In the early 1980s, as soon as scientists and clinicians suspected that the pathogen responsible for AIDS was sexually transmitted, they advised sexually active individuals to use condoms to protect themselves and others from infection. At that time, condoms were seen as an old-fashioned pregnancy prevention method unpopular among heterosexuals, who favored “the pill,” and almost unheard of among men who have sex with men. Faced with the appalling spread of AIDS, its dramatic physical symptoms, and a barrage of AIDS-related deaths, condom use increased significantly, especially among men who have sex with men.

Although this was hailed as one of the biggest changes in U.S. health behavior history, it did not go far enough. Cross-sectional studies conducted during the last 15 years have generally shown that about half of sexually active men who have sex with men do not use condoms consistently for anal sex. A recent study of 23- to 29-year-old men who have sex with men in six U.S. cities showed that the prevalence of unprotected sex during the prior six months was 46 percent, with the prevalence of HIV infection reaching 30 percent among African Americans, 15 percent among Latinos, 7 percent among European Americans, 3 percent among Asians, and 10 percent among “other” racial and ethnic groups.1

**Condom Fatigue**

Social scientists have identified reasons for lack of condom use and developed programs to promote safe behavior, including individual, group, and community level interventions, that have shown varying levels of success.2 However, it has proven difficult to transfer experimentally designed interventions to community settings where they can be implemented on an ongoing basis. As newly “out” gay men become sexually active, and as more experienced gay men endure fatigue in the maintenance of safer sex, there is a continuous need to revitalize condom campaigns. Most men who have sex with men use condoms out of necessity, not pleasure, and maintaining consistent condom use over time is difficult. The question is whether there are alternative means of protection for sexually active men who engage in anal sex with partners of discordant or unknown serostatus.

In the general marketplace, products that are unpopular among consumers are replaced by new ones. However, in the case of condoms, there have been repeated attempts to modify the consumer rather than the product. Although advocates for women have long pointed out the need for alternative methods, especially female-controlled techniques or devices that do not depend on the collaboration of the male partner, there has been a disappointing lack of creativity and initiative devoted to developing alternatives to penile condoms. This article discusses microbicides and “female” condoms as two potential alternative prevention methods for men who have sex with men.

**Microbicidal Options for Anal Sex**

Most men who have anal sex with men use lubricants. They state that lubricants facilitate penetration, enhance pleasure, and decrease pain and discomfort. Lubricant use for anal sex preceded the AIDS epidemic and has continued despite little organized effort to promote it. The possibility of developing a lubricant with an active, microbicidal component that could provide protection against HIV and other sexually transmitted diseases (STDs) is tantalizing for most gay men, since it
Editorial: Condom-Prop

It is surprisingly difficult for many of us who work with HIV to truly appreciate the difference between risk reduction and risk elimination. Our minds know that the goal of HIV prevention is to reduce risk, but our hearts whisper to us that what we really, really, really want is to annihilate it. We seek to be client-centered in our approaches, “meeting people where they are,” even if that means accepting that someone will use condoms only some of the time. But our hearts scream, No! No! you must use condoms all the time, or you will get infected. It’s only a matter of time.

The penile condom is the perfect prop for the closet risk eliminators among us. Used properly and consistently, it approaches 100 percent protection! But, the only penile condom that would truly eliminate risk would be one that was surgically attached—permanent protection, the HIV-blocking equivalent of a vasectomy. The penile condom enables us to believe that risk elimination is possible, when the absolutely consistent use it requires is almost impossible—particularly for those at highest risk, those whose only consistent HIV response is to be inconsistent about condom use.

Alex Carballo-Diéguez makes this point simply and eloquently in this month’s FOCUS, stating: “In the general marketplace, products that are unpopular among consumers are replaced by new ones. However, in the case of condoms, there have been repeated attempts to modify the consumer rather than the product.”

The Triumph of Desire

There’s something a little disorienting about all of this, mind racing one way, heart the other. But, the fact is that desire is far stronger than HIV education and often more robust and immediate than the fear of death. Survival as the paramount goal of living is a myth of some pure Darwinian state of being that may have existed in the primordial soup, but is notably absent from San Francisco’s Castro District or New York’s Christopher Street. (Perhaps the triumph of desire over prudence occurs when the mating instinct—survival of the species—takes precedence over the life instinct—the survival of the individual organism. But that’s another issue.)

