The Safety and Feasibility of Female Condom Reuse: Report of a WHO Consultation

28-29 January 2002

Geneva

Acronyms

AQL	Accepted Quality Levels
FHI	Family Health International
HIV	Human Immunodeficiency Virus
IEC	Information, Education, and Counselling
STI	Sexually Transmitted Infection
QA	Quality Assurance
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization

Table of Contents

Executive Summary

Background

The female condom is a polyurethane sheath that loosely lines the vagina. The device is designed and approved as a contraceptive and as a method to prevent sexually transmitted infections (STI). Due in part to the relatively high cost of the female condom as a single use product, wide-scale distribution by donors and national or local health programmes has been limited. It is believed that limited availability and high cost have led some women to reuse female condoms; use of the same device for more than one act of intercourse, including with different partners, has been reported. In order to provide guidance to programme managers and policy-makers on the advisability of reuse, the World Health Organization (WHO) and the United States Agency for International Development (USAID) have funded research on the safety of this practice.

In June 2000, WHO and UNAIDS convened a meeting of experts in order to evaluate knowledge on the safety of female condom reuse and consider the programmatic implications of the practice. The meeting participants concluded that the available evidence on safety was not sufficient to recommend reuse of the female condom. However, the group recognized the urgent need to provide guidance to women who do reuse the female condom despite current instructions for single use. The group outlined a draft protocol for safe handling and preparation of used female condoms; this protocol included disinfection in a bleach solution prior to washing. The draft protocol needed to be evaluated for its safety and effectiveness, and studies were commissioned by WHO and USAID to: 1) assess the impact of the protocol on the structural integrity of the female condom; 2) establish the minimum disinfection procedure required to inactivate infectious organisms; and 3) determine the impact of the disinfection/cleaning regimen on human tissue.

WHO convened a second consultation in January 2002, to review the results of the new research together with other recently completed studies, and to discuss in more detail programmatic issues related to reuse of the female condom.

New results

The research results on the physical properties of the female condom were encouraging. 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 for used condoms, but at considerably higher concentrations of bleach and for longer durations. In the "disinfection" step of each cycle, the condoms were soaked in a 1:4 dilution of bleach for 30 minutes. All female condom batches met the manufacturing quality assessment specifications after the test cycles.

The microbiological study demonstrated that a relatively simple disinfection procedure was effective in inactivating the infectious organisms that cause gonorrhoea, chlamydia, herpes and HIV infections when these organisms are added to bull semen. A one-minute exposure to a 1:80 dilution of household bleach was sufficient to inactivate herpes simplex virus; a 1:40 dilution of the bleach solution also killed *gonococci* and human immunodeficiency virus (HIV) within one minute. All of the organisms, including *chlamydia,* were inactivated following a one-minute exposure to a 1:20 dilution of household bleach.

The results of a human use safety study supported by USAID were also encouraging. Couples not at risk for STI or HIV infection who used the same female condom for five consecutive acts of intercourse had no more urogenital lesions or clinical findings on colposcopy than did couples who used a new female condom for each of five sex acts.

In light of the new research findings, the draft (June 2000) protocol for safe reuse of the female condom was reconsidered. The disinfection step was simplified to a 1:20 dilution of household bleach for 1 minute and the maximum number of uses was set at five. The generic protocol and instructions on safe reuse must be adapted to local circumstances and settings.

Practicality and feasibility

Issues related to multiple uses of female condoms were extensively discussed. Meeting participants examined cultural and social contexts and personal circumstances under which female condom reuse would be acceptable, feasible and safe. Other contexts and circumstances in which reuse would not be acceptable or practical were also discussed; reuse in such settings could not be considered safe or advisable. It was agreed that the final decision on whether or not to support reuse of the female condom will ultimately need to be taken locally, since the balance of risks and benefits varies according to individual settings.

Disinfection of the female condoms prior to any further handling had been strongly recommended by the consultation in June 2000; the research conducted as a result of that consultation had addressed different aspects of a bleach disinfection step. A minimum bleach soak that adequately disinfected the condoms had been determined, there was a safety margin with respect to the physical properties of the condoms, and there was no evidence of damage to the vagina or penis from any residues of bleach that might have remained on the condom after rinsing. However, the requirement to disinfect was perceived as a barrier to reuse in some circumstances and arguments were advanced that the disinfection step was neither necessary nor practical. After lengthy discussion the majority view was that disinfection remain in the protocol. Simply washing used condoms in soap and water could pose considerable safety risks when used in circumstances of high STI/HIV risk. Since one of the main reasons for using a female condom was to protect women and their partners from STI, disinfection of used condoms was deemed necessary. There was no evidence that soap and water washing alone was safe; it would be almost impossible to generate such evidence, and there were compelling reasons expressed by the microbiologists to insist on disinfection.

