Sex, Intimacy and HIV Prevention: What do women & their partners really want?

End-user research & implementation science to facilitate PrEP delivery from the POWER study

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Connie Celum and Jared Baeten, Project Co-Directors, on behalf of the POWER Team
Where POWER fits in the PrEP implementation landscape

• Oral PrEP works if taken; young women had low adherence in trials
• To date, PrEP open-label studies have had sample sizes of a few hundred young women, operating principally in research settings
• We know little about PrEP delivery for larger-scale implementation
  • Feasibility of mobile services, youth clinics, & family planning clinics for PrEP delivery?
  • Who will start PrEP?
  • Adherence and continuation rates with simple adherence support?
• Program planning must integrate with existing health systems and other HIV prevention activities
• Successful, integrated implementation will require understanding potential users and their healthcare providers
Objective

Develop cost-effective and scalable models for implementation of ARV-based HIV prevention products for young women in Cape Town and Johannesburg (South Africa) and Kisumu (Kenya).

Consortium Partners
Understanding End Users & their influencers’ perceptions of HIV risk & PrEP: A Mental Models Assessment

Nichole Argo
on behalf of the POWER team
What is mental models research?

• How people interpret risk information and the subsequent choices they make are informed by their own intricate web of beliefs and theories – i.e., their “mental models”

• Mental models methodology, grounded in behavioral decision research, characterizes these mental models with respect to a specific decision or set of decisions
  • Unsafe sex, HIV testing, taking 1st PrEP pill, taking Nth PrEP pill

• Interview methods:
  • Begin with open-ended questions designed to elicit participant’s own language and framing
  • Prompts become more and more specific, eventually eliciting risk estimates as well as causal logic.
MM Methods

- **Expert Interviews**
  - From which to generate interview protocol; establishes what people *should* know/do

- **In-Depth Participant Interviews**
  - Establishes range of what people *do* know/do
  - Coded then compared to expert models, by site and by gender, in a “gap analysis”

- **Follow-up Survey**
  - Determines prevalence of beliefs; relationships between demographics and ideas, attitudes and beliefs; pre-testing of communications
  - Recommendations tailored to sub-populations
Characteristics of Mental Models respondents

- 28 young women from Kisumu, Cape Town & Johannesburg
  - Most in 18-22 yo age group
- 27 men (not sexual partners of the women)
- Majority had secondary education or less
- Average age of sexual debut of 17 yrs
- Analysis being completed Fall 2016
Perceptions of relationships & sex

**Condoms**
- Women report *sometimes* use condoms with main partners (3.5/5).
- Despite narratives depicting less trust of “side” partners, they report nearly the same usage with them (3.3/5).

**“Side” partners**
- Most women say they don’t have a “side” partner now, but they think most women have 2.9 partners at one time.
- Most men say they have a side now (.77), and think most men have 4.8 partners at a time.

**Norms**
- Men & women reported they perceive 4 of 10 couples in the community to be monogamous.

**Trust**
- Seeming paradox with above, men and women say they trust their main partner.
Clinic experiences

• Clinic visits per year
  • Women reported 2.7 visits past year; 1.9 for men

• Travel time
  • Women report it taking longer to get to clinic (walking and transport): ~27 minutes vs. 19 minutes for men.

• Wait
  • Average wait is reported to be ~2 hours for women & 1 hr 40 minutes for men
  • A majority of participants had stories about waiting many many hours, or a day. This possibility is at the front of their minds.
Mental Models of young South African women (& men): PrEP Initiation

Rectangles = decisions or actions.
Ovals = inputs to those decisions or actions.
Line width = frequency of mention
Blue shading = input from men only
Gap Analysis of Challenges

Anticipatory Emotions – Forecasting of risks associated with PrEP initiation

• Effort surrounding anticipating and experiencing relationship turbulence with partners, friends or family
• Moral reflections in terms of risk compensation
• Uncertainty about how long they will be at risk

Risk Perception

• Young women and men understand some aspects of increased risk, but not deeply
  • Differential risks associated with circumcision, rough vs. not rough sex, STIs

Providers

• Averse to feeling stigmatized at clinics, many participants mentioned seeking health care input informally, via actual providers out of the clinic context or via traditional healers (men)
Perceptions of Risk

• HIV looms larger than pregnancy for most women
  • Participants see the risk of pregnancy < risk of contracting HIV.
  • 60% believe it would be worse to become infected with HIV than to get pregnant.

