UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

DEPARTMENT OF PUBLIC HEALTH

QUALITY ANALYSIS OF MALE LATEX CONDOMMS AVAILABLE IN PRIVATE AND PUBLIC FACILITIES OF LUSAKA DISTRICT OF ZAMBIA – A COMPARATIVE STUDY

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EXECUTIVE SUMMARY

The presence of poor quality condoms on the market has posed a serious challenge in the fight against HIV/AIDS. Quality, especially poor quality, affects popular perception of the value of condoms, which can in turn have a major impact on the success of prevention program. Condoms need to be of high quality especially when they are available for use to the public. If condoms have holes or break during use, they are no longer effective in preventing pregnancies and STIs including HIV. These structural flaws could be due to deficient manufacturer production standards or procedures. While many manufacturers routinely test their products, this is not always the case. Another possibility is that condoms could be of high quality when acquired by a national AIDS programme, but deteriorate due to conditions during transport or storage. Many environmental factors can also affect the quality of condoms.

A comparative study was designed to assess quality of condoms by comparing the physical parameters, packaging and labeling standards of the condoms from retail outlets and the Service Delivery Points in accordance with the Standards as Prescribed in the official monographs.

4 batches of condoms from public and 4 from private outlets were collected. From each batch, physical inspection was conducted and information was extracted. All the 8 batches were then exposed to lab tests according to the standard specification. From each batch, 315 pieces of condoms were exposed to freedom from holes tests, 30 pieces to package seal integrity tests, 15 to lubricant quantity test, 39 pieces to dimension tests and 315 to air bursting pressure and volume.

This study shows that the prevalence of quality of male latex condoms available in private and public facilities of Lusaka Urban District is 98.77%. The study also shows that compliance of condom samples to physical parameter requirements, packaging and labelling standards are similar. Therefore, male latex condoms available in private and public facilities of Lusaka Urban District of Zambia do not differ in meeting the standard specifications for quality.

The Government to be regulating the suppliers and distributors of male latex condoms to ensure, appropriate procurement, transportation and storage conditions for condoms.

DEDICATION

I dedicate this research to my father, Mr Joseph Khunga and my mother, Mrs Margret Muwowo Khunga.

ACKNOWLEDGEMENTS

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I wish also to thank the Pharmaceutical Regulatory Authorities management for permitting me to carry out the study in the private facilities of Lusaka Urban District.

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Above all I thank the Lord Jesus, 'my everything' for giving me the grace to accomplish my research project.

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ACRONYMS

AIDS: Acquired Immune Deficiency Syndrome

AQL: Acceptable quality limit

GMP: Good manufacturing practice

ISO: International Standards Organisation

MDG: Millennium Development Goal

QA: Quality assurance

SDP: Service Delivery Points

UNAIDS: Joint United Nations Programme on HIV/AIDS

UNFPA: United Nations Population Fund

USAID: United States Agency for International Development

USP: United States Pharmacopoeia

STI: Sexually Transmitted Infection

WHO: World Health Organisation

OPERATIONAL DEFINITIONS

Acceptable quality limit: The lowest allowable limit of quality in a lot.

Brand name: The registered trademark name given to a specific product by its manufacturer

Condom: a sheath or covering intended to be worn on the penis during sexual intercourse for the purpose of preventing conception or reducing the risk of transmission, or both.

Defective: a condom that fails, in one or more respects, to comply with the relevant requirements of the specification.

Expiration date: stated date after which a condom should not be used.

Good manufacturing practice: A code of practice covering all aspects of the manufacturing process, including the supply of raw materials, record-keeping, and a quality management programme, which is generally recognized to be essential to the production of uniform, high-quality products.

Lot/Batch: collection of condoms of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed with the same lubricant and any other additive or dressing in the same type of individual container.

Lot, batch, serial, or identification number: A series of numbers or letters, or both, established to record production and control of a product; unless otherwise specified, the lot number is the series of numbers or letters that identifies a single, uniform, and homogeneous quantity produced from one compounding formulation, and/or in one manufacturing and production operation, and that has received entirely the same processing treatment; lot size varies by product, product type, dosage form, and manufacturing process.

Official monographs – all Pharmaceutical Standard Reference Books such as the British Pharmacopoeia, the United States Pharmacopoeia and the Zambia Bureau of standards manual.

Packaging: The primary wrapping and marking of a product

Packing: The assembling of packaged product into multiple units; prepared for shipment in appropriate cartons or crates with all necessary blocking, bracing, cushioning, weatherproofing, reinforcement, and marking

Procurement method: Process a purchaser uses to reach an agreement with a seller

Quality: Combination of attributes or characteristics of a product that determine the degree of acceptability and efficacy of the product.

Specification: A definitive description of the commodity to be procured.

Shelf-life: time from date of manufacture to the claimed expiry date.

United Nations Population Fund: A UN agency working to ensure universal access to reproductive health, including family planning and sexual health, to all couples and individuals; operates a global procurement service for public-sector purchasers of contraceptives and related products

Visual inspection: An examination of the product and various aspects of the packaging, labeling and markings

DECLARATION

I hereby declare that this research report has not been submitted for a Degree in this or any other University.

Name: ……..…….…..... **Signature:** …….…… **Date:** ……..

SUPERVISORS

I have read this dissertation and approved it for examination.

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APPROVAL

This dissertation of Morton Khunga is approved in partial fulfillment of requirement for the award of a Masters in Public Health (MPH) by the University of Zambia.

Examiner: …… Date: ……..

Examiner: …… Date: ……..

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Head of Department:

Signature: …….. Date: …….....

CHAPTER ONE

1.0.INTRODUCTION

Condoms of one form or another have been recognized for centuries as effective means of preventing pregnancy (Hatcher et al. 2004). A condom is a sheath or covering intended to be worn on the penis during sexual intercourse for the purpose of preventing conception or reducing the risk of transmission of infections, or both. Although what is generally called a condom is the 'male' condom, a sheath or covering which fits over a man's penis, and which is closed at one end, there is also now a female condom, or vaginal sheath, which is used by a woman and which fits inside her vagina. In their present latex form, condoms are also widely known for their ability to prevent the transmission of sexually transmitted infections (STIs) (Holmes et al. 2004). With the relatively recent advent of HIV/AIDS, the condom has quickly taken on an important role toward the prevention of HIV. Condom promotion is now an integral part of any national AIDS programme as the use of barriers which prevent contact with infectious sores or fluids is one strategy for reducing risk (Babatunde 2010).

