Building Better Barriers

What's in a name? When it comes to condoms, a lot.

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Donte Smith likes pretty much everything about the female condom—except its name. "It's a little annoying," the 27-year-old Chicagoan, a self-described queer man of color, says of the condom's moniker. "It's more of a receptive condom. The gender of the person doesn't have to be female." Calling it the female condom "really turns people off," says Smith, an outreach worker at a community center for LGBT youth.

And yet, driven by dissatisfaction with conventional male condoms, Smith counts himself among a sizable minority of gay men, as well as heterosexual couples, who are opting to use the female condom—there's just one on the U.S. market so far—for anal sex, even though, like male condoms, it has been designed and tested only for vaginal sex.

The conventional male condom leaves a lot to be desired: Most condoms are made of latex, and some people are allergic. Some men lose their erection when they try to put them on. Others hate the way they feel and refuse to use them, despite their partner's urging. And sometimes they break.

Public health experts, scientists and manufacturers have been listening. More than any time since the latex condom came on the market nearly a century ago, they are focused on building better condoms, both male and female—and even one specifically for anal sex. But most of the new condoms in the pipeline probably won't become available in the United States for several years, if ever.

Any company that wants to market the first condom made for anal sex faces daunting regulatory hurdles. Considering that anal sex was illegal in some states until 2003, it's probably not surprising that scientists and manufacturers have shied away from investigating whether condoms are effective for it.

After losing all of his friends in the 1980s to AIDS-related complications, 64-year-old Danny Resnic became religious about using condoms. But despite his diligence, Resnic tested HIV positive in

1993 after a condom broke. “That was the impetus for considering something new and different,” Resnic says.

The major condom manufacturers “have no incentive for innovation, because they’re all making the same thing,” Resnic says. “They’re so heavily invested in latex as a material. The population is conditioned to accept the rolled condom as the standard, but it doesn’t have to be.”

Resnic, who studied art in college and has a background in package design, decided to go back to the drawing board and create a better condom. He founded Origami Condoms, a Los Angeles–based company so named because its condoms fold, not roll.

“I threw everything we knew about condoms out the window and started with a checklist of consumer complaints. Our goal is to create a consumer-driven product, not just a product in a pretty package. We’re not going for entertainment,” like glow-in-the-dark condoms, Resnic says. “We’re going for pleasure.”

He has designed male, female and anal intercourse condoms—“radical new condoms for the 21st century,” as his company’s homepage puts it—and says the National Institutes of Health (NIH) has funded four studies of them with a total of $2.5 million.

Scientists and regulatory experts from around the world have offered their expertise, Resnic says, and he’s hopeful that the non-latex Origami male condom, made from a material he declined to reveal yet, will launch in Europe and the United States in 2014. “We’re putting a lot of development behind the male condom, primarily because the regulatory path is considerably easier,” Resnic says.

The U.S. Food and Drug Administration (FDA) holds female condoms to a higher standard “because there is less clinical data on their safety and effective-ness as compared to male condoms,” FDA spokes-woman Morgan Liscinsky says. “This lack of data is the reason why female condoms undergo our most rigorous pre-market review.”

That might help explain why there’s only one female condom on the U.S. market, the FC2. Although it was designed to be inserted into the vagina, pretty much anyone involved in HIV research and treatment will tell you it’s also being used for anal sex.

“I’ve heard men say it’s the only condom they’ll use now,” says Elizabeth Kelvin, PhD, MPH, a researcher at the HIV Center of Clinical and Behavioral Studies at the New York State Psychiatric Institute and also Columbia University. FC2 is more expensive than male condoms, but many LGBT organizations and health depart-ments buy them in bulk and distribute them for free.

A few years ago, in a small study of male clients at a New York City HIV/AIDS service organization, Kelvin found that about one in six had used the female condom for anal intercourse, most with only male partners but a few with both male and female partners. “The safety and efficacy of the female condom for anal intercourse are unknown and should be evaluated,” she and her co-

authors wrote in the American Journal of Public Health.

Washington, DC–based Kimberly Whipkey, an advocacy and communications specialist for PATH, an international nonprofit organization that developed a “woman’s condom” approved in Europe, China and South Africa, says she was “shocked” on a recent trip to Kenya by the interest health providers and HIV activists had in using it for anal sex. “So many people were asking about anal sex and female condoms,” Whipkey recalls.

