HIV/AIDS makes dual protection a must

Most heterosexual individuals who have sexual intercourse desire to protect themselves from unwanted pregnancy most of the time. Virtually all individuals all of the time wish to avoid infections that can be sexually transmitted, particularly of the most deadly and increasingly prevalent variety, the HIV infection. It is not surprising therefore that people have started to ask: can both objectives be achieved simultaneously?

Certainly, most family planning methods do not provide protection against infection. And the methods available for infection prevention may not protect effectively against unwanted pregnancy. Sterilization, intrauterine devices (IUDs), injectables, implants and oral contraceptives, for example, provide no protection against infection, and the protective efficacy of most existing female-controlled barrier methods—caps, diaphragms, and foams or gels—is not as well proven as is the protective effect of condoms against infection.

In fact, today, the condom is the only method that, when used correctly and consistently, can at one and the same time effectively protect against both pregnancy and infection.

A gap in the dual protection armamentarium that reproductive health services and their users would sorely like to see filled is a safe, effective, dual-purpose microbicide-spermicide. HRP-supported research is looking at a promising product, a cellulose sulfate gel, but it is still in the early stages of clinical testing (page 6). Another product, nonoxynol-9, which was also considered promising, has just been found not to be effective as a microbicide (page 6).
Dual protection—who needs it and why

Family planning programmes have made considerable progress in providing contraception to couples—witness the fact that nearly two-thirds of couples use contraceptives today, up sixfold from the 1970s. However, sexually transmitted infections (STIs) continue to spread rapidly throughout the world, especially in developing countries. The spread of HIV certainly heightens the need for dual protection, particularly in areas where HIV is prevalent and where women wishing to adopt or continue using contraceptives would probably welcome a method that protects them—and thereby their future offspring—against HIV/AIDS. (Most HIV-infected children under ten have contracted the infection from their mothers).

In counselling their clients about the different methods of contraception, reproductive health services should convey the fact that many methods (e.g. hormonal methods of contraception, intrauterine devices, and sterilization), although highly effective against pregnancy, offer no protection against STIs, including HIV infection. By contrast, the condom, when used correctly and consistently, not only prevents these infections but can also be an effective contraceptive.

Governments and reproductive health programmes, both public and private, should ensure that service providers and users understand how effective condoms are for dual protection, so that they can provide the most useful and appropriate information to their clients who are sexually active and at risk.

Dual protection is needed by:

- sexually active people between the ages of 15 and 24—a population group that accounts for over half of newly acquired HIV infections;
- men and women who put their partners at risk because of their own risky sexual behaviour or who are put at risk by the sexual behaviour of their partners;
- sexually active people in settings where STIs and/or HIV are highly prevalent;
- sex workers and their clients;
- people who actually have an STI and/or HIV, and their partners.

The International Conference on Population and Development (ICPD), and the recent review of progress made since that Conference (ICPD + 5), clearly identified family planning and the prevention of HIV/AIDS as major objectives. Putting dual protection into practice to fulfill both of these objectives simultaneously requires governments, international agencies, and reproductive health programmes, among others, to ensure:

- maximum integration of family planning and STI/HIV prevention services;
- the training and retraining of service providers and counsellors to enable clients to make free and informed decisions about dual protection;
- availability of condoms at service delivery points and other outlets;
- the appropriate introduction of female condoms into reproductive health programmes;
- the incorporation of dual protection into programmes for the prevention of mother-to-child transmission of HIV;
- continuing support for research on the development of a female-controlled microbicide.

Source:
Research has clearly documented the effectiveness of male latex condoms both in preventing unintended pregnancy and in providing a barrier to sexually transmitted bacteria or viruses.

Condoms have long been the mainstay of HIV prevention. In 1999, a meta-analysis of 25 studies found condoms to be 87–96% effective in preventing HIV transmission between "discordant" couples, i.e. with one partner infected (1). What is more, women whose partners use condoms are at a lower risk of hospitalization for pelvic inflammatory disease, a condition that can result in infertility, than those whose partners do not use condoms (2).

Condoms—dual-purpose barriers

The effectiveness of condoms, whether for single- or dual-purpose protection, depends very much on how assiduously people, particularly men, use them. And that depends on how highly they rate the importance and convenience of condoms both as contraceptives and as barriers to infection, and in relation to other single-purpose contraceptive methods.

To find answers to both questions, HRP has launched a wide-ranging series of social science studies in countries where HIV is highly prevalent or threatens to become so in the near future.

A project involving six sub-Saharan African countries—Kenya, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe—has been probing the reasons why more people do not use condoms more often for dual protection. The project involves a total of 4000 men and women and uses focus group discussions, in-depth interviews, and a survey questionnaire to explore their views.

