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Medical Device Integration with Electronic Health Records: A Case Study of University of Nairobi Health Services, Kenya

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Abstract

In this study, we describe a demonstration in which available electronic medical records system (EMR) was successfully integrated with a wireless blood pressure monitor (BPM). This was implemented by adopting the use of RESTful Application Programming Interface (API) technologies and commonly established standards designed for medical devices interoperability. Before deploying the prototype, we conducted pilot tests at the University of Nairobi, nursing station to get feedback on the time spent using the conventional blood pressure data capture methods and the newly integrated application. Clinical data from the device was exchanged adhering to the HL7/XML standard communication protocol. The findings indicate a positive outcome was availed on the time taken for the blood pressure readings, time spent by the patient at the nursing station, doctor's time to search the patients' blood pressure readings as well as the data accuracy fed in the EMR system.

Keywords: EMR, BPM, Interoperability, Restful, API, Integration, HL7/XML

1. Introduction

Over the recent years, there has been a country wide drive for both public and private hospitals institutions to adopt the use of information technology in the health care system. The Kenyan Government formulated the Kenya National eHealth Policy 2016-2030 with the goal of ensuring attainment of the highest standard of health through adoption and use of information and communication technology (GoK, 2016). Adoption of information technologies in the health sector has been shown to lead to enhanced access, reduction in costs, improved quality of health services, improved decision making and efficiency in the health sector (Odhiambo, 2015).

Despite the significant progresses towards enhancement of these technologies, numerous barriers continue to impede the realization of health information technology's potential. Lack of functional medical device integration is one of the most significant limitations. A question could be asked as to what benefit there is in having expensive secluded medical devices and at the same time have health care providers noting down patient vitals on paper then later manually keying the parameters in the electronic record system? The lack of device integration is a serious problem; potentially preventing clinicians from having timely access to observational data that would help them give the safest and most effective patient care. Having a coordinated, consistent and enhanced care needs complete, accurate, and technologically supported data gathering methods.

Purposeful medical device Integration embroils the ability for medical devices to exchange information with each other and with patient data repositories such as electronic health records. Medical device integration enables clinical medical devices to communicate in a consistent, predictable and reliable way and exchange



clinical data with electronic health records (EHRs) seamlessly. A complete electronic health record (EHR) system that is integrated with other automated medical devices has significant potential to improve quality, safety, and efficiency of care delivered. These improvements are made possible with the all-embracing objectives of medical device integration which includes; error reduction in data entry and faster, convenient and timely access to data as well as improved workflows.

1.1 Medical device integration

Integration explains the degree to which isolated devices and systems are able to exchange and understand shared data. Two systems are considered to be interoperable if they are capable of exchanging data and consequently present that data in a format that can be comprehended by a user (WHO, 2011). Medical device integration also known as interoperability denotes information sharing between one medical device and another or amongst the medical devices and EHRs. Successful interoperability ensures the efficient communication between the connected medical devices in a predictable, consistent, efficient, and reliable manner. This makes health systems more reliable and safer and can be used to address transcription and administrative errors in health care delivery. Seamless connectivity and workflow are the most important ingredients to device connectivity solution, whether the medical device is PC-based or purpose-built. Medical device interoperability provides tangible improvements in safety and efficiency of medical processes in a clinical process. Such enormous benefits can be measured in savings in the provision of health care, yet, regardless of the significant paybacks, there is a scanty use of medical device interoperability.

1.2 Medical Device Integration with Electronic Health Records

Healthcare providers across the globe are adopting the application of the electronic medical records (EMR) systems in the concerted effort to enhance patient care (Mugo & Nzuki, 2014). In this regard, the integration of medical devices enables healthcare services' providers to directly send or access point of care patient data, such as temperature and blood pressure directly to an individual's medical record, and thereby significantly reducing the transcription errors and at the same time ensuring the timely transfer or sharing of important clinical data (Venkatraman *et al.*, 2008). It can, therefore, be argued that medical devices can play a significant and integral role in the provision of healthcare by delivering crucial healthcare data essential to guiding life-saving procedures (Jitterbit, 2014). Nevertheless, many medical devices are not being maximized to attain their full potential by having them connected to the EMR systems that drive patient care. Although integration of medical devices with EMR systems is possible, little has been documented on strategies for ensuring the success of the integration. Additionally, the technology that is involved can be, to a large extent, deceptively simple, and in the scheme of the implementation of an ambitious EMR the healthcare device portion is often regarded as relatively insignificant, yet its benefits are huge in the management of patient care (Lau *et al.*, 2012).

