

Antepartum weight gain and adverse pregnancy outcomes in IMPAACT 2010

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Background and Rationale

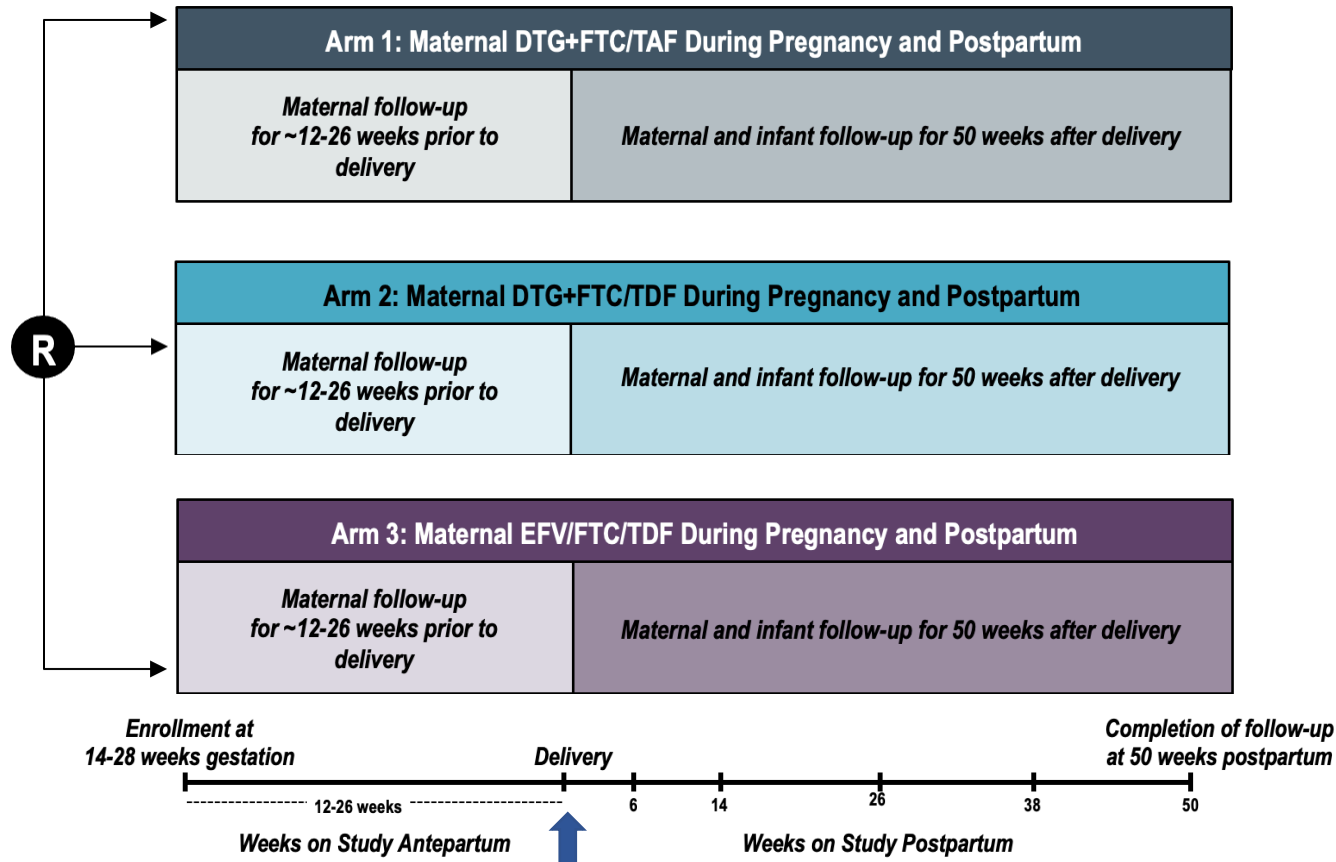
- ▶ ART containing dolutegravir (DTG) and/or tenofovir alafenamide fumarate (TAF) is associated greater weight gain in both non-pregnant and pregnant women^{1,2}
- ▶ Efavirenz (EFV) and tenofovir disoproxil fumarate (TDF) have been associated with low weight gain in pregnancy²
- ▶ Both insufficient and excessive weight gain in pregnancy have been associated with adverse pregnancy outcomes³
- ▶ IMPAACT 2010: pregnant women with HIV-1 randomized to start treatment with DTG+FTC/TAF, DTG+FTC/TDF, or EFV/FTC/TDF
 - ▶ Significantly lower rate of adverse pregnancy outcomes in women in DTG+FTC/TAF arm than other two arms⁴