An expert panel debates dual protection

In the past two years, questions have been raised about the effectiveness of male condoms in preventing STIs generally and HIV infection in particular. In June 2000, a panel convened in the USA by the US National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), with the participation of WHO, concluded that male condoms, when used correctly and consistently, are effective for preventing HIV infection in both women and men, and gonorrhoea in men. For other STIs, however, more data are needed and should be forthcoming from studies already under way or in the planning stages.

The panel reviewed the evidence and came to the following conclusions:

• The consistent use of male latex condoms significantly reduces the risk of HIV infection in men and women and of gonorrhoea in men.

• Laboratory studies have demonstrated the impermeability of male latex condoms to infectious agents contained in genital secretions, including the smallest viruses.

• Male condoms may be less effective in protecting against those STIs that are transmitted by skin-to-skin contact (such as herpes, human papilloma virus, and syphilis) since the infected areas may not be covered by the condom.

An "information note" issued in August 2001 pointed out that the panel's report underscores the effectiveness of condoms against HIV and "nothing in it challenges WHO and UNAIDS' conviction about the importance of condoms in HIV prevention programmes". On the contrary, the note continues, "unclear presentation of the report's conclusions by some commentators may detract from the vital effort to reduce risk of HIV infection through the use of condoms. It is imperative to continue promoting condoms for HIV prevention while undertaking further studies on their effectiveness for prevention of other STIs. As more studies are conducted to fill the gaps in knowledge identified in this report, WHO and UNAIDS will continue to monitor and assess the new information and will keep countries informed of the importance of any new findings".

Sources


Public health authorities are pinning considerable hope on the female condom as a means of preventing STIs, particularly HIV infection.

Condoms for women hold promise

The female (or vaginal) condom is a strong, loose-fitting polyurethane sheath about 17 cm long with two flexible rings at either end: one ring lies within the condom and facilitates insertion and anchoring of the condom at the distal end of the vagina; the other ring remains outside the vagina and covers the vulva.

Since its introduction in Europe in 1992 and in the USA the following year, the female condom has become increasingly popular. The Female Health Company, in London, United Kingdom, manufacturer of the only female condom on the market, has sold about 30 million of its female condoms in over 45 countries and is currently selling well over four million a year, compared with just over one million four years ago.

A major advantage of the female condom is that a woman can use it without the cooperation of her partner. Unlike its male counterpart, the female condom can be inserted and worn several hours before intercourse. However, the female condom is much larger than the male condom and some women complain that it is unattractive, difficult to insert, or noisy and hard to keep in place during intercourse. It certainly costs much more—62 US cents for bulk purchases vs 3 US cents for the male condom.

The efficacy of the female condom in preventing pregnancy has been documented in three studies conducted in developed countries (1,2,3): it is roughly as effective as the male condom (a 5-21% failure rate over 12 months, depending on how carefully it is used, vs 3–14% for the male condom).

Public health authorities are pinning considerable hope on the female condom as a means of preventing STIs, particularly HIV infection. Laboratory research has shown the female condom to be impermeable to bacteria and also to HIV. Solid clinical evidence, however, is still lacking regarding the effectiveness of the female condom in preventing sexually transmitted infections and more extensive data are needed on its effectiveness in preventing pregnancy. One HRP study is comparing the contraceptive effectiveness of the female condom with the male condom in women attending family planning clinics in China, Nigeria, Panama, and South Africa. A second HRP study will compare the two condoms for efficacy in preventing sexually transmitted infections, notably...
gonorrhoea, chlamydial infection, and trichomonas vaginitis. These infections, in addition to being troublesome in their own right, are known to favour HIV infection.

One drawback of the female condom is its cost. In some countries, cost considerations have prompted women to reuse the condom several times. The polyurethane material used to make the female condom is very resistant, but reuse without proper washing and disinfecting could increase the risk of infection.

In response to requests from country officials, programme managers, and individuals for advice on the safety of reusing the female condom, in June 2000, WHO and UNAIDS convened a consultation on the subject, which concluded that insufficient information existed to recommend reuse of the female condom. The June 2000 meeting prepared a draft reuse protocol of which a key step was disinfection, the only known way of inactivating potentially infectious organisms. The meeting also commissioned research to test the safety and efficacy of this draft protocol.

The research was carried out by three groups.

• In work conducted by a British group based in London and backed by WHO, batches of new, unused female condoms were subjected to seven cycles of disinfection, washing, drying, and re-lubrication. All the batches met the required specifications for structural integrity after the test cycles.
• Research conducted by a second group, in Johannesburg, South Africa, also with backing from WHO, found that the organisms that cause gonorrhoea, chlamydia, herpes, and AIDS, when added in large amounts to bull semen, were killed by a solution of common household bleach in 1–2 minutes.
• Research sponsored by the United States Agency for International Development and conducted by a team from Family Health International in Norfolk, Virginia, USA, revealed no significant adverse effects from up to five uses of a single female condom in couples not at risk of pregnancy or sexually transmitted infection, including 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.

