

Addressing the Gaps Between Products and People at Risk



Albert Liu, MD, MPH

Clinical Research Director, Bridge HIV

SF Department of Public Health

Assistant Clinical Professor of Medicine, UCSF

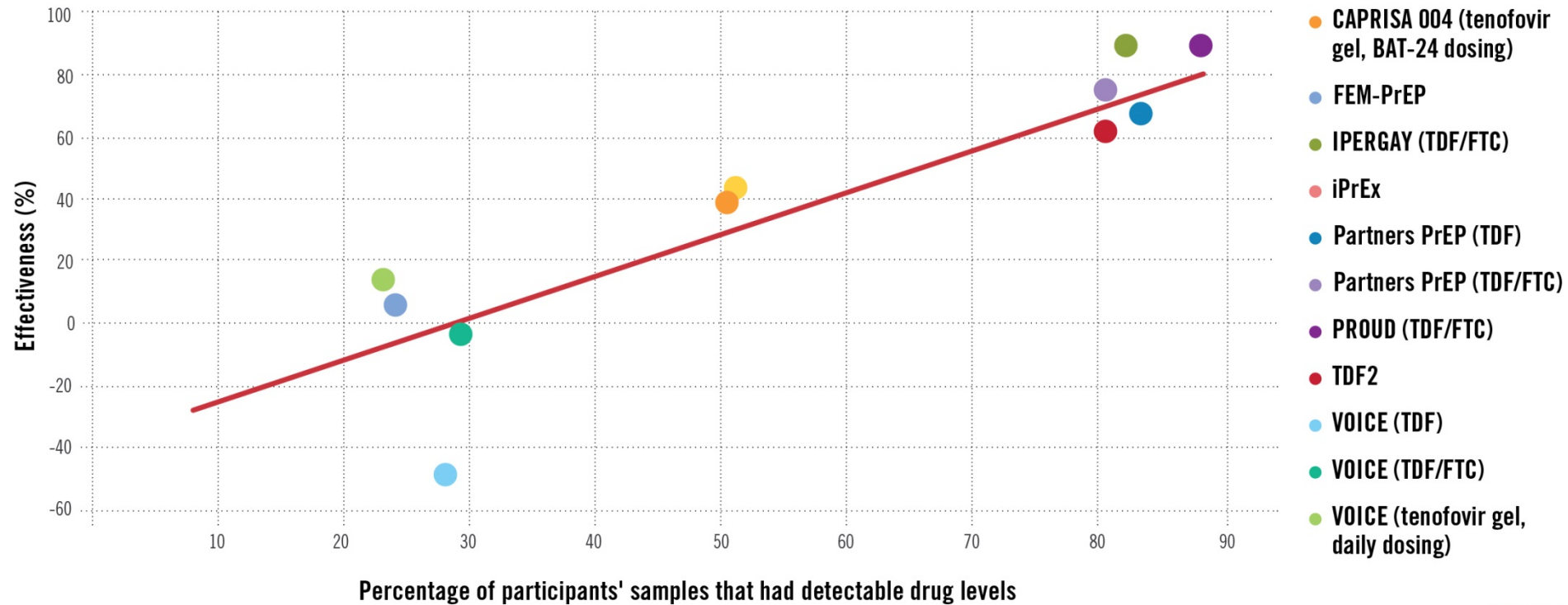
MTN Annual Meeting, March 21, 2017

Roadmap

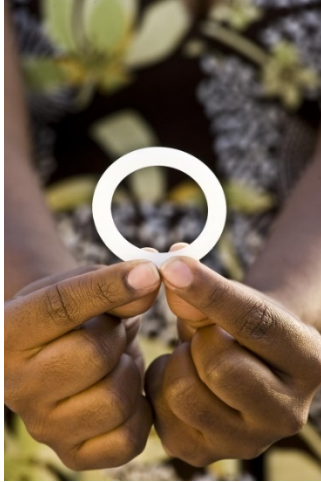
- HIV prevention in 2017
 - Successes and gaps with oral PrEP implementation in US
- Why choice matters? Lessons learned from contraception
- Matching and optimizing products for people who use them
- Messaging is important



Oral PrEP is highly effective, *if you take it*



Promising research on long-acting prevention




ASPIRE
A Study to Prevent Infection
with a Ring for Extended Use









































HPTN 083
an HIV prevention clinical trial











































**So... do we really need other
prevention strategies??
(*Where are the gaps?*)**







































“Scorecard” for prevention modalities

Modality	Efficacy	Low user burden	Low Cost	Low systemic side effects	Reversibility	Low risk of Resistance	Increases sexual pleasure	MPT (STIs, pregnancy)
Daily oral PrEP								
On demand PrEP								
Injectable PrEP								
PrEP implant								
Vaginal ring								
Rectal lube or insert								
Rectal douche								
bNAb/HIV Vaccine								







































“Scorecard” for prevention modalities

Modality	Efficacy	Low user burden	Low Cost	Low systemic side effects	Reversibility	Low risk of Resistance	Increases sexual pleasure	MPT (STIs, pregnancy)
Daily oral PrEP								
On demand PrEP								
Injectable PrEP								
PrEP implant								
Vaginal ring								
Rectal lube or insert								
Rectal douche								
bNAb/HIV Vaccine								

