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FEM-PrEP: Risk Perception and Perception of Partnerships

Amy Corneli, PhD, MPH
Social and Behavioral Health Sciences
FHI 360

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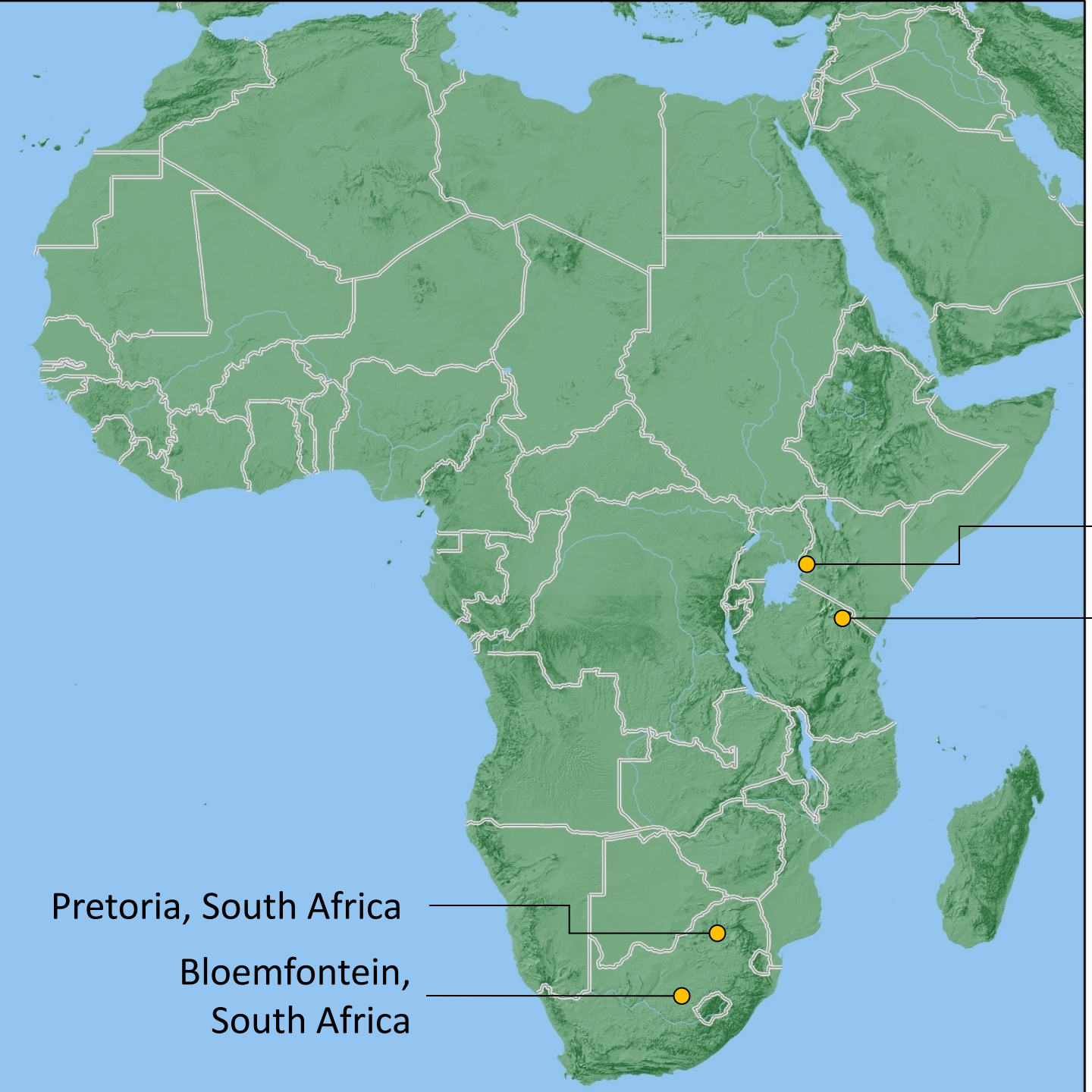
FEM-PrEP Clinical Trial Sites



