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Prevention Options for
Women Evaluation Research

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

October 21, 2016

Connie Celum and Jared Baeten, Project Co-Directors,
on behalf of the POWER Team

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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
  - Feasiblity 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

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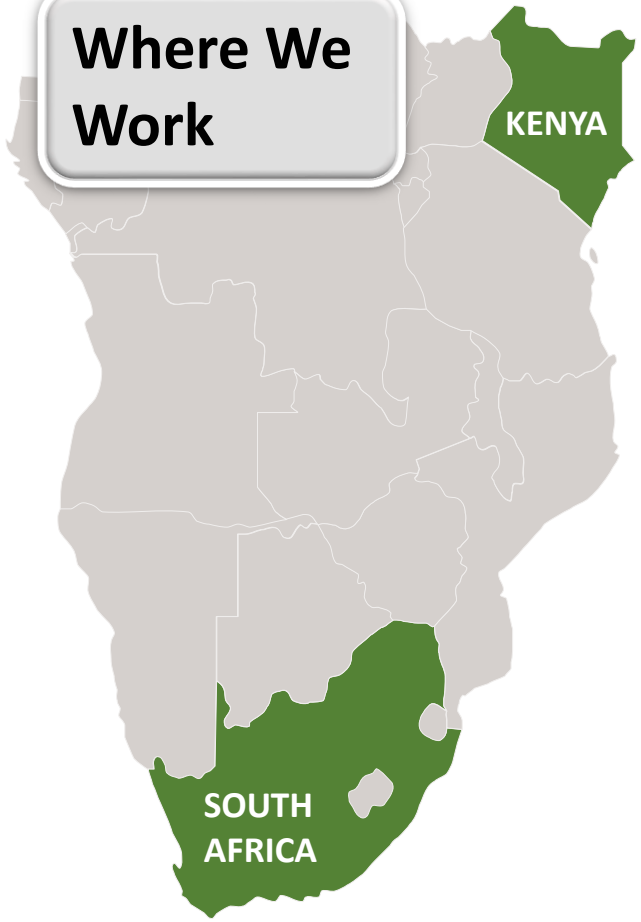
Where We Work



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

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Understanding End Users & their influencers' perceptions of HIV risk & PrEP: **A Mental Models Assessment**

Nichole Argo
on behalf of the POWER team

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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.

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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

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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

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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 a

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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.

