

DRUG SHOPS COMPLIANCE WITH LICENSING AND INSPECTION REGULATION IN
LANGO SUB REGION

OBOTE AMOS

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DECLARATION

I, **Obote Amos**, declare that this dissertation is my original work that has never been submitted for publication or award of a degree in any higher institution of learning.

Author:

Signature.....

Date.....

Obote Amos

APPROVAL

This is to certify that this dissertation has been submitted for examination with my approval as the University Research Supervisor.

Signature.....

Date.....

Dr. Evelyn Nabankema

DEDICATION

This dissertation is dedicated to my wife, Jenifer Obote and daughters; Anyango Abigail and Ayoo Neria. Thanks for the support and may God reward you abundantly.

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ABBREVIATIONS

NDA: National Drug Authority

NDPA: National Drug Policy and Authority

MOH: Ministry of Health

WHO: World Health Organization

STI: Sexually Transmitted Infections

DMPA: Depot medroxy progesterone acetate

ABSTRACT

Introduction: Drug shops increase access to essential medicine, fill the gap left by the government health care facilities and they remain the most preferred source of medicine. But there are regulations that stipulate the conditions under which drug shops must operate if they are to promote the health of the public , unfortunately there are wide spread noncompliance with these regulations and therefore I set out to assess the drug shop compliance with licensing and inspection regulations in regulating drug shop practices in Lango Sub region.

Methodology: The study was a survey that targeted at all the drug hops in Lango sub region and a census of 298 drug shops conducted in the randomly sampled districts of Amolatar, Alebtong, Lira, Kole and Lira municipality between 20th November and 19th December 2013. Researcher administered questionnaires were administered to drug shop operators, inspections of drug shops done using inspection checklist and in depth interview was done to three NDA staffs using the interview guide.

Results: Findings have shown that, most (74.4%) drug shops were located in trading centers and half (50.3%) of these drug shops were being operated by employees. Across all the districts, only 30.9% of drug shops had valid operation permits. Only 8.4% of the drug shop operators across the districts were being operated by qualified personnel and all of them were enrolled nurses. No drug shop was found selling only class C drugs as prescribed in the regulation, but other services which were being offered includes laboratory services; sale of class A and B drugs, offering surgical and clinical services; and no drug shop was following good dispensing practices. Although 30.9% of drug shops had certificates of suitability of premises, no drug shop met all the criteria of suitability of premises in the study. Awareness of licensing and inspection regulations, presence of regulatory documents, inspections and sanctions were the factors

influencing compliance to licensing and inspection regulations by drug shop operators. Inadequate resources were the main factor hampering enforcement of these regulations by NDA. Binary logistic regression analysis revealed by the wald statistic that regulation of persons ($w=3.106$) highly determines drug shops' compliance to licensing and inspection regulations compared to regulation of practices (0.246) and regulation of premises (0.13). More so independence T-test revealed that awareness of regulations ($t=-4.869$, $p<0.05$), presence of regulatory documents ($t=2.471$, $p<0.05$), the frequency of drug shop inspection ($t=9.966$, $p<0.05$), sanctions imposed on drug shops ($t=-2.01$, $p<0.05$) significantly influence drug shops' compliance to licensing and inspection regulations.

Conclusion: Drug shops were not complying with licensing and inspection regulations due to inadequate enforcement of regulations and regulations that only allow the sale of class C drugs in Drug shops.

Recommendations: NDA should revise regulations to include essential drugs in the class C group and provision other services; creating a provision in the regulation that involves local leaders, civil society organizations and consumers in the implementation of these regulations; and organizing them in to groups/associations to improve on the enforcement of these policies.

The Government of Uganda should invest in training more health workers to ensure that qualified people operate the drug shops and consider giving soft loans and incentives to registered drugshop operators to improve on drug shop services and premises.

Scholars/Researchers, Health Institutions and NDA should conduct further research on the areas and scope of involvement of local leaders, civil society organization and consumers in the implementation of the policy.

OPERATIONAL DEFINITION OF TERMS

Compliance: For purposes of this study, compliance refers to the drug shop conformity with licensing and inspection regulations.

Drug shop: An authorized retail establishment selling only Class “C” drugs.

Class “A” drugs: These are the most dangerous drugs as treated by the law, some of which are totally prohibited and others can only be obtained under the prescription of a doctor. They have very high abuse potentials, no medicinal use and very severe safety concern.

Class “B” drugs: These are drugs that can only be obtained under the prescription of a doctor. They have acceptable medicinal use, low potential for addiction and abuse.

Class “C” drugs: these are drugs that can be obtained over the counter.

CHAPTER ONE: INTRODUCTION

1.1.Back ground to the study.

Drug shops are the smallest retail medicine outlet, which are licensed to sell class C drugs (nonprescription drugs) by non-pharmacists (Stanback J et al, 2011).

Retailing of medicines in the private sector in the world is governed by regulations and drug shops are no exceptions. These regulations prescribe standards for premises, persons and their practices which aim at ensuring that medicines sold to the public are safe and effective; and the implementation of these regulations determines their success in promoting public health. (Ratanawijitrasin S, et al, 2002).

Licensing and inspection regulation ensure that medicines used by final consumers are safe and of acceptable quality. Licensing of retail outlets is a legal mandate which provide appropriate condition for storage and dispensing of medicines, and ensures that medicines are dispensed under guidance and supervision of a qualified and authorized person. Inspection therefore ensures that the licensing conditions are met and maintained in the process of storage and dispensing of medicines to the final consumers (Ratanawijitrasin S, et al, 2002).

Governments through its National Drug Regulatory Authorities, have the responsibility of ensuring that medicines consumed by her population are safe and effective in promoting public health. However there are significant differences in the abilities of drug regulatory authorities of developed and developing countries in regulating the quality of medicines (Brant J, et al, 2011). The drug regulations are more effective in developed countries than in developing countries. For example, Germany is able to ensure that medicines in the 21,500 pharmacies are dispensed by qualified and registered pharmacists and the sale of non-prescribed, outdated and illegal drugs is prevented (Lowe R. F, et al,

2009). But even with more effective regulations, about 1% of fake drugs were estimated in United States of America's pharmaceutical market but this cannot be compared to the level of fake drugs in low income countries, where in Cambodia, 65% of quinine in pharmaceutical market was fake (Hill S, et al, 2004). This indicates that regulatory compliance in retail pharmacy sector, which includes drug shops, is very low in low income countries (Lowe R. F, et al, 2009).

In sub-Saharan Africa, episodes of common illness like malaria, sexually transmitted diseases are treated in the private sector, through the purchase of medicines from drug shops and peddlers; and yet most of these drug shops are informal (Mills A, et al, 2002). They are most preferred due to close proximity, perceived as being more personal, offers flexible payment methods, more widely distributed than licensed pharmacies in rural areas and because of the frequent stock outs in public facilities (Maija A, 2012)

Regulatory infringements are common in drug shops in East Africa where most of them do not have valid permits, stock illegal prescription only medicines and unpackaged tablets. Serving staffs do not meet the required qualification. For example in Tanzania a study on drug shop regulation and malaria treatment revealed that 24 out of 26 drug shops stocked antibiotics, which are totally prohibited to be sold in a class C drug shop. This may indicate infrequent regulatory inspections to ascertain compliance with the licensing requirements (Goodman C, et al, 2007)

In Uganda, NDA was established in 1993 to enact and enforce pharmaceutical regulation as a measure of protecting and promoting public health. NDA has established regional offices in all the regions in the country and District Assistant Drug Inspectors have been appointed in every district in Uganda to implement these regulations.

Pharmacies and drug shops are the major outlets in Uganda for distributing drugs from manufacturers to final consumers. Most people turn to drug shops for advice and medicines, especially when there

are stock outs in public health facilities (Office of the Auditor General, 2010). Drug shops therefore increases access to essential medicines to the underserved communities where public facilities are lacking and studies have revealed that it is feasible to expand the scope of services offered in drug shops in Uganda. For example it has been found to be feasible to distribute rapid diagnostic test in drug shops to improve the management of malaria (Cohen J, et al, 2012). However all the drug shops in Uganda were not licensed by 31st January 2010 as the law requires and National Drug Authority officials believe that only 50% drug shops in Uganda may be licensed; and in Northern Uganda 56% of the drug shops were not licensed by august 2009 (Office of the Auditor General, 2010). Even in the 6363 licensed drug shops, unauthorized drugs were being sold in them by unqualified personnel under unsatisfactory storage conditions (Maija A, et al, 2011). These raises questions as to whether the regulations that apply to the drug shops are being complied with and it may pose uncertainties in the quality and efficacy of drugs and services provided in the drug shops. This would further undermine the efforts to ensure quality of drugs at the level of development and manufacturing; and expanding the scope of services offered in the drug shops without understanding whether drug shops comply with the current regulation and making provisions to regulate these new services basing on the knowledge of success or failure to comply with the current regulation; and their respective drivers to compliance may expose the public to substandard drugs and poor services that have a direct effect on health of the people.

It is against this background that I intend to assess the drug shops compliance to licensing and inspection regulation in Lango Sub Region.

1.2. Problem statement.

Section 14 (3) of the National Drug Policy and Authority act (NDPA) states that it is an offence for one to operate a pharmacy or sell drugs without a valid license (The Republic of Uganda, 1993). NDA

has the legal mandate to issue licenses to drug outlets by 31st January every year and the license is valid until 31st December of that year (NDA, 2013).

However, in August 2009, 56% of the drug shops in northern Uganda were unlicensed but they were operating normally without any legal sanction by NDA (Office of the Auditor General, 2010). This encourages illegal operators of drug shops and exposes people to the risk of substandard drugs in the market and risky medical procedures. These can result in therapeutic failure, exacerbation of disease and resistance to antibiotics. The use of counterfeit medical products may cause death, disability and injuries; economic loss to patients and the nation; loss of confidence in health systems, health professionals, pharmaceutical manufacturers and distributors (WHO, 2010).

