Application of Barcode Technology to Enhance Electronic Quality-Assured Data Collection and Analysis in Operational Research EAPHLN project study sites in Kenya

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The East Africa Public Health Laboratory Networking Project (EAPHLNP) is a regional project involving five East African countries, Namely: Burundi, Kenya, Rwanda, Uganda and Tanzania and it is supported by the World Bank.

Summary

BACKGROUND

Barcode Technology is a replacement for the traditional keyboard data entry. The East Africa Public Health Laboratory Networking (EAPHLN) Project operational research activities anticipated enormous data generation from different geographical sites and health care site teams which necessitated the development of the system. This paper describes the use of barcode technology to enhance electronic quality assured data collection and analysis in operational research studies in Kenya.

METHODOLOGY

Barcode labels consisting of an encoded 9-digit unique identification figures were generated and centralized at KEMRI for nine study sites. At the sites, the label placement was done in the following sequence: patient card, consent form, questionnaire and clinical forms by the clinicians. Specimens and shipment form from the same patient with two matching identifier labels by the laboratory staff. The specimen barcode label contained additional information including specimen type and collection date. On receipt at the KEMRI laboratories, the specimen barcodes were scanned in the reception module of the electronic data management system (eDMS). An additional barcode label was generated with a laboratory number that was affixed to the specimen and scanned into the testing equipment that generated outputs.

FINDINGS

Implementation of the barcode technology in the study sites, involved introduction of a new workflow methodology. This impacted positively on patient recruitment and sample collection process. The barcode labels served as identifiers when used during enrollment which provided an accurate patient and specimen tracking system. This was evident as all specimens delivered had complete accompanying documents with 92% of all barcodes being successfully scanned. Poor storage and handling of the barcode labels contributed to the inability to the scanning. Clinical, demographic and laboratory information to be viewed directly without the need to track down the patient's source documents. The barcode system ensured the following: the confidentiality

of patients was maintained; Automation specimen identification on tests eliminating need for relabeling result output reports; fewer errors.

CONCLUSION

Patients' data linkages and verification from all study sites and the reference laboratory leading to increased efficiency and effectiveness in maintaining patient records. We recommend refresher trainings and supervisory visits to ensuring proper implementation and utilization of the barcode labels.

Keywords: Barcode Scanning; Data Linkages; Patients; Operational Research, Datalogic Powerscan

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Introduction

The availability of information communication technology (ICT) does not in isolation improve the quality of patient care, if improperly implemented may inadvertently increase data errors [1] However, when properly designed and implemented it can produce better outcomes by improving various aspects of health care delivery. Major challenge includes inconsistent coding of data that requires mapping codes between systems. This kind of mapping requires significant time and resources and adds an additional barrier of information exchange. Accurate mapping was essential whenever exchanged information will be used at the point of care [2].

However, the main source of errors in paper-based data collection was when data is extracted from patient medical records and transcribed to the electronic case report form [3].

In established health care system, users have been given unilaterally access to computing capabilities, such as server computing time and/or network storage. The characteristics of cloud computing and the flexibility of the services rapid and inexpensively re-provision technological infrastructure resources can be developed [4]. A barcode is a machine readable, graphic representation of data that allows the use of a combination of bars and spaces of varying widths to obviate the need for manual keyboard data entry [5]. Barcode technology is a replacement for traditional keyboard data entry [6], It has been incorporated in health care systems especially in critical areas such as blood transfusion and pharmacy to improve medication and patient safety [7, 8].

The EAPHLN-OR activities anticipated enormous data generation from different geographical sites and health care site teams (i.e. clinicians and laboratory personnel) which necessitated the development of the system. This paper describes the use of barcode technology to enhance electronic quality assured data collection and analysis in operational research studies in Kenya.