The reality is that it is foolish after all these years of condom education not to see its failures, as well as its successes: penile condoms offer only one type of protection to passive partners: a protection over which they have no control, only varying degrees of influence. As both Carballo-Diéguez and Nancy Padian demonstrate in this issue of FOCUS, there are alternatives—rectal and vaginal microbicides, the “female condom,” and variants on the cervical cap—that while not as effective as penile condoms are not ineffective. They offer passive partners significantly more control and protection than any other prevention tool, including especially the appropriately touted “negotiation skills” that nonetheless require insight, emotional strength, and most importantly, alternatives, like the ability to walk away from a situation.

Researchers like Carballo-Diéguez and Padian have been advocating for new approaches for years. The real tragedy here is that the cost of developing and distributing these approaches is far less than the cost of developing and distributing HIV antiviral drugs, demonstrating once more the immense value of prevention.

References

include sulphated and sulphonated polymers such as carrageenan (Carraguard), Pro 2000, and dextrin 2 sulphate.

Examples of microbicides that prevent infection from taking hold include antiretroviral agents like PMPA gel, which stops HIV from replicating in cells, and “plantbodies,” anti-HIV antibodies genetically engineered from plants that would combat pathogens before infection occurs. Finally, products that enhance natural defense mechanisms seek, for example, to amplify the vagina’s naturally acidic environment and to increase its production of hydrogen peroxide, both of which are hostile to pathogens including HIV. Examples include BufferGel and Acidform, which help the vagina to maintain natural levels of acidity in the presence of semen, and suppositories containing lactobacillus, bacteria that normally live in the healthy vagina and that produce hydrogen peroxide.

BufferGel, Pro 2000, and Carraguard are in advanced stages of human trials. However, these studies have focused almost exclusively on vaginal use. This is problematic since research has shown that once a substance becomes available for vaginal use, gay men are likely to use it for anal sex regardless of label warnings that indicate the product has been tested only for vaginal sex. This was the case with products containing nonoxynol-9, a detergent employed as a spermicide for many years and currently sold over the counter. As soon as it was suggested that nonoxynol-9 was effective against HIV during vaginal intercourse, word quickly spread among gay men who started using lubricants with nonoxynol-9 for anal sex. Unfortunately, the safety and efficacy of nonoxynol-9 for anal sex had not been demonstrated, and recent studies have uncovered worrisome findings. One small study showed rapid exfoliation of sheets of rectal epithelium in specimens collected 15 minutes after nonoxynol-9 application. The results of this study were recently confirmed in studies conducted with monkeys. In other words, nonoxynol-9 seems to damage, rather than protect, the rectal mucosa, thus potentially facilitating the entry of HIV. This underscores the need to develop products that are safe for both vaginal and anal sex. There are many possible microbicide agents being tested that, unlike nonoxynol-9, are not detergents and do not injure the rectal mucosa.

Acceptability and Protection of Microbicides

Beyond the issue of product development and safety, there is a need to test the acceptability of microbicides among different populations, including gay men. Little would be gained from developing an effective microbicide if people refused to use it. Acceptability research needs to explore how potential users greet different formulations, mode of use, and applicators.

To date, only a few studies have explored this issue. One study found that more than three-quarters of 3,093 men who have sex with men and who had anal sex used lubricants more than 80 percent of the time; about two-thirds said they were definitely or probably willing to participate in rectal microbicide clinical trials. In a sample of 307 Latino men who have sex with men and who engage in anal sex, another study found that 93 percent used lubricants (59 percent always and 74 percent in at least 80 percent of sexual encounters) regardless of condom use. Ninety-two percent said that they would use a lubricant with an anti-HIV microbical agent, and 87 percent expressed interest in participating in an acceptability trial.

Finally, in a study of 385 men who have sex with men recruited in West Hollywood, researchers found that men with negative attitudes toward condoms were more likely than men with positive attitudes to say that they would use a rectal microbicide by itself, provided that it reached the efficacy standard that they expected. Furthermore, the authors found that as the percentage of unprotected anal intercourse partners in the prior year increased, participants were increasingly likely to say they would use an effective microbicide gel by itself.

Another important issue is what level of protection may be expected from microbicides. It appears unlikely that microbicides will achieve the 95 percent level of protection that correct and consistent condom use offers. However, this percentage declines dramatically when condom use is
occasional or nonexistent. A less effective product that is consistently used may offer as much protection as a more effective product that is only seldom used.

The prevailing view is that microbicide development is technically feasible. Yet, progress has been slow. Although there are many scientific challenges to the development of microbicides, a central problem seems to be the scarcity of resources dedicated to this endeavor. Advocacy groups, including the Alliance for Microbicide Development, have lobbied Congress to increase the allocation of public funds, contacted major pharmaceutical companies to stimulate microbicide development, and encouraged private philanthropies to provide support.

