



# RM: From Acceptance to Desire

**Alex Carballo-Diéguez, Ph.D.**

**Rebecca Giguere, MPH**

**Titcha Ho, MA**

**HIV Center for Clinical and Behavioral Studies at NY State  
Psychiatric Institute and Columbia University, New York, USA,**

**MTN “Creating Desire for Rectal Microbicides”**

**May 13, 2014**

Since the first cases of (AIDS) were diagnosed, gay men have been heavily affected.

**RARE CANCER SEEN  
IN 41 HOMOSEXUALS**

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**Outbreak Occurs Among Men  
in New York and California  
— 8 Died Inside 2 Years**

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By **LAWRENCE K. ALTMAN**

Doctors in New York and California have diagnosed among homosexual men 41 cases of a rare and often rapidly fatal form of cancer. Eight of the victims died less than 24 months after the diagnosis, ~~was made.~~

The cause of the outbreak is unknown, and there is as yet no evidence of contagion. But the doctors who have made the

June 5, 1981 / Vol. 30 / No. 21

**CDC**

**MMWR**  
MORBIDITY AND MORTALITY  
WEEKLY REPORT

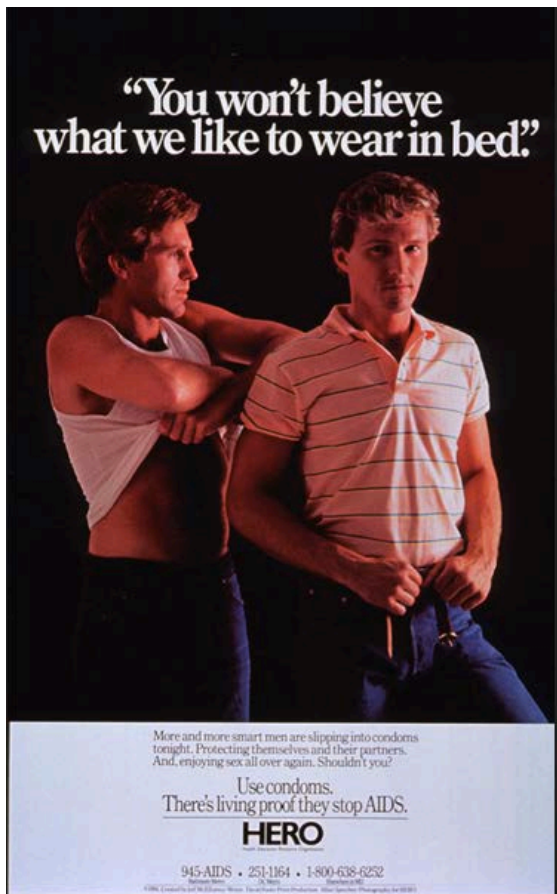
249 Dengue Type 4 Infections in U.S. Travelers to the Caribbean  
250 Pneumocystis Pneumonia — Los Angeles  
252 Measles — United States, 19 Weeks  
253 Risk-Factor Prevalence-Surveillance of Childhood Lead Poisoning — United States  
254 Quarantine Measures

**Pneumocystis Pneumonia — Los Angeles**

In the period October 1980-May 1981, 5 young men, all active homosexuals treated for biopsy-confirmed *Pneumocystis carinii* pneumonia at 3 different times in Los Angeles, California. Two of the patients died. All 5 patients had lab-confirmed previous or current cytomegalovirus (CMV) infection and candidal infection. Case reports of these patients follow.

1. A previously healthy 39-year-old man developed *P. carinii* pneumonia in March 1981 after a 2-month history of fever associated with weight loss. The serum compleme

As soon as it became evident that the causal agent was sexually transmitted, campaigns for safer sex, mainly condom use, were launched targeting gay men.



