

PA-43: Electronic diaries for reactogenicity self-reporting: Experience of a rural South-African site

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Background: Reactogenicity symptoms are important safety outcomes of vaccine trials. We report our experience of using e-diaries in a phase 1b TB vaccine trial in a rural under-resourced community in South Africa.

Methods: The Africa Health Research Institute (AHRI) clinical trials unit is based in an under-resourced rural setting in the KwaZulu-Natal province of South Africa. A phase 1b trial (ClinicalTrials.gov: NCT05547464) involving 2 novel TB vaccines involves participant completion of a reactogenicity e-diary, daily for 7 days after each of 3 vaccine doses. Mobile phones were provided for completion of e-diaries. Literate participants were targeted as a way of assessing if they would meet data entry requirements and were able to complete e-diaries in their home language of isiZulu. Participants were called daily to remind them to complete their e-diary.

Results: Of a total of 40 participants enrolled, 27 completed high school education (67.5%), of which 3 had some tertiary education. Results from all 89 completed e-diaries are reported here. Seventy-one (80%) e-diaries were fully completed, while 1 (1%) had 4 missed entries, 1 (1%) had 3 missed entries, 5 (6%) had 2 missed entries and 11 (12%) had 1 missed entry. Of 28 missed single entries, 15 (53%) were ascribed to the participant having forgotten, 7 (25%) due to device error, 3 (11%) due to data capture error by CTU personnel and 3 (11%) due to network connectivity issues. Twenty of 606 single entries (3%) were captured incorrectly, mostly due to reading the thermometer in Fahrenheit rather than the requested Celsius, or due to mistyping.

Discussion: The use of e-diaries for vaccine reactogenicity is feasible in a rural, under-resourced setting. The high completeness rate compared favorably, or is even better, than historical paper-based diaries for similar trials. Targeting literate participants, offering e-diaries in their home language and using daily reminders contributed to our high completion rate.

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Conflicts of Interest

None