

CENTRE FOR SEXUAL AND REPRODUCTIVE HEALTH

WHO CONSULTATION ON THE REUSE OF THE FEMALE CONDOM

GENEVA

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by

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Acronyms and abbreviations

AIDS	Acquired Immune Deficiency Syndrome
CDC	Centre for Disease Control
CFR	Code of Federal Regulations
CSWs	Commercial Sex Workers
EVMS	Eastern Virginia Medical School
FDA	Food and Drug Administration
FHI	Family Health International
PH	Public Health
STD	Sexually Transmitted Diseases
STIs	Sexually Transmitted Infections
WHO	World Health Organisation

1. EXECUTIVE SUMMARY

The objectives and anticipated outcomes of the consultation were to:

- Review the results and evaluate the implications of the recently completed structural integrity and microbiological experiments.
- Develop a protocol or set of instructions for disinfecting and cleaning female condoms for use in further feasibility and safety of re-use in different contexts.
- Outline further research required to determine the balance or risks and benefits of female condom use in various contexts and settings.

A set of guidelines was agreed recommending the use of bleach to disinfect the condom and soap to wash it. The guidelines (see Appendix 1) are in their most condensed form and a guide for programme managers will be completed in March 2002.

Arguments between risk reducers and absolute scientists characterised the meeting. In terms of the specifics of the guidelines, it would appear that the absolute scientists won the day. However, by not outlawing any regime apart from washing with water only, the door was left open for other risk reduction regimes most notably the use of soap and water.

Within the absolute science group, it was also vocalised that the error that had been made in recommending microbicides should not be repeated, and that the guidelines should be based on evidence as opposed to 'it has got to be better than nothing'. (The microbicide made women more at risk of infection, including HIV). This caused another point of friction between the two groups.

The specific details of the experiments are available in the blue consultation file, overheads and the written paper. This report first gives a summary of the three experiments, including results, and the subsequent discussion in the meeting.

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2. STRUCTURAL INTEGRITY DISCUSSION

Structural integrity study	
Presenter – William Potter (Independent Consultant).	
Aim:	To examine the impact on structural integrity of repeated washing and disinfection
Methods:	<p>3 batches of 300 female condoms were washed and disinfected seven times according to the following regime.</p> <ul style="list-style-type: none"> • <u>Re-lubrication</u> (except for the first cycle) • <u>Disinfection</u> – bleach (Domestos) 1 in 4 concentration for 30 minutes • <u>Wash</u> <ul style="list-style-type: none"> Soak in fresh water for 5 minutes Soak in dilute washing up liquid for 5 minutes Remove to fresh water Hand wash in diluted washing up liquid – 30-45 seconds Rinse • <u>Dry</u> <ul style="list-style-type: none"> Air dried on pegs for minimum of one hour.
Results:	<p>All three batches met the manufactures release specifications after 7 cycles. However, of the five integrity tests, two have no specification, burst pressure and burst volume (i.e. there is no level of pressure or volume defined as acceptable)</p> <p>All of the condoms discoloured slightly.</p>
Study Limitations:	The study did not examine female condoms used for sexual activities

The majority of the comments made on this study concerned clarifications on the study design. The WHO standard of 1 in 4 bleach dilution for 30 minutes had been used to provide information on the worst case scenario in order to probe structural integrity. Washing up liquid was used for the same reason, as it is more aggressive than bar soap. The study conducted 7 cycles of washing and disinfection in order that there be a margin of safety for recommending 5 re-uses of the female condom.

Other issues raised included the recent evidence that small holes in the male condom are not of concern, and that the distinction has to be made between handling holes and catastrophic failure (See Appendix 2 for evidence and reference). Holes in the female condom are less of a concern since the female condom is under less pressure during intercourse than the male condom. It was also highlighted that a real life study into the re-use of the female condom is necessary to examine the feasibility and acceptability of this washing and disinfecting regime.

3. MICROBIAL DISINFECTION DISCUSSION

Microbial Disinfection Study	
Presenter – Ron Ballard (CDC)	
Aim:	To examine the effectiveness of disinfection.
Methods:	<p>Preliminary studies with bull semen Preliminary beaker studies -semen + bleach Studies using new, washed and relubricated condoms – semen + bleach</p> <p><u>Semen</u> The bull semen contained the following infective agents; HIV, herpes, gonorrhoea and clamidia. <u>Bleach</u> The following concentrations of hypochlorite, 1%, 0.5%, 0.25%, 0.125% and 0.06% at 1, 2 and 4 minutes was investigated.</p>
Results:	<p>Chlamydia was found to be the most resistant to hypochlorite. Based on the results of the study, soaking in 0.25% hypochlorite solution for 1 minute was recommended. This recommendation was effective for all three (new, washed and relubricated) condom types.</p>
Study Limitations:	Bull as opposed to human semen was used in this study and during the course of the study it was found that bull semen restricts gonorrhoea even in the absence of bleach.

