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Sanitary Surveillance of Male Condoms: A Public Health Question

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ABSTRACT

Background: The increased incidence of sexually transmitted infections (STIs) in Brazil represents a significant Public Health issue. The natural latex male condom is a resource available to both men and a woman that meets the dual protective function. In Brazil, male condoms need to be certified. The certification process evaluates the manufacturing and quality of the final product in detail. However, the post market surveillance is not part of the normal practice. Public health officials have warned of the emergence of new Sexually Transmitted Infections caused by four bacteria and superbugs.

Methods: Two brands of male condoms, one purchased in the Brazilian trade (Sample A) and the other distributed by the Brazilian government program (Sample B) were evaluated. The quality control of the male condom involves the important insufflation test, which evaluates the resistance determining the volumetric capacity and the rupture pressure. The microbiological assay was performed as a complement. For the inflation test, we tested 200 units per brand, according to the criteria established in the Resolution of the National Agency of Sanitary Surveillance nº. RDC 62/2008 that allows up to seven nonconforming units. Microbiological analyzes were tested following the Standard Operational Procedure (SOP) of the National Institute of Health Quality Control (INCQS), Oswaldo Cruz Foundation, Rio de Janeiro, Brazil, number 65.3210.008 rev. 15 according to the guidelines established by the Brazilian Pharmacopoeia, 5th Edn, 2010.

Results and conclusion: Both brands met the criteria established in the Resolution of the National Sanitary Surveillance Agency no. RDC 62/2008 for the inflation test, which allows up to seven nonconforming units. However, the microbiological tests pointed out the presence of pathogens. We conclude that, in addition to certification, there is a need to monitor this product in view of the sanitary risk observed.

Keywords: Male condoms, Public health, Sanitary risk, Sanitary surveillance

INTRODUCTION

Background of the study

The incidence of STIs had increased in Brazil and now represents a significant Public Health issue. This increase is predominantly due to low socioeconomic status, poor cultural conditions and lack of adequate sex education, particularly among young individuals. Today, STIs are among the most common diseases worldwide [1].

Globally, the health impact of STIs had led to allocation of huge funds for treatment of young individuals in a range of countries. The World Health Organization (WHO) estimated the rise in incidence of curable STIs in Brazil from 10 million to 12 million annually, covering the age group of 15-49 years [2]. In Brazil, the use of condoms remains an important prevention policy, the Ministry of Health, in response to the increase in cases of STIs and considering the potential consequences evaluated inconsistencies in the quality of condoms and the population disinterest in use of condoms. To remedy this, post exposure prophylaxis concomitant has been introduced for the treatment of all high-risk individuals following sexual intercourse (vaginal, anal and oral) since October 2010. This involves the administration of medications up to 72 h, after sexual intercourse, if condoms were not used or failed during intercourse [3].

The male condom serves a dual function by protecting against both pregnancy and STIs [4]. It does not have any side effects except to individuals who are allergic to latex.

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New diseases emerge all the time and sexually transmitted infections are no exception. Gonorrhea, chlamydia and syphilis are still the most common STIs, but public health officials are increasingly warning of the prevalence of four bacteria and superbugs [5].

Neisseria meningitidis can cause invasive meningitis, a potentially deadly infection of the brain and spinal cord's protective membranes, more commonly; it's gaining a reputation as a cause of urogenital infections. Roughly 5-10% of adults carry *N. meningitidis* in the back of the nose and throat. Studies suggest they can potentially transmit the bacteria to partners through oral sex, deep kissing or other kinds of close contact that transmit infected droplets. Researchers are not yet sure which of these transmission routes have caused outbreaks of invasive forms of the disease among gay and bisexual men in Europe, Canada and the US. However, one study of urethritis caused by *N. meningitidis* in a separate group of men (all but one of whom were heterosexual) suggested that they contracted it from receiving oral sex [5].

A *Mycoplasma genitalium* bacterium, one of the smallest bacteria known, is gaining an outsized reputation as a worrisome STI. Identified in the 1980s, the bacterium today infects an estimated 1-2% of people and is especially common in adolescents and young adults [5].

M. genitalium infection, though often symptom-free, can mimic chlamydia or gonorrhea with persistent irritation of the urethra and cervix. Because it may trigger pelvic inflammatory disease in the female reproductive system, it has been associated with infertility, miscarriage, premature birth and even stillbirth. While condoms can help prevent infection, researchers have sounded the alarm about *M. genitalium*'s growing resistance to treatment with the antibiotics azithromycin and doxycycline [5].