As a measure of protecting the health of the public, some drug shops have been closed and their drugs impounded by NDA due to noncompliance with the regulation, but illegal operation of drug shops and provision of services beyond the sale of class C drugs in licensed drug shops have persisted; and yet suggestions and research have been done that builds a strong case to expand access to injectable contraceptive (Stanback J et al, 2011) and use of rapid diagnostic test through the drug shop because they serve a big proportion of the population in Uganda especially in rural areas (Management Sciences for Health, 2012).

This could further pose health risks to the population if the scope of services offered in the drug shops are expanded beyond selling class C drugs without understanding the level of compliance to licensing and inspection regulations; and the determinants to compliance to these regulations.

1.3. Objectives.

1.3.1. Broad objective.

To assess drug shops compliance with licensing and inspection regulations in in Lango Sub Region.

1.3.2. Specific objectives.

- i. To determine the proportion of drug shops that meets regulatory requirements in Lango Sub Region.
- ii. To find out the range of services being offered in drug shop in Lango Sub Region.
- iii. To describe factors that influence compliance to licensing and inspection regulations among drug shop operators in Lango Sub Region.
- iv. To describe factors that influence enforcement of licensing and inspection regulations by the National Drug Authority in Lango Sub Region.

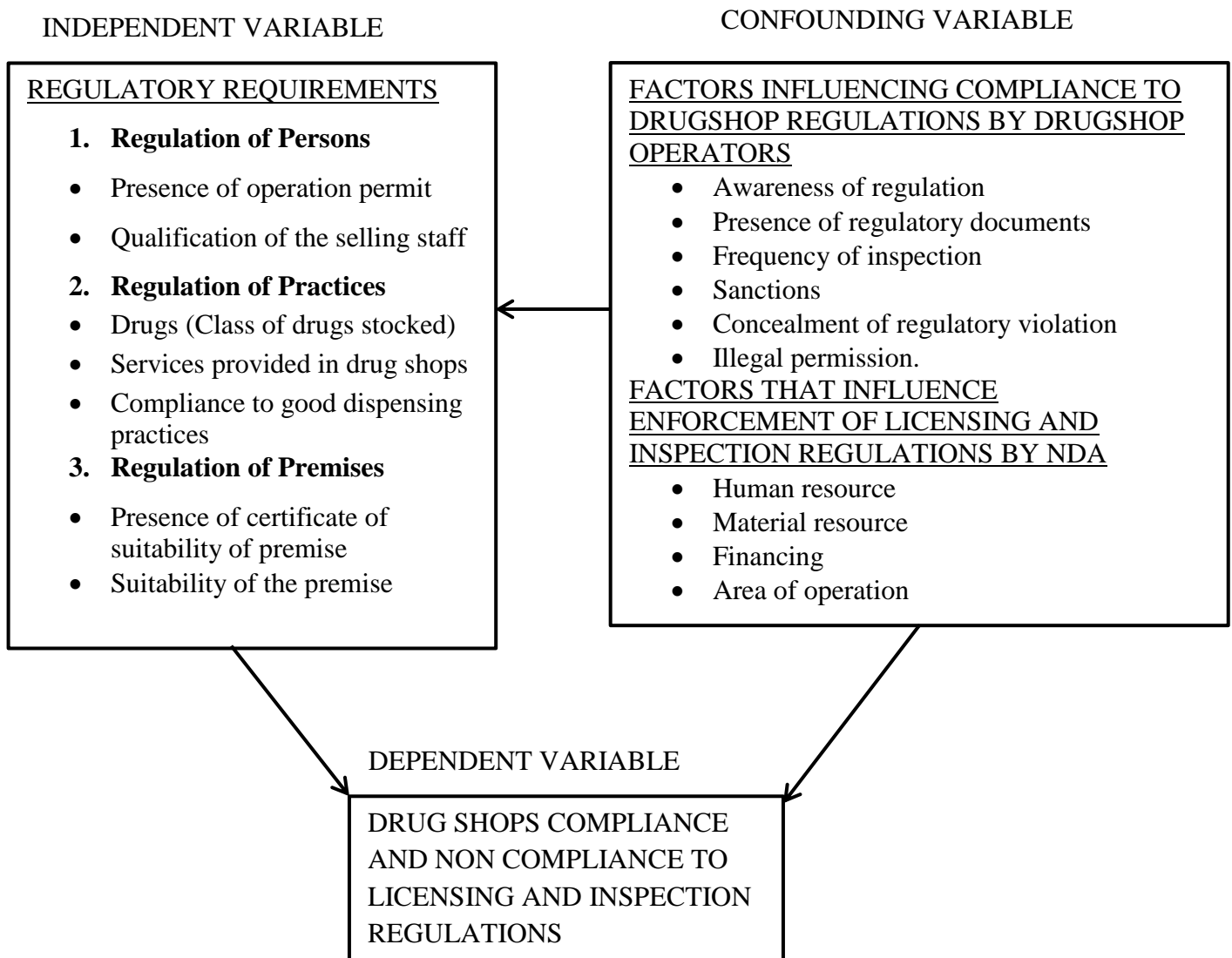
1.4. Research questions

- i. What is the proportion of drug shops that meets regulatory requirements in Lango Sub Region?
- ii. What is the range of services being offered in drug shops in Lango Sub Region?
- iii. What are the factors that influence compliance to licensing and inspection regulations among drug shop operators in Lango Sub Region?
- iv. What are the factors that influence enforcement of licensing and inspection regulations by the National Drug Authority in Lango Sub Region?

1.5. Significance of the study

A deeper knowledge on whether drug shops are complying or not complying with the regulations; and the factors influencing compliance from the perspectives of drug shop operators and NDA officials in Lango Sub Region would help NDA adjust its policies and the implementation strategies. Safe medicines from well regulated drug shops would be available to communities. Therefore, it is important to describe drug shops compliance to licensing and inspection regulations in Laango sub region.

1.6. Conceptual framework.



MEASURE OF COMPLIANCE TO LICENSING AND INSPECTION REGULATIONS

Regulation of persons: The proportion of licensed drug shop compared to the total number of drug shops and the proportion of drug shop operators that meets the required qualification.

Regulation of practices: The proportion of drug shops stocking only class C drugs, proportion of drug shops selling only class C drugs, proportion of drug shops that counsel and refer clients and proportion of drug shops that comply with good dispensing practices.

Regulation of premises: The proportion of drug shops that meets all conditions for suitability of premise and the proportion of drug shops with certificate of suitability of premise.

CHAPTER TWO: LITERATURE REVIEW.

2.0. Introduction.

This chapter reviews literatures related to licensing and inspection regulations of premises, persons and practices in drug shops. Literatures that further illuminate factors that influence compliance to these regulations from the perspectives of drug shops operators and regulatory authority have been reviewed in this chapter.

2.1. Regulation of persons

2.1.1. Presence of operation permit

Drug shops in Uganda must be licensed by 31st/January of each year and if by this date NDA has not licensed it, then it is considered unlicensed and should immediately close its operation to the public (NDA, 2013). An audit of the database of registered drug shops from July 2006 to June 2010 revealed that all drug shops were not licensed by NDA by 31st/ January but they continued with their normal operations. This may encourage illegal operations, (Office of the Auditor General, 2010).

A study aimed at increasing access to quality essential medicines by accreditation of private drug sellers and drug outlets in rural areas of Uganda where there are no licensed pharmacies and drug shops using both quantitative and qualitative pre and post intervention design. A baseline and end line study was done in 2008 and 2010 respectively. Kibale was the pilot district and Mpigi was the control District. A mystery shopper approach using malaria in a child under five year was used to measure prices and availability of tracer medicines and pharmaceutical service quality in 45 class C drug shops in Kibale and 43 in Mpigi. A base line study revealed that only 85 drug shops were licensed and 160 drug shops were licensed at the end line study. This gave a strong evidence that accreditation of drug

shops would increase access to quality essential drugs in underserved areas (Kikule K., 2013). Much as there was no accredited drug shop at the baseline study, there were 72 accredited drug shops at the end line study but all these drug shops were selling amoxicillin capsules which are not a class C drug. The research and the methodology was applied to drug shops only and left out the regulatory authorities whose activity influences directly the compliance of drug shops to licensing and inspection regulations.

A survey of 124 drug shops and small clinics that were offering DMPA in the districts of Nakasongola, Luwero and Nakaseke, the operators of these facilities who were interviewed revealed that 77% of the facilities identified were drug shops of which only 35% of them were licensed. This study concluded that drug shop operators can be trained to provide DMPA and bridge the extensive unmet need for family planning in rural areas, (Stanback J et al, 2011). The number of reported licensed drug shops may have been lower than 35% if they were observed. Interviews therefore needed to be complimented by inspection.

A licensed drug shop should have the license displayed in a clearly visible area in the drug shop. However a study of drug shops regulations and malaria treatment in Tanzania where a detailed census of drug retailers in the rural districts of Ulanga, Kilombero and Rufinji was done. Interview with the person most engaged in the management of the drug outlet, inspection of the drug outlet and in depth interview using semi structured interview guide with purposely selected five drugstores were the data sources. Findings showed that violation of regulations were common where 19 of the 30 drug shops in kilombero and Ulanga had their permits displayed but two of the permits were outdated and seven shops sellers specified on the permit were not serving there (Goodman C, et al, 2007)

2.1.2. Qualification of the drug shop operator

Proper use of medicines requires a trained person to prescribe and dispense properly; and give accurate and complete information to clients/patients.

The Uganda NDA licensing requirements and guidelines for 2013 stipulates that drug shops can only be supervised by a qualified health professional who are active members of their professional councils. These professionals includes pharmacy technicians, registered and enrolled nurses, registered and enrolled midwives, comprehensive nurses, anesthetic assistants and clinical officers (orthopedic, psychiatric, medical and dental). They should supervise the operations of the drug shop on full time basis and drug shop should be locked whenever they leave the premises less they employ another person with the required qualification, (NDA, 2013)

A survey of drug shops to assess the treatment of fever before introducing rapid diagnostic test for malaria in registered drug shops in Uganda. A survey of 20 geographically clustered drug shops was done and data collected using structured questionnaires for providers and patients. Findings revealed that 68% of drug shop operators were qualified health workers (Mbonye K M, et al, 2013). This survey focused only on registered drug shops yet many drug shops in Uganda are informal (Office of the Auditor General, 2010), but still a considerable proportion (30%) of drug shop operators were not qualified, (MOH, 2009).