1.3 Medical Device Integration standards

The establishment of standards for the medical device interoperability exists to enable medical information systems to engage across organizational, system, as well as across regional and global boundaries (Franz, Schuler & Krauss, 2015). As such, in order to support and facilitate the daunting complex task of medical device interoperability, it is important to establish a number of standards. There are some organizations that have initiated adoptable standards to support the device interoperability. Many of these standards operate in tandem to facilitate functional as well as the semantic interoperability of healthcare devices and EMRs. The commonly used standards for data exchange in medical device integration include messaging standards, application standards and architectural standards.

Messaging standards are used to define the content, data and structural requirements that appertain to electronic messages in order to enable and support the effectiveness and accuracy of the shared information. Some of the available examples include HL7 v2.x used for health care administrative data. Another example is the Digital Imaging and Communications in Medicine (DICOM) for radiology images. Application standards

determine the adoption of business rules and regulations for the application of software systems in their interaction. For instance, the standards can permit one user to have access to different information systems within a given environment which allows for efficient access to the essential and applicable health data. Architecture standards are used to define and apply, for instance, a generic model for medical information systems. These standards enable the possible integration of medical information systems through the provision of guidance to help in designing and planning of systems as well as enabling the integration of existing healthcare systems. The integration is achieved through the deification of common data elements coupled with the established business logic that exist across systems. For instance, the CEN standard ENV12967 (Healthcare Information Systems Architecture or HISA) offers what is described as an open architecture which is largely independent of complex, and sometimes confusing technical specifications.

1.4 Challenges of Medical Device Integration

Medical device integration with EHRs is a difficult and complex process which requires work at various levels, from developing software to building a network of bridges and gateways for the medical devices and the data collecting devices. The challenges associated with medical devices integration include development of intuitive interfaces capable of providing a link between the medical devices to the EMR which require highly skilled technical personnel and dedicated resources which many health care providers often lack. Handling cross-vendor integrations remains a challenge too. Traditionally, most manufacturers of medical devices have developed devices in isolation in order to protect their own interests. Data obtained from various medical devices lack unified global standards and often may not comply with emerging cross-vendor standards.

Another challenge is that there are a few well-defined use cases which can demonstrate the challenges and achievements associated with medical devices integration. In the absence of such cases, any organization that wishes to engage in medical device integration has to basically start from the beginning in obtaining the essential information and making a determination on the best practices that would guide the project implementation and management.

Finally, it is necessary to have the necessary staff compliance that would guarantee adherence to a consistent workflow of data entry into the correct EHR data centers since most patient encounter presents a significant challenge. In numerous situations, there is inadequate clinical staff, which makes the transfer of knowledge on the optimized application of EHRs and essential medical devices a significant challenge.

So far it is apparent that the problem of medical device integration is a hard procedure for two major reasons. First, it is the fact that medical device connectivity becomes a complex process since there is no "one model" solution for the establishing connection among all medical devices and secondly, the local databases of the hospitals also vary from one place to another. The main objective of this study was to develop an application that interfaces a wireless Blood Pressure Monitors (BPM) to an existing Electronic Medical Records system. Nokia BPM device and Nokia's Application Development Interface (API) for integration were used to generate the artefact.

