Female condoms: new choices, old questions

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As the only methods available for dual protection against pregnancy and sexually transmitted infections (STIs), male and female condoms have a vital role in sexual and reproductive health. Mags Beksinska and colleagues therefore are to be commended for their randomised crossover trial in this issue,[1] which establishes that three types of female condom (Woman's Condom, VA w.o.w., and Cupid) have similarly low rates of self-reported problems as the FC2, the only female condom approved by the US Food and Drug Administration (FDA). Beksinska and colleagues' findings will fulfil a key step for public-sector programmes to procure the new products for distribution in developing countries. Despite this achievement, however, critical questions remain.

First, will an expansion of choices in female condom types lead to increased use of these products? Beksinska and colleagues suggest that increasing the variety of female condom devices available could increase method coverage and, consequently, reduce incidence of unintended pregnancy and disease. In general, having a wider selection of contraceptive methods that differ in important attributes (eg, cost, duration of effect, timing with respect to coitus, and real or perceived side-effects) would be expected to increase overall use.[2] Yet randomised trials in four countries found that men given a choice of types of male condom had similar rates of unprotected sex[3] and STIs[3,4] as those not offered a choice of condoms. The male condom products offered in the intervention groups might not have varied sufficiently to affect rates of use. Do the new types of female condoms offer enough distinct advantages (eg, improved designs and reduced cost) to increase the number of sex acts protected?

Second, are different data required to move policy makers and providers, and ultimately women, to embrace the female condom? Some have argued that low uptake of female condoms does not stem from negative perceptions among users as much as higher-level lack of support for the device on the part of policy makers, with resultant insufficient procurement of supplies and inadequate promotion of the product to women.[5] Yet the anaemic response is perhaps not surprising. The FDA product labelling for the FC2 recommends its use for disease protection only if latex male condoms will not be used. This qualifier stems from a lack of comparative effectiveness data between female and male condoms, rather than evidence of the former's inferior protection. Given this labelling, hesitancy to embrace the female condom is understandable; data to show whether female condoms are as effective for disease prevention as male condoms might increase support among decision makers.

Third, do regulatory and international bodies require the best type of data for measuring non-inferiority? Beksinska and colleagues measured self-reports of product failure (defined as use problems such as breakage, slippage, invagination, and misdirection) to satisfy a regulatory hurdle for product approval. However, the questionable accuracy of self-reported condom data makes this a poor proxy for pregnancy and disease incidence.[6] For example, women might have been differentially able to detect, and thus report, problems with condom performance. As an alternative to self-report, detection of prostate-specific antigen (PSA) is a cost-effective method (estimated at US$4·50 per rapid test and $20 per quantitative test[6]) to measure objectively women's exposure to semen. Two trials assessed the effectiveness of the original female condom in the USA relative to male condoms by having women self-swab to compare PSA concentrations in specimens collected immediately before and after coital acts using the study condoms.[7,8] This design could provide superior data in future trials to assess device effectiveness.

Finally, will female condoms follow the trajectory of tampons or of menstrual cups? Globally, use of female condoms has remained disappointingly low: the product represents only 0·7% of total condoms distributed by donor countries in 2010.[9] Are female condoms like tampons in North America and Europe, which languished largely unused for nearly 30 years before eventually becoming an enormously popular—perhaps indispensable—reproductive health product?[10] Or are they more analogous to menstrual cups, which have been around for decades, but have been adopted by only a small subset of women, despite numerous design tweaks. Implementation research to understand and replicate the enthusiastic uptake among some female condom users is critical to gauge the amount of funding and effort that should be invested into the device's development and promotion.

In summary, female condoms could bring great benefit in pregnancy and disease prevention, and the findings reported by Beksinska and colleagues will be useful as advocates work to expand female condom choices available worldwide. Barriers at many levels—cost, availability, lack of evidence of health effect, and promotion relative to other products—have hampered women's adoption of female condoms. Answering the critical questions posed here might better equip country-level sexual and reproductive health advocates and funding agencies to expand access to female condoms, and catapult the method to more widespread use by women wishing to prevent pregnancy and STIs.

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