Condoms need to be of high quality every time. If condoms have holes or break during use, they are no longer effective in preventing pregnancies and STIs including HIV. These structural flaws could be due to deficient manufacturer production standards or procedures. While many manufacturers routinely test their products, this is not always the case. Another possibility is that condoms could be of high quality when acquired by a national AIDS programme, but deteriorate due to conditions during transport or storage. Many environmental factors can affect the quality of condoms. Heat, UV light, ozone, humidity, chemicals and oils are known to affect elasticity of the latex, sometimes in as little as 8 hours of exposure. Good packaging can be effective in moderating the contact of the condom with these elements, but the reality of the harsh environments of many tropical developing countries may preclude complete preservation of the product. Monitoring condom quality at retail outlets, service delivery points and central storage can point toward a need for more stringent procurement regulations or improved transport or storage procedures.

Good Manufacturing Practice is very critical in ensuring that good quality condoms are produced. It refers to the code of practice covering all aspects of the manufacturing process,

including the supply of raw materials, record-keeping, and a quality management programme, which is generally recognized to be essential to the production of uniform, high-quality products. It is the performance standards for pharmaceutical and medical device manufacturers established by WHO and many national governments. It includes criteria for personnel, facilities, equipment, materials, manufacturing operations, labelling, packaging, quality control, and in most cases, stability testing. It is an important factor which determines the quality of condoms that is distributed to the end user.

1.1. BACKGROUND

In the last 2 decades, World Health Organisation and their cooperating partners took the issue of condom quality very seriously (WHO et al. 2004). They strived to advocate for the development of a new and rigorous quality assurance procedures for the production, procurement and distribution of condoms. The manufacturing community has developed improved technologies, and research has generated more awareness of the type of quality assurance systems and laboratory tests needed to ensure that a quality product is manufactured and distributed. The latest version of the International Standard for the manufacture of the natural rubber male latex condom was published in 2002 (WHO 2003). The 'Specification and Guidelines for Condom Procurement' was first published by the World Health Organisation (WHO 1989). It has been periodically updated to provide the latest information both on the capability of the condom industry to manufacture high-quality male latex condoms and the quality assurance procedures that must be followed to manufacture, procure and promote such a product (WHO et al. 2003).

In many countries, especially in developing countries, the presence of poor quality condoms on the market is a serious issue which has been underreported (ZABS 2009). Poor quality condoms have led to, failure to provide adequate protection; quickly destroy the credibility of any condom promotion programme; create a negative publicity, cause endless logistical problems such as expiration and shortages; and low usage (WHO 2003). The poor quality condoms have the implications for political, financial and social crisis. Funds would have to be sought to replace the poor quality condoms, potentially making condoms unavailable for use (WHO 2000). This scenario could not be different in Zambia, as there have been a lot of different brands on the Market.

In Zambia, no studies have been done about the quality of male latex condoms and this has led to inadequate information.

1.2 STATEMENT OF THE PROBLEM

The presence of poor quality condoms on the market has posed a serious challenge in the fight against HIV/AIDS. Quality, especially poor quality, affects popular perception of the value of condoms, which can in turn have a major impact on the success of prevention program (WHO/GPA 1994). Some condom makers have been reported to have dumped their substandard products on the African market and Africans have been risking their lives on brittle, leaky or ill-fitting condoms (McNeil 1998).

At the global level, the WHO has been fighting production and distribution of counterfeit Pharmaceuticals for some decades now. Studies show that an estimate of 1 in 4 packets of Pharmaceutical products sold in street markets in developing countries could be substandard (WHO 2006). This problem was first identified by the Pharmaceutical industries that saw their products being counterfeited (WHO 2006). WHO has worked with many partners to generate the evidence and gain the consensus needed to recommend the specification and guidelines for the procurement of the latex condom. They have emphasized that following procedures in manufacturing, procuring and distribution of condoms is very important as it addresses the issues related to the performance of condoms, the comfort and confidence of the user, and the health and safety of the population at large. They have also recommended sampling for independent testing of condoms which should be done by the independent laboratory or by an independent sampling organization and not by the factory producing the condoms. Such sampling is required for pre-qualification, compliance testing and confirmatory testing (WHO 2003).

Although many scientists say that consistent and correct use of the condom is vital for achieving the level of protection required to prevent unwanted pregnancy and the transmission of HIV, another vital factor which has not been emphasized is the quality of the condom. If condoms leak or break, they cannot offer adequate protection. In many programmes, attention tends to be focused on the condom user and the promotion of condoms. Inadequate attention is often paid to ensuring that a quality product is manufactured, purchased, stored, distributed and handled

properly. In many cases, policy-makers, programme managers, providers, procurement officers and national regulatory bodies are not aware of condom quality and have ended up purchasing, promoting and distributing poor quality condoms (WHO 2003).

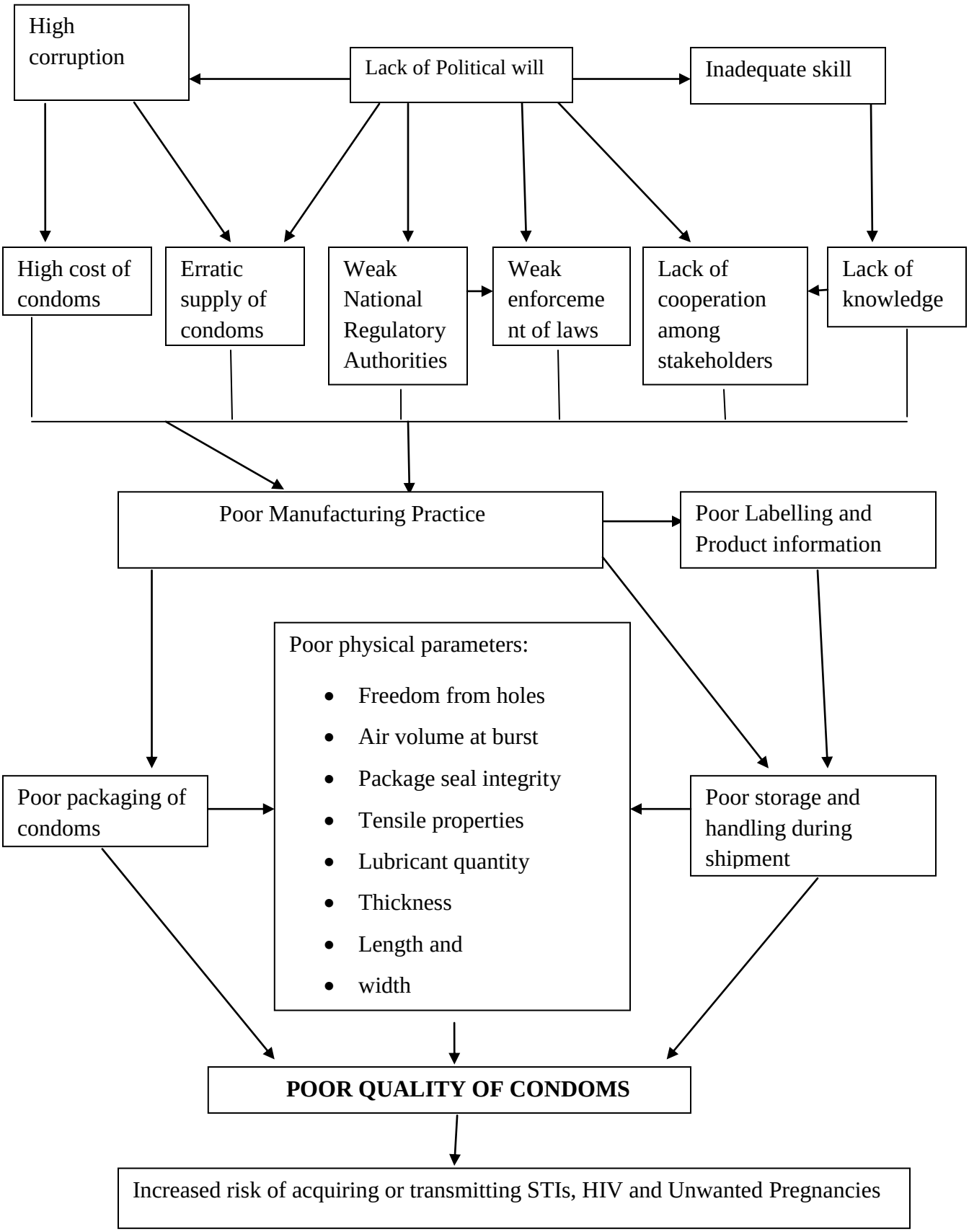
In Zambia, there is currently little information on the quality of condoms being distributed for use in Service Delivery points and Retail outlets. There is also little information which shows whether there are poor quality condoms on the market in Zambia and Lusaka in particular.