Methodology

This undertaking was part of an ongoing studies carried out at the Kenya Medical Research Institute (KEMRI) in collaboration with nine EAPHLN Project study sites in Kenya which included Malindi, Lamu, Busia, Kitale, Nyahururu, Wajir, Machakos, Narok and Kisii. Training of the clinicians and laboratory personnel on storage, handling, and affixing of barcodes was carried out concurrently at the various sites during the rolling-out of the enteric and TB studies. Data collected in study sites was done using questionnaires, clinical forms, shipment forms and specimens by study clinicians and laboratory staff in nine public hospitals. More data was generated in the Mycobacteriology and Microbiology research laboratories in KEMRI.

The data collection processing in all clinical sites involved first entering data in source hard copy forms which were then transcribed into an eDMS specifically designed with different data entry modules. All the study documents and specimens from the consented study participants were linked by the barcode labels identifiers.

The barcodes on the label were computer generated and printed centrally at KEMRI. This consisted of an encoded 9-digit unique identification figures. The unique code was labeled with Code 39 symbology system consisting of texts characters and numbers. Each label measured 38.1x 21.2 millimeters. Label fixing was done at the study sites in the following sequence: patient card, consent form, questionnaire, clinical forms, specimens and shipment form. Specimens from the same patient were affixed with two matching identifiers. This specimen barcode labels however, contained additional information including specimen type and collection date to differentiate them.

Once specimens were received at the KEMRI laboratories, the specimen barcodes were scanned in the reception module of the eDMS. An additional barcode label was generated with a laboratory number was affixed to the specimen with analogous barcode labels being stuck to the laboratory worksheets and tests containers (mycobacterium growth indicator tubes and GeneXpert cartridges). The barcodes generated for the laboratory were affixed on specimen containers then scanned into the testing equipment that generated outputs with laboratory identification numbers for subsequent data entry.

Data entry on the eDMS was done using the clinical module of the database. For data security purpose, users required authentication by authorized user (database administrator) through a password. The eDMS was a software application custom made using MySQLTM platform. The software was installed only on computers used for data entry and was designed to perform double entry. Two different data clerks entered the information from source documents independently. The initial step was manual scanning of the patient identifier into the patient ID field using a barcode scanner then subsequent entry of other fields as required. The data was transferred to a different computer for analysis.

Findings

Participating study sites used the barcode labels as identifiers to code enrolled study participants from the clinic; where a written consent was given to the laboratory for specimen collection and identification. This provided an effective patient tracking system that allowed issue of study specimen collection material, patient follow-up in the study site and in ensuring all study documentation and specimens were received in KEMRI.

The use of the barcodes allowed compilation and organization of patients‖ study documents (consent form, questionnaires, clinical forms and shipment forms) from the sites using their unique identifier on the barcode before shipping and also in the data entry process and document archival at KEMRI.

At the KEMRI laboratories the samples for the test (GeneXpert and mycobacterium indicator growth tube-MGIT) tagged with barcodes were scanned onto respective machine systems. These systems gave the accurate laboratory identifier in result output reports.

Linkage of patient data from patient documents from study sites and information generated from analysis of specimens in KEMRI occurred when barcode readers (Datalogic powerscanTM) were used to capture the patient and specimen details into the eDMS reception module. The readers successfully scanned 92% of all the patient ID barcode labels into the eDMS, only eight percent of documents from the 1,952 ID barcode labels could not be captured. The inability of readers to scan labels into the eDMS was due to the labels being blurred/ smudged which was attributed to poor storage and handling by site teams.

The barcode labels enhanced data merging and quality assurance through verification after double entry. Whenever there were queries on the data, scanning of the patient barcode accurately assisted viewership of the electronically completed form for comparison with source documents and subsequent editing. This system also allowed for an entire patient clinical history, demographic information and laboratory information to be viewed at a glance without the need to track down the patient‖s source documents.

Using the laboratory module, the eDMS system offered a convenient link to recruited study participants demographic and clinical information. It also prompted user intervention where results had gaps for any immediate action. It ensured confidentiality of patients was maintained at all times, since only barcode identifiers were used in all of the process of specimen processing and document handling. Automating specimen identification in tests with bar-coding eliminated the need for relabeling result output reports resulting to fewer errors being observed when data was re-typed into an electronic format.