**“You won’t believe what we like to wear in bed.”**

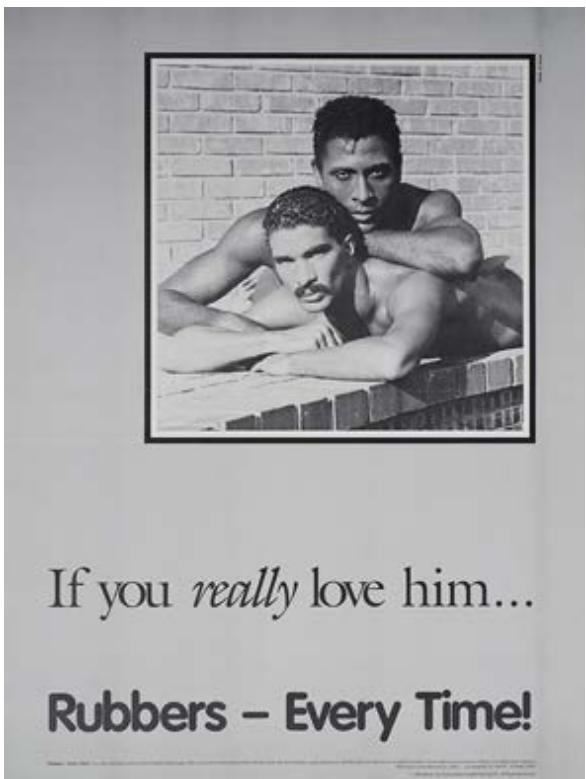
More and more smart men are slipping into condoms tonight. Protecting themselves and their partners. And, enjoying sex all over again. Shouldn’t you?

Use condoms.  
There’s living proof they stop AIDS.

**HERO**

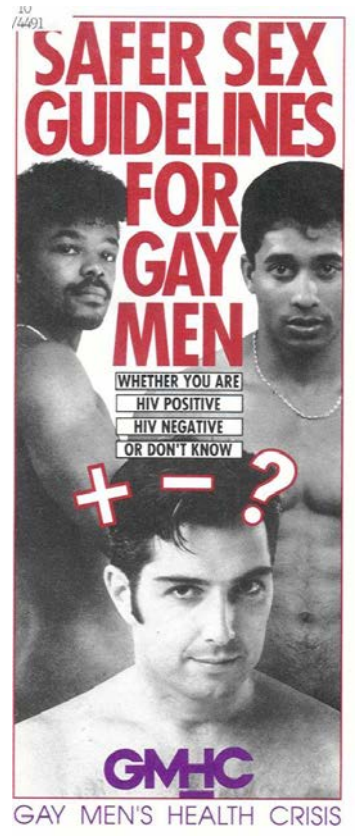
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If you *really* love him...

**Rubbers – Every Time!**



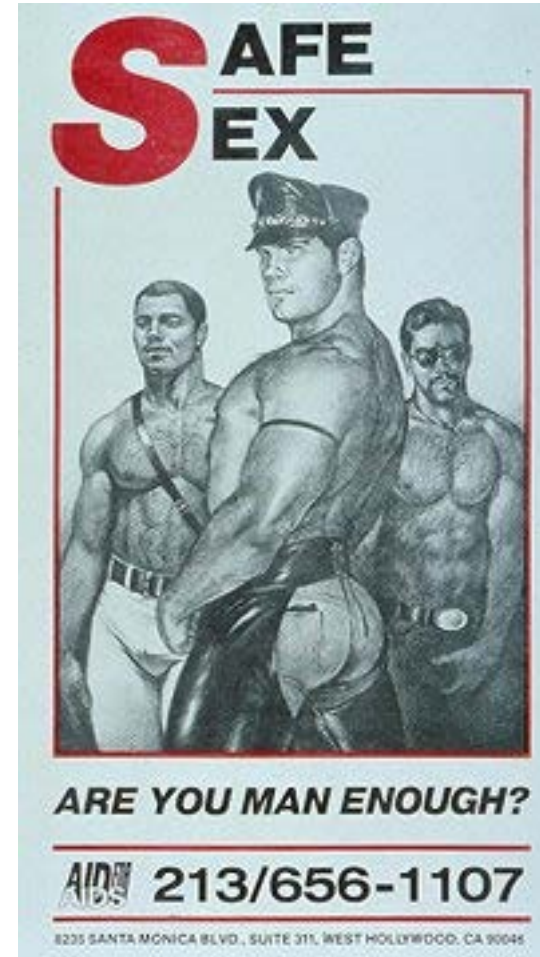
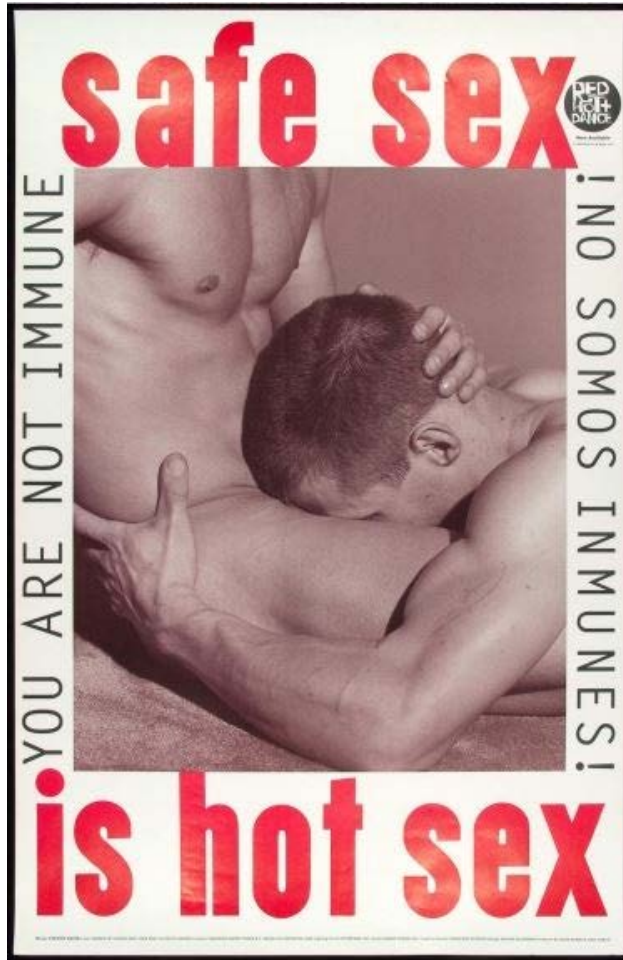
SAFER SEX GUIDELINES FOR GAY MEN

