

PB47 The challenge of collecting, collating and reporting adverse event data in microbicide trials

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ABSTRACT TEXT

Background:

Phase III microbicide trials are recruiting thousands of women, and assessing safety at regular intervals. In order to achieve consistency of data collection across sites, the Microbicides Development Programme (MDP) has developed case record forms (CRFs) that minimise the free text description of genital events, and facilitate mapping to MedDRA codes.

Methods:

Safety data collected during phase I microbicide trials were reviewed and CRFs designed to collect key data systematically during a Pilot Study, which was conducted in 6 sites (3 in South Africa, 1 each in Tanzania, Uganda and Zambia) with a target of 50 HIV negative, non-pregnant women per site. The clinical visits were conducted by trained nurses in most settings. A structured interview was followed by naked eye genital examination (modified CONRAD/WHO) at enrolment and 4 weeks after starting placebo gel.

Results:

A total of 383 women were screened, 257 enrolled and 249 attended the week 4 follow-up. The following solicited genital events were identified: non-menstrual bleeding (NMB), sores/ulcers, erythema, discomfort, oedema and sloughing. Comparing enrolment to week 4, the proportion of 221 and 247 completed forms available for analysis reporting solicited genital events were: NMB=16% and 7%; sores/ulcers=3% and 3%; erythema=8% and 6%; discomfort=6% and 6%; oedema=1% and 0%; sloughing=0% and 0%. Although it was possible to populate tables describing each event, and generate event lists by participant, the latter were not ideal as there was no mechanism to group events and map to diagnoses when it may have been clinically appropriate to do so. Cross-site comparisons by event highlighted some differences in reporting which results in an overestimate of non-menstrual bleeding.

Conclusion:

The Pilot Study was invaluable in expanding the CRFs to incorporate a summary mapping genital symptoms and signs to diagnoses, and subsequently to MedDRA codes where available. Cross-site comparisons were helpful in identifying reporting inconsistencies, which have been subsequently addressed through training.

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