Outlook: Celebrating 20 years of providing reproductive health information worldwide.

OUTLOOK

Re-examining the Role of Cervical Barrier Devices

Cervical barrier methods—including diaphragms and cervical caps—are among the oldest known contraceptives. Ancient texts document the use of crocodile-dung pessaries, lemon halves, and beeswax plugs. A century ago, diaphragms and cervical caps were popular contraceptives in clinics in many European countries, including Holland, Germany, England, and France.[1] During the early part of the twentieth century, diaphragms and cervical caps often were inserted and removed by a woman's physician and left in place for several weeks at a time.[2]

Today, cervical barrier methods are approved for use in family planning programs around the world. Distribution is limited, however, and only a minority of women of reproductive age use them. Cervical barrier methods offer many advantages. They are woman-initiated and simple to use. Because they are typically re-usable and durable, they can be low-cost methods. They are appealing to women who prefer methods used only on days when couples are sexually active, and to women who want to avoid the hormones found in other types of contraceptives, such as implants, injectables, and oral contraceptives. The devices also are reasonably effective; as with many contraceptive methods, however, effectiveness depends on using them correctly and consistently.

In addition to offering protection from pregnancy, some researchers believe diaphragms and cervical caps have the potential to offer women protection from some sexually transmitted infections (STIs), including HIV. The possibility that cervical barrier methods may provide "dual protection"—that is, simultaneous protection against pregnancy and STIs, including HIV—has led to renewed interest by researchers and policy makers. Researchers representing a range of disciplines—including the scientific, regulatory, and product-development fields—are examining the potential of existing or modified devices to protect against infections.

Building on discussions held at a 2002 meeting focusing on the role of cervical barriers (see box, page 2), this issue of *Outlook* reports on recent developments and discusses the potential advantages and disadvantages of these devices. It provides information on existing cervical barrier devices, explores safety and acceptability issues, and discusses the role that cervical barrier methods may have in disease prevention.

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The Diaphragm Renaissance Meeting

On September 9 and 10, 2002, the Program for Appropriate Technology in Health (PATH), the University of California at San Francisco (UCSF), and Ibis Reproductive Health co-hosted a meeting that brought 80 international experts together in Seattle, Washington, to re-examine the role that physical barriers of the cervix can play in protecting women from HIV and STIs. This "Diaphragm Renaissance" conference aimed to focus new attention on diaphragms and cervical caps as methods that may protect women from HIV. Dr. Jay Levy, UCSF; Dr. Tsungai Chipato, University of Zimbabwe; and Marianne Callahan, Contraceptive Research and Development Program (CONRAD), provided keynote addresses. Presenters included researchers specializing in virology, immunology, and anatomy, as well as clinicians, regulatory experts, public health officials, and women's health advocates. Product developers also presented information on devices that currently are available or are in late stages of development (see box, page 4).

In many ways, this conference built on discussions that took place in a 1993 meeting organized in the Dominican Republic by CONRAD.[3] At that time, researchers knew little about the specific role of the cervix in HIV acquisition, particularly in comparison with the roles of the vagina and other parts of the female reproductive tract, and did not recognize that the cervix may be a primary site of infection. They also knew much less about potential microbicides (see page 5). Many researchers believed that nonoxynol-9 (N-9) appeared to be a particularly promising candidate for woman-initiated protection against STIs, and they supported N-9 as the first priority for testing in large HIV-prevention trials. Ten years later, these hopes for N-9 have not been fulfilled (see box, page 6), although promising new candidate microbicides have emerged.

The need for woman-initiated STI protection remains strong, however, and participants in the Diaphragm Renaissance meeting have been reconsidering devices that cover the cervix.[4] In addition to evaluating existing devices, participants are exploring issues such as acceptability, gender dynamics, provider training needs, and strategies to ensure access, as well as regulatory concerns and advocacy approaches.

To help cervical barriers achieve any potential they might hold as STI-prevention options, the participants made the following recommendations.

