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Adding the Female Condom to the Public Health Agenda on Prevention of HIV and Other Sexually Transmitted Infections Among Men and Women During Anal Intercourse

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Abstract

Legal barriers to conducting public health research on methods of protection for anal intercourse were lifted in the United States in 2003 when the US Supreme Court invalidated all state antisodomy laws. Although research funding has been available for the development of rectal microbicides, the female condom, which has already been approved for vaginal use, has not been evaluated for anal use. Although there is no evidence that the female condom is safe for anal intercourse, it has already been taken up for off-label use by some men who have sex with men. This demonstrates the urgent need for more protection options for anal intercourse and, more immediately, the need to evaluate the safety and efficacy of the female condom for anal intercourse.

IN THE UNITED STATES, ANAL intercourse is a common practice. Among men aged 25 to 44 years in the United States, 3.9% report having had anal intercourse with another man, and 40% report having had anal intercourse with a woman. Among women aged 25 to 44 years in the United States, 35% report having had heterosexual anal intercourse.[1] Hence, discussions about anal intercourse should not assume that the practitioners are all men who have sex with men (MSM). In fact, there are an estimated 4 times more women than there are MSM practicing receptive anal intercourse in the United States.[2] Unprotected anal intercourse is the sexual activity associated with the highest risk of HIV infection.[3]

THE CRIMINALIZATION OF ANAL INTERCOURSE

Despite the fact that it is a common practice among heterosexual as well as homosexual couples,[1] anal intercourse has long been subject to religious prohibition, criminal sanction, and social stigma worldwide.[4] Scriptures in Leviticus 18:22 and 20:13 have traditionally been interpreted to prohibit anal intercourse, at least between men, under punishment of death for both partners, and the story of Sodom in Genesis chapter 19 provided a name for the act: sodomy. Medieval Christianity condemned anal intercourse along with other nonprocreative activities such as fellatio, homosexual contact, and sexual activity with animals.[5] With the emergence of secular governments, “sins against nature” became codified in the law as “crimes against nature”

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through the enactment of anti-sodomy statutes. Although, in theory, any sexual activities not leading to procreation, such as male–female oral and anal sexual intercourse, were illegal, in practice, these statutes were applied primarily in cases of male–male sexual activity.[5]

As late as 1961, antisodomy laws in the United States were included in the criminal statutes of all 50 states of the union. By 1985, half of the states had repealed or struck down these laws, but in that year the US Supreme Court upheld the constitutionality of the remaining laws in the case of *Bowers v Hardwick*. The court ruled that the equal protection provisions of the 14th Amendment did not extend to anal intercourse and that majority disapproval of such a sexual activity was sufficient to pass a "rationalbasis" standard under US constitutional law.[6]

Bowers v Hardwick occurred during the early years of the AIDS epidemic, which was understood at that time to affect mainly MSM. The ruling effectively reinforced the US government in its reluctance to sponsor research on the particular sexual activity associated with the highest risk of HIV infection.[2] The US Food and Drug Administration has never approved a male or female condom specifically for use in anal intercourse, at least in part because antisodomy laws made anal intercourse an illegal activity in some states.[7,8]

PAVING THE WAY FOR A HEALTH AGENDA ON ANAL INTERCOURSE

In 2003, the US Supreme Court, in the case of *Lawrence v Texas*,[9] invalidated the remaining state antisodomy laws as they apply to behavior between consenting adult civilians in private. In overturning their own precedent in *Bowers v Hardwick* just 17 years earlier, the Supreme Court may have been responsive to rapidly evolving social attitudes and scientific knowledge about homosexuality, as well as about HIV transmission and human sexuality in general.

The 6-to-3 ruling in *Lawrence v Texas* was notably broad, stating that "liberty gives substantial protection to adult persons in deciding how to conduct their private lives in matters pertaining to sex" and that the antisodomy law in question "furthers no legitimate state interest which can justify its intrusion into the individual's personal and private life."[9] Thus, the period following *Lawrence v Texas* marks the first time in US history that anal intercourse has not been subject to criminal prosecution. It also offers an ideal opportunity for the development of a new public health research agenda on anal intercourse—one unfettered by legal constraints.

In 2004, the National Institute of Allergy and Infectious Diseases awarded a grant to UCLA and collaborative institutions to develop a pipeline for testing the anal use of microbicides. In 2007, the first rectal microbicide safety trial was conducted to evaluate the candidate product, UC-781.[4] However, we do not yet have an effective microbicide for vaginal use, and the development of candidate rectal microbicides lags farther behind that of vaginal products.[10] Consideration of whether technology already available for vaginal intercourse should be evaluated for anal intercourse is surely overdue. One candidate that might be considered for this crossover from vaginal to anal use is the female condom.

