

**Tools for Active Safety Surveillance  
of Maternal and Infant Health  
Outcomes for Pregnant and  
Breastfeeding Users of Oral PrEP  
and PrEP Ring**

**SUMMARY BRIEF, SURVEILLANCE  
REGISTER, AND CASE REPORT  
FORM**



# Summary Brief

## 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 (P/BF). This recommendation, found in the WHO technical brief '[Preventing HIV During Pregnancy and Breastfeeding in the Context of PrEP,](#)' 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. Although this framework allows for inclusion of pregnant women, it does not include surveillance of many important maternal and child health outcomes. The surveillance tools included in this package, including a PBFP PrEP Surveillance Register and a PBFP PrEP Case Report Form are meant to serve as templates for countries to adapt to fit their own surveillance systems.

## Surveillance Tools Overview

The *Surveillance Tools for tracking outcomes by PrEP users during pregnancy and breastfeeding* include a template PBFP PrEP Case Report Form and PBFP PrEP Surveillance Register which can be adapted to country contexts/needs for tracking maternal and newborn health outcomes among PBFP PrEP users. Both oral PrEP and the PrEP ring have been integrated into these materials, but countries using them should look to their current guidelines when deciding what to extract from the tools.

Tool	Description
PBFP PrEP Surveillance Register	The sample paper clinic register can be adapted for use to monitor PrEP use and outcomes for PBFP.
PBFP PrEP Case Report Form	This case report form facilitates a standardized approach to collection of recommended data for active surveillance of adverse outcomes of PrEP users during pregnancy and breastfeeding.

# PBFP PrEP Surveillance Register

Record if any PrEP use (initiation, discontinuation, method switch) by a pregnant or breastfeeding person															Update when infant is 1, 3, and 6 months old.			
Full Name	ID #	Age	Method of PrEP Started <i>(Indicate oral PrEP or PrEP ring)</i>	Start Date for PrEP method	Gestational Age in Weeks at PrEP Start <i>(If PrEP use started prior to becoming pregnant, indicate 'Pre-pregnancy'; If PrEP use started during pregnancy indicate gestational age; If PrEP use started during breastfeeding period, indicate weeks postpartum)</i>	PrEP Method Switch or Discontinuation During Pregnancy or Breastfeeding <i>(If Applicable)</i>	Date of PrEP Method Switch or Discontinuation During Pregnancy or Breastfeeding <i>(If Applicable)</i>	Reason for Discontinuation or Method Switch During Pregnancy or Breastfeeding	Pregnancy Outcome	Gestational Age at Pregnancy Outcome	Birth-weight <i>(in grams)</i>	Major Congenital Anomaly	Maternal Death	Any Other Medications used During Pregnancy or Breastfeeding	Infant health and development			
						1=Switched to oral PrEP 2=Switched to PrEP ring 3=Discontinued all methods of PrEP	<i>(If PrEP discontinued or switched during pregnancy indicate gestational age; If PrEP use discontinued or switched during breastfeeding period, indicate weeks postpartum)</i>	1=Side effects noted by client (write-in main side effects) 2=Client no longer wishes to be on PrEP 3=Client wants to try a different PrEP method 4= Other (write-in reason)	1=Pregnancy loss (specify cause of death if known) 2=Stillbirth 3=Livebirth	Estimated gestational age in weeks at time of pregnancy outcome					1=Yes (specify) 2=No 3=Unknown	1=Yes (specify cause of death if known) 2=No	Record name of medication(s)	1=Alive and well 2= Suspected growth or development issue (write-in/specify) 3=Deceased 4=N/A (stillbirth) 5=Unknown

# PBFP PrEP Case Report Form

## SECTION 1 (PRIORITY OUTCOMES TO MONITOR)

<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 (include which method of PrEP: Oral PrEP or PrEP ring)	
Code for drug name	
Dose	
Drug start date and stop date	
Trimester of exposure	

**SECTION 2 (ADDITIONAL INFANT OUTCOMES TO CONSIDER MONITORING)**

**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	
<b>INFANT STATUS AT AGE 6 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	
<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	