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Consumers' Perception on Safety and Microbiological Assessment of Sanitary Pads Sold in The Federal Capital Territory (FCT), Nigeria

Mercy I. Aboh*, Marlene Ekpo, Fahd A. Khalid--Salako and Peters O. Oladosu

Department of Microbiology and Biotechnology, National Institute for Pharmaceutical Research and Development, Abuja, Nigeria.

ABSTRACT

Urinary tract infections (UTI) a known public health problem is common in females. The objectives of this study were to assess consumers' knowledge on possible contamination of sanitary pads, determine the quality of some commercial brands of sanitary pads and evaluate the effect of different storage conditions on their integrity. To assess consumers' knowledge on possible contamination of sanitary pads, determine the quality of some commercial brands of sanitary pads and evaluate the effect of different storage conditions on their integrity. A cross-sectional analysis of 500 female respondents was done by a close ended, structured, interviewer dispensed inquiry form through stratified random sampling. Ten brands of sanitary pads were stored at conditions to simulate possible storage habits of consumers and at different time intervals (0, 1, 7, 14, 21 and 28 days) samples were assessed for total bacterial count (TBC) and total fungal count (TFC) via the pour plate method. Standard methods were used to isolate and identify pathogens. Results revealed that 69.4 % of respondents stored their pads in sealed enclosures, 11.8 % were not aware of the dangers of poor storage and 51.4 % agreed that poor storage could result in microbial contamination. The results on microbial burden revealed that none of the pads were contaminated at the beginning of the study (Day 0). The presence of microorganisms (*B. subtilis, S. aureus* and *Mucor* spp) were observed after 24h of storage, especially in samples with open packages and stored in open shelves, followed closely by those unsealed in enclosed environments. These microbial growths can therefore be attributed to the storage conditions of the sanitary pads. Sanitary pads can harbour pathogenic microorganisms; there is a need to properly store them and once opened use them within 14 days to prevent environmental contamination.

Keywords: *Sanitary pads, Microbial assessment, Safety, Storage.*

***Corresponding author:** Dr. Aboh Mercy I.

mercybenaboh@gmail.com

+2348061586188

Department of Microbiology and Biotechnology, National Institute for Pharmaceutical Research and Development, Abuja, Nigeria.

ORCID: 0000-0003-3171-1318

INTRODUCTION

Sanitary pads for the most basic reason are worn by menstruating women to absorb menstrual discharge in their reproductive phase (1). Women have throughout history used different types of menstruation protection and before the 1900s, napkins of various kinds were mostly used (2). Today, sanitary napkins are available in a wide variety of designs that not only put into consideration women's comfort but also style and fashion sensibilities. The pads also come in individual wrappers so they are easy to carry and can be wrapped when soiled before disposal in appropriate trash cans to ensure proper sanitation (3). Sanitary pad, which is also known as sanitary napkin or menstrual pad, is a thin pad made of absorbent material that absorbs the menstrual fluid during menstruation. The materials used as absorbents vary from, reusable towels (clothes torn from dresses of women and cotton fabric) to commercially disposable pads (1). The preference of sanitary protection material (pads) is based on personal choice, cultural acceptability, economic status and availability in local market. Menstrual hygiene management practices vary worldwide and depend on the individual's socioeconomic status, personal preferences, local traditions and beliefs, access to water and sanitation resources (3).

Practices related to menstruation hygiene are of major concern as it has a health impact, if neglected it leads to reproductive tract infections (RTI), potentially associated with an abnormal change of microbial flora in the vagina like toxic shock syndrome which can appear as a severe toxemia, sometimes rapidly becoming fatal, it's symptoms are high fever, vomiting, diarrhea and rash. This disease is caused by *Staphylococcus aureus* that commonly colonizes the Vagina (4). Disposal of menstrual waste is of major concern as it affects health and environment there is need for effective

menstrual materials which needs less and cost-effective management, companies dealing with manufacturing of sanitary pads should disclose information on the pads regarding the chemical composition of the pads so that appropriate technologies could be used for their disposal and treatment (5).