In another a study of drug shops regulations and malaria treatment in Tanzania where a detailed census of drug retailers in the rural districts of Ulanga, Kilombero and Rufinji was done. Interview with the person most engaged in the management of the drug outlet, inspection of the drug outlet and in depth interview using semi structured interview guide with purposely selected five drugstores were the data sources. 37 staffs which were serving in the drug shops did not have any health qualification and most

of them were nursing assistants who had one year training and therefore not qualified to operate a drug shops (Goodman C, et al, 2007).

2.2. Regulation of practice.

Drug shops are licensed to sell only non-prescription medicines (Class C drugs). The sale of prescription only medicine is therefore an offence. The licensing requirements and guide lines for 2013 section 1.6 (b) clearly states that license shall be withdrawn where it is confirmed that the drug shop is stocking and/or selling drugs beyond those prescribed by the license, or unauthorized, unregistered counterfeit or smuggled drugs (NDA, 2013).

Interviews with drug shop operators in the rural districts of Kilombero, Ulanga and Rufiji in southeastern Tanzania revealed that 16 of the 30 drug shops had stocked prescription only medicine. These were self-reported and if inspections were done in these drug shops, the number of drug shops that stocked prescription only medicine may have been higher than reported. Unregistered antimalarial drugs were also found in 19 drug shops. Even expired antimalarial drugs were found in 2% of these drug shops. 29 and 22 drug shops sold loosed painkillers and antimalarial drugs respectively from pots against the policy of selling these medicines in unit packs. These drugs were carried away in home-made envelopes with the hand written abbreviated labels of drug names and incorrect or inconsistent dose information written on (Goodman C, et al, 2007).

In a cross sectional study of drug sellers in private drugstores in eight district of Tanzania to assess the role and contribution of private drugstores in STI management using simulated client methods and interviews with drug sellers, 74% of the drug sellers denied that there were no STI-related drugs in the stores. However, 80% of male and 90% of female simulated cases were dispensed STI-related drugs recommended in the guidelines for syndromic management of urethral and vaginal discharge for

Tanzanian. Antibiotics were dispensed to 76% of male and 35% of female simulated client during the visits. Simulated clients were provided incorrect doses and incomplete syndromic management. Drug use information was always provided but advice was seldom given and questions occasionally asked (Viberg N. et al, 2009).

A study carried out in Nakasongola, Nakaseke and Luwero districts in Uganda where local informants and snow ball techniques were used to contact drug shops and small clinics, only 35% were licensed and yet 96% administered DMPA in the drug shops. Those who did not administer the injection did refer clients to qualified providers in the private or public facilities. 94% of operators reported taking clients medical history before administering DMPA. 40% reported keeping a register of DMPA clients. A mean of 10 injections were reported per week of which three were for DMPA. Less than half (43%) of drug shops disposed of sharps in sharps containers immediately and 41% of the facilities had visible loose used sharps in open containers. These sharps were disposed of in pit latrines or by burning (Stanback J et al, 2011).

Section 24 (1&2) of the National Drug Policy and Authority act states that every person who supplies class A, B and C shall keep records of the drugs supplied in a book called classified drugs book and he or she shall enter or cause to be entered records of class A, B and C before issuing them (The Republic of Uganda, 1993).

2.3. Regulation of premises

Pharmaceutical products which include medicines should be stored under conditions that assure their quality and the principles of first expire/first out (FEFO). Medicines should be handled in a way that prevents cross contamination mix-up and contamination (WHO, 2003).

According to the guidelines on equitable distribution of pharmaceutical services in Uganda, no person shall open up a drug shop anywhere without prior approval of NDA. Application for pre inspection of the proposed premise location should be submitted to NDA and a written approval obtained after pre inspection (a mandatory pre inspection) (NDA, 2013), together with a sketch plan of the premise indicating the arrangement of the room and minimum floor area of 16 square meters for retail drug shops before issuing certificate of suitability of the premise (NDA, 2013). Operation license is only issued to applicants with certificate of suitability of the premise (Office of the Auditor General, 2010)

Medicine sellers often store and handle drugs in ways which are not appropriate, where drugs are kept in conditions of excessive light, moisture and heat which endangers their potency. Laboratory testing identified poor quality antimalarial on the private markets in Cameroon, Nigeria, Tanzania and Kenya. For example samples collected from urban and rural areas of Cameroon found that 12% of folate, 38% of chloroquine and 74% of quinine samples had either insufficient ingredients, unknown ingredients, unknown ingredients or no active ingredients. This was partly attributed to unsatisfactory storage conditions (Goodman C, et al, 2007)

2.4. Factors influencing compliance to licensing and inspection regulations by drug shop operators.

In a study of drug shop regulations and malaria treatment in Tanzania, poor knowledge of regulations was one of the causes of regulatory infringement by drug shop operators. Very few drug store staff had copies of the Pharmacy Board regulations, most of which were outdated. Both drug store staff and district-level regulators had no lists of registered medicines. Drug shop staffs were confused about which drugs they were legally allowed to stock. Much as drug store staffs were aware that the sale of antibiotics was prohibited, antibiotics were widely stocked (Goodman C, et al, 2007).

Infrequent regulatory inspection was another factor. Irregular environmental health and drug regulatory inspections were conducted. 8 out of the 26 interviewees, who recalled the date of the visit, reported that the visit took place within the previous 3 months, and 19 within the previous 6 months. In another interview where 24 shops staffs recalled drug regulatory visits date, 4 reported a visit within the previous 3 months, 15 within the previous 6 months, and 18 within the last year. All these patterns of visits did not reveal clearly any impact on regulatory violation (Goodman C, et al, 2007).

Difficulties in imposing sanctions were revealed during the interview by the regulatory officials. Comments from the officials revealed that obtaining court convictions were so difficult and could take years. This shows that the penalties of being caught were since no heavy sanctions were levied on the culprits. The cost of confiscation of few bottles of antibiotic syrup was small when compared with the profits made from selling high value and popular products (Goodman C, et al, 2007).

Concealing regulatory violations: Some regulatory violations may have been difficult to detect during an inspection visit, such as verifying whether the current seller was the person registered on the permit. Similarly, while prescription-only products were sometimes openly displayed, they were usually concealed from view in a side room or in a box under the counter. However, the availability of prescription-only drugs was well known by the customers who regularly purchased them. In addition, all the regulatory officials interviewed were aware of widespread regulatory infringements, such as the use of under-qualified persons (Goodman C, et al, 2007).

Tacit permission: It appeared that drug inspectors were at least aware of regulatory violations, but still allowed them to continue. This may have reflected the links between drug stores and the formal health care system. Of the 30 drug stores, nine owners and one server had jobs in the formal health sector, the majority being health care workers at local government facilities. Inspectors may also have been

personal acquaintances of shop staff, as in the case of this owner. Perhaps more importantly, inspectors may have given their tacit permission, recognizing that shops met a genuine need in communities without Part I pharmacies, in particular acting as a reserve drug source for government facilities (Goodman C, et al, 2007).

2.5. Factors that influence enforcement of licensing and inspection regulations by the National Drug Authority.

In many WHO member states in African region, many drug regulatory authorities do not have the capacity to enforce regulations effectively. Legislation on substandard drugs is lacking in some states and where the regulation exists they are ineffectively enforced. Properly trained staffs are important in the effective enforcement of regulations particularly when their number is adequate. However many national medicines regulatory authorities have inadequate financial and human resources. Inadequate staffs, low staff morale, low salaries, and lack of incentives contribute to low staff turnover which further weakens regulatory capacity (WHO, 2010).

A result of a pilot study of mapping the regulatory architecture for health care delivery in mixed health systems in low- and middle-income countries revealed that regulation of registered facilities was being impeded by personnel constraints, and difficulties to coordinate inspections with the police and a magistrate. Furthermore, reports of inspections were frequently being contested. Physical closure of premises was rare, since it requires interdepartmental coordination which can compromise the health department's relationships with the owners of the establishments, whose cooperation is required for other functions (Kabir S. et al, 2013).

Scrutiny of the database of operating drug outlets and the list of the licensed drug outlets as at 31st January of each calendar year by the office of the auditor general revealed that no license had been

issued within the stipulated timeframe. 100% of the respondents in regional offices confirmed that no license had been issued by 31st January, and they believed that half (50%) of the existing drug outlets may be licensed. The audit further revealed that licenses were being issued throughout the year from January to December. Lack of adequate staff to carry out mandatory inspections and issue licenses in time was the main reason explaining the situation. One person was managing the regional office which serves an average of about 15 districts. This makes it impossible to handle the volume of work. Interviews with regional inspectors also revealed that such delays were caused by inadequate facilitation in terms of transport. These delays in issuing licenses promote illegal operators of drug outlets which may pose a risk of exposing the consumers of medicines to sub-standard drugs. NDA may not be able to finance its activities as a result of low collection of revenue which cannot finance the budget (Office of the Auditor General, 2010).

CHAPTER THREE: METHODOLOGY.

3.0. Introduction.

This chapter presents the methodology which was used to conduct this study. This chapter includes the details of study area, study design, study population, inclusion criteria, study variables, sample size calculation, sampling procedure, data collection tools and procedures, quality control, ethical consideration, study limitations and dissemination of study findings.

3.1. Study area

The study was conducted in Lango Sub Region.

Lango sub-region is a region in Northern Uganda that consists of eight districts of Alebtong, Amolatar, Apac, Dokolo, Kole, Lira, Oyam and Otuke. It is bordered by Acholi Sub Region in the North and West; Lake Kioga in the South and Teso Sub Region in the East. It is inhabited by approximately 2.13 million people who are majorly Lango tribe (Atim T. et al, 2013). The predominant language spoken is “Leb Lango”. It is among the sub regions which were most affected by decades of LRA war and as a result majority of the people were displaced and they were living in IDP camps. This rendered some parts of Lango Sub Region inaccessible and classified as hard to reach and underserved areas. This affected service delivery in the rural areas of the region as services are mostly concentrated in towns.

