



Rectal Microbicides: The Basics

6 July 2010

Amsterdam

Marc-André LeBlanc, IRMA Secretary

This presentation



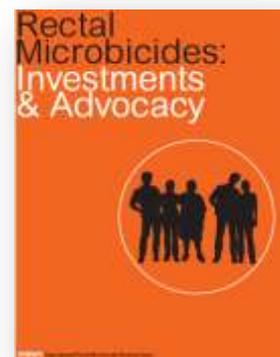
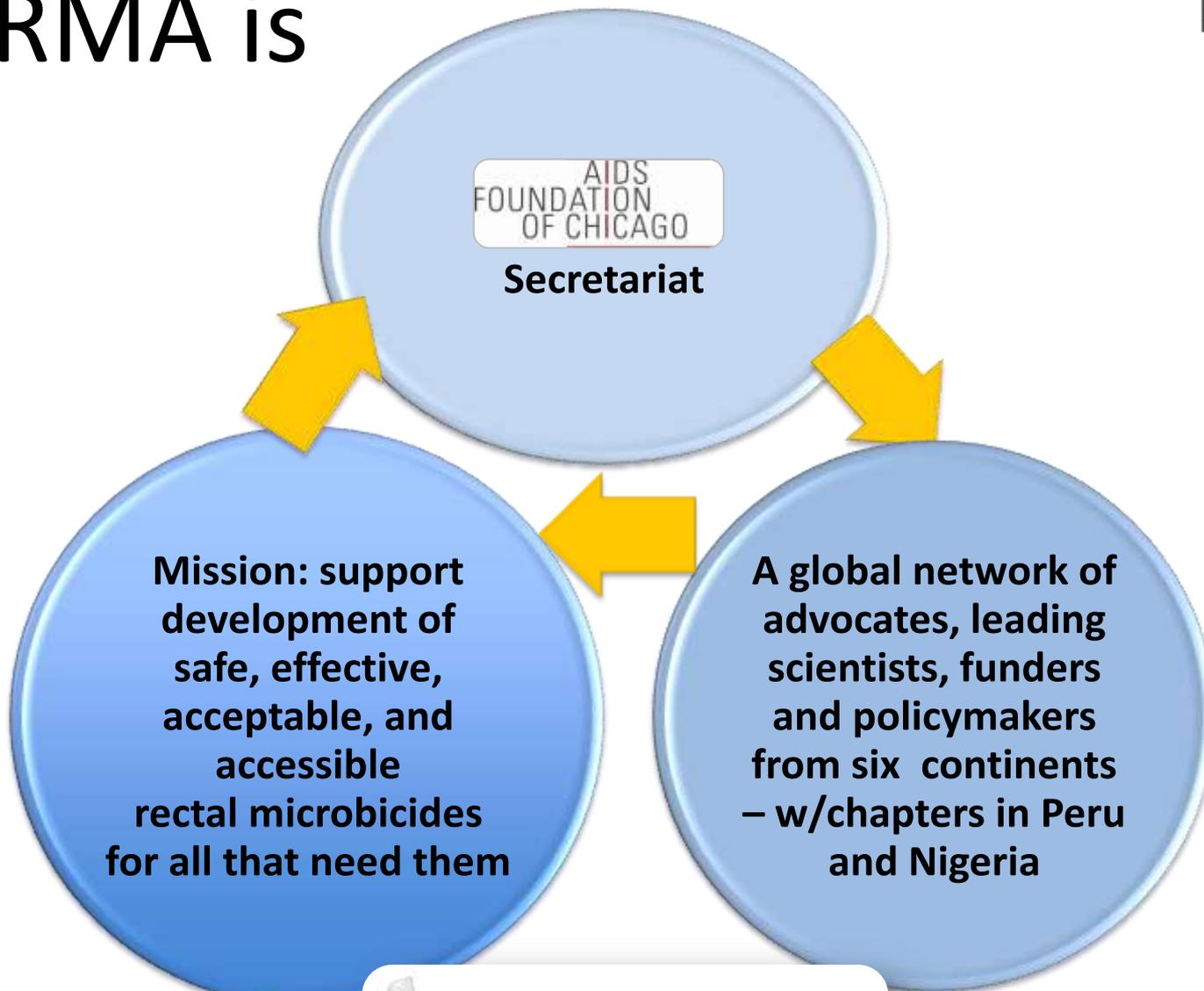
- Who is IRMA?
- Rectal microbicide research – the basics
- IRMA goals and objectives
- Rectal microbicide advocacy and you