Clinical studies. Studies of cervical barriers' effectiveness against STIs, particularly HIV, are complex and costly. To help prioritize devices for such trials, meeting participants recommended developing ways to predict which devices might best protect the cervix from exposure to semen. Possibilities include post-coital swabs taken from either side of the device to detect semen, tests measuring the presence of prostate-specific antigen (a marker for semen) inside the devices, or direct-imaging techniques that allow investigators to visualize whether the device inhibits the ascent of contrast material into the upper genital tract. Participants also recommended that researchers who are planning trials should select devices for study based on their field effectiveness, acceptability, and availability.

Acceptability. Even if they are intrinsically effective, cervical barrier devices will prevent infections only if women find the devices acceptable and use them consistently and correctly. When addressing acceptability issues, researchers should target three specific audiences: women (users), providers, and women's partners. If data support the claim that cervical barriers protect against STIs, product manufacturers should reposition the devices in this context, and emphasize that cervical barriers are woman-initiated, safe, and reasonably effective forms of dual protection with few side effects.

Regulatory issues. New classes of products, or existing ones with a new potential claim, often face regulatory challenges. For cervical barriers, the issue is further complicated: using the devices together with spermicides, future microbicides, or even inert jellies could subject the methods to regulatory requirements for combination drug-device products. Researchers can actively help regulatory agencies by clearly outlining the rationale for exploring new products, and by collectively serving as a resource to regulatory agencies. At the same time, they should work to develop a stronger scientific foundation that provides clear evidence of the role cervical barriers can play in reducing disease transmission. Inter-agency involvement and coordination among groups such as the World Health Organization (WHO), U.S. Centers for Disease Control and Prevention (CDC), United States Agency for International Development (USAID), National Institutes of Health (NIH), and the United Nations Population Fund (UNFPA) should be encouraged.

Resources. Meeting participants discussed the resources available for supporting development of new cervical barriers and evaluating the effectiveness of new and existing methods of HIV and STI prevention. They agreed that greater leveraging and coordination among researchers and agencies are needed. Researchers can help in both facilitating this coordination and assisting with any new fundraising.

Copies of many of the Diaphragm Renaissance presentations are available online in the "Contraceptive Methods" section of the Reproductive Health Outlook website (www.rho.org).

The Role of Cervical Barriers in Disease Prevention

The renewed interest in cervical barrier methods has resulted in part from new evidence about the role that the cervix may play in reproductive health and the transmission of disease.

The cervix is defined as the lower opening of the uterus (Figure 1). The vagina and the ectocervix are lined with approximately 30 layers of tough, squamous cells, which are coated with a layer of dead cells. By contrast, the endocervix (inside and around the cervical os, which functions as a passage through the cervix to the uterus), is covered with delicate, columnar epithelial cells. These cells form just one layer above a basement membrane. The transformation zone is the area on the ectocervix where new squamous epithelium has been formed from the columnar epithelium that originally covered the ectocervix at the time of puberty.

The columnar epithelium of the endocervix appears to be particularly vulnerable to STI infection; chlamydial and gonococcal infections take hold most easily there (Table 1). The transformation zone is the region most vulnerable to dysplasia (precancerous changes), and new research seems to indicate that receptors for HIV are concentrated there as well. Since HIV can infect women who have had hysterectomies, the cervix clearly cannot be the only site of infection in women, but researchers believe it may be a primary site.

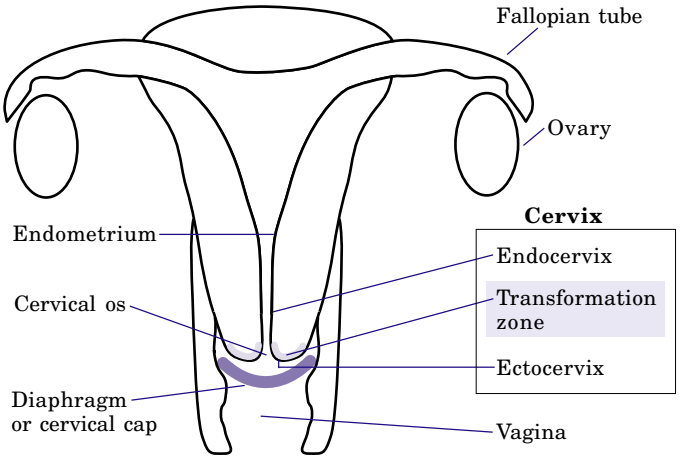
At the 2002 meeting, virologist Dr. Jay Levy and immunologists Dr. Deborah Anderson and Dr. Charles Wira reported on current knowledge of the pathways of HIV infection in women. Their research findings implicate the uterus, and thus the cervix, as sites that are particularly vulnerable to HIV, largely because many of the receptors known to take in HIV particles (including CCR5 and CXCR4) are concentrated on the cervix. The cervix is also the gateway to the vulnerable upper genital tract. As they also explained, however, the cervix produces immunological substances that may help protect against some of the pathogens that cause disease. This raises the possibility that a cervical barrier device, with or without a topical substance, could interfere with natural protection, thus increasing the vulnerability to infection.

