

Lessons from PrEP delivery for young African women in POWER, 3P & HPTN 082

Connie Celum MD MPH
Departments of Global Health and Medicine
University of Washington



PrEP in Africa 2012-2018

- HIV incidence remains high in young women, key populations & geographic hot spots
- Demographic urgency: steep growth in youth
- Many dubious about PrEP delivery & young women's ability to take daily PrEP
- PrEP delivery through small demonstration projects & PEPFAR DREAMS program



Effective implementation requires

- Clear framework & expectations
- Demand creation
 - Positive messaging
 - Champions
- Tools to facilitate uptake
 - Risk assessment tools
 - Decision support tools
- Simple delivery
 - Integrated with other desired services (e.g., FP, STI testing & treatment)

Primary Objectives of HPTN 082

- To assess the proportion and characteristics of young HIV-uninfected women who accept versus decline PrEP.
- To assess the difference in PrEP adherence in young women randomized to enhanced adherence support (using drug level feedback) versus standard of care adherence support.

HPTN 082: Screening for risk & motivation

HPTN 082: Evaluation of daily oral PrEP as a primary prevention strategy for young African women



Study Population

Uninfected women
Ages 16-25 yrs

Johannesburg & Cape Town,
South Africa
Harare, Zimbabwe

Target Enrollment

- 400 women who accept PrEP at enrollment
- ≤ 200 women who decline PrEP at enrollment

Screening procedures:

- VOICE risk score
 - ≥ 5 to be eligible
- HIV prevention readiness
 - adapted from ATN HIV treatment readiness measure

Primary objectives:

Assess the proportion and characteristics of women who accept versus decline PrEP
Assess PrEP adherence using drug levels in young women

Importance of demand creation: Get PrEPed! video

Get PrEPed:
What African women need to know!



- Explains PrEP using youth-friendly graphics
- Filmed and edited by Umuzi (South Africa)
- Script, graphics and film developed in collaboration with and evaluated by youth in South Africa and Zimbabwe

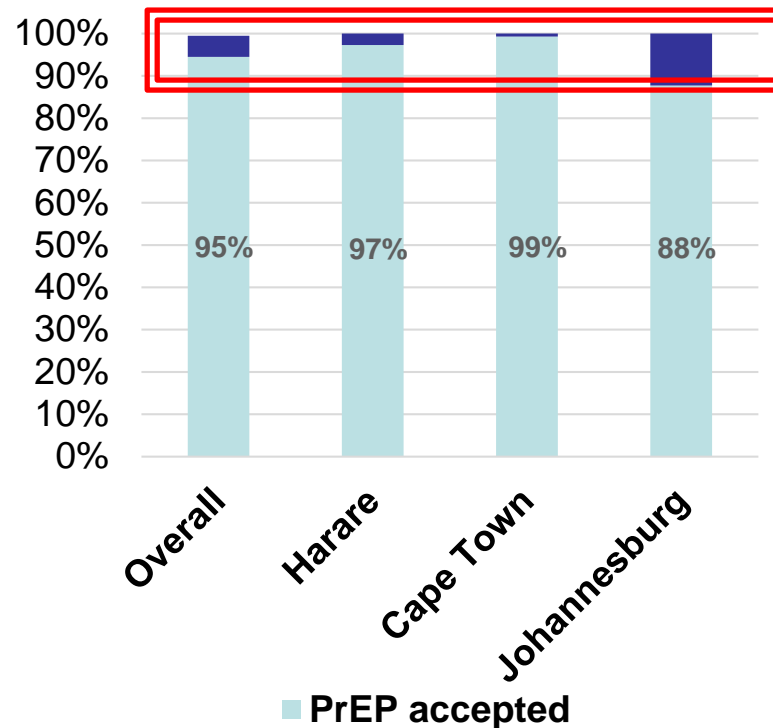
Young women screening for HPTN 082 shared the video with peers on social media

Young women have less questions about how PrEP works after viewing the video in the waiting room

<https://www.youtube.com/watch?v=tt-O4ZORrYQ>

HPTN 082: Design & PrEP uptake

Figure 1: PrEP uptake overall and by site



Pill containers



Two-way SMS



Adherence clubs



In half of HPTN 082 participants



≥ 4 doses per week (>700 fmol/punch at wk 8)
Key message: You are doing great! Keep up the good work and remember that taking one PrEP pill every day is needed for strong protection against HIV.



$\sim 1-3$ doses per week (*detectable to 699 fmol/punch at wk 8*)
Key message: It looks like you are trying to take the PrEP medication, but are having some difficulties. Remember that taking one pill every day is needed for strong protection against HIV. How can we help you do even better?



No TFV-DP detected
Key message: It looks like you haven't been able to take the PrEP medication. Is PrEP something that you are still interested in? If yes, how can we help you?