1. Materials And Methods

2.1 Study Site

This study was conducted at the University of Nairobi Health Services (UHS) staff clinic. The hospital provides in-patient and out-patient services for a population of approximately 85,000 people made up of both students and staff. The clinic has an in-house developed health information system named University Health Management Information System (UHMIS). This system has various modules including, Pharmacy, Triage, Records, Prescription and Administration. Patients who visit the facility go through the Nursing section, where vitals like blood pressure, height, weight and body temperature are recorded. At the nursing station there are a few medical devices including a standalone Philips VM6 Vital sign Monitor, digital weighing scale with a height meter scale and digital thermometers. Despite having these devices and the existing health information



system, none of these devices is connected to the University Health Management Information system. Patient's clinical vital readings data measured by the devices electronically are read by clinicians, written on a small piece of paper or Blood pressure log paper cards. These paper based logs are stored in the patients' physical files which medical doctors refer to them during consultation and treatment of the patients.

2.2 Data Collection

This study was aimed at developing and implementing a seamless integrated patient's blood pressure data capture system at the nursing station, University of Nairobi Health Services. Nokia wireless BPM device and Health Mate API were used to facilitate data capture and data reading respectively. Necessary approvals were sought from the relevant authorities and structured interviews were conducted to establish the feasibility of the study. Workflows for the blood pressure capture process were studied through observations to ensure the proposed integrated solution was not going to introduce delays.

This integration pilot study encompassed both quantitative and qualitative methods to gather data. Sampling was done and three groups of users identified as nurses, doctors and the patients. Online questionnaires were also administered to each group of users and responses analyzed using excel. A total of eight doctors, thirteen nurses and ninety six patients responded. After analysis of preliminary data a low fidelity prototype was developed and validated by the different users. This was done iteratively using User Centred Design Approach until all the users were satisfied that their requirements were met. User satisfaction survey questionnaires were administered to the different groups of users and the responses analyzed. This was very important to ensure the solution was user friendly, useful and reliable. Three software modules were developed and tested. First the custom API named BP-Easy to fetch the data from the Health mate application, web interface for the different users and lastly a mobile application.

Data on number of clinical staff and patients utilizing the device was to be monitored on daily basis. In-order to demonstrate time saved, we used stop watch to time how long the BP-Easy solution took during BP readings capture compared to the conventional BP data capture method at the nursing station. We analyzed the time taken for both integrated solution and the conventional methods used. Further, we compared the blood pressure values that were taken by the traditional, manual device and the newly integrated, automated device, to understand the rate of agreement between what was measured, and what was actually entered into the manual files.

2.3 Prototype development approach

This study used an agile methodology which promotes empirical processes over prescriptive processes (Larman, 2003). These processes are decomposed into self-contained mini-projects (sprints) and releases (Sliger & Broderick, 2008). In order to convert the blueprints into a practical software development process, we used the Agile Unified Process (AUP) (Koch, Kraus & Hennicker, 2007). The rationale was to use an approach that adheres to ISO 9241- 210:2010 (2010) standard on user-centred design. In our case, the software release was designed in such a manner that it is releasable after each one. Agile phases include inception, elaboration, construction and transition.

At the inception phase emphasis was on conceptualization to identify stakeholders' needs through business modeling and requirement elicitation. The need was to integrate the isolated blood pressure monitor at the nursing station. It was established that the old standalone Philips VM6 Vital sign Monitor could not be integrated with the existing EMR due to vendor incompatibilities. A Wireless Nokia BPM device was considered because of its high-accuracy blood pressure monitoring, Bluetooth synchronization, iOS and android compatibilities, offline data capabilities and also availability and support of the Health mate API for data exchange. Patient's blood pressure readings were read from the device and written in to small papers presented to the doctors to administer treatment. Patients' blood pressure records were kept in manual files making it quit difficult for the doctors to get patients history. Due to this, hypertensive patients could not

access their records remotely for self-monitoring instead they were forced to carry a physical paper log to record their blood pressure readings.

