



Biomedical Prevention and Anal Sex

AMSHer Sexual Health and Rights Institute

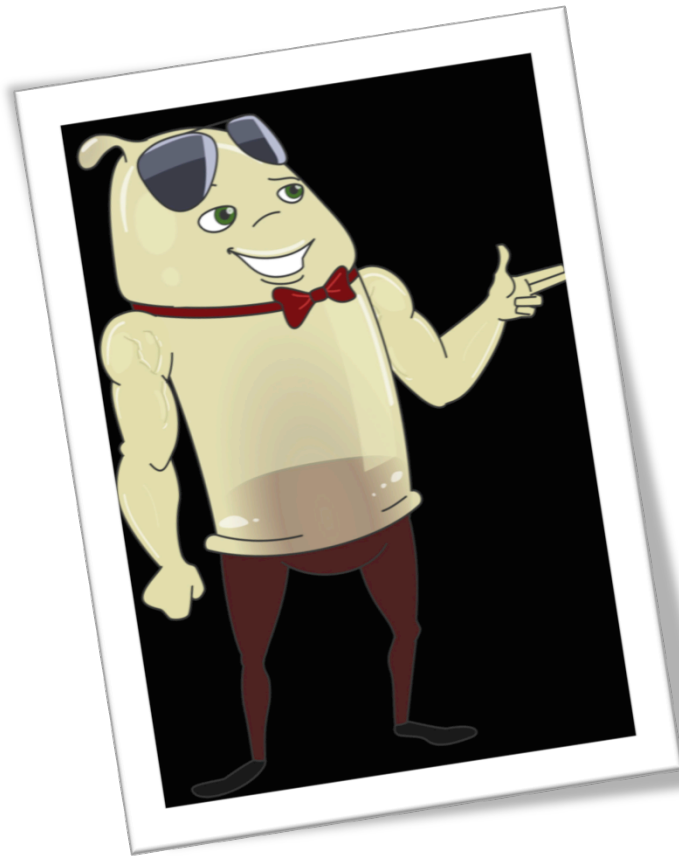
17th ICASA – 5.12.13



Our time together

- *Discussion*

- Update on biomedical ARV-based prevention and advocacy
- Video screening: “The Rectal Revolution is Here: An introduction to rectal microbicide clinical trials”
- Focus on rectal microbicide research and advocacy





“Turning the Tide
Together” Is:

HONEST DISCUSSION
~~OF~~ OF
ANAL SEX

RECTAL MICROBICIDES

Our time together



*Please share your knowledge
and your expertise with us*

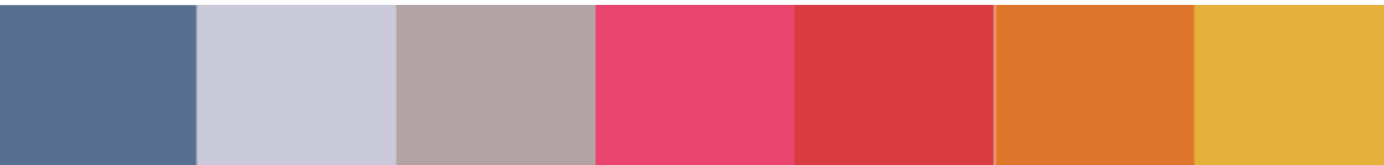
SMILE
IF YOU LIKE

ANAL **sex**



Condoms work.

So why do we need new strategies to halt the sexual transmission of HIV?



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

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act^a

Type of Exposure	Risk per 10,000 Exposures
Parenteral	
Blood Transfusion	9,000 ^b
Needle-sharing during injection drug use	67 ^c
Percutaneous (needle-stick)	30 ^d
Sexual	
Receptive anal intercourse	50 ^{e, f}
Receptive penile-vaginal intercourse	10 ^{e, f, g}
Insertive anal intercourse	6.5 ^{e, f}
Insertive penile-vaginal intercourse	5 ^{e, f}
Receptive oral intercourse	low ^{e, i}
Insertive oral intercourse	low ^{e, i}
Other^h	
Biting	negligible ^j
Spitting	negligible
Throwing body fluids (including semen or saliva)	negligible
Sharing sex toys	negligible

**Anal intercourse
is a human behavior.**



Anal intercourse is a human behavior.



A growing prevention toolkit

Prior to exposure

- Rights-focused behavior change
- Voluntary counseling & testing
- STI screening & treatment
- Male medical circumcision
- Pre-exposure prophylaxis (PrEP)
- Preventive Vaccines*

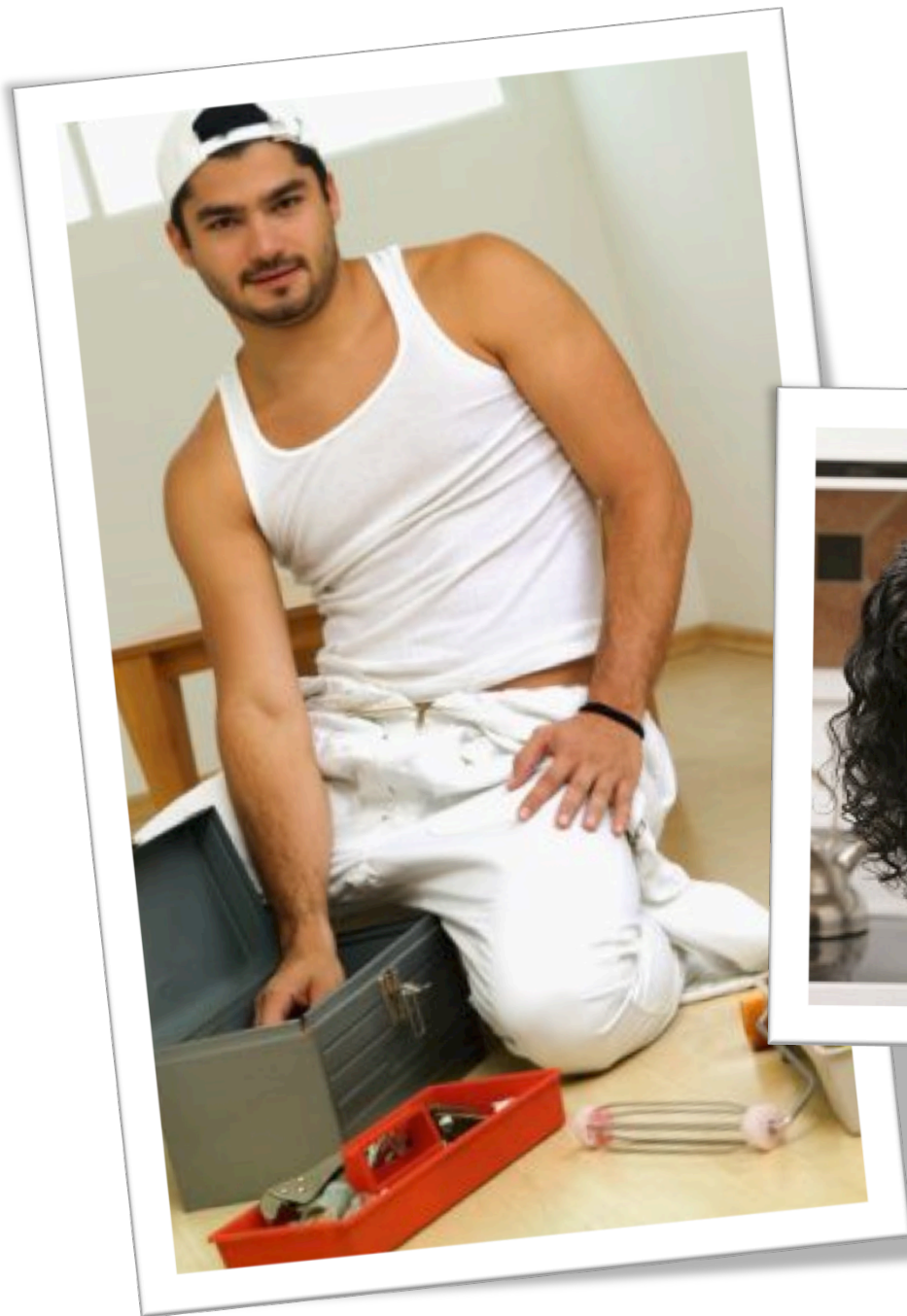
Point of transmission

- Male and female condoms and lube
- ARV treatment to prevent vertical transmission (PMTCT)
- Clean injecting equipment
- Post-exposure prophylaxis (PEP)
- Vaginal and rectal microbicides*

