Application of a Double-Loop Learning Approach for Healthcare Systems Design in an Emerging Market*

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ABSTRACT

The healthcare industry is driven by multiple stakeholders including health ministries, private and public hospitals, and vendors who provide technology to the patients, with each of them playing important health system roles in order to balance high quality and accessibility with cost-effectiveness and sustainability[1]. This becomes particularly important for chronic cardiovascular disease patients in emerging markets such as Malaysia where sophisticated advanced therapy are often too costly for the underserved patient population. These patients most often live very far from major hospitals and rely on subsidies from the Ministry of Health (MOH) for a significant portion of their healthcare. Thus worldwide, vendors face a unique challenge in delivering cost effective, affordable and accessible therapy to this patient demographic in emerging markets. This paper presents our findings on the challenges to delivering continuous care to the remote heart failure patients in Malaysia. We will also report the work in progress in applying a Double-Loop Learning approach as a collaboration model with the MOH, its cardiac centers, and a multinational medical technology company to mitigate the challenges faced by Malaysia healthcare providers by the design of a real-time embedded system applying artificial intelligence method to realize the Connected Health concept.

CCS CONCEPTS

• Requirements engineering • Healthcare Innovation

KEYWORDS

Connected Health; Healthcare Innovation; Double-Loop Learning; Pacemakers; Artificial Intelligence

1 INTRODUCTION

Malaysia, which is considered a part of the emerging market in the South East Asia region, manages its critical cardiovascular diseases patients at the nine-dedicated cardiac centres in the Ministry of Health (MOH) system, which are distributed across the country to serve the population. Patients in MOH hospitals are referred to the cardiac centers only when they have completed the required diagnostic workups at the district hospitals. Therefore, they have often progressed to an advanced stage of disease and require costly treatment because of this gap in assessment and intervention.

An internal feasibility report was prepared for the purpose of the project collaboration with the MOH in a cardiac centre in Kuala Lumpur, Malaysia. The report shown a 50% increase in hospitalization of heart failure patients within the past two years, with the youngest age of diagnosis being 23 years old. The rural patient population comprises the most challenging group of patients to manage due to their relatively lower education levels, difficulty reaching cardiac care centres due to distance and significant impact

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of the cost of travel to their budgets. Implantable medical pacemakers provide a great opportunity for improving the outcomes of the heart failure patients especially for those who live remotely from major medical centres if the data is analysed with other clinical health data in a manner timely enough to support early intervention [7].

1.1 The challenges to delivering a continuous care

The challenges reported in this section were identified from the interviews with the Malaysia healthcare providers and from the observation study conducted by the first author in the cardiac centers as part of the feasibility report. Presently, pacemaker vendors sell external devices that patients can use to transmit both pacemaker function and heart health information wirelessly to hospitals for cardiologist review. However, there are significant challenges in providing this health service to underserved patients in emergent regions. Firstly, the purchase cost of external remote monitoring devices represents an unreasonable and prohibitive financial burden for lower income patients. Secondly, rural areas often have limited or unreliable wireless coverage. Thirdly, hospitals have limited resources to manage the workload associated with monitoring and assessing the volume of data transmitted when such capabilities are made available to a wider population. In countries with limited availability of clinicians with the required specialized training, the need to manage remote data in hospitals becomes a barrier to the implementation of an effective and efficient remote monitoring system for patients who have pacemaker with wireless communications capabilities.

This paper describes our ongoing efforts to mitigate the challenges faced by the Malaysia healthcare providers when implementing high quality care using modern technology while maintaining cost effectiveness. The next section will describe the background and motivation of our study. This is then followed by the work in progress in our efforts to apply a Double-Loop Learning to develop a collaboration model (i.e., MOH, cardiac center, a medical technology multinational company (MNC), research institutions) for the development of a future real-time embedded system based on the Connected Health concept applying artificial intelligence (AI) method. The aim of the project is to develop a continuous care system that can improve outcomes, while providing cost-effective treatment.