At the second phase detailed analysis of requirements was done using system models. Relational database modeling was used where various database entities were identified which included; staff, dependants, authorization_code, access_code and blood_pressure. Dataflow diagrams were drawn using e-draw software and UML diagrams developed to depict the process flow of the system. Design and implementation of system artefact suitable for the stakeholders' needs was done. Low fidelity prototype was developed then deployed to the user environment. Users evaluated the system and gave feedback based on their requirements. Iteratively all the changes were incorporated into the system until users were satisfied. Different data visualization interfaces for the various users were developed to display data only relevant to each user group. A working system dubbed BP-Easy was developed and tested and validated. System deployment at the user environment was done. Due to data confidentiality user accounts were created in the newly integrated blood pressure data capture solution and passwords created. Various groups were sensitized and trained on the system separately. All the processes and workflows were documented. User manuals and Frequently Asked Questions documents were developed and issued to the users. Lastly a user satisfaction survey was conducted using online questionnaires and feedback recorded and analyzed.

2.4 Blood Pressure Monitor Device Used for Integration

In this integration solution, the Nokia Wireless Blood Pressure Monitor device which enables the measurement and tracking of diastolic and systolic blood pressure, as well as the heart rate was used. This device is convenient, smart and automatically compares its readings to National Health Institute standards. The choice to use the device was further guided by the fact that Nokia BPM offers both plug for compatible smart devices and wireless connectivity via Bluetooth technologies to record blood pressure readings.

2.5 Technical Overview

The BPM device sends data requests to the Health Mate Application using Bluetooth. Nokia Health Mate App writes the BP reading obtained from the BPM device to the Nokia Health API. The Blood Pressure readings data exchanged at the API is stored at the Nokia Health Cloud for retrieval when required. The BP-Easy application reads BP readings data from the Nokia API and sends the patient readings to the custom BP-Easy API which subsequently stores the data into the patient's database. The web interface reads and writes in to the patient's database providing customized views of data for patients, doctors and Nurses. Data is represented in different visualizations in form of graphs and tabulated reports.