Smith *et al* (6) found a major association between menstrual flow and the frequency of isolation of *Staphylococcus aureus*, but found no significant differences in the innoculum size of the

organism in users of tampons (a type of sanitary napkins inserted into the vagina) compared with users of menstrual pads. The reported information dealt with the frequency of recovery of bacterial species and did not include quantitative information. Hence, it has not been possible from obtainable information to find out if the presence of a tampon affects significantly the microbial flora of the genital tract during menses. The US Pharmacopoeia (USP) stipulates suitable measures to be taken during the manufacture, packaging, storage and distribution of sanitary pads to ensure their microbial quality. They should be produced aseptically and handled with utmost care to avoid microbial contamination that will cause serious health issues (7). The acceptance criteria for microbial quality of non-sterile pharmaceutical preparations according to the USP states that *Pseudomonas aeruginosa, Staphylococcus aureus* and *Candida albicans* should be absent in 1g or 1mL of the dosage forms intended for vaginal use where the total aerobic microbial maximum acceptable count is 200 and the total combined yeasts/molds (CFU/g or CFU/mL) maximum acceptable count is 20.

Some females have reported itching, dermatitis, redness and irritation of the vagina following the use of some sanitary pads (8, 9, 10). These reactions could be due to contamination with pathogenic microorganisms. This serves as a basis for conducting a study on commercially available sanitary pads to assess their microbial burden and what effect storage has on their microbial stability. This study will provide much needed information on the possible effects of storage on the microbial loads of sanitary pads, help understand to what extent various storage conditions affect the microbial stability of sanitary pads and by extension, provide a basis for understanding the implications of the various storage conditions females subject sanitary pads to using FCT, Nigeria as a case study.

METHODOLOGY

Survey Locations

The Federal Capital Territory (FCT), the capital of Nigeria is located in the North Central geopolitical region. It lies between latitude 8.25 and 9.20 north of the equator and longitude 6.45 and 7.39 east of Greenwich meridian and has a landmass of approximately 275.3km^2. According to the National Bureau of Statistics (2017), The Federal Capital

Territory has a projected population of 3,564,126 in the year 2016 (11) making it one of the 10 populous cities in Nigeria and one of the fastest growing cities in the world; Abuja Municipal Area Council (AMAC) is the largest area council in the Federal Capital Territory (FCT). The larger populace comprises mainly of low-middle age income earners mainly petty traders and low-ranking civil servants which reside in the rural areas. The urban settlement on the other hand is home to those with higher socioeconomic status.

Sampling techniques

Consumers' perception on quality of commercial sanitary pads

The study involved a cross-sectional survey of 500 randomly selected females aged 11 and above from different locations in Abuja, Nigeria who are expected to have knowledge on the use of sanitary pads with the help of a pre-designed questionnaire. The results obtained were computed.

Inclusion Criteria: Females aged 11 and above with knowledge on the use of sanitary pads.

Exclusion Criteria: Inability to speak or understand English language or absence of a translator, females below 11 years of age and men.

Microbial burden of commercial sanitary pads

Ten (10) different brands of pads were randomly procured from FCT of Abuja and retail shops within Abuja Municipal Area Council, (AMAC). One pack of each brand were stored at different conditions; sealed (in a sterile zip lock bag) and kept in a closed cabinet (SC), unsealed (package left open) but stored in a closed cabinet (UC), unsealed (package left open) and stored in an open shelf (UO), sealed (ziplock bag) and stored in an open shelf (SO). Samples were collected from the stored pads and processed on days; 0, 1, 7, 14, 21 and 28.

Sample processing and analysis

One gram of sample from each brand of sanitary pad under the various storage conditions was cut with the aid of a sterile scissors (sterilized by flame) and weighed using a balance in the laminar flow unit, immersed in 15 mL of sterile tryptic soy broth (TSB) and allowed to stand for 3 h. One millilitre of the stock was serially diluted in 9 ml of TSB up to 10^{-2}. One hundred microliters of the diluted samples were plated out on tryptic soy agar and Sabouraud dextrose agar (SDA) plates in duplicates. The

TSB plates were incubated at 37°C for 24 h for bacteria growth while the SDA plates were incubated at 25 to 28°C for fungal growth (12). The colonies observed after incubation were sub-cultured on nutrient agar for purity and identification. The total viable aerobic bacteria (TVAB) and fungal count (FC) were calculated from the number of colonies that appeared on the plates.