WHETHER YOU ARE  
HIV POSITIVE  
HIV NEGATIVE  
OR DON'T KNOW

**GMHC**

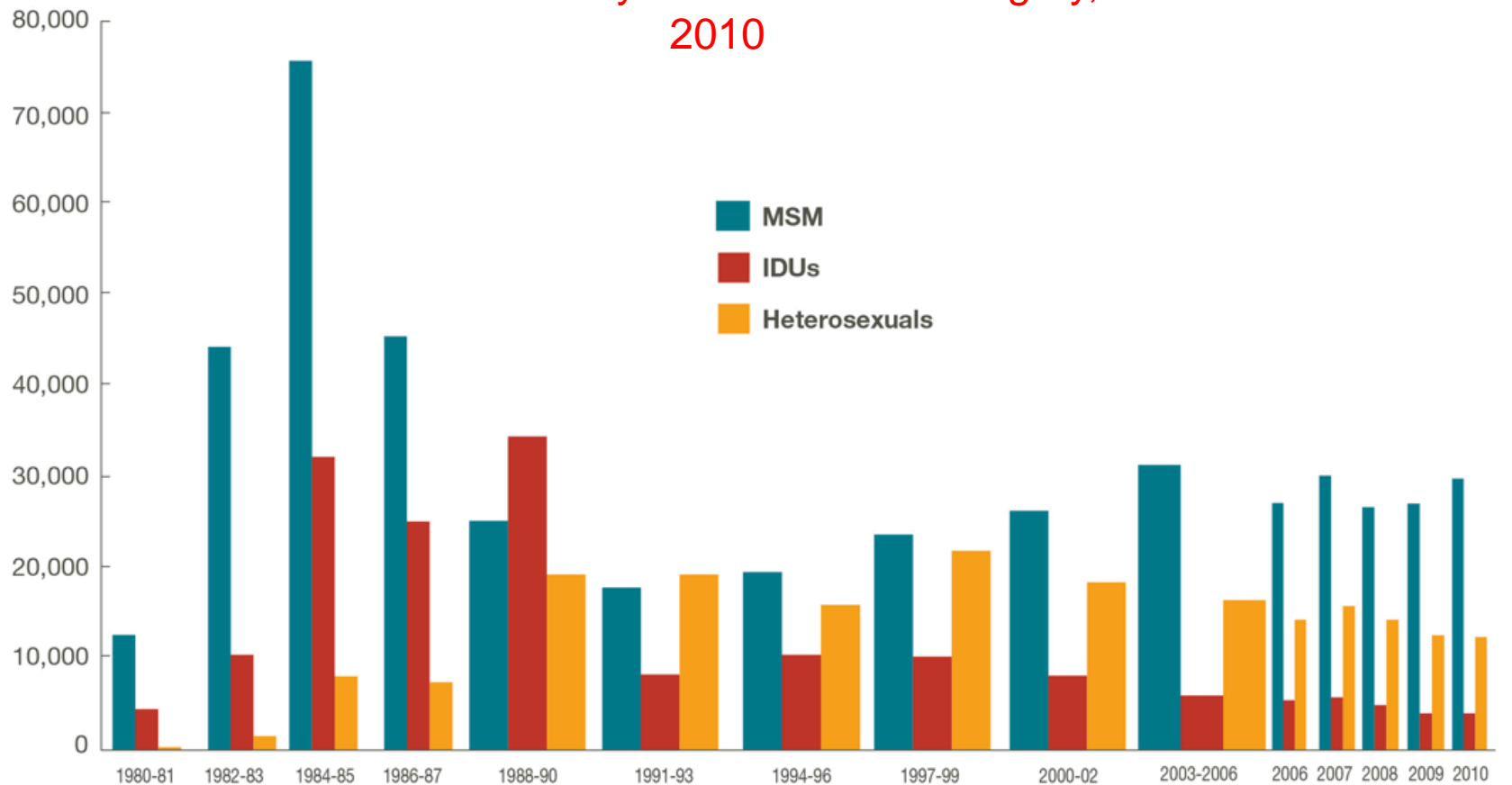
GAY MEN'S HEALTH CRISIS

But an efficacious HIV prevention technology was never enough. It needed to be sexy.



# Despite efforts to eroticize safer sex, condom uptake has been neither universal nor consistent among MSM

New HIV Infections by Transmission Category, 1980-2010



Source: <http://www.cdc.gov/nchhstp/newsroom/HIVFactSheets/Progress/Trends.htm>



# Alternatives to condoms could build on existing behaviors



# Frequent Use of Lubricants for Anal Sex Among Men Who Have Sex With Men: The HIV Prevention Potential of a Microbicidal Gel

*Alex Carballo-Diéguez, PhD, Zena Stein, MB, BCh, Helga Sáez, MD, Curtis Dolezal, PhD, Luis Nieves-Rosa, MSW, and Francisco Díaz, MD*

American Journal of Public Health July 2000, Vol. 90, No. 7

- Butler LM, Osmond DH, Graves Jones A, Martin JN. *Use of saliva as a lubricant in anal sexual practices among homosexual men.* JAIDS 2009;50(2):162-167.
- Kinsler JJ, Galea JT, Peinado J, Segura P, Montano SM, Sánchez J. *Lubricant use among men who have sex with men reporting receptive anal intercourse in Peru: implications for rectal microbicides as an HIV prevention strategy.* Int J STD AIDS 2010;21:567-572.
- Javanbakht M, Murphy R, Gorbach P, LeBlanc M-A, Pickett J. *Preference and practices relating to lubricant use during anal intercourse: implications for rectal microbicides.* Sexual Health 2010;7(2):193-198.
- Clark JL, Salvatierra HJ, Segura ER, et al. *Frequency, patterns, and preferences of lubricant use during anal intercourse within male sexual partnerships in Lima, Peru: Implications for a rectal microbicide HIV prevention intervention.* AIDS Care 2013;25(5):579-585.

