EISSN: 2707-0425

East African Journal of Science, Technology and Innovation, Vol. 1 (3): 2020.

A mobile digital technology (Fionet™) to improve accuracy, completeness and timeliness of research data compared with a non-digital system in Kenya

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Abstract

Background: The World Health Organization's Global Malaria Program implemented a multi-country study to assess the entomological and epidemiological impact of long-lasting insecticide treated nets (LLINs) and indoor residual spray (IRS). Study activities included home visits to perform a LLIN survey and malaria testing of children in the household. In Kenya, Fionet™, a technology for automated malaria Rapid Diagnostic Test (mRDT) processing and interpretation at point-of-care, was evaluated against traditional paper-based methods and manual mRDT processing. Objective: To measure and compare the accuracy of diagnosis, completeness, and timeliness of data transmission between a digital mobile solution (Fionet™) and a paper-based system. Methodology: A randomised cluster sampling design of two cohorts: 1) an Active Infection Detection cohort, and 2) an Active Case Detection cohort was undertaken between November 2013 and April 2014. Community Health Workers (CHWs) visited rural households to: 1) measure malaria prevalence in children under the age of five using mRDTs, and 2) survey the use and physical status of LLINs in the household. Ten clusters were randomly assigned to Fionet™ to perform automated testing, interpretation, and survey data capture. Fionet™ transmitted all the tests and survey data to a cloud-based database. Results: A total of 1770 households were visited, 437 children tested, and 742 LLINs inspected. Fionet™ significantly improved the quality of data gathered; a two-fold increase in adherence to study protocols using Fionet™ resulted in more accurate data, data completeness was 10 times higher than with paper-based collection methods, and 87% of data were available in less than one day. Conclusion: Fionet™ significantly improved data quality and management, which enhanced the health system's ability to meet the research objectives. This technology can help ensure accurate, complete, and timely availability of data. Future studies should incorporate mobile technologies such as Fionet™ to improve RDT based diagnostics of malaria and data quality.

Keywords: *Accuracy; Completeness; Data; Research; Timeliness; mHealth;*

Cite as: *Kinoti et al, 2020* ***A mobile digital technology (Fionet™) to improve accuracy, completeness and timeliness of research data compared with a non-digital system in Kenya;*** *East African Journal of Science, Technology and Innovation 1(3)*

Received: 22/02/20
Accepted: 23/05/20
Published: 24/06/20

Introduction

Despite advances in malaria control over the past decade, malaria remains a major global public health problem. According to the latest world malaria report from the World Health Organization (WHO), in 2018 an estimated 228 million cases of malaria occurred worldwide (95% confidence interval [CI]: 206–258 million). This compares with 231 million cases in 2017 (95% CI: 211–259 million), and 251 million cases in 2010 (95% CI: 231–278 million). Over 93% of estimated cases and 94% of estimated malaria deaths occur in Africa (World Health Organization, 2019).

In Kenya, the National Malaria Control Program's preventative measures include widespread availability and guidelines for the correct use of long-lasting insecticide-treated nets (LLINs) and the use of indoor residual spraying (IRS). However, the effectiveness of these measures may be compromised by the emergence of insecticide resistance in vector species (World Health Organization, 2012). The WHO initiated a multi-country prospective insecticide resistance study to assess the entomological and epidemiological impact of LLINs and IRS in areas where at least one major vector species was found to be resistant to insecticides (Kleinschmidt, et al., 2015). The five countries selected included Benin, Cameroon, India, Kenya, and Sudan. The Kenyan arm of the study was implemented by the Kenya Medical Research Institute (KEMRI).