Treatment

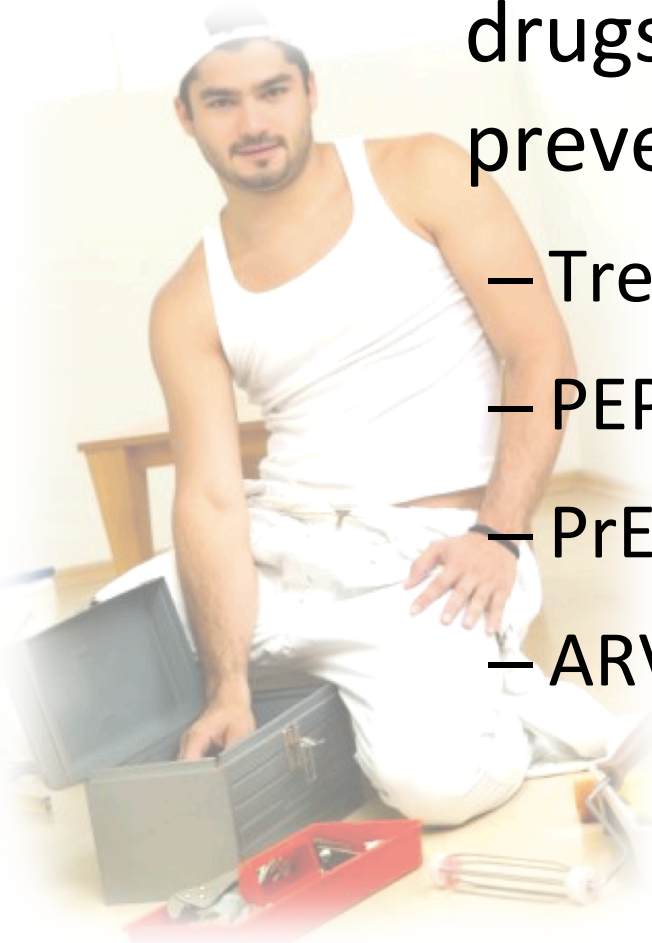
- **Treating POZ individuals has prevention benefits**
- Basic care/nutrition
- Prevention for positives
- Education & rights-focused behavior change
- Therapeutic vaccines*

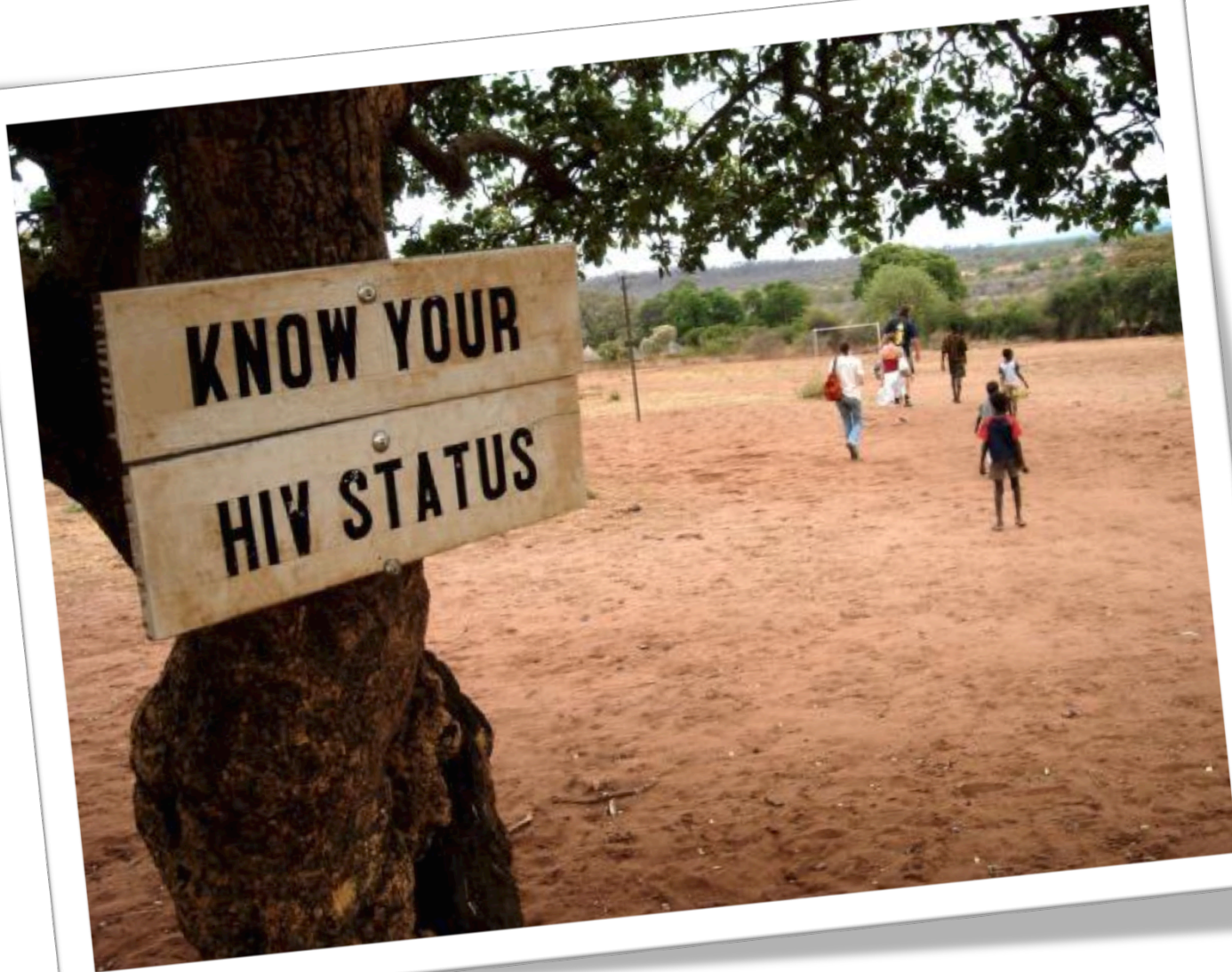
***still in development**



What is ARV-based prevention?

- Strategies that use HIV treatment drugs (antiretrovirals or “ARVs”) to prevent HIV infection
 - Treatment as Prevention (TasP)
 - PEP (post-exposure prophylaxis)
 - PrEP (pre-exposure prophylaxis)
 - ARV-based microbicides





Testing is the gateway to all ARV-based prevention





Love

Intimacy

Connection

Emotion

Pleasure





TasP



Treatment as Prevention (TasP)



- Also known as Treatment for Prevention (T4P), Test and Treat (TNT) and TLC+ (Test, Link to Care, Plus Treatment)
- **Early use** of ARVs in HIV-positive people to reduce the risk passing HIV to others
- The strategy is a secondary benefit of ARV treatment
- The **primary benefit** is the individual's health

Treatment as Prevention (TasP)



- The rationale is that ARVs reduce viral load, which decreases infectiousness
- Recently proven to work in HPTN 052 study— **early treatment reduces risk of transmission by 96% in heterosexuals**
 - June 2013: WHO updates its guidelines to start treatment at 500 CD4 count (*Consolidated guidelines for the use of ARVs for treating and preventing HIV infection*)
 - But what about ANAL INTERCOURSE?

