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## BACKGROUND

- Dolutegravir (DTG) and efavirenz (EFV) have been associated with neuropsychiatric symptoms, which may impact adherence to antiretroviral therapy (ART).
- Limited information is available on the impact of DTG and EFV on mental health in the postpartum period.
- We compared depression, sleep disturbances and anxiety during pregnancy and through 50 weeks after delivery in women living with HIV receiving DTG and EFV-containing treatment in nine countries.

## METHODS

Pregnant women with HIV were randomized to start ART regimens at 14-28 weeks of gestation:

<b>EFV Group</b> efavirenz/ tenofovir disoproxil fumarate/ emtricitabine	<b>DTG Group</b> dolutegravir + tenofovir alafenamide / Emtricitabine	<b>DTG Group</b> dolutegravir + tenofovir disoproxil fumarate / emtricitabine
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Outcome measures were assessed as follows, and the evaluation was translated into local languages:

### Depression:

- Edinburgh Postnatal Depression Scale (EPDS), ranging from 0 (better) to 30 (worse), was administered by trained study staff at Postpartum (PP) Weeks 6 and 50.
- Depression was defined as EPDS  $\geq 9$  or expressed suicidal ideation (Response of "Yes, quite often" to question 10: "The thought of harming myself has occurred to me").

### Anxiety:

- Generalized Anxiety Disorder 7-item (GAD-7), ranging from 0 (better) to 21 (worse), was administered by trained study staff at Entry, Antepartum (AP) Week 8 and PP Week 38.
- Anxiety was defined as GAD-7 score  $\geq 10$ .

### Sleep disturbances:

- Pittsburgh Sleep Quality Index (PSQI), ranging from 0 (better) to 21 (worse), was administered by trained study staff at Entry, AP Week 8 and PP Week 38.
- Sleep disturbances was defined as PSQI score  $\geq 5$ .

- 1) Depression, anxiety and sleep disturbances occurred at similar rates during 50 weeks postpartum in women who started DTG-based vs EFV-based ART during pregnancy.
- 2) Roughly 1 in 5 women were affected by postpartum depression in both ART regimens.

