

Treatment

Less Silence Around Anal Intercourse, More Science for Rectal Microbicides

Jim Pickett

In his opening speech at the Microbicides 2008 Conference (M2008) held in February in New Delhi, India's Minister of Health and Family Welfare, Dr. Anbamani Ramadoss spoke about the importance of developing safe and effective rectal microbicides. Just hearing a public official talk about rectal microbicides was thrilling. It was a significant victory for all of us doing rectal microbicide research and advocacy.

Rectal microbicides are products that could be available in the form of a cream,

gel, douche, or enema, and may be used to protect against HIV transmission when used during anal intercourse. They do not exist yet, but researchers and scientists are working on them. The lion's share of resources in the field are devoted to vaginal microbicides, which are similar products in development to topically protect against transmission of the virus during vaginal intercourse.

Despite the potential benefits of a "user friendly" prevention technology like microbicides, the gaps in knowledge exacerbate major obstacles to creating universal access to a safe, effective and acceptable rectal microbicide. There must be honest discussion around the globe about the practice of anal intercourse. It is especially critical in the regions and communities hardest hit by

HIV and AIDS, where homosexuality is often criminalized and heterosexual anal intercourse is hidden, and where rectal microbicides have the potential to save thousands of lives.

Around the world, almost all anal intercourse is unprotected. Compared to unprotected vaginal intercourse, unprotected anal intercourse (UAI) is ten to 100 times more likely to transmit HIV. The lining of the rectum is more fragile than the lining of the vagina, and the cells that protect the body

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from infection exist much closer to the surface. During anal intercourse the lining may rupture, allowing HIV to break through and infect these cells.

Unprotected anal intercourse is quite likely one of the most common ways of spreading HIV. Unfortunately, our knowledge of who is having anal intercourse, with whom, and in what context is not clear. We do know that gay men, and men who have sex with men (MSM) in both developed and developing countries are acquiring HIV by engaging in this behavior, and we can presume the same for significant numbers of heterosexual women and men. However, by focusing almost exclusively on gay men, MSM, and the Western world (the Americas, Europe, and Australia) when thinking about the role

1 Less Silence, More Science
Advocating for Rectal Microbicides

3 A Call to Action
The U.S. is past due for a National AIDS Strategy

of anal intercourse in the HIV epidemic, we fail to see that anal intercourse is a behavior that also happens between women and men and could be playing an important role in the epidemic among heterosexuals.

Lack of clarity in the language policy makers, advocates, and researchers use to describe populations and the behaviors that put them at risk obscures the role of anal intercourse in the general epidemic. Sex acts are conflated with identity and populations: equating gay men with anal intercourse, for instance. Phrases like “heterosexual transmission” allow for assumptions about behavior—heterosexuals engage in vaginal intercourse and that is how they acquire HIV—that hide women and men who identify as heterosexual and engage in anal intercourse. This lack of clarity and honesty means that in addressing the significant portion of the pandemic that is often described as “driven by heterosexual HIV infection,” we could actually be missing the role of unprotected anal intercourse. Stigma and homophobia around anal sex is perpetuated, and we miss the opportunities to teach heterosexual men and women how to make anal intercourse safer and to invest in the technologies that reduce their risk.

Many countries and jurisdictions make anal intercourse a criminal act, and there is strong stigma, taboo, and homophobia associated with anal sex. Some countries go so far as to criminalize homosexuality itself. Meanwhile, global and national policies also tend to ignore the very existence of gay men and other MSM in Asia, Africa, and other parts of the developing world. This neglect costs lives. Studies performed in Senegal, Ghana, Kenya, and Sudan show that HIV is much more common among MSM than in the general population. Similar rates of HIV among MSM have also been demonstrated in most countries of Latin America and in several countries and cities in Asia. In its groundbreaking report, *Off the Map*, the International Gay and Lesbian Human Rights Commission decried the wall of silence that surrounds AIDS and same-sex practices in Africa. The situation in developing countries outside of Africa: gay men and MSM are left out of educational programs and programs offering HIV prevention, testing, treatment, and care, and not a word about anal sex practices between women and men.