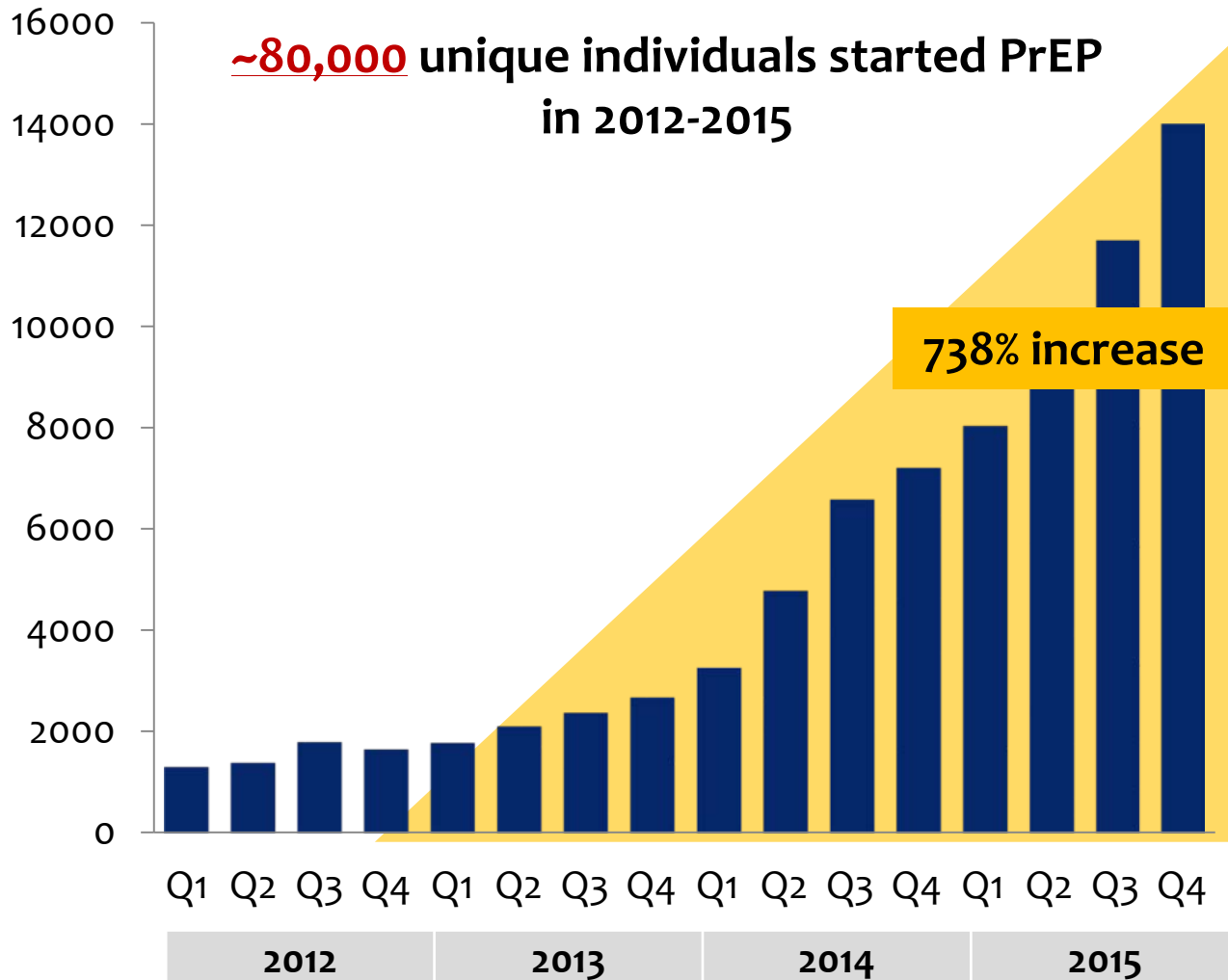
“Scorecard” for prevention modalities

Modality	Efficacy	Low user burden	Low Cost	Low systemic side effects	Reversibility	Low risk of Resistance	Increases sexual pleasure	MPT (STIs, pregnancy)
Daily oral PrEP								
On demand PrEP								
Injectable PrEP								
PrEP implant								
Vaginal ring								
Rectal lube or insert								
Rectal douche								
bNAb/HIV Vaccine								

“Scorecard” for prevention modalities

Modality	Efficacy	Low user burden	Low Cost	Low systemic side effects	Reversibility	Low risk of Resistance	Increases sexual pleasure	MPT (STIs, pregnancy)
Daily oral PrEP								
On demand PrEP								
Injectable PrEP								
PrEP implant								
Vaginal ring								
Rectal lube or insert								
Rectal douche								
bNAb/HIV Vaccine								

Rapid rise in PrEP use in the US



But lower uptake in:

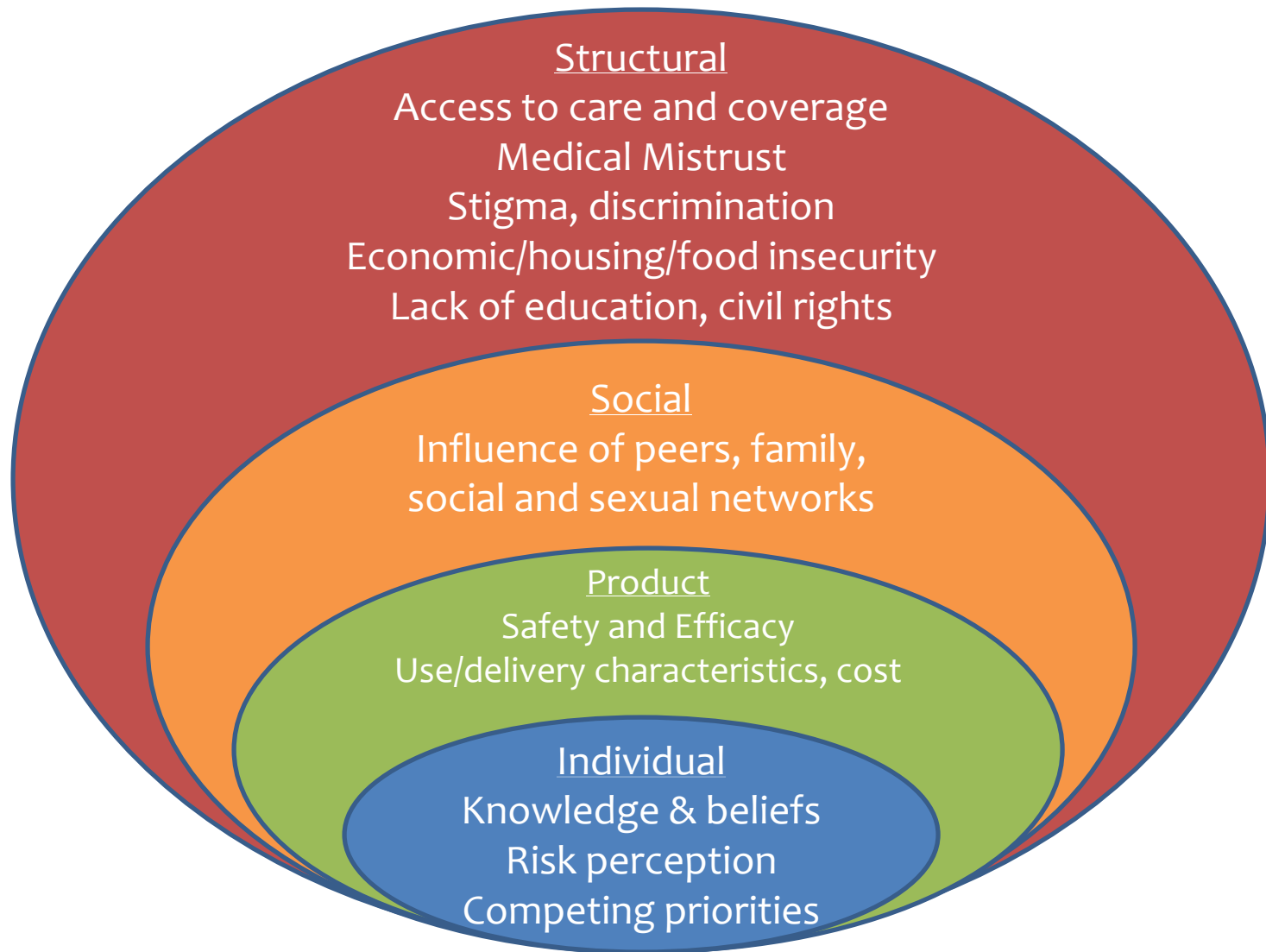
- People of color
 - African Americans
 - Latinx
- Youth
- Transgender people

