Development and Validation of the MedITNet Assessment Framework

Improving Risk Management of Medical IT Networks

Silvana Togneri MacMahon, Fergal McCaffery, Frank Keenan
Department of Computing & Mathematics
Dundalk Institute of Technology
Co Louth, Ireland
{silvana.macmahon, fergal.mccaffery, frank.keenan}@dkit.ie

ABSTRACT

The use of networked medical devices can provide a number of benefits such as improved patient safety, reduced costs of care and a reduction in adverse events. Traditionally, medical devices were placed onto a proprietary IT network provided by the manufacturer of the device. Today, medical devices are increasingly designed for incorporation into a hospital's general IT network enabling devices to exchange critical information. However, this can introduce risks and negate the potential benefits to patients. While the IEC 80001-1 standard has been developed to aid Healthcare Delivery Organisations (HDOs) in addressing these risks, HDOs may struggle to understand and implement the requirements. The MedITNet framework has been developed to allow HDOs to assess the capability of their risk management processes against the requirements of IEC 80001-1. MedITNet provides a flexible assessment framework enabling HDOs to gain a greater understanding of the requirements of the standard and to improve risk management processes by determining their current state and highlighting areas for improvement. This paper examines the challenges faced by HDOs in the risk management of medical IT networks and briefly explains the components of the MedITNet framework and how the framework addresses these challenges. This paper also details how Action Design Research (ADR) was used in the development and validation of MedITNet.

Categories and Subject Descriptors

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

General Terms

Management, Measurement, Documentation, Standardization

Keywords

Risk Management, Medical IT networks, IEC 80001-1, Action Design Research

1. INTRODUCTION

Health IT systems and medical devices are increasingly being called upon to share network resources, with devices being placed onto hospitals IT networks.[1]. Interoperability of medical devices can provide a number of benefits in patient care [2-4]. However, in order to realize the benefits of interoperable medical devices fully, medical devices must be placed onto IT networks in a way that ensures that the safe operation of the device is not impacted [5].

This section examines the challenges faced by HDOs in the risk management of medical IT networks and how MedITNet addresses these challenges. Section 2 presents a brief description of the components of the MedITNet framework. Section 3 details how ADR was used to both develop MedITNet and ensure its utility in addressing the identified challenges. To provide an example of the use of ADR, Section 4 focuses upon the development of the assessment questions which form part of the assessment method within MedITNet. Section 5 describes the final stage of validation of MedITNet using expert review, and finally, Section 6 presents the conclusions of the paper.

The recent downturn in the global economy has led to an increased focus on interoperability of medical devices as a means of ensuring that a high standard of care is provided to the patient while reducing the cost of care [2, 6, 7]. The potential benefits of the use of interoperable medical devices and Health Information Technology (HIT), such as Electronic Health Records (EHRs), has resulted in government incentives to promote their meaningful use [8, 9]. In addition, the prevalence of chronic conditions such as diabetes has resulted in a move away from acute episodic care. This move has resulted in the establishment of an ongoing relationship between the patient and their care team facilitated by carefully designed care processes and requiring the support of information technology [3, 10-13]. Due to their utility in the management of chronic disease, the number of networked medical devices in use has increased and continues to increase [14-16].

Networked medical devices provide a number of benefits such as reducing the instances of adverse events improving patient safety, reducing the time spent by clinicians manually entering information, reducing redundant testing due to inaccessible information, improving patient care, reducing healthcare costs and ensuring comprehensive and secure management of health information [17, 18]. As a result of these benefits, medical IT networks have become a critical, integral component of the medical system [19]. However, while networked medical devices provide benefits as medical devices increasingly interface with other equipment and hospital information systems the integration complexity of the systems is increased and this presents additional operational risks [16, 20-22]. Proprietary networks are being used less with medical devices being designed to be placed onto the hospitals general IT network meaning that medical

Conference'10, Month 1–2, 2010, City, State, Country.

device manufacturers no longer have control over the configuration of the network [23]. This complexity can lead to risks which result in unintended consequences which are outside the control of the medical device manufacturer as the placement of the device onto the hospital network creates a new system in which the device has not been validated [1, 24]. These risks can result in the incorrect and degraded performance of the medical device [25, 26] compromising patient safety, effectiveness and the security of the IT network.[27-29]

IEC 80001-1:2010 [30] was developed as a step towards addressing the risks associated with placing a device onto an IT network. The standard outlines the roles, responsibilities and activities to be carried out in the management of these risks. However, HDOs face challenges when implementing the requirements of this standard [31]. HDOs vary in size and in terms of the capability of their risk management processes [19, 32] and provide care in different regulatory environments meaning that the implementation of the requirements of the standard will vary depending on the regulation of the region in which the HDO provides care. In addition, the effective performance of risk management activities requires interaction between different stakeholder groups to understand the context of the HDO and manage identified risks accordingly [20, 33]. However, HDOs may be unprepared for the organisational changes that are required to facilitate this level of interaction among stakeholders [16] who typically operate in silos [3]. These challenges make the requirements of the standard confusing and difficult to implement. These difficulties in implementing the requirements of the standard highlighted the need for the development of an assessment framework which would provide HDOs with a flexible approach to assessing the capability of their current risk management processes relating to medical IT networks while enabling communication among stakeholders groups and allowing HDOs to implement the requirements of the standard. The following section of this paper describes the MedITNet framework which was developed in order to assist HDOs in addressing the challenges associated with implementing the requirements of IEC 80001-1 and to provide a means to assess the capability of risk management processes in order to provide a foundation for the improvement of the risk management of medical IT networks.

2. THE MEDITNET FRAMEWORK

The MedITNet assessment framework consists of three components: a Process Reference Model (PRM), a Process Assessment Model (PAM) and an Assessment Method (AM). Each of these components is described briefly in this section.

The PRM contains 14 processes, each of which is concerned with a different aspect of the life cycle risk management approach as outlined in IEC 80001-1. The PRM and PAM components of MedITNet have been developed in compliance with the requirements of ISO/IEC 15504-2 [34, 35]. This standard outlines requirements for "performing process assessment as a basis for use in process improvement and capability determination" [36]. Compliance with the requirements of this standard, ensures that the requirements of IEC 80001-1 are expressed at a process level which enables the use of the PRM, regardless of the geographical location of the HDO, for assessment of the requirements of the IEC 80001-1 standard, regardless of the regulations which apply to the implementation of these requirements. The processes within the PRM are described in terms of the purpose of performing the process and the outcomes which will be achieved as a result of performing the process. The processes which are contained in the PRM and PAM are illustrated in Figure 1 [35].