FEM-PrEP

Description of study populations*

Demographics	Bondo (N=720)	Bloemfontein (N=530)	Pretoria (N=749)
Age in years, n (%)			
18-24	279 (39)	397 (75)	517 (69)
25-29	200 (28)	109 (21)	155 (21)
30+	241 (33)	24 (5)	77 (10)
Education			
Finished primary school, n (%)	202 (28)	507 (96)	665 (89)
Education in years	8.5 (8) 0-16	11.7 (12) 2-18	11.4 (12) 0-19
Married, n (%)	529 (74)	32 (6)	54 (7)
Occupation, n (%)			
None	152 (21)	216 (41)	501 (67)
Student	16 (2)	238 (45)	164 (22)
Wage job	444 (62)	70 (13)	84 (11)
Others	108 (15)	6 (1)	0 (0)

*excluding Arusha

Introduction: Risk Perception

- Perception of risk for a particular illness is a core construct in many behavior change theories
  - Health Belief Model
  - Protection Motivation Theory
- The main principle is that individuals may be motivated to take action to reduce their risk behaviors if they perceive some chance of acquiring the particular illness
- On the other hand, individuals may be unlikely to modify their risk behaviors if they do not believe they are at risk

Introduction: Risk Perception in FEM-PrEP

- We explored risk perceptions in multiple ways in FEM-PrEP
  - During trial:
    - HIV-negative trial participants from all sites
    - Women who seroconverted in two sites
  - Post trial:
    - Former FEM-PrEP participants in two sites
    - HIV-negative women who did not participate in FEM-PrEP but who resided in two of the FEM-PrEP communities

Methods: Data Collection, Quantitative

- We conducted quantitative, face-to-face interviews at enrollment and at quarterly follow-up visits
- Participants were asked to categorize their belief in the likelihood of becoming infected with HIV in the next 4 weeks
- Response options were:
  - no chance — no possibility of becoming infected with HIV
  - a small chance — could happen but not likely
  - a moderate chance — some possibility of becoming infected with HIV
  - a high chance — likely to become infected with HIV
- We also collected blood specimens at each study visit for analysis of drug concentrations after trial closure