The Female Condom

The “female” condom is a strong but soft, transparent polyurethane pouch designed to be inserted in the vagina before sexual intercourse to provide protection against both pregnancy and STDs, including HIV. It is stronger than latex, odorless, causes no allergic reactions, and, unlike latex, may be used with both oil-based and water-based lubricants. It can be inserted prior to intercourse, is not dependent on the male erection, and does not require immediate withdrawal after ejaculation. It has no known side effects or risks. The pouch has two semi-rigid rings, one that remains external to the vagina and the other that fits against the cervix.

As with other disease prevention methods, gay men have experimented to see if the female condom could be used for anal sex. They removed the internal ring and inserted the condom into the rectum. In one study, researchers examined the opinions of men who have sex with men about the experience of using the female condom for anal sex. Out of the 100 men who responded to the survey, 86 percent said they would use the condom again, and 54 percent reported they would rather use female condoms than penile condoms. Acceptability was higher among men who were HIV-positive, were in non-monogamous relationships, or had serodiscordant partners. Negative experiences included difficulty inserting (33 percent), irritation (17 percent), bunching up (12 percent), unpleasant texture (10 percent), and noise (9 percent). Breakage was reported three times in 334 episodes of use.

There are no available data to compare the efficacy of the female condom to the penile condom. Nevertheless, the female condom almost certainly reduces HIV transmission when compared with unprotected anal sex and, therefore, may be an alternative for men who have difficulty consistently using penile condoms. Clearly, the acceptability of the female condom among men who have sex with men requires further study.

Conclusion

To bring the HIV epidemic under control, new infections need to be averted. This task requires many different approaches. Some individuals may abstain from sex, others may only have sex with a monogamous serodiscordant partner, others may avoid penetration, and still others may use penile condoms every time they have penetrative sex. Yet, for many sexually active people these are not valid options, as evidenced by the levels of new infections documented among young people. Increasing the number of available HIV-protection methods may improve primary prevention. Methods that may be effectively integrated into people’s habitual sexual behaviors may be more likely to be used for protection against HIV and other STDs.

Clearinghouse: Non-Condom Barriers

References


Uckun FM, D’Cruz OJ. Prophylactic contraceptives for HIV/AIDS. Human...
Female-Controlled 
HIV Prevention Methods
Nancy Padian, PhD

In heterosexual relationships, when a man does not offer to use a male condom, the best a woman can do is to negotiate their use or refuse to have sex. Although numerous interventions have been devised to “empower” women by teaching them negotiation skills, such skills depend on a woman’s ability to master them, and even so, negotiation may not be possible in all situations. Widespread violence against women, the imbalance of power in many sexual partnerships, and double standards of sexual behavior by which women requesting that their male partners use condoms are accused of cheating—all make prevention difficult. There are a greater number of protected sex acts when women are offered a choice of methods that are controlled by women critically important. Among these methods are microbicides, the “female” condom, the diaphragm, and the cervical cap.

Microbicides and Female Condoms
Vaginal microbicides are topical chemical barriers that protect against a variety of sexually transmitted disease (STD) pathogens, including HIV. Compared to condoms, microbicides should interfere less with intimacy and pleasure, and are more discreet. Studies of nonoxynol-9, the principal existing microbicide, have demonstrated modest protection against chlamydia and gonorrhea, but mixed results against HIV. In fact, a recent study showed enhanced HIV transmission in the women using nonoxynol-9, possibly due to compromise of the epithelial barrier after intensive use.1 New microbicides are being developed for vaginal protection. (See “Alternatives to Male Condoms for Men Who Have Sex with Men,” page 1.)

The female condom is a transparent polyurethane pouch bound by two rings, one inner ring that is squeezed together and used for insertion, and an outer ring that remains outside the vagina and partly covers the labia. Although few studies have evaluated the efficacy of the female condom in protecting against STDs and HIV, those that have support its value. In one study, researchers followed 108 U.S. women with trichomoniasis for 45 days.2 No repeat infection was detected among the 20 percent who used female condoms consistently, while there was a 14 percent reinfection rate among inconsistent users and non-users.

In one Kenyan study, there was no difference in STD or HIV incidence among women who were counseled to use female condoms or male condoms versus women in a control group who were counseled to use only male condoms. This was true even though male condoms were not used as frequently in the intervention group as they were in the control group.3 Comparable rates of infection in the two groups suggest that female condoms are as effective as male condoms.

References


Resources
Alliance for Microbicide Development, 8701 Georgia Avenue, Suite 804, Silver Spring, MD 20910, 301-588-8091, 301-588-8390 (fax), http://www.microbicide.org (web site). Manages microbicide research projects and distributes educational materials regarding microbicide development.