As accuracy of malaria Rapid Diagnostic Tests (mRDTs) can be significantly reduced by human processing and interpretation errors, ensuring optimal quality of diagnostic tests in the field through elimination of such errors is important for research and malaria case management activities (Maltha, et al., 2013). Remote supervision of community health workers (CHWs), who are frequently the ones performing RDTs, can improve the quality control of mRDT test results. Survey data is often manually collected, transported, transcribed, and aggregated into a centralized data system. Each step in this process is a source of potential errors, and human errors often lead to incomplete or erroneous data in a database. Without receiving complete data in a timely fashion, researchers are unable to effectively respond to study problems as they arise. This impacts the overall quality and generalizability of the research findings. Whereas the data quality evaluation was not the core question for the insecticide resistance research, KEMRI found it necessary so evaluate the performance of a novel mobile technology to improve quality of the IRR research data through enhancing accuracy, completeness, and timeliness of the data emanating from the research.

KEMRI selected Fionet™ (Fio Corporation, Toronto, Canada), an integrated mobile health data collection and reporting system, to support CHWs serving within the insecticide resistance study. KEMRI hypothesized that Fionet™ could improve: 1) field performance and oversight of mRDTs performed by CHWs, thereby improving the validity of mRDTs; 2) completeness of data collected; and 3) timeliness of data reaching supervisors and researchers. This paper evaluates these three hypotheses by comparing the quality of data collected using the Fionet™ system with a paper-based system.

Materials and methods

Study Design

This study was nested inside the Kenyan Insecticide Resistance Research (IRR) study. The IRR study in Kenya consisted of two cohorts in each randomized cluster sample: 1) an Active Infection Detection (AID) cohort, and 2) an Active Case Detection (ACD) cohort. The IRR study is described in-depth in other publications (Kleinschmidt, et al., 2015; Kleinschmidt, et al., 2018).

Between November 13th, 2013 and April 30th, 2014 CHWs performed household visits as required by the study protocol in 20 clusters across four regions in Kisumu County (Figure 1). Clusters were chosen to be villages with at least 500 houses that were each at least two kilometres apart. Clusters were also chosen to cover both high and low insecticide resistance levels across the four regions in Kenya (regions are shown in Figure 1 and described in Table 1). Ten of these clusters were randomly assigned to implement electronic data collection using the Fionet™ system, while in the remaining 10 clusters CHWs used paper-based data collection methods.

