Towards an architectural design of a guideline-driven EMR system: A contextual inquiry of Malawi

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ABSTRACT

Computerised clinical practice guidelines are a key component of effective clinical decision support systems, especially in low-resource regions such as Malawi. To address shortages in staffing and budgets for training, the practice of *task-shifting*, the clinical practice guidelines (CPGs) enable health workers with limited training to provide a standardised level of care. However, CPGs are traditionally paper-based, with only a few CPGs having been integrated for Malawi's national electronic health record system. These CPGs have been hard-coded into the system, necessitating significant additional work to add support for future and revised CPGs. CPG computerisation challenges are further investigated in order to understand the motivations for the current computerised CPGs implementation. Semi-structured interviews, code reviews, and observations were used in Malawi. Most significantly, existing understanding of software engineering principles is extended to the context of low-resource environments, noting that the tensions between conflicting stakeholder requirements, deadline and deliverable expectations, and good software engineering often result in systems that are harder to maintain, further exacerbating potential problems with longevity of ICTD deployments. It is further suggested that a component-based approach in conjunction with communities of open source developers might help alleviate this problem by providing more scalable and robust CPG support.

Categories and Subject Descriptors

J.3 [**Computer Applications**]: Life and Medical Sciences—*Medical Information Systems*

General Terms

Design, Human factors

Keywords

Clinical practice guidelines, protocols, clinical decision support, ICT4D

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1. INTRODUCTION

Malawi, one of the least developed countries in sub-Saharan Africa, faces a double disease burden of communicable and non-communicable diseases [17]. In addition, the country is facing a crisis in human health resources due to a shortage of health workers [29]. Malawi has one of the lowest doctor to patient ratios estimated at about 1 for every 100,000 [18].

Malawi, like most other low-resource regions, has adopted task shifting to cope with the human resource crisis for health. Task-shifting refers to a process of delegation of tasks to health workers with lower qualifications [22]. The task-shifting process requires the development of standardised protocols, including simplified clinical practice guidelines (CPGs), simplified recording and reporting systems and simplified monitoring and evaluation [29]. CPG representations that allow practitioners with limited training to effectively manage the most prevalent manifestations of disease are essential for national treatment programs like those in Malawi [14].

Electronic Health Records (EHRs) are the future of documenting and delivering healthcare as such systems can decrease medical errors and improve quality of care [11]. The potential of EHR systems to transform medical care practice has been recognised over the past decades, including the enhancement of healthcare delivery and facilitation of decision-making processes [26]. Improving the quality of care through an EHR depends on an effective Clinical Decision Support System (CDSS) as such a system provides a recommendation at the time of decision-making as part of the clinician's workflow, which reduces practice variation, and is based on best-practice guidelines [11].

Many academic articles and agency reports have argued that Information and Communications Technologies (ICTs) can make a substantial contribution to improving health and healthcare in developing countries [15]. Even so, most developing countries face many challenges ranging from epidemics and civil wars to natural disasters and they also lack a robust healthcare infrastructure to ensure patient health [26]. Development practitioners have learned from bitter experience that initial small-scale success does not guarantee sustainable large-scale benefits [15].

To devise a lasting solution for computerisation of CPGs, it is essential to understand the motivations for the current suboptimal implementations of computerised CPGs. We investigate these challenges for Malawi by means of a contextual inquiry of 13 health professionals in 7 facilities, 9 software developers, and some of the implementation details. We further propose future work for Malawi's computer-based clinical decision support system that can support new and revised national clinical practice guide-

lines.

2. BACKGROUND

In this section we introduce some preliminaries on CPGs and their computerisation, and the well-established non-governmental organisation that develops Electronic Medical Record (EMR) systems in Malawi, Baobab Health Trust.

2.1 Baobab Health Trust

Baobab Health Trust (BHT), a non-governmental organisation, develops EMR systems in partnership with the Ministry of Health in Malawi. BHT has been designing point-of-care solutions in various domains in healthcare in Malawi since 2001 [20].

In 2005, a task-force created by the Department for HIV and AIDS, Ministry of Health, Malawi, investigated the feasibility of introducing computers to capture patient data and produce cohort reports at anti-retroviral therapy (ART) clinics. Thereafter, a pilot implementation of an EMR system started at the ART clinic at Queen Elizabeth Central Hospital, Blantyre, in April 2006, funded by the Global AIDS Program of the Centers for Disease Control and Prevention in Malawi. Patient treatment cards and clinic registers were maintained until there was evidence that the EMR was working reliably, had been incorporated into daily use, and was institutionalised within the clinic. [7]

BHT has since developed EMR systems that support health workers through treatment, diagnosis and cohort-reporting for a number of national treatment programs such as ART [7] and diabetes [8]. These disease-specific EMR systems are designed to lead healthworkers in-line with national clinical practice guidelines [7][8].