Table 1. Portals of Entry in the Female Reproductive Tract for STI Pathogens

Infection	Vulva	Vagina	Cervix
Chlamydia			x
Gonorrhea			x
Trichomoniasis		x	x
Syphilis	x	x	x
Chancroid	x	x	x
Genital herpes	x	x	x
Ano-genital papillomavirus infection	x	x	x
Hepatitis B	Not known	x	x
HIV infection/AIDS	Not known	x	x

Adapted from Stone, 1994.[5]

Figure 1. Female reproductive tract.



Adapted from Anderson, D.J., 2002.[6]

Researchers are beginning three studies to determine whether diaphragms could indeed protect women against STIs, perhaps including HIV. Drs. Ann Duerr (CDC) and Craig Cohen (University of Washington) are leading a study testing the diaphragm for protection against recurrent infections among Kenyan women who have already been diagnosed with chlamydia or gonorrhea. A second study, to be led by Dr. Sandra Garcia of the Population Council, will work with sex workers in the Dominican Republic to evaluate the diaphragm's protective effects against chlamydia and gonorrhea. The third study, a randomized, controlled trial in Zimbabwe and South Africa, will test the diaphragm in preventing HIV acquisition. This trial, which will include more than 4,000 women, will be led by Dr. Nancy Padian from UCSF.

Cervical Barrier Methods: An Overview

The currently available physical barriers of the cervix include diaphragms, cervical caps, and sponges. Table 2 summarizes the guidelines for using these devices for pregnancy prevention, the only use for which barriers are now approved. All of the diaphragms and caps are inserted before intercourse, are designed to be used with a spermicide, and should be left in place for some hours after intercourse.

Cervical barrier methods can provide good contraceptive protection if they are used consistently and correctly at every act of intercourse. Pregnancy rates vary by device as well by group of women.[7] Consistent and correct diaphragm users, whether parous or not, achieve excellent protection, with 94 percent avoiding unintended pregnancy during the first year of use. Nulliparous users of the cervical cap and sponge achieve almost equivalent rates. Among parous users of the cervical cap, however,

Cervical Barriers: Current Devices, Potential Developments

Of the 13 cervical barrier devices described below, 11 are currently available, and 9 are approved by U.S. or European regulatory authorities. Descriptions include the name of the manufacturer, material, sizes, and availability.[8–15] Diaphragms and caps require prescriptions in the United States. For a discussion of sponges, see page 5.

Approved Diaphragms

Ortho All-Flex

Ortho-McNeil Pharmaceutical. Latex. Arcing spring. Nine diameter sizes from 55 to 95 mm, in 5-mm increments. Available in the United States and elsewhere. Market leader in the United States and world.

Ortho Coil Spring

Ortho-McNeil Pharmaceutical. Latex. Coil spring. Nine diameter sizes from 55 to 95 mm, in 5-mm increments. Available in the United States and elsewhere. Popular in the United Kingdom.

Semina

Semina Industries and Commerce Ltd. Silicone. Arcing spring. Six diameter sizes from 60 to 85 mm, in 5-mm increments. Available in Brazil.

Wide Seal

Milex Products, Inc. Silicone. Arcing or omniflex spring. Has a skirt around the rim intended to hold spermicide in place and improve the seal. Eight sizes from 60 to 95 mm, in 5-mm increments. Available in the United States, Canada, Europe, Asia, and the Middle East.