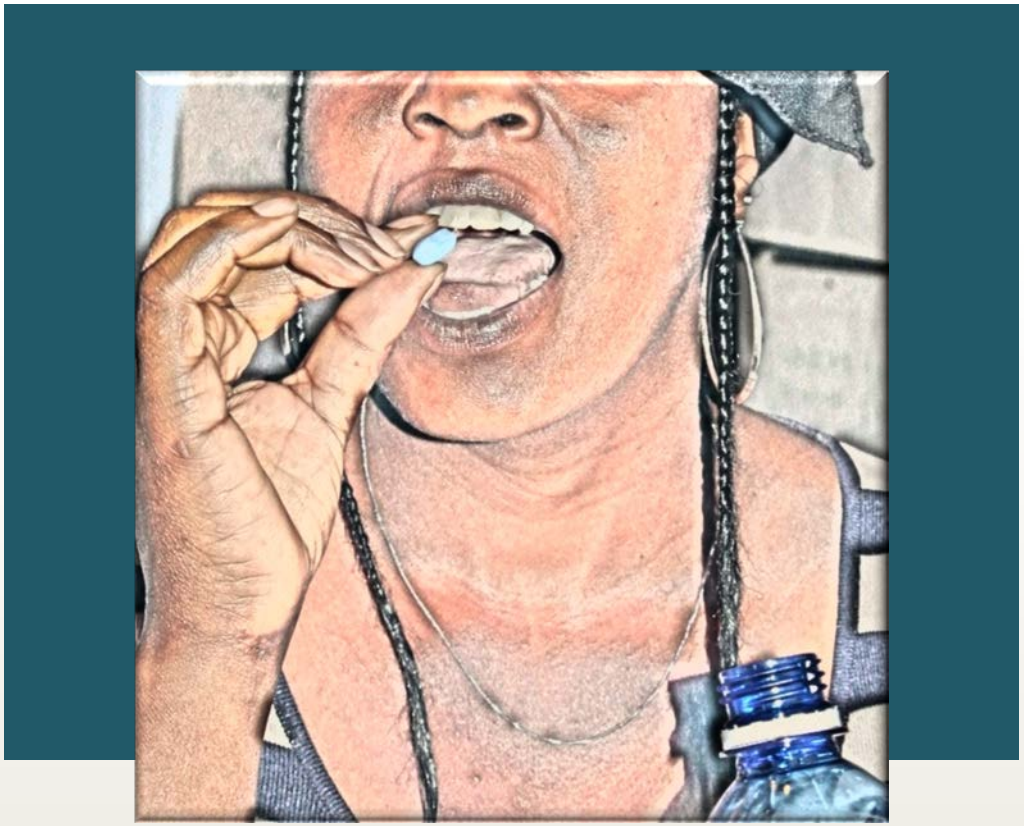
Methods: Data Collection, Qualitative

- We conducted qualitative, semi-structured interviews (SSIs) with women who seroconverted at weeks 1, 4, and 8 after HIV diagnosis
  - 56 women (Pretoria, n=32; Bondo, n=24) participated in at least one SSI
  - An inclusion rate of 94% for Pretoria and 89% for Bondo
- We asked women to retrospectively describe whether or not they worried about getting HIV prior to diagnosis

Results

- We identified four main findings/implications from the trial data
  - Perceived risk was associated with adherence to investigational PrEP
  - Many women who seroconverted underestimated their risk of HIV
  - Many women rationalized their risk and believed they were not vulnerable to acquiring HIV
  - Women need access to novel HIV prevention options now

Risk Perception in FEM-PrEP – Finding #1



Perceived risk was associated with adherence to investigational PrEP

(Corneli et al., JAIDS, in press)

Analysis and Results

- We used logistic regression with robust variance estimation to assess the association between:
  - risk perceptions (none versus some – small, moderate, high) reported at enrollment and at weeks 12, 24, and 36, and
  - good adherence (having both a TFV concentration in plasma exceeding 10 ng/mL and an intracellular TFV-DP concentration in ULPCs exceeding 100,000 fmol/mL) based on drug concentrations in specimens collected 4 weeks later, at weeks 4, 16, 28, and 40
- Assessed among a sub-cohort of 150 randomly selected participants assigned FTC/TDF (50 each from Bondo, Pretoria, and Bloemfontein)
- A significant association was found: OR: 2.0; 95% CI: 1.1 to 3.5; p=0.016

Risk Perception in FEM-PrEP – Finding #2

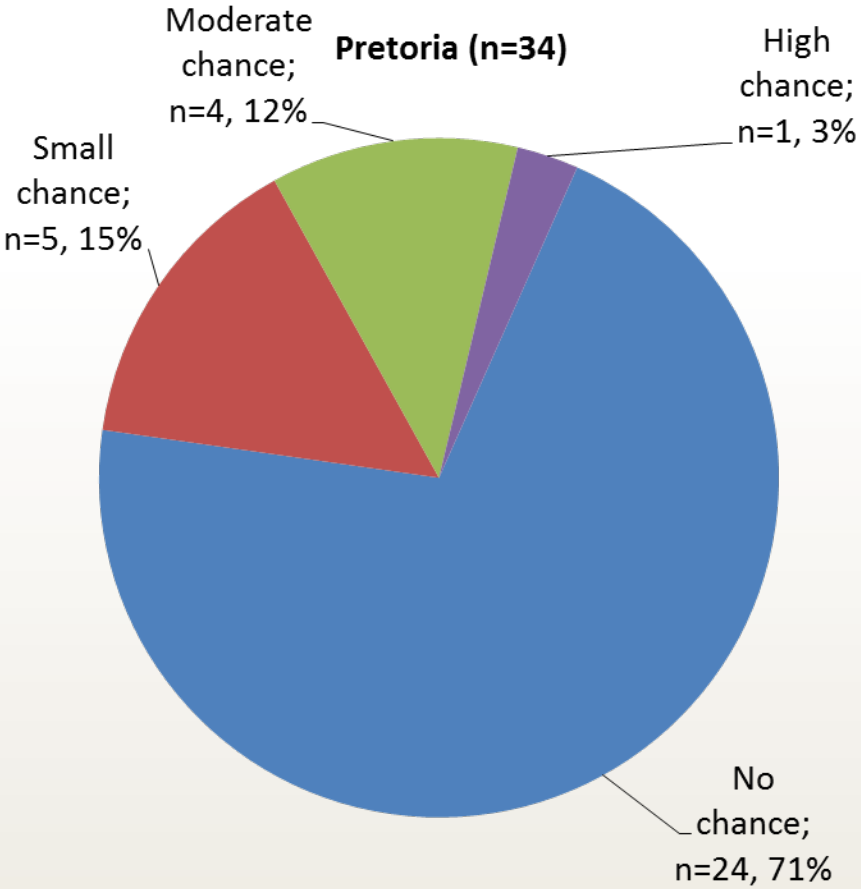
Many women who seroconverted underestimated their risk of HIV

