



# IPPF Medical Bulletin

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## Use of the male condom within marriage

*John Cleland*

The male sheath or condom was originally devised as a means of preventing sexually transmitted infections (STIs) and has a long history of use for this purpose. In the mid-decades of the 20th century, the device became commonly used as a method of family planning, particularly in industrialised countries. From the 1960s onwards its role was eclipsed by the advent of more effective contraceptive methods. Nevertheless, the condom remains the preferred method for 10% or so of married couples in many European countries and in North America. In Japan it is still the dominant method, used by 42% of married couples.<sup>1</sup>

In developing countries, between 1960 and 2000 the estimated percentage of couples who used contraception rose from 9% to 60%, and fertility fell from six to under three children per woman. Typically, highly effective methods, including contraceptive sterilisation, have been promoted at the expense of barrier methods. Only 3% of couples in developing countries use condoms for family planning.<sup>1</sup> The HIV pandemic, together with increasing awareness of the high incidence of other STIs and their role as cofactors in HIV transmission, represents a powerful new consideration in the relative priority that should be given to different contraceptive methods. Specifically, the condom takes on a new importance because of its dual function in protecting against both conception and sexually transmitted infections.

## Condom acceptability

UNAIDS classifies countries into three groups according to stage of HIV epidemic – “low level” when no risk group has more than 5% HIV prevalence; “concentrated” when prevalence is consistently over 5% in at least one risk group but remains below 1% in pregnant women in urban areas; and “generalised” when prevalence is consistently over 1% in pregnant women. The number of countries with generalised epidemics rose from 25 in 1990 to 54 in 2000.<sup>2</sup> In settings with low level or concentrated epidemics, it is justifiable to focus HIV prevention campaigns largely on high-risk activities such as commercial sexual encounters and intravenous drug use. However, in countries with generalised epidemics, the preventive strategy needs to take into account the fact that over half of HIV infections occur to spouses with stable partners, either because of previous infection or because of sexual infidelity.<sup>3,4</sup> The high prevalences of

infection found among single teenage girls in some African sites imply a risk to their future husbands and abundant evidence has accumulated on sexual infidelity after marriage, particularly by men. In severe generalised epidemics, up to 20% of couples may be HIV-discordant, where one but not the other partner is infected.<sup>5</sup> With the advent of drug therapy for AIDS, resort to voluntary testing and counselling is bound to become more frequent, and thus the number of couples who are aware of their discordant status will also increase, thereby raising the demand for protection within marriage.

In the past 15 years huge efforts have been made to promote condoms as one of the three main ways of checking the spread of HIV through sexual intercourse. The major promotional emphasis has been on their use outside marriage and some success has been achieved.<sup>6</sup> In contrast, little progress has been made in terms of their use within marriage. In 30 countries with generalised epidemics, the percentage of contracepting couples who use condoms remained static at 8% between 1983 and 1997, and there are few signs of change in the past 8 years.<sup>7</sup>

The reasons for the resistance to condom use by married or cohabiting couples as a means of preventing STIs are well understood. One obvious factor is that condoms hinder childbearing, though this consideration is steadily diminishing in importance as family size preferences decline. The biggest single obstacle is the implied lack of trust in the partner's fidelity.<sup>8,9</sup> HIV control campaigns may have unwittingly heightened this resistance by reinforcing the link between condoms, STIs, and illicit sex, while neglecting their potential role as contraceptives.

However, not all the research evidence is pessimistic in its implications. A study sponsored by the World Health Organization in five East and Southern African countries with very severe epidemics showed that about 20% of married or cohabiting couples “sometimes” used condoms with their partner (though only 3% claimed consistent use).<sup>10,11</sup> Such occasional use suggests that the opposition to condoms is not insurmountable. The results from the study also challenge widely held views that husbands are more hostile to this method than wives and dominate decisions on use. In answer to a question about who has more influence over use of condoms, 34% of wives claimed that the woman has more influence, with similar proportions citing the husband or both equally. In answer to the same question, 20% of husbands acknowledged the women to have more influence and 45% said the influence of man and woman was equal. A statistical analysis of factors influencing condom use confirmed that the wife's and husband's attitudes to condom use and their perceived risks of HIV infection were of approximately equal importance. The lesson here is that women in long-term stable relationships are by no means as powerless, nor are many husbands as intransigently hostile to condoms, as they are frequently portrayed to be.

