

Development of the MedITNet Assessment Method

Enabling Healthcare Delivery Organisation Self Assessment against IEC 80001-1

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Abstract— The provision of care to patients has moved away from episodic acute care due to the increase in chronic diseases such as diabetes. This has changed the relationship between the patient and the care team. The management of chronic disease requires the use of information technology including networked medical devices to facilitate the establishment of an ongoing relationship between the patient and care team. The use of networked medical devices can provide benefits to patients such as reduced cost of care, reductions in adverse events and improved care through the provision of accurate and up-to-date information. However, the placement of a medical device onto an IT network can lead to risks to the device. These risks may lead to incorrect or degraded performance of the device impacting patient care and negating the potential benefits of using the device. While, IEC 80001-1 was developed to assist Healthcare Delivery Organisations (HDOs) in addressing these risks, HDOs may struggle in implementing the requirements of the standard. This paper discusses the development of an Assessment Method which forms part of MedITNet, an assessment framework which can be used by HDOs to assist them in implementing the requirements of the standard by providing a flexible, consistent and repeatable approach to assessing the capability of their risk management processes relating to networked medical devices. The assessment highlights weaknesses in the process and can be used as a foundation to improve these processes.

Keywords- Risk Management; Medical IT Networks; IEC 80001-1; MedITNet; Assessment Framework; Assessment Method.

I. INTRODUCTION

The recent downturn in the global economy has led to an increased focus on ensuring that a high standard of care is provided to the patient while reducing the cost of care. Interoperability of medical devices has been recognised for its potential to achieve this goal [1]-[3]. Such is the potential that governments have provided incentives to promote the meaningful use of interoperable medical devices and Health Information Technology (HIT), such as Electronic Health Records (EHRs) [4]-[6]. The use of interoperable medical devices has resulted from the increased prevalence of chronic conditions such

as diabetes which has resulted in a move away from acute episodic care. The management of chronic disease requires 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 [7]-[10]. As a result of this change, the number of networked medical devices in use continues to increase [11]-[13].

A number of benefits of the use of networked medical are recognised. These include 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 [14]-[15]. These benefits have resulted in medical IT networks becoming a critical, integral component of the medical system [16]. However, 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 [13][17]-[19]. Proprietary networks were traditionally used when a device was placed onto a network. However, these are being used less with medical devices being designed to be placed onto the hospitals general IT network. This means that medical device manufacturers no longer exercise control over the configuration of the network [20]. This lack of control can lead to risks which result in unintended consequences outside the control of the medical device manufacturer. The placement of the device onto the hospital network creates a new system in which the device has not been validated [21]. These risks can result in the incorrect and degraded performance of the medical device [22][23] compromising patient safety, effectiveness and the security of the IT network [24]-[26].

IEC 80001-1: *Application of risk management for IT-networks incorporating medical devices* [27] was published in 2010 to address the risks associated with the incorporation of a medical device into an IT network. However, HDOs face challenges when implementing the

requirements of this standard [28]. HDOs vary in size and in terms of the capability of their risk management processes [16] [29] and the regulatory requirements of the region in which they provide care differ meaning that the implementation of the requirements of the standard will vary depending on the relevant regulatory requirements. The effective performance of risk management activities requires interaction between different stakeholder groups. An understanding of the context of the HDO is also required in order to manage the identified risks [17][30]. In addition, organisational changes are required to facilitate the necessary level of interaction among stakeholders and HDOs may be unprepared for this [13] due to the fact that departments within the HDO typically operate in silos [7]. 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 to provide HDOs with assistance. This research has focused on the development of an assessment framework which provides HDOs with a flexible approach to assessing the capability of their current risk management processes relating to medical IT networks. The use of the assessment framework enables communication among stakeholders groups allowing HDOs to implement the requirements of the standard.

The rest of this paper is organized as follows. Section II describes the development of the Assessment Method component of the MedITNet assessment framework while Section III described the stages of the Assessment while the validation of the resultant Assessment Method is discussed in Section IV. The conclusions are presented in Section V.