AIDS Behav (2008) 12:860–866  
DOI 10.1007/s10461-007-9301-0

ORIGINAL PAPER

## The Use of Rectal Douches among HIV-uninfected and Infected Men who Have Unprotected Receptive Anal Intercourse: Implications for Rectal Microbicides

Alex Carballo-Diéguez · José A. Bauermeister ·  
Ana Ventuneac · Curtis Dolezal · Ivan Balan ·  
Robert H. Remien

Published online: 18 August 2007

ARTICLES

## Why Rectal Douches May Be Acceptable Rectal-Microbicide Delivery Vehicles for Men Who Have Sex With Men

Alex Carballo-Diéguez, PHD,\* José Bauermeister, PHD,† Ana Ventuneac, PHD,\*  
Curtis Dolezal, PHD,\* and Kenneth Mayer, MD‡§

Sexually Transmitted Diseases • Volume 36, Number 11, December 2009

- Galea JT, Kinsler JJ, Imrie J, Nureña CR, Sánchez J, Cunningham WE. *Rectal douching and implications for rectal microbicides among populations vulnerable to HIV in South America: a qualitative study.* Sex Transm Infect 2013;0:1-3.
- Javanbakht M, Stahlman S, Pickett J, LeBlanc M-A, Gorbach PM. *Prevalence and types of rectal douches used for anal intercourse: results from an international survey.* BMC Infectious Diseases 2014;14:95.
- Leyva FJ, Bakshi RP, Li L, et al. *Isoosmolar enemas demonstrate preferential gastrointestinal distribution with hyperosmolar and hypoosmolar enemas as a potential delivery vehicle for rectal microbicides.* AIDS Res Hum Retroviruses 2013;29(11):1487-95.
- Noor SW, Rosser BRS. *Enema use among men who have sex with men: A behavioral epidemiologic study with implications for HIV/STI prevention.* Arch Sex Behav 2013, Epub ahead of print.