Conclusions and further work

Additional research on the feasibility of correctly following the guidelines for safe reuse, and on the resulting structural integrity of female condoms exposed to the disinfection and washing procedure, combined with actual use of the devices, is planned in South Africa with WHO support. Decision-makers should be encouraged to conduct similar or other formative and programmatic research in specific individual settings prior to issuing recommendations regarding female condom reuse. Other outstanding research questions related to the efficacy of reused female condoms and to the programmatic impact of the introduction of reuse guidance were identified.

While the consultation concluded that local decision-makers must establish the feasibility, benefits and suitability of promoting female condom reuse, WHO will develop summary guidance of issues for programme managers to consider when making such an assessment.

Introduction

Many women face difficulties in negotiating the use of male condoms. The female condom may therefore be an important option to assist women in protecting themselves and their partners from both unwanted pregnancy and sexually transmitted infections (STI).

Some women have reported using the same female condom for multiple sex acts, a behaviour said to be motivated by the high cost or limited availability of the device as well as by its perceived strength. Such practices may expose women or their partners to pathogens during washing or subsequent reuse of the female condom, especially for populations living in areas of high STI/HIV prevalence.

In response to requests for advice on the practice of reuse of the female condom, WHO and UNAIDS convened an experts' consultation in June 2000 on the safety and feasibility of multiple uses of a single female condom. The consultation concluded with the recognition of the need for risk-reduction strategies for women with limited resources who may be at risk of unplanned pregnancy and/or sexually transmitted infections including HIV. The consultation determined that currently available evidence regarding the safety of reuse was not conclusive and that reuse of a single female condom could not be recommended. However, the panel also recognized the urgent need to provide guidance to women who may currently be reusing the female condom. It was agreed that used female condoms should be disinfected before being washed and handled in order to reduce the risk of exposure to HIV and other pathogens. A draft protocol for safe preparation of used female condoms for additional use, based on theoretical considerations regarding disinfection, washing, drying, storage and re-lubrication, was formulated. The panel recognized the absence of data on the effectiveness of inactivating or eliminating microorganisms while maintaining the structural integrity of the device. Two key research studies addressing these issues were subsequently commissioned by WHO. A third study supported by USAID was designed to evaluate the effect of the disinfection/cleaning protocol on human urogenital tissue.

According to the recommendations of the first consultation, this second meeting (January 2002) was planned to review the resulting data and to develop further guidance on the safety of reuse of the female condom. The specific objectives and anticipated outcomes of this second consultation were to:

- Review the results and evaluate the implications of the recently completed microbiology and structural integrity experiments and the human use study;

- Develop a protocol or set of instructions for disinfecting and cleaning used female condoms safely;

- Outline future research areas and related issues for programme managers to consider when determining the balance of risks and benefits of female condom reuse in various contexts and settings.

While it is anticipated that correctly following the guidance of the reuse protocol may reduce the risk of infection associated with reuse, other questions of safety and feasibility of this practice remain unresolved. While not exhaustive, the list below presents some examples of questions that were discussed at the consultation:

- Do women have the resources to follow the reuse protocol correctly? What are the risks if they do not?

- Are used or reused female condoms, prepared and used according to the instructions, free of potentially infectious organisms and safe to use?

- What are the effects on normal vaginal and cervical epithelium or flora of any residuals from disinfection, washing, re-lubrication, or of possible damage to or contamination of the prepared and reused female condom?

As did the previous consultation, this meeting brought together experts in microbiology, sexually transmitted infections, condom production and quality assurance testing, and programmatic issues. Two members of the Department of Reproductive Health and Research's Gender Advisory Panel, a representative of the Specialist Panel on Social Science and Operations Research, and representatives of in-country female condom programmes also attended. Overall, nineteen participants, ten representatives of collaborating agencies and donors, and two observers were invited to attend the consultation.

Reports on the New Research Data

Structural integrity

Dr Bill Potter reported on the results of the structural integrity study that was commissioned by WHO following the first consultation on reuse. A copy of the draft manuscript and of Dr Potter's presentation was included in the meeting background documents.

