

BHIVA 'Best of CROI' feedback webinars 2023

Prevention Strategies

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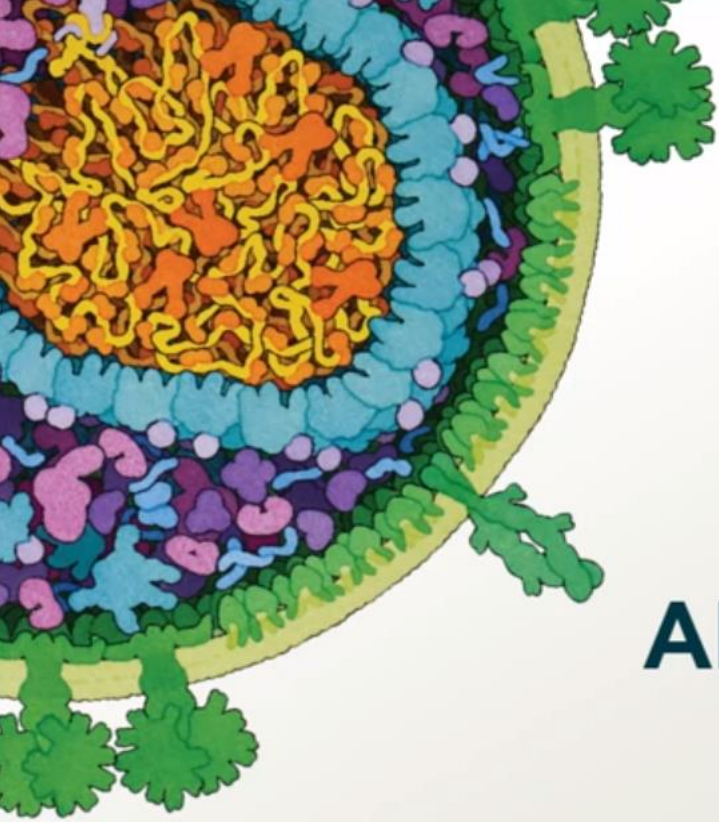
With thanks to those presenting research for permission to use slides for 'Best of CROI'



Conflict of Interest

I have been in receipt of conference support, speakers fees and advisory board honoraria from Gilead, Janssen, MSD, and ViiV.

I have received research support from Gilead.



ORAL ABSTRACT: OA-3

Monday, February 20, 2023

ANRS 174 DOXYVAC: AN OPEN-LABEL RANDOMIZED TRIAL TO PREVENT STIs IN MSM ON PrEP

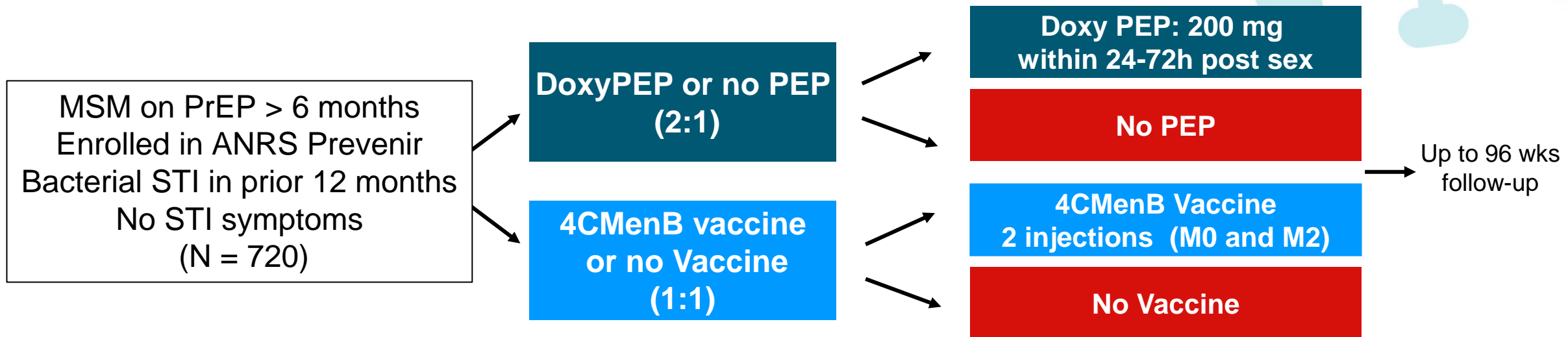
Jean-Michel Molina

University of Paris Cité, Paris, France

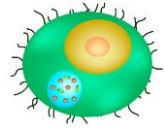
ANRS 174 DoxyVAC



- Phase III Multi-centre, open-label factorial randomised controlled trial to prevent STIs in GBMSM taking PrEP