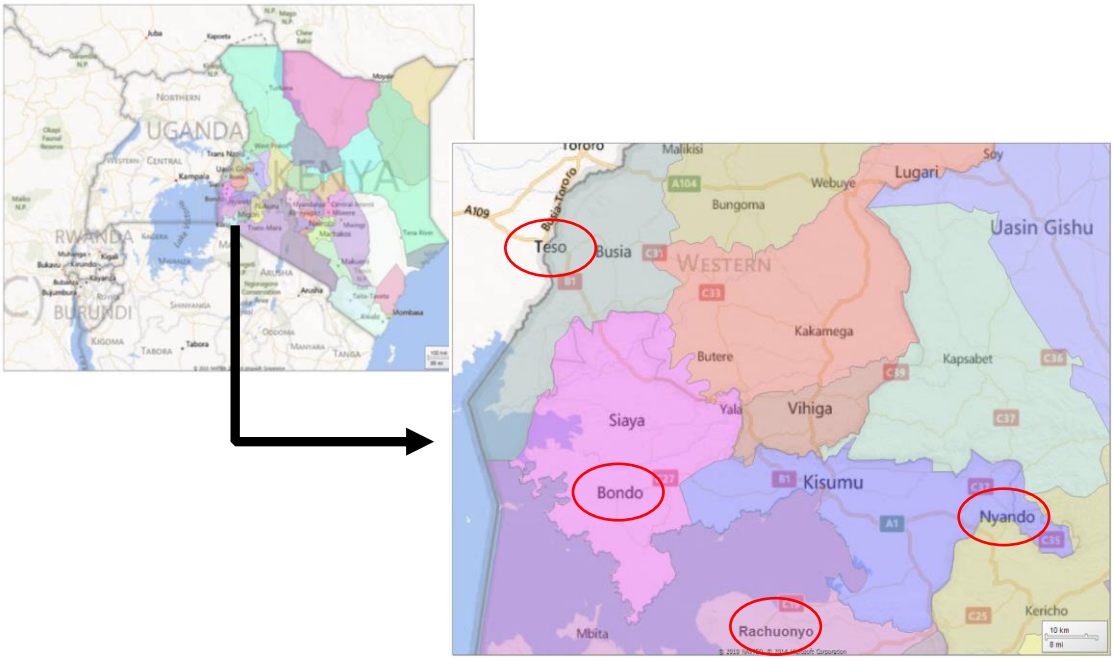

Figure 1. Map showing the KEMRI IIR study locations in Kenya.

Table 1. Distribution of records collected on the Fionet™ system by study cluster.

Cluster	District	Resistance Status	Unique IDs	Number of Records	RDTs	Positivity Rate
Bondo	Barchando	High	72	192	10	70.0%
	Masala	Low	101	411	121	27.9%
	Nyangoma	Low	99	252	28	32.1%
Nyando	Jimo West	Low	64	138	59	16.9%
	Muhoroni East	Low	82	179	37	10.8%
Rachuony	Kagwa Seka	High	54	107	59	50.8%
	Kobuya West	High	55	83	57	24.6%
	Koguta Homa Lime	Low	24	33	32	40.6%
Teso	Akiriamasi	High	84	122	5	100%
	Kengatunyi	Low	99	253	29	44.8%
Total	10		734	1,770	437	32.0%

Fionet™ System

Fionet™ is an integrated mobile health data collection and reporting system. Fionet™'s Deki Reader is a portable in vitro diagnostic device that interprets commercially available RDTs (Figure 2a). The Deki Reader provides CHWs with guidance on RDT processing, alerts them of errors, performs quality control checks, and provides consistent, automated interpretation of test results. The performance of the Deki Reader as an in vitro diagnostic tool has been validated in field conditions (Herrera et al., 2014; Shekalaghe et al., 2013; (Noble et al., 2020). The Deki Reader is equipped with a touch-screen

interface. Survey forms can be easily integrated into the Deki Reader software (Figure 2b). CHWs can use the Deki Reader to administer surveys and collect patient information in the field.

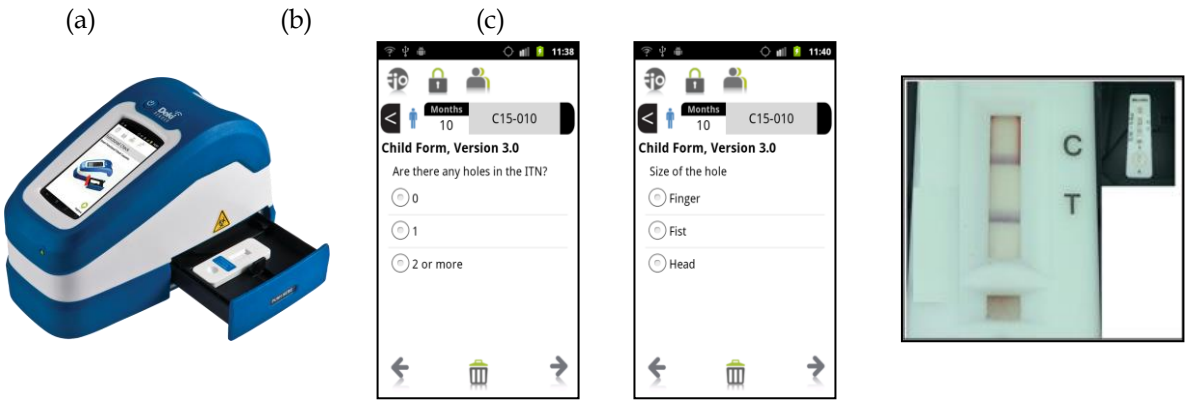

Figure 2. (a) Image of a Deki Reader V100, (b) A screen capture of one page of the electronic survey form, (c) Sample image of an mRDT captured by the Deki Reader and viewed via the web portal.