The Pharmaceutical Regulatory Authorities (PRA) and the Zambia Bureau of Standards (ZABS) have been working hard to ensure that good quality condoms are provided to the end users. In 2009 two brands of condoms, 'Hot' and 'Evolution', failed the freedom from holes test when test was conducted. They were banned and recalled from the market by the Zambia Bureau of Standards which found them not meeting the standard specification (ZABS 2009).

Based on observations some condoms have been found with stains of lubricants on the outside of their packaging materials in different health facilities in Lusaka.

Therefore, it is possible that there could be poor quality condoms in Zambia and the aim of this study is to uncover and evaluate the magnitude of the problem in detail and suggest the solutions.

FIGURE 1.1: Problem Analysis Diagram: Factors Relating to the Quality of Condoms



From the Problem Analysis Diagram in figure 1, poor quality of condoms arises from poor packaging, poor physical parameters and poor storage and handling during shipment which arise due to poor manufacturing practice which is the product of weak National Regulatory Authority, weak enforcement of laws, lack of cooperation, lack of knowledge, high cost and erratic supply of condoms which are caused by high corruption, lack of political will and inadequate skill. Poor Quality of Condoms in turn leads to increased risk of acquiring or transmitting STIs, HIV and unwanted pregnancies (Adam et al. 2000).

Lack of political will is the root cause as it leads mainly to high corruption. In any country high corruption raises the cost of running business which may in turn cause high cost and erratic supply of condoms. Lack of political will also has negative impact on the enforcement of laws and cooperation among stakeholders. This will make condom traders to compromise the means of procuring and distributing condoms. This ends up putting a lot of pressure on the condom manufacturing industries which, in trying to meet the demand, compromises the standards leading to poor manufacturing practice. Poor manufacturing practice results in the production of condoms that are poorly packaged or with poor physical parameters such as poor dimensions, holes, inadequate lubricant and poor elasticity. Condoms exhibiting such flaws are referred to as poor quality condoms and may not serve the purpose of preventing transmission of diseases and pregnancies.

Condoms can deteriorate if not stored properly as they are affected by both heat and light. Therefore, if not stored and handled properly at any time they may not be of good quality. Such condoms may in most cases end up feeling sticky or very dry as their packaging have probably been damaged. Condoms thickness is another important aspect of the condom quality. It is recommended for condoms manufacturers to avoid very thick or very thin condoms, because they are both considered less effective as this may be associated to breakage (WHO 2003). Although some authors have encouraged users to choose thinner condoms for greater durability, sensation, and comfort, experts have warned that "the thinner the condom, the smaller the force required to break it"(Corina 2007; WHO 2003). Poor packaging of condoms can also cause deterioration as this would expose the condoms to stresses such as heat, light or moisture which disrupts the latex condoms. This mainly affects the physical parameters which are the main determinants of the quality of condoms. In turn condoms will fail to provide adequate protection

which may lead to transmission or acquisition of infections including HIV and unwanted pregnancies.

1.3 JUSTIFICATION OF THE STUDY

Different types and brands of condoms are becoming increasingly available in developing countries including Zambia. To date, little information is available on condom quality versus label claims for these products in Zambia. There is no available documentation on the prevalence of poor quality condoms in Zambia and yet the country is faced with the challenge of preventing the spread of HIV/AIDS which is highly prevalent.

The purpose of this study is to assess quality of condoms by comparing the physical parameters of the condoms from retail outlets and the Service Delivery Points to the Standards as Prescribed in the official monographs. No research regarding the quality of condoms has been done in Zambia and yet Zambia is one of the countries that have taken up the use of condoms as a strategy in preventing HIV/AIDS.

Since the condom is a key preventing tool of one of the drivers in HIV/AIDS transmission, the health status of the Zambians will improve once the control and fight against HIV/AIDS succeeds, leading to increased productivity, increased economic growth and reduced poverty levels, hence attaining MDG 1.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 GLOBAL LEVEL

The percentage of substandard pharmaceutical products is estimated at 1% in developed countries whereas in the developing world e.g. Asia and Africa the overall percentage is significantly higher than the global market average (Aria 2008). In India, Pharmaceutical companies, in 2002 suggested that in major cities 1 in 5 medicines sold was a fake (WHO 2000).

Globally, studies have shown that, the failure rate of condoms is about 2%, with poor countries having a higher prevalence compared to developed countries (Adam et al. 2000). This failure rate has been attributed to the presence of poor quality condoms on the market. Condoms may slip off the penis after ejaculation, break due to improper application or physical damage (such as tears caused when opening the package), or break or slip due to latex degradation (typically from usage past the expiration date, improper storage, or exposure to oils). Three studies which were done in the USA showed that estimates of condom breakage ranged from 0.4-2.3%. Slippage rates from these three studies ranged from 0.6% to 1.3%. Slippage rates include both slippages during intercourse and during withdrawal. The combined method failure (slippage plus breakage) is estimated at 1.6% – 3.6%. Even if no breakage or slippage is observed, the studies showed that 1–2% of women would test positive for semen residue after intercourse with a condom (Adam et al. 2000).