Other Approved Cervical Barrier Methods

Lea's Shield

Yama, Inc. Silicone. Removal loop. One size. Available in the United States and Europe. Approved for 48 hours of continuous use. No need to add extra spermicide for additional acts of intercourse.

Lily

Shanghai Lily Life Rubber Product Co., Ltd. Latex. Four sizes: 54, 58, 62, and 66 mm. The only size currently available is the 58 mm. Available in China.

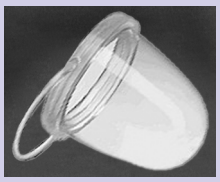
Approved Cervical Caps

Dumas

Lamberts (Dalston) Ltd., UK. Latex. Also known as the "Dutch cap." Shallow and bowl-shaped. Covers cervix and part of vaginal tract. Five sizes, equivalent to 50, 55, 60, 65, and 75 mm external diameter. Available in Europe, Australia, and elsewhere.

FemCap

FemCap, Inc. Silicone. Removal strap over dome. Groove between brim and dome is designed to hold spermicide and trap sperm. Covers cervix and part of vaginal fornices. Three sizes: 22, 26, and 30 mm. Available in Europe. May be worn for 48 hours.



Ovès

Veos UK Ltd. Silicone. Removal loop. Covers cervix. Three sizes: 26, 28, and 30 mm. Available in Europe. Disposable.

Prentif

Lamberts (Dalston) Ltd., UK. Latex. Thimble-shaped with tight fit over cervix. Four sizes: 22, 25, 28, and 31 mm. Approved for 48 hours of continuous use in the United States and up to 72 hours in Europe.

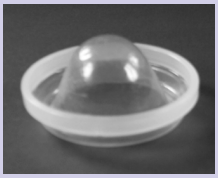
Vimule

Lamberts (Dalston) Ltd., UK. Latex. Bell-shaped with flanged rim. Covers cervix and part of upper vaginal tract. Three sizes, equivalent to 42, 48, and 54 mm external diameter. Available in Europe, Australia, and elsewhere. U.S. FDA recall in 1983 due to a high incidence of vaginal lesions.

Diaphragms Under Development

SILCS (PATH)

SILCS, Inc. Silicone. Arcing ring and grip enable easier insertion. Has a pre-shaped rim to cling high in the vaginal vault. Finger cup on one edge is intended to simplify removal. One or two sizes. Can contain spermicide on both sides of cup.



BufferGel Cup

ReProtect LLC. Dipped polyurethane. Clear. Disposable. One size. Will be marketed pre-filled with BufferGel, a candidate microbicide and contraceptive.

only 74 percent can expect to avoid pregnancy during the first year, even with consistent and correct use. Parous sponge users may experience a first-year pregnancy rate of 20 percent. When factoring in typical use patterns, pregnancy rates for all devices are higher, largely linked to acts of intercourse when the devices are not used. In one year of typical use, 20 percent of diaphragm users, 20 percent of nulliparous sponge and cap users, and 40 percent of parous cap and sponge users become pregnant.

Diaphragms. Diaphragms have firm but flexible rims and shallow domes that can be coated with spermicide and then folded for insertion. All are designed to be held in place by the vaginal walls, the posterior fornix, and the pubic arch as they block the entrance to the cervix. Diaphragms generally are easier to insert and remove than cervical caps. Current directions for use indicate that diaphragm users should insert an extra dose of spermicide before additional acts of intercourse, and leave the device in place for a minimum of 6 hours after intercourse. The devices should not be worn for more than 24 hours.

