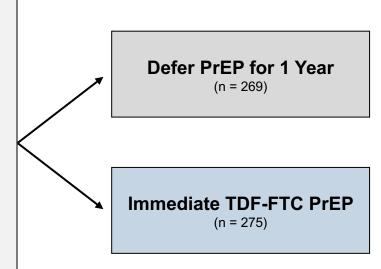


# Immediate versus Delayed HIV PrEP for MSM **PROUD Study**



# Immediate versus Delayed HIV PrEP for MSM PROUD Study: Study Design

- 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

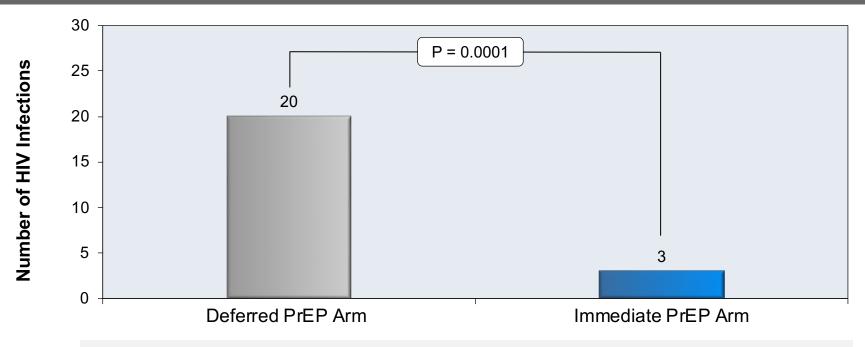




Source: McCormack S, et al. Lancet. 2016;387:53-60.

### Immediate versus Delayed HIV PrEP for MSM PROUD Study: Results

Number of HIV Infections

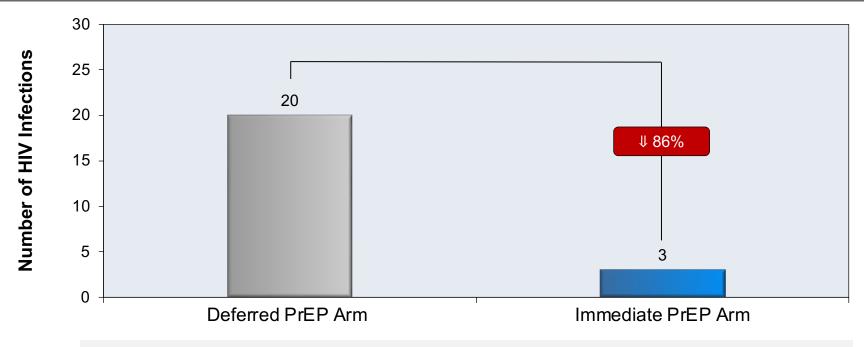


Due to high effectiveness of PrEP, participants unrandomized and all offered PrEP



### Immediate versus Delayed HIV PrEP for MSM PROUD Study: Results

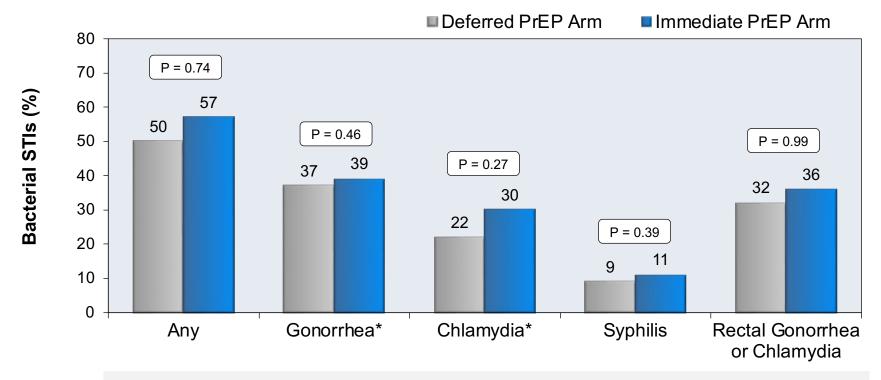
Number of HIV Infections and Risk Reduction



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



## Immediate versus Delayed HIV PrEP for MSM PROUD Study: Bacterial STIs



\*Detected in throat, urethra, or rectum



#### Immediate versus Delayed HIV PrEP for MSM PROUD Study: Conclusions

**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."



#### Acknowledgments

The National HIV Curriculum is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.