All the data captured by the Fionet™ devices at point-of-care is automatically sent to a central database, stored securely, and made accessible through a web portal interface (Figure 3). The Fionet™ web portal allows health program managers to remotely monitor performance in the field in a timely fashion.

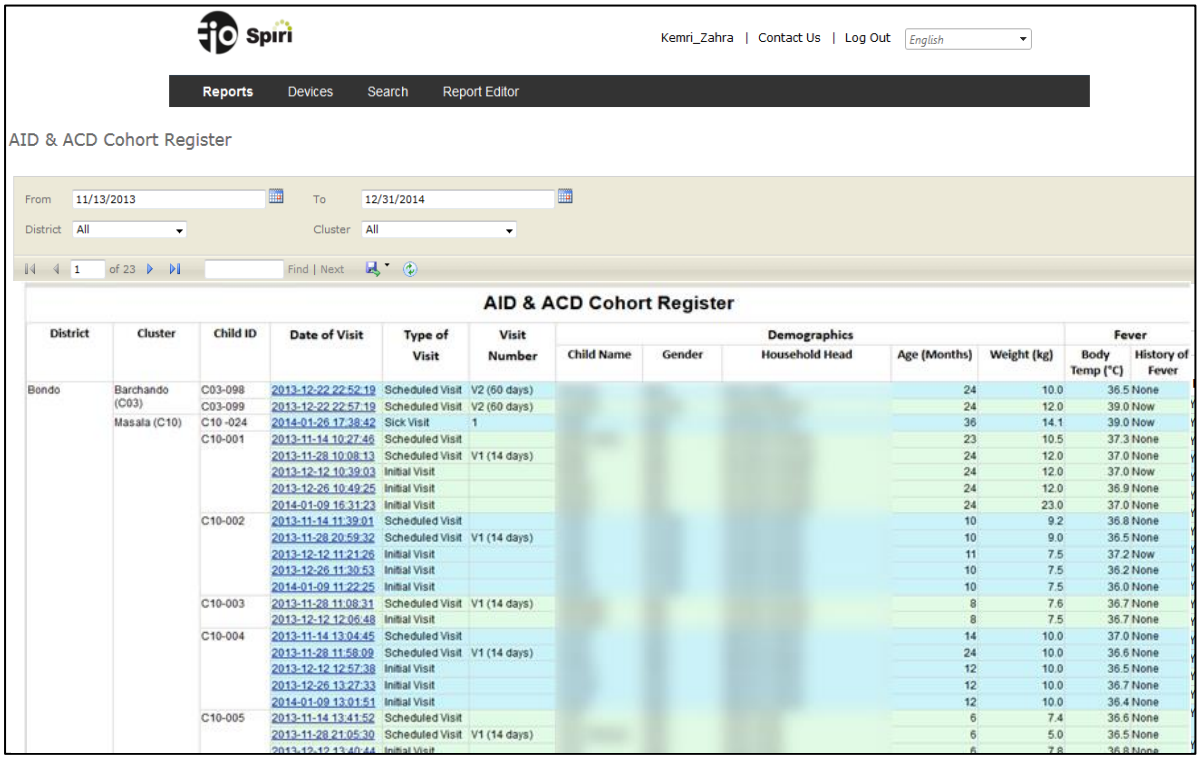

Figure 3. Fionet web portal that met the specifications of the KEMRI IIR study electronic register.