Shigellosis (or *Shigella dysentery*) is passed on by direct or indirect contact with human feces. The infection causes severe stomach cramps and explosive bouts of blood- and mucus-filled diarrhea, which helps perpetuate transmission of the bacteria. Although the disease is most commonly associated with young children and travellers in some low- and middle-income countries, researchers began documenting cases of shigellosis in gay and bisexual men in the 1970s. *S. flexneri*, scientists believe, essentially exploited a new niche for transmission through anal-oral sex and has led to multiple STI outbreaks around the world since then [5].

Lymphogranuloma venereum (LGV) an STI caused by unusual strains of *Chlamydia trachomatis*, can cause an "awful infection", according to Christopher Schiessl, a doctor at the One Medical clinic in San Francisco's Castro neighborhood. LGV may first produce a temporary genital pimple, blister or ulcer and then invade the body's lymphatic system. Rectal infection can mimic inflammatory bowel disease and lead to chronic and severe colon and rectal abnormalities such as fistulas and strictures [5].

Over the past decade, LGV has become increasingly common in Europe and North America and has been associated with multiple disease outbreaks, especially among gay and bisexual men. As with chlamydia, LGV can increase the risk of contracting HIV [6].

The risk relationship, calculated on causes and effects, related to probabilities, uncertainties, contrasts with several studies that point to the existence of models, assumptions and techniques of subjective evaluation of risk very different from the scientific models, for which the phases of the processes are integrated, taking into account the social, environmental, political and economic parameters [7].

For Sanitary Surveillance, risk is evaluated in processes, procedures, environments, products and services of interest to health and the purpose of their actions is to inhibit or minimize their effects on the health of the population. With a focus on risk control, its practices integrate prevention of diseases, protection and health promotion [8].

In Brazil, the quality of available male condoms is under the jurisdiction of the National Health Surveillance Agency (ANVISA) of the Ministry of Health of Brazil. The Resolution of the Collegiate Board of Directors, RDC 62/2008, based on ISO 4074: 2002 establishes the Technical Regulation for certification of this product [9,10].

Male condoms, like other products that may cause some kind of impact on health, consumer safety or the environment, are compulsorily certified, that is, they can be circulated for commercialization or distribution with the seal of conformity, which certifies that that product meets the minimum requirements of the quality established according, the standards that foresee its use. However, the certification process, although it evaluates the production and the product in detail at the end of the production, does not address the issue of commercialization in several establishments such as pharmacies, drugstores and supermarkets, considered typical sanitary surveillance actions[9].

The revisions of ISO 4074 in November 2015 highlight the importance of microbiological evaluation in male condoms to prevent possible risks of microbiological contamination. According to the revision of ISO 4074/2015, "It is recommended that manufacturers establish procedures for periodically monitoring microbial contamination (bio burden) as part of their quality management system, including requirements for the absence of pathogens and limits on the total viable count on specific finished condoms; methods of determining "bio burden" levels for condoms [10,11]".

The presence of poor quality condoms on the market represents a serious challenge in the fight against STIs. The lack of quality of this product affects the popular perception

of the value of the condom, which, in turn, can have a significant impact on Public Health. Therefore, they can harm not only the health of users, but also the reputation of agencies or the national agency that provides condoms [12]. The objective of this study was to evaluate, due to the disclosed perspective of the emergence of new STDs [5], to show that we should adopt a system of monitoring male condoms in a broad and active way in an attempt to minimize sanitary risks, taking into account complementary essay in the set of physical tests established in legislation [9,10].

METHODS

Two samples of condoms were collected for evaluation, following ISO 4074/2015. Samples of condoms were available on the market, through of consultation to the ANVISA database and using a random draw to choose a brand from the selected manufacturer. The other sample consisted of condoms from a free distribution campaign conducted by the Brazilian Health Ministry. Sampling of samples followed ISO 2859 [14].

Two brands of male condoms, anonymized by marking with letters, one purchased in the Brazilian trade (sample A) and the other distributed by the Brazilian government program (sample B). The analytical tests carried out on the brands were the insufflation test and the microbiological.