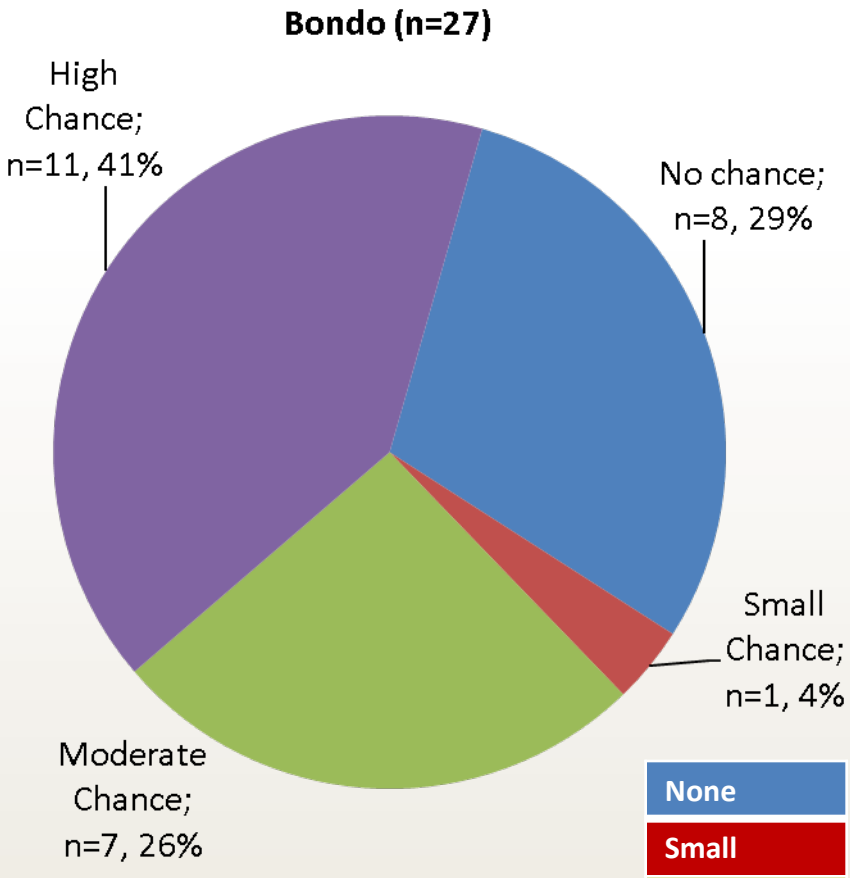
(Corneli et al., JIAS, in press)

Sample, Analysis, and Results

- Among women who seroconverted from Pretoria (n=34) and Bondo (n=27), we calculated the frequencies of their responses to the quantitative risk perception questions asked at the visit conducted closest to, but before, HIV acquisition
- 52% reported that they had *no chance* of acquiring HIV in the next four weeks
- Perception of HIV risk varied significantly between the two sites ($p<0.0001$)

Site Specific Results





None
Small
Moderate
High

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Risk Perception in FEM-PrEP – Finding #3

Many women rationalized their risk and believed they were not vulnerable to acquiring HIV

(Corneli et al., JIAS, in press)

Results

- From the qualitative SSI data conducted among women who seroconverted, we learned that women rationalized their risk in certain ways and this led them to worry or not worry about becoming HIV infected – labeled as "risk rationalization processes"
- Two rationalization processes were described among women **who did not worry** about becoming HIV infected
  - Included most of the participants from Pretoria

Protective Behaviors

- In a rationalization process we labeled “protective behavior”:
  - Participants engaged in well-known HIV risk reduction practices
  - These actions made them feel that they were not vulnerable to HIV
- The two commonly mentioned protective behaviors were:
  - Using condoms, albeit inconsistently
  - Having only one sexual partner

Protective Behaviors (2)

- A participant from Pretoria said:

  "I never thought I would get infected with HIV. My own behavior did not give it a chance. I only had one partner, and I never slept around."

