

The MedITNet Assessment Method – Development and Validation using Action Design Research

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 in addressing these risks, HDOs may struggle in implementing the requirements of the standard. This paper discusses the development of an Assessment Method that forms part of MedITNet, an assessment framework that can be used by Healthcare Delivery Organisations 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. This paper also discusses the development and validation of the Assessment Method using Action Design Research.

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

I. INTRODUCTION

This paper extends the discussion of the development of the MedITNet assessment method in [1] by extending the discussion of the pilot implementation of the assessment method and examining the recommendations that were implemented as a result of the implementation. This paper also discusses the expert review of the overall assessment framework.

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 [2-4]. 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) [5-7]. 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 [8-11] As a result of this change, the number of networked medical devices in use continues to increase [12-14].

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 [15, 16]. These benefits have resulted in medical IT networks becoming a critical, integral component of the medical system [17]. 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 [14, 18-20]. 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 [21]. This lack of control can lead to risks potentially resulting 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 [22]. These risks can result in the incorrect and degraded performance of the medical device [23, 24] compromising patient safety, effectiveness and the security of the IT network [25-27].

IEC 80001-1: *Application of risk management for IT-networks incorporating medical devices* [28] was published in 2010 to address the risks associated with the incorporation of a medical device into an IT network. However, Healthcare Delivery Organisations (HDOs) face challenges when implementing the requirements of this standard [29]. HDOs vary in size and in terms of the capability of their risk management processes [17, 30] 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 [18, 31]. In addition, organisational changes are required to facilitate the necessary level of interaction among stakeholders and HDOs may be unprepared for this [14] due to the fact that departments within the HDO typically operate in silos [8]. 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 stakeholder 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 that make up the MedITNet assessment framework [32, 33]. 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 presence of the PRM and PAM within the MedITNet framework mean that the framework can be used regardless of the context of the HDO, including the regulatory environment in which the HDO provides care.

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 used as presented in the technical report or can be tailored for use based on the context in which the HDO provides care. In order to tailor the Assessment Method, the HDO can rephrase the questions that are being asked in order to address specific aspects of the context in which they provide care. For example, there may be additional regulatory requirements for risk management that apply to HDOs due to the geographical location in which they provide care. The HDO can either rephrase the questions to take into account the regulation or may choose to add additional questions during the performance of the assessment. Any alterations to questions or additional questions that are added, must be reviewed against the relevant base practices in the PAM. The HDO must ensure that the questions continue to address the assessment of the performance of these base practices before making any amendments or additions. This ability to tailor the Assessment Method addresses the issue of HDOs providing care within differing regulatory environments. In addition, the ability to tailor the Assessment Method allows HDOs to take into account the size of the HDO and also the capability of the HDO in terms of the risk management of medical IT networks. For HDOs operating at a lower level of maturity, the PRM and PAM can be used to identify processes and practices that need to be implemented to achieve a higher level of maturity. These HDOs may wish to perform an initial assessment of the capability of risk management processes using the Assessment Method, which will highlight areas for improvement. Based on the assessment, the HDO can then refer to the PRM and PAM to assist in the definition and implementation of processes at a higher capability level. The HDO can then perform a follow-up assessment at a later date to ensure that the identified improvements have been implemented and that the target capability level has been achieved.

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 [34] used in the development of the Assessment Method and also in the development of the MedITNet Assessment framework. The focus of the Practice Inspired Research phase of the ADR process is to validate the findings of the literature review, which in this case focused on an examination of the risk management of medical IT networks and the challenges experienced by HDOs in the implementation of risk management processes, and confirm that these challenges are experienced in practice within HDOs. This phase of the research process is useful in ensuring that the solution, in this case the assessment framework, will be suited for use in the context in which it will be used.

B. Literature Review

The Assessment Method was developed following the development of the PRM and PAM components of the MedITNet Assessment Framework. During the development of the PRM and PAM, a literature review in the area of process assessment, focusing on process assessment standards was conducted. This literature review was extended in order to develop the Assessment Method.

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 [35] and Appraisal Requirements for CMMI [36] Domain specific including Rapid Assessment for Process Improvement in Software Development (RAPID) [37], Express process appraisal (EPA) [38], Adept [39], Med-Adept [40] and Tudor IT Service Management Process Assessment (TIPA) [41] 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 that 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 [42] using criteria for Assessment Methods as outlined by Anacleto et al. [43]. 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 seeking 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 described 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. HDOs may use the Assessment Method in its form within the technical report and without reference to the PRM and PAM. This means that the process for conducting the assessment outlined in the Assessment Method and the questions that are used

during the assessment must be understandable to a range of risk management stakeholders.