The meeting participants were reminded that the study was designed to assess an extreme way of disinfecting the female condoms, in order to build in or establish a margin of safety in an eventual set of reuse instructions.

Background: In prior studies, limited numbers of condoms had been analysed for structural integrity following multiple use/washing cycles according to various protocols. The impact of a disinfection step on the integrity of female condoms had not been adequately assessed. The purpose of the present study was to evaluate the effects of a bleach disinfection step on the structural integrity of sufficient numbers of female condoms from different production batches to obtain statistical power. The disinfection involved a 30-minute exposure to a 1 in 5 dilution of sodium hypochlorite bleach in water (1% sodium hypochlorite).

Methods: The study was conducted at the Female Health Company manufacturing facilities in August-September 2000. The integrity of condoms was evaluated following seven cycles, each made up of the following steps: disinfect – wash – dry – re-lubricate. Three batches of 300 condoms/batch were treated. Vegetable oil was chosen as a lubricant because of its wide availability, the likelihood that it would be used in real life settings, and the concern that the oil could damage the condoms. In keeping with the draft protocol developed in June 2000, which recommended that the condoms not be stored while lubricated, but that the lubricant be added just prior to use, condoms were re-lubricated 30 minutes prior to the initiation of the subsequent disinfection cycle. The structural integrity assays required that the condoms be lubricated, so an additional, final re-lubrication step immediately before testing was incorporated. Inner rings were removed for all procedures, as they are not evaluated in tests of structural integrity.

Results: Washing is an effective means by which to remove the lubricant. The condoms were fully dry in 1 hour's time (dried over pegs). The original quality assurance (QA) testing revealed no holes in the batches before the condoms were subjected to the disinfection and washing. Following the 7 cycles of disinfection and washing, 3 of 600 condoms tested with the water leakage test had holes. The tears appeared to have been caused by physical, not chemical, damage. While this result was within the accepted quality levels (AQL), the evidence indicates that there probably is an increase in the number of holes following this amount of handling. All other tests (peak pressure, burst pressure, burst volume, seam strength) indicated a change in the structure of the condoms, though all data remained within the manufacturer's release specifications.

Conclusions & Recommendations: Although there was a small increase in the number of holes as a result of this process, all 3 batches met release specifications after 7 disinfection cycles. Based on these data, it was decided that use of a single female condom to a maximum of 5 times is safe and acceptable. This upper limit was set below the number of cycles tested to provide a margin of safety. Condoms should be disinfected as soon as possible after use and washed following the disinfection step. They should not be exposed to greater concentrations of, or time in, bleach solution than that evaluated in this protocol. Condoms should be washed gently with diluted liquid dish soap or the lather from bar soap in order to avoid the use of abrasive cleansers or cleaning practices. The condoms should be dried with a clean paper towel or air-dried. Visual inspection of the condoms for holes is recommended. The condom should be stored dry and lubricated just prior to use.

General discussion: The meeting participants were encouraged by the data, since the condom material appears to be robust and able to withstand the chemical effects of the disinfection and washing steps, as tested. While there was an acknowledgement that the mechanical action of intercourse could increase the risk of holes, it was not expected that the use of different lubricants or soaps would lead to significant levels of damage to the condoms. It was also noted that careful handling during washing would be necessary to maintain condom integrity and avoid tearing the device.

Microbial disinfection

Dr Ron Ballard presented data from the WHO-commissioned study to evaluate the minimal duration and concentration of bleach exposure required to inactivate HIV, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and herpes simplex virus type 2 (HSV-2) in bull semen. A copy of the report and presentation was available to the meeting participants.

Background: At the June 2000 consultation, it was agreed that used female condoms should be disinfected before being washed and further handled in order to protect women and their close contacts (including sexual partners and others who may come in contact with the used device either while handling it following use or during a subsequent act of intercourse) from exposure to HIV and other sexually transmissible pathogens. These follow-up studies were conducted to determine the minimal concentration and duration of a soak in liquid household (sodium hypochlorite) bleach, following use and prior to subsequent washing and reuse, in order to inactivate a variety of such pathogens prior to cleaning, drying, storing and reusing used female condoms.