TasP and gay men



- Studies among gay/MSM in EU and Australia
- Serodiscordant gay couples
 - Risk of transmission with POZ partner on treatment
 - Reasons for not using condoms

Europe (14 countries)

- Partner Study
- <http://www.partnerstudy.eu/>

Australia

- Opposites Attract study
- <http://www.oppositesattract.net.au/>

TasP benefits



- Individual survival rates increase
 - Reduce disease and death
 - Control of TB and other HIV/AIDS-related illnesses
- Population levels of HIV decrease
 - 2004-2011 Kwazulul Natal (30-40% of HIV-infected on ART, decreased incidence by 38%)
 - 2002-2008 San Francisco: Increased tx, decreased community viral load and decreased HIV infections
- Simplified clinical management
- Reduce stigma with routine testing

TasP issues of note



- Ongoing research
 - **Anal sex** (Partners and Opposites Attract studies)
 - Definitive benefit of early treatment for HIV-positive individuals (START study)
 - Early treatment effects on the population level (TasP Study, PopART, etc.)
 - Studies looking at how best to improve the treatment cascade by getting people tested, treated sustained in care and virally suppressed (TLC+)

TasP issues of note



- Advocacy to start treatment earlier, at least 500 or over, and immediately in serodiscordant couples, pregnant women (Option B-plus), active TB and other clinical needs



PEP





FIRE
EXTINGUISHER



***PEP**

Post-exposure prophylaxis (PEP)



Provide 2 or 3 ARV drug regimen after HIV exposure to prevent infection

- Occupational – offered to health care providers exposed to HIV, e.g. via needle stick
- nPEP – offered for non-occupational exposure, meaning sexual exposure, injection drug use exposure, rape
- Must be taken within 72 hours of initial exposure
- ARVs must be taken for 28 days

THE CONDOM BROKE.

PEP MAY HELP PROTECT YOU
FROM HIV UP TO **72 HOURS**
AFTER EXPOSURE



WE PARTIED LAST NIGHT.

PEP MAY HELP PROTECT YOU
FROM HIV UP TO **72 HOURS**
AFTER EXPOSURE



talk
pep.org FENWAY HEALTH

WHAT WAS HIS STATUS?

PEP MAY HELP PROTECT YOU
FROM HIV UP TO **72 HOURS**
AFTER EXPOSURE



talk
pep.org FENWAY HEALTH





Questions?

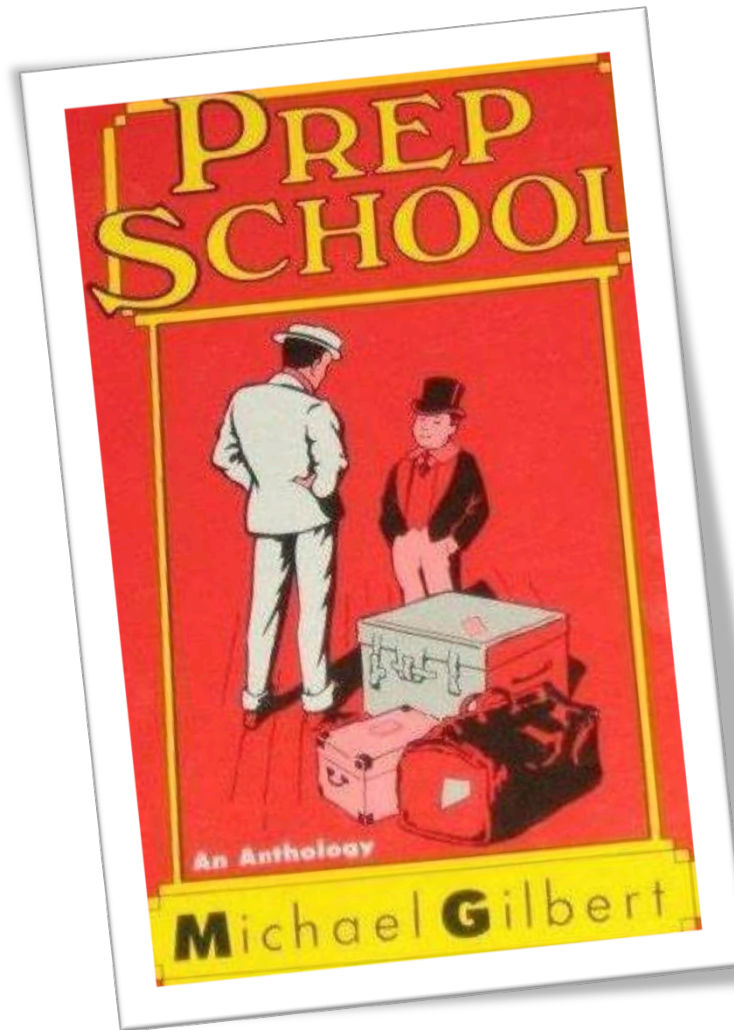




PrEP



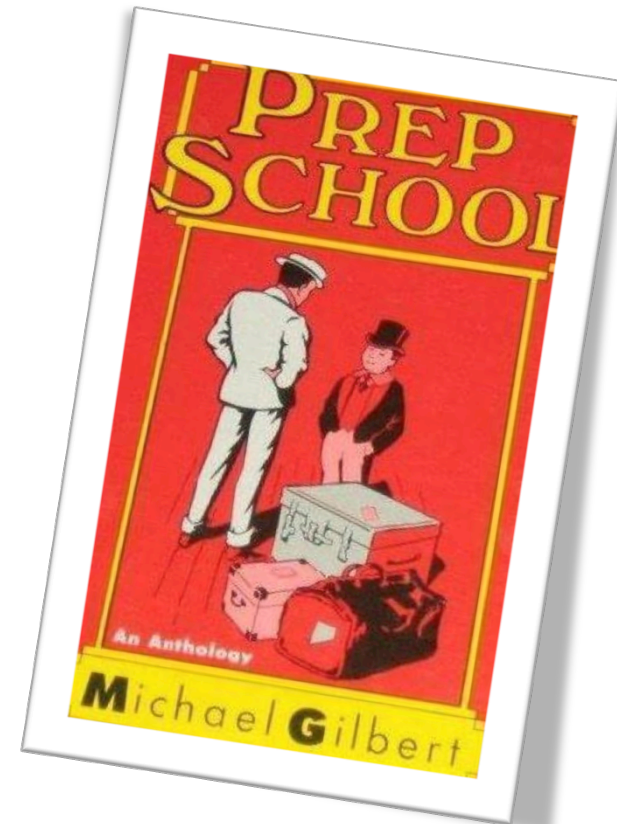
What is PrEP?*



*pre-exposure prophylaxis

Hold up, what is prophylaxis?

- Prophylaxis is simply the provision of medications prior to germ or virus exposure to prevent infection.
- This is not a new concept.
- This is not a new practice.
- Example: taking allergy meds
- What are examples of similar concepts?



PrEP for HIV prevention

- PrEP involves HIV-neg person taking ARVs to reduce risk of infection BEFORE HIV exposure.
- PrEP prevents HIV from reproducing in a person's body.
- In current form, PrEP is taken in a single pill once a day, every day (Truvada).