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 use of ADR also ensures that all components of the framework are developed initially based on a combination of the results of the literature review combined with Practice-Inspired Research. The resultant components are then validated by both practitioners in the field and end users. This ensures that the components are both suited to use in a particular context and suited for use across a range of 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 outside the scope of that process. This was due to the fact that the discussion of the Risk Analysis and Evaluation process led to a discussion of the overall HDO risk management policy and also to a discussion on the evaluation and subsequent application of risk control measures. The discussion also revealed how risk was documented in the HDO. 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, a number of steps were followed [44]. Firstly, 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. The base practices in the PAM describe the activities that must be performed in order to bring about the process outcomes and achieve the overall purpose of the process. 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. This was useful for the participants as it provided an understanding of how the requirements of the standard were expressed in the PAM in terms of activities to be performed.

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. This assisted the participants in identifying how the requirements of the standard were and could be implemented in the specific context of their HDO.

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 that 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. This was an iterative process and resulted in discussions around how the questions should be phrased. This discussion was useful as it allowed participants to examine and understand the terms used in the standard and ensure that a common understanding of the concepts related to risk management was established. The approach outlined in this section was also noted by participants as being a useful way in which to gain a better understanding of the standard and the context in which the HDO provides care. Participants also suggested that this approach would also be useful in the tailoring of questions to a specific context as the questions could be reviewed to see where amendments should be made to take into account the context of the HDO in which the assessment is being performed.

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 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. When reviewing the questions related to this process, the CIM and the researcher rephrased some of the questions to ensure that they were more closely based on the base practices of the process. The original set of questions was determined to be too specific to the context of the HDO in which the question development had taken place. In addition, some questions were, on review, considered to be unnecessary, again being too context specific and were removed accordingly.

TABLE I. SAMPLE ASSESSMENT QUESTIONS

<i>Base Practice Summary:</i>	<i>Question Number:</i>	<i>Question:</i>
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?

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 developed using the same steps as those outlined in section C sub-section a). 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.

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.

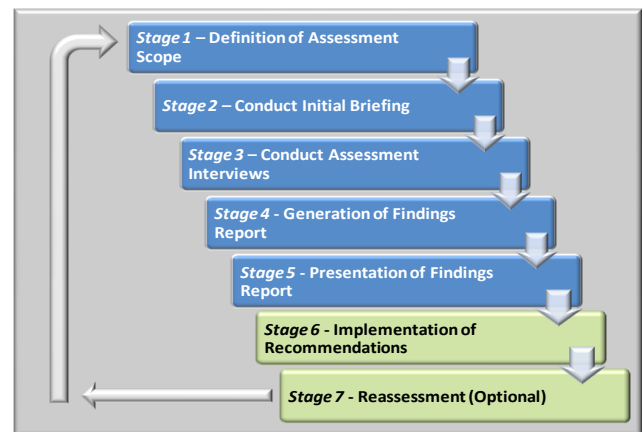


Figure 1. Stages of the Assessment Process

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. The inclusion of participants external to the HDO is more typical during the procurement phase of a new system or devices. However, it should be noted that the IEC 80001-1 standard notes the importance of the participation of external risk management stakeholders throughout the life of the medical IT network. The participation of relevant internal and risk management

stakeholders is necessary to perform the successful risk management of the medical IT network.

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 focus group 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. The responses to these questions will highlight areas of weakness in the risk management process. The identification of these weaknesses forms the basis for the findings report that will be generated during the next stage of the assessment. Relevant work products are reviewed at this stage to highlight areas where risk management documentation may be missing or incomplete.

d) *Stage 4*

A findings report is prepared based on the data gathered and the weaknesses identified 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 recommendations are made for actions to address these issues and to facilitate process improvement are outlined and discussed.

e) *Stage 5*

The findings report is presented. The lead assessor presents the findings of the assessment. The finding will generally be reported to Top Management within the HDO and to relevant risk management stakeholders. It is important that the findings report is thoroughly reviewed and that recommendations are carefully considered. The

findings report may be referred to during follow-up assessments and may also be used as a source of information for the identification of risks on future projects.

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. At this stage participants may schedule a reassessment to be conducted at a later date.

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.

It should be noted that the interviews conducted during Stage 3 are conducted as focus group interviews. The focus group interviews are conducted with risk management stakeholders. Prior to the commencement of an assessment, HDOs should ensure that all relevant risk management stakeholders are identified and are available to participate in the focus group interviews. Participation of relevant risk management stakeholders in the focus group interviews ensures: that a shared understanding of the concepts related to the risk management of medical IT networks are understood; that risk management stakeholders, through the assessment process and discussion of risks, gain a greater understanding of the IEC 80001-1 standard, greater level of communication are established between risk management stakeholder groups as the assessment process requires that these groups operate outside of their "silos".

