uhambo
A Journey of Hope to Prevent HIV

# Public-Facing HVTN 702 Q&A

1. **What HIV prevention tools are available to HVTN 702 study participants now?**

   Throughout the trial, the study sites ensured that participants were informed about and provided access to oral medication to take daily for HIV prevention, a highly effective practice called pre-exposure prophylaxis (PrEP). Participants will continue to have access to PrEP through the study while they remain in follow-up. When participants leave the study, the sites will refer them to available local programs for PrEP.

   In addition, the study team has given participants counseling on how to reduce behaviors that increase risk for HIV acquisition, access to management of other sexually transmitted infections, information on voluntary medical male circumcision and referral to circumcision services, and counseling and referral for antiretrovirals to take immediately following suspected exposure to HIV (post-exposure prophylaxis, or PEP). The study team also has ensured that participants were given condoms and lubricant.

2. **Are participants who acquired HIV during the trial receiving antiretroviral therapy?**

   Study participants who acquired HIV during the trial have been referred to local medical providers for care and treatment and have been counseled on how to reduce their risk of transmitting the virus. The study team is following these participants for about 6 months after confirmation of diagnosis.

3. **How long will study participants be followed?**

   The study protocol team is in the process of determining how long participants will be followed. During the follow-up period, participants will continue to receive HIV counseling and testing and will be monitored for safety.

4. **What do these results mean for participants in other HIV vaccine clinical trials?**

   The lack of efficacy found in HVTN 702 is specific to the HVTN 702 vaccine regimen in that study population and should not be generalized to other HIV vaccine candidates nor other HIV prevention tools.

   Two other major, late-stage, ongoing HIV vaccine clinical trials—HVTN 705 (Imbokodo) and HVTN 706 (Mosaico)—are testing very different HIV vaccine regimens than the one tested in HVTN 702:

   - The HVTN 702 vaccine regimen consisted of two experimental vaccines: a canarypox-based vaccine called ALVAC-HIV and a bivalent gp120 protein subunit vaccine with an adjuvant designed to enhance the body's immune response to the vaccine.

- The vaccine regimens being tested in Imbokodo and Mosaico are based on "mosaic" immunogens—vaccine components designed to induce immune responses against a wide variety of global HIV strains. The experimental regimen in Mosaico uses an engineered common-cold virus that does not cause illness to deliver four mosaic immunogens. The regimen also includes a combination of clade C gp140 and mosaic gp140 envelope proteins, as well as an aluminum phosphate adjuvant. Imbokodo is evaluating essentially the same vaccine regimen, except that it does not include the mosaic gp140 protein.

In addition, the Imbokodo and Mosaico vaccine regimens are being tested in different countries and populations than HVTN 702. HVTN 702 took place in men and women in South Africa. The Imbokodo vaccine is being tested in women in Malawi, Mozambique, South Africa, Zambia and Zimbabwe, while the Mosaico vaccine is being tested in men who have sex with men and transgender people in Europe and the Americas.

**5. Why did the HVTN 702 vaccine not work at all in South Africa if it was an optimized, southern Africa-specific version of a vaccine that had modest efficacy in Thailand?**

In order to test the RV144 vaccine concept outside of Thailand, several changes had to be made to the vaccine regimen. Scientists changed three different aspects of the RV144 vaccine to adapt it for South Africa and try to improve it. The immune responses elicited by the RV144 and HVTN 702 vaccine regimens were examined and found to be comparable. Scientists will continue to analyze data from HVTN 702, and their findings may help clarify why the vaccine regimen did not prevent HIV.

**6. Slightly more people were infected in the vaccine group than the placebo group. Does this mean the vaccine caused HIV?**

No. While six more people acquired HIV in the vaccine group than in the placebo group, this is a very small number compared to the overall number of trial participants (5,407) and is not statistically significant. That means the risk for acquiring HIV was no different whether a participant received the vaccine or the placebo. The design of HVTN 702 ensured that investigators would be able to detect a true difference in the risk of acquiring HIV between the vaccine and placebo groups, and the answer is very clear: there is no difference.