The descriptions of the 14 processes in the PRM are extended in the PAM to include base practices and work products allowing an assessment to be performed. Base practices are the activities which are performed in order to contribute to the achievement of the process purpose while work products are artifacts which are used in, or produced as a result of the execution of a process.

In addition to the PRM and PAM, MedITNet also contains an AM. The AM provides a consistent and repeatable approach to the performance of an assessment. The assessment method consists of seven stages during which the assessment scope is defined; focus group interviews are conducted with risk management stakeholders in order to make an assessment of the capability of the risk management processes. Following the interviews, a findings report is generated and presented to the HDO. The assessment method also contains an initial set of assessment questions to be used during the interviews. The questions allow for an assessment of each of the base practices defined in the PAM to be performed. The assessment questions can be used in their current form or can be tailored to take into account the context of the HDO. For example assessment questions can be used to take into account the scale and maturity of the HDO or to assess the implementation of specific requirements of IEC 80001-1 in terms of specific regulations applicable to the HDO. This ensures a flexible approach to assessment. The use of focus groups, which include internal risk management and external risk management stakeholders, ensures that the required level of communication among risk management stakeholders is achieved. The following section describes the rationale for the use of ADR in the development and validation of the components of MedITNet.

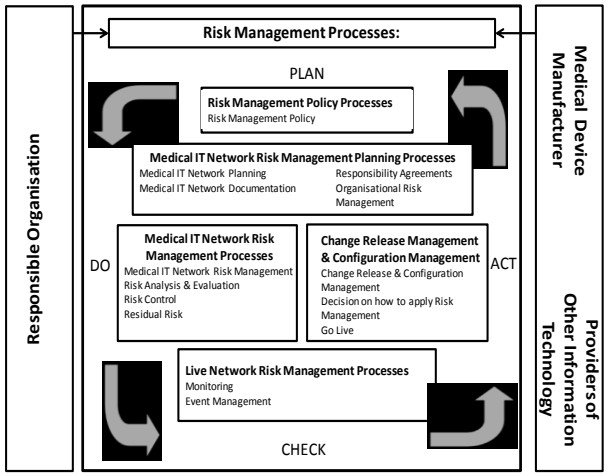

Figure 1 – IEC 80001-1 Process Map

3. USE OF ACTION DESIGN RESEARCH IN THE DEVELOPMENT OF MEDITNET

ADR is a specific approach within the broader Design Science Research (DSR) paradigm. DSR is characterized by Hevner et al. as follows: "In the design-science paradigm, knowledge and understanding of a problem domain and its solution are achieved in the building and application of the designed artifact" [37, p.77]. The focus of DSR is to address real-world challenges and solve authentic problems [38]. DSR is particularly useful in

addressing "wicked problems" that is problems which cannot be easily understood and solved without considering the development of a solution [39] due to the involvement of the perspective of multiple stakeholders [40]. DSR has been used previously in the development of ISO/IEC 15504-2 compliant assessment models [41] and in the development of a Healthcare IT maturity model [42].

A number of approaches to DSR have been outlined all of which involve some elements of the following: identification of the problem; design of the solution; followed by its evaluation [43]. The evaluation of design artifacts can be conducted in a number of ways including the use of Action Research (AR) [43]. This approach led to the development of the ADR approach by Sein et al. [44], building on the work of Cole et al. [45]. While Cole et al. highlight the similarities between AR and DR and show how the criteria from one may be applied to the other through sequencing and interleaving of activities, Sein et al. advocate ADR as a new approach in the DSR where building, intervention and evaluation of the designed artifacts occur concurrently. Sein et al. describing the ADR process as "*as containing the inseparable and inherently interwoven activities of building the IT artifact, intervening in the organization, and evaluating it concurrently"*. ADR has been used in the development of the components of the MedITNet framework.

The use of ADR in the development of MedITNet was chosen as ADR provides a means to develop an artifact, in this case each of the components of MedITNet, which address a class of problems, in this case the challenges which are experienced by HDOs in the risk management of medical IT networks. The ADR approach allowed for the development of a framework which does not assume a "concrete client" [46] but is suitable to be tailored for use in the varying context of different HDOs. Sein et al. outline a number of steps and principles in the ADR process. Each of these steps and principles are discussed in the context of the application of the ADR approach in the development and validation of the MedITNet components and the overall MedITNet framework.

3.1 Phase 1 - Problem Formulation

The Problem Formulation stage of the ADR approach contains two principles: Practice-Inspired Research and Theory-Ingrained Artifact. In this stage of the process, the researcher investigates the identified problem. This is achieved through interaction with experts in the problem area in the form of "practitioners" and "end users". During this phase of the research, the researcher secured commitment from these experts for the duration of the research. Firstly, Practice-Inspired Research is conducted as a means to viewing field problems. This is then supplemented with the principle of the Theory-Ingrained Artifact where existing theories are considered for use in the development of the design artifact.

During the development of MedITNet both of these principles were used during the Problem Formulation stage of the research process. A literature review was conducted into the challenges which are faced by HDOs in the risk management of medical IT networks. The identified challenges were then validated through the use of focus group sessions within a HDO. The focus group session centered on gaining an understanding of the context in which the specific HDO performs risk management activities and of the challenges reported by HDOs in the implementation of the requirements of the IEC 80001-1 standard. The literature review combined with the Practice-Inspired Research revealed that, while IEC 80001-1 can be used to address the identified challenges, HDOs may struggle to apply the requirements of the standard to their organisational context and may be unprepared for the organisational changes that implementation of the standard may require [16].

In addition the literature review revealed similarities between the IEC 80001-1 standard and Service Management standards [47-49] and examined the approach to the development of assessment models for these standards. As a result of the literature review in the broader area of process assessment standards, MedITNet was developed in compliance with the requirements of ISO/IEC 15504-2:2003 [34] and ISO/IEC TR 24774:2010 [50] using the TIPA transformation process. The TIPA transformation process is a goal oriented requirements engineering technique which allows for the transformation of a set of requirements into process assessment models which are compliant with the requirement of these standards [51]. The identification of these theories for the development of the proposed design artifact is consistent with the principle of a Theory-Ingrained Artifact. The approach to the problem formulation phase is illustrated in Figure 2. This phase informed the development and evaluation of MedITNet which takes place during Phase 2.

