

Healthcare Software Process Model

Doctoral Consortium

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1 RESEARCH PROBLEM

Software can provide opportunities for innovation and competitive differentiation. There are challenges to this, for example software in products increases complexity and, in turn, can compromise quality. By improving process efficiencies, industries are able to focus on areas such as innovation and reduce time to market.

Health Information Systems (HIS) are used in healthcare to make decisions on:

- Diagnosis and treatment
- Financial and administrative matters
- Best practices
- Manipulation of clinical data which needs to be secure, accurate and timely

Developing Health Information Systems (HIS) is a complex task for a number of reasons. For example healthcare mistakes can have serious consequences that can affect patients' lives as well as having a high financial cost all within a highly regulated industry

Currently there is no comprehensive methodology for developing HIS. Relevant HIS regulations state what needs to be done to comply but not how. Technology is evolving quickly.

2 OUTLINE OF OBJECTIVES

This PhD research has carried out case studies and action research of various areas within health and innovation to inform the research development. A research fellowship in innovation was undertaken for a duration of 10 months. A further 3 months was spent in a medical device company observing how change is managed. Interviews were also carried out in hospitals with key staff members to tease out the key concepts/issues/concerns/etc. of implementing a new IT healthcare system.

The following research objectives are addressed in this PhD:

- To improve the way software is developed in a highly competitive regulated domain such as Healthcare informatics
- To identify areas that aid successful design, development and implementation of health information systems using a model to support it
- To develop a model that addresses the needs of complex healthcare projects
- To develop an integrated set of process models that combine recommended practices with the needs of the information systems domain with inputs from literature, medical device industry, hospitals and a successful innovation programme.

3 STATE OF THE ART

Software development within the health domain is different from other domains for a number of reasons. Healthcare is a fragmented industry with, for example, independent hospitals, medical device companies etc. Within healthcare, different stakeholders have different objectives such as non-profit, profit etc. There are specific industry-focused regulations. There are also healthcare regulations. For such reasons, change becomes a complex task within healthcare. Indeed, change management requires a specific approach to transition an organisation to a desired future state (Benjamin and Levinson 1993). Within a hospital context, the various steps required to achieve a desired future state is of particular importance to ensure that patient safety is a priority and quality is not jeopardized (Cazzaniga and Fischer 2015). The objective of change management is typically to provide a structured approach to implement change in a controlled manner while adhering to specific requirements on functionality, budget and time through various deliverables or milestones. The Oxford handbook of innovation (2006) points out that innovation in healthcare and software industries is more complex due to regulators sometimes

restricting innovation. Gottlieb and Makower (2013) point out that innovation in technology offers perhaps the best chance to tackle rising healthcare costs while maintaining high-quality care. In the healthcare industry medical devices are manufactured to aid patients. To safeguard patient safety and minimize risk such devices are regulated. In America the regulatory body is the Food and Drug Administration (FDA) whereas in Europe the regulatory body is the European Commission (EC) using the Medical Devices Directive (MDD) (Travers and Richardson 2015). The FDA issues guidance on development stating what needs to be done but how to do it is up to the software producer. Regulators can approve standards also. Recently the MDD amended its definition of a medical device to include software; therefore software could be classed as a standalone medical device (Travers and Richardson 2015). This clarified that standalone software can be a device in its own right, software can be embedded within a medical device or be used in the manufacturing of a device (Travers and Richardson 2015). Travers and Richardson (2015) point out that the medical device industry faces challenges, including competitors, government regulations, and productivity and quality issues. Standards and guidelines have been developed to aid in achieving the safest possible product and individual companies can decide which methodology to use (Travers and Richardson 2015). There does not seem to be a method for quantifying just how much process is enough (Travers and Richardson 2015). To ensure high quality products companies attempting to improve their products, also have to change their development processes (Travers and Richardson 2015). Companies implementing process change can benefit from using a change management model but usually published models relate to organization change as opposed to process changes (Travers and Richardson 2015).