II. DEVELOPMENT OF THE ASSESSMENT METHOD

The Assessment Method described in this paper is one of three components which make up the MedITNet assessment framework [31][32]. In addition to the Assessment Method, MedITNet contains a Process Reference Model (PRM) and Process Assessment Model (PAM). The PRM provides a description of 14 processes which address the requirements of IEC 80001-1. The processes within the PRM are described in terms of the purpose of the process and the outcomes achieved as a result of performing the process. The PAM extends the description of the processes by including a description of the base practices or activities performed during the process and the work products used or produced as a result of performing the process. The PAM also introduces the concept of a measurement framework or scale on which the capability of the process can be measured. The Assessment Method provides a consistent approach to assessing the capability of the processes in the PAM using questions related to each of the base practices. The Assessment Method can be tailored for use based on the context in which the HDO provides care.

A. Development Approach

The approach to the development of the Assessment Method combines the learnings from a literature review with knowledge of risk management practices in a HDO. In order to understand the risk management practices within the HDO, focus groups sessions were conducted with risk management stakeholders within a HDO. These sessions were performed during the Practice-Inspired Research phase of the Action Design Research (ADR) process [33] which was used in the development of the Assessment Method and also in the development of the MedITNet Assessment framework.

B. Literature Review

In order to inform the development of the Assessment Method, a review of Assessment Methods for similar standards was completed. This review focused on ISO/IEC 15504-3 [34] and Appraisal Requirements for CMMI [35] Domain specific including Rapid Assessment for Process Improvement in Software Development (RAPID) [36], Express process appraisal (EPA) [37], Adept [38], Med-Adept [39] and Tudor IT Service Management Process Assessment (TIPA) [40] were also reviewed. While this review informed the development of the Assessment Method, the results of the review were not sufficient in themselves to develop the Assessment Method. In order to develop the Assessment Method, the results of the literature review were combined with the knowledge gained during the Practice-Inspired Research conducted as part of this study. This approach allowed the researcher to take into account the concerns which HDOs express in relation to the implementation of the IEC 80001-1 standard.

The literature review provided an understanding of the challenges that HDOs encounter when incorporating a medical device into an IT network. Each of the identified challenges was considered when developing the requirements for the Assessment Method, using a similar approach to that used by Mc Caffery and Coleman [41] using criteria for Assessment Methods as outlined by Anacleto et al. [42]. The criteria were adapted to take into account the domain in which the Assessment Method will be used, that is, within the HDO rather than in the context of software development. The development of the requirements for the Assessment Method also took into account the challenges related to the management of risk associated with the incorporation of a medical device into an IT network which were highlighted as part of the Literature Review and Practice-Inspired Research. The requirements for the Assessment Method were defined as follows:

- Due to the constraints on resources within HDOs, the Assessment Method should be lightweight in its approach and facilitate self-assessment;

- The Assessment Method should be based on the processes described in the MedITNet PAM;
- Guidance should be provided for tailoring the Assessment Method for use in various scales of HDOs and in different geographical contexts. The Assessment Method should also facilitate assessments based on conformance with the standard as well as those which seek to assess the capability level with which risk management processes are being performed;
- The Assessment Method should support the identification of risks and improvement opportunities;
- The Assessment Method should not assume any previous knowledge of process assessment on the part of those conducting the assessment;
- The Assessment Method should facilitate the development of tool support in the future;
- The Assessment Method should be publicly available;
- The Assessment Method should encourage a culture of communication among various multidisciplinary risk management stakeholders including those within and external to the HDO;
- The Assessment Method should be validated for use within the HDO context.

In addition to the literature review and, to augment the Practice-Inspired Research, members of the Clinical Engineering team (CE) and the Clinical Informatics team in a HDO were consulted throughout the development of the questions for the Assessment Method. This was an iterative process which is in the following section.

C. Question Development

The involvement of HDO risk management stakeholders in the development of the Assessment Method was considered to be vital as HDOs may use the Assessment Method in its form within the technical report and without reference to the PRM and PAM. The Assessment Method assesses against ISO/IEC 15504-2 compliant models i.e. the MedITNet PRM and PAM. These models describe processes at the level of the *process purpose, outcomes, practices and work products*. This approach to the development of the Assessment Method ensures its applicability beyond the HDO assisting with its development, across varying geographical and regulatory contexts. The development of the assessment questions, which form part of the Assessment Method, was completed in two phases.

a) Question Development – Phase 1

During phase 1 of the question development process, a meeting was held in the HDO with the Principal Physicist and a Physicist/Clinical Engineer. Both had taken part in

the initial phase of the Practice-Inspired Research and were already familiar with the provisions of the standard and the proposed MedITNet framework.