During the data validation stage, the study statistician was able to link laboratory results to individual's dataset. The statistician could also verify reports on the eDMS by scanning specific barcodes on the report module.

Continuous training and supervisory visits were important for ensuring proper implementation and utilization of the barcode labels. At the initial phase of study four, out of the nine study sites (Busia, Kitale, Lamu and Nyahururu) revealed inconsistent plucking and affixing of barcode labels to the various forms (see Figure 1). Comparison of clinical and laboratory barcode labels enabled the M&E team to identify mismatch in the orderly plucking out of the labels.

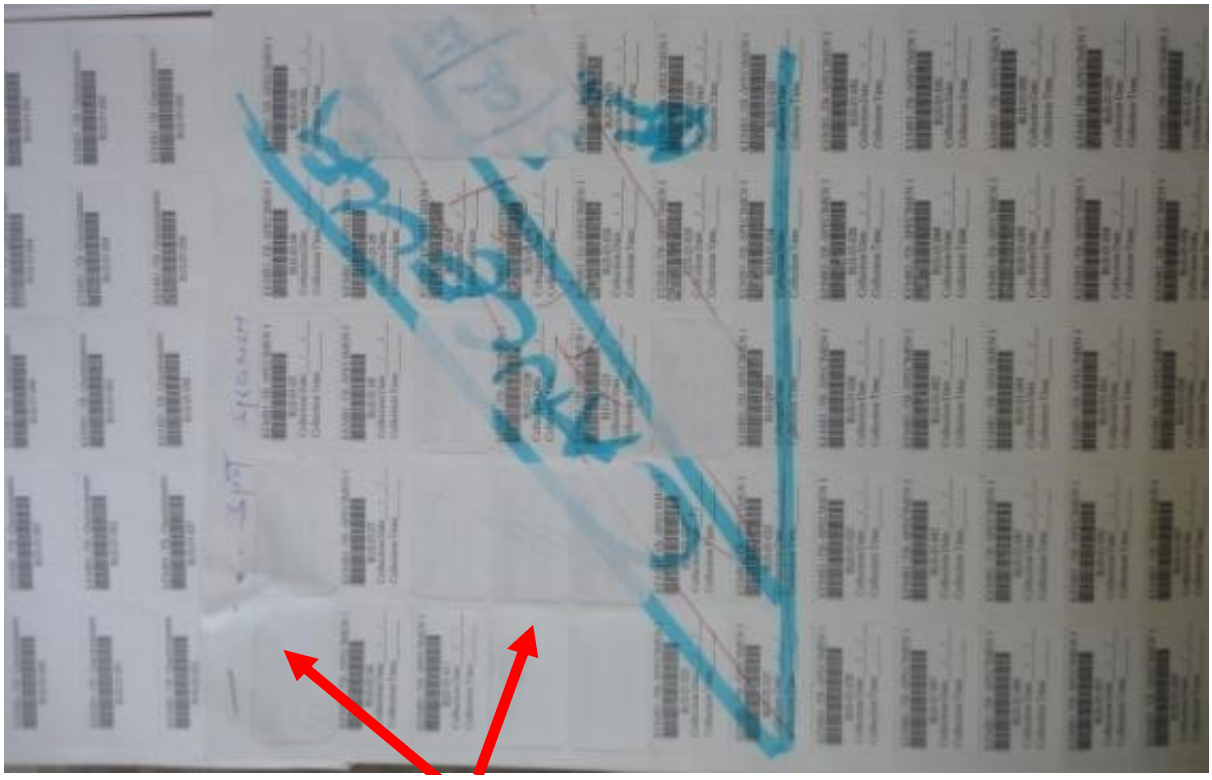

Figure 1: *Inconsistency Plucking of Bar-code Labels*

Discussion

Implementation of the technology at the 9 study sites involved introduction of a new workflow that impacted positively patient recruitment and sample collection process. The participating study sites personnel were trained during study initiation but there were challenges with proper affixing of the labels and this prompted the need for frequent supervision to ensure the recruitment flow was maintained. At this point the use of the barcode labels was mainly to prevent transcription errors in patient identifiers when they were being transcribed to different documents. Nahm and associates [9] in their publication indicated that the steps known to introduce error into data collection and management processes was in medical record abstraction and transcription.