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See also references cited in articles in this issue.
Physical Protection of the Cervix

Because both chlamydia and gonorrhea preferentially infect “columnar epithelium,” the skin cells characteristic of the cervix, there is good reason to suspect that coverage of the cervix would offer protection against these pathogens. In addition, the cervix itself may be particularly vulnerable to HIV. Moreover, since chlamydia and gonorrhea infections increase susceptibility to HIV infection, protection from these pathogens should further protect against HIV. Finally, several observational studies have found that diaphragms, when used with a spermicide, decrease susceptibility to STDs, suggesting the value of protecting the cervix.

The diaphragm is only one prototype for recently developed, women-controlled, physical barrier methods. Several other barrier methods for the cervix are under development or at various stages of testing. These methods include Leah’s shield (similar to a loose fitting cervical cap made of rubber, with a loop for easy removal) the Femcap (also similar to a cervical cap, but a bit softer with a snugger fit, that may be possible to use without spermicide), and disposable diaphragms, some of which release spermicide during use. There are no STD or HIV prevention data for these methods.

Acceptability of Female-Controlled Methods

An HIV prevention method can only be effective if it is used. The acceptability of female-controlled barrier methods has generally been evaluated in longitudinal studies: female condoms or spermicides were distributed to women, with or without male condoms, but without the option to choose from among a range of products as a woman might in the more natural environment of a pharmacy or clinic. Although many of these studies have indicated that the female condom is acceptable, it is unclear whether these results would be sustained beyond the study period. In those studies that have been able to examine method preference and choice from among a range of products, women were generally allowed to choose from male condoms, spermicides in various formulations (gel, film, cream), and the female condom. No method was preferred across all studies, reinforcing the importance of providing a range of method options.

Even fewer studies have been conducted on the acceptability of the diaphragm. In these few studies, women who chose the diaphragm reported a higher frequency of intercourse than women who chose other methods and cited safety and freedom (the fact that use did not require negotiation with the male sex partner) as factors significantly associated with their choice.

It seems obvious that internal barrier devices would be more acceptable if their disease-preventive efficacy were proven through further study.

Just as not all women find the same product acceptable, not all women use the same products all the time. In fact, several studies have shown that there are a greater number of protected sex acts when women are offered a choice of protective methods compared to when they are offered only a single method regardless of the frequency of intercourse.

In the Kenyan study cited above, women counseled to use male and female condoms reported more protected acts of intercourse than women in the male condom-only group due to increased use of the female condom. Another study found similar results when it compared the use of the male condom only to a choice of the male condom or a spermicide. Although women who had the choice reported lower rates of male condom use, they also reported a greater number of protected acts of intercourse.

Conclusion

Overall, much attention has been focused on the development of new methods that women can use to protect themselves against STDs and HIV. Equally important should be research focused on evaluation of existing methods, such as the diaphragm or cervical cap. Expanding method choice may itself prove to be an effective prevention strategy. Although male condoms may in fact be more efficacious than other prevention methods, finding a method or methods that can be used consistently may be more important than prescribing a better method that is used occasionally or even frequently.
In a comprehensive review of HIV prevention programs for women, the most effective interventions were specifically directed toward women, focused on relationships and negotiation skills, and involved multiple, sustained contacts. Researchers reviewed 16 studies of HIV prevention programs, including pre- and post-intervention data, to help establish the program’s effectiveness. All interventions were conducted in the United States, Canada, or Puerto Rico and described a psychological, behavioral, or educational component that addressed sexual risk reduction.

Relational skills-based interventions included topics such as partner negotiation, problem-solving, and communication. Of eight studies that evaluated relational skills-based interventions, four yielded significant results. Each of these specifically targeted women and lasted five or more sessions. All four found that interventions effectively increased condom use, and one study’s follow-up report confirmed the maintenance of these behavioral changes 15 months later. Relational skills-based interventions that did not report significant results were targeted at both men and women or lasted two or fewer sessions.

Although brief testing and counseling programs generally did not lead to significant behavior change, two interventions of this type—targeting injection drug users and homeless people—resulted in decreased numbers of sex partners, according to a two-week post-intervention assessment. Brief informational interventions without a skills component had limited effectiveness in decreasing sexual risk behavior. Community-based interventions that included outreach and encouraged change of risk behaviors and community norms also appeared promising.

According to a Los Angeles study, men who have anal sex with other men would be willing to try a rectal microbicide gel as their only means of protection only if it was, on average, at least 84 percent effective in preventing HIV infection. Fifty-three percent of the men said the microbicide would have to be at least 95 percent effective.

