# *Incidence and Predictors of STIs and Effect on Immune Activation Among Women in the HVTN 705/HPX2008 trial*

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## BACKGROUND

- The HVTN 705 study was a phase 2b placebo-controlled efficacy trial of Ad26.Mos4.HIV and aluminum phosphate-adjuvanted clade C gp140 in preventing HIV-1 infection.
- Understanding patterns of STIs among participants can verify that trial participants were engaging in behaviors that might expose them to HIV
- Chlamydia and other STIs are associated with increased immune activation, which could affect immune responses to HIV vaccines.

## METHODS

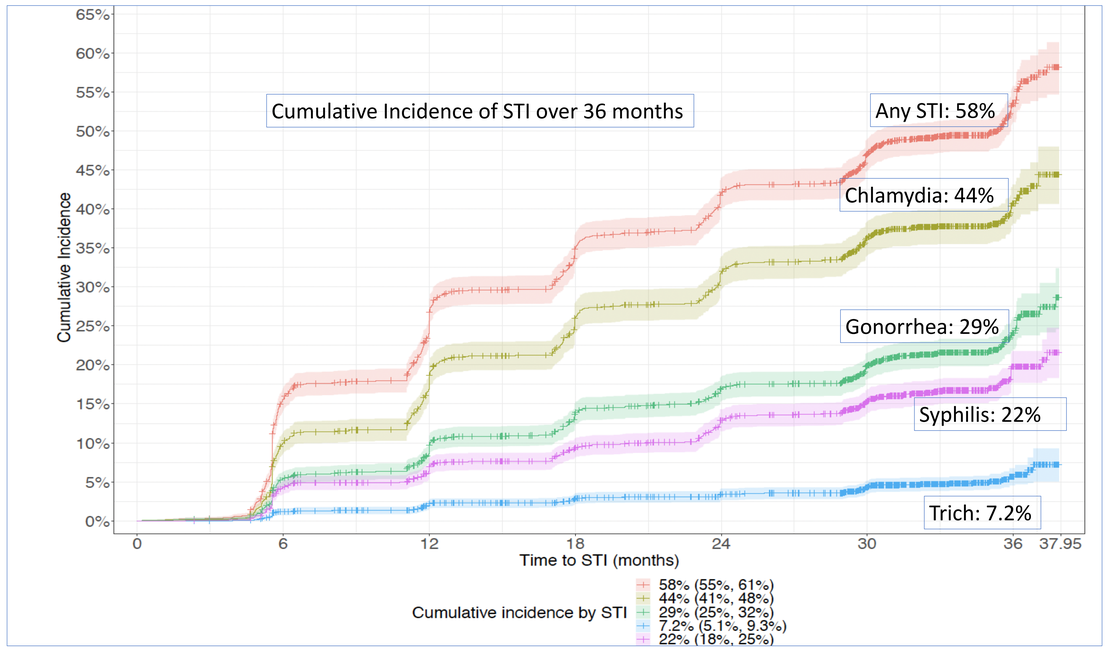
- A secondary analysis included all enrolled women aged 18 to 35 in Malawi, Mozambique, South Africa, Zambia and Zimbabwe.
- We estimated **baseline prevalence** of **Chlamydia, gonorrhea, trichomoniasis and syphilis**, and calculated the **incidence** and **cumulative incidence** of the first occurrence of STI between enrollment and month 36.
- We assessed **predictors** of incident STIs using a multivariate Cox proportional hazards model.
- We compared immune activation markers (**IgG, IgG3, IgA, antibody dependent cellular cytotoxicity [ADCC](luc), and antibody dependent cellular phagocytosis [ADCP]**) among a subset of women with and without baseline chlamydia using weighted geometric mean ratios (GMR)

| STI Category | N event | Person-years at risk | Incidence rate in % per 100 person years (95% CI) |
|---|---|---|---|
| **Chlamydia** | **742** | **4257.0** | **17.4 (16.2, 18.7)** |
| **Gonorrhea** | **498** | **5559.8** | **9.0 (8.2, 9.8)** |
| **Trichomoniasis** | **378** | **5609.4** | **6.7 (6.1, 7.5)** |
| **Syphilis** | **117** | **6327.6** | **1.8 (1.5, 2.2)** |
| **Any STI** | **1228** | **4860.9** | **25.3 (23.9, 26.7)** |

**STIs were common among women in the HVTN 705 HIV vaccine trial. Prior STI and younger age were associated with increased risk of incident STIs. Chlamydia infection was associated with higher CD123+ but no other immune activation markers.**

## RESULTS

- Among 2,636 participants enrolled in the HVTN 705 study, 841 (31.9%) had baseline STIs
- Among 841 with baseline STIs, most were between 21 and 30 years (66.2%) with secondary education (82.4%).




## RESULTS CONT.

- Median sexual partners in the past month was 2 (IQR 1,4), sexual acts was 8 IQR (4,16).
- Few reported having a known partner living with HIV (1.4%), consistent condom use (10.0%) and prior diagnosis of an STI (4.5%).
- Prior STI diagnosis was associated with increased risk of acquiring any STI (adjusted HR (aHR) =1.38, 95% CI: 1.06, 1.80).
- Older age was associated with decreased risk of any STI (aHR =0.95, 95% CI: 0.94, 0.97).
- Chlamydia infection was associated with CD123+ cells [GMR 1.23 (95% CI: 1.06, 1.43)], but did not show differences in other immune activation markers.
- No differences were observed in weighted GMR for the rest of baseline immune markers between women with and without chlamydia at study entry.

## CONCLUSIONS

- STIs were common among participants in HVTN 705/HPX2008 trial.
- Risk of incident STIs was higher among women with recent anal sex or prior STI.
- Chlamydia infection did not result in broad differences in baseline immune activation, suggesting that it should not alter immune responses to vaccination.

## ACKNOWLEDGEMENTS

We'd like to acknowledge all the clinical research sites and women who participated in the HVTN 705 study.

IMBOKODO

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