Further encouraging signs come from the South African segment of the WHO study. A strong socioeconomic gradient in occasional or consistent condom use was found: use rose from 10% among less educated rural couples to 30% among their better educated urban counterparts.<sup>12</sup> This is

encouraging because behavioural innovations usually start in privileged strata and diffuse over time to less privileged ones. The results suggest that the incorporation of condoms into married life has started and will spread.

### **Dual-method protection or condoms alone?**

Dual protection against unwanted pregnancy and STIs among sexually active married couples can be achieved in two main ways – by use of condoms together with a non-barrier method of contraception or by use of condoms alone. The relative merits of these two approaches are finely balanced.

Under conditions of perfect use, male condoms are subject to an annual contraceptive failure rate of 3%. Under real-life conditions this rises to 10% or more, about double the real-life failure rate of 5% for oral contraceptives.<sup>13</sup> A further disadvantage of the condom is the apparent difficulty of sustaining prolonged use. An analysis of data from 16 developing countries found that about 60% of married condom-users abandon the method by the end of twelve months for a mixture of reasons including inconvenience, husband's dislike, and desire to switch to a more effective contraceptive method.<sup>14</sup> However, these were mostly countries that did not have serious HIV problems. Motivation to persevere with condom use would probably be higher where the risk of contracting HIV was greater.

These considerations obviously favour the double-method strategy but the latter also has potential disadvantages. First, when pregnancy protection is guaranteed by a non-barrier method, adherence to condom use is likely to be more difficult to achieve and thus protection against STIs is lessened. Second, it is almost certainly more difficult for either spouse to negotiate condom use when the wife is already protected against pregnancy by pills, injectables, or an intrauterine device. One possible way around this dilemma, for the wife, is to conceal the use of a non-barrier method from her husband, a strategy already favoured by 10% or so of women in some African countries.<sup>15</sup>

Ultimately, of course, the choice has to be a fully informed one made by individuals and couples, taking into account local factors such as access to emergency contraception or safe abortion. Evidence from the WHO five-country study suggests that, in countries where highly effective non-barrier methods are widely used and well accepted, most women will be reluctant to give up the sense of contraceptive security that these methods offer. For instance, in South Africa over 90% of couples using condoms also used another method, mainly the injectable. Conversely in Uganda, where use of modern contraceptives is still low, condoms were more likely to be used without other contraceptive devices.

### **The role of family planning providers**

If the promotion of condoms for married couples is a top but neglected priority, what contribution can family planning service providers make? Some obvious limitations need to be acknowledged from the outset. The great majority of family planning clients are women but the main purchasers of condoms are men, who get them from social marketing or commercial marketing outlets rather than from health or family planning facilities. Nevertheless, family planning staff are in a uniquely privileged position to guide married women in their contraceptive and HIV/STI prevention choices. In settings where HIV/STI infection levels are high, counselling should include the following: ascertaining the client's subjective sense of the HIV risk; emphasis on the dual function of condoms; and explanation of the role of emergency contraception, pregnancy testing and early

abortion (where lawful) as a back-up in instances of inconsistent condom use, breakage, and slippage. Counsellors should also recognise that adoption of condoms will depend on the husband's attitudes and the wife's powers of persuasion. Little is known about the relative effectiveness of various persuasive strategies that wives can deploy, but one study in Zimbabwe found that a stress on the high prevalence of HIV in the community was the argument most closely associated with subsequent use of condoms.<sup>16</sup> Above all, staff need to give the impression that condom use within marriage is a realistic option.

*John Cleland, MA, is Professor of Medical Demography at the London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7T, UK. E-mail: John.Cleland@lshtm.ac.uk*

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page 1.