Objectives and Methods

- ▶ Estimated by-arm differences in average antepartum weekly weight gain using generalized estimating equations
- ▶ Evaluated associations between weight gain and adverse pregnancy outcomes using Cox-proportional hazards regression*:
 - ◆ Composite outcome of stillbirth (≥ 20 wks GA), preterm delivery (< 37 wks GA) and small for gestational age (SGA: $< 10^{\text{th}}$ percentile)
 - ◆ Individual components of the composite outcome
 - ◆ Neonatal death
- ▶ Weight categories: low weight gain < 0.18 kg/week and high weight gain > 0.59 kg/week (Institute of Medicine Guidelines)

*Weight included as a time-varying covariate; analyses adjusted for gestational age at baseline

IMPAACT 2010 Study Design



Key Eligibility Criteria

- Pregnant women 14-28 weeks gestation

- ART-naïve

Enrollment and Weight Data Availability

Screened = 810

Enrolled = 643 (79%)
Jan 2018 – Feb 2019

Antepartum weight data
available = 643 (100%)

Antepartum weight and pregnancy outcome data
available = 632 (98.3%)

**Participants were enrolled at
22 sites in 9 countries**

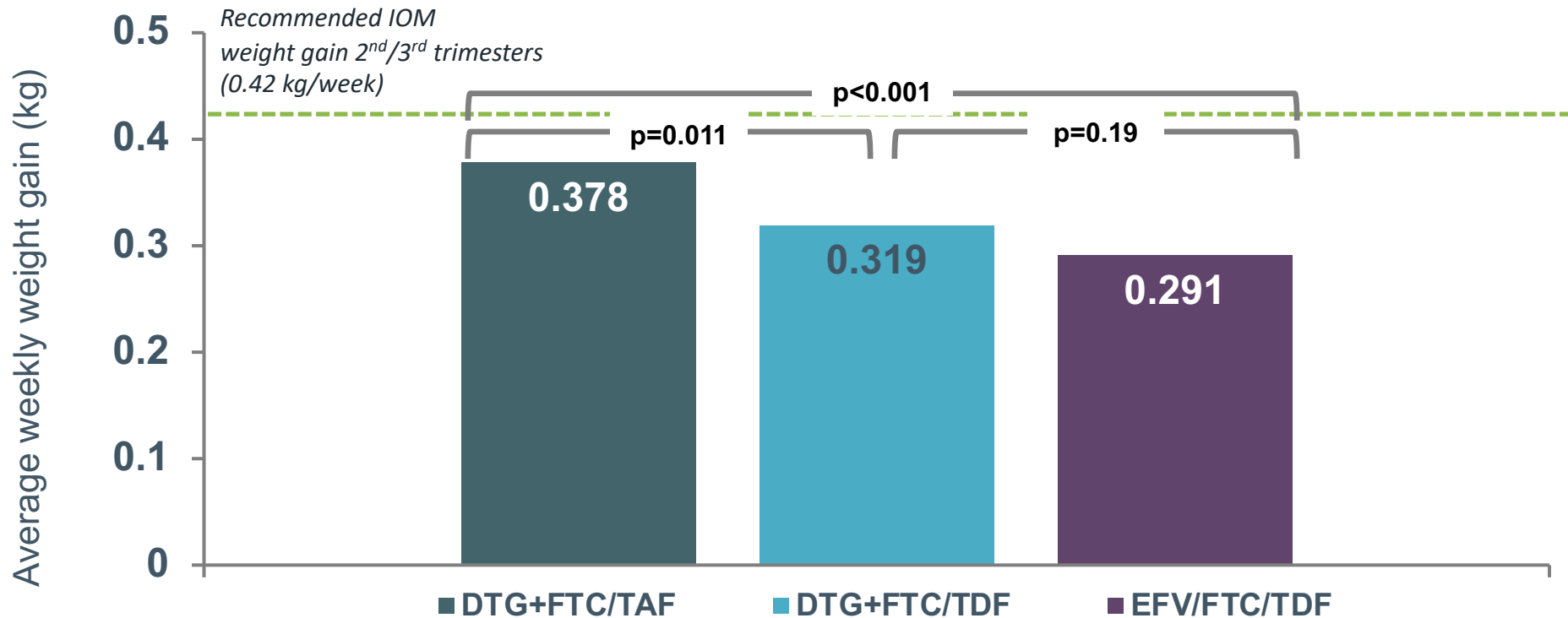
(Botswana, Brazil, India, South Africa,
Tanzania, Thailand, Uganda, US,
Zimbabwe)