PrEP research

- All completed trials done on tenofovir & Truvada
- 4 trials = PrEP reduced risk of HIV infection
 1. i-PrEX (Truvada in gay men and trans women)
44% reduction overall (reported 2010)
Efficacy at 90% + with good adherence
 2. Partners PrEP (Truvada and tenofovir in het couples)
75% reduction Truvada (reported 2011)
 3. TDF2 (Truvada heterosexual men & women)
63% reduction overall (reported 2011)



PrEP research

- 4. June '13 - Bangkok Tenofovir Study (BTS)
 - CDC study of **injection drug users** (2,400 +)
 - Median age 31, 80% male
 - Daily tenofovir (75% chose directly-observed therapy)
 - **It works. 49% overall, 74% high adherers**



PrEP research

- 2 trials = PrEP did not work
 - FEM-PrEP (Truvada in women – stopped 2011)
 - VOICE (Truvada, tenofovir – reported 2013)
 - Both had very low adherence – though self-reports were high)
 - Low/undetected drug levels

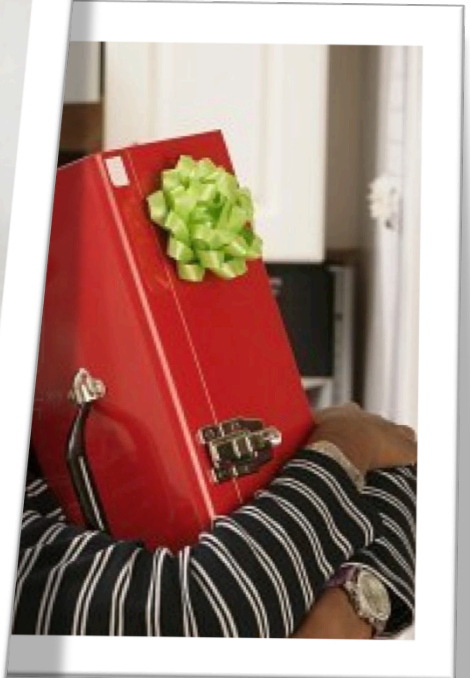


What PrEP *does not* do

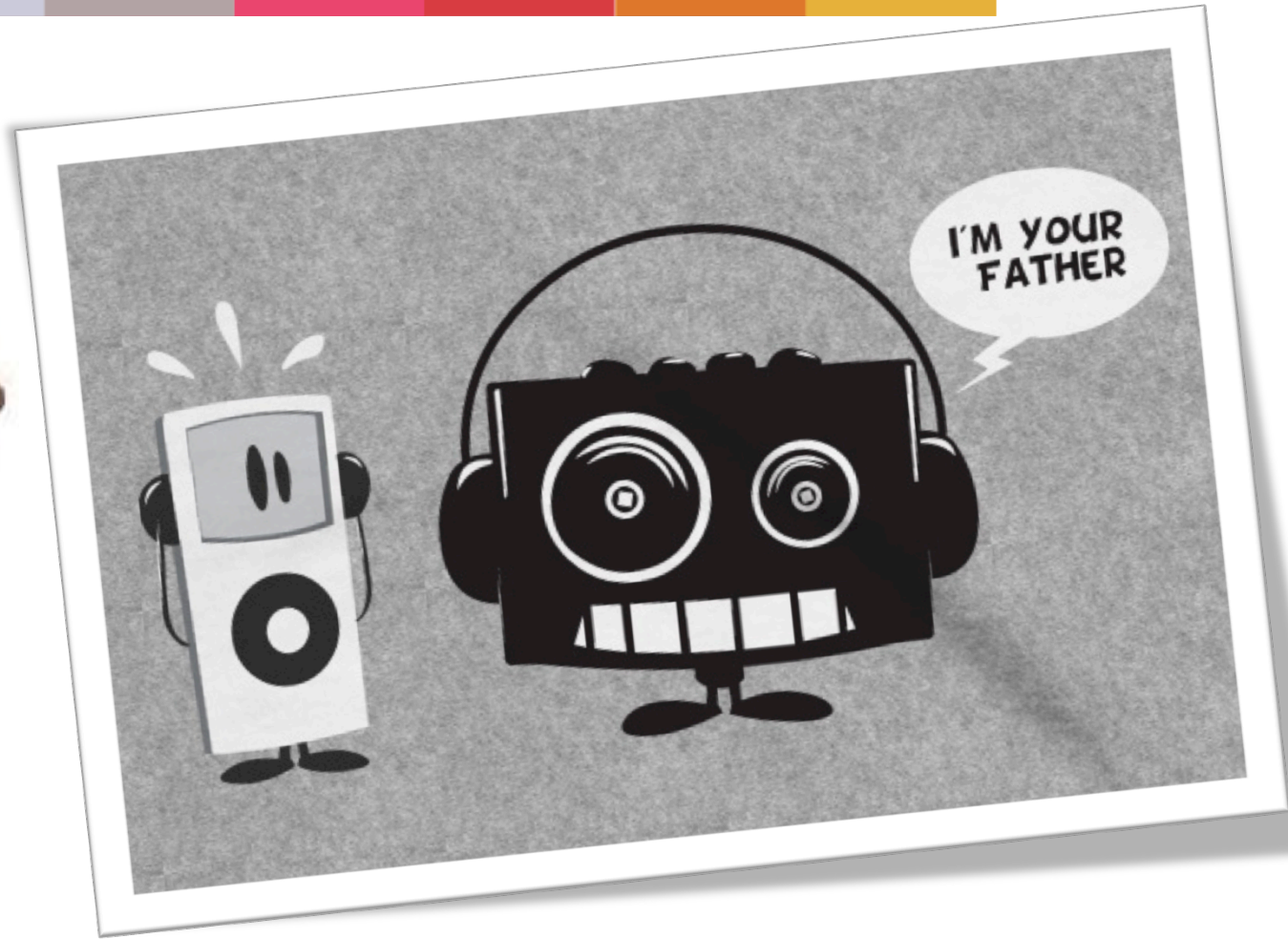
- **Truvada as PrEP *does not***
 - **Guarantee 100% protection from HIV**
 - **Protect a person against other STIs like chlamydia, syphilis, herpes, or gonorrhoea**
 - **Prevent pregnancy**
 - **Cure HIV**
 - **Function, on its own, as a treatment regimen for someone already living with HIV.**
 - **Why is Truvada, on it's own, not considered adequate for treatment?**

**Seat belts don't do
everything, either**





PrEP \neq Truvada





WHO Guidelines - PrEP



WHO PrEP Guidelines for MSM, TG

Countries that decide to proceed with introducing oral PrEP should undertake demonstration projects to ascertain most appropriate groups and best delivery approaches:

- HIV testing, retesting
 - Adherence
 - Side effects
 - Drug supply
- Referrals, resistance testing for seroconverters
 - PrEP before achieving universal Tx access?

WHO PrEP Guidelines for MSM, TG

“In countries where HIV transmission occurs among men and transgender women who have sex with men and additional HIV prevention choices for them are needed, daily oral PrEP (specifically the combination of tenofovir and emtricitabine - Truvada) may be considered as a possible additional intervention.

Conditional recommendation, high quality of evidence*.”



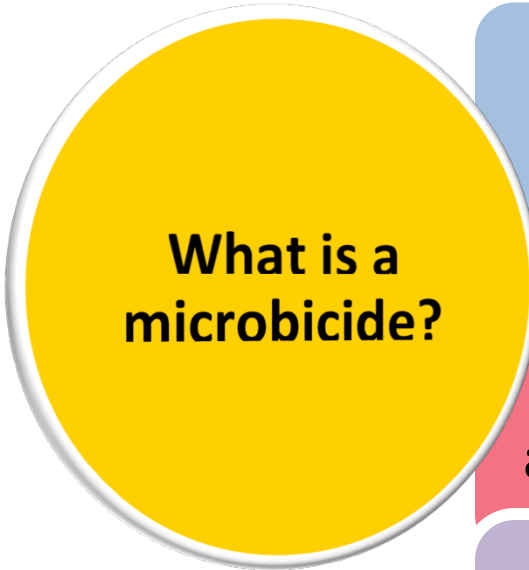
Questions?