As with the previous presentation, some discussion concerned the study design. For example, it was explained that bull semen was used due to the difficulty, for cultural reasons, to collect sufficient human sperm in South Africa.

It was after this presentation that the debate between the microbiologists and others, predominantly from the public health/programmatic perspective, began. Some stated that while bleach is best, there is a hierarchy and washing with soap is likely to be better than washing with water only. However, this requires examination if for no other reason than to be able to tell women that solely washing with soap is unsafe.

Drying was another issue that generated debate, the 'PH' group felt that drying the condom would reduce the transmission of certain pathogens. A microbiologist stated that it was irrelevant, as there was a need to "decontaminate". This exchange typified subsequent exchanges, risk reduction vs biological decontamination.

Another issue that first arose after this presentation and subsequently, was dilution and the limit for detection of certain pathogens. The effect of washing and rinsing dilutes the concentration of pathogens such that they are undetectable to scientific tests. Finally, it was highlighted that the viral load of the pathogens required for infection is unknown.

One participant noted that the recommendations made by the group would have to be a balance of wisdom and science.

4. PHYSICAL IMPACT DISCUSSION

In vivo safety of reuse of the female condom.	
Presenters– Carol Joanis (FHI) and Susan Ballagh (EVMS)	
Aim:	To examine the physical impact of the female condom under re-use conditions
Methods:	Examined the impact on men and women of condom reuse by comparing a group who used a new female condom for five consecutive acts of vaginal intercourse in 15 days to a group who used the same device. The effects on the body were compared pre and post use. The cervix was examined visually using a colposcopy.
Results:	Re-use was not associated with excess penile discharge, symptomatic vaginal infection or excess colposcopy findings. The condom remained in place better when reused, the disinfectant smell was not pleasant and the sensitivity of the condom improved over time.
Study Limitations:	The study reported fewer ‘adverse’ events following use of the female condom i.e. less physical damage. However, this is achieved by comparing the number at baseline to new events, and therefore those injuries what we present pre and post intervention were not considered. Insufficient is known about what is ‘normal’ in terms of injury due to sexual relations to fully interpret these results.

It was stated that care needs to be taken when presenting colposcopy results, as they may appear worse than they are. In addition, little is known about the effect of unprotected sex on the cervix and therefore interpretation of the colposcopy results is limited.

5. ISSUES AND DISCUSSION

The issues raised and discussion that took place in the formulation of the minimum guidelines, the examination of programmatic implications and areas for future research are summarised below under the following broad headings: minimum guidelines, the use of soap and water for disinfection, drying the condom, bleach, the broader economic impact of reuse, programmatic issues, future research and issues related to monitoring the introduction of the re-use guidelines.

5.1 Minimum guidelines

Is the use of a hierarchy for the minimum guidelines a double standard? According to WHO’s mandate “*to identify safe practices that if introduced would constitute risk reduction and improved health status for individuals and for communities, with a focus on the developing world*” and the fact that there is a precedent for hierarchical guidelines in WHO, the answer is no. (See H. Rees presentation).

There was discussion around the timing of lubrication. It was pointed out that in the case of a polyurethane condom, being stored in a lubricant is not required. In addition, lubrication immediately prior to use is the norm, and in addition this has the cosmetic advantage of minimising the amount of debris e.g. dust that might become attached to the condom via the lubricant.

Recommendations were made that advice must be given to limit excess handling of the condom as this is perhaps the greatest risk to its structural integrity.

There is a need to be careful that the guidelines avoid the 'fried egg' effect whereby all of the semen would not come into contact with the bleach. The fried egg effect could occur when the semen forms a glutinous lump, akin to a fried egg, on contact with the bleach.

5.2 Soap and water

Recommendation of the use of soap and water to reuse the female condom was the key area of dispute in the meeting. There is data, presented in the previous meeting, that suggests that washing the condom in soap and water reduces the risk of transmission of STI's. The key word here is 'reduces'. While to reduce the risk was good for the public health/programmatic group, it was unacceptable to the microbiology group for whom the detection of any microbe was a problem. As stated by the PH/programmatic group, women will not always (be able to) follow the protocol and therefore is it important to know the effect of soap and water.