Analysis of Data:

Data obtained was visualized and analysed with Microsoft Excel 2016 package, SPSS version 20 (SPSS IN(c) Chicago IL, USA) and Graph Pad Prism 5 for windows, Graphpad software, La jolla, California, USA, www.graphpad.com.

RESULTS

Consumers demographics

The consumer's demographics is represented in Table 1. Among the subjects examined, age group 21 - 30 year (43.8%) was the most common and they were mainly single (61.4%) with most of them having higher education (55.8%) and mostly unemployed (33.8%) and residing in urban settlements (64.4%). Analysis of data obtained from the survey revealed that 95.8% of 500 respondents use sanitary pads with Always sanitary pads being the most used (69.2%), as opposed to the respondents that have never used sanitary pads (3.8%).

Table I: Socio-Demographic data of Respondents

Parameter	Data	Frequency (%)
Age	11yrs-20yrs	108 (21.6)
	21yrs-30yrs	219 (43.8)
	31yrs-40yrs	123 (24.6)
	>40yrs	49 (9.8)
Marital Status	Single	307 (61.4)
	Married	168 (33.6)
	Divorced	16 (3.2)
	Widowed	8 (1.6)
Education	None	23(4.6)
	Primary school	24(4.8)
	Secondary school	172(34.4)
	Higher Institution	279(55.8)
Place of Residence	Rural	176 (35.2)
	Urban	322 (64.4)
Occupational status	Self-employed	130 (26)
	Private	95 (19)
	Government employed	105 (21)
	Unemployed	169 (33.8)

The results (Table II) revealed that 95.8 % of the 500 respondents were sanitary pads users with 91.6% of them preferring sanitary pads to other absorbent materials for reasons including convenience (92.2%), affordability (4.6%), and thickness (0.2%). About eight percent (8.2) of respondents preferred using other absorbent materials such as cotton wool (0.6%), tampons (0.2%), towels (4.2%) and tissue paper (1.6%). These were claimed to be more comfortable (1.4%), cheaper (0.6%) and reusable (0.4%).

Table II: Consumers' Perception on the use of commercial sanitary pads

Question	Frequency (%)
Have you ever used a sanitary pad?	
• Yes	479 (95.8)
• No	19 (3.8)
Do you prefer sanitary pads to other absorbent materials?	
• Yes	458 (91.6)
• No	41 (8.2)
What is your reason for your above answer? (if yes)	
• Convenience	461 (92.2)
• Cost	23 (4.6)
• Thickness	1 (0.2)
• Others	0.4 (2)
(if No)	
• Affordability	3 (0.6)
• Comfort	7 (1.4)
• Reuseable (as in towels)	2 (0.4)
Other materials used by respondents	
• Tampons	1 (0.2)
• Tissue paper	8 (1.6)
• Cotton wool	3 (0.6)
• Towels	21 (4.2)
How often do you change your sanitary pad daily?	
• Once	11 (2.2)
• Twice	193 (38.6)
• Thrice	226 (45.2)
• More	68 (13.6)

On the storage of sanitary pads (Table III), 69.4% of respondents reported keeping them properly sealed, 16% left them open while 11.8% of respondents did not think the way sanitary pads are stored mattered. On exposure prior to use (Table III), 38.8 % of respondents admitted to leaving them open for some time; 5mins-10mins (36.6 %), 10 mins - 20 mins (0.8 %) and > 20 mins (1.4 %) before use.

Table III. Consumers' storage habits and knowledge on the effect of storage on the quality of commercial sanitary pads.