Methods: The experiments were conducted in three phases. The first was designed to determine whether bull semen could be used in subsequent experiments. The second phase was designed to determine which concentrations of bleach should be tested in the final phase

together with the minimum duration of exposure required to inactivate the four pathogens. The third and final phase was performed in female condoms to obtain a definitive bleach concentration and duration of exposure that would be effective in inactivating the pathogens in the presence of silicone lubricant (used in the manufacture of new condoms) or vegetable oil (which may be used to lubricate condoms that had been previously used, disinfected, washed and dried).

Results: Phase I: The bull semen dispersed easily into the sodium hypochlorite solution and no clumping or precipitation of proteins occurred. Samples from the water control yielded numerous *N. gonorrhoeae* colonies, indicating that the assay system was valid according to this positive control. Sodium hypochlorite was an effective disinfectant for this bacterium, even at the lowest concentration tested (0.125%, 1 in 40) at all times tested (1-16 minutes). Bleach concentrations of 0.25% (1 in 20), 0.125% (1 in 40), and 0.0625% (1 in 80) and disinfectant exposure times of 1, 2, and 4 minutes were selected for testing in the subsequent experiments. Phase II: *C. trachomatis* was found to be marginally more resistant to disinfection than the other STI organisms tested. This pathogen required exposure to 0.25% sodium hypochlorite for 1 minute or more for the complete destruction of its DNA. All other organisms were inactivated by a 1 minute exposure to 0.125% sodium hypochlorite. Phase III: The results of experiments conducted in female condoms reflected those obtained from the studies done in beakers (Phase II). No differences in the susceptibility of the pathogens to disinfection were detected when comparing new condoms with those that had been previously washed, dried and re-lubricated with vegetable oil.

Conclusions & Recommendations: Bull semen was used as a surrogate for human semen in experiments to determine the most appropriate bleach concentration and duration of exposure required to disinfect female condoms after use. Exposure to a concentration of 0.125% sodium hypochlorite for as short a period as 1 minute resulted in disruption of the HIV, *N. gonorrhoeae*, and HSV-2 organisms. *C. trachomatis* was consistently found to be the most resistant to disinfection, with 100% inhibition occurring at a concentration of 1 in 20 (0.25%) sodium hypochlorite when exposed for 1 minute. Exposure to a 1 in 20 dilution of sodium hypochlorite for 1 minute is the minimum concentration and duration that could be recommended to adequately disinfect female condoms from four common sexual pathogens if reuse is to be considered.

General discussion: The discussion following the presentation focused heavily on the possible effects of soap and water washing alone and of air-drying on infectious and potentially infectious organisms. While it was agreed that soaps could remove pathogens from a used condom, these products will not kill or inactivate pathogens, and are therefore not recognized by microbiologists or the public health community as being disinfectants. Despite a soap wash, the organisms could remain viable and infectious. Air-drying could reduce the number of infectious organisms on a used female condom, but, again, would not act as a disinfectant. These practices may not protect the person who is handling the used condom from exposure to potentially infectious pathogens if they were present on the condom at the time of washing. Moreover, due to the shape and structure of the female condom, complete air-drying may be difficult to achieve, and should not be relied upon to kill pathogens.

Any guidance to be issued by WHO must be supported by evidence of its safety and efficacy. Soap and water are not recognized disinfectants. Bleach is a widely available disinfectant and is effective in removing and inactivating, or killing, a number of pathogens, including several of those that cause STI. Due to the lack of evidence regarding the safety or efficacy of a soap and water wash in inactivating infectious organisms, and strong concerns that disinfection is

necessary for inactivation, any regimen that does not include a disinfection step cannot be recommended. Guidelines will be limited to the inclusion of recognized and defined practices of disinfection.

Limitations of the study were discussed. It was agreed that several pathogens of potential interest were not tested. Sodium hypochlorite bleach was selected for evaluation because it had been agreed at the first consultation that this was the most commonly available disinfectant. However, interpretation of results is limited to this particular bleach type, and cannot necessarily be extrapolated to other disinfectants.

It was acknowledged that condom users and any sexually active person might be exposed to infectious pathogens through the sex act or through contact with used male or female condoms, even if they are not intended for reuse. Providers and programmes that supply condoms, either male or female, should ensure that their clients understand that, once used, the products may contain potentially infectious material and should encourage appropriate disposal of these products. Any message developed as a result of the consultation will be specifically tailored to those who choose to reuse female condoms, so that they can do so as safely as possible.