• Overestimation of risk estimates
  • Single exposure estimates greatly overestimated by 100-fold
  • Risk of infection accumulates over repeated exposures, but people estimate accumulation poorly.

• Overestimation of risk HIV leads to create stories about HIV protection
  • Given the expectation that they should contract HIV if exposed, some ascribe their neg status to “being immune,” not trusting risk information, or being “protected by God.”
  • HIV risk loses salience.
PrEP Interest & Factors influencing Use

• **Interest.** Women are very interested in trying PrEP (4.6 out of 5 point scale)

• **Control.** Women say they would feel more in control of their HIV risk if they took PrEP, although they also profess to feeling in good control now.

• **Factors that would influence choice to take PrEP** (1-5 scale)
  • Having to pay (3.5); side effects (3.4); travel distance (3.2); private storage (3.1); take it daily (3); partner not supportive (2.9)

• **PrEP Risks:** Uncertainty and forecasting relationship and other issues obscures decision-making
  • Brings negative affect and cognitive load into decision-making.

• **PrEP Benefits:** Feeling empowered, in control, more intimacy
Synthesis of mental models findings about PrEP

• When women forecast PrEP use, a key driver of their anxiety is that these issues have no resolution in their minds.
  • In essence, they're imagining taking an action that could *generate uncertainty* (across relational and identity domains) rather than decreasing it, e.g., risk, the medical view.

• If an individual is anxious about their HIV risk, it may ‘trump’ the forecasting anxiety activated by imagining PrEP.
  • However, those who report exposure to HIV think they should have contracted it (because of local risk messaging around HIV), and since they didn't, they create a "story" to explain why they're less at risk. Alongside the large amount of present-bias that attends living amidst scarcity, it's unclear how personally salient HIV risk is

• The mental models follow-up survey should identify the value proposition of PrEP among those a) who are at greatest risk,; and b) those who feel at greatest risk.
Implications from mental models findings

• Communications
  • Need to account for young women’s uncertainty in forecasting relationship consequences from taking PrEP
    • Need positive affective push, e.g. empowerment, bravery, norms
    • Framing – longer horizon with cumulative risk, other/self, stories, positive models

• Delivery
  • Bring PrEP (and services) to users through mobile trucks, home visits, refill delivery, etc.
  • Provider attitude change is needed, including empathy
  • PrEP advocates could be useful
PrEP Perspectives from Key Informant Interviews

Danielle Wagner, Alexandra Lutnick, Shannon O’Rourke, Ariane van der Stratten on behalf of the POWER team
Key informant (KI) interviews

• The findings represent data from 46 key informant users:
  • DTHF: Cape Town, South Africa
  • WRHI: Johannesburg, South Africa
  • KEMRI: Kisumu, Kenya

• Interviews focused on KI’s perspectives on:
  • Young women’s health-seeking behaviors, concerns about HIV & family planning
  • Young women’s potential interest in PrEP
  • KI’s thoughts on PrEP implementation
Key Informants:
Young women’s concerns about family planning

• 40% of KIs felt YW are very concerned about preventing pregnancy

• Barriers to young women’s use of family planning include:
  • Concerns about side effects and return to fertility after long-term use
  • Resistance from male partner
  • Myths/misconceptions around family planning products
  • Stigma (as young women who have sex)
  • Lack of education about contraception
  • “Laziness” (key informants’ perception of young women’s lack of motivation)
Key Informants’ knowledge of oral PrEP

• Level of knowledge:
  • 40% had never heard of PrEP prior to the interview
  • 40% had varying levels of knowledge
    • Kisumu site had the greatest number of key informants who had heard about PrEP. The Cape Town site had fewest key informants who had heard about PrEP.
  • 14% said they had heard about PrEP (but actually described PEP or ART)
KI concerns about PrEP implementation

• **Accessibility**
  - Cost
  - Medication supply – stock availability and storage

• **Staffing concerns**
  - Time availability
  - Low knowledge of PrEP, training needs
  - Staff judging young women
KIs: Young women will be interested in PrEP

- **Can be “in charge”** – use without partner consent
- **Stay safe** – don’t know if their partners have other partners
- **Reversibility** – can stop taking it when they feel they are no longer at risk

- Continue with **“lifestyle” of not using condoms**, or not use condoms when sexual feelings are “high”
- **Advertise** they are HIV- by using PrEP
Key Informants: Possible issues with delivering PrEP to young women

• **Issues with taking pills**
  • Daily burden, possibility of forgetting
  • Fear-related
    • Side effects, drug resistance
    • Concern about discovery: family, partner, general
    • Myths/misconceptions – fear of unknown, being a “guinea pig”
  • Stigma of taking a pill (implies HIV+)
  • Difficult to take pills when not sick

