

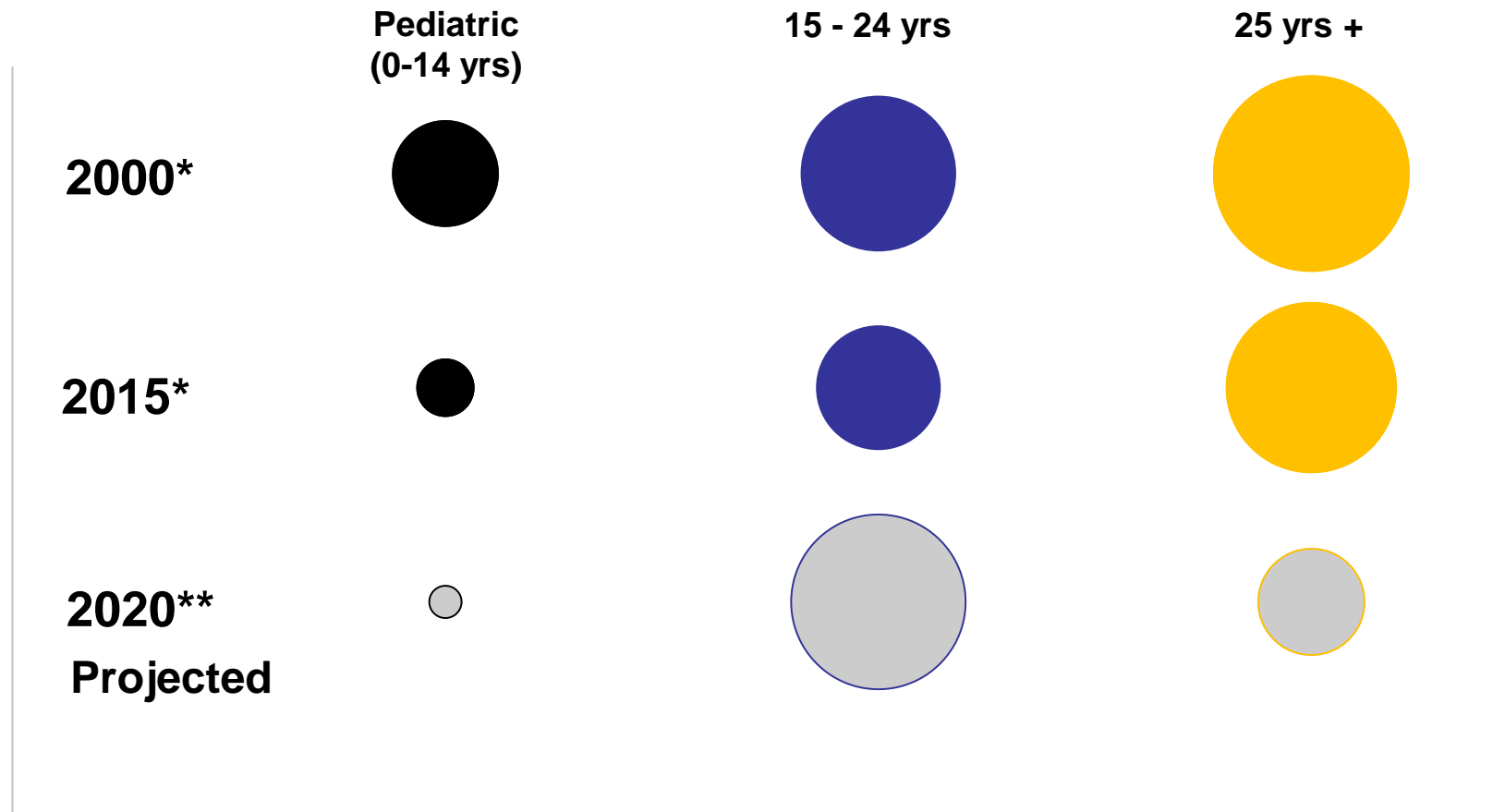
PrEP in young African women: Rationale & lessons from HPTN 082 (and other studies)

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Disproportionate Success in Epidemic Control by Age Group