Safety in human use

Ms Carol Joanis and Dr Susan Ballagh introduced and presented a study supported by Family Health International, through funding from USAID, and conducted in collaboration with the Eastern Virginia Medical School in Norfolk, VA, USA. Copies of the presentations of this study were available to meeting participants.

Background: The study was designed to evaluate the safety of female condom reuse by assessing the possible impact of residual bleach and soap, if any, on vaginal, cervical, and penile tissues. The study evaluated evidence of genital findings; vaginal or penile discharge; non-menstrual bleeding; signs, symptoms or reports of irritation; device breakage; and use of lubricants and cleaning agents. It was hypothesized that the proportion of participants experiencing a genital finding in the reuse group would not be higher than that in a control (single-use) group. A secondary objective was to evaluate the structural integrity of the used condoms following intercourse, disinfection, washing and re-lubrication.

Methods: This was a comparative, randomized, single-masked clinical trial in a population protected from pregnancy and not considered to be at risk of STI or HIV infection. Couples were recruited to use a single female condom for 5 acts of intercourse (reuse group), or to use a new female condom for each of 5 acts of intercourse (control group). Couples in the reuse group were instructed to adhere to a specified disinfection and cleaning procedure (as identified in June 2000) following each use of the female condom. The bleach disinfection step in these experiments was a 30-minute soak at 1 in 5 dilution. Couples in the control group were also instructed to disinfect and clean each condom after use. All couples were instructed to use their condom(s) for 5 consecutive acts of vaginal intercourse over a fifteen-day period. Colposcopy was used to evaluate the female partner for any signs of irritation; magnification was used to inspect the male genitalia. These examinations were carried out at baseline and at the end of the study. The condoms from the control group were tested for holes after one use, disinfection and washing; the condoms used by the reuse group were tested after the 5^{th} use, disinfection and washing.

Results: In the reuse group 35 couples completed the study; 39 couples completed their participation in the control group. Colposcopy was used to evaluate the vaginal epithelium and the cervix for colour changes, disruption of the epithelium, disrupted blood vessels, and other genitourinary adverse events. No differences in any of the endpoints were described for either of the groups compared to baseline or to each other. Similarly, there were no differences in genitourinary findings described for the male partner. Of the 195 condoms used by the control group, 17 leaked in laboratory testing as a result of holes. Sixteen of these 17 holes were in the 0-4 mm zone at the base of the condom; such holes are generally caused by the test methodology and, therefore, the manufacturing standards do not consider holes found in this region of the condom. Two control condoms broke in use, one each during the processes of removal and cleaning. Of the 35 female condoms used by the reuse group, one leaked in laboratory testing due to a hole in the 0-4 mm zone; two of these condoms broke during use - one during insertion and one during intercourse. Participants reported that the condom stayed in place better, i.e. there was less slippage, when the condoms were reused. They also indicated that the female condom became less sensitive with each use. Study participants had difficulties in selecting the appropriate amount of lubricant to apply, and they found the disinfectant smell unpleasant.

Conclusions & Recommendations: This trial did not demonstrate any significant difficulty with a total of 5 uses of a single female condom, based on adverse events for the couples or findings evident on examination. Disinfection, washing, drying, re-lubrication and reuse of the female condom, as evaluated in this study of couples not at risk of pregnancy or STI or HIV infection, is feasible and not associated with penile discharge, symptomatic vaginal irritation, or adverse colposcopic findings.

General discussion: The participants found the presentation of this data to be encouraging, as it indicated that the condom was not significantly damaged and that any residue of the disinfectant or soap was either thoroughly removed or did not pose a safety risk to either partner. The colposcopy findings presented in the data are normal for sexually active women and were not considered to be pathological or otherwise significant. There was some discussion about the utility of evaluating the same endpoints in women who used a male condom during intercourse and women who had abstained from intercourse to compare the effects of intercourse on the numbers and kinds of colposcopic findings. It was noted that these results were obtained in couples not at risk of STI.

The women in the study used K-Y liquid to re-lubricate the used condoms. There were several questions related to the effects of alternative lubricants or soaps on the vaginal epithelium, and Dr Ballagh proposed that the use of these products carried little or no safety risk, especially considering that the exposure time of the vagina to the female condom is, in most cases, rather short.

The number of breaks in the reuse group was noted. Of 35 condoms that were used a maximum of 5 times, 2 broke during insertion or intercourse. The participants in the study were instructed to handle the condoms gently, but the disinfection and washing procedures did require significant handling of the condoms. Additionally, the physical stress caused by intercourse could have compromised the condoms. In previous studies, women had noted some holes on visual inspection of the condoms; however, additional holes were discovered during the laboratory testing. Ms Joanis indicated that similar breakage rates are reported in studies of male condoms.

