PrEP for High-Risk MSM
The PROUD Study
Study Design: PROUD

- **Background**: Randomized, open-label phase 4, placebo-controlled trial conducted at 13 sexual health clinics in England that examined the efficacy and safety of tenofovir DF-emtricitabine as preexposure prophylaxis for men who sex with men.

- **Inclusion Criteria** (544 enrolled)
  - 18 years of age or older
  - HIV seronegative
  - Men who have sex with men
  - Unprotected anal sex in prior 90 days
  - Excluded if HBsAg-positive

- **Treatment Arms**:
  - Defer: PrEP delayed for 1 year
  - Immediate: Tenofovir DF-emtricitabine 1 pill daily

**Defer PrEP for 1 Year**
(n = 269)

**Immediate TDF-FTC PrEP**
(n = 275)

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The PROUD Study: Results

Due to high effectiveness of PrEP, participants unrandomized and all offered PrEP

Interpretation: “In this high incidence population, daily tenofovir-emtricitabine conferred even higher protection against HIV than in placebo-controlled trials, refuting concerns that effectiveness would be less in a real-world setting. There was no evidence of an increase in other sexually transmitted infections. Our findings strongly support the addition of PrEP to the standard of prevention for men who have sex with men at risk of HIV infection.”
Acknowledgment

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