Doxycycline PEP: Time to First STI



Chlamydia

26 participants
21 in No PEP arm (incidence: 19.3/100 PY),
5 in Doxy PEP arm (incidence: 2.1/100 PY)

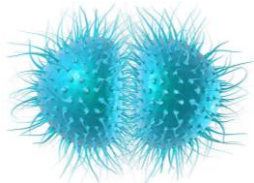
Adjusted Hazard Ratio:
0.11 (95% CI: 0.04-0.30, p<0.0001)



Syphilis

26 participants
18 in No PEP arm (incidence: 16.3/100 PY),
8 in Doxy PEP arm (incidence: 3.4/100 PY)

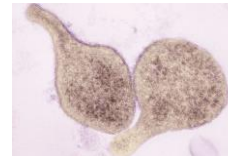
Adjusted Hazard Ratio:
0.21 (95% CI: 0.09-0.47, p<0.001)



Gonorrhoea

84 participants
40 in No PEP arm (incidence: 41.3/100 PY),
44 in Doxy PEP arm (incidence: 20.5/100 PY)

Adjusted Hazard Ratio:
0.49 (95% CI: 0.32-0.76, p=0.001)



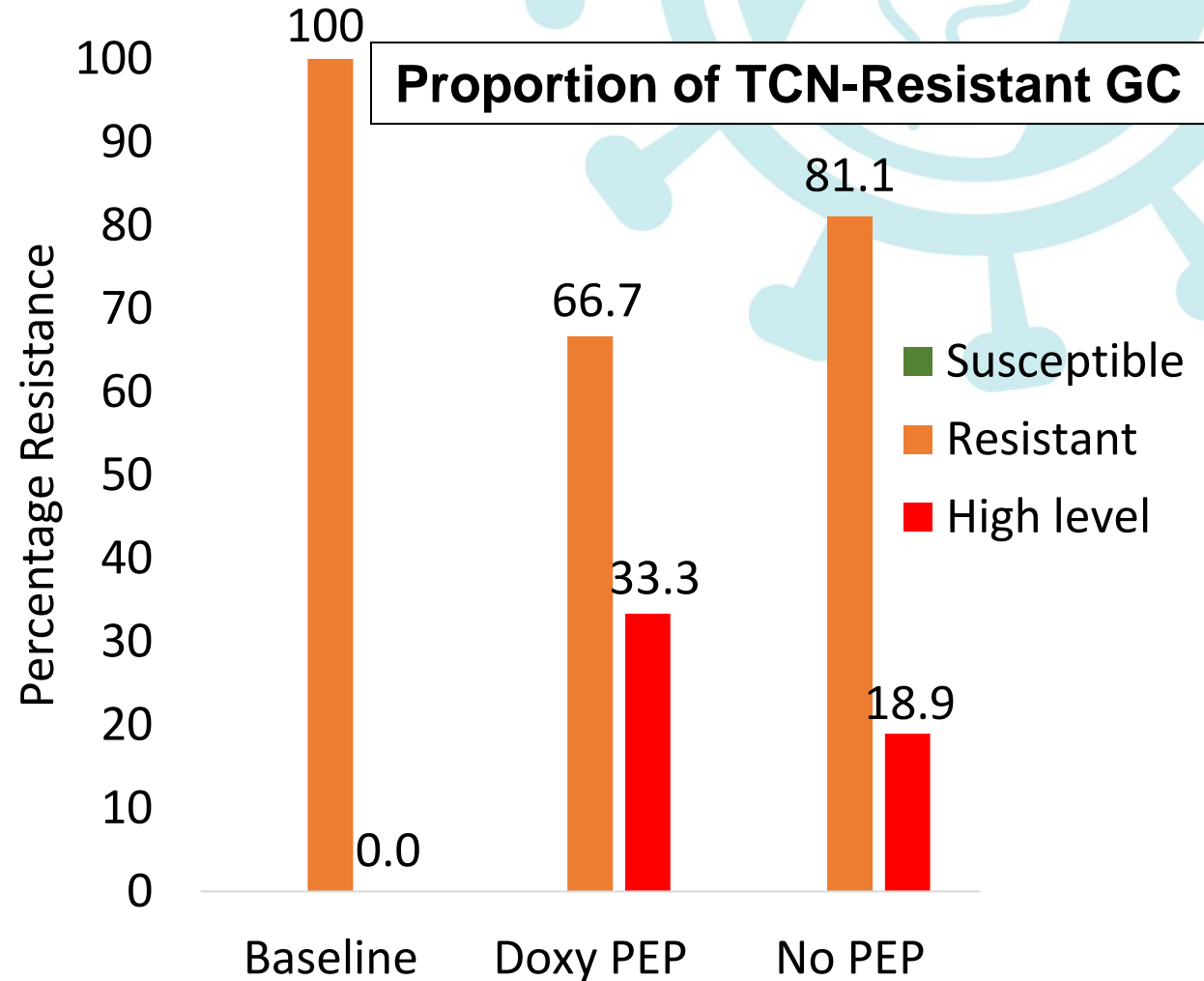
Mycoplasma Genitalium

68 participants
31 in No PEP arm (incidence: 29.4/100 PY),