The issues of storage of a used female condom and monitoring the number of uses of each device were raised but were considered more appropriate for a discussion of programmatic issues.

The group agreed that issues related to the instructions for and implementation of a safe protocol for preparation of used condoms for reuse would be context-specific and would need to be adapted for individual settings.

Minimum Requirements for Safe Preparation of Used Female Condoms

The discussion was opened with the suggestion to develop two levels of instruction - an optimum level, based on Dr Ballard's microbiological results, and another, minimum level that provided a functional level of pathogen removal and which would presumably be simpler. However, it was felt that this was inappropriate at this time, since no evidence exists to support the safety of any regimen other than sodium hypochlorite disinfection.

There was general agreement and support for developing an appropriate cleaning protocol including disinfection, along the lines suggested by Dr Ballard's research results. Indeed, in light of the need to inactivate pathogens in order to prevent infection and the lack of evidence regarding the potential of any other regimen to do so, it was agreed that a protocol that includes a disinfection step would be the only kind that would be evidence-based and therefore ethical to develop.

Several participants felt that a simpler protocol that did not involve bleach, but relied on adequate (undefined) washing and drying, could also be considered for development as a minimal approach. However, there is no scientific evidence that any process, other than using a known disinfectant, will kill potentially infectious organisms. It was generally accepted that there was insufficient information available on the safety or efficacy of any alternative approach. The need for disinfection was expressed and generally supported; any protocol that did not require bleach disinfection was therefore not pursued, but left open to be re-considered if more information becomes available.

Some participants expressed their concern that, due to a lack of appropriate resources such as running water and bleach in some settings, promoting reuse in these contexts would not be advisable. Specific policy realities in the region may also provide a broad context in which the promotion of reuse would be inappropriate. Specifically, needle disinfection programmes have not succeeded in Brazil, and the public health community discourages the reuse of any disposable medical or health equipment. The endorsement of female condom reuse may communicate conflicting messages to the public.

The participants addressed the issue of revising the draft reuse instructions developed at the June 2000 meeting. It was agreed that instructions written for users would be different from those for programme managers. The meeting participants nonetheless worked on a single set of core instructions, which was intended to be adapted to local conditions. The programmatic questions would be considered separately.

The modified (January 2002) protocol for preparing female condoms for reuse is attached in the Appendix. This draft protocol is not a WHO recommendation for reuse of the female condom or a recommended protocol for reuse. Rather, it is provided for further investigation so that local authorities can determine the feasibility, benefits and suitability of its use. It is

applicable only to the polyurethane female condom as manufactured by the Female Health Company.

WHO continues to recommend the use of a new male or female condom for every act of intercourse for those individuals who use condoms for pregnancy prevention or STI/HIV prevention, or both.

Programmatic Issues

Ms Perveen Rasheed presented an overview of programmatic issues related to reuse of the female condom. She began her presentation by stating that, currently, we have only a limited and superficial knowledge of the prevalence of reuse and the range of reuse practices that are being exercised; however, with increased provision of female condoms in country programmes, the number of women who reuse the device may also increase. Ms Rasheed presented the factors influencing reuse and the factors that may influence the discontinuation of reuse. She highlighted the factors that may impede safe reuse in resource-poor countries including access to clean water, costs and types of disinfection and cleaning agents, time costs, space for washing, climate conditions, psychosocial factors, the context of commercial sex work, and – most importantly, according to Ms Rasheed – compliance to a safe protocol. She also raised questions related to the assumption of responsibility in the case of problems resulting from the distribution of information on female condom reuse through a formal protocol – would liability rest with the manufacturer, WHO, or the local health programme? She discussed the potential confusion that may result from mixed messages regarding health products that are promoted for one-time use and the fear that these products may be reused as well, if female condoms are promoted as reusable. Ms Rasheed raised the concern that any protocol for female condom reuse must be "doable," that is feasible and acceptable, and that in cases of local adaptation there would need to be local standards that would prevent slippage away from safe practices. She felt that, if a recommendation for female condom reuse is put in place, research would be required to evaluate the costs of IEC and staff training and to test the implementation of such a protocol and the implications of following or deviating from that protocol. Her final point was that the balance of risks and benefits will vary in different settings; in some settings reuse may not make sense.