Question	Frequency (%)
How do you keep your sanitary pads after opening?	
● Properly sealed	347 (69.4)
● Left open	80 (16)
● I don't think it matters how I keep it	59 (11.8)
Where do you store your sanitary pad?	
● Bag	211 (42.2)
● Box	48 (9.6)
● Drawer	29 (5.8)
● Wardrobe	(37) 7.4
● Storage cart	2 (0.4)
● Cupboard	13 (2.6)
● Bathroom	3 (0.6)
Do you open your sanitary pads right before you wear them?	
● Yes	299 (59.8)
● No	194 (38.8)
How long do you leave it exposed?	
● 5-10mins	183 (36.6)
● 10-20mins	4 (0.8)
● More	7 (1.4)
Do you feel there are any risks to the use of sanitary pads?	
● Yes	153 (30.6)
● No	318 (63.6)
● I don't know	23 (4.6)
Do you think one could get an infection through sanitary pads?	
● Yes	257 (51.4)
● No	193 (38.6)
● I don't know	50 (10.0)
Have you or anyone you know had health issues you would associate with the use of sanitary pads?	
● Yes	107 (21.4)
● No	381 (76.2)
● I don't know	12 (2.4)
How best can you describe the experience?	
● Redness	29 (5.8)
● Irritation	58 (11.6)
● Itching	69 (13.8)
● Foul smell	18 (3.6)
How was the condition managed?	
● It resolved on its own	87 (17.4)
● Self-medication	14 (2.8)
● Prescribed medications	4 (0.8)

Figure I showed that 51.4 % of the respondents agreed that infections can be contracted through the use of contaminated sanitary pads. In treating the condition, 2.8 % of the respondents reported to have self-medicated, 0.8 %

used prescribed medications, 0.4 % used herbal medicines and 17.4 % reported that the condition resolved untreated.

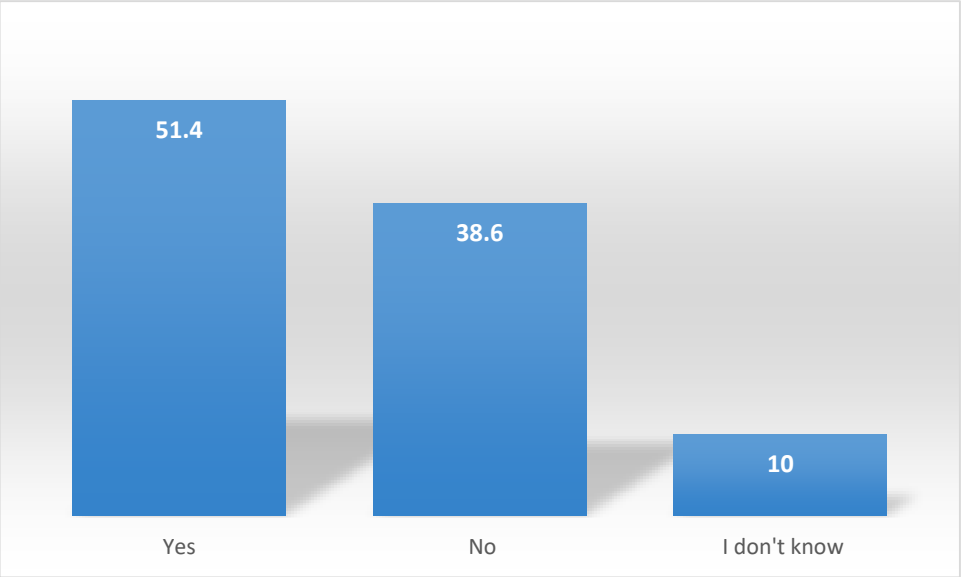

Fig I: A chart showing percentage of respondents that think sanitary pads can serve as carriers of infectious organisms

Figure II reported that 21.4 % admitted to having or knowing people with health concerns they thought can be attributed to the use of sanitary pads best described as redness (5.8 %), irritation (11.6 %), itching (13.8 %) and foul smelling (3.6 %).

