

## Exposure to dolutegravir in pregnant HIV positive women in Central and Eastern Europe, and neighboring countries - data from ECEE Network Group.

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### Background

- The EMA and WHO recently issued a recommendation to use dolutegravir (DTG) in women with caution due to possible risk of neural tube defect.
- We aimed to identify the utilization of DTG in real life among women in Central and Eastern Europe and neighboring countries (CEEN) where epidemiological data are usually sparse and HIV prevalence is low- or moderate-level.

### Methods

- We have approached centers from 20 countries participating in the Euroguidelines in Eastern and Central Europe Network Group
- We asked about DTG availability, the scale of its use among women and exposure to the drug in pregnancy.
- Twelve centers confirmed DTG availability in their country and eight confirmed use of DTG in pregnancy.
- Six countries (seven centres) provided detailed information on the DTG exposure in pregnancy: Czech Republic, Finland, Greece, Poland, Slovakia, Turkey.
- Follow-up was censored at 31<sup>st</sup> May 2018.

### Results

- In total 415 women were exposed to DTG and of those 28 in pregnancy (four started drug during pregnancy).
- In terms of conventional risks four women were smoking before pregnancy (two continued in pregnancy), two were drinking alcohol before pregnancy (one continued in pregnancy), three were using psychoactive substances (1 continued in pregnancy).
- The status of TORCH diseases was known in 25 women and for all it was negative.
- Twenty two (78.6%) women were using folic acid during pregnancy.
- Median number of earlier pregnancies was 2 (IQR: 1-3).
- Twelve women had prior obstetric procedures: seven had abortion (five spontaneous and one due to trisomia) and five had cesarean section in the past.
- Five (17.8%) women had prior health problems: two had diabetes, one lupus erythematosus, one Rh conflict and one autoimmune hepatitis.
- Concurrent use of prescribed medication was reported in seven (25%) women (thyroid hormone, azathioprine, methadone, insulin, mirtazapinum). Two (8%) women had detectable HCV RNA before pregnancy.
- Four pregnancies were ongoing at the time of data collection.
- Of 24 pregnancies with the outcome there were two (8.3%) abortions, three (12.5%) preterm births and nineteen (79.2%) term deliveries.

Euroguidelines in Central and Eastern Europe (ECEE) Network Group was established in February 2016 to review standards of care for HIV in the region



### Conclusions

- As presented in this work many factors may contribute to pregnancy outcome in HIV positive women.
- Conventional risk factors and concurrent use of prescribed medication should be carefully investigated besides antiretroviral use in pregnancy, in order to properly weigh the risks and benefit of antiretroviral treatment.
- The number of women exposed to DTG in CEEN countries with low- and moderate prevalence is substantial and this work does not include all pregnancies with DTG exposure in the region. **Including those countries in drug safety initiatives is vital.**

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