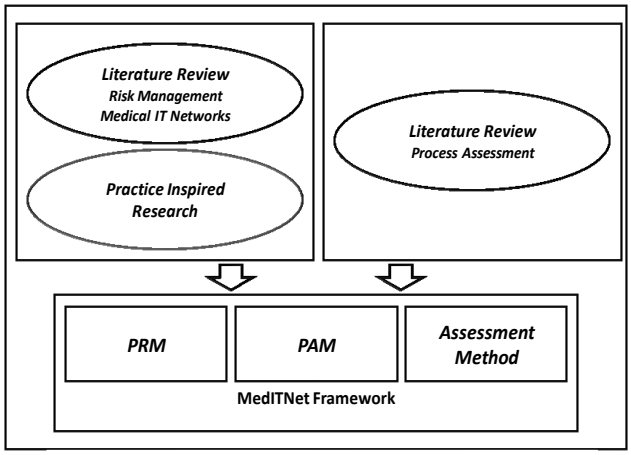

Figure 2 – Phase 1 – Problem Formulation

3.2 Phase 2 - Building, Intervention and Evaluation

The Building, Intervention and Evaluation (BIE) phase of the ADR process contains three principles: Reciprocal Shaping; Mutually Influential Roles; and Authentic and Concurrent Evaluation. The principle of Reciprocal Shaping recognises that the design artifact is shaped by the organisational context in which it is used. In turn, the use of the design artifact shapes the design of the artifact by informing the design theories used in its development during the iterative BIE phase. The ADR process also emphasises the importance of mutual learning between the researcher and research participants in the principle of Mutually Influential Roles. The researcher provides insight into theoretical approaches while research participants provide insight into the practical application of the proposed theories. ADR differs from other DSR approaches in that evaluation is not a separate phase of the research process that follows building. This is embodied in the principle of Authentic and Concurrent Evaluation which advocates that design decisions are based on the ongoing evaluation of the artifact. Each of these principles is discussed in the context of the components of MedITNet. MedITNet was developed in two stages. The first stage focused on the

development of the PRM and PAM while the second stage focused on the development of the AM.

The findings from the Problem Formulation Phase of the research were used to inform the development of the initial version of the PRM and PAM. Following their development, the PRM and PAM were subject to evaluation through expert review. The PRM and PAM were subject to review by two separate groups of "practitioners". An iterative approach to the review was taken with each group reviewing the PRM and PAM twice. The feedback from each review was incorporated into the next version of the model. Firstly, the PRM and PAM were subject to review by members of IEC SC62A and ISO TC215 Joint Working Group 7 (JWG7). JWG7 was responsible for the development of the IEC 80001-1 standard and as such reviewed the PRM and PAM for their ability to assess against the requirements of the standard. In addition, the PRM and PAM were reviewed by experts in the development of similar ISO/IEC 15504-2 compliant assessment models (this group is referred to as SPICE in Figure 3). The focus of this review was on ensuring that the developed PRM and PAM were consistent with the requirements in terms of the development of PRMs and PAMs as expressed in the relevant process assessment standards. Where feedback from the two groups conflicted, each group was recognised for their own area of expertise and the feedback was addressed accordingly.

This approach to the BIE phase using practitioners is consistent with the principles of the BIE phase. Practitioners bring knowledge of the context in which the MedITNet PRM and PAM will be used and influence the design principles used in their development accordingly. Practitioners also provide feedback of the practical application of the chosen design theories, in this case the utility of the development of an ISO/IEC 15504-2 compliant PRM and PAM for use by HDOs in assessment of their risk management processes. The use of an iterative *approach also facilitates the principle of Authentic and Concurrent Evaluation of the PRM and PAM.*

Stage 2 of the development of MedITNet focused on the development of the remaining component of MedITNet, the AM, and was performed concurrently with stage 1. As with Stage 1, the principles associated with the BIE phase of the ADR process are used. Development of the initial version of the AM was based on the findings from the literature review combined with the finding of the Practice-Inspired Research. In addition, a set of assessment questions was developed which formed part of the assessment method. The approach to the development of these questions is discussed in Section 5. The AM was subject to two forms of review. Similar to the PRM and PAM, the assessment method was reviewed by "practitioners" in the form of members of JWG7 to ensure that the assessment adequately addressed the requirements outlined in IEC 80001-1. In addition, a pilot implementation of the AM in a HDO was also performed. The pilot implementation within the HDO ensured that the AM, while performing an assessment of a process outlined in the MedITNet PRM and PAM, was suited for use by the "end user", in this case risk management stakeholders from within the HDO. The process used in the pilot implementation was Risk Analysis and Evaluation Process. This is the main process concerned with the performance of risk management activities. An assessment of this process can provide information about the capability of the overall risk management processes. The performance of risk analysis and evaluation activities requires discussion of other organisational processes which facilitate the performance these activities. For example, discussion of risk analysis and evaluation activities can provide insight into the risk management policy in place in the HDO and the allocation of resources to risk management activities. This approach builds on the BIE principles used in Stage 1. The pilot implementation places the AM in the context in which it will be used and feedback gathered during its use is incorporated into the next iteration of the AM. This is consistent with the principles of: Reciprocal Shaping where use of the AM influences design decisions about its next iteration; Mutually Influential Roles where end-users provide feedback on the practical application of the chosen design theories and; Authentic and Concurrent Evaluation where the AM is built and evaluated, while intervening in the HDO and improving risk management processes. The performance of the BIE phase of the ADR process can also provide insight into the problem which is under investigation which can then provide insight into the appropriateness of the chosen design. In this way, phases 1 and 2 of the ADR process are performed iteratively.

3.3 Phase 3 - Reflection and Learning

While phases 1 and 2 of the ADR process are being performed iteratively, phase 3 is also being performed concurrently and contains a single principle: Guided Learning. The principle of Guided Learning means that the designed artifact not only contains the features of the original design but will also be shaped by the influence of the organisational context of the artifact using an iterative approach where feedback gathered during the BIE phase is incorporated into the next version of the artifact. This has certainly been the case in the development of MedITNet. MedITNet forms the basis of a technical report aimed at facilitating HDO self assessment against the requirements of IEC 80001-1. The original version of the technical report contained the PRM and PAM only as the AM had not yet been developed. This version of the technical report was circulated to members of JWG7 who reported that the length of the technical report was too long which would impact its adoption due to the constraints on the resources within the HDO. To address this, the technical report was restructured prior to being re-circulated to members of JWG7. The new version contained the newly developed AM in the main body of the technical report. The assessment questions, sample assessment documentation and the PRM and PAM were moved to the annexes of the technical report. The PRM and PAM were also greatly reduced in size with relevant text from the ISO/IEC 15504 family of standards being removed but with references provided. This facilitated the dual purpose of the technical report. The first focused allowing HDOs to use the assessment method as provided in the TR to perform an initial assessment of compliance with the requirements of the standard. The second provided a means for tailoring of the assessment method, to account for the context of the HDO by reference to the PRM and PAM and to facilitate the performance of an assessment of the capability of risk management processes. Following the performance of the first three phases of the ADR process, Phase 4 is performed.