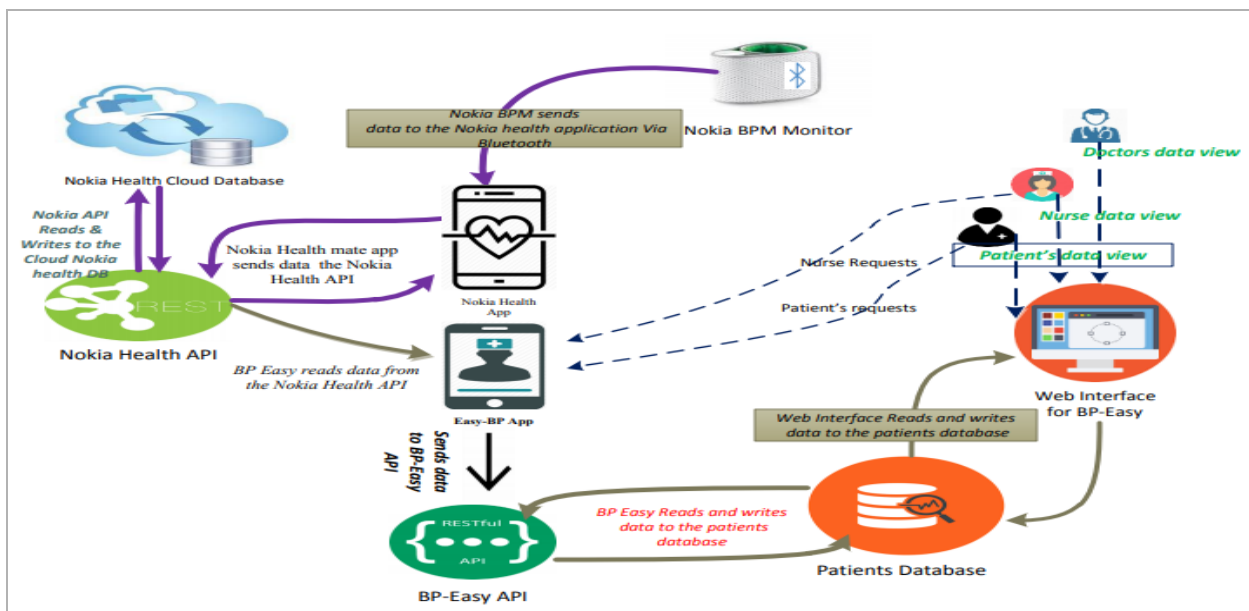


Figure 1: High level BP-Easy Model Diagram

The BP-Easy solution is segmented into three functional components which include the Mobile App, the Web Application Interface and the Nokia Health API. The Mobile App was developed on Apache Cordova which can be ported for different platforms such as Android, Microsoft and IOS. The implementation of the BP-Easy solution for this study was done on Android version. The mobile App had two modes of operation based on the different user roles. Three main roles namely Triage, Nurse and Doctor were implemented. More roles can be added into the system depending on user rights and functionality. The App data exchange used the OAuth Version 2 between the Nokia Health API which retrieves data from the Nokia Health Cloud Database.

The Web Application Interface was a web based solution that helped manage the BP information and also mobile App operations. Different users were provided with customized data visualizations and intuitive interfaces to manipulate the data. The web interface was constructed on the Yii version 2.0 PHP Framework. Yii helped create BP-Easy quickly, simplified security and was also highly extensible and allowed implementation of HL7 for data transfer. The Nokia Health API is a REST based Web Service provided by Nokia which implements OAuth version 2 for exchange of data. Using the Nokia App, it was possible to capture the readings by the Nokia BPM monitor and store them in the Nokia Health Cloud Database. The information was then synchronized with the BP-Easy solution providing each user with customized user views.

2.6. Deployment environment workflow

The overall patient care workflow was analyzed to ensure a seamless process for collection of blood pressure readings without introducing any additional steps or significant slow-downs. This was considered very important to capture clinicians buy-in and sustainability of the overall project. Medical assistants and nurses who commonly collected blood pressure information during the patient care visit were active participants in the evaluation of the new workflow. This helped determine changes in the intake process necessary to incorporate use of the integrated blood pressure monitor system. The Nursing room was reorganized by adding extra chair where clients had to rest as blood pressure readings were taken.

2.7 User Training

User sensitization sessions organized by the Chief Medical Office at the staff clinic were conducted first. Later training was conducted to the care givers and all installations done. All users were trained based on their roles on how to interact with the BPM device and EMR simultaneously to ensure data accuracy while providing

attentive health care. A Computer Tablet device and the Wireless BPM device were provided for use during the exercise. Training manuals, a frequently asked questions (FAQ) document were developed and shared with these members of staff, complete with screenshots and detailed steps on what to do during the patient visit.

2.8. Integration challenges

Before integration, we carried out an evaluation of the available wireless blood pressure monitors based on their capabilities to exchange of data between the Device and the Electronic Medical record system available. At first we started with the I-health wireless blood pressure monitor without success. It was observed that I-health elaborate Application Programming Interface (API) had issues with user support and it was infeasible to receive the authorization key to continue with the integration process. Secondly the Software Development Kit (SDK) for Integration was expensive to purchase. This led to abandoning of i-Health device and use of Wireless Nokia BPM Monitor. There was a lot of resistance from medical staff in adopting the new technology. Due to health data security reasons we did not use the University live database for its patients instead we created a local database to simulate the environment. All records were encrypted and access controlled by well-defined user groups, access levels and secured passwords.

1. Results And Discussion

According to the observational data on the duration of blood pressure data collection, we found a measurement difference in time before and after device integration. On average, the amount of time it took the blood pressure cuff on the patient's arm was 123 seconds before device integration, after integration it took 83 seconds. Further, after the device integration, there was a significant reduction in overall time spent by the nurses at the room from average of 370 seconds to 240 seconds. At the doctor's station, the average time taken to search for the blood pressure readings dropped from average of 360 seconds to a low of 54 seconds. This was more than half the time spent to search for the records from the manual files. In terms of data accuracy 0.38% of the readings searched in the manual files had inconsistencies in both diastolic and systolic and 0.23% of the data not readable. 0.42% of the files had no records on blood pressure readings yet it is a mandatory requirement for all patients to take the readings before treatment. 0.85% of all users reported the new integrated solution was user-friendly, with 0.95% agreeing that the solution was useful, usable and effective.