Implementation

The community health workers responsible for the 10 selected clusters each received a Deki Reader and participated in a two-day training session. The training session established proficiency in the use of the Deki Reader and in processing mRDTs according to manufacturer's guidelines. The Deki Reader itself provided: 1) step-by-step guidance for processing mRDTs, 2) an objective interpretation of test results, and 3) electronic capture of patient information and survey responses. All information captured during each patient session was bundled into an individual "patient record" and transmitted to KEMRI's online Fionet™ database over local mobile networks (Figure 2). The survey form implemented to capture the research data had fields to record 18 potential variables. Fionet™ surveys can be customized to designate fields as optional or required, restrict data formats (e.g. only numeric), and extract information from the system (e.g. date and time). The collection fields for the aforementioned survey included: CHW name, visit date, visit type, child ID, cluster number, cluster name, head of household, child name, age, gender, temperature, history of fever, LLIN use, holes in LLIN, and size of holes if applicable.

A separate one-day session was held to train program managers in the use of the Fionet™ web portal for supervision, monitoring, and evaluation activities. This included direct oversight of all mRDTs performed in the field with reports on real-time processing errors, visual interpretation results, and reports on survey data collected.

Electronic Survey Forms

The IRR study managers reviewed the paper household survey forms in order to translate them into electronic versions. The approved forms were then programmed into the Deki Reader software for use by the CHWs (Figure 2b). In addition, the IRR study database was replicated as a report on the Fionet™ web portal for ease of comparison between the electronic and paper data collected (Figure 3).

Analysis

Electronic data collected using Fionet™ was compared with paper records collected across the same 10 clusters during the same time span. Both modalities of data collection were evaluated across the following measures of data integrity: incongruous records, erroneous data, and completeness of records. The absolute number of errors and the frequencies of data quality issues are summarized for both Fionet and the paper-based method (Table 2). Data quality issues were categorized as incongruous records, erroneous data, and missing data. To test whether the proportions were significantly different between the two methods a chi-square test for significance was used.

The Fionet™ system has the ability to improve the accuracy of mRDT testing by capturing, detecting, and recording mRDT errors. The Deki Reader has the ability to detect common mRDT processing errors and invalid test results. If an error was detected, the Deki Reader provided immediate feedback to the CHW and prompted the CHW to repeat the mRDT. Additionally, the error message and an image of the mRDT was available on the web portal for supervisors to monitor. The accuracy of mRDT diagnosis in the field was assessed by the proportion of patients with a valid mRDT result. Only results from the Fionet™ system will be presented because this data was not captured by the paper-based records thus, it was not possible to compare the difference in mRDT accuracy between the two systems.

Timeliness of records was automatically calculated in the Fionet™ system as the difference between the time of record completion and the time the database received the record. The timeliness of the paper-based methods was estimated as the difference between the time of data collection from the field and the time point where the cleaned data was made available by the KEMRI team to the Fio program lead.

For all outcome measures, standard descriptive statistics are presented to describe the frequency of each metric. The frequencies of data quality measures were compared using a chi-square test for statistical significance.

Results

Data used for this analysis was collected between November 13th, 2013 and April 30th, 2014. A total of 1,770 patient records from household visits were collected and uploaded by the Fionet™ system from the 10 clusters. These included mRDT processing and

interpretation data from 437 unique patients (Table 1). In the same period, CHWs in clusters assigned to the paper-based collection tool collected 1,021 records, which were then entered into a database for analysis. In the paper-based database, 207 paper records from these 10 clusters lacked a corresponding visit date and were therefore excluded from the analysis as they may have been collected outside of the study period.

Data Quality

Incongruous Records

The data in the databases were analysed to determine if the entered values aligned with the correct variable. There were no instances of misalignment in the Fionet™ database; however, there were 83 instances (8.1%) of misalignment in the paper-based database. Misalignment appeared to cause additional duplicates in the database as the original record may not have been found during data entry and thus double-entered. Once misalignment of patient records was resolved, exact duplicates of patient records were identified and removed in both databases. The Fionet™ database contained 18 duplicate records in total, which was a frequency of 1.0%, compared with 120 duplicate records in the paper database, which was a frequency of 11.8%. The frequencies of misalignment and duplicate records were statistically significantly different, using a chi-square test, with p-values <0.01 (all data summarized in Table 2).

