies were obtained.

5.2 Conclusions

From this study, the following conclusions were drawn.

The use of traditional herbs in Bushenyi was associated with side effects which led to many herbal users abandoning treatment.

That very few herbal users reported the side effects to the herbalists and a small number went to hospital after experiencing the side effects.

The process of collecting herbal drugs in Bushenyi was crude and did not follow standard guidelines.

The herbs used in Bushenyi did not cause life threatening adverse drug reactions.

There was negligible concomitant use of herbal medicines with conventional drugs.

5.3. Recommendations

The government of Uganda should integrate traditional herbal medicines into the National health system in combination with National policy and regulation for products, practices and providers in order to ensure the use of safe, effective and quality herbal products and practices and should ensure patient care by upgrading the skills and knowledge of herbalists.

The national drug authority should train the herbalists on scienti ic methods of collecting herbs.

Herbalists should be able to appreciate the side effects of traditional herbal remedies, always counsel their patients on the side effects of the herbal medicines and encourage patients to report the side effects back to them and also advise patients not to abandon treatment.

The prescribers in health facilities should always ask patients about their traditional medicine use history and whether the patient is still taking herbs since some patients only went to hospital after failing to realize therapeutic effect from the herbal medicines. This would help to prevent signi icant drug interactions between herbal medicines and conventional ones.

Government should fund research into herbal medicines in order to enable the standardization of the herbs and to con irm the therapeutic ef icacy of the commonly used herbs.

Appendices:

APPENDIX 1 TIME FRAME/WORK PLAN

bjectives	Activities	June-Jul 2013	Aug 2013	Sept 2013	Oct 2013	Nov 2013	Dec 2013	Jan 2014	Feb 2014	Mar 2014
roposal ubmission	Research proposal review and approval by the KIU research committee									
roposal :eview	Institutional Research Committee									

ign of estionna	Formulating appropriate questions, typing and handing in for approval									
ta lection 1	Face to face interview of herbalists.									
ta lection 2	Interview of community									
'st ɔgress ɔort	Filtering data, initial data analysis									
ıal ɔort 'iting	. Data analysis and compilation of results									
ɔmpiling	Data presentation, recommendations and submission of final report									

Chapter Five:

5.0 Budget

APPENDIX 2: Budget with Justification

ITEM	JUSTIFICATION	UNIT PRICE (Ug.shs)	AMOUNT (Ug.shs)
Hiring research assistants to help interpret local language	3 Asistants	10,000per day for 14days	420,000=
Meals during	Lunch	5000pr person for 14 days	280,000=

data collection	Researcher inclusive		
Transport to and from the field	Hiring a boda bodas for 20,000 per person for 14 days The whole day		1,120,000=
Stationary and printing	2reams of plain paper Printing and photocopying fee		40,000= 400,000=
Result Dissemination	Abstract presentation at local and regional conferences Journal article processing fees		150,000 700,000
Miscellaneous			
TOTAL			**3,110,000=**

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Appendix 1

QUESTIONNAIRE FOR HERBAL USERS

A RESEARCH STUDY ON THE POSSIBLE SIDE EFFECTS AND ADVERSE DRUG REACTIONS OF COMMONLY USED HERBAL PRODUCTS IN BUSHENYI DISTRICT.

QUESTIONAIRE

BIO DATA

AGE.....

GENDER.....

OCCUPATION.....

LEVEL OF EDUCATION.....

1. Which of the following herbal products have you used before?

Ekokorutanga(Aloe ferox).....

Niim(Azadirachta indica).....

Embiribiri(Crassocephalum vitellinum).....

Omuko (Erithrina abyssinica).....

Omujaaja(Ocimum suave).....

Orutotoimya(Hoslindia opposita).....

Omuboroboro(Nuxia congesta).....

Omunyaara(Spathodia campanulata).....

Omubirizi(Vernonia amygdalina).....

Tangawuzi(Zingiber o cinale).....

Kivu(Solanecio cydonifolius).....

Omutatembwa(Zonthoxylum gille).....

Others please specify

.....

.....

.....

.....

2. What disease condi on was the herbal product used for

Herbal product	**Disease condi on(s)**
Ekokorutanga (Aloe ferox)	.....
Niim(Azadirachta indica)	.....
Embiribiri(Crassocephalum vitellinum)	.....
Omuko (Erithrina abyssinica)	.....
Omujaaja(Ocimum suave)	.....
Orutotoimya(Hoslindia opposita)	.....
Omuboroboro(Nuxia congesta)	.....
Omunyaara(Spathodia campanulata)	.....
Omubirizi(Vernonia amygdalina)	.....
Tangawuzi(Zingiber o cinale)	.....
Kivu(Solanecio cydonifolius)	.....
Omutatembwa(Zonthoxylum gille)	.....

Others please specify

Herbal product	**Disease condi on**
i)	.....
ii)	.....

iii) ....

iv) ....

3. Which herbal product are you currently using?

Herbal product	**Disease condi on**
i)	.....
ii)	.....
iii)	.....
iv)	.....

b) Which side e ect did you experience while using the herbal product?