2 BACKGROUND AND MOTIVATION

Healthcare systems in emerging markets face unique obstacles to providing sustainable, high-quality, and continuously cost-effective health systems due to rapid economic development and population expansion. Access is typically impacted by location and proximity to major health institutions, a shortage of specialists and limited information technology infrastructure due to a country's geography and population distribution [9].

Our work practice observations and interviews with Malaysia healthcare providers suggest that healthcare providers face two major challenges when implementing technology developed in established markets (i.e., by companies that operate multi-nationally). First, advanced technology, such as pacemaker, are designed and developed mainly with respect to the needs of and data from the patient population in the countries that represent the manufacturer's primary market. Furthermore, the emerging market population may differ greatly in socio-economics, genetic predisposition, diet, etc., from the population studied during device development and clinical trials. Secondly, systems such as remote monitoring systems are designed based on the hospital process in these same countries where the practice of medicine, policies, roles, guidelines, procedures, including the culture belief-systems of patients may vary greatly when compared to a country in South East Asia and other emerging markets.

The healthcare providers in an emerging market need to find cost-effective, high quality and accessible technology for their population, while the MNC would like to leverage their existing intellectual property to expand the market for their products. Often the technology-based systems require a configuration custom fit to the total work system of the hospital (hospital process, policy, etc.), and this can incur high implementation cost when the work systems differ substantially. In the end, stakeholders (patients, health care providers and device manufacturers) would lose potential benefit if the technology offered is too costly for the population, if the population cannot access it, or if the efficacy of these high quality advanced technologies cannot be validated in the emerging market population. Therefore, it is very important that technology innovation in emerging markets involve local key stakeholders very early on so that technology "fits" within the total patient care management. This will help to avoid unintended consequences and unnecessary costs in developing functionalities which are not necessarily required or that are "hard-wired" in a way that makes reconfiguration for the local population difficult.

We seek, in collaboration with the Ministry of Health Malaysia, a medical technology MNC, and international leaders in the field of AI and human-centred computing to tackle these current challenges by exploring a new model of healthcare technology innovation in Malaysia that could be replicated in other emerging markets in South East Asia. Specifically, our new model would allow a continuous care and a cost-effective way to provide "connected health" early interventions for patients with heart failure who live in remote rural regions by exploiting the data available from various devices already in use. At the same time improving the data management process within the existing clinical infrastructure and intervention systems work practice using AI method. Connected Health is defined as "patient-centred care resulting from process-driven health care delivery undertaken by healthcare professionals, patients and/or careers who are supported by the use of technology (software and/or hardware)" [6]. Through the exploitation of technological innovations, healthcare providers can generate accurate and timely information for patients and clinicians to make informed decisions [5].

3 APPROACH

Double-Loop Learning is an educational concept and process that involves teaching people to think more deeply about their own assumptions and beliefs. It concerns changing the objectives itself

(i.e., "doing the right things") rather than just "doing things right" [3]. A real-time embedded system in our work refers to the wireless enabled implantable devices based on the concept of Connected Health where data analytics are computed in real time using AI methods (i.e., multi agent system, machine learning) integrated efficiently into hospital processes. Applying the Double-Loop Learning incorporates multiple levels of organization learning in the development process, whereby healthcare technology is developed using closed-loop feedback: the healthcare providers learn about the patients; the institutions and vendors learn about effectiveness and opportunities afforded by the "infomated" work system; and university scientists and engineers learn about new problems meriting basic research. Viewing it this way, applying the Double-Loop Learning should enable easily configured software that is "situated" in the context of use, designed and iteratively improved within the work system. At the same time, immediate challenges are solved by new intervention methods, and future innovation is improved incrementally. In this paper, we will report on our experiences to date in using various foundational principles in requirements elicitation [1, 2] to develop the envisioned implementation for the Malaysia heart failure patient population.