The main social economic activity in the Sub region is subsistence farming. Commercial businesses are located in towns and trading canters, comprising of whole sale and retail traders. Network of murum roads crisscross the region which are sometimes impassable during rainy seasons. Tarmac road is only located within Lira town and the great north rod which pass through the region.

3.2. Study design

A survey was employed in this study. This was the most appropriate design for this study because not all the drug shops were registered and therefore the exact numbers of drug shops were not known in Lango Sub Region. A census of all the drug shops in the sampled area elicited a comprehensive information on the extent to which drug shops comply with licensing and inspection regulations; and helped show clearly the extent to which licensing and inspection regulations were working in ensuring that safe and efficacious drugs were sold in drug shops.

3.3. Sources of data.

Both primary and secondary data sources were used in this study.

Primary data were generated through interviews using interview guide and researcher administered questionnaires, observations using observation checklist and documents from NDA.

Secondary data were gathered from website, reports, and books, documents from web site, journal articles and conference proceedings.

3.4. The target population.

The study targeted at all the drug shops (licensed and unlicensed) and enforcers of drug regulations in Lango Sub Region

3.5. The study population.

The study population comprised of the drug shops (licensed and unlicensed), drug shop operators and National Drug Authority officials in Lango Sub Region.

3.6. Sampling techniques and procedures

A multistage sampling method was used. At the first stage list of all the eight districts in Lango Sub Region was drawn and four districts were randomly selected using a lottery method. There was only one municipality in Lango sub region and it was automatically selected. At the second stage a list of all the sub counties in each selected districts and divisions in the municipality were drawn. Depending on the number of sub counties in each district divisions in the municipality, a proportion to sample was done where half of the sub counties in each sampled district and half of the divisions in municipality were sampled and all the drug shops in the selected sub counties were surveyed. Assumption were made that in each of the sub counties selected, there were drug shops.

Table 1. Sample selection from Lango Sub region

Number of districts and municipality in Lango sub region	Districts sampled	Total number of sub counties/division	Number of sub counties sampled/division	Number of drug shops surveyed
8 districts and 1 municipality	Alebtong	8	4	61
	Amolatar	11	6	41
	Kole	8	4	57
	Lira	8	4	79
	Lira municipality	4	2	60
	Total		39	20

3.7. Study variables.

3.7.1. Dependent variables.

The dependent variable was drug shop compliance/noncompliance to licensing and inspection regulations.

3.7.2. Independent variables.

Independent variables were the regulations of persons, practices and premises in licensed and unlicensed drug shops.

Compliance to regulation of persons

In describing compliance to regulation of persons, the researcher looked out for the licensing status of the selling staff and the qualification of the drug seller working in the drug shop.

The indicators were the proportion of licensed drug shop compared to the total number of drug shops and the percentage of drug shop operators that met the required qualification.

Compliance to regulation of practice.

The classes of drugs stocked, services provided and general compliance to good dispensing practices in drug shops was assessed.

The indicators of compliance to regulation of practice was the proportion of drug shops that stocked class C drugs, proportion of drug shops that was selling class C drugs and the proportion of drug shops that complied with good dispensing practices.

Compliance to regulation of premises

The suitability of drug shop premise (Cleanness and adequacy of the premise (cemented floor, swept floor, walls painted with bright colors, Minimum floor area of 16 square meters), proper storage of

drugs (Presence of shelves without dust, counter with glass make up, presence of lockable cupboard for prescription drugs), Drugs protected from heat and direct sun light (presence of ceiling board and drugs exposed to sun light), sanitation and hygiene (Presence and use of hand washing facility, presence of a pit latrine); and the presence of certificate of suitability of premise was assessed

The indicators to drug shops compliance to regulation of premise were the proportion of drug shops with clean and adequate premise, proper storage facilities for drugs, drugs protected from heat and sun light, hygiene and sanitation facilities and the proportion of drug shops with certificate of suitability of premise.

3.8. Data collection tools.

The data collection tools comprised of observation checklist used to assess suitability of premises and class of drugs stocked, researcher administered questionnaires administered to drug shop operators and semi structured interview guide administered to NDA officials.

3.9. Data collection technique.

Observation checklist was used to assess 298 drug shops for suitability of the premise, presence of license and services offered; researcher administered questionnaires were administered to 298 drug shop operators to assess their practices and factors that influence compliance to regulation and a semi structured interview guide was used to assess factors that influence enforcement of licensing and inspection regulation by the regulatory authority. The data for the study was collected by the researcher and two research assistants. A multi stage sampling technique were used to select the districts and sub counties and census of all the drug shops in the selected sub counties were assessed and drug shop operators interviewed. An interview was also held with NDA staffs.

3.10. Data analysis

Immediately up on completion of data collection in each sub county, IBM SPSS statistics version 20 was used to code and enter data. After collecting, coding and entering data, data was analyzed. Frequencies and percentages of general drug shop information by district, drug shops that met regulatory requirements by district, current practices of drug shop operators by district were obtained. Factors that influence compliance to licensing and inspection regulations and enforcement among drug shop operators and NDA respectively were analyzed and presented in tables

A binary logistic regression model was used to assess the perceived effect of regulatory require on drug shops compliance to licensing and inspection regulations. A dependent variable was whether or not a drug shop complies to licensing and inspection regulations while independent variables were the regulatory requirements described by regulation of persons obtained by the sum of scores of the factors; the presence of operation permit and qualification of the drug shop selling staff, regulation of practices obtained by the sum of scores of the factors; class of drugs stocked, sell of class C drugs, counseling and referring of patients and regulation of premises obtained by the sum of scores of the factors; presence of certificate of suitability of drug shop premises and the suitability of the drug shop premises respectively. Binary logistic regression model was used because the dependent variable takes on two values, specifically whether or not a drug shop complies with licensing and inspection regulations.

The omnibus chi square test of model coefficients was used to establish the general effect of the regulatory requirements on the drug shops compliance to licensing and inspection regulations and the model summary statistics explained by the Cox & Snell R square and the Nagielkerke R square values were used to explain how variations in the regulatory requirements explain the dependent variable

which generally describes the usefulness of the model. The binary regression model is presented below;

$$Y_i = \alpha + \beta F_i + \Omega D_i + \mu X_i + \vartheta P_i + e$$

α =intercept coefficient; β , Ω , μ , ϑ are slope coefficients of the respective predictor variables.

$Y_i=1$ if the drug shop complies to licensing and inspection regulations.

$Y_i=0$ if the drug shop does not comply to licensing and inspection regulations

F_i =describes drug shops with regulation of persons

D_i =describes drug shops with regulation of practices

X_i =describes drug shops with regulation of premises

e = is the error term.

An independence sample t-test was also used to test for the relationship between factors that influence drug shops compliance with licensing and inspection regulations.

3.11. Quality control

A pretest of the questionnaires was done after the selection of the districts to be surveyed. Questionnaires were administered to 10 drug shops in Dokolo District which was not sampled. This was done to ensure that the questions were well structured; spelling errors and ambiguity were corrected.

Two research assistants were trained by the researcher to assist in the administration of questionnaire and observation checklist. Semi structured interview guide were administered by the researcher himself. The research assistants were diploma holders and they were trained for two days to ensure that they understand the subject matter, the objectives of the study, the questions and the techniques for administering the data collection tools.

Questionnaires and inspection checklist were prepared by referring to N.D.A licensing requirements and guidelines (2013). The instruments' validity was tested. The Cronbach's alpha was used to measure internal consistency among a set of parameters that define the dependent and the independent variables. The test gave an overall alpha of 0.721 which is high. This indicates that there is a high level of internal consistency among the parameters that define drug shop compliance to licensing and inspection regulations.

3.12. Ethical consideration.

Permission was sought from International Health Sciences University, Institute of Health Policy and Management. Introductory letter was issued by the faculty office to NDA and the Chief Administrative officer, which was used for getting approval. There after the researcher met the sub county chief and chairperson LCIII of the selected sub counties to inform them of the study and its purpose.

Using the local informants and guides, who were the village health teams; the researcher reached every drug shop within the sampled area that was open. The guides first introduced themselves and reassured the drug shop operator that the purpose of the visit was purely for research and that there was no connection to the NDA. The researcher then introduced himself to the person operating the drug shop and explained the purpose of the study with a proof of the introductory letter from International Health Sciences University; and sought for the consent of the person operating the drug shop. No drug shop operator declined to participate in the study. They were thanked for having participated in the study and the researcher together with the guide moved to another drug shop until all the drug shops in the sampled areas were assessed.

On securing a clearance Executive Secretary of NDA, the researcher presented the introductory letter to Regional Drug Inspector and other staffs in the office; and explained the purpose of the study and sought for their consent. The regional drug inspector and the secretary were interviewed

3.13. Study limitation.

Initially the researcher and research assistants were mistaken to be officials from NDA and the first drug shop operator that we interviewed sent wrong message to his colleague and all the drug shops in Awei subcounty were closed. Data collection was delayed for two days. We managed to assess all those drug shops through the VHT who were familiar to the drug shop operators and information shared from the interviewed drug shop operators

3.14. Plan for dissemination.

Results of the study will be submitted to International Health Sciences University, Institute of Health Policy and Management as partial fulfilment of the requirements for the award of Master of Science in public health. The results will also be availed to NDA.

CHAPTER FOUR: RESULTS

4.0. Introduction.

The results of the study and their interpretations were presented in this chapter. Tables were used to present the findings in accordance with the objectives; beginning with the general information about the drug shop, the proportion of drug shops that meets regulatory requirements, the current drug shop practices, drug shops' compliance with licensing and inspection regulations, factors influencing compliance to these regulations, the effects of regulatory requirements on drug shop compliance to licensing and inspection regulation; and the relationship between factors that influence compliance by drug shop operators and compliance to licensing and inspection regulation.