When provided PrEP access, PrEP uptake varies in the real-world (US)

Cohort	Population	PrEP uptake*
US PrEP Demo	MSM and transwomen in SF, Miami, DC	61%
ATN 110	Young MSM (age 18-22) across 12 US cities	57%
ATN 113	Young MSM (age 15-17) across 6 US cities	33%
HPTN 073	Black MSM in LA, DC, Chapel Hill	79%
EleMENT PrEP	Young (16-29) Black MSM in Atlanta	34%

*Among those who were preliminarily eligible, % who enrolled/initiated PrEP

Factors influencing uptake and adherence



Reasons for PrEP refusal

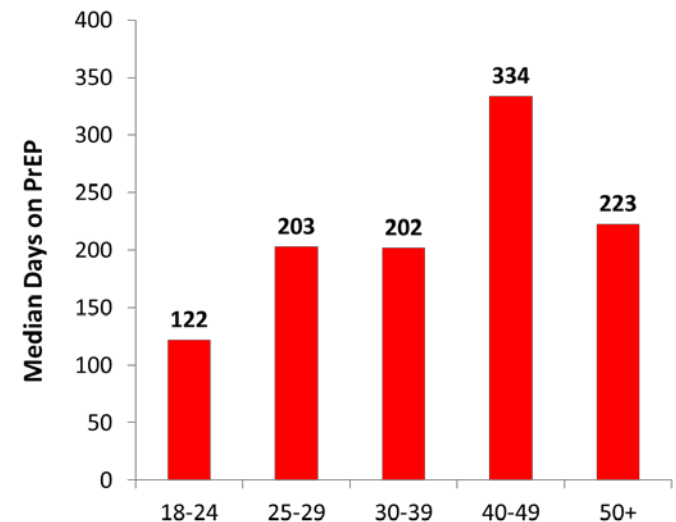
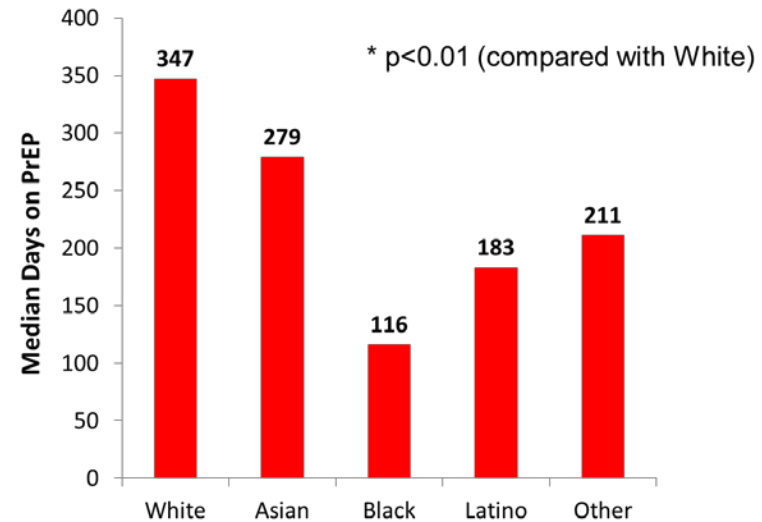
Recent testers in Southern CA (2013-2015)

Table 1: Reasons for PrEP refusal

Top Reasons for PrEP Refusal			p value	
Overall	Perceived lack of HIV risk	37%		
	Lack of Doctor Recommendation	27%		
	Side Effects Concerns	24%		
	Not interested in taking pills	17%		
	In monogamous relationship	16%		
MSM	Side Effects Concerns	45%		
	Not interested in taking pills	30%		
	Lack of Doctor Recommendation	23 %		
	Perceived lack of HIV risk	18%		
	Not sure if it will be effective	17%		
Gender	Lack of Behavioral concerns	Women	101/150 (67%)	<0.001
		Men	52/132 (39%)	
	Medication Related concerns	Women	27/150 (18%)	<0.001
		Men	77/132 (58%)	

