



Rectal microbicides, need & advocacy

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Presentation objectives

- What microbicides?
- Why we need rectal microbicides
- Potential for rectal microbicides
- What products are currently being developed
- Campaigning and advocacy needs
- Introducing microbicides and effects on behaviour



What are microbicides?

- Microbicides are substances that can reduce the transmission of HIV and other STD pathogens when applied vaginally and, possibly, rectally
- They could be produced in many forms, including: gels, lubes, films or suppositories
- Most 1st generation microbicides will be gels that lubricate, reducing discomfort and minor trauma



Need for rectal microbicide for anal male-to-male sex

- 70% of kothi identified men among males who have sex with males indulge in anal sex (N = 800)
- Condom usage was only 36 %

Source: FHI 4 city assessment carried out by NFI



Need for rectal microbicide for male-female rectal sex

- 13% of respondent heterosexual urban women in the India had anal sex (Source: India Today Survey, September 15, 2003)
- 7% of the respondent women reported to have sex outside marriage (Source: India Today Survey, September 15, 2003)
- Various studies show that rural women also practice anal sex.



When will microbicides be available?

	1st Generation	2nd Generation	3rd Generation
Expected launch	2007	2012	2017
Formulation	Vaginal only	Vaginal & rectal	Vaginal & rectal
Indications	HIV, possibly other STIs, possibly other Contraceptive	HIV, herpes, gonorrhoea, HPV, Chlamydia, choice of contraceptive or non-contraceptive	HIV, herpes, gonorrhoea, HPV, Chlamydia, choice of contraceptive or non-contraceptive
HIV effectiveness	50% - 60%	70% - 80%	85% - 97%
Usages	With condom/device	Used alone	Used alone
Sales channel			
Developed countries	Prescription only	Over the counter	Over the counter
Developing countries	Over the counter	Over the counter	Over the counter

Source: The Microbicides Initiative



How would a microbicide work?

- Killing or inactivating pathogens
- Creating physical barriers
- Strengthening the body's normal defences
- Prohibiting viral entry
- Inhibiting viral replication
- Eventually, microbicide products will probably combine some of these approaches



Rectal microbicide challenges

“The biggest challenges in developing a microbicide are, in understanding the physical and immunological mechanisms by which the virus crosses the [anal] mucosa, and which cells are the first to become infected, and hence must be protected.”

Source: AMREF: Rectal Microbicides that Protect Against HIV Infection Report from the Workshop: Baltimore, Maryland, June 7-8, 2001



Current microbicides in development

- 60 product leads are under development
- 6 potential products about to enter stage III trials in the next few years
- Average time for a product lead to go through required testing and registration is 10.5 years
- 45 additional products that are still in pre-clinical testing

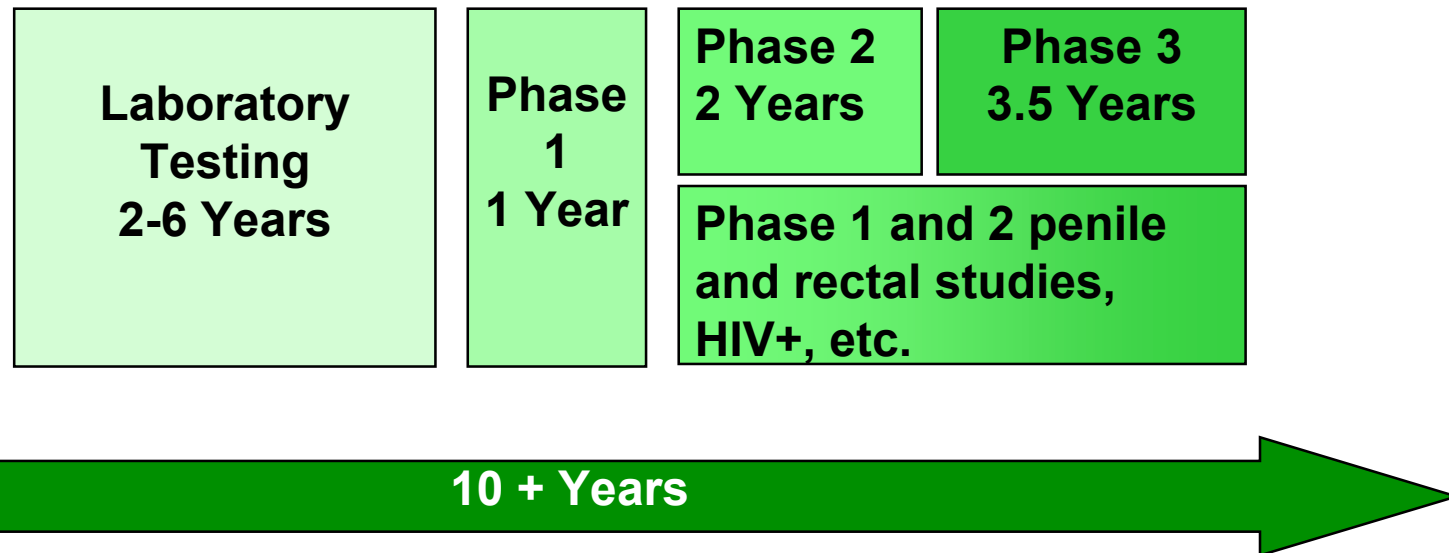


Rectal microbicides: Current research

- Baseline studies on the impact of rectal intercourse
- “Male tolerance” studies (impact of candidate microbicides on the penis and urethra)
- In vitro testing to examine the effects on rectal flora
- Rectal safety studies being designed



Current microbicide development times



Source: Tufts Center for the Study of Drug Development



Barriers to microbicide development?

- Large pharmaceutical companies have relatively little interest in pursuing microbicides
 - perceived low profitability
 - liability concerns
 - lack of in-house expertise
 - uncertain regulatory environment
- For the last 20 years, almost all funding for contraceptive development and related research has come from governments and foundations.



Global Campaign for Microbicides



- A worldwide effort co-sponsored by organisations involved in:
 - HIV/AIDS
 - reproductive health
 - gay health
 - women's empowerment
- Working to educate, raise awareness and generate collective advocacy for increased political and public investment in microbicide development.

www.global-campaign.org



Indian Campaign for Microbicides objectives

- Increasing Awareness and Advocacy
- Accelerating Scientific Research and Development
- Ensuring Effective Access and Use



What do we want for anal sex?

- Products that are:
 - inexpensive
 - easily accessible
 - easy to use
 - safe, non-irritating
 - available in various formulations (in lubes, suppositories, on condoms)
 - effective -- how effective?
- consultation and involvement



What can you do now?

- Get your organisation sign up to the Global Campaign
- Get more information and stay up to date with new developments; sign up for email updates from Global Campaign (www.global-campaign.org)
- Join the Indian Campaign



Behavioural change

- On average, gel to be 84% effective in preventing HIV infection before used as the only means of protection during anal intercourse; 53% of the men wanted the gel to be at least 95% effective.
- 37% of the men who always used a condom during anal sex in the past year said they would be more likely to use a microbicide gel than a condom in the future; however, 85% of this subgroup wanted the gel to offer protection comparable to a condom before they would use it alone.

CDC study 1996-98



Conclusions

- Rectal microbicides will be another HIV prevention tool
- We will have to campaign though for appropriate research and development of rectal microbicides
- We will have to ensure that products that we will be accessible to all who need them



Thanks

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