Microbicides





**What is a
microbicide?**

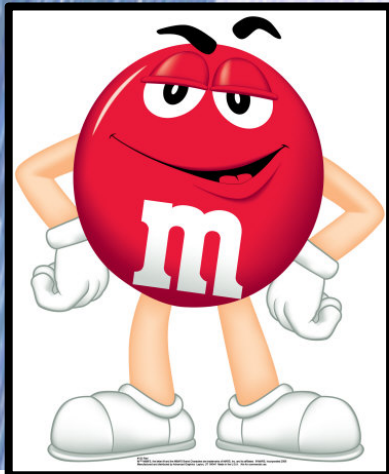
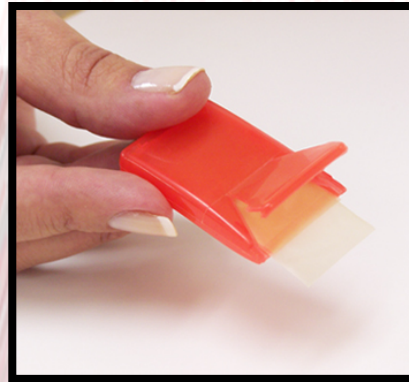
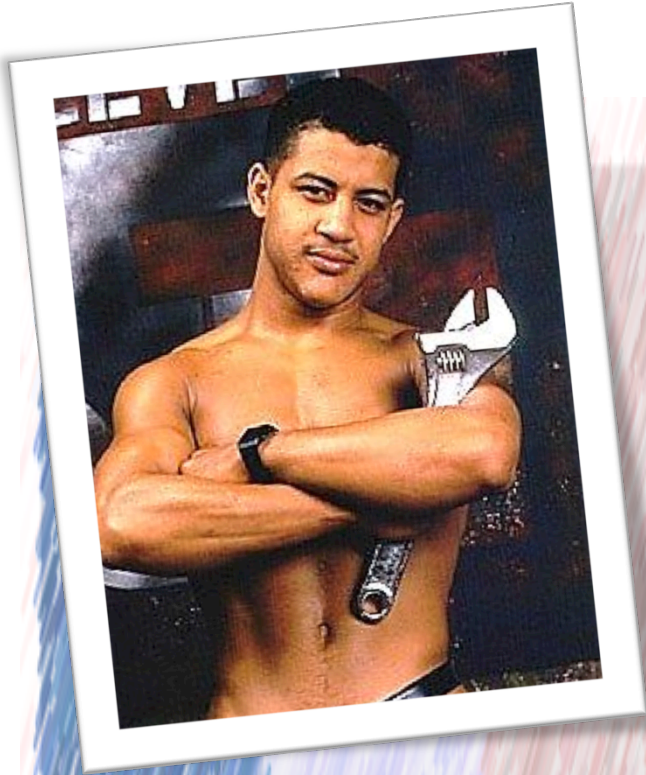
A product applied in the vagina or the rectum that offers protection against HIV and, ideally, other sexually transmitted infections

Ideally, contraceptive version, and another to allow for pregnancy – ARV/non-ARV

Formulated as a gel/lubricant, film, or vaginal ring

A rectal microbicide might be delivered via gel/lubricant, douche/enema, or ...

Microbicides are still in development - they are not available yet!







Questions?



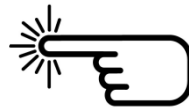
FACILITATOR'S GUIDE

THE RECTAL REVOLUTION IS HERE:

AN INTRODUCTION TO
RECTAL MICROBICIDE CLINICAL TRIALS



tinyurl.com/rectalvid



GUIDE

MORE RESULTS
rectal microbicide



00:26 / 14:47

The Rectal Revolution is Here (full length)



IRMAadvocacy · 4 videos

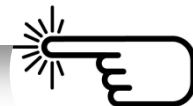
Subscribed

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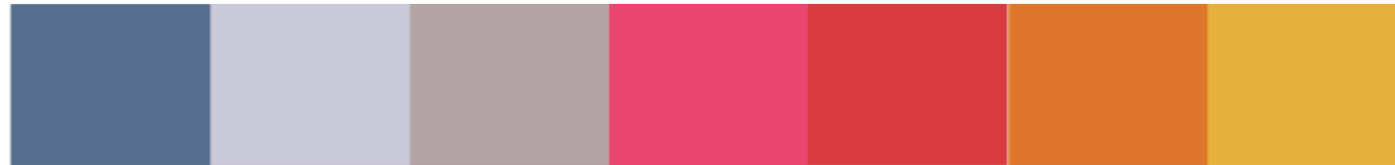
21 likes 0 dislikes



tinyurl.com/rectalvid



Rectal Microbicide Advocacy





Who is IRMA?





**1200+
advocates,
scientists, funders,
policymakers from
6 continents**



AIDS Foundation of Chicago is the IRMA secretariat

**Mission: support
development of
safe, effective,
acceptable, and
accessible
rectal microbicides
for all that need them**



AIDS Foundation of Chicago is the IRMA secretariat



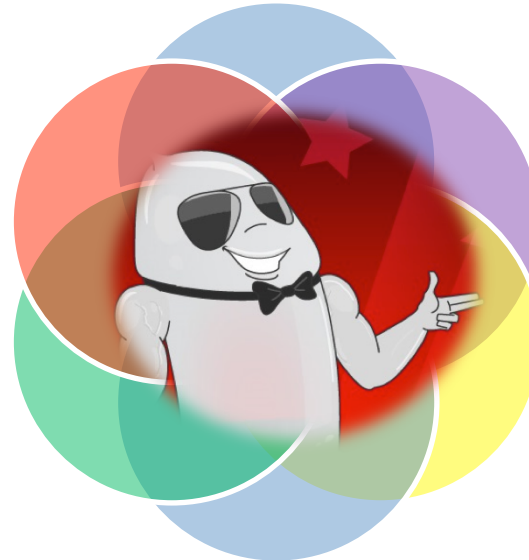
RECTAL PRIDE
WITH MICROBICIDES
VISIT IRMA
RECTALMICROBICIDES.ORG



**Materials,
presentations**

**Global
teleconferences**

**Highly active
moderated
listserv**



Website

**Blog,
Facebook,
Twitter,
YouTube**





RECTAL PRIDE
WITH MICROBICIDES
VISIT IRMA
RECTALMICROBICIDES.ORG



**Engage w/
science and
community**

**Funding, civil
society
support**

**RM advocacy
and education**



**Lubricant
safety/access**

**Engage w/
clinical
research**

Anal health, anal sex



Rectal microbicide science



CHARM Program

- Combination HIV Antiretroviral Rectal Microbicide Program
- Development of rectal specific ARV microbicides
- Humanized mouse model
- Phase 1 studies (rectal specific)
 - Tenofovir , Maraviroc
 - Tenofovir & Maraviroc





MTN-017





MTN-017



A Phase 2 Randomized Sequence Open Label Expanded Safety and Acceptability Study of Oral Emtricitabine/Tenofovir Disoproxil Fumarate Tablet and Rectally-Applied Tenofovir Reduced-Glycerin 1% Gel



017 participants, locations

N = 186

Participants
Gay/MSM,
transgender
women

Study sites

- US (4)
- Thailand (2)
- RSA (1)
- Peru (1)



DESMOND TUTU
HIV FOUNDATION

017 in brief



- Study regimens include:
 - Rectal tenofovir gel used daily
 - Rectal tenofovir gel used before and after sex
 - Truvada tablets taken daily
- Each participant will follow all of the study regimens for eight weeks, with a weeklong break between regimens when no product will be used
 - The order in which participants follow study regimens will be based on random assignment
- All participants receive standard HIV prevention package

Vaginal applicator



017 primary objectives



– Safety

- Compare the safety profiles of rectal tenofovir gel used daily and before and after sex, and Truvada tablets

– Acceptability

- Evaluate and compare the acceptability of Truvada tablets to rectal tenofovir gel
- Did they like the product? Would they use it in the future, if available?