In all HPTN 082 participants



Demographics of PrEP ‘acceptors’

	N
PrEP Accepted at Baseline	412
Age	
Median (IQR)	21 (19,22)
Education	
Completed secondary school or higher*	404 (98%)
Ever dropped out of school*	122 (30%)
Age difference ≥ 5 years with primary partner	139 (44%)
HIV status of main partner	
HIV negative	204 (59%)
HIV positive	3 (0.9%)
He doesn't know his status	8 (2%)
She doesn't know his status	58 (17%)
Any transactional sex in past month	95 (23%)
Vaginal sex acts past month (median, IQR)	4 (2,8)
Condom use with vaginal sex, past month	
Never	65 (20%)
Rarely	48 (15%)
Sometimes	104 (33%)
Often	37 (12%)
Always	65 (20%)

STIs, risk, risk perception, IPV & depression

Enrollment characteristics	Overall
Curable STI	161 (39%)
Gonorrhea	33 (8%)
Chlamydia	120 (29%)
Syphilis	9 (2%)
Trichomonas vaginalis	27 (7%)
VOICE risk score* (median, IQR)	7 (6,8)
Chances of getting HIV in next year	
No risk at all	193 (47%)
Small chance	127 (31%)
Moderate chance	33 (8%)
Great chance	33 (8%)
Depression	171 (42%)
CES-D score ≥ 11	
≥ 1 episode of intimate partner violence, past year	200 (49%)

* Maximum VOICE risk score of 10
(score ≥ 5 associated with 6-8% in prior HIV prevention trials among young African women)

Risk perception & narrative sexual histories

- A ‘participant-empowered approach’
- ‘Action-orientated’ data collection
- Visual data – useful for conveying depth & detail beyond verbal expression
- Promotes more dialogue
- Enhances complexity and nuance in the data

GLOBAL PUBLIC HEALTH, 2016
VOL. 11, NOS. 5–6, 699–718
<http://dx.doi.org/10.1080/17441692.2016.1170869>



Routledge
Taylor & Francis Group

Using participant-empowered visual relationship timelines in a qualitative study of sexual behaviour

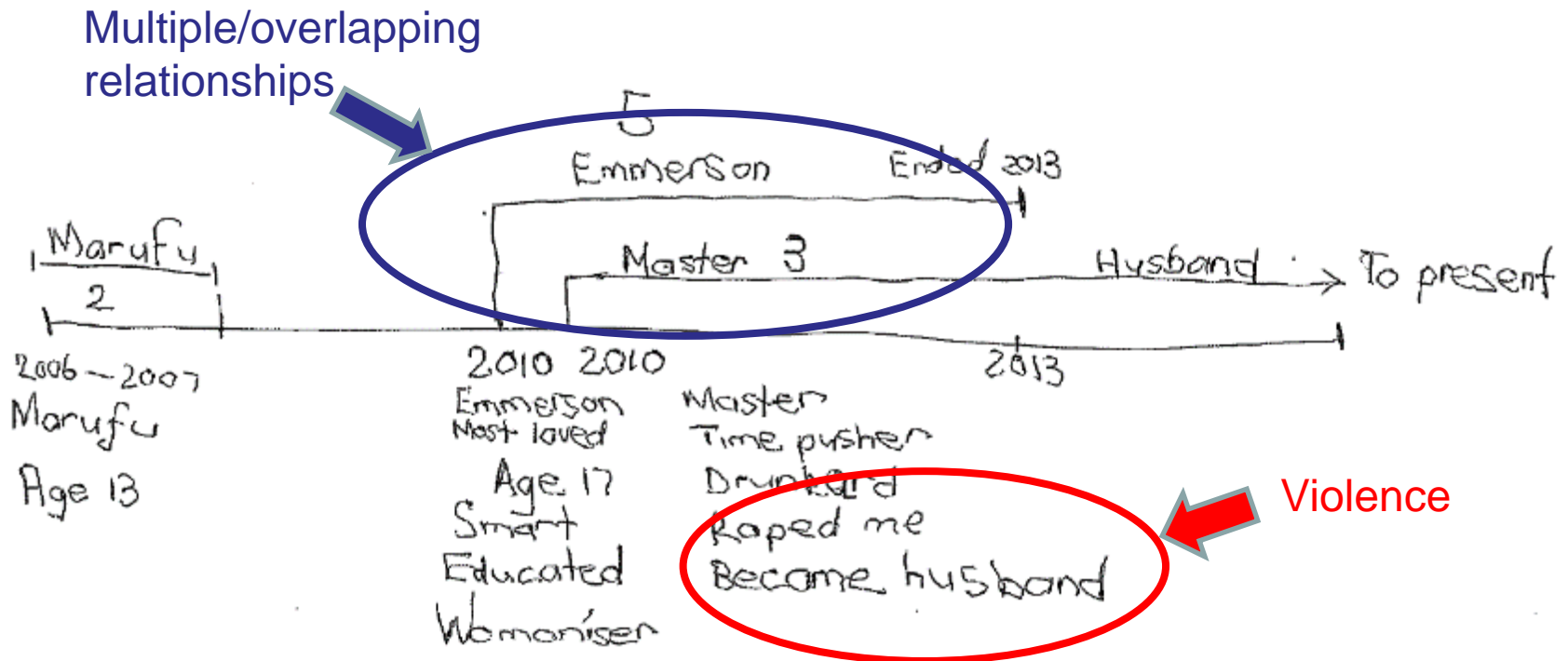
Tamar Goldenberg^{a,b}, Catherine Finneran^c, Karen L. Andes^c and Rob Stephenson^{a,b}

^aDepartment of Behavior and Biological Sciences, University of Michigan School of Nursing, Ann Arbor, MI, USA; ^bCenter for Sexuality and Health Disparities, University of Michigan, Ann Arbor, MI, USA; ^cHubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, GA, USA