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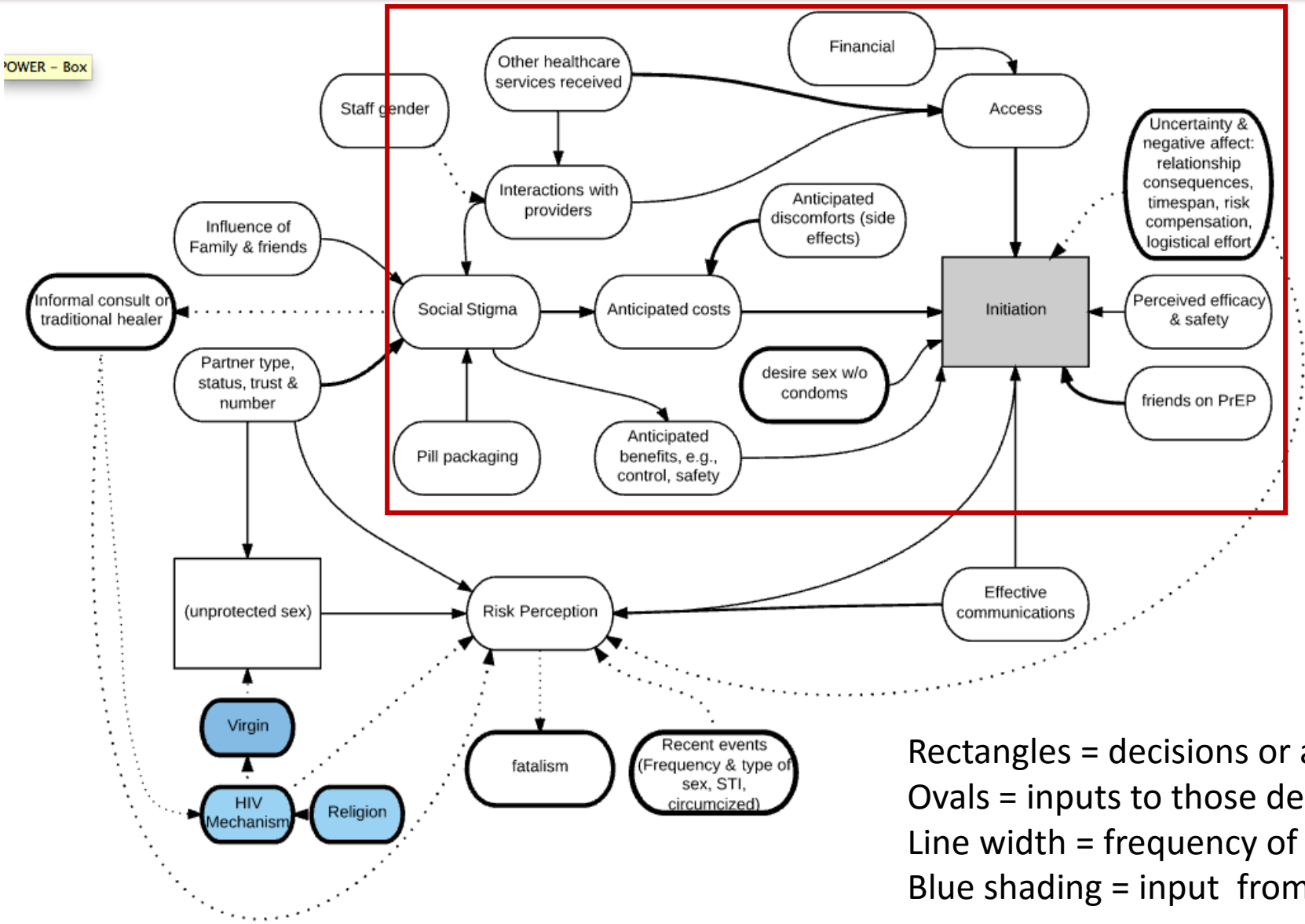
Mental Models of young South African women (& men): PrEP Initiation



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

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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)

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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 need 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.

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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

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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.

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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

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PrEP Perspectives from Key Informant Interviews

Danielle Wagner, Alexandra Lutnick, Shannon O'Rourke, Ariane van der Stratten on behalf of the POWER team

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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

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Key Informants:
Young womens' 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)

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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)

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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

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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

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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

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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)

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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

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Demand creation strategies to create awareness

Connie Celum, Linda-Gail Bekker, Brie Ferriano, & Mo Mashilo from McCann Global Health