3.1 Step One: High Level Fact Finding

An intensive two months preparation was carried out by the first author to gather high-level data on the existing patient management challenges to prepare for a collaboration proposal with MOH and MNC. We focused the study by selecting one of the major heart centers in Kuala Lumpur, Malaysia. The steps developed and applied are detailed below and methods used in each step are explained correspondingly:

3.1.1 Identify current patient management challenges faced by clinician specialist and identify potential champion.

At this first step, we applied the following method:

- Focused discussions with the cardiac EP centered around "What, Why and How" questions. For example:
  - What type of patient population is the most challenging in diagnosing and managing?
  - Why is it difficult and challenging to diagnose and manage these patients?
  - How do you manage this group of patients currently?
  - What do you suggest that we do to improve the diagnosis and management of these patients?
- Hospital work practice observation was conducted in the work setting of the cardiac EPs. The aim was to understand the overall work practice in the diagnosis and management of the specific patient population - how current tools, information systems, and procedures are used. This step was conducted iteratively with interviews and discussion. A report was produced based on the various data collected.

This first step resulted in identifying opportunities for early identification of potential atrial fibrillation episodes in patients through using a Connected Health concept [6].

3.1.2. Identify the major challenges formulated with "How?"

From the work practice observation report, we identify the major challenges pertaining to the overall work practice in need of improvement to better support the identified challenging patient population. This second step resulted in several questions that encompass the level of diagnosis, management from clinician perspectives and hospital management of remote data. For example, we phrased the problem into the following "How" statement: *"How can AI techniques be used to diagnose potential individuals with atrial fibrillation in real-time when the symptoms are asymptotic and only can be diagnosed by electrocardiogram?"*

3.2 Step Two: High Level Problem Domain Scoping

The next step involved developing an international working group meeting led by the first author. The aim of the working group meeting was to conduct a very high-level problem domain scoping exercise across healthcare stakeholders at the organizational levels deemed essential for a double-loop learning when new technology is implemented in practice.

3.2.1 Identify relevant stakeholders needed in tackling the challenges together with the cardiac EP champion.

At this step, we have identified the following key stakeholders:

- In the field of cardiology (prominent Malaysian heart failure cardiologists and cardiac EP)
- In the field of medical technology (a leader in the field of implantable devices in the multinational company)
- Policy maker in healthcare innovation (Agency Innovation Malaysia and MOH)
- In the field of AI, human-centred computing methodology and clinical sciences research (local and international universities and research institutes)
- Chairman for the working group meeting (a leader in the field of human-centered computing, and a leader with a management position in the heart center was appointed).

3.2.2 Identify the high-level problem domain.

Based from our finding from the major challenges identified, we constructed representative concept maps (Cmaps [8]) and a concept of operations [4]. We formulated the challenges as Cmaps to create a model that the stakeholders could jointly navigate, criticize and refine. We formulated a Concept of Operations (ConOps) document that describes future system characteristics from a user's perspective. Based on the multiple views, we have categorized two problem domains, representing social and technical perspectives:

- The problem domain pertaining to the patient population: diagnosing early onset of atrial fibrillation in cardiovascular diseases patients.
- The problem domain pertaining to the real-time system: multi-agent system and machine learning (i.e., AI) technology design and implementation.

3.2.3. Define the main focus of the project challenges.

3.2.4. Refine further the challenges by groping it under the problem domain using "What' and "How" statement that must be tackled to attain the Focus statement.

As an example: *"What design methods and tools would efficiently*

and reliably improve our current healthcare system, given that current approaches often result in information technology that is costly, complex, and unsatisfactory?"

3.2.5. A SWOT analysis template (Strength, Weaknesses, Opportunities and Threat) was prepared for the summarization of the working group discussion.

The working group discussion resulted in the following:

- Further problem scoping by aligning the specific disease management challenges both locally (Malaysia) and globally (world-wide).
- Formalizing constraints identified by each stakeholder (resources, budget, policy).
- Formulation of a shared vision.
- Tabulation of strategies in attaining the shared vision.

The discussion led to the design of a pilot project that applied the Double-Loop Learning concept focused on patients with implantable cardiac devices (i.e., pacemakers) and potential arrhythmia problems. The aim of the pilot study is twofold: 1) to find new intervention method (Connected Health) through the use of existing technology that could be configured cost-effectively to solve immediate challenges; 2) to develop an implementation model for an embedded real-time system that would lead to a future cost-effective healthcare technology for emerging markets using AI methods.