- Another participant from Pretoria said:

  "I never got worried...I knew myself."

  - She elaborated on her reason for not previously worrying about HIV when describing her response to learning she had HIV:

"I never thought I could be infected by this…[because] of the way I behaved myself...My condition was good. I behaved myself very well. I have one partner."

Protective Reasoning (1)

- In another rationalization process that we call “protective reasoning”:
  - Participants actively reflected upon their HIV risk
  - But rationalized, based on certain events or beliefs, that their vulnerability towards acquiring HIV was low
  - Believed that risk reduction behaviors, such as using condoms, were unnecessary

Protective Reasoning (2)

- Perceptions about HIV testing influenced SSI participants' protective reasoning
  - Many described that having multiple HIV-negative test results before or during the trial led them to not worry about acquiring HIV. A participant from Bondo said:

"I have never thought of that. Depending on the days that I have always come for my visits, I always tested negative. Even when I came I never thought I would test HIV positive."

Protective Reasoning (3)

- Some participants described that knowing their partner's previous HIV-negative status made them not worry
  - A participant from Pretoria said:

"I don't know what to say, but I did not expect that at this moment I would be HIV-positive…The person I was involved with got tested and the results came out negative. I was also getting tested and I was negative so I did not expect it."

- Assuming to know a partner's HIV status based on one's own HIV status was also mentioned by some participants in Pretoria:

"I never thought that my boyfriend could be HIV infected. I knew that I was not infected with HIV, so I never thought that he might be sick."

Protective Reasoning (4)

- Trust was another concept that informed several participants' protective reasoning, primarily in Pretoria
  - Some participants described trusting their partners because they assumed they were in monogamous relationships
    - A participant from Pretoria, who was in multiple, non-concurrent relationships, said:

"I trusted my boyfriends…
because I did not see them cheating on me."

  - A few believed their partners would never infect them
    - A participant from Bondo said:

"I also have one sexual partner, whom I trusted and knew cannot make me get there [interviewer note: be HIV positive]. And, I also would not like to put him there."

Protective Reasoning (5)

- For some participants, trust was also formed based on assumptions they had about their partners' sexual behaviors given their own sexual behaviors
  - A participant from Pretoria explained:

"I knew I was behaving well

and I thought he was behaving well too."

Recommendation (1)

- Based on these findings, we recommend that:
  - Risk rationalizations be included in the HIV prevention discourse, as they are likely important precursors for **any risk reduction measures**
  - Risk reduction counseling must help women to align their feelings about their risk with their actual level of risk
- This focus is particularly relevant among populations similar to Pretoria's:
  - Low perceptions of HIV risk, low perceived vulnerability towards acquiring HIV
  - High overall HIV incidence in FEM-PrEP (6.0/100 person years, placebo arm)

Recommendation (2)

- An intricate balance is needed to simultaneously:
  - Encourage women to more appropriately evaluate the potential likelihood of HIV infection
  - Ensure couple harmony
  - Be sensitive to adverse consequences, such as denial and defensive coping

Risk Perception in FEM-PrEP – Finding #4

Women need access to novel HIV prevention options now

Results

- From the qualitative SSI data conducted among women who seroconverted, one rationalization process — "recognition of vulnerability" — was identified among women **who DID worry** about becoming HIV infected
  - Most participants were from Bondo
- These women described specific reasons why they worried about getting HIV
  - Narratives suggested that they were unable to engage in risk-reduction behaviors to reduce their perceived vulnerability

Recognition of Vulnerability

- Participants described two main reasons for their HIV worry:
  - knowing that their partners have other sexual partners or being uncertain of their partners' monogamy
  - not knowing their partners' HIV status
- A participant from Bondo said:

"That [HIV] is something I knew was there and I could get it at any time…because I know my status but I don't know his status. I don't know his sexual behavior. I just know my sexual behavior."