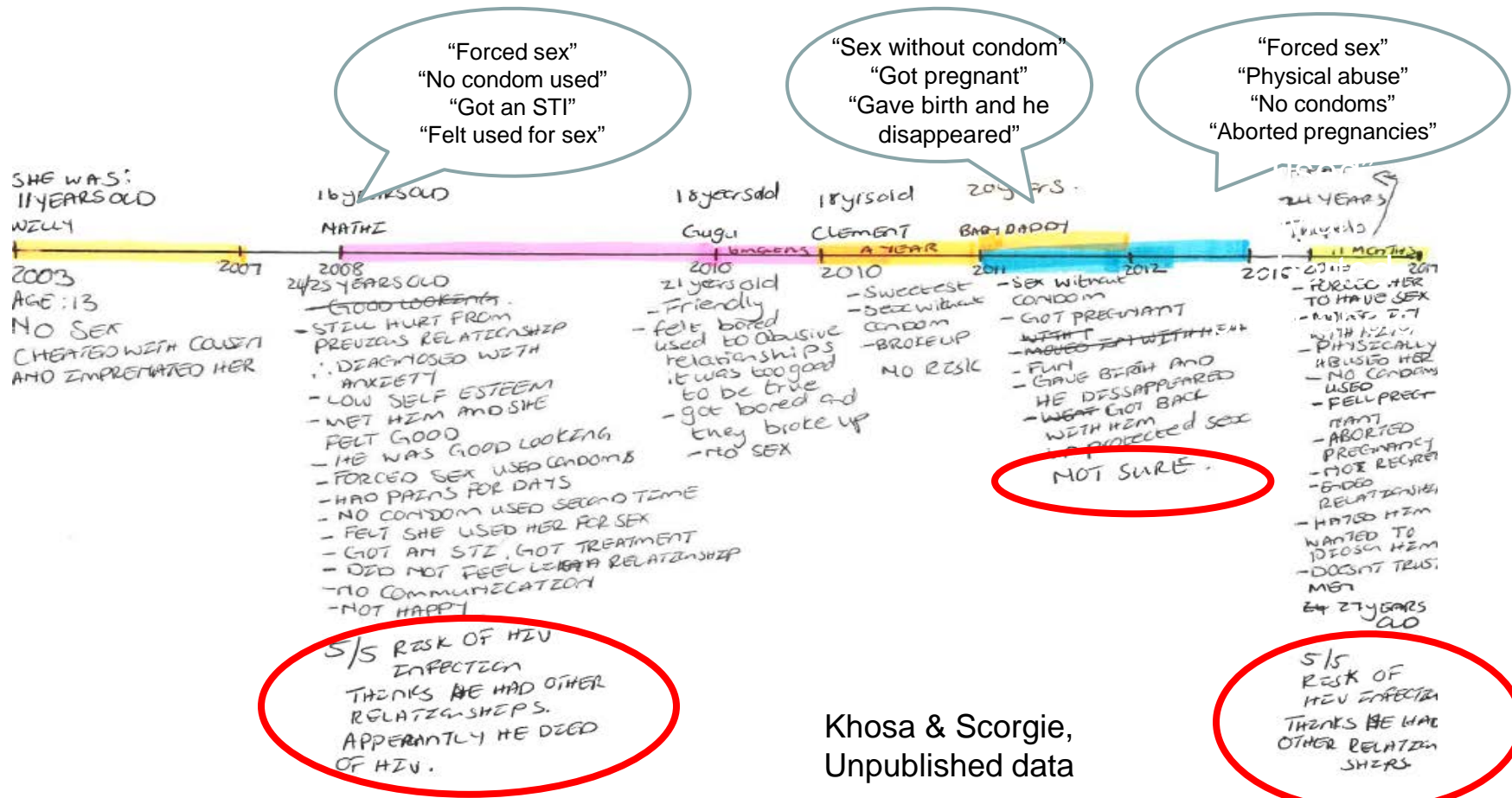
Risk perception: Narrative sexual histories