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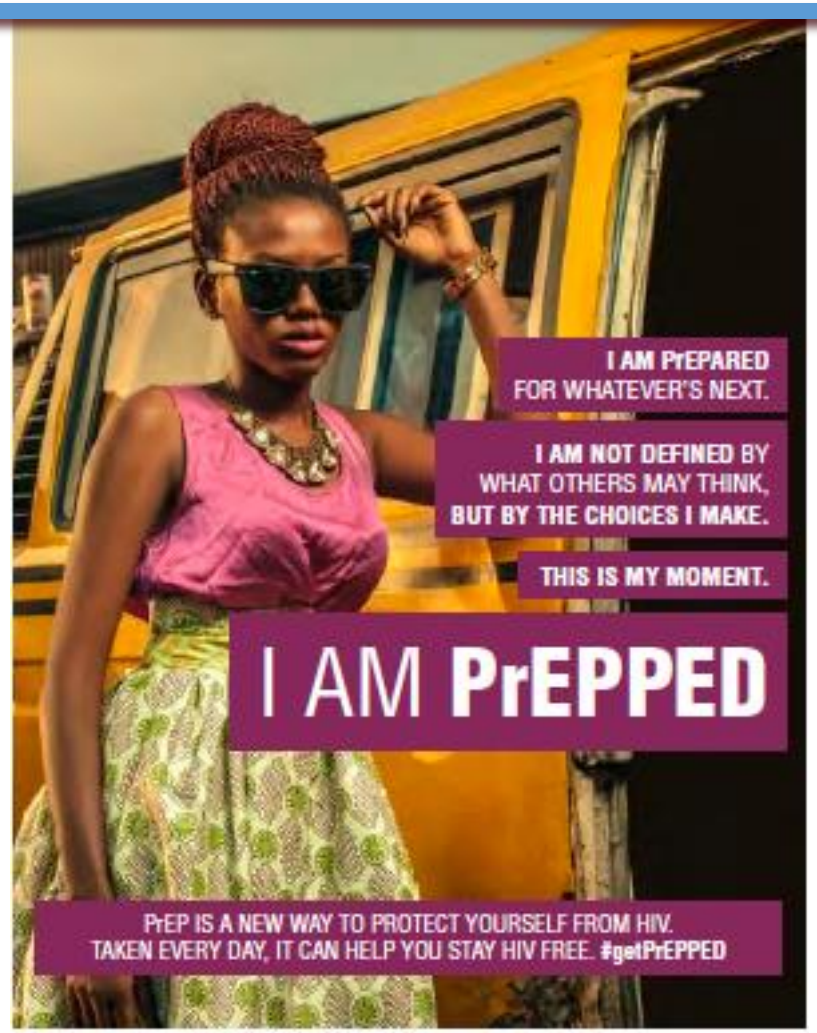
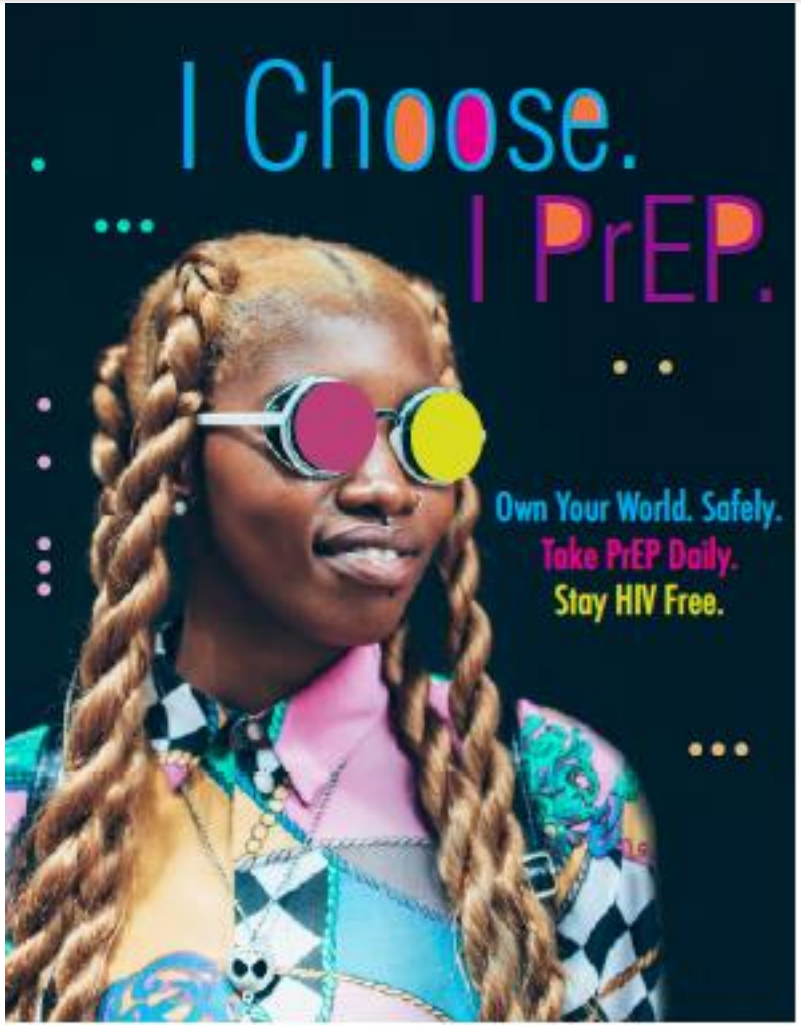
3P Study:
Risk Perception, Partners & PrEP