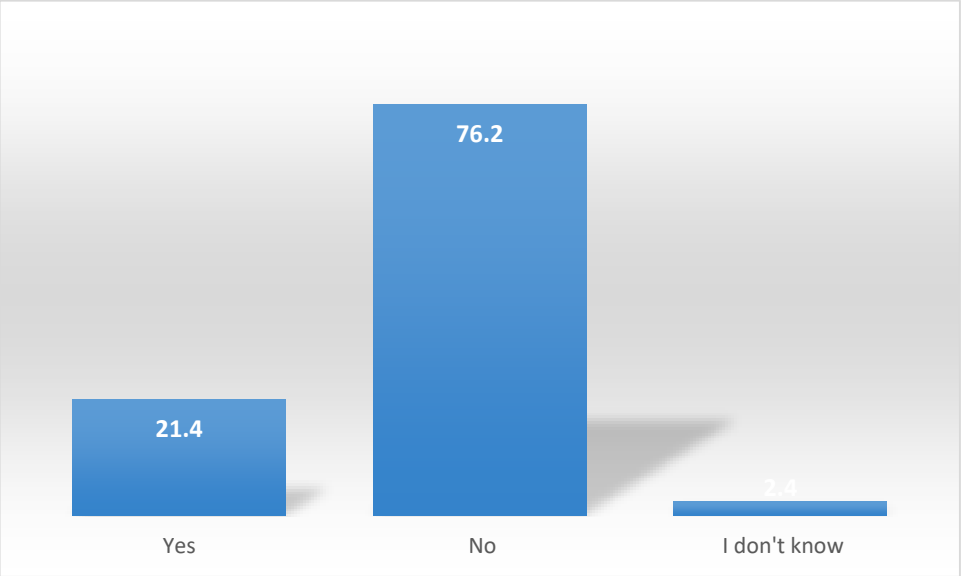

Fig II: A chart showing reported cases of infections suspected to result from the use of sanitary pads.

Effect of storage and microbial contamination of sanitary pads

The microbial species isolated from the sanitary pads after storage in different environmental conditions is represented in Table IV. The microorganisms isolated include *Bacillus spp., S. aureus* and *Mucor spp.* (Table IV).

Table IV: Microbial species identified from the analysed sanitary pads during the 28 days storage

Days	Identified species			
	UO	**UC**	**SO**	**SC**
0	-	-	-	-
1	*Bacillus* spp	-	-	-
7	*Bacillus* spp, *S. aureus*	*S. aureus*	-	-
14	*Bacillus* spp	*Bacillus* spp	*Mucor* spp	*Bacillus* spp
21	*Bacillus* spp, *S. aureus, Mucor* spp	*Bacillus* spp, *S. aureus*	*Bacillus* sp, *S. aureus, Mucor* sp	*Bacillus* spp, *S. aureus*
28	*Bacillus* spp, *S. aureus, Mucor* spp	*Bacillus* spp, *S. aureus*	*Bacillus* spp, *S. aureus, Mucor* sp	*Bacillus* spp, *S. aureus*

UO- unsealed in open environment
UC- unsealed in an enclosed environment
SO- sealed in open environment
SC- sealed in an enclosed environment

These organisms were absent at the beginning of the study (Day 0). All sanitary pads were contaminated after 14 days of storage including those that were sealed and kept in enclosed environments. This can be attributed to contaminants in the environment to which the pads were exposed to and not from the manufacturer. The level of contamination was however, lower with samples stored in an enclosed environment than those left open and kept in an open shelf as seen in the results on total bacteria and mold/yeast count (Fig III and IV). For samples kept in proper enclosures, there were relatively low counts of microorganisms until the 14th day.

Average Aerobic Bacteria and Fungal Counts in Sanitary Pads Stored Under Various Conditions.

All the samples recorded no aerobic bacterial or fungal growth after procurement on day 0 of the study. The values obtained on day 0 therefore serve as control against which aggregated data collected on days 1, 7, 14, 21 and 28 are compared. None of the samples showed significant aerobic bacterial growth after day 1 ($p > 0.05$) as compared with control (day 0). After day 7, none of the samples showed significant aerobic bacterial growth ($p > 0.05$) except UC ($p = 0.004610$). After days 14, 21 and 28, all the samples showed significant aerobic bacterial growth ($p < 0.05$) compared with control (day 0). Tukey's multiple comparisons tests as carried out showed no significant differences in the aerobic bacterial growth pattern among the different storage conditions.