IV. VALIDATION OF THE ASSESSMENT METHOD

The Assessment Method was validated from the perspective of its utility in a specific HDO context. The validation of the Assessment Method was performed in two stages. The first involved a pilot assessment performed in a HDO, while the second stage involved the validation of the assessment method by the standards community. Both of these stages of the validation of the Assessment Method, which were conducted using ADR, are discussed in this section.

a) *Stage 1- Validation – Pilot Assessment*

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 summary of the recommendations is provided in Table II. 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.

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 risks which have been considered so low as not to require additional risk control measures

A follow-up focus groups session took place nine months later to review which recommendations had been implemented. Not all of the recommendations made during the assessment were implemented by the HDO [44]. However, 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. Participants also confirmed that the recommendations, which were made in the findings report, were considered to be appropriate. Where recommendations had not been implemented, this was due to the constraints on resources within the HDO. Recommendations which had not been implemented at the time of the follow-up focus group session were scheduled for implementation at a later date. Participants had also highlighted the importance of the implementation of the requirements of the IEC 80001-1 standard in future medical IT network projects.

At the time of the follow-up session, the CE team had secured agreement from Top Management that a Medical

IT Network Risk Manager would be recruited for an upcoming medical IT network project. The responsibilities of the medical IT network risk manager role was to be defined based on those as outlined in IEC 80001-1. The agreement to recruit for this position and to base the responsibilities of the role on IEC 80001-1 requirements was agreed with Top Management based on the results of the pilot assessment. The CE team identified this as a major improvement in risk management processes as prior to this they felt that the skills required to perform effective risk management of the network were not currently present in the HDO. The CE team noted that the performance of the assessment was instrumental in gaining Top Management engagement in the promotion and adoption of the standard. This sentiment was repeated during an expert review of the overall MedITNet framework where experts contended that without this type of assessment instrument, adoption of the standard may follow a shallow trajectory [44].

The performance of this stage of the validation:

- confirmed the utility of the Assessment Method in a specific HDO context
- confirmed that the questions used in the assessment were understandable to various risk management stakeholders
- confirmed that the Assessment Method could be tailored for use in various HDO contexts.
- confirmed that the Assessment Method could be used to provide appropriate recommendations for the improvement of the risk management process
- confirmed that the use of the Assessment Method improved communication among risk management stakeholders
- confirmed that the use of the Assessment Method may be useful in promoting Top Management engagement with and promotion of the adoption of the standard

This stage of the validation process was conducted as part of the ADR process as part of the “Build, Intervene and Evaluate” stage of the ADR process [34]. During this stage of the process “end-users” of the developed artifact, in this case the Assessment Method, trial the artifact in the context in which it will be used, in this case in a HDO setting. The focus of this phase is to ensure the utility of the developed artifact in a specific context.

b) Stage 2 Validation – Standards Community

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 that 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.

Table III presents the approach adopted for reviewing the comments. Each of the comments was assigned to one of the four categories listed in Table III and addressed accordingly. All comments were discussed during the comment resolution meetings and resolution was based on the expertise of the JWG7 group which included representatives from HDOs, medical device manufacturers and providers of other information technology. As the Assessment Method had been previously validated in a trial assessment, the comments received from JWG7 were largely editorial in nature and did not result in changes to the questions within the Assessment Method. In total, 298 comments were received related to the Assessment Method. A large number of duplicate comments were received. This was due to one reviewer who raised a comment for each instance of a particular issue, leading to a large number of comments being duplicated.

During the comment resolution period, a total of 298 comments related to the Assessment Method were received from members of JWG7. During an initial review of comments 202 comments were found to be duplicate comments and an additional four comments were deemed to be not applicable. Therefore, those 206 comments required no changes to be made to the Assessment Method and have not been included in the following analysis of comments. An initial review of the remaining 92 comments was completed.

While a large number of the comments received on the Assessment Method were small wording changes, some of the comments required changes to the overall structure of the technical report. These changes included the following:

- Assessment stages were listed before a description of each stage was provided
- Assessment questions were removed from the description of the stages of the Assessment Method and placed in the annex of the Assessment Method.
- Templates for conducting the assessment including a sample question template and a findings report template were also developed and placed in the annex.

These changes were suggested to improve the usability of the Assessment Method and facilitate performance of both conformance and capability assessments and as such were made to the Assessment Method. The Assessment Method developed as part of this research along with the MedITNet PRM and PAM were published as ISO TR 80001-2-7, a Technical Report in the IEC 80001-1 family of standards [45].