- 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)

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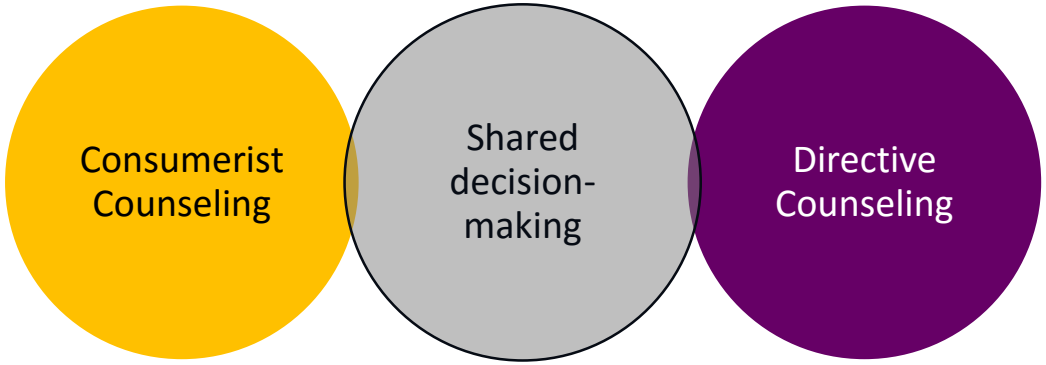
Bedsider/UCSF collaboration to develop a decision support tool for contraceptive decision-making