New HIV Infections by Population and Year



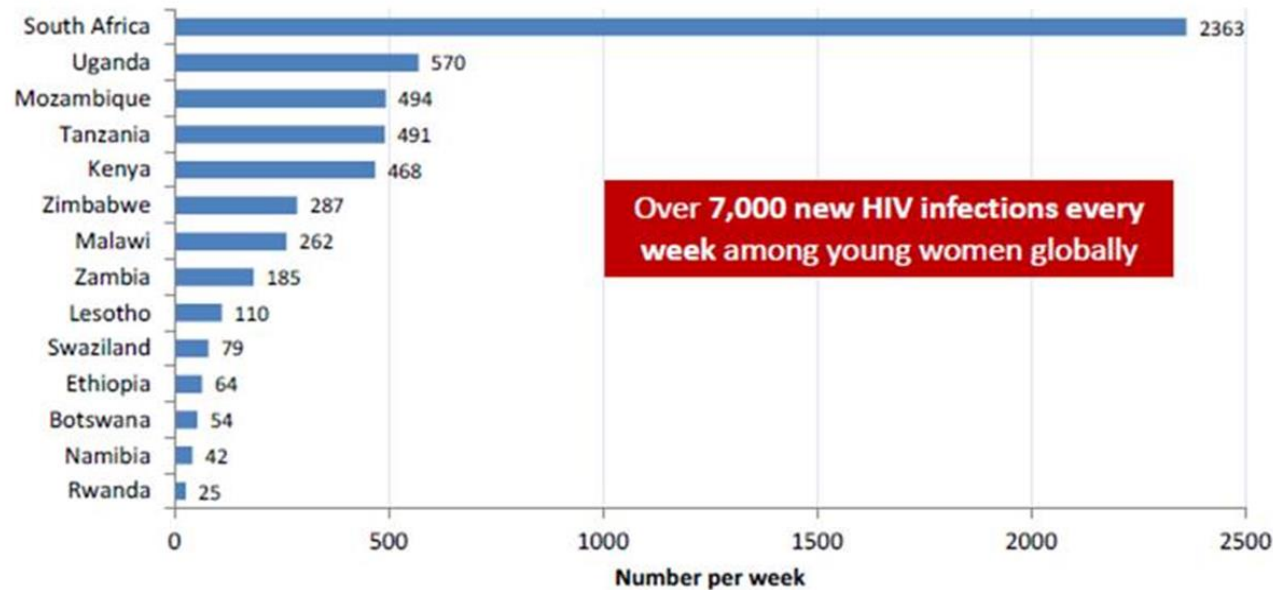
Young African Women at Risk

HIV Incidence among Young Women

More than 1/3 New HIV Infections Globally Occur among Young Women in Africa

Estimated number of new HIV infections *per week* among young women aged 15-24 years in East and Southern Africa, 2012

Data source: UNAIDS 2013



1 out of 3 new HIV infections are in youth in SSA

2 out of 3 new HIV infections are in sub-Saharan Africa

Get on the Fast-Track

The life-cycle approach to HIV

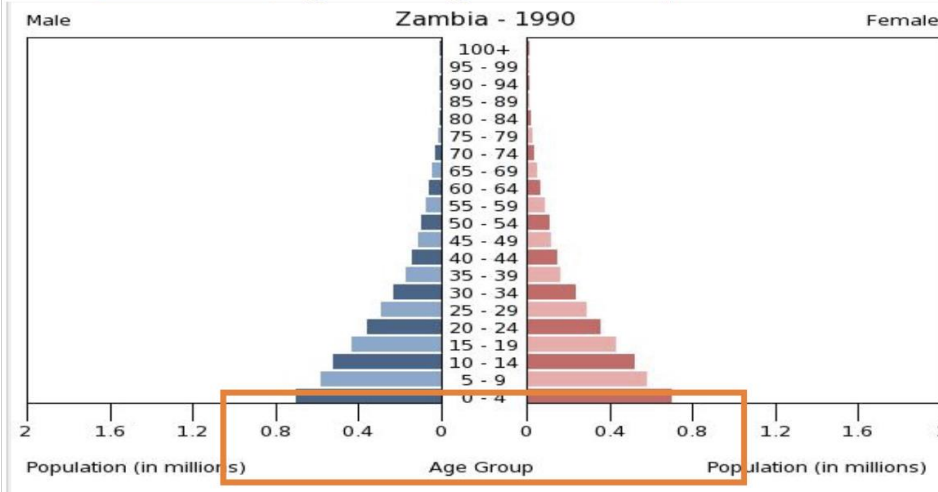
Finding solutions for everyone at every stage of life