4.1. General information about drug shops.

The total number of drug shops surveyed was 298, which included 61 drugshops from Alebtong, 41 from Amolatar, 57 from Kole, 79 from Lira and 60 from Lira Municipality. Lira district had the highest number of drug shops that were reached. Majority (74.5%) of these drug shops were located in trading centers while very few (1.3%) were located in villages. The persons interviewed in their positions comprised of owners and employees of the drug shops with the percentage of employees being slightly higher (50.3%) than that run by owners (49.7%). The details of general information about drug shop are given in table 2 below.

Table 2. Distribution of frequencies and percentages of general information about drug shops by district.

General information about drug shops	Districts [n (%)]						Total
	Alebtong	Amolatar	Kole	Lira	Lira municipality	Lira n =60 (20.1)	
	n = 61 (20.5)	n = 41 (13.8)	n= 57 (19.1)	n= 79 (26.5)			298
Location of drug shops							
Village	2(0.7)	2(0.7)	0(0.0)	0(0.0)	0(0.0)		4(1.3)
Trading Centre	59(19.8)	27(9.1)	57(19.1)	79(26.5)	0(0.0)		222(74.5)
Town	0(0.0)	12(4.0)	0(0.0)	0(0.0)	60(20.1)		72(24.2)
Position of the person interviewed							
Owner	31(10.4)	25(8.4)	32(10.7)	41(13.8)	19(6.4)		148(49.7)
Employee	30(10.1)	16(5.4)	25(8.4)	38(12.8)	41(13.8)		150(50.3)

4.2. The proportion of drug shops that meets regulatory requirements.

Across all the districts, only 30.9% of the drug shops had valid operation permits. Lira Municipality had the highest proportion (76%) of the drug shops with valid operation permits, while Alebtong district had the lowest proportion (6.7%) of the drug shops with the lowest valid operation permits. Looking at the qualification of the drug shop operators, only 8.4% of the drug shops across all the districts had qualified personnel operating the drug shops. Lira municipality had the highest proportion of drug shops with qualified operators (28.3%) while Amolatar and Lira districts had none.

Regarding the recommended drug shop practices, no drug shop was found stocking only class C drugs, selling only class C drugs and carrying out good dispensing practices. Interestingly all the drug shop operators reported that they counsel and refer clients to another level of care.

Few drug shops (30.9%) had certificate of suitability of premise. The highest proportion of these drug shops (76%) were found in Lira district. Alebtong district had the lowest proportion (7.6%) of drug shop with certificate of suitability of premise. Surprisingly no drug shop met all the conditions/criteria for suitability of the drug shop. Details are shown in table 3 below.

Table 3: Distribution of frequencies and percentages of drug shops that meets regulatory requirement by district.

Regulatory requirements	Districts [n (%)]											
	Alebtong n = 61 (20.5)		Amolatar n = 41 (13.8)		Kole n= 57 (19.1)		Lira n= 79 (26.5)		Lira municipality n =60 (20.1)		Total 298	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Regulation of persons.												
Presence of valid operation permit	4 (6.7)	57 (93.3)	8 (19.5)	33 (80.5)	11 (19.3)	46 (80.7)	24 (30.4)	55 (69.6)	45 (76)	15 (25)	92 (30.9)	206 (69.1)
Operators with the required qualification	6 (9.8)	55 (90.2)	0 (0)	41 (100)	2 (3.5)	55 (96.5)	0 (0)	79 (100)	17 (28.3)	43 (71.7)	25 (8.4)	273 (98.1)
Regulation of practice												
Stocking only class C drugs	0 (0)	61 (100)	0 (0)	41 (100)	0 (0)	57 (100)	0 (0)	79 (100)	0 (0)	60 (100)	00 (00)	298 (100)
Selling only class C drugs.	0 (0)	61 (100)	0 (0)	41 (100)	0 (0)	57 (100)	0 (0)	79 (100)	0 (0)	60 (100)	00 (00)	298 (100)
counselling and referral of clients	61 (100)	0 (0)	41 (100)	0 (0)	57 (100)	0 (0)	79 (100)	0 (0)	60 (100)	0 (0)	298 (100)	00 (00)
Carry out good dispensing practices	0 (0)	61 (100)	0 (0)	41 (100)	0 (0)	57 (100)	0 (0)	79 (100)	0 (0)	60 (100)	0 (0)	298 (100)
Regulation of premises												
Presence of certificate of suitability	4 (6.7)	57 (93.3)	8 (19.5)	33 (80.5)	11 (19.3)	46 (80.7)	24 (30.4)	55 (69.6)	45 (76)	15 (25)	92 (30.9)	206 (69.1)
Meets all conditions of suitability	0 (0)	61 (100)	0 (0)	41 (100)	0 (0)	57 (100)	0 (0)	79 (100)	0 (0)	60 (100)	00 (00)	298 (100)

4.3. The range of services being offered in drug shops.

All drug shops (100%) in all the districts reached were not only selling class C drugs which are recommended for sale in drug shops but also selling class A and B drugs which are not recommended for sale in drug shops. All the drug shops across districts were offering other services not recommended for drug shops besides selling drugs. All the drug shops had some form of record keeping and reporting. 67.2%, 90.2%, and 98.3% of the drug shops in Alebtong, Amolatar and Lira municipality respectively carried out clinical work. All the drug shops in Kole and Lira district carried out clinical diagnosis. 63.9%, 80.5% and 78.9% of the drug shops in Alebtong, Amolatar, and Kole districts respectively provided laboratory services with 82.3% of the drug shops in Lira district and 91.7% in Lira municipality providing laboratory services. More than 90% of all the drug shops across all the districts reached carry out medical and surgical procedures. All (100%) drug shops reached did not totally comply with good dispensing practices. Details are shown in table 4 below.

Table 4: Reveals the range of services being offered in drugshops by District.

Current drug shop practices		Districts [n (%)]					
		Alebtong	Amolatar	Kole	Lira	Lira municipality	Total
carrying out clinical work	Yes	41 (67.2)	37 (90.2)	57 (100)	79 (100)	59 (98.3)	272(91.6)
	No	20 (32.8)	4 (9.8)	0 (0)	0 (0)	1 (1.7)	25(8.4)
provision of laboratory services	Yes	39 (63.9)	33 (80.5)	45 (78.9)	65(82.3)	55 (91.7)	237(79.5)
	No	22 (36.1)	8 (19.5)	12 (21.1)	14(17.7)	5 (8.3)	61(20.5)
presence of class A and/or B drugs	Yes	61 (100)	41 (100)	57 (100)	79 (100)	60 (100)	298(100)
	No	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0(0)
carrying out medical and surgical procedures	Yes	56 (91.8)	39 (95.1)	54 (94.7)	75(94.9)	58 (96.7)	282(94.6)
	No	5 (8.2)	2 (4.9)	3 (5.3)	4 (5.1)	2 (3.3)	16(5.4)
sale of class C drugs	Yes	61 (100)	41 (100)	57 (100)	79 (100)	60 (100)	298(100)
	No	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0(0)
Noncompliance to good dispensing practices	Yes	61 (100)	41 (100)	57 (100)	79 (100)	60 (100)	298(100)
	No	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0(0)

Source: primary data

4.4. Drug shops' compliance to licensing and inspection regulations in Lango Sub region.

Table 5: Reveals the proportion of drug shop that complies with licensing and inspection regulation.

Regulatory requirements	Comply n(%)	Did not comply n(%)
Regulation of persons.	17(5.7)	281(94.3)
Presence of valid operation permit	92(30.9)	206(69.1)
Operators with the required qualification	25(8.4)	273(98.1)
Regulation of practice	00(00)	298(100)
Stocking only class C drugs	00(00)	298(100)
Selling only class C drugs.	00(00)	298(100)
counselling and referral of clients	298(100)	00(00)
Carry out good dispensing practices	0(0)	298(100)
Regulation of premises	00(00)	298(100)
Presence of certificate of suitability	92(30.9)	206(69.1)
Meets all conditions of suitability	00(00)	298(100)

Source: primary data

The table above shows that, overall, only 5.7% of drug shops complied with the regulation of persons. 30.9% and 8.4% of the entire drug shops had valid operation permits and the operators with required qualification respectively.

No drug shop totally complied with the regulation of practice. No drug shop was stocking and/or selling class C drugs only; and carrying out good dispensing practices. However all drug shops reported that they were counselling and referring clients.

No drug shop complied with the regulation of persons, but 30.9% of drug shops had valid certificates of suitability of premise and no drug shop met all the conditions for suitability of premise.

4.5. Factors that influence compliance to licensing and inspection regulations among drug shop operators in Lango Sub Region.

Across all the districts, majority (84.6%) of respondents mentioned that they were aware of the regulations that govern the operation of drug shops. All drug shop operators (100%) in Lira district mentioned that they were aware of the regulations. Drug shop operators in Alebtong district reported a lower level of regulatory awareness (73.8%) compared to the other districts. This finding is further supported by the regional inspector who stated that *“Yes the drug shop operators are really aware because many times when they hear of any inspections they close the drug shops and whenever inspections are done, recommendations made are always based on the regulations”*.... he further continued by stating that *“To ensure that the drug shop operators get to know these regulations, we organize workshops/seminars, we hold talk shows and we welcome inquiries from our office on the required conditions to operate the drug shops”*

No drug shop had any regulatory document. Less than half (46.6%) of drug shops across the districts reported that their drug shops were ever inspected by the authorities. The highest numbers of inspected drug shops were reported in Lira municipality (73.8%) while the rest of the districts had less than 50% of the drug shops inspected; with the lowest number of inspected drug shops reported in Amolatar district (31.7%). All the drug shop operators reported that they have ever heard or experienced

sanctions imposed by the regulatory authorities. Furthermore all the operators accepted they hide/conceal the regulatory violations from the authorities. This finding is further expounded by the secretary to regional inspector who stated that, *“There is a high level of coordination between drug shop operators, using the mobile phone to inform their colleagues whenever there are inspections and those without the license will definitely close the drug shop”*

Across all districts, 26.2% of drug shop operators reported that NDA officials recommend them to operate while processing the licenses, most of which were reported in Lira district (58.3%) while Alebtong district had the lowest proportion (7.3%). Details are shown in table 6 below.