IRMA, b.2005

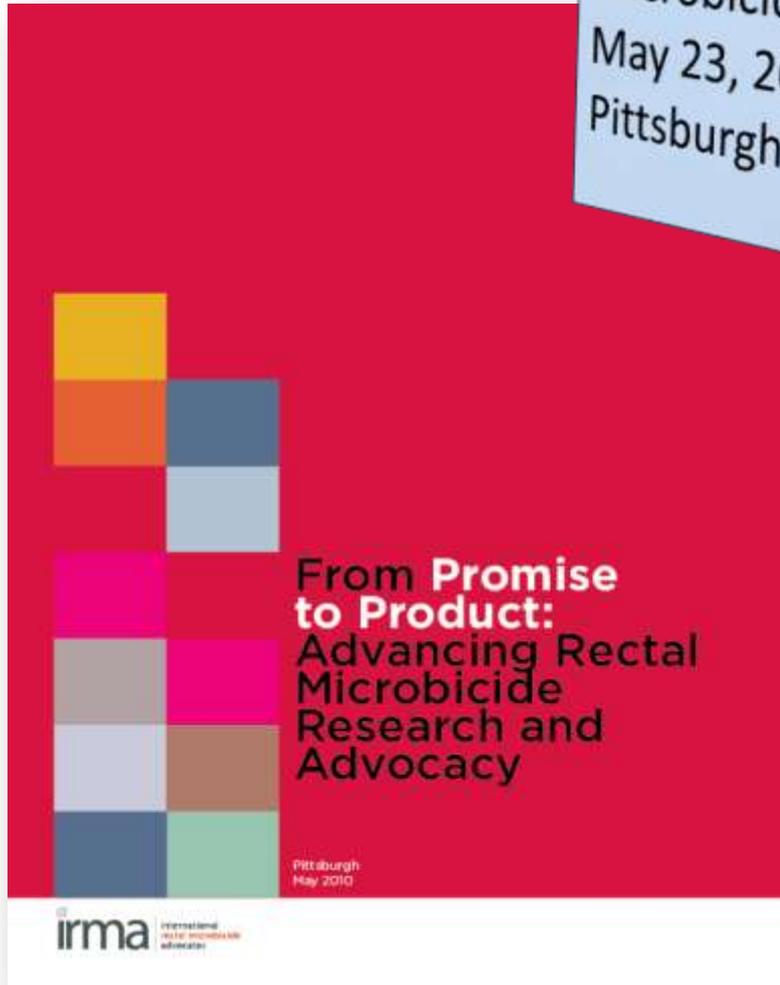


4 people, 4 agencies, 2 countries

IRMA is



Released
Microbicides 2010
May 23, 2010
Pittsburgh



Report includes:

Advocacy goals

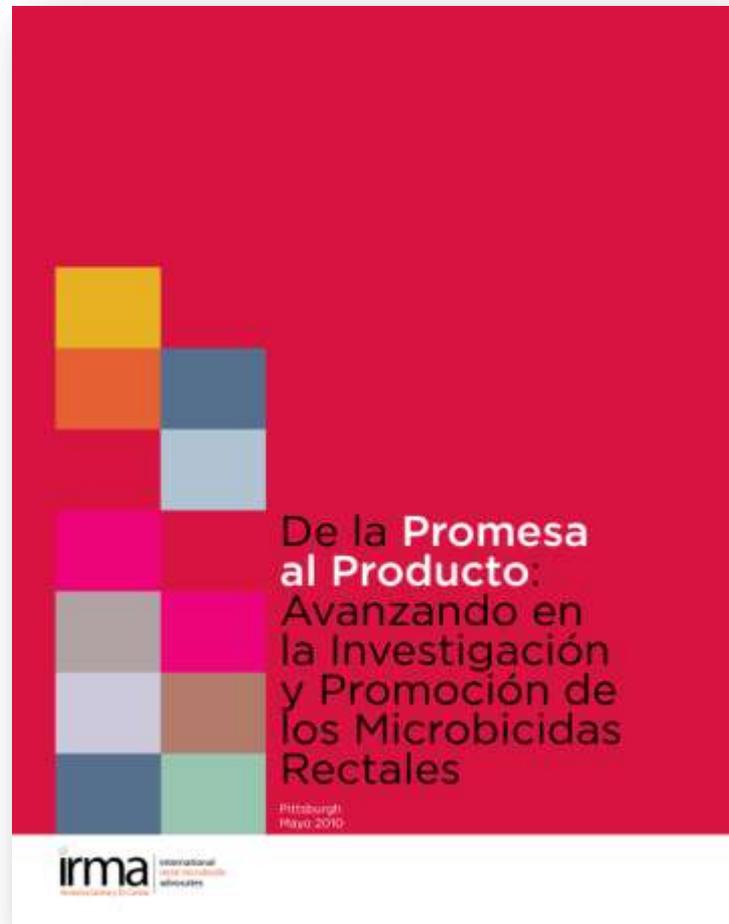
Updated Research snapshot

Global context

Updated resource tracking & funding projections

Overview IRMA activities





Making it Work



Listserv

May 2010
880 members



TC

15 calls '08-
'09, 500 ppl



Website

2009
6,906 visits



Blog/Feed

2009
14,244 visits



FB

May 2010
365 pals



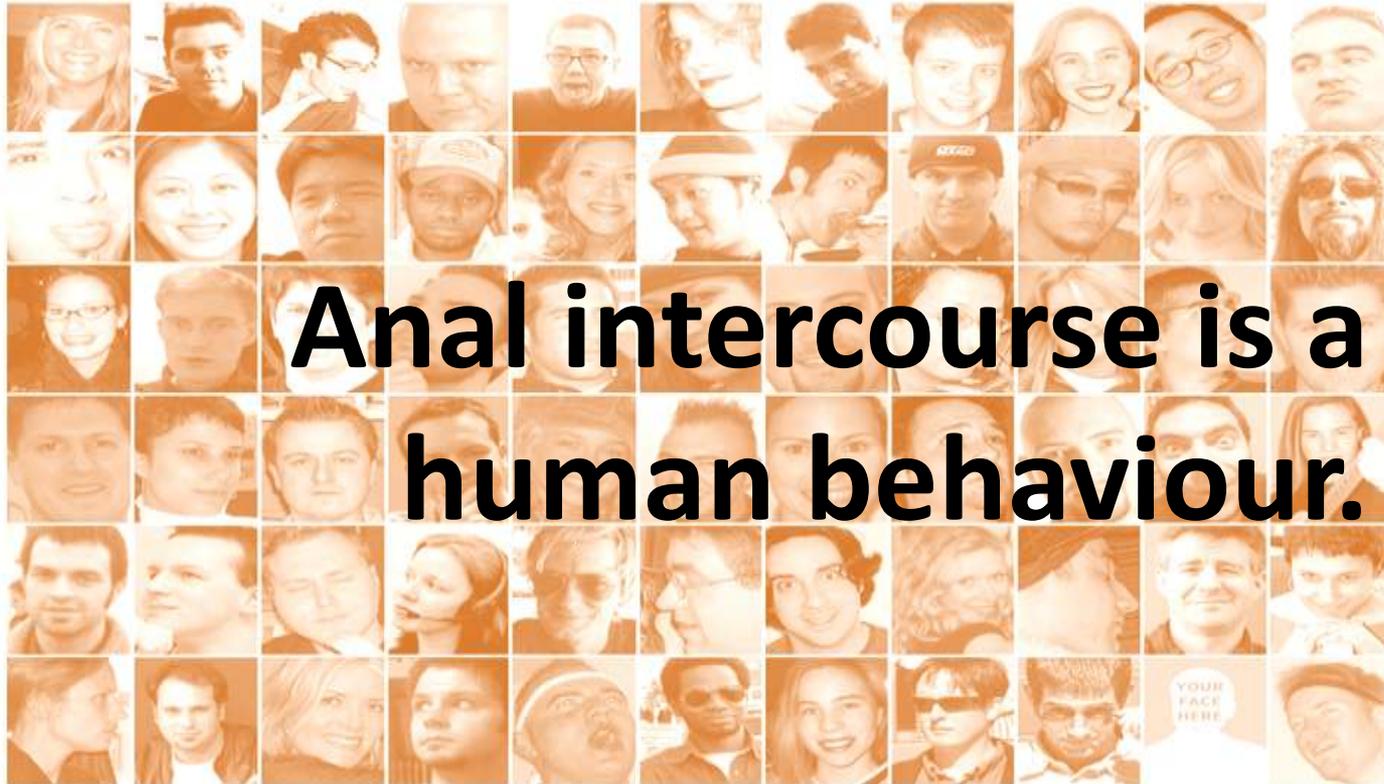
Twitter

May 2010
832 followers





Anal Intercourse



**Anal intercourse is a
human behaviour.**

Anal intercourse and women

- In absolute numbers, 7x more heterosexual women than gay men and MSM in the US practice receptive anal intercourse (AI) - a conservative estimate
[Halperin DT.]
- Prevalence of AI among heterosexuals not well defined
 - Varies regionally by age, population, co-risk
 - AI is relatively common globally, 5 – 10% in gen. pop. and up to 30-50% of women with other HIV risks engage in AI
 - Unprotected AI may be a significant source of HIV transmission in many contexts, including those labelled as “heterosexual epidemics.”



Anal Intercourse

Gay men and other men who have sex with men (MSM)

- Most HIV infections due to unprotected AI
- Globally, MSM are 19x more likely to be infected with HIV than general population
- In North America, Western Europe, Latin America :
 - Gay men and MSM make up most HIV infections
- In many African, Asian and Latin American countries:
 - HIV among MSM significantly higher than general population
- Globally, only 9% of MSM in 2006 received any type of prevention



Challenges in rectal microbicide development

Compared to microbicides for vaginal use, rectal microbicides are in much earlier stages of development because of:

- Political and cultural reluctance to address anal sex among gay men, MSM and between women and men
 - Stigma
 - Denial
 - Homophobia
- Lack of understanding of need
- Scientific and biological challenges
- More complex safety issues – rectum very fragile
- Lack of adequate resources