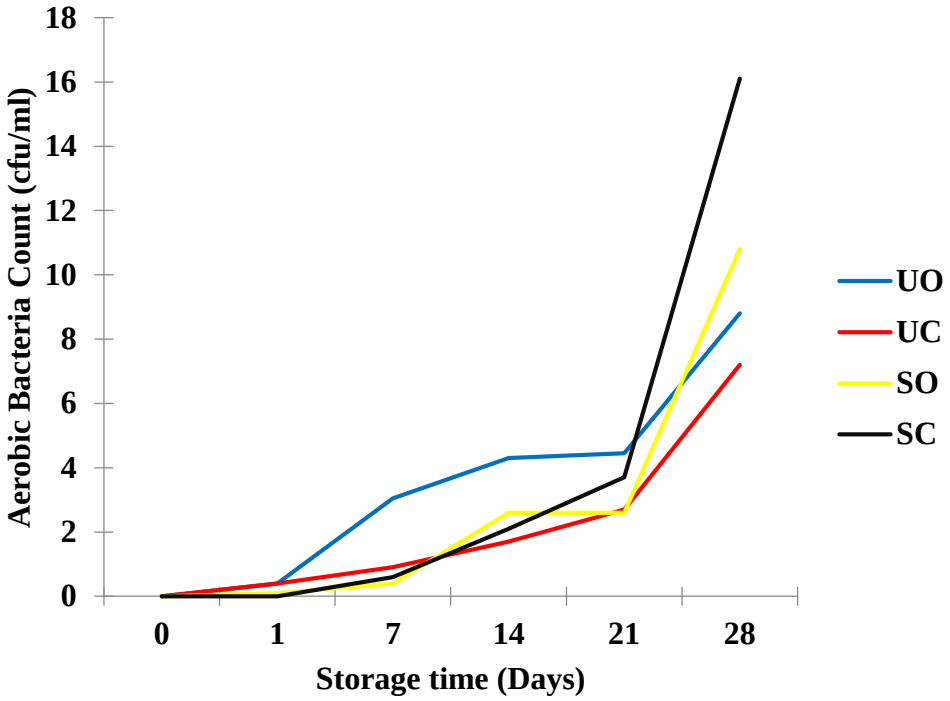

Fig III: Average Aerobic Bacterial Counts of Sanitary Pads Under Various Storage Conditions.

Key: UO- unsealed in open environment UC - unsealed in an enclosed environment
SO - sealed in open environment SC - sealed in an enclosed environment

None of the samples showed significant fungal growth after days 1 and 7 ($p > 0.05$) as compared with control (day 0). After day 14, UO showed no significant fungal growth ($p > 0.05$) while SO showed significant growth ($p = 0.024770$). After days 21 and 28, both samples UO and SO showed significant fungal growth ($p < 0.05$) as compared with the control. A student's t-test comparing fungal growth patterns between UO and SO showed no statistically significant difference between both conditions ($p = 0.6487$). Sanitary pads stored in sealed packages in an enclosed environment (SC) as well as those stored in open packages in an enclosed environment (UC) had no fungal growth over the duration of the study.