Table 6: Reveals factors that influence compliance to licensing and inspection regulations among drug shop operators in Lango Sub Region.

Factors that influence compliance		Districts [n (%)]					Total
		Alebtong	Amolatar	Kole	Lira	Lira municipality	
Awareness of regulations	Yes	44 (72.1)	37 (90.2)	57 (100)	79 (100)	59 (98.3)	276 (92.6)
	No	17 (27.9)	4 (9.8)	0 (0)	0 (0)	1 (1.7)	22 (7.4)
Presence of regulatory documents	Yes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	No	61 (100)	41 (100)	57 (100)	79 (100)	60 (100)	298 (100)
Inspection of drug shops	Yes	28 (45.9)	13 (31.7)	20 (35.1)	34 (43)	44 (73.8)	139 (46.6)
	No	33 (54.1)	28 (68.3)	37 (64.9)	45 (57)	16 (26.2)	159 (53.4)
Ever heard or experienced Sanctions by the authorities	Yes	61 (100)	41 (100)	57 (100)	79 (100)	60 (100)	298 (100)
	No	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Conceal the violation of regulations	Yes	61 (100)	41 (100)	57 (100)	79 (100)	60 (100)	298 (100)
	No	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Authorities recommend them to operate while processing the license	Yes	13 (21.7)	3 (7.3)	11 (19.3)	16 (20.3)	35 (58.3)	78 (26.2)
	No	48 (78.3)	38 (92.7)	46 (80.7)	63 (79.7)	25 (41.7)	220 (73.8)

4.6. Factors that influence enforcement of licensing and inspection regulations by the National Drug Authority in Lango Sub Region.

4.6.1. Human resource.

There were only four staffs who were working for NDA in Lango sub region. Two technical staffs (the regional drug inspector and the zonal drug inspector) and two support staffs (the driver and the secretary). Due to inadequate staffing, NDA have resorted to working with district local governments where a registered nurse or a clinical officer working in the district is assigned a duty of assistant district drug inspector to carry out inspection of drug shops, issuing registration forms and collecting filled registration form. Once these people are identified, they are trained and supported by the NDA to carry out these duties. “Currently, the process of identification and training of these staffs is going onsaid the regional drug inspector”

4.6.2. Financial and material resources.

There was only one vehicle for northern region. “The major source of financing was license and inspection fees levied on drug shops which is insufficient. Sometimes there are grants from government for specific purposes but these grants have no specific schedule for their release which makes it difficult to plan for operations.....said the regional drug inspector”.

4.6.3. Area of coverage.

All the interviewed staffs did admit that the area where they operate is so wide that cannot be effectively served by only two technical staffs, coupled with inadequate finances and only one vehicle; operations are severely hampered and this partly explains why inspections are done where problems (regulatory violations) are reported.

4.7. Effect of regulatory requirements on drug shop compliance to licensing and inspection regulation.

The results of binary logistics regression analysis of effect of regulatory requirements on drug shops compliance with licensing and inspection regulation showed that, the more a drug shop met regulatory requirements, the more likely it was that, drug shop complies to licensing and inspection regulations.

The regulatory requirements were the regulation of persons obtained by the sum of scores of the factors; the presence of operation permit and qualification of the drug shop selling staff, regulation of practices obtained by the sum of scores of the factors; class of drugs stocked, sale of class C drugs, carrying out good dispensing practices, counseling and referring of patients; and regulation of premises obtained by the sum of scores of the factors; presence of certificate of suitability of drug shop premises and the suitability of the drug shop premises. This is revealed by the positive B values in the table below. The Wald statistic revealed by regulation of persons ($w=3.106$) is greater than the Wald statistics revealed by Regulation of practices (0.246) and regulation of premises (0.13). This therefore means that regulation of persons highly determines a drug shops' compliance to licensing and inspection regulations compared to regulation of practices and regulation of premises.

The drug shops that meet the requirement of regulation of persons ($\text{Exp (B)}=1.252$, a value greater than one) indicates that for every extra requirement in relation to regulation of persons, the odds of that drug shop complying to licensing and inspection regulation increases by a factor 1.252 keeping other factors constant. Similarly drug shops that meet the requirements of regulation of practices ($\text{Exp (B)} =1.578$) and regulation of premises ($\text{Exp (B)} =1.691$), all values greater than 1, indicate that for every extra requirement in relation to regulation of practices and regulation of premises, the odds of that drug shop complying to licensing and inspection regulation increases by a factor 1.578 and 1.691 respectively keeping other factors constant

The table also shows the binary logistic model estimates with omnibus chi square tests on regulatory requirement effects on drug shop compliance to licensing and inspection regulations. The results revealed that a combined variation of Regulation of persons, Regulation of practices and Regulation of premises were statistically significant ($\chi^2 = 43.780, p = 0.000$) at 95% confidence interval hence highly attributed to Regulatory requirements of persons, Regulation of practices and Regulation of premises. The model summary estimates reveal a Cox & Snell R square value of 0.137 and a Nagelkerke R square value of 0.764. This shows that between 13.7% and 76.4% of the variations in drug shop compliance to licensing and inspection regulations can be explained by regulatory requirements of regulation of persons, regulation of practices and regulation of premises. Details are shown in table 6 below.

Table 7: Binary logit model estimates of regulatory requirement effects on drug shop compliance to licensing and inspection regulations.

Variables in the Equation	B	S.E.	Wald	df	Sig.	Exp(B)
Regulation of Persons	17.068	14535.677	3.106	1	0.052	1.252
Regulation of Practices	35.562	3058.028	0.246	1	0.02	1.578
Regulation of premises	33.700	14922.732	0.13	1	0.047	1.691
Constant	147.258	13152.097	0.000	1	0.999	6.19

Omnibus Tests of Model Coefficients			
	<i>Chi-square (χ^2)</i>	<i>df</i>	<i>Sig.</i>
Step	43.780	3	0.000**
Block	43.780	3	0.000**
Model	43.780	3	0.000**

Model summary		
-2 log likelihood	Cox & Snell R square	Nagelkerke R square
14.963	0.137	0.764

Source: *Primary data (Multiple responses)*; significant at 95% **

4.8. Relationship between factors that influence compliance by drug shop operators and compliance to licensing and inspection regulation.

An independent sample t-test was used to test for the factors that influence compliance of drug shops' compliance to licensing and inspection regulations. The variable was drug shops' compliance with licensing and inspection regulations and the test variables were the factors that influence compliance defined by the following factors; Awareness of regulation (1), Presence of regulatory documents (2),

Frequency of inspection (3), Sanctions (4), Concealment of regulatory violation (5), and Illegal operational permission (6). Results are presented in table 7 below.

The table reveals that awareness of regulations ($t=-4.869$, $p<0.05$), presence of regulatory documents ($t=2.471$, $p<0.05$), the frequency of drug shop inspection ($t=9.966$, $p<0.05$), sanctions imposed on drug shops ($t=-2.01$, $p<0.05$) significantly influence drug shops' compliance to licensing and inspection regulations. The other two factors, that is concealment of regulatory violation ($t=0.948$, $p>0.05$) and illegal operational permission ($t=0.474$, $p>0.05$) do not significantly influence drug shops' compliance to licensing and inspection regulations.

Table 8: shows Independent sample T-test for independence between compliance and the factors that influence compliance to licensing and inspection regulations.

Factor		F	Sig.	t	df	Sig. (2- tailed)	Mean Difference	Std. Error Difference
1	Equal variances assumed	2.302	0.13	-0.697	296	0.486	-0.075	0.108
	Equal variances not assumed			-4.869**	291	0.000	-0.075	0.015
2	Equal variances assumed	0.522	0.471	0.354	296	0.724	0.021	0.058
	Equal variances not assumed			2.471**	291	0.014	0.021	0.008
3	Equal variances assumed	75.599	0.000	1.196	138	0.234	0.42	0.352
	Equal variances not assumed			9.966**	137	0.000	0.42	0.042
4	Equal variances assumed	0.34	0.56	-0.288	296	0.774	-0.014	0.048
	Equal variances not assumed			-2.01**	291	0.045	-0.014	0.007
5	Equal variances assumed	58.762	0.000	4.121	296	0.000	0.316	0.077
	Equal variances not assumed			0.948	5.01	0.386	0.316	0.333
6	Equal variances assumed	1.07	0.302	0.449	296	0.654	0.08	0.178
	Equal variances not assumed			0.474	5.23	0.655	0.08	0.169

Dependent variable: drug shops' compliance to licensing and inspection regulations

*** Significant at 95% confidence interval*

CHAPTER FIVE: DISCUSSIONS.

5.1. Discussions.

Findings from this study indicate that the proportion of licensed drug shops in Lango sub region is so low (30.9%). Majority of licensed drug shops were found in Lira Municipality and Lira District which are closer to National Drug Authority Offices and this may justify that the area of operation of the authority does not match with the resources availed for the enforcement of licensing and inspection regulation since enforcement is done to drug shops located closer to the NDA office, which requires less resource for the enforcement of these regulations. This may further be supported by findings that the most inspected drug shops (73.3%) were in Lira Municipality. This finding concurs with the audit report done between July 2006 and June 2010 by Office of the Auditor General (2010) where no drug shop had operation permit by 31st January of every year and findings of Kikule K, (2013) in a baseline survey of drug shops in Kibale and Mpigi where only 85 drug shops had the operation permit. This may not certainly indicate that the licensing regulation is ineffective but it could be an indication of inadequate enforcement owing to the inadequate human, material, financial resources available for the enforcement of these regulations; the wide area of operation of the authorities and the method used for the enforcement of these regulations.