During the previous discussions on the current risk management practices within the HDO, it was agreed that the *Risk Analysis and Evaluation Process* was the main process relating to the identification and classification of risks. It was noted during the previous focus groups session that discussion of the Risk Analysis and Evaluation process lead to discussion of other aspects of risk management which are outside the scope of that process. Therefore, it was decided that questions should be developed for this process first.

The development of these questions would inform the development of the assessment questions for the remaining processes. In order to develop the questions for the Risk Analysis and Evaluation process, each of the base practices was reviewed and the participants were asked to formulate a question that could be used to assess the base practice being described. To facilitate gaining an understanding of each of the base practices, each base practice was discussed in the context of the standard with the relevant section of the standard being consulted and reviewed if required. Once all participants were clear on the meaning of the base practice, the participants from the clinical engineering team were encouraged to think of a “real” scenario where the relevant base practice had been implemented in the past. The discussion of the scenario would focus on how the base practice was implemented in the context and any constraints that may have affected the implementation of the base practice.

Once the practice had been discussed in context, the participants were encouraged to formulate questions that could be used to assess the degree to which the base practice had been implemented during the proposed scenario. All questions which were formulated by the participants were recorded and the participants were encouraged to rephrase the questions in order to decrease the number of questions used to assess each base practice. The Risk Analysis and Evaluation Process contains five base practices against which 14 questions were eventually formulated. This draft of questions was used in the validation focus group within HDO A which was conducted as part of the ADR process. However, the set of questions (presented in Table I) does not represent the final set of questions which were developed to be used in the assessment of this process.

b) Question Development – Phase 2

During the second phase of the development of the questions, the questions for the remaining 13 processes were developed. These questions were developed with the assistance of the Clinical Informatics Manager (CIM) of the HDO. The CIM is a former nurse who oversees the systems administration tasks of the Clinical Information

System within the Intensive Care Unit. The CIM was briefed on the research being carried out on the development of the Assessment Method and was given the PRM and PAM to review and was briefed on the requirements of the IEC 80001-1 standard. Following the development of the assessment questions for the remaining 13 processes, the CIM was also shown the questions developed during phase 1 for the Risk Analysis and Evaluation Process. The CIM was asked to review and reformulate the questions, as required, for this process based on their experience of development of the questions for the remaining processes.

In general, one question was related to each of the base practices. However, the assessment of some base practices required more than one question. The CIM was asked to participate in the development of the questions in order to ensure that the questions were phrased in a way that could be understood by various risk management stakeholders within the HDO. The questions were also developed based closely on the base practices defined within the PAM to ensure that the questions could be applied across multiple HDO contexts and were not specific to the HDO in which the research was being carried out.

TABLE I – SAMPLE ASSESSMENT QUESTIONS

Base Practice Summary:	Question Number:	Question:
BP.1 - Identify likely hazards.	BP.1 Q.1	How do you identify likely safety hazards for individual devices?
	BP.1 Q.2	How do you analyse the system as a whole to identify likely safety hazards?
	BP.1 Q.3	How do you consider the impact of the device on the environment?
	BP.1 Q.4	How do you consider the impact of the device in terms of effectiveness?
	BP.1 Q.5	How do you consider the impact of the device in terms of data and system security?
BP.2 - Estimate associated risks.	BP.2 Q.1	Do you have a procedure for estimating risk?
	BP.2 Q.2	What approach do you use to estimate the risk associated with each source of harm?
	BP.2 Q.3	What information sources do you use to estimate the risks associated with each source of harm?
	BP.2 Q.4	Are risks reviewed throughout the life cycle?
BP.3 - List possible consequences of harm.	BP.3 Q.1	How do you identify possible consequences of harm?
BP.4 - Record results of Risk Analysis and Evaluation activities.	BP.4 Q.1	How are risk management activities recorded?
	BP.4 Q.2	Are instances where risk estimate is so low that risk reduction is not required recorded?
BP.5 - Implement Risk Control Measures.	BP.5 Q.1	How are risk control measures implemented?
	BP.5 Q.2	Are risk control measures implemented in line with risk management policy?