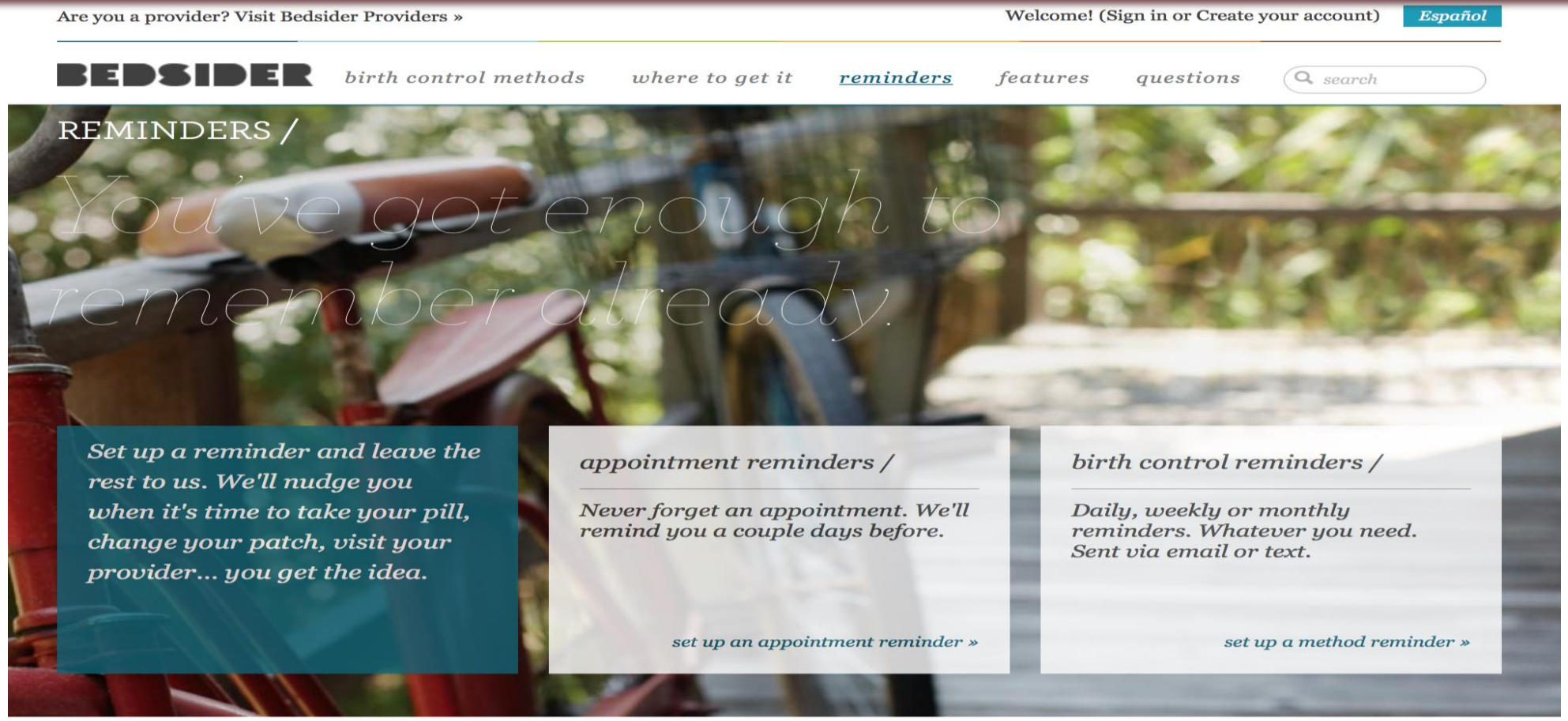
- Counseling can influence contraceptive use, but women are frequently dissatisfied with their contraceptive counseling
- Facilitating shared decision making is desirable given that choice of contraception is a preference-sensitive decision
- Difficult to provide comprehensive counseling in clinic visit 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