Very few drug shops (8.4%) were being operated by staffs that met the required qualification, of which all of them were enrolled nurses. This does not match with the proportion of licensed drug shop (30.9%). Only 5.7% of drug shops had valid operation license and were being operated by qualified personnel, indicating that some licensed drug shops were being operated by unqualified persons and some of the unlicensed drug shops were being operated by qualified personnel. The licensed drug shops that are not being operated by qualified personnel may have hired or borrowed academic

testimonials from qualified persons for purposes of securing the operation license but the unqualified person remains the sole owner and the operator. This may not reflect that the licensing of personnel is ineffective but could be due to low number of qualified health workers, the high number of nursing assistants trained illegally by doctors that owns clinics in the region and the remoteness of some places with inadequate social and recreational services that does not attract qualified health workers and therefor leaving unqualified people to operate drug shops in those areas. The few enrolled nurses found operating the drug shops could be due to the opening up of many private Nurses training schools causing an increase but still inadequate number of qualified health workers in the region. The few qualified health workers operating drug shops without the license may have been hired by unqualified drug shop owners who fears meeting the cost of registering the drug shop or fears that they may not meet other regulatory requirements. This can also be viewed that if regulation of persons was the only regulatory requirement and if strictly enforced, only 5.7% of the current drug shops would be serving the entire Lango Sub region and this would deprive people in the region access to essential medicines and the gaps currently being filled by the drug shops would be so wide. This may appear a generous view but the high proportion of drug shop operators who do not meet the regulatory requirement of person may mean the majority of the population is quietly being harmed by the services offered by these people. This finding concurs with that of Goodman C et al, (2007) where all drug shop operators in Ulanga and Kilombero in Tanzania were nursing assistants who had a one year training and therefore do not meet the regulatory requirement of person to operate a class C drug shop. Binary regression analysis of effects of regulatory requirements on compliance with licensing and inspection regulation further reveals that regulation of persons highly determines a drug shops' compliance to licensing and inspection regulations compared to regulation of practices and regulation of premises as shown by the wald statistic for the regulation of persons ($w=3.106$) being greater than

the wald statistics for the regulation of practices (0.246) and regulation of premises (0.13). Therefore ensuring that qualified people operate drug shops would definitely lead to increase in the number of licensed drug shops because they would have the necessary papers that allow them to obtain the license. Even the quality of services offered in the drug shop would improve because of the knowledge and skills that the qualified people would be having; and probably the professional ethics would move them to comply with the scope of services prescribed to be offered in the drug shop. More so suggestions about increasing the scope of services to be offered in the drug shop would be viable because of the knowledge and skills that the drug shop operators would be having. It is important that drug shops be run by qualified people but this can only be ensured by enforcing licensing and inspection regulations.

Drug shops are licensed to stock and sell only class C drugs; counsel and refer clients to other levels of care, but there was no drug shop found stocking and selling only class C drugs but all the drug shops admitted counselling and referring patients therefore the entire drug shops were not complying with the regulation that governs the class of drug stocked and sold in drug shops. A broad range of services were also being offered ranging from clinical services, laboratory test, giving injections and carrying out surgical procedures were being offered in these drug shops. This indicates that drug shops are offering services beyond their scope and totally outside the regulation and therefore not complying at all to the regulation of practice. This could be due to inadequate enforcement of regulation owing to inadequate resources but it could also be due to the demand placed on drug shops by communities as many clients are always sent to drug shops whenever there are stock outs in government health centers, the desire to make money by drug shop operators by providing other services apart from selling class C drug, affordability of services offered in drug shops that attracts clients and lack of qualified and recognized providers in the area. Much as these services benefits the clients in situations

where there are no better options, on another hand it poses risks to clients since a greater proportion of these drug shops are being operated by unqualified persons and offering services that are not recommended by the NDA. This situation can also be viewed that the scope of services prescribed by the regulation is too narrow that can't allow drug shops to make profits which is in this case, the primary reason for their establishment. Much as the regulation of person highly determines compliance to licensing and inspection regulations, the scope of services needs to be clearly defined and within a range that allows for services that can be provided by the operators; services that meets the needs of the community and that of the drug shop operators because the qualified operators can be tempted to provide services beyond their capacity and facilities. Therefore there is need to re define the scope of services to be offered in the drug shop and these services should be informed by careful evaluation of the range of services that can safely be provided at the drug shops, which meets the needs of the community and allows making of profits by the operators.

No drug shop was found carrying out good dispensing practices. This could be due to inadequate knowledge on good dispensing practices and inadequate facilities like dispensing trays to enhance the practice. Training of drug shop operators would improve on the dispensing practices.

In all the districts, only 30.9% of drug shops had certificate of suitability. This proportion is the same as that of drug shops with valid licenses. No drug shop had all the attributes of suitability including drug shop with certificates of suitability meaning that no drug shop totally complied with the regulation of premise. It is a regulatory requirement that all drug shops be inspected before issuing the certificates of suitability. This means that drug shops are licensed and issued certificate of suitability without first inspecting the drug shop. Even if inspections were to be carried out, houses in some trading centers were without windows and the materials used for constructions (e.g. Mud blocks and grass) can't ensure suitability for operation of drug shops. In most cases these houses are rented and

the tenant has no right or money to change the structure to fulfill the suitability criteria and enforcement of inspection wouldn't do much since it cannot change the structures in any way; and in situations where all the houses in a particular location cannot meet the suitability criteria, closing these drug shops would definitely deny communities drug shop services that most times feel the gap left by government health facilities but the drugs stored in these premises may lose their potency and may be harmful to clients, lead to drug resistance and clients waste money on drugs that can't help them. This may indicate that the structures cannot permit compliance to regulations that applies to the premises and therefore compliance to this regulation cannot be observed uniformly but this does not disregard suitability of premise as a regulatory requirement that must be complied with. Extending support to drug shops in terms of soft loans to help them improve on the premises or construct premises would be a better way to go.

Results also indicated that awareness of regulations ($t=-4.869$, $p<0.05$), presence of regulatory documents ($t=2.471$, $p<0.05$), the frequency of drug shop inspection ($t=9.966$, $p<0.05$), sanctions imposed on drug shops ($t=-2.01$, $p<0.05$) significantly influence drug shops' compliance to licensing and inspection regulations. The drug shop operator can be aware of the regulations and have all the regulatory documents but he/she can't secure the license if he is not qualified and enforcement of these regulations through inspections and sanctions would ensure compliance. Unfortunately resources couldn't permit effective enforcement. Findings indicated that there was no plan laid down for inspection by the authority, the inspections that were carried out and sanctions imposed had no proper records kept by the authority and less than half (46.6%) of the drug shops in the region reported that their drug shops were inspected. This can be seen as a failure in the execution of inspection regulations and may explain the high numbers of unlicensed drug shops being operated by unqualified people. It is therefore important that drug shop operators be made aware of the regulations that governs drug shops

and copies of these regulations availed to them. More resources be availed for inspections and sanctions, which should not be restricted to NDA staffs only but it should include drug shop operators, local leaders, and civil society organizations

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS.

6.1. Conclusion

Findings from this study have shown that, most (74.4%) drug shops were located in trading centers and half (50.3%) of these drug shops were being operated by employees.

Across all the districts, only 30.9% of drug shops had valid operation permits. Only 8.4% of the drug shop operators across the districts were being operated by qualified personnel and all of them were enrolled nurses. Overall only 5.7% of drug shops totally complied with the regulation of persons.

No drug complied with the regulation of practice as no drug shop was found stocking and selling only class C drugs as prescribed in the regulation, but other services being offered were laboratory services, sale of class A and B clinical; surgical and clinical services. All drug shops admitted that they were counselling and referring clients to another level of care. No drug shop was also found totally complying with good dispensing practices.

No drug shop complied with regulation of premise. Much as 30.9% of drug shops had certificate of suitability of premise but no drug shop met all the criteria for suitability of premise. Binary logistic regression analysis revealed by the wald statistic that regulation of persons ($w=3.106$) highly determines drug shops' compliance to licensing and inspection regulations compared to regulation of practices (0.246) and regulation of premises (0.13). More so independence T-test revealed that awareness of regulations ($t=-4.869$, $p<0.05$), presence of regulatory documents ($t=2.471$, $p<0.05$), the frequency of drug shop inspection ($t=9.966$, $p<0.05$), sanctions imposed on drug shops ($t=-2.01$, $p<0.05$) significantly influence drug shops' compliance to licensing and inspection regulations.

The enforcement of these regulations by NDA in the region was widely constrained by inadequate human, financial and material resources; and the wide area of operation piled more challenges on regulatory authority.

The licensing and inspection regulations were not being complied with due to few qualified people in the region, low level of regulatory awareness, inadequate enforcement of these regulations due to inadequate resources and weaknesses in the regulations that only allow the sale of class C drugs in Drug shops, does not include other stake holders in the enforcement. This has left drug shops to operate without permits, mostly being operated by unqualified personnel in unsuitable premises and providing services that are far beyond the scope of the drug shop. All these have a threat to public health.

6.2. Recommendations.

Finding the most suitable intervention that would ensure that all drug shops comply with the regulations; where drug shops would be operated by qualified staff in suitable premises still looks far beyond our eye sight, especially in this situation where legal control is the only focus and its implementation is hampered by inadequate resources. If these regulations were strictly implemented in its current state, it would be likely that the communities would be deprived of essential medicines and services that drug shops offer to complement government facilities.

The NDA should revise the regulations to include essential drugs in the class C group and to include services, for example simple rapid test for malaria which contributes to the health care of rural communities and allows drug shop operators to make profits; creating a provision in the regulation that involves local leaders, civil society organizations and consumers in the implementation of these

regulations would level the ground that brings the private providers and the public consumers to collaborate in the improvement of services offered by the drug shops.

The government of Uganda should invest more in training of health workers to increase the number of health workers who are qualified to operate drug shops.

The NDA should take a lead in organizing drug shop operators should in to groups or associations at the district level to help in implementation of these regulations as well as setting standards among them which are in line with the regulations.

The government of Uganda should provide incentives and soft loans to drug shop operators through their groups or associations to help in improving the premises and drug shop services.