Travers and Richardson (2015) state that introducing change must be a formalised planned process. There are many change models in existence but the three more common ones are:

- Lewin's Change Management Model
- McKinsey 7-S Model
- Kotter's 8 Step Change Model (2005)

Lewin's Change Management Model was developed in the 1950s. It is easy to use but it is timely to implement. McKinsey 7-S Model was developed in the 1970s. It provides a more holistic approach and each part is interrelated so changes affect all parts. Kotter's model was developed in the 1990s it also provides a more holistic approach but the focus is on

preparing for change instead of the actual change

Kotter's model was chosen as the most appropriate model to research innovation and change management in this research. The healthcare industry can learn a lot from existing business models that have successfully been used in other industries. Kotter's 8 step change model (2005) lists the following:

1. Establish a Sense of Urgency
2. Form a Powerful Guiding Coalition
3. Create a Vision
4. Communicate the Vision
5. Empower Others to Act on the Vision
6. Plan for & Create Short-Term Wins
7. Consolidate Improvements and Produce Still More Change
8. Institutionalise new approaches

4 METHODOLOGY

To understand innovation in health a 10 month research fellowship was undertaken. This fellowship uses immersion and observation in hospitals to facilitate an understanding of procedures and innovations in health.

A single case study was commenced within a Medical Device company. The researcher spent three months onsite. In addition to being a participant-observer on the project, the researcher held one-to-one interviews with software team members.

To study hospitals within healthcare the approach taken was to undertake a single case study considering the unique opportunity to capture an empirically-rich account of specific phenomena (Yin 2013) within a healthcare context. Thus from an epistemological and analytical standpoint, a single case study was deemed suitable to test and build a hypotheses on IT change management within a publically funded hospital.

One-to-one interviews were held with eleven key staff members who were all involved in IT change to various degrees. Since the interviewees were healthcare experts within public hospitals, some were difficult to access. To overcome this, a snowballing sampling strategy was employed to identify other experts in this field within the sample population. This proved to be useful since each expert was able to recommend the next relevant expert. Through a structured interview technique, this provided a more balanced insight to uncover the

change process. The structured interviews supported the research methodology by ensuring consistency, i.e. each interview was presented with exactly the same questions in the same order. The questions had to be short as the health experts had limited time available to partake in the case study.

The interviewees' answers were reliably aggregated and comparisons were made between the different interviewees. A number of emerging themes were identified using coding to categorise the text – this allowed the building of a story around specific events, facts, and interpretations.

The eleven interviewees were all experienced in software change and processes. They included software developers, clinicians and IT managers. The interviewees' work experience spanned from 4 to 30 years. Participant's interview data was analyzed to understand the change process within the case study. The data was reviewed within the structure of Kotter's change model steps 1 to 8, which allowed the researcher to understand how change had been made within the hospital setting. This facilitated gaining a rich insight of the working environment.

5 EXPECTED OUTCOME

Currently there is no comprehensive methodology for developing HIS

- Relevant HIS regulations state what needs to be done to comply but not how
- Technology is evolving quickly

The proposed methodology has the potential to:

- Improve decision-making, monitoring and cost management
- Improve communication and learning
- Create better quality of life for patients

Innovation usually begins with an idea. An idea is just the first step on a sometimes-long path to successful innovation. Technical change usually requires organizational changes also. Organisation and process support or buy-in is required for successful implementation as this type of change is difficult due to potential resistance, competing ideas, or failure to be sustained. Therefore innovators not only need their original idea but also a vision of how things would change if the innovation succeeds. Organizational and process change is needed for implementation of ideas in achieving success. Significant innovations can be resisted, fall victim to competing ideas, or fail to be sustained.

For the medical device company case study Kotter's change model was appropriate. Travers and Richardson (2015) point out that process improvement should be managed through the use of a model so that the change is implemented completely in an organisation. Travers and Richardson (2015) state that Kotter's change model was a good basis, but note that there were aspects of the model that were overlooked and some elements were unnecessary. Travers and Richardson (2015) point out that a more tailored and specific model is required.