TABLE III. COMMENT REVIEW APPROACH

Comment Category:	Review Approach:
Duplicate	Multiple comments received related to each instance of a specific issue. Comments are addressed based on the decision relating to first instance of the comment
Editorial Comments	Editorial comments are those that address the structure and flow of the technical report. Editorial comments are accommodated when they improve the structure, understanding and usability of the document and do not impact IEC 80001-1 requirements. Agreement is by consensus
Wording Comments	Wording comments relate to the wording or terms used within the technical report and include grammatical and typographical errors. Wording comments are accommodated when they improve the structure, understanding and usability of the document and do not impact IEC 80001-1 requirements. Agreement is by consensus
Not Applicable	Comments which are received that do not require any update to the Assessment Method. Examples of these comments include a statement of abstention or approval of the

The performance of this stage of the validation:

- confirmed the utility of the Assessment Method in a range of HDO contexts. This was possible due to the composition of JWG7 with members being drawn international experts representing a range of risk management stakeholders
- confirmed that the questions used in the Assessment Method were understandable to various risk management stakeholders
- confirmed that the structure of the Assessment Method was appropriate for use across a range of HDO contexts.
- confirmed that the questions used in the Assessment Method are suited for use or can be tailored for use across a range of contexts.

This stage of the validation process was conducted as part of the ADR process, again as part of the “Build, Intervene and Evaluate” stage of the ADR process [34]. During this stage of the process “practitioners” in the field of the developed artifact, review the artifact in terms of its ability to be generalised and used across a range of contexts, in this within differing regulatory environments in which the HDOs provide care. Practitioners from JWG7 reviewed the Assessment Method, as well as the PRM and PAM. The focus of this phase is to ensure the utility of the developed artifact(s) across a range of contexts.

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. This again was conducted using a “Practitioner Review” approach as part of the ADR process [44]. The reviewers were asked to comment on:

1. The utility of the assessment framework
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 the MedITNet framework
5. Suggestions for improvements to the assessment framework

While the comments discussed the review focused on the overall MedITNet framework, a number of comments related to the Assessment Method specifically.

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 expert noted that being asked questions related to specific requirements of the standard gave participants in an assessment a greater understanding of the requirements than they would have gained by reading the standard alone [44]. It was also noted that, by having a means to assess the capability of the risk management processes, Top Management understood the weaknesses in the current processes and had a better understanding of why adoption of the standard was important.

The performance of an assessment and the subsequent improvement of risk management processes also provides Top Management with a means to ensure that the benefits, which were intended to be provided to patients through the use of networked medical devices, were realised as expected. 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. Experts further noted that the Assessment Method questions are beneficial as a starting point but noted that most HDOs would need to tailor the questions, not only based on the regulatory environment in which they provide care, but also based on the maturity level of the HDO in which the assessment is being performed. One expert taking part had been involved in a trial assessment in a different HDO to the one in which the trial assessment was performed. The expert noted that, while the questions in the Assessment Method are directly related to the base practice that is being assessed, these were rephrased during the assessment to use more open ended questions which were more appropriate to the context of the HDO being assessed. The rephrased questions did not focus as directly on assessing whether the base practices had been implemented but rather were phrased in a more open way that prompted a more general discussion of overall risk management processes before targeting the base practice in question.

Experts also noted that the requirements of the IEC 80001-1 standard had been covered in the MedITNet framework and also noted that the approach taken in the framework was consistent with the approach taken in IEC 80001-1. The experts noted that an improvement may be made to the framework following more trial implementations. These implementations may be able to provide guidance on how the framework could be tailored based on the maturity of the HDO. Experts also suggested the inclusion of a document map within the framework and suggested that a mapping from the Assessment Method questions back to the requirements of the standard may be helpful.

The performance of this stage of the validation:

- confirmed the utility of the MedITNet Framework including the Assessment Method in a range of HDO contexts. This review served as a final “expert” and “enduser” review of the final version of the MedITNet Framework
- confirmed that the usability of the framework across a range of HDO contexts and maturity levels
- confirmed that the requirements of IEC 80001-1 had been covered in the MedITNet framework
- gathered suggestions for improvements to the MedITNet framework

Each of these validation 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 using Action Design Research in order to assist HDOs in addressing these challenges. The use of ADR ensures that the MedITNet Assessment Framework, including 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. The use of ADR ensures that the framework that was developed can be used in a specific context but is also suited for use across a range of HDO contexts. 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.

ACKNOWLEDGMENT

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.

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