

MPTs for rectal use: Implications for women and MSM at risk of STIs and HIV

Bridget Haire

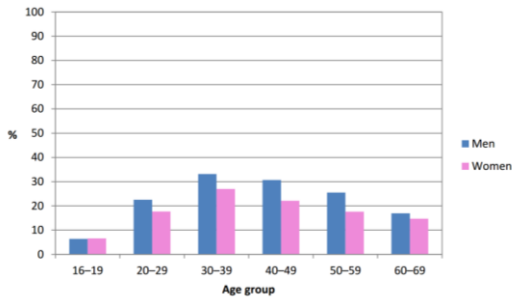


Multipurpose Prevention Technologies (MPTs): Developing interventions to simultaneously prevent STIs, HIV and pregnancy

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Lifetime experience of anal intercourse



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Who has anal sex?

- Heterosexual couples
 - 1 in 5 heterosexual reported heterosexual anal intercourse ever (<1% most recent sex)
- Gay/Bisexual/Men who have sex with men:
 - 1 in three reports anal sex, 58% condom use
- Australian Study of Health and Relationships 2, 2014
 - Survey of 20,094 people, representative sample
 - 6.5% of men identified as gay, bisexual or MSM

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What are multipurpose prevention technologies in the anal sex context?

- Products that serve a dual purpose
 - Sexual lubricants with antiretroviral and/or other antimicrobial action (rectal microbicides);
 - Douche products that combine cleaning with antiretroviral and/or other antimicrobial action
- Products suitable for rectal and vaginal use
- Oral products or regimens that prevent STIs and HIV (pre-exposure prophylaxis for multiple infections)

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Examples of how a rectal microbicide might be delivered

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Target viruses adapted from José Fernández Romero

- Herpes simplex virus (HSV); and
- Human papillomavirus (HPV)
- Not curable
 - Associated with huge public health burden
 - Associated with increased susceptibility to HIV
 - HPV vaccination is not universally available

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Oral regimens

- HIV PrEP (tenofovir and emtricitabine)
- Metronidazole plus (ceftriaxone or cefixime) plus (azithromycin or doxycycline) – antimicrobial regimen for chlamydia, gonorrhoea and trichomonas (sexual assault context)
- HIV PrEP plus doxycycline currently tested in France for HIV, chlamydia, gonorrhoea and syphilis

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Tenofovir 1% gel

- Being tested as a rectal gel
- Rectal delivery of the gel results in higher vaginal concentrations than oral delivery
- “[Rectal delivery] delivers lower systemic exposure and higher vaginal exposure than do similar doses of oral delivery, with rectal tissue accumulation of TFVdp over time, likely due to the long intracellular half-life.”
- Anton PA, Cranston RD, Kahuba A, et al. 2012

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Tenofovir gel and HSV

- ~50 reduction in HSV acquisition in women in the CAPRISA 004 and the VOICE trials.
- Could the rectal formulation of the gel also reduce HSV transmission?

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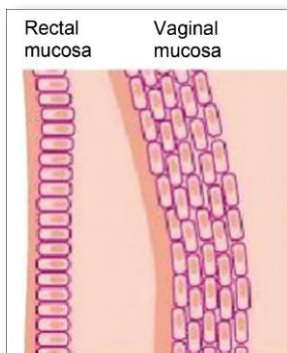
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Dual Compartment Topical Formulation Challenges

José Fernández Romero

- Physiological and anatomical differences between vaginal and rectal compartment
 - Vagina has stratified squamous epithelium and rectum/lower gastrointestinal tract has simple columnar epithelium
 - Vaginal tract is a closed cavity while rectal compartment is longer/opened
 - Vaginal normal pH is acidic (4 - 4.5); rectum is neutral/slightly alkaline

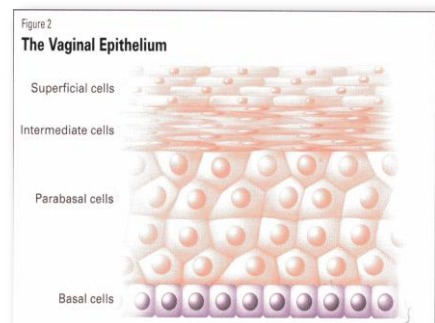
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Source: Indian Journal of Sexually Transmissible Diseases

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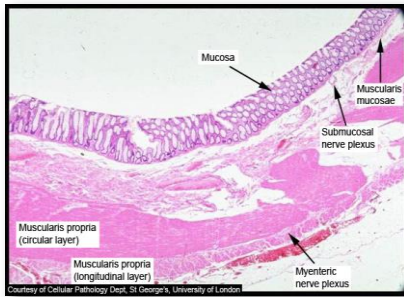
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Source: www.bladderhealthcenter.com

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Other products in development

- MIV-150 (an antiretroviral drug) - M
- Zinc acetate (an antiviral active against HIV and HSV-2) - Z
- Carrageenan (a seaweed derived product active against HPV) – C
- Griffithsin (an algae-derived protein active against HIV in the lab and against HSV and HPV in preclinical studies)

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Research considerations for MPTs active against multiple viruses

- Difficult to test HIV, HPV efficacy in placebo-controlled trials (ethical reasons)
- Testing for efficacy against HSV will be a simpler task

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Conclusion

- Great public health value in:
 - Products that prevention more than one non-curable STI
 - Products that can be used in the rectum *and* the vagina (or that cross from one compartment to the other)
- Promising products in the development pipeline
- www.cami-health.org www.mpts101.org.
- An important area in STI control, requires funding and advocacy

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Thanks

José Fernández Romero
Jim Pickett (IRMA)



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