DESMOND TUTU
HIV FOUNDATION

IAPAC Summit

2012

Daily And Intermittent PrEP

Working with MSM in South Africa

The Desmond Tutu HIV Foundation

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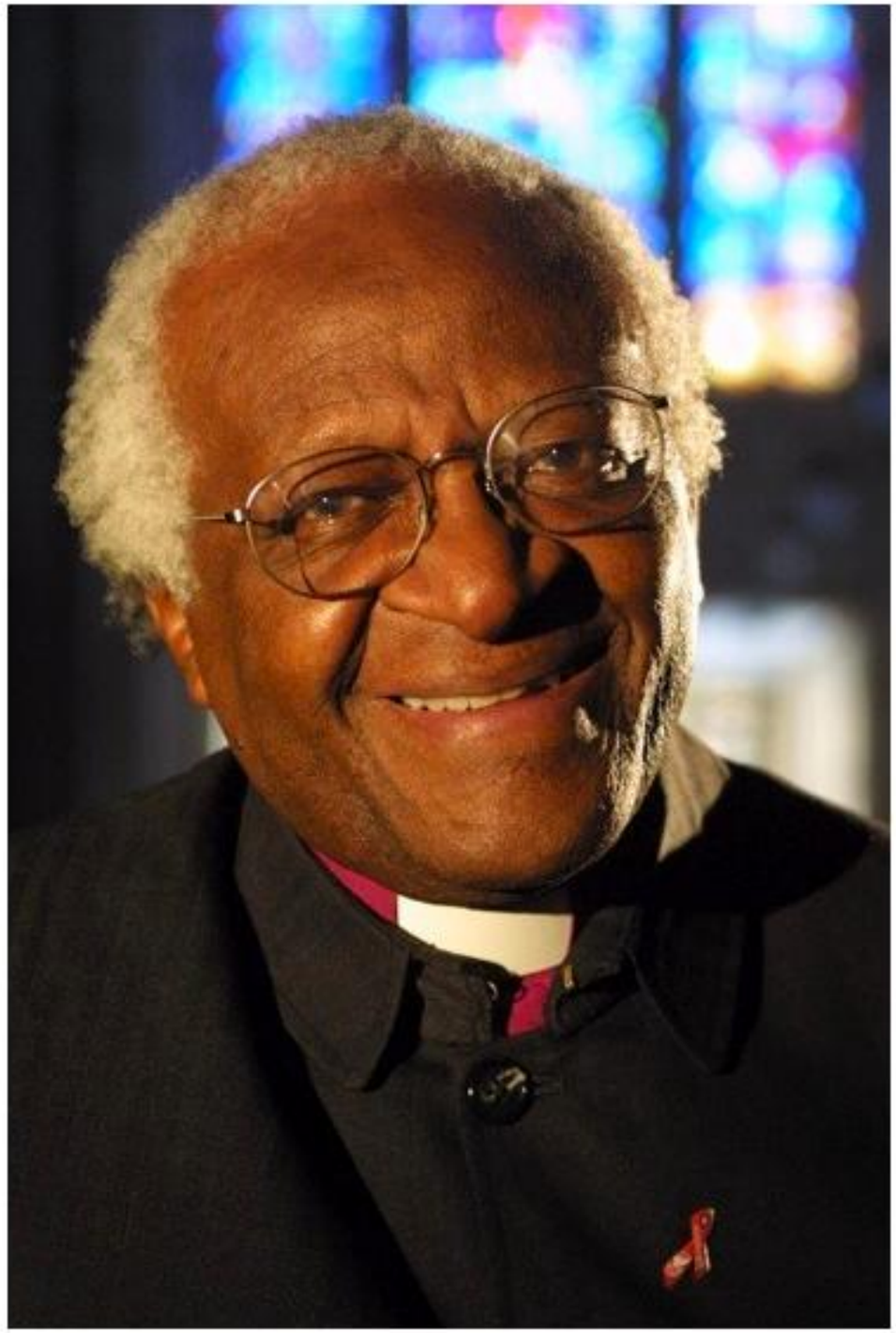
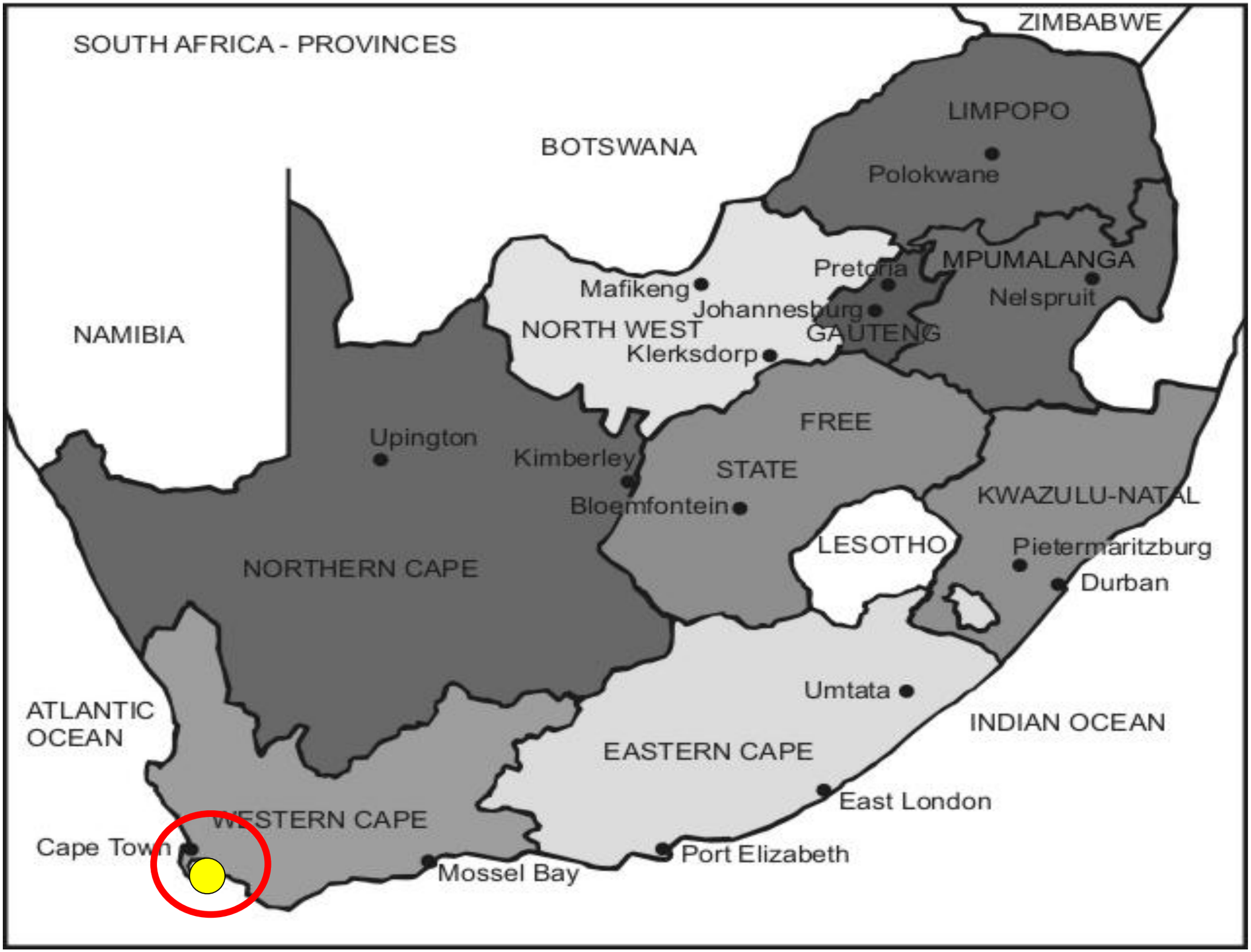
Masibambane Ngezandla