2. Conclusions And Recommendations

Despite most Medical device technologies being developed in isolation, the integration of a commercially-developed medical devices and an existing EMR system is possible. This study has shown that a fully functional integrated medical device is faster, reliable, effective and provides accurate and consistent data that can be used to aid in clinical decision making during patient treatment. The staff indicated that they prefer to use the integrated system to the old manual way of collecting and recording the Blood Pressure readings. The findings suggest that there is tremendous reduction in total time spent by the patients at the nursing station and also when doctors are searching for the data from the manual records. Accuracy of data was also a concern and now the various users could believe in the data captured because there was no manual recording. No transcription errors during the data capture as well as data being stored in the EMR system were noted. In this demonstration project, sample sizes were small and most of them not repetitive, so further study is needed to see if our results are replicable on a larger scale. Further, the solution needs to be deployed in the outpatient setting, and eventually home setting towards improving care by enabling the patients and the Doctors to share data remotely. Given the rapid adoption of medical device technology, EMR integration is critical for safe, efficient, and effective care.

References

1. Berg, M. (2001). Implementing information systems in health care organizations: Myths and Challenges. *International Journal of Medical Informatics*, 64(2-3), 143-156.



2. GoK(2016). Kenya National eHealth Policy 2016-2030. Available online: <https://www.medbox.org>
3. Mugo, D. M & Nzuki, D. (2014). Determinants of Electronic Health in Developing Countries. *International journal of Arts and Commerce*, 3(3), 49-60
4. R. Hofmann. Modeling medical devices for plug-and-play interoperability. Master's thesis, MIT, June 2007.
5. H. Burgsteiner, S. Sabutsch, A. Kollmann, J. Morak, "Communication and Integration of Health related Data in Electronic Health Records using International Medical Standards," *Proceedings of the eHealth (2009)*, pp. 229 234
6. R. L. Craft. Toward technical interoperability in telemedicine. *Telemedicine and e-Health*, 11(3):384–404 June 2005.
7. Leikas, J. and Stromberg, H. (2005): Novel User Interfaces for Promoting Social Interaction in Multiplayer Games. *ENACTIVE/05*, November 17-18, Genoa, Italy.
8. Hull, E, Jackson, K & Dick, J 2005, *Requirements engineering*, 2nd edition, Springer, London.
9. H. Burgsteiner, S. Sabutsch, A. Kollmann, J. Morak, "Communication and Integration of Health related Data in Electronic Health Records using International Medical Standards," *Proceedings of the eHealth (2009)*, pp. 229 234
10. HL7 Implementation Guide: CDA Release 2 Continuity of Care Document (CCD). A CDA implementation of ASTM E2369-05. Health Level 7. 1 Apr. 2007.
11. Odhiambo, M. E. (2015). A framework for implementation of e-health in Kenya public hospitals (Thesis). Strathmore University. Retrieved from <http://su-plus.strathmore.edu/handle/11071/4875>
12. Franz, B., Schuler, A. & Krauss, O. (2015). Applying FHIR in an Integrated Health Monitoring System. *EJBI* (11), 51-56
13. Valerie Gay, P. (2017). Bringing Health and Fitness Data Together for Connected Health Care: Mobile Apps as Enablers of Interoperability. [online] PubMed Central (PMC). Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4704968>
14. W3C, "WebServices Architecture," 2012. Available: <http://www.w3.org/TR/2004/NOTE-ws-arch-20040211/technology>
15. What is Agile model – advantages, disadvantages and when to use it. istqbexamcertification.com. Available at: <http://istqbexamcertification.com/what-is-agile-model-advantages-disadvantages-and-when-to-use-it/>
16. World Health Organization. (2017). UN Task Force: Kenya's fight against noncommunicable diseases aims to improve health, strengthen development. [online] Available at: <http://www.who.int/nmh/ncd-task-force/unf-kenya/en/>
17. [Yiiframework.com](http://www.yiiframework.com). (2017). About Yii - Introduction - The Definitive Guide to Yii 2.0. Available at: <http://www.yiiframework.com/doc-2.0/guide-intro-yii.html>