Language matters. Inaccurate, over-generalized descriptions of the epidemic have consequences on how we design HIV/AIDS programs, who we design them for, and the kind of research we choose to

undertake. Ignoring populations and behaviors means important voices are silenced, and it also means these vulnerable groups are not served by prevention programs.

These dangerous silences—the denial of anal sex, and the denial (or persecution) of MSM—among communities, funders, policymakers and even among key players in the microbicide community help to create the unfortunate circumstances we are in. Namely, the necessary resources have not been allocated to the research and development of safe, effective and acceptable rectal microbicides, a breakthrough that could have a drastic impact on the spread of HIV.

So, when the top health official in India simply mentions the words “rectal microbicides,” it really IS a big deal. We need to push for more research into human sexual behaviors so we have a better understanding of the epidemic, who it impacts, and how the virus is passed from person to person, and ending the silence is the first step to getting the amount of funding we need to push science forward.

“Rectal microbicides are an essential technology that could allow men and women to protect themselves, without fear, without shame, without taboo,” says Ghana’s Manju Chatani, coordinator of the African Microbicides Advocacy Group and member of the Steering Committee of the International Rectal Microbicides Advocates (IRMA).

IRMA, a network with over 600 members from 50 countries on six continents released the report *Less Silence, More Science: Advocacy to Make Rectal Microbicides a Reality at M2008*. The report, available on IRMA’s web site (www.rectalmicrobicides.org), calls for a Global Rectal Microbicide Development Plan and serves as an authoritative reference on recent developments and current efforts in rectal microbicide research. Specifically, IRMA calls for at least a five-fold increase in funding for rectal microbicide research by 2010, from the current US\$7 million per year to US\$35 million per year.

In 2007, IRMA conducted the world’s largest survey on anal sex. Almost 9,000 people responded from 107 countries. The survey showed that a rectal microbicide formulated as a lubricant would provide an excellent opportunity to provide protection to those who engage in anal intercourse. A lube formulation of a rectal microbicide would be highly acceptable, especially if it has no flavor, colour or smell, and is available in both thick and liquid consistencies, and with the option of a water or silicone

base. The survey also showed that when testing lubricant products for rectal safety and testing candidate rectal microbicides for safety and efficacy, researchers should consider the implications of other substances (saliva, water, vaginal fluid) added to the product.

In mid-2008, the University of California, Los Angeles (UCLA) concluded the world's first rectal microbicide safety trial. This trial tested the rectal safety of an antiretroviral (ARV) drug called UC-781 formulated as a gel and was sponsored by CONRAD in partnership with the National Institute of Allergy and Infectious Diseases. Two more Phase I rectal safety trials are in the planning stages, and should begin in the U.S. and U.K. later this year, or early 2009.

"This work is so incredibly important. Every day we don't move forward, thousands more get infected," says Peter Anton of University of California Los Angeles, principal investigator of the UCLA trial. "There is an ethical obligation here to advance the research and development of rectal microbicides, with good science and community awareness."

Anton presented several times at the M2008 conference, sharing some especially interesting preliminary data from his study. The study was small and designed to look specifically for indicators of harm caused by the product. While the results are blinded and not likely to be released until early 2009, Anton noted that there were intriguing signs of possible efficacy, meaning that the product is not only safe, but may actually work to protect against HIV infection. It's an encouraging sign for the rectal microbicide field. Anton's slide presentations from the conference are available on the IRMA web site, and Gus Cairns provides a concise summary of the study in an article at www.aidsmap.com (search for UC-781 to find it).

Rectal microbicide advocacy includes you. If you have only a few minutes, you can be part of the solution. Visit www.rectalmicrobicides.org and read a fact sheet, peruse a news item, or flip through a presentation to learn more. Sign up for IRMA's highly active listserv to stay in the loop. And share the love! Pass along the IRMA web address to another advocate, researcher, policy maker, or potential funder. You too can help end the silence!