Maternal Baseline Characteristics

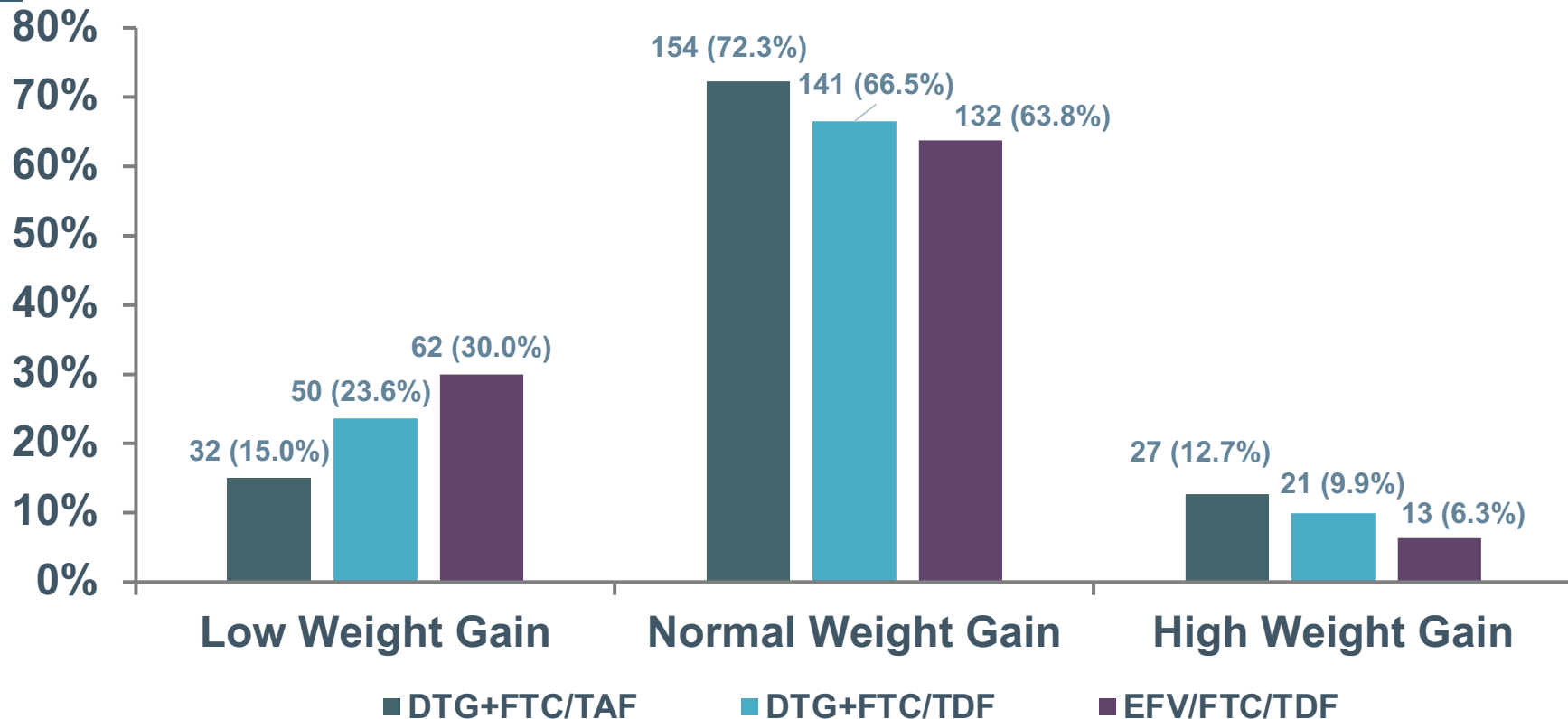
	DTG+FTC/TAF (N = 217)	DTG+FTC/TDF (N = 215)	EFV/FTC/TDF (N = 211)	Total (N = 643)
Age (median years)	26.8	26.0	26.6	26.6
Enrolled in Africa	187 (86%)	189 (88%)	188 (89%)	564 (88%)
Gestational age (median weeks)	22.1	21.3	22.1	21.9
CD4 count (median cells/mm ³)	467	481	439	466
HIV-1 RNA (median copies/mL)	781	715	1357	903
Enrollment weight, mean kg (SD)	67.7 (15.1)	66.3 (16.8)	64.5 (13.3)	66.2 (15.2)

