# Pregnancy Outcomes Among Women Living with HIV who received the Quadrivalent HPV Vaccine During Pregnancy

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# Background

- Women living with HIV (WLWH) experience poorer outcomes associated with HPV infection compared to women without HIV 1-5
- HPV vaccines have shown good immunogenicity and efficacy in WLWH to date <sup>6,7</sup>
- Studies among women without HIV who received HPV vaccine during pregnancy have found no increased risk of adverse pregnancy outcome 8-10
- No studies have assessed pregnancy outcomes following HPV vaccination during pregnancy in WLWH

## Objective

The objective of this analysis was to assess pregnancy outcomes among WLWH vaccinated against HPV during pregnancy or near conception (within three months of last menstrual period)

1. Blitz et al. 2013. 2. Massad et al. 2014. 3. Branca et al. 2004. 4. Ferenczy et al. 2003. 5. Silverberg et al. 2002. 6. Money et al. 2016. 7. McClymont et al. 2019. 8. Faber et al. 2019. 9. Scheller et al. 2017. 10. Goss et al. 2015.

### Methods

**Study Design:** Prospective longitudinal cohort study to assess vaccine immunogenicity

#### **Study Population:**

- 415 girls and WLWH aged ≥9 years from 14 clinical sites across Canada were enrolled to receive 3 doses of quadrivalent HPV (qHPV) vaccine at months 0, 2, and 6
- Participants were not pregnant at the time of study enrolment (by urine pregnancy test) and were willing to avoid pregnancy for the vaccination phase

#### **Data Collected:**

- Demographics, ongoing health and medication history, adverse events, and clinical data were collected
- If conception occurred prior to or shortly after a vaccine dose was administered, pregnancy and infant outcomes were documented

### Results

353 WLWH received ≥1 dose of qHPV vaccine

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Characteristic	N (%) or Median (IQR)
Age (years)	36 (27-43)

Characteristics of Eligible Participants (n=353)

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CD4 count (cells/mm³)	523 (384-710)
CD4 nadir (cells/mm³)	242 (123-367)
HIV viral load suppressed Yes No Unknown	236 (66.9%) 96 (27.2%) 21 (5.9%)
Vaccinated	

8 (2.3%)

9 (2.5%)

While pregnant

Within 3 mo. of conception

- 8 WLWH were vaccinated while pregnant (Median gestational age 0.4 months, IQR: 0.1-0.7)
- 9 WLWH were vaccinated pre-conception (Median time pre-conception was 1 month, IQR: 0.9-2.5)

Pregnancy/Infant Outcomes of WLWH Vaccinated While Pregnant or Within 3 Months of Conception (n=17)

Outcome	N (%) or Median (IQR)
Pregnancy outcome Live birth Therapeutic abortion Spontaneous abortion Stillbirth	9 (52.9%) 7 (41.2%) 1 (5.9%) 0
GA at delivery (n=9 live births)	39.4 (38.6-40.1)
Birth weight (grams, n=9)	2830 (2698-3755)
Apgar score - 1 min (n=9)	9 (9-9)
Apgar score - 5 min (n=9)	9 (9-9)

- 3/7 TA occurred to women vaccinated while pregnant; reason for TA was not documented
- 1 SA occurred to a woman vaccinated while pregnant,3 months after vaccine dose
- There were too few pregnancies among WLWH vaccinated during/near pregnancy to statistically compare their pregnancy outcomes with those of controls

### Conclusion

- Adverse pregnancy outcomes were uncommon among qHPV-vaccinated WLWH in our cohort
- These findings are consistent with reproductive safety data for qHPV vaccines in cohorts of women without HIV

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