2.2 REGIONAL LEVEL

In Africa, a lot of reports have shown the presence of poor quality condoms in circulation especially in Sub-Saharan Africa.

In 2009, the Kenyan Bureau of Standards banned a condom which was being retailed under the brand name “Hot” on leakage grounds. The product was reported to have a 100% failure rate and could have posed a risk on the consumers if it was left on the market. According to the regulators the product did not meet both the Kenyan and ISO standards (Daily Nation 2010; KEBS 2010).

In May, 2002 the Tanzanian Government blocked a shipment of 10 million condoms imported by the UN Population Fund (UNFPA) for nationwide free distribution after a US laboratory confirmed defects in samples submitted for testing (Lufeyo 2009).

In 2004, consumers in Uganda complained that one of the brands "Engabu" had a bad odour. Tests by the National Drug Authority showed that the condoms did not meet the safety standards and were recalled immediately resulting in a national wide shortage. This prompted the Government of Uganda to come up with the policy of doing the pre- and post- shipment quality testing. The brand was re-launched in 2006, but received a lot of skepticism and this led to low demand for the brand (Ouma 2007).

In 2007, the South African health department recalled 20 million condoms after media reports alleged that a testing manager at the South African Bureau of Standards, responsible for quality testing all locally produced condoms, had accepted money from the manufacturer in return for certifying defective condoms. Another scandal occurred where a brand called "Kenzo" was distributed before being tested. Complaints from Cape Town prostitutes flooded in to the Sex Workers Education and Advocacy Task Force (SWEAT), a community aid agency, which handed them out free. 4 million condoms of this brand were sent back to India. According to the Authorities in South Africa, some condoms were found with sand inside the foil packets, the cartons had water and were disintegrating. A consignment of Twin Lotus condoms from China also was recalled, and there have been problems with other brands (Lufeyo 2009).

There have been reported problems in Zimbabwe, Cameroon, Rwanda, and Malawi. In 1993 in Zimbabwe, 24 million condoms made in Malaysia by Dongkuk Techo Rubber and paid for by the British government failed tests. Fortunately, the results came in before any were distributed, but fearing they would be stolen and end up on the black market, Zimbabwe, a country where 25 percent of adults were then infected, burned them. Dongkuk later said its goods were rejected only because the standards were raised after they were made. A British Embassy AIDS educator denied that, calling it "an excuse," but acknowledged that Dongkuk was selling condoms elsewhere without problems (McNeil.1998).

2.3 NATIONAL LEVEL

The Zambia's National HIV and AIDS Strategic Framework 2006-2010 outlines ambitious goals for the prevention of HIV. These goals would be achieved by addressing and halting the six key drivers of the Zambian epidemic. One of the goals identified is 'low and inconsistent condom use'. It has been noted that condom use has not risen enough to impact significantly on HIV transmission (Shakinovsky et al. 2009).

Condom distribution has increased in the recent past as a result of a mix of channels, including non-traditional channels. Partnership with traditional and religious leaders has been found to be helpful in raising condom awareness and distribution. Increased funding has been identified to be important in determining the need for, and to ensure the necessary quantities of both male and female condoms. One aspect that has not been emphasized so much is that of quality assurance by putting up rigorous measures to regulate condom import and distribution by NGO's, pharmaceutical companies and private companies (Shakinovasky et al. 2009).

In August, 2009 the Zambia Bureau of Standards withdrew 59 cases (1,189 pieces) of "Hot" condoms and another 59 cases of "Evolution" from the market after they failed the electronic freedom-from-holes test (CDC 2009).

CHAPTER THREE

3.0 STUDY OBJECTIVES

3.1 RESEARCH QUESTION

Does the quality of condoms in retail outlets and public Service Delivery Points in Lusaka District differ in meeting the national and international standards?

3.2 HYPOTHESIS

The quality of Condoms dispensed in private and public facilities of Lusaka District do not differ in meeting the set standards as prescribed in official monographs.

3.3 OBJECTIVES

3.3.1 General Objective

To assess and compare the quality of Condoms dispensed in private and public facilities of Lusaka District in accordance with the official monographs.

3.3.2 Specific Objectives

1. To examine the packaging standards of male latex Condoms dispensed in private and public facilities of Lusaka District with reference to official monographs.
2. To assess the labelling standards on the packets of latex condoms in private and public facilities of Lusaka District in accordance with the standard specifications.
3. To compare the physical parameters of male latex condoms in private and public facilities of Lusaka District in accordance with the official monographs
4. To make recommendations to the Ministry of Health and the Pharmaceutical Regulatory Authorities pertaining to the quality of condoms in Lusaka District.

CHAPTER FOUR

4.0. METHODOLOGY

***Table 4.1*:** Variables of the Study

TYPE OF VARIABLE	INDICATOR	SCALE OF MEASUREMENT
1. Dependent variable Quality of condoms dispensed	❖ Proportion of condoms with appropriate physical properties ❖ Proportion of condoms with appropriate labelling and packaging requirements.	❖ Percentage ❖ Percentage
2. Independent variable		
❖ Package	❖ Numbers of containers of condoms with detected leaks: ➢ From air-bubbles and fluid inside the container	
❖ Labelling	❖ Number of containers of condoms which bear: ➢ Name or trade name of the manufacturer ➢ Lot number ➢ Expiry date ➢ The nominal width of the condom ➢ Instruction for use of the product. ➢ A statement to store the condom in cool dry place away from direct sunlight.	

❖ Physical Parameters: ➢ Freedom from holes	➢ Proportion of condoms not exhibiting visible holes or tear before mounting on the apparatus	
➢ Air volume at burst	➢ Number of condoms bursting at not less than 1.0kpa with bursting Volume not less than 18.0dm^3	
➢ Lubricant quantity	➢ Number of condoms with recommended lubricant quantity of 400-700mg	
➢ Dimensions		
▪ Length	▪ Number of condoms with length between 180-190mm	
▪ Width	▪ Number of condoms with width +_ 2 of the stated nominal width	
▪ Thickness	▪ Proportion of condoms with width of 0.065±0.015 mm foot diameter and foot pressure of (22+_4)kpa	

4.1. STUDY DESIGN, SETTING AND POPULATION

The study was a comparative study and was conducted in Lusaka District of Zambia. It was carried out in different private and public facilities which were selected using random sampling technique. The study was quantitative and tested the relationships, differences and cause-effect interactions among and between variables using reference ranges according to the standards in the official monographs of the ISO 4074. The study was undertaken in Lusaka district because it was the city with most distributors and also where most public and private facilities were concentrated. The laboratory tests were done at the Zambia Bureau of Standards in Lusaka.