Cervical caps. Smaller and firmer than diaphragms, cervical caps typically are designed to adhere to the cervix by suction. They also hold spermicide inside the cup. Many women find cervical caps convenient because they can be left in place longer than diaphragms (they are approved for up to 48 hours in the United States and 72 hours in Europe). Caps also are more acceptable to some women, since users do not need to insert additional spermicide if they have intercourse more than once. Pregnancy rates for the cervical cap are much higher among parous women than among nulliparous women.[7]

Sponges. Three sponges currently are approved in some countries for contraception. The Today Sponge is a small, pliable, polyurethane foam sponge containing nonoxynol-9 (N-9). It was removed from the U.S. market in 1995 for commercial reasons, but should soon be available in Canada. A concave depression on one side fits against the cervix and a soft loop on the other side can be grasped for removal. The sponge is designed to protect against pregnancy for 24 hours regardless of the number of acts of intercourse; users are counseled to allow at least 6 hours between intercourse and sponge removal. The Protectaid Contraceptive Sponge, available in Canada and Europe, has slots for easy insertion and removal, and contains a combination of three spermicides: N-9, benzalkonium chloride, and sodium cholate. According to the manufacturer, it is effective for up to 12 hours after insertion. The Pharmatex Sponge, which contains benzalkonium chloride but not N-9, is available in Europe.

Other Woman-Initiated Methods

In addition to cervical barriers, female condoms are an effective and acceptable woman-initiated option for contraception and disease protection. In the future, microbicides also may offer some protection for women seeking to avoid STIs.

Table 2. Guidelines for Use of Cervical Barrier Methods

	Diaphragm	Cervical Cap	Sponge
Clinician fitting recommended	Yes*	Yes*	No
Separate spermicide supplies needed before insertion	Yes	Yes	No
Additional spermicide (and applicator) needed for repeat intercourse	Yes	No	No
Disposable	No	No†	Yes
Can be used during menses	Yes	No	No
Recommended removal time	6 hours	48 hours	12–24 hours
Longest wear recommended	24 hours	48–72 hours	30 hours

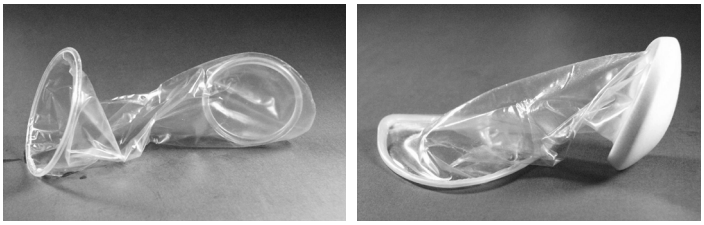
*Except Lea's Shield and FemCap.
†Except the Ovès cap, which is disposable.
Source: Adapted from Stewart, 1998.[2]

Female condoms. Female condoms are barrier devices designed to protect the cervix, vagina, and part of the vulva and perineum. They are highly acceptable to some women[16] and have excellent potential to protect against HIV and other STIs. Relative to the diaphragm and cervical cap, however, they are less discreet and thus more difficult for women to use without their partners' cooperation.

Three brands are commercially available (two of which are shown in Figure 2). The FC Female Condom (formerly Reality) uses a soft, flexible, polyurethane pouch to line the vagina. The pouch itself is strong and thin. Each end of the pouch contains a firm but flexible ring. A free-floating inner ring aids insertion and holds the device in place during intercourse. An attached ring at the outer end holds the opening of the pouch outside the vagina, partially covering the labia. The Reddy female condom has been available in Germany since December 2002, where it is marketed as the V-Amour Women's Condom. This device is made of latex and uses a soft, polyurethane sponge to hold it in place inside the vagina. An outer ring anchors the Reddy female condom outside the vagina. Use effectiveness data for pregnancy and STI prevention are not available for the V-Amour. The Natural Sensation Panty Condom is made of a synthetic material that is thinner than latex, and is shaped and worn like a woman's panty with a built-in condom. It is available in Colombia.

Microbicides. In the future, candidate microbicides formulated as gels, creams, foams, or films may prove protective against STIs (particularly in combination with a barrier method). Although these chemical substances are often collectively referred to as microbicides, only a few are designed to kill microbes directly. The others are designed to inactivate microbes, block viral entry into vaginal or cervical cells, inhibit viral replication once entry has taken place, or enhance the vagina's natural defense mechanisms against pathogens. It is also possible that inert jellies, foams, or creams could help protect against STI transmission simply by coating the vagina or cervix. If used with a barrier device, jellies or creams might enhance

Figure 2. FC and Reddy female condoms.



a seal to the cervix, but would also introduce new costs and complexities.