Median duration of antepartum follow-up: 17.4 weeks

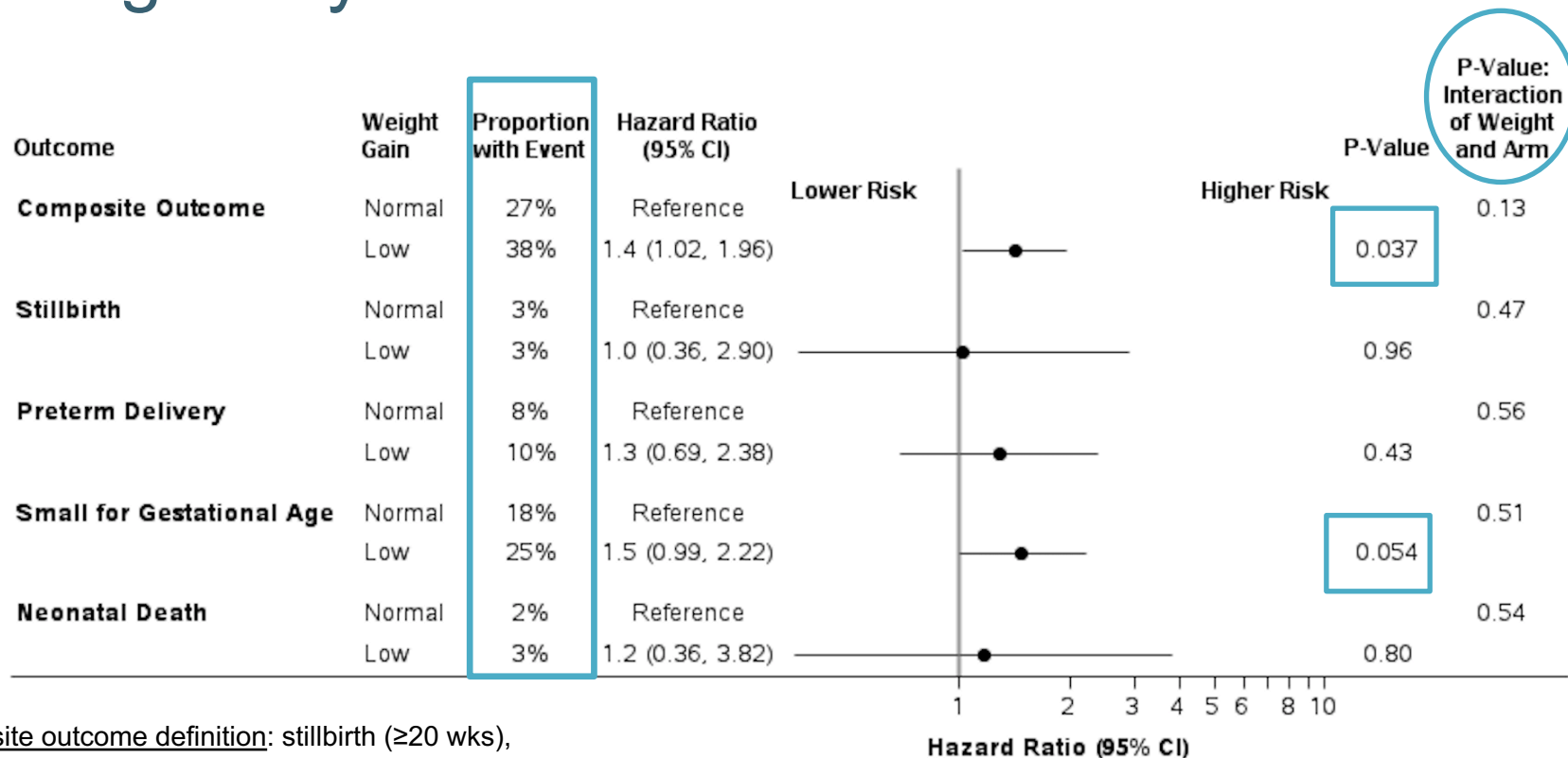
Results: Average Weekly Maternal Weight Gain by Arm