Dehlendorf: *Contraception*, 2013
Dehlendorf: *AJOG* 2016

UCSF
University of California San Francisco

Bedsider.Org: Youth-friendly information about birth control with reminders

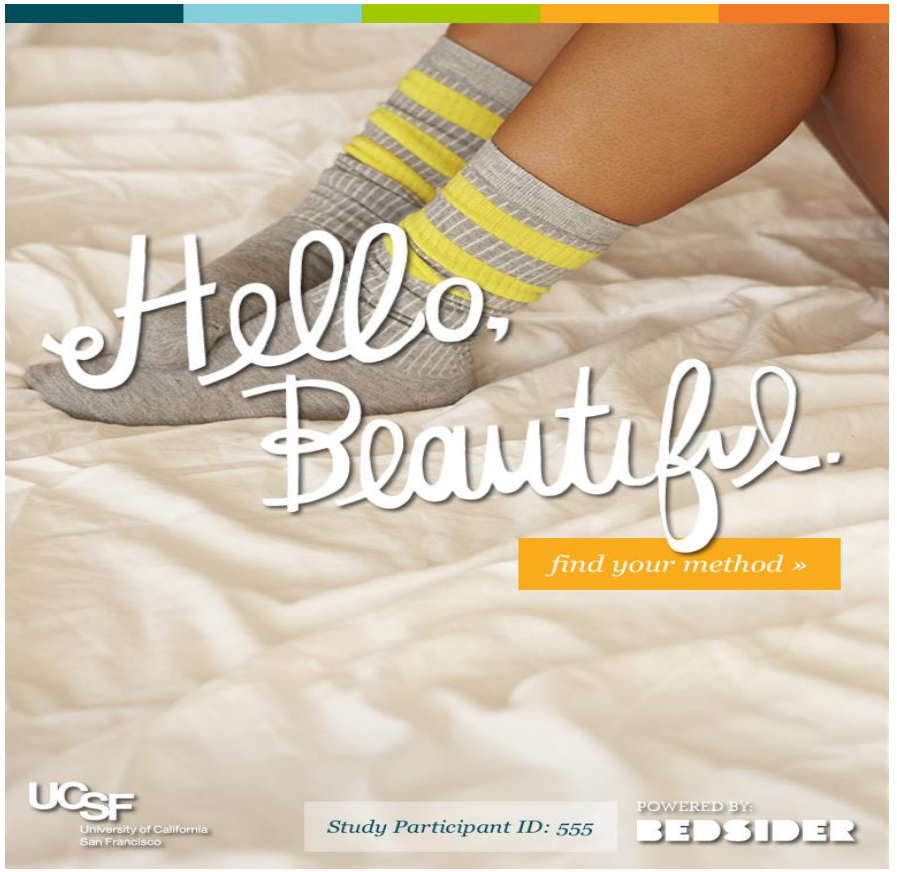


My Birth Control decision support tool

- 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

My Birth Control: Simple information about efficacy, user experience & side effects of contraception options

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 /

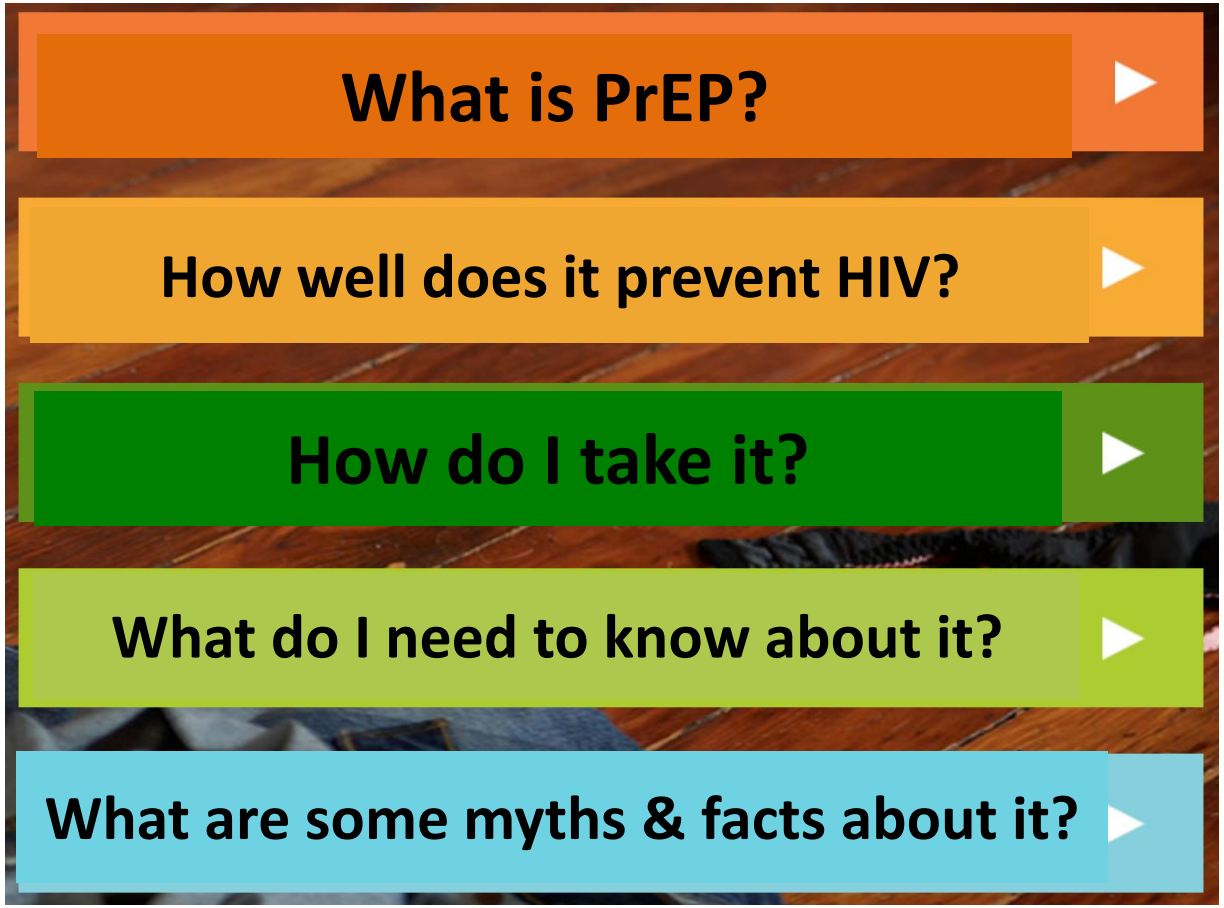
- For the first few months you may have nausea and breast tenderness.