4.2. SAMPLING CRITERIA

The sampling frame of all the facilities that stock condoms and the approximate number in the district was made. The major types of facilities were stratified into private and public facilities. From each category of facilities, 4 facilities which were more likely to stock condoms were selected using simple random sampling. The 8 selected facilities were visited for data and sample collection. The results collected from this were assessed and reviewed. The procedure was designed in such a way that if the first source visited did not have adequate stocks of condom samples, the second most likely source of the same category was visited. If the second source also did not have adequate stocks, the third most likely source was selected until the sample size was met and the process was repeated. From each facility visited, 700 condom samples were collected for physical inspection and laboratory testing. Only male latex condoms that are not expired were included in the study.

4.3. LABORATORY TESTING PROCEDURES

Laboratory testing of the condoms was conducted at the Zambia Bureau of Standards in Lusaka. From each of the 8 batches collected 315 condom samples were subjected to the freedom from holes test, 30 was subjected to package seal integrity, 13 to the lubricant quantity test, 39 to the dimensions tests and 315 to the air burst volume and pressure. Freedom from holes test was done using electrical test which is based on the principle that a condom without a hole will act as an insulator and allows no current to flow in an electrical circuit, while a condom with a hole will allow a current to pass. For a package seal integrity test individual condom containers were

submerged in a vacuum chamber containing water. The chamber was then evacuated at an absolute pressure of (20±5)kPa. As the vacuum increased the condom containers were observed for leakage in the form of a steady progression of bubbles. The vacuum was then released and condom containers were then observed for the presence of water inside. The lubricant quantity was obtained from the mass loss determined by removing the lubricant from the pack and condom by washing with a solvent. The difference between the initial mass and the final mass after removing the lubricant is the lubricant quantity of one condom container. For the bursting volume and pressure, a specified length of the condom was inflated with air, and the volume and pressure required to burst the condom were recorded. The length mandrel, the ruler and the micrometer gauge were used to measure the length, width and thickness respectively.

4.4. ETHICAL CONSIDERATIONS

Though the study did not involve human subjects, clearance was sought from the University of Zambia Biomedical Research Ethics Committee (UNZA REC). The investigator also sought authority from the Lusaka District Health Office (LDHO) to use their health centers, the Pharmaceutical Regulatory Authorities (PRA) to collect samples from private facilities and the Zambia Bureau of Standards (ZABS) to use their laboratory for the study.

4.5. DATA COLLECTION AND STATISTICAL ANALYSIS

The data collection form was designed before the search for data took place for physical inspection. This was used to collect data from samples for physical inspection, batch number, nature and material of packaging, appearance of the label on the packaging, instructions on the label for use of the product, expiry and manufacturing dates and the details of the manufacturer. Results for bursting volume and pressure and freedom from holes were automatically recorded from the laboratory equipment into a computer program. Dimensions, package seal integrity and total lubricant quantity were manually entered into the computer. Data analysis was done using a computer program designed to analyze condom quality data according to the International Standards (ISO 4074:2002). SPSS version 16 was used for statistical analysis to calculate the t-test to compare the two groups of samples in the study.

CHAPTER FIVE

5.0. RESULTS

In this study, eight (8) different batches of condoms were collected, four (4) from public and another four (4) form private facilities. All the samples were male latex condoms with general details as given in table 5.0 below. From each batch 712 condoms were collected (making a total of 5696 condoms) and subjected to different tests for physical inspection and laboratory testing (Annex I). This was done to explore all the variables and to provide answers to the research question given above.

Table 5.0: General details of condom samples used in the study

Batch Number	Source	Material	Man. Date	Expiry Date	Width
2011/11	Private	Latex	12/2011	11/2015	53
X41216	Private	Latex	10/2010	09/2014	53
XR45060	Private	Latex	08/2010	07/2014	53
DN101137	Private	Latex	01/2009	12/2013	53
DE01012	Public	Latex	09/2009	08/2013	53
MEM035	Public	Latex	03/2011	02/2015	53
11N2474	Public	Latex	05/2010	04/2014	53
201002	Public	Latex	12/2010	11/2014	53

Table 5.0 shows the general details of all the condom samples that were used in the study. Each batch was given a code and the information regarding nature of material, batch numbers, manufacturing dates, expiry dates, and nominal width which was 53mm for all the samples was collected.

5.1: Results for Packaging

Table 5.1.1: Package seal integrity for samples

Batch Number	ᵅNo air bubbles and no fluid inside	ᵝWith air bubbles and/or fluid inside	Total
2011/11	30	0	30
X41216	30	0	30
XR45060	30	0	30
DN101137	30	0	30
Total	120	0	240
DE01137	30	0	30
MEM035	30	0	30
11N2474	30	0	30
201002	30	0	30
Total	120	0	240

ᵅ no air bubbles and no fluid inside means compliance with the standards.

ᵝ with air bubbles and/or fluid inside means noncompliance with the standards.

Table 5.1.1 shows that both groups of samples had 120(100%) condoms with no air bubbles and no fluid inside.

5.2 Results for compliance to Labelling

Table 5.2.1: Compliance of batches of condoms to labelling in accordance with standards

Labels	**Batch Numbers**							
	2011/11	X41216	XR45060	DN101137	DE01137	MEM035	11N2474	201002
Name or trade name of manufacturer	√	√	√	√	√	√	√	√
Batch/Lot number	√	√	√	√	√	√	√	√
Manufacturing date	√	√	√	√	√	√	√	√
Expiry date	√	√	√	√	√	√	√	√
Nominal width	√	√	√	√	√	√	√	√
Instruction for use of the product	√	√	√	√	√	**X**	√	**X**
Statement for conditions of storage	√	√	√	√	√	√	√	√

√**:** compliance with standard specification

X: noncompliance with standard specification

Table 5.2.1 indicates the batches and the appropriate labels present on the packages. Of the 8 batches of condoms sampled 2 did not have the instructions for use on the individual containers. Comparing the samples by source showed that the two samples that failed were public facility samples. All the samples gave 100% compliance for exhibiting the batch numbers, expiry dates, manufacturing date, name or trade name of the manufacturer, nominal width, and a statement for storage conditions.

