

A New Look at an Old Method: The Diaphragm

By S. Marie Harvey,
Sheryl Thorburn
Bird and Meredith
Roberts Branch

S. Marie Harvey is director of the Research Program on Women's Health, and Meredith Roberts Branch is senior research assistant, both at the Center for the Study of Women in Society, University of Oregon, Eugene, OR. Sheryl Thorburn Bird is associate professor of public health at Oregon State University, Corvallis, OR.

*“For decades before we had oral contraceptives, untold and unstudied millions of women used the vaginal diaphragm lubricated with spermicide as a contraceptive. They experienced no major ‘new’ epidemics of sexually transmitted diseases or pelvic inflammatory diseases but rather the opposite, and they probably also gained some protection against cancer of the cervix.”*¹

Invented in 1842, the vaginal diaphragm is one of the oldest contraceptive methods. Despite several decades of legal restrictions in the United States that slowed the method's introduction into the market, the diaphragm had become the most frequently prescribed form of birth control in America by the 1930s.² Currently, however, very few U.S. women who practice contraception use the diaphragm: In 1995, only 2% of contraceptive users aged 15–44 used the method.³ As a result, most public health professionals perceive the diaphragm as having low acceptability.

In a society that seeks “magic bullets” and values technological fixes, the old-fashioned diaphragm is viewed with skepticism by practitioners and women alike. We contend, however, that the diaphragm has much to offer women, and that it could play an important role in the prevention of unintended pregnancy and sexually transmitted diseases (STDs), including HIV. The purpose of this viewpoint is to dissuade skepticism about the diaphragm and to argue for taking a new look at this old method.

WHY THE DIAPHRAGM? WHY NOW?

It Is Female-Controlled

Women need methods to protect themselves against HIV and other STDs. Few public health professionals will dispute this need, particularly in light of the dramatic increases in AIDS among U.S. women that occurred in the 1990s and the rise in the proportion of women infected via heterosexual contact.⁴ Notably, 42% of AIDS cases among women reported through 2002 resulted from heterosexual transmission of HIV.⁵ As Zena Stein—a pioneer in the movement to provide women with female-controlled methods for HIV prevention—once stated, “there is an urgent need for the development, testing and distribution of prophylactic methods on which women might rely to protect themselves from heterosexual transmission of HIV and help stem the epidemic.”⁶ Her comments were made in the early 1990s, at a time when heterosexual transmission of HIV was just beginning to draw attention; now, more than a decade later, the epidemic she foresaw has become an unfortunate reality for women. The AIDS epidemic, however, is not the only significant danger that sexually active women face.

Other STDs, including chlamydia, herpes and trichomoniasis, are considerably more common than HIV⁷ and are also major public health threats.

The male condom—when used consistently and correctly—is the most effective method for protecting against STDs;⁸ however, some men are unwilling to use condoms, and some women may be unable to negotiate use because of gender-based power imbalances or other cultural factors.⁹ Moreover, individuals having heterosexual intercourse use condoms consistently only about 19% of the time.¹⁰

Clearly, multiple methods for preventing STDs are needed so that women have choices. Of particular importance are female-controlled methods, which women can use with or without their partner's knowledge or cooperation. We acknowledge that female-controlled methods are not intended to replace the male condom; rather, they provide women with an alternative method of protection if condoms are not an option or are not used consistently.

It May Protect Against STDs

The diaphragm is a mechanical barrier contraceptive that provides physical coverage of the cervix. Substantial epidemiologic and biological evidence suggests that protecting the cervix can reduce the risk of acquiring HIV and other STDs.¹¹ Although the first clinical trial designed to measure the diaphragm's efficacy in preventing HIV is just now getting under way, several observational studies have shown that the diaphragm used with spermicide is effective in preventing some STDs (e.g., gonorrhea and trichomoniasis) and their long-term sequelae.¹² Furthermore, because untreated STDs can increase women's risk of HIV infection, primary prevention of STDs can have a major effect on the sexual transmission of HIV.¹³

The potential of the diaphragm to offer women protection from STDs has recently begun to attract greater attention. In September 2002, prominent researchers, clinicians, public health officials, regulatory experts and product developers participated in a meeting entitled *Diaphragm Renaissance: The Role of Cervical Barriers*. One of the goals of the meeting was to focus new attention on the diaphragm and the cervical cap as methods that may protect women against HIV.¹⁴

Three studies are under way to determine the diaphragm's effectiveness in protecting women against STDs.¹⁵ The first two are evaluating the diaphragm's protective effects against chlamydia and gonorrhea, while the third is a randomized controlled trial among 4,500 women in Zimbabwe and South Africa testing the safety and effi-

cacy of the vaginal diaphragm specifically for the prevention of HIV transmission. Findings from these studies will have profound implications not only for the direction and development of research on the diaphragm and similar products, but also for how women and health care providers view such methods.

