

July 17, 2007  
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Dear Dr. Hellman and Dr. Ridzon:

Here is an open letter.

Reeling from the disappointing news about the diaphragm, we are not alone in recognizing that the support for testing diaphragm effectiveness given by Gates and its implementation by Nancy, Gita and others has made an outstanding contribution to our understanding of HIV transmission. But now we have to move on.

As the accompanying editorial in Lancet noted, intercourse-related protection has at least two domains of difficulty, one being use-efficacy, the other adherence.

The first of these, use-efficacy of the vaginal diaphragm, was unknown before the trial. The theory was that because the cervix seemed to be the main point of access for the virus, and because the cervix was protected by the diaphragm, use of this device would be protective. Now, although it still remains likely that the cervix is important, it is probably not completely protected by the diaphragm, partly because it's difficult to place precisely and partly because it shifts with coitus. Certainly, these remain possibilities, because conception occurs even with perfect use, as many users will confirm.

A second challenge to the theory remains the possibility that at least some transmission of HIV takes place across the vaginal mucosa, which is of course not protected by the diaphragm.

A third and important possibility is that, owing to the design imposed on the study, these questions cannot be fully interpreted.

One way to go to answer this first question of use-efficacy would be to spend more dollars and years on exploring this same question with use of a variant of the diaphragm: either an existing one, or a cervical cap: several exist, the dollars and the time can be calculated almost perfectly from the trial just completed. On the other hand, these studies would preferably develop an alternative design to answer these questions.

A second option is to develop another barrier: add time and money for this.

A third option is pragmatic: leave aside the effort of exploring use-efficacy with other barriers but concentrate on the second domain, adherence. To do this, would be much faster and simpler to accomplish. Expand and monitor the effect of greatly enhancing access to the female condom. Because, with the female condom, use-efficacy can be assumed, attention must be focused on adherence. At this time, UNFPA is distributing female condoms widely across the world, but with minimal operational research support: such support is necessary for optimal effect.

These options are not of course mutually exclusive, but to neglect the third is to ignore the urgency of the international situation. Moreover, whatever is learned about adherence with the female condom is likely to inform the use of all other barriers, those we have and those that might become available.

Adherence puts us into the domain of behavior. At least two basic areas of knowledge will win or lose the battle for a barrier, before we start with behavior change. One is the desire for pregnancy, widespread, and obviously incompatible with all physical barriers, and useless to attempt. (Not attempted in this most recent trial, but must be kept in mind, especially with microbicide development). The second is pleasure or enjoyment of sex, for each partner.

Lessons learned about adherence in the diaphragm study still need interpretation, but let us turn now once again to the Gates Foundation for support for the female condom, proposed already on many many occasions.

With male and female condoms, use-efficacy (apart from breakage and slippage, which can be recognized and reported) has to be assumed. Regarding pleasure in their use, some decrease in pleasure is often reported, in the use of each of these condoms. One aspect of pleasure that is sometimes mentioned is a lack of "spontaneity". The male condom has to be readied for use, and applied at the time of erection. The female condom can be applied earlier: this is seemingly an "advantage." In both cases, the device reduces sense of touch, part of the pleasure for many women and men. But a sense of relaxation from fear: whether of pregnancy or infection, is reported by some as a compensation.

An on the ground evaluation "not a randomized controlled trial" of the potential role of building female condoms into all preventive programs--which many think of major importance- relies on making them widely available together with the male condom; working with distributors and trainers to understand the gender dynamics among partners in the particular setting; adapting training of trainers to meet the local situations. There are many preliminary studies that can be helpful, e.g. Liku, Williamson et al among stable couples in Uganda.

The critical question to be asked is the one that was asked by the government in Brazil (Barbosa et al, Intl J STD AIDS;18:261-266,2007): did including the female condom into public clinics along with the male condom increase the total number of sexual encounters that were protected, compared to those that were not. Designs to answer this question, although not simple, have been devised, and can and should be put into place wherever and whenever the distribution is initiated. Both condoms should be demonstrated to women and to men and their responses used to adapt use to enhance pleasure.

Will raising the proportion of sexual encounters that are likely to be protected reduce the incidence of HIV and other STIs? Almost certainly, if sufficiently normalized, across populations. Should this activity be delayed unless and until we have coitus independent methods or proven microbicides of comparable use- efficacy? ABSOLUTELY NOT.

Female condoms, and often also male condoms, are or can be women-initiated. Mutual trust is the key to their use. Communication between partners can mediate that trust. These are underlying concepts that are the concern of behavioral scientists and social scientists. Although there is a continuum of preferences between devices and methods (invisible, undetectable, or erotogenic) that women can initiate in sex, and discrete methods may be preferred, this is not the only nor the major consideration in devising methods for women to initiate. Communication and pleasure will overcome the appearance of a device, if there is pleasure in its use and if there is trust.

Sincerely,

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