• **Burden of testing for HIV every 3 months**

• **Access issue**
  • Knowledge/clinic location/long wait/inconsistent stock
KI suggestions - Facilities

• **Necessary facility characteristics:**
  - Near young women
  - **Convenient**, well-known, routine schedule
  - **Multiple options** (to fit the needs of various women, lifestyles)

• **Recommended facilities:**
  - General clinics/health centers (14)
  - Youth friendly/campus clinics (10)
  - Mobile clinics (10)
  - Pharmacies/chemists – preferred by young people (8)
KI suggestions – Counseling & PrEP delivery

- Provide counseling via young staff/peer educators & support groups (& provide PrEP refills during meetings)
  - Emphasize:
    - Unpacking myths
    - Ways to make pill routine (alarm/with meals/storage suggestions)
    - Communication with partners/parents about PrEP – improves adherence
    - Condoms
- Need to address deeply embedded biases and judgments among providers
- Peer PrEP ambassadors for outreach and education
- Youth-friendly spaces and providers for PrEP delivery
Demand creation strategies to create awareness

Connie Celum, Linda-Gail Bekker, Brie Ferriano, & Mo Mashilo from McCann Global Health
3P Study: Risk Perception, Partners & PrEP

• Formative research in Masiphumulele township, Cape Town, 2015-16:
  • Pilot narratives to see if they are a salient way for young women to consider their risk
  • How knowledge of partner’s HIV status inform young women’s perception of risk
  • Feasibility of reaching male partners & acceptability to men of different HIV testing strategies
  • Behavior-centered design to evaluate motivators & environmental factors that could influence young women’s decision & ability to use PrEP

• Collaboration with McCann Global Health (NY & Johannesburg) to develop demand creation strategies for a cohort of PrEP users in Masiphumulele township, Cape Town

NIMH & BMGF funding; Bekker & Celum co-PIs
Demand creation strategies (in development)
Collaboration with DTHF, & McCann

Empowerment examples

Community & social norms
Decision support tool to aid decision-making of prospective PrEP users & counseling by providers

Connie Celum, Christine Dehlendorf (UCSF), & Larry Swiader (Bedsider.org)
Bedsider/UCSF collaboration to develop a decision support tool for contraceptive decision-making

- Counseling can influence contraceptive use, but women are frequently dissatisfied with their contraceptive counseling
- Facilitating shared decision making is desirable given that choice of contraception is a preference-sensitive decision
- Difficult to provide comprehensive counseling in clinic visit given complexity of decision
- Best method for an individual depends on her preferences; shared decision-making allows women to weigh effectiveness differently relative to other characteristics
Bedsider.Org: Youth-friendly information about birth control with reminders
My Birth Control decision support tool

• Developed a tablet-based decision support tool (DST), *My Birth Control*, to help women with their choice of a contraceptive method

  https://clinic.mybirthcontrol.org

• Designed to promote shared decision-making approach to counseling

• Currently conducting a cluster RCT of 750 participants

Collaboration between POWER and Dr. Christine Dehlendorf, UCSF & Bedsider.org
Structure of *My Birth Control* tool

- Digital format for tablets
- Educational modules
- Interactive component to elicit preferences
- Health history evaluating eligibility for methods
- Interactive “method chooser” screen
- Question screen
- Final printout
A CLOSER LOOK AT SIDE EFFECTS

Now that you know about the potential side effects of birth control, take a closer look and review them by method.

THE SHOT

good stuff /

😊 Can make your period go away completely, which some women like
😊 Lowers your risk of ovarian and uterine cancer

annoying stuff /

😢 Can cause spotting or irregular periods
😢 Can make your period go away completely, which some women don’t like
😢 Some women may feel sad or have decreased interest in sex when using this method, but most feel fine.
😢 May cause weight gain

THE PILL

good stuff /

😊 Can make your periods less heavy and less crampy
😊 Can help clear up your acne
😊 Lowers your risk of ovarian and uterine cancer

annoying stuff /

😢 For the first few months you may have nausea and breast tenderness.

stuff not to worry about /

😢 Unlike what some people think, doesn’t cause depression or weight gain in most women.
PrEP decision support tool could address multiple barriers to PrEP delivery in Africa to young women

- POWER mental models & key informants:
  - Limited provider and client knowledge about PrEP
  - Judgmental attitudes of providers about young unmarried African women’s sexual activity
  - Limited training of African providers in informed choice and patient-centered counseling
  - Limited time with patients in busy clinics

What is PrEP?

