In utero exposure of dolutegravir and efavirenz assessed via hair levels in IMPAACT 2010 trial

Abstract # 804

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BACKGROUND

- Data are limited on the extent of *in utero* transfer of dolutegravir (DTG) and efavirenz (EFV), two drugs widely used in pregnancy over the past 15 years.
- To evaluate *in utero* fetal exposure to these agents, we measured drug concentrations in hair among women living with HIV (WHIV) and their newborns in the randomized IMPAACT 2010 trial

METHODS

- 643 WHIV in 9 countries (predominantly Africa, Figure 4) were randomized at 14-28 weeks gestation to start DTG+emtricitabine(F)/tenofovir alafenamide (TAF), DTG+F/tenofovir disoproxil fumarate(TDF), or efavirenz (EFV)/F/TDF.
- Maternal and infant hair samples were collected shortly after delivery. DTG and EFV levels were analyzed using validated liquid chromatography/tandem mass spectrometry methods in the UCSF Hair Analytical Laboratory (HAL).
- The lower (LLOQ) and upper (ULOQ) limits of quantification were 0.02 and 20 ng/mg (hair) for DTG and 0.05 and 20 ng/mg for EFV, respectively.
- Weight-normalized drug levels in hair were log-transformed (due to heavily skewed concentrations)
- Ratios of log-transformed infant-to-maternal concentrations were calculated to assess transfer.
- Linear regression models were fit to assess associations between maternal hair drug levels with adverse perinatal outcomes

Figure 1. Hair collection process



Fetal DTG exposure was higher than EFV exposure based on hair concentrations, but the extent of drug exposure was not associated with adverse birth outcomes

RESULTS

Figure 2. Flowchart of inclusion for IMPAACT 2010 participants

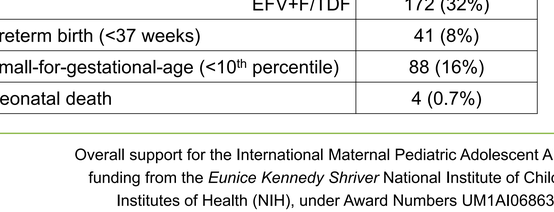
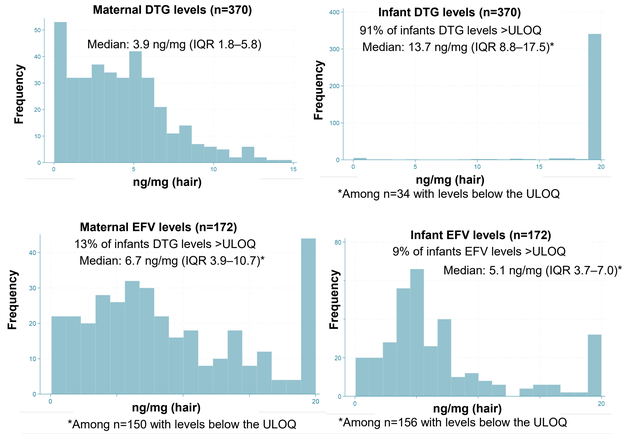


Table 1. Characteristics of mother-infant pairs included in the analysis (n=542)

	% or Median (IQR)
Maternal age (years)	26 (22–31)
Gestational age at ART initiation (weeks)	22 (18–25)
Gestational age at birth (weeks)	40 (39–41)
Timing of hair collection postpartum (days)	6 (3-8)
ART regimen	
DTG+F/TAF	189 (35%)
DTG+F/TDF	181 (33%)
EFV+F/TDF	172 (32%)
Preterm birth (<37 weeks)	41 (8%)
Small-for-gestational-age (<10th percentile)	88 (16%)
Neonatal death	4 (0.7%)

Figure 3. Weight-normalized drug levels in maternal and infant hair collected at birth



- The infant-to-mother ratio of mean $\log_{10}$ DTG concentrations was 0.62 (95% CI 0.38 to 0.86)* with no difference in ratios between DTG+FTC/TAF vs. DTG+FTC/TDF (0.48 vs. 0.79; p=0.202).
- The infant-to-maternal ratio of mean $\log_{10}$ EFV concentrations was –0.15 (95% CI –0.21 to –0.10)*, representing approximately 90% lower mean transfer than for DTG transfer (p<0.001).

*Among those with levels below the ULOQ (n=34 and n=146, respectively)

Table 2. Associations between maternal DTG & EFV concentrations in hair and birth outcomes

		Mean $\log_{10}$ DTG concentrations (95% CI) (n=370)	Univariable linear regression Absolute Difference (95% CI)	p-value	Mean $\log_{10}$ EFV concentrations (95% CI) (n=150)	Univariable linear regression Absolute Difference (95% CI)	p-value
Preterm birth							
	Yes	0.24 (-0.01, 0.48)	-0.20 (-0.42, 0.01)	0.066	0.74 (0.56, 0.91)	-0.00 (-0.22, 0.22)	0.971
	No	0.44 (0.39, 0.50)	ref		0.74 (0.67, 0.81)	ref	
SGA							
	Yes	0.45 (0.32, 0.58)	0.03 (-0.11, 0.17)	0.670	0.82 (0.64, 0.99)	0.09 (-0.09, 0.27)	0.330
	No	0.42 (0.36, 0.48)	ref		0.73 (0.65, 0.80)	ref	
Neonatal death							
	Yes	0.58 (-0.96, 2.13)	0.16 (-0.58, 0.89)	0.674	0.71 (-4.67, 6.09)	-0.03 (-0.61, 0.54)	0.907
	No	0.43 (0.37, 0.48)	ref		0.74 (0.67, 0.81)	ref	

SGA=small-for-gestational-age (<10th percentile); preterm birth = <37 weeks

Figure 4. IMPAACT 2010 study sites



CONCLUSIONS

- Our results suggest infant DTG exposure was higher than EFV exposure based on hair concentrations.
- The extent of maternal drug exposure was not associated with adverse birth outcomes for either drug.
- Our findings support current recommendations for prenatal DTG use.

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PLAIN LANGUAGE SUMMARY

Women with HIV taking HIV treatment can pass those medications on to their babies during pregnancy. Hair levels of HIV therapy among newborns reflect cumulative exposure during pregnancy. Dolutegravir (DTG) is the main treatment (with two other drugs) for people with HIV worldwide and transferred to the baby at higher levels than the previous treatment (efavirenz) in our study.. However, that transfer of HIV treatment from mother to baby did not result in any problems for the babies.

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