While he is well aware of the dearth of information about its effectiveness in anal sex, Donte Smith says he has been using the FC2 for about five years. He says he wasn’t using any kind of condom when he got HIV in 2009, a couple of years after he’d left his native Houston for Chicago. Smith says it was a “difficult” time in his life—and one of the ways he coped was sometimes not using condoms.

After he was newly diagnosed, Smith decided to try the FC2 around the time it replaced the first-generation female condom, which had been made of polyurethane and developed a reputation for squeaking during sex.

“It’s both pleasure and choice,” explains Smith, whose partner of two years, Sy Bar-Sheset, is HIV negative. “The material just feels better. It breathes more.” Instead of latex, FC2 condoms are made out of a synthetic material called nitrile that users say conducts heat better than latex or polyurethane.

And, Smith says, he likes being able to insert the female condom into himself instead of having to depend on his partner to use a male condom. The fact that women can take the initiative to protect themselves and their partners by inserting the female condom into themselves is one of its main selling points, especially for women in developing countries.

Smith is glad to have a different option to discuss with the young people who drop in at the community center where he works. “People are tired of just this one version of safer sex,” Smith says of the traditional male condom.

While health departments and community health organizations in major cities such as New York, Chicago and Washington, DC, distribute the female condom to men for anal sex with the idea that it’s safer than not using any condom, Kelvin and her colleagues note that’s not necessarily the case.

“They have clients who can’t or won’t use the male condom, and they don’t know what else to tell them,” she says. “At the moment, there’s nobody doing the tests that need to be done. We’re all in this position without the information, and people need the protection. It’s unfortunate that we can’t help them make an informed decision.”

From a public health perspective, “I would not promote the female condom for anal sex,” says Kelvin’s colleague Joanne Mantell, PhD, a professor of clinical psychology at Columbia and a

researcher at the HIV Center of Clinical and Behavioral Studies. If someone asks about it, she'd discuss the pros and cons, but "I would not be actively giving it out."

Intuitively, it makes sense that the female condom is better than nothing for anal sex, but consider what happened with nonoxynol-9, an over-the-counter sper-micide, Kelvin says. In the 1990s and early 2000s, many consumers had come to believe that gels and foams containing nonoxynol-9, marketed as a vaginal contra-ceptive, could protect against HIV and other sexually transmitted infections (STIs).

However, a major study in Africa and Thailand a decade ago found that women using a gel containing nonoxynol-9 were actually at a higher risk for HIV than women using a placebo gel. Vaginal and rectal irritation from the compound facilitated transmission from infected partners. Theoretically, at least, the same thing could happen when FC2 is used for anal sex, Kelvin says.

The FC2 is shaped like a tube with rings at each end. One ring is designed to be inserted internally, past the woman's pubic bone, while the other is supposed to cover her external genitalia.

Like many men, Smith removes the inner ring to make the FC2 more comfortable. Removing the inner ring alters the condom's integrity, but leaving it in could irritate the mucous membrane lining the anus, Kelvin says.

Mantell, who has studied the promotion of the female condom among South African students and anal sex practices among women and men in South Africa, says she very much wants to do a study about the acceptability and effectiveness of a female condom for anal sex but has been unable to get NIH funding for it.

The NIH, like many sexual health scientists, is more interested in developing invisible weapons against STIs, namely microbicides, than testing barrier methods that are already on the market, Mantell says.

"I feel that there is in general a bias against the female condom by researchers," says Mantell, who also conducts research into microbicides. "The higher-level muckety-mucks that do these trials, which are very often physician-dominated, see it as thick. They've heard it makes noises. They've never used it."

In 2013, the National Female Condom Coalition sent a letter to the NIH urging it to promote research that evaluates the FC2 and any future insertive vaginal condoms for use in anal intercourse. The coalition also called on the NIH to support research that helps formulate "appropriate and consistent messaging around use of the FC2 for anal intercourse" that health departments, health care providers and prevention educators can use.

"Today, the topics of greater interest are products like PrEP [pre-exposure prophylaxis] and even the new Origami condom, not male and female condoms that have been around for a while," Kelvin says.