Disparities in PrEP Persistence in San Francisco public health clinics

PrEP Persistence		
	Yes %	Total n (%)
Overall	67	148 (100)
Sex at birth		
Male	67	188 (85)
Female	69	32 (15)
Age		
18-24	67	18 (8)
25-29	61	44 (20)
30-39	71	85 (39)
40-49	60	35 (16)
50+	73	37 (17)
Race/Ethnicity		
Latino	57	35 (18)
Asian	75	16 (8)
Black	50	18 (9)
White	68	84 (43)
Other	69	36 (19)



PrEP Stigma and medical mistrust

- Survey of 285 MSM and transwomen attending gay pride festival in Southeast US (47% African American)
- 44% interested in PrEP
- 23% believed PrEP was for promiscuous individuals (PrEP stigma) – associated with lower interest in PrEP (and higher risk behavior)
- Among Blacks, 57% believed CDC cannot be trusted in their messaging regarding PrEP – associated with lower interest in PrEP



Barriers in the transgender community

- Low PrEP awareness in trans community
- Misperceptions about PrEP
 - Side effects, PrEP efficacy
- HIV and PrEP are gay men's issues
 - “All the language around PEP and PrEP is targeted towards gay men. And that is really alienating to be put in this demographic that I'm not in”
- Concern about drug interactions with hormones



**Vulnerable populations
are disproportionately
impacted by stigma and
HIV.**

***These populations need to
be prioritized in the
development of new HIV
prevention strategies.***



HIV Stigma Scars
Heal the Pain. End the Shame.

Learn how to stop HIV stigma at:
camba.org/antistigma
facebook.com/cambainc

**CAMBA**
where you can

The project was funded in part by the New York City Department of Health and Mental Hygiene through a contract with Public Health Solutions.

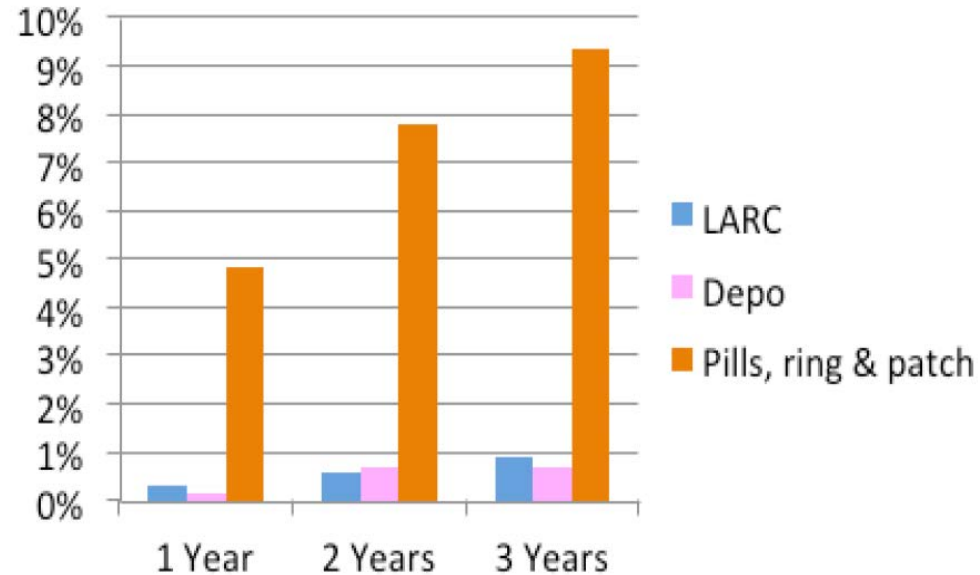
METHOD EXPLORER /

- ★ *most effective*
- 🍷 *party-ready*
- 🛡️ *STI prevention*
- 🚫 *hormone-free*
- 🔍 *easy to hide*
- ❤️ *do me now*



Contraceptive CHOICE Project

LNG-IUS	46.0	} 75%
CuT380A	11.9	
Implant	16.9	
DMPA	6.9	
Pills	9.4	
Ring	7.0	
Patch	1.8	
Other	<1.0	



- At baseline, 40% of ppts in CHOICE were non-users, and 20% relied on condoms
- All ppts used contraception after intervention began (75% LARC)
- 79% lower birth rates (compared with national sample of sexually active teens)



... but how much of impact of CHOICE was due to LARC use?

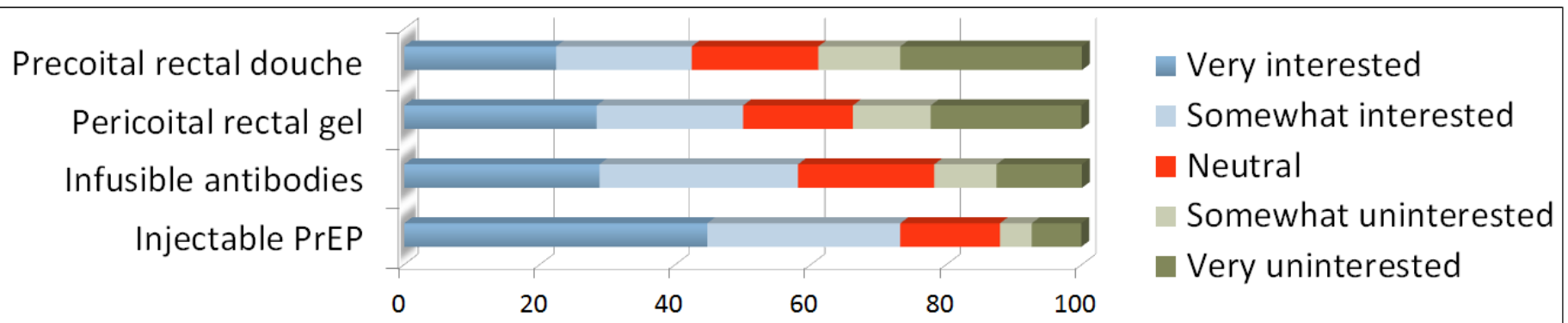
- Microsimulation model of CHOICE intervention vs. adoption of shorter-acting female-controlled methods (PPR = pill, patch, ring)

Intervention	Specifications	Pregnancy rate	% reduction
Baseline	4% LARC, 19% PPR, 32% condoms, 44% no methods	23.9%	(ref)
CHOICE	75% LARC, 25% PPR	4.2%	82%
PPR	4% LARC, 96% PPR	9.6%	60%