UNAIDS 2016

Youth Bulge in Zambia

At the beginning of the Epidemic



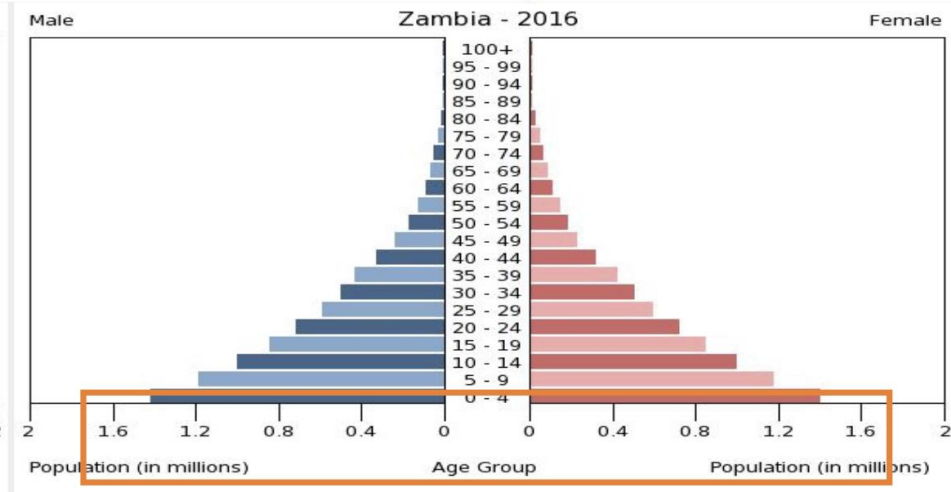
Young Men Population: 781,000

Young Men PLHIV: 38,000

Young Women Population: 772,000

Young Women PLHIV: 66,000

Today



Young Men Population: 1.6 million

Young Men PLHIV: 48,000

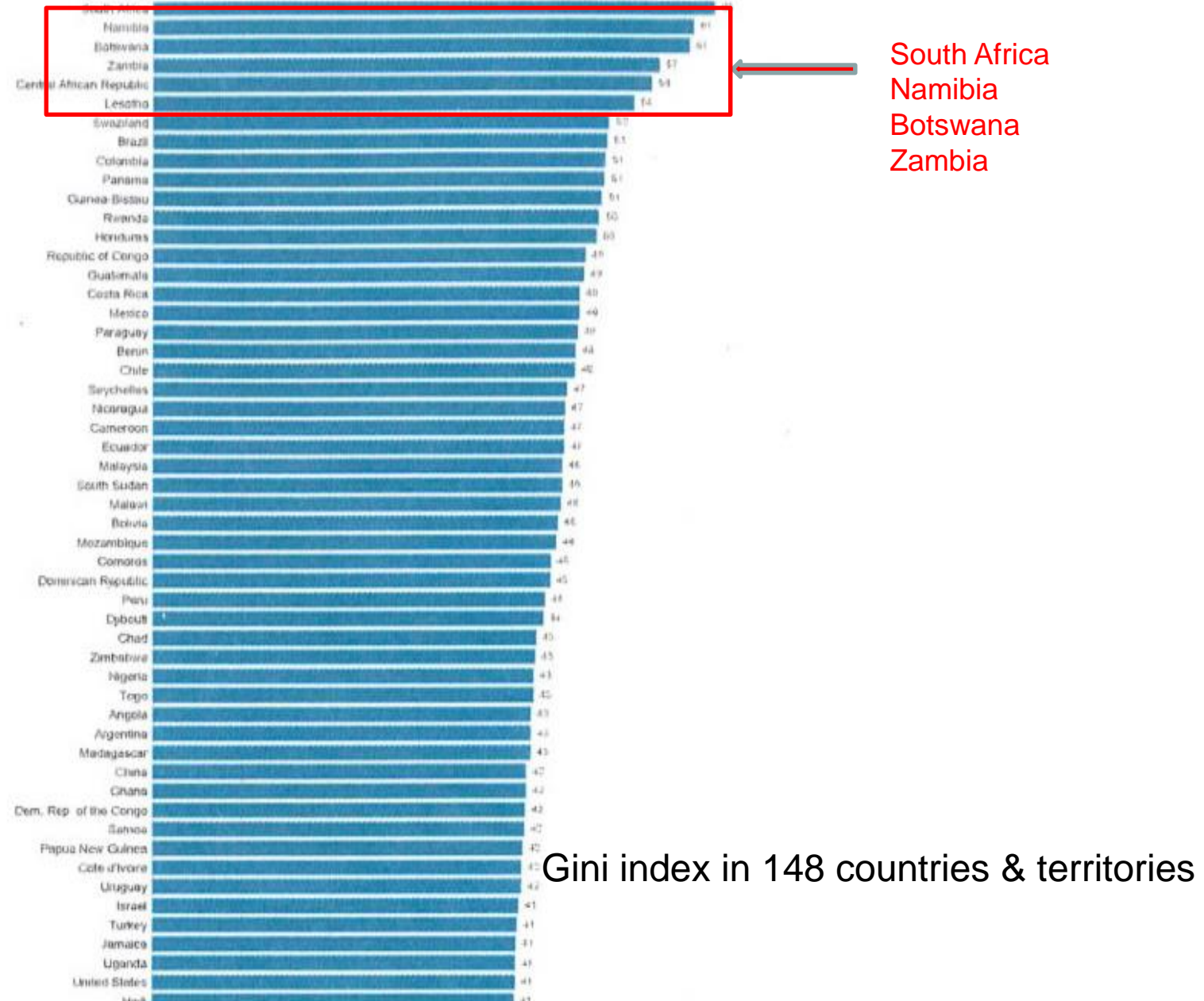
Young Women Population: 1.6 million

Young Women PLHIV: 77,000

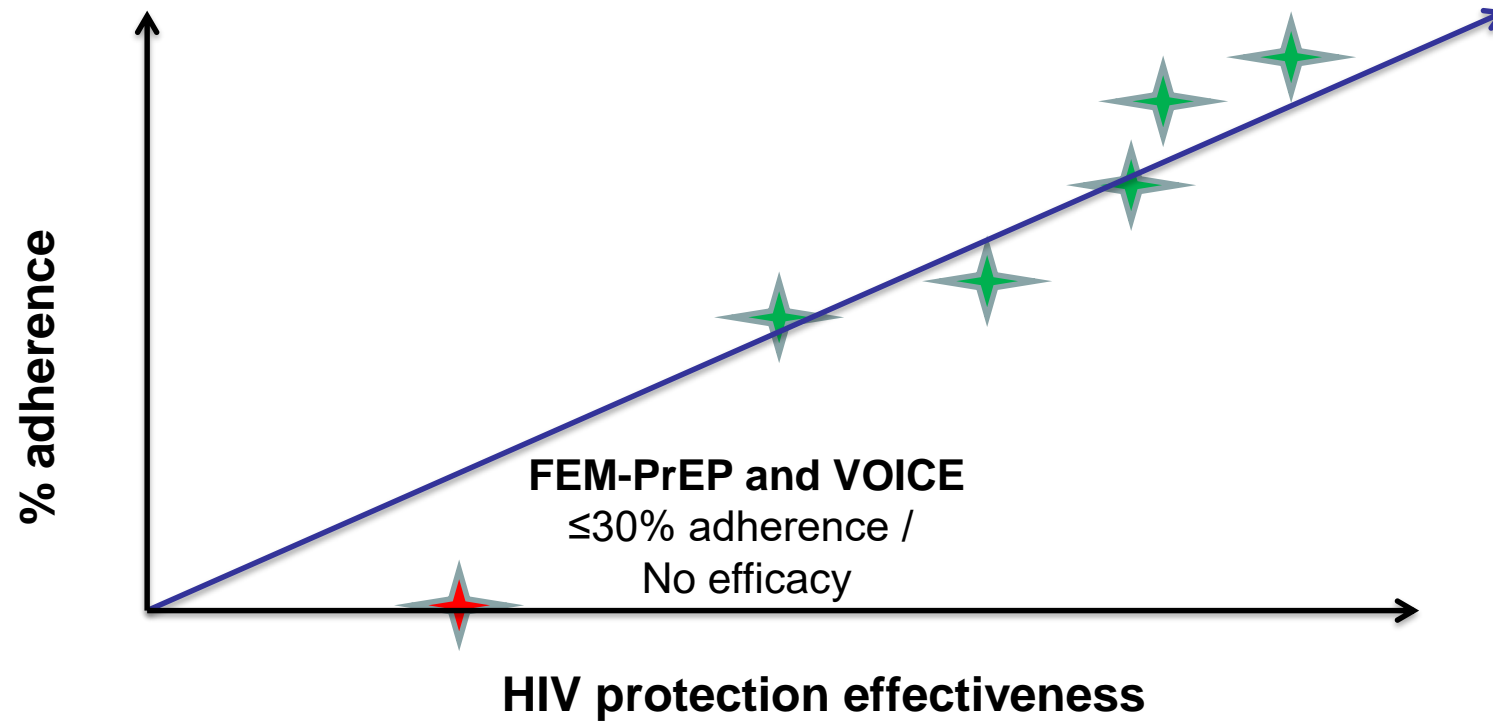
What factors increase young women's vulnerability to HIV ?

- **Poverty & transactional sex:**
 - Young girls have sex with older men to access resources.
- **Limited livelihood opportunities:**
 - Women's economic dependence on partner, labor migration, separation of families
- **Gender inequality & violence:**
 - Women have difficulty negotiating sex or condom use when economically dependent on partner &/or fear violence
- **Stigma & discrimination:**
 - Prevents those most vulnerable to HIV from accessing HIV testing & services
- **Risk-taking & self-efficacy in adolescence**
- **Limited availability of youth-friendly services**

World Bank Estimate of Income Inequalities



Trials of PrEP



Trials where only a minority were adherent did not demonstrate HIV protection.

Does PrEP work in young women?

- Yes, if taken; PrEP efficacy $\approx 70\%$ in all subgroups of women in Partners PrEP
 - Age <30 , high risk, high plasma viral load in partner
 - Adherence $\approx 80\%$ based on drug levels (Murnane, et al, *AIDS* 2013)
- No efficacy with low uptake in VOICE & FEM-PrEP
 - $<30\%$ with drug detected
 - Disconnect between low perceived risk and high STI incidence in FEM-PrEP (Van Damme *NEJM* 2012)
 - Low uptake due to low risk perception, low motivation for prevention, need for social support and/or challenges with daily pill-taking (remembering, product storage)?