Table 2. Summary of frequency of data quality issues observed by using Fionet and the paper-based systems

Data Quality Category	Data Quality Item	Fionet™ Records	Paper-based Records
Incongruous Records	Duplicate Records	18 (1.0%)	120 (11.8%)
	Misaligned Records	0 (0.0%)	83 (8.1%)
Erroneous Data Points	Outside valid range	6 (0.3%)	20 (2.0%)
	Incorrect format	0 (0.0%)	14 (1.4%)
Completeness of Records	Records with Empty Fields	3 (0.1%)	918 (89.9%)

Erroneous Data

Erroneous data points were defined as variables with values outside a valid range or data entered in an incorrect format. Examples of values outside of the pre-determined valid range include, but are not limited to: cluster numbers that do not exist, age values outside the study age restrictions, and extreme body temperatures. Data entered in an incorrect format can make it difficult to extract insights in a timely manner. Non-uniform data may then require extensive quality control procedures prior to analysis. Some of the incorrect data formats observed include but are not limited to: non-standard date formats, non-standard ID formats, and non-standard cluster ID formats. The Fionet™ survey forms can use a variety of input methods, such as drop down menus, numeric fields, free form fields, etc. Additionally, input restrictions (e.g. data formats, input length) can be specified to help ensure quality of the data entered in the field. In the Fionet™ database, there were a total of six erroneous entries (0.3%). All the erroneous entries were values entered outside a pre-determined valid range. The paper-based method had a total of 20 entries (2.0%) outside of the pre-determined valid range. An additional 14 entries with an incorrect cluster ID format were resolved. There were significantly more erroneous data entries in the paper-based system compared with the electronic system (all data summarized in Table 2).

Data Completeness

Each patient record contained 18 potential variables. For all patient records there should have been a minimum of 15 variables completed in the database. These 15 variables were: CHW name, visit date, visit type, child ID, cluster number, cluster name, head of household, child name, age, gender, temperature, history of fever, LLIN use, holes in LLIN, and size of holes if applicable. The three additional variables concerned mRDT results and treatment, which were not applicable to all patient records. If a patient record contained all 15 required variables in the database, then the record was considered complete. In Fionet™'s database 99.9% of patient records were complete

compared with only 10.1% of records in the paper-based system. The difference in the data completeness between the two systems was statistically significantly ($p<0.01$) (data summarized in Table 2). The Fionet™ survey form can make fields mandatory to ensure that they are completed. A paper-based system relies on the user to fill out each form on the paper. A potential source of incomplete records could be that some households did not provide the required information. However, non-response rate to questions would not be expected to vary by the data collection method.

Monitoring mRDT Errors

Community health workers using the Deki Reader received feedback on performance and were remotely supervised to ensure that mRDTs were processed according to national guidelines and protocols. Errors detected by the Deki Reader included: no control line present, blood added to the buffer well, too much blood added to the mRDT, and incubation period elapsed. It was observed that 8.7% of mRDTs processed had errors. In these cases, Fionet™ quality control measures prompted health workers to repeat the mRDT until a valid test result was obtained. After being prompted to repeat invalid tests, 98.4% of patients received valid mRDT results. The paper-based method did not allow for real-time quality control of CHW mRDT performance and therefore did not provide the opportunity to correct or evaluate the frequency of errors as they occurred.

Adherence to study protocol

The IRR research required a rapid diagnostic test for be administered by the CHW at specified point in the care protocol. Failure to do so would mean non-adherence to protocol. Protocol adherence rate for data gathered using Fionet™ was 65% while adherence for data gathered using paper methods was 36%. The difference in protocol adherence was statistically significant (p-value <0.01). The most common non-adherence to study protocol that was observed with the Fionet™ system was not administering a mRDT when the study protocol required a test to be administered. No information was collected regarding the availability of mRDTs; a lack of supply of mRDTs may have limited their use, but this would not be expected to vary between the data collection methods.

