

# Active Safety Surveillance of Maternal and Infant Health Outcomes for Pregnant and Breastfeeding Users of HIV Pre-Exposure Prophylaxis (PrEP)

SAMPLE CASE REPORT FORM



## Background

Although available data are reassuring regarding the safety of pre-exposure prophylaxis (PrEP) use during pregnancy and breastfeeding, the World Health Organization (WHO) has recommended additional active surveillance of mother and infant outcomes during PrEP use in pregnancy and breastfeeding. This recommendation, found in the WHO technical brief *Preventing HIV During Pregnancy and Breastfeeding in the Context of PrEP*,<sup>1</sup> advises that active surveillance of PrEP exposure during pregnancy and the breastfeeding period focus on the following three areas:

1. Maternal adverse outcomes: Monitoring treatment-limiting toxicities associated with antiretroviral therapy in pregnant women, particularly mortality.
2. Adverse birth outcomes: Monitoring toxicity in the fetus in utero, manifesting as stillbirths, preterm births, low birthweight, major congenital anomalies, or early infant deaths. Adverse birth outcomes may be routinely monitored by integrating an additional indicator into the national monitoring and evaluation system.
3. Adverse infant and child outcomes: Monitoring health outcomes in infants and young children exposed to antiretroviral (ARV) drugs in utero or via breast milk, particularly any impact on growth and development.

More broadly, WHO has encouraged countries to implement active toxicity surveillance for ARV use, including during pregnancy and breastfeeding. The [WHO Implementation Tool for Monitoring the Toxicity of New Antiretroviral and Antiviral Medicines in HIV and Viral Hepatitis Programmes](#) provides a framework for pharmacovigilance monitoring within the context of national treatment programs.<sup>2</sup> Although this framework allows for inclusion of pregnant women, it does not include surveillance of many important maternal and child health outcomes. Thus, to generate additional evidence on drug safety during pregnancy, WHO has encouraged participation in the WHO [central registry for epidemiological surveillance of drug safety in pregnancy](#). Having a central pregnancy registry allows WHO to pool safety data collected by local or national pregnancy exposure registries or via birth outcome surveillance programs. Pooling such safety data across many countries facilitates the early detection of safety signals and provides evidence to inform guidelines for pregnant patients. Countries, surveillance projects, and researchers may contribute data to this registry.

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<sup>1</sup> <https://apps.who.int/iris/bitstream/handle/10665/255866/WHO-HIV-2017.09-eng.pdf>

<sup>2</sup> <https://apps.who.int/iris/bitstream/handle/10665/273053/9789241514231-eng.pdf>

## Sample Case Report Form

The sample case report form is designed for collection of active safety surveillance data for users of HIV PrEP during pregnancy and/or breastfeeding. Data may be collected for local (national) surveillance and/or for submission to the WHO central registry for epidemiological surveillance of drug safety in pregnancy.

- **Section 1** of this form includes fields for all data needed for electronic submission to WHO and should be completed as recommended by the associated [central pregnancy registry data dictionary](#).<sup>3</sup>
- The variables in **Section 2** are included to address the WHO recommendation in the WHO technical brief *Preventing HIV During Pregnancy and Breastfeeding in the Context of PrEP* regarding collection of “health outcomes in infants and young children exposed to ARV drugs in utero or via breast milk, particularly any impact on growth and development.” These fields are designed to complement a country’s central pregnancy registry data by capturing additional outcomes during the infant’s first year of life.

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<sup>3</sup> [https://www.who.int/tdr/research/tb\\_hiv/drug-safety-pregnancy/en/](https://www.who.int/tdr/research/tb_hiv/drug-safety-pregnancy/en/)

<b>SECTION 1 (COMPATIBLE WITH WORLD HEALTH ORGANIZATION CENTRAL REGISTRY)</b>	
<b>IDENTIFIER (Case ID)</b>	
Case ID number	
<b>FACILITY INFORMATION</b>	
Country	
Facility name	
Site identifier	
<b>MOTHER AND INFANT IDENTIFIERS</b>	
Mother local ID number	
Infant's local ID number	
<b>MATERNAL AND FAMILY INFORMATION</b>	
Mother's date of birth	
Maternal age at delivery	
Mother's height	
Mother's weight	
Total number of previous deliveries	
Maternal chronic diseases or diseases during pregnancy	
Blood pressure	
Family with congenital anomaly	
<b>PREGNANCY</b>	
Last menstrual period	
Date of pregnancy outcome	
Gestational age at pregnancy outcome	
Method for gestational age calculation	
Fetal presentation	
Type of delivery	
Gestational age at enrollment	
<b>FETUS/INFANT DATA</b>	
Outcome of pregnancy	

Sex of infant/fetus delivered	
Infant length at birth	
Infant weight at birth	
Infant head circumference at birth	
Results of surface examination	
Congenital anomaly detected	
Child HIV status	
Child death	
Age at death	
Infant postmortem autopsy	
Karyotype	
<b>EXPOSURE: SUBSTANCES AND MEDICAL TREATMENTS</b>	
Alcohol	
Tobacco	
Illicit drugs/substance abuse	
Drug name	
Code for drug name	
Dose	
Drug start date and stop date	
Trimester of exposure	

**SECTION 2 (ADDITIONAL VARIABLES RECOMMENDED BY WORLD HEALTH ORGANIZATION)**

**INFANT STATUS AT AGE 1 MONTH**

Infant length

Infant weight

Infant head circumference

Results of surface examination

HIV status

Developmental screening

Child death

Age at death

Infant postmortem autopsy

**INFANT STATUS AT AGE 3 MONTHS**

Infant length

Infant weight

Infant head circumference

Results of surface examination

HIV status

Developmental screening

Child death

Age at death

Infant postmortem autopsy

**INFANT STATUS AT AGE 6 MONTHS**

Infant length

Infant weight

Infant head circumference

Results of surface examination

HIV status

Developmental screening

Child death

Age at death	
Infant postmortem autopsy	
<b>INFANT STATUS AT AGE 12 MONTHS</b>	
Infant length	
Infant weight	
Infant head circumference	
Results of surface examination	
HIV status	
Developmental screening	
Child death	
Age at death	
Infant postmortem autopsy	