Analysing the findings from the hospital study key themes were identified. The results indicate that some aspects of Kotter's change model is useful to successfully manage change but would need to be modified for a healthcare context. This case study facilitated analysis from a hospital perspective and the findings informed and enhanced a proposed model which is called the Healthcare Innovation and Quality Change (HIQC) Model (See Figure 1). The HIQC model is split into three relevant sections which acknowledges that change occurs through key iterative processes namely identification, ideation and strategy. These three phases are similar to the phases in the innovation research fellowship. Each phase comprises of a number of requirements and practices which emerged from the research.

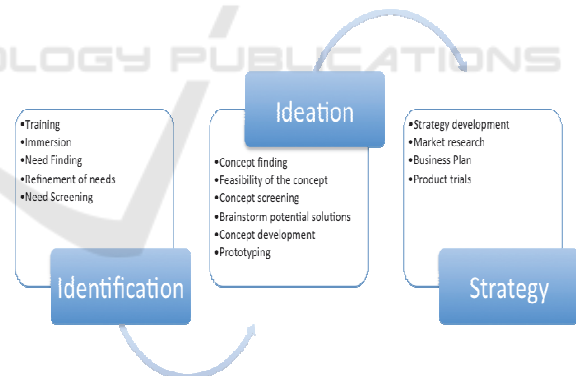


Figure 1: Proposed model version 1.

6 STAGE OF THE RESEARCH

A literature review was undertaken to understand the health, software and innovation requirements of the healthcare industry. This identified gaps, which are reflected in the research questions. An innovation research fellowship was completed which involved access to both public and private hospitals in Ireland to ascertain where innovations could help improve

existing practices or treatments. A placement in a medical device company was also completed to understand how process improvement is undertaken in such a regulated healthcare industry. A model has been researched and developed (see figure 1). The next step is the further refinement and validation of this model, which will be useful as currently there is no model currently available. Figure 2 is a diagram that illustrates my Phd progression to date by identifying the various phases involved in this research.

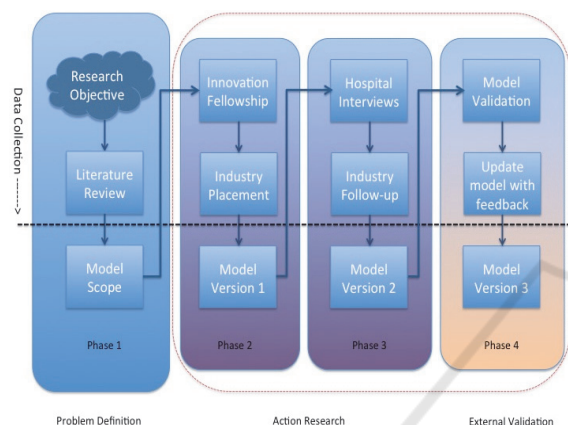


Figure 2: Research plan.

Each phase above the dotted line in the diagram above starts with extensive data collection.

Phase 1:

The problem definition involved extensive data gathering by analysing existing research and software engineering practices to aid in scoping an initial model.

Phase 2:

Action research involved carrying out case studies and action research to aid in the research and development and enhancement of a version 1 of the model. The case studies were an innovation research fellowship and an industry placement in a medical device company. This allowed the researcher to gain an understanding of healthcare innovation.

Phase 3:

Action research involved carrying out more case studies to aid in the development of a version 2 of the model again enhancing it. The case studies were hospital interviews and a follow-up industry placement in a medical device company. Currently the researcher is completing this phase. This allowed the researcher to gain an understanding of healthcare process improvement.

Phase 4:

External Validation involves legitimising the model proposed in this PhD research. This involves evaluating said model by validating it with experts such as entrepreneurs or software engineers. After validation the model will have to be then updated after gathering feedback and the results disseminated. The model identified has the potential to aid the development of innovation in health software.

It is envisaged that this validation and update stage should take 6 months. This research builds a new model to address shortcomings identified in my research. As part of future research it is planned to hold focus groups to use expert opinion to validate the new healthcare model. This new model will be used in a follow-up case study to examine the implementation of a new IT healthcare system. Moving forward the new model will act as a guide for IT personnel considering the implementation of a new hospital system, i.e. they use the framework as a step-by-step guide.

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