5.3 Results for Physical parameters

Table 5.3.1: Results of physical parameters of condom samples from private and public facilities

	Private	Public			
Parameter	%Compliance	%Compliance	t-test	P-value	95% CI
Freedom from holes	100.00	100.00			
Airburst volume	98.01	97.86	1.732	0.225	-1.484 - 3.484
Total lubricant quantity	100.00	100.0			
Length	94.23	82.69	2.646	0.118	-1.461 - 6.128
Width	96.15	96.15	1.732	0.182	-0.419 - 1.418
Thickness	100.00	96.15	1.732	0.182	-0.418 - 1.419

5.4: Overall compliance in accordance with the standards

Table 5.4.1: Compliance of condom samples

Batch Number	Complied with standards	Did not comply with standards	Total
2011/11	703	9	712
X41216	705	7	712
XR45060	706	6	712
DN101137	704	8	712
Total	2818	30	2848
DE01137	698	14	712
MEM035	705	7	712
11N2474	705	7	712
201002	700	12	712
Total	2808	40	2848

Table 5.4.1 shows that only about 30(1%) did not comply with the standard specification for private facility samples which was similar to the failure rate for the public facility samples. The overall compliance of male latex condom samples was 98.77%.

Table 5.4.2: t-test: Comparison of overall compliance of condom samples from private and public facilities

	Test Value = 0					
	T	Df	Sig. (2-tailed)	Mean Difference	95% CI of the Difference	
					Lower	Upper
Overall Compliance	2.100	3	0.127	2.500	-1.2879	6.2879

Table 5.4.2 shows that the p-value is 0.127, t-test value of 2.100 and 95%CI of -1.2879 to 6.2879.

CHAPTER SIX

6.0. DISCUSSION

This study shows that, the quality of male latex condoms in private and public facilities do not differ in meeting the national and international standards. It also shows that the prevalence of good quality condoms was 98.77% (*Table 5.4.1*). This is in line with the study done by Adam et al which showed that, the failure rate of condoms globally is about 2%, with poor countries having a higher prevalence compared to developed countries (Adam et al. 2000). The failure rate has been attributed to the presence of poor quality condoms on the market. Packaging, lubricant quantity, freedom from holes and thickness gave 100% compliance to standard specification for all the batches, while dimensions, labelling and lubricant quantity had a lower compliance which ranged from 82.69 to 98.95%.

Lower compliance, although it was minimal, of some parameters to standard requirements should be a source of concern. The choice of length, width and thickness of condoms is important because these are the factors that determine whether the condom is easy to put on, stays on during use, and is comfortable to the user. The dimensions of the condom need to conform to the intended population of users. There are considerable variations between individuals and, generally, there is no established market of differently sized condoms even in developed countries (WHO/UNAIDS 1998). The sizes most commonly marked are 49mm and 53mm for the width, 0.065±0.015mm for the thickness and between 180mm and 190mm for the length (ISO 4074: 2002). Higher or lower dimensions, as in the case of the length of one of the batches tested in this study, may lead to ill-fitting of condoms. This in turn may lead to breakage and slippage of condoms during use.

The Zambian Government through the Pharmaceutical Regulatory Authorities should strengthen their guidelines for the procurement of condoms. All condom samples entering the country should be tested to ensure that only high quality products are allowed on the market. This can be achieved if there is political will on the part of the policy makers. Failures of 2 out of the 4 batches from public facilities on the basis of physical inspection i.e. lack of instructions for use of the product is a sign of negligence on the part of the manufacturer and the distributor. It is of paramount importance to ensure that the condom packages have adequate instructions for use of

the product. Lack of instructions can lead to incorrect usage of the condoms which may in turn render condoms ineffective. The size of the labels is equally important as it helps the user of the product to read without problems. Condoms may not be opened correctly, used appropriately, or may even be reused if consumers are not provided with adequate information. Some people may also end up using lubricants which are not appropriate for the latex condoms.

To achieve high quality, male latex condoms must be well designed and formulated, and carefully made. To maintain that quality until the condom is supplied to the user, storage and distribution systems need to be effective. Both the manufacturer and the large-volume purchaser should develop and maintain a quality management programme to establish the procedures, structures and record-keeping necessary for effective and sustainable quality management. A well designed factory and product, together with an effective top-down quality management system, form the foundation for consistent quality over the long term (WHO/UNAIDS 1998).

It is important, firstly, to consider that condoms should be made so as to fit the population they are intended for. Zambia, which depends on imported condoms, is more likely to be affected by the fact that manufacturers may not have specifications for our populations. A condom that is too narrow or too wide, or has too much or too little lubricant or powder, or is of a colour that has negative connotations, will not be acceptable to a large segment of the population. If a condom is not acceptable, it is not fit for use.

Secondly, the condom must meet the user's expectation and not place them at undue risk. It must have adequate strength and elasticity, so that it will not break during use. It must be free from holes, so it will not allow body fluids (and possibly the HIV virus) to pass through. Moreover, it must have a package that remains securely sealed to protect the condom throughout its shelf-life. If procurement specifications and quality assurance requirements are correct, condoms shipped from the factory will be newly manufactured, of good quality, and in good condition. Condoms made from latex rubber are perishable if exposed to excessive heat, humidity, light or air pollution. With the changing environmental conditions in Zambia, there is need to encourage proper storage of condoms in all the facilities. Otherwise condoms may lose their strength and thus put the user at risk of breakage.

Although this study brought out important findings which can contribute greatly to the body of knowledge, it had several limitations. The key limitation is that the tensile property test was no conducted. This is an important test that defines the elasticity of the condom and also determines the force of elongation at break. This could have provided more information on the quality of the products and which facilities are more likely to have poor quality condoms. The other limitation is that the stability studies to ascertain the shelf life of condoms was not done. This could have helped us understand how long condoms can be stocked in relation to the expiry dates on the label claim. It is important also to state that the laboratory tests in this study did not take into account of the quality of condoms after aging. Lack of financial resources was also a big challenge and is what led to the failure of performing the above mentioned tests. Although this study was comparing public and private facilities it was hard to find adequate samples from some institutions especially the private.

CHAPTER SEVEN

7.0. CONCLUSION AND RECOMMENDATIONS

This study shows that the quality of male latex condoms available in private and public facilities of Lusaka Urban District is good. The prevalence of good quality condom was found to be 98.77%. The study also shows that compliance of condom samples to physical parameter requirements, packaging and labelling standards did not differ. Therefore, male latex condoms available in private and public facilities of Lusaka District of Zambia do not differ in meeting the standard specifications for quality.

It is important for the Government to be regulating the suppliers and distributors of male latex condoms to ensure appropriate procurement, transportation and storage conditions for condoms. The Pharmaceutical Regulatory Authorities to be carrying out random sampling of condoms for visual inspection. If any of the condoms or their packaging appears damaged or in any way different from the norm, the sample should be sent from the affected batch to the qualified laboratory for testing. The Pharmaceutical Regulatory Authorities to take up and intensify regulation of rubber latex condoms.