Studies to understand PrEP uptake & adherence among young African women

- HPTN 067 ADAPT (Bekker)
- Plus Pills in Cape Town (Bekker)
- **HPTN 082/HERS: Uptake & adherence to PrEP**
(Celum & Delany-Moretlwe)
- 3P: Uptake of PrEP & role of conditional incentives on motivating adherence in Cape Town (Bekker & Celum)
- POWER: Prevention Options Research for Women
(Baeten & Celum)

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: Metrics of Success

- **Reaching those who need PrEP**
 - Measures of vulnerability at enrollment
- **PrEP uptake**
 - Among women with greater vulnerability & who think PrEP will benefit them
- **PrEP adherence**
 - Goal: >50% detectable tenofovir at weeks 4 & 8
 - Goal: Adherence levels during periods of higher risk
 - Testing effect of drug level feedback on subsequent adherence

HPTN 082: Design & PrEP uptake

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

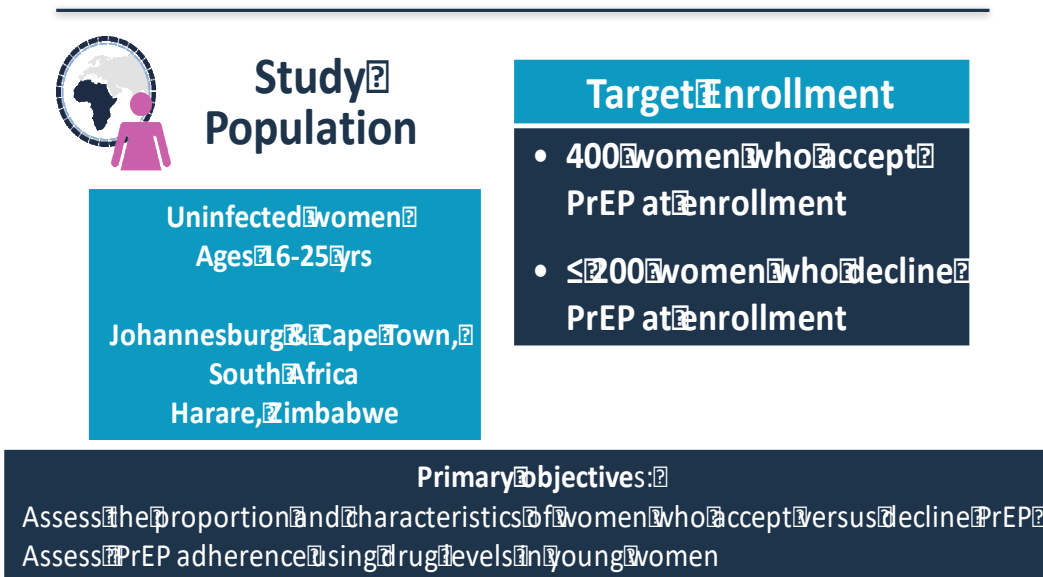
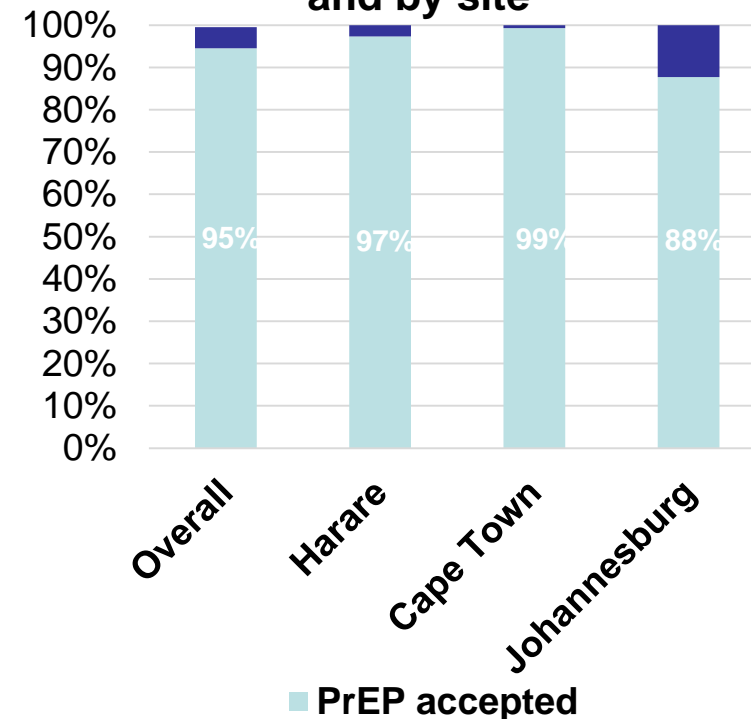


Figure 1: PrEP uptake overall and by site



Get
PrEPared:
What
African
women
need to
know!



HPTN Q82
HERS

Get PrEPed!