# Acceptability of a Hypothetical RM among MSM/TGW

AIDS Behav  
DOI 10.1007/s10461-006-9128-0

ORIGINAL PAPER

© Springer Science+Business Media, Inc. 2006

## **Awareness and Attitudes Regarding Microbicides and Nonoxynol-9 use in a Probability Sample of Gay Men**

Alex Carballo-Diéguez · Lucia F. O'Sullivan ·  
Peter Lin · Curtis Dolezal · Lance Pollack ·  
Joseph Catania

- Kinsler JJ, Cunningham WE, Nureña CR, et al. *Using conjoint analysis to measure the acceptability of rectal microbicides among MSM in four South American cities.* AIDS Behav 2012;16(6):1436-1447.
- Newman PA, Rongprakhon S, Tepjan S. *A social ecology of rectal microbicide acceptability among young men who have sex with men and transgender women in Thailand.* J Int AIDS Soc 2013;16(1):18476.
- Peinado J, Lama JR, Galea JT, et al. *Acceptability of oral versus rectal HIV preexposure prophylaxis among men who have sex with men and transgender women in Peru.* J Int Assoc Provid AIDS Care 2013;12(4):278-283.

# Women's anal intercourse

AIDS Education and Prevention, 20(2), 148-159, 2008  
© 2008 The Guilford Press

## WOMEN'S ANAL SEX PRACTICES: IMPLICATIONS FOR FORMULATION AND PROMOTION OF A RECTAL MICROBICIDE

T.M. Exner, J. Correale, A. Carballo-Diéguez, L. Salomon,  
K.M. Morrow, C. Dolezal, and K. Mayer

## Women's Experiences with Anal Sex: Motivations and Implications for STD Prevention

By Emily Maynard,  
Alex Carballo-  
Diéguez, Ana  
Ventuneac,  
Theresa Exner and  
Kenneth Mayer

**CONTEXT:** Heterosexual anal intercourse is a highly efficient mode of HIV transmission, yet little is known about the contexts in which women engage in it, or when and with whom they use condoms. Similarly, sexuality and reproductive health research has paid little attention to female desire and pleasure-seeking.

**METHODS:** In-depth interviews were conducted in Boston in 2006 with 28 women who reported having had unprotected anal intercourse in the last year with a man who was HIV-positive or whose serostatus was unknown. Sexual scripting theory guided analyses of their experiences with and motivations to practice anal intercourse.

*Perspectives on Sexual and Reproductive Health*, 2009, 41(3):142-149, doi: 10.1363/4114209

- Dube Z, Colvin C. *Conceptualizations of heterosexual anal sex and HIV risk in five East African communities*. J Sex Res 2014 Mar 10. Epub ahead of print.
- Alexander M, Mainkar M, Deshpande S, Chidrawar S, Sane S, Mehendale S. *Heterosexual anal sex among female sex workers in high HIV prevalence states of India: need for comprehensive intervention*. PLoS One 2014 Feb 20;9(2):e88858.
- Stulhofer A, Ajdukovic D. *A mixed-methods exploration of women's experiences of anal intercourse: meanings related to pain and pleasure*. Arch Sex Behav 2013;42(6):1053-1062.
- Livak BS, Prachand NG, Benbow N. *Anal intercourse and HIV risk among low-income heterosexual women: findings from Chicago HIV behavioral surveillance*. Open AIDS J 2012;6:142-148.

# Acceptability of RM in clinical trials

- Gross M, Tabet SR, Kelly CW, Coletti AS, Chesney MA. *Acceptability of a bioadhesive nonoxynol-9 gel delivered by an applicator as a rectal microbicide*. Sex Trans Dis 1999;26(10):572-578.

AIDS Behav  
DOI 10.1007/s10461-009-9611-5

ORIGINAL PAPER

## **Acceptability of UC781 Gel as a Rectal Microbicide Among HIV-Uninfected Women and Men**

Ana Ventuneac · Alex Carballo-Diéguez · Ian McGowan · Robert Dennis · Amy Adler · Elena Khanukhova · Charles Price · Terry Saunders · Chomchay Siboliban · Peter Anton

Sept. 2009

- McGowan I, Hoesley C, Cranston RD, et al. *A phase 1 randomized, double blind placebo controlled rectal safety and acceptability study of tenofovir 1% gel (MTN-007)*. PLoS One 2013;8(4):e60147.



