Editorial

The Female Condom

Beyond Acceptability to Public Health Impact

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THE UNITED NATIONS General Assembly's recent Declaration of Commitment on HIV/AIDS[1] included expanded access to the female condom among its recommended preventive strategies in the global fight against AIDS. This United Nations endorsement may be puzzling to STI/HIV control program planners and other interested observers. Despite distribution efforts in over 70 countries since the female condom's 1993 launch, the product has yet to "take off" in terms of sales and reported use. Negative notions abound about the female condom's design and use characteristics, leaving many to wonder if anyone actually manages to use the device. Yet according to Jivasak-Apimas and colleagues' acceptability study in Thailand, presented in this issue of the journal,[2] the majority of women provided the female condom under trial conditions reported overall satisfaction with the device. This finding corroborates the optimistic results of scores of acceptability studies that have gone before it.[3] Jivasak-Apimas et al's study has some notable strengths, for instance, their analysis which accounts for cluster-randomization, and their collection of female condom use data. Their sample size is larger than most other female condom acceptability studies, an advantage attenuated somewhat by substantial missing data and high loss to follow-up. Despite the now substantial body of evidence documenting female condom acceptability, an important question remains: Could that expressed satisfaction ever translate into sustained use of the female condom at levels sufficient to impact transmission rates of HIV and other STIs?

Examining the results of acceptability studies is a reasonable initial strategy for seeking an answer to that question. The main finding from Thailand[2] is that two-thirds of women remaining in the study at 8 weeks reported that they were "satisfied" with the female condom. The dichotomous variable used as the satisfaction indicator is a blunt measure, one that is particularly hard to interpret given culturally specific definitions of satisfaction. The investigators supplement this satisfaction measure with data reflecting the proportion of respondents experiencing problems with female condom use: difficulties with insertion, pain, itchiness, excessive length, excessive lubrication, and noise during intercourse. It would have been informative, however, if they had compared the frequency of complaints among respondents reporting overall satisfaction with the female condom to the frequency of complaints among those reporting dissatisfaction. Such a comparison would have revealed whether some women find the female condom generally acceptable despite use problems, or whether nuisances are sufficiently serious to serve as a decided predictor for dissatisfaction with the method. For example, the investigators reported that 18 of the 88 sustained female condom users at the 8-week evaluation were classified as "not satisfied" with the method, suggesting that some women who are not content with the method might nonetheless find reason to use it.

Results of acceptability studies conducted in sub-Saharan Africa,[4–6] Asia,[7,8] Latin America,[9] and the United States[10] have converged on the same set of use problems described in this Thailand study. While each study documents similar complaints about the female condom, in each setting a subset of women likes the device and succeeds in sustaining its use. Apparently some women are sufficiently motivated to use this mode of barrier protection that they manage to ignore or overcome the commonly reported difficulties associated with an admittedly cumbersome method. Use prob-

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lems are known to diminish with practice,[11] regardless of the study setting or type of study cohort.

If acceptability studies have produced predominantly positive findings worldwide, why do sales statistics and research on use patterns show that the majority of women exposed to the female condom are not inclined to use it on a sustained basis? For example, in a recent community intervention trial of the impact of introducing the female condom in rural Kenya, most women who used the device reported they liked it, preferred it to male condoms, and stated they would be willing to purchase it in the future. Yet only a small proportion of women at the study sites used female condoms consistently, and the female condom had no measurable impact on STI prevalence.[12] Broader-based availability of the female condom has had somewhat disappointing results as well. For instance, social marketing sales in Zimbabwe and Zambia declined after early enthusiasm and trial use,[13,14] although sales may be picking up in both countries. Continued purchase and use are concentrated in more educated and affluent urban dwellers,[15] who may be the same sort of women using the device in the US and Europe.

A more convincing satisfaction indicator for future acceptability studies, therefore, would be the proportion of individuals with access to the female condom who actually use the device on a sustained basis. The multilevel factors that encourage or hinder female condom acceptance are of particular interest. Future studies should extend beyond the device's basic design and use characteristics, already adequately examined, to consider the broader range of social and cultural factors impacting the female condom's true acceptance as a method for contraception and STI prevention. Our work in rural Kenya, for example, revealed how female condom acceptance may be low in a setting in which a female-initiated contraceptive device threatens traditional gender roles in sexual decision-making. We also saw that community members associated female condom use with infidelity and promiscuity, a stigma commonly assigned the male condom. Future investigators must assess acceptability from the perspective of the woman, the male partner, the couple, and the society in which the couple lives, all factors strongly influencing the decision to use the female condom.[16]

Assuming research is able to document female condom acceptability more comprehensively, the question remaining is whether its use produces a public health benefit. A major argument against investing in the female condom is its cost. At present the public sector purchase price is US$ 0.63, very expensive compared to the US$ 0.04 typical wholesale price for a male condom. The only way the female condom can achieve an acceptable degree of cost-effectiveness is if it protects a substantial proportion of high-risk sex acts that have little chance of ever being protected by a male condom. Regrettably, opportunity remains for the female condom to fill a major protection gap left by the male condom, despite wide-scale promotion programs. Studies have documented that male condom promotion programs fall far short of achieving consistent use of protection in high-risk acts,[17] including in the context of commercial sex.[18] Even in Thailand, where the 100% condom program has led to a reported >90% male condom use in brothels, a level of unprotected high-risk intercourse occurs that could potentially be protected by the female condom.[19]

Studies in Brazil,[20] the United States,[21,22] and Zambia[23] have demonstrated substantial increases in the proportion of protected sex acts with female condom availability. Assuming the female condom does serve as a complement to rather than a substitute for the male condom, does heightened use of protection translate into detectable decreases in HIV/STI transmission rates? Unfortunately, data are still scant that allow us to evaluate the female condom's public health impact by means of biological outcomes. Targeted intervention research with both behavioral and biologic outcomes is needed to assess the extent to which the female condom can fill that protection gap. Towards this end, the authors' original randomized trial[24] is more useful than the current secondary analysis.

Future studies must also determine whether the greatest public health impact can be achieved by targeting the female condom toward sex workers and other women at very high risk for STI transmission who have already achieved a high but imperfect level of male condom use. Or would the device provide greater benefit to the larger numbers of women at moderate risk who have little chance of incorporating male condoms into their sexual relationship, such as married women with unfaithful partners in HIV-endemic regions? Future studies should attempt to document more systematically the extent to which both male and female condom distribution programs decrease both the number of unprotected high-risk sex acts and STI prevalence and incidence. To draw valid conclusions, techniques must be developed for obtaining more accurate estimates of condom use frequency and for reconciling discrepancies between biologic and behavioral outcome data.[25]

This current acceptability study[2] whets the reader's appetite for more conclusive data confirming the female condom's potential contribution to STI control. In developing countries with severely limited resources, partner objections to condom use, social stigma, provider bias, and service delivery constraints all plaguing male condom promotion, female condoms may be a valuable addition to the prevention arsenal. But that potential remains to be tested and confirmed. Continued and expanded female condom distribution will be difficult to justify without demonstrated impact.

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