# *Maternal ART use and preterm delivery: impact of data sources and data quality*

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## BACKGROUND

- Studies investigating association between maternal antiretroviral therapy (ART) use and adverse birth outcomes have had inconsistent findings.
- Majority of studies investigating associations between maternal ART and preterm delivery (PTD) are observational and subject to bias, possibly contributing to heterogeneity in findings.
- We investigated the impact of participant selection, data source and data quality on observed associations between maternal ART and PTD.

## METHODS

- Pregnant women accessing health care at public sector antenatal facilities in the Western Cape Province (Cape Town, South Africa) were enrolled into a multi-component study (B-Positive), collecting data from the same underlying population the same time period (January 2017-July 2018).

- Data from 3 related sources were compared.
  - Province-wide pregnancy surveillance
    - Routine electronic health data - records linked across health services by Provincial Health Data Centre (PHDC).
  - Facility-based pregnancy exposure registry (PER)
    - Digitisation of patient-held booklet recording pregnancy-related clinical information. Gestational age (GA) based on best available (ultrasound, SFH and/or LMP)
  - Prospective cohort study
    - Active follow-up with ultrasound determined GA, questionnaire-based data collection and clinical records abstraction.
- Data availability, detail and quality of baseline characteristics varied by data source.
- Associations between maternal ART and PTD examined separately to assess impact of data source.
- PTD compared by:
  - HIV status (HIV+ vs HIV-)
  - ART status (initiation preconception vs during pregnancy).

**Significant differences in preterm delivery risk by HIV/ART status only detectable in large population level dataset, likely because size of effect is now smaller**

## RESULTS

- Median age (27yrs) similar across data sources, however proportions of HIV+ women differed:
  - PHDC (n=183593): 19% HIV+ of whom 56% on ART preconception
  - PER (n=9476): 32% HIV+ of whom 66% on ART preconception;
  - Cohort study (n=989): 48% HIV+ of whom 70% on ART preconception (82% TDF+FTC+EFV, 7% PI-based regimens).

- Among women with live singleton births, increased PTD risk in HIV+ women (**ARR 1.15, 95% CI 1.11 - 1.18**) and women on preconception ART (**ARR 1.08, 95% CI 1.01 - 1.14**) was only observed in PHDC (Figure 1).
- Associations observed in the PER and cohort study populations were less pronounced, with no significant differences seen by HIV status and timing of ART initiation (Figure 1).
- Differences in the representativeness of HIV-infected women seen across the data sources and differing data quality did not appear to impact the association estimates observed.

## RESULTS Cont.

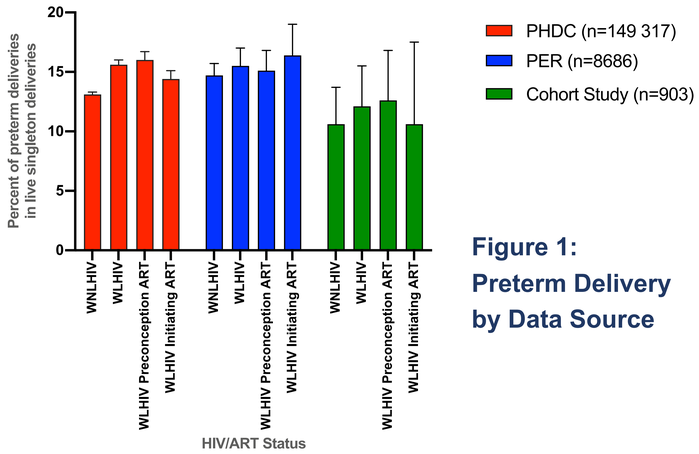


**Figure 1: Preterm Delivery by Data Source**

## CONCLUSIONS

- In this comparison of routine care cohorts across different data sources, the risk of PTD was increased in HIV-infected women in the larger PHDC population.
- In high HIV burden settings, even those with arguably the more mature digital health systems, the risks of bias due to measurement issues will be difficult to rule out.
- Findings demonstrate that because size of effect is smaller, future investigations of the association between HIV/ART status and adverse birth outcomes should include both population level data (to achieve precision for meaningful inferences) and prospective studies (to enable detailed measures of exposures and outcomes) in order to leverage the benefits of both sets of data sources.

## ADDITIONAL KEY INFORMATION

- Funded by NICHD: Grant Number R01HD080465
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