III. STAGES OF THE ASSESSMENT METHOD

The stages of the assessment process are illustrated in Figure 1 and discussed in the remainder of this section.

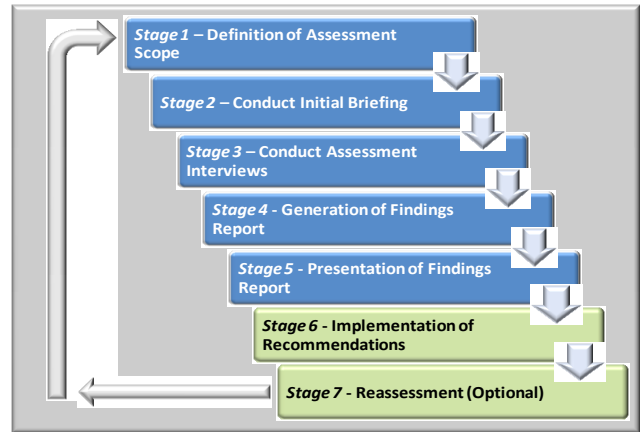


Figure 1. Stages of the Assessment Process

Participants in the assessment process include the lead assessor, a risk management stakeholder from within the HDO, who will manage the assessment on behalf of the Top Management (TM) of the HDO. Focus group interviews are used during the assessment to ensure communication among risk management stakeholders. An additional Assessor (A) may be required to assist the LA. In addition to sponsoring the assessment, TM will ensure that Risk Management Stakeholders (RMS) are available to participate in the assessment. The RMS will be drawn from a multi-disciplinary team from within the HDO and will include members of the IT, CE and Clinical Teams and any other relevant RMS as required. The RMS may also include participants who are external to the HDO such as MDMs. It should be noted that Stages 1 to 5 above complete the assessment activities. Stage 6 involves the implementation of recommendations made during the assessment. Where a follow-up assessment is required, stage 7 is performed. A reassessment can be used to confirm that the recommendations for improvements to the risk management process have improved risk management processes as envisaged.

a) Stage 1

The lead assessor meets with Top Management and the scope of the assessment is discussed. The system which is to be the focus of the assessment is defined and the context of the system is understood. At this time, the availability of relevant risk management stakeholders to participate in the assessment is confirmed.

b) Stage 2

The lead assessor meets with relevant risk management stakeholders who will be taking part in the assessment to explain the Assessment Method and give details of what their participation will involve.

c) *Stage 3*

The lead assessor conducts interviews based on the scripted questions with the relevant risk management participants and evaluates the responses. The assessor makes notes on the interviews and additional questions are asked if clarification is required. Relevant work products are reviewed at this stage.

d) *Stage 4*

A findings report is prepared based on the data gathered at stage 3. Each process is reviewed in turn and where relevant particular strengths and weaknesses are identified based on the evaluation and interview notes. Suggested actions to address these issues and to facilitate process improvement are outlined and discussed.

e) *Stage 5*

The findings report is presented.

f) *Stage 6*

Having allowed time for the contents of the report to be considered, the findings are discussed and a plan for improvement of the processes with specific improvement objectives is agreed.

g) *Stage 7*

The HDO having implemented the agreed improvements have the option of performing a reassessment to ensure that improvements have been implemented and that risk management processes have improved accordingly.

