

Rectal Microbicides 101

What are rectal microbicides?

- ✚ Currently in development, a rectal microbicide (RM) is an agent that could be formulated as a lubricant, gel, douche, or an enema and used rectally to reduce a person's risk of HIV infection. Rectal microbicides could offer both primary protection in the absence of condoms and back-up protection if a condom breaks or slips off during anal intercourse (AI). Vaginal microbicides are also being studied.
- ✚ For those unable or unwilling to use condoms, RMs could be a safe and effective alternative way of reducing risk, especially if they enhanced sexual pleasure and were unobtrusive enough to motivate consistent use.
- ✚ Such alternatives are essential if we are to address the full spectrum of prevalent sexual practices and the basic human need for accessible, user-controlled HIV and STI (sexually transmitted infection) prevention tools.

Why do we need rectal microbicides?

- ✚ At the end of 2008, UNAIDS estimated that 33.4 million people were living with HIV/AIDS worldwide, and that 2.7 million people were newly infected that year.
- ✚ Because an act of unprotected anal intercourse (AI) is 10 to 20 times more likely to result in HIV infection compared to unprotected vaginal intercourse, and because AI is a common human behaviour – in both men *and women* – it is likely that unprotected AI is a significant driver in the global HIV epidemic.
- ✚ While condoms are an effective barrier to HIV transmission during AI, many people do not use them due to a number of issues including power dynamics in sexual relationships, stigma, and a serious lack of availability. According to the Global HIV Prevention Working Group, only 9% of individuals at risk for HIV infection had access to condoms in 2008. We need better access to condoms, as well as alternatives.

We need more tools in
the prevention toolbox.

Who needs rectal microbicides?

- ✚ Anal intercourse (AI) is a common human sexual behaviour, practiced by heterosexual men and women, gay men, and other men who have sex with men (MSM).
- ✚ Approximately 5 –10% of the world’s general population engages in AI.
- ✚ Among women with multiple risk behaviours for HIV acquisition, an estimated 30 –50% engage in AI.
- ✚ Gay men and other MSM are 19 times more likely to be infected with HIV compared to the world’s general population – in both developed and developing countries. Most of these infections are due to unprotected AI.



Most anal intercourse around the world is unprotected.

What is happening in research and development?



- ✚ The field of rectal microbicide (RM) research is more vibrant than ever.
- ✚ Researchers are developing and testing products in laboratory tests and animal studies.
- ✚ Safety trials look to see if the RM does not cause harm and is well tolerated. One safety trial has been completed, and other safety trials have begun. Once candidate RMs are shown to be safe, they can move into efficacy trials to determine if they actually work to prevent HIV infection.
- ✚ Acceptability and behavioural studies help determine the characteristics of products people would most likely use, and determine who is engaging in AI.
- ✚ Baseline studies investigate what normally happens physiologically during AI.
- ✚ Formulation studies explore how different chemicals and substances would be put together to create a safe and effective RM.
- ✚ Distribution studies ask the question - where do RMs need to go in the human body?
- ✚ Lubricant safety studies seek to establish whether currently available lubricants are safe to use rectally. The lubricants being tested are not designed to specifically block the transmission of HIV, but it is important to know whether they are causing any harm.

To learn more about the current RM research and the development pipeline in detail, as well as related scientific activities, read IRMA’s report, *From Promise to Product: Advancing Rectal Microbicide Research and Advocacy*, available on the IRMA website –

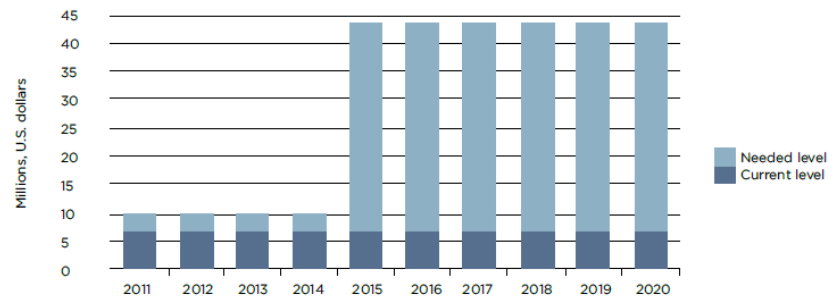
www.rectalmicrobicides.org.

What are the field's challenges?

There are significant biological, socio-cultural and political issues surrounding the research and development of safe, effective and acceptable RMs. A great deal of denial, stigma and shame surround the act of AI, hampering efforts to collect accurate sexual behavioural data. And adequate funding is lacking.

There was U.S. \$7.2 million spent globally on RM research in 2010. Annual investments must increase by 40% from 2011-2014 and must increase six-fold in the years 2015-2020 to ensure a minimum of candidate products enter late-stage testing for effectiveness in humans.

ANNUAL RECTAL MICROBICIDE RESEARCH FUNDING NEEDS (2011-2020)



In consultation with leading researchers in the field, IRMA calculated these approximate annual funding needs for RM research and development over the next 10 years based on a number of assumptions regarding future activities. One assumption was that the field would move forward rectal microbicides based on antiretroviral (ARV) products, combination ARV products, and non-ARV products. See Section 3 of *From Promise to Product: Advancing Rectal Microbicide Research and Advocacy* to learn more about these estimates and assumptions.

**Now is the time
for rectal
microbicides.**

Here's the bottom line.

Any RM must be safe and effective. It must also be acceptable, readily available and easy to use for all people who engage in AI. Unprotected AI is a significant driver of new HIV infections among gay men and other MSM, and likely plays a large role in the epidemic among heterosexuals. Partners of all genders need and deserve prevention methods beyond condoms. We need choices.

Who is IRMA?

International Rectal Microbicide Advocates (IRMA) is a global network of advocates, scientists, policy makers and funders from six continents working together to advance a robust RM research and development agenda. IRMA is based in the United States with chapters in Latin America and Nigeria.

Get involved and learn more. Visit www.rectalmicrobicides.org.

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