Educational video

- 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

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

*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*

Demographics of PrEP ‘acceptors’

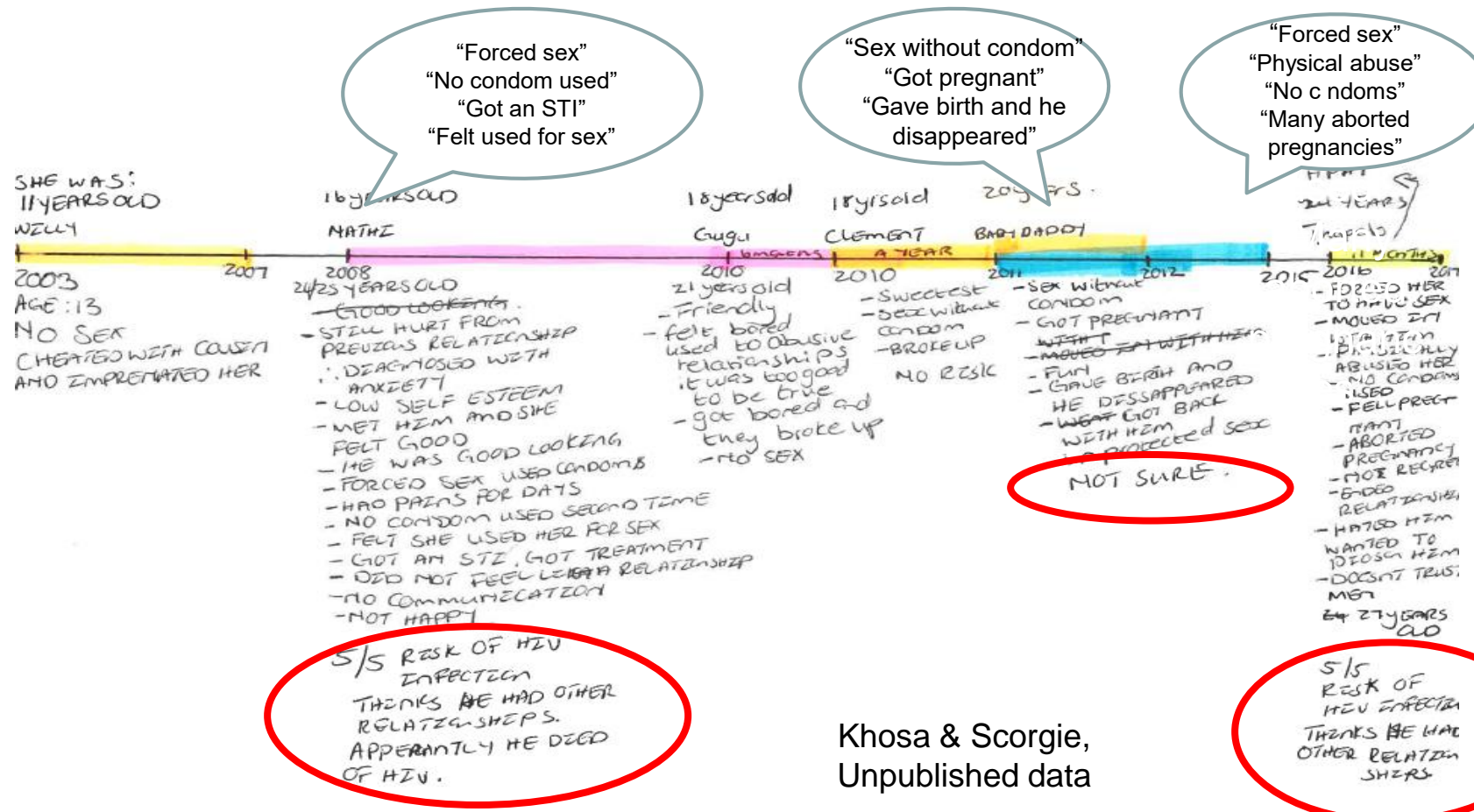
	N
PrEP Accepted at Baseline	412
Age	
Median (IQR)	21 (19,22)
Education	
Completed secondary school or higher*	404 (98%)
Ever dropped out of school*	122 (30%)
Age difference ≥ 5 years with primary partner	139 (44%)
HIV status of main partner	
HIV negative	204 (59%)
HIV positive	3 (0.9%)
He doesn't know 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)

Insights from qualitative research: Narrative sexual histories



Khosa & Scorgie,
Unpublished data

HPTN 082: Preliminary Conclusions

- High uptake (95%) of PrEP
 - Despite reported low perceived risk of HIV
- 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
- High prevalence (39%) of curable STIs (& incidence)
 - Need etiologic diagnoses (rather than) syndromic management & effective interventions for young African women.
- High demand for PrEP among women at risk for HIV
 - Adherence data will indicate proportion with effective use
 - Randomization will assess effect of drug level feedback at wks 8 and 13

HPTN 082: Metrics of Success

✓ **Reaching those who need PrEP**

- Measures of vulnerability at enrollment

✓ **PrEP uptake**

- Among women with greater vulnerability & who think PrEP will benefit them

□ **PrEP adherence**

- Goal: >50% detectable tenofovir at weeks 4 & 8
- Goal: Adherence levels during periods of higher risk
- Testing effect of drug level feedback on subsequent adherence

What about adherence in HPTN 082?