37 in Doxy PEP arm (incidence: 16.8/100 PY)

Adjusted Hazard Ratio:
0.55 (95% CI: 0.34-0.89, p=0.015)

Doxycycline: Resistance & microbiome effects

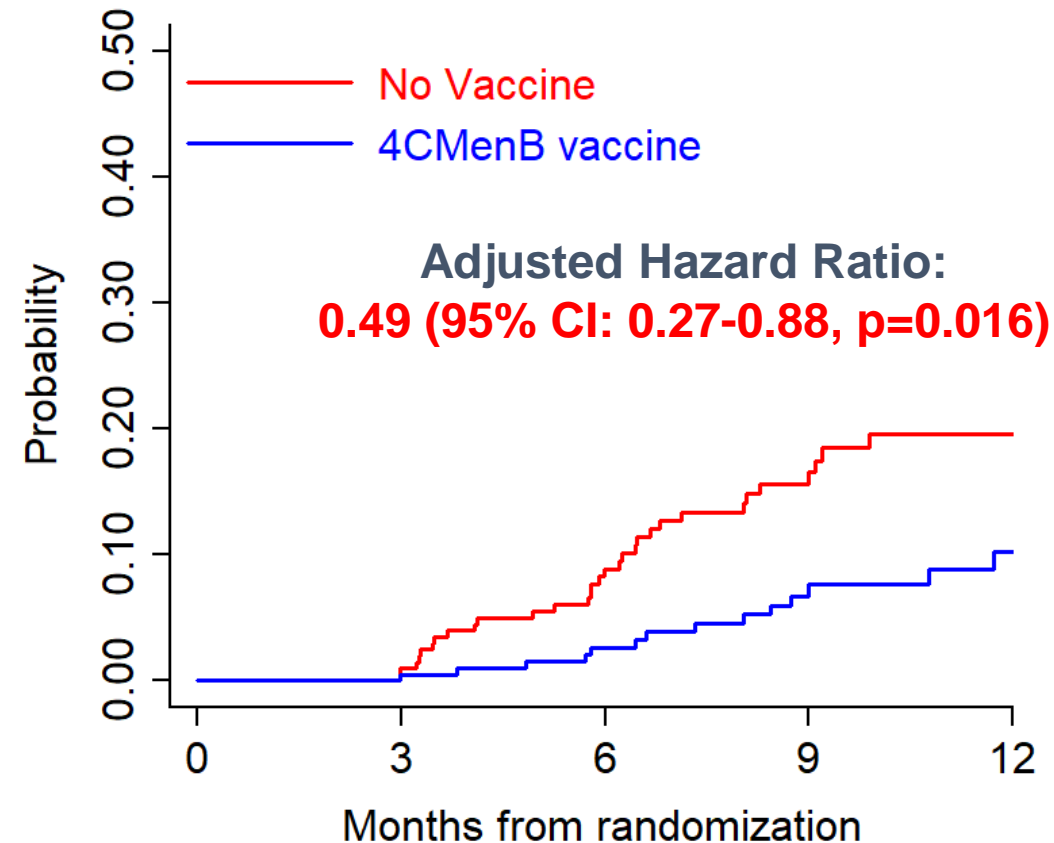
- **GC:**
 - 65 cultures available (15% of PCR+ve samples)
MICs determined by Etest, Resistance by EUCAST 2023 breakpoints
 - Resistance: MIC > 0.5 mg/L
 - High level resistance: MIC > 8 mg/L
- **CT:**
 - No CT Tetracycline resistance seen
 - 4/23 strains tested for TCN-R in culture: no resistance (but none from PEP arm)
 - 53/65 PCR+ swabs with 16S rRNA sequenced: no TCN-R mutation (only 3 from PEP arm)
- **Microbiome:**
 - No difference in detection of MRSA on throat swab or ESBL from rectal swabs between PEP and no-PEP groups