The microbiological group reported that for methodological reasons, investigating the effectiveness of soap and water was not possible. This is primarily due to the fact that the dilution of the microbes makes them impossible to detect, but also due to difficulties in standardising soap and the washing action. This issue also led to a heated exchange. One suggestion, rejected by the microbiologists, was the use of soap to remove the lubricant¹, thereby standardising the washing via a defined endpoint.

Finally, one additional area of conflict was the concern of the microbiologists about how the water from washing would be disposed of so as to limit the risks to others.

Such was the debate that it is not believed that any progress was made by either side towards understanding the other's point of view. From the programmatic/public health perspective, it is advantageous that in the final guidelines the question of using soap and water to clean the female condom was left open and not stated as dangerous.

5.3 Drying

The issue of rinsing and then drying the female condom was also contentious. A study presented at the meeting in 2000 found that rinsing and then patting dry the female condom reduced the number of microbes on the condom. The microbiologist's response to this was that while desiccation reduces the microbial load, it does not disinfect.

¹ The soap's main function in the agreed minimum standards is to remove the lubricant.

5.4 Bleach

It was highlighted that hypochlorite bleach is unstable and therefore the higher dilution factor than suggested by the trials was recommended (0.25%). In addition, the recommendations only apply to hydrochloride bleaches and appropriate guidelines would have to be developed for any alternative type of bleach.

Representatives from Bangladesh and India pointed out that in their countries bleach comes in powder as opposed to liquid form. The group did not appear to have a strong feeling for the global bleach usage, and therefore it was difficult to gauge how easy or difficult the use of the protocol would be.

5.5 The broader economic impact of reusing the female condom.

The broader impact in terms of making the female condom more cost effective was only mentioned once in the meeting, in the final presentation on risk benefit assessment.

5.6 Programmatic issues

A number of programmatic issues were raised throughout the meeting. Many of the examples given are from Bangladesh taken from the presentation given by the General Manager of the Social Marketing company in Bangladesh. However, the issues raised serve to highlight the need for context specific guidelines.

Concerns were raised about a public health message condoning/promoting reuse, considering the strength of messages to the contrary, e.g. needles. The participant from Mexico stated that none of the Latin America AIDS directors were in favour of reuse of the female condom. However, a few of these countries have promoted the method anyway.

The risk benefit analysis of reuse has to be undertaken locally and it is accepted that reuse is not for everyone everywhere. The representative from Brazil stated that they would not be adopting re-use since it is not "in their reality". The WHO guidelines for programme managers will be developed in March 2002 so that they can be field tested at the same time as the feasibility and acceptability of the recommendations are examined in South Africa.

Context specific issues

- The type of oil used for lubrication must be context specific and proven.
- In Bangladesh, women are more likely to use a liquid antiseptic, for example savlon or dettol, to disinfect the condom. This practice needs to be examined in terms of the guidelines given.
- The CSWs in Bangladesh stated that they liked the lubrication they were given due to its 'cooling' properties – this was highlighted as an important issue in relation to the development of microbicides.
- Also with reference to Bangladesh, women know that new is new and that recycled is substandard, this point should be borne in mind by those who argue that women will adopt the lowest in the recommendation hierarchy as opposed to the highest.

- What is the impact of the arsenic in the water in Bangladesh on the guidelines?
- How realistic is it for women to be able to carry out the guidelines? In Dhaka, the CSWs have to pay for water and it would not be possible for any woman in Bangladesh to wash condoms in a public place.
- It was suggested that the additional costs of female condoms could be built into the CSWs fee, this is done in Bangladesh and Cambodia.
- The oil that is recommended for lubrication has to be considered in view of the possibility that immediately following use of the female condom a male condom may be used, upon which the oil will have a destructive effect.

5.7 Future research

The most immediate research, a proposal for which is already written, examines the feasibility and acceptability of the minimum guidelines in the 'real world'. It is believed, by the public health/programme group that within the 'real world' context there maybe opportunities to examine the feasibility of the soap only option.

Other required research includes:

- The efficacy of new as opposed to re used female condoms

5.8 Monitoring of the introduction of guidelines

Included within future research is the need for careful monitoring and evaluation of the introduction of the guidelines, including allowance for the negative effects.

Specific questions include:

- Will the promotion of reuse cause migration, i.e. movement away from other methods to the female condom?

Appendix 1

DRAFT PROTOCOL FOR PREPARING FEMALE CONDOMS FOR RE-USE

The present protocol is applicable only to the polyurethane female condom as manufactured by the Female Health Company.

Implementation of this protocol while retaining all steps of the procedures, should be adapted to local conditions.

