# HIGH INCIDENCE OF CURABLE SEXUALLY TRANSMITTED INFECTIONS IN HPTN 084: A TERTIARY ANALYSIS

Harriet Nuwagaba-Biribonwoha<sup>1</sup>, Brett Hanscom<sup>2</sup>, Daniel Haines<sup>2</sup>, Yaw Agyei<sup>3</sup>, Joseph Makhema<sup>4</sup>, Juliet Mpendo<sup>5</sup>, Nyaradzo Mgodi<sup>6</sup>, Victor Mudhune<sup>7</sup>, Jennifer Farrior<sup>8</sup>, Lydia Soto-Torres<sup>9</sup>, James F. Rooney<sup>10</sup>, Alex Rinehart<sup>11</sup>, Mina Hosseinipour<sup>12</sup>, Sinead Delany-Moretlwe<sup>13</sup>, and the HPTN 084 team.

<sup>1</sup>Eswatini Prevention Center CRS, ICAP at Columbia University, Mailman School of Public Health, New York, NY, USA; <sup>2</sup>Statistical Centre for HIV/AIDS Research Institute, Seattle, WA, USA; <sup>3</sup>Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, MD, USA; <sup>4</sup>Botswana Harvard AIDS Institute Partnership, Gaborone, Botswana; <sup>5</sup>Uganda Virus Research Institute, International AIDS Vaccine Initiative, Entebbe, Uganda; <sup>6</sup>University of Zimbabwe Clinical Trials Research Centre, Harare, Zimbabwe; <sup>7</sup>Kenya Medical Research Institute, Center for Global Health Research, Kisumu, Kenya; <sup>8</sup>FHI 360, Durham, NC, USA; <sup>9</sup>Division of AIDS, National Institute for Allergy and Infectious Diseases, Rockville, MD, USA; <sup>11</sup>ViiV Healthcare, Durham, NC, USA; <sup>12</sup>University of North Carolina, Chapel Hill, NC, USA; <sup>13</sup>Wits RHI, University of the Witwatersrand, Johannesburg, South Africa

#### BACKGROUND

Sexually transmitted infections (STIs) can signal ongoing risk of HIV acquisition and have adverse reproductive health sequelae.

We assessed STI disease burden among women participating in the HPTN 084 trial during the blinded and unblinded period.

#### METHODS

HIV uninfected women ages 18-45 years (y) enrolled in HPTN 084 were tested and treated for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoea* (NG) and *Trichomonas vaginalis* (TV) at baseline and every 6 months. We assessed:

- Baseline STI prevalence
- Post-baseline STI incidence rates
- STI recurrence (≥2 episodes of CT, NG or TV >5 months apart)
- Concurrent STIs (≥2 STIs diagnosed within 7 days)

Correlates of incident STIs were estimated using multiple regression. Cabotegravir (CAB) PrEP efficacy in the blinded study period was compared for people with and without STIs using Cox regression.

**Table 1.** STI Prevalence at baseline by demographic characteristics

		Any STI	СТ	NG	TV
	N	900 (28.1%)	604 (18.9%)	210 (6.6%)	270 (8.4%)
Age Group					
18-24 years	1578	513 (32.5%)	371 (23.6%)	125 (7.9%)	134 (8.7%)
25+ years	1620	387 (23.9%)	233 (14.5%)	85 (5.3%)	136 (8.6%)
Country					
Botswana	91	26 (27.8%)	22 (24.4%)	5 (5.6%)	0 (0.0%)
Kenya	66	11 (16.7%)	10 (15.2%)	1 (1.5%)	0 (0.0%)
Malawi	224	57 (25.4%)	23 (10.4%)	16 (7.2%)	26 (11.8%)
South Africa	1290	398 (30.9%)	319 (24.8%)	98 (7.6%)	66 (5.1%)
Eswatini	152	41 (27.0%)	25 (16.9%)	8 (5.4%)	10 (6.6%)
Uganda	596	144 (24.2%)	89 (15.0%)	36 (6.1%)	50 (9.0%)
Zimbabwe	779	224 (28.8%)	116 (14.9%)	46 (5.9%)	118 (15.3%)
Education					
None/Any Primary	538	125 (23.2%)	66 (12.3%)	35 (6.5%)	55 (10.8%)
Any Secondary	2316	683 (29.5%)	464 (20.1%)	154 (6.7%)	203 (8.9%)
Any Post Secondary	344	92 (26.7%)	74 (21.6%)	21 (6.2%)	12 (3.5%)
Marital Status					
Married or living as married	564	100 (17.8%)	50 (8.9%)	19 (3.4%)	44 (8.0%)
Has partner, not living together	1708	512 (30.0%)	376 (22.1%)	120 (7.1%)	122 (7.3%)
Single/Divorced Widowed	917	285 (31.1%)	177 (19.4%)	69 (7.6%)	103(11.6%)

28.2% Women who had STIs at baseline

STI events per 100 35.0 person years over the follow-up period

Women who had 14.7% recurrent STIs over the follow-up period

### RESULTS

- Of 3198 women tested for STIs (median age 25y), 28.2% had an STI at baseline, most commonly CT (Table 1).
- Among 2983 (92.5%) women with follow-up data, 2646 incident STI events occurred over 7557 person years (PY), incidence rate (IR) 35.0 events/100PY [95% CI 33.7-36.4]) (Fig 1).
- STI IRs ranged from 16.6 events/100PY in Kenya to 41.6 events /100PY in Eswatini.
- STI recurrence occurred among 438/2981 (14.7%) of the women, CT recurred commonly (among 297/2981, 10.0% women).
- Concurrent STIs were observed among 171/3198 (5.1%) of women at baseline and 272/2981 (9.1%) during follow-up.
- In multivariable analyses, STI incidence was significantly higher among women 18-24y vs. women 25+y; among single women and women not living with their partners vs. women married/living as married; and women with no/primary education and secondary education vs. those with higher education (Fig 2).
- There was no difference in CAB efficacy by STI status. The hazard ratio [HR] comparing HIV risk in the CAB group versus the TDF/FTC group was 0.08, 95% CI 0.02-0.35 among women who had STIs vs 0.14, 95% CI 0.03-0.61 among women without STIs, p=0.62.

**Figure 1**. STI disease burden among women 18-49 years participating in the blinded and unblinded period of the HPTN 084 PrEP trial, Nov-2017 to Sep-2023.

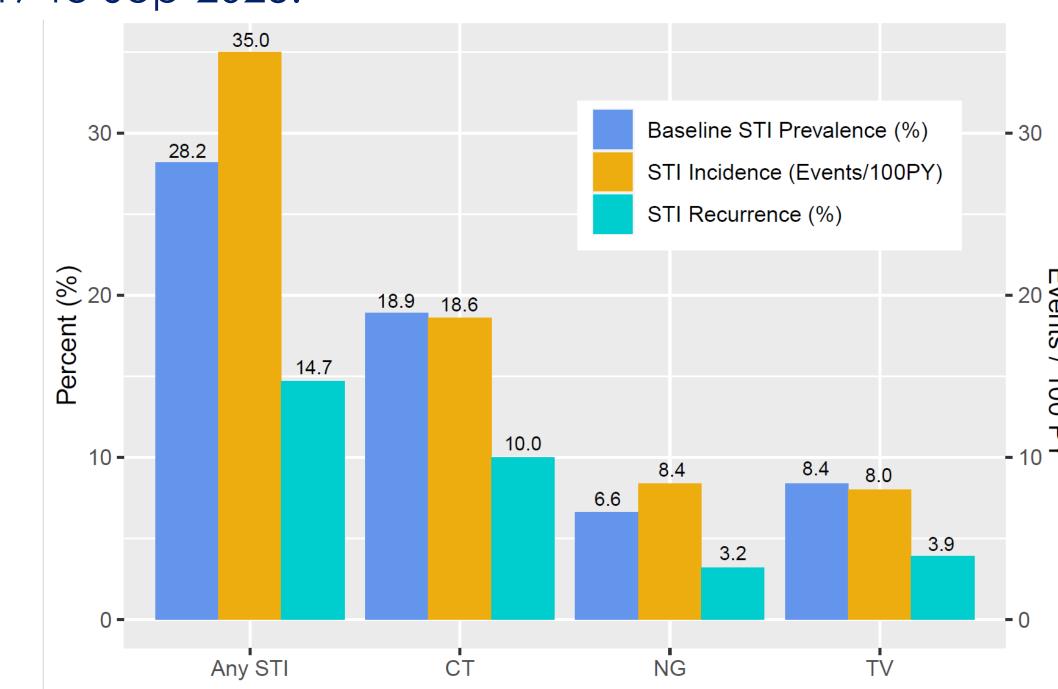
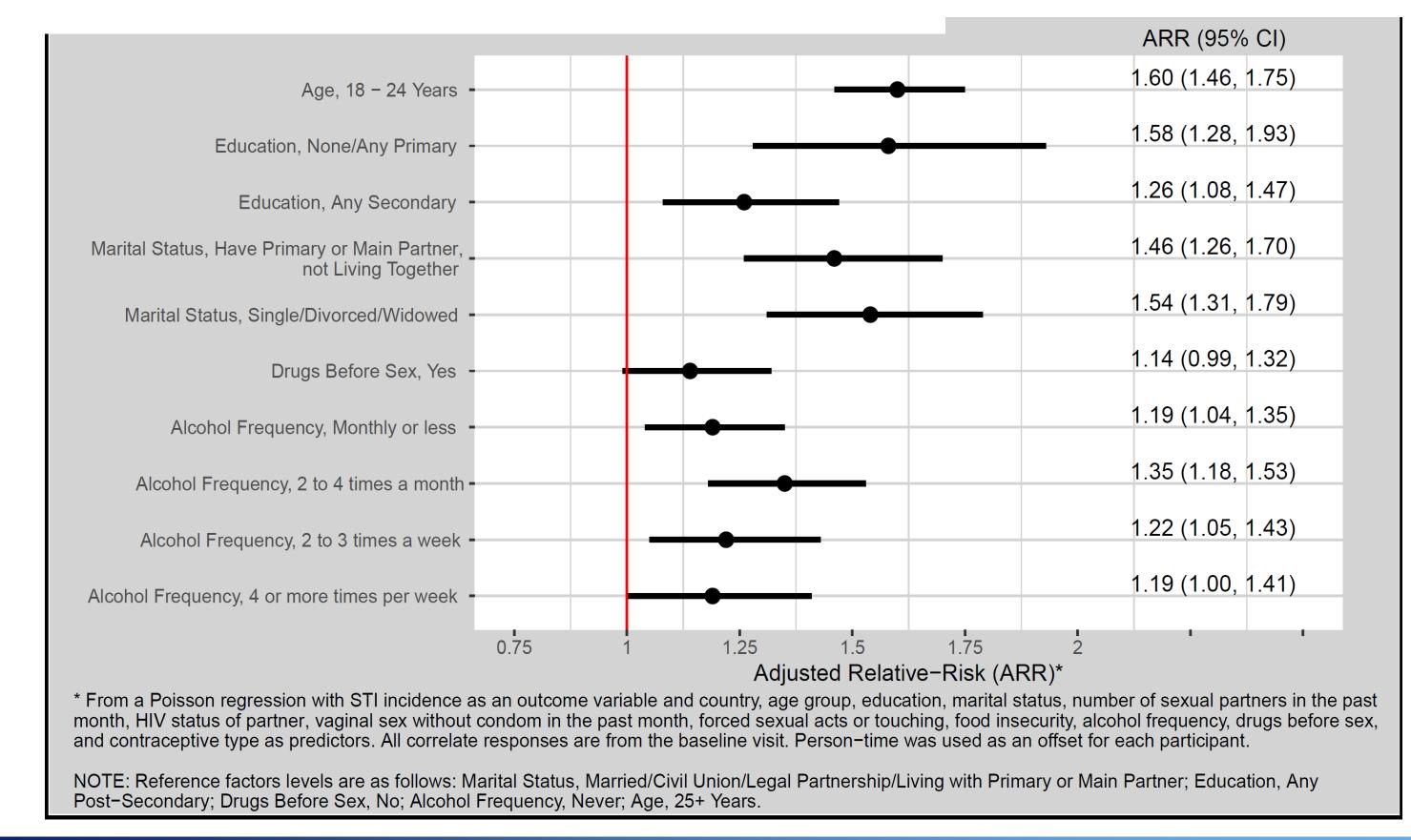


Figure 2. Correlates of incident STIs over the observation period



## CONCLUSIONS

The prevalence, incidence and recurrence of curable bacterial STIs was high in this cohort of women accessing PrEP and HIV prevention services. These findings highlight the urgent need to prioritize investments in novel, multipurpose, and scalable interventions to prevent STIs and HIV among these women and their partners.

#### ACKNOWLEDGEMENTS

With appreciation to HPTN 084 study participants, the investigator team, participating sites and staff, and collaborators.





Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619-15 (HPTN Leadership and Operations Center), UM1AI068617-15 (HPTN Statistical and Data Management Center), and UM1AI068613-15 (HPTN Laboratory Center). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

A major global health organization with projects in more than 40 countries, ICAP at Columbia University works to transform the health of populations through innovation, science, and global collaboration. Since its founding in 2003 at the Columbia Mailman School of Public Health, more than 2.8 million people have received HIV care through ICAP-supported programs. Learn