CASE STUDY

Supporting the Evaluation of a New TB Diagnostic Tool - XTEND

The XTEND trial (Xpert for TB – Evaluating a New Diagnostic) funded by the Bill and Melinda Gates Foundation is a cluster randomised trial (CRT) nested within the NHLS roll out of the Xpert MTB/Rif technology to all laboratories to evaluate Xpert MTB/Rif technology compared with smear microscopy for the diagnosis of TB. The aim of the trial is threefold: to evaluate (1) the effectiveness and (2) the cost effectiveness of Xpert MTB/RIF in the investigation of TB and TB drug resistance, and (3) its impact on patient and programme outcomes and transmission at a population level.

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Further Reading:

Access more Mobenzi Researcher case studies at http://www.mobenzi.com/researcher/case-studies

ABOUT THE PROJECT

During the rollout, and in the XTEND trial, intervention laboratories implemented the GenXpert diagnostic platform and the use of the Xpert MTB/RIF cartridges. Facilities in sub-districts using these laboratories implemented the nationally agreed-upon algorithm for the diagnosis of TB; this algorithm replaced the algorithm using smear microscopy. During the study, around 4700 persons suspected of having TB have been recruited from 20 intervention and control clusters, and are being followed up for 6 months. The primary end point – mortality in each arm of the study- will be assessed after completion of the 6 month follow up period.

In addition to 4700 TB suspects, the project also enrolled 4000 participants in an 'Exit survey', and 400 persons receiving TB treatment as part of an economics evaluation.

Participants were enrolled from 40 primary health care clinics across 4 provinces – Eastern Cape, Gauteng, Free State and Mpumalanga, in sites including the most remote rural areas of the Eastern Cape (Luyengweni, and Katkop near Mount Frere and Mount Fletcher respectively).

MOBENZI IMPLEMENTATION

Mobenzi Researcher underpins the project's extensive data collection requirements. The project protocol includes complex elements such as longitudinal record-keeping of individual participants, scheduling, clinic data linking and real-time data validation and cleaning. These requirements necessitated the implementation of a back-end to support the project workflow.

Mobenzi Outreach was configured to support the core data collection activity by automating the generation of follow up forms, mapping multiple data sources to cohort records and generating consolidated data files for the Aurum data management team.

80 enumerators (fieldworkers) deployed across 40 sites are responsible for administering a variety of questionnaires to participants in each cohort at enrolment and specified time points. Questionnaires were developed and deployed to the enumerator handsets using Mobenzi Researcher. Forms were designed to guide enumerators through screening and enrolment of potential participants by applying eligibility criteria and generating eligibility assessments automatically. Once enrolled, Mobenzi Outreach was configured to process each form and respond by generating contextually relevant forms including follow-up interviews, case note abstractions, and reference and lab data extractions at specified time points during follow-up.
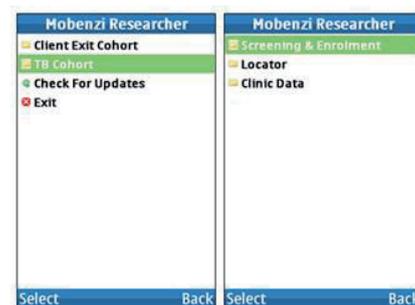
KEY ADVANTAGES

The use of the Mobenzi Researcher web console with built-in filtering functionality allows for real-time monitoring of fieldworkers and data. This facilitates remote supervision of sites, assisting with staff management, and in meeting data submission targets and deadlines. Close real-time monitoring of submitted data by XTEND data monitors, and regular communication with the Mobenzi team facilitates early and flexible correction of errors.

The use of the Mobenzi platforms demonstrates the potential for mobile technology to support the rapid roll-out of a large-scale, complex evaluation within a rural clinic setting. The flexibility of the platforms allowed a phased approach to be adopted, allowing incremental implementation of the protocol in line with the ambitious project timelines.

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