# Desirable Characteristics for RM

- Consistency: Smooth, slippery; not sticky, runny or oily
- Color: Clear or light
- Scent: Unscented or light fruity/floral; non-medicinal
- Taste: No taste
- Refillable? Single-use, disposable, portable applicator
- Packaging: Cool, not look like a drug
- Price and effectiveness: similar to condoms
- Covert use: Desirable for casual partners
- **Several formulations to meet different needs and tastes**

# Adherence to RM (placebo) use concurrent with RAI > 80%

AIDS Behav

DOI 10.1007/s10461-014-0768-1

ORIGINAL PAPER

## **Adherence to Rectal Gel Use Among Mainly Ethnic Minority Young Men Who have Sex with Men During A 3-Month Placebo Gel Trial: Implications for Microbicide Research**

**Alex Carballo-Diéguez · Rebecca Giguere · Curtis Dolezal · José Bauermeister ·  
Cheng-Shiun Leu · Juan Valladares · Timothy Frasca · Rita Labbett ·  
Ross D. Cranston · Irma Febo · Kenneth Mayer · Ian McGowan**



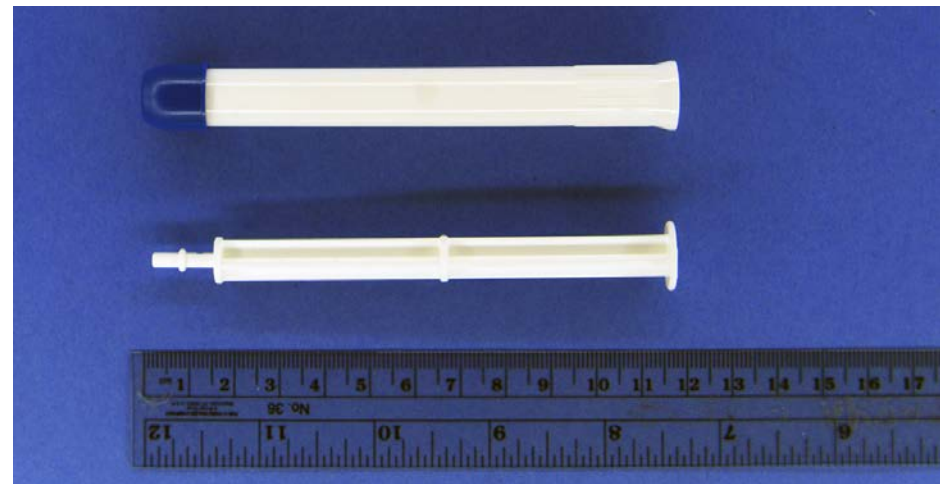
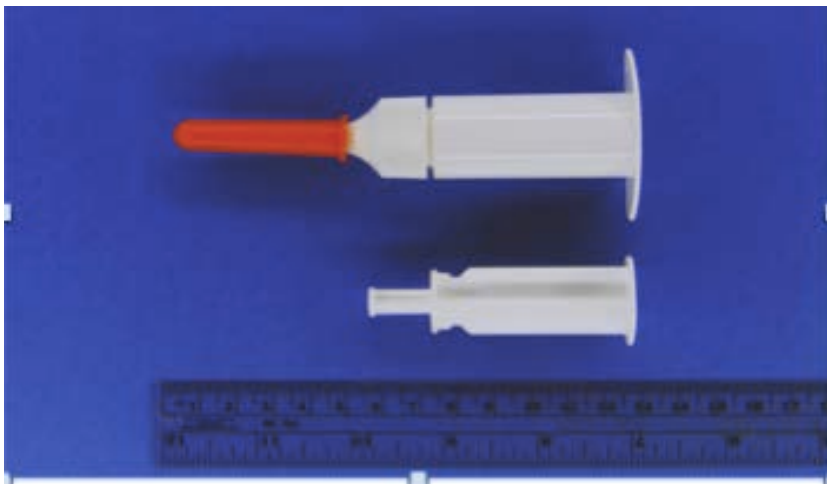


# **There is still work to do to improve adherence to product use**

- Increase acceptability (decrease barriers)**
- Increase desirability, something that people really want to use.**

# Increasing acceptability of a gel

## □ Improve the applicator



- Bauermeister JA, Giguere R, Dolezal C, Leu, C-S, Valladares J, Frasca T, Febo I, Cranston RD, Mayer K, McGowan I, Carballo-Diéguez A. The intersecting importance of gel and applicator satisfaction on Young MSM's future rectal microbicide use. Poster presentation at AIDS 2014, July 20-25, 2014, Melbourne, Australia.