Bursting volume and bursting pressure (insufflation test) were measured in accordance to standards established by the Brazilian National Health Oversight Agency Resolution no RDC 62/2008, using an eight-head automated inflation system (Enersol™, Sydney, Australia). For this analysis, we used the ISO 2859 single sampling plan, with a normal inspection regime, at inspection level I (acceptable quality level (AQL)=1.5, less than 1.5% of units defective). The number of units assessed was 200 per lot and the acceptance criteria reject the lot if at least eight nonconforming units were identified. The male condoms were placed in the eight-head automated inflation system the flow of compressed air was set at 24-30 dm^3 min^{-1}, as defined in the standards. For each condom, the bursting pressure (1 kPa=N force applied uniformly over an area of 1 m^2) and bursting volume (in dm^3) were logged via the EInflation3 software [13]. During the insufation test, the condom is inflated like a balloon, stretching the latex film until its rupture, thereby indicating its maximum resistance. The inflation system is accompanied by software that logs the pressure and volume at bursting. The compressed air that supplies the system is generated by a dry, oil-free air compressor [9,14].

Microbiological analyzes consist of quality control of non-sterile drugs, cosmetics, health articles and supplies, treated water for dialysis and polyelectrolyte concentrate for dialysis, as well as raw materials used in its manufacture. The tests followed the Standardized Operational Procedure (SOP) of the National Institute of Quality Control in Health (INCQS), Oswaldo Cruz Foundation, Rio de Janeiro, Brazil, number 65.3210.008 rev. 15 according to the guidelines established by the Brazilian Pharmacopoeia, 5th edition of 2010, aiming at proving the existence of microorganisms such as Enterobacter, *Staphylococus aureus* and *Pseudomonas aeruginosa* specified in the Resolution [15].

RESULTS

For physical tests, **Table 1** presents AQL, amount of sample test and the criteria established in accordance with RDC 62/2008.

Table 1. Criteria established by RDC 62/200 for physical tests for male condoms.

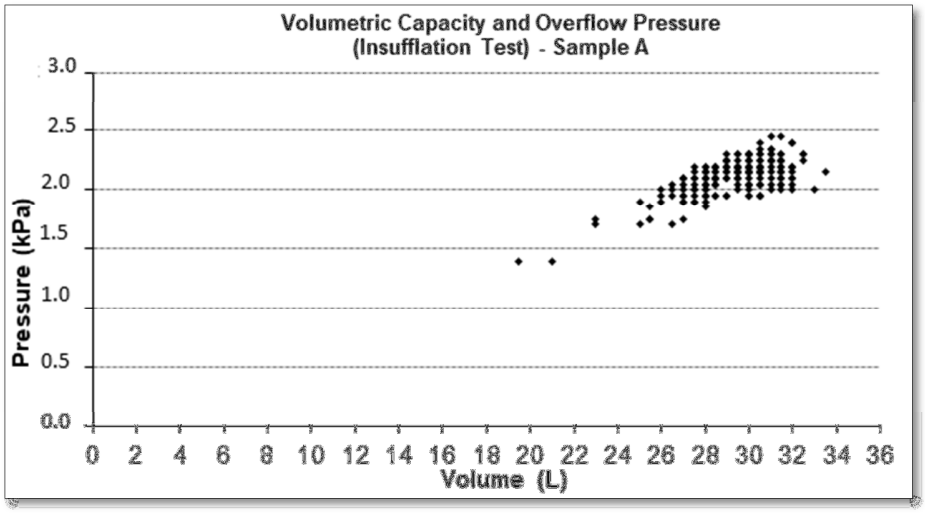
Physical tests	AQL	Amount of sample tested	Maximum acceptable non-conforming units
Length, width, thickness	4.0	13	2
Holes	0.25	315	3
Primary packaging integrity	2.5	20	2
Bursting volume and bursting pressure	1.5	200	7
Label and secondary packaging	1.0	13	1

