Abstract

Background

Mucosal specimens are essential to evaluate compartmentalized immune responses to HIV vaccine candidates and other mucosally targeted investigational products. We studied the acceptability and feasibility of repeated mucosal sampling in East African clinical trial participants at low risk of HIV and other sexually transmitted infections.

Methods and Findings

The Kenya AIDS Vaccine Initiative (KAVI) enrolled participants into three Phase 1 trials of preventive HIV candidate vaccines in 2011–2012 at two clinical research centers in Nairobi. After informed consent to a mucosal sub-study, participants were asked to undergo collection of mucosal secretions (saliva, oral fluids, semen, cervico-vaginal and rectal), but could opt out of any collection at any visit. Specimens were collected at baseline and two additional time points. A tolerability questionnaire was administered at the final sub-study visit. Of 105 trial participants, 27 of 34 women (79%) and 62 of 71 men (87%) enrolled in the mucosal sub-study. Nearly all sub-study participants gave saliva and oral fluids at all visits. Semen was collected from about half the participating men (47–48%) at all visits. Cervico-vaginal secretions were collected by Softcup from about two thirds of women (63%) at baseline, increasing to 78% at the following visits, with similar numbers for cervical secretion collection by Merocel sponge; about half of women (52%) gave cervico-vaginal samples at all visits. Rectal secretions were collected with Merocel sponge from about a quarter of both men and women (24%) at all 3 visits, with 16% of men and 19% of women giving rectal samples at all visits.

Conclusions

Repeated mucosal sampling in clinical trial participants in Kenya is feasible, with a good proportion of participants consenting to most sampling methods with the exception of rectal samples. Experienced staff members of both sexes and trained counselors with standardized messaging may improve acceptance of rectal sampling.