# Participants' complaints about applicators

- ✓ **Too big and rigid, don't fit in jeans pocket, not easily portable**
- ✓ **Require assembly, get rid of the plunger**
- ✓ **Some don't have a lubricated tip, tip may be painful**
- ✓ **Vaginal applicator does not have finger grip or indicator that it was sufficiently inserted in rectum**
- ✓ **Deliver air in the rectum**

# We need a better rectal applicator



# No applicator would be better

- M&M
- How about a suppository?





# Prior studies on suppository acceptability

Preference for gel over suppository as delivery vehicle for a rectal microbicide: results of a randomised, crossover acceptability trial among men who have sex with men

A Carballo-Diéguez,<sup>1</sup> C Dolezal,<sup>1</sup> J A Bauermeister,<sup>1</sup> W O'Brien,<sup>2</sup> A Ventuneac,<sup>1</sup>  
K Mayer<sup>2,3</sup>

*Sex Transm Infect* 2008;**84**:483–487. doi:10.1136/sti.2008.030478

- Pines HA, Gorbach PM, Weiss RE, et al. *Acceptability of potential rectal microbicide delivery systems for HIV prevention: a randomized crossover trial.* *AIDS Behav* 2013;18(7):1002-1015.

Packaging would need to protect them from heat and pressure (if carried in back pocket)



## KCH116 Capsule Keychain

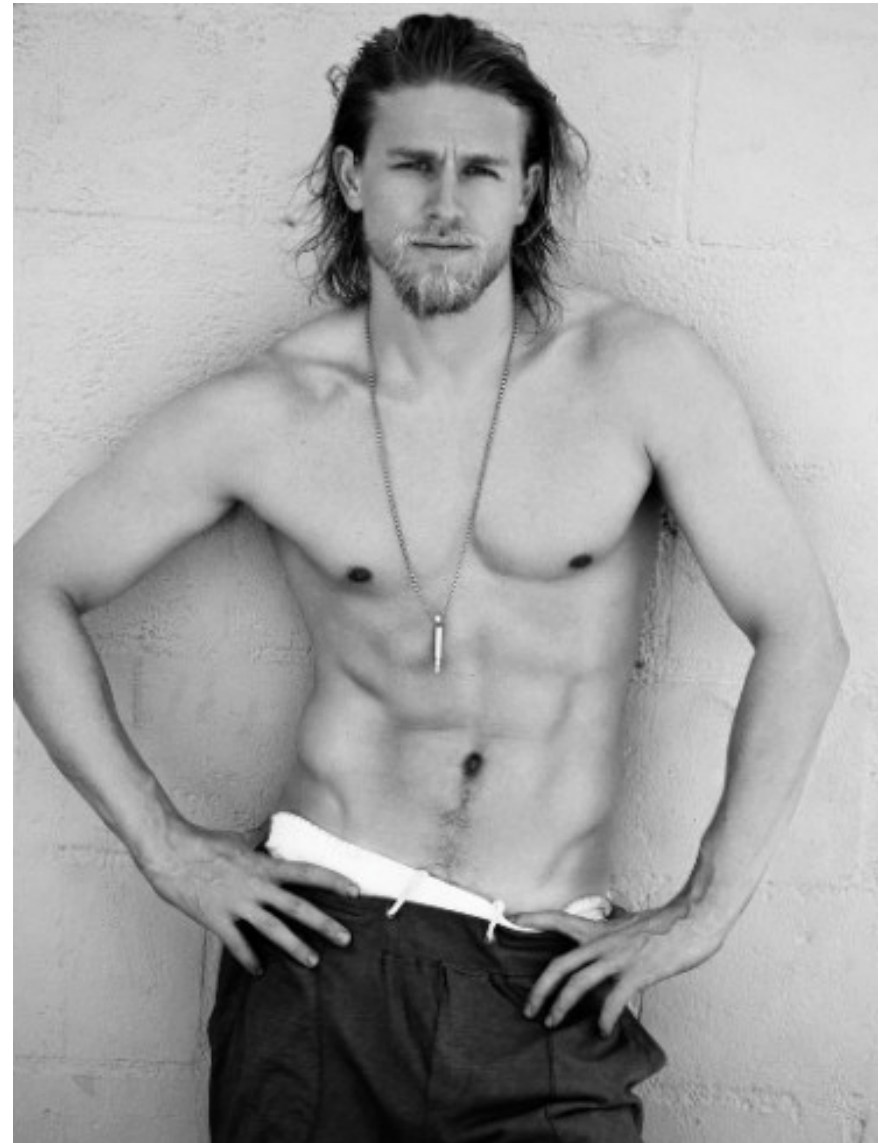
Material: Aluminium

Size: 45mm\*14mm

may choose color, 1000pcs/color



GENTLERSHOP



# Increasing acceptability of a douche

- Portability may be an issue, but we could have a soluble microbicide (C. Hendix U19 application)



Princess Folding Douche Bag,  
eBay \$19.95

# Increasing acceptability

- Easy to open wrapping!!!