Timeliness

Fionet™'s Deki Reader transmitted 82% of collected records to the database within 1 hour after completion of the survey form, and 87% within the next 24-hour period (Figure 4). Within one week after collecting the data, 94% of the records had been transmitted to the database in the portal (Figure 4). Data gathered with Deki Readers are stored locally if a network is not available and then uploaded when a network becomes available. Data gathered using paper was manually transported and transcribed by data clerks and available to researchers between three and six months after the data was originally collected.

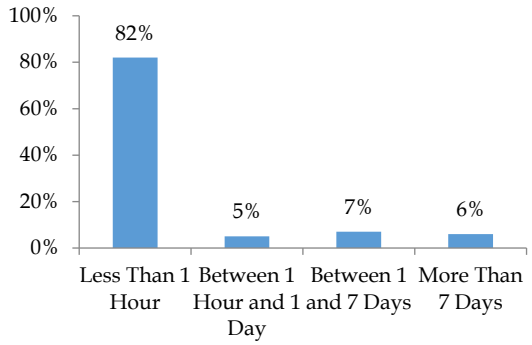

Figure 4. Record upload speed to the web portal from the Deki Reader.

Discussion

The application of mobile electronic devices and related technologies to healthcare, known as Mobile Health or mHealth, is improving patients' access to treatment and advice. mHealth tools work to enhance the existing healthcare systems and health research by providing more accurate and timely information. The potential uses and applications of mobile electronic mobile include data capture, quality control measures, tracking of resource availability, and guidance of healthcare workers' performance in the field. Today, this network of connected diagnostic devices offers new possibilities when applied to infectious diseases; it is able to increase efficiency of diagnoses, disease tracking, and improvement of control measures. The use of electronic means of data capture in healthcare, also known as EDC, has been widely adopted in clinical research over the past few decades. EDC can increase data accuracy and quality, as well as decrease the time required to collect data for

research studies of drugs, vaccines and medical devices. Given the considerable reduction in the time from data collection to database completion, combined with equal or better data quality, EDC is the current standard for data collection in clinical trials and field epidemiology studies (Bart, 2003; Walther, et al. 2011).

Mobile health technologies, such as Fionet, can be used by CHWs to facilitate data collection, testing, and patient management in remote areas and hard to reach communities. Arming CHWs with mobile technology makes healthcare more accessible to patients who may not live near a healthcare facility (Otieno-Odawa, and Kaseje, 2014). By facilitating communication between CHWs and their supervisors in nearby health posts and health centers, the use of mHealth applications empowers CHWs to overcome many of the challenges they face in the field, such as the balance of multiple priorities, a lack of appropriate tools to provide services and collect data, and limited access to training and supervision. CHWs play a pivotal role by connecting their communities to a formal healthcare system. In addition, supervisors can provide feedback to improve CHW performance with use of high quality and timely data coming from the field. mHealth applications can be used to make program adjustments, provide supplementary training for CHWs, and track supply levels.

Implementation of novel technology in the field can be challenging. Technological literacy of CHWs is essential for adoption and use of a novel mobile health system. Fionet ensures that there is adequate training and ongoing support to ensure a successful implementation. Previous reports have shown the feasibility of the Fionet™ system in a remote setting in Kenya (Soti, et al., 2015). As described in Soti et al 2015, health workers at 11 sites in Kisumu County, Kenya were trained to use Deki Readers to process mRDTs. Health managers at these sites were trained to use the Fionet™ web portal to access the data uploaded from the Deki Readers (Soti, et al., 2015). The study concluded that the use of the Fionet™ system to collect and organize data in this setting is feasible. Previous studies have also shown the utility of CHWs when compared with doctors; CHWs can accurately and reliably collect certain types of community data at a lower cost than highly trained specialists (Braun et al, 2013). Technology such as the Fionet™ system can further improve CHW performance by providing data quality checks and guiding data collection in the field.