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

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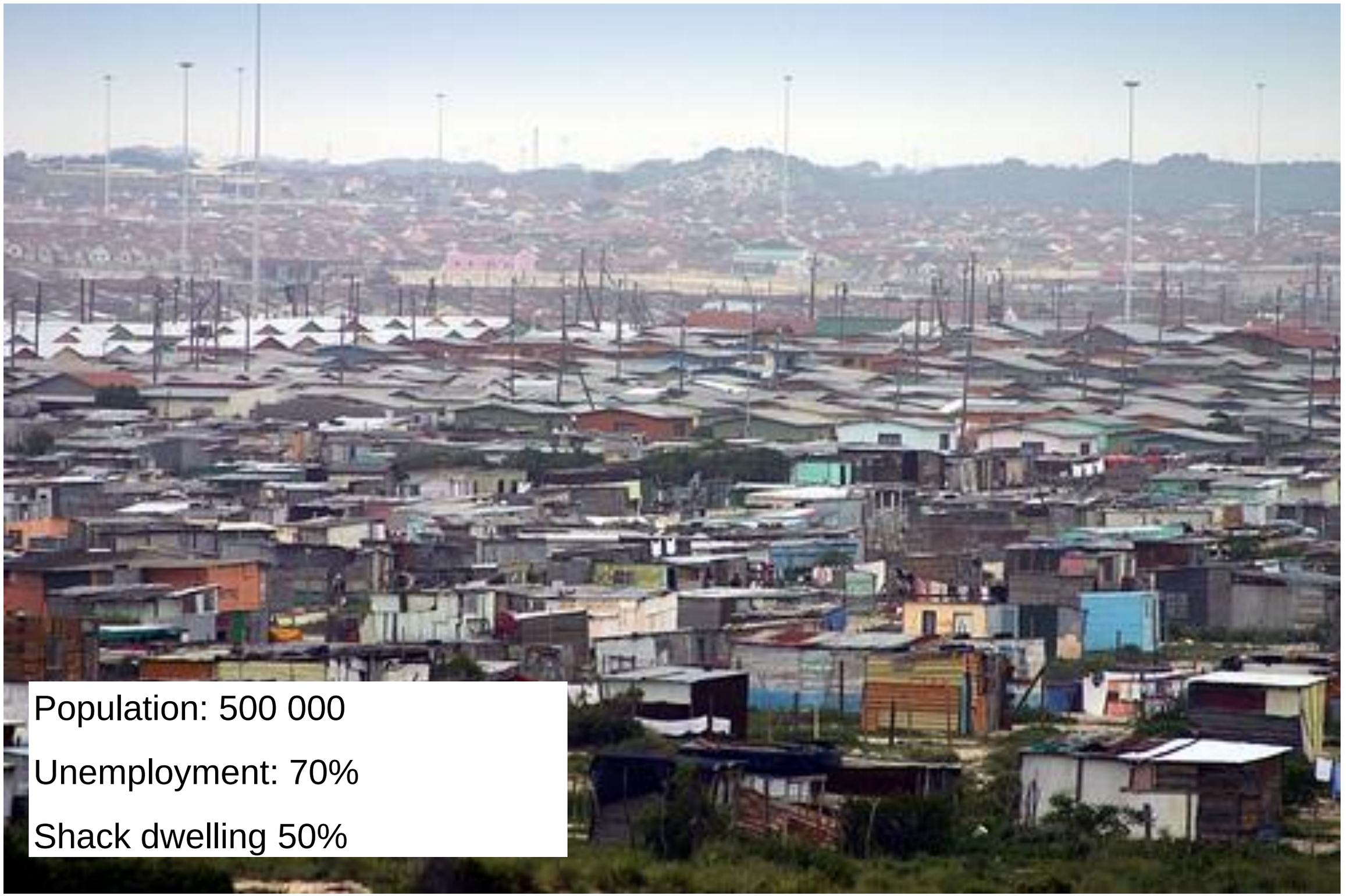