Adherence Support

1. Counselling
2. Weekly SMS
3. Adherence clubs

Standard

4. Drug Level Feedback at 8 & 13 wks

Enhanced

Counseling Categories



4 or more doses per week (>500 fmol/punch at wk 4 and >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.



~1-3 doses per week (between detectable – 499 fmol/punch at wk 4 and 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 (confirm BLQ level)

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?

Discrete, non-medical product storage

Pill cases & carrying bags



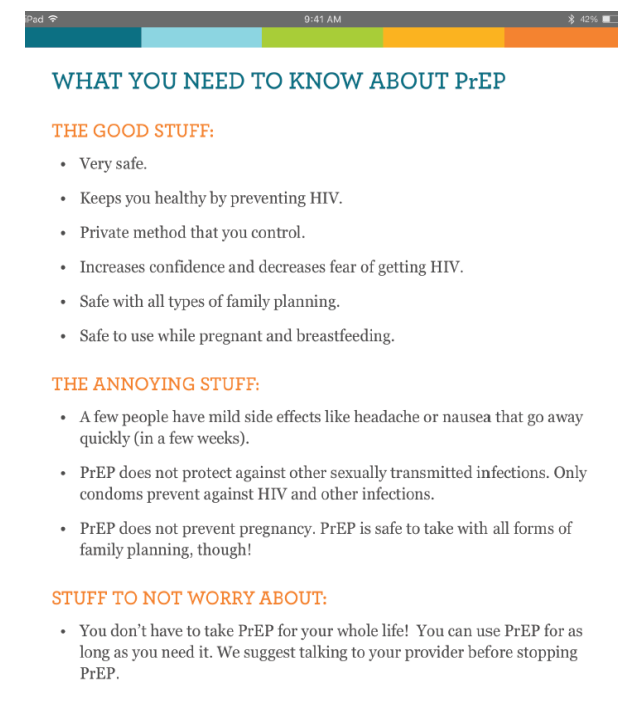
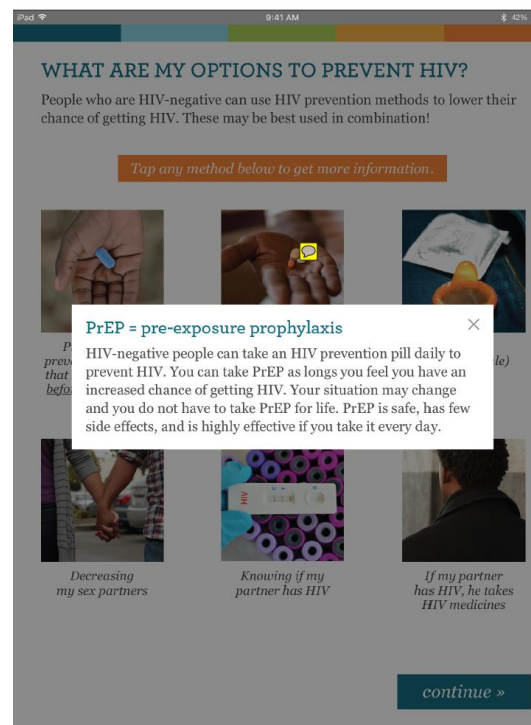
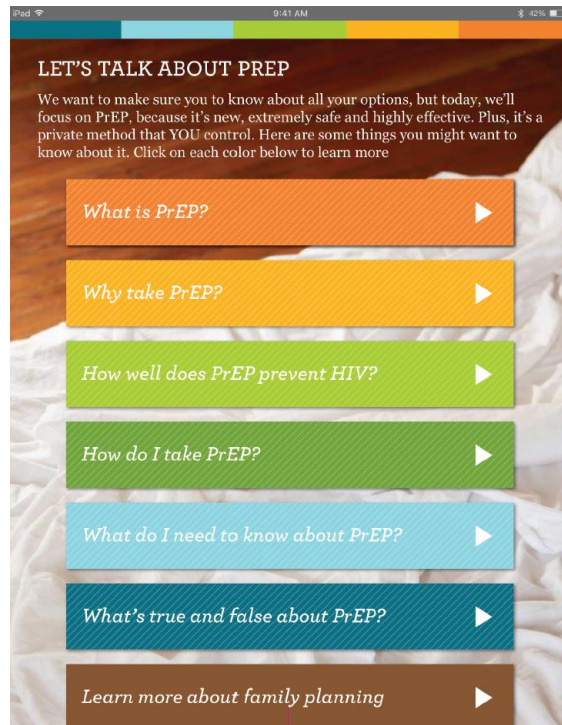
HPTN 082 closing thoughts

- Young African women are a priority population for PrEP
- Young women face challenges but also have “agency”
- High uptake (95%) of PrEP in HPTN 082/HERS
 - Key role of peers & social influencers
 - Risk behavior, depression, and IPV are high in HPTN 082
 - Innovative qualitative methods can help us understand their lived experiences & perspectives about ‘risk’
 - Women at risk are accepting PrEP
- High prevalence & incidence of curable STIs
- Oral PrEP isn’t for everyone
 - Important to learn about messaging & delivery of a proven method
 - Increasing options will increase uptake, adherence & persistence