The fact that respected researchers like Mantell and Kelvin have been unable to get funding to study the use of a female condom for anal sex "is just proof of institutional bias against people like me," Smith says, calling it "stigma around the butt."

Don't look for the Female Health Company (FHC), manufacturer of the FC2, to invest in anal sex studies, says Mary Ann Leeper, PhD, senior strategic advisor for the Chicago–based company and, from 1996 to 2006, its president and chief operating officer. "We don't have the resources to do that," Leeper says. "It's just an enormous amount of work, an enormous amount of time, an enormous amount of money."

Anticipating that gay men and heterosexual couples would want to use the female condom for anal sex, FHC included two small studies, a total of 60 participants, in its application to the FDA to market the first-generation female condom back in the 1990s, Leeper says.

But, she adds, the FDA told the company it would need to conduct more research before it could market the female condom for anal sex. "I would imagine there are some at FDA who would be interested, but the process is so tedious, and the reward we don't know."

The Bill & Melinda Gates Foundation promises to pick up the slack in funding research for all condoms. In 2013, it awarded 11 separate $100,000 grants to researchers working on the next generation of condoms. A second round of $100,000 grants will be awarded this spring. Down the road, successful projects can earn up to $1 million more apiece from the foundation.

"We wanted to look at innovative ideas to overcome the main barriers as to why men and women aren't using condoms," says Papa Salif Sow, MD, MSc, the foundation's senior program officer in HIV prevention and treatment implementation. "People are afraid about loss of sensation and erections. The idea is to have a new condom that is thinner and stronger and might improve the heat transfer between partners."

Another major barrier, especially in countries where people always have sex in the dark, is how cumbersome it is to put on a condom, Sow says.

Among the grant recipients was a British team that plans to design a male condom out of a material that will fit everyone and tighten gently during intercourse, enhancing sensation and reliability. Another winner was a South African scientist who will test an easy condom applicator.

"We know that even in heterosexual populations, anal sex is very frequent," says Sow, who has been working in Africa for more than 25 years. "We do believe that a new-generation condom that's more enjoyable, more reliant, can be used for both vaginal and anal sex."

Until then, organizations such as the AIDS Foundation of Chicago (AFC) and Fenway Health in Boston will continue to distribute and promote both male condoms and the FC2.

"There aren't other tools for receptive partners," says Jessica Terlikowski, co-founder of the

National Female Condom Coalition (NFCC), who works at AFC on emerging HIV prevention technology. “Somebody who’s a bottom doesn’t have another option that he can control. I think that’s really powerful and can’t be underestimated. That’s why we promote it for both vaginal and anal sex. We’re very clear in the education and training we do that we currently don’t have any efficacy data on this.”

As Donte Smith noted, though, the female condom’s name is a turnoff as far as many gay and bisexual men are concerned, a viewpoint backed up by Jon Vincent, program director for prevention, education and screening at Fenway Health. Vincent raised that issue about two years ago at an NFCC meeting, where one agenda item was the successful marketing of useful tools.

Eric Knudsen, men’s health project manager of the AIDS Support Group of Cape Cod, which is based in Provincetown, Massachusetts, came up with the idea of printing stickers that said “catcher’s mitt” to place on FC2 packages.

“We can’t actually tamper with the packaging,” Vincent says, because the FDA regulates labeling. “However, we can put condoms in bags.” His legal department approved, so Fenway designed little sleeves in which to place individual FC2 packages.

They come in two styles: catcher’s mitt and manhole cover, the latter the brainchild of a Fenway Health graphic designer. “The manhole cover appeals much more to the leather and denim crowd,” Vincent says.

Both styles include directions on how to use the condom for anal intercourse, with or without the inner ring. “We’re not telling people that they shouldn’t use regular condoms,” Vincent emphasizes.

Beginning in 2013, Fenway Health printed about 12,000 of each style. The organization has shipped the sleeves to other groups that serve the LGBT community and invited them to print their own copies.

“I don’t think that the internal condom is for everyone,” Vincent says. “I think some people don’t want to have that hanging out of them. But there are so many reasons why they’re valuable for some people. C’mon, seriously, how can that not work?”

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