017 adherence



PK monitoring, “real time” PK

Layered approach to monitoring

- SMS (text messages)
- Product returns
- CASI (computer assisted self interview)

Rectal Microbicide Timeline*

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Phase 1		→								
Phase 2				→						
Phase 2B						→	→	→		
Review									→	
Available										→
Vaginal microbicides						→				

*An approximation based on tenofovir 1% gel

Slide courtesy of the Microbicide Trials Network







Questions?



PROJECT ARM

AFRICA FOR RECTAL MICROBICIDES





**Africa needs a rectal
microbicide research
and advocacy strategy
specific to the continent**

- **Birth of Project ARM**
 - Working/strategy meeting before ICASA 2011
 - Addis, Ababa, Ethiopia
December 2 – 3, 2011
 - 45 individuals:
Africans/allies





Our diverse sexualities in Africa shouldn't be defined only by the prevention tools we have available. HIV prevention tools must be adapted to our sexualities.

Alliance Nikuze, Rwanda



Communication/education materials



Video project with Population Council

Uncovering a taboo:

**Raising awareness for
safer **anal sex** in Africa**

Communication/education



WORK IN
PROGRESS

Video presentation

Uncovering a taboo:

Raising awareness for
safer **anal sex** in Africa

AND LUBE

GLOBAL LUBE ACCESS MOBILISATION

GLAM



The tag line for the Global Lube Advocacy Mobilisation sums it up. Whenever someone says “condoms,” we say “And Lube.” You cannot say one without the other. Too often that is exactly what happens. Access to condom-compatible lubricant is deplorable all across Africa—it’s unacceptable, and we are working to change that.

Tian Johnson, South Africa

PROJECT ARM



Whenever
anyone says
“condoms” –
we say “AND
LUBE!”



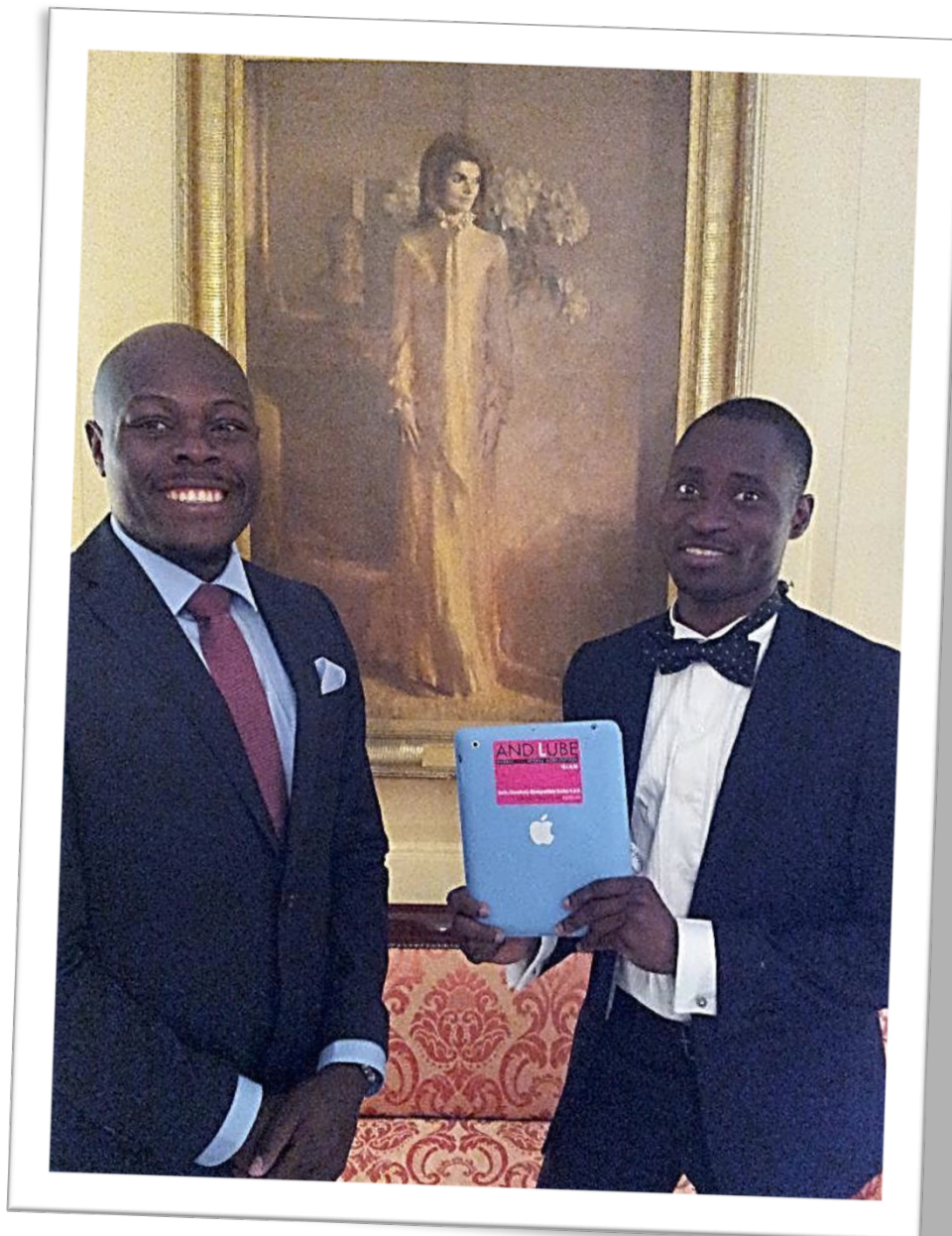


irma | international
rectal microbicide
advocates

amfAR
MAKING AIDS HISTORY



Visit <http://tinyurl.com/AndLube>



Visit <http://tinyurl.com/AndLube>

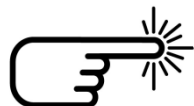
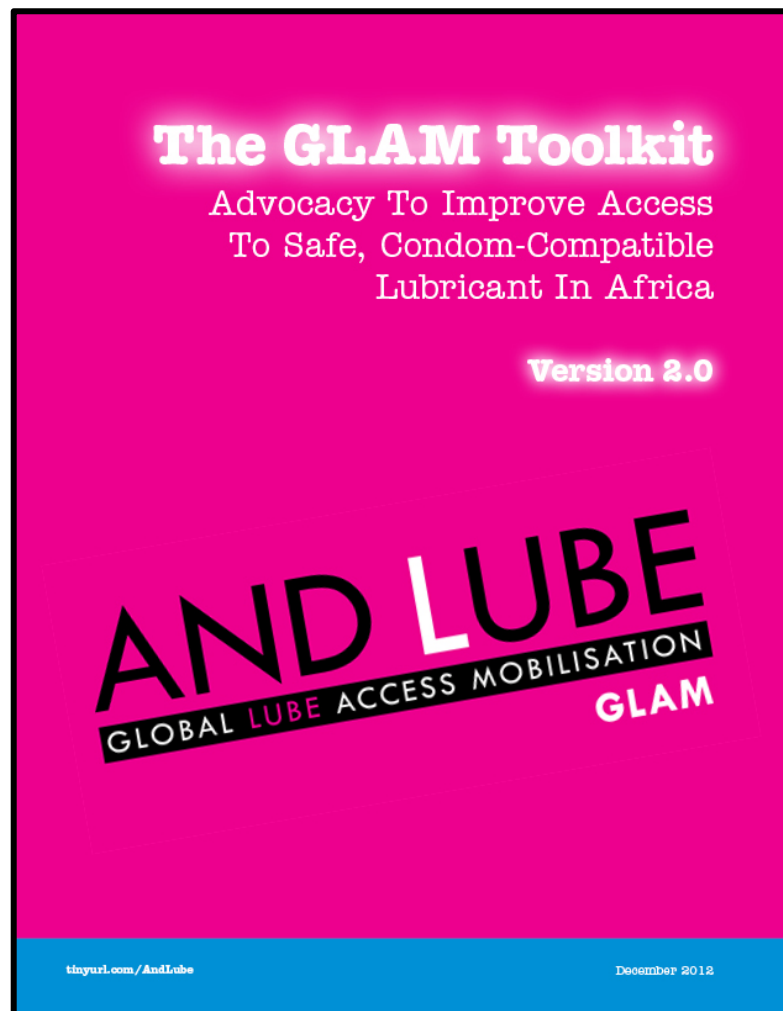
AND LUBE