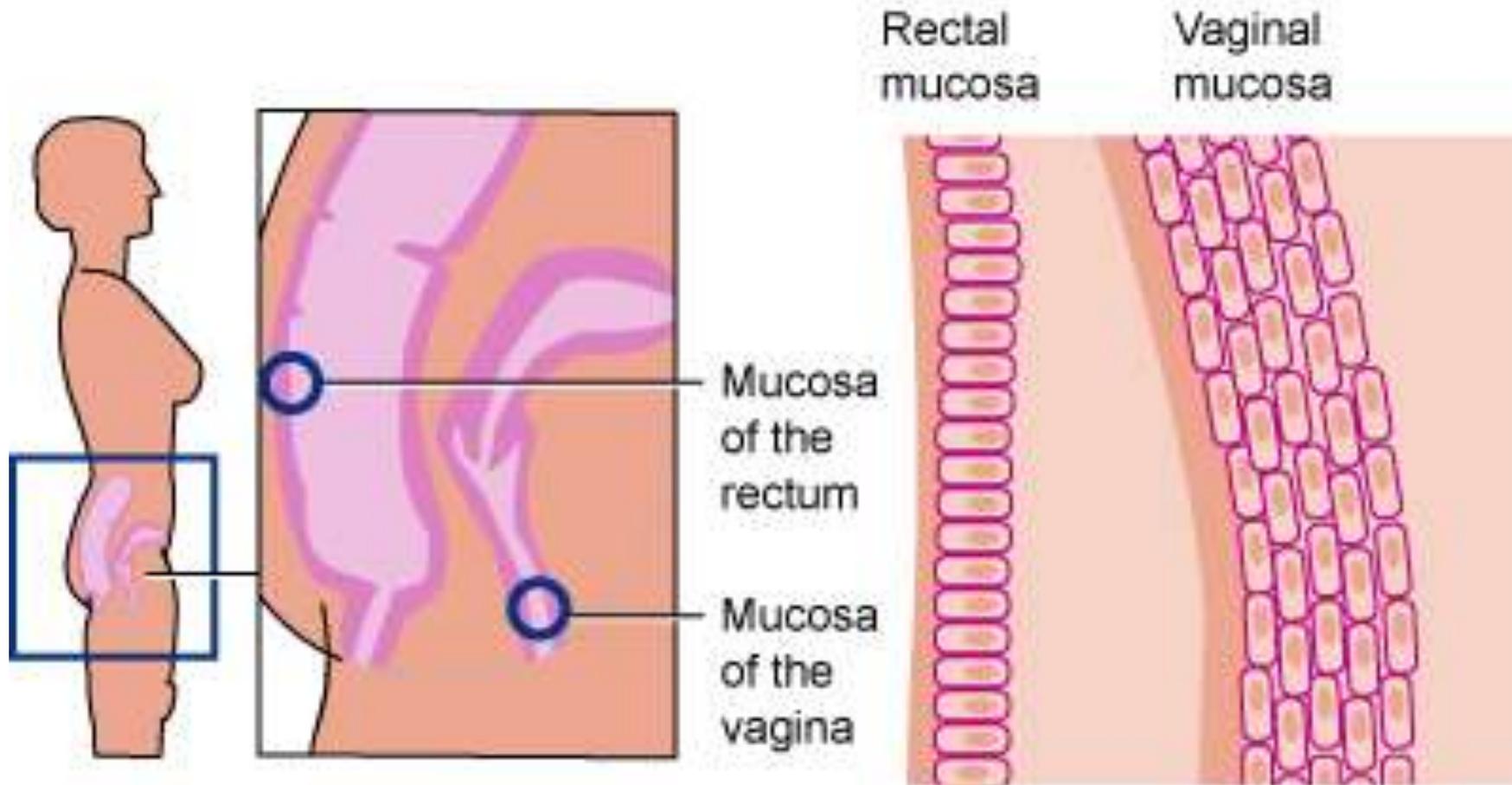


Biological challenges

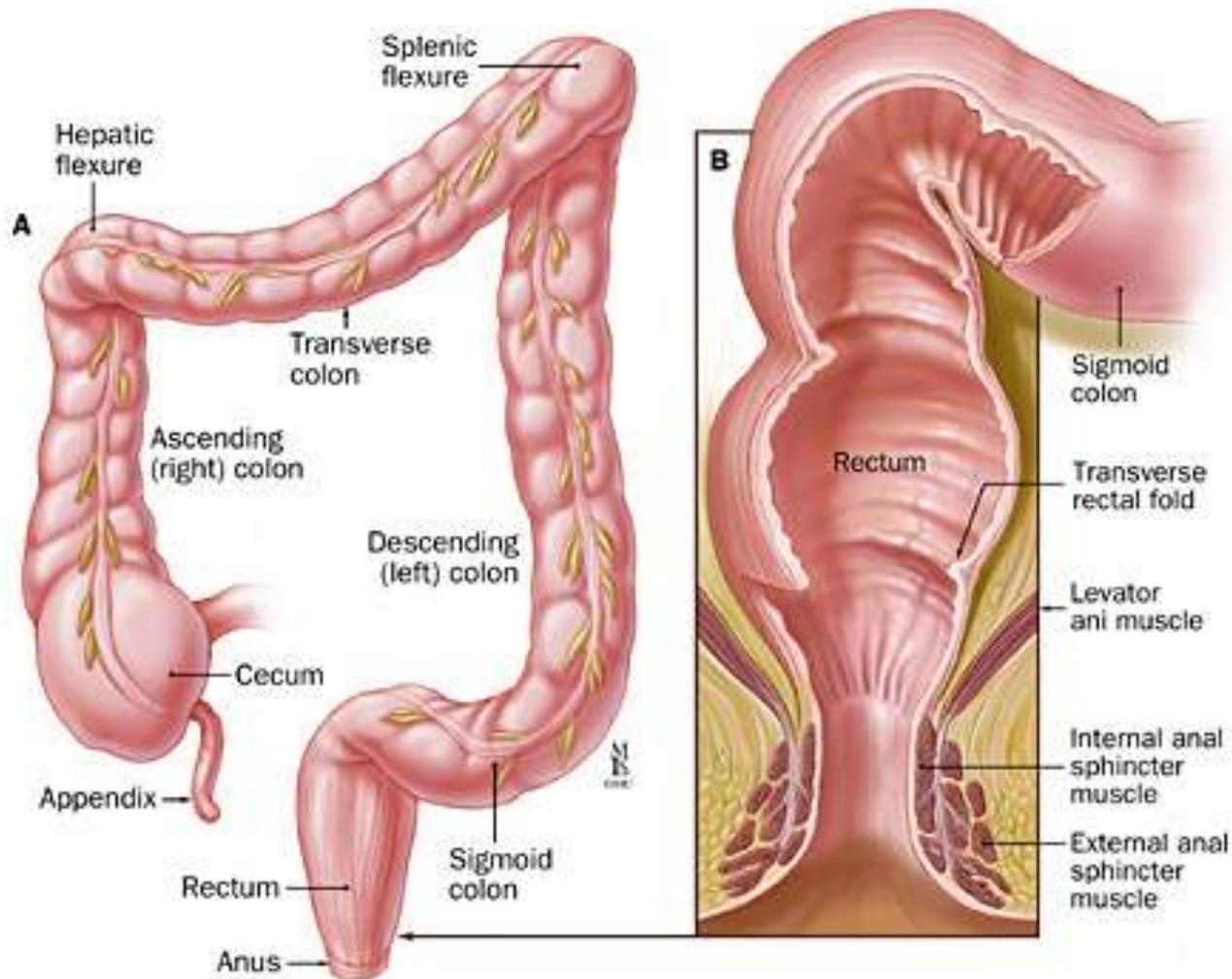
<i>Vagina</i>	<i>Rectum</i>
Most of the epithelium is 40 cell layers thick	Very fragile epithelium, 1 cell layer thick
Fewer CD4 cells than rectum	More inflammatory cells under surface (CD4 receptors)
Acidic pH	Alkaline, rather than acidic pH
Enclosed pouch	Open-ended tube

Anatomy 101

Mucosa of the Vagina and Rectum



The anus and rectum





An act of unprotected anal intercourse is ***10 to 20 times more likely*** to result in HIV transmission than an act of unprotected vaginal intercourse.



Science



Research activities

- Pre-clinical/basic science
 - developing and testing products in labs and in animal studies
- Clinical trials – safety and efficacy
 - Are these RMs safe? Do they work?
- Acceptability & behavioural studies
 - What kinds of products would people use?
 - Who is having AI?



Research activities

- Baseline studies
 - What normally happens during AI?
- Formulation studies
 - How will different chemicals and substances be put together to make a safe, effective RM?
- Distribution studies
 - Where do RMs need to go?



Research activities

Section	Research project	Year
2.1	The Microbicide Development Program (MDP)	2004–2010
2.2	Combination HIV Antiretroviral Rectal Microbicide (CHARM) Program	2010–2014
2.3	Microbicide Safety and Acceptability in Young Men	2010–2013
2.4	Combined Highly-Active Antiretroviral Microbicides (CHAARM) Programme	2010–2014
2.5	RMP-02/MTN-006: Phase I rectal microbicide safety and acceptability trial of topically applied tenofovir compared with oral tablet	2009–2011
2.6	MTN-007: Phase I rectal safety and acceptability study of tenofovir gel	2010–2011
2.7	Biomedical, social, and behavioural research funded by amfAR	2007–2010
2.8	Aptamer microbicide development program	2005–2011
2.9	Evaluating rectal safety and efficacy of microbicides in macaques	2008–2009
2.10	Assessing user preferences for rectal microbicide formulations: Gel vs. suppository	2005–2007
2.11	Assessing the rectal safety of sexual lubricants	2009