Next Steps:

Evaluation of PrEP decision support tool

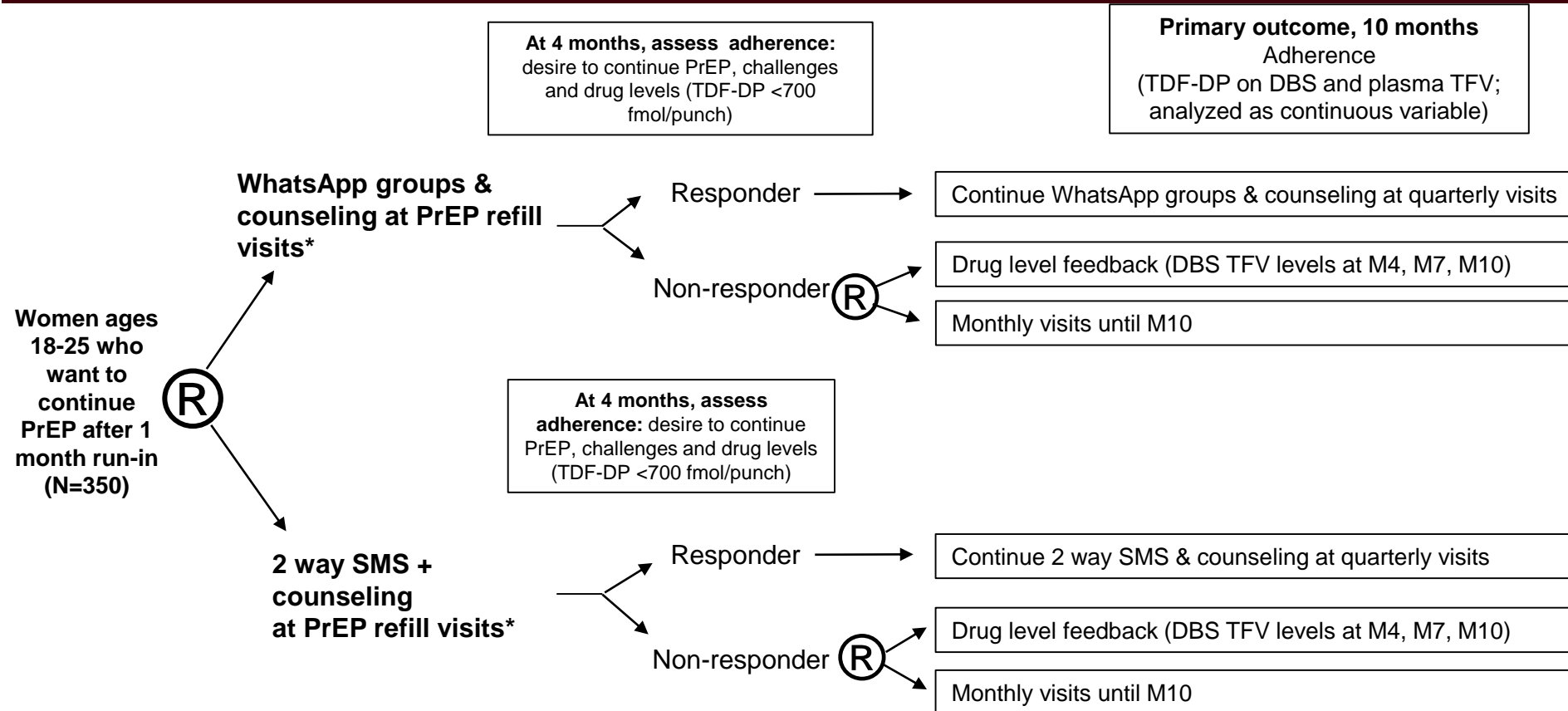
Celum & Delany-Moretlwe, R01MH114544



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

Next steps: SMART design of scalable PrEP adherence strategies

Celum & Delany-Moretlwe, R01MH114544



ACKNOWLEDGEMENTS

- The youth CABs for their ideas and feedback
- The young women who are participating in HPTN082/HERS
- The HERS team with special thanks to the site teams at Ema, Spilhaus and Ward 21

ACKNOWLEDGEMENTS

- Sinead Delany-Moretlwe
- Bonnie Dye
- Jared Baeten
- Linda-Gail Bekker
- Sybil Hosek
- HPTN 067/ADAPT, Plus Pills, HPTN 082/HERS, 3P, & POWER study teams
- Funders: NIH (HPTN 082, ADAPT, 3P), BMGF (3P demand creation & enumeration, USAID (POWER)

ACKNOWLEDGEMENTS

The HIV Prevention Trials Network is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068619, UM1AI068613, UM1AI1068617), with co-funding from the National Institute of Mental Health, and the National Institute on Drug Abuse, all components of the U.S. National Institutes of Health.

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