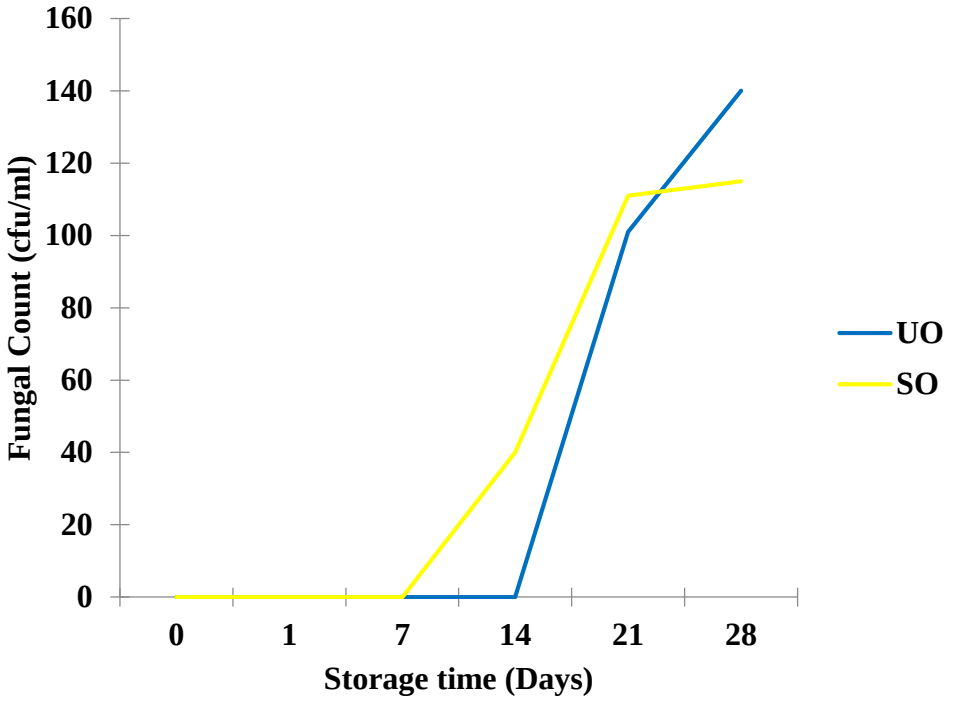

Fig IV: Average Fungal Counts of Sanitary Pads Under Various Storage Conditions.

Key: UO- unsealed in open environment SO - sealed in open environment

4.0 DISCUSSION

Sanitary pads are considered low risk (class 1) medical devices by the FDA, which recommends that they are subjected to pre-clinical microbiological tests to show that they are not contaminated with pathogenic microorganism of public health importance such as *Staphylococcus aureus* and alter the growth of normal vaginal microflora as they come in direct contact with the vagina (13). Following that microorganisms are ubiquitous, lack of proper storage of sanitary pads could lead to their contamination. The use of poorly stored (ergo, contaminated) sanitary pads and products raises concerns due to the sensitivity of the vagina. The physiology of the vagina makes it a significant route through which causative organisms of various UTIs, Pelvic Inflammatory Disease (PID), sexually transmitted disease (STDs), bacterial vaginosis and other vaginal infections gain entry. The vagina is a complex organ with an essential microbiota (most notably, *Lactobacillus sp.*) that protects it from infections (14).

Any external factors that tamper with the environment created by this microbiota in the vagina exposes it to adverse events ranging from immune responses to infertility (15).

The microorganisms isolated from the samples are *Bacillus spp*, *S. aureus*, and *Mucor spp* as presented in Table IV. Species of the *Bacillus* genus are generally known for their ubiquity in nature, spore production and ability to survive harsh conditions. While they are usually not indicated in pathological conditions, some species including *B. licheniformis* and *B. pumilus* have been known to cause diseases in immunocompromised patients (16). *Staph. aureus* is another microorganism commonly found as a normal human flora, it is a commensal bacterium that asymptomatically colonizes the human body. It however in some cases, causes serious infections like bacteremia, endocarditis and skin and soft tissue infections particularly when a mucosal barrier has been breached (17). Species of the *Mucor* genus are filamentous fungi chiefly found in the soil, plant and decaying fruit. Usually, they do not cause diseases as they mostly do not survive temperatures as high as 37 ^{o}C. However, some species are more adapted to surviving such conditions and cause diseases in endothermic animals collectively known as zygomycosis or mucormycosis. It commonly affects the sinuses, eye, brain or the lugs after inhalation leading to facial swelling, blurred vision, blindness and thrombosis especially in individuals with immunodeficiency (18). The microbial loads of the sanitary pads as obtained by the total viable bacterial count and fungal count (Fig III and Fig IV) generally remained at levels lower than the limits set by the FDA throughout the duration of the study (20 cfu/ml and 200 cfu/ml respectively) and can be said to pose little or no health risk to the product users.

The results of our study as shown in Fig. III and IV revealed that proper sealing of the sanitary pads as well as storage in an enclosed environment significantly prevents contamination until about 14-21 days after first opening the manufacturer's packaging. The results also revealed a sharp increase in microbial load at about 28 days under these conditions. Statistical analysis showed that under all the storage conditions explored, contamination (as measured by cfu/mL of aerobic bacteria and fungi obtained) generally became

significantly different from day 14 ($p < 0.05$). Differences in levels of contamination and growth/contamination patterns were not statistically significant ($p < 0.05$) among the various storage conditions (as obtained on day 1, 7, 14, 21 and 28).