- All participants described infrequent or inconsistent condom use — or never using condoms at all
  - Condoms not used because sexual partners disliked them and because of cultural traditions

In Summary

- Perceived risk appeared to have influenced some participants' decisions to adhere to the study pill within the context of a placebo-controlled clinical trial
- The findings suggested that perceived HIV risk may have also influenced the use of effective HIV risk reduction approaches
- Women's perceptions of their HIV risk, including their risk rationalizations, should be included as part of the HIV prevention discourse as they are likely to be important precursors for adopting any risk-reduction measures, whether it is condoms, PrEP, a microbicide gel, or a vaginal ring
- Women who have high HIV risk perceptions, feel vulnerable to HIV, or are unable to use condoms need alternative HIV prevention options

Acknowledgements

Study Participants

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Pretoria — Setshaba Research Centre: Khatija Ahmed, Mookho Malahleha, Malebo Ratlhagana, Shumani Makatu, Joseph Short Skhosana, Modie Constance Monedi, Elizabeth (Thupi) Rammutla

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Reasons for potential risk compensation when taking pre-exposure prophylaxis among women at high risk of HIV in Kenya and South Africa

Amy Corneli, Emily Namey, Kawango Agot, Khatija Ahmed, Jacob Odhiambo, Joseph Skhosana

The 20th International AIDS Conference
Melbourne, Australia
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Introduction/Methods

- Pre-exposure prophylaxis (PrEP) has been proven effective in reducing HIV risk (Grant, 2010; Baeten, 2012; Thigpen, 2012)
- With the introduction of PrEP, users could reduce or stop using their current HIV risk-reduction strategies — a concept referred to as "risk compensation" (Eaton, 2007; Cassell, 2006)
- We conducted multi-phased research to explore this concept among women at high risk of HIV in Bondo, Kenya, and Pretoria, South Africa
  - **Phase I**:
    - Survey with 799 women
    - Asked about sexual behavior intentions in four different risk situations
    - Results: 27% and 40% of participants, depending on the risk situation, would engage in riskier sexual behavior if PrEP becomes available (Poster #**MOPE296)**
  - **Phase II**:
    - Follow-up qualitative interviews with participants (n=60, 30 per site) who were more likely to engage in riskier sexual behaviors if taking PrEP, to explore the context surrounding participants' risk-reduction decisions

Results (1)

- Three interrelated themes were identified for engaging in risker behavior if taking PrEP:
  - "**PrEP protects**" – PrEP was viewed as an effective HIV prevention method that replaced or reduced the need for condoms
    - *PrEP will act as a condom....Yes, [condoms will be used less often] because women feel that if they are taking PrEP, they feel that PrEP is more secure compared to condoms…* – A 23-year-old married woman from Bondo
  - **PrEP alleviates existing challenges in using condoms** – PrEP would provide an opportunity to resolve or avoid conflict
    - *As women we get tempted very easily. We like to satisfy our partners. If I insist that we use condoms then my partner would run away. We like to sacrifice ourselves and make our partners happy....*
      – A 27-year-old married woman from Pretoria

Results (2)

- **PrEP provides an opportunity for financial gain** – primary reason for women who exchange sex for money, but also mentioned by other women
  - *These men are sometimes smooth talkers. They lie to us or sometimes it is an issue of money. When you say you want to have sex with him with a condom, he doesn't want. You are looking at the fact that he gives you money. So you will think that if you end up saying you want to use condoms, he might end up leaving you.*
    - A 31-year-old single woman from Pretoria

Conclusion

- Women in this study population perceived PrEP as an opportunity to resolve current conflicts or struggles by discontinuing condom use or to have sex with new partners while still feeling safe
- Enhanced prevention efforts are needed to –
  - Maximize adherence to PrEP (because high adherence provides high protection against HIV acquisition)
  - Minimize risk compensation among women who may be inconsistent PrEP users
  - Promote informed decision making on sexual health when using PrEP (e.g., to establish a plan for preventing other sexually transmitted infections and pregnancy), particularly among women who believe PrEP alone is a sufficient risk-reduction strategy
- We are currently developing these counseling materials

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Thank you

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