# Acceptable -> Desired

- Increase acceptability (decrease barriers)
- **Increase desirability, something that people really want to use.**

# Participants comments

- Poor aesthetics (*like tampons, medical looking, like Elmers glue*)
- Wrong color
- *Make it sexier –and streamline the design to resemble a sex toy or prostate stimulator*
- *I am blessed to not be diabetic, but this feels as though I have one of those mechanisms in my pocket*
- *Make it in a fun, curvaceous container*

# We need good branding

EN | ES | FR | DE



## URANUS™

**BOLDLY GO TO THE UNEXPLORED™**

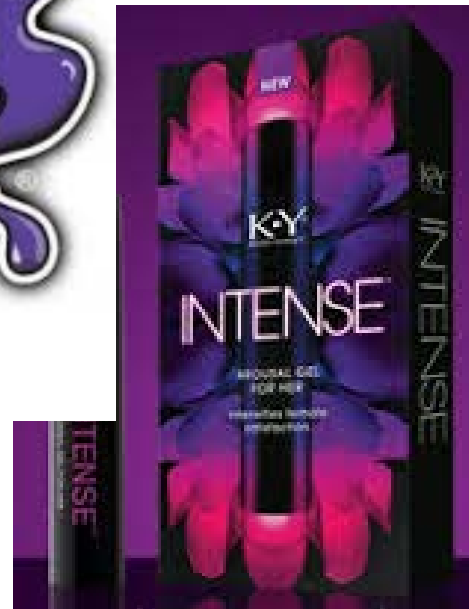
<b>Water-Based Formula</b>	<b>Silicone-Based Formula</b>
<ul style="list-style-type: none"><li>• Thicker Water-Based</li><li>• Non-Staining</li><li>• FDA Accepted Medical Device</li></ul>	<ul style="list-style-type: none"><li>• Thicker Silicone-Based</li><li>• Works Under Water</li><li>• Guaranteed Never Sticky</li></ul>

These formulas are recommended for those who are looking to Boldly Go to the Unexplored!™



Both of these formulas are thicker the Platinum® to give long-lasting lubrica for anal play. They are paraben-free & lubricating so it is essential to use a c time you engage in anal play. Now ki

Available in both Water-Based and



# We need the right color



# We need an attractive, fun presentation





We need diverse products for diverse users

A FORMULA FOR EVERY DESIRE!

SEARCH NOW!

# We need protection + sexual enhancement



A slow release or long acting microbicide may solve problems associated with timing of use





# We need a clever marketing campaign



The image shows a website banner for Fleet Naturals. At the top left, the brand name "Fleet Naturals" is displayed in a green and brown font. To the right, a navigation bar contains three links: "Product Details", "Where to Buy", and "Contact Us". The background is a scenic landscape of a green valley with mountains in the distance. The main headline, "Keep your backcountry clean", is written in a large, white, serif font with a decorative flourish on the letter 'K'. Below the headline, there is a white text box containing promotional text and a product image. The text box includes a bolded statement, a paragraph of descriptive text, and a "Learn More" link with a right-pointing arrow. To the right of the text box is a product shot of a Fleet Naturals cleansing enema box, which is white with green accents and features the brand name and "Aloe" branding.

**Fleet Naturals**

[Product Details](#) | [Where to Buy](#) | [Contact Us](#)

## Keep your backcountry clean

**No laxatives. No drugs. Just natural cleansing gentle enough for daily use.**

Fleet Naturals is a hygienic approach to personal cleansing ready to use right from the box. Each non-medicated enema is fragrance-free, with all-natural aloe and a flexible Comfortip® pre-coated with a water-based lubricant. For an easy way to clean from a brand you can trust, look no further than the digestive care aisle for clinically tested, doctor-recommended Fleet Naturals.

[Learn More](#) 



We need a clever marketing campaign

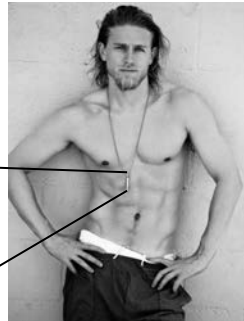




# My recipe for success



1 TRUVADA





**Thank you!**