HPTN 082 STUDY IN DEPTH INTERVIEW TIMELINE TOOL

PTID 2378 23002-2 DATE 07 MAR 18



Insights about risk perception: Narrative sexual histories

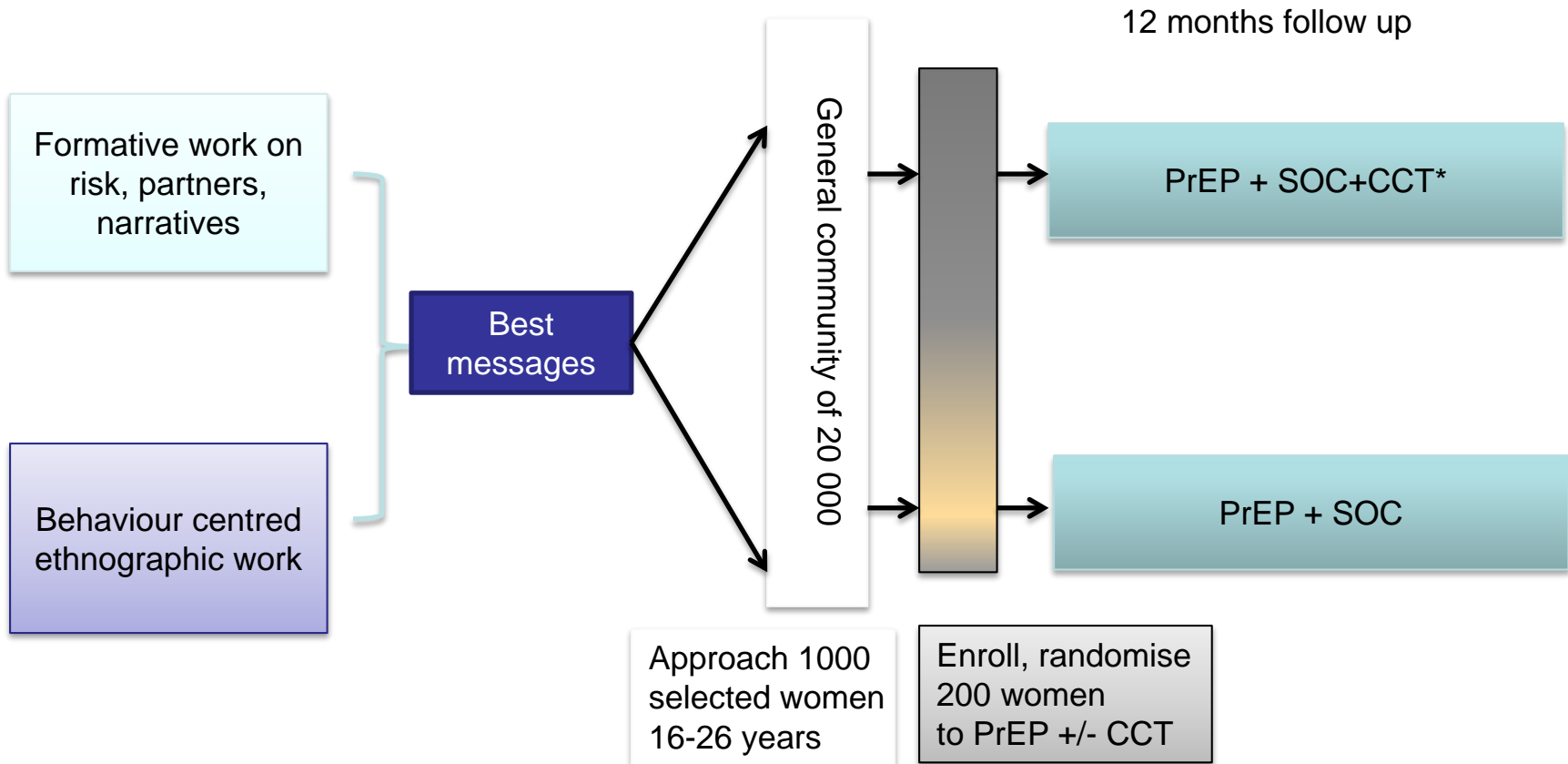


Khosa & Scorgie,
Unpublished data

HPTN 082: Preliminary Conclusions

- High uptake (95%) of PrEP
- Risk behavior is high; we are reaching women at risk
 - Median score on the VOICE risk score was 7
 - Half had symptoms of depression and IPV in past year
- Narrative histories elicit & inform risk perception
- High prevalence (39%) of curable STIs
 - Incidence is also high: 30% incidence of chlamydia
 - Need etiologic diagnoses & effective STI interventions
- Encouraging adherence data (TFV-DP levels at 3 months)
 - Will learn whether drug level feedback increases adherence & is worth the cost of drug levels in supporting adherence