3.4 Phase 4 - Formalisation of Learning

The final phase of the ADR process contains a single principle: Generalised Outcomes. This phase moves away from the highly situated nature of the ADR process to a conceptual move where the findings from the ADR process are expressed in terms of generalised outcomes. Sein et al. contend that this conceptual move happens on three levels: (1) generalisation of the problem instance, (2) generalisation of the solution instance, and (3) derivation of design principles from the design research

outcomes [44, p.44]. Each of these principles is discussed in the context of the generalisation of the learning from the development of MedITNet.

The first level in the generalisation of findings examines the problem instance in order to generalise the learning. In the case of MedITNet the generalisation of the problem instance was performed in a number of ways. Firstly, a literature review was performed to examine the challenges which are experienced by HDOs in the risk management of medical IT networks. A focus group sessions with risk management stakeholders confirmed that the identified challenges were consistent within the challenges experienced by the HDO in question. The context of the HDO was also examined. The HDO is a large teaching hospital which operates a category 2b network as defined in Table C.1 of IEC 80001-1. This category is described as follows:

> *Medical and non-Medical Devices incorporated by one Medical Device manufacturer and Medical and non-Medical Devices incorporated by other Medical Device manufacturers as well as non- Medical Devices and applications interconnected on a shared IT-Network by a 3rd party*[1].

The pilot implementation in the HDO resulted in an improvement in the Risk Analysis and Evaluation Processes within the HDO. In addition, the overall risk management of the medical IT network was improved showing the utility of MedITNet in this type of HDO.

The second level of generalisation looks as the generalisation of the solution instance. As in the first stage, the literature review identified the challenges which are faced by HDOs in the risk management of medical IT networks. The literature review revealed that although HDOs provide care in differing regulatory environments, the challenges which are faced are similar regardless of the location in which care is provided. To ensure that MedITNet addressed the identified common challenges, expert review of the components of MedITNet by members of JWG7 was performed. Members of JWG7 have been identified by member bodies as experts in their field and are representative of the risk management stakeholders as identified in IEC 80001-1. Members include representatives from various departments within HDOs such as clinical engineering, IT and management. Medical device manufacturers and providers of other information technology solutions are also represented. The process of expert review by this group and the use of their feedback in the development and refinement of MedITNet ensured that MedITNet is suitable for tailoring for usage across a number of HDO contexts. In addition, the definition of the requirements of IEC 80001-1 at a process level, consistent with the requirements of ISO/IEC 15504-2, ensures that the requirements can be applied regardless of the context which is the intent of the IEC 80001-1 standard.

The final level in the generalisation of learnings ensures that the design principles from the ADR process are understood and communicated. While ISO/IEC 15504-2 compliant process assessment models have been developed for Service Management standards, which are similar to IEC 80001-1 in their lifecycle approach, no such model had been developed for use in this domain prior to this research. During the focus group sessions in the Practice-Inspired Research, it was revealed that risk management stakeholders found the IEC 80001-1 standard to be "new" in its approach in that it places the responsibility for the risk management of the network with the HDO. While medical device manufacturers are familiar with the use of standards in the development of medical devices [52, 53], HDOs are not as familiar and may struggle to implement the requirements of IEC 80001-1. The presence of a model such as MedITNet has been identified as essential in increasing adoption of IEC 80001-1 in assisting HDOs in addressing the challenge of understanding and implementing the requirements of the standard. This was revealed during a focus group session which was performed by selected expert members of JWG7. This session focused on validating the overall MedITNet framework and is discussed in more detail in Section 6. This level of generalisation of learnings also calls for the dissemination of the results of the research. MedITNet will be published as *ISO/TR 80001-2-7: Application of risk management for IT networks incorporating medical devices –Application Guidance – Part 2 – 7: Guidance for Healthcare Delivery Organisations (HDOs) on how to self-assess their conformance with IEC 80001-1*. Figure 3 illustrates the iterative Problem Formulation and BIE phases in the development of MedITNet. The following section discusses the approach taken in the development of the assessment questions which form part of the AM.

4. DEVELOPMENT OF THE ASSESSMENT METHOD QUESTIONS

As part of the AM component of MedITNet, a set of assessment questions was developed which can be used by HDOs to perform an assessment of their risk management processes related to medical IT networks. As the questions perform an assessment of the capability of the base practices as outlined in the MedITNet PAM, the questions can be used as written or can be tailored to the context of the HDO and the scope of the assessment. In order to develop the assessment questions, the ADR approach was utilised with the researcher working closely with representatives from the HDO in the development of the assessment questions. This approach was taken as it allowed the perspective of different risk management stakeholders to be considered. Focus group interviews were used during some phases of the question development which also allowed the use of focus group interviews during an assessment to be trialled.

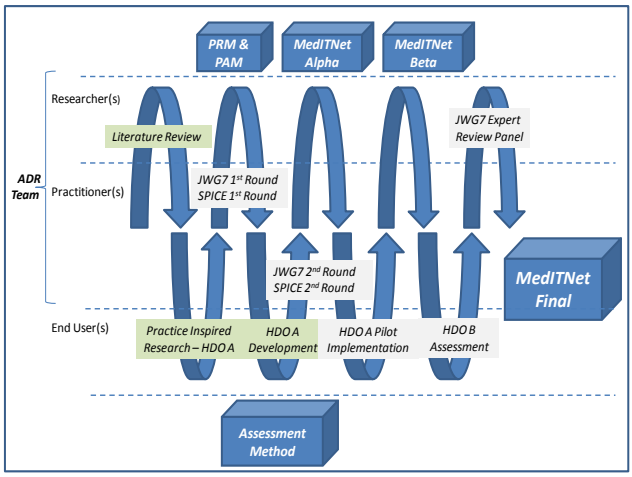

Figure 3 – Phases of the ADR process

[1] Previous definitions of system categories in Table C.1 note that a 3rd party may be a hospital.

This section presents the approach that was taken to the development of the questions and outlines how this approach may also be useful to HDOs when performing a self assessment using MedITNet.

The initial phase of the question development focused on the development of questions to assess the base practices of the Risk Analysis and Evaluation Process. This process would later be used in the pilot implementation of the AM as mentioned previously. Focus group participants in the initial question development session had previously been involved in the Practice-Inspired Research and as such were familiar with the IEC 80001-1 standard and the approach being taken in the development of MedITNet. In order to develop the assessment questions, participants were asked to complete six steps as follows:

1. Review the base practice;
2. Formulate an initial question(s);
3. Review the base practice in the context of the standard;
4. Review the base practice with reference to a "real" implementation of the practice;
5. Review/reformulate the question to assess the degree to which the base practice has been implemented;
6. Rephrase the question(s) to ensure fewest questions are used to assess the base practice.