A meeting of experts convened by WHO in January 2002 reviewed these findings and revised the draft protocol, retaining the bleach disinfection step 4.

In a July 2002 "information update"(4) WHO noted a number of unresolved safety questions requiring additional clinical and laboratory testing. They include the following:

• How does the structural integrity of female condoms 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?

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.

WHO pronouncement on the reuse of female condoms

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 and, based on two expert consultations, 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 consultations 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.

Sources


Scientists are working on some 60 promising compounds, of which 11 have reached the clinical testing stage, but lack of funds is slowing progress.

Progress and pitfalls on the path to a usable microbicide-spermicide

Safe, effective, acceptable, and self-administered topical preparations with both microbicidal and spermicidal activity are likely to have a major positive impact on reproductive health, especially in areas with a high prevalence of STIs, including HIV infection. Scientists are working on some 60 promising compounds, of which 11 have reached the clinical testing stage, but lack of funds is slowing progress. Although the potential market is large—an estimated 340 million cases of curable reproductive tract infections occur each year—most cases are in resource-poor developing countries.

Cellulose sulfate gel on trial

One preparation, a cellulose sulfate gel, has been shown to have good spermicidal and anti-HIV activity in vitro, and has been tested for local tolerance in animal studies and also in a Phase I clinical trial in women volunteers carried out by the CONRAD Program, a nongovernmental organization administered through the Eastern Virginia Medical School in the USA. In this trial, the gel proved slightly less irritating to the vaginal mucosa than other vaginal preparations.

An expanded Phase I clinical trial has started in three centres in India, Nigeria and Uganda. Each centre will study two cohorts of women: one cohort will be required not to have intercourse or use other vaginal products for the duration of the study. The women in the other cohort will be expected to have at least two acts of intercourse during the study period. This study will assess not only the general performance of the product but also its tolerability and ease of use.

Nonoxynol-9 ineffective in preventing HIV infection

Spermicides containing nonoxynol-9 do not protect against HIV infection and may even increase the risk of HIV infection in women using these products frequently, according to a meeting of experts convened by WHO and the CONRAD Program (see Box on page 7). The experts recommended that women at high risk of HIV infection should not use nonoxynol-9 spermicides for contraception. They also concluded that spermicides containing nonoxynol-9 do not protect against two other common sexually transmitted infections—cervical gonorrhoea and chlamydia.

Nonoxynol-9 is present in most spermicides on the market today. It has been used over the past half-century in a wide range of spermicidal products—vaginal gels, creams, foams, suppositories, sponges, and films, used alone or with other contraceptive devices, such as the diaphragm. While it had been hoped that these products might reduce the risk of sexually transmitted infections, including HIV infection, they have primarily been used as methods of contraception. Estimated numbers of women of reproductive age using spermicides vary from country to coun-
try, from less than 1% in Asia to nearly 17% in some Latin American countries.

In the 1970s and 1980s, laboratory tests showed that nonoxynol-9 could inactivate the organisms that cause gonorrhoea, chlamydial infections, and other sexually transmitted infections, as well as HIV. These findings fuelled hopes that it could be used not only for contraceptive but also for microbicidal purposes. Clinical trials conducted to date do not support these hopes.

On the contrary, studies reviewed by the experts point to an increased risk of sexually transmitted infections, including HIV infection, in women using nonoxynol-9 products frequently. A possible reason is that nonoxynol-9 can disrupt the epithelium, or wall, of the vagina, thereby potentially facilitating acquisition of HIV infection. The frequency of this epithelial disruption seems to depend on the intensity of use of the product. The experts concluded that women who have multiple daily acts of intercourse should choose another method of contraception. However, for women who do not use spermicides frequently and who are not at a high risk of HIV infection, spermicides that contain low doses of nonoxynol-9 are probably safe.

Regarding the use of spermicides for contraception, the report concluded that when used alone nonoxynol-9 is only moderately effective for pregnancy prevention but better than no contraceptive method at all. Although far less effective than the pill, intrauterine devices, or injectable or implantable contraceptives, nonoxynol-9 spermicides offer some advantages: they are readily accessible as over-the-counter products, available just about everywhere in the world, and under the woman’s control.

Nonoxynol-9—do's and don'ts in a nutshell

Here are the conclusions and recommendations of a meeting of experts convened in October 2001 by WHO and the US-based CONRAD Program, to review the safety of nonoxynol-9 and its effectiveness for protection against pregnancy and sexually transmitted infections (STIs).