AQL: Acceptable Quality Level

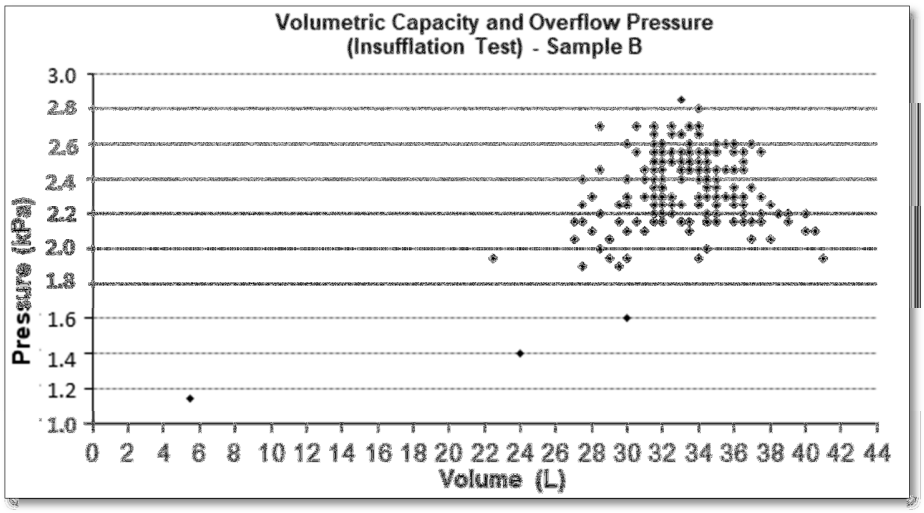
For all regulations the overflow requirement is linked to the width of the condom, measured at (75 ± 5) from the closed end of the condom. The overflow volume should not be less than 16.0 dm^3, for condoms with nominal width less than 50.0 mm; 18.0 dm^3, for condoms with nominal width greater than 50.0 mm and less than 56.0 mm; 22.0 dm^3, for condoms greater than 56.0 mm and less than 65.0 mm; 28.0 dm^3, for condoms greater than or equal to 65.0 mm and less than or equal to 75.0 mm.

Graphs 1 and 2 represent the insufflation tests performed in samples A and B, respectively. The variability for pressure and burst volume shows that the units are not uniform. However, the distribution stretches to the left, both for pressure and for volume, characterizing a non-normal distribution contaminated by outliers, but within the

conformity area, except for sample B that presented unit of pressure and volume below the established values.



Graph 1. Insufflation test: Sample A.



Graph 2. Insufflation test: Sample B.

By the characteristics of the graphs, we noticed variability in the samples studied. This can be explained by the fact that it is a mass produced product, influenced by the properties of the latex film, the type of storage of the product to its use among others, which highlights the importance of post-market monitoring beyond certification **(Table 2)**.

Table 2. Dispersion measurements for the test of insufflation of samples A and B.

Sample	Pressure (kPa)				Volume (L)			
	$\bar{x}$	Std. dev	Se	Variance	$\bar{x}$	Std. dev	Se	Variance
A	2.112	0.159	0.011	0.025	29.32	2.032	0.143	4.13
B	2.345	0.232	0.016	0.054	32.98	3.468	0.245	12.024

$\bar{x}$: Mean; Std. dev: Standard Deviation; Se: Standard error

Microbiological analysis

The results for the microbiological tests of both samples (A and B) indicated the presence of pathogenic microorganisms. **Table 3** presents the microbiological test results for samples A and B, respectively.

Table 3. Microbiological test results for samples A and B.

Samples	Date	Total aerobic bacteria (U.F.C/un.)	*Escherichia coli*	*Staphylococus aureus*	*Pseudomonas aeruginosa*	*Candida albicans*	Molds and yeasts
Sample A	04 Feb 2019	1.0×10^5	Presence/un.	Absence/un.	Absence/un.	Absence/un.	1.0×10^3/un.
Sample B	04 Feb 2019	1.5×10^6	Absence/un.	Presence/un.	Absence/un.	Presence/un.	1.2×10^3/un.

The bacteria found are among the dominant etiological agents responsible for more than 85% of cases of urinary tract infection, including Gram-negative bacilli that are normal inhabitants of the intestinal tract. The most common is *Escherichia coli*, followed by the genera *Proteus*, *Klebsiella* and *Enterobacter*. Among Gram positive bacteria are *Enterococcus fecalis* and species of the genus *Staphylococcus*. However, virtually all other bacterial and fungal agents can also cause urinary tract infection (UTI) [16].