CONCLUSION

The study showed that proper storage of sanitary pads is essential in ensuring the quality and exclusion of contaminants which may be hazardous to health. It may then be inferred that microbial contamination from improper storage of sanitary pads can be significantly reduced if they are properly sealed, stored in properly enclosed spaces and more importantly, used within 14 days of opening the manufacturer's packaging.

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References

1. Nyoni, A.B., Sibanda, P., Nkiwane, L.C. and Gonde, P. (2014). Performance characteristics of local and imported sanitary pads. Zimbabwe J. Sci. Technol., 7(2011): 1-9.
2. Larsson, L. and Olsson, M. (2014). History of menstruation products. In a conceptual female hygiene product. Ed. 2014. Pg 23.
3. Das, P., Baker, K.K., Dutta, A., Swai, I., Sahoo, S. Das, B.S. et al. (2015). Menstrual hygiene practices, WASH access and the risk of urogenital infection in women from Odisha, India. Plos One 10(6): 1-16. https://doi.org/10.1371/journal.pone.0130777.
4. Dhingra, R. and Kumar, A. (2009). Knowledge and practices related to menstruation among tribal (Gujjar) adolescent girls. Studies on Ethno-medicine, 3 (1): 43-48.
5. Kaur, R., Kaur, R. and Kaur R. (2018). Menstrual hygiene management and waste disposal: Practices and challenges faced by girls/women of developing countries. J of Environ. Pub.

Health, 2018 :1-10. https://doi.org/10.1155/2018/1730964.

6. Smith, C.B., Noble, V., Bensch, R., Ahlin, P.A., Jacobson, J.A. and Latham, R.H. (1982). Bacterial flora of the vagina during the menstrual cycle: findings in users of tampons, napkins, and sea sponges. Ann Intern Med, 96(6 Pt 2) : 948–51.

7. USP. (2016). Microbiological Examination of Non-Sterile Products. Test For Specified Micro-organisms in US Pharmacopeia (61). Pharm Forum, pp. 1722–33.

8. Williams, J.D., Frowen, K.E. and Nixon, R.L. (2007). Allergic contact dermatitis from methyldibromo glutaronitrile in a sanitary pad and review of Australian clinic data. Contact Derm., 6(3) : 164–7.

9. Rademaker, M. (2004). Allergic contact dermatitis to a sanitary pad. Australias J Dermatol, 45(4) : 234–5.

10. Wiwanitkit, V. (2009). Sanitary pad dermatitis. Indian J Dermatol, 54(4) : 391.

11. Akerele, J.O. and Ukoh, G.C. (2002). Aspects of microbial contamination of tablets dispensed in hospitals and community pharmacies in Benin City, Nigeria. Tropical Journal of Pharmaceutical Research, 1(1): 23-28.

12. National Bureau of Statistics (2017). Demographic statistics bulletin. May 2017 pp. 8.

13. F D A. (2005). Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s). US Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health. http://www.fda.gov/cdrh/ode/parad510.html.

14. Petrova, M.I., Lievens, E., Malik, S., Imholz, N. and Lebeer, S. (2015). Lactobacillus species as biomarkers and agents that can promote various aspects of vaginal health. Front Physiol., 6: 81.

15. Smith, S.B. and Ravel, J. (2017). The vaginal microbiota, host defence and reproductive

physiology. J Physiol (Lond). 595(2) : 451–63.

16. Ozkocaman, V., Ozcelik, T., Ali, R., Ozkalemkas, F., Ozkan, A., Ozakin, C., et al. (2006). Bacillus spp. among hospitalized patients with haematological malignancies: clinical features, epidemics and outcomes. J Hosp Infect., 64(2) : 169 – 76.

17. Tong, S.Y.C., Davis, J.S., Eichenberger, E., Holland, T.L. and Fowler, V.G. (2015). *Staphylococcus aureus* infections: epidemiology, pathophysiology, clinical manifestations, and management. Clin Microbiol Rev., 28(3) : 603–61.

18. Actor, J.K. (2012). Mycology. Elsevier's integrated review immunology and microbiology. Elsevier, p. 139–146.