Using these steps participants were encouraged to review the base practice before formulating the initial question(s). Having formulated the question participants are then asked to review the base practice in the context of the standard. Participants were encouraged to consider how the base practice formed part of the process under consideration and how the Risk Analysis and Evaluation process formed part of the overall risk management process. Following this review, participants were asked to think of "real" examples of medical IT network projects that had taken place in the HDO where the base practice under consideration had been implemented. Participants were then asked to revisit the initial question(s) and rephrase as necessary based on the understanding gained during the review process. Finally, participants were asked to review the question(s) to ensure that the fewest number of questions were used to assess the base practice. The researcher participated in this process acting as moderator during the focus group and providing clarifying aspects of the requirements of the standard as required. These steps were also used in the development of the assessment questions for the remaining 13 processes. These questions were also developed with input from HDO end users.

The steps outlined above may also assist HDOs when performing an assessment. These steps were recognized by focus group participants as being useful to HDOs for use in the tailoring of assessment questions for their own context. Participants suggested that reviewing the base practices and considering examples of the implementation of base practices during previous network projects may help in understanding how the requirements can be applied in their specific HDO context. This approach also facilitates the rephrasing of assessment questions to assess how the base practices are implemented while ensuring that regulatory requirements are met. Expert reviewers of MedITNet as described in Section 6 also noted that it is only through consideration of the requirements of IEC 80001-1 in the context of their own HDO that implementers of the standard could begin to understand the requirements in a way that would be difficult to gain by simply reading the standard, the associated technical reports and other material on the subject.

5. EXPERT REVIEW OF MEDITNET

The use of the ADR approach in the development and validation of the component part of MedITNet have been discussed in the previous sections of this paper. The latest version of MedITNet (incorporating feedback from all previous phases of the BIE process) was then subject to review by a select group of experts from JWG7. This formed the final stage of validation of MedITNet as illustrated in Figure 3.

Each of the experts chosen had been actively involved in the development of the IEC 80001-1 or the associated technical reports. In addition, each of the review participants were considered to be a leading expert in their field and representative of the risk management stakeholders defined in IEC 80001-1. In total, five expert reviewers participated. In order to conduct the review a focus group session was held. While the intent of the previous phases of the ADR process was to validate specific aspects of the components of MedITNet, the focus of this session was to review the overall MedITNet framework. The author acted as moderator during the focus group session. During the focus group, which lasted approximately two hours, 17 questions were posed to participants. These questions had been devised by the author prior to the focus group session and focused on five specific areas as follows:

1. The utility of the assessment framework (MedITNet) within the IEC 80001-1 family of standards;
2. The usability of the assessment framework for self-assessment of risk management processes within a Healthcare Delivery Organisation;
3. The scalability and generalisability of the assessment framework;
4. The coverage of the requirements of IEC 80001-1 by ISO/TR 80001-2-7;
5. Suggestions for improvements to the assessment framework.

These areas were identified as being important areas for review as they represent the requirements that were established for MedITNet during the Problem Formulation phase of the ADR process. The findings from the expert review in each of these areas will be discussed in the remainder of this section.

5.1 Utility of MedITNet

In order to assess the utility of MedITNet in the IEC 80001-1 family of standards, four questions were posed to the review participants as follows:

- Q1 - How does the assessment framework benefit the IEC 80001-1 family of technical reports?
- Q2 - To what degree do you feel that use of the Assessment Method will improve HDOs understanding of IEC 80001-1?
- Q3 - To what degree do you feel that use of the assessment framework will encourage Top Management engagement with IEC 80001-1?
- Q4 - To what degree do you feel that use of the Assessment Method will contribute to the adoption of IEC 80001-1?

For Q1, experts reported that the assessment framework benefits the IEC 80001-1 family of technical reports as it allows HDOs to have an objective measurement of the capability of risk management processes. One expert commented that without this framework, "every 80001 practitioner would have to invent an approach for assessment including the PRM and PAM, representing a significant barrier to the implementation and utilization of 80001". The expert also commented that the assessment framework "promotes consistent evaluation and benchmarking when the standard and guidance are applied". Experts also observed that "the assessment framework aids

HDOs in discussions about IEC 80001-1 and how it may apply to the HDO".

In response to Q2, the assessment framework was also deemed beneficial to the HDOs' understanding of the standard. The format of the framework using the assessment questions gives an understanding to HDOs which is not gained by simply reading the standard. Experts reported that having to answer a set of questions requires HDOs to think about what they do in terms of IEC 80001-1 and how they will implement it within the HDO in practical terms. This facilitates a better understanding of the standard. One expert, who had carried out a trial assessment, reported that, during the assessment, all assessment participants had first received training on the standard and the applicable guidance documents. However, it wasn't until "they grappled with answering the assessment questions that the theory of 80001 connected with their day-to-day reality of managing networked medical technology".

In discussing Q3, one expert reported that the trial assessment revealed an "appetite" among Top Management in the HDO to be able to independently measure capability against the requirements. The expert advised that HDO Top Management, are primarily focused on the "ultimate value proposition of safer, more effective, more secure technology usage versus 80001 requirements". The expert reported that Top Management within the HDO recognised the benefit of having "an industry standard against which they could evaluate their own policies, procedures, competencies and deployed technology, and the use of improvement plans to provide an executable strategy for improving". Another expert remarked that having a measure of the capability of risk management processes means that Top Management can use this measurement of capability in the governance of the HDO.

Experts, in relation to Q4, agreed that the benefits accruing from the adoption of the standard are related to sponsorship of the standard by Top Management within the HDO. There is a perceived need among Top Management for a means to assess the capability of risk management processes in order to ensure that the technology provides the expected benefits to patients. One expert commented that "this should have a huge impact for adoption, because it provides the basis for evaluation and maturity models, creation of improvement plans, and thus a path to realizing the benefits of 80001. Documenting HDO experiences realising these benefits will have a huge impact for advancing IEC 80001 adoption. It could be argued that without something like this, adoption may be stuck in its current very shallow trajectory".