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



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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

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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

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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)

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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

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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.

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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

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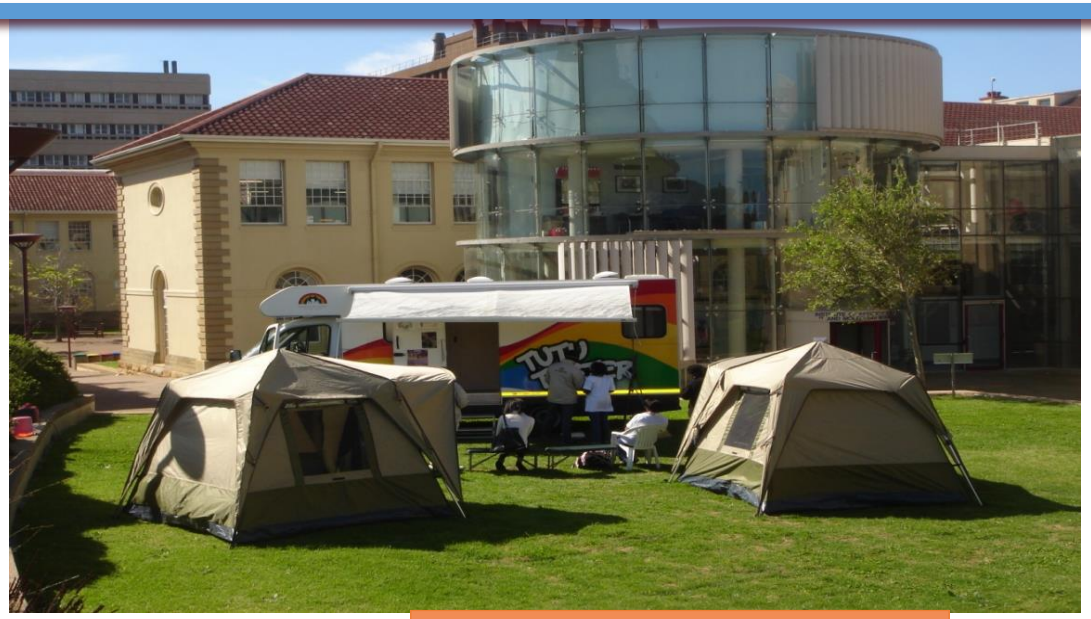
Tutu Teen Tester, Cape Town



Accessible
Efficient
Friendly
Tailored
Comprehensive
One STOP
Shopping

Contraception- Oral, IM, implant
EmergencyContraception
HIV, STI, Preg screening
Mental health screens
Basic primary care
CD4, VL
ART, PrEP
BMI, Blood sugar
CV writing, ID books
Hairbraiding, manicures