## NuvaRing

Edith Weisberg

Two prospective studies have shown that, of women using oral contraceptives, between 47% and 74% miss one or more pills and 22% miss two or more pills per cycle.<sup>1,2</sup> In France 21% of women seeking abortion, and in Australia 14%, stated they had been using the pill at the time they became pregnant.<sup>3,4</sup> Such observations have encouraged the development of longer-acting hormonal methods of contraception which, with their lesser requirement for user action, potentially give better efficacy rates. One of the most recently marketed methods is NuvaRing (Organon) – a soft vaginal ring that releases 15 µg ethinylestradiol (EE) and 120 µg etonogestrel (ENG), the active metabolite of desogestrel, per day via a controlled delivery system.<sup>5</sup> NuvaRing is kept in the vagina for three weeks and the woman then has a ring-free week before inserting a new ring. If necessary the ring can be removed for intercourse but it should not be outside the vagina for longer than 3 hours at a time during the scheduled three weeks' use. When the period of non-use exceeds 3 hours the manufacturers recommend an additional method of contraception for the next seven days. If the NuvaRing is left in situ for up to two weeks longer than recommended, ovulation is still inhibited, and inhibition is also maintained during a cycle where reinsertion has been delayed up to the development of a 13 mm follicle (days 8–21 after last ring use); the safety margin is thus high.

### Pharmacokinetics and metabolism

When NuvaRing was compared with a combined oral contraceptive (COC) containing desogestrel 150 µg and EE 30 µg, systemic exposure to ENG was similar but exposure to EE was about half.<sup>6</sup> Maximum serum concentrations of EE and ENG are achieved within one week after insertion of the ring, and ovulation is completely inhibited throughout the cycle.<sup>7</sup> Concomitant use of vaginal antimycotics, spermicides, or tampons does not appear to affect efficacy.<sup>8–10</sup>

The metabolic effects of NuvaRing are similar to those of a low-dose COC. When compared with a 30 µg EE / 150 µg levonorgestrel COC, NuvaRing caused a greater increase in thyroid stimulating hormone but free thyroxine levels were the same; cortisol binding globulin and total cortisol rose more with the COC and both agents caused small increases in insulin.<sup>11</sup> Triglycerides increased in both groups, more with the ring than with the COC. HDL and LDL cholesterol concentrations were unchanged with ring use whereas in COC users HDL decreased and LDL increased.<sup>12</sup> Neither contraceptive had a pronounced effect on coagulation factors. Factor VII increased in the NuvaRing group and decreased in the COC group; antithrombin and protein C activity were somewhat higher in NuvaRing users.<sup>13</sup>

### Efficacy

Efficacy rates for NuvaRing are similar to those for the COC. In a randomised study of the ring versus a COC containing 30 µg EE and 150 µg levonorgestrel, completion rates in the 1030 women were similar (70.9% and 71.2%). Five pregnancies occurred in each group, giving a Pearl index of 1.23 for the NuvaRing and 1.19 for the COC.<sup>14</sup> An earlier non-randomised study of the ring gave a Pearl index of 0.65 (confidence interval 0.24–1.41) for 12 109 cycles of exposure.<sup>15</sup> In the latter study 90% of participants adhered correctly to the usage schedule; in 4.1% of cycles the ring-free interval was longer than recommended, but in most instances only by one or two days. Temporary removal (up to 3 hours, for intercourse) occurred on 1% of all ring days, but about 90% of women completed the thirteen months of the

study without any unscheduled ring removals.

With COCs the quality of cycle control tends to depend on the dose of oestrogen. Nevertheless NuvaRing, which in 24 hours releases only half the amount of EE yielded by a regular COC, gives good cycle control. In a twelve-month study of over 1000 women, withdrawal bleeds occurred on schedule in 98.8% of cycles.<sup>5</sup> Early withdrawal bleeding occurred in 5.6% of cycles, and in 24.2% of cycles the withdrawal bleed (mainly in the form of spotting) extended into the next ring-use cycle. Breakthrough bleeding, again mainly in the form of spotting, occurred in 4.4% of cycles. In a comparative study with a COC (30 µg EE / 150 µg levonorgestrel) breakthrough bleeding was more frequent in the COC group.<sup>16</sup>

### Adverse events

Adverse events that relate specifically to the contraceptive ring are an increase in vaginal discharge, vaginitis, and expulsion of the ring. The Netherlands Pharmacovigilance Foundation Lareb received 8 reports of ring expulsion in fourteen months, with resultant pregnancy in 2.<sup>17</sup> The women had not always been aware of ring expulsion. Factors associated with expulsion are prolapse of the uterus, cystocele, rectocele, and severe or chronic constipation. In acceptability studies, 15% of users and 30% of their partners said they could feel the NuvaRing at least occasionally during intercourse but only 6% of partners objected to it.<sup>18</sup> In a one-year open study of 1145 women using the NuvaRing, the reported side-effects were headaches (6.6%), leucorrhoea (5.3%), vaginitis (5%), nausea (2.8%), and breast tenderness (1.9%). 15% of women stopped using it because of an adverse event; 41% of women reported no adverse events.<sup>15</sup>