5.2 Usability of MedITNet for Self Assessment

The next area which was subject to review was that of the usability of MedITNet in the performance of a self assessment. Expert reviewers were asked four questions in relation to this area as follows:

- Q5 - How suitable is the assessment framework for performing an assessment of risk management processes against the requirements of IEC 80001-1 within a Healthcare Delivery Organisation?
- Q6 - How easy is it to perform a self-assessment of risk management processes against the requirements of IEC 80001-1, within a Healthcare Delivery Organisation, using the assessment framework?
- Q7 - How suitable are the questions within the Assessment Method for use in performing a self-assessment of risk management processes against the requirements of IEC 80001-1, within a Healthcare Delivery Organisation?
- Q8 - To what degree is the measurement framework suited for use in the assessment of the capability of risk management processes?

In Q5, experts reported that it is difficult to say how "suitable" the framework is for performing and assessment of risk management processes as the suitability is determined by the level of maturity of the HDO who are using the framework. One expert, who had used the model in a trial assessment, found the framework to be "well formed" but noted that specific questions had to be adapted based on the maturity of the HDO involved in the assessment and the scope of the assessment and in some cases based on the care context of the technology being assessed. The expert highlighted that other variables which may require questions to be adapted are identified in the IEC/TR 80001-2-4:2012 HDO guidance document [54]. Experts also advised that a mapping from the AM to the specific sections of IEC 80001-1 should be included to demonstrate that it does specifically correlate with the requirements of the standard.

During discussion of Q6 and Q7, experts noted that the ease of use of the assessment framework is dependent on the maturity level of the HDO and the awareness, knowledge and skill of the person performing the self-assessment. During the assessment, while the questions in the technical report were used as a starting point, a different set of questions were used by the assessors to allow objective evidence required to be gathered which would allow them to answer the questions in the Assessment Method. Questions were phrased to ask, for example, how documentation gathered from manufacturers is managed. This type of question was used rather than the more direct questions in the Assessment Method which ask, for example, whether the HDO has a risk management policy in place. It was noted that the intent of the Assessment Method is to be tailored to the specific context in which it is being used and that the intent of the document is to be a starting point rather than used as presented. While this "tailoring" of the AM through the use of an alternate set of questions was performed during the assessment, this may present challenges when a self-assessment is being performed in a HDO at a lower maturity level. A HDO that has started to implement IEC 80001-1 would find it easier to do an assessment than a HDO who was taking its first steps in implementing the standard. Experts advised that the suitability of the assessment framework will be better understood when more feedback is received from HDOs of varying types.

While the measurement scale used in ISO/IEC 15504 is useful for determining the capability level of a process, experts, in response to Q8, commented that a maturity framework identifying which parts of IEC 80001-1 are more fundamental would be useful. This would provide a valuable implementation roadmap in terms of what parts of the standard should be implemented first and then be built upon to achieve a higher maturity level. Experts also observed that "in all organisations, process assessment will initially focus on a check box exercise of determining conformance and once this has been achieved, the focus moves towards providing a plan or roadmap or improvement plans towards achieving a higher capability and maturity level."

5.3 Generalisability and Scalability of MedITNet

The focus groups session also sought feedback from expert reviewers on the scalability and generalisability of MedITNet. Three questions were posed to participants as follows:

- Q9 - How suitable is the framework in performing an assessment of risk management processes against the requirements of IEC 80001-1 within Healthcare Delivery Organisations of varying sizes?
- Q10 - How suitable is the assessment framework in performing an assessment of risk management processes against the requirements of IEC 80001-1 within Healthcare Delivery Organisations within different geographical locations or regulatory frameworks?
- Q11 - To what degree does the information provided in the assessment framework allow for tailoring of the assessment framework for use in different geographical locations or regulatory frameworks?

In Q9, experts confirmed that, as the assessment framework is based on an assessment at a process level, it is suitable for use in HDOs of varying sizes. Experts suggested that tailoring of the Assessment Method may be required based on the expertise within the organisation with more tailoring required for smaller organisations with less specific expertise in this area.

Experts, in discussion of Q10, similarly confirmed that the assessment framework, due to its definition on a process level, is suitable for use in different locations and different regulatory frameworks. However, the assessment framework will again require tailoring with regard to interpretation of IEC 80001-1 within the legislative and regulatory requirements of the region in which it is implemented.

In response to Q11, experts who have been involved in using the assessment framework to perform an assessment confirmed that the information provided was sufficient to allow the Assessment Method to be tailored to the specific context in which it was to be used.

5.4 MedITNet Coverage of the Requirements of IEC 80001-1

In order to examine the extent to which MedITNet provides coverage of the requirements of IEC 80001-1, four questions were posed to participants as follows:

- Q12 - To what degree does the assessment framework address all the requirements of IEC 80001-1?
- Q13 - To what degree does the Assessment Method provide correct references to other technical reports within the IEC 80001-1 family of standards?
- Q14 - Is the assessment framework consistent with the overall approach to risk management as defined in IEC 80001-1?
- Q15 - Are the 14 processes which have been defined in the assessment framework consistent with the risk management requirements defined in IEC 80001-1?

Traceability from the requirements is maintained from the standard to the outcomes in the PRM, which are then phrased as base practices within the PAM. The questions in the Assessment Method are used to assess the capability of the base practices. While this traceability to each requirement has been maintained during the study, experts discussing Q12 noted that a simple and easily understandable mapping of questions to IEC 80001-1 requirements would be helpful. It has been suggested that this traceability should be provided in order to increase the usefulness of the technical report.

In Q13, experts advised that not all references had been checked but the references were generally thought to be correct. It was noted that there may be some confusion in that the guidance provided is not normative but this may have been misinterpreted. The researcher advised participants that a comment was raised in relation to this, in an earlier draft of ISO/TR 80001-2-7, where a reviewer suggested that the references to the guidance documents be made in the PAM. This comment was not accepted as the PAM contains base practices which assess against the requirements of IEC 80001-1 and are based on the normative requirements of the standard. Instead the references to the technical report were provided in the Assessment Method as guidance.

Experts confirmed that the overall approach to risk management within the assessment framework is consistent with that defined in IEC 80001-1 (Q14). Experts also noted that IEC 80001-1 is not a process standard and confirmed that the processes are consistent with the requirements of IEC 80001-1 in as much as they had to be derived from the standard (Q15).

5.5 Suggestions for Improvements to MedITNet

In addition to providing feedback on MedITNet, participants were given the opportunity to provide highlight weaknesses in the framework or make suggestions for its improvement. Two questions were used to facilitate discussion in this area as follows:

- Q16 - Do you see any problems with the overall assessment framework or any component of the assessment framework?
- Q17 - Do you have any suggestions for any improvements to be made to the assessment framework?

