



WHO Information Update: Considerations regarding Reuse of the Female Condom July 2002

The World Health Organization (WHO) recommends use of a new male or female condom for every act of intercourse where there is a risk of unplanned pregnancy and/or sexually transmitted infection, including HIV. Since access to female condoms may be limited and reuse of female condoms has been reported, WHO has convened two consultations to address considerations regarding such reuse. Based on these consultations, WHO does not recommend or promote reuse of female condoms. Recognizing the urgent need for risk-reduction strategies for women who cannot or do not access new condoms, the consultation developed a draft protocol for safe handling and preparation of female condoms intended for reuse. This protocol is based on the best available evidence, but has not been extensively studied for safety and has not been evaluated for efficacy in human use.

Given the diversity of cultural and social contexts and personal circumstances under which female condom reuse may be acceptable, feasible and safe, and since the balance of risks and benefits varies according to individual settings, the final decision on whether or not to support reuse of the female condom must ultimately be taken locally.

WHO continues to support research on female condom reuse and will disseminate relevant information, study results and guidelines for policy makers as additional data on reuse become available.

BACKGROUND

The burden of sexually transmitted infections (STI), including infection with the Human Immunodeficiency Virus (HIV), the cause of the Acquired Immunodeficiency Syndrome (AIDS), continues to increase worldwide. Use of barrier methods, in particular consistent and correct use of the male latex condom, is strongly recommended as a primary means to reduce the spread of STI, including HIV. Because of the difficulties many women face in negotiating male condom use, the female condom may be an important option for women to protect themselves and their partners from both unplanned pregnancy and STI.

This information update relates only to the female condom that is currently available: a polyurethane device marketed by the Female Health Company for single use only. Reuse of the female condom has been reported, and may be motivated in part by lack of access to the device as well as its apparent robustness.

In response to requests to advise countries, programme managers and individuals on the safety of reuse practices, WHO and UNAIDS convened a consultation on the safety and feasibility of reuse of the female condom in June 2000. The consultation recognized the urgent need for risk-reduction strategies for women with limited resources who may be at risk of unplanned pregnancy and/or STI

including HIV. However, because reuse of the female condom may expose women and/or their partners to pathogens from prior acts of intercourse, either during washing or subsequent use, the meeting concluded with the determination that insufficient information on the safety of the practice existed to recommend reuse of the female condom. WHO and UNAIDS released a statement to that effect in July, 2000.¹

At the June 2000 consultation, a draft protocol for reuse was outlined and additional research to test the safety and efficacy of this protocol was commissioned. A critical feature of the protocol was a disinfection step, incorporated as the only known means of inactivating potentially infectious organisms.

CONSULTATION ON FEMALE CONDOM REUSE JANUARY 2002

WHO convened a consultation in January 2002 to review the results of the new research and to discuss programmatic issues related to reuse of the female condom.

NEW DATA

Key new information was reviewed at the meeting; highlights follow.

- Batches of new, unused female condoms were subjected to seven cycles of disinfection, washing, drying and re-lubrication, reflecting the steps and procedures in the draft protocol, but at considerably higher concentrations of bleach and for longer durations. All female condom batches met the manufacturing quality assessment specifications for structural integrity after the test cycles. (WHO-sponsored research conducted in London, United Kingdom).
- The organisms that cause gonorrhoea, chlamydia, herpes, and AIDS, when added in high titres to bull semen, were killed by a solution of common household bleach in two minutes (1:40 dilution of bleach in water) or one minute (1:20 dilution). (WHO-sponsored research conducted in Johannesburg, South Africa).
- No significant adverse effects were associated with up to five uses of a single female condom in couples not at risk of pregnancy or STI or HIV infection. Disinfection, washing, drying, re-lubrication and reuse of the device were not associated with penile discharge, symptomatic vaginal irritation or adverse colposcopic findings in study volunteers. (USAID-sponsored research conducted by Family Health International in Norfolk, VA, USA).

Based on the new research results, the draft protocol to prepare female condoms for reuse developed in 2000 was revised, retaining the bleach disinfection step in order to ensure safety.

The full report from the January 2002 consultation is available on the WHO/RHR web site.²

UNRESOLVED ISSUES

While correctly following the revised protocol may reduce the risk associated with female condom reuse, there are a number of unresolved safety questions that warrant additional clinical and laboratory testing. These include:

- How does the structural integrity of female condoms that are actually used and reused according to the protocol compare with that of unused devices?
- Following disinfection and washing, are used or reused female condoms completely free of potentially infectious organisms?

¹ WHO/UNAIDS Information Update Consultation on Re-use of the Female Condom, July 2000. Available at http://www.who.int/reproductive-health/rtis/consultation_on_re-use_of%20female_condom_Durban.en.html

² Available on <http://www.who.int/reproductive-health/rtis/index.htm>

- Does the use of alternative disinfectants, washing agents or lubricants irritate or damage cervical, vaginal, or penile tissue or alter vaginal flora?

PROGRAMMATIC ISSUES REGARDING REUSE

Given the diversity of cultural and social contexts and personal circumstances under which female condom reuse may occur, and the potential complexity of the reuse protocol, it was agreed that the final decision on whether or not to support reuse of the female condom ultimately will need to be taken locally, since the balance of risks and benefits vary according to individual settings. Programme managers should be encouraged to conduct formative and programmatic research in specific settings prior to consideration of a recommendation for reuse of female condoms, in order to establish the feasibility, benefits, risks and suitability of the practice. Some relevant questions include:

- How can the reuse protocol be best adapted to local circumstances so that potential users can easily understand and follow the instructions?
- What are the safety or health risks associated with failure to follow all of the steps of the protocol, including disinfection?
- What are the implications of female condom reuse on the correct use of other single use health care products, including male condoms?

NEXT STEPS

WHO is sponsoring research in South Africa to adapt the protocol to local conditions and evaluate the ability and willingness of sex workers and family planning clients to follow the instructions. Batches of condoms used and reused according to the instructions will be tested for structural integrity and for the presence of infectious organisms.

WHO has drafted a summary of issues for programme managers to consider when making decisions regarding female condom reuse in their local contexts. This document is currently under review and will be released as soon as it is available.

CONCLUSION

Given the available data and remaining gaps in knowledge, WHO recommends use of a new male or female condom for every act of intercourse, where there is a risk of unplanned pregnancy and/or STI/HIV infection. Recognizing the urgent need for risk-reduction strategies for women who cannot or do not access new condoms, WHO has developed a draft protocol for the safe handling and preparation of used female condoms intended for reuse. The protocol was developed using the best available evidence in order to protect the woman and her partner who have used the device, the person who washes the device, and those who may subsequently reuse the device. According to established microbiological principles, the protocol includes a disinfection step. Other practices are not known to be safe or effective in removing pathogens from the surface of the female condom or from the environment, including the water in which the devices have been washed. This protocol has not yet been studied extensively for safety or evaluated for efficacy in human use.

The feasibility and usefulness of such a protocol must be tested and established in specific contexts and settings. Decisions about the utility and risks and benefits of introducing such a protocol must ultimately be made at the country or local level.

Based on the recommendations of the January 2002 consultation, WHO does not recommend or promote reuse of female condoms, but will make available the protocol, together with guidelines on programmatic issues, to programme managers who intend to evaluate its feasibility and application in local settings. The Organization continues to support research on female condom reuse and will disseminate relevant information, study results and guidelines for policy makers as additional data on reuse become available.

For further information about reuse of the female condom, please contact Dr Tim Farley:

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