

Making Sense of STEP and Phambili

I recently heard that an HIV vaccine trial ended because people got infected with HIV, is this true?

1. You cannot get HIV from a vaccine.
2. STEP and Phambili are two HIV vaccine studies that recently stopped giving shots to participants because early results showed that the vaccine candidate being tested did not work.
3. An unexpected finding from the study *seems to suggest* that certain groups of people who received the vaccine candidate may have a higher chance of getting HIV than those who didn't get the vaccine; however, this is not yet proven. It's currently unknown whether it could be the vaccine, something not related to the vaccine, or chance.

How did people in the study get infected if not from the vaccine?

4. The study recruited people who could benefit most from a vaccine, people who describe themselves as high risk for infection. Despite effective risk reduction counseling, this cannot eliminate all possible exposure.

Where were the STEP and Phambili studies conducted?

5. STEP was conducted in the United States, Caribbean, South America and Australia. Phambili was conducted in South Africa.
6. In the U.S. the trial was conducted in Atlanta GA; Birmingham AL; Boston, MA; Chicago, IL; Denver, CO; Houston, TX; Los Angeles, CA; Miami, FL; New York, NY; Philadelphia, PA; Rochester, NY; San Francisco, CA; St. Louis, MO; San Juan, PR; Seattle, WA.

When will we know the answer about whether or not the vaccine tested in the STEP study increased the risk of HIV infection?

7. Researchers are working around the clock analyzing huge amounts of data to see if this suggested result is actually true.
8. It is possible that we may never know the reason why those who got the vaccine seemed to have a higher risk of getting HIV than those that didn't.

How do you expect communities of color or gay men / MSM to become involved in future trials when safety concerns are in question?

9. The safety and well-being of all trial volunteers is always the top priority in HIV vaccine research.
10. Every study has an institutional review board and a community advisory board to ensure the safety of trial volunteers.
11. The STEP study stopping vaccinations is an excellent example of the safety processes working.
12. While there may be some level of risk in clinical trials, you cannot get HIV from a vaccine.

13. Full disclosure and partnership in the research process is imperative for engaging communities most affected by HIV/AIDS.

Has the community been involved in decisions made to discontinue vaccinating volunteers or unblind the trial?

14. An independent scientific review board (Data and Safety Monitoring Board) made the recommendation to cease vaccinating volunteers after review of data indicated the vaccine was not effective.
15. Researchers, in full collaboration with the community representatives, have decided to unblind the trial, which means to tell all the participants whether they received the placebo or the vaccine candidate.

Do volunteers who sero-convert receive treatment and care?

16. Yes, participants who become infected during the trial will be referred to an appropriate doctor or medical agency for medical care, including antiretroviral therapy, and counseling.

What does this mean for the STEP volunteers?

17. Although the trial sites are no longer providing the vaccine or recruiting new volunteers, all study participants are asked to continue coming to their follow-up visits.
18. If you are a study participant or know someone that has participated in the STEP trial, they should be encouraged to direct their questions and concerns to their clinical trial unit

What does this mean for the HIV vaccine field?

19. We cannot and will not give up in the search for a safe effective and affordable HIV vaccine.
20. Although this study result is disappointing the learning from it will inform future HIV vaccine research.