Side E ect	**Herbal Medicine**
Nausea	.....
Vomi ng	.....
Abdominal Discomfort	.....
Diarrhea	.....
Cough	.....
Headache	.....
Dizziness	.....
Skin Rash	.....
Cons pa on	.....
Tiredness	.....
Fever	.....
Taste Disturbances	.....
Dispepsia	.....

Flatulance .....

Tongue Discolora on .....

Darkening of Urine .....

Oesophageal Irrita on .....

Others please specify

Herbal product **Side e ect(s)**

a)..... .....

b)..... .....

c)..... .....

4. Where you taking the herbal product alone or with conven onal (Western) medicine(s)

i) Yes.....

ii) No.....

If yes which herbal product were you combining with conven onal (Western) medicine.

Herbal product **Conven onal (Western)medicine(s)**

i)..... .....

ii)..... .....

iii)..... .....

5. How were you taking the herbal product?

Herbal product **Dose** **Frequency** **Dura on**

i)..... ....

ii)..... ....

iii)..... ....

iv)..... ....

6. Tick the adverse drug reac ons if any which happened as a result of taking the herbal product.

Adverse Drug Reac on	**Herbal product**
Photosensi vity	.....
Ur caria	.....
Pruritus	.....
Angioedema	.....

7. What did you do when you encountered the side e ect or adverse drug reac on?

a) Stopped taking the herbal product .....

b) Reported to the herbalist.....

c) Went to the hospital.....

d) Went to another herbalist.....

Appendix 2

QUESTIONNAIRE FOR HERBALIST

A RESEARCH STUDY ON THE POSSIBLE SIDE EFFECTS AND ADVERSE DRUG REACTIONS OF COMMONLY USED HERBAL PRODUCTS IN BUSHENYI DISTRICT.

QUESTIONAIRE (Herbalist)

BIO DATA

AGE.....

GENDER.....

OCCUPATION.....

LEVEL OF EDUCATION.....

ADDRESS.....

1. Name the common disease condi ons managed with the named herbal product.

Herbal product	**Disease condi on(s)**
Ekokorutanga (Aloe ferox)	.....
Niim(Azadirachta indica)	.....
Embiribiri(Crassocephalum vitellinum)	.....
Omuko (Erithrina abyssinica)	.....
Omujaaja(Ocimum suave)	.....
Orutotoimya(Hoslindia opposita)	.....
Omuboroboro(Nuxia congesta)	.....
Omunyaara(Spathodia campanulata)	.....
Omubirizi(Vernonia amygdalina)	.....
Tangawuzi(Zingiber o cinale)	.....

Kivu(Solanecio cydonifolius) .....

Omutatembwa(Zonthoxylum gille) .....

Others please specify

	Herbal product	**Disease condi on**
i)	.....	.....
ii)	.....	.....
iii)	.....	.....
iv)	.....	.....

2. Which of the following side e ect(s) is/are associated with the named herbal product(s)?

Side e ect(s)	**Herbal product(s)**
Nausea	.....
Vomi ng	.....
Abdominal Discomfort	.....
Diarrhea	.....
Cough	.....
Headache	.....
Skin Rash	.....
Cons pa on	.....
Tiredness	.....
Itching	.....
Oesophageal Irritation	.....

Others please specify

	Herbal product	**Disease condi on**
i)	.....	.....
ii)	.....	.....
iii)	.....	.....
iv)	.....	.....

3. How do you administer the following herbal medicines?

Herbal product	**Dose**	**Frequency**	**Dura on**
Ekokorutanga (Aloe ferox)	.....	.....	.....
Niim(Azadirachta indica)	.....	.....	.....
Embiribiri(Crassocephalum vitellinum)	.....	.....	.....
Ekiko (Erithrina abyssinica)	.....	.....	.....
Omujaaja(Ocimum suave)	.....	.....	.....
Orutotoimya(Hoslindia opposita)	.....	.....	.....
Omuboroboro(Nuxia congesta)	.....	.....	.....
Omunyaara(Spathodia campanulata)	.....	.....	.....
Omubirizi(Vernonia amygdalina)	.....	.....	.....
Tangawuzi(Zingiber o cinale)	.....	.....	.....
Kivu (Solanecio cydonifolius)	.....	.....	.....
Omutatembwa(Zonthoxylum gille)	.....	.....	.....

Others please specify

	Herbal product	**Dose**	**Frequency**	**Dura on**
i)	.....	.....	.....	.....
ii)	.....	.....	.....	.....

iii) ....

4. **Have you encountered any of the following adverse drug reac ons in your prac ce as an herbalist?**

Adverse drug reac on	**Herbal product**
Photosensi vity	.....
Ur caria	.....
Used for food.	.....
Pruritus	.....
Angioedema	.....

5. **How do you manage the side e ects?**

a) Change the medicine.
b) I give another drug to reduce the side e ects.
c) I tell them to con nue with the drug.
d) I send them to the hospital.
e) I give them the same drug but in di erent form.
f) Other please specify.....

6. **Quality control of herbal drugs**

a) Where do you collect your drugs?

.....

b) How do you process your herbal products?

.....

.....

c) How do you preserve your herbal products?

.....

.....

d) How do you determine the expiry date of your products?

.....

7. **How do you determine the dose, frequency and course of your herbal products**

.....

.....