How well does it prevent HIV?

How do I take it?

What do I need to know about it?

What are some myths & facts about it?
What do I need to know about PrEP?

The Good Stuff

✓ Very safe
✓ Keeps you healthy
✓ 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
✓ Most side effects go away quickly
Putting end user research into action: Open cohorts of HIV-uninfected women to pilot PrEP service delivery models

Connie Celum and Jared Baeten, University of Washington, on behalf of the POWER team
Overall objectives for POWER cohort, 2017-2020

• Prevention cohorts of women in Kisumu, Cape Town, & Johannesburg
  • Sexually active women can enroll *regardless of their initial interest in PrEP*
  • Offer prevention options, including oral PrEP
  • Will provide a non-randomized measure of HIV incidence in PrEP vs non-PrEP users

• Minimize research procedures to focus on scalable PrEP delivery in different settings

• These cohorts to provide a scaffolding for nested, smaller pilot studies
  • Recruitment to prevention - Adherence support - Decision tool for prospective users - Implementation tools for providers

• Leading to ultimate evaluation of uptake, adherence & acceptability when given **choice** of PrEP options (e.g., oral pills and hopefully, dapivirine ring)
Cohort objectives: evaluate PrEP use

• Who initiates PrEP
  • Motivation
  • Readiness to use
  • Perceptions of risk, decision-making, experience

• Persistence and patterns of use
  • Associations with contraceptive use and sexual activity
  • Objective measures of adherence

• HIV incidence
Objective 1: Demonstrate delivery models

- In Kisumu, Johannesburg, Cape Town, conduct PrEP delivery using delivery platforms tailored to each setting.
- Assess operational feasibility, technical needs, acceptability, and efficiency of the delivery platforms to users and providers, and community messaging.
- Assess health care provider perspectives about PrEP delivery and ways to facilitate PrEP integration with other health care services, such as mobile outreach, youth clinics, FP, & primary care clinics.
POWER Delivery Sites

• Ultimate goal is getting close to real world implementation

• We will implement ‘deliverables’ from formative work (i.e., decision support tool, provider training, adherence support, etc.)

• Proposed PrEP delivery sites for cohort:
  • Cape Town: mobile testing van (Teen Tutu Tester)
  • Johannesburg: youth clinic
  • Kisumu: family-planning clinic
Tutu Teen Tester, Cape Town

Accessible
Efficient
Tailored
Comprehensive
One STOP Shopping

Contraception- Oral, IM, implant
Emergency contraception
HIV, STI, Preg screening
Mental health screens
Basic primary care
CD4, VL
ART, PrEP
BMI, Blood sugar
CV writing, ID books
Hairbraiding, manicures
Wits RHI Youth clinic, Johannesburg
Kisumu public family planning clinic (JOORTH)
Visit Schedule

• Screening and enrollment
  • Open cohort, can enroll without uptake of PrEP

• Frequency of visits thereafter
  • 1 month after enrollment + quarterly

• Follow up time
  • Up to 36 months

• Streamlined data collection in order to approximate real world setting, yet learn about uptake & adherence

• Interviews with providers and data collection about delivery operations
Objective 2: Assess cost & cost-effectiveness

- Time-motion studies to optimize PrEP delivery efficiency and minimize opportunity costs of providing PrEP
- Micro-costing of PrEP delivery by site and model cost-effectiveness of PrEP in terms of HIV infections averted
- Budget impact analyses of PrEP affordability
- Empiric data on HIV incidence from the cohort to model population-level impact
Qualitative research:
Motivations & barriers for PrEP initiation & continuation

• Influencers: Peers, partner, family, relatives, teachers, & others
• Past intimate partner violence
• Context: Living situation, privacy for product storage
• Access to health services, including family planning
• Alcohol use
• Ability to disclose and get support for PrEP use
Definitions of success in POWER cohort

• Success ≠ 100% of young women in POWER who hear about PrEP take it
• Success ≠ 100% of women continue PrEP throughout cohort
• Success = If young women (ages 16-25) are motivated to learn about PrEP & make informed choices about PrEP (& if approved, dapivirine ring)
• Success = Identifying feasible strategies for PrEP delivery & ways to facilitate delivery
• Success = Learning how to support PrEP use among young women (e.g., HIV self testing to reduce clinic visits, simple adherence support, community resupply)
• Success = Increasing community interest in PrEP
POWER Study Team

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