- **73% of CHOICE effect could have been achieved by adoption of PPR methods by nonusers and condom users**
- ***Most impactful interventions will be those that increase uptake of ANY female-controlled contraceptive method, long-acting or otherwise***

Most US MSM have heard of oral PrEP, but are very interested in other prevention modalities

- Online survey of 4638 at-risk MSM in US (March 2016)
- 78% heard of PrEP, 15% had taken oral PrEP
- 44% experienced side effects on PrEP



- MSM of color, younger men, those reporting condomless anal sex with >1 partner, and were PrEP naïve preferred injectable PrEP

Voices from young MSM and transgender people: Concerns about injectable PrEP

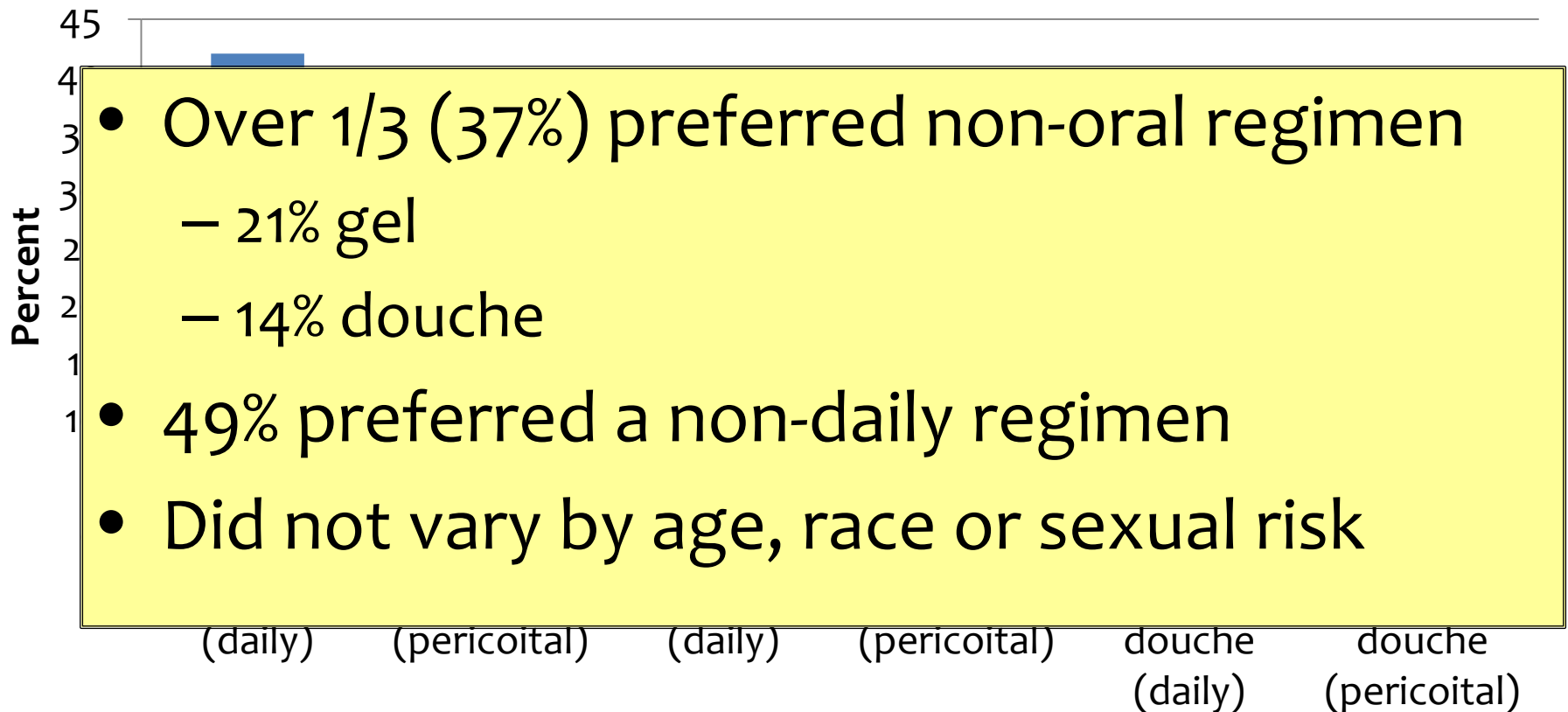
- *“If you miss your injection appointment, how many more days of protection would you have? What if I can’t reschedule the appointment in time?”*
- *“Are you going to have side effects the whole 3 months with the injection? Or just the first few days, if any?”*
- *“I don’t like shots. I don’t like needles. I’d prefer to stay away from those”*