3 Ps for Prevention : Partners, PrEP and Payment

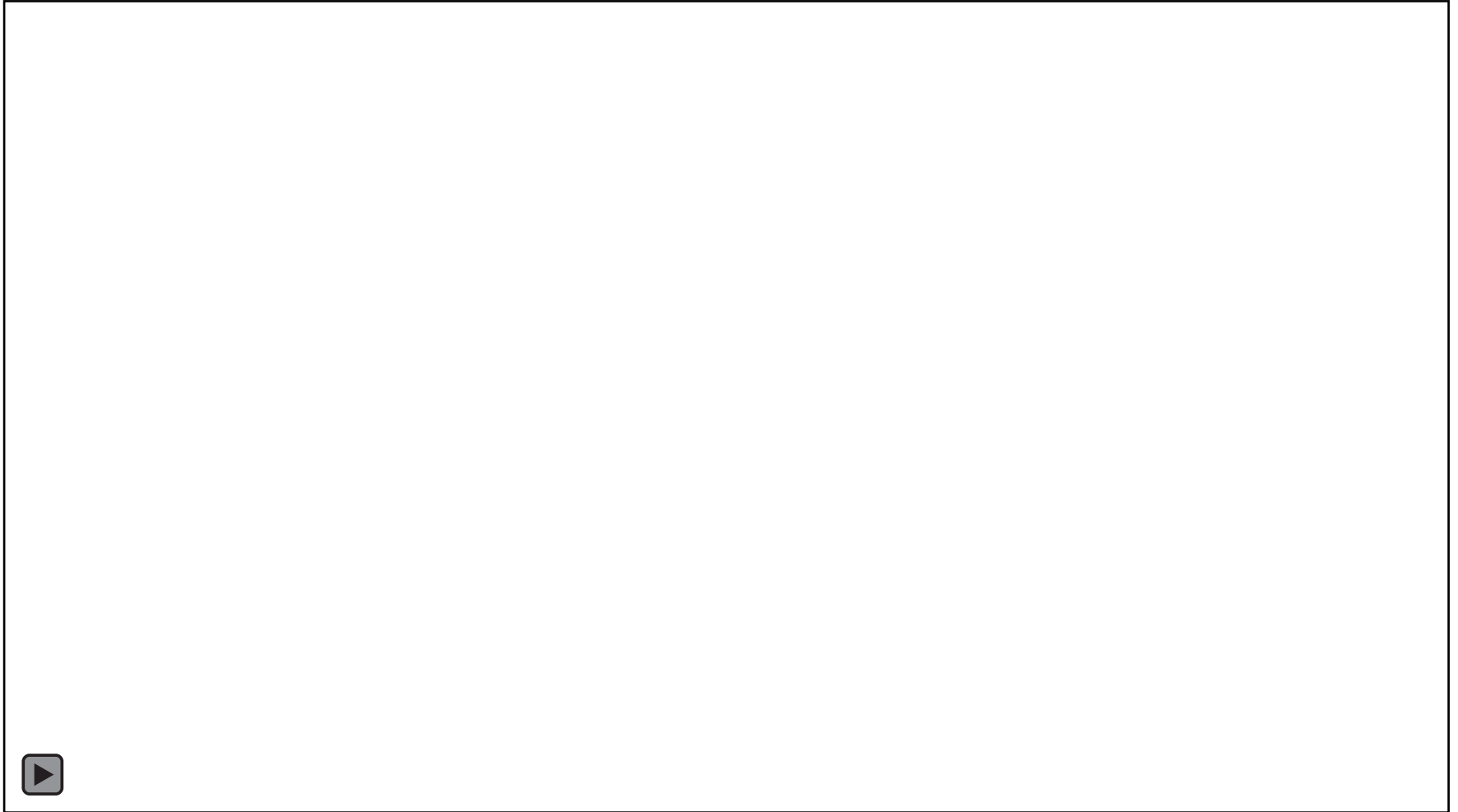


*Incentive contingent on high drug levels in first 3 months.

Demand creation based on what PrEP offers

- **What PrEP-takers say PrEP offers** (Gilmore et al. IAPAC 2014; Ware et al. JAIDS 2012; Ware et al. AIDS & Beh 2014; Grant & Koester Curr Opin HIV AIDS 2016)
 - Decreased anxiety
 - Increased communication, disclosure, trust
 - Increased self-efficacy
 - Increased sexual pleasure & intimacy
- Themes from formative work with women in Cape Town
 - PrEP associated with empowerment & more control over their sexual lives
 - Prefer messages about intimacy & empowerment (positive framing) rather than risk of HIV (negative framing)

PrEP demand creation for Cape Town township: 3P study (Bekker & Celum)



In collaboration with McCann Global Health



Positive PrEP messaging

**A PILL
A DAY
HELPS
KEEP
HIV
AWAY**

How does PrEP work?

PrEP is an antiretroviral pill, Truvada, which helps HIV negative people stay negative. When taken regularly, PrEP has been shown to reduce the chance of getting HIV by more than 90%. You should take PrEP every day to be sure you are protected against HIV. When the medicine is in your blood, it will stop HIV from taking hold and spreading in your body. If you want to protect yourself against STIs and have extra HIV protection, use condoms. If you want to prevent pregnancy, use contraception.

**PREP CAN STOP HIV.
IT'S UP TO EACH OF US TO DO OUR PART.**

**#HIVfreegeneration
SPREAD THE WORD. NOT THE VIRUS.**

**WE ARE
THE GENERATION
THAT WILL END
HIV**

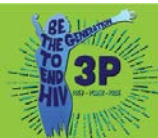
THIS IS MY MOMENT

**I AM MY OWN WOMAN.
I AM IN CONTROL.**

**I AM PrEPARED
FOR TODAY. FOR THE FUTURE.
FOR LIFE'S TWISTS AND TURNS.**

I AM PrEPPED

PREP IS A NEW WAY TO PROTECT YOURSELF FROM HIV.
TAKEN EVERY DAY, IT HELPS YOU STAY HIV FREE. #getPrEPED



Predictors of PrEP interest in 3P

- In multivariate model, characteristics associated with moderate or high interest in taking PrEP ascertained in household survey are:
 - Having a primary sexual partner ($p < 0.01$);
 - Shorter partnership duration ($p = 0.04$); and
 - Being a person who takes risks ($p = 0.04$)
- Most common sources of information about 3P were video, social media, word of mouth



3P cohort characteristics

N=200

- Young (median age 19)
- Most had a primary partner; 71% of whom reported suspecting he had other partners
- 30% had CT, GC or trichomonas at baseline
- 19% reported IPV in the past year
- All but one had detectable TFV-DP in first 3 months
- Unblinding in March 2019; will learn effect of incentives conditioned on adherence





POWER Project (Prevention Options for Women Evaluation Research)



Carnegie Mellon University



MASSACHUSETTS GENERAL HOSPITAL



PrEP Delivery in POWER



- Evaluate ‘real-world’ PrEP delivery & use
 - Mobile teen tester (Cape Town)
 - Youth clinic and primary health clinic (Johannesburg)
 - Family planning clinics (Kisumu)
- Access to PrEP, contraception & STI services
- Streamlined visits with minimal data collection
- 1084 enrolled as of Sept 2018
- PrEP uptake is high (87%) across all sites