The evidence and arguments supporting the need to cover the cervix and protect it from pathogens has spurred the development of new female-controlled mechanical barrier devices that are similar to the traditional diaphragm but are more flexible, easier to insert or remove, or are able to deliver microbicide to the areas surrounding the cervix and vagina;¹⁶ no data exist on the efficacy of these methods in protecting against HIV infection, and only one has Food and Drug Administration (FDA) approval as a contraceptive. The diaphragm serves as an excellent analogue for these methods. Findings from research on the traditional diaphragm could be applicable to new methods and, thus, could inform their design, development and dissemination.

And It Has Other Advantages

Chemical barriers (microbicides) are a potential female-controlled method of STD prevention; however, even though numerous microbicidal products are in development,¹⁷ the most optimistic estimates indicate that it will be a number of years before a microbicide is available.¹⁸ Moreover, the regulatory mechanisms necessary to approve microbicides could delay the use of a product once it is deemed safe and effective.¹⁹ Meanwhile, like others, we believe that acceptability and efficacy for STD prevention of existing contraceptive methods must be investigated.²⁰ The diaphragm is approved by the FDA and is available in the United States. Thus, we argue that it is an excellent candidate for such research.

Despite the low numbers of women currently using the diaphragm, we believe that the method has characteristics that could make it desirable. As a contraceptive, the diaphragm is safe, has limited side effects, does not interfere with natural hormones and only has to be used during sex. Also, the diaphragm has advantages over other female-controlled barrier methods. For example, although a woman inserts the female condom, she cannot use it without her sexual partner's knowledge or cooperation; in contrast, a woman can insert the diaphragm up to six hours before intercourse, and she can often use it without her partner's knowledge. In addition, because the diaphragm is worn completely inside the vagina, it avoids the obtrusiveness of the female condom and is less likely to interfere with intimacy and sexual pleasure. Finally, the diaphragm can be reused for up to three years.

Another distinct advantage of the diaphragm is that it could be used to hold microbicidal products in place, if and when they become available. It is reasonable to assume that internal devices will add to the efficacy of microbicides for disease protection, just as they have added to the efficacy of spermicides for pregnancy prevention.²¹ More to the point, use of the diaphragm in conjunction with microbi-

cides would provide physical protection for the fragile cervix, increase the contact time between semen and microbicides, reduce the transport of semen and pathogens to the upper reproductive tract, and enhance the distribution and retention of the microbicidal product.²²

BARRIERS TO USE

Currently, the diaphragm is not a popular method with women, especially young women. Their willingness to choose this unfamiliar, infrequently used method will be a critical factor in whether the diaphragm will be useful in the prevention of STDs. In the current environment, where easy-to-use, highly effective, coitus-independent hormonal methods dominate the market, many women are likely to see the diaphragm as outdated, messy, unreliable and generally inconvenient. Although the diaphragm clearly will never be acceptable to all women, some may find it preferable to hormonal contraceptives.²³

Provider knowledge and acceptability are also key components of the diaphragm's successful reintroduction into the array of methods offered patients. Some health care providers who have ignored this method for decades may hold the same negative perceptions of the diaphragm that some women do. Because providers offer critical support for the use of certain methods and serve as gatekeepers for prescription-only methods, such as the diaphragm, their reticence to offer the diaphragm to women represents a significant barrier to the method's reintroduction.

Much of providers' bias against the diaphragm can undoubtedly be attributed to their lack of familiarity with the method and to their focus on fertility control rather than on STD prevention. An additional barrier that may deter providers from recommending the diaphragm is that counseling women about and fitting them with the diaphragm is likely more time-consuming than providing hormonal methods. Finally, as with all methods, providers have assumptions about appropriate candidates for the diaphragm.²⁴ We believe that providers' familiarity and comfort with the method will be highly influential in determining whether women initiate and sustain use of the diaphragm.

NEXT STEPS

For the diaphragm to become a widely used, acceptable method for pregnancy prevention—and, perhaps, for STD prevention—both women and providers will need to become familiar with and knowledgeable about the method. In addition, family planning providers will need to be convinced that the diaphragm is effective in preventing pregnancy and is an important method to include in the array of choices. It is critical, therefore, to thoroughly understand what factors contribute to the acceptability of the diaphragm among both potential users and providers.

