74. Maternal Dolutegravir (DTG) Use During Pregnancy and Birth Outcomes: The Antiretroviral Pregnancy Registry (APR)
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Background. The APR is prospective exposure-registration cohort study, monitoring for early warning signals of major teratogenic effects of antiretrovirals (ARVs) used during pregnancy. This analysis aimed to assess maternal demographics, pregnancy and neonatal outcomes including birth defects among infants with periconception and prenatal exposure to DTG using APR data.

Methods. Descriptive analysis with frequency tabulation of pregnancy and neonatal outcomes is reported. Periconception is defined as any exposure within two weeks prior to or through 28 days after conception.

Results. There were 1010 prospectively reported pregnancies with exposure to DTG through 31 January 2021, with 526 periconception exposures, 105 exposures later during 1st trimester, 260 during 2nd trimester and 119 during 3rd trimester. Maternal median age at conception was 30 years and 77.0% of pregnancies were reported from the United States. At the time of reporting, 46.6% had CD4 count ≥500 cells/µl, 31.8% had <200–499 cells/µl, 12.5% had <200 cells/µl, and 9.1% unknown.

The 1010 DTG exposed pregnancies resulted in 1036 outcomes: 956 (92.3%) live births (26 twin pairs), 12 (1.2%) stillbirths, 28 (2.7%) induced abortions, and 38 (3.7%) spontaneous abortions. Among live births, 39 (4.1%) reported birth defects. For 1st trimester exposures, overall defect prevalence was 3.3% (19/576, 95% CI 2.0-5.1) and for 2nd/3rd trimester exposures defect prevalence was 5.3% (20/380, 95% CI 3.2-8.0).

One neural tube defect (NTD) case of aneuploidy with periconception DTG exposure was reported.

Among the 873 singleton, live births without birth defects, 92 (10.5%) were preterm (<37 weeks of gestation); 103 (11.8%) had low birth weight (LBw) <2500 grams including 22 (2.5%) <1500 grams.

Conclusion. APR data do not demonstrate an increased risk of overall birth defects with DTG use above the population expected rate of defects (2.7/2 to 4.17 per 100 live births from Metropolitan Atlanta Congenital Defects Program [MACDP] and Texas Birth Defects Registry [TBDR] respectively). The number of periconception exposure outcomes is not yet sufficient to evaluate potential association of DTG with NTD. The Registry continues to closely monitor birth defects, including NTDs in pregnancies exposed to DTG and other integrase inhibitors.

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75. High Rates of Virologic Suppression with DTG/3TC in Newly Diagnosed Adults with HIV-1 Infection and Baseline Viral Load $>500,000$ c/mL: 48-Week Subgroup Analysis of the STAT Study

**Background.** The primary analysis of the STAT study demonstrated the feasibility, efficacy, and safety of using DTG/3TC as a first-line regimen in a test-and-treat setting through 24 weeks, with therapy adjustments for baseline resistance or hepatitis B virus (HBV) co-infection. Here we present secondary analyses through Week 48 of virologic outcomes in participants by baseline viral load (VL).

**Methods.** STAT is a single-arm study of treatment-naive adults with HIV-1 infection who initiated DTG/3TC ≤14 days after HIV-1 diagnosis without availability of screening/baseline laboratory results. If baseline testing indicated DTG or 3TC resistance, or creatinine clearance <30 mL/min/1.73 m², then antiretroviral therapy (ART) was potentially adjusted and participants remained on study. Efficacy analyses included proportion of participants with HIV-1 RNA $<50$ c/mL regardless of ART regimen at Week 48, among all participants (ITT-E missing = failure analysis) and among participants with available HIV-1 RNA data at Week 48 (observed analysis).

**Results.** Of 131 enrolled, DTG/3TC treatment was adjusted in 10 participants with baseline VL $\geq 1,000,000$ c/mL, 90% (9/10) achieved HIV-1 RNA $<50$ c/mL at Week 48; the remaining 2 withdrew from study. Of participants with baseline VL $\geq 1,000,000$ c/mL, 90% (9/10) achieved HIV-1 RNA $<50$ c/mL at Week 48 (Table); the remaining participant withdrew consent. Of the 17 participants with baseline VL $\geq 500,000$ c/mL with available data through Week 48, 76% (13/17) achieved virologic suppression by Week 24. One participant with baseline VL $\geq 500,000$ c/mL switched from DTG/3TC before the Week 48 assessment. Of the 9 participants with baseline VL $\geq 1,000,000$ c/mL with available data through Week 48, 76% (7/9) were suppressed by Week 24.

**Conclusion.** These data provide evidence for the feasibility and efficacy of using DTG/3TC as a first-line regimen in a test-and-treat setting, including among participants with very high baseline VL.

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76. Effects of the "Undetectable = Untransmittable" ("U=U") Educational Campaign on Treatment Outcomes and Perceptions among People Living with HIV in North American Countries

**Background.** The educational campaign "Undetectable = Untransmittable" ("U=U") began in 2016 to improve the well-being of people living with HIV (PLHIV) and recalculate HIV-related social norms. As medical practice can vary by region, we examined reports from PLHIV in North American countries to identify if the campaign affected healthcare provider (HCP) communication of U=U and if positive health outcomes differed by U=U-informed status or country.

**Methods.** Data were collected from the 2019 Positive Perspectives survey of PLHIV in Canada (n=120), Mexico (n=63), and the United States (n=400) and stratified by country. Outcomes were self-rated mental and sexual health ("Good"/"Very good"), viral suppression, and sharing of HIV status. Treatment perceptions were also assessed.