1. Remove the condom from the vagina, taking care to avoid spillage of semen.
2. Disinfection: As soon as possible, prepare about 250ml of approximately 1:20 dilution of hypochlorite (household) bleach, giving a final concentration of 0.25% sodium hypochlorite, tip about half of this into the female condom and then drop the female condom into the remainder of the solution. Swirl and ensure that the bleach solution covers all the surfaces of the condom. Soak condom for 2-5 minutes.
 - Do not attempt to remove the ejaculate or otherwise cleanse the condom prior to submersion in the bleach/water solution.
 - Handle the used condom in a manner that minimizes exposure to the ejaculate until it is placed in the bleach/water solution.
 - It is not recommended to soak the condom in bleach overnight. (Put this in companion document).
 - Do not attempt to disinfect the condom by boiling it or otherwise applying heat as high temperatures can degrade the condom material.
3. Washing: Handle condoms gently. Remove disinfected female condom from bleach solution and wash with soap and water in order to remove bleach and any residual lubricant.
 - Remove the inner ring.
 - Hands should be lathered with non-abrasive soap (avoid washing with any abrasive material).
 - The external surfaces of the female condom should be washed carefully, using lathered hands, and taking care to avoid tearing the condom.
 - Turn the condom inside out, and wash condom and ring with soap and water.

Make sure all lubricant is removed by washing.

- Rinse both sides of the condom and the ring carefully with clean water to remove residual soap.
4. Drying: The female condom and ring should be dried completely inside and outside by blotting with a clean cloth. Alternatively, the condom can be air-dried. Turn condom inside out to dry both sides.

5. Visual inspection: Some colour change may be noted. This is normal and does not affect the function of the condom. After complete drying, hold the condom up to the light to inspect for holes. If any holes or tears are observed, the condom should be disposed. If no holes are observed, replace the inner ring.

6. Storage: The clean, unlubricated condom should be stored in a clean dry place, taking care to avoid exposure to sunlight, direct heat and/or sharp objects.

- Extended exposure to direct sunlight and heat sources may degrade the female condom and may lead to breakage during use. (Move elsewhere).

7. Relubrication: Lubrication is necessary to replace the lubricants removed by disinfection and washing. Relubricate just prior to re-use.

- Optimal lubricants include silicone and water-based lubricants, such as (to be identified in-country)
- Inert oil-based lubricants (petrolatum – i.e., petroleum jelly, baby oil, vegetable oil or shortening/local word) may be used,
- (Move – although these cannot be used with male latex condoms.)
- Lubricants which contain substances which may induce allergies or inflammation, such as peanut oil or hand or body lotions containing lanolin's or fragrances, should not be used.

8. Number of re-uses possible: Each female condom may be used at most five times, with appropriate disinfection, washing and other preparation steps after each use.

Appendix 2

WORKSHOP SUMMARY: SCIENTIFIC EVIDENCE ON CONDOM EFFECTIVENESS FOR SEXUALLY TRANSMITTED DISEASE (STD) PREVENTION

Manufacturers must conduct real-time studies to confirm the expiration date (21 CFR 801.435) (<http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi>). Properly packaged and properly stored, condoms maintain their physical integrity over several years.

FDA researchers have also developed an assay for condom leakage using high concentrations of a laboratory virus (78). The laboratory virus penetration assay is not used routinely as a quality control test, but its sensitivity and relevance are arguably greater than the conventional water leakage test. Using this virus assay, FDA scientists tested many different types of male condoms and showed that condom's are highly effective barriers to virus passage with a very small chance of leakage (76, 77). Intact condoms (i.e., pass the water leak test) are essentially impermeable to particles the size of STD pathogens (including the smallest sexually transmitted virus, hepatitis B). Moreover, these studies show that fluid flow, not virus size, is the most important determinant of viral passage through a hole. Even holes many times larger than the virus impeded fluid flow such that few of the test particles passed though (78).

Applying results from the laboratory tests (12, 76, 77, 78), the hypothetical relative risk of exposure to semen, as a function of semen column attributable to various independent condom use events, was presented and is shown in the table below. The purpose of this relative risk assessment is to model the expected degree of protection of exposure to semen afforded by condom use, condom non-use, and condom use in the events of breakage or leakage.

Hypothetical Relative Risk Model of Condom Use

Condom Use Event	Semen Exposure (Volume, averaged over event probability)	Relative Risk Compared to Non-Use
Failure to Use a Condom	3.3 ml	1.0
Condom used , but it breaks	1 ml x 2/100	0.006
Condom used , no break but has visibly detectable hole (by water leak test)	10^{-2} ml x 1/400	0.000008
Condom used , no break, no visibly detectable holes, but still passes virus	6×10^{-6} ml x .023	0.00000004
Condom used , no break, no leak	0.0 ml	0.0



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