CONCLUSION

Inflation tests are internationally standardized and have great importance in the factor of evaluation of the product. According to World Health Organization specifications and condom quality standards, insufflation tests, integrity of the primary packaging and the amount of lubricant together are useful for evaluating condom performance. These properties are the best indicators of product performance. The insufflation tests measures both properties and is performed on most of the product with proven sensitivity in the relationship between these parameters and the degradation of the product. Hereafter, the results found, although the samples are within the limits of conformity established by the standards, illustrates the importance of carrying out the quality analyzes in a wide way, since, in most cases, the manufacturing lot indicates nonconformity in a or more tests, allowing to indicate the need, besides the certification, Sanitary Surveillance action on the product in the market. The bacteria found are among the dominant etiological agents responsible for more than 85% of cases of urinary tract infection, including Gram-negative bacilli that are normal inhabitants of the intestinal tract. The most common is *Escherichia coli*, followed by the genera *Proteus*, *Klebsiella* and *Enterobacter*. Among Gram positive bacteria are *Enterococcus faecalis* and species of the genus *Staphylococcus*. However, virtually all other bacterial and fungal agents can also cause urinary tract infection (UTI). In the microbiological evaluation, the results indicate the need to include, as acceptance criteria, the presence or not of pathogenic microorganisms, since the tests are complementary and are not necessarily correlated. This study reinforced the importance of monitoring the actions of this product in world trade [11,17-19].

REFERENCES

1. Scaramuzza MC (2014) DST'S. Publicado por: http://www.boasaude.com.br/artigos
2. Nichiata LYI, Bertolozzi MR, Takahashi RF, Fracolli LA (2008) The use of the "vulnerability" concept in the nursing area. Rev Latino-am Enfermagem 16: 923-928.
3. ORGANIZAÇÃO PAN-AMERICANA DE SAÚDE (OPAS) (2010) Módulos de Princípios de Epidemiologia para o Controle de Enfermidades. Módulo 3: medida das condições de saúde e doença na população/Organização Pan-Americana da Saúde. Brasília. Organização Pan-Americana da Saúde: Ministério da Saúde. 94p: il. 7 volumes. ISBN 978-85-7967-021-3.
4. Bertolozzi MR, Nichiata LYI, Takahashi RF, Ciosak SI, Hino P, et al. (2009) The concepts of vulnerability and adherence in Collective Health. Rev Esc Enferm USP 43: 1320-1324.
5. Bryn N (2018) Four emerging STDs that you can't afford to ignore. Mosaic.
6. Strelow VL, Vidal JE (2013) Invasive meningococcal disease. Arq Neuro-Psiquiatr 71: 653-658.
7. Costa EA (2004) Vigilância sanitária: proteção e defesa da vida. São Paulo: Sobravime.
8. Costa EA (2009) Vigilância Sanitária: temas para debate. Salvador: EDUFBA.
9. AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA (2014) Resolução RDC nº 62, de 03 de setembro de 2008. Estabelece os requisitos mínimos a que devem obedecer aos Preservativos Masculinos de Látex de Borracha Natural. Brasília, 2008. Available in: http://azt.aids.gov.br/documentos/inventario/RDC%20n%C2%BA%2062-ANVISA.pdf
10. (2002) International Organization for Standardization. ISO 4074: Rubber Condoms. Switzerland.
11. (2015) International Organization for Standardization. ISO 4074:3: Natural latex rubber condoms - Requirements and test methods. Switzerland.

12. Tremelling J, All A, Lleras L, Cancel A, Jenkins D, et al. (2019) Poor quality male latex condoms found in Dominican Republic: Quality assurance evaluation and public health impact. PLoS One 14: e0210150.

13. Enersol Consulting Engineers (2010) EInflation 3. Sidney, 2006. Biological METHODS. In: FARMACOPÉIA BRASILEIRA, 5 Edn. São Paulo: Atheneu.

14. (1999) International Organization for Standardization. ISO 2859-1: Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality (AQL) for lot-by-lot inspection. Switzerland, p: 87.

15. (2010) Biological methods. In: FARMACOPÉIA BRASILEIRA, 5th Edn. São Paulo: Atheneu.

16. Robbins SL, Rim IN (2000) Patologia Estrutural e Funcional. 6 Edn. Rio de Janeiro: Ed. Guanabara. Koogan, pp: 834-892.

17. (1997) American Society for Testing and Materials. ASTM D 1976: Standard specification for rubber – Concentrated, ammonia preserved, creamed and centrifuged natural latex. Philadelphia, p: 12.

18. Gerofi J, Shelley G, Donavan B (1991) A Study of the relationship between tensile testing of condoms and breakage in use. Contraception 43: 177-185.

19. Word Health Organization (2013) Effectiveness of male latex condoms in protecting against pregnancy and sexually transmitted infections. Geneva, Available at: http://www.who.int/mediacentre/factsheets/