

## Implications of HIV Testing Outside of the Study During Preventative HIV Vaccine Trials in the US

<i>Abstract Category:</i>	Diagnosis in HIV Vaccine Recipients
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### OBJECTIVE

Participants on HIV vaccine trials who receive an HIV vaccine may test positive for HIV antibody, increasing their risk of social harms and potentially unblinding participants who receive a standard HIV test by providers outside of the study.

### METHODS

US participants enrolled in 15 phase I and one phase II preventative HIV vaccine trials were routinely queried about whether they received any HIV testing outside of that provided by the study and about any social harms related to trial participation (social impact). Participants were counseled to receive all HIV testing through the study site to avoid false positive tests.

### RESULTS

Among 1378 participants, 61 had 78 HIV tests performed outside the study. The rate of outside testing was 0.07 per person year of follow-up [95% CI 0.05,0.09]. Participants may have had outside testing for multiple reasons. The most common reason cited was “part of a routine medical exam or medical provider recommended” (27 participants). Other reasons, cited by fewer than 10 participants each, included requirement for jail or a drug treatment program, required by another research study, blood donation, recent or possible high-risk exposure, wanted to be tested with partner, take advantage of free testing programs, insurance requirement, and wanted to know HIV status. Among the 1378 participants, 8 participants reported social impact events related to the study requirement to avoid outside HIV testing: 7 were judged by the participant to have a minor or moderate impact on their quality of life and 1 event was reported to have a major impact related to a health care provider refusing to provide care unless an HIV test was performed. In 1 of the 8 reported social impact events, HIV testing was performed outside of the study, the participant was tested and denied enrollment due to a positive HIV test in a research study at another institution.

### CONCLUSIONS

Although outside testing rates and social impacts related to HIV testing are relatively low, the updated CDC HIV testing guidelines potentially increase the likelihood of participants receiving HIV testing outside of the study, with increasing risk for social harm for participants.