Acceptability Among Potential Users

Acceptability research is particularly crucial for user-controlled methods like the diaphragm because the effectiveness of these methods is determined not only by how

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well the product *should* work, but by how well it *does* work when people use it.²⁵ In other words, because methods must be used consistently and correctly to be effective, their acceptability will determine actual use and, consequently, effectiveness in real life.²⁶ This research must include more than product characteristics; it must examine the complex interrelationship between contextual factors in a woman's life and her perceptions of the method's characteristics.

Over the past 5–10 years, acceptability research has focused on women's use of the female condom, as well as on renewed efforts to increase consistent use of the male condom. Only a few studies have examined the acceptability of the diaphragm—the majority of which were conducted in international settings and were primarily focused on diaphragm use for the prevention of pregnancy.²⁷ Taken together, these studies indicate that the diaphragm is most likely to be acceptable to women for whom safety and side effects related to hormonal methods are a significant concern. Moreover, they all demonstrated the importance of provider training and support for women's satisfaction with and continued use of the diaphragm.

Although the studies focused on using a diaphragm to prevent pregnancy, the fact that the diaphragm is a safe alternative to other methods and is user-controlled bodes well for its acceptance among women interested in protecting themselves from disease. Given the epidemics of HIV and other STDs, the attractiveness of the diaphragm will likely increase substantially, especially among high-risk women, if clinical trials demonstrate that this device helps protect against HIV.

In addition, men's viewpoints must be factored into the acceptability equation. Studies indicate that men actively participate in decision-making about sexual behavior, including contraceptive use.²⁸ Moreover, men and women differ in what they find important in a contraceptive method: Compared with women, men have more favorable attitudes toward coitus-dependent methods, including the condom, diaphragm and spermicides.²⁹

To our knowledge, very few studies have examined the acceptability of the diaphragm among sexually active men. However, we contend that men will find the diaphragm acceptable because it is relatively unobtrusive and they rarely can feel it during intercourse.³⁰ Similarly, a review of acceptability of new reproductive technologies reports that many men prefer methods that are not constricting, more "natural" and female-applied.³¹

Acceptability Among Providers

Finally, because the diaphragm is a provider-dependent method, health care providers play a crucial role in increasing acceptability and accessibility. Further research is needed to evaluate providers' perceptions of the diaphragm and their willingness to include it among the methods they recommend for the prevention of unintended pregnancy and STDs. Research is also needed on the feasibility of improving health care practitioners' knowledge, attitudes and skills in providing barrier methods for disease prevention.

Additional studies should examine what impact these provider characteristics might have on correct, consistent and sustained use of these methods.

Provider training that not only covers the technical aspects of the method but also addresses counseling strategies will go far in improving providers' knowledge and acceptance of the diaphragm. Furthermore, providers need to recognize that although certain characteristics of the diaphragm may be unacceptable to some women, other women may find the method an acceptable alternative to hormonal contraceptives. Researchers need to design, implement and evaluate interventions that address the source of provider bias and enhance skills in the promotion of non-hormonal contraceptive methods such as the diaphragm.

CONCLUSION

Without question, latex male condoms are the best method available to prevent the transmission of STDs. Yet, condoms are not enough. Despite extensive promotion efforts, the consistent use of male condoms among sexually active heterosexual men and women remains dismally low.³² Moreover, observational studies of the effect of condoms, diaphragms and spermicides on the risk of STD acquisition find lower risk among users of female-controlled devices than among condom users.³³

Women and men need choices. There is growing evidence that providing method choice is beneficial.³⁴ Findings from a study that utilized a hierarchical, risk reduction approach indicated that compared with a single-method approach, a strategy of providing education about a range of methods was associated with an increase in the proportion of protected sexual acts.³⁵ Notably, the data suggest that the existence of method choice—in particular, the choice of two female-controlled methods, spermicide and female condoms—empowered women to not only use these methods, but negotiate the use of male condoms with their partner. We agree with the argument that multiple methods, even if they are imperfect, should be promoted, rather than waiting for the "one perfect solution" that may never arrive.³⁶

Two million women worldwide were newly infected with HIV in 2002.³⁷ Public health professionals cannot afford to wait for the availability of a microbicide product before taking action with the methods already on hand. Although the potential of microbicides is enormous, numerous obstacles impede the development and introduction of this new class of products. Meanwhile, women are continuing to contract HIV and other STDs, and to experience the devastating consequences. In the short term, the acceptability and efficacy for STD prevention of existing contraceptive methods must be investigated. The traditional diaphragm is an ideal candidate for such research, and we advocate for a new look at this old method.

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Author contact: mharvey@oregon.uoregon.edu