The barcode labels as identifiers when used during enrollment provided an accurate patient and specimen tracking system which was evident as all specimens delivered had complete accompanying documents. This observation is in line with a study conducted by Poon [10] who observed that when the barcode/medication administration record technology was used, resulted to a high level of nurses' satisfaction

and their performance scores increased in all the subscales of efficacy, safety, and access indicators.

The printing of duo-sequential label numbers for same patient identifier at the KEMRI laboratories, provided exclusive efficiency in identifying specimens during laboratory and data analysis. The advantage that we observed when using barcode identifiers in the laboratories was that transcriptional errors which commonly occurs when patient study identifier are transcribed from one paper form into the laboratory worksheets were prevented. This was due to the use of an additional unique barcode that was affixed on specimens, test containers and laboratory documents. In turn they ensured patients‖ confidentiality was maintained and result outputs from machines had imprints with corresponding accurate laboratory numbers.

When all the forms were matched, gaps where identified which indicated that some patients had not reached the next service point. Especially in the enteric study, barcode matching pointed out that the adult patients recruited at the recruitment clinics did not go to the laboratory for specimen collection.

The barcodes labels had a limitation of being smudged or getting blurred when handled poorly, even though they were placed correctly on the study documentation or specimens. This resulted in manually transcribing identifiers on the eDMS system.

During the study‖s M&E visits, mismatch in barcode label sheets was seen in some study sites where clinicians did not understand the plucking order [11]. This lead to cancelling of some labels preventing the predictable misidentification of patients. As mitigation, handson training, close supervision and guidance was implemented. This is in line with Early and colleagues [12], who indicated that the preposition of using the barcode technology, process and solutions required systematic deployment, training and constant inspection.

The eDMS utilized in this study was custom made to permit simultaneous access of the database by multiple users on the different modules. When barcodes scanning process was combined with the eDMS, a repeat entry of patient identifiers was system prohibited because the primary key was used. Only on the repeat data module was a record duplicated which was for data verification process making the barcoding provide a critical role during double checking. This was also observed by Huang and lee [5] in their study when they applied the barcode technology in nurses' medication administration.

Real-time data entry and synchronization was possible with the eDMS. Password authentication was required to access the modules updating data at different levels. This provided data access security and maintenance of privacy for patients‖ data. By using analogous identifiers in all source documents used in all steps of data collection, integration of study site data was possible with data generated in KEMRI by the eDMS.

Identifier scanning increased efficiency in data entry and authentication. Scanning was 92% accurate in identifying patients correctly from all source documents and alleviated possible transcriptional errors. The accumulated data from each update allowed efficient merging process with no mismatches. Errors that occurred during data entry were captured during data verification, management and analysis processes. The placement of high quality labels and proper handling impacted positively the efficiency and data entry process.

Conclusion and Recommendations

The application of barcode technology facilitated patients data linkages and verification from all study sites and the KEMRI research laboratories. It enhanced efficiency and effectiveness in maintaining patient records. Successful implementation of barcode technology and supporting information communication infrastructure requires involvement and support of a number of aspects such as human resource. Although this paper did not address the aspect of barcode technology on a local area network environment, there is potential for future implementation and scaling up of the technology to address quick response code (QR). This can be done by mounting the technology on virtual private networks (VPNs) via cloud computing server accessible to remote study sites via mobile technologies thereby replacing paper work. This will result in improved real time data capture.

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