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EMAVUNDLENI CENTR

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

Sites	11
Participants	2,499

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

1,248 (50%)
Randomized to Placebo

25 No Follow Up HIV Test

23 No Follow Up HIV Test

1,226 (98%)
Followed

1,225 (98%)
Followed

GLOBAL iPrEx

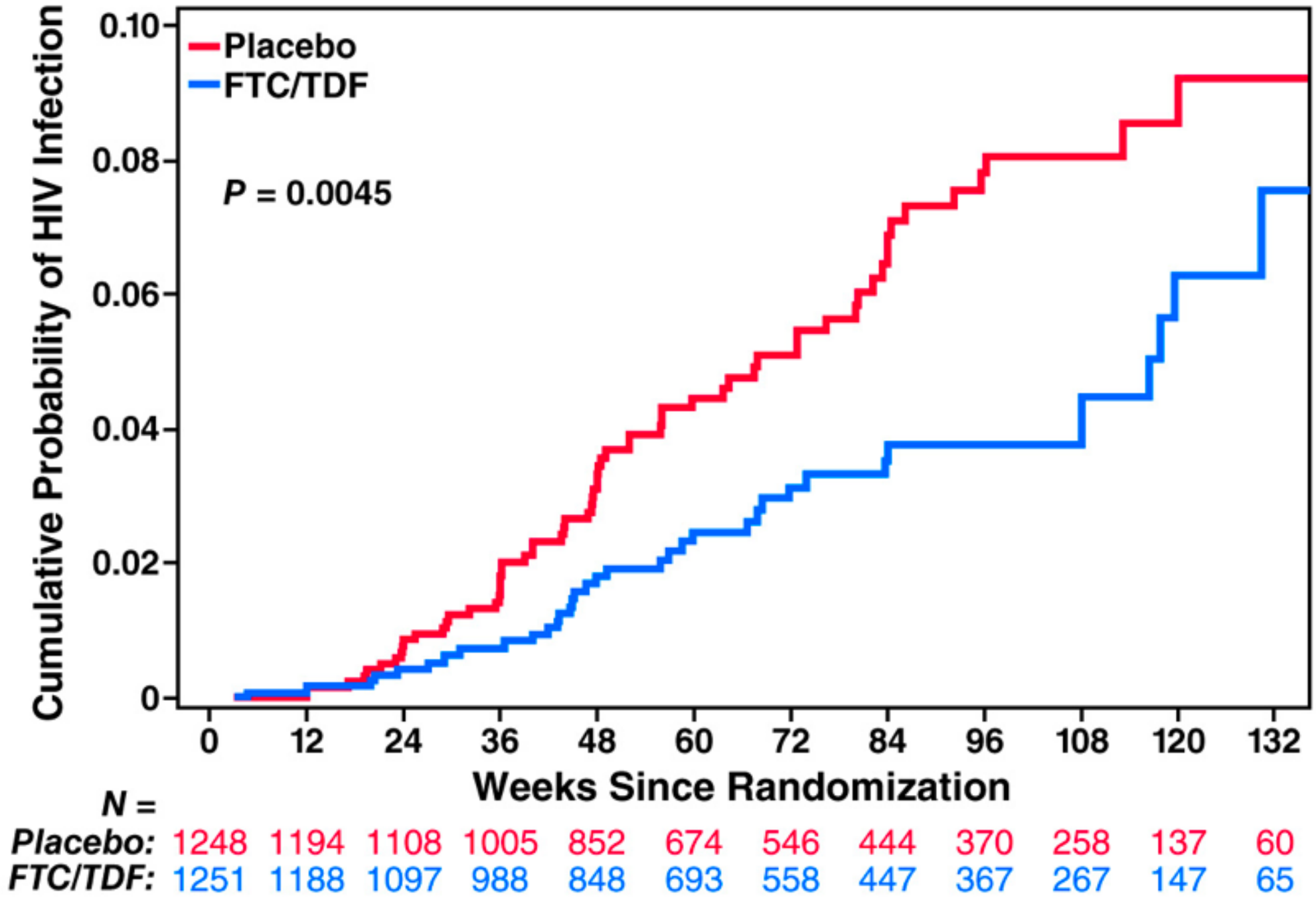
“Next Step” Counseling For PrEP Pill Taking

- 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



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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%)