Advocacy, Funding, IRMA and You



Advocacy Goals

One

✓ Increase and diversify funding

Two

✓ Increase research activities

Three

✓ Increase knowledge

- For instance:

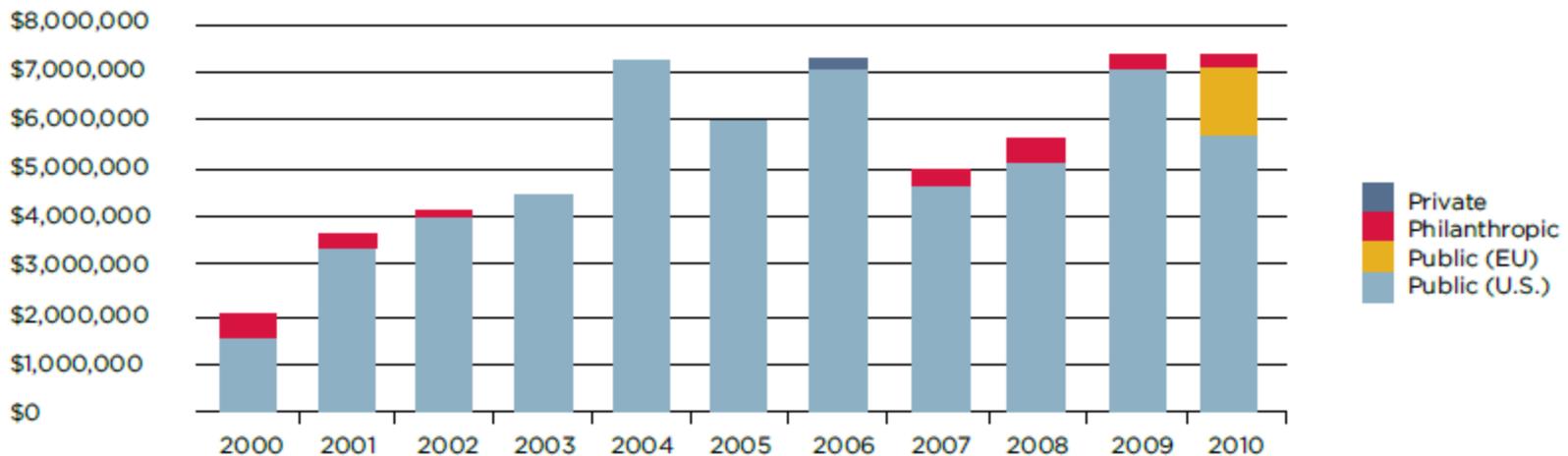
- Learn more about heterosexual anal sex
- Learn more about anal sex behaviours and practices general