MSM in Vietnam prefer rectal microbicides

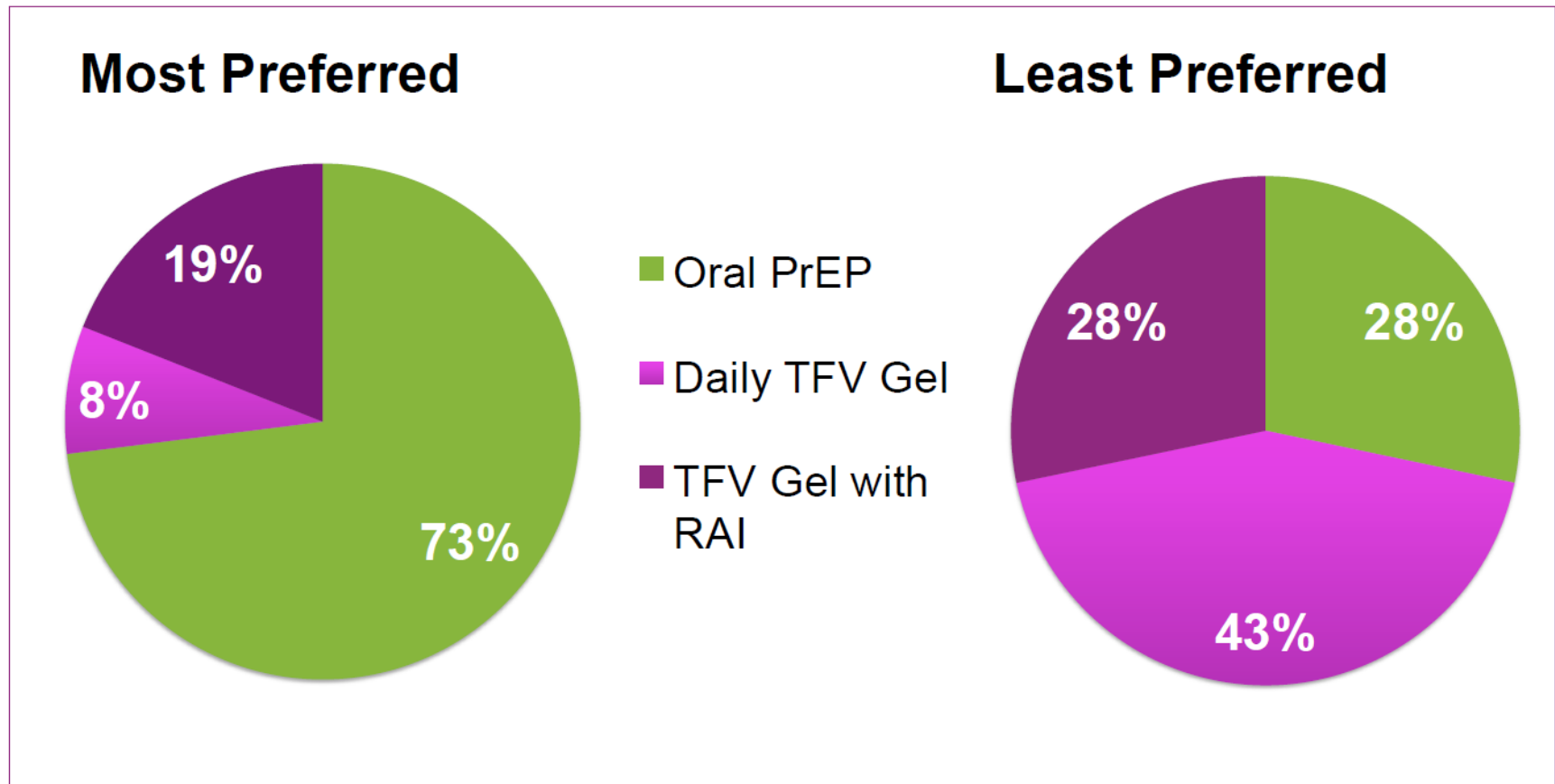
- 548 MSM completed online survey in Vietnam in 2015 (median age 22)
- 27% had heard of PrEP
- Concerns about oral PrEP: side effects (48%), concerns about taking daily pill (32%); difficulty remembering (69%)
- **Most preferred a rectal microbicide (66%) compared with long-acting injectable (17%) or daily oral PrEP (17%)**
- Reasons for preferring RM: enjoyed using lube while having sex (79%), perception easier to remember than daily pill (55%)

Product preferences in MTN-017 (baseline)

% listing product as first choice for prevention



Product preferences in MTN-017 (study completion)



Ease of use of rectal gel increased with use

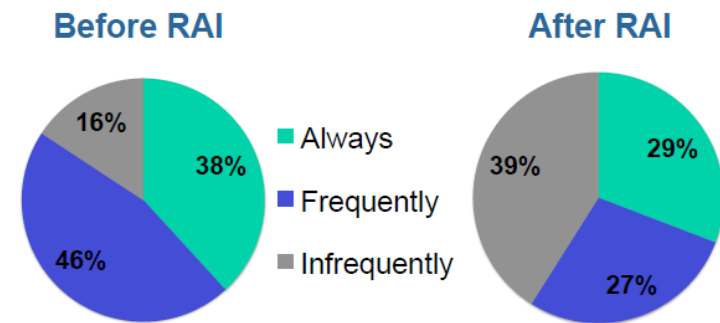
Voices from young MSM and transgender people: Some prefer pericoital gel/lube

- *“I’d prefer the gel. With the pill you gotta take it every day and just do the gel only when you have sex.”*
- *“I mean a lube would be cool you just sell it.”*
(OTC)

Douching and use of lube common in MSM and Transwomen

- YMSM (aged 18-30) surveyed in 3 US cities
 - 44% douched in past 3 months for hygiene (76%) and pleasure (25%)
 - 60% reported likelihood of using a douche that provided some protection against HIV
- MSM and TGW in MTN-017
 - 57% douched in the past 8 weeks
 - 40% always, 29% frequently
 - 81% frequently or always used sexual lubricant