4 Discussion

In our project domain, we sought to develop a novel cost-effective intervention method in the existing practice of remote management. We found that the problem scoping and requirements specification was the most critical and challenging process throughout the ideation of a future project. This was due to several reasons, such as having limited understanding about the current IT infrastructure in remote areas, and of how to incorporate hospital processes and medicolegal issues Connected Health concept. We experimented with different methods (i.e., observation of work practice), and organized discussion (i.e., working group) involving tools (i.e., Cmaps) needed to elicit and understand stakeholders' problems to define functional requirements.

5 Conclusion and Future Work

This paper described our ongoing efforts applying a Double-Loop Learning in a collaboration model with MOH and a MNC for the development of a future Connected Health concept based on AI methods. Some principles of the Double Loop Learning approach was applied to the working group session which led to an agreement of a pilot project that could solve immediate challenge while developing future innovation that applies AI method. It also led to challenge the belief and assumptions that present manufacturing methods were adequate enough to serve the rapid changing heart population needs in the South East Asia.

Most often, system design of a healthcare technology is based on a piecemeal approach such as focusing on cost or quality control [10]. However, we cannot simply start at one end, such as sensor, and expect to add a device that will make everything better because costs go up to provide these new systems. When developing real-time embedded system based on AI methods, we face an even greater challenge because of the possible legal implications in the event that the automation results in unintended consequences in patients. Thus, we needed to view the system design as a complex and critical systems composed of interaction with the people, medical technology, healthcare policies and processes. The overarching objective of our proposed pilot study is to improve the methodology of medical technology systems design by empirical requirements analysis and verification conducted in parallel with a clinical study. Design requirements could then be validated by modeling and simulation of concepts of operation developed *in situ* before product development, using a total work system design approach [11].

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REFERENCES

[1] M.G. Christel and K.C. Kang. 1999. *Issues in Requirements Elicitation.* DTIC Document. DOI: http://www.dtic.mil/docs/citations/ADA258932.

[2] B. Nuseibeh and S. Easterbrook. 2000. *Requirements Engineering: A Roadmap*. In ICSE '00: Proceedings of the Conference on The Future of Software Engineering, pages 35– 46. ACM.

[3] C. Agyris. 2005. Double-Loop learning in organizations: a theory of action perspectives. In Smith, Ken G., Hitt, the process of theory development. Oxford; New York: Oxford University Press. Pp. 261-279.

[4] Guide for Information Technology 2003.System Definition—Concept of Operations (ConOps) Document. IEEE Std 1362-1998.

[5] N. Carroll and I. Richardson. 2016. Aligning Healthcare Innovation and Software Requirements through Design Thinking. In the Proc. Int'l Workshop on Software Eng. in Healthcare Systems (SEHS 16).

[6] I., Richardson. 2015. Connected Health: People, Technology and Processes. Lero-TR-2015-03, Lero Technical Report Series, University of Limerick.

[7] SA. Virani, V. Sharma, M. McCann, J, Koehler, B.Tsang, S.Zieroth. 2016. Integrated diagnostics for heart failure: The Triage-HF study. Canadian Journal of Cardiology. 2016 Oct 1;32(10):S148-9.

[8] A.J, Canas, G.Hill et al. 2004.CmapTools. A Knowledge Modeling and Sharing Environment. In Concept Maps: Theory, Methodology, Technology, In the Proc. Int'l Conference on Concept Mapping '04

[9] A. Mukherjee,R. Singh. 2015. Healthcare for the bottom of the pyramid", International Journal of Pharmaceutical and Healthcare Marketing, Vol. 9 Issue: 3

[10] Y. Bar-Yam, S. Bar-Yam, K.Z. Bertrand, N. Cohen, A.S. Gard-Murray, H.P. Harte, and L. Leykum, 2013. A Complex Systems Science Approach to Healthcare Costs and Quality. Handbook of Systems and Complexity in Health (Springer 2013): 855-877.

[11] W.J. Clancey, Seah, C., M. Shafto. 2013. Work Practice Simulation of Complex Human-Automation Systems in Safety Critical Situations: The Brahms Generalized Uberlingen Model. NASA Technical Publication 2013-216508, Washington D.C.