

## ABSTRACT

**Background:** Participation in HIV prevention trials may have important positive or negative social impacts for the volunteer. We assessed self-reported social impact in 3 phase 1 HIV vaccine clinical trials in 5 African countries. **Methods:** Three phase 1 HIV vaccine clinical trials in Kenya, Uganda, Rwanda, Zambia and South Africa enrolled volunteers at low-risk for HIV, who received 2-4 injections and were followed for up to 16 months with repeated HIV testing and counseling, plus mucosal sampling at the Kenyan sites. At the final study visit, self-reported data on potential social impact of trial participation was collected using a standardized questionnaire. Volunteers rated whether the impact was harmful or not, and graded harmful impacts as mild, moderate, major. Comparisons of categorical factors were conducted using the Fisher's exact test. A two-sided  $p < 0.05$  was considered statistically significant. **Results:** Social impact data was collected on 383 trial volunteers. 42% (162/383) reported one or more (256 total) social impacts. The majority (175/256, 68%) were reported as positive impacts, with the most common being 'affecting your feelings on the AIDS epidemic' 58% (101/175), and 'affecting feelings about yourself' 14% (24/175). The most common negative impacts were 'affecting health' 33% (27/81) and 'affecting relationship with friends' 17% (14/81). Negative social impacts were not more common in women (12%) than men (17%) ( $p = 0.15$ ), but varied by country (Uganda 28%, Kenya 22%, Zambia 8%, Rwanda 6%, South Africa 0%,  $p < 0.0001$ ). A total of 7 negative impacts were rated as major: low libido (4), falling sick frequently (1), believed infected by HIV (1) and dental problems (1); and 24 were rated as moderate. **Conclusions:** Trial volunteers reported largely positive social impacts and few major negative impacts after participation in phase 1 HIV vaccine trials. These data will inform appropriate counseling messages in future phase 1 and larger vaccine efficacy trials in Africa.