Jim Pickett, who chairs the International Rectal Microbicide Advocates (IRMA) and is Advocacy Director of the AIDS Foundation of Chicago, has been living with HIV for 13 years. He can be reached at jpickett@aidschicago.org.

A Call to Action: The U.S. is Past Due for a National AIDS Strategy

Brian Bonci

HIV/AIDS remains one of the most significant public health problems in the United States. More than one million people are now living with the disease. HIV infection rates have not fallen in over a decade, and those rates may be up to 50% higher than previously thought.¹ Half of those living with HIV/AIDS are not receiving lifesaving healthcare. One quarter of Americans who have HIV do not even know it. This epidemic requires a strategic plan of action that promotes coordination across agencies, accountability, evidence-based policy, and a focus on improved outcomes.

Numerous governmental and private studies have pointed to the need for better planning of national policy and programming. In 2004, the Institute of Medicine determined that current federal financing of AIDS-related health care "does not allow for comprehensive and sustained access to quality HIV care" nationwide.² A 2003 study found that failure to meet the government's then goal of reducing HIV infections by half would lead to \$18 billion in excess expenses through 2010.³ A 2005 Rand Corporation study determined that if CDC's HIV prevention funds were allocated based on cost-effectiveness research, total annual HIV infections could be reduced by half.⁴

A national plan can rectify disparities by ensuring prevention, treatment, care, and support reach the communities most affected and at risk. For example, half of new infections are among African Americans, who compose only 13% of the population, and half are among gay and bisexual men. African Americans are not only at disproportionate risk of infection but also suffer poorer treatment outcomes. Between 2000 and 2004, deaths among whites living with HIV declined 19 percent compared with only seven percent for blacks.⁵

The international community, including UNAIDS, has encouraged and supported governments to create national AIDS strategies based on evidence and best practices, human rights frameworks and community input. Other countries, including Brazil and Thailand,

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have had measured success in addressing AIDS with comprehensive strategies. Through a coordinated response, Thailand reduced its number of new HIV infections from 143,000 in 1991 to 19,000 in 2003.⁶ Brazil has also shown success in the fight, by increasing condom use, targeting disproportionately affected communities, and increasing access to ARVs.⁷

The U.S. government appears to agree that a central strategy is important and makes a country operational plan a condition of foreign aid. Under the President's Emergency Plan for AIDS Relief (PEPFAR), the 15 focus countries, including violence riddled Haiti and Uganda, cannot receive funding without a country operational plan, a roadmap for effective delivery of services and steadily improved results. A similar approach to the domestic epidemic, however, has not followed.

Several hundred organizations have declared their support for a National AIDS Strategy, and individuals and organizations can add support at www.NationalAIDSstrategy.org. Collectively, these advocates state that a successful plan will require clear objectives, goal-oriented strategies, and mechanisms for monitoring and evaluation. They recommend the following priorities:

- Improve prevention and treatment outcomes through reliance on evidence-based programming;
- Set ambitious and credible prevention and treatment targets and require annual reporting on progress towards goals;
- Identify clear priorities for action across federal agencies and assign responsibilities and timelines for follow-through;
- Include, as a primary focus, the prevention and treatment needs of African Americans, other communities of color, gay men of all races, and other groups at elevated risk;
- Address social factors that increase vulnerability to infection;
- Promote a strengthened HIV prevention and treatment research effort; and
- Involve many sectors in developing the national strategy: government, business, community, civil rights organizations, faith based groups, researchers, and people living with HIV/AIDS.

Moving forward, Senator Obama, if elected, has pledged to implement a national HIV/AIDS strategy within the first year of his presidency.⁸ Senator McCain, at the time this article went to press, had not committed to such an idea. On June 17, 2008 the U.S. House of Representatives Financial Services Appropriations Subcommittee approved a bill that includes \$1.4 million to the White House Office of National AIDS Policy for the development of a National AIDS Strategy. Public health experts, service providers, and advocates nationwide applauded this official first step toward a plan. At the time this article was printed, the Senate was expected to take similar action in July.

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