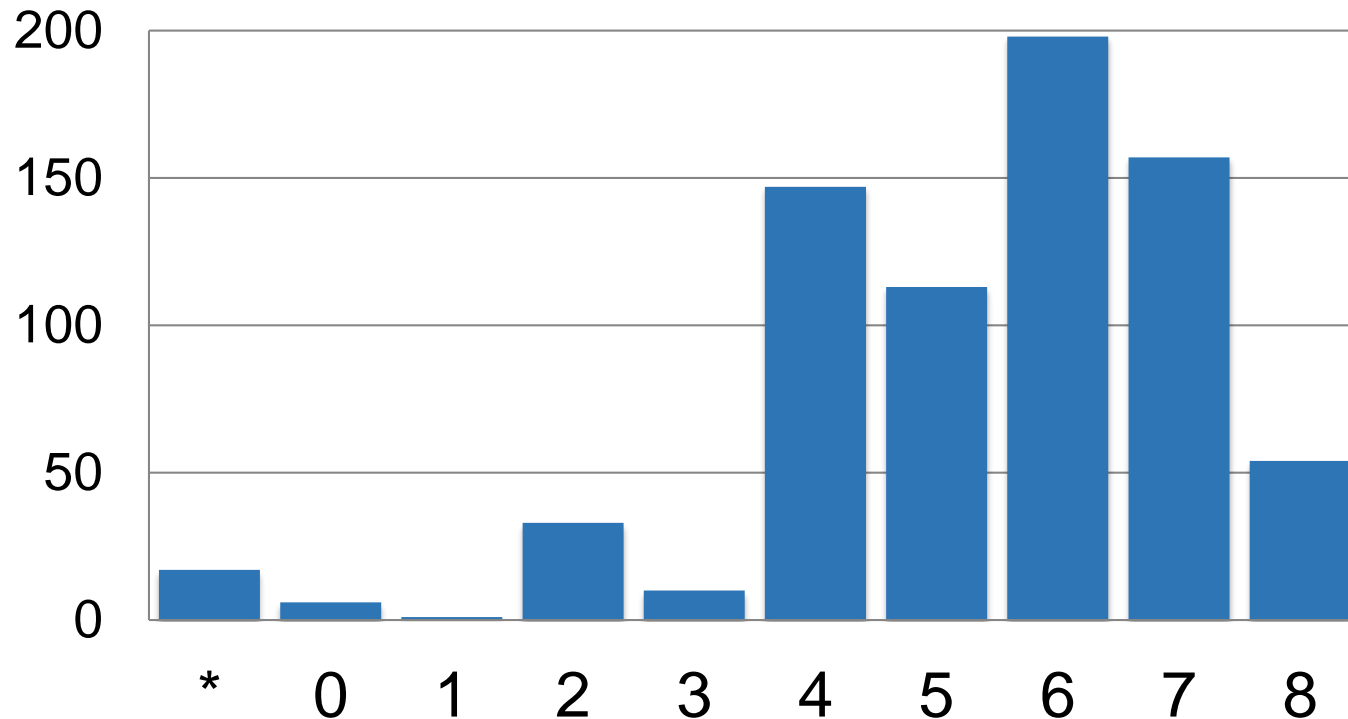


Tutu teen tester,
Cape Town



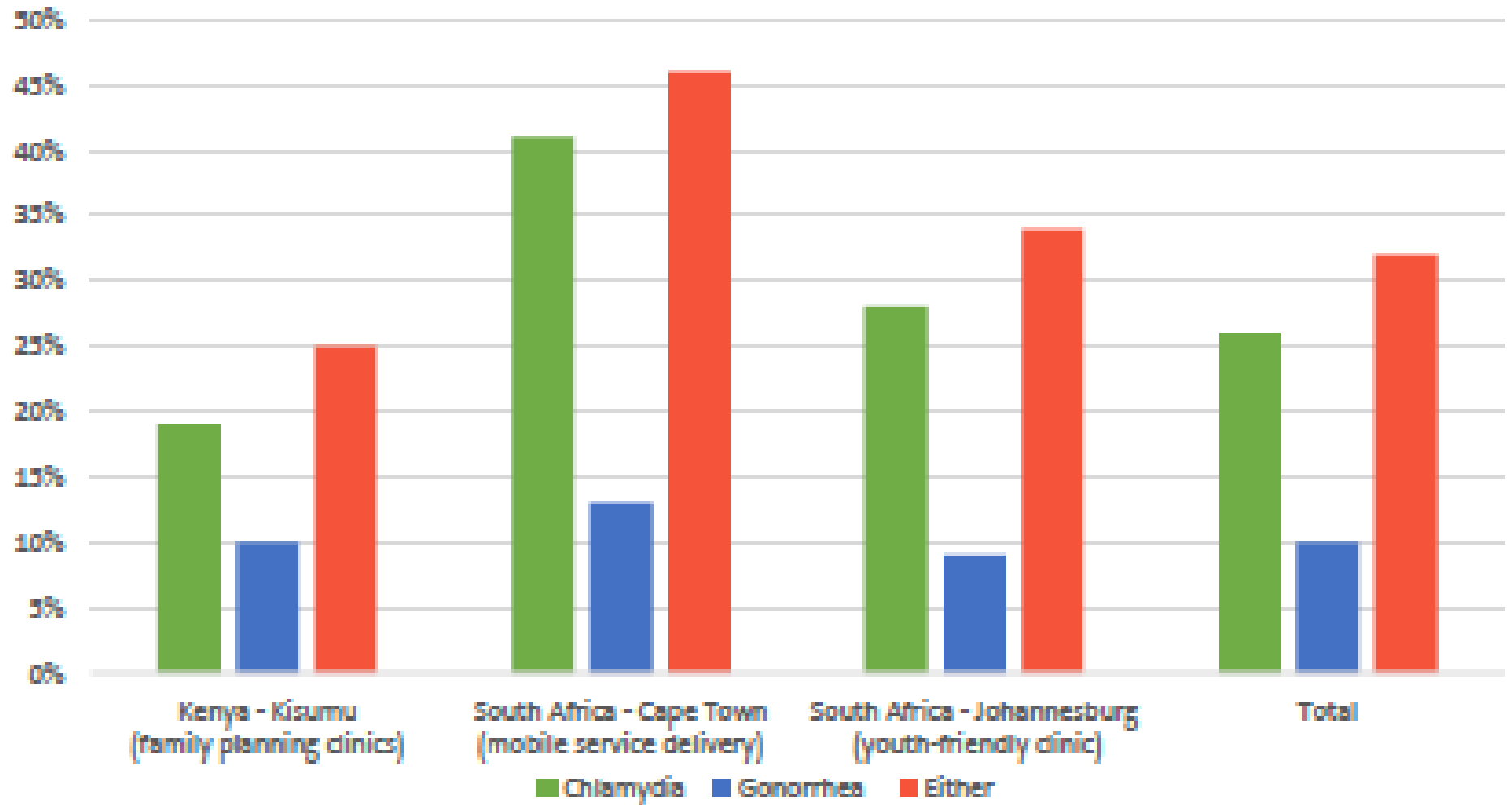
Youth peer educator,
Kisumu

Modified VOICE risk score among women enrolled in POWER



91% of women had a score ≥ 4 and 71% had a score ≥ 5
(Voice risk score ≥ 5 predicts an annual HIV incidence $\geq 6\%$)

High STI prevalence in POWER



Sub-study of expedited partner STI treatment in Kisumu starting Sept 2018

Lessons from HPTN 082, 3P & POWER

- PrEP uptake is very high, in context of limited demand creation & access
- Minority perceive their risk of HIV as high
 - Need better strategies to help young women reflect on their behaviors & partners
- Early drop-off in POWER
 - Curiosity, side effects, challenges with pill-taking & accessing services
- Strategies for adherence support
 - Drug level feedback, 2 way SMS, adherence clubs
 - SMART design to evaluate stepped, scalable strategies starting



Closing thoughts

- There is demand for PrEP & ability to take PrEP among African AGYW
- Messaging should be positive & engaging
- Majority demonstrate medium to high adherence
- Need to focus on understanding PrEP persistence
- Delivery needs to be simple & accessible
- Lessons from oral PrEP delivery are relevant to longer acting methods
 - Need products that work, people want & will use
 - Increasing options and formulations will likely increase uptake & coverage
 - Need tools to help them make informed choices

PrEP decision-making: Evaluation of client PrEP decision support tool

