

Laboratory Informatics and AIDS Indicator Surveys

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Background and Purpose: National AIDS indicator surveys generate large volumes of specimens and associated data, necessitating the preparedness of systems and processes in the reference laboratory. Specimen management is often more routine while management of data becomes secondary. However, complete and accurate laboratory results are essential to ensure data quality. Robust laboratory informatics solutions for managing data are needed to increase data accuracy and reduce turnaround time.

Methods: During the 2012 Kenya AIDS Indicator Survey (KAIS), 62,435 samples were collected from respondent households and transferred to the National HIV Reference Laboratory (NHRL) for testing. The Association of Public Health Laboratories (APHL) collaborated with the Kenya Ministry of Health in laboratory process improvement, laboratory information system design and governance focusing on preparing the laboratory to manage the large volume of samples and associated data.

This task included developing detailed work flow and data flow diagrams for the entire process, from field specimen and data collection, to receipt, testing and storage. These diagrams were used for training and for reference during the survey process. They were also used to define KAIS 2012 requirements for the existing laboratory information management system (LIMS). Laboratory processes were documented and matched up with the configurations developed in the LIMS. The team also designed specimen tracking and receiving forms based on KAIS 2012 protocol and LIMS requirements. They matched these forms with data elements in the LIMS for data harmonization.

The KAIS survey team developed contingency plans for every KAIS 2012 laboratory activity to ensure NHRL implemented uniform procedures when normal operations did not occur. These plans focused on the management and standardization of human resources as appropriate personnel and associated procedures are integral to optimal information system performance. The team defined staff roles and responsibilities and developed procedures for managing forms, specimens and electronic data, including quality and use aligned with survey protocols. During the project, the KAIS team provided knowledge transfer to NHRL to ensure the development of local capacity and long-term sustainability.

Results: Due to the informatics processes in place, NHRL was able to share laboratory test results from KAIS with other stakeholders within a day of being received. NHRL was also able to immediately access data on storage locations of all samples that were previously managed using paper systems – a significant challenge before the project.

Visualization, mapping and contingency planning for each step of the process ensured that laboratory support to KAIS 2012 was timely, and of high quality, regardless of digressions from standard operating procedures caused by unexpected circumstances. While contingency plans are not routine, they can be critical to the success of the survey.

Conclusions: Preparedness is key. Finalization of the survey protocol three months before the pilot, training and piloting all aspects of laboratory services a month prior to the survey ensured informatics solutions are appropriate and robust. Engaging all stakeholders -- particularly survey, laboratory and LIMS staff -- in laboratory informatics solutions planning, implementation, monitoring is critical to

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developing the most efficient systems and processes for a large national sero survey. During execution, constant and ongoing communication is essential to adapt to the evolving needs of the survey and its participants.

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