GLOBAL LUBE ACCESS MOBILISATION

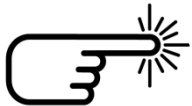
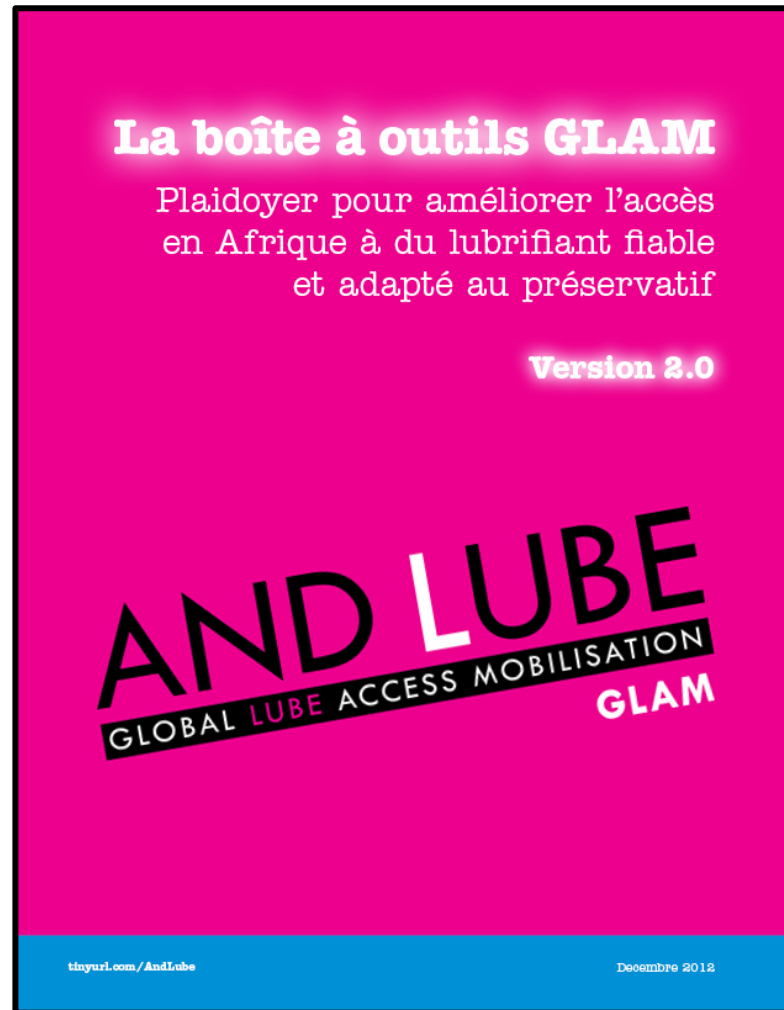
GLAM

Safe, Condom-Compatible Lube 4 All

Visit <http://tinyurl.com/AndLube>

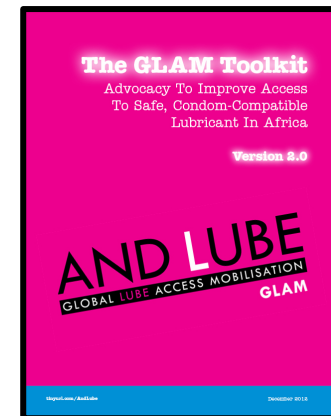


Visit tinyurl.com/AndLube

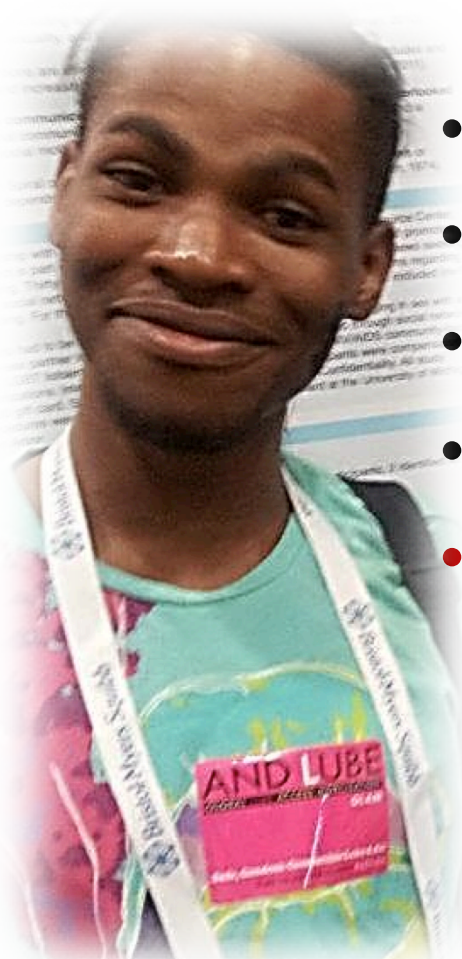


Visit tinyurl.com/AndLube

What is in the GLAM Toolkit?



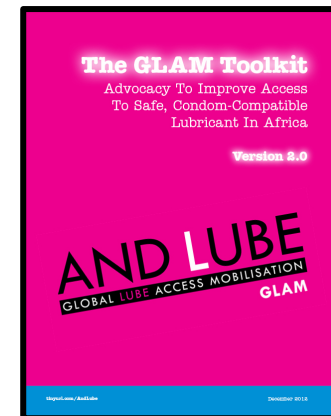
- Lube Access and Safety
- African National Strategic Plans
- National Case Studies
- Survey Findings Lube Distribution, Access
- Advocacy Steps for Improving Access to Safe, Condom-Compatible Lubricant



Visit tinyurl.com/AndLube



What is in the GLAM Toolkit?



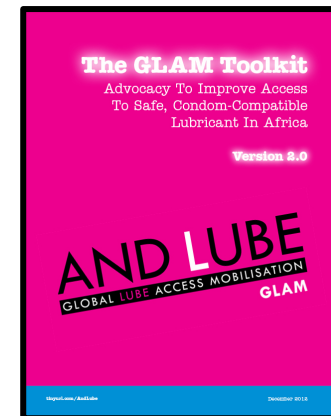
Lube Access and Safety Info

- **Many people use some type of lubricant during anal and vaginal intercourse.**
- **Some lubricants (water- and silicone-based) are safe to use with condoms; others (petroleum-based products) are not safe to use with condoms.**
- **Using condom-compatible lube reduces the risk of condoms breaking or slipping.**

A photograph of a man in a white short-sleeved shirt and shorts leaning over the edge of a swimming pool. The scene is set outdoors with a building and trees in the background. The image is framed by a circular border with a red and yellow gradient. The word "Pleasure" is written in a bold, yellow, italicized font across the center of the image.