Advocacy Goals

- Increase and diversify funding

RECTAL MICROBICIDE RESEARCH SPENDING BY YEAR (2000-2010), IN U.S. DOLLARS



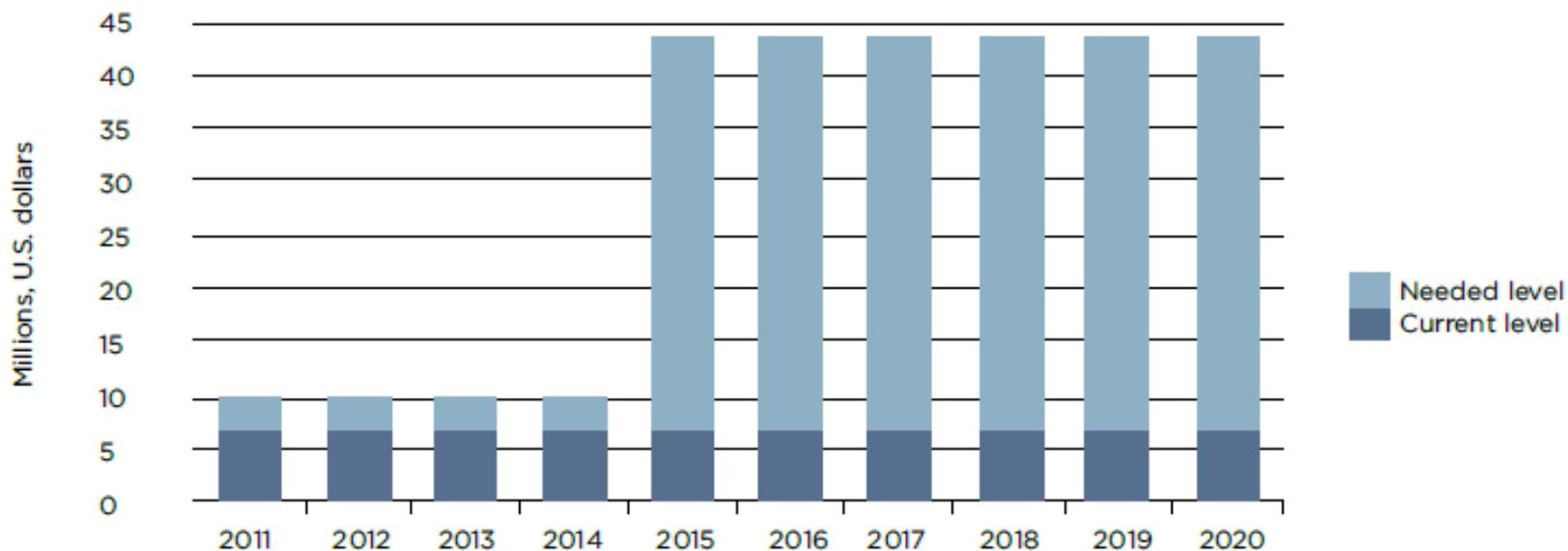
Over the 11-year period of investments in RM research IRMA has tracked, the public sector has provided 97.3% of the funding (mostly from the U.S.), the philanthropic sector has provided 2.5% of funding, and the commercial sector has provided 0.2%.



Advocacy Goals

Projected funding needs

ANNUAL RECTAL MICROBICIDE RESEARCH FUNDING NEEDS (2011-2020)





Advocacy Goals

- Develop Global Rectal Microbicide Development Plan
 - **Every R&D dollar/euro needs to be spent smartly and strategically**
 - Find consensus on research priorities among stakeholders
 - Coordinate research activities, from discovery through Phase III
 - Monitor progress



Advocacy Goals

- Recruit researchers, advocates
- Recognise anal intercourse as an important driver in the HIV epidemic among gay men, MSM, and heterosexuals
- Address burden of HIV among gay men and MSM – particularly in the developing world
- Promote anal health
- Determine safety of lubricants for rectal use



**MEN & WOMEN
DEMAND
RECTAL MICROBICIDES**

What can you do?



What you can do in 5 minutes

- Join IRMA - sign up for IRMA listserv through website
- Read one fact sheet or news item from website or blog
- Join us on Facebook and Twitter
- Share web address and contact information w/another advocate, researcher, policy maker, potential funder



What you can do in 30 - 60 minutes

- Join one of IRMA's regular free teleconferences featuring world leaders in RM research, advocacy
- Read "From Promise to Product: Advancing Rectal Microbicide Research and Advocacy" or read one of the presentations from researchers, community members
- Talk to members of your community about your interest in rectal microbicides





Want to do more?

- Become your community's rectal microbicide expert and spokesperson
 - Recruit new members, enlist organisational support for RMs
 - Conduct presentations in your community – use this one as a template!
 - Write an article, a blog or a Facebook update on RMs - IRMA will help!





Want to do more?

- Join one of IRMA's working groups
 - Lubricant Safety
 - European Outreach
 - Communications
 - Fundraising
- Connect with IRMA ALC, IRMA Nigeria



Special thanks to IRMA funders

- AIDS Foundation of Chicago
- amfAR – The Foundation for AIDS Research
- Broadway CARES – Equity Fights AIDS
- Elton John AIDS Foundation

Thank you



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