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LIST OF APPENDICES

APPENDIX I: GANTT CHART

Task to be performed	**December 2010**	**June 2011**	**July 2011**	**September 2011**	**November 2011**	**February 2012**	**March 2012**	**April 2012**
Proposal development	→	→						
Presentation to graduate forum		→	→	→				
Submission to the REC				→				
Data collection				→	→			
Data Analysis					→	→		
Report writing						→	→	
Submission of 1st draft						→	→	
Submission of 2nd draft							→	
Dissemination of Results							→	→

APPENDIX II: BUDGET

No.	ACTIVITY	QUANTITY	UNIT COST(K)	TOTAL(K)
1	Printing proposals	5	45 000	225 000
2	Binding of proposals	5	20 000	100 000
3	Typing and printing proposal summaries	5	50 000	250 000
4	Review of proposal by Ethics Committee	1	250 000	250 000
5	Purchase of the International Standards	1	300 000	300 000
6	Cost of doing the tests	8	600 000	4 800 000
7	Transport for the principle researcher for data collection	1	200 000	200 000
8	Purchase of condoms	2800		2 800 000
9	Printing and binding of final report	1	50 000	50 000
10	Contingency			2 000 000
	TOTAL			**10 725 000**

APPENDIX III: DATA COLLECTION SHEET

QUALITY OF CONDOM CLINICAL ASSESSMENT CHECKLIST FOR RETAIL OUTLETS AND PUBLIC SERVICE DELIVERY POINTS: LUSAKA DISTRICT: JAN 2011–AUG 2011.

CONDOM CLINICAL ASSESSMENT CHECKLIST No. | | | |

Product Identification

TO BE FILLEDOUT WHEN CONDOM SAMPLE COLLECTED:	TO BE FILLED OUT WHEN TESTED
Facility type (Retail outlet or Service Delivery Point)……	Tested by ……..
Outlet ID: …….	Date tested…….
Location:……	Package material ……
Sampled by:……	Average width of condoms……
Description of Brand: …….……	
Lot number …….	
Expiry date …….	
Number in a sample ……	

Condom Number	Freedom from holes test:	Pass/ No pass	Results
1			
2			Total Passing:
3			Total Sample:
			Percentage:
			Notes:
315			

316		
Condom number	Length	Pass/ No pass
1		
2		
3		
11		
12		
13		
Condom number	Lubricant quantity	Pass/ No pass
1		
2		
3		
12		
13		
Condom number	Thickness	Pass/ No pass
1		
2		
3		
12		
13		

Condom number	Tensile Properties	Pass/ No pass	
1			
2			
3			
12			
13			
Condom	Package seal integrity	Pass/ No pass	
number			
1			
2			
3			
12			
13			
Condom number	Air Volume at Burst	Pass/ No pass	
1			
2			
3			
315			
316			
Condom	Width	Pass/ No pass	

number			
1			
2			
3			
15			
16			

Physical Appearance

Shape and Texture

1. The surface of the condoms is non-textured throughout ……...(Yes) (No).
2. The condoms have straight and parallel sides, without constrictions, and with a visible shoulder leading to a reservoir tip…….....…….(Yes) (No).

Integral Bead

3. The open end of the condom have a rolled ring of latex, called an integral bead…….(Yes)(No).

Colour

4. Are the condoms translucent and without added colouring? ……..……(Yes) (No).

Scents and Flavourings

5. Do condoms give off an unpleasant odour when the package is opened other than a characteristic odour of rubber which tends to dissipate quickly once the package is opened?.....(Yes) (No).
6. (i)Are the condoms flavoured? ……..……(Yes) (No).
   (ii) if 'Yes', is the flavour irritant..…….……...(Yes) (No).

General requirements

Materials

7. Is the condom made up of natural rubber latex? ……..…(Yes) (No)
8. Does the condom contain the dusting powder?……(Yes) (No)

Shelf-life

9. Is the shelf-life between 3 and 5 years?.....(Yes) (No)

Individual Package Materials and Markings

10. Is the manufacturer's name indicated?.....(Yes) (No).
11. Is the colour, print design and identification markings visible? ……(Yes) (No).
12. Is there any evidence of leakage? …….(Yes) (No).
13. Is the outside surface of the package clean? …….(Yes) (No).
14. Is there a separation of the layers of the laminate? ……(Yes) (No).
15. Is the package easy to open without damaging the condom? ……..……..(Yes) (No).
16. Are the individual packages square in shape and not distort the rolled condom?..... (Yes) (No).

APPENDIX IV: LETTERS FOR PERMISSION TO CARRY OUT A STUDY

The University of Zambia

School of Medicine

P. O Box 50110

Lusaka.

The Director General

Pharmaceutical Regulatory Authority

Lusaka.

Dear Sir/Madam

RE: PERMISSION TO CARRY OUT A RESEARCH ON "QUALITY ANALYSIS OF MALE LATEX CONDOMS AVAILABLE IN LUSAKA DISTRICT OF ZAMBIA – A COMPARATIVE STUDY"

With reference to the above captioned statement, I wish to request for permission to carry out a research.

I am a University student pursuing a masters degree programme in Public Health. I wish to undertake this research as part of my requirement to qualify for this programme. My research will involve collecting condoms from different outlets such as Chemists, Health centers and supermarkets.

The favour of your response will be highly appreciated.

Yours faithfully,

Morton Khunga.

The University of Zambia

School of Medicine

P. O Box 50110

Lusaka.

2nd February, 2011

The District Medical Officer,

Lusaka District Health Office

P. O Box

Lusaka.

Dear Sir/Madam,

RE: PERMISSION TO CARRY OUT A RESEARCH PROJECT

With reference to the above captioned statement, I wish to carry out a research project in the health facilities of Lusaka District Health Office.

I am a University student pursuing a masters degree programme in Public Health. I wish to undertake a research entitled "Quality analysis of male latex condoms available in Lusaka Urban District of Lusaka- a comparative study" as part of my requirement to qualify for this programme. My research will involve testing condoms which will be sampled from different outlets of Lusaka.

Your favourable response will be greatly appreciated.

Yours faithfully,

Morton Khunga.

APPENDIX V: CONSENT FORM

To: ……

…….

…….