LET'S TALK ABOUT PREP

We want to make sure you to know about all your options, but today, we'll focus on PrEP, because it's new, extremely safe and highly effective. Plus, it's a private method that YOU control. Here are some things you might want to know about it. Click on each color below to learn more

What is PrEP?

Why take PrEP?

How well does PrEP prevent HIV?

How do I take PrEP?

What do I need to know about PrEP?

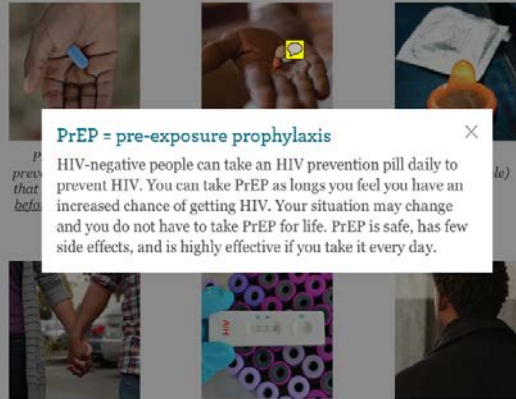
What's true and false about PrEP?

Learn more about family planning

WHAT ARE MY OPTIONS TO PREVENT HIV?

People who are HIV-negative can use HIV prevention methods to lower their chance of getting HIV. These may be best used in combination!

Tap any method below to get more information.



PrEP = pre-exposure prophylaxis

HIV-negative people can take an HIV prevention pill daily to prevent HIV. You can take PrEP as long as you feel you have an increased chance of getting HIV. Your situation may change and you do not have to take PrEP for life. PrEP is safe, has few side effects, and is highly effective if you take it every day.

Decreasing
my sex partners

Knowing if my
partner has HIV

If my partner
has HIV, he takes
HIV medicines

continue >

WHAT YOU NEED TO KNOW ABOUT PrEP

THE GOOD STUFF:

- Very safe.
- Keeps you healthy by preventing HIV.
- Private method that you control.
- Increases confidence and decreases fear of getting HIV.
- Safe with all types of family planning.
- Safe to use while pregnant and breastfeeding.