In response to Q16, experts did not note any problems with the assessment framework but suggested that further implementations were required to fully judge its utility. Based on Q17, it was suggested that feedback should be sought from use of the assessment framework in different contexts and on different sized projects. For example, a large HDO implementation of a small project and vice versa. Experts remarked that this future use of the framework would not only highlight improvements that may be made to the framework but would also provide insight into needed revisions of the IEC 80001-1 standard. The expert reviewers did note some improvements that may be made to the assessment framework. These suggestions included:

- The inclusion of a document map in the technical report to make it easier to navigate;
- The inclusion of a mapping from the assessment questions back to the requirements in the technical report;
- The inclusion of an additional stage in the assessment process for the implementation of the improvement plan;
- Tailoring of the framework to address the varying levels of maturity among HDOs.

6. CONCLUSIONS

MedITNet is a flexible assessment framework which can be used by HDOs to assess the capability of their risk management processes. In order to ensure the utility of MedITNet across varying HDO contexts, ADR was used in the development and validation of the assessment framework. The iterative approach

used enabled the combination of expert review by practitioners in the area with the pilot implementation of components of MedITNet by end users in the HDO context. The overall use of ADR in the development and validation of MedITNet has been discussed in this paper. In addition, examples of the use of ADR in the development of assessment questions and during the expert review of MedITNet have been discussed. The MedITNet framework is scheduled for publication as technical report in the IEC family of standards.

The development of MedITNet provides a standardised and repeatable approach to the assessment of the capability of risk management processes related to medical IT networks. An assessment can highlight areas of weakness in the risk management process, and therefore, can be used as a foundation upon which improvements to the process can be made. By improving risk management processes, HDOs can place medical devices onto their IT network and ensure that risks to the safety, effectiveness and security of the device and network are mitigated. This enables the potential benefits associated with networked medical devices to be realized such as reduced cost, reduction in adverse events and improvements to patient safety.

MedITNet provides HDOs performing self assessment with a means to understand and implement the requirements of the IEC 80001-1 standard which is suited to the context in which they provide care. By providing this assistance to HDOs in applying the requirements and by providing a method in which the capability of the processes, MedITNet can potentially increase the level of adoption of the standard. This is achieved by allowing Top Management within the HDO to ensure that the potential benefits to patients through the use of medical devices are achieved. MedITNet can be used to provide assistance to HDOs taking their first steps implementing IEC 80001-1 and can be used for assessment in HDOs operating at a higher maturity level. MedITNet has been developed to promote communication among risk management stakeholders through using focus groups interviews allowing for the perspectives of internal and external stakeholders to be represented.

7. ACKNOWLEDGMENTS

This research is supported by the Science Foundation Ireland Principal Investigator Programme, grant number 08/IN.1/I2030 (the funding of this project was awarded by Science Foundation Ireland under a co-funding initiative by the Irish Government and European Regional Development Fund),and by Lero - the Irish Software Research Centre (http://www.lero.ie) grant 10/CE/I1855 & 13/RC/20194.

8. REFERENCES

[1] T. Cooper, Y. David, and S. Eagles, *Getting Started with IEC 80001: Essential Information for Healthcare Providers Managing Medical IT-Networks*: AAMI, 2011.

[2] West Health Institute, "The Value of Medical Device Interoperability - Improving patient care with more than $30 billion in annual health care savings," 2013.

[3] Institute of Medicine. (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Available: https://download.nap.edu/catalog.php?record_id=10027

[4] President's Council of Advisors on Science and Technology (PCAST), "Report to the President - Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward," Executive Office of the President, Ed., ed, 2010.

[5] M. Logan and B. Patel, "Medical Device Interoperability - A Safer Path Forward " AAMI, Arlington, VA2012.

[6] A. Hamilton, R. Nau, R. Burke, S. Weinstein, C. K. B. Dlatt, S. Fiore*, et al.*, "Summary of the August 2011 Symposium on the Role and Future of Health Information Technology in an Era of Health Care Transformation," The George Washington University2011.

[7] I. Lee, G. J. Pappas, R. Cleaveland, J. Hatcliff, B. H. Krogh, P. Lee*, et al.*, "High-confidence medical device software and systems," *Computer,* vol. 39, pp. 33-38, 2006.

[8] N. Milenkovich. (March 15, 2013, 16/07/2013). *OCR issues new HITECH regulations* Available: http://drugtopics.modernmedicine.com/drug-topics/news/drug-topics/health-system-news/ocr-issues-new-hitech-regulations

[9] Centers for Medicare & Medicaid Services, "42 CFR Parts 412, 413, 422 et al. Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule ", Health and Human Services Ed., ed, 2010.

[10] E. H. Wagner, "The role of patient care teams in chronic disease management," *BMJ: British medical journal,* vol. 320, p. 569, 2000.

[11] E. H. Wagner, B. T. Austin, C. Davis, M. Hindmarsh, J. Schaefer, and A. Bonomi, "Improving chronic illness care: translating evidence into action," *Health affairs,* vol. 20, pp. 64-78, 2001.

[12] C. Hoffman and D. Rice, "Chronic care in America: A 21st century challenge," *Princeton, NJ: The Robert Wood Johnson Foundation,* 1996.

[13] A. Soceanu, A. Egner, and F. Moldoveanu, "Towards Interoperability of eHealth System Networked Components," in *Control Systems and Computer Science (CSCS), 2013 19th International Conference on*, 2013, pp. 147-154.

[14] J. Comstock. (2013, 23/01/2014). *14M networked medical devices to ship by 2018*. Available: http://mobihealthnews.com/28295/14m-networked-medical-devices-to-ship-by-2018/

[15] Agency for Healthcare Research and Quality (AHRQ), "Health IT for Improved Chronic Disease Management," Department of Health and Human Services, Ed., ed, 2013.

[16] M. Castañeda, "Connecting devices and data on the healthcare network," *Biomedical Instrumentation & Technology,* vol. 44, pp. 18-25, 2010.

[17] J. Goldman and S. Whitehead, "Advancing the Adoption of Medical Device "Plug-and-Play" Interoperability to Improve Patient Safety and Healthcare Efficiency," 2010.

[18] K. K. Venkatasubramanian, S. K. S. Gupta, R. P. Jetley, and P. L. Jones, "Interoperable Medical Devices - Communication Security Issues," *IEEE Pulse,* vol. Sept/Oct 2010, 2010.

[19] R. Hampton and R. Schrenker, "What Does IEC 80001-1 Mean to You?," *24x7 - Technology and Service Solutions for Biomeds,* 2011.

[20] S. R. Rakitin, "Networked Medical Devices: Essential Collaboration for Improved Safety," *AAMI.org,* 2009.

