Daily And Intermittent PrEP
Working with MSM in South Africa
The Desmond Tutu HIV Foundation

Our mission is to pursue excellence in research, treatment, training, and prevention of HIV and related infections in Southern Africa
Nyanga District

Population: 500 000
Unemployment: 70%
Shack dwelling 50%
Background

• The Global iPrEx Study Design
  – Double blind, placebo controlled
  – Safety and efficacy
  – Once a day, daily oral use of an ARV drug for HIV prevention

• Study medication
  – Tenofovir 200 mg. Emtricitabine 300 mg
Fully enrolled as of December 2009

<table>
<thead>
<tr>
<th>Sites</th>
<th>11</th>
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<tbody>
<tr>
<td>Participants</td>
<td>2,499</td>
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4,905 Screened

- 1,564 (32%) Ineligible
  - 410 HIV Positive
  - 405 Lab Ineligible
  - 247 Low HIV Risk
  - 502 Other Reasons

- 842 Eligible, Not Enrolled

2,499 Randomized

- 1,251 (50%) Randomized to FTC/TDF
  - 1,226 (98%) Followed

- 1,248 (50%) Randomized to Placebo
  - 1,225 (98%) Followed

- 25 No Follow Up HIV Test
  - 1,226 (98%) Followed

- 23 No Follow Up HIV Test
“Next Step” Counseling For PrEP Pill Taking

• Separation of roles
  — Monitoring
  — Promotion

• Monitoring is neutral

• Promotion focus
  — On barriers and facilitators
  — Blind to actual reported use
Background

• Study results
  – iPrEx showed that daily use of oral PrEP provided 44% additional protection in preventing HIV infection
  – All participants received comprehensive HIV prevention services

• The study was sponsored by the US-NIH and the Bill & Melinda Gates Foundation. Drug was donated by Gilead Sciences
Efficacy (MITT) 44% (15-63%)
Infection Numbers: 64 – 36 = 28 averted
iPrEx Next Steps

• iPrEx Open Label Extension
  – Aimed at providing additional safety data regarding long-term PrEP use among those rolling over from the active arm
iPrEx Next Steps (cont.)

• Rationale:
  – Information about PrEP efficacy might decrease perception of HIV risk
  – Risk compensation: increased risk behavior (decreased use of condoms or more sex partners)
  – Information about PrEP safety and efficacy may increase pill use and drug exposure
iPrEx Next Steps (cont.)

• Study Implementation
  – Every participant enrolled in the blinded phase will be unblinded
  – Invited to enroll in the Open Label Extension
    • HIV (-) participants will be offered Truvada®
    • HIV (+) participants will receive HIV Viral Load and CD4 count monitoring and Referrals of ART treatment when needed
iPrEx Next Steps (cont.)

- Visit schedule: 4, 8, 12 and every 12 weeks after enrollment for 72 weeks
- Participants will be monitored for biological and behavioral safety
iPrEx Open Label Extension

• The iPrEx Open Label Extension will provide unique opportunities to address questions about how information about PrEP safety and efficacy might affect risk behavior and pill use
Daily Dosing vs. Intermittent Dosing
1. Quantitative research using survey methodology
   • Self-completed
   • 11 questions: 5 demographics, 6 sexual planning
   • n=40 completed surveys

2. Qualitative research using focus group methodology
   • 7 focus groups
   • n=6-8 participants per group
   • 1 x female, 2 x male, 2 x mixed, 2 x counselor groups
   • Trained facilitator with assistant note-taker
   • 1 to 2 hours per group
   • Audio-recorded (with consent), transcribed, translated
   • 217 pages of data
• 64% of days on which sex occurred had been ‘planned’
• 51% of those reporting sex in the past week said they were generally able to predict it the day before.
• → Significant gender difference: 75% of men able to predict 32% of women
• Facilitators of sex prediction:
  • - Plans discussed with partner – endorsed by 67% overall but more characteristic of men (83%) than women (33%) (p=.03)
  • - Expecting certain situations to lead to sex – endorsed by 28% overall but more characteristic of women (50%) than men (17%)
Fig 1. Proportion of sample reporting sex by day
“I don’t use a condom. I know I’m risking with my life because I know HIV exists and it kills. But I sometimes I don’t use this condom thing. I think to myself, ‘No, if I have it, I have it, I’ll just treat it.’”
“I don’t even like any kind of pills”

“They may be afraid to take this pill when they are not sick”
“Pills have side effects if you take them too much”
“After they take this pill some people will want to go sleeping around”
“When there is no time I will not cope”

“I would say that everyday drug is challenging. If they say you eat one pill for the whole month it’s fine”
HPTN 067: The ADAPT Study

- A phase II randomized Open-Label Clinical Trial of FTC/TDF

- Behavioural Study to evaluate the feasibility of intermittent dosing of a pre-exposure prophylaxis Regimen
HPTN 067: Methods

- Participants include 180 WSM and 180 MSM

- Randomly Assigned into one of three dosage groups
  - 1. Daily Dosing
  - 2. Time-Driven Dosing
  - 3. Event Drive Dosing
HPTN 067: Objectives

• Will recommending intermittent usage of oral FTC/TDF chemophrophylaxis, compared with daily usage, be associated with:
  
  – equivalent coverage of sex events with pre and post exposure dosing
  – lower number of pills needed for coverage and fewer pills used
  – decreased self-report of symptoms/side effects
Special Thanks

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