All the suggestions above needs to be evaluated before implementations, more especially on the scope of services that should be provided safely by drug shops, which meets the needs of communities and that of drug shop operators.

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APPENDIX I: CONCENT FORM FOR PARTICIPATION IN THE STUDY.

As part of the requirements for the award of a master degree of International Health Sciences University, I have to carry out a research study. The study is about assessing the effectiveness of licensing and inspection regulation in regulating drug shop practices in Lango Sub Region. You are therefore invited to participate in the study. Your participation will involve answering short questions that will provide data for the study. This will take at most 15 minutes. The study has totally no risk and to ensure confidentiality, your identity is not required in this study; any extract from what you say will be anonymous. The study will provide information that will help improve and expand services offered at the drug shops.

Your participation in this study is voluntary and you may withdraw before the commencement of the study. If you agree to the study, you will have to sign a consent form given below

In case you have any concerns or questions concerning this study, please contact OBOTE AMOS (0782743563) at International Health Sciences University, Kampala.

Consent

I have read this consent form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's signature _____ Date: _____

APPENDIX II: QUESTIONNAIRE FOR DRUGSHOP OPERATORS.

QUESTIONNAIRE TO ASSESS EFFECTIVENESS OF LICENSING AND INSPECTION REGULATIONS IN REGULATING DRUGSHOP PRACTICES IN LANGO SUBREGION.

Questionnaire number..... Date Time.....

SECTION A: GENERAL INFORMATION

NO	GENERAL INFORMATION
1	District:
2	Sub county:
3	Location: a. Village, b. Trading Centre c. Town
4	Position of the person interviewed: a. seller b. owner

SECTION B: REGULATION OF PERSONS

1. What is the highest qualification of the drug seller working in the drug shop?
.....
2. Which training was last attended by the drug seller?.....
3. When was the training attended?.....
4. Is the drug shop licensed? Yes/No
5. If yes, who is licensed?
 - a. Owner
 - b. supervisor
 - c. employee

SECTION C: REGULATION OF PRACTICES

1. Which drugs do you commonly sell in this drug shop?
.....
.....
2. Does the shop provide the following services?
 - a. Injecting patients
 - b. Clinical diagnosis
 - c. Lab services
 - d. Wound and burn treatment/ dressing
 - e. Admission of patients
 - f. Other services not mentioned above.....
3. How do you serve the drugs in tins?

- a. Counting tray
 - b. Counting spatula/spoons
 - c. hands
4. Which container do you use for packing the dispensed drugs?
.....
 5. Which information do you write on the container for packing drugs?
.....
 6. Does the container provide adequate surface for attaching or writing the information? Yes/No
 7. Which information do you give to your clients before they leave the drug shop?
.....
.....
.....
 8. Have you ever referred clients/patients to other service points? Yes/no
 9. If yes, where did you refer them to?
 10. What were the reasons for referral?
 11. Do you have any reference (drug) books Yes/NO
 12. If yes, what is the title and the year the book was published?.....
 13. Do you have records of drugs sold? Yes/No
 14. What do you do to expired drugs in case they get expired
.....
.....

SECTION D: FACTORS INFLUENCING COMPLIANCE TO DRUGSHOP REGULATIONS BY DRUGSHOP OPERATORS.

1. Do you know any regulation/ guidelines or law that governs the operation of drug shop?
Yes/No
2. If yes, how did you learn about these regulations from?
3. Do you have any copy of regulation available? Yes/No.
4. Can you mention what the regulation says about:
 - a. The qualification of the person who should sell drugs
 - b. The class of drugs that should be sold in a drug shop
 - c. The drug shop premise
 - d. The services that should be provided in the drug shop
5. Have you ever heard of any drug shop that violated the regulations? Yes/No
6. If yes to (5) above, what did the authority do to that drug shop?
 - a. Took the drugs away

- b. Closed it
 - c. Arrested and prosecuted the drug shop operator
 - d. Did nothing
7. What were the reasons for the actions in 6 above?.....
.....
8. What do you do to avoid the above actions?
9. Why do some drug shops operate illegally.....
10. Has any authority ever inspected this drug shop? Yes/No
11. If yes, how many times have they inspected this drug shop this year?
- a. Once
 - b. Twice
 - c. Thrice
12. If yes to (12) above, when was the last time the shop was inspected by the government authority?
13. What did they tell you on inspection?
14. If any recommendations were made, have they been implemented? Yes/ No
15. If no, why?
16. Do you have any record of inspection kept here in the drug shop? Yes/No

APPENDIX III: INSPECTION CHECKLIST FOR CLASS C DRUG SHOPS.

REGULATION OF DRUG SHOP PREMISES

	LICENSING STATUS OF THE DRUGSHOP	yes	no
	Presence of valid NDA license		
	Regulation of practices		
	Presence of only class C drugs		
	Presence of class A, B and C drugs		
	Presence of expired drugs		
	Presence of public medicines with UG label		
	Presence of any reference medicine document		
	Current practices		
	Are proper records of drug purchases kept		
	Are proper records of drug sales kept		
	Evidence of referral of patients/clients		
	Are the pharmaceutical products stored in the manufacturer's original packaging?		
	Are injections being offered in the drug shops		
	Are laboratory services being offered		
	Evidence of surgical/clinical procedures		
	Regulation of premises		
	Is the floor clean?		
	Are the walls inside clean and well painted?		
	Is there dust on the shelves?		
	Is the ventilation sufficient?		
	Is the light sufficient?		
	Is the ceiling in good condition?		
	Is there a hand washing facility in the premise?		
	Does the hand washing facility have functional water and soap?		
	Is the cleanliness of the surroundings of the premise adequate?		
	Is the toilet clean and in good working condition?		
	Are there sliding glass shelves in the premise?		
	Are there lockable cupboards for prescription medicines?		
	Is there a counter with glass makeup in the premise?		
	Is there an appropriate device for counting tablets/ capsules?		
	Are the dispensing containers for tablets/ capsules appropriate?		

APPENDIX V: SEMI STRUCTURED INTERVIEW GUIDE FOR NDA STAFFS.

1. How many drug shops are there in the sampled districts?
2. How many of these drug shops are licensed?
3. Do you have any records of licenses issued?
4. How often are inspections of drug shops done?
5. Who does the inspection?
6. Do you have any records of inspections carried out within this year?
7. How many inspected drug shops had qualified operators?
8. How many inspected drug shops had suitable premises?
9. How many of the inspected drug shops stocked class C drugs only?
10. Any follow up made incase drug shops are cautioned?
11. Are the drug shop operators aware of the laws that govern the operation of the drug shops?
12. What do you do to ensure that drug shop operators get to know these regulations?
13. Why do other drug shops comply with regulations and others don't?
14. How many staffs do you have in this region and what are their qualifications and responsibilities?
15. Do you have a budget for your operations?
16. How are your operation budget financed?
17. How do you enforce these regulations? What challenges do you face in enforcing these regulations?
18. Is it possible to enforce these regulations in all the drug shops in this region?
19. If no/yes, why/why not?
20. What should be done and by who if these regulations are to be enforced in all the drug shops in the region?

APPENDIX V: INTRODUCTORY LETTER FROM THE INSTITUTE OF HEALTH POLICY AND MANAGEMENT, IHSU.

**INTERNATIONAL HEALTH SCIENCES UNIVERSITY
INSTITUTE OF HEALTH POLICY AND MANAGEMENT
APPROVAL OF A STUDENT'S PROPOSAL BY THE SUPERVISOR**

I have examined the proposal of

..... OBOTE Amos REG. NO. 2012-MPH-FI-001

entitled

..... DRUG SHOP COMPLIANCE WITH
..... LICENSING AND INSPECTION REGULATIONS
..... IN KANO SUB REGION
.....
.....

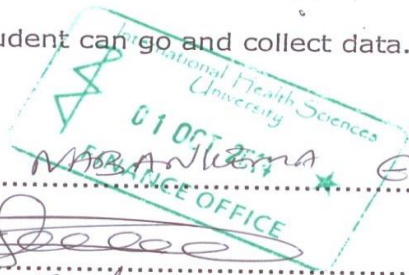
and I am satisfied that it meets our standards.

I recommend that the student can go and collect data.

Supervisor: Dr. ANTHONY E

Signature: [Signature]

Date: 12th March 2014



APPENDIX VI: INTRODUCTORY LETTER FROM NDA



Date: 18th Nov. 2013

Our Ref: 611/ID/NDA/11/13

The Regional Inspector of Drugs
NDA Northern Region
Erute Road
Lira

PROVISION OF INFORMATION FOR RESEARCH PURPOSES TO MR. OBOTE AMOS

This is to introduce to you Mr. Obote Amos, a student of the International Health Sciences University, Kampala.

He would like to research on the *"Effectiveness of Licensing and Inspection Regulation in regulating Drug shop practices in Lango Sub-region"*.

Please provide the necessary information to enable him complete his research.


Mwesigwa Denis (Mr.)

For HEAD, DRUG INSPECTORATE SERVICES

Copy to: Executive Secretary/Registrar
" Mr. Amos Obote

HEAD OFFICE

Plot 46-48 Lumumba Avenue
P.O. Box 23096, Kampala, Uganda
Tel: (+256) 414 255665/347391/347392
Fax: +256 414 255758
Hotline: (+256) 414 344052, 776 110 008, 712 001 199
Website: www.nda.or.ug, Email: ndaug@nda.or.ug
Facebook: Uganda National Drug Authority
Twitter: @UNDAuthority

OUR MISSION

To ensure access to quality, safe and efficacious human and veterinary medicines and other healthcare products through the regulation and control of their production, importation, distribution and use

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Western Nile Region, Arua -Tel: +256 372 260 085/7,
South Western Region, Mbarara -Tel: +256 485 421 088,
South Eastern Region, Jinja -Tel/Fax +256 434 122 176,
Eastern Region, Tororo -Tel: +256 454 445 195,
Western Region, Hoima - Tel/Fax +256 465 440 688,
Northern Region, Lira -Tel/Fax +256 473 420 652.