USE OF THE FEMALE CONDOM FOR ANAL INTERCOURSE

Although there is some research supporting equal efficacy of the female condom compared with the male condom in preventing sexually transmitted infections (STIs) when used vaginally,[11–15] there is at present no data on female condom efficacy during anal use. However, because both male and female condoms act similarly as physical barriers, it may be reasonable to assume that using a female condom for anal intercourse would be safer than using no protection at all. Observational studies in the United States indicate that some MSM already use the female condom for anal intercourse.[16–18] According to interviews we conducted in 2002 with 78 health care providers in 5 different health care settings in New York, some health care providers in the United States are presenting the female condom as an option for their

MSM clients,[19] and Population Services International, a nonprofit, social marketing organization, has implemented social marketing of the female condom to MSM in Thailand[20] and Myanmar.[21]

Furthermore, our search on the Internet for the phrase "female condom for anal sex" or variants thereof found that numerous Web sites address use of the female condom for anal intercourse, in some cases providing detailed instructions. We also looked at the Web sites of all 50 state departments of health in the United States to see if use of the female condom for anal intercourse was mentioned. Although we found anal use of the female condom mentioned on 7 state department of health Web sites, the content of the messages was inconsistent. For example, although the Web sites of 5 health departments in the United States and Canada support the use of the female condom for anal intercourse and even provide instructions on how to insert the device,[22–26]the Web site of the New York State Department of Health warns that "female condoms should not be used for anal sex, as they do not provide adequate protection."[27]

In addition, among those health departments that do support anal use of the female condom, the specific instructions provided on their Web sites differ with regard to use of the inner ring. The Massachusetts[22] and Hawaii[23] state department of health Web sites indicate that the inner ring should be removed prior to use for anal intercourse, whereas the Web sites of the District of Columbia Department of Health,[24] the Seattle and King County Department of Health,[25] and the STD Resource.com site of the Vancouver Department of Health[26] instruct users to leave the ring in or take it out, depending upon individual preference. Finally, the "STDs and Condoms Fact Sheet" of the Texas State Department of Health provides no instructions to potential users and simply states, "Most condoms go over a man's penis. A new type of condom was designed to fit into a woman's vagina. This 'female' condom can also be used to protect the anus.'[28] Thus, the absence of consistent messages and rigorous research has relegated use of the female condom for anal intercourse to a subject of conjecture, contradiction, and potential misinformation rather than one based on sound scientific evidence.

Because of the current lack of alternatives for protection during anal intercourse, people have experimented with the off-label use of new products to meet their needs. The determination of some couples to find new forms of protection for anal intercourse underscores the need for alternatives to the male condom. However, before promoting the female condom for anal intercourse, research is urgently needed. With the male condom, the sexual anatomy of the penetrative partner, the penis, is the same in both anal and vaginal intercourse, and therefore, the lack of US Food and Drug Administration approval of male condoms for anal intercourse has not been problematic. However, the female condom has features specifically designed for insertion into the vagina, most notably a flexible inner ring that is secured by the cervix. When used in the anus, the female condom may not be easy to insert, comfortable, or even safe. In addition, the female condom can be inserted into the vagina up to 8 hours prior to intercourse, [29] but this may not be true when using the product in the anus.

Therefore, studies are needed to determine the optimal methods for using the female condom during anal intercourse, especially with regard to the inner ring. The few safety studies that have been conducted to date have provided different instructions regarding the inner ring and have had numerous other flaws, including small sample size, high loss to follow-up, and poor adherence to protocol, making them inconclusive (M. A, Leeper, PhD, Female Health Company, written communication, March 18, 2008).[16,30] Additional research on the safety of the female condom for anal intercourse is needed to address the limitations of the previous studies, and clinical trials comparing the efficacy of the female condom to that of the male condom are also needed to help those who practice anal intercourse decide how to best protect themselves from rectal acquisition of HIV and other STIs.

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Once the necessary studies have been conducted and safety and efficacy have been demonstrated, the marketing of the female condom for anal intercourse should be widespread and must consider the diversity of the potential users in terms of gender, sexual orientation, and sexual practices. Perhaps one reason why the female condom has not become more popular is because it is being marketed only to women and only for vaginal sexual intercourse. The more popular male condom, on the other hand, is recommended for both vaginal and anal intercourse and, although it is worn by a male partner, it is generally marketed to and purchased by both men and women. One study among women who practice anal intercourse found that they frequently do so in conjunction with vaginal intercourse and, thus, need a condom that can be used for both activities.[30] By making the female condom less gender specific and diversifying its use to include anal intercourse, the female condom may become even more acceptable than it is now. A first step toward this end would, obviously, be a different name for the female condom.

The public health community needs to advocate for studies to examine the safety and efficacy of current vaginal products, as well as new products, for anal use. Because we lack an effective microbicide at this time, the potential of the female condom as an HIV- and STI-prevention barrier for anal intercourse urgently needs to be explored. In addition, this research may help guide future studies on microbicides for anal use when they become available. The goal of the public health agenda must be to provide more safer-sex options to all, regardless of gender, sexual orientation, and sexual practices, as soon as possible.

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