AB37 Piloting biological sample testing and tracking for the Microbicides Development Programme (MDP) 301 study in Umkhanyakunde District, KwaZulu Natal, South Africa.

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ABSTRACT TEXT

Background:
During the Microbicides Development Programme (MDP) pilot study at the Africa Centre site, the feasibility of all biological specimen related procedures was assessed. The aim was to optimize specimen related study procedures in preparation for the MDP phase III clinical trial.

Methodology:
147 women were screened from district clinics and 51 enrolled. Blood was collected during the screening visit for HIV and STI testing; urine, vaginal and cervical specimens were collected at enrolment. These were sent to 3 different laboratories in Durban (250km away). Specimen integrity had to be maintained for precise and accurate results. Specimen tracking systems, including electronic systems and paper trails, had to be put in place to maintain the chain of custody of 508 specimens and over 1000 results.

Results:
75% of the results were reported within acceptable time lines of 2 weeks. Problems experienced included: 1.5% of the results were wrongly reported, as identified during quality assurance checks; 1 specimen went to the wrong laboratory; 4 out of 150 (2.6 %) of the HIV rapid results were transcribed on the laboratory forms incorrectly, and another 2.6% were missed during transcription. To improve turn-around times and sample tracking for the phase III study, the following plan of action has been implemented: (1) new training modules focusing on good specimen collection and preservation, completion of various laboratory forms, management of source documentation; (2) Standard Operating Procedures (SOPs) and guidelines were redesigned; (3) Laboratory agreements were implemented to ensure protocol compliance; (4) Additional laboratory forms were designed to ensure that all stages in the specimen chain of custody were documented; (5) Recommendations were put forward for upgrading the specimen database for optimal tracking of specimens and results, with an evaluation and validation to be completed before the start of the trial.

Conclusion:
Specimen and result tracking systems that include both electronic and manual systems have to be implemented, validated and verified before conducting a clinical trial in rural settings where referral laboratories are located far away. Ongoing staff training is essential as well as close collaboration with the referral laboratories.

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