Fionet™ customized the data collection form to include EDC and mRDT processing by the CHWs. Fionet™ system allowed for the inclusion of dropdown menus, data format restrictions, creation of mandatory fields, auto-capture of information (such as RDT images) and timestamps. This reduced the number of entry errors, eliminated the need for transcription and thereby increased the data integrity at the point of care and in the database to which these data were uploaded. This is important to ensure accuracy of data.

Adherence to protocol is a critical part of care delivery and data collection. CHWs who perform these tasks are trained, tested, given resources, and then deployed to the field. Even in the best of circumstances CHWs receive very little support or supervision as they perform their tasks using standard manual systems. However, EDC systems such as Fionet™ enable feedback at the time of data capture and processing of mRDTs. In this study, this resulted in improved quality of care and quality of data captured. It helped CHWs to adhere to study protocol, thereby ensuring that all survey fields were filled out and no data was missing. RDTs are very powerful diagnostic tests due to their simplicity, low cost, and accuracy in terms of sensitivity and specificity. However, as with any other laboratory diagnostic test, they require strict adherence to testing protocols to obtain reliable results. Since RDTs are commonly performed by peripheral field healthcare workers, including CHWs, who are not trained lab technicians and work in less than ideal settings, it is not unusual to experience deviations from the recommended protocol and mistakes in interpreting the test results (Harvey, et al., 2008; Rennie et al., 2007)). In the current study, 8.7% of mRDTs in the clusters assigned to Fionet™ had a processing error. The electronic system was able to provide immediate feedback to the user and most of these faulty tests were repeated to obtain a valid result. In addition, the automated digital interpretation of the tests precludes misinterpretation by healthcare workers (Herrera, et al., 2014; Shekalaghe, et al., 2013). All information collected, including tests with processing errors, was transmitted to the

portal database, thus enabling researchers to detect users with repeated mistakes in mRDT processing and perform re-training as necessary. Unfortunately, no comparison could be made with the paper system in this respect as there is no information available related to mRDT processing performance by CHWs from the clusters assigned to the traditional paper-based method.

Additionally, timeliness of data receipt by program managers and researchers allows them to monitor CHWs in real time, enabling remote oversight of the program without having to physically be in the field. Without receiving data in a timely fashion, managers are unable to effectively respond to study or programmatic problems that frequently arise. When data is collected and entered manually, there are inevitable delays in data analysis, reporting, and publication. Administration of quality control measures and collection of paper records is more costly to research programs compared with electronic-based collection systems. Sites using Fionet™ delivered more accurate and more complete data several months faster compared with sites using paper-based method.

Conclusion

The Fionet™ mobile electronic data system showed significantly higher data quality, integrity and timeliness. There were significantly fewer erroneous data points in the dataset; a ten-fold increase in data completeness, and complete data was made available to researchers within one week of being collected, compared to several months using a paper system. Fionet™ significantly improved the overall data quality and management and enhanced the ability to meet the National Malaria Program objectives. Future studies should strive to incorporate mobile technologies such as Fionet™ to improve data collection and mRDT based diagnostics of malaria. Utilization of technology can help ensure accurate, complete and promptly available research data.

Acknowledgements

The authors wish to acknowledge and thank The Kenya Medical Research Institute (KEMRI) for selecting the Fionet™ system to evaluate as a mobile tool to improve data collection. Nesting the evaluation within the Kenyan Insecticide Resistance Research (IRR) study provided a good setting for this research. We wish to thank the Ministry of Health Kenya and the Kisumu County leadership for their approvals of the study. We recognize the field enumerators who diligently used the Fionet™ system as well as the standard research procedures to conduct the evaluation successfully. We thank Fio Corporation for providing the technology, KEMRI for supporting the field operations and Fio East Africa for providing field supervision.

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