Safety
• Animal studies and human trials have shown nonoxynol-9 to be an irritant.
• Nonoxynol-9 is known to cause epithelial disruption in the vagina and rectum—the risk increases with increasing frequency of use.

Contraceptive effectiveness
• Used alone, nonoxynol-9 is only moderately effective as a contraceptive, but better than no contraceptive method at all.
• Used with a female mechanical barrier method (for example a cervical cap or diaphragm), nonoxynol-9 is more effective than when used alone.
• It is not known whether the contraceptive effectiveness of nonoxynol-9 differs with different formulations (film, sponge, gel, suppository, and foam) and doses.
• There is no evidence that condoms lubricated with nonoxynol-9 are more effective in preventing pregnancy than condoms not lubricated with it.

Microbicidal effectiveness
• Nonoxynol-9 does not reduce the risk of sexually transmitted infections (STIs), including HIV infection, among sex workers or in women attending STI clinics (the only population groups in which the product has been studied for this purpose).

Recommendations
• Nonoxynol-9 should not be used to prevent STIs, including HIV infection—condoms should be used for this purpose.
• Nonoxynol-9 should not be used for contraception in women who have frequent intercourse (i.e. several times a day) or have a high risk of HIV infection.
• Nonoxynol-9 should not be used rectally.

For full report, see http://www.who.int/reproductive-health/rtis/index.htm
Experts recommend that condoms lubricated with nonoxynol-9 should no longer be promoted. However, it is better to use a nonoxynol-9-lubricated condom than no condom at all.

Nonoxynol-9 is sometimes added to lubricants used with male condoms. The experts found no evidence that nonoxynol-9-lubricated condoms provide any more protection against pregnancy or sexually transmitted infections than condoms lubricated with silicone, used as a lubricant for the majority of condoms available in developing countries. Since nonoxynol-9 may cause some adverse effects, the experts recommended that such condoms should no longer be promoted, but noted that it is better to use a nonoxynol-9-lubricated condom than no condom.

Nonoxynol-9 is also present in many lubricants used by people engaging in anal intercourse. Some users may be under the impression that it can also protect against HIV infection. The evidence reviewed by the experts is particularly disturbing in this regard. Studies in mice and in human subjects revealed significant sloughing of sheets of rectal epithelium, suggesting that an increased risk of infection soon after the application of products containing nonoxynol-9 is likely.

While spermicides containing nonoxynol-9 remain a contraceptive option for women at low risk of HIV infection, they are substantially less effective in preventing pregnancy than most other methods. Women at risk of HIV infection who want contraception should be informed that consistent and correct condom use is highly effective for pregnancy prevention and prevention of sexually transmitted infections, including HIV Infection.

**New Publications**

**Department of Reproductive Health and Research (RHR): 2000-2001**

This CD-ROM contains the full text of the Department's two reports for the 2000-2001 biennium: Reproductive health research at WHO (report of the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction) and Better reproductive health—implementing the global agenda. Both reports, which together outline the department's activities in a style accessible not only to scientists but also to a wider general audience, are in addition available in print. The CD also includes succinct point-by-point highlights of the main activities described in greater detail in the two reports, and these highlights are also available in print form. The department's Annual Technical Report for 2000 and for 2001, which are written for a more technical audience, are only available in electronic form on this CD.

**WHO Antenatal Care Randomized Trial: Manual for the Implementation of the New Model**

Document No. WHO/RHR/01.30

This manual provides instructions on how to implement a new WHO antenatal care model that limits the number of visits a pregnant women has to make to the clinic and restricts tests, clinical procedures, and follow-up actions to those scientifically demonstrated, in rigorously designed multicentre trials, to improve the outcomes for the woman and her baby.

**Reproductive health indicators for global monitoring**

Report of the second interagency meeting

Document No. WHO/RHR/01.19

The Second Interagency Meeting on Reproductive Health Indicators for Global Monitoring had three main objectives: to reach a consensus on the inclusion of two HIV/AIDS indicators; to develop a plan of work for further research on reproductive health indicators; and to develop a plan of work to help countries to strengthen their capacity to collect data. This 50-page report documents the proceedings of the meeting. It includes an up-to-date list of recommended indicators for global monitoring of reproductive health.

**Information, education and communication: lessons from the past, perspectives for the future**

Document No. WHO/RHR/01.22

This occasional RHR paper is based on a retrospective qualitative study covering 25 years of experience in carrying out information, education, and communication (IEC) interventions. The study involved a literature search, a field survey, and in-depth interviews. Public health professionals conversant with IEC (but not necessarily experts in the field) will find in the paper useful guidelines for planning, implementing, monitoring, and evaluating IEC activities.

To receive a free copy of any of these documents, please write to:

Documentation Centre
RHR, World Health Organization,
1211 Geneva 27, Switzerland
email: rhrpublications@who.int