Introduction

- Tenofovir disoproxil fumarate (TDF), a nonnucleoside reverse transcriptase inhibitor (NNRTI), is recommended for post-exposure prophylaxis of HIV infection and in combination with other antiretroviral drugs (ARV) during the second and third trimesters of pregnancy.

- As a Food and Drug Administration (FDA) Pregnancy Category B drug, there is insufficient data to warrant a separate analysis, no increases in risk of birth defects have been detected.


- In reviewing all reported defects from the prospective registry, informed by clinical studies and retrospective reports of antiretroviral drugs exposure, the Registry Advisory Committee recommends pregnancy registries.

- To simplify, the expected number of observed cases is calculated as the product of the incidence and the denominator.

- Cases lost to follow-up (e.g., no outcome information is obtained).

- Exposure was defined as any use of anti-hepatitis B virus drugs in hepatitis B virus mono-infected pregnant patients.

- Excludes reported defects in pregnancy losses <20 weeks.

- Earliest exposure in the 1st trimester (tenofovir disoproxil-fumarate-containing regimens).

- Informed by clinical studies and retrospective reports of antiretroviral drugs exposure, the Registry Advisory Committee recommends pregnancy registries.

- While ARV drugs have proven useful for treating infected women, studies have not detected increases in the risk of major birth defects.

- In the 1st vs. 2nd or 3rd trimester, TDF regimen exposure vs. all other ARV regimens.