A safe and effective microbicide, however, still remains some years off. Only a handful of substances are ready to enter the large-scale effectiveness trials that will demonstrate whether they do protect women. The websites maintained by the Alliance for Microbicide Development (www.microbicide.org) and the Global Campaign for Microbicides (www.global-campaign.org) provide detailed information on these efforts.

Cervical Barrier Safety

In general, existing cervical barrier methods are associated with minimal safety risks. The main safety concerns are toxic shock syndrome (TSS) and urinary tract infections. TSS is rare but potentially serious and occasionally fatal. Caused by the *Staphylococcus aureus* bacterium, it most often is associated with extended tampon use during menstruation. Of the few TSS cases in women that are not related to menstruation, most are associated with cervical barrier devices. A study performed in 1986 and 1987 found that sponge and diaphragm use considerably increased the risk of non-menstrual TSS.[17] As with tampons, timely removal of vaginal barrier devices reduces the risk of infection. TSS is normally treated by intravenous antibiotics.

Evidence linking diaphragm use to urinary tract infections (UTIs) is mixed. Some observational, case-control, and cohort studies, including one very large study, show an increased incidence of UTIs among diaphragm users,[18–21] but others do not.[22,23] The studies varied as to whether they controlled for possible confounding factors, such as coital frequency. In addition, it is possible that the N-9, rather than the diaphragms themselves, could cause UTIs. One study measured *Escherichia coli* bacterium colonization among 104 women before sexual intercourse, the morning after intercourse, and 24 hours later.[24] Women taking oral contraceptives showed slight colonization increases after intercourse, but women using condoms with N-9, foam, or diaphragms with N-9 jelly showed dramatically higher levels that persisted one day later. Furthermore, exposure to N-9 seems directly correlated with UTIs. Another study[25] documented almost twice as many UTIs among women whose partners used N-9–lubricated condoms more than once a week than among age-matched controls; the odds of getting a UTI were nearly six times as high among women whose partners used N-9 condoms more than twice a week than among the controls. Women whose partners used condoms without N-9, however, had no more UTIs than the controls.

Are Diaphragm Fittings Necessary?

Most family planning guidelines state that women need to be individually examined and measured by a clinician to determine their diaphragm size. A fitting visit takes time for both women and health care providers, and can be embarrassing or uncomfortable, leading many to consider it an obstacle to diaphragm use. The role of the fitting, however, has never been rigorously evaluated. Indeed, some experts have contended for decades that custom fitting of diaphragms for pregnancy prevention is not necessary. They point to several types of evidence.

Anatomical. Early work from Masters and Johnson[26] showed dramatic changes in the vaginal anatomy during sexual arousal: the lower third of the vagina contracts in diameter by as much as 50 percent, while the upper two-thirds lengthens by 3 to 5 centimeters and distends significantly. Diaphragms filmed during simulated intercourse do not hug the vaginal walls as they are fitted to do, but float freely around the cervix.

Historical. Records from the early twentieth century suggest that diaphragm-fitting requirements were imposed

Nonoxynol-9 and STIs

Most diaphragms and cervical caps are intended to be used with spermicide. Nonoxynol-9 (N-9) is the most widely available spermicide and has been in use for more than 50 years. It is approved in jelly, cream, film, suppository, and foam formulations. All are marketed for the prevention of pregnancy.

Until recently, many public health experts believed that N-9 also held promise for helping women protect themselves from STIs, including HIV. Their initial hopes were based on *in vitro* and animal studies. Subsequent clinical research, however, including several randomized trials, failed to confirm these positive preclinical results.

In 2002, the Cochrane Library published a meta-analysis[27] of all available studies. The review concluded that N-9 may pose harm by increasing the frequency of genital lesions, possibly increasing the likelihood of STI transmission. WHO and CONRAD warned that spermicides containing N-9 do not protect against HIV, gonorrhea, or chlamydia, and may even increase the risk of STIs in women using these products frequently.[28] N-9 alone is only moderately effective for pregnancy prevention, and women at high risk of HIV infection should be advised against using N-9 spermicides for contraception unless no other form of contraception is available.[28] The authors cautioned, however, that the advisory does not apply to women at low risk of HIV.

for social, economic, and political reasons.[1] Early family planning advocates decided to promote fitting requirements in order to place contraception under physician supervision. In the United States, physician supervision was one means of circumventing oppressive obscenity laws that were being used to criminalize all contraceptives. These fitting requirements also gave doctors an economic incentive to provide family planning.