2.2 Clinical practice guidelines

Across most domains in medicine, practice has lagged behind knowledge that is usually available in form of clinical practice guidelines. Evidence exists that many guidelines, even those that are broadly accepted, are not followed. A core part of practising evidence-based medicine is considering guidelines when they do exist. [1]

CPGs are defined as systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. The term *'Clinical Practice Guideline'* serves as an umbrella label for practice standards, protocols, parameters, algorithms and various other types of statements about appropriate clinical care. [9]

CPGs describe the evidence-based procedures to be followed during diagnosis, treatment and decision making for a specific disease based on years of accumulated medical experience [10]. The fundamental value of CPGs is to ensure that tasks are carried out uniformly and a CPG serves as a guide or reminder in situations in which it is likely that steps will be forgotten, are difficult to follow, or where errors can be expensive [4]. CPGs aim to improve the quality of care, reduce unjustified variations, reduce healthcare costs and support introduction of new knowledge into clinical practice [21][23].

2.3 Computer-based clinical practice guidelines

Computer-based guidelines have been developed to integrate clinical guidelines or protocols into ICT-supported environments [10]. Attempts have been made to promoting computerised CPGs as part of the general computerisation within healthcare either as Computer Interpretable Guidelines (CIGs), Computer Executable Guidelines (CEGs) or integrated into the EHR [16]. Furthermore, modeling CPGs in a computer interpretable form is a pre-requisite for various computer applications to support CPG application [13].

Computerisation of CPGs is a complex task that has several approaches classified into two main categories. The first is the documentary approach that uses the CPG document as a medium of representation based on markup text using markup languages like XML. Examples of the documentary approach are Hypertext Guideline Markup Language (HGML) and Guideline Elements Model (GEM) [6]. The second category represents CPG knowledge as rules in a specific format as used in languages such as GuideLine Interchange Format (GLIF), Asbru or Proforma [6]. Each approach for specifying computer-based guidelines has its own motivations and features as some focus more on guideline standardisation and interoperability while others focus more on guideline development and decision support. These different foci have their implications and influence on representation approaches of CIGs. [5]

The automation and computerisation of the daily management of both clinical guidelines and patient data can lead to improvement of physicians' adherence to clinical guidelines and makes this a basic step towards widespread use in medical practice [12]. Moreover, implementing guidelines in active computer-based CDSSs promises to improve guideline adherence because these systems are able to monitor the actions and observations of care providers and to provide guideline-based advice at the point of care [5].

CPGs formalisation into computer-based guidelines is necessary for medical decision support. CPG formalisation as CIGs make it possible to develop CIG based CDSSs which have a better chance of impacting clinician behaviour than narrative guidelines [21]. In addition, the medical community has started to recognise that CIGs can further increase CPG advantages by providing relevant benefits such as automatic linkage to patient data and decision support to care providers and patients [3]. Guideline-based CDSSs are in fact necessary for the future of medical decision making in general [5].

The next section describes the methods that were deployed to investigate how CPGs are integrated into the BHT EMR. Thereafter, the resulting findings from the investigation are described.

3. METHODS

A contextual inquiry was carried out in order to understand how clinical guidelines are incorporated into Malawi's EMR systems. One tertiary, one referral and five primary care health facilities were selected in Malawi for observation of routine clinical practice. The observations were carried out for one month in July 2014. Clinical encounters were observed during consultations and ward rounds for outpatients and inpatients respectively. In addition, semi-structured interviews were carried out with the healthcare workers that were observed.

Nine members of the software development team that develop and maintain the national EMR systems at BHT were also observed. In addition, semi-structured interviews were carried out with the members of the software development team that were observed. Furthermore,

code inspections of the EMR systems were carried out through BHT's publicly accessible open source repository at ***https://github.com/BaobabHealthTrust***. The national ART and diabetes EMR systems for Malawi were accessed and inspected.

