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Uptake and tolerability of repeated mucosal specimen collection in two Phase 1 AIDS preventive vaccine trials in Kenya

G Mutua[1], G Omosa-Manyonyi[1], H Park[2*], P Bergin[3], D Laufer[2], PN Amornkul[2], J Lehrman[2], P Fast[2], J Gilmour[3], O Anzala[1], B Farah[1]

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Background

Mucosal specimens are useful to evaluate local immune responses in AIDS preventive vaccine trials, but the acceptability and tolerability of mucosal sampling in Africa remains unknown.

Methods

The Kenya AIDS Vaccine Initiative (KAVI) initiated two AIDS preventive vaccine trials in Nairobi in 2011. After informed consent for a mucosal substudy, participants were asked to provide any of several types of mucosal secretions: saliva, oral fluids, semen, cervico-vaginal and rectal. Specimens were collected at baseline, one month after final vaccination, and at the next scheduled trial visit. A tolerability questionnaire was administered at the final visit.

Results

Of 80 trial participants, 65(81.3%) consented to the mucosal sub-study and provided at least one specimen, 7/65(10.8%) gave all specimens at least once and 2/65 (3.1%) gave all possible specimens at all visits. Saliva and oral fluids were given at all time-points by 62/65(95.4%) participants. Of 48 men, 21(43.8%) provided semen at baseline, 18/21 completed all 3 time-points. Of 17 women, 15(88.2%) gave vaginal sponge and SoftCup specimens at least once; 8/15(53.3%) gave both at all eligible time-points. Rectal sampling was the least acceptable method: 13/65(20%) participants agreed at baseline [4/17 women (23.5%), 9/48 men (18.8%)]. Of these, 4 men and 2 women gave samples at all time-points. The most common reason for accepting mucosal sampling was a desire to contribute to HIV research and for refusal, embarrassment/emotional discomfort.

Conclusion

Repeated saliva, oral fluid, semen and cervico-vaginal mucosal sampling in AIDS vaccine preventive trials in Kenya is feasible; this study however re-affirms the challenge of repeated rectal mucosal sampling in low-risk participants, noted in an earlier observational study at KAVI (AIDS Vaccine 2010 P10.07). Possible explanations include cultural and religious reasons contributing to embarrassment and emotional discomfort in low-risk participants. Including more qualitative research in vaccine trials with mucosal sampling could help elucidate these findings.

Author details
[1]Kenya AIDS Vaccine Initiative, Nairobi, Kenya. [2]International AIDS Vaccine Initiative, New York, NY, USA. [3]International AIDS Vaccine Initiative Human Immunology Laboratory, London, UK.

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[2]International AIDS Vaccine Initiative, New York, NY, USA
Full list of author information is available at the end of the article

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