[21] S. Loughlin and J. S. Williams, "The top 10 medical device challenges," *Biomedical Instrumentation & Technology,* vol. 45, pp. 98-104, 2011.

[22] T. Mehta and C. Mah, "Auto-Provisioning of Biomedical Devices on a Converged IP Network," *Biomedical Instrumentation & Technology,* vol. 43, pp. 463-467, 2009.

[23] T. Gee. (2008, 27/1/2012). *Medical Device Networks Trouble Industry*. Available: http://medicalconnectivity.com/2008/12/18/medical-device-networks-trouble-industry/

[24] S. Eagles, "An Introduction to IEC 80001: Aiming for Patient Safety in the Networked Healthcare Environment," *IT Horizons,* vol. 2008, 2008.

[25] National Cybersecurity and Communications Integration Center, "Attack Surface: Healthcare and Public Health Sector," ed, 2012.

[26] D. Talbot. (2012, Computer Viruses Are "Rampant" on Medical Devices in Hospitals. *MIT Technology Review*. Available: http://www.technologyreview.com/news/429616/computer-viruses-are-rampant-on-medical-devices-in-hospitals/

[27] J. Graham and C. Dizikes, "Baby's death spotlights safety risks linked to computerized systems," in *Chicago Tribune*, ed, 2011.

[28] J. Shuren, "Health Information Technology (HIT) Policy Committee Adoption/Certification Workgroup - Testimony of Jeffrey Shuren, Director of FDA's Centre for Devices and Radiological Health," ONC, Ed., ed, 2010.

[29] S. Eagles, "IEC 80001: An Introduction," 80001-1 Experts,, Presentation from 19th Annual NCBA ConferenceSeptember 13, 2012 2012.

[30] IEC, "IEC 80001-1 - Application of Risk Management for IT-Networks incorporating Medical Devices - Part 1: Roles, responsibilities and activities," ed. Geneva, Switzerland: International Electrotechnical Commission, 2010.

[31] F. J. Hegarty, S. T. MacMahon, P. Byrne, and F. McCaffery, "Assessing a Hospital's Medical IT Network Risk Management Practice with 80001-1," *Biomedical Instrumentation & Technology,* vol. 48, pp. 64-71, 2014.

[32] T. Cooper and K. Fuchs, "The Wireless Challenge - Technology Risk Assessment In Healthcare Facilities," *Biomedical Instruments and Technology,* vol. May/June 2013, 2013.

[33] M. Janssen and R. Schrenker, "Guidelines From 80001: Maintaining a Medical IT Network," *Biomedical Instrumentation & Technology,* vol. 45, pp. 295-299, 2011/07/01 2011.

[34] ISO/IEC, "ISO/IEC 15504-2:2003 - Software engineering — Process assessment — Part 2: Performing an assessment," ed. Geneva, Switzerland, 2003.

[35] S. T. MacMahon, F. Mc Caffery, and F. Keenan, "Risk Management of Medical IT Networks: An ISO/IEC 15504 Compliant Approach to Assessment against IEC 80001-1," presented at the International Conference on Software and System Process (ICSSP), San Francisco, 2013.

[36] ISO. (2014, November 3rd). *The International Organization for Standardization*. Available: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=37458

[37] A. R. Hevner, S. T. March, J. Park, and S. Ram, "Design Science in Information Systems Research," *MIS Quarterly,* vol. 28, pp. 75-105, 2004.

[38] A. Pascal, C. Thomas, and A. G. L. Romme, "Developing a Human-centred and Science-based Approach to Design: The Knowledge Management Platform Project," *British Journal of Management,* pp. n/a-n/a, 2012.

[39] H. W. Rittel and M. M. Webber, "Dilemmas in a general theory of planning," *Policy sciences,* vol. 4, pp. 155-169, 1973.

[40] J. Zimmerman, J. Forlizzi, and S. Evenson, "Research through design as a method for interaction design research in HCI," in *Proceedings of the SIGCHI conference on Human factors in computing systems*, 2007, pp. 493-502.

[41] D. Tuffley, "Modelling Organisational Behavior with Process Reference Models," 2012.

[42] J. Kenneally, M. Curley, B. Wilson, and M. Porter, "Enhancing Benefits from Healthcare IT Adoption Using Design Science Research: Presenting a Unified Application of the IT Capability Maturity Framework and the Electronic Medical Record Adoption Model," in *Design Science: Perspectives from Europe*, ed: Springer, 2013, pp. 124-143.

[43] P. Offermann, O. Levina, M. Schönherr, and U. Bub, "Outline of a design science research process," presented at the Proceedings of the 4th International Conference on Design Science Research in Information Systems and Technology, 2009.

[44] M. Sein, O. Henfridsson, S. Purao, M. Rossi, and R. Lindgren, "Action design research," 2011.

[45] R. Cole, S. Purao, M. Rossi, and M. K. Sein, "Being proactive: Where Action Research meets Design Research," presented at the Proceedings of the Twenty-Sixth International Conference on Information Systems, 2005.

[46] J. Iivari and J. Venable, "Action research and design science research–seemingly similar but decisively dissimilar," in *17th European Conference on Information Systems*, 2009, pp. 1-13.

[47] ISO/IEC, "ISO/IEC 20000-1:2011 - Information technology —Service management Part 1: Service management system requirements," ed. Geneva, Switzerland, 2011.

[48] ISO/IEC, "ISO/IEC 20000-2:2005 - Information technology -- Service management -- Part 2: Code of Practice," ed. Geneva, Switzerland, 2012.

[49] The Cabinet Office, "ITIL 2011 - Summary of Updates," ed. Norfolk, England: Crown Copyright, 2011.

[50] ISO/IEC, "ISO/IEC TR 24774:2010 - Systems and software engineering — Life cycle management — Guidelines for process description," ed. Geneva, Switzerland, 2010.

[51] B. Barafort, A. Renault, M. Picard, and S. Cortina, "A transformation process for building PRMs and PAMs based on a collection of requirements – Example with ISO/IEC 20000," presented at the SPICE Nuremberg, Germany, 2008.

[52] M. McHugh, F. McCaffery, and V. Casey, "Standalone software as an active medical device," in *Software Process Improvement and Capability Determination*, ed: Springer, 2011, pp. 97-107.

[53] Center for Devices and Radiological Health (CDRH), "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards," CDRH, Ed., ed, 2007, p. 10.

[54] IEC/TR, "PD IEC/TR 80001-2-4 - Application of Risk Management for IT-Networks incorporating Medical Devices - Part 2-4: Guidance for Healthcare Delivery Organizations ", ed. Geneva, Switzerland: International Electrotechnical Commission, 2012.