4. RESULTS

80 minutes worth of interviews were recorded with thirteen healthcare workers in the seven health facilities we observed. Of these healthcare workers, five were medical doctors that had spent a minimum of six years in medical school; three were nurses that had spent a minimum of three years in nursing school; and five were medical assistants that had spent a minimum of a year in health sciences school. All of the healthcare workers that were interviewed indicated that they use clinical practice guidelines during routine clinical practice. Of the seven health facilities that were observed, four had a version of the national EMR system deployed in at least some part of the health facility. 50.7% of the healthcare workers we interviewed indicated that they had used computers since medical or nursing school. 30.8% of the healthcare workers indicated that they use digital devices or computers routinely to support them during clinical consultation.

82 minutes worth of interviews were also recorded with the members of the software development team. Of the nine team members we observed and interviewed, four were team leaders. The software developers that were interviewed had implemented CPG rules in an EMR before and had varying experiences developing guideline-driven EMR systems. From the interviews and the code inspections, it was indicated that there was no uniform way of encoding CPG rules into the EMR systems. Furthermore, the CPG rules that were encoded, were either hard-coded in software programs or encoded as records in the database depending on developer preference. All the developers found maintenance of CPG rules within the EMR systems challenging. The developers indicated that CPGs are revised on a regular basis which necessitates updates to the corresponding rules in the EMR systems. For instance, the Malawi clinical guidelines for managing HIV services were revised in 2008, 2011 and 2014, warranting significant efforts in maintaining the national ART EMR. One developer said that *'changes in guidelines requires a deep understanding of the software implementation and it is hard to maintain guidelines that apply across multiple EMRs or multiple versions of a particular EMR'*. The developers also indicated that they are given very tight deadlines to deliver working software. For instance, one software developer stated that *'we get unrealistic demands from end-users'* and another developer further said that *'we are given unrealistic deadlines by product owners'*. The developers preferred that CPG rules be separated into their own layer or component on the software stack for ease of maintenance.

5. DISCUSSION

As Malawi seeks to scale up application of computerised guidelines, the current approach that has been adopted requires a lot of software maintenance effort likely to make it an unsustainable practice. In collaboration with the software engineers, CPG users, and other stakeholders, a direction is proposed that may enable generalised CPG support, that will make it easier to develop and maintain support for new and revised clinical guidelines. The failure of large complex systems to meet their deadlines, costs, and stakeholder expectations are not, by and large, failures of technology, rather, these projects fail because they do not recognise the social and organisational complexity of the environment in which the systems are deployed [2].

Component based software engineering is the process of defining, implementing, and integrating or composing loosely coupled, independent components into systems. It has become an important software development approach because software systems are becoming larger and more complex. The only way that we can cope with complexity and deliver better software more quickly is to reuse rather than reimplement software components. [24]

Separating the CPG rules and their execution engine into a separate component of the software architecture can improve the maintainability of the EMR systems. A healthcare system adapting to the effects of growing expenditures and a diminishing primary workforce needs the support of a flexible information infrastructure that facilitates innovation in wellness, healthcare and public health [19]. All the CPG rules can be encoded in a uniform way making it easier for developers to identify and update specific CPG rules every time corresponding national guidelines are revised. The CPG rules could be interpreted by a separate component, a guideline execution engine, that is part of the overall EMR architecture. A key characteristic of this approach to software design is that the system components should be not only interoperable but substitutable [19].

It is further proposed that the CPG execution component be based on open standards using free and open source software (FOSS). Another key characteristic of a component-based approach to software design for a flexible health information infrastructure is that the platform should be built to open standards to facilitate customisation, extension and innovation [19]. FOSS shows promise as a means to achieving the true potential of EMR software in improving healthcare [25]. Any open source software initiatives to develop EMR systems would draw on the same ethos of peer review and open discovery that drives much of the research component of the health industry [27][28].

6. CONCLUSION AND FUTURE WORK

EMR systems are increasingly being deployed to support healthcare delivery in Malawi. There is currently no standard way of encoding CPGs in the national EMR systems. Significant effort is required in maintaining the current EMR systems whenever new guidelines are introduced or existing guidelines are revised.

A component based software engineering approach as a reuse-based software engineering strategy has the potential to support the introduction of generalised CPG support to the current national EMR's architecture in Malawi. It is proposed that the architecture of the EMR systems in Malawi include a separate component that supports generalised CPG encoding and execution. It is further proposed that communities of open source developers be used. This approach, noting that the tensions between conflicting stakeholder requirements, deadline and deliverable expectations should enable the development and support for new and revised clinical practice guidelines.

7. ACKNOWLEDGMENTS

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