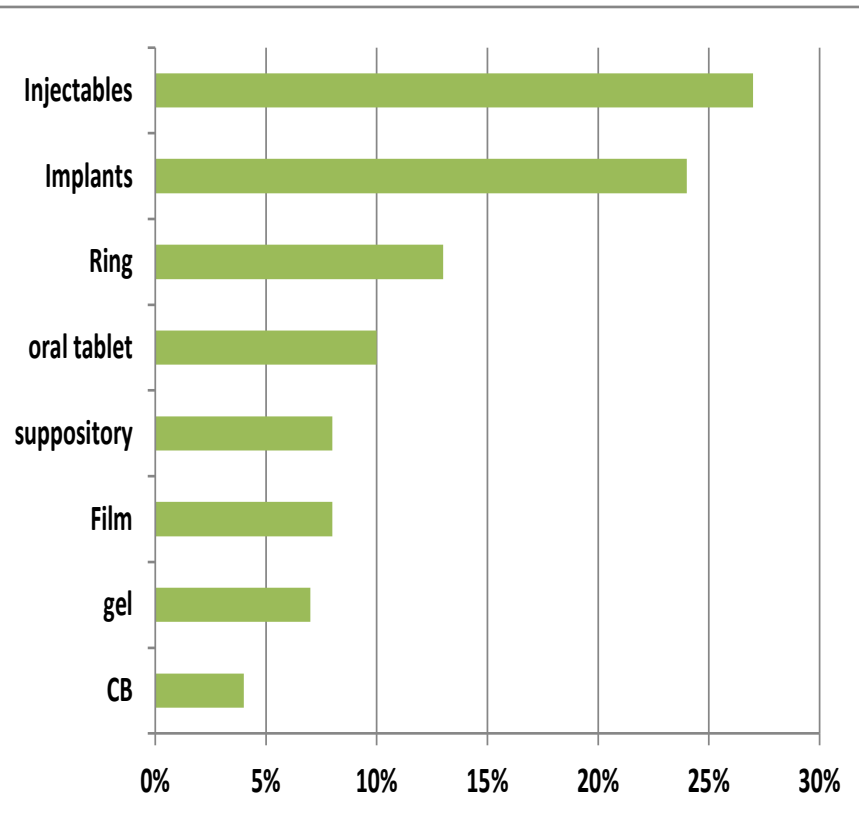
Douching Frequency



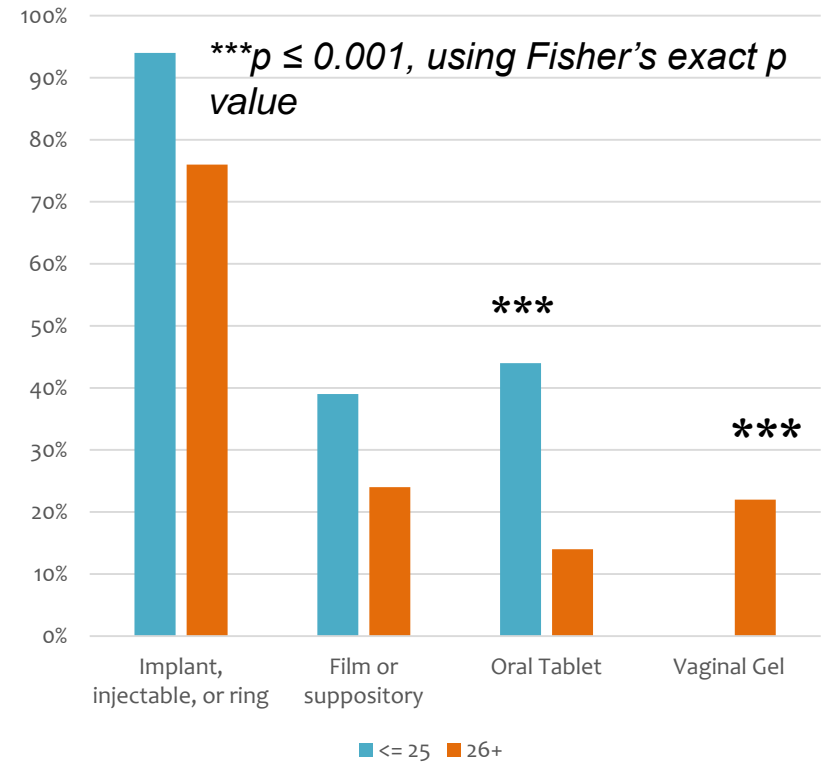
Preferences for prevention products among women in VOICE-D: (N=68)

Percent of products selected*

* Multiple selections allowed (median 2, range 0-6)



Young age associated with tablets preference. Gel not selected by any young person



ASPIRE qualitative component @ exit: HIV Prevention Product Formulations and Preferences (N=71)

- Long acting agents preferred, but some ambivalence about injections and implants: invasive, potential toxicity, low reversibility
- For several participants, high product efficacy trumped formulation
- Products administered vaginally were less favored among young women (<25)
 - But women liked ring due to monthly re-administration, perceived safety, reversibility, lack of side effects, familiarity, comfort and discretion once in place
- Knowledge of contraceptive methods (based on perceptions or experience) influenced formulation & attribute preferences for HIV PrEP

Preferred:

■ MOST % ■ LEAST %



Significantly less favored in
<25 age group

Human-centered Design

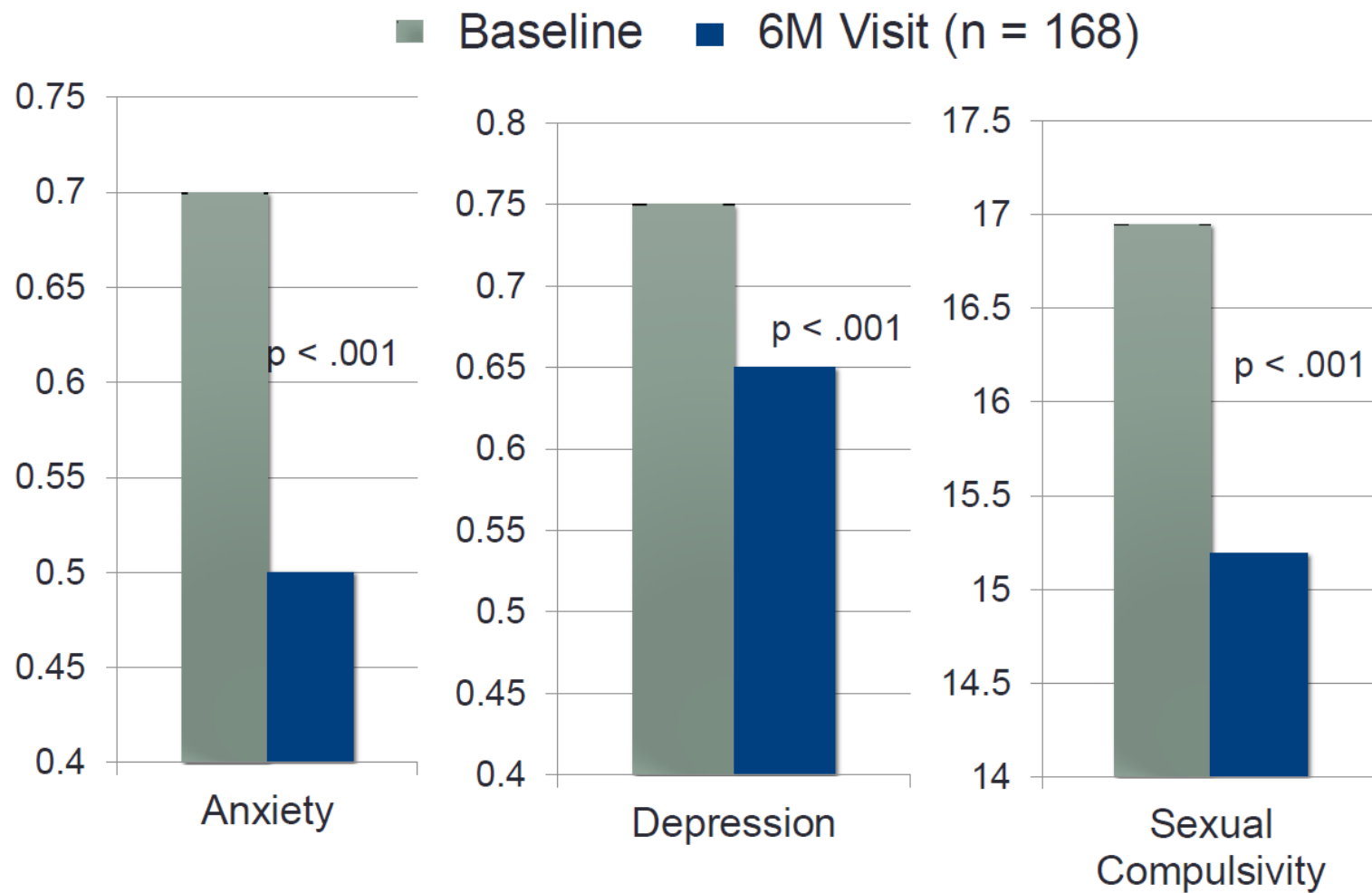


Messaging matters



- Most people are not “High Risk”
- Pathologizes sexual activity
- Difference between being on PrEP vs. being targeted as a PrEP candidate

PrEP can do more...



Pickett CROI 2016
Prep4Love.org

PrEP

**ONE PILL.
ONCE A DAY.
Protect Against HIV.**



Love is contractible. Lust is transmittable. Touch is contagious.
Catch feelings, not HIV.

Social influencers are very important



PrEP messaging for the Trans Community



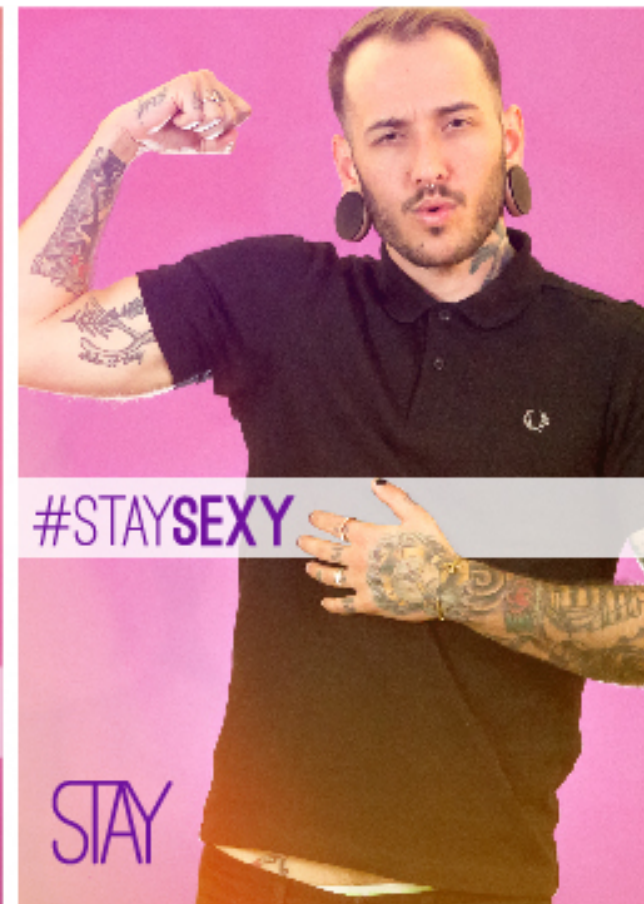
STAY

NOW THERE'S A PILL THAT CAN HELP PREVENT HIV INFECTION FOR TRANS PEOPLE. IT'S CALLED PrEP. IT'S SAFE. IT'S FREE. IT CAN HELP YOU STAY HIV-NEGATIVE SO YOU CAN STAY

AWARE

Get PrEP for free, the support you need to take it every day and \$250.

Text "stay" to (XXX) XXX-XXXX to find out how or visit us at xxxxxx.org



Closing thoughts

- Men and women (including trans people) have diverse sexual health needs at different times in their lives (HIV, STIs, pregnancy)
- ALL people deserve safe and effective HIV prevention tools
- Oral and long-acting agents aren't for everyone
- Increasing options will increase uptake of methods
- Incorporating user input into design may help increase uptake and acceptability
- Need to test methods empirically for efficacy, uptake and persistence
- Messaging and role of social influencers are key

Words of wisdom from Marc-Andre LeBlanc



“A highly effective product that stays in the wrapper/in pill bottle/on the shelf/in the syringe will prevent fewer infections than a less effective but more acceptable product that people actually use.”

So if people tell us that the currently available products and the current pipeline does not meet their needs, then by all means, bring on imperfect products that will be used more often.”

Thank you!

- Jared Baeten
- Katie Biello
- Jill Blumenthal
- Susan Buchbinder
- Alex Carballo-Diéguez
- Ross Cranston
- Rebecca Giguere
- Holly Gundacker
- Ishana Harkoo
- Laura Harrison
- Elske Hoornenborg
- Sharon Hillier



- Javier Lama
- Marc-Andre LeBlanc
- Ken Mayer
- Ian McGowan
- Sheldon Morris
- Catherine Oldenburg
- Charlotte-Paige Rolle
- Rupa Patel
- Jim Pickett
- Darryl Wheeler
- Ariane van der Straten
- Janie Vinson