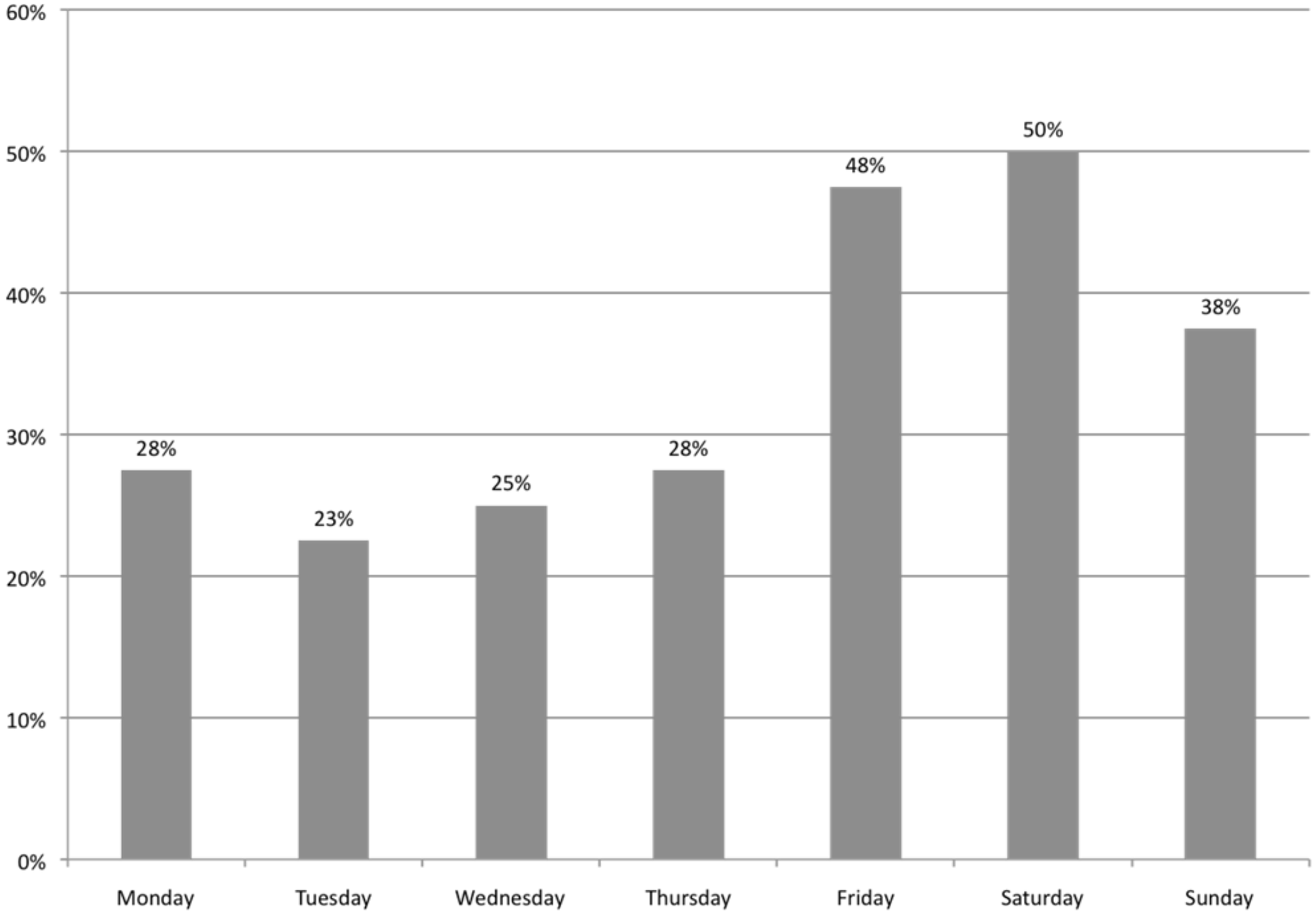

Fig 1. Proportion of sample reporting sex by day

“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 daiily 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

- Bob Grant, Rivet Amico, and the iPrex Team

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