Professor Helen Rees then introduced "Risk benefit of female condom reuse. The next steps?", a presentation in which she described a hierarchical model of risk reduction. According to Dr Rees' thesis, the risks related to reuse are: hand contamination with pathogens, other exposure to pathogens, lack of acceptability, non-compliance with a complex protocol, and the non-use of bleach. Most of the risk stems from possible deviations from the recommended protocol, specifically the omission of the bleach soak. On the other hand, the described benefits might include: increased uptake of the female condom in high HIV/STI prevalence settings, a possible increase in the number of protected sex acts, and a subsequent decrease in unplanned pregnancy, STI, and HIV infections. A hierarchical model based on informed choice would offer an option of the following, listed in preferential order: new male condom, new female condom, used female condom disinfected with bleach, used female condom washed with soap and water, if this is shown to be safe; the recommendation would indicate that it is not safe to wash the female condom in water alone. Dr Rees discussed the issue of monitoring and surveillance and indicated that the feasibility and acceptability of any protocol, especially regarding the disinfection step, will have to be evaluated locally.

The discussions following the presentations centred mainly on various cultural contexts which would be enabling or disabling for safe reuse of the female condom. A summary of the discussion follows.

1. The final decision on whether or not to introduce the concept and protocol for female condom reuse will need to be taken locally and will require consideration of the following:

    - Existing local practices regarding female condom use and reuse;
    - Access to new male and female condoms;
    - Local availability of suitable disinfection, cleaning and lubricating materials as well as suitable utensils and water;
    - Local attitudes to handling soiled articles and access to private washing facilities;
    - The risks associated with non-compliance with the recommended reuse procedures;
    - The local risk/benefit balance, i.e. the potential to achieve increased numbers of protected sexual acts versus the risk of migration from the preferred use of new male and female condoms to the less preferred reuse of female condoms.

2. In order to assist programme managers and health counsellors to reach an appropriate decision regarding reuse, very careful consideration will have to be given to the wording of all guidance documentation.

3. The core reuse protocol needs to be interpreted and adapted by programme managers and health care providers, taking into account local conditions and the availability of suitable disinfection, cleaning and lubrication materials. Local instructions should be developed with the cooperation of representative female condom users and health care workers. The core protocol and guidelines on reuse need to be sufficiently comprehensive to ensure that adequate direction is given to programme managers and providers to allow them to develop appropriate reuse instructions.

4. Strategies for counselling, training and monitoring reuse practices need to be developed. Feasibility studies on reuse prior to general implementation are strongly recommended.

5. Implications for the effects that advice and directions on the reuse of female condoms may have on behaviour, especially as related to the use of other barrier methods, and indeed other health care products, need to be considered carefully. For example, advice on the reuse of female condoms may result in reuse of the male condom or the use of inappropriate lubricants with male condoms.

In light of the many complexities related to female condom reuse and the importance of the country-level messages, Drs Tim Farley and Mary Latka invited a sub-group of meeting participants to work together to identify programmatic issues relevant for programme managers in their work to adapt a reuse protocol to local circumstances. The group convened in New York (NY, USA) in May 2002. The report of the group will include an outline of issues that a programme manager needs to consider when determining the local balances of risks and benefits of female condom reuse.

Outstanding Research Issues

Three main areas of research were identified:

1. The issue of whether washing used female condoms in soap and water could make them safe for reuse was identified as a major research question. Some participants pressed for experiments to determine whether infectious STI pathogens would be left on the condom after a soap and water wash alone. However, such research would be difficult to standardize and conduct. Soap and water washing, even in large quantities of water, can dilute potentially infectious materials, but is not a method of disinfection.

2. Decision makers and consumers need information about the comparative efficacy of methods. In this case, they will want to know something about the *in vivo* efficacy of reused female condoms compared to new female condoms. For example, would the pregnancy or STI rate be higher among women using reused female condoms compared to women who use a new device for each act of intercourse? Methodologies or designs that could give this information would need to be refined.