Clinical. No randomized, controlled trials to assess the effect of fitting have been performed, but the collective results of cohort and randomized studies that include fitting among the study parameters suggest that fitting may not be necessary. The results are not definitive, though, because women in the studies not only used unfitted diaphragms, but also did not use spermicides with the diaphragms. In a large (n=997) observational study conducted in 1985, women using the fit-free, non-spermicide diaphragm regimen had very few pregnancies (1 per 100 woman-years).[29] An evaluation performed in 1995, however, demonstrated a much higher pregnancy rate (24 per 100 woman-years).[30]

Changes in fitting approaches over the past century also seem unrelated to success rates. During the 1920s, for example, the accepted approach was to fit small diaphragms high and snug in the vaginal vault. By the 1970s, the trend was to wedge diaphragms, in a size as large as the woman could comfortably tolerate, low against the vaginal wall, where they were held in place behind the pubic symphysis. No prospective studies have tracked the failure rates associated with these approaches, but the clinical literature has not suggested any difference in effectiveness. In addition, two retrospective studies showed no correlation between weight change and diaphragm size.[31,32] These issues primarily pertain to the diaphragm's use for pregnancy prevention, but they may also factor into its potential for STI protection.

Experience From Developing Countries

Most of the experience with diaphragms and cervical caps comes from developed countries, but the methods are suitable for women in developing countries as well. Studies in the 1980s documented use in Egypt[33] and a few other developing countries. Studies in the mid-1990s explored reactions to the devices among women in Turkey,[34,35] Colombia,[35] the Philippines,[35] Brazil,[36] and India.[37] In general, these studies indicate that where women receive information from providers and support from their partners, they find diaphragms very acceptable and successful as a method of family planning. The study from India particularly emphasized that women can use diaphragms successfully even when they do not have access to private bathrooms or running water in the house.

Where women receive information from providers and support from their partners, they find diaphragms very acceptable and successful as a method of family planning.

At the Diaphragm Renaissance meeting, several speakers presented their experience providing and studying diaphragms in Turkey, Colombia, the Philippines, and Zimbabwe. All confirmed that with adequate information and support, women in developing countries can use diaphragms successfully for family planning. They noted, however, that commercial interest in registering and marketing diaphragms in many developing countries has been weak, despite the efforts of women's health advocates and women themselves.

Modest changes in clinical guidelines could help product developers adapt the method for easier use in developing countries. Given supportive research results, modifying fitting requirements would be an important step. Fittings are nearly impossible for community-based distribution programs. Even in clinic-based programs, fittings are time-consuming for busy providers. Although researchers at the 2002 meeting disagreed about the need for fitting, most concurred that two or three sizes (rather than the nine sizes available for the most widely marketed diaphragms) would suffice for most women. One randomized, controlled trial now in the late planning stages at Ibis Reproductive Health intends to test the need for fitting the Ortho All-Flex, the diaphragm market leader. If the device performs well without clinician fitting, that diaphragm and perhaps others could be offered in a standard size. Participants at the 2002 meeting also placed priority on evaluating the effectiveness of new one-size or two-size devices such as Lea's Shield, BufferGel Cup, and the SILCS diaphragm.

Conclusion

Cervical barrier devices may be able to contribute to reducing the spread of HIV/AIDS. Given the seriousness of the HIV pandemic and the long time required to develop viable microbicides and vaccines, physical barriers should be re-examined and evaluated. Currently accepted usage guidelines, particularly those that are not evidence-based, should be critically reviewed. Researchers must assess cervical barrier methods' effectiveness against HIV and other STIs, identify a replacement spermicide for N-9 for high-frequency users at high risk of HIV (or show that this is unnecessary), and overcome supply and provision issues (including the need for clinical fittings) in developing countries. The potential of cervical barrier devices for pregnancy and, possibly, disease prevention—particularly for women and programs in low-resource settings—deserves greater attention.

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