IV. VALIDATION OF THE ASSESSMENT METHOD

The Assessment Method was validated from the perspective of its utility in a specific HDO context. The first stage of validation consisted of performing an assessment of current risk management practices within a HDO context using the Assessment Method. This phase consisted of a pilot implementation of the Assessment Method by performing an assessment of the Risk Analysis and Evaluation process using the questions from the Assessment Method. A focus group session took place in the HDO with participants from various risk management stakeholder groups taking part. The assessment allowed for areas of weakness in the current risk management processes related to medical IT networks to be highlighted and addressed. A findings report was provided to the HDO and a follow-up focus groups session took place nine months later to review which recommendations had been implemented. A summary of the recommendations is provided in Table 2. This phase of the validation ensured that the developed questions could be understood by risk management stakeholders and were suited for use for the performance of an assessment in the specific HDO context. The performance of the assessment resulted in improvement to not only the risk analysis and evaluation process within the HDO, but participants also reported improvements in the overall risk management of medical

IT networks within the HDO. The performance of this stage of the validation confirmed the utility of the Assessment Method in a specific HDO context.

TABLE II - SAMPLE ASSESSMENT RESULTS SUMMARY

<i>BP.1 - Identify likely hazards</i>
Develop a standardised process for the identification of hazards, including the identification of hazards during the tendering process
Maintain the same level of documentation in the recording of identified hazards, regardless of when in the lifecycle the hazard is identified
Store information related to risk management in a manner which can be accessed as an information source for the estimation of future risks
<i>BP.2 - Estimate associated risks</i>
Establish a policy detailing risk acceptability criteria
Formalize and document a procedure for the estimation of risk which stipulates which risk management stakeholders should be involved
<i>BP.3 - List possible consequences of harm</i>
Consider consequences of harm based on the risk acceptability criteria
Consider consequences of harm based on the risk management policy
<i>BP.4 - Record the results of Risk Analysis and Evaluation activities</i>
Record Risk Analysis and evaluation activities in the risk management file
Ensure accessibility of emails containing information on Risk Analysis and Evaluation activities
<i>BP.5 - Implement Risk Control Measures</i>
Establish a process for risk control
Ensure that risk control measures are implemented in line with the risk control process
Document risk which have been considered so low as not to require additional risk control measures

In order to confirm the generalisability of the Assessment Method across a range of HDO contexts, the Assessment Method was also validated through expert review by members of the standards community from the International Electrotechnical Commission (IEC) Sub-Committee 62A and the International Organization for Standardization (ISO) Technical Committee 215 Joint Working Group 7 (JWG7). Members of this group are drawn from risk management stakeholders within HDOs, medical device manufacturers and providers of other IT technology. They are recognised as experts in their field and represent their country in this capacity. The focus of this stage of the validation is to ensure that the Assessment Method can be used across multiple HDO contexts, regardless of the regulatory environment in which the HDO operates. During this phase of the validation the Assessment Method was circulated to members of JWG7 for review. The Assessment Method was circulated with the MedITNet PRM and PAM and members were invited to make comments on any aspect of these components of MedITNet. The review by members of this group resulted in a number of changes to the Assessment Method including the provision of sample templates which could be used by HDOs during the performance of an assessment and in the preparation of the findings report for circulation to Top Management of the HDO. In addition to the review by members of JWG7, a focus group session was conducted with a selection of experts from the group. These experts were asked to

comment on various aspects of the overall MedITNet framework. During this session experts reported that the use of the Assessment Method and specifically the assessment questions resulted in risk management stakeholders having a greater understanding of the requirements of the IEC 80001-1 standard. The experts also noted that the definition of the requirements of the standard at the level of processes in the PAM enabled the assessment questions to be tailored to take into account of the context in which the HDOs provide care. This was

Each of these phases was performed iteratively as part of the ADR process and changes suggested by each phase of the validation were incorporated into the next version of the Assessment Method and the overall MedITNet framework.

V. CONCLUSIONS

While IEC 80001-1 takes steps to address the risks associated with the placement of a medical device onto an IT network, HDOs may face challenges in understanding and implementing the requirements of the standard. The MedITNet framework has been developed in order to assist HDOs in addressing these challenges. The Assessment Method provides a consistent, repeatable and tailorable approach to the assessment of the capability of risk management processes related to the management of medical IT networks. An assessment of these processes can highlight weaknesses therein and can be used as a foundation for an improvement of risk management processes. Effective risk management of medical IT networks ensures that the potential benefits of networked medical devices are realised while ensuring the safety of the patient is protected, the effectiveness of the device is assured and the security of the data and system are preserved.

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