3. Operational research after the introduction of guidelines for reuse would include:

    a) Studies to assess whether the suggested reuse protocol is safe *in vivo*. These studies could be conducted through passive surveillance for adverse outcomes (a phase IV approach) or by enrolling participants into a trial of the protocol for reuse (a phase III approach).

    b) It may be possible to evaluate the safety of other cleaning and reuse practices, such as one that does not include a disinfection step, either before or after the introduction of any reuse guidelines. This could be accomplished either through phase III clinical trials (if these are deemed ethical) or through phase IV surveillance for adverse events. However, an observational approach would be subject to selection bias that would make interpretation of the results very difficult.

    c) Studies to determine whether the "method mix" is altered by introduction of any guidance for female condom reuse. That is, does dissemination of a protocol for reuse increase the reuse of the device and/or encourage migration away from use of the male condom or single use of the female condom? Would the availability of such a protocol increase the percentage of protected sex acts? Would it increase access to and availability of the female condom in country programmes?

Additional research questions were also identified:

- The feasibility and acceptability of performing the protocol as prescribed;

- *In vitro* studies to determine: (a) the required concentration and exposure time for alternative disinfectants, and (b) the effects of various lubricants on the structural integrity of the material from which the condoms are manufactured.

Advice to WHO

It was proposed that WHO should craft a statement regarding female condom reuse, based on the results discussed and the conclusions drawn at the consultation. Much of the discussion

revolved around the differences between promoting/encouraging reuse and providing a safe protocol for women who practice reuse. It was suggested that the purpose of any WHO statement should not be to promote the female condom as a reusable device, but instead to offer guidance to local authorities who can, in turn, make a local determination of how best to advise women who, for whatever reason, do not avail themselves of new male or female condoms as needed.

Conclusions

Based on the evidence to date, it is possible to develop a protocol for the safe handling of used female condoms intended for reuse. Such a protocol must protect the woman and her partner who have used the device, the person who will be washing the device after use, and those who may come in contact with the used device. According to established microbiological principles, such a protocol would require a disinfection step. Other practices are not known to be safe or effective in removing pathogens from the surface of the female condom and from the environment, including the water in which the devices are washed.

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. WHO will continue to advise the use of a new male or female condom for couples at risk of unplanned pregnancy and/or STI/HIV infection. WHO will not recommend or promote reuse of the female condom, but will make available the protocol, together with programmatic guidelines, to programmes that wish to test its feasibility or efficacy in local settings. The Organization will continue to support research on female condom reuse and disseminate relevant information, study results and service delivery guidelines as additional data become available.

Appendix: Draft Protocol for Preparing Female Condoms when They are Reused

This protocol is **not** a WHO recommendation for reuse of the female condom or a recommended protocol for reuse. Rather it is provided for further investigation so that local authorities can determine the feasibility, benefits, and suitability of its use. It 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.

Comments contained in brackets [] were raised at the consultation and should be incorporated into a companion document for programme managers, to guide them in the development of context-specific instructions.

WHO continues to recommend use of a new male or female condom for every act of intercourse for those individuals who use condoms for pregnancy prevention and/or STI/HIV prevention.

1. Remove the condom from the vagina, taking care to avoid spillage of semen.

2. Disinfection: As soon as possible, prepare about 250 ml of approximately 1:20 dilution of sodium 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.

   - [Do not soak the condom in bleach overnight, as the extended exposure to bleach can degrade the condom material.]

   - 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 body fluids and lubricant.

   - Remove the inner ring.

   - Hands should be lathered with non-abrasive soap. [Avoid washing female condom 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.

- Wash condom thoroughly to make sure that all lubricant is removed.

- 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 or paper towel. 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 female 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 discarded. If no holes are observed, replace the inner ring.

6. Storage: The cleaned, dry, 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 increased levels of breakage during use.]

7. Re-lubrication: Replacing the lubricants removed by disinfection and washing is necessary to make insertion of the condom easier and to make intercourse more comfortable. Re-lubricate just prior to reuse.

   - Optimal lubricants include silicone and water-based lubricants. [Examples to be identified and provided in-country.]

   - Inert oil-based lubricants (petroleum jelly, baby oil, vegetable oil or shortening) may be used. [Although these cannot be used with male latex condoms.]

   - Lubricants which contain substances which may induce allergies or inflammation, such as peanut or groundnut oil, or hand or body lotions containing lanolin or fragrances, should not be used.

8. Number of reuses possible: Each female condom may be used at most 5 times, with the appropriate disinfection, washing and other preparation steps after each use. [It may be difficult for users to track the number of times any individual device is used. With additional use, the condom material may weaken and may tear during use. Excessive handling, in addition to disinfection, washing, drying and re-lubrication, may contribute to tearing. Tearing is most likely when condoms are not handled gently.]