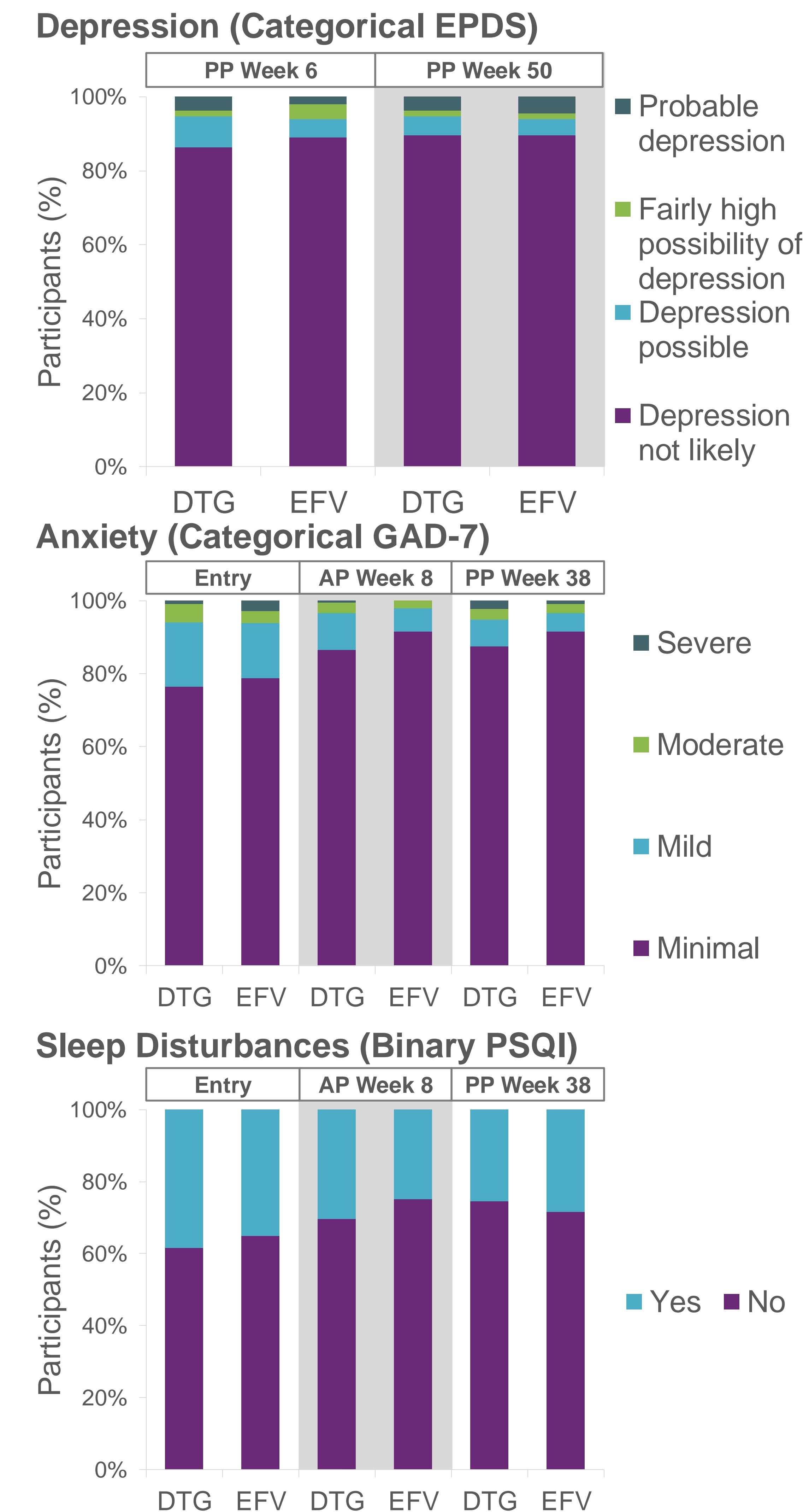
## RESULTS & CONCLUSIONS

- 643 participants were randomized (432 to DTG group and 211 to EFV group), with a mean (SD) age of 27.4 (6.0) years and 91.0% (585/643) as Black African.
- The percentage of participants with depression at PP Weeks 6 and/or 50 was 19.6% (82/419) in DTG group and 17.6% (36/205) in EFV group, with a difference (DTG - EFV) of 2.0% (95% CI: -4.4%, 8.5%).
- No statistically significant mean difference in EPDS scores between DTG and EFV groups at PP Week 6 (p-value = 0.33) or at PP Week 50 (p-value = 0.87).

TABLE 1. Estimates of Between-Treatment Group Differences in Outcomes

Outcome Measure	Visit	DTG	EFV	Method (Estimator)	Estimate (95% CI)
EPDS Total Score (mean (SD))	PP Week 6	3.63 (4.29)	3.30 (3.86)	Two-sample t-test with unequal variances (mean difference)	0.33 (-0.34, 1.01)
	PP Week 50	2.99 (4.18)	2.93 (3.97)		0.06 (-0.63, 0.74)
GAD-7 Total Score (mean (SD))	Entry	2.96 (3.41)	2.99 (4.01)	Generalized estimating equations (mean difference)	-0.12 (-0.66, 0.42)
	AP Week 8	1.70 (2.88)	1.32 (2.36)		0.18 (-0.20, 0.57)
	PP Week 38	1.69 (3.77)	1.18 (2.68)		0.41 (-0.02, 0.85)
PSQI Total Score (mean (SD))	Entry	4.29 (3.03)	4.19 (2.93)	Generalized estimating equations (mean difference)	0.05 (-0.42, 0.52)
	AP Week 8	3.69 (2.81)	3.19 (2.42)		0.40 (-0.002, 0.80)
	PP Week 38	3.17 (2.85)	3.10 (2.64)		0.02 (-0.41, 0.44)
Depression (n/N (%))	PP Week 6 and/or PP Week 50	82/419 (19.6)	36/205 (17.6)	Point estimates (difference in proportion)	2.01% (-4.44%, 8.46%)
Anxiety (n/N (%))	AP Week 8 and/or PP Week 38	19/406 (4.7)	7/198 (3.5)	Logistic model (odds ratio)	1.39 (0.64, 3.23)
Sleep Disturbances (n/N (%))	AP Week 8 and/or PP Week 38	62/266 (23.3)	34/137 (24.8)		1.00 (0.67, 1.50)

FIGURE 1. Distribution of Depression, Anxiety and Sleep Disturbances Outcomes



## ACKNOWLEDGEMENTS

The IMPAACT 2010/VESTED Protocol Team gratefully acknowledges the dedication and commitment of the 643 mother-infant pairs, their communities, and CAB representatives, without whom this study would not have been possible. The authors also wish to acknowledge the IMPAACT 2010/VESTED Protocol team, NIAID, NICHD, and NIMH, and the twenty-two IMPAACT sites and staff. The study products were provided by ViiV Healthcare Ltd, Gilead Sciences, Mylan.