Men who engaged in anal intercourse with men in the prior 12 months were recruited from the streets of West Hollywood, California, to complete a self-administered survey. Participants read a description of a potential rectal microbicide gel and reported their preferences regarding efficacy level and intention to use. Of the 385 participants, 24 percent were African American, 29 percent were Hispanic, and 47 percent were White. Twenty-six percent were 18 to 24 years old, 35 percent were 25 to 30, and 39 percent were older than 30.

Participants did not use condoms with an average of 39 percent of their anal sex partners in the previous year. Men under the age of 25 reported that 48 percent of their anal sex experiences were unprotected, significantly higher than the other men. Intent to use the microbicide gel without a condom was associated with negative attitudes toward condoms, high levels of unprotected anal sex in the last 12 months, and a higher requirement for product efficiency. Among participants who had consistently used condoms during the prior year, 37 percent said they would prefer to use a rectal microbicide product instead of a condom in the future. However, 85 percent of these men wanted the microbicide gel to be as effective as a condom before they would use it as their only HIV prevention method.

The Female Condom as STD Prevention


In a six-month follow-up study investigating female condom use among women at high risk for contracting a sexually transmitted disease (STD), 8 percent of participants
had used female condoms exclusively, 15 percent had used male condoms exclusively, 73 percent had used both types of condoms, and 3 percent had not used condoms.

Researchers interviewed 1,159 STD clinic patients in Birmingham and Huntsville, Alabama, and provided study participants with a behavioral intervention promoting condoms, including an opportunity to practice inserting the female condom, a physical examination, a six-week supply of male and female condoms, and instructions on completing a sexual diary. Participants were between 18 and 35 years of age and had no immediate plans for becoming pregnant.

Among 895 women who reported having engaged in heterosexual vaginal intercourse during the study period, half had sex with only one partner, one-quarter had sex with two partners, and one-quarter had sex with three or more partners. A total of 731 women reported using the female condom at least once during the follow-up period, 85 percent of whom reported use during the first month. Participants who were employed and those with regular sex partners at baseline were significantly more likely to try the female condom.

Twenty percent of women who tried the female condom used it only once, 13 percent used it twice, 20 percent used it between five and nine times, and 32 percent used it 10 or more times. Of the 309 consistent condom users, 75 percent predominantly used both types of condom, 18 percent exclusively used the male condom, and 7 percent exclusively used the female condom. Women who used the female condom exclusively or who mixed condom types were more likely than exclusive users of the male condom to be Black, to be employed, and to have a regular partner.

Female Condom Attitudes among Adolescents

A small study of homeless, high-risk adolescents found that they continued to prefer male condoms over female condoms, even after extensive education about the female condom.

Researchers gathered a convenience sample of 65 sexually active adolescents between the ages of 13 and 18 at an emergency homeless shelter in a major northeastern city. Participants completed a peer-led intervention and pre- and post-study interviews, all of which explored barriers to female condom use. The intervention consisted of small group sessions discussing various aspects of female condoms, including their construction, their efficacy, and the proper way to use them.

Sixty-three percent of participants used male condoms as their primary contraceptive method: 48 percent said they always used male condoms, but 44 percent reported having sex without a condom at least once in the two weeks prior to the study. Ninety-five percent had heard of the female condom, but only 15 percent had ever used one before the study.

Twenty-two participants completed the extended post-study interview, and all 22 gave reasons why they might use female condoms: the female condom provided protection against STDs and pregnancy (68 percent), the female condom’s polyurethane is stronger than latex (14 percent), and the female condom offers women more control over contraception and STD protection (9 percent). Seventeen participants reported reasons not to use the female condom, including difficulty inserting and using it (47 percent), discomfort or irritation (29 percent), and dislike of the female condom (18 percent). Finally, 73 percent of the post-study participants reported that they would still prefer the male condom to the female condom, citing availability and discomfort with inserting the device as major obstacles.

Next Month
Living in the shadow of the epidemic for 20 years magnifies the effects of living with HIV in the moment. In the April 2001 issue of FOCUS, Steven Schwartzberg, PhD, Assistant Clinical Professor of Psychology at Harvard Medical School, identifies the broad trends experienced by the gay community, explores their mental health implications, and proposes four chronologi-
ical phases of adaptation: disbelief/terror, action/belonging, burnout/despair, and early recuperation/fragmentation.

Also in the April issue, Lena Nilsson Schönnesson, PhD, Associate Professor of Social Work, University of Göteborg, Sweden, and Michael W. Ross, PhD, MPH, MHPEd, Professor of Public Health, University of Texas, Houston, define and examine the concept of “chronic risk,” the challenge faced by people living in communities with particularly high HIV seroprevalence.
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