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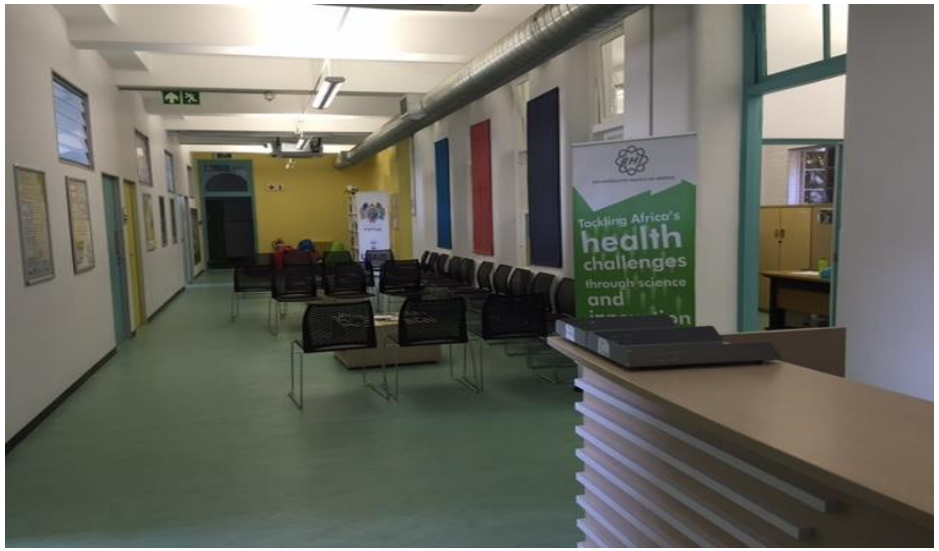
Wits RHI Youth clinic, Johannesburg



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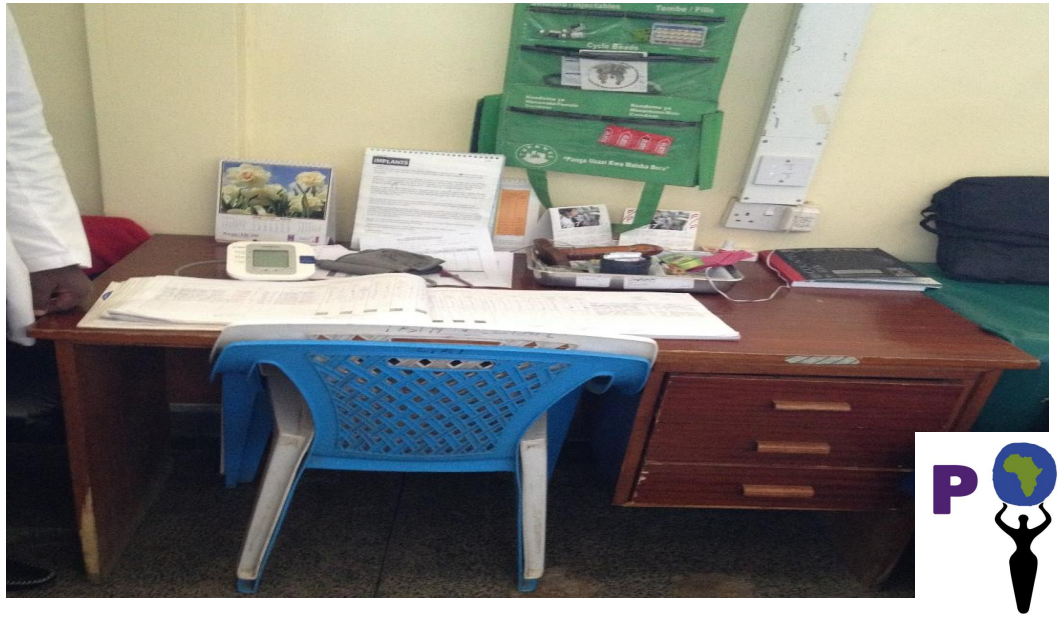
Kisumu public family planning clinic (JOORTH)



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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

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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

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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

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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

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POWER Study Team

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- Research Triangle Institute (RTI): Ariane van der Straten and Alexandra Lutnick
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- Bedsider.org: Larry Swiader

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