Low, Normal, and High Antepartum Weight Gain by Arm



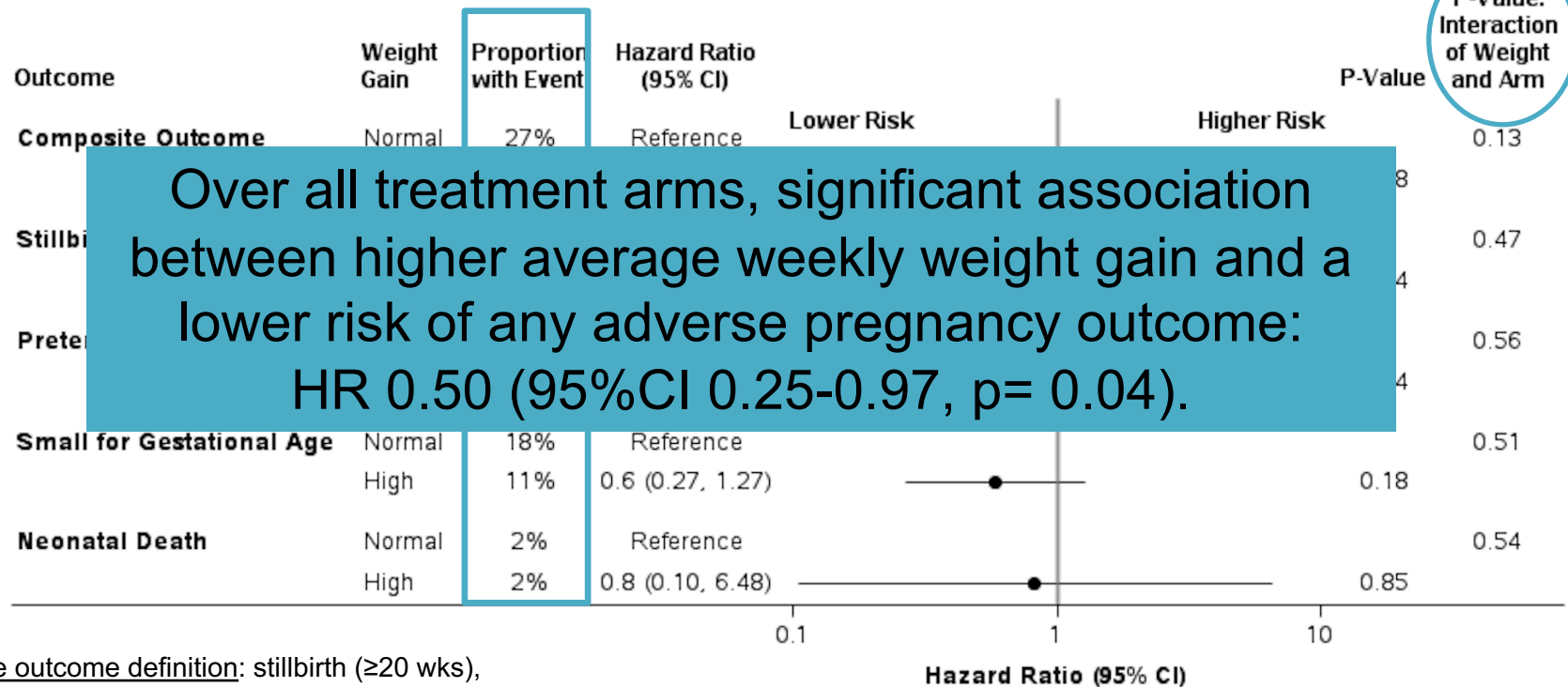
Low Antepartum Weight Gain and Adverse Pregnancy Outcomes



Composite outcome definition: stillbirth (≥ 20 wks), preterm delivery (< 37 wks), and small for gestational age ($< 10^{\text{th}}$ percentile)

