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Quality Analysis of Male Latex Condoms Available in Private and Public Facilities in Lusaka, Zambia – A Comparative Study

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ABSTRACT

Background: 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 design 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.

Methods: 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.

Results: 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 labeling standards are similar.

Conclusion: 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.

INTRODUCTION

Condoms of one form or another have been recognized for centuries as effective means of preventing pregnancy[1]. 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. 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[2].

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[3]. 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[4].

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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[5].

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. The aim of this study was to uncover and evaluate the magnitude of the problem in detail and suggest the solutions.

METHODS AND MATERIALS

Study design, Setting and Population

The study was a comparative study and was conducted in Lusaka Urban District of Zambia. It was carried out in different private and public facilities which were selected using random sampling technique. The principal investigator was in charge of collection of samples, doing laboratory tests and analyzing of data. Laboratory tests were done with the help of laboratory technician from the Zambia Bureau of Standards. 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.

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.

Laboratory Testing Procedures

The Principal investigator conducted the laboratory testing of the condoms at the Zambia Bureau of Standards in Lusaka with the help of the laboratory technician. 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.

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.

Data Collection

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.

Validity for this study was ensured by obtaining data that covered all important variables under study. The researcher also ensured that the data appropriately addressed the research question.

The researcher will work closely with the Analysis Manager at Zambia Bureau of Standards and the Drug Analysis Manager at Pharmaceutical Regulatory Authority (PRA) in order to ensure quality data is obtained. Data was only collected and analyzed according to the standard specification of the international standards for the requirements and test method of the natural latex condoms.

Statistical Analysis

SPSS version 16 was used for statistical analysis to analyze quantitative data. Chi-square was used for categorical variables and t-test was used for continuous variables to compare variances between variables of the two groups of samples in the study. P-value and confidence interval were used to test the hypothesis. An already existing computer program designed to analyze condom quality according to the International Standards was also used to determine percentages and frequencies.

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 1* 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.

Table 1: 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 1 shows the general details of all the condom samples that were used in the study. Inspection generated information regarding nature of material, batch numbers, manufacturing dates, expiry dates, and nominal width which was 53mm for all the samples was collected.

Results for Packaging

Table 2: Package seal integrity for samples from private facilities

Batch Number	□ No air bubbles and no fluid inside	□ With 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

Table 3: Package seal integrity for samples from public facilities

Batch Number	□ No air bubbles and no fluid inside	□ With air bubbles and/or fluid inside	Total
DE01137	30	0	30
MEM035	30	0	30
11N2474	30	0	30
201002	30	0	30
Total	120	0	240

□ no air bubbles and no fluid inside means compliance with the standards.
□ with air bubbles and/or fluid inside means noncompliance with the standards.

Table 2 and Table 3 show that both groups of samples had 120(100%) condoms with no air bubbles and fluid inside and therefore had appropriate packaging requirements. The two tables also show that there was no difference between the samples from the two different sources in meeting the standards.

Results for Physical parameters

Table 4 shows that there was 100% compliance for freedom from holes and total lubricant tests after laboratory tests. The rest of the physical parameters, in ***table 4*** show that the difference between condom samples in terms of percentage compliance from the two sources was not significant. For airburst volume the t-test was 1.732, p-value was 0.225 and the 95%CI was -1.848 to 3.848. The p-value for the length was 0.118 and the 95% CI of -1.4612 and 6.1279. Thickness and width had equal p-value and t-test values of 0.182 and 1.732, respectively. The 95%CI for width was -0.419 to 1.418 while that for thickness was -0.418 to 1.419. All the p-values of all the parameters were above 0.05 indicating that the difference between the samples from the two sources was not significant. The 95%CIs for all the parameters included zero which also shows that the difference was not significant.

Table 4: 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

Prevalence of quality condoms

The overall prevalence of good quality male latex condoms was found to be 98.77%. This study also showed that the prevalence of male latex condoms from private facilities was 98.95% while that from public facilities was 89.60%. Among the variables studied, packaging, lubricant quantity, freedom from holes and thickness recorded 100% compliance to standard specification for all the batches.

DISCUSSION

This study shows that, the quality of male latex condoms in private and public facilities are not different in meeting the national and international standards. It also shows that the prevalence of good quality condoms was 98.77%. This is in line with the study done by Adam et al which showed that, the failure rate of condoms globally is about 2%[6]. Packaging, lubricant quantity, freedom from holes and thickness gave 100% compliance to standard specification for all the batches, while dimensions, labeling and lubricant quantity had a lower compliance which ranged from 82.69 to 98.95%.

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.

Lower compliance, although it was minimal, of some parameters to standard requirements should be a source of concern. This could have come about as a result of exposure to environmental factors such as heat, humidity and chemicals. The quality of condoms can also be affected by handling during transportation. 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[7]. 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[8,9]. Higher or lower dimensions may lead to ill-fitting of condoms. This in turn may lead to breakage and slippage of condoms during use.

Condoms, when being manufactured, 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.

The other important factor is that, 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[10]. 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 also not conducted. 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.

CONCLUSIONS

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 labeling standards did not differ. 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.

RECOMMENDATIONS

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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REFERENCES

1. Hatcher R, Trussell J, Warner D.L. 1998.Condom performance during vaginal intercourse: Comparison of Trojan-Enz and Tactylon condoms. Contraception. 45(1):11-19
2. Babatunde Adetunji Musibau. 2010. Economic Analysis of the demand for Male Condoms and Implication for the Prevalence of HIV/AIDS in Nigeria, *Medwell Journal,* Scientific Research Publishing Company.
3. WHO/GPA .1994. *Evaluation of a national AIDS programme: A methods package.* (WHO/GPZ/TCO/SEF/94.1)

4. McNeil G. Donald Jr .1998. Faulty Condoms Thwart AIDS Fight in Africa, The New York Times: The Dead Zones.
5. Messiah A. 1997. Condom Breakage and Slippage during Heterosexual Intercourse: A French National Survey. *Am J Public Health*, 87(3):421-424.
6. Adam B. M, Auerbach J. D, Buehler J. W, Burk R, Cohen P. R, Fitch J.T, Gerofi J, W. Hager D, Hildesheim A. 2000. Scientific Evidence on Condom Effectiveness for STD Prevention, Virginia.
7. WHO/UNAIDS. 1998. *The Male Latex Condom: Specifications & Guidelines for Condom Procurement*. (WHO/RHT/FPP/98.15, UNAIDS/98.12).
8. CDC. 2009. Zambia Rejects Batch of Holes Condoms, CDC HIV/Hepatitis/STD/TB Prevention News update.
9. Lufeyo. 2009. Africa: Condoms-the hole truth, Citizen Journalism in Africa, Plusnews.
10. Ahmed G, Liner EC, Williamson NE. 1990. Characteristics of condom use and associated problems: experience in Bangladesh. *Contraception.*