

THE CARE PREP STUDY AIMS TO LEARN MORE ABOUT PREP USE DURING PREGNANCY

WHAT IS PREP

PrEP is a type of **HIV prevention method that contains antiretrovirals (ARVs)**. People without HIV can use PrEP to prevent HIV before they are exposed.

People are more likely to get HIV when they are pregnant or during the time after delivery (postpartum) compared to other times in their lives, and getting HIV at these times carries a higher risk of passing HIV to their babies. For most people who live in places where HIV is common, there can be more benefits than risks of using an HIV prevention method, such as PrEP, during pregnancy and postpartum.



WHAT ARE THE CATALYST AND CARE PREP STUDIES?

CATALYST is a study that is offering a choice of three methods to protect against HIV: oral PrEP, PrEP ring, and CAB PrEP (injectable). The **CARE PrEP** Study will seek to enroll those from CATALYST who are pregnant while using any of these PrEP methods.



WHAT IS THE PURPOSE OF THE CARE PREP STUDY?

The purpose of this study is to add to what is already known about the **safety of PrEP use during pregnancy**, in particular, CAB PrEP (injectable) and ring PrEP, which are newer PrEP methods.

WHO WILL PARTICIPATE IN CARE PREP

CARE PrEP will enroll about 500-800 pregnant participants without HIV who used or are using PrEP through CATALYST. The study is taking place in Lesotho, Kenya and Zimbabwe. Babies from these pregnancies will also be enrolled.



WHAT WILL PREGNANT PARTICIPANTS WHO JOIN CARE PREP BE ASKED TO DO?

- Have study visits every three months during their pregnancy and within a few days after delivery
- Attend visits with their babies at 3- and 6-months following birth. These visits can occur at home, if preferred.
- Provide information about their pregnancy, health, and PrEP use.
- Receive an antenatal ultrasound, HIV, and syphilis testing.
- Provide information about their babies' health and allow the babies to have health exams
- Allow study staff to access their medical records to have complete and accurate health information
- Receive referrals for care for themselves and their babies.



WHAT IS THE RISK OF JOINING THE STUDY?

Some participants may feel anxious about receiving their test results. They may feel uncomfortable answering some questions about their and their baby's health. Other people may find out about the research study and may treat participants or their babies poorly or unfairly.



IS THE STUDY VOLUNTARY?

Yes. People are free to make their own choice about joining the study and may leave at any time. The decision to be in this study does not impact participation in CATALYST. Participants are encouraged to ask questions and involve their partner(s), parent(s), or other individuals who are important to them in their decision-making. Staff can provide study information to share with loved ones or invite them to the clinic to learn more.



WHAT ARE THE BENEFITS?

Pregnant participants and their babies will receive health exams, an ultrasound, and referrals for care. This study does not replace antenatal or other health care for participants or their babies. Importantly, being in the study will help provide more information about the safety of using HIV prevention methods during pregnancy.



DOES BEING IN THE STUDY COST ANYTHING?

No, there is no cost to participate in the study. The study staff will reimburse participants for their time and effort, and cost of trips to come for visits.

FOR MORE INFORMATION ABOUT CARE PREP, CONTACT: <NAME & CONTACT INFO> OR GO TO:



CARE PrEP is supported by the [country, health department/ministry] and reviewed by [relevant IRB].

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