### Acceptability

In two studies more than 90% of women reported being satisfied or very satisfied, and 97% of those who completed twelve months said they would recommend the method to a friend.<sup>18</sup> Of the women who prematurely discontinued ring use, 60% were satisfied and 75% would recommend the method. Reasons for liking the ring were “not having to remember anything” (45%) and ease of use (27%).

### Conclusion

The advantages of NuvaRing include the low doses of hormones, avoidance of gastrointestinal metabolism, and a rapid return to ovulation after discontinuation. The controlled-release delivery avoids fluctuations in daily hormone levels of the kind seen in COC users and produces excellent cycle control. The ring is easy to insert and remove from the vagina, is generally not felt when in situ, gives women control without requiring medical intervention, and is well-tolerated.

*Dr Edith Weisberg is director of research, Sydney Centre for Reproductive Health Research, Research Division of FPA Health, 328 Liverpool Road, Ashfield, NSW 2131, Australia. E-mail: edithw@fpahealth.org.au*

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## News

### Contraceptive practice before and after over-the-counter availability of hormonal emergency contraception

In January 2001 hormonal emergency contraception (EC) became available in Great Britain without the medical prescription formerly required. Women aged 16 and over were free to buy EC directly from pharmacists (“over the counter”), at a cost of £20–25 (US\$36–46); they were still able to obtain EC without charge from medical sources such as general practitioners, family planning clinics, and hospitals. Such a relaxation of the rules has been opposed in some countries because of fears that over-the-counter availability will increase the use of EC at the expense of more reliable methods of contraception. A study from the UK, looking at practice before and after the change, provides reassuring data.

Cicely Marston and her co-workers<sup>1</sup> analyzed data on contraceptive practice for women aged 16–49 years from the Omnibus Survey – a multipurpose survey in Great Britain in which some 7600 adults living in private households are interviewed each year. Data covered the year before over-the-counter availability of EC (2001) and the two subsequent years.

The data yielded the following noteworthy findings. First, the use of regular forms of contraception changed hardly at all after EC became more widely available and the frequency of unprotected sex did not change. Second, there was no increase in use of EC overall; nor was there any rise in the (very small) proportion of women who used EC twice or more in a year. Third, among those women who had used EC, an increasing number chose to obtain it from pharmacists rather than other sources: in 2000, 62% of EC users had obtained the pills on prescription from a general practitioner; by 2002 this figure had fallen to 48.8%, and nearly one-third (32.6%) were purchasing them from a pharmacist. Finally, an analysis of variables such as age, educational level, marital status, and income showed only age and marital status to be significant predictors of EC use: single women were nearly three times as likely to report EC use as married women; women aged 20–24 were nearly three times as likely to report EC use as women aged over 30, and teenagers were twice as likely to report use of EC as women over 30. Although neither income nor educational level was related to the likelihood of using EC, income did significantly influence the source from which it was obtained. Women with high income

were five times more likely to obtain EC over the counter than those with low income.

In some countries, proposals for off-prescription availability continue to meet with strong opposition. For example, in the USA in 2004, the Food and Drug Administration blocked an application for over-the-counter sales despite a recommendation by its own scientific panel to approve it. Opponents have argued that easy access will lead women to abuse the method, that it will encourage unsafe sex and that it will lead to a decrease in the use of regular contraception. The British study yields evidence to the contrary on all these points, as well as indicating that women appreciated having this option.

Marston and her co-workers are not the first to report that uptake of non-prescription EC is limited by high cost.<sup>2</sup> The present uptake is low, and clearly there are several other reasons. In the UK and elsewhere,<sup>3–8</sup> the barriers include lack of awareness of the method and where it can be obtained, worries about potential side-effects, and ethical concerns about the mechanism of action. Healthcare providers are not always well informed on these matters. Any strategy for increased provision needs to be coupled with wider education about this important back-up method.

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