THE ANNOYING STUFF:

- A few people have mild side effects like headache or nausea that go away quickly (in a few weeks).
- PrEP does not protect against other sexually transmitted infections. Only condoms prevent against HIV and other infections.
- PrEP does not prevent pregnancy. PrEP is safe to take with all forms of family planning, though!

STUFF TO NOT WORRY ABOUT:

- You don't have to take PrEP for your whole life! You can use PrEP for as long as you need it. We suggest talking to your provider before stopping PrEP.

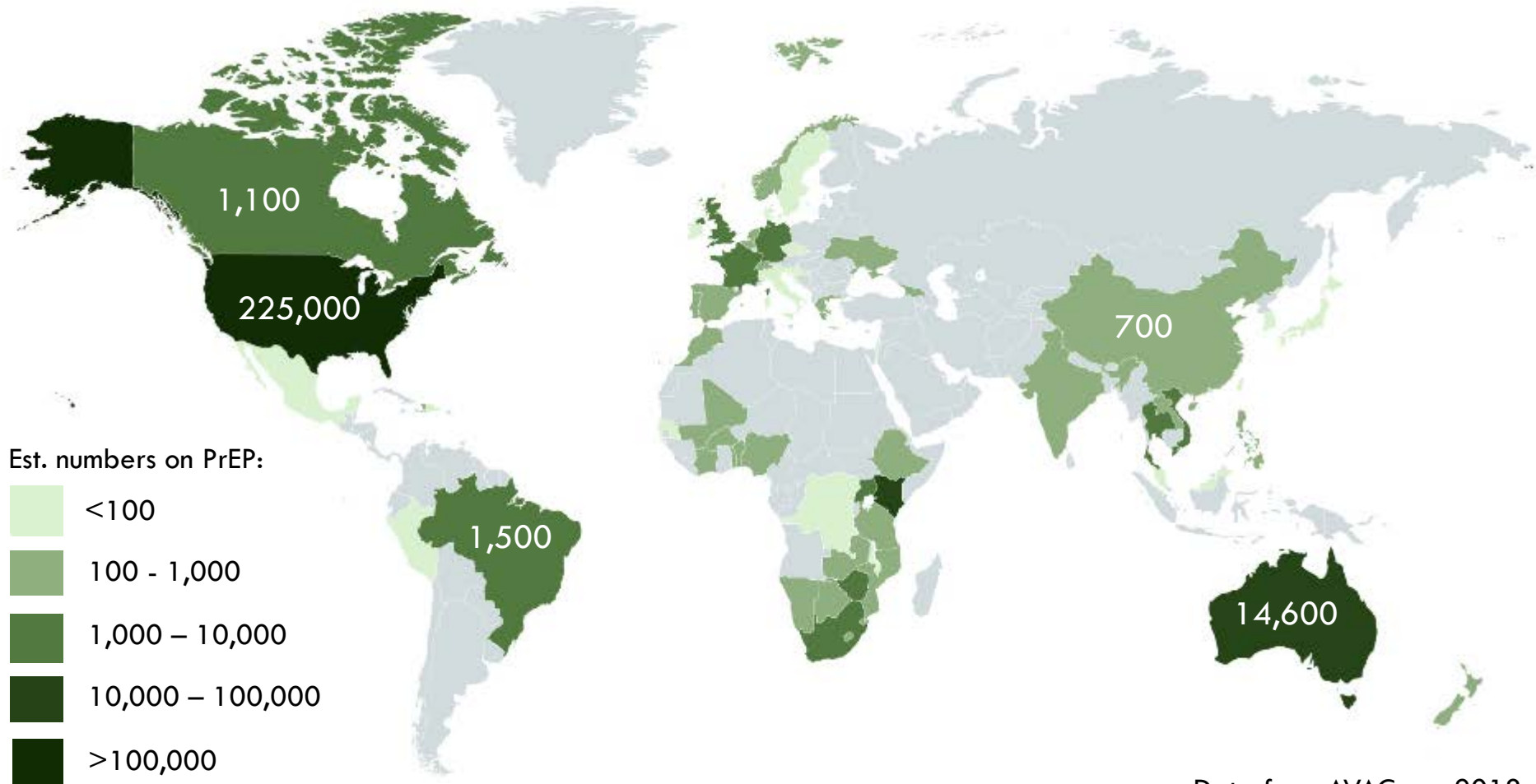
Shared decision-making approach to counseling
<https://bedsider.org> / <https://clinic.mybirthcontrol.org>



Celum & Delany-Moretlwe, R01MH114544

Oral PrEP Global Roll-out in 2018

- 40 countries with Truvada approved for PrEP
- We have come a long ways but we have a long way to go



PrEP delivery: Be bold, be innovative, go faster



HEGPP/DL

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While waiting for approval of the dapivirine ring ,
be prepared for success, learn from oral PrEP delivery, & go faster

Acknowledgments

- The young women who were 'prevention pioneers' with PrEP
- HPTN 082/HERS, 3P, & POWER teams
- Jared Baeten
- Linda-Gail Bekker
- Elizabeth Bukusi
- Nyaradzo Mgodzi
- Sinead Delany-Moretlwe
- Sybil Hosek
- Ariane van der Straten
- Funders: NIH (HPTN 082, 3P), BMGF (3P demand creation), USAID (POWER)

