

HIV vaccines may induce HIV antibodies in trial participants, can cause false-positive test result

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During trials of preventive HIV vaccines, trial participants may develop HIV-related antibody responses that could lead to a positive HIV test by routine antibody detection methods (called vaccine-induced seropositivity/reactivity [VISPR]), and the potential for false-positive test results and an incorrect HIV diagnosis, according to a study in the July 21 issue of *JAMA*, a theme issue on HIV/AIDS.

Lindsey R. Baden, M.D., of Brigham and Women's Hospital and Harvard Medical School, Boston, presented the findings of the study at a *JAMA* media briefing at the International AIDS conference in Vienna.

"With an estimated 7,500 new [human immunodeficiency virus](#) (HIV) infections occurring each day worldwide, there is an urgent need to develop an effective prophylactic HIV [vaccine](#). Over the last 20 years many potential vaccine candidates have been developed and assessed in human clinical trials in more than 30,000 participants," the authors write. They add that induction of protective anti-HIV immune responses is the goal of an HIV vaccine. However, this may cause a reactive result in routine HIV testing in the absence of HIV infection, and has the potential of confounding (factors that can improperly skew outcomes) interpretation of HIV tests because of the antibody induced by vaccination. "Participants in early phase clinical trials, who are typically at low risk of HIV infection, may encounter difficulties with obtaining medical or disability/life insurance, donating blood or organs,

employment, and immigration owing to a false-positive HIV test result."

Dr. Baden and colleagues assessed the occurrence of VISP associated with different vaccine delivery systems and HIV inserts (targets) studied by the HIV Vaccine Trials Network (HVTN). Three common U.S. Food and Drug Administration-approved enzyme immunoassay (EIA) HIV antibody kits were used to determine VISP, and a routine diagnostic HIV algorithm was used to evaluate VISP frequency in healthy, HIV-seronegative adults who completed phase 1 (n = 25) and phase 2a (n = 2) vaccine trials conducted from 2000-2010 in the United States, South America, Thailand, and Africa. The majority of participants (82 percent) in the analysis were from the United States.

VISP occurred in 908 of 2,176 participants (41.7 percent). Rates of VISP varied greatly by type of HIV vaccine administered. For poxvirus products given alone or as a boost to a DNA or poxvirus prime, 53.4 percent (295 of 552) of recipients had VISP; 86.7 percent (399 of 460) of adenovirus 5 product recipients developed VISP, as did 35 of 555 (6.3 percent) of DNA-alone product recipients.

Overall, the proportion of VISP among the various HIV testing kits tested ranged from about 41 percent to 9 percent. The researchers also found that among the 901 participants with VISP and a Western blot result (a technique in molecular biology, used to separate and identify proteins), 92 (10.2 percent) had a positive result, 592 (65.7 percent) tested indeterminate, and 217 (24.1 percent) tested negative; however, the distribution of results varied by product.

"These data demonstrate that VISP is a common but highly variable outcome of trials of preventive HIV vaccines," the authors write.

"Because participants with VISP may subsequently become infected with HIV, it is imperative that appropriate follow-up testing be conducted, including HIV RNA testing, to minimize potential

misinterpretation of HIV test results."

"Testing for VISP at the end of the study and providing participants with their VISP status is critically important to prevent social harms, incorrect HIV diagnosis, and inaccurate reporting to health agencies. A misinterpretation of VISP can be minimized by clinicians obtaining a complete patient history (e.g., participation in an HIV vaccine trial) and interpretation of the Western blot and [HIV](#) RNA."

More information: JAMA. 2010;304[3]:275-283.

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