Pleasure

What is in the GLAM Toolkit?



Lube Access and Safety Info

- Condom-compatible lubes are inaccessible to most people around the world, esp. Africa.
- **Promotion and distribution of condoms and safe condom-compatible lube should go hand in hand.**
- However, more research is needed on the safety of lubricants to determine which products are safest.

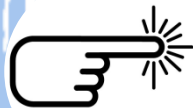


THE BOTTOM LINE:
**MORE RESEARCH IS URGENTLY NEEDED TO
EXPLORE IF THERE IS A LINK BETWEEN LUBE
USE AND ACQUIRING HIV AND /OR RECTAL
STIs**



Lube Fact Sheet, Lube QA

- **Safety of lubricants for rectal use:
A fact sheet for HIV educators and
advocates**
- **Safety of lubricants for rectal use:
Questions & Answers for HIV educators
and advocates**



rectalmicrobicides.org/materials.php



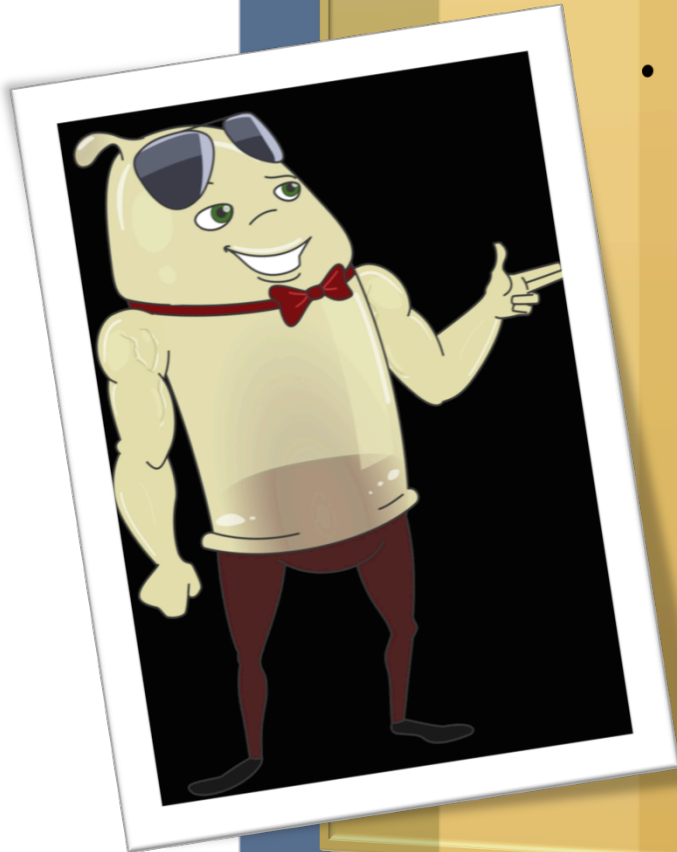
More lube advocacy work needed



Questions?



Special thanks to IRMA supporters



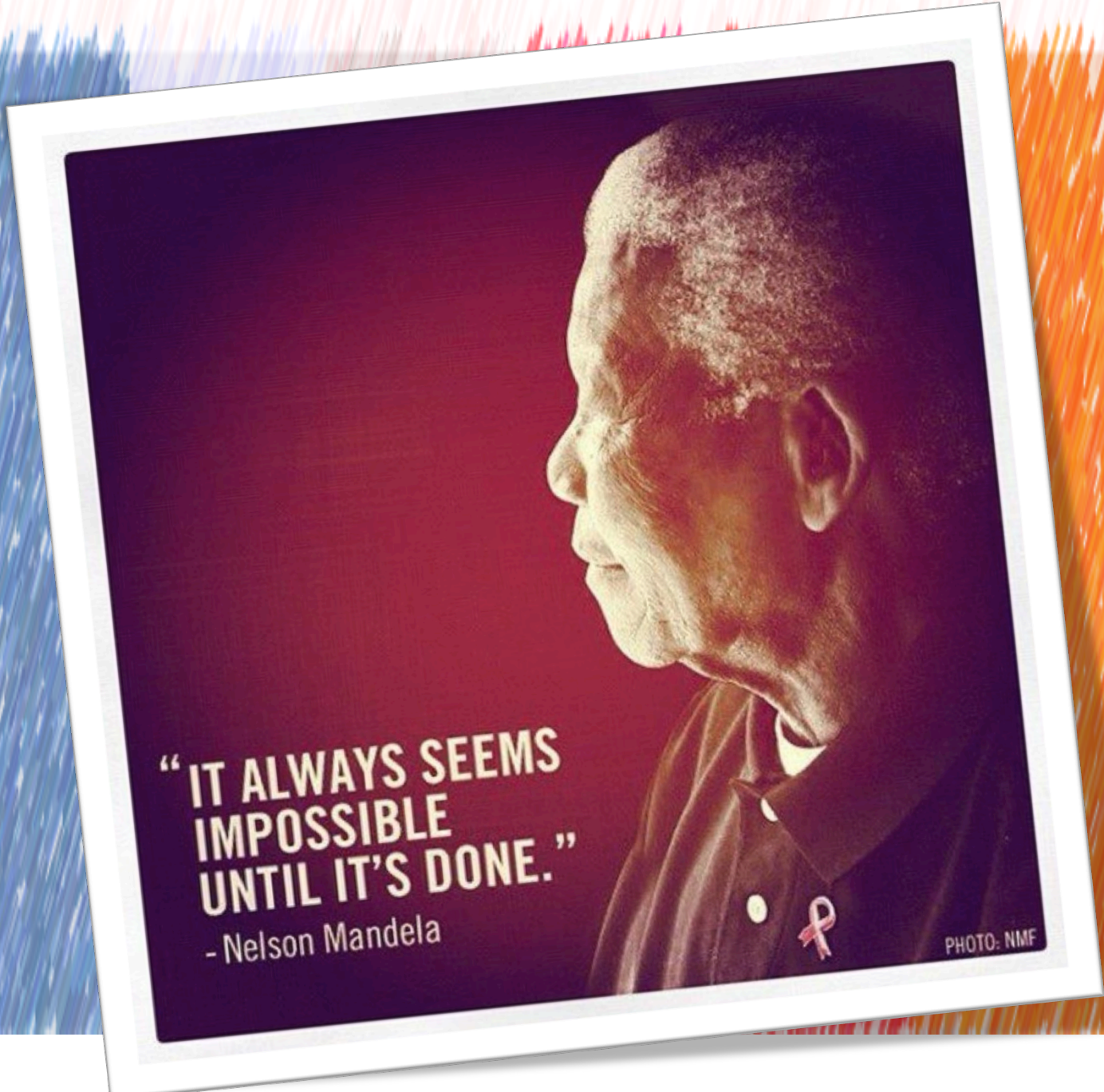
- AIDS Foundation of Chicago
- amfAR – The Foundation for AIDS Research
- Broadway CARES /Equity Fights AIDS
- Elton John AIDS Foundation
 - New Venture Fund
- NIH Office of AIDS Research
 - AVAC
 - MAC AIDS Foundation
- Microbicide Trials Network
 - Population Council
- Individuals - like my partner

Thank you





IT AIN'T EASY BEING GREEN



**“IT ALWAYS SEEMS
IMPOSSIBLE
UNTIL IT’S DONE.”**

- Nelson Mandela

PHOTO: NMF

Stay in touch



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Jim Pickett jpickett@aidschicago.org

Visit www.rectalmicrobicides.org