Dear sir/madam,

RE: PERMISSION TO COLLECT SAMPLES FROM YOUR INSTITUTION

I am a student at the University of Zambia pursuing a Masters Degree programme in Public Health. As a requirement for the award of the Masters Degree certificate, I must undertake a research related to public health. The research I wish to undertake is titled "QUALITY ANALYSIS OF MALE LATEX CONDOMS AVAILABLE IN PRIVATE AND PUBLIC FACILITIES OF LUSAKA URBAN DISTRICT OF ZAMBIA – A COMPARATIVE STUDY". Therefore, I would like to ask for permission to collect or buy samples of condoms for analysis as a requirement of this study.

The study is purely academic for the award of the Masters Degree in Public Health, and the information that will be gathered through this study will be kept strictly confidential.

SIGNED:

Names: ……

Signature: ……

Date: ……..……..

WITNESSED:

Names: ……..…..

Signature: ……

Date: ……

LIST OF ANNEXES

ANNEX 1.0: DETAILED QUALITY ANALYSIS OF CONDOM SAMPLES

ANNEX 1.1: PHYSICAL INSPECTION

Physical inspection of condom samples was done visually to search for labels, nature and material of packaging. Products were also inspected to see if they had batch numbers, manufacturing and expiry dates, names and address of the manufacturer, instructions for use of the product. The information that was collected from the inspection was recorded in the data collection sheet.

ANNEX 1.2: LABORATORY TESTS

1. Determination of bursting volume and Pressure

A specified length of the condom was inflated with air, and the volume and pressure required to burst the condom were recorded. This was conducted using the Air Inflation System that has the inflation apparatus suitable for inflating the condom with clean oil-free and moisture-free air at a specified rate, provided with equipment for measuring volume and pressure. The system also had a clamping device that had no sharp edges or protrusions, and the inflation cabinet with a facility for viewing the condom during inflation, and of sufficient size to allow the condom to expand freely without touching any part of the cabinet.

The procedure was carried out under the controlled temperature of (25±5) ºC. The condom was moved inside the package such that it was away from the area where the package was to be torn. The package was torn to remove the condom. No sharp instruments were used to open the package. The condom was then unrolled, mounted on the rod, clamped appropriately and inflated. If the condom exhibited any obvious leaks, or leaks were detected during the inflation, the test was discontinued. The condom was deemed to have failed the test, and the bursting volume and pressure were recorded as zero. If the condom did not leak, the bursting volume was measured and recorded by the computer, in cubic decimeters rounded to the nearest 0.5dm^3, and the bursting pressure, in kilopascals rounded to the nearest 0.05kPa.

2. Tests for Package Seal Integrity

The apparatus used included vacuum chamber, capable of withstanding approximately one atmosphere pressure differential, fitted with a vacuum pump, a vacuum gauge and the possibility to inspect the interior during the test, and the immersion fluid with a wetting agent.

Individual condom containers were submerged in water contained in a vessel within the vacuum chamber. The uppermost surface of the containers was covered by not less than 25mm of water.

The chamber was evacuated to an absolute pressure of (20±5)kPa. As the vacuum increased, the condom containers were observed for leakage in the form of a steady progression of bubbles. Isolated bubbles caused by entrapped air are not considered as leaks. Flexible packaging with little or no headspace cannot be reliably evaluated with this test method. The vacuum was held for 1 minute. The vacuum was then released and the lid was removed. Condom containers were then examined for the presence of water inside.

3. Determination of total lubricant for condoms in individual containers

This test is based on knowing the mass loss which is determined by removing the lubricant from the pack and condom by washing with a solvent. Washing is carried out either in an ultrasonic bath or by manual agitation. A minimum sample size of 13 condoms is recommended. The apparatus used was the ultrasonic cleaning bath, a balance and a solvent propan-2-ol.

Each individual container of condoms was weighed and the results recorded to the nearest 1mg. Condoms were then opened, unrolled and the lubricant wiped as much as possible. The condoms together with the container were then immersed in the ultrasonic bath of propan-2-ol and washed for 2 to 10 minutes. Washing was repeated as many times as possible and then individual condoms with their containers were dried to a constant mass at the temperature not exceeding 55ºC. Each dry condom with the container was then weighed to the nearest 1mg and the result was subtracted from the initial weight to give the total quantity of the lubricant.

4. Determination of length

The unrolled condom was allowed to hang freely over a graduated mandrel and its length, excluding the reservoir end, observed and recorded.

The condom was moved inside the package such that it was away from the area where the package was to be torn. The package was then torn and the condom removed. In no circumstance

was the scissors used or other sharp instruments to open the package. The condom was unrolled, stretched slightly twice but by no more than 20mm to smooth out the wrinkles caused by the condom having been rolled up. Lubricants were removed and suitable powders were added to avoid sticking. The condom was put over the mandrel and allowed to hang freely, stretched only by its own mass, and the length was then recorded.

5. Determination of width

The unrolled condom was allowed to hang freely over the edge of a ruler and its width was observed and recorded. The condom was moved inside the package such that it was away from the area where the package was to be torn. The package was then torn and the condom removed. In no circumstance was the scissors used or other sharp instruments to open the package.

The condom was unrolled and laid flat over the edge of the ruler, perpendicular to the condom's axis, allowing it to hang freely. The lubricant was removed and suitable powders added to avoid sticking. The width of the condom was measured to the nearest 0.5mm at a point specified in the standard.

6. Determination of thickness

The unrolled condom was cut at three different points and its thickness measured using the micrometer gauge and recorded.

The condom was moved inside the package such that it was away from the area where the package was to be torn. The package was then torn and the condom removed. The unrolled condom was cut at three points where measurements were taken. The points were 30mm from the open end, the midpoint and 30mm from the closed end. Using the micrometer gauge, measurements were taken at these three points. The average of the points was the thickness of the condom.

7. Testing for holes

The condoms were initially screened electrically to detect holes. A condom which had no holes acted as an insulator and allows no current to flow in an electrical circuit. A condom with a hole would allow a current to pass. This was done on an electrical testing equipment that used a

voltage of (10±0.1)V, resistance of (10±0.5)kΩ, accuracy of the voltmeter ±3mV. 10g/l sodium chloride was used as an electrolyte at a temperature of (25±5)ºC.

The condom was moved inside the package such that it was away from the area where the package was to be torn. The package was then torn and the condom removed. In no circumstance was the scissors used or other sharp instruments to open the package. The condom was unrolled to ensure that it was no excessively stretched in any direction. The condom was examined visually under normal or corrected vision. Any condom which exhibited a visible hole or tear was deemed as failed, and the test was discontinued. The non-leaking condom was submerged in a container also containing electrolyte such that all but at least from the open end was submerged. A 10V stabilized continuous voltage source was applied in series with a high precision electrical resistance between the electrode in the container and the electrode inside the condom. The voltage at the resistor was measured after (10±2)s and the result record.