Adjusted for gestational age stratum at baseline

High Antepartum Weight Gain and Adverse Pregnancy Outcomes

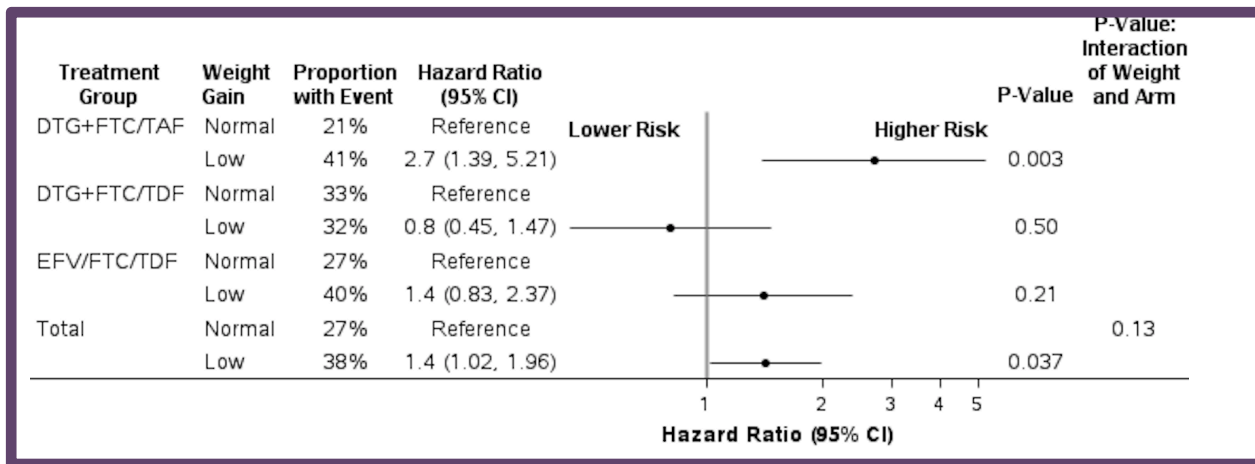


Composite outcome definition: stillbirth (≥ 20 wks), preterm delivery (< 37 wks), and small for gestational age ($< 10^{\text{th}}$ percentile)

Adjusted for gestational age stratum at baseline

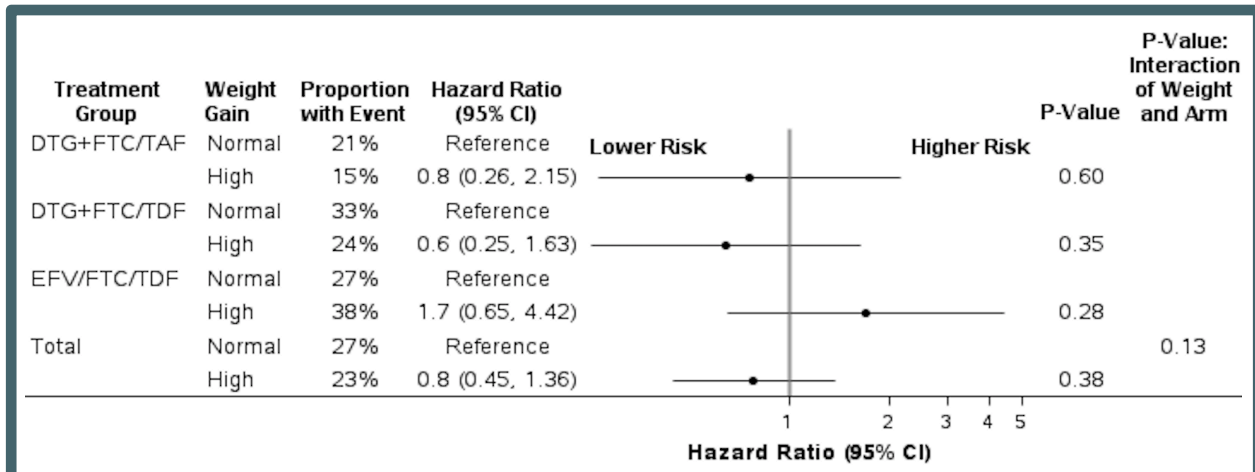
Weight Gain and Composite Adverse Pregnancy Outcome* by Arm

Low vs Normal Weight Gain



Adjusted for gestational age stratum at baseline

High vs Normal Weight Gain



*Composite outcome definition: stillbirth (≥ 20 wks), preterm delivery (< 37 wks), and small for gestational age ($< 10^{\text{th}}$ percentile)

Future Analyses and Limitations

- ▶ Further planned analyses
 - ▶ Comparison of average weekly weight gain by arm within low/normal/high groups
 - ▶ Further study of by arm weight trajectories over antepartum period
 - ▶ Detailed analysis of postpartum weight through 50 weeks
- ▶ Limitations: lack of pre-pregnancy weight/BMI; predominantly an African population, all women initiating ART in pregnancy

Conclusions

- ▶ Low weight gain during pregnancy was most common in women starting EFV/FTC/TDF and least common with DTG+FTC/TAF
- ▶ Low but not high weight gain associated with adverse pregnancy outcomes
- ▶ Weight gain on DTG+FTC/TAF approached average weight gain recommended in the 2nd/3rd trimester based on IOM standards
- ▶ The lower rate of adverse pregnancy outcomes observed in the DTG+FTC/TAF arm could be related to higher antepartum weight gain

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