4CMenB Vaccine: Time to first GC infection

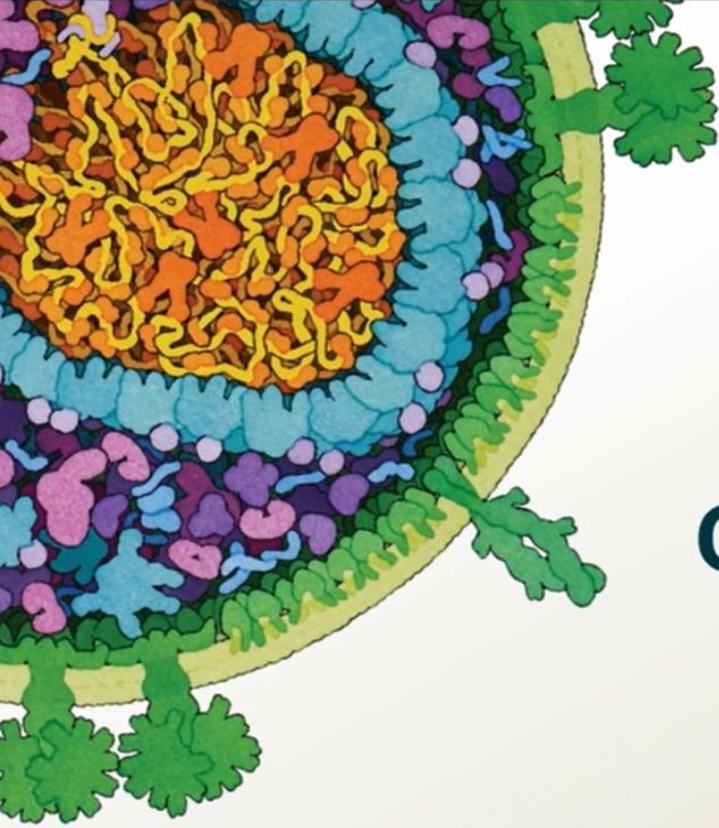
49 participants had GC
32 in No Vaccine arm
(incidence: 19.7/100 PY),
17 in 4CMenB vaccine arm
(incidence: 9.8/100 PY)

GC infections were considered from M3 visit (1 month after 2nd vaccine dose)



Number at risk

No Vaccine	245	208	150	91	49
4CMenB vaccine	257	208	170	102	49



ORAL ABSTRACT: OA-8

Tuesday, February 21, 2023

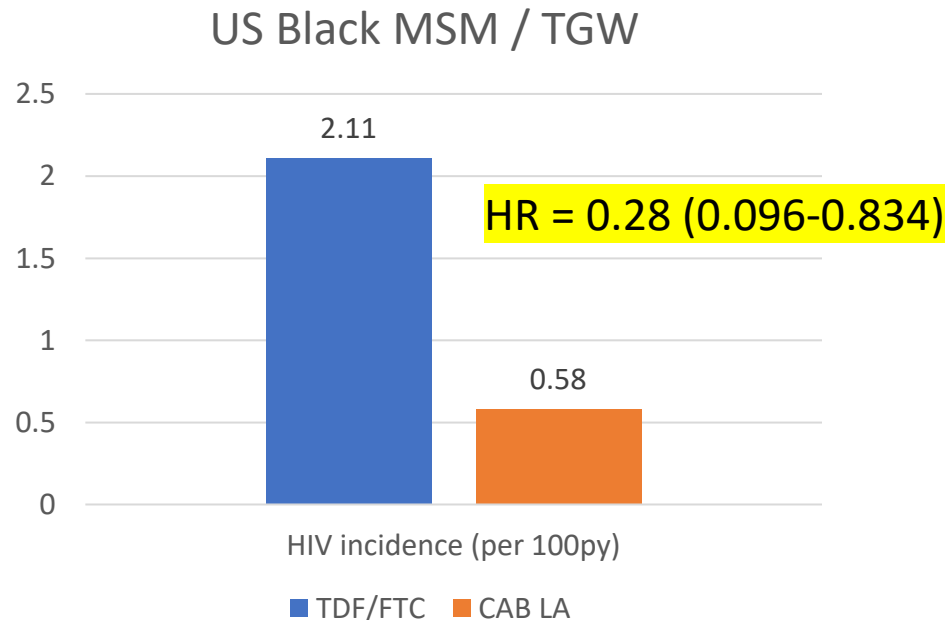
CABOTEGRAVIR FOR HIV PrEP IN US BLACK MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN

Hyman Scott

San Francisco Department of Public Health, San Francisco, CA, United States

HPTN083 – US Black MSM & TGW sub-group analysis

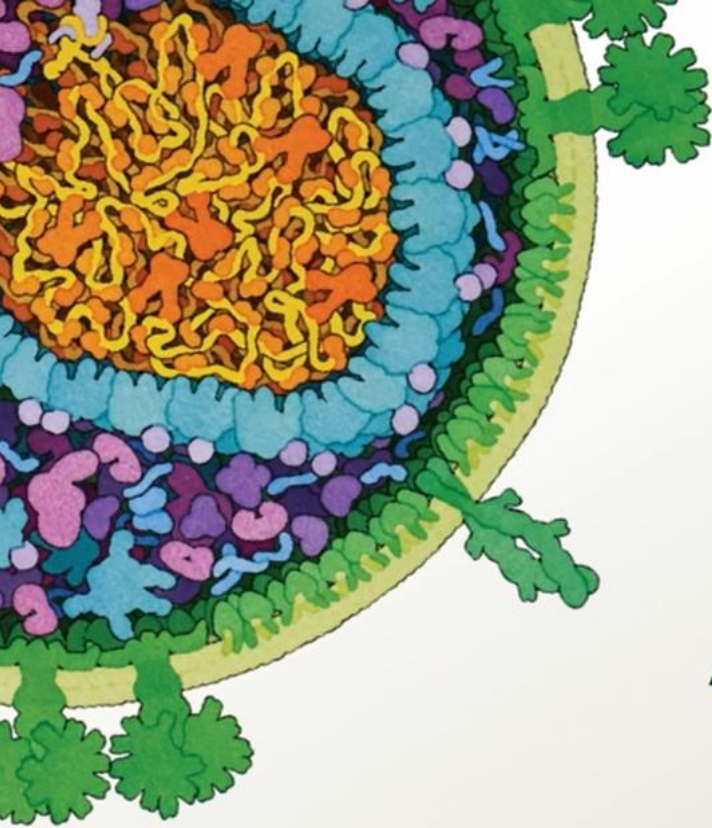
- US Black MSM +TGW, n = 844 (49.7%)
 - Equivalent / lower markers of behavioural transmission risk (no. sex partners, condomless AI acts, recreational drug use)
 - Higher rates of STIs (e.g. syphilis 4.0% vs 1.9%)



Adherence

TFV levels in DBS consistent with ≥ 4 tabs per week:

- 65% in Black US
- 81% in non-Black US



ORAL ABSTRACT: OA-8

Tuesday, February 21, 2023

8+ YEARS POOLED ANALYSIS: ADHERENCE AND HIV INCIDENCE IN 6000 WOMEN ON F/TDF FOR PrEP

Jeanne MARRAZZO

University of Alabama at Birmingham, Birmingham, AL, United States

8+ year pooled analysis: adherence & HIV incidence in 6000 women on F/TDF for PrEP

- 11 TDF/FTC studies from 6 countries over an 8yr period (n=6296)
- Adherence explored for 2955 participants – adherence declined over time in general for this cohort by objective and subjective measures
- Overall: low incidence of HIV infection - 32 women acquired HIV
- Higher levels of adherence was directly associated with lower risk of HIV acquisition
- Effectiveness of TDF/FTC was similar for those demonstrating consistently high (7tabs/wk) or high (>4tabs/wk) levels of adherence
- >50% of participants did not use F/TDF consistently - ?role for LA preparations

Pre-clinical prevention interventions

Human



- **TAF/EVG rectal insert** (Abs #164, Riddler et al)
 - Phase 1: n=21
 - 71% male
 - Good safety
 - High tissue levels – TFV present up to 72 hours after administration
 - Good ex vivo HIV inhibition in rectal tissue explants

- ~~Islatravir~~ **monthly oral PrEP** (Abs #192 – Squires)

Macaque



- **Lenacapavir** (Abs #992, Bekerman et al)
 - Development of target drug concentration for complete protection from single sub-cut injection with rectal SHIV challenge
- **Islatravir Implant** (Abs #989, Daly et al)
 - Protection against vaginal challenge
- **TAF/EVG vaginal insert